



Federatie
Medisch
Specialisten

Gliomen

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Startpagina - Gliomen

Waar gaat deze richtlijn over?

De richtlijn is van toepassing op alle volwassen patiënten met een glioom. De richtlijn gaat in op astrocytomen en oligodendrogliomen. Ependymomen, gliomen op ruggenmergniveau en gliomen die vooral op de kinderleeftijd voorkomen, zoals het pilocytair astrocytoom, worden buiten beschouwing gelaten.

De richtlijn gliomen geeft aanbevelingen over diagnostiek, behandeling, nazorg en organisatie van zorg bij patiënten met een (mogelijk) glioom. De richtlijn beoogt hiermee de kwaliteit van de zorgverlening te verbeteren, het klinisch handelen meer te baseren op wetenschappelijk bewijs dan op ervaringen en meningen, de transparantie te vergroten en de diversiteit van handelen door professionals te verminderen.

Voor wie is deze richtlijn bedoeld?

De richtlijn is bestemd voor zorgverleners in de tweede (of derde) lijn die betrokken zijn bij de diagnostiek, behandeling en begeleiding van patiënten met een (verdenking op een) glioom. Deze zorg vereist een multidisciplinaire aanpak waarbij neuroloog, neurochirurg, radioloog, patholoog, radiotherapeut, internist-oncoloog, verpleegkundigen, verpleegkundig specialisten, klinisch neuropsychologen, huisartsen, IKNL-consulenten palliatieve zorg en het palliatief consult team betrokken kunnen zijn.

Voor patiënten

Het grootste deel van de kwaadaardige tumoren die in de hersenen ontstaan zijn tumoren van het steunweefsel. De cellen (de glia-cellen) die het steunweefsel vormen, steunen, voeden, beschermen en isoleren de zenuwcellen. Een tumoren van het glia-weefsel heten gliomen, deze zijn meestal kwaadaardig. Deze richtlijn heeft betrekking op patiënten met gliomen, die in de tweede of derde lijn behandeld worden. De richtlijn richt zich op diagnostiek, behandeling en nazorg. Patiënteninformatie over gliomen is te vinden op de website van Thuisarts via: *[in ontwikkeling]*

Status van de richtlijn

In de laatste herziening (2023) zijn de volgende modules herzien/ontwikkeld:

- Epidemiologie
- Typering/gradering diffuse gliomen
- Beeldvorming ter nadere differentiatie
- Indicatie geriatrisch assessment
- Behandeling van ouderen/kwetsbaren
- Beeldvorming ten behoeve van behandeling

De werkgroep heeft ook bekeken of de overige modules konden worden aangepast aan de laatste WHO-classificatie. Dit is niet haalbaar gebleken omdat de onderliggende literatuur berust op eerdere WHO-classificaties.

Verantwoording

Laatst beoordeeld : 11-07-2023

Laatst geautoriseerd : 11-07-2023

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Epidemiologie

Gliomen zijn een relatief zeldzame vorm van kanker. Jaarlijks krijgen ongeveer 1300 volwassen patiënten in Nederland de diagnose diffuus glioom (grafiek 1), waarvan 1000 bevestigd door weefselonderzoek. De incidentie is al jaren stabiel en ligt gestandaardiseerd voor de Europese bevolking rond 6 per 100.000 inwoners voor tumoren bevestigd door weefselonderzoek, en rond 8 per 100.000 als klinisch verdachte gevallen worden meegerekend. Deze laatste groep betreft patiënten die niet zijn geopereerd, bijvoorbeeld vanwege hun slechte conditie.

Diffuse gliomen komen vaker voor bij mannen (Ostrom, 2022). Hoewel verschillende risicofactoren zijn onderzocht, heeft alleen therapeutische, ioniserende straling een duidelijke etiologische invloed. Vooral degenen die als kind radiotherapie ondergingen, bijvoorbeeld vanwege leukemie, hebben een hogere kans op het ontwikkelen van een glioom (Ohgaki, 2005).

Gliomen worden geclassificeerd volgens de Wereldgezondheidsorganisatie (WHO, 2021), zie tabel 1.

Tabel 1. WHO-classificatie (2021) van diffuse gliomen

WHO-indeling	Type
Graad 1	<i>Pilocytair astrocytoom</i> <i>Astroblastoom, MN1-mutatie</i>
Graad 2	Oligodendroglioom, IDHmut + 1p/19q-codeletie, WHO graad 2 Astrocytoom, IDHmut, WHO graad 2 <i>Pleiomorf xanthoastrocytoom (PXA)</i> <i>Chordoid glioom</i>
Graad 3	Oligodendroglioom, IDHmut + 1p/19q-codeletie, WHO graad 3 Astrocytoom, IDHmut, WHO graad 3 <i>Pleiomorf xanthoastrocytoom (PXA)</i>
Graad 4	Astrocytoom, IDHmut, WHO graad 4 Glioblastoom, IDHwt, WHO graad 4 [¥] Diffuus hemisferisch glioom, H3 G34 mutant* Diffuse midline glioma, H3 K27 mutant

Tabel 1. Hoofdgroepen gliomen. In de WHO classificatie 2021 worden de gliomen onderverdeeld in voorkomend op kinderleeftijd versus volwassen leeftijd. De gliomen van de kinderleeftijd vallen buiten het bestek van deze richtlijn. Cursief gedrukte gliomen zijn circumscrepe astrocytaire gliomen en zijn minder frequent voorkomend dan de diffuse gliomen.

* Zeldzame tumoren die ook op jongvolwassen leeftijd voorkomen.

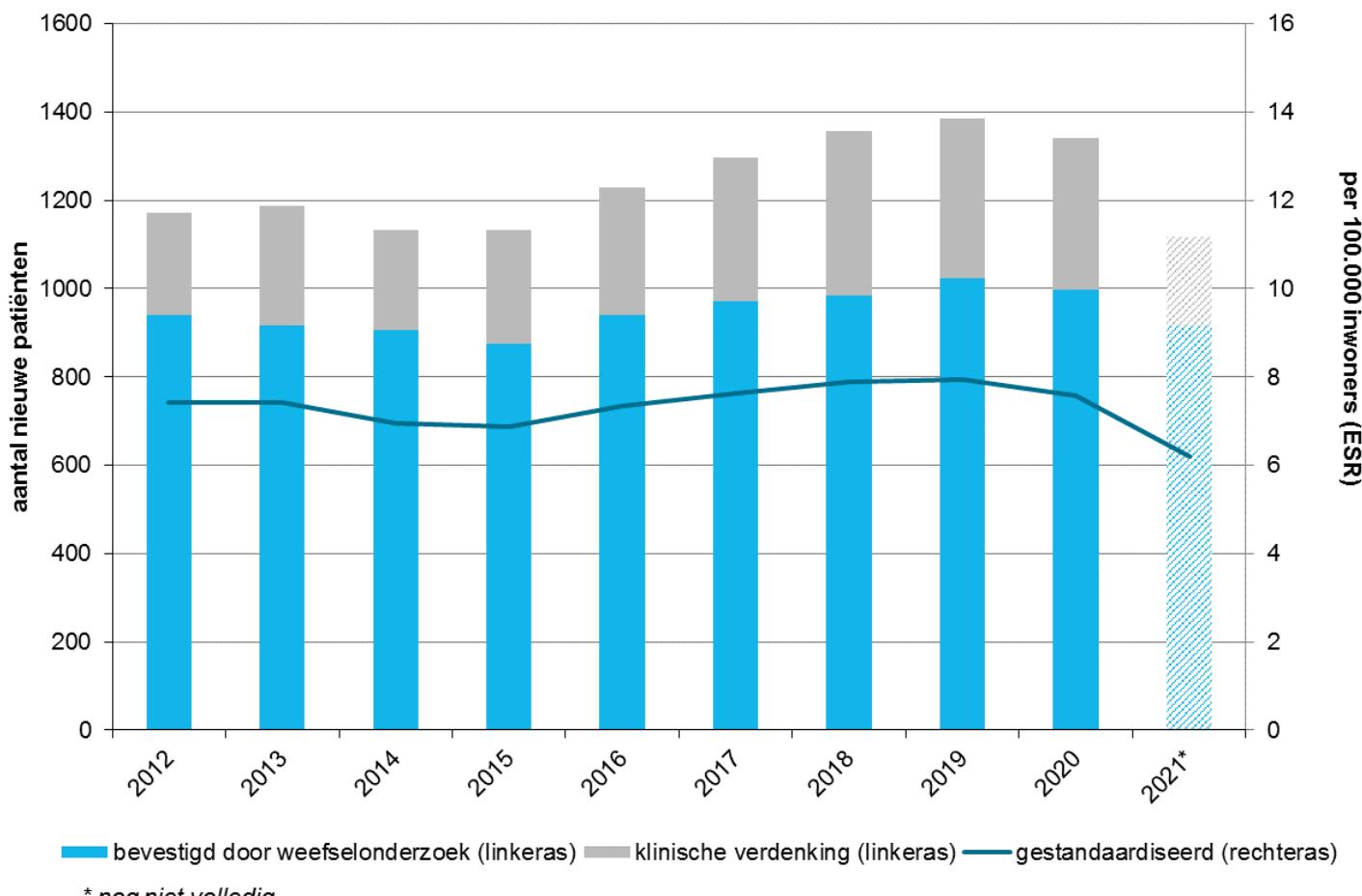
¥ Subtypes: reuscel glioblastoom (kunnen ook IDHmut zijn), gliosarcoom, epithelioid glioblastoom.

Van de door weefselonderzoek bevestigde diffuse gliomen betreft het merendeel (75%) een glioblastoom (grafiek 2).

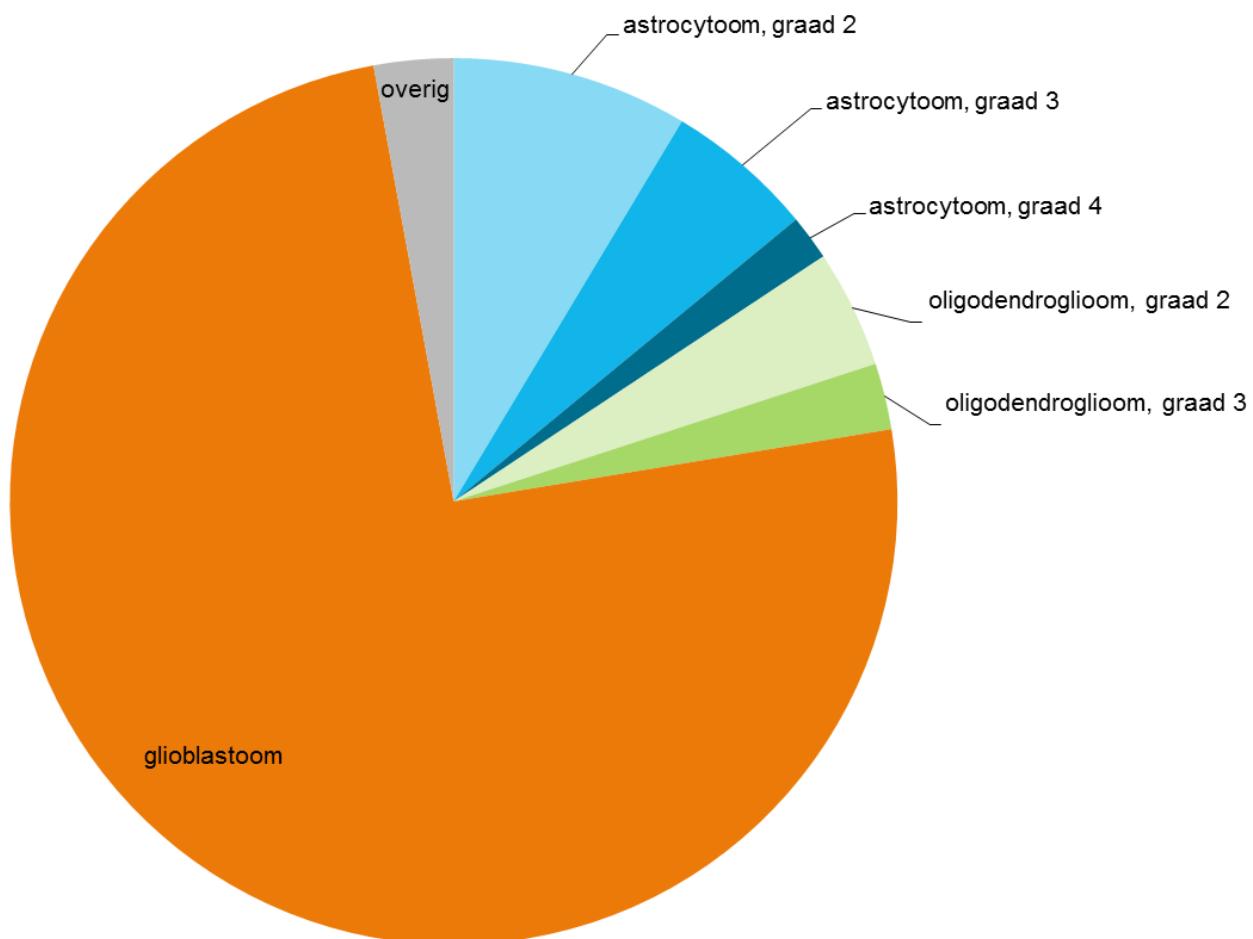
Gliomen groeien vaak uitgebreid in het omliggende hersenweefsel, wat adequate behandeling bemoeilijkt. Metastasering naar andere delen van het lichaam komt vrijwel niet voor. Afhankelijk van het tumortype en de tumorgraad krijgen vrijwel alle patiënten te maken met recidiefgroei na een eerste behandeling.

De overleving van patiënten met een glioom is sterk afhankelijk van de WHO-graad: in de periode 2012–2021 in Nederland was de 1-jaarsoverleving van patiënten met een door weefselonderzoek bevestigd WHO graad 2 glioom 90%, van degenen met een WHO graad 3 glioom 69%, en van degenen met een WHO graad 4 glioom 42% (grafiek 3). De 5-jaarsoverleving van deze patiënten bedroeg respectievelijk 70%, 38% en 5%.

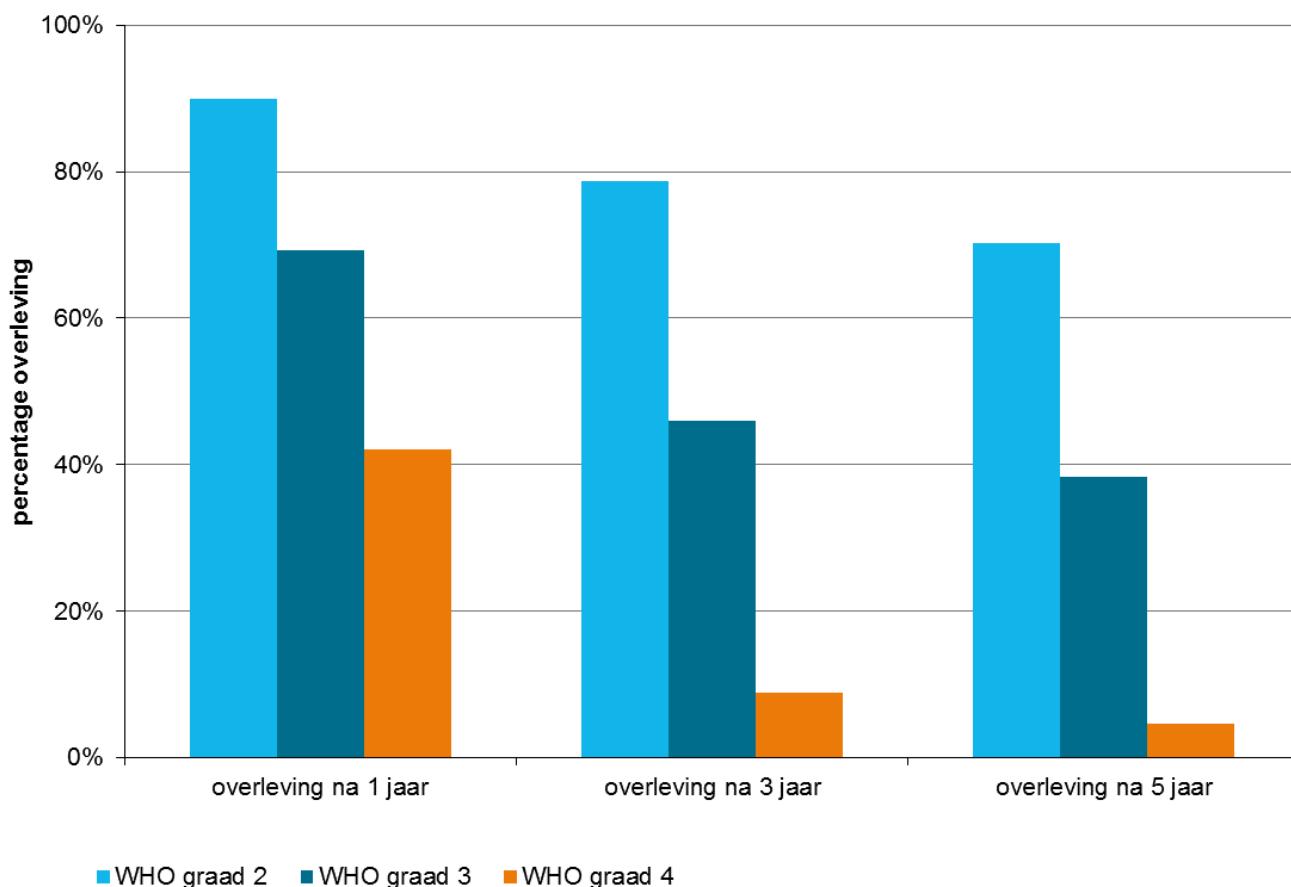
Grafiek 1. Aantal nieuwe gevallen van diffuse gliomen per incidentiejaar (Nederland) in de periode 2012–2021, absoluut (staaf) alsmede gestandaardiseerd voor de leeftijdsopbouw van de Europese bevolking (ESR; lijn)



Grafiek 2. Subtypes diffuse gliomen door weefseldiagnostiek bevestigd in de periode 2012–2021, in Nederland.



Grafiek 3. De 1-, 3-, 5-jaarsoverleving voor de diagnose diffuus glioom per WHO gradering ((WHO graad 2, 3 en 4) in Nederland.



■ WHO graad 2 ■ WHO graad 3 ■ WHO graad 4

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Diagnostiek bij Gliomen

Deze module is onderverdeeld in de volgende submodules en sub-submodules:

- Beeldvormende diagnostiek
 - Initiële beeldvorming
 - Aanvullende beeldvorming
- Neuropathologie
 - Typering/gradering diffuse gliomen
 - Moleculaire veranderingen diffuse gliomen

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Beeldvormende diagnostiek bij Gliomen

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Initiële beeldvorming
- Aanvullende beeldvorming

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Beeldvorming ter nadere differentiatie

Uitgangsvraag

Wat is de gewenste beeldvorming bij patiënten met een verdenking glioom ter vaststelling van de diagnose?

Aanbeveling

Overweeg het gebruik van DWI en perfusie MRI voor het onderscheid tussen glioom en lymfoom of hersenmetastase.

Overweeg perfusie MRI voor het onderscheid tussen hoog- en laaggradig glioom.

Overleg bij klinische consequenties en twijfel in een neuro-oncologisch MDO met aanwezigheid van terzake kundig radioloog.

Overwegingen

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Het doel van deze uitgangsvraag was om de aanvullende waarde van geavanceerde beeldvorming bij patiënten met een verdenking op een glioom (bij wie al iets is gezien op beeldvorming), in vergelijking met alleen conventionele beeldvorming te beoordelen. Er is één systematische review (Dunet, 2016), waarin FET-PET vergeleken werd met FDG-PET. Naast methodologische beperkingen werd de vergelijking niet getrokken met conventionele beeldvorming alleen (indirect bewijs). Bewijskracht voor de kritieke uitkomstmaten was zeer laag. Dit betekent dat andere studies kunnen leiden tot nieuwe inzichten. Er kunnen op basis van enkel de literatuur geen sterke aanbevelingen geformuleerd worden over de aanvullende waarde van geavanceerde beeldvorming vergeleken met conventionele beeldvorming alleen voor patiënten een verdenking op een glioom.

Meest relevante studies ter beschrijving

Diverse systematische/meta-analyses werden niet meegenomen in de literatuursamenvatting omdat deze niet voldeden aan de PICO. Deze studies betroffen over het algemeen onderzoeken waarbij de geavanceerde techniek niet werd vergeleken met conventionele MRI als controle. Daarnaast hadden veel studies een geselecteerde populatie met reeds bevestigd glioom (danwel andere laesie) waarbij retrospectief of in een case-control /two gate design de techniek werd onderzocht. Aangezien de literatuursamenvatting slechts één van de geavanceerde beeldvormende techniek beschrijft, zijn beknopt in tabel 1 en 2 de resultaten van studies naar andere geavanceerde technieken uitgelicht. Voor het onderscheid tussen gliomen en andere laesies (lymfoom, metastasen) zijn perfusie MRI met DSC en ASL, MRS en DTI/DWI onderzocht (tabel 1). Hooggradig glioom en lymfoom werden met hoge sensitiviteit en specificiteit onderscheiden middels DSC (Liang, 2014). Metastase en hooggradig glioom konden eveneens met hoge sensitiviteit en specificiteit van elkaar worden onderscheiden middels perfusie MRI met DSC, ASL of DCE (Suh, 2018), ASL (Fu, 2019) en MRS (Wang, 2017). Zhang et al (2020) rapporteert hoge sensitiviteit en specificiteit in het onderscheiden van glioblastoom, metastase en lymfoom met DWI en DTI. Overigens werd bij deze laatste studie geen referentietechniek gerapporteerd. Mede gezien het gehanteerde studie-design in veel van deze studies dienen deze resultaten met voorzichtigheid te worden geïnterpreteerd.

Ook in het onderscheid tussen hoog- en laaggradige gliomen (tabel 2) wordt er een hoge sensitiviteit en specificiteit gerapporteerd van diverse perfusie MRI technieken en parameters (DSC, ASL, DCE). De gerapporteerde sensitiviteit en specificiteit van MRS is iets lager, hoewel nog steeds >70% (Wang, 2019). Een directe vergelijking tussen perfusie MRI en MRS is in deze studies overigens niet verricht. Ook hier geldt dat de resultaten met voorzichtigheid geïnterpreteerd dienen te worden.

In de studie door Shaw (2019) werd onderzocht of FDG-PET-CT alleen, of in combinatie met MRI kan bijdragen aan het differentiëren tussen hooggradige histologie (WHO IV glioblastoom, WHO III glioom en metastasen) en laaggradige histologie (WHO II glioom en benigne afwijkingen). De studiepopulatie bestond voor een deel uit patiënten die diagnostiek voor verdenking glioom ondergingen en voor een deel uit patiënten met reeds vastgesteld glioom. Vanwege beperkte sensitiviteit en negatief voorspellende waarde, concludeerden de auteurs dat een negatieve FDG-PET-CT alleen of in combinatie met MRI, niet leidend moet zijn in de beslissing voor observatie waar anders chirurgie aanbevolen zou worden.

Tabel 1 Differentiatie gliomen ten opzichte van niet gliomen

Study ID	N studies (totaal patiënten)	Differentieert tussen	Techniek (interventie)	Conventionele beeldvormende techniek (controle)	Techniek (referentie)	Diagnostische accuratessemaat (95% CI)	QUADAS beoordeelbaar
Liang, 2014	3 (79)	Hooggradig/lymfoom	DSC-MRI (rCBV)	-	Histopathologie	Sensitiviteit: 0.90 (0.76 tot 0.97) Specificiteit: 0.98 (0.89 tot 1.00)	Ja
Zhang, 2020	19 (1558)	Glioblastoom/lymfoom/metastasen	DTI	-	NR	Sensitiviteit: 0.87 (0.78 tot 0.93) Specificiteit: 0.91 (0.83 tot 0.96) AUC: 0.95 (0.93 tot 0.97)	Nee
			DWI	-	NR	Sensitiviteit: 0.81 (0.71 tot 0.88) Specificiteit: 0.84 (0.78 tot 0.89) AUC: 0.90 (0.87 tot 0.92)	

Suh, 2018	18 (900)	Glioom/ metastasen	Perfusie MRI: DSC (13), ASL (4), DCE (2) – m.n. <i>peritumorale</i> rCBV/rCBF	-	Histopathologie	Sensitiviteit: 0.90 (0.84 tot 0.94)	Ja
						Specificiteit: 0.91 (0.84 tot 0.95)	
						AUC: 0.96 (0.94 tot 0.98)	
Fu, 2019	5 (346)	Hooggradig/ metastasen	ASL	-	Histopathologie/ klinische follow- up	Sensitiviteit: 0.88 (0.65 tot 0.96)	Ja
						Specificiteit: 0.85 (0.74 tot 0.92)	
						AUC: 0.92 (0.89 tot 0.94)	
Wang, 2017	7 (261)	Hooggradig/ metastasen	MRS	-	Histopathologie en/of klinische follow-up	Sensitiviteit: 0.85 (0.79 tot 0.90)	Ja
						Specificiteit: 0.84 (0.75-0.90)	
						AUC: 0.90 (NR)	

Tabel 2 Differentiatie hooggradige /laaggradige gliomen

Study ID	N studies	Techniek (interventie)	Conventionele beeldvormende techniek (controle)	Techniek (referentie)	Diagnostische accuratessemaat	QUADAS beoordeeld
Luan, 2020	20	ASL (rCBF)	-	Pathologie	Sensitiviteit: 0.88 (0.83 tot 0.92)	Ja
					Specificiteit: 0.91 (0.84 tot 0.94)	
					AUC: 0.95 (0.93 tot 0.97)	
	22	DSC-MRI (rCBV)	-	Pathologie	Sensitiviteit: 0.92 (0.83 tot 0.96)	

					Specificiteit: 0.81 (0.73 tot 0.88)	
					AUC: 0.91 (0.89 tot 0.94)	
Liang, 2018	13	DCE-MRI (K ^{trans})	-	Pathologie	Sensitiviteit: 0.88 (0.81 tot 0.93)	Ja
					Specificiteit: 0.80 (0.72 tot 0.86)	
					AUC: 0.90 (0.87 tot 0.92)	
	6	DCE-MRI (V _e)	-	Pathologie	Sensitiviteit: 0.85 (0.73 tot 0.92)	
					Specificiteit: 0.84 (0.75 tot 0.91)	
					AUC: 0.88 (0.85 tot 0.91)	
	5	DSC-MRI (rCBF)	-	Pathologie	Sensitiviteit: 0.88 (0.77 tot 0.94)	
					Specificiteit: 0.68 (0.56 tot 0.77)	
					AUC: 0.73 (0.69 tot 0.77)	
Abrigo, 2018	7	DSC-MRI (rCBV) (n= 6) DCE-MRI (K ^{trans}) (n= 1)	-	Histopathologie	Sensitiviteit: 0.83 (0.66 tot 0.93)	Ja
					Specificiteit: 0.48 (0.09 tot 0.90)	
Wang, 2016	19	MRS (Cho/Cr)	-	Histopathologie en/of klinische follow-up	Sensitiviteit: 0.75 (0.71 tot 0.79)	Ja
					Specificiteit: 0.60 (0.55 tot 0.66)	
					AUC: 0.83 (NR)	
	16	MRS(Cho/NAA)	-	Histopathologie en/of klinische follow-up	Sensitiviteit: 0.80 (0.76 tot 0.84)	
					Specificiteit: 0.76 (0.70 tot 0.82)	
					AUC: 0.87 (NR)	

11	MRS NAA/Cr)	-	Histopathologie en/of klinische follow-up	Sensitiviteit: 0.71 (0.65 tot 0.77) Specificiteit: 0.70 (0.61 tot 0.78) AUC: 0.78 (NR)
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Abbreviations: ASL, arterial spin labeling; CBV, cerebral blood flow; DCE-MRI, Dynamic Contrast Enhanced-MRI; DSC-MRI, dynamic susceptibility contrast--MRI; DTI, diffusion tensor imaging; DWI, diffusion weighted imaging; MK, mean kurtosis; MRS, Magnetic resonance spectroscopy; NR, not reported

Waarden en voorkeuren van patiënten (en evt. hun naasten/ mantelzorgers)

Geavanceerde MRI-technieken zijn relatief weinig belastend voor de patiënt, aangezien deze over het algemeen worden toegevoegd aan de standaard MRI scan. Een PET-scan is meer belastend, aangezien dit een separaat en – de voorbereidingstijd in ogenschouw nemend – meer langdurig onderzoek is. Daarnaast gaat dit gepaard met (beperkte) stralenbelasting, hetgeen sommige patiënten als meer ingrijpend beschouwen. Niet alle geavanceerde technieken zijn overal allemaal beschikbaar. Het kan zijn dat patiënten wel een bepaalde voorkeur hebben voor een bepaalde techniek. Omdat er geen eenduidig bewijs is dat een specifieke techniek beter is dan een andere, is er geen reden om te denken dat de topografische variatie invloed heeft op de behandeling of uitkomst.

Kosten (middelenbeslag)

Het aantal nieuwe patiënten met een glioom in Nederland bedraagt ±1300 per jaar.

De kosten van geavanceerde MRI zullen over het algemeen met name betrekking hebben op een verlenging van het standaard uitgevoerde MRI-onderzoek. Deze verlenging is relatief beperkt (5-15 min), maar is gezien de schaarste van MRI-capaciteit wel van belang. PET betreft een geheel additioneel onderzoek dat duurder is dan MRI, en waarvoor de tracer (FET) niet standaard overal beschikbaar is. Bij de werkgroep zijn geen studies naar kosteneffectiviteit voor deze geavanceerde technieken bekend.

Aanvaardbaarheid, haalbaarheid en implementatie

DWI en DSC MRI zijn in Nederland breed beschikbaar en geïmplementeerd. De overige geavanceerde MRI-technieken (ASL, DCE, MRS) zijn niet in alle centra beschikbaar. PET is minder toegankelijk en de tracer (FET) is niet standaard overal beschikbaar.

De werkgroep is van mening dat bij klinische consequenties en twijfel de patiënt besproken dient te worden in een neuro-oncologisch multidisciplinair overleg met aanwezigheid van een terzake kundig radioloog. Zie document 'Kwaliteitscriteria neuro-oncologie' (LWNO, 2022 voor de kwaliteitseisen van terzake kundig radioloog.

Rationale van de aanbeveling: weging van argumenten voor en tegen de diagnostische procedure

Er is onvoldoende bewijs dat PET-onderzoek bijdraagt aan de differentiële diagnostiek bij patiënten met een verdenking op glioom. Hierbij is de sensitiviteit van FDG-PET beduidend lager (en onder de norm) dan FET-PET.

De breed beschikbare geavanceerde MRI-technieken DWI en perfusie MRI lijken van waarde bij het differentiëren tussen hooggradig glioom, metastase en lymfoom en voor het onderscheid tussen hoog- en laaggradig glioom, maar bij het ontbreken van goede studies valt niet te zeggen wat de daadwerkelijke diagnostische kracht van deze technieken is. MRS lijkt iets minder goed te zijn voor het onderscheid tussen hoog- en laaggradig glioom.

Onderbouwing

Achtergrond

Nadat er een afwijking in de hersenen is vastgesteld die zou kunnen passen bij een glioom (middels CT dan wel MRI) blijft de diagnose soms onzeker. Belangrijke differentiële diagnosen zijn andere maligne aandoeningen (zoals metastase of lymfoom), demyelinisatie, abces, een infectie anderszins, of vasculaire aandoeningen. Deze vereisen alle een andere behandeling, die soms met spoed moet worden ingezet. Daarnaast is het type en graad van een vermoedelijk glioom van belang. Onzekerheid omtrent de diagnose leidt nu soms tot onnodig of onvolledig operatief ingrijpen en zou kunnen worden voorkomen met betere niet-invasieve, beeldvormende diagnostiek. Het is echter de vraag of en welke aanvullende beeldvormende technieken een toegevoegde waarde hebben boven de conventionele, structurele beeldvorming die routinematig wordt verricht, bestaande uit T2-gewogen (al dan niet met vochtonderdrukking: FLAIR) en pre- en post-contrast T1-gewogen sequenties.

Conclusies

1. Sensitivity (glioma or non-glioma) (critical)

Very low GRADE	<p>It is unclear whether add-on FET-PET is more sensitive compared to add-on FDG-PET in discriminating between glioma and non-glioma lesions in patients suspected of glioma.</p> <p><i>Source: Dunet, 2016</i></p>
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2. Specificity (glioma or non-glioma) (critical)

Very low GRADE	<p>It is unclear whether add-on FET-PET is more specific compared to add-on FDG-PET in discriminating between glioma and non-glioma lesions in patients suspected of glioma.</p> <p><i>Source: Dunet, 2016</i></p>
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3. Positive predictive value, negative predictive value (PPV, NPV) (important)

No GRADE	<p>No information was found regarding the effect of initial imaging followed by add-on advanced imaging on positive predictive value or negative predictive value when compared with initial imaging only in patients suspected of glioma.</p> <p><i>Source: -</i></p>
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4. Area under the curve (important) (glioma or non-glioma)

Very low GRADE	<p>It is unclear whether add-on FET-PET had a higher discriminative value compared to add-on FDG-PET in discriminating between glioma and non-glioma lesions in patients suspected of glioma.</p> <p><i>Source: Dunet, 2016</i></p>
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Effect of initial imaging followed by add-on advanced imaging (any outcome)

No GRADE	<p>No information was found regarding the effect of initial imaging followed by add-on advanced imaging on any outcome when compared with initial imaging only in patients suspected of glioma.</p> <p><i>Source: -</i></p>
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Samenvatting literatuur

Description of studies

In the systematic review with meta-analysis by Dunet (2016), five diagnostic accuracy studies were included (190 patients). Eligible studies used both ¹⁸F-fluoro-ethyl-L-tyrosine (FET) positron emission tomography (PET) and ¹⁸F-fluoro-deoxy-glucose (FDG)-PET and compared both with histology (reference). Patients were newly diagnosed with brain lesions or suspected of a recurrent brain tumor and did not undergo treatment before diagnostics. The available data from the five studies were combined in the meta-analysis (n= 119), resulting in a pooled AUC for FDG-PET and for FET-PET separately. Histology was used as a reference, distinguishing between glioma and non-glioma and between low-grade and high-grade glioma. In 3 studies (Floeth, 2006; Lau, 2010; Pichler, 2010), histology as reference standard was not possible in all patients, thus longitudinal observation (clinical follow-up, imaging) was used as reference in some cases. In three studies, not all patients were included in the analysis (Floeth, 2006; Lau, 2010; Pichler, 2010). A more elaborate explanation is provided in the risk of bias tables.

Table 1. Description of included studies in Dunet (2016)

Study	Study characteristics						
	n	Gender (F:M)	Mean age in years (SD)	Patients with a tumor	Diagnostic trajectory	Prevalence of glioma	
Floeth, 2006	14	0:11	54 (12)	4	Contrast enhanced MRI à FET-PET and FDG-PET à histology (biopsies or clinical follow-up)	4/14 (29%)	
Pauleit, 2009	52	16:36	46 (14)	45	MRI à FET-PET and FDG-PET à histology (biopsy)	43/52 (83%)	
Lau, 2010	21	5:13	42 (16)	12	Contrast enhanced MRI à FET-PET and FDG-PET à histology (surgical or clinical/imaging course)	10/21 (48%)	
Plotkin, 2010	15	9:6	44 (11)	15	MRI à FET-PET and FDG-PET à histology (surgical)	15/15 (100%)	
Pichler, 2010	88	NR	NR	14	MRI à FET-PET and FDG-PET à histology (surgical) or longitudinal observation	10/88 (11%)	

Abbreviations: ¹⁸F-fluoro-deoxy-glucose; FDG, ¹⁸F-fluoro-ethyl-L-tyrosine; FET, NR; not reported

Results

1. Sensitivity (glioma or non-glioma) (critical)

For the sensitivity of FET-PET in discriminating between glioma and non-glioma lesions, data from four studies (Floeth, 2006; Pauleit, 2009; Lau, 2010 and Pichler, 2010) could be combined in meta-analysis. Pooled sensitivity was 0.92 (95% CI 0.75 to 0.98). For sensitivity of FDG-PET, pooling the same studies led to a sensitivity of 0.35 (95% CI 0.11 to 0.71).

2. Specificity (glioma or non-glioma) (critical)

For the specificity of FET-PET in discrimination between glioma and non-glioma lesions, data from four studies (Floeth, 2006; Pauleit, 2009; Lau, 2010 and Pichler, 2010) could be combined in meta-analysis. Pooled specificity was 0.62 (95% CI 0.43 to 0.79). For specificity of FDG-PET, pooling the same studies led to a specificity of 0.65 (95% CI 0.48 to 0.79).

3. Positive predictive value, negative predictive value (PPV, NPV) (important)

Neither positive predictive value nor negative value were reported.

4. Area under the curve (important) (glioma or non-glioma)

Data from all five studies could be combined in the meta-analysis for a pooled AUC. The AUC for FET-PET in discriminating between glioma and non-glioma lesions was 0.76 (95% CI 0.67 to 0.84) and for FDG-PET 0.49 (95% CI 0.40 to 0.58).

Level of evidence of the literature

1. Sensitivity (glioma or non-glioma) (critical)

The level of evidence regarding the outcome measure sensitivity was downgraded by three levels because not all study participants were included in the analyses and inclusion of participants with a confirmed diagnosis of a brain tumor or suspected recurrence of a known low-grade glioma (Plotkin, 2010) (-2 risk of bias) and conflicting results within studies for FDG-PET compared with histology (-1, inconsistency).

2. Specificity (glioma or non-glioma) (critical)

The level of evidence regarding the outcome measure specificity was downgraded by two levels because not all study participants were included in the analyses and inclusion of participants with a diagnosis of a brain tumor or suspected recurrence of a known low-grade glioma (Plotkin, 2010) (-2, risk of bias); and two additional advanced imaging techniques were compared (-1, indirectness).

3. Positive predictive value, negative predictive value (PPV, NPV) (important)

The level of evidence regarding the outcome measure PPV and NPV could not be graded.

4. Area under the curve (important) (glioma or non-glioma)

The level of evidence regarding the outcome measure AUC was downgraded by three levels because not all study participants were included in the analyses and inclusion of participants with a diagnosis of a brain tumor or suspected recurrence of a known low-grade glioma (Plotkin, 2010) (-2, risk of bias); two additional advanced imaging techniques were compared (-1, indirectness).

Zoeken en selecteren

A systematic review of the literature was performed to answer the following question: is initial imaging followed by advanced imaging recommended versus initial imaging or additionally imaging techniques only in patients suspected of glioma?

Patients: Patients suspected of glioma in whom a lesion has been seen with imaging (CT or conventional MRI)

Intervention: Initial imaging followed by advanced imaging technique¹

Comparator: Initial imaging (CT, conventional MRI, structural MRI, pre- and post-contrast, T1w, T2w and/or FLAIR)

Reference: Clinical course, histopathology

Outcomes: Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value, Area Under the Curve (AUC))

Timing and setting: Outpatient clinic (neurology/neurosurgery/oncology)

Timing: Advanced imaging after initial imaging (term: <4 weeks)

Relevant outcome measures

The guideline development group considered sensitivity and specificity as a critical outcome measure for decision making; and negative predictive value, positive predictive value and AUC as important outcome measures for decision making.

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies.

The working group defined minimal clinically (patient) important thresholds for accuracy measures as $\geq 70\%$

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2014 until January 24th, 2022. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 248 hits. Studies were selected based on the following criteria:

- Systematic review (searched in at least two databases, and detailed search strategy, risk of bias assessment and results of individual studies available) or observational study;
- Full-text English language publication;
- Studies according to PICO.

A total of 29 studies were initially selected based on title and abstract screening. After reading the full text, 28 studies were excluded (see the table with reasons for exclusion under the tab Methods), and one studies was included (Dunet, 2016).

Results

One study was included in the analysis of the literature (Dunet, 2016). Important study characteristics and results are summarized in table 1 and the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Verantwoording

Laatst beoordeeld : 11-07-2023

Laatst geautoriseerd : 11-07-2023

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

- 1 - Dunet V, Pomoni A, Hottinger A, Nicod-Lalonde M, Prior JO. Performance of 18F-FET versus 18F-FDG-PET for the diagnosis and grading of brain tumors: systematic review and meta-analysis. Neuro Oncol. 2016 Mar;18(3):426-34. doi: 10.1093/neuonc/nov148. Epub 2015 Aug 4. PMID: 26243791; PMCID: PMC4767236.
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- 3 - LWNO,2014 https://richtlijnendatabase.nl/uploaded/docs/IKNL_in_ontw/Kwaliteitscriteria_Gliomen_def_mei2014.pdf
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- 5 - Wang S, Kim S, Chawla S, Wolf RL, Knipp DE, Vossough A, O'Rourke DM, Judy KD, Poptani H, Melhem ER. Differentiation between glioblastomas, solitary brain metastases, and primary cerebral lymphomas using diffusion tensor and dynamic

susceptibility contrast-enhanced MR imaging. AJNR Am J Neuroradiol. 2011 Mar;32(3):507-14. doi: 10.3174/ajnr.A2333. Epub 2011 Feb 17. PMID: 21330399; PMCID: PMC8013110

Beeldvorming ten behoeve van chirurgie/radiotherapie

Uitgangsvraag

Wat is de plaats van nieuwe radiologische technieken bij patiënten met een glioom t.b.v. planning van chirurgie/radiotherapie?

Aanbeveling

Overweeg het gebruik van neuronavigatie tijdens resectie van een glioom.

Overweeg bij (verdenking op) een glioom in of nabij eloquente gebieden functie localiserende beeldvorming te gebruiken zoals DTI en/of fMRI voorafgaand aan de resectie.

Overweeg voor het identificeren van de meer maligne tumorcomponenten gebruik te maken van aanvullende beeldvorming zoals PET, perfusie MRI (ASL, DSC, DCE) of MRS.

Overweeg voor een (supra)maximale resectie de infiltratie beter af te beelden door bijvoorbeeld PET, perfusie MRI, MRS of intra-operatieve echografie.

Overwegingen

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Het doel van deze uitgangsvraag was om te achterhalen wat de waarde van geavanceerde beeldvorming (DTI, fMRI, MRS, CEST, ASL DSC, DCE, MRS, intra-operatieve echografie, neuronavigatie, PET) is bij het plannen van de lokale behandeling bij patiënten met een verdenking op een glioom, in vergelijking met conventionele beeldvorming. Er is voor neurochirurgie één gerandomiseerde trial beschreven (Willems, 2006), waarin resectie met neuronavigatie vergeleken werd met resectie zonder neuronavigatie. Naast methodologische beperkingen was de studiepopulatie zeer klein en divers (zowel glioblastoom als metastase). Bewijskracht voor de kritieke uitkomstmaten was zeer laag. Dit betekent dat andere studies kunnen leiden tot nieuwe inzichten. Er kunnen op basis van enkel de literatuurgeen sterke aanbevelingen geformuleerd worden over de waarde van geavanceerde beeldvorming vergeleken met conventionele beeldvorming voor lokale behandeling van patiënten een verdenking op een glioom.

Ondanks de uitkomst van deze underpowered RCT is neuronavigatie voor vermoedelijke glioom chirurgie wereldwijd als standaard geaccepteerd en wordt deze techniek ook wereldwijd toegepast. De werkgroep is niet bekend met eventuele lopende studies naar deze techniek. In alle Nederlandse klinieken wordt neuronavigatie toegepast en door vele neurochirurgen als effectief en veilig ervaren voor gliomchirurgie.

Voor andere geavanceerde beeldvormende technieken (PET, DTI, fMRI, MRS, CEST, ASL DSC, DCE, intra-operatieve echografie) werden geen artikelen gevonden die aan de PICO voldeden. Wel zijn er twee systematische reviews over dit onderwerp gepubliceerd, alle in het kader van het plannen van een operatie. Caras et al (2020) includeerden uit 435 geïdentificeerde artikelen drie studies over DTI, vijf studies over fMRI en 21 over intra-operatieve MRI. Intra-operatieve MRI wordt in deze richtlijn buiten beschouwing gelaten, omdat deze faciliteit niet in Nederland beschikbaar is noch verwacht te zullen komen. Geen van deze studies

betrof een RCT. Hoewel patiënten met deze geavanceerde technieken vaker een totale resectie en minder permanente neurologische uitval leken te hebben, was er geen statistisch significant verschil in vergelijking met neuronavigatie. In een Cochrane review (Barone, 2016) werden vier RCT's geïncludeerd met elk een andere geavanceerde beeldvormende techniek: intra-operatieve MRI, 5-ALA fluorescentie, neuronavigatie (de hierboven beschreven RCT van Willem et al 2006), DTI. Alle studies hadden een groot risico op bias, metname de DTI-studie. Vanwege de grote heterogeniteit was een meta-analyse niet mogelijk. Ook in deze review was er in de individuele studies een grotere mate van resectie met geavanceerde beeldvorming (behoudens neuronavigatie), maar de bewijskracht was zeer laag. Er was geen bewijs voor verbeterde overleving. Op basis van de beschikbare literatuur is er geen bewijs dat het al dan niet toepassen van een van deze beeldvormende technieken zou leiden tot een verandering van operatierisico. Desalniettemin acht de werkgroep het verstandig om bij (verdenking op) een glioom in of nabij eloquente gebieden functie localiserende beeldvorming te gebruiken zoals DTI of fMRI als extra informatie tijdens de resectie. Het kan daarnaast verstandig zijn om voor het identificeren van de meer maligne tumorcomponenten gebruik te maken van aanvullende beeldvorming zoals PET, perfusie (ASL, DSC, DCE) of MRS. De werkgroep is eveneens van mening dat het verstandig kan zijn voor een (supra)maximale resectie de infiltratie beter af te beelden door bijvoorbeeld PET, MRS of intra-operatieve echografie. Eenduidig bewijs voor een individuele aanvullende vorm van beeldvorming naast conventionele MRI ontbreekt echter. Over het gebruik van geavanceerde beeldvormende technieken ten behoeve van het bepalen van het doelgebied voor bestraling is geen afdoende literatuur beschikbaar en acht de werkgroep dat er hiervoor geen indicatie is.

Waarden en voorkeuren van patiënten (en evt. hun naasten/ mantelzorgers)

Veel patienten zullen het advies van het neurochirurgisch en radiotherapeutisch team volgen, dat ingevuld wordt naar overtuiging, lokale beschikbaarheid en middelen. Neuronavigatie, DTI en intraoperatieve echografie lijken niet extra belastend voor de patiënt. Het uitvoeren van CEST, fMRI en ASL neemt meer tijd in beslag, maar wordt door de werkgroep als vergelijkbaar belastend voor de patiënt ingeschat. PET (-CT) wordt door de werkgroep ingeschat als zijnde extra belastend.

Een deel van deze beeldvorming kan bijdragen aan het localiseren van functionele structuren (DTI, fMRI), een ander deel kan bijdragen aan het localiseren van de meest maligne tumorcomponenten (PET, CEST, perfusie, MRS) of aan het localiseren van de infiltratieve tumorzone (MRS, intraoperatieve echografie). Deze technieken zijn niet overal beschikbaar en worden niet altijd toegepast, zonder dat dit betekent dat de kwaliteit van de behandeling hiermee verminderd.

Kosten (middelenbeslag)

Naar inschatting van de werkgroep gaan kosten gepaard met pre-therapeutische MRI-scan met apparatuur. Het is onduidelijk of onder de streep een van de technieken leidt tot hogere danwel lagere kosten.

Aanvaardbaarheid, haalbaarheid en implementatie

DSC-MRI, intra-operatieve echografie en neuronavigatie zijn alle breed beschikbaar, aanvaardbaar en haalbaar. MRI-beeldvorming met ASL, CEST, fMRI, DTI, DCE en MRS behoren niet tot de diagnostische standaard, en zijn niet overal geïmplementeerd in de MRI protocollen. Wel zijn ASL, fMRI, DTI, DCE en MRS

in de academische centra beschikbaar. CEST bevindt zich nog overwegend in het onderzoeksdomain, maar is potentieel wel implementeerbaar op bestaande MRI-scanners. PET, en met name met aminozuur tracers, is daarnaast niet overal beschikbaar.

Onderbouwing

Achtergrond

Momenteel wordt neurochirurgische en radiotherapeutische behandeling van een (verdenking op) glioom gebaseerd op structurele, conventionele beeldvorming met MRI, bestaande uit pre- en post-contrast T1-gewogen beelden en T2-gewogen (al dan niet met vochtonderdrukking: FLAIR) beelden. Het is bekend dat de afwijkingen die hiermee zichtbaar worden gemaakt niet volledig overeenkomen met de microscopische tumoruitbreiding, noch met de meest agressieve delen van de tumor. Daarnaast verschaffen structurele, conventionele MRI-beelden geen informatie over functionele hersengebieden, noch over het verloop van essentiële witte stofbanen. Ten derde is het de vraag of beeldvorming tijdens een operatie de resectie kan ondersteunen en daarmee de uitkomst voor de patiënt kan verbeteren.

Met meer geavanceerde beeldvormende technieken kan meer informatie worden verkregen over tumoruitbreiding en functioneel relevante hersenstructuren. Het is echter de vraag of deze daadwerkelijk kunnen of zouden moeten worden ingezet voor het plannen van behandeling, zoals het bepalen van de uitgebreidheid van operatie in relatie tot eloquente hersengebieden, het identificeren van het optimale target voor een biopsie, of het bepalen van doelgebied van bestraling.

Conclusies

1. Overall survival (critical)

No GRADE	No sufficient information was found regarding the effect of an advanced imaging technique on overall survival when compared with non-neuronavigation surgery in patients suspected of glioblastoma for whom a treatment is planned. <i>Source:</i> -
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2. Extent of resection (critical)

Very low GRADE	The evidence is very uncertain about the effect of neuronavigation on extent of resection when compared with standard surgery in patients suspected of glioblastoma in whom gross total resection is planned. <i>Source:</i> Willems (2006)
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3. Quality of life (critical)

Very low GRADE	The evidence is very uncertain about the effect of neuronavigation on quality of life when compared with standard surgery in patients suspected of glioblastoma in whom gross total resection is planned. <i>Source:</i> Willems (2006)
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4. Progression free survival and (intracranial) response (important)

No GRADE	No information was found regarding the effect of an advanced imaging technique on progression free survival and (intracranial) response when compared with using only conventional imaging in patients suspected of glioblastoma for whom a treatment is planned. <i>Source:</i> -
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5. Neurological/cognitive deterioration (important)

Very low GRADE	The evidence is very uncertain about the effect of neuronavigation on neurological/cognitive deterioration when compared with non-neuronavigation surgery in patients <i>suspected</i> of glioblastoma in whom gross total resection is planned. <i>Source:</i> Willems (2006)
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6. PET, DTI, fMRI, MRS, CEST, ASL DSC, DCE, intra-operative ultrasound

No GRADE	No information was found regarding the effect of advanced imaging techniques on any outcome when compared with conventional, structural MRI in patients suspected of glioma for whom a local treatment (surgery/radiotherapy) is planned. <i>Source:</i> -
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Samenvatting literatuur

Description of study

In the RCT by Willems (2006), 45 participants were randomly assigned to either surgery involving neuronavigation ($n= 23$) or 'standard' surgery ($n= 22$), between 11-1999 and 12-2002. Patients with a solitary intracerebral space-occupying lesion with (partial) contrast enhancement, eligible for surgical debulking with intention of gross-total resection were included. Patients who already received surgical treatment, or with other known primary tumors elsewhere in the body, were excluded. All included participants were preoperatively evaluated using 0.5T MRI. In participants assigned to surgery involving neuronavigation, a surgical plan was made by localizing the fiducial markers, determination of surgical trajectories and segmentation of the tumor boundaries on the MR image. Neuronavigational equipment could include (when applicable) an infrared pointer device and a mechanically tracked operating microscope with heads-up display. In participants assigned to 'standard' surgery, no use was made of the MR images during surgery. Final diagnosis in patients receiving 'standard' and neuronavigation surgery was glioblastoma in 16 respectively 15, anaplastic glioma in 5 respectively 3, and metastasis in 1 respectively 5. No subgroup analyses by diagnosis were performed. Relevant outcome measures included extent of resection, (subjective) cognitive deterioration and quality of life.

Table 1. Description of included studies

Studie	Intervention		Comparator		Follow-up	Outcomes
	Characteristics	Interventie type/ dose	Characteristics	Type of usual care		
Willem's (2006)	Arm 1 (n= 23) <u>Mean age (SD):</u> 60.6 (12.1) <u>Female:</u> 74% <u>Mean total tumor volume in cm³ (SD):</u> 54.2 (31.4) <u>Mean KPS (SD):</u> 77.4 (19.4) Median KPS: 80 (IQR not reported)	Surgery involving neuronavigation	Arm 2 (n= 22) <u>Mean age (SD):</u> 60.8 (12.1) <u>Female:</u> 64% <u>Mean total tumor volume in cm³ (SD):</u> 68.4 (48.9) <u>Mean KPS (SD):</u> 78.6 (15.5) Median KPS: 80 (IQR not reported)	Standard surgery	72-hours postoperative (extent of resection) 3-month postoperative ((subjective) neurological/cognitive deterioration, quality of life)	Extent of resection (%), (subjective) cognitive deterioration (EORTC QLQ-C30 (cognitive functioning subscale)), quality of life (EORTC QLQ-C30 (global health status))

Abbreviations: EORTC QLQ-C30; European organization for Research and Treatment of Cancer quality of life questionnaire C30

Results

Since no dispersion measures were reported, bar graphs for all outcomes were analyzed using the web-application WebPlotDigitizer.

Surgery with neuronavigation versus conventional MRI without neuronavigation

1. Overall survival (critical)

Median survival time was 5.6 months for participants in the group assigned to surgery involving neuronavigation, and 9 months for participants in the group assigned to 'standard' surgery. The corresponding hazard ratio was 1.6, however measures of dispersion were not reported.

2. Extent of resection (critical)

Willem's (2006) reported on extent of resection using a bar graph showing the change between preoperative and 72-hours postoperative tumor volumes (range 0%-100%). In the group assigned to surgery involving neuronavigation (n= 15), a mean of 13.6% (SD 27.7) of the preoperative tumor volume was left. In the 'standard' surgery group (n= 18), a mean of 28.7% (SD 63.5) of the preoperative tumor volume was left. The mean difference between these residual volumes was -15.10 (95% CI -47.61 to 17.41). This difference was not clinically relevant.

3. Quality of life (QoL) (critical)

Willems (2006) measured quality of life using the EORTC QLQ C30, reported as the difference between pre-operative and 3-months' post-operative QoL. Results for global health status were extracted for the purpose of this chapter (range 0-100, higher scores indicating a higher quality of life). In the group assigned to surgery with neuronavigation (n=8), the mean difference score was 4.8 (SD 24.7). In the 'standard' surgery group (n=11), the mean difference score was 8.5 (SD 53.7). The mean difference between the groups was -3.7 (95% CI -39.76 to 32.36). This difference was not clinically relevant.

4. Progression free survival and (intracranial) response (important)

These outcomes were not assessed in the study by Willems (2006).

5. Neurological/cognitive deterioration (important)

Willems (2006) measured subjective cognitive status with the European organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ C30) cognitive subscale (range 0-100, higher scores indicating a higher level of cognitive functioning), reported as the difference between pre-operative and 3-months' post-operative cognitive status. In the group assigned to surgery with neuronavigation (n=8), the mean difference score was 3.9 (SD 27.3). In the 'standard' surgery group (n=11), the mean difference score was 5.6 (SD 45.9). The mean difference between the groups was -1.70 (95% CI -34.77 to 31.37). This difference was not clinically relevant.

In the group assigned to surgery involving neuronavigation, 4 participants (18.2%) exhibited new or worsened neurological deficits, compared with 10 participants (45%) in the 'standard surgery' group. This resulted in an RR of 0.38 (95% CI 0.14 to 1.04). In 1 participant in the neuronavigation surgery group, and in 8 participants in the 'standard surgery' group, these deficits subsequently subsided either completely or partially. It is not reported how neurological deficits were defined in the study.

Level of evidence of the literature

1. Overall survival (critical)

The level of evidence regarding the outcome measure overall survival was not assessed due to lack of measures of dispersion.

2. Extent of resection (critical)

The level of evidence regarding the outcome measure extent of resection started as high as it was based on an RCT and was downgraded by three levels to very low because lack of blinding, incomplete outcome data (Willems, 2006) (-2 risk of bias), and confidence interval includes both harm and benefit (-1 imprecision).

3. Quality of life (critical)

The level of evidence regarding the outcome measure quality of life started as high as it was based on an RCT and was downgraded by three levels to very low because lack of blinding, incomplete outcome data (Willems, 2006) (-2 risk of bias), and confidence interval includes both harm and benefit (-1 imprecision).

4. Progression free survival and (intracranial) response (important)

The level of evidence regarding the outcome measures progression free survival and (intracranial) response was not assessed.

5. Neurological/cognitive deterioration (important)

The level of evidence regarding the outcome measure neurological/cognitive deterioration started as high as it was based on an RCT and was downgraded by three levels to very low because lack of blinding, incomplete outcome data (Willems, 2006) (-2 risk of bias), and confidence interval includes both harm and benefit (-1 imprecision).

Zoeken en selecteren

A systematic review of the literature was performed to answer the following question: What is the effectiveness of advanced imaging for the benefit of treatment planning (radiotherapy, neurosurgery), compared to conventional MRI in patients with glioma?

Patients: Patients with glioma or suspected of glioma for whom a treatment is planned

Intervention: Advanced imaging technique^[1]: PET, DTI, fMRI, MRS, CEST, ASL DSC, DCE, intraoperative ultrasound, neuronavigation

Comparitor: Conventional MRI, structural MRI

Outcomes: Overall survival, progression free survival, (intracranial) response, neurological/cognitive deterioration, extent of resection, quality of life

[1] DTI = diffusion tensor imaging; PET = positron emission tomography; fMRI = functional MRI; MRS = MR spectroscopy; CEST = chemical exchange saturation transfer; ASL = arterial spin labeling; DSC = dynamic susceptibility contrast; DCE = dynamic contrast enhanced.

Relevant outcome measures

The guideline development group considered overall survival, extent of resection and quality of life as a critical outcome measure for decision making; and progression free survival and neurological/cognitive deterioration as important outcome measures for decision making.

The working group defined the following minimal clinically (patient) important differences:

Survival (progression-free, or overall): hazard ratio < 0.7

Intracranial response: 0.5 SD

Extent of resection: 0.5 SD

Neurological/cognitive deterioration: EORTC cognitive functioning subscale ≥10 points

Quality of life: The minimum important difference (MID) has been estimated to be a difference of 0.08 or more points for the EQ-5D utility index, seven or more points for the EQ-5D VAS (Pickard, 2007), or EORTC global health status subscale ≥10 points

In all other cases, the working group defined the GRADE-standard limit of 25% difference for dichotomous outcomes ($RR < 0.8$ or > 1.25), and 0.5 SD for continuous outcomes as a minimal clinically (patient) important difference.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2014 until January 24th, 2022. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 248 hits. Studies were selected based on the following criteria:

- Systematic review (searched in at least two databases, and detailed search strategy, risk of bias assessment and results of individual studies available), randomized controlled trial or observational study comparing advanced imaging technique (PET, DTI, fMRI, MRS, CEST, ASL DSC, DCE, intra-operative ultrasound) with conventional MRI/structural MRI);
- Full-text English language publication;
- Studies according to PICO.

A total of 29 studies were initially selected based on title and abstract screening. After reading the full text, 28 studies were excluded (see the table with reasons for exclusion under the tab Methods), and one study was included (Willems, 2006). One systematic review matched the predefined PICO (Barbosa, 2014). This review reported on six studies including Willems (2006), however only the randomized controlled trial by Willems et al. (2006) matched the predefined PICO.

Results

One study was included in the analysis of the literature (Willems, 2006). Important study characteristics and results are summarized in table 1 and the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Verantwoording

Laatst beoordeeld : 11-07-2023

Laatst geautoriseerd : 11-07-2023

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Neuropathologie bij Gliomen

Deze submodule is onderverdeeld in de volgende sub-submodule:

- Typering/gradering diffuse gliomen

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Typering/gradering diffuse gliomen

Uitgangsvraag

Op welke wijze dient typering/gradering van diffuse gliomen plaats te vinden?

Aanbeveling

Typeren en graderen van gliomen dient te worden gedaan conform de meest recente WHO-classificatie.

Bepaal de mutatiestatus van IDH bij alle gliomen. Bij patiënten van 55 jaar of jonger met negatieve immuunhistochemie dient dit gevolgd te worden door sequencing voor IDH1 en 2 mutaties.

Onderzoek bij alle gliomen met IDH-mutatie de aan- of afwezigheid van 1p/19q-codeleties. Dit dient onderzoek van de hele arm 1p en 19q te betreffen. Indien verlies van ATRX-expressie of een ATRX-mutatie is aangetoond kan dit achterwege blijven.*

Verricht uitgebreide moleculaire karakterisering bij twijfel over de diagnose en verdenking op een glioom.

Onderzoek op de aanwezigheid van H3F3-K27-mutatie bij patiënten met een glioom in de midline, met name in de thalamus, hersenstam, cerebellum of ruggenmerg.

Bepaal tenminste de MGMT-methyleringsstatus bij oudere patiënten en/of patiënten met een slechte conditie met een glioblastoom (zie module Behandeling ouderen/kwetsbaren).

Overwegingen

In de in 2016 uitgebrachte, gereviseerde WHO-uitgave 'WHO Classification of Tumors of The Central Nervous System' is een belangrijke verandering aangebracht in de definitie van de verschillende tumoren (Louis, 2016). Waar in voorgaande edities de definities van de representanten van de diffuus infiltrerende gliomen steeds gebaseerd waren op morfologische aspecten, zijn deze sinds de editie van 2016 bepaald door discriminerende genetische mutaties die constant voorkomen en prognostische waarde vertegenwoordigen. Dit betreft mutaties van het isocitraat-dehydrogenase-gen (IDH-mutant) en het gecombineerde verlies van de chromosoomarmen 1p en 19q (1p/19q-codeletie). IDH-mutatie (IDHmut) is een prognostisch gunstig teken bij astrocytaire tumoren en is diagnostisch voor de zogeheten IDHmut-astrocytomen (Wick, 2009; Eckel-Passow, 2015; Louis, 2016). Codeletie van 1p/19q tezamen met een IDH-mutatie is diagnostisch voor een oligodendroglioom (Cairncross, 2013; van den Bent, 2015; Louis, 2016). Ook voor zeldzaam voorkomende tumoren is de genetische handtekening definiërend geworden. Subsets van tumoren zoals het bij kinderen voorkomend 'diffuse midline glioma' met een H3F3AK27M-mutatie gelden als een aparte diagnose.¹ Het voorkomen van de H3K27M-mutatie zonder de klinische context van een tumor op een midlinelocatie is echter onvoldoende om de diagnose te stellen (Louis, 2016; Meyronet, 2017; Louis, 2018).

¹Het gaat om mutaties positie K27 van de histon-coderende genen H3F3A, HIT1H3B of HIST1H3C. De mutatie H3F3A (kortweg H3.3 K27M) komt echter het meest voor en is als zodanig opgenomen in de WHO).

Ook voor de gliomen uit de 'circumscripte' groep (pilocytair astrocytoom, ganglioglioom) hebben moleculaire karakteristieken een belangrijke klinische betekenis verworven. Het pilocytair astrocytoom wordt genetisch gekenmerkt door mutaties in de genen geassocieerd met mitogen-activated proteïne kinase (MAPK), in het bijzonder het BRAF-gen. Afgezien van relevantie voor tumorclassificatie zijn bepaalde mutaties ook geassocieerd met de tumormaligniteitsgraad. Zo zijn mutaties in astrocytaire IDH-wildtype (wt) tumoren van TERT, PTEN of EGFR indicatief voor de diagnose glioblastoom.

In 2021 werd een herziene editie van de WHO-classificatie uitgebracht, waarin nieuwe inzichten in tumornomenclatuur en gradering worden geïntroduceerd, en er een nog grotere rol voor moleculaire diagnostiek is weggelegd. Het is belangrijk zich te realiseren dat de diagnostiek op basis van de thans in de classificatie opgenomen mutaties op DNA-niveau een 'moving target' is. Het is goed mogelijk dat toekomstige classificaties niet alleen andere mutaties zullen includeren, maar ook zullen worden uitgebreid met karakteristieke expressiepatronen op RNA- en eiwitniveau en vooral op basis van verschillen in methyleringsprofiel.

De transitie van de voorgaande WHO-edities naar de edities uit 2016 en 2021 waarin genetische definities worden gehanteerd, is gecompliceerd. De problemen die zich kunnen voordoen zijn:
De aansluiting van de oude op de nieuwe terminologie; in het verleden op morfologie / immunohistochemie gebaseerde diagnoses kunnen op basis van huidig moleculaire diagnostiek veranderen. Zo is de diagnose oligoastrocytoom in essentie verdwenen.

In de herziene editie van de WHO-classificatie van hersentumoren wordt de term 'NOS' (not otherwise specified) en 'NEC' (not elsewhere classified) toegepast. Indien moleculair onderzoek niet is verricht (om welke reden dan ook) of indien het technisch niet mogelijk was, zou 'niet anders omschreven' (NOS) moeten worden toegevoegd aan de diagnose, bijvoorbeeld: astrocytoom, WHO graad 2, NOS. Indien moleculair onderzoek wel is verricht en valide resultaten opleverde, maar er geen diagnose binnen de WHO classificatie aan kan worden gehangen, zou 'niet elders te classificeren' (NEC) moeten worden toegevoegd aan de diagnose, bijvoorbeeld histologisch een oligodendrogloom, maar zonder IDH-mutatie: oligodendrogloom, WHO graad 2 (of 3), NEC (Louis, 2018)

Diagnostische groepen

In onderstaande figuur worden de verschillende groepen diffuse gliomen weergegeven (Figuur 1). (kopie uit Weller, 2021)

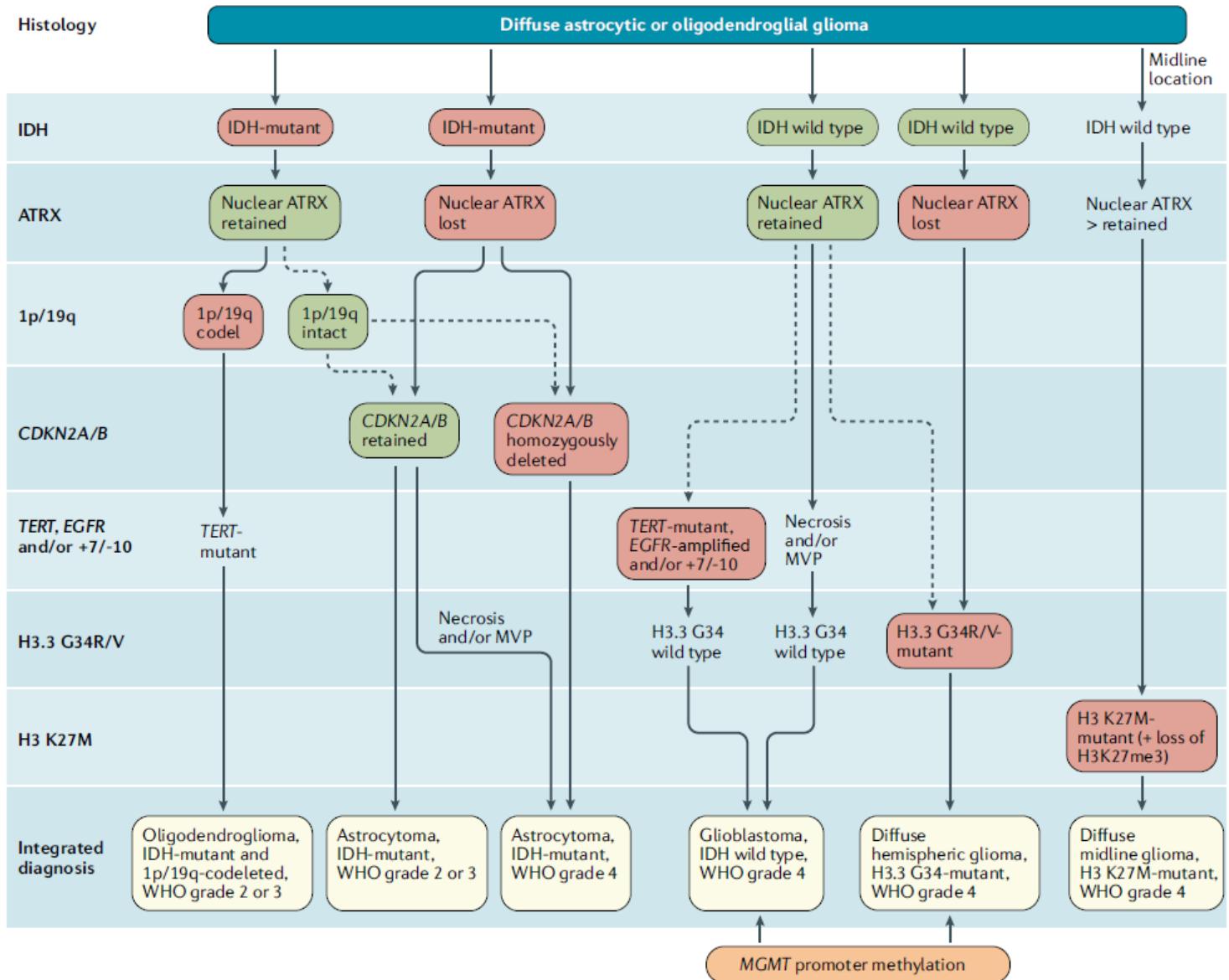


Fig. 1 | Diagnostic algorithm for the integrated classification of the major diffuse gliomas in adults. Tissue specimens obtained through biopsy sampling in patients with diffuse gliomas are routinely assessed by immunohistochemistry for the presence of R132H-mutant IDH1 and loss of nuclear ATRX. In patients aged >55 years with a histologically typical glioblastoma, without a pre-existing lower grade glioma, with a non-midline tumour location and with retained nuclear ATRX expression, immunohistochemical negativity for IDH1 R132H suffices for the classification as IDH-wild-type glioblastoma¹. In all other instances of diffuse gliomas, a lack of IDH1 R132H immunopositivity should be followed by IDH1 and IDH2 DNA sequencing to detect or exclude the presence of non-canonical mutations. IDH-wild-type diffuse astrocytic gliomas without microvascular proliferation or necrosis should be tested for EGFR amplification, TERT promoter mutation and a +7/-10 cytogenetic signature as molecular characteristics of IDH-wild-type glioblastomas². In addition, the presence of histone H3.3 G34R/V mutations should be assessed by immunohistochemistry or DNA sequencing to identify H3.3 G34-mutant diffuse hemispheric gliomas, in particular in young patients with IDH-wild-type gliomas (such as those <50 years of age with nuclear ATRX loss in tumour cells). Diffuse gliomas of the thalamus, brainstem or spinal cord should be evaluated for histone H3 K27M mutations and loss of nuclear K27-trimethylated histone H3 (H3K27me3) to identify H3 K27M-mutant diffuse midline gliomas. The presence and absence of the diagnostically most relevant molecular alterations for each tumour type are highlighted with red and green boxes. MVP, microvascular proliferation.

Gradering van gliomen

In de WHO-classificatie wordt bij de gliomen allereerst onderscheid gemaakt tussen diffuse en circumschrepte gliomen. Circumschrepte gliomen betreffen bijvoorbeeld pilocytaire astrocytomen met een essentieel andere genetische opmaak (geen IDH-mutaties, wel vaak andere mutaties zoals BRAF-KIAA), pleomorf xanthoastrocytoma (PXA) en subependymale reuscel astrocytoma (SEGA). Deze richtlijn betreft alleen de diffuse astrocytaire en oligodendrogliale tumoren; de circumschrepte blijven gezien de zeer lage prevalentie buiten beschouwing. De verschillende diagnostische categorieën zijn weergegeven in tabel 1.

De diffuse gliomen worden allereerst onderverdeeld in gliomen met en zonder IDH-mutatie; de IDH-gemuteerde tumoren worden vervolgens onderverdeeld in astrocytomen of oligodendrogliomen op basis van 1p/19q-status. Oligodendrogliale tumoren zijn per definitie IDH-gemuteerd, dit geldt in de nieuwe classificatie ook voor astrocytomen. IDH-mutant astrocytomen worden verder onderverdeeld in verschillende tumorgraderingen op basis van CDKN2A/B status en histologische kenmerken (microvasculaire proliferatie en necrose). IDH-wildtype gliomen worden glioblastoom genoemd. Patiënten met een graad 4, IDH-mutant astrocytoom hebben een significant betere overleving dan patiënten met een IDH-wildtype glioblastoom. (Shirahata 2018).

Tabel 1 Hoofdgroepen gliomen, conform WHO classificatie 2021

Diagnose	Moleculaire karakteristieken
Oligodendrogioom WHO graad 2	IDH mutant, 1p/19q codeletie
Oligodendrogioom WHO graad 3	IDH mutant, 1p/19q codeletie
Astrocytoom, IDHmut, WHO graad 2	IDH mutant, CDKN2A/B wildtype, frequent ATRX en/of TP53 mutatie
Astrocytoom, IDHmut, WHO graad 3	IDH mutant, CDKN2A/B wildtype, frequent ATRX en/of TP53 mutatie
Astrocytoom, IDHmut, WHO graad 4	IDH mutant, CDKN2A/B homozygote deletie, frequent ATRX en/of TP53 mutatie
Glioblastoom, IDHwt	IDH wildtype, vaak TERT mutatie, EGFR amplificatie, +7/-10
Diffuus 'midline' glioom	IDH wildtype, H3K27 mutatie
Diffuus hemisferisch glioom	H3 G34-mutant

Astrocytoom, IDHmut, WHO graad 2, 3 en 4

In de vorige classificatie (2016) werden er twee soorten diffuse astrocytomen gedefinieerd: astrocytomen IDHmut en astrocytomen IDHwt. In de huidige classificatie is er voor gekozen om alle IDH-mutante diffuse astrocytomen onder dezelfde noemer te scharen (astrocytoom, IDH mutant) en binnen deze groep te graderen als WHO graad 2, 3 of 4. De term glioblastoom is daarmee voor IDH-mutant astrocytomen in onbruik geraakt en alleen nog gereserveerd voor IDH wildtype WHO graad 4 astrocytomen.

IDHmut astrocytomen bestaan uit cellen die de voor astrocyten typische cytoplasmatische uitlopers of een meer afgeronde cytoplasmatische contour hebben (gemistocytair fenotype). De celkern is daarbij vaak

vergroot en kan een abnormale vorm hebben. Zodra de polymorfie en pleomorfie van de cellen sterker zijn en de astrocytaire kenmerken van astrocyten minder duidelijk zijn, veelal in combinatie met een hogere celrijkdom en tevens het frequent voorkomen van mitosen, is de diagnose astrocytoom graad 3 morfologisch van toepassing. Met name de morfologische afgrenzing tussen astrocytoom WHO-graad 2 en astrocytoom WHO-graad 3 is subjectief.

Moleculaire veranderingen

De meeste diffuse astrocytomen hebben naast de kenmerkende IDH-mutaties ook mutaties in TP53 en ATRX. In de context van een astrocytaire tumor met zowel IDH-mutatie als verlies van ATRX-expressie en/of sterke p53-positiviteit kan de diagnose diffuus astrocytoom, IDH-mutant ook gesteld worden zonder testen van 1p/19q (Louis, 2018). Een homozygote deletie van CDKN2A/B is een belangrijke diagnostische en prognostische marker in IDH-mutant astrocytomen. Omdat gebleken is dat een homozygote CDKN2A/B deletie een zeer slechte prognose met zich meebrengt, rechtvaardigt de aanwezigheid van deze mutatie een WHO graad 4 toekenning (astrocytoom, IDH-mutant, WHO graad 4), onafhankelijk van de histologische gradering. (Brat, 2020) Indien dit type tumor geen mutatie in CDKN2A/B heeft, maar histologisch wel microvasculaire proliferaties en/of necrose laat zien, is het nog steeds een graad 4 tumor, maar is de prognose beter dan wanneer er wel een homozygote CDKN2A/B deletie aanwezig is. (Shirahata, 2018)

Oligodendroglioom

Het oligodendroglioom wordt gedefinieerd als een glioom met zowel een IDH-mutatie als het verlies van zowel de hele korte arm van chromosoom 1 en de gehele lange arm van chromosoom 19 (gecombineerd 1p/19q-verlies). De klassieke morfologie bestaat uit cellen met ronde kernen waar omheen cytoplasma, waarin geen intermediaire filamenten voorkomen, en dat door fixatie meestal verdwenen is. Hierdoor ontstaat een honingraatstructuur van het tumorweefsel.

Oligodendroglomen worden onderverdeeld in WHO-graad 2 en WHO-graad 3. Voor de morfologische diagnose oligodendroglioom graad 3 is het voorkomen van microvasculaire proliferatie nodig, al of niet vergezeld door gebieden met necrose. Morfologisch kunnen oligodendroglomen graad 3 overlappen met glioblastomen, die per definitie tot de astrocytaire tumoren behoren, echter de moleculaire eigenschappen zijn leidend voor de diagnose.

Moleculaire veranderingen

Naast de diagnostische combinatie van IDH-mutatie en 1p/19q-codeletie zijn mutaties in de TERT-promotor doorgaans aanwezig. De oligodendrogliale morfologie kan gezien worden bij andere tumoren zoals clearcell ependymomen, neurocytomen, dysembryoplastische neuro-epitheliale tumoren, sommige metastasen, maar deze tumoren missen de 1p/19q-codeletie. Anderzijds kan de oligodendrogliale genetische signatuur ook gevonden worden in tumoren met overwegend astrocytaire morfologie, bijvoorbeeld tumoren met veel gemistocytaire cellen, of in de randen van oligodendroglomen, waar de morfologie van fibrillaire astrocyten kan overheersen. De moleculaire signatuur is echter leidend voor de diagnose en prognose.

Glioblastomen, IDHwt, WHO graad 4

Glioblastomen zijn diffuus infiltrerende astrocytomen van de hoogste maligniteitsgraad (WHO-graad 4), gekenmerkt door kernatypie, mitosen, microvasculaire proliferatie en necrose waarin in wisselende mate nog astrocytaire differentiatie wordt gezien.

Moleculaire veranderingen

Voor IDH-wildtype diffuse astrocytomen geldt dat de aanwezigheid van een *TERT* promotor (*TERTp*) mutatie, en/of een *EGFR* gen amplificatie, en/of +7/-10 een graad 4 toekenning rechtvaardigt. De diagnose *glioblastoom, IDH-wildtype, WHO graad 4* kan worden gesteld in IDH-wildtype gliomen met aanwezigheid van necrose en/of microvasculaire proliferaties, en/of met aanwezigheid van één of meer van genoemde moleculaire afwijkingen (Brat, 2018). Hoewel enige voorzichtigheid betracht dient te worden bij histologisch graad 2 tumoren met enkel een *TERTp* mutatie (Berzero, 2021).

MGMT-promotormethylering

Patiënten met een WHO graad 4 glioom (IDHwt glioblastoom) met een gemethyleerde MGMT-promotor hebben na behandeling met temozolamide mediaan een langere overleving dan patiënten zonder deze methylering (Hegi, 2005; Wick, 2012). Echter ook bij patiënten zonder (aangetoonde) methylering van de MGMT-promotor wordt de mediane overlevingsduur verlengd door behandeling met temozolamide, zij het veel minder uitgesproken (Perry, 2017). Derhalve heeft de methyleringsstatus van MGMT zowel een prognostische als predictieve waarde.

Diagnostische procedure

Histologische beoordeling (laesional, tumor of geen tumor, primair of metastatisch, diffuus of circumschrift, astro- of oligodifferentiatie, WHO-graad) dient altijd plaats te vinden op zo representatief mogelijk materiaal. Het vaststellen van moleculaire kenmerken kan vervolgens op twee manieren gedaan worden. Middels een next generation sequencing (NGS-)panel gericht op gliomen kunnen vrijwel alle voor gliomen relevante moleculaire veranderingen worden opgespoord¹. In geval van een histologisch niet diagnostisch biopt kan moleculaire analyse soms toch een glioom op het spoor komen (Synhaeve, 2018). Een alternatieve en minder kostbare manier om moleculaire veranderingen vast te stellen, is middels immuunhistochemie van gemuteerde of overmatig tot expressie komende eiwitten. Mutatie van IDH1, EGFRvIII, TP53 en H3K27A leidt tot expressie van een gemuteerd eiwit dat middels immuunhistochemie kan worden aangetoond. Ook ATRX-mutatie kan immuunhistochemisch worden aangetoond door verlies van ATRX-expressie en sluit een oligodendroglioom uit (Cancer Genome Atlas research Network, 2015).

¹ MGMT promotormethyleringsstatus wordt meestal in een aparte test bepaald.

De immunohistochemische test voor de expressie van het MGMT-eiwit correleert niet goed met gevoeligheid voor alkylerende chemotherapie (Quillien, 2012).

Conclusie

De uiteindelijke diagnose is een geïntegreerde diagnose op basis van de morfologische en moleculaire kenmerken. De gelaagde diagnose bestaat uit de histologische diagnose (tumorcategorie en WHO-graad), gevolgd door (alle) resultaten uit het moleculair onderzoek.

Onderbouwing

Achtergrond

In de richtlijn gliomen voor 2015 werd de diagnostiek van gliomen nog uitsluitend bepaald door microscopie, eventueel met immunohistochemie. In 2018 werd de richtlijn gereviseerd aan de hand van de criteria zoals neergelegd door de WHO in de gereviseerde vierde editie die in 2016 verscheen (Louis, 2016). In de laatste jaren is de moleculaire karakterisering verder toegenomen en verbeterd. In 2021 is er een nieuwe, vijfde, WHO-classificatie van centraal zenuwstelsel tumoren verschenen. Deze nieuwe classificatie is meegenomen in de herziening van de richtlijn in 2022/2023.

Zoeken en selecteren

Om de uitgangsvraag te kunnen beantwoorden is geen systematische literatuuranalyse verricht maar is de WHO-classificatie (Louis, 2016) gebruikt. Naast deze editie verschenen publicaties van auteurs van de WHO-editie onder de titel cIMPACT-NOW (Consortium to Inform Molecular and Practical Approaches to CNS Tumor Taxonomy – Not Official WHO) waarin additionele, bijgewerkte aanbevelingen worden gedaan. Ook deze publicaties zijn meegenomen in deze modules. In '22/'23 is de module aangepast op basis van de vijfde WHO-classificatie (2021).

Verantwoording

Laatst beoordeeld : 11-07-2023

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Behandeling Laaggradig glioom

Deze module is onderverdeeld in de volgende submodules en sub-submodules:

- Klinisch prognostische factoren laaggradig glioom
- Neurochirurgie
 - Resectie versus watchful waiting
 - Minimale mate van resectie bij laaggradig glioom
- Radio-/Chemo-/systeemtherapie
 - Behandelingen bij laaggradig glioom
 - Recidief laaggradig glioom

Verantwoording

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Laatst geautoriseerd : 15-04-2015

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Klinisch prognostische factoren laaggradig glioom

Uitgangsvraag

Wat zijn de klinisch prognostische factoren bij het laaggradig glioom?

Aanbeveling

De werkgroep is van mening dat onderstaande factoren nuttig zijn voor een onderbouwde inschatting van de levensverwachting voor patiëntenvoorlichting en/of voor het identificeren van patiënten met een ongunstige levensverwachting voor vroege behandeling bij het laaggradig glioom. Deze prognostische factoren zijn niet gevalideerd voor toepassing als indicatiecriteria voor behandeling:

- hogere leeftijd (afkapwaarde 40 jaar)
- astrocytair subtype
- grotere tumor (afkapwaarde 4 of 5 cm)
- een tumor over de middenlijn
- een slechtere conditie (KPS ≤ 80)
- eloquente lokalisatie van de tumor
- grotere diameter expansie

De werkgroep is van mening dat het bfhouden van een volume diametercurve prognostische informatie kan geven over progressievrije overleving en levensverwachting en van pas kan komen bij timing van behandeling.

Overwegingen

De prognostische factoren kunnen van pas komen om een onderbouwde inschatting van progressievrije overleving en levensverwachting te kunnen geven in het kader van voorlichting. Belangrijk is hierbij te realiseren dat de betrouwbaarheidsintervallen van deze schattingen groot zijn en dus de precisie van deze schattingen van beperkte waarde.

Over het algemeen geldt dat bij aanwezigheid van een of meer ongunstige prognostische factoren vroege behandeling en eventueel combinaties van behandelingen geadviseerd wordt. Daarbij is het belangrijk te realiseren dat onbekend is of de effectiviteit van deze behandelingen verschilt tussen patiënten met een hoger of lager risicoprofiel voor de levensverwachting. Deze prognostische factoren zijn daarom niet gevalideerd voor toepassing als indicatiecriteria voor behandeling.

Het bfhouden van een volume diametercurve in de tijd gedurende de behandeling en follow-up geeft additionele prognostische informatie over progressie en levensverwachting. Dit zou van meerwaarde kunnen zijn voor de timing van vervolgbehandeling, maar dit is niet aangetoond.

Onderbouwing

Conclusies

Het is aannemelijk dat hogere leeftijd (afkapwaarde 40 jaar), astrocytair subtype, en grotere tumor

(afkapwaarde 4 of 5 cm) ongunstige prognostische factoren zijn voor totale overleving en progressievrije overleving.

Pignatti 2002²⁶¹, Gorlia 2013¹¹³, Chang 2008⁵¹, Youland 2013⁴⁰⁴

Het is aannemelijk dat tumoruitbreiding over de middenlijn, een slechtere conditie, eloquente lokalisatie en grotere diameterexpansie ongunstige prognostische factoren zijn.

Chang 2008⁵¹, Pallud 2009²⁴⁶

Samenvatting literatuur

Pignatti [2002²⁶¹] beschreef prognostische factoren voor totale overleving op basis van data van 322 patiënt met een laaggradig glioom uit een klinische studie naar radiotherapie (constructieset) en valideerde de prognostische factoren met data van 288 patiënten met een laaggradig glioom uit een andere klinische studie (validatieset). De mediane follow-up was 6,6 jaar. In de multivariate analyse werden de volgende ongunstige prognostische factoren vastgesteld: leeftijd ≥ 40 jaar, astrocytair subtype, grootste diameter ≥ 6 cm, tumor over de middenlijn en aanwezigheid van neurologische functiestoornis. Een nieuwe analyse van dezelfde constructieset werd beschreven door Gorlia [2013¹¹³] waarbij de aanwezigheid van neurologische functiestoornis, een korte ziektegeschiedenis (<30 wk), astrocytair subtype, en tumordiameter >5 cm werden vastgesteld als ongunstige prognostische factoren voor progressievrije overleving en totale overleving. De factoren werden gevalideerd bij 450 patiënten van twee klinische studies. Drie risicogroepen (low, intermediate en high) werden onderscheiden.

Chang beschreef prognostische factoren voor progressievrije overleving en totale overleving op basis van 281 patiënten met een laaggradig glioom uit een cohort van een centrum. De mediane follow-up was 5,8 jaar. In de multivariate analyse werden deze ongunstige prognostische factoren vastgesteld: eloquente lokalisatie, KPS ≤ 80 , leeftijd >50 jaar en tumordiameter >4 cm [Chang 2008⁵¹]. Chang valideerde deze prognostische factoren bij data van 256 patiënten van drie andere ziekenhuizen. De som van deze prognostische factoren met een weging van 1 per factor correspondeert met vier risicogroepen voor progressievrije overleving en totale overleving.

De studie van Pallud beschrijft de volumetrische diameterexpansie (de diameter van het tumorvolume als bolvorm; $[2 \times \text{volume}]^{1/3}$, in de tijd) als prognostische factor voor maligne progressievrije overleving en totale overleving op basis van 407 patiënten met een laaggradig glioom. De mediane follow-up was 7,2 jaar [Pallud 2012²⁴⁸, Pallud 2013²⁴⁵]. Een expansie van ≥ 8 mm per jaar was een ongunstige prognostische factor voor maligne progressievrije overleving (tijd tot maligne transformatie of overlijden) en totale overleving onafhankelijk van leeftijd, tumorvolume, tumor over de middenlijn, contrastaankleuring en mate van resectie.

De studie van Youland beschrijft een groot cohort van 852 patiënten met een laaggradig glioom. De mediane follow-up was 11,4 jaar. De volgende ongunstige prognostische factoren werden bevestigd in multivariate analyse: leeftijd >40 jaar, astrocytaire subtype, tumordiameter ≥ 5 cm [Youland 2013⁴⁰⁴].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Neurochirurgie bij laaggradig glioom

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Resectie versus watchful waiting
- Minimale mate van resectie bij laaggradig glioom

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Resectie versus watchful waiting bij laaggradig glioom

Uitgangsvraag

Wat is de beste behandelingsstrategie bij een patiënt met een vermoedelijk laaggradig glioom in termen van kwaliteit van leven, symptoom vrije overleving, progressie vrije overleving, morbiditeit, mortaliteit en totale overleving: resectie versus 'watchfulwaiting'?

Aanbeveling

Voor een patiënt met een vermoedelijk laaggradig glioom dienen de risico's en de voordelen van de verschillende behandelstrategieën, waaronder vroege resectie, biopt of watchful waiting, individueel afgewogen te worden in een multidisciplinaire hersentumorwerkgroep.

De beslissing over de eerste behandelstappen bij een patiënt met een vermoedelijk laaggradig glioom dient in multidisciplinair overleg genomen te worden waarbij tenminste aanwezig is: een neurochirurg met ervaring met intraoperatieve stimulatiemapping van hersenfuncties, een neuroloog met oncologische expertise, een neuroradioloog, een radiotherapeut, een oncoloog en optioneel een klinisch neuropsycholoog. Idealiter wordt in de werkgroep een eerste behandelkeuze met de alternatieven geformuleerd.

De patiënt met een vermoedelijk laaggradig glioom dient daarna zo goed mogelijk geïnformeerd te worden over het natuurlijk beloop en de verschillende behandelmogelijkheden op basis van de recente literatuur. De onzekerheden van het effect van de behandelingen op overleving, kwaliteit van leven, progressievrije overleving, morbiditeit en mortaliteit zijn onderdeel van de voorlichting.

Mogelijke argumenten voor een watchful waiting beleid kunnen bestaan uit:

- twijfel aan de radiologische diagnose diffuus laaggradig glioom (ten opzichte van een benigne aandoening)
- het ontbreken van gerandomiseerd onderzoek naar het verschil in uitkomst tussen watchful waiting en een resectie;
- onzekerheid over het effect van een resectie op cognitie of kwaliteit van leven
- het uitstellen van risico's op morbiditeit en mortaliteit van een vroege resectie
- comorbiditeit die gepaard gaat met hogere morbiditeit en mortaliteit van een resectie.

Mogelijke argumenten voor een biopt kunnen bestaan uit:

- twijfel aan de radiologische diagnose diffuus laaggradig glioom
- het bepalen van moleculaire markers
- de verwachting van een beperkte mate van resectie
- uitgebreide infiltratie die past bij gliomatosis (zie module behandeling Gliomatosis cerebri)
- het vermijden van risico's op morbiditeit en mortaliteit (bijvoorbeeld door comorbiditeit) van een resectie.

Mogelijke argumenten voor een vroege resectie kunnen bestaan uit:

- het verkrijgen van een representatieve histopathologische diagnose
- het bepalen van moleculaire markers
- het verminderen van neurologische en cognitieve symptomen
- het verminderen van epileptische verschijnselen of nastreven van aanvalsvrijheid
- het verlengen van tijd tot progressie
- het verlengen van tijd tot hooggradige dedifferentiatie
- het verlengen van levensverwachting
- het verbeteren van respons op radiotherapie of chemotherapie
- het voorkómen van een resectie van een grotere tumor op hogere leeftijd.

Over het algemeen zal bij een patiënt met één of meer risicofactoren (zie module Klinisch prognostische factoren laaggradig glioom) eerder een vroege resectie overwogen worden.

Onderbouwing

Conclusies

Voor de zoekvraag werd 'watchful waiting' aanvankelijk gedefinieerd als een beleid zonder vroege tumorbehandeling (operatie, bestraling of chemotherapie), zonder een weefseldiagnose bij een vermoedelijk laaggradig glioom op basis van een MRI. Omdat voor deze vraag geen vergelijkende studies werden gevonden, werd de zoekvraag uitgebreid en 'watchful waiting' gedefinieerd als een beleid zonder vroege tumorbehandeling met een weefseldiagnose door een hersenbiopt.

Kritische uitkomstmaten

Voor de overleving van patiënten met een diffuus laaggradig glioom is op basis van het beschikbare bewijs geen directe vergelijking mogelijk tussen vroege resectie en watchful waiting **zonder** biopt, omdat geen vergelijkende studies zijn gevonden.

Er is wetenschappelijk bewijs van lage kwaliteit dat de totale overleving van patiënten met een diffuus laaggradig glioom na vroege resectie langer is dan na watchful waiting **met** een biopt. De invloed van patiëntenselectie hierop is niet vastgesteld.

Pallud 2013²⁴⁷, Jakola 2012¹⁴⁹, Jakola 2013¹⁵⁰, De Mecado Bianco 2012, Sahgal 2013²⁸⁸, Schomas 2009³⁰²

Enkel voor de subgroep van patiënten met een laaggradig astrocytoom in niet-eloquente gebieden is er bewijs van lage kwaliteit dat de totale overleving significant beter is na resectie dan na biopsie, maar bij gebrek aan risicotransfer is deze resultaten onbetrouwbaar.

Bianco 2013¹⁷

Er is geen wetenschappelijk bewijs beschikbaar over het effect van resectie versus biopsie / watchful waiting van een laaggradig glioom op de kwaliteit van leven.

Belangrijke uitkomstmaten

Voor patiënten met een diffuus laaggradig glioom is er bewijs van lage kwaliteit dat de progressievrije overleving na resectie significant beter is dan na biopsie / watchful waiting.

Jakola 2012¹⁴⁹, Jakola 2013¹⁵⁰, Pallud 2013²⁴⁵

Er is geen wetenschappelijk bewijs beschikbaar over het effect van resectie versus biopsie / watchful waiting van een diffuus laaggradig glioom op de symptoomvrije overleving.

Voor patiënten met een diffuus laaggradig glioom is er bewijs van lage kwaliteit dat het aantal neurologische en chirurgische complicaties en de operatieve mortaliteit na resectie niet significant hoger is dan na biopsie / watchful waiting.

Jakola 2013¹⁵⁰, Jakalo 2012¹⁴⁹, Bianco 2013¹⁷

Voor patiënten met een laaggradig glioom is er bewijs van lage kwaliteit dat het aantal maligne transformaties na biopsie / watchful waiting significant hoger is dan na resectie. Bij gebrek aan risicocorrectie zijn deze resultaten echter onbetrouwbaar.

Jakola 2012¹⁴⁹

Samenvatting literatuur

Voor de zoekvraag werd 'watchful waiting' aanvankelijk gedefinieerd als een beleid zonder vroege tumorbehandeling (operatie, bestraling of chemotherapie), zonder een weefseldiagnose bij een vermoedelijk laaggradig glioom op basis van een MRI. Omdat voor deze vraag geen vergelijkende studies werden gevonden, werd de zoekvraag uitgebreid en 'watchful waiting' gedefinieerd als een beleid zonder vroege tumorbehandeling met een weefseldiagnose door een hersenbiops. Diffuus laaggradig glioom werd gedefinieerd als WHO graad II glioom, zoals astrocytoom, oligodendroglioom of oligoastrocytoom (te onderscheiden van WHO graad I gliomen, zoals pilocytair astrocytoom, ganglioglioom of dysembryoplastic neuro-epitheliale tumor). Publicaties werden geïncludeerd indien gepubliceerd na 2003 en met tenminste 30 patiënten.

Met deze zoekvraag werden een Cochrane review [Veeravagu 2013³⁶⁴] en vier vergelijkende observationele studies, beschreven in vijf publicaties [Jakola 2012¹⁴⁹, Jakola 2013¹⁵⁰, De MecadoBianco 2012, Sahgal 2013²⁸⁸, Schomas 2009³⁰¹] geïdentificeerd. Na het uitwerken van de zoekvraag (23 oktober 2013) werd nog een vijfde studie gepubliceerd die aan de criteria voldeed [Pallud 2013²⁴⁵].

Kwaliteit van het bewijs

De Cochrane review is van goede kwaliteit. Het risico op bias in de vijf vergelijkende observationele studies is hoog. De vijf studies zijn retrospectief uitgevoerd. De vijf studies rapporteerden allen risicofactoren. Twee studies corrigeerden voor risicofactoren in de analyse voor totale overleving [Jakola 2012¹⁴⁹, Pallud 2013²⁴⁵]. In geen enkele observationele studie werden de uitkomsten blind beoordeeld. In alle studies was selectiebias aanwezig (selection on indication). Hierdoor zijn de gerapporteerde verschillen weinig betrouwbaar.

Gewenste effecten

Effect op totale overleving (cruciale uitkomst)

In zes publicaties van vijf studies werd het effect op de totale overleving vergeleken tussen resectie en

watchful waiting.

Een Cochrane review beoordeelde studies naar de klinische effectiviteit van een hersenbiopt vergeleken met resectie bij nieuwe patiënten met een vermoedelijk laaggradig glioom [Veeravagu 2013³⁶⁴]. Veeravagu vond geen gerandomiseerde gecontroleerde studies over deze vraag en beschrijft twintig studies die niet aan de criteria voldeden in meer detail. De Cochrane review concludeert dat behandelaars vanwege het ontbreken van gerandomiseerde studies voor elke patiënt de risico's en de voordelen van elke interventie individueel moeten wegen totdat meer bewijs beschikbaar is.

Jakola [2013¹⁵⁰] beschrijft een populatiestudie met parallelle consecutieve cohorts bestaande uit 153 patiënten met een supratentorieel diffuus laaggradig glioom (WHO graad II) tussen 1998 en 2009 en een mediane follow-up van 7 jaar: 66 patiënten uit een kliniek met een behandelvoorkleur voor watchful waiting met biopt (47 ondergingen een biopt, 19 een vroege resectie) en 87 patiënten uit een kliniek met een behandelvoorkleur voor vroege resectie (12 ondergingen een biopt, 75 een vroege resectie). De mediane overleving in de kliniek met watchful waiting voorkeur was 5,9 jaar (95%CI 4,9 -7,3). De mediane overleving in de kliniek met vroege resectie voorkeur werd in 10 jaar follow-up niet bereikt. De totale overleving was significant verschillend in het voordeel van de kliniek met vroege resectie voorkeur (log-rank p=0,01). De 5-jaarsoverleving bedroeg 60% in de kliniek met watchful waiting voorkeur versus 74% in de kliniek met vroege resectie voorkeur; de 7-jaarsoverleving bedroeg respectievelijk 44% en 68%. In de multivariate analyse met correctie voor risicofactoren (leeftijd, preoperatieve tumor diameter, midlijn betrokkenheid, histologische typering en neurologische symptomatologie) was de overleving ook significant verschillend in het voordeel van de kliniek met vroege resectie voorkeur (HR 1,8; 95%CI 1,1-2,9; p=0,03).

Jakola beschrijft een subgroepanalyse gebaseerd op dezelfde studie [Jakola 2013¹⁵⁰] van de 117 patiënten met een laaggradig astrocytoom: 55 uit de kliniek met een behandelvoorkleur voor watchful waiting (43 ondergingen een biopt, 12 een vroege resectie), 62 uit de kliniek met een behandelvoorkleur voor vroege resectie (11 ondergingen een biopt 51 een vroege resectie). De mediane overleving in de kliniek met watchful waiting voorkeur was 5,6 jaar (95%CI 3,5-7,6). De mediane overleving in de kliniek met vroege resectie voorkeur was 9,7 jaar (95%CI 7,5-11,9). De totale overleving was significant verschillend in het voordeel van de vroege resectie kliniek (log-rank p=0,047). De 5-jaarsoverleving bedroeg 56% in de kliniek met watchful waiting voorkeur versus 66% in de kliniek met vroege resectie voorkeur; de 7-jaarsoverleving bedroeg 39% en 64%, respectievelijk. In multivariate analyse met correctie voor risicofactoren (leeftijd, Karnofsky, preoperatieve tumor diameter, vroege radiotherapie) was de overleving ook significant verschillend in het voordeel van vroege resectie voorkeur (HR 1,77; 95%CI 1,02-3,05; p=0,041).

De MacedoBianco beschrijft een cohort bestaande uit 82 patiënten met een hemisferisch laaggradig astrocytoom tussen 1999 en 2008 met een mediane follow-up van 5 jaar [De MacedoBianco 2013]. Voor tumoren in niet-eloquente gebieden werd een langere overleving gevonden bij 33 patiënten na vroege resectie vergeleken met 9 patiënten na biopsie (4,7 versus 1,9 jaar, p=0,013). Voor tumoren in eloquente gebieden werd geen verschil in overleving gevonden tussen 23 patiënten na vroege resectie en 17 patiënten biopsie (4,5 versus 2,1 jaar; p=0,33).

Sahgal beschrijft een cohort van verschillende universiteitsziekenhuizen, bestaande uit 182 patiënten met een laaggradig astrocytoom tussen 1992 en 1996 en met een niet- beschreven follow-up duur [Sahgal 2013²⁸⁸]. De gemiddelde overleving was 5,5 jaar voor 84 patiënten na vroege resectie en 3,4 jaar voor 98 patiënten na biopsie; statistische analyse werd niet gerapporteerd.

Schomas beschrijft een subgroepanalyse van een cohort van de Mayo Clinic, Rochester, VS, bestaande uit 32 patiënten ouder dan 55 jaar met een niet-pilocytair laaggradig glioom tussen 1960 en 1992 en een mediane

follow-up van 17 jaar [Schomas 2009b³⁰²]. De mediane overleving van 16 patiënten na een vroege resectie was 3,0 jaar en van 16 patiënten na een biopt was 2,2 jaar ($p=0,57$).

Pallud beschrijft een cohort van verschillende universiteitsziekenhuizen bestaande uit 1509 patiënten met een diffuus laaggradig glioom tussen 1992 en 2011 en een mediane follow-up van 7 jaar. Ten opzichte van 619 patiënten na biopt bestond geen verschil in overleving van 427 patiënten na partiële resectie (HR 0,95; 95%CI 0,76-1,19, $p=0,663$), een langere overleving van 313 patiënten na subtotalresectie (HR 0,62; 95%CI 0,47-0,82, $p=0,001$, en een langere overleving van 150 patiënten na totale resectie (HR 0,32; 95%CI 0,20-0,53, $p<0,001$). In de multivariate analyse met correctie voor risicofactoren (geslacht, leeftijd, epilepsie, preoperatieve tumor diameter, midlijn betrokkenheid, tumor lokalisatie, pathologische typering, radiotherapie en chemotherapie) bestond ten opzichte van de patiënten na biopt geen verschil in overleving na partiële resectie (HR 1,10; 95%CI 0,87-1,40; $p=0,409$) of na subtotalresectie (HR 0,81; 95%CI 0,59-1,10; $p=0,169$), wel na totale resectie (HR 0,51; 95%CI 0,30-0,88; $p=0,016$).

Kwaliteit van leven (cruciale uitkomst)

In geen van de gevonden studies werd het effect op kwaliteit van leven vergeleken tussen resectie en watchful waiting.

Effect op progressievrije overleving (belangrijke uitkomst)

In drie publicaties van twee studies werd het effect op progressievrije overleving vergeleken tussen resectie en watchful waiting [Jakola 2012¹⁴⁹, Jakola 2013¹⁵⁰, Pallud 2013²⁴⁵].

Jakola [Jakola 2012¹⁴⁹] beschrijft voor patiënten met een diffuus laaggradig glioom een significant verschil in progressie (nieuwe contrastaankleuring op MRI of WHO graad III/IV in nieuwe histopathologie) tussen biopt en vroege resectie. Progressie werd geobserveerd in 56% van de 66 patiënten uit een kliniek met watchful waiting voorkeur vergeleken met 37% van de 87 patiënten uit een kliniek met vroege resectie voorkeur gedurende de follow-up ($p=0,02$). In de subgroep van patiënten met een laaggradig astrocytoom beschrijft Jakola [Jakola 2013¹⁵⁰] geen verschil in progressie tussen 56% van 66 patiënten uit een kliniek met watchful waiting voorkeur vergeleken met 43% van de 62 patiënten uit een kliniek met vroege resectie voorkeur gedurende de follow-up ($p=0,163$).

Pallud [Pallud 2013²⁴⁵] beschrijft voor patiënten met een diffuus laaggradig glioom een significant verschil in progressie (nieuwe contrastaankleuring op MRI of WHO graad III/IV in nieuwe histopathologie) tussen biopt en vroege resectie. Ten opzichte van 619 patiënten na biopt bestond een significant verschil in progressie met 427 patiënten na partiële resectie (HR 0,83; 95%CI 0,71-0,97; $p=0,019$), met 313 patiënten na subtotalresectie (HR 0,51; 95%CI 0,42-0,62; $p<0,001$) en met 150 patiënten na totale resectie (HR 0,29; 95%CI 0,21-0,41; $p<0,001$). In de multivariate analyse met correctie voor risicofactoren bestond ten opzichte van de patiënten na biopt ook een significant verschil in progressie na partiële resectie (HR 0,68; 95%CI 0,58-0,81; $p<0,001$), na subtotalresectie (HR 0,43; 95%CI 0,35-0,53; $P<0,001$) en na totale resectie (HR 0,22; 95%CI 0,16-0,32; $p<0,001$).

Ongewenste effecten

Twee studies rapporteerden over neurologische complicaties na de ingreep [Jakola 2012¹⁴⁹, Jakola 2013¹⁵⁰, Bianco 2013¹⁷]. Jakola vond geen significant verschil in nieuwe of toegenomen neurologische afwijkingen binnen de 30 dagen na de ingreep (biopsie / watchful waiting 18% versus resectie 21%; $p=0,70$) [Jakola 2012a¹⁴⁹]. Ook in de subgroep van 117 patiënten met een laaggradig astrocytoom vonden ze geen significant

verschil (13% versus 21%; $p=0.27$) [Jakola 2013¹⁵⁰]. Bianco rapporteerde een nieuwe blijvende neurologische afwijking ten gevolge van de chirurgische ingreep bij 5% van de patiënten, maar zonder een vergelijking tussen de twee behandelgroepen te rapporteren [Bianco 2013¹⁷].

Dezelfde twee studies rapporteerden ook over de perioperatieve mortaliteit. Jakola rapporteerde geen significant verschil in 30-dagen mortaliteit tussen beide behandelgroepen (biopsie / watchful waiting 1% versus resectie 0%; $p=0.25$) [Jakola 2012¹⁴⁹]. Bianco vond geen operatieve mortaliteit voor de totale populatie [Bianco 2013¹⁷].

Jakola vond geen significant verschil in chirurgische complicaties (biopsie / watchful waiting 9% versus resectie 8%; $p=0.82$), zonder een goede definitie van deze complicaties te geven [Jakola 2012a¹⁴⁹]. Bianco rapporteerde een chirurgische infectie bij 2% van de patiënten, maar zonder een vergelijking tussen de twee behandelgroepen te rapporteren [Bianco 2013¹⁷].

Tenslotte, Jakola rapporteerde significant meer maligne transformaties in de biopsiegroep (56% versus 37%, $p=0.02$), maar zonder de cijfers te corrigeren voor risicofactoren [Jakola 2012a¹⁴⁹].

Aanvullende consensus based samenvatting van de literatuur

Achtereenvolgens worden beschreven: andere (internationale) richtlijnen met aanbevelingen voor het beleid bij diffuus laaggradig glioom, de literatuur van vóór 2004, observationele cohort studies van resectie of watchful waiting, reviews over morbiditeit of mortaliteit van resectie of biopt en literatuur over een aantal behandeldilemma's.

Twee recente richtlijnen zijn gepubliceerd over het beleid bij diffuus laaggradig glioom en doen aanbevelingen voor de behandeling van het vermoedelijk laaggradig glioom op basis van een systematische literatuursearch.

De richtlijn van de European Association for Neuro-Oncology doet aanbevelingen op basis van level B bewijs [Soffietti 2010³²⁰]. In deze richtlijn wordt resectie als eerste behandeloptie geadviseerd, met als doel aan de ene kant maximaliseren van tumorverwijdering, en aan de andere kant minimaliseren van postoperatieve morbiditeit. Een biopt (stereotactisch of open) zou kunnen plaatsvinden met als doel een histologische diagnose, als een operatie niet haalbaar is (door de lokalisatie, uitgebreidheid of comorbiditeit).

De National Comprehensive Cancer Network beveelt, indien mogelijk, een maximale resectie aan met vaststellen van de mate van resectie door een MRI binnen 72 uur na operatie [NCCN 2013²²⁵].

In de literatuur vóór 2004 werd een resectie vergeleken met watchful waiting met een biopt in zes niet-gerandomiseerde vergelijkende observationele studies [Shaw 2002³⁰⁸, Jeremic 1998¹⁵⁹, Van Veelen 1998³⁶², Rajan 1994²⁷⁰, Philippon 1993²⁵⁹, North 1990²³²]. In vijf van de zes studies werd een verschil beschreven in totale overleving ten gunste van resectie, vergeleken met een biopt; in twee van de studies werd gecorrigeerd voor risicofactoren. In één studie werd een verschil in progressievrije overleving vastgesteld ten gunste van een uitgebreidere resectie.

Shaw includeerde 211 patiënten tussen 1986 en 1994 met een laaggradig glioom in een gerandomiseerde studie naar lage en hoge dosis radiotherapie [Shaw 2002³⁰⁸]. Na vijf jaar was 71% van 103 patiënten na biopsie in leven, vergeleken met 56% van 71 patiënten na een subtotaal resectie en met 88% van 29 patiënten na een totale resectie ($p=0,0151$) na een mediane follow-up van 6,4 jaar. Tussen een totale resectie en biopt (HR 0,38; $p=0,07$) en tussen subtotaal resectie en biopt (HR 1,03; $p=0,89$) werd geen significant verschil in overleving gevonden in multivariate analyse met correctie voor risicofactoren (leeftijd,

preoperatieve tumor diameter, midlijn betrokkenheid, pathologische typering, radiotherapie en instituut). Jeremic includeerde 37 patiënten tussen 1988 en 1993 met een supratentorieel laaggradig glioom [Jeremic 1998¹⁵⁹]. Na vijf jaar was 58% van 19 patiënten na biopsie in leven, vergeleken met 94% van 14 patiënten na een resectie ($p=0,009$) met een mediane follow-up van 6,2 jaar.

Van Veelen includeerde 90 patiënten tussen 1975 en 1989 met een supratentorieel laaggradig glioom [Van Veelen 1998³⁶²]. Na vijf jaar was 33% van 18 patiënten na biopsie in leven, vergeleken met 18% van 59 patiënten na een resectie <75% en met 62% van 13 patiënten na een resectie >75% ($P<0,001$). Na 5 jaar was 28% na biopsie progressievrij, vergeleken met 10% na een resectie <75% en 46% na een resectie >75% ($p<0,001$).

Rajan includeerde 82 patiënten met een laaggradig glioom [Rajan 1994²⁷⁰]. De overleving na vijf jaar was 90% bij 11 patiënten na een totale resectie, 52% bij 30 patiënten na subtotale resectie, 50% na partiële resectie en 42% na een biopsie ($p<0,05$) met een mediane follow-up van 4,2 jaar.

Philippon includeerde 174 patiënten tussen 1978 en 1987 met een supratentorieel laaggradig astrocytoom. Na vijf jaar was 45% van 33 patiënten na een biopsie in leven, 50% van 69 patiënten na een subtotale resectie en 80% van 16 patiënten na totale resectie ($p=0,00022$). De operatieve behandeling was een significante prognostische factor voor overleving ($p<0,01$) in multivariate analyse met correctie voor de risicofactoren (leeftijd, lokalisatie, lateralisatie, contrast aankleuring, cyste, histologie en radiotherapie).

North includeerde 77 patiënten tussen 1975 en 1984 met een supratentorieel laaggradig glioom [North 1990²³²]. Na vijf jaar was 43% van 26 patiënten na biopsie in leven, vergeleken met 64% van 43 patiënten na een subtotale resectie en met 85% van 8 patiënten na een totale resectie ($p=0,002$) met een mediane follow-up van 5,8 jaar.

In de literatuur werden niet-vergelijkende observationele studies beschreven waarin de patiënten die een biopsie ondergingen werden ingedeeld bij patiënten met een beperkte resectie, of waarin de mate van resectie als continue variabele werd geanalyseerd, of waarin patiënten na meer of minder uitgebreide resectie werden beschreven [Capelle 2013⁴³, Youland 2013⁴⁰⁴, Jung 2011¹⁶⁰, Ahmadi 2009², Smith 2008³¹⁹, McGirt 2008²¹⁴, Schomas 2009³⁰¹, Claus 2005⁶², Karim 1996¹⁶³, Laws 1984¹⁹⁷]. In negen van de tien niet-vergelijkende observationele studies werd een verschil in totale overleving vastgesteld ten gunste van uitgebreidere resectie, met in zeven studies correctie voor risicofactoren. In vier van de zes niet-vergelijkende observationele studies werd een verschil in progressievrije overleving vastgesteld ten gunste van uitgebreidere resectie, met in vier studies correctie voor risicofactoren.

Capelle includeerde 1097 patiënten tussen 1985 en 2007 met een laaggradig glioom [Capelle 2013⁴³], waarvan 272 patiënten na biopsie, 332 na een resectie met een tumorrest >10 ml, 262 na een resectie met een tumorrest 0-10 ml en 80 na een totale resectie op basis van MRI. De totale overleving is in univariate analyse sterk geassocieerd met het percentage tumorverwijdering ($p<0,0001$) met een mediane follow-up van 7,4 jaar. In de multivariate analyse is overleving eveneens geassocieerd met de mate van tumorverwijdering (RR 0,569; 95%CI 0,382-0,847; $p=0,0199$) met correctie voor risicofactoren (leeftijd, Karnofsky, lokatie, preoperatief tumorvolume, epilepsie).

Youland includeerde 852 patiënten tussen 1960 en 2011 met een laaggradig glioom [Youland 2013⁴⁰⁴], waarvan 321 na biopsie, 211 na totale resectie op basis van MRI, 85 na resectie van 90-99%, en 235 na resectie <90%. Na tien jaar was 60% van 296 patiënten na resectie >90% in leven en 33% van 556 patiënten na resectie <90% ($p<0,0001$) met een mediane follow-up van 11,4 jaar. Na tien jaar was 34% van 296 patiënten na resectie >90% progressievrij en 16% van 556 patiënten na resectie <90% ($p<0,0001$). In de

multivariate analyse is er een verschil in overleving (HR 0,51; 95%CI 0,40-0,65; p<0,0001) en in progressievrije overleving (HR 0,44; 95%CI 0,36-0,54; p<0,0001) ten gunste van een resectie >90% in vergelijking met een resectie <90% met correctie voor risicofactoren (leeftijd, hoofdpijn, epilepsie, taalstoornis, sensomotorische stoornis, histologische subtypering, preoperatieve tumorgrootte, diepe ligging, contrastaankleuring, radiotherapie en chemotherapie).

Jung includeerde 86 patiënten tussen 2000 en 2009 met een laaggradig glioom [Jung 2012], waarvan 40 patiënten na 'totale' resectie, 22 na 'subtotale' resectie en 24 na 'partiële' resectie of biopt. Het type operatie was geassocieerd met overleving (p<0,001) en met progressievrije overleving (p=0,001). De overleving is niet geassocieerd met type operatie met correctie voor risicofactoren (leeftijd, Karnofsky, lokalisatie, histologische subtypering, radiotherapie). In vergelijking met 'partiële' resectie of biopt is de progressievrije overleving gunstiger na 'totale' resectie (HR 0,312; 95%CI 0,101-0,966; p=0,043) met correctie voor risicofactoren (lokalisatie, diffuus groeipatroon, histologische subtypering, radiotherapie).

Ahmadi includeerde 130 patiënten tussen 1985 en 2003 met een laaggradig glioom [Ahmadi 2009²]. De totale overleving bij 91 patiënten na totale resectie was gunstiger dan bij 39 patiënten na partiële resectie of biopt (Logrankp=0,024) met een mediane follow-up van 7,8 jaar. De hazard ratio verschildde ten gunste van totale resectie (HR 4,179; 95%CI 1,527-11,435) na correctie voor de risicofactoren (histologie, lokalisatie en chemotherapie).

Smith includeerde 216 patiënten tussen 1989 en 2005 met een laaggradig glioom, waarbij biopten werden geëxcludeerd [Smith 2008³¹⁹]. Postoperatieve tumorrest (in mL) gemeten op MRI was geassocieerd met overleving (HR 1,010; 95%CI 1,001-1,019, p=0,03) en met progressievrije overleving (HR 1,007; 95%CI 1,001-1,014; p=0,035) in multivariate analyse met correctie voor risicofactoren (leeftijd, Karnofsky, lokalisatie, histologische subtypering) met een mediane follow-up van 4,4 jaar. Het percentage tumorverwijdering was geassocieerd met overleving (HR 0,972; 95%CI 0,960-0,983; p<0,001) in multivariate analyse met correctie voor risicofactoren, en niet met progressievrije overleving (HR 0,992; 95%CI 0,984-1,001; p=0,088).

McGirt includeerde 170 patiënten tussen 1996 en 2007 met een laaggradig glioom [McGirt 2008²¹⁴], waarvan 65 patiënten na totale resectie op basis van MRI, 39 na een bijna totale resectie met <3 mm resttumor en 66 na subtotale resectie met >3 mm resttumor. Na vijf jaar was 95% van 65 patiënten na totale resectie in leven, 80% van 39 na bijna totale resectie en 70% van 66 na subtotale resectie met een mediane follow-up van 4 jaar. Na tien jaar was dit 76%, 57% en 49%, respectievelijk. In vergelijking met patiënten na een subtotale resectie was de overleving na een totale resectie gunstiger (HR 0,36; 95%CI 0,16-0,84, p=0,017) met correctie voor risicofactoren (leeftijd, Karnofsky, histologische subtypering, preoperatieve, tumordiameter), maar niet na een bijna totale resectie. De mediane progressievrije overleving na totale resectie was 7 jaar, na bijna totale resectie 4 jaar en na subtotale resectie 3,5 jaar. In vergelijking met patiënten na een subtotale resectie was de progressievrije overleving na een totale resectie gunstiger (HR 0,56; 95%CI 0,32-0,98, p=0,043) in multivariate analyse met correctie voor risicofactoren (leeftijd, Karnofsky, histologische subtypering, preoperatieve, tumordiameter), maar niet na een bijna totale resectie.

Schomas includeerde 134 patiënten tussen 1960 en 1992 met een laaggradig glioom, waarvan 41 patiënten na 'totale' resectie, 33 na 'radicale subtotale' resectie, 130 na subtotale resectie en 110 na biopsie [Schomas 2009a³⁰¹]. Na tien jaar was 30% van 240 patiënten na 'subtotale' resectie of biopt in leven vergeleken met 57% van 74 patiënten na uitgebreidere resectie (p<0,001) met een mediane follow-up van 13,6 jaar. Een uitgebreidere resectie was geassocieerd met totale overleving (RR 0,63; 95%CI 0,48-0,79; p=0,03) in multivariate analyse met correctie voor risicofactoren (tumorgrootte, histologische subtypering, symptomatologie, radiotherapie). Na tien jaar was 21% van 240 patiënten na 'subtotale' resectie of biopt

progressievrij vergeleken met 47% van 74 patiënten na uitgebreidere resectie ($p<0,001$). Een uitgebreidere resectie was geassocieerd met progressievrije overleving (RR 0,74; 95%CI 0,55-0,96; $p<0,001$) met correctie voor de risicofactor tumorgrootte.

Claus includeerde 156 patiënten tussen 1997 en 2003 met een laaggradig glioom [Claus 2005⁶²]. Geen verschil werd gevonden tussen minder dan totale resectie en totale resectie in totale overleving (HR 4,9; 95%CI 0,61-40) of progressievrije overleving (HR 1,4; 95%CI 0,7-3,1) na correctie voor leeftijd met een mediane follow-up van 3 jaar.

Karim includeerde 379 patiënten in een gerandomiseerde studie naar lage dosis versus hoge dosis radiotherapie [Karim 1996¹⁶³]. De mate van tumorverwijdering (156 patiënten na biopsie of <50% resectie, 103 patiënten na 50-89% resectie en patiënten na resectie >90%) was geassocieerd met overleving ($p<0,01$) en met progressievrije overleving ($p<0,001$), ook in multivariate analyse met correctie voor risicofactoren (leeftijd, conditie, en histologie) ($p<0,05$) met een mediane follow-up van 6,2 jaar.

Laws includeerde 461 patiënten tussen 1915 en 1975 met een supratentoriaal laaggradig glioom. Na 5 jaar was 32% van 356 patiënten na een biopt of 'subtotale' resectie in leven, vergeleken met 44% van 48 patiënten na 'radicale subtotale' resectie en met 61% van 57 patiënten na 'totale' resectie ($p<0,0001$).

In de literatuur werden twee niet-vergelijkende observationele studies beschreven met patiënten die watchful waiting zonder biopt ondergingen [Reijneveld 2001²⁷⁷, Recht 1992²⁷⁴].

Reijneveld includeerde 24 patiënten tussen 1998 en 1999 met een vermoedelijk laaggradig glioom op basis van beeldvorming en matchen deze cases met 24 controle patiënten met een laaggradig glioom na biopt of resectie. Er werd geen verschil gevonden in Barthel Index, Neurologic Functional Status Scale, Karnofsky Performance Scale en Cognitive Functioning Scale. In één van acht domeinen (vitaliteit, $p<0,05$) van de SF-38, in twee van elf domeinen (motor dysfunctie, blaascontrole) van de BCM-20 en in een van vier domeinen (psychomotor functioneren, $p<0,005$) van de Cognitive Performance Status werd een verschil gevonden ten gunste van watchful waiting zonder biopt. Totale overleving of progressie-vrije overleving werd niet geanalyseerd.

Recht includeerde 26 patiënten met een vermoedelijk laaggradig supratentoriaal glioom op basis van CT of MRI die geen vroege behandeling ondergingen en 20 patiënten met een supratentoriaal laaggradig glioom die vroege behandeling ondergingen [Recht 1992²⁷⁴]. Bij 15 van 26 patiënten die aanvankelijk geobserveerd werden, vond na uitstel van 4 tot 123 maanden alsnog een operatie plaats vanwege groei (4), epilepsie (4), symptomatologie (3), en maligne transformatie (3). Bij 9 van 15 uitgestelde operaties werd een hooggradig glioom vastgesteld (5 WHO graad III en 4 WHO graad IV). In 11 van 26 patiënten vond na 15 tot 98 maanden observatie plaats. Er werd geen verschil in overleving gevonden ($p=0,65$) met een mediane follow-up van 3,8 jaar.

Een aantal reviews beschrijft argumenten die betrokken kunnen worden bij een behandeladvies voor patiënten met een laaggradig glioom.

In een systematische review werd het therapeutisch effect van mate van resectie bij glioom beschreven, onder andere voor laaggradig glioom [Sanai 2008²⁹¹]. Sanai identificeerde drie studies met volumetrische data op basis van MRI metingen na operatie voor laaggradig glioom, waarvan drie studies een gunstiger 5-jaarsoverleving beschreven na uitgebreidere resecties.

In een meta-analyse werd de neurologische morbiditeit en mortaliteit van resectie bij glioom beschreven [De Witt Hamer 2012⁷⁶]. Op basis van 90 publicaties met 8091 patiënten werd een permanente nieuwe

neurologische functiestoornis beschreven bij 7,1% (95%CI 5,3-9,0%), een permanent ernstige functiestoornis bij 4,6% (95%CI 3,3-6,1%) en operatieve mortaliteit bij 0,26% (95%CI 0,01-0,50%). Resecties met intraoperatieve stimulatie mapping van hersenfuncties gingen gepaard met minder permanent ernstige neurologische functiestoornissen dan resecties zonder stimulatie mapping (OR 0,39; 95%CI 0,23-0,64). In een review werden de effecten van resectie op de cognitie beschreven en werd geconcludeerd dat dit niet systematisch onderzocht is, maar dat zowel verbetering als achteruitgang werd waargenomen [Klein 2012¹⁷⁷]. Satoer includeerde 45 patiënten met een resectie van een glioom met eloquente lokalisatie, waarvan 27 met een laaggradig glioom [Satoer 2014²⁹⁸]. In vergelijking met gezonde controles onderpresteerden patiënten met een laaggradig glioom voor en na operatie in alle cognitieve domeinen. Drie maanden na operatie trad cognitieve verbetering op voor geheugen (verbalrecall: $t=-1,931$; $p=0,034$) en cognitieve achteruitgang voor taal (category fluency: $t=2,517$; $p=0,030$) ten opzichte van preoperatief. Tussen 3 maanden en 1 jaar na operatie verbeterde de taal (naming: $t=-2,781$; $p=0,026$ en letter fluency: $t=-1,975$; $p=0,047$). Ernstige cognitieve achteruitgang werd niet waargenomen (taal, geheugen, aandacht en executie).

Een review over de morbiditeit en mortaliteit van een biopsie bij glioom werd niet gevonden. In twee publicaties na 2003 met meer dan 100 patiënten werd morbiditeit en mortaliteit van een biopsie beschreven. McGirt beschreef een permanente nieuwe neurologische functiestoornis bij 13 (5%) en postoperatieve mortaliteit bij 3 (1%) van 270 patiënten na een hersenbiopsie [McGirt 2005²¹⁶]. Kongkham beschreef een permanente neurologische functiestoornis bij 9 (1,5%) en postoperatieve mortaliteit bij 8 (1,3%) van 622 patiënten na een hersenbiopsie [Kongkham 2008¹⁸⁰].

De radiologische diagnose 'vermoedelijk laaggradig glioom' op basis van MRI is niet accuraat volgens de literatuur. Scott beschreef bij 21 (36%) van 58 patiënten met vermoedelijk laaggradig glioom op basis van afwezigheid van contrastaankleuring een histologische gradering van WHO graad III [Scott 1992]. Meyer beschreef bij 12 (46%) van 26 patiënten met vermoedelijk laaggradig glioom een histologische gradering van WHO graad III [Meyer 2001²¹⁷]. Pallud beschreef bij 143 (16%) van 927 patiënten met een WHO graad II glioom contrastaankleuring [Pallud 2009²⁴⁶].

De histologische diagnose na een biopsie komt niet overeen met de histologische diagnose na een resectie volgens de literatuur: Jackson beschrijft bij 40 (49%) van 82 patiënten na een biopsie voor een glioom een andere histologische diagnose na resectie binnen 60 dagen na het biopsie [Jackson 2001¹⁴⁷]. Dit had therapeutische consequenties bij 27 (33%) patiënten. Bij 13 (72%) van 18 patiënten met een histologische diagnose WHO graad II na biopsie was sprake van een WHO graad III of IV. Jackson reviewde 6 studies en concludeerden dat de diagnostische precisie van een biopsie 62-95% was in vergelijking met een histologische diagnose op materiaal van een resectie.

Tot slot komt een aantal behandeldilemma's in de praktijk voor, dat gepaard gaat met meer onzekerheid over de behandelstrategie op basis van de literatuur: ten eerste een vermoedelijk laaggradig glioom als toevalsbevinding op beeldvorming, ten tweede een supratotale resectie voor een vermoedelijk laaggradig glioom.

Beeldvorming bijvoorbeeld na een neurotrauma of de controlegroep in radiologisch onderzoek doet een laaggradig glioom als toevalsbevinding, vermoeden bij 1 op 2000 MRI-onderzoeken [Morris 2009²²²]. Er bestaat geen vergelijkend onderzoek tussen vroege en late behandeling bij patiënten met een laaggradig glioom als toevalsbevinding. Voorstanders van een vroege resectie argumenteren dat de voordelen van resectie van een laaggradig glioom in een zeer vroeg stadium groter kunnen zijn, omdat de tumor nog kleiner is en completer operatief te verwijderen, terwijl de morbiditeit lager kan zijn [Kelly 2010¹⁶⁸; Pallud 2010²⁴⁷;

Duffau 2012⁸⁵; Potts 2012²⁶³]. Voorstanders van een late behandeling argumenteren dat de nadelen van een resectie veilig uitgesteld kunnen worden als MRI-follow-up plaatsvindt [Shah 2011³⁰⁷].

Er bestaat geen vergelijkend onderzoek voor een resectie met een ruime marge van niet-MRI-afwijkend weefsel, een zogenaamde supratotale resectie. Voorstanders van een supratotale resectie argumenteren dat een supratotale resectie waarschijnlijk een groter deel van de infiltrerende glioomcellen kan verwijderen mits uitgevoerd met intraoperatieve stimulatie mapping voor hersenfuncties [Yordanova 2011⁴⁰²].

In de meerderheid van bovengenoemde studies wordt een betere overleving bij resectie gemeld dan bij de 'watchful waiting' benadering. Dit behoeft enige nuancering. Alle genoemde artikelen zijn retrospectief van aard of betreffen cohortstudies en kunnen dus geen uitsluitsel geven over welke benadering superieur is.

Prospectief gerandomiseerde studies zullen zeer waarschijnlijk niet snel uitgevoerd worden vanwege ethische bezwaren. De belangrijkste problemen in de genoemde studies zijn de selectie bias en de eerder genoemde sampling error bij biopsie en beeldvorming bij een vermoedelijk laaggradig gliom. Zeer waarschijnlijk spelen de publicatiebias en conformation bias ook een rol, maar deze worden nu buiten beschouwing gelaten.

Hoewel een aantal studies corrigeert voor pathologische, klinische en radiologische karakteristieken in de multivariate analyse, kan niet worden uitgesloten dat onbekende factoren een rol kunnen spelen bij de selectie door de chirurg om te kiezen voor een radicalere benadering in plaats van watchful waiting. Een voorbeeld is de delineatie van de tumor op MRI. Hier wordt in geen van de genoemde artikelen voor gecorrigeerd. Een tumor met scherpe delineatie op MRI is over het algemeen makkelijker en 'radicaler' te opereren, maar heeft ook een betere prognose dan een infiltrerend laaggradig astrocytoom volgens sommigen [Ius 2012¹⁴⁵], terwijl andere auteurs dit weerspreken [Chang 2008⁵⁰]. Hoe scherper de delineatie op MRI, hoe eerder een chirurg zou kunnen beslissen om te opereren. De betere overleving kan zo gemakkelijk gerelateerd worden aan chirurgie, terwijl patiënten met een dergelijke tumor in feite al op voorhand een betere prognose hebben.

De keuze voor een behandeling kan afhankelijk zijn van veel factoren (zie aanbeveling). Belangrijk is om de patiënt goed te informeren over de voor- en nadelen van de verschillende behandelopties. Vooralsnog blijkt uit de literatuur niet dat een watchful waiting behandeling nadelig is voor geselecteerde patiënten met een laaggradig gliom [Whittle 2010³⁸⁵]. De benadering van Whittle kan misschien dienen als voorbeeld, waarbij het uitgangspunt is dat de patiënt zich comfortabel moet voelen met zijn of haar keuze voor een behandelstrategie, en dat het behandelteam dit beter vanuit een zekere flexibiliteit kan benaderen dan vanuit dogma.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Minimale mate van resectie bij laaggradig glioom

Uitgangsvraag

Wat is de minimale mate van resectie die zinvol is bij een patiënt met een laaggradig glioom?

Aanbeveling

Er is geen minimale mate van resectie aan te geven die zinvol is bij de indicatiestelling voor een operatie bij een patiënt met een vermoedelijk laaggradig glioom. Er zijn aanwijzingen dat een grotere mate van resectie zinvol kan zijn, maar er is geen minimaal zinvol percentage tumorverwijdering aan te geven en de betrouwbaarheid van de preoperatieve inschatting van de mate van resectie door de neurochirurg is onzeker.

In het geval een resectie wordt uitgevoerd, is het meten van de mate van resttumor en de mate van tumorverwijdering met behulp van pre- en postoperatieve MRI (flairopnames) te overwegen (zie module Beeldvormende diagnostiek).

Overwegingen

Omdat de mate van resectie alleen na een operatie vastgesteld kan worden en niet voorafgaand of tijdens een operatie, is de uitgangsvraag ook in de toekomst niet te beantwoorden met een gerandomiseerde studieopzet. Een grote of kleine mate van resectie kan niet tussen patiënten worden gerandomiseerd.

Bij de interpretatie van bovengenoemde studies is het evenwel een gegeven dat resultaten retrospectief zijn en sterk beïnvloed kunnen zijn door selectiebias. Fittere patiënten ondergaan immers de meer uitgebreide resecties, maar omdat gerandomiseerde data ontbreken kan geen uitspraak worden gedaan of de goede performance vooraf óf de mate van resectie de belangrijkste parameter voor langere overleving is.

In de besproken literatuur werden verschillende methodes gebruikt om het resectiepercentage van de tumor te meten. Tegenwoordig is volumetrie met flairopnames gebruikelijk, maar nog niet gestandaardiseerd. Studies waarin gebruik gemaakt wordt van de impressie van de chirurg als mate van resectie via operatieverslagen zijn onvoldoende betrouwbaar [Orringer 2012²⁴¹].

De patiënten die in deze publicaties werden beschreven zijn geselecteerd op basis van de histopathologische gradering die pas dagen na een operatie bekend is. Voor patiënten waarbij een inschatting gedaan wordt over de minimale mate van resectie voorafgaand aan een operatie staat in de klinische praktijk (nog) niet vast dat het daadwerkelijk een laaggradig glioom betreft. Wellicht verschilt de minimale mate van resectie bij een anaplastisch glioom van een laaggradig glioom.

Het is niet bekend in hoeverre de preoperatieve schatting van mate van resectie correspondeert met de behaalde mate van resectie voor deze patiënten. Zodoende is de waarde hiervan voor het selecteren van patiënten voor een 'zinvolle' resectie onduidelijk.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat een grotere mate van resectie bij een laaggradig glioom gepaard gaat met een

langere overleving en langere tijd tot progressie.

Pallud 2014²⁴⁴, Youland 2013⁴⁰⁴, Capelle 2013⁴³, Ius 2012¹⁴⁵, Schomas 2009³⁰¹, McGirth 2008²¹⁴, Smith 2008³¹⁹

Er zijn aanwijzingen dat bij een laaggradig glioom een langere overleving wordt behaald bij een minimaal percentage tumorverwijdering van respectievelijk 40%, 50%, 70%, 90%, of 100%; of als alternatieve mate van resectie uit een maximaal restvolume van nul mL, 10 mL, 15 mL, of 30 mL. Er is dus geen eenduidige minimale mate van resectie die de overleving verlengt.

Smith 2008³¹⁹, Capelle 2013⁴³, Ius 2012¹⁴⁵, Youland 2013⁴⁰⁴, Schomas 2009³⁰¹, McGirth 2008²¹⁴, Pallud 2014²⁴⁴

Samenvatting literatuur

In de literatuur werd geen publicatie gevonden die deze uitgangsvraag als onderzoeksvorag direct beantwoordt. In vergelijkend onderzoek in cohorten van patiënten die een operatie ondergingen voor een laaggradig glioom werd de mate van resectie weergegeven als percentage verwijderd tumorvolume of als restvolume. Deze parameters werden verschillend gecategoriseerd zonder dat duidelijk wordt op welke gronden deze categorieën tot stand kwamen.

Hiernavolgend worden de publicaties besproken die (a) meer dan 100 patiënten na operatie voor laaggradig glioom beschreven, (b) de mate van resectie baseerden op MRI-metingen, en (c) na 2000 werden gepubliceerd.

In zeven retrospectieve chirurgische series werd een significante associatie vastgesteld tussen overleving en uitgebreidere mate van resectie, waarbij de mate van resectie soms gekwantificeerd werd als percentage tumorverwijdering, soms als rest tumorvolume in mL.

Pallud [Pallud 2014²⁴⁴] beschreef 1509 patiënten tussen 1992 en 2011, waarvan 890 een resectie ondergingen en 619 een biopsie. Pre- en postoperatieve tumorvolumes werden gemeten op de flair- opnames van de MRI. Partiële resectie werd gedefinieerd als een restvolume ≥ 10 mL (427 patiënten), subtotal resectie als een restvolume < 10 mL maar > 0 mL (313 patiënten), en een totale resectie als afwezigheid van restvolume (150 patiënten) op de MRI. Ten opzichte van de subgroep met biopsie of partiële resectie was de overleving langer bij totale resectie (HR: 0,51; 95%CI 0,30-0,88; p = 0,016) en bij subtotal resectie (HR: 0,81; 95%CI 0,59-1,10; P = 0,169). De tijd tot overlijden of maligne transformatie was langer na totale resectie (HR: 0,22; 95%CI 0,16-0,32; p <0,001) en na subtotal resectie (HR: 0,43; 95%CI 0,35-0,53; p <0,001) ten opzichte van de subgroep na biopsie of partiële resectie.

Youland [Youland 2013⁴⁰⁴] beschreef 852 patiënten tussen 1960 en 2011, waarvan een subgroep van 517 patiënten werd behandeld tussen 1990 en 2011, waarbij 349 patiënten een resectie ondergingen en 222 patiënten een biopsie. De mate van resectie werd bepaald door pre- en postoperatieve beeldvorming te vergelijken of, indien dit niet beschikbaar was, via de operatieverslagen. Totale resectie werd gedefinieerd als afwezigheid van resttumor op MRI (176 patiënten), radicale subtotal resectie als een verwijderd volume van > 90% (55 patiënten), en subtotal resectie als een verwijderd volume van < 90% (118 patiënten). Na totale of radicale subtotal resectie leefden patiënten langer ten opzichte van de subgroep met biopsie of subtotal

resectie (gecorrigeerde risico ratio: 0,61; 95%CI 0,43-0,86; p = 0,004). Na totale of radicale subtotalresectie was de tijd tot progressie langer dan in de subgroep na biopsie of subtotalresectie (gecorrigeerde risico ratio: 0,45; 95%CI 0,35-0,59; p < 0,001).

Capelle [Capelle 2013⁴³] beschreef 1091 patiënten die behandeld werden tussen 1985 en 2007, waarvan 674 een resectie ondergingen, 619 een biopsie, en bij 165 behandeling werd uitgesteld. Pre- en postoperatieve tumorvolumes werden gemeten op T1-, T2- en flairoppnames. Er werd onderscheid gemaakt in het percentage tumor dat verwijderd was. Bij 80 patiënten was de tumor voor 100% verwijderd, bij 418 patiënten was tussen 50 en 99% van de tumor verwijderd en bij 431 patiënten was minder dan 50% verwijderd. Complete resectie werd gedefinieerd als geen restvolume op MRI (80 patiënten), subtotalresectie als een restvolume <10 mL en > 0 mL (266 patiënten), een partiële resectie als een restvolume >10 mL (583 patiënten). Het percentage tumorverwijdering als continue parameter was geassocieerd met een gunstiger overleving (gecorrigeerde relatieve risico: 0,569; 95%CI 0,382-0,847; p = 0,0199). De overlevingscurves van complete, subtotalresectie, en partiële resectie lopen uiteen tot 14 jaar follow-up zonder dat hiervoor statistische significantie werd berekend.

Ius [Ius 2012¹⁴⁵] beschreef 190 patiënten die behandeld werden tussen 1998 en 2011, en die een resectie ondergingen van een laaggradig glioom in een eloquente lokalisatie. De mate van resectie werd bepaald door pre- en postoperatieve volumetingen op T2-gewogen MRI-opnames. Dit werd gemeten als percentage tumorverwijdering en als volume resttumor. Zo werd bij 30 patiënten minder dan 70% tumor verwijderd, bij 69 werd tussen 70 en 89% en bij 91 werd meer dan 90%. Bij 11 patiënten bestond een tumor restvolume van minder dan 10mL, bij 41 patiënten tussen 11 en 20 mL, bij 16 patiënten tussen 21 en 30 mL en bij 22 patiënten meer dan 31mL. Patiënten met een percentage tumorverwijdering tussen 70 en 89% leefden korter dan patiënten met meer dan 90% tumorverwijdering (HR: 4,85; 95%CI 1,79-13,1; p = 0,002). Ook patiënten met minder dan 70% tumorverwijdering leefden korter dan patiënten met meer dan 90% tumorverwijdering (HR: 19,7; 95%CI 7,01-54,8; p < 0,0001). Een hoger percentage tumorverwijdering als continue parameter was significant geassocieerd met langere overleving (HR per procent: 0,933; 95%CI 0,915-0,952; p < 0,0001). Bij patiënten met een rest tumorvolume van minder dan 10 mL was de overleving langer dan bij een rest tumorvolume tussen 11 en 20 mL (HR: 3,28; 95%CI 1,34-8,04; p = 0,009), bij een rest tumorvolume tussen 21 en 30 mL (HR: 6,50; 95%CI 2,43-17,4; P < 0,0001), en bij een rest tumorvolume meer dan 30 mL (HR: 14,0; 95%CI 5,68-34,4; p < 0,0001). Een kleiner rest tumorvolume als continue parameter was geassocieerd met een langere overleving (HR per mL tumorrest: 1,02; 95%CI 1,01-1,03; P < 0,0001). Ten opzichte van de patiënten met meer dan 90% tumorverwijdering hadden de patiënten met tussen 70 en 89% tumorverwijdering kortere tijd tot maligne transformatie (HR: 2,55 (95%CI 1,35-4,84; p = 0,004), evenals de patiënten met minder dan 70% tumorverwijdering (HR: 9,77; 95%CI 4,85-19,7; p < 0,0001). Meer tumorverwijdering per procent was geassocieerd met kortere tijd tot maligne transformatie (HR: 0,944; 95%CI 0,928-0,960; p < 0,0001). Ten opzichte van de patiënten met een rest tumorvolume van minder dan 10 mL was de tijd tot maligne transformatie korter voor patiënten met een rest tumorvolume tussen 11 en 20 mL (HR: 1,54; 95%CI 0,80-2,97; p = 0,20), evenals voor patiënten met een rest tumorvolume tussen 21 en 30 mL (HR: 2,98; 95%CI 1,37-6,50; p = 0,006), evenals voor patiënten met een rest tumorvolume van meer dan 31 mL (HR: 8,74; 95%CI 4,41-17,3; p < 0,0001). Meer tumorrest per mL was geassocieerd met een kortere tijd tot maligne transformatie (HR: 1,02; 95%CI 1,01-1,03; P < 0,0001).

Schomas [Schomas 2009³⁰¹] beschreef 314 patiënten tussen 1960 en 1992, waarvan 204 een resectie ondergingen en 110 een biopsie. De mate van resectie werd bepaald door het operatieverslag, de impressie van de chirurg en postoperatieve beeldvorming, indien aanwezig. Totale resectie werd gedefinieerd als afwezigheid van resttumor (41 patiënten), radicale subtotalresectie als een verwijderd volume van meer dan 90% (33 patiënten), en subtotalresectie als een verwijderd volume van minder dan 90% (130 patiënten). Patiënten leefden na biopsie of subtotalresectie korter dan patiënten na totale of radicale subtotalresectie (gecorrigeerde relatieve risico: 0,74; 95%CI 0,55-0,96; P < 0,001).

McGirth [McGirth 2008²¹⁴] beschreef 170 patiënten die tussen 1996 en 2007 een resectie ondergingen. De mate van resectie werd door de radioloog bepaald op pre- en postoperatieve flairoopnames van de MRI. Als 'gross total resection' werd gedefinieerd de afwezigheid van resttumor (65 patiënten), als 'near total resection' een rest met een dikte minder dan 3 mm rond de resectieholte (39 patiënten), en als subtotalresectie een nodulaire resttumor (66 patiënten). Ten opzichte van de patiënten met een subtotalresectie leefden patiënten na een 'gross total resection' langer (gecorrigeerde HR: 0,36; 95%CI 0,16-0,84; p = 0,017), evenals na een 'near total resection' (gecorrigeerde HR: 0,87; 95%CI 0,38-1,98; p = 0,63). Ten opzichte van de patiënten na een subtotalresectie was de tijd tot progressie langer na 'gross total resection' (gecorrigeerde HR: 0,56; 95%CI 0,32-0,98; p = 0,043) evenals na 'near total resection' (gecorrigeerde HR: 1,01; 95%CI 0,69-1,99; p = 0,75).

Smith [Smith 2008³¹⁹] beschreef 216 patiënten, behandeld tussen 1989 en 2005, die een resectie ondergingen. Pre- en postoperatieve tumorvolumes werden gemeten op de flairoopnames van de MRI. De mate van resectie werd berekend als percentage tumorverwijdering op MRI. Bij 21 patiënten werd een resectie met 0 tot 40% tumorverwijdering uitgevoerd, bij 94 patiënten met 41 tot 89%, bij 26 patiënten met 90 tot 99% en bij 75 patiënten met 100%. Daarnaast werd het tumor- restvolume berekend. Bij 75 patiënten resteerde 0 mL tumor, bij 37 patiënten tussen 1 en 5 mL, en bij 38 patiënten tussen 5,1 en 15mL. Een hogere mate van tumorverwijdering als percentage was geassocieerd met een langere overleving (gecorrigeerde HR per procent: 0,972; 95%CI 0,960-0,983; p <0,001) en een langere tijd tot maligne transformatie (gecorrigeerde HR per procent: 0,983; 95%CI 0,972-0,995; p = 0,005). Een kleinere mate van resttumor in mL was eveneens geassocieerd met een langere overleving (gecorrigeerde HR per mL: 1,010; 95%CI 1,001-1,019; p = 0,03) en een lange tijd tot maligne transformatie (HR: 1,005; 95%CI 0,996-1,014; p = 0,32).

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Radio-/chemotherapie bij laaggradig glioom

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Behandelingen bij laaggradig glioom
- Recidief laaggradig glioom

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Behandeling bij nieuw gediagnosticeerd laaggradig glioom

Uitgangsvraag

Welke patiënten met een laaggradig glioom komen in aanmerking voor een vervolgbehandeling na operatie?

De zoekvraag omvat de volgende deelvragen:

- Wat is het effect van chemotherapie bij patiënten met een laaggradig glioom?
- Wat is het effect van radiotherapie bij patiënten met een laaggradig glioom?
- Wat is het effect van chemotherapie en radiotherapie bij patiënten met een laaggradig glioom?

Aanbeveling

Bespreek een 'wait and scan' beleid met de patiënt indien er geen negatieve prognostische factorer¹ zijn EN er sprake is van een radicale resectie.

Geef radiotherapie gevolgd door chemotherapie bij:

- minstens twee negatieve prognostische factoren¹ waarbij een grote rest tumor en/of farmacoresistente epilepsie postoperatief ook als negatieve prognostische factoren gelden;
- patiënten bij wie om andere redenen de indicatie voor nabehandeling gesteld is.

Geef radiotherapie 50,4 Gy bij patiënten met een laaggradig glioom zonder moleculaire hooggradige kenmerken. Het is niet aangetoond dat meer dan 50,4 Gy de overleving verbetert.

Geef bij voorkeur bij tumoren met 1p/19q-codeletie zes kuren PCV-combinatietherapie en bij tumoren zonder 1p/19q-codeletie bij voorkeur 12 kuren temozolomide monotherapie.

Beschouw tumoren met een IDHwt en met moleculaire kenmerken van een glioblastoom als een glioblastoom.

Pas shared decision making toe waarbij de te verwachten effecten en voor- en nadelen van de verschillende behandelopties met de patiënt besproken worden.

Bespreek dat sequentiele radio- en chemotherapie de gemiddelde overleving verlengt, maar dat een langere overleving de kans op cognitieve verslechtering vergroot

¹ Zie module 'Klinisch prognostische factoren laaggradig glioom.'

Overwegingen

In de nieuwste WHO-classificatie speelt moleculaire diagnostiek een grote rol, echter studies gepubliceerd voor 2016 hielden daar geen rekening mee (Louis, 2016) (zie module Diagnostiek - neuropathologie - typering/gradering diffuse gliomen). Bij een glioom die pathologisch gegradeerd wordt als een laaggradig

glioom heeft de afwezigheid van een IDH-mutatie een slechte prognose. In combinatie met een EGFR-amplificatie, +7/-10-mutatie en/of aanwezigheid van een TERT-promotormutatie kan de tumor worden gekarakteriseerd als glioblastoom (zie module Diagnostiek - neuropathologie - typering/gradering diffuse gliomen).

Alle gerandomiseerde studies geïncludeerd in de literatuursamenvatting zijn van toepassing op supratentoriële laaggradige gliomen. Er kunnen dus geen uitspraken gedaan worden over infratentoriële of ruggenmerggliomen.

Voorts ontbreekt een controlegroep zonder behandeling in de studies vanwege ethische overwegingen. Het natuurlijk beloop van laaggradige gliomen kennen we daarom niet.

Als er geen negatieve prognostische factoren zijn (zie module Klinisch prognostische factoren laaggradig glioom) EN er sprake is van een radicale resectie, dan kan er een afwachtend beleid volgen.

Chemotherapie

Vanwege de lage bewijskracht van de studie van Baumert (2016) kan geen harde uitspraak over het tijdstip van inzetten van aanvullende behandeling gedaan worden, al wordt wel een periode van maximaal twaalf weken tussen chirurgie en de aanvang van chemotherapie aanbevolen.

Radiotherapie

Alhoewel de EORTC-22854-studie kwaliteit van leven niet analyseerde, werd een significant lagere frequentie van epilepsie na één jaar gezien in de groep patiënten die postoperatieve radiotherapie kreeg (25%) ten opzichte van de groep met uitgestelde radiotherapie (41%) ($p=0,0329$), waardoor bij geselecteerde patiënten met onbehandeld laaggradig glioom en moeilijk behandelbare epilepsie te overwegen valt om eerder te bestralen (van den Bent, 2005).

Twee studies die niet in de literatuursamenvatting zijn meegenomen omdat deze de uitgangsvraag niet beantwoordden, maar wel de effecten op cognitie na radiotherapie onderzochten, zijn Brown (2003) en Douw (2009). Brown (2003) vond bij 203 volwassen patiënten, gerandomiseerd in twee groepen met lage of hoge dosis radiotherapie, geen onderling verschil in MMSE-scores in 7,4 jaar follow-up. In beide groepen werd wel een significante verbetering in cognitie gezien ten opzichte van de baselinemeting. Douw (2009) heeft in een cohortstudie met een follow-up van twaalf jaar cognitie gemeten door middel van uitgebreide testen bij patiënten met een laaggradig glioom behandeld met of zonder radiotherapie. Terwijl er zes jaar na diagnose geen verschil in cognitie te zien was, bleek de concentratie beduidend verminderd te zijn twaalf jaar na radiotherapie. Overigens zijn deze resultaten mogelijk gebiased doordat patiënten met progressieve ziekte werden geëxcludeerd. Daarom is het aan te raden om prognostische factoren (zie module Klinisch prognostische factoren laaggradig glioom) door de behandelaar mee te laten wegen bij het al dan niet vroegtijdig starten van radiotherapie (Pignatti, 2002; Douw, 2009; van den Bent, 2012; Shields, 2014).

Aanvullend is een Pubmed search op de termen "cognitive effects" en "neurocognition" in combinatie met "low grade glioma" verricht. Hieruit kwamen 83 titels waarvan de meeste niet standaard therapie-effect op neurocognitie onderzochten. Uiteindelijk werden 14 titels nader onderzocht op abstract waarbij opnieuw een

aantal afvielen wegens pediatrische studie, enkel MMSE of niet gericht op effect van chemo- of radiotherapie. Naast drie artikels uitgezocht op full tekst werd een artikel van Klein (2012) toegevoegd.

Correa (2007) onderzocht neurocognitief effect van radiotherapie en chemotherapie versus "wait-and-scan beleid" bij 41 patiënten met een laaggradige glioom door middel van een uitgebreid gestandaardiseerd neuropsychologische testpanel. Er mocht geen tumorprogressie tijdens follow-up zijn ontstaan bij een mediane therapie interval van 3 jaar ten opzichte van testafname. Ondanks de kleine aantallen bleek de behandelde groep significant lagere neurocognitieve scores te hebben ten opzichte van de onbehandelde groep. Deze effecten bleken meer uitgesproken indien de behandeling langer geleden was dan 3 jaar.

Laack (2005) onderzocht neurocognitief effect van radiotherapie door middel van uitgebreide testbatterij naast MMSE bij twintig patiënten met een laaggradig glioom. Metingen werden vooraf de bestraling en vervolgens elke 18 maanden tot max 5 jaar na bestraling verricht. Er werd geen effect gezien in dosering van bestraling tussen een groep met 50,4 Gy of 64,8 Gy. Hierbij dient bemerkt te worden dat dit om kleine aantallen gaat.

Klein (2002) onderzocht neurocognitie in een veel grotere groep patiënten (n=195) met follow-up van 1 tot 22 jaar na bestraling van een laaggradig glioom. Ook in deze studie werden meerdere neuropsychologische domeinen onderzocht middels testbatterijen. Ook hier werd leek bestraling een negatief effect op neurocognitie te hebben echter het effect van de tumor zelf en het gebruik van anti-epileptica hadden een groter effect op cognitie dan radiotherapie. In een vervolgstudie met langere follow-up van gemiddeld 12 jaar (n=65), echter, laat de helft van de bestraalde patiënten een achteruitgang zien van aandachtsfuncties in vergelijking met 27% in de onbehandelde groep. Concluderend lijken er aanwijzingen te zijn dat radiotherapie op lange termijn de cognitie (met name aandacht) negatief beïnvloedt.

Een bestralingsdosis van 50 tot 54 Gy in fracties van 1,8 Gy wordt wereldwijd het meest gebruikt en geadviseerd bij de behandeling van patiënten met een laaggradig glioom. Indien de beslissing, in overleg met de patiënt, genomen is om te bestralen, heeft het de voorkeur om sequentieel chemokuren toe te dienen (op basis van CATNON- en NOA-04-studies), tenzij er specifieke contra-indicaties of wensen van de patiënt zijn om dit niet te doen (Wick, 2009; van den Bent, 2017).

De radiotherapie en beeldvorming technieken hebben over de tijd een grote evolutie doorgemaakt, waardoor het radiotherapie doelvolume nauwkeuriger kan worden bepaald en behandeld. De uitkomsten op cognitie van de besproken studies zijn verkregen met radiotherapie technieken die niet representatief zijn voor de huidige praktijk.

De definitie van het radiotherapie-doelvolume is gebaseerd op een recente MRI (Kwaliteitscriteria neuro-oncologie 2017). Het te bestralen gebied omvat het hyper intense gebied op de T2- of FLAIR-sequenties met een beperkte marge voor microscopische ziekte. Het gebruik van geavanceerde radiotherapietechnieken zijn de norm (Werkafspraken volgens Landelijk Platform Neuro-oncologie van de NVRO).

Chemotherapie en radiotherapie

De studie van Buckner (2016) liet zien dat patiënten met IDHmut tumoren een langere progressievrije

overleving hebben ten opzichte van IDHwt tumoren, ongeacht de behandelarm (echter was de subgroep met IDHwt te klein voor een statistische analyse). Gunstige prognostische factoren zijn: behandeld met chemotherapie gecombineerd met radiotherapie, oligodendroglioom als histologie en leeftijd jonger dan 40 jaar. De overall survival (OS) was superieur voor de gecombineerde therapie voor alle histologische groepen, al was het verschil voor de astrocytoma groep niet significant. De beperkte data die er zijn lieten geen afname in kwaliteit van leven of cognitie zien door toevoeging van PCV-kuren aan radiotherapie (Prabhu, 2014; Habets, 2014). Daarom wordt aangeraden dat de behandelaar altijd de gecombineerde behandeling in overweging neemt.

Studies die temozolamide in plaats van PCV bij patiënten met laaggradige gliomen onderzoeken, ontbreken. Bij de anaplastische gliomen werd echter in de gerandomiseerde fase III NOA-04-studie geen verschil aangetoond in progressievrije overleving tussen PCV en temozolamide, maar de studie was hier ook niet voor gepowered (Wick, 2009) (zie ook module Chemotherapie nieuw gediagnosticeerd anaplastisch glioom). De CATNON-studie vergelijkt postoperatieve bestraling met en zonder temozolamide (van den Bent, 2017). De interimresultaten van deze studie bij 745 patiënten met nieuw gediagnostiseerde anaplastische gliomen laat zien dat de HR voor OS 0,65 (95%BI: 0,45-0,93) was. De OS na vijf jaar was 55,9% (95%BI: 47,2- tot 63,8) vergeleken met 44,1% (36,3-51,6) bij respectievelijk met en zonder temozolamide. In analogie zou hierdoor dus ook bij laaggradige gliomen de toevoeging van twaalf kuren temozolamide na bestraling overwogen kunnen worden in plaats van zes PCV-kuren (Wick, 2009; van den Bent, 2017).

Shared decision making

In alle gevallen dient er sprake te zijn van shared decision making waarbij de te verwachten effecten en voor- en nadelen van de verschillende behandelopties met de patiënt besproken worden.

Onderbouwing

Achtergrond

De behandeling van patiënten met een laaggradig glioom blijft een controversieel onderwerp. Door recente ontwikkelingen in de moleculaire diagnostiek, de kennis over de diagnostische, prognostische en predictieve waarde hiervan is er meer kennis over welke patiëntengroep welke behandeling (radiotherapie, chemotherapie of beide) zou moeten krijgen. Het is van belang deze patiëntengroep te definiëren.

Conclusies

Chemotherapie

Laag GRADE	<p>Progressievrije overleving</p> <p>Er is mogelijk een klinisch relevant verschil in progressievrije overleving tussen alleen chemotherapie versus alleen radiotherapie in het voordeel van alleen radiotherapie bij patiënten met een laaggradig glioom. Dit verschil is mogelijk meer uitgesproken bij patiënten zonder gecombineerd verlies van 1p en 19q.</p> <p><i>Bronnen: (Baumert, 2016)</i></p>
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Laag GRADE	<p>Algehele overleving</p> <p>Er zijn aanwijzingen dat er geen verschil in algehele overleving is tussen alleen chemotherapie versus alleen radiotherapie bij patiënten met een glioom (al heeft de huidige data geen power om dit te berekenen).</p> <p><i>Bronnen: (Baumert, 2016)</i></p>
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Laag GRADE	<p>Kwaliteit van leven</p> <p>Er zijn aanwijzingen dat er geen verschil in kwaliteit van leven is tussen chemotherapie en radiotherapie bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Reijneveld, 2016)</i></p>
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Laag GRADE	<p>Cognitie</p> <p>Er zijn aanwijzingen dat er geen verschil in cognitie, gemeten met de MMSE-vragenlijst, is tussen radiotherapie en chemotherapie na operatie in de eerste drie jaar na behandeling bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Reijneveld, 2016)</i></p>
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Radiotherapie

Laag GRADE	<p>Progressievrije overleving</p> <p>Postoperatieve radiotherapie leidt mogelijk tot een toename in progressievrije overleving vergeleken met radiotherapie die pas bij progressie van ziekte wordt gegeven bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Van den Bent, 2005)</i></p>
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Redelijk GRADE	<p>Progressievrije overleving</p> <p>Er is waarschijnlijk geen verschil tussen hoge of lage dosis postoperatieve radiotherapie op progressievrije-overleving bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Shaw, 2002; Karim, 1996)</i></p>
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Laag GRADE	<p>Algehele overleving</p> <p>Er zijn aanwijzingen dat er geen statistisch significant verschil in algehele overleving tussen lage of hoge dosis radiotherapie na operatie. Er zijn aanwijzingen dat er geen statistisch significant verschil in algehele overleving is in de timing van radiotherapie direct na operatie of bij ziekteprogressie bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Van den Bent, 2005; Shaw, 2002; Karim, 1996)</i></p>
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Zeer laag GRADE	<p>Kwaliteit van leven</p> <p>Er zijn voorzichtige aanwijzingen dat patiënt gerapporteerde vermoeidheid/malaise en slapeloosheid direct na hoge dosis radiotherapie (59,4 Gy) significant erger zijn dan na lagere dosis radiotherapie (45 Gy) bij patiënten met een laaggradig glioom. Op langere termijn lijken patiënten na hogere dosis bestraling significant lager te scoren op vrijetijdsbesteding en emotioneel functioneren.</p> <p><i>Bronnen: (Kiebert, 1998)</i></p>
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Chemo- en radiotherapie

Laag GRADE	<p>Progressievrije overleving</p> <p>Patiënten met een laaggradig glioom die zowel radiotherapie als chemotherapie (PCV) krijgen na een operatie, hebben mogelijk een veel langere progressievrije overleving dan patiënten die alleen radiotherapie krijgen.</p> <p><i>Bronnen: (Buckner, 2016)</i></p>
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Laag GRADE	<p>Algehele overleving</p> <p>Patiënten met een laaggradig glioom die zowel radiotherapie als chemotherapie (PCV) krijgen, hebben mogelijk een veel langere algehele overleving dan patiënten die alleen radiotherapie krijgen.</p> <p><i>Bronnen: (Buckner, 2016)</i></p>
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Laag GRADE	<p>Cognitie</p> <p>Er is mogelijk geen verschil in cognitieve uitkomsten tussen chemo- en radiotherapie en alleen radiotherapie, gemeten met de MMSE-vragenlijst, bij patiënten met een laaggradig glioom.</p> <p><i>Bronnen: (Buckner, 2016; Prabhu, 2014)</i></p>
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Samenvatting literatuur

Eén van de dertien geïncludeerde artikelen bleek een systematische review die het effect van chemotherapie na operatie beschrijft bij patiënten met een laaggradig glioom (Ziu, 2015). Omdat deze review maar één RCT (Shaw, 2012) includeerde die ook afzonderlijk is geïncludeerd, is ervoor gekozen deze RCT afzonderlijk te beschrijven en de review van Ziu alsnog te excluderen. Er zijn dus 12 artikelen opgenomen in de literatuuranalyse die beschreven wat het effect is van chemotherapie, radiotherapie, of chemo- en radiotherapie na operatie bij volwassen patiënten met een laaggradig glioom op algehele overleving, progressievrije overleving, kwaliteit van leven en/of cognitie. Het gaat om twee systematische literatuurreviews en tien RCT's. In enkele studies werden de resultaten uit eenzelfde trial gebruikt om verschillende vragen te beantwoorden. De belangrijkste studiekarakteristieken en resultaten van de 12 artikelen zijn opgenomen in de evidencetabellen. De beoordeling van de individuele studieopzet (risk of bias) is opgenomen in de risk of biastabellen.

Chemotherapie

Baumert (2016) en Reijneveld (2016) vergeleken het effect van chemotherapie (dose-dense temozolamide) met radiotherapie voor de uitkomstmaten algehele overleving en progressievrije overleving (Baumert, 2016) en kwaliteit van leven en cognitief functioneren (Reijneveld, 2016). Beiden beschreven de resultaten van de EORTC-22033-26033-studie. In deze studie werden 477 volwassen patiënten met diffuus astrocytoom (WHO-graad II), oligodendroglioom of gemengd oligoastrocytoom met een WHO-performance score van 2 of lager, gerandomiseerd in een groep die radiotherapie kreeg ($n=237$) en een groep die chemotherapie kreeg ($n=240$).

Progressievrije overleving

De progressievrije overleving was voor dose-dense temozolamide 39 maanden (95%BI: 35 tot 44) ($n=237$) en voor radiotherapie 46 maanden (95%BI: 40 tot 56) ($n=240$), hazard ratio (HR) 1,16 (95%BI: 0,9 tot 1,5, $p=0,22$). Aanvullend bleek uit exploratieve analyse dat dit verschil in progressievrije overleving meer uitgesproken was in de groep patiënten met gemuteerd IDH maar zonder verlies van 1p/19q (radiotherapie: 55 maanden (95% BI:47-66); chemotherapie 36 maanden (95%BI: 28-47) ($n=165$) HR 1,86 (95%BI: 1,21 tot ,87).

Algehele overleving

Hoewel Baumert (2016) algehele overleving als secundair eindpunt had gedefinieerd, werd bij de mediane follow-up van 48 maanden de mediane algehele overleving niet bereikt in zowel de radiotherapiegroep als in de chemotherapiegroep.

Kwaliteit van leven

Reijneveld (2016) vergeleek de verschillen in aan gezondheid gerelateerde kwaliteit van leven (HRQoL) tussen patiënten behandeld met radiotherapie en met chemotherapie. Het verschil in HRQoL tussen de twee behandelgroepen was niet significant gedurende 36 maanden follow-up (gemiddeld over alle tijdstippen: 0,06, 95%BI: -4,64 tot 4,75, p=0,98). In beide groepen bleven de gemiddelde algehele gezondheid en de kwaliteit van leven stabiel door de tijd.

Cognitie

Reijneveld (2016) vergeleek cognitie tussen patiënten behandeld met radiotherapie en patiënten behandeld met chemotherapie gedurende een follow-up van drie jaar. Op baseline hadden 32 (13%) van de 239 patiënten die radiotherapie kregen en 32 (14%) van de 236 patiënten die temozolamide-chemotherapie kregen een verminderde cognitieve functie volgens de Mini Mental State Examination-scores (MMSE). Na randomisatie hadden 5 (8%) van de 63 patiënten die radiotherapie kregen en 3 (6%) van de 54 patiënten die temozolamide-chemotherapie kregen, een verminderde cognitieve functie volgens MMSE-scores. Er werd geen significant verschil gevonden tussen de twee behandelgroepen.

Radiotherapie

Er zijn zeven studies gevonden die effecten van radiotherapie na operatie bij patiënten met een laaggradig glioom onderzochten, waaronder twee systematische reviews (Ryken, 2015; Sarmiento, 2015) en vijf RCT's (Karim, 1996; Kiebert, 1998; Karim, 2002; Shaw, 2002; van den Bent, 2005).

Systematische reviews

De systematische review van Ryken (2015) includeerde 142 studies waaronder zes RCT's (Eyre, 1993 (past niet binnen de uitgangsvraag); Karim, 1996; Kiebert, 1998; Karim, 2002; Shaw, 2002; van den Bent, 2005). Deze RCT's zijn allen apart geïncludeerd door de werkgroep en apart beschreven in deze module. De andere studies geïncludeerd in Ryken zijn van mindere methodologische kwaliteit en daarom wordt Ryken hier niet verder beschreven.

In de Cochrane review van Sarmiento (2015) werden de effecten van postoperatieve radiotherapie versus radiotherapie uitgesteld tot tumorprogressie na biopsie of chirurgische resectie onderzocht. Sarmiento (2015) includeerde slechts één studie: een multicenter RCT met patiënten met een laaggradig glioom (van den Bent, 2005; EORTC-22845). De patiënten werden gerandomiseerd in een postoperatieve radiotherapiegroep (n=157) of in de groep met uitgestelde radiotherapie tot het optreden van progressie (n=157). Voor het beschrijven van de studieresultaten wordt daarom gerefereerd aan van den Bent (2005).

RCT's

Karim (2002) beschreef de eerste resultaten van bovengenoemde EORTC-studie (van den Bent, 2005). Middels de RCT van Shaw (2002) werden de effecten van lage versus hoge dosis radiotherapie in 203 volwassenen met een supratentoriaal laaggradig glioom onderzocht. Karim (1996) onderzocht eveneens de effecten van lage versus hoge dosis radiotherapie in een RCT met 379 volwassenen met laaggradig glioom. Kiebert (1998) onderzocht in dezelfde RCT als Karim (1996) de kwaliteit van leven, gerapporteerd door patiënten zelf en door artsen, bij patiënten met laaggradig glioom welke een lage of een hoge dosis radiotherapie kregen.

Progressievrije overleving

Van den Bent (2005) liet zien dat postoperatieve radiotherapie geassocieerd is met een toename in tijd tot progressie van de ziekte in vergelijking tot observatie/afwachtend beleid (en uitgestelde radiotherapiebehandeling tot ziekteprogressie) voor mensen met een laaggradig glioom. De mediane progressievrije overleving was 5,3 jaar in de postoperatieve radiotherapiegroep en 3,4 jaar in de uitgestelde radiotherapiegroep (HR: 0,59, 95%BI: 0,45 tot 0,77; p<0,0001).

De studie van Shaw (2002) toonde geen significant verschil aan tussen een lage dosis (50,4 Gy, n=101) en hoge dosis radiotherapie (64,8 Gy, n=102) in de tijd tussen de start van behandeling en progressie van de ziekte (TTP) (log rank P = 0,65). De gemiddelde TTP was 5,5 jaar.

Ook de studie van Karim (1996) vond geen significante verschillen in progressievrije overleving tussen lage dosis (45 Gy, n=171) en hoge dosis radiotherapie (59,4 Gy, n=172). Het aantal overlevenden zonder progressie van ziekte na 5 jaar is 47% bij lage dosis radiotherapie en 50% bij hoge dosis radiotherapie.

Algehele overleving

De mediane algehele overleving in de groep die postoperatieve radiotherapie kreeg, was 7,4 jaar, terwijl de groep die late radiotherapie kreeg (bij ziekteprogressie) een mediane algehele overleving had van 7,2 jaar (HR 0,97, 95%BI: 0,71-1,33; p= 0,872). Dit verschil was niet significant (van den Bent, 2005).

De studie van Shaw (2002) vond geen significant verschil tussen lage (50,4 Gy) en hoge (64,8 Gy) dosis radiotherapie in algehele overleving (log rank P = 0,48). De 2- en 5-jaars overleving waren iets beter in de lage dosis radiotherapie. De mediane overleving was 9,25 jaar.

De studie van Karim (1996) vond ook geen significante verschillen in algehele overleving tussen lage dosis (45 Gy) en hoge dosis (59,4 Gy) radiotherapie.

Kwaliteit van leven

De studie van Kiebert (1998) onderzocht de door patiënten zelf gerapporteerde kwaliteit van leven na lage dosis radiotherapie (45 Gy) en na hoge dosis radiotherapie (59,4 Gy). Direct na bestraling rapporteerden de patiënten in de hoge dosisgroep lagere niveaus in functioneren en meer klachten dan de patiënten in de lage dosisgroep. Deze verschillen waren significant voor vermoeidheid/malaise ($p=0,03$) en slapeloosheid ($p=0,05$). Na 7 tot 15 maanden na randomisatie scoorde de hoge dosisgroep significant slechter op vrijetijdsbesteding ($p=0,01$) en emotioneel functioneren ($p=0,01$) dan de lage dosisgroep. Er waren geen verschillen in de verschillende aspecten van kwaliteit van leven in beide groepen voor en na behandeling.

Cognitie

Er zijn geen studies geïncludeerd die voldoen aan de selectiecriteria en cognitie beschreven bij radiotherapie.

Chemo- en radiotherapie

Er zijn drie RCT's die de effecten van chemo- en radiotherapie na operatie bij patiënten met een laaggradig glioom onderzochten (Shaw, 2012; Prabhu, 2014; Buckner 2016). Shaw (2012) beschrijft de eerste resultaten van de RTOG-9802 studie van Buckner (2016) en is daarom niet apart beschreven. Prabhu (2014) onderzocht

het effect van additionele chemotherapie bij radiotherapie op cognitief functioneren (MMSE-scores) in vergelijking tot alleen radiotherapie bij 251 patiënten met een laaggradig glioom. Hiervoor zijn resultaten van de RTOG-9802-studie geanalyseerd. Buckner (2016) beschreef de lange termijneffecten van behandeling met procarbazine, lomustine en vincristine na radiotherapie bij 251 patiënten met een astrocytoom, oligoastrocytoom of oligodendrogloom, in vergelijking met enkel radiotherapie. Patiënten werden geïncludeerd indien jonger dan 40 jaar met subtotal resectie of biopsie; of ouder dan 40 jaar met elke vorm van resectie of biopsie.

Progressievrije overleving

Buckner (2016) vond een significant verschil in progressievrije overleving tussen 125 patiënten behandeld met radiotherapie gevolgd door chemotherapie (PCV-kuren) (gemiddelde progressievrije overleving: 10,4 jaar, 95%BI: 6,1-niet behaald) en 126 patiënten met alleen radiotherapie als behandeling (gemiddelde progressievrije overleving: 4,0 jaar, 95%BI: 3,1-5,5) (HR voor ziekteprogressie of sterfte: 0,50; $p<0,001$). Het verschil in progressievrije overleving werd pas zichtbaar nadat 25% van de patiënten ziekteprogressie had en het verschil nam toe gedurende de tijd.

Algehele overleving

Buckner (2016) beschreef bij patiënten met gecombineerde behandeling een langere mediane algehele overleving dan bij patiënten met alleen radiotherapie (13,3 versus 7,8 jaar respectievelijk, HR voor overlijden: 0,59; $p=0,003$).

De algehele overleving na vijf jaar was 72% (95%BI: 64-80) in de groep die radiotherapie plus chemotherapie kreeg versus 63% (95%BI: 55-72) in de groep die alleen radiotherapie kreeg. Deze percentages waren na 10 jaar 60% (95%BI: 51-69) en 40% (95%BI: 31-49) respectievelijk.

Kwaliteit van leven

De uitkomstmaat kwaliteit van leven is niet beschreven in de geïncludeerde studies die chemo- en radiotherapie onderzochten.

Cognitie

In de RTOG-9802 studie heeft Prabhu (2014) gedurende vijf jaar een MMSE-score afgenoemt. Het toevoegen van chemotherapie (PCV) aan radiotherapie gaf geen significant grotere afname in MMSE-scores dan alleen radiotherapie gedurende vijf jaar follow-up. Beide groepen ervaarden een statistisch significante toename van de gemiddelde MMSE-score gedurende de tijd. Er was geen verschil tussen beide groepen ($P=0,57$).

Bewijskracht van de literatuur

Volgens de GRADE-beoordeling starten RCT's op een hoog niveau van bewijskracht.

Chemotherapie

De bewijskracht voor de uitkomstmaat progressievrije overleving is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (risk of bias, gebrek aan blinding van de beoordelaars MRI) en vanwege het overschrijden van de grens voor klinische relevantie (imprecisie). De bewijskracht voor algehele

overleving is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (risk of bias, mediane overleving niet bereikt, twee niveaus afgetrokken). De bewijskracht voor de uitkomstmaten kwaliteit van leven en cognitie is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (risk of bias, gebrek aan blinding) en het geringe aantal patiënten (imprecisie).

Radiotherapie

De bewijskracht voor de uitkomstmaat progressievrije overleving voor de vergelijking postoperatieve radiotherapie versus radiotherapie bij progressie is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (risk of bias, vanwege gebrek aan blinding) en imprecisie (doorkruisen van de grens voor klinische relevantie). De bewijskracht voor de uitkomstmaat progressievrije overleving voor de vergelijking lage versus hoge dosis radiotherapie is met één niveau verlaagd tot 'redelijk' gezien beperkingen in de onderzoeksopzet (risk of bias, vanwege gebrek aan blinding en onduidelijkheid in de manier van randomiseren). De bewijskracht voor de uitkomstmaat algehele overleving is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (geringe aantal patiënten en onduidelijkheid in de manier van randomiseren). De bewijskracht voor de uitkomstmaat kwaliteit van leven is met drie niveaus verlaagd gezien een aantal beperkingen in de onderzoeksopzet (risk of bias, waaronder gebrek aan blinding). Daarnaast wordt veel zaken in het artikel niet nader toegelicht, zoals manier van randomiseren en hoeveel patiënten er tijdens de studieduur zijn uitgevallen).

Chemo- en radiotherapie

De bewijskracht voor de uitkomstmaat progressievrije overleving en algehele overleving is met twee niveaus verlaagd tot 'laag' gezien beperkingen in de onderzoeksopzet (risk of bias, gebrek aan blinding/het geringe aantal patiënten). De bewijskracht voor de uitkomstmaat cognitie is met twee niveaus verlaagd gezien beperkingen in de onderzoeksopzet (risk of bias, gebrek aan blinding, relatief hoge loss-to-follow-up) en het geringe aantal patiënten (imprecisie).

Zoeken en selecteren

Om de uitgangsvraag te kunnen beantwoorden is er een systematische literatuuranalyse verricht naar de volgende zoekvraag:

Wat is bij volwassen patiënten met een laaggradig glioom het effect van chemotherapie/radiotherapie/chemo- en radiotherapie op progressievrije overleving, algehele overleving, kwaliteit van leven en/of cognitie?

Relevante uitkomstmaten

De werkgroep achtte progressievrije overleving, algehele overleving, kwaliteit van leven en cognitie voor de besluitvorming cruciale uitkomstmaten.

Zoeken en selecteren (Methode)

In de databases Medline (via OVID) en Embase (via Embase.com) is op 29 maart 2018 met relevante zoektermen gezocht naar studies die bovengenoemde uitgangsvraag beantwoorden. De zoekverantwoording is weergegeven onder het tabblad Verantwoording. De literatuurzoekactie leverde 514 artikelen op. Studies werden geselecteerd op grond van de volgende selectiecriteria: systematische reviews of meta-analyses, gerandomiseerde gecontroleerde studies of klinische studies, gepubliceerd na 1990 die voldeden aan de

vooraf opgestelde PICO. Op basis van titel en abstract werden in eerste instantie 66 artikelen voorgeselecteerd. Na raadpleging van de volledige tekst, werden vervolgens 53 artikelen geëxcludeerd (zie exclusietabel onder het tabblad Verantwoording) en 13 artikelen definitief geselecteerd.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Recidief laaggradig glioom

Uitgangsvraag

Wat is de rol van chemotherapie bij een patiënt met een recidief bij een laaggradig glioom?

Aanbeveling

De voorkeur gaat uit naar behandeling in studieverband (TAVAREC NCT01164189 voor patiënten zonder co-deletie van 1p en 19q). Indien geen studie beschikbaar, wordt geadviseerd behandeling met 12 kuren temozolamide te overwegen; voor tumoren met een 1p-19q co-deletie is PCV een optie.

Verdere lijnsbehandeling, bijvoorbeeld PCV of lomustine monotherapie na temozolamide of temozolamide na PCV kan in geselecteerde patiënten overwogen worden.

Overwegingen

Data over welk schema je moet kiezen ontbreken omdat er geen vergelijkende studies zijn in deze setting, maar het ligt voor de hand om bij tumoren met een co-deletie van 1p-19q te kiezen voor PCV, en de patiënten met een tumor zonder 1p/19q co-deletie te behandelen met temozolamide.

Onderbouwing

Achtergrond

Deze module beschrijft de rol van chemotherapie bij een patiënt met een recidief bij een laaggradig glioom, waarbij er sprake is van progressie op beeldvorming na resectie en aanvullende behandeling.

Conclusies

Er zijn aanwijzingen voor respons op temozolamide en PCV bij recidief laaggradige gliomen.

Pace 2003²⁴³, Van den Bent 2003³⁵⁸, Van den Bent 2006³⁵², Van den Bent 2013³⁵¹, Quinn 2003²⁶⁹, Levin 2006²⁰¹

Samenvatting literatuur

Er zijn verschillende studies die de meerwaarde van chemotherapie bij recidief laaggradige (astrocytaire en oligodendrogliale) gliomen aantonen voor zowel PCV [Pace 2003²⁴³, Van den Bent 2003³⁵⁸, 2006³⁵², 2013³⁵¹] als temozolamide [Quinn 2003²⁶⁹, Levin 2006²⁰¹]. De huidige behandelopties geven een kans op respons van ongeveer 50-75% afhankelijk van de morfologie, moleculaire opmaak en voorbehandeling. Voor verdere lijnsbehandeling, bijvoorbeeld PCV of lomustine monotherapie na temozolamide of temozolamide na PCV, is er slechts beperkte data uit ongecontroleerde patiëntseries [Triebels 2004³⁴⁴]

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Behandeling Hooggradig glioom

Deze module is onderverdeeld in de volgende submodules en sub-submodules:

- Neurochirurgie
 - Chirurgische behandelingsstrategie hooggradig glioom
 - Minimale mate van resectie hooggradig glioom
 - Waarde en mate van re-resectie glioblastoom
- Radiotherapie
 - Indicatie radiotherapie anaplastisch glioom
 - Indicatie radiotherapie glioblastoom
 - Radiotherapie bij progressie hooggradig glioom/recidief
- Chemotherapie/systeemtherapie
 - Chemotherapie nieuw gediagnosteerd anaplastisch glioom
 - Chemotherapie recidief anaplastisch glioom
 - Chemotherapie nieuw gediagnosteerd glioblastoom
 - Chemotherapie recidief glioblastoom

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Neurochirurgie bij hooggradig glioom

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Chirurgische behandelingsstrategie hooggradig glioom
- Minimale mate van resectie hooggradig glioom
- Waarde en mate van re-resectie glioblastoom

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chirurgische behandelingsstrategie hooggradig glioom

Uitgangsvraag

Wat is de beste neurochirurgische behandelingsstrategie bij een patiënt met een vermoedelijk hooggradig glioom op beeldvorming?

Aanbeveling

Er wordt geadviseerd een resectie te verrichten zo maximaal als mogelijk is met behoud van kwaliteit van leven. Zie module Minimale mate van resectie hooggradig glioom.

Voor een patiënt met een vermoedelijk hooggradig glioom dienen de risico's en de voordelen van een zo maximaal mogelijke resectie individueel afgewogen te worden in een multidisciplinaire hersentumorwerkgroep, waaraan tenminste een neurochirurg, neuroloog, neuroradioloog, radiotherapeut, een internist-oncoloog en optioneel een klinisch neuropsycholoog deelnemen. In de multidisciplinaire werkgroep wordt een eerste behandelkeuze met alternatieven geformuleerd.

Onder een zo goed mogelijke neurochirurgische behandeling wordt verstaan een zo maximaal mogelijke resectie van tumorweefsel en necrotisch tumorweefsel waarbij kwaliteit van leven behouden wordt. Verschillende operatietechnieken kunnen naar inzicht en ervaring van het neurochirurgisch team gebruikt worden, zoals neuronavigatie, DTI, 5-ALA, intraoperatieve MRI of mapping met behulp van corticale en subcorticale stimulatie. Er zijn geen argumenten in de literatuur dat het achterwege laten van een of meer van deze technieken de patiënt benadeelt. De effectiviteit van carmustine wafers lijkt te klein in verhouding tot de kostprijs om toe te passen.

Prognostisch ongunstige factoren, zoals hoge leeftijd, lage Karnofsky performance status, multifocaliteit en bilaterale uitbreiding, dienen betrokken te worden in het advies voor de neurochirurgische behandelstrategie. Over het algemeen zal een terughoudender strategie geadviseerd worden bij meer prognostisch ongunstige factoren.

Overwegingen

Hiernavolgend zullen aanbevelingen uit andere richtlijnen en een aantal klinische dilemma's bij de neurochirurgische behandelstrategie worden toegelicht.

De National Comprehensive Cancer Network (Verenigde Staten) beveelt multidisciplinaire indicatiestelling voor een operatie aan in de vorm van, indien mogelijk, een maximale tumorverwijdering met minimale morbiditeit en vaststellen van de mate van resectie door een MRI binnen 72 uur na operatie [NCCN2013]. Indien dit niet haalbaar is, wordt een bipt of een incomplete tumorverwijdering geadviseerd.

Een aantal dilemma's kan zich voordoen rondom behandelbeslissingen bij de verdenking op een hooggradig glioom. Een selectie daarvan zal hier besproken worden aan de hand van de literatuur: de neurochirurgische behandelstrategie voor anaplastisch glioom, voor multifocaal hooggradig glioom, voor bilateraal glioom en voor de oudere patiënt.

In literatuur van de jaren 1980 en 1990 werden patiënten met een anaplastisch glioom (WHO graad III) veelal samengenomen met patiënten met glioblastoom onder de noemer 'hooggradig glioom'. In studies vanaf

ongeveer het jaar 2000, naar het effect van een resectie bij patiënten met een anaplastisch glioom, wordt de mate van resectie als onafhankelijke gunstige prognostische factor gevonden voor overleving en tijd tot progressie [Keles 2006¹⁶⁷], Puduvali 2003²⁶⁵]. Op het moment dat een besluit over de neurochirurgische behandelstrategie genomen moet worden is de histopathologische gradering nog niet bekend. Een deel van de - achteraf - anaplastische gliomen toont geen of beperkte aankleuring met contrast waarbij een T2/FLAIR-geleide resectie werd beoogd. Een ander deel bestaat echter voornamelijk uit contrastaankleuring, waarbij een T1 met contrast gerichte resectie werd uitgevoerd. Er werd geen literatuur gevonden met vergelijkend onderzoek tussen een T1 met contrast gerichte resectie of uitgebreidere T2/FLAIR-resectie bij deze patiënten.

Aan patiënten met meerdere foci van een hooggradig glioom wordt over het algemeen geen resectie geadviseerd. Uit de literatuur is niet duidelijk of een resectie minder effectief is bij multifocaliteit dan bij unifocaliteit. Aan de ene kant is multifocaal glioblastoom geassocieerd met een kortere overleving in case-control onderzoek van 47 patiënten, gematcht voor leeftijd, conditie en mate van resectie: 6 maanden (95%CI 4-10 maanden) bij multifocale lokalisatie, vergeleken met 11 maanden (95%CI 10-19 maanden) in geval van unifocale lokalisatie ($p = 0.02$) [Patil 2012²⁵⁰]. Aan de andere kant wordt in een ander case-control onderzoek van 20 patiënten met een multifocaal glioblastoom, gematcht voor leeftijd, conditie, eloquentie en mate van resectie met een groep met een unifocale lokalisatie, een vergelijkbare overleving gevonden: 9,7 maanden vergeleken met 10,5 maanden ($p = 0.34$) [Hassaneen 2011¹²⁸].

Aan patiënten met een bilateraal hooggradig glioom (zogenaamd vlinderglioom of balkglioom) wordt over het algemeen geen resectie geadviseerd. Uit de literatuur is echter niet duidelijk of een resectie bij deze groep minder effectief is dan bij een unilaterale lokalisatie. In een beschrijving van 23 patiënten met een bilateraal glioblastoom tussen 1990 en 2000 ondergingen 12 een biopt en 11 een resectie [Dziurzynski 2012⁸⁷]. De groep na resectie had een mediane overleving van 8,8 maanden (95%CI 3-14.6 maanden). Er bestaat discussie over de neurochirurgische behandeling bij patiënten met een hooggradig glioom op hogere leeftijd (met als arbitraire grens 70 jaar of ouder). Aan de ene kant is hoge leeftijd een ongunstige prognostische factor voor overleving en voor perioperatieve morbiditeit [Bauchet 2014¹²], aan de andere kant is mate van resectie ook in deze subgroep een onafhankelijke gunstige prognostische factor voor overleving. In een gerandomiseerde klinische studie bij patiënten met een glioblastoom ouder dan 65 jaar werd vastgesteld, dat een resectie resulteerde in een significant langere overleving dan een biopt [Vuorinen 2003³⁷¹].

Tanaka beschreef 105 patiënten met een glioblastoom ouder dan 65 jaar, die werden behandeld tussen 2003 en 2008, waarvan 52 patiënten een biopt ondergingen en 53 een resectie [Tanaka 2013³⁴⁰]. In multivariate analyse was een resectie geassocieerd met een langere overleving (RR 0.54, 95%CI 0.31-0.94, $p = 0.04$) na correctie voor leeftijd, unifocaliteit en adjuvante therapie. Adjuvante therapie lijkt hiervan de belangrijkste factor. Patiënten die adjuvante therapie ondergingen na een resectie leefden langer (11,5 maanden) dan die na een biopt (6,5 maanden). Postoperatieve complicaties werden beschreven bij 26 (25%) patiënten waarvan 16 na biopt. Postoperatieve mortaliteit ontstond bij 4 (4%) patiënten, allen na biopt.

Scott beschreef 206 patiënten met een glioblastoom, ouder dan 70 jaar, behandeld tussen 1979 en 2007, waarvan 113 een biopt ondergingen en 93 een resectie, waarvan 23 een radiologisch complete resectie betrof [Scott 2011³⁰⁴]. In multivariate analyse hadden patiënten na een biopt een kortere overleving dan na een resectie (HR: 3.09, 95%CI 2.09-4.56, $p <0.001$) na correctie voor conditie, bestraling en chemotherapie. Na een biopt werd een mediane overleving van 2,8 maanden geobserveerd en na een resectie van 7,3 maanden ($p <0.001$).

Ewelt beschreef 103 patiënten met een glioblastoom, ouder dan 65 jaar, behandeld tussen 2002 en 2007 [Ewelt 2011⁹³]. De mediane overleving was 2,2 maanden na biopt (95%CI 1,6-2,7 maanden, 43 patiënten), 7,0 maanden na partiële resectie (95%CI 6,3-7,7 maanden, 37 patiënten) en 13,9 maanden na radiologisch complete resectie (95%CI 11,8-15,9 maanden, 23 patiënten) ($p < 0.05$). In multivariate analyse, was een uitgebreidere resectie geassocieerd met een langere overleving (HR 1.987, $p < 0.05$) na correctie voor leeftijd en conditie.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat een resectie voor een hooggradig glioom de levensduur verlengt.
 Hart 2011¹²⁴, Tsitlakidis 2010³⁴⁶, Stummer 2008³²⁸, Lacroix 2001¹⁹⁰, Chaichana 2014⁴⁸, McGirt 2009²¹⁵, Graus 2013, Bauchet 2010, Filippini 2008⁹⁵

Er zijn aanwijzingen dat na een resectie voor een hooggradig glioom de kwaliteit van leven en cognitie niet verslechtert. Bij ongeveer de helft van de patiënten verbetert de conditie. Bij 5 tot 10% van de patiënten leidt de resectie tot complicaties of verminderde conditieën bij minder dan 2% van de patiënten tot postoperatieve mortaliteit.

Daigle 2013⁶⁷, Brown 2005³⁵, Yoshii 2008⁴⁰³, Talacchi 2011³³⁹, Satoer 2014²⁹⁸, Chang 2003⁵², De Witt Hamer 2012⁷⁶, McGirt 2009²¹⁵, Chaichana 2014⁴⁸

Hogere leeftijd, lagere Karnofsky performance status, multifocaliteit en bilaterale uitbreiding zijn geassocieerd met een kortere levensverwachting.

Patil 2012²⁵⁰, Hassaneen 2011¹²⁸, Dziurzynski 2012⁸⁷, Bauchet 2014¹³, Vuorinen 2003³⁷¹, Tanaka 2013³⁴⁰, Scott 2011³⁰⁴

Samenvatting literatuur

De literatuur voor de neurochirurgische behandeling van een vermoedelijk hooggradig glioom wordt achtereenvolgens beschreven aan de hand van een Cochrane review, een systematische review en een meta-analyse en publicaties over effectiviteit van een resectie in termen van overleving, progressievrije overleving, verbetering van verschijnselen en kwaliteit van leven. Daarna wordt het risico van een resectie beschreven. Tot slot de gerandomiseerde klinische studies die over operatietechnieken zijn gepubliceerd.

In een Cochrane review werd één klinische studie geïdentificeerd, waarin tussen biopsie en resectie werd gerandomiseerd bij patiënten ouder dan 65 jaar in Finland tussen 1993 en 1996 [Hart 2011¹²⁴]. De mediane overleving was korter voor de 16 patiënten na biopsie (85 dagen, 95%CI 55-157) dan voor de 14 patiënten na resectie (171 dagen, 95%CI 146-278; $p = 0.0346$). De hazard ratio, gecorrigeerd voor tumorgrading, was 2.621 (95%CI 1.035-6.641; $p = 0.0422$) en, gecorrigeerd voor radiotherapie, 2.729 (95%CI 1.035 7.195; $p = 0.0423$). Hoewel statistisch significante verschillen werden gevonden in overleving is deze studie underpowered en zijn er methodologische beperkingen.

In een meta-analyse naar het verschil tussen een biopt en resectie in termen van overleving, progressievrije overleving en kwaliteit van leven, identificeerde Tsitlakidis dezelfde gerandomiseerde studie en vier retrospectieve studies waarvan de gegevens van 1111 patiënten gepoold werden [Tsitlakidis 2010³⁴⁶]. Een resectie was geassocieerd met een langere overleving dan een biopt (hazard ratio 0.61, 95%CI 0.52-0.71, p

<0.0001). Statistische analyse was niet mogelijk voor progressievrije overleving en kwaliteit van leven, vanwege het ontbreken van voldoende gegevens.

In vier studies is de relatie tussen de mate van resectie en overleving onderzocht in tertiaire verwijsscentra voor hersentumoren, rekening houdend met bekende prognostische factoren als potentiële confounders. Stummer verrichtte een posthoc analyse van prospectief verzamelde gegevens van 243 patiënten met een glioblastoom in het kader van een gerandomiseerde multicenter studie in Duitsland naar conventionele wit licht microscopie versus 5-ALA fluorescentie microscopie [Stummer 2008³²⁸]. De 122 patiënten waarbij na resectie geen tumorrest aantoonbaar was op de MRI hadden een significant langere overleving (16,9 maanden) dan de 121 patiënten met een tumorrest (11,8 maanden) ($p <0.0001$). De hazard ratio voor overleving na een complete versus incomplete resectie was 1.752 (95%: 1.258-2.438; $p = 0.0004$), na correctie voor leeftijd, conditie, preoperatief tumorvolume, eloquentie, midline verplaatsing, oedeem en ependymale infiltratie.

Lacroix beschreef 416 patiënten met een glioblastoom die geopereerd werden tussen 1993 en 1999 [Lacroix 2001¹⁹⁰]. Een uitgebreidere mate van resectie (>98%) was geassocieerd met een langere overleving (mediane overleving 13 maanden, 95%CI 11,4-14,6 maanden), vergeleken met beperktere resecties (8,8 maanden, 95%CI 7,4-10,2 maanden; $p <0.0001$). In multivariate analyse was de hazard ratio 1.4 (95%CI 1.1-1.9) na correctie voor leeftijd, conditie en radiologische necrose. Een langere overleving werd gevonden vanaf 89% tumorresectie (rate ratio 1.3, 95%CI 1.1-1.6, $p = 0.04$).

Sanai beschreef 500 patiënten met een glioblastoom, die geopereerd werden tussen 1997 en 2009 [Sanai 2011²⁹²]. In multivariate analyse was de hazard ratio per procent resectie 0.99 (95%CI 0.98-0.99, $p=0.004$) na correctie voor leeftijd, conditie en resttumor volume. Een langere overleving werd gevonden vanaf 78% tumorresectie.

Chaichana beschreef 259 patiënten met een glioblastoom, die geopereerd werden tussen 2007 en 2011 [Chaichana 2014⁴⁸]. In multivariate analyse was de hazard ratio per procent resectie 0.992 (95%CI 0.987-0.997, $p = 0.003$) na correctie voor leeftijd, chemotherapie wafer, temozolomide, bestraling en preoperatief tumorvolume.

McGirth beschreef 949 patiënten met een WHO-graad III of IV astrocytoom die geopereerd werden tussen 1996 en 2006 [McGirth 2009²¹⁵]. In multivariate analyse was een uitgebreidere resectie geassocieerd met langere overleving (radiologisch complete resectie vergeleken met een incomplete resectie HR: 0.449, $p = 0.001$; radiologisch bijna-complete resectie vergeleken met een incomplete resectie HR 0.614, $p = 0.002$) na correctie voor leeftijd, conditie, chemotherapie wafer, temozolomide en vervolgbehandeling.

In drie studies is de relatie tussen mate van resectie en overleving onderzocht in behandelpatronen van ziekenhuizen zonder specifieke verwijfsfunctie voor gliomen uitgevoerd in verschillende landen.

Vanuit Spanje werden door Graus 834 patiënten met een operatie voor glioblastoom tussen 2008 en 2010 in 19 ziekenhuizen beschreven [Graus 2013]. In multivariate analyse was de overleving van patiënt na een resectie langer dan na een biopt (HR: 0.50; 95%CI, 0.41-0.60; $p<0.001$) na correctie voor leeftijd, conditie, radiotherapie en chemotherapie.

Vanuit Frankrijk werden door Bauchet 952 patiënten met een operatie voor glioblastoom tussen 2004 en 2006 in 43 ziekenhuizen beschreven [Bauchet 2010]. In multivariate analyse was de overleving korter voor patiënten na een biopt dan na een resectie (HR: 1.606, 95%CI 1.255-2.056, $p=0.0002$) na correctie voor leeftijd en tumorlokalisatie.

Vanuit Italië werden door Filippini 676 patiënten met een operatie voor glioblastoom tussen 1997 en 2003 beschreven [Filippini 2008⁹⁵]. In multivariate analyse was de overleving langer voor patiënten na resectie dan

na biopt (HR 0.55, 95%CI 0.42 - 0.72, p<0.001) na correctie voor leeftijd, conditie, tumoruitbreiding, chemotherapie en radiotherapie.

Een aantal studies beschreef het effect van een resectie op de kwaliteit van leven. In een studie met 35 patiënten met een glioblastoom, geopereerd in 2010 en 2011, werd beschreven dat een uitgebreidere resectie gepaard ging met een verbetering in functioneel welbevinden ($r=0.616$, $p=0.005$), een verbetering in neurocognitief functioneren ($r=0.51$, $p=0.026$) en een verbetering in globale kwaliteit van leven ($r=0.68$, $p=0.001$) drie maanden na operatie ten opzichte van voor operatie [Daigle 2013[157]]. In een andere studie met 220 patiënten met een WHO-graad III of IV glioom geopereerd tussen 1999 en 2002 en verzameld in drie klinische studies werd beschreven dat in multivariate analyse patiënten na een radiologisch complete resectie minder risico op een slechte kwaliteit van leven hadden dan patiënten na een biopt (odds ratio: 0.14, 95%CI 0.04-0.57, $p= 0.006$) [Brown 2005³⁵].

Andere studies beschreven de relatie tussen operatie voor hersentumoren, waarvan een deel hooggradig glioom betrof, en cognitie. Yoshii beschreef 31 patiënten, waarvan 23 met een hooggradig glioom, die voor en een maand na operatie neuropsychologisch onderzoek ondergingen [Yoshii 2008⁴⁰³]. De cognitie verbeterde voor patiënten die een operatie ondergingen in de rechter hersenhelft, maar niet in de linker hersenhelft. Talacchi beschreef 29 patiënten waarvan 17 met een hooggradig glioom, die voor en een week na operatie neuropsychologisch onderzoek ondergingen [Talacchi 2011³³⁹]. Tenminste één cognitief domein verbeterde bij 6 (21%) patiënten; tenminste één cognitief domein verslechterde bij 7 (24%) patiënten. Satoer beschreef 45 patiënten waarvan 17 met een hooggradig glioom die voor en drie maanden en een jaar na operatie neuropsychologisch onderzoek ondergingen [Satoer 2014²⁹⁸]. Drie maanden na operatie waren er geen veranderingen in aandacht en executieve vaardigheden, een verbetering in geheugen ($p=0.034$) en een kleine maar significante verslechtering in taalfunctie ($p=0.030$). Tussen drie maanden en een jaar na operatie verbeterde de taalfunctie ($p=0.026$).

Het risico op permanente neurologische en neuropsychologische functiestoornissen na een resectie is 6,2% (3.2-11.5%) in de subgroep van patiënten met een hooggradig glioom in een meta-analyse van 2104 patiënten in 18 studies [De Witt Hamer 2012⁷⁶]. Het risico op postoperatieve mortaliteit is 0,26% (0.01-0.50%).

Stummer beschreef bij 34 (14%) van 235 patiënten met een glioblastoom een functionele achteruitgang zes weken na operatie en bij 95 (40%) een functionele vooruitgang in termen van NIH stroke score (National Institutes of Health) [Stummer 2006³²⁷]. Postoperatieve mortaliteit deed zich voor bij 8 (3%) patiënten.

Chaichana beschreef bij 19 (7%) van 259 patiënten met een glioblastoom een permanente neurologische functiestoornis [Chaichana 2014⁴⁷].

McGirth beschreef bij 63 (7%) van 949 patiënten met een glioblastoom een nieuwe motorische functiestoornis, bij 48 (5%) een nieuwe taalstoornis, bij 22 (2%) een infectieuze complicatie, bij 11 (1%) een postoperatief hematoom, en bij 23 (2%) een longembolie [McGirth 2009²¹⁵].

Chang beschreef bij 8,1% van 408 patiënten met een hooggradig glioom na een operatie een functionele achteruitgang, en bij 53% een functionele verbetering [Chang 2003⁵²]. Een regionale complicatie, zoals een wondinfectie of liquorlekage, ontstond bij 10%; een systemische complicatie, zoals een diepe veneuze trombose of pneumonie, bij 9,2%. Postoperatieve mortaliteit deed zich voor bij 6 (1,5%) patiënten.

Verschillende operatietechnieken zijn geïntroduceerd en geëvalueerd in gerandomiseerde klinische studies: chemotherapie wafer implantatie en beeldgeleide operatie met intraoperatieve MRI, 5-ALA fluorescentie en functionele MRI en diffusion tensor imaging. Deze worden hier achtereenvolgens besproken.

In een Cochrane review [Hart 2011¹²⁴] naar de effectiviteit van chemotherapie geïmpregneerde wafers in de

resectieholte na operatie voor nieuw gediagnosticeerd hooggradig glioom, identificeerden de auteurs twee gerandomiseerde studies met in totaal 272 patiënten, waarin radiotherapie alleen vergeleken werd met radiotherapie plus carmustine wafers [Valtonen 1997³⁴⁸], Westphal 2003³⁸⁴]. Na wafer implantatie werd een langere overleving waargenomen (HR: 0.65, 95%CI 0.48-0.86, p=0.003), zonder verschil in complicaties. De mediane overleving was 13,9 maanden voor de carmustine wafer groep vergeleken met 11,6 maanden voor de placebo groep, met een jaar overleving van 59,2% en 49,6%. Hoewel statistisch significant werd dit verschil geïnterpreteerd als minimaal klinisch relevant. Carmustine wafers worden in Nederland niet vergoed door zorgverzekeraars.

In een Cochrane review [Barone 2014⁹] naar verschillende beeldgeleide operatietechnieken voor optimaliseren van de mate van resectie werden vier gerandomiseerde studies geïdentificeerd: een voor intraoperatieve MRI [Senft 2011³⁰⁶], 5-ALA fluorescentie geleide resectie [Stummer 2006³²⁷], neuronavigatie [Willems 2006³⁸⁹] en DTI-neuronavigatie [Wu 2007³⁹²]. De mate van resectie werd uitgebreider na intraoperatieve MRI (risk ratio voor incomplete resectie: 0.13, 95%CI 0.02-0.96, lage kwaliteit bewijs), na 5-ALA (RR 0.55, 95%CI 0.42-0.71) en DTI-neuronavigatie (RR 0.35, 95%CI 0.20-0.63, erg lage kwaliteit van bewijs). De rapportage van complicaties was onvoldoende voor analyse, terwijl vroege neurologische functiestoornis vaker voorkwamen na 5-ALA resectie. Een overlevingsvoordeel kon niet worden vastgesteld voor 5-ALA (HR: 0.82, 95%CI 0.62-1.07) of DTI-neuronavigatie (HR 0.57, 95%CI 0.32-1.00) voor patiënten met een hooggradig glioom. Progressie-vrije overleving werd niet gerapporteerd.

Senft verrichtte een prospectief gerandomiseerde studie (NCT01394692) naar het effect van intraoperatieve MRI op radiologisch complete resectie bij contrast-aankleurend glioom [Senft 2011³⁰⁶]. Het primaire eindpunt was de mate van tumorresectie op postoperatieve MRI. Secundaire eindpunten waren het resttumor volume op postoperatieve MRI en progressievrije overleving na zes maanden. Er werden 58 patiënten geïncludeerd, waarvan 8 geëxcludeerd werden na randomisatie vanwege de diagnose metastase en 1 op eigen verzoek. Na randomisatie werden 24 patiënten geopereerd met intraoperatieve MRI en 25 zonder. In de intraoperatieve MRI-groep werd een radiologisch complete resectie bij 24 patiënten (96%) vastgesteld en in de controlegroep bij 17 patiënten (68%) (p=0.023). In de intraoperatieve MRI-groep werd minder resttumor geobserveerd dan in de controlegroep (een mediaan resttumorvolume van 0 versus 0.03 mL, p=0.0015). Na zes maanden bestond progressie bij 8 patiënten (33%) in de intraoperatieve MRI-groep en bij 16 patiënten (64%) in de controlegroep (p=0.046).

Wu verrichtte een prospectief gerandomiseerde studie naar het effect van DTI-gebaseerde neuronavigatie tijdens operatie voor gliomen nabij de pyramidebaan op motorische functiestoornissen, de mate van resectie en overleving [Wu 2007³⁹²]. Eindpunten werden niet gedefinieerd. Na randomisatie van 238 patiënten werden er 118 geopereerd met DTI-geleide neuronavigatie en 120 zonder. Een radiologisch complete resectie werd vastgesteld bij 72% in de DTI-geleide neuronavigatie groep en bij 52% in de controlegroep (p=0.002). Na operatie bestond een motorische functiestoornis bij 18 patiënten (15,3%) in de DTI-geleide neuronavigatie groep en bij 39 patiënten (32,8%) in de controlegroep (p<0.001). De gemiddelde KPS bij zes maanden was 86 in DTI-geleide neuronavigatie groep en 74 in de controlegroep (p<0.001). Survivalanalyse werd alleen in de subgroep van 81 patiënten met hooggradig glioom verricht. De mediane overleving in de DTI-geleide neuronavigatie groep met hooggradig glioom was 21,2 maanden en in de controle groep 14,0 maanden (p=0.048).

Stummer verrichtte een prospectief gerandomiseerde studie (NCT00241670) naar het gebruik van porphyrin fluorescentie voor maligne glioom na toedienen van 5-aminolevulinezuur om de mate van resectie op postoperatieve MRI te verbeteren en om de effecten van resectie op progressievrije overleving,

neurologische morbiditeit en vervolgbehandeling te analyseren [Stummer 2006³²⁷]. De primaire eindpunten waren het percentage patiënten zonder aankleurende resttumor op MRI en de progressievrije overleving na zes maanden. Secundaire eindpunten waren het resttumorvolume op MRI, overleving, neurologisch functiestoornissen en toxiciteit. Na interimanalyse bij 270 van 350 benodigde patiënten werd de studie vroegtijdig beëindigd. Na randomisatie werden 139 patiënten geopereerd met 5-ALA fluorescentie licht door de microscoop en 131 met conventioneel witlicht. Contrast-aankleurende tumoren werden in de 5-ALA groep bij 90 (65%) patiënten totaal verwijderd ten opzichte van bij 47 (36%) in de controle groep ($p<0.0001$). In de 5-ALA groep was 41,0% van patiënten progressievrij bij zes maanden vergeleken met 19,9% in de controle groep ($p=0.0003$). De groepen verschilden niet in overleving of postoperatieve complicaties.

Willems verrichtte een prospectief gerandomiseerde studie naar het effect van neuronavigatie op de mate van tumorverwijdering bij contrast-aankleurende hersentumoren [Willems 2006³⁸⁹]. Eindpunten werden niet geformuleerd. Er werden 46 patiënten geïncludeerd (39 hooggradig gliomen, 6 metastasen en 1 later geëxcludeerd meningeoom), waarvan na randomisatie 23 een resectie met neuronavigatie ondergingen en 22 zonder. De mate van tumorverwijdering en de resttumor verschilden niet. De mediane overleving was 5,6 maanden in de groep van resectie met neuronavigatie en 9 maanden in de controle groep ($p=0.037$).

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Minimale mate van resectie hooggradig glioom

Uitgangsvraag

Wat is de minimale mate van resectie die zinvol is bij een patiënt met een hooggradig glioom?

Aanbeveling

Er is geen minimale mate van resectie aan te geven die zinvol is bij de indicatiestelling voor een operatie bij een patiënt met een vermoedelijk hooggradig glioom. Er zijn echter aanwijzingen dat bij een glioblastoom een langere overleving wordt behaald bij een uitgebreidere resectie.

Zie voor de beste neurochirurgische behandelingsstrategie bij een patiënt met een vermoedelijk hooggradig glioom, de module [Chirurgische behandelingsstrategie hooggradig glioom](#).

Het is onduidelijk of de te behalen mate van resectie preoperatief betrouwbaar is in te schatten. In het geval een resectie wordt uitgevoerd, is het meten van de mate van resttumor en de mate van tumorverwijdering met behulp van pre- en postoperatieve MRI aan te bevelen ter verslaglegging (zie module [Beeldvormende diagnostiek](#)).

Overwegingen

Het is maar zeer de vraag of een eenduidige afkapwaarde bestaat waarboven een resectie zinvol is en waar beneden een resectie zinloos is. Deze argumenten zijn verwoord door Solheim [2014³²³]. Ten eerste is een continuüm tussen verlengde overleving door verminderde tumorlast waarschijnlijker dan een exacte afkapwaarde op basis van 'biologica'. Ten tweede moeten klinische relevantie en statistische significantie duidelijk onderscheiden worden: studies met grotere patiëntaantallen zullen kleinere verschillen in overleving als statistisch significant kunnen aantonen, terwijl het natuurlijk gaat om de waarde van de mate van levensverlenging. Ten derde is het onduidelijk of pre-operatief een goede inschatting te geven is van de te verwachten mate van resectie.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat een grotere mate van resectie en minder resttumor na operatie voor een glioblastoom gepaard gaat met een langere overleving.

Chaichana 2014⁴⁸, Sanai 2011²⁹², Lacroix 2001¹⁹⁰, Stummer 2008³²⁸

Er zijn aanwijzingen dat bij een glioblastoom een langere overleving wordt behaald bij minimale resectie van respectievelijk 70% -100%; of als alternatieve mate van resectie uit een maximaal restvolume van nul mL of 5 mL.

Chaichana 2014⁴⁸, Sanai 2011²⁹², Lacroix 2001¹⁹⁰, Stummer 2008³²⁸

Samenvatting literatuur

In de literatuur werden vier publicaties gevonden die deze uitgangsvraag als onderzoeksraag direct

proberen te beantwoorden voor glioblastoom.

Lacroix beschreef 416 patiënten, geopereerd voor glioblastoom tussen 1993 en 1999, waarvan 183 patiënten eerdere tumorbehandeling in een ander centrum ondergingen [Lacroix 2001¹⁹⁰]. De mate van resectie werd op basis van MRI-volumetrie gemeten. In multivariate survivalanalyse werd een afkapwaarde van 98% tumorresectie onderzocht, met correctie voor leeftijd, conditie en radiologische parameters (necrose en aankleuring). Een tumorresectie van 98% of meer was significant geassocieerd (adjusted rate ratio 1.6, 95%CI 1.3-2, p < 0.0001) met een langere overleving: 13 maanden (95%CI 11,4-14,6 maanden) vergeleken met 8,8 maanden (95%CI 7,4-10,2 maanden, p < 0.0001) voor patiënten met minder dan 98% tumorresectie. In univariate analyse werden verschillende afkapwaarden voor mate van resectie geëxploereerd. Tot een minimale afkapwaarde van 89% werd in deze groep een associatie met overleving gevonden.

Stummer beschreef 243 patiënten, geopereerd voor glioblastoom tussen 1999 en 2004, in het kader van een multicenter klinische studie naar een operatietechniek (operatiemicroscopie met 5-ALA fluorescentie) [Stummer 2008³²⁸]. De mate van resttumor werd op basis van MRI-volumetrie gemeten. In een multivariate survivalanalyse werd afwezigheid van aankleurende resttumor onderzocht, met correctie voor leeftijd, conditie, preoperatief tumorvolume, eloquentie, midlijn shift, mate van oedeem en ependymale tumorinfiltratie. Afwezigheid van resttumor was significant geassocieerd (adjusted hazard ratio 1.75, 95%CI 1.26-2.44, p < 0.001) met een langere overleving: 16,9 maanden vergeleken met 11,8 maanden voor patiënten met resttumor. In kaplan meier survivalanalyse naar de afkapwaarde voor de mate van resttumor bleken alle categorieën van resttumor (minder dan 0.7 mL, 0.7-1.5 mL, 1.5-4.1 mL, en meer dan 4.1 mL) significant te verschillen in overleving (p = 0.0006) van de patiënten met afwezigheid van resttumor.

Sanai beschreef 500 patiënten, geopereerd voor glioblastoom tussen 1997 en 2009. De mate van resttumor werd op basis van MRI-volumetrie gemeten [Sanai 2011²⁹²]. In een multivariate survivalanalyse werden zowel het volume resttumor als de mate van tumorresectie onderzocht, met correctie voor leeftijd en conditie. Een uitgebreidere resectie (adjusted hazard ratio per procent tumorverwijdering 0.99, CI95% 0.98-0.99, p = 0.004) en minder resttumor (adjusted hazard ratio per mL 1.07, 95%CI 1.04-1.11, p < 0.0001) waren significant geassocieerd met langere overleving. In kaplan meier survivalanalyse werd een langere overleving waargenomen tot een minimale afkapwaarde van 78%.

Chaichana beschreef 259 patiënten, geopereerd voor glioblastoom tussen 2007 en 2011 [Chaichana 2014⁴⁸]. De mate van resttumor werd op basis van MRI-volumetrie gemeten. In een multivariate survivalanalyse werd zowel de mate van tumorresectie als het volume resttumor onderzocht, met correctie voor leeftijd, conditie, carmustinewafer implantatie en chemoradiatie. Een uitgebreidere resectie (adjusted hazard ratio per vijf procent: 0.948, 95%CI 0.918-0.978, p=0.0005) was significant geassocieerd met een langere overleving. De minimale afkapwaarde voor de mate van tumorresectie die nog geassocieerd was met langere overleving is 70% (adjusted hazard ratio: 0.631, 95%CI 0.462-0.875, p=0.0006). De mediane overleving van patiënten met meer dan 70% tumorverwijdering was 14,4 maanden, vergeleken met 10,5 maanden voor patiënten met minder tumorverwijdering (p=0.0003). Een kleiner resttumorvolume (adjusted hazard ratio per 5 mL resttumor: 1.147, 95%CI 1.053-1.261, p=0.001) was eveneens significant geassocieerd met langere

overleving. De maximale afkapwaarde voor volume resttumor was 5 mL (adjusted hazard ratio: 0.725, 95%CI 0.534-0.991, p=0.01). De mediane overleving van patiënten met minder dan 5 mL resttumor was 14,4 maanden, vergeleken met 10,5 maanden voor patiënten met meer resttumor (p = 0.0003).

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Waarde en mate van re-resectie glioblastoom

Uitgangsvraag

- Wat is de waarde van een re-resectie bij progressie van een glioblastoom?
- Hoe groot moet de resectie zijn bij een patiënt met progressie van een glioblastoom?

Aanbeveling

Patiënten met een recidief glioblastoom dienen in een multidisciplinair neuro-oncologisch overleg te worden besproken. In de recidiefsetting dienen palliatieve behandelingen zoals chirurgie, radiotherapie en chemotherapie telkens in overweging genomen te worden.

Er wordt geadviseerd een re-resectie bij recidief glioblastoom te overwegen bij een patiënt met gunstige prognostische factoren (lagere leeftijd, betere conditie, localisatie tumor, lagere verwachte morbiditeit).

Voor de indicatiestelling van een re-resectie kan de NIH-schaal (National Institutes of Health) gebruikt worden, waarbij meerdere prognostisch ongunstige factoren (tumor eloquent of nabij arteria cerebri media gelegen, KPS <=80, tumorvolume >= 50 mL) geassocieerd zijn met een kortere levensverwachting en dus een terughoudender beleid voor re-resectie.

Overwegingen

Verschillende oorzaken kunnen bijdragen aan bias in de genoemde publicaties. Ziekteprogressie is niet eenduidig gedefinieerd waardoor patiënten met pseudoprogressie kunnen zijn geïncludeerd. Selectie van patiënten speelt waarschijnlijk een rol, waardoor patiënten met een gunstiger prognose oververtegenwoordigd zijn in de groep die een re-resectie onderging en dus de prognose en niet de re-resectie oorzaak is van de langere overleving.

De morbiditeit en mortaliteit varieert tussen de studies. Er worden percentages gemeld voor morbiditeit van 4,1% [Hoover 2013¹⁴¹] tot 45% [De Bonis 2013⁷⁴]. De oorzaak van deze variatie is niet onderzocht. De mortaliteit varieert van 0 % [Pinsker 2001²⁶²] tot 5% [Mandl 2008²⁰⁹].

Het lijkt te overwegen re-resectie te verrichten wanneer post-operatief zinvolle tumorremmende behandeling mogelijk is, al dan niet in studieverband.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat een re-resectie bij progressie van een glioblastoom gepaard gaat met een langere overleving en progressievrije overleving. De mate van selectiebias is onduidelijk en is in de recidief setting groter dan bij de novo tumoren. De resultaten van deze studies moeten daarom met grote voorzichtigheid worden geïnterpreteerd.

Guyotat 2000¹²², Xu 2011³⁹⁵, De Bonis 2013⁷⁴, Bloch 2012²⁰, McGirt 2009²¹⁵

Er zijn aanwijzingen dat een re-resectie gepaard gaat met morbiditeit en mortaliteit, vergelijkbaar met een eerste resectie.

Dutzman 2012⁸⁶

Voor de indicatiestelling van een re-resectie kan de NIH schaal (National Institutes of Health) gebruikt worden, waarbij meerdere prognostisch ongunstige factoren (tumor eloquent of nabij arteria cerebri media gelegen, KPS <=80, tumorvolume >= 50 mL) geassocieerd zijn met een kortere levensverwachting en dus een terughoudender beleid voor re-resectie.

Park 2010²⁴⁹

Er is geen literatuur over de minimale mate van resectie bij progressie van een glioblastoom.

Samenvatting literatuur

In de literatuur worden artikelen gevonden die een resectie bij recidief hooggradig glioom hebben onderzocht. Het betreft niet-vergelijkend cohortonderzoek. Vergelijkend gerandomiseerde studies die deze vraag direct beantwoorden, werden niet gevonden. Alleen publicaties waarin specifiek gekeken is naar overleving en/of progressievrije overleving, en/of morbiditeit en/of mortaliteit met betrekking tot resectie bij recidief hooggradig glioom zijn geïncludeerd. Alleen publicaties na 2000 zijn geïncludeerd.

Guyotat vergeleek 2 groepen patiënten met progressief glioblastoom: 18 patiënten kregen een resectie en 36 patiënten kregen geen resectie [Guyotat 2000¹²²]. De groepen werden gematcht voor leeftijd, conditie, mate van resectie bij eerste operatie en het interval tot progressie. Beide groepen kregen de conventionele nabehandeling (chemo-radiatie). De mediane overleving van patiënten na resectie was vijf maanden versus twee maanden zonder resectie. Het verschil was statistisch significant in de univariate analyse. De mediane overleving met een Karnofsky performance status (KPS) score >60, was voor patiënten na resectie vier maanden, vergeleken met één maand voor patiënten zonder resectie.

Pinsker beschreef 38 patiënten met progressief glioblastoom die een resectie ondergingen tussen 1993 en 1998 (17% van 224 patiënten met een glioblastoom) [Pinsker 2001²⁶²]. De mediane overleving was 57 weken. Een KPS van meer dan 90 was geassocieerd met een langere overleving. Functionele achteruitgang deed zich niet voor. Er was geen perioperatieve mortaliteit.

Mandl onderzocht de effecten op overleving en complicaties van resectie bij progressief glioblastoom voor 32 (25%) van 126 glioblastoom patiënten tussen 1999 en 2005 [Mandl 2008²⁰⁹]. De mediane overleving na progressie was 34 weken (95%CI 24,7-43,4) voor 11 patiënten die resectie gevolgd door nabehandeling ondergingen, 13 weken (95%CI 1,3-24,7) voor 9 patiënten die resectie zonder nabehandeling ondergingen en 28 weken (95%CI 12,1-43,9) voor 12 patiënten die alleen chemotherapie of bestraling ondergingen ($p<0.0005$). Chirurgische morbiditeit ontstond bij drie patiënten (15%); één (5%) patiënt overleed na operatie.

Xu beschreef 63 patiënten met progressie van een glioblastoom tussen 2006 en 2008, waarvan 21 patiënten een resectie ondergingen en 42 niet [Xu 2011³⁹³]. De mediane overleving was voor de geopereerde patiënten zeven maanden en voor de niet geopereerde patiënten vier maanden ($p<0.001$). De tijd tot progressie van tumorgroei was voor de geopereerde patiënten vijf maanden en voor de niet geopereerde

patiënten 2,5 maanden ($p<0.001$).

Clarke beschreef een posthocanalyse van gecombineerde data van fase II studies naar chemotherapie bij progressie van een glioblastoom [Clarke 2011⁶⁰]. Oudere studies (1998-2005) bevatten 105 patiënten van 511 die een operatie (biopsie of resectie) ondergingen en nieuwere studies (2005-2008) bevatten 103 patiënten van 247 die een operatie (biopsie of resectie) ondergingen. De overleving of progressievrije overleving van patiënten die een operatie (biopsie of resectie) ondergingen verschilde niet van patiënten die geen operatie ondergingen.

Dutzman onderzocht het risico op ischemie en neurologische uitval bij re-resectie bij recidief groei van het glioblastoom [Dutzman 2012⁸⁶]. Van de 177 beschreven patiënten werden 130 patiënten (73,3%) één maal geopereerd en 47 (26,5%) twee of meerdere malen geopereerd. Bekende prognostica waren evenredig verdeeld over beide groepen. 46 patiënten (26%) hadden ischemie (DWI) op de postoperatieve MRI. Bij 18 patiënten (10,2%) was de ischemie groter dan 4 cm³. Elf van deze patiënten (6,2%) hadden ook neurologische uitval. Er was echter geen verschil in ontstaan van ischemie (27.7 vs. 21.3%, $p=0.77$) en neurologische uitval (10.0 vs. 10.6%, $p=1.0$) tussen de groepen die één maal of meer dan één maal werd geopereerd. Tumorlocatie in de insula, operculum en temporaalkwab was wel geassocieerd met ontstaan van nieuwe ischemische laesies.

Moiyadi onderzocht in een cohort de postoperatieve complicaties bij patiënten met progressie van een glioblastoom [Moiyadi 2012²¹]. Er werden 41 re-operaties in een database van 196 operaties voor gliomen geëvalueerd. Neurologische achteruitgang werd beschreven bij 22,2% van de patiënten. Bij 44% van de patiënten was er sprake van neurologische verbetering na de re-operatie. Bij 14,2% van de patiënten werden regionale en bij 4,8 % werden systemische complicaties gemeld. De morbiditeit was 29,3% en de mortaliteit was 2,4%.

De Bonis onderzocht de effectiviteit van resectie en adjuvante behandeling op overleving bij 76 patiënten met progressie van een glioblastoom behandeld tussen 2002 en 2008 [De Bonis 2013⁷⁴]. Zeventien patiënten ondergingen alleen een resectie, 24 alleen adjuvantetherapie, 16 resectie en adjuvante therapie, en 19 geen behandeling. Dit ging gepaard met een mediane overleving van 6, 8, 14 en 5 maanden ($p=0.01$). Patiënten met een KPS <70 hadden een significant hoger risico om te overlijden (HR 2.8; $p=0.001$). Subgroepanalyse toonde geen significante verschillen in overleving tussen een radiologisch complete of incomplete resectie. Ook was er geen verschil in patiënten die verschillende adjuvante therapieën kregen. Postoperatieve complicaties deden zich voor bij 16 (48%) van de 33 geopereerde patiënten.

Bloch onderzocht de relatie tussen de mate van resectie en de overleving bij 107 patiënten, die een tweede resectie ondergingen bij progressie van een glioblastoom tussen 2005 en 2009 [Bloch 2012²⁰]. De mediane overleving vanaf de eerste diagnose was voor 31 patiënten met een radiologisch complete resectie bij zowel eerste als tweede resectie 20,4 maanden. Voor 21 patiënten met een radiologisch complete resectie bij eerste en een partiële resectie bij tweede operatie was deze 18,4 maanden. Voor 26 patiënten met een partiële resectie bij eerste en een radiologisch complete resectie bij tweede operatie was deze 19 maanden. En voor 29 patiënten met zowel bij eerste als tweede operatie een partiële resectie was deze 15,9 maanden ($p = 0.004$). De mediane overleving vanaf progressie verschilde eveneens: respectievelijk 11.5, 8.5, 16.7 en

7.4 maanden ($p = 0.001$). In multivariate analyse was een uitgebreidere resectie geassocieerd met een langere overleving (HR: 0.62, 95%CI 0.41-0.93, $p = 0.03$) na correctie voor leeftijd, conditie bij eerste resectie, conditie bij tweede resectie en mate van eerste resectie.

Hong beschreef 42 patiënten met progressief glioblastoom die werden geopereerd tussen 2006 en 2010, waarvan 34 patiënten een radiologisch complete re-resectie ondergingen en 10 patiënten met herhaalde re-resecties [Hong 2013¹⁴⁰]. De overleving na radiologisch complete re-resectie was 16 maanden en na incomplete resectie 14 maanden (HR 1.86, 95%CI 0.86-3.92; $p=0.112$).

Park beschreef 34 patiënten met een progressief glioblastoom op basis waarvan een prognostisch model voor overleving na re-resectie werd opgesteld [Park 2010²⁴⁹]. Een kortere overleving na re-resectie was geassocieerd met tumor in eloquente of kritische gebieden, een KPS ≤ 80 , en een tumorvolume ≥ 50 mL. Met deze drie factoren werden een totaalscore samengesteld van 0 tot 3 (voor aan-/afwezigheid van elk van deze factoren). Een score van 0, 1-2 en 3 was respectievelijk geassocieerd met een postoperatieve overleving van 10.8, 4.5 en 1.0 maanden ($p <0.001$). In een validatie cohort van 109 patiënten met een progressief glioblastoom werd deze score geverifieerd, waarbij de prognostische waarde bevestigd werd met 9.2, 6.3 en 1.9 maanden, respectievelijk (HR 3.0, 95%CI 1.54-5.83, $p<0.001$).

McGirt beschreef 949 patiënten met een WHO-graad III of IV astrocytoom die geopereerd werden tussen 1996 en 2006, waarvan 400 een re-resectie ondergingen [McGirt 2009²¹⁵]. Na een radiologisch complete re-resectie was de mediane overleving elf maanden, na een bijna complete re-resectie negen maanden en na een subtotalresectie vijf maanden. In multivariate analyse was een uitgebreidere re-resectie geassocieerd met langere overleving (radiologisch complete resectie vergeleken met een subtotalresectie HR 0.566, $p = 0.002$; radiologisch bijna-complete resectie vergeleken met een subtotalresectie HR 0.630, $p = 0.004$) na correctie voor leeftijd, conditie, motorische uitval, temozolamide en vervolgoperaties.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Radiotherapie bij hooggradig glioom

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Indicatie radiotherapie anaplastisch glioom
- Indicatie radiotherapie glioblastoom
- Radiotherapie bij progressie hooggradig glioom/recidief

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Indicatie radiotherapie anaplastisch glioom

Uitgangsvraag

Wat is de indicatie voor radiotherapie bij een patiënt met een anaplastisch glioom (WHO graad III) en hoe dient dit uitgevoerd te worden?

Aanbeveling

Het meest gangbare fractioneringschema voor het anaplastisch glioom bedraagt 59.4 Gy in 33 fracties van 1.8 Gy gegeven in vijf fracties per week. De werkgroep is van mening dat dit tenminste met 3D conformal radiation therapy (3DCRT-techniek) dient te worden gegeven.

Er wordt geadviseerd, in afwachting van de resultaten van de EORTC-26053-studie (CATNON), patiënten met een anaplastisch glioom zonder gecombineerde 1p/19q-deletie te behandelen met postoperatieve radiotherapie alleen.

Patiënten met een anaplastisch glioom met een 1p/19q-deletie dienen post-operatief behandeld te worden met radiotherapie gevuld door zes kuren PCV, volgens het EORTC-26951-protocol.

De werkgroep is van mening dat op indicatie, bijvoorbeeld bij groot bestralingsvolume en daardoor verhoogd risico op toxiciteit van radiotherapie, overwogen kan worden patienten met een anaplastisch glioom te behandelen met chemotherapie (PCV of temozolamide) in plaats van radiotherapie.

Overwegingen

Naar aanleiding van de resultaten van de NOA-4 studie, waarbij geen verschil tussen RT, PCV of temozolamide werd gevonden in de mediane tijd tot progressieve ziekte bij postoperatieve nabehandeling van anaplastische gliomen zonder 1p/19q-deletie, zou bij een zeer groot doelvolume en een hierbij te verwachten grote kans op toxiciteit van radiotherapie, overwogen kunnen worden te kiezen voor temozolamide als postoperatieve behandeling [Wick 2009³⁸⁶].

Moderne radiotherapie dient tenminste uitgevoerd te worden met 3D conformal radiation therapy. In veel centra worden geavanceerde technieken als intensity modulated radiotherapy, volumetric arc therapy of tomotherapy gebruikt, teneinde het hoge dosis gebied zo optimaal mogelijk te laten aansluiten bij het doelgebied. Er bestaat echter geen bewijs dat geavanceerde planningstechnieken de prognose verbeteren of het risico op complicaties verminderen. Vanwege vroege veranderingen in het operatiegebied en de mogelijkheid van snelle progressie bij het hooggradig glioom is het aan te bevelen de MRI zo kort mogelijk aan te laten sluiten bij het begin van de radiotherapie. In gevallen waarbij er een langer interval tussen de operatie en start radiotherapie bestaat, dient de postoperatieve MRI dan ook herhaald te worden ten behoeve van accurate vaststelling van doelgebieden. Het te bestralen gebied omvat de resectieholte, het (resterende) aankleurende gebied op de T1-contrastsequentie van de (postoperatieve) MRI met 1,5-2 cm marge voor microscopische ziekte, waarbij het hyperintense gebied op de T2/FLAIR-sequenties wordt

geïncludeerd conform de recente en lopende EORTC studies (CATNON, CODEL). Tenslotte worden de natuurlijke barrières in acht genomen. Wanneer er alleen een biopsie is verricht, volstaat de preoperatieve MRI-scan.

Onderbouwing

Conclusies

Het is aannemelijk dat voor het anaplastisch glioom, een bestralingsdosis van 59.4 Gy in 33 fracties van 1.8 Gy gegeven in 5 fracties per week, effectief is. Er zijn geen aanwijzingen dat een hogere bestralingsdosis effectiever is.

Bleehen 1991¹⁸

Toevoeging van PCV aan postoperatieve radiotherapie resulteert in een aanzienlijke verbetering van de overleving bij anaplastische gliomen met een 1p/19q-deletie ten opzichte van postoperatieve radiotherapie alleen.

Cairncross 2013⁴¹, Van den Bent 2013³⁵¹

Er is geen bewijs dat de toevoeging van PCV chemotherapie aan postoperatieve radiotherapie een toegevoegde waarde heeft in de behandeling van het anaplastische glioom zonder een 1p/19q-deletie.
Cairncross 2013⁴¹, Van den Bent 2013³⁵¹

De gecombineerde behandeling met postoperatieve radiotherapie en PCV bleek geen verslechtering van cognitie of kwaliteit van leven te veroorzaken op de lange termijn ten opzichte van radiotherapie alleen.
Van den Bent 2013³⁵¹, Habets 2014¹²³, Wang 2010³⁷⁵

Samenvatting literatuur

Tot de anaplastische gliomen, ook geduid als WHO graad III tumoren, worden de verschillende subtypes anaplastisch astrocytoom, anaplastisch oligodendrogloom en anaplastisch oligoastrocytoom gerekend [Louis 2007²⁰⁴].

Postoperatieve radiotherapie is van oudsher het standaard beleid bij anaplastisch glioom, hoewel de exacte bewijsvoering hiervoor beperkt is. De hierover gerapporteerde studies bevatten een combinatie van patiënten met hooggradige gliomen (HGG), waarbij het aantal geïncludeerde patiënten met een anaplastisch glioom veelal te gering was voor subanalyses. Daarnaast waren de studies verschillend van opzet wat betreft bestralingsdoses, definitie van doelgebieden en het al dan niet gecombineerd toedienen van bestraling en chemotherapie [Walker 1978³⁷³, Kristiansen 1981¹⁸³, Gannett 1994¹⁰⁶, Laperierre 2002¹⁹¹, Mukherjee 2013]²²³.

De meest gangbare bestralingsdosis voor het anaplastisch glioom bedraagt 59.4 Gy in 33 fracties van 1.8 Gy gegeven in 5 fracties per week, waarbij de kans op late neurotoxiciteit wordt verlaagd door het gebruik van een lage dosis per fractie. Voor hooggradig glioom WHO graad III en IV, werd een dosis respons relatie tussen 45 Gy en 60 Gy aangetoond in een oudere MRC studie; er bestaan geen gerandomiseerde data over het nut van een hogere bestralingsdosis [Bleehen 1991¹⁸].

In toenemende mate spelen moleculaire markers een rol in de diagnose en de behandeling van het anaplastisch glioom, zoals bijvoorbeeld de MGMT-promotor methylatie, IDH-mutaties en het gecombineerde verlies van 1p/19q [Roth 2013²⁸³, Gorlia 2013¹¹³], zie ook de module Moleculaire veranderingen diffuse gliomen. Het betrekken van de histologie, moleculaire markers met name het gecombineerde 1p/19q-verlies, en andere individuele patiëntkarakteristieken geeft richting aan het bepalen van postoperatieve therapie bestaande uit radiotherapie, een gecombineerde behandeling of chemotherapie alleen.

Het anaplastische astrocytoom is het meest voorkomende subtype van het anaplastisch glioom, waarbij gecombineerd 1p/19q-verlies vrijwel niet wordt gezien (gemistocytair type 0%, fibrillaire-type 7%) [Ohgaki 2005²³⁵]. De standaardbehandeling van anaplastische astrocytoom bestaat uit postoperatieve radiotherapie zonder chemotherapie. Omdat door velen het anaplastische astrocytoom wordt gezien als een voorloperstadium van het glioblastoom wordt internationaal veelvuldig volgens het EORTC 'Stupp-schema' behandeld met gelijktijdig en adjuvant temozolamide (TMZ), zonder dat hier bewijsvoering voor is. Om de waarde van concomitante en adjuvante chemotherapie vast te stellen bij het anaplastische astrocytoom dienen de resultaten van de lopende CATNON-studie (EORTC-26053) afgewacht te worden. In deze studie worden patiënten met een anaplastische astrocytoom (en het anaplastisch oligodendroglioom en anaplastisch oligoastrocytoom zonder 1p/19q-verlies) gerandomiseerd naar een van de vier armen (radiotherapie alleen, radiotherapie met alleen concomitante TMZ, radiotherapie met alleen adjuvante TMZ, of radiotherapie met concomitante en adjuvante TMZ).

Op het gebied van de anaplastisch oligodendroglioom en anaplastisch oligoastrocytoom-subtypes hebben zich de laatste jaren veel ontwikkelingen voorgedaan. Gecombineerd verlies van 1p/19q komt, in tegenstelling tot bij anaplastische astrocytoom, zeer frequent voor, bijvoorbeeld bij ongeveer 76% van het anaplastisch oligodendroglioom en 24% bij het anaplastisch oligoastrocytoom in de hierna besproken RTOG-studie [Cairncross 2013⁴¹]. De langetermijnresultaten van de EORTC-26951-studie en de RTOG-9402 studie, waarbij werd gerandomiseerd werd tussen radiotherapie alleen of in combinatie met PCV (procarbazine, lomustine, vincristine), lieten beiden een significant voordeel zien voor de gecombineerde behandeling bij patiënten met 1p/19q-verlies (14,7 versus 7,3 jaar in de RTOG-studie - mediane overleving niet bereikt - versus 112 maanden in de EORTC-studie) [Van den Bent 2013³⁵¹, Cairncross 2013⁴¹]. In de groep patiënten zonder 1p/19q-verlies werd geen voordeel van de gecombineerde behandeling gevonden (2,6 versus 2,7 jaar). Hoewel de gecombineerde behandeling met PCV meer vroege (hematologische) toxiciteit veroorzaakt, is hiervan geen negatief effect op de cognitie of kwaliteit van leven aangetoond [Van den Bent 2013³⁵⁴, Habets 2014¹²³, Wang 2010³⁷⁵]. Deze resultaten maken radiotherapie gecombineerd met PCV de huidige standaardbehandeling voor patiënten met anaplastisch oligodendroglioom of anaplastisch oligoastrocytoom met gecombineerd 1p/19q-verlies. Voor patiënten zonder deze gecombineerde deletie is, in afwachting van de resultaten van de CATNON-studie, postoperatieve radiotherapie alleen de standaardbehandeling.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Indicatie radiotherapie glioblastoom

Uitgangsvraag

Wat is de indicatie voor radiotherapie bij een patiënt met een glioblastoom (WHO graad IV) en hoe dient dit uitgevoerd te worden?

Aanbeveling

Bij patiënten met een glioblastoom in goede klinische conditie, jonger dan 61 jaar dient post-operatief een radiotherapiedosis van 30 x 2 Gy gegeven te worden, gecombineerd met concomitant en adjuvant temozolamide. Voor de behandeling van oudere patiënten met een glioblastoom wordt verwezen naar de module Behandeling van ouderen.

Er wordt geadviseerd geen hogere bestralingsdosis toe te dienen. De werkgroep adviseert hypofractionering te overwegen bij patiënten die in een matige conditie zijn.

De werkgroep is van mening dat het doelgebied van de bestraling de resectieholte, het (resterende) aankleurende gebied op de T1-sequentie met contrast van de postoperatieve MRI, met een marge van 1,5-2 cm voor microscopische ziekte, het doelgebied zou moeten zijn. Hierbij wordt rekening gehouden met het hyperintense gebied op de T2- en FLAIR-sequenties en de anatomische barrières.

Overwegingen

De gecombineerde behandeling van hoge dosis radiotherapie en temozolamide toont de meeste winst in overleving in de groep patiënten <50 jaar in een goede postoperatieve conditie. Bij patiënten met een KPS <70 en een leeftijd ≥50 jaar is de winst van de gecombineerde behandeling beperkt.

Als er tijdens het behandelen klachten ontstaan die veroorzaakt worden door (radiotherapie-geïnduceerd) oedeem, kan het starten met (een lage dosis) dexamethason geïndiceerd zijn.

De planning en uitvoering van de bestraling dient tenminste plaats te vinden met behulp van een 3DCRT-techniek. Teneinde het hoge dosis gebied zoveel mogelijk te beperken tot het doelgebied, wordt het gebruik van meer geavanceerde technieken zoals intensity modulated radiotherapy (IMRT), volumetric arc therapy of tomotherapie, aangemoedigd. Er bestaat echter geen bewijs dat geavanceerde planningstechnieken de prognose verbeteren of het risico op toxiciteit verminderen. Vanwege vroege veranderingen in het operatiegebied en de mogelijkheid van snelle progressie bij het GBM is het aan te bevelen de MRI zo kort mogelijk aan te laten sluiten bij het begin van de radiotherapie. In gevallen waarbij er een langer interval tussen de operatie en start radiotherapie bestaat, dient de postoperatieve MRI dan ook herhaald te worden ten behoeve van accurate vaststelling van doelgebieden.

Onderbouwing

Conclusies

Postoperatieve radiotherapie is standaardbeleid na resectie van een glioblastoom, indien de klinische situatie van de patiënt dit toelaat. Een overlevingsvoordeel is aangetoond bij een dosis van 60 Gy ten opzichte van 45

Gy, echter de mediane overleving lijkt niet te verbeteren bij verdere ophoging van de totale bestralingsdosis. Walker 1979³⁷⁴, Bleehen 1981¹⁹, Nelson 1988²²⁶, Nakagaya 1998²²⁴, Chan 2002⁵⁰

Er zijn aanwijzingen dat postoperatieve hypofractionering een gelijkwaardige uitkomst geeft als conventioneel gefractioneerde radiotherapie, maar dit is met name onderzocht bij patiënten met een ongunstige prognose in een niet gerandomiseerde setting en bij oudere patiënten. Slotman 1996³¹⁷, Sayin 2007²⁹⁹, Hingorani 2012¹³⁵

Het is aangetoond dat een hogere lokale bestralingsdosis met behulp van een stereotactische radiochirurgie of brachytherapieboost geen voordeel biedt ten opzichte van standaarddosis bestraling. Souhami 2004³²⁴, Laperriere 1998¹⁹²

Het is aangetoond dat gecombineerd postoperatieve radiotherapie (60 Gy/30 fracties) met gelijktijdig en adjuvant temozolamide een voordeel in overleving biedt ten opzichte van radiotherapie alleen. Stupp 2005³³¹, 2009³³⁰

Samenvatting literatuur

Bij ongeveer 80% van de patiënten die zich presenteren met een hooggradig glioom is sprake van een glioblastoom (WHO graad IV) [Omuro 2013²³⁸]. Zowel tumor- als patiëntgerelateerde factoren, zoals de mate van resectie, de leeftijd en de klinische/neurologische conditie (Karnofsky performance score, KPS), hebben een impact op de prognose en dienen meegenomen te worden bij het afstemmen van de postoperatieve behandeling en het bestralingsschema. Gezien het palliatieve karakter van de behandeling moet overlevingswinst worden afgewogen tegen de morbiditeit van de behandeling en het effect op de kwaliteit van leven. De behandeling van het glioblastoom bij de oudere patiënt wordt afzonderlijk in de module Behandeling van ouderen besproken.

De waarde van postoperatieve radiotherapie bij de behandeling van patiënten met een glioblastoom is in meerdere gerandomiseerde studies aangetoond, waarbij er een winst in mediane overleving wordt gezien van rond de 5 maanden ten opzichte van resectie alleen [Walker 1979³⁷⁴, Kristiansen 1981¹⁸³].

Het bestralingsvolume omvat de resectieholte, het (resterende) aankleurende gebied op de T1- sequentie met contrast van de postoperatieve MRI. Een marge van 1,5-2 cm voor microscopische ziekte (clinical target volume, CTV) wordt aangehouden, waarbij het hyperintense gebied op de T2- en FLAIR-sequenties wordt geïncludeerd. Het CTV kan worden aangepast op basis van anatomische barrières. Er zijn echter geen aanwijzingen dat krappere marges het patroon van recidiveren van het glioblastoom beïnvloedt (80% recidiveert binnen 2 cm van de oorspronkelijke tumor) [McDonald 2011²¹³, Paulsson 2014²⁵²]. Wanneer er alleen een biopsie is verricht volstaat de preoperatieve MRI-scan.

In oudere gerandomiseerde studies is een overlevingsvoordeel aangetoond van een dosis van 60 Gy ten opzichte van een dosis van 45 Gy [Walker 1979³⁷⁴, Bleehen 1981¹⁹]. De mediane overleving werd niet verbeterd bij het verhogen van de dosis van 60 naar 70 Gy (9.3 versus 8.2 maanden) [Nelson 1988²²⁶, Nakagaya 1998²²⁴, Chan 2002⁵⁰]. In een gerandomiseerde studie werd geen voordeel gezien van de toevoeging van stereotactische radiochirurgie (SRS) als boost aan conventionele radiotherapie [Souhami 2004³²⁴]. Evenmin kon een gerandomiseerde studie een verbetering van de overleving door de toevoeging

van brachytherapie aan conventionele radiotherapie aantonen [Laperriere 1998¹⁹²]. Gezien de beperkte levensverwachting van patiënten met een glioblastoom heeft men in verschillende studies gekeken naar het verkorten van de behandelduur met behulp van hypofractionering, vooral bij patiënten met een ongunstige prognose [Slotman 1996³¹⁷, Sayin 2007²⁹⁹]. Een overzichtsartikel over hypofractionering bij het glioblastoom concludeert aan de hand van studies met verschillende bestralingsschema's, uiteenlopend van 30 Gy in 6 fracties tot 54 Gy in 18 fracties, dat hiermee een gelijkwaardige uitkomst wordt gezien als met conventionele fractionering; dit ondanks een lagere totale bestralingsdosis. Er werd geen toename van toxiciteit gezien van hypofractionering [Hingorani 2012¹³⁵]. In de groep patiënten van 60 jaar of ouder met een glioblastoom is behandeling met hypofractionering in een gerandomiseerde setting vergeleken met conventionele fractionering, waarbij een vergelijkbare overleving werd gezien [Roa 2004²⁷⁹]. In de module Behandeling van ouderen wordt verder ingegaan op de Nordic trial die bij patiënten van 60 jaar of ouder met een glioblastoom gerandomiseerd heeft tussen behandeling met een gehypofracioneerd bestralingsschema, conventionele fractionering en TMZ [Hingorani 2012¹³⁵].

De toevoeging van chemotherapie in de vorm van temozolomide (TMZ) aan postoperatieve radiotherapie in een dosis van 60 Gy in fracties van 2 Gy, is sinds de uitkomst van de EORTC- 26981/22981-NCIC CE3-studie de standaardbehandeling na resectie van het glioblastoom [Stupp 2005³³¹]. In een update van de resultaten van de genoemde EORTC-studie werd het significante voordeel van de gecombineerde behandeling bevestigd met een 5-jaars overleving van 10% voor de gecombineerde behandeling versus 2% met radiotherapie alleen. Het overlevingsvoordeel van de gecombineerde behandeling was het grootst in de groep patiënten jonger dan 50 jaar met een KPS van 90-100, waarbij de 2-jaars overleving toenam van 20% naar 43% en de 5-jaars overleving 28% was [Mirimanoff 2006²²⁰, Stupp 2009³³⁰]. Bij patiënten, waarbij zowel de KPS <70 was als de leeftijd ≥50 jaar, en bij patiënten met neurologische uitval, was de winst van de gecombineerde behandeling beperkt: 10 maanden ten opzichte van 9 maanden voor radiotherapie alleen [Mirimanoff 2006²²⁰, Stupp 2009³³⁰]. In enkele kleine prospectieve- en retrospectieve studies is gehypofracioneerde radiotherapie gecombineerd met TMZ bestudeerd, vooral bij oudere patiënten [Hingorani 2012¹³⁵].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Radiotherapie bij progressie hooggradig glioom/recidief

Uitgangsvraag

Wat is de indicatie voor radiotherapie bij een patiënt met een recidief of progressie van een hooggradig glioom in een eerder bestraald gebied en hoe dient deze uitgevoerd te worden?

Aanbeveling

Patiënten met een recidief hooggradig glioom dienen in een multidisciplinair neuro-oncologisch overleg besproken te worden. In de recidiefsetting dienen alle palliatieve behandelingen, waaronder radiotherapie en chirurgie, telkens mede in overweging genomen te worden.

De werkgroep is van mening dat behandeling in studieverband de voorkeur verdient.

De werkgroep is van mening dat een minimaal interval van zes tot twaalf maanden aangehouden dient te worden tussen de initiële bestraling en re-irradiatie.

Bij de afweging of re-irradiatie een reële optie is, speelt de definitie van het doelgebied de belangrijkste rol. De toepassing van kleinere marges dan in de primaire setting wordt geadviseerd.

Om het risico op radiatie-geïnduceerde complicaties zoveel mogelijk te beperken wordt geadviseerd re-irradiatie te plannen met moderne bestralingstechnieken zoals stereotactische radiotherapie, intensity modulated radiotherapy (IMRT) of volumetric modulated arc therapy (VMAT).

De werkgroep is van mening dat er vanuit de literatuur geen optimaal fractioneringsschema vast te stellen is. Voor zowel conventioneel gefractioneerde schema's, hypofractionering of een enkele fractie radiochirurgie zijn series in de literatuur beschreven.

Overwegingen

Er bestaat geen standaardbehandeling voor een recidief hooggradig glioom (HGG), zodat de werkgroep van mening is dat de eerste keuze voor patiënten in goede conditie een behandeling in studieverband is.

Patiënten met een recidief HGG dienen in een neuro-oncologisch multidisciplinair overleg besproken te worden, temeer daar er verschillende behandelopties, zoals reresectie, (tweedelijns)chemotherapie, gerichte medische therapieën, re-irradiatie of combinaties bestaan.

Onderbouwing

Conclusies

Vanwege het ontbreken van gerandomiseerde studies die reresectie, re-irradiatie, (tweedelijns)chemotherapie of gerichte medische therapieën met elkaar hebben vergeleken, bestaat er geen standaardbehandeling voor patiënten met een recidief hooggradig glioom.

Amichetti 2011⁵

Er zijn aanwijzingen dat een minimaal interval van zes tot twaalf maanden moet worden aangehouden tussen de initiële bestraling en re-irradiatie.

Niyazi 2011²³¹

Het is aannemelijk dat de definitie van het doelgebied de belangrijkste afweging is met betrekking tot de mogelijkheid en verwachte toxiciteit van re-irradiatie [Nieder 2011[220]]. In de meeste series wordt het doelgebied bepaald door de contrast-aankleurende gebieden op MRI met geringe marges van 0,5-1 cm. Henke 2009¹³³, Fokas 2009¹⁰¹, Combs 2005⁶⁴, Vordermark 2005³⁶⁹

Er zijn aanwijzingen dat moderne bestralingstechnieken zoals stereotactische radiotherapie, intensity modulated radiotherapy (IMRT) of (volumetric modulated arc therapy) VMAT, het eerder bestraalde hersenweefsel minder belasten, waardoor het risico op radiatie-geïnduceerde complicaties kleiner wordt. Fogh 2010¹⁰⁰

Gezien de diversiteit van de studies is er geen goede aanbeveling voor het optimale fractioneringschema te verkrijgen uit de literatuur.

Hoewel niet gerandomiseerd onderzocht, lijkt de toevoeging van chemotherapie aan re-irradiatie de overleving niet te verbeteren.

Amichetti 2011⁵

Samenvatting literatuur

Hoewel er de laatste jaren vooruitgang is geboekt in de behandeling van geselecteerde patiënten met een hooggradig glioom (HGG) met de combinatiebehandeling bestaande uit chirurgie, radiotherapie en chemotherapie, ontstaat een recidief in ongeveer 90% van de patiënten binnen het eerdere bestralingsgebied [Niyazi 2011²³¹, Amichetti 2011⁵, Weller 2013³⁷⁸]. Het onderscheid tussen radiatie-geïnduceerde veranderingen en tumorprogressie op grond van de beeldvorming kan lastig zijn en wordt besproken in evidence based vraag 1. Bij blijvende twijfel is histologische verificatie noodzakelijk voor het starten van tweedelijnsbehandeling, zeker ook indien re-irradiatie wordt overwogen.

Omdat bij een recidief HGG verschillende palliatieve behandelmogelijkheden vorhanden zijn zoals reresectie, (tweedelijns)chemotherapie, re-irradiatie of combinaties hiervan, dient bespreking in een neuro-oncologisch MDO plaats te vinden. Er bestaan geen gerandomiseerde studies in de recidief HGG setting die de genoemde behandelmogelijkheden vergelijken. In module 2.1 en 2.2 wordt ingegaan op de rol van reresectie en (tweedelijns)chemotherapie en gerichte medische therapieën bij een recidief HGG. De keuze van behandeling wordt vooral bepaald door factoren als klinische conditie, interval tussen initiële behandeling en diagnose van recidief, en de uitgebreidheid en lokatie van het recidief. Door het bovenstaande bestaat er geen standaardbehandeling voor patiënten met een recidief HGG en is de eerste keuze voor patiënten in goede conditie een behandeling in studieverband [Amichetti 2011⁵].

In tegenstelling tot de radiotherapie voor het primair HGG bestaat er geen consensus in de literatuur over het optimale fractioneringsschema of de vaststelling van doelgebieden bij re-irradiatie van HGG. Wel wordt in de meeste studies een minimaal interval van zes tot twaalf maanden aangehouden tussen de eerdere bestraling en re-irradiatie [Niyazi 2011²³¹]. De belangrijkste afweging met betrekking tot de mogelijkheid en verwachte toxiciteit van re-irradiatie betreft niet zozeer de gebruikte bestralingsdosis, maar de definitie van

het doelgebied [Nieder 2011²²⁸]. In de meeste gerapporteerde studies wordt het doelgebied bepaald door de contrast-aankleurende gebieden op MRI met geringe marges van 0,5-1 cm, zonder de witte stof afwijkingen op de T2 sequenties te includeren zoals gebruikelijk in de primaire behandeling [Henke 2009¹³³, Fokas 2009¹⁰¹, Combs 2005⁶⁴, Vordermark 2005³⁶⁹]. Moderne bestralingstechnieken zoals stereotactische radiotherapie, intensity modulated radiotherapy (IMRT) of volumetric modulated arc therapy (VMAT) maken precisiebestraling mogelijk, waardoor de dosis van het eerder bestraalde hersenweefsel en daarmee het risico op radiatie-geïnduceerde complicaties kleiner wordt. Een belangrijke ondersteunende studie voor het belang van moderne technieken en beperkte doelgebieden is de studie van Fogh et al, waarbij re-irradiatie van recidief HGG werd uitgevoerd in 147 patiënten met behulp van hypofractionering met stereotactische precisie tot een mediane totale dosis van 35 Gy in fracties van 3,5 Gy. In deze studie werd uitsluitend het aankleurende gebied op de T1-contrast MRI als doelgebied gebruikt. Niet alleen toonde deze relatief grote studie een mediane overleving van tien tot elf maanden in zowel anaplastische gliomen als glioblastomen, maar werd er eveneens vrijwel geen graad ≥ 3 toxiciteit gezien (slechts in 1 patiënt behandeld met een dosis boven de 40 Gy) [Fogh 2010¹⁰⁰]. Bij de afweging of re-irradiatie een reële optie is, speelt naast de tumorlokatie ten opzichte van kritische normale organen, de definitie van de RTH doelgebieden, ook de grootte van het contrast-aankleurende gebied op de MRI een rol, waarbij er in de literatuur geen consensus is over de maximale grootte hiervan. In de praktijk blijkt men terughoudend te zijn bij re-irradiatie van een aankleurend tumorrecidief dat groter is dan 5 cm.

Wat betreft het optimale fractioneringsschema is geen goede aanbeveling te verkrijgen uit de literatuur. Niet-gerandomiseerde, veelal retrospectieve studies zijn gepubliceerd voor een enkele fractie radiochirurgie, extreme of minder extreme hypofractionering, of conventioneel gefractioneerde (stereotactische) schema's met uiteenlopende doses, en de resultaten hiervan zijn over het algemeen vergelijkbaar, evenals de toxiciteit. Een vergelijkende studie tussen deze radiotherapie technieken ontbreekt echter, zodat het niet goed mogelijk is een aanbeveling te doen. Een aantal studies rapporteren over de toepassing van brachytherapie (meestal ¹²⁵I of ¹⁹²Ir), met eveneens wisselende resultaten en toxiciteit [Amichetti 2011⁵]. Het risico op (symptomatische) radionecrose waarvoor reresectie noodzakelijk blijkt te zijn wordt zeer wisselend gerapporteerd voor de verschillende behandelingen, maar kan oplopen tot 31% [Amichetti 2011⁵]. Herbestraling met ge(hypo)fractioneerde stereotactische radiotherapie werd in een aantal series gecombineerd met chemotherapie, meestal temozolamide. Hoewel ook dit niet gerandomiseerd werd vergeleken, verbeterde de toevoeging van chemotherapie de overleving niet ten opzichte van radiotherapie alleen [Amichetti 2011⁵, Fogh 2010¹⁰⁰].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chemotherapie/systeemtherapie bij hooggradig glioom

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Chemotherapie nieuw gediagnostiseerd anaplastisch glioom
- Chemotherapie recidief anaplastisch glioom
- Chemotherapie nieuw gediagnostiseerd glioblastoom
- Chemotherapie recidief glioblastoom

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chemotherapie nieuw gediagnostiseerd anaplastisch glioom

Uitgangsvraag

Wat is de indicatie voor chemotherapie bij een patiënt met een nieuw gediagnostiseerd anaplastisch glioom?

Aanbeveling

Patiënten met een anaplastisch glioom met een 1p/19q-deletie dienen post-operatief behandeld te worden met radiotherapie (zie module Indicatie radiotherapie anaplastisch glioom) gevolgd door zes kuren PCV, volgens het EORTC-26951-protocol.

Er wordt geadviseerd, in afwachting van de resultaten van de EORTC-26053-studie (CATNON), patiënten met een anaplastisch glioom zonder gecombineerde 1p/19q-deletie te behandelen met postoperatieve radiotherapie alleen.

Bij te verwachten grote neurotoxiciteit van radiotherapie door een zeer groot doelvolume zou overwogen kunnen worden te kiezen voor temozolamide als postoperatieve behandeling bij anaplastische gliomen zonder 1p/19q-deletie [Wick 2009³⁸⁶].

Overwegingen

Bij te verwachten grote neurotoxiciteit van radiotherapie door een zeer groot doelvolume zou overwogen kunnen worden te kiezen voor temozolamide als postoperatieve behandeling bij anaplastische gliomen zonder 1p/19q-deletie [Wick 2009³⁸⁶].

Onderbouwing

Conclusies

Bij anaplastische gliomen met een 1p/19q-deletie is een verlenging van de overleving aangetoond, door PCV chemotherapie aan de radiotherapie toe te voegen.

Van den Bent 2013³⁵¹, Cairncross 2013⁴¹

Er zijn aanwijzingen dat er geen verschil is in progressievrije overleving tussen nabehandeling met monotherapie radiotherapie, PCV of TMZ.

Wick 2009³⁸⁶

Samenvatting literatuur

Chemotherapie voorafgaand aan resectie (neoadjuvant)

Er zijn geen data die het toevoegen van chemotherapie voorafgaand aan een resectie, met als doel de tumor kleiner te maken zodat een betere resectie kan worden verkregen, ondersteunen.

Adjuvante chemotherapie (= aanvullende chemotherapie direct na resectie) al dan niet in combinatie met radiotherapie, zonder dat er op de scan sprake is van tumorprogressie.

Oligodendrogliale tumoren zijn gevoeliger voor chemotherapie dan tumoren die geen oligodendrogliale

kenmerken hebben. De waarde van adjuvante chemotherapie voor patiënten met een 1p/19q-deletie werd aangetoond in zowel de EORTC-26951 [van den Bent 2013³⁵¹] als de RTOG-9402 [Cairncross 2013⁴¹] studie. In de EORTC-26951 zijn 368 patiënten geïncludeerd met anaplastisch oligodendroglioom en gemengd anaplastisch oligoastrocytoom (ten minste 25% oligodendrogliale-component) die werden gerandomiseerd tussen radiotherapie (RT) en RT plus 6 kuren procarbazine, lomustine en vincristine (PCV). In 2006 werd na een mediane follow-up van 5 jaar een verschil in progressievrije overleving (PFS) gevonden, echter geen statistisch significant verschil in overleving [Van den Bent 2006³⁵²]. Na langere follow-up bleek echter dat de overleving in de RT/PCV-arm significant langer was; 42.3 vs. 30.6 maanden in de RT-arm ([HR] 0,75; 95%CI 0,60-0,95). Ook kwamen data beschikbaar over de 1p/19q-status van patiënten. Voor de patiënten met een 1p/19q-deletie werd een mediane PFS van 157 vs. 50 maanden voor de gecombineerde behandeling ten opzichte van RT alleen gevonden, en een trend naar verbeterde totale overleving (OS) (mediaan niet bereikt vs. 112 maanden (HR 0,56; 95%CI 0,31-1,03)).

In de RTOG-9402 werden 291 patiënten met anaplastisch oligodendrocytoom en anaplastisch oligoastrocytoom gerandomiseerd tussen vier cycli intensified PCV met een hogere dosering lomustine, namelijk 130 mg/m² i.p.v. 110 mg/m² op dag 1 en zonder dosisbeperking per gift vincristine (de doses van de verschillende middelen waren niet gelijk aan die van de EORTC-26951) gevuld door RT vs. RT alleen. Voor patiënten met een 1p/19q-deletie werd een overlevingswinst gevonden (mediaan 14,7 versus 7,3 jaar, HR 0,59; 95%CI 0,37-0,95) in de gecombineerde behandelingsarm. In de groep patiënten zonder 1p/19q-verlies werd geen voordeel van gecombineerde behandeling gevonden (2,6 versus 2,7 jaar). Daarnaast lijkt er op basis van deze studie een voordeel voor de patiënten waarbij de tumor geen 1p/19q-deletie bevat maar wel een IDH1/2-mutatie voor PCV gevuld door RT. Dit betreft echter een post-hoc analyse bij een relatief kleine subgroep van 66 patiënten.

De NOA-4-studie is een gerandomiseerde fase III-studie bij patiënten met een anaplastisch glioom die als postoperatieve behandeling 2:1:1 RT (arm A) ten opzichte PCV (arm B1) vs. temozolamide (TMZ) (arm B2) heeft vergeleken [Wick 2009³⁸⁶]. Patiënten die in eerste instantie behandeld waren met postoperatieve radiotherapie (arm A), werden bij onacceptabele toxiciteit of progressie opnieuw gerandomiseerd tussen chemotherapie alleen met TMZ of PCV (arm B1 of B2). Andersom werden patiënten die direct chemotherapeutisch behandeld waren, na progressieve ziekte behandeld middels RT (arm A). Er werden 274 patiënten geïncludeerd, waarbij geen verschil tussen de behandelarmen werd gevonden voor het primaire eindpunt van de studie: gemiddelde (mediane) tijd tot progressieve ziekte. Voor geen van de subgroepen anaplastisch astrocytoom, anaplastisch oligodendrocytoom of anaplastisch oligoastrocytoom was een van de behandelarmen superieur. Er was geen verschil in progressievrije overleving tussen de patiënten die behandeld werden met TMZ ten opzichte van PCV. Het is van belang om te vermelden dat deze patiënten niet gerandomiseerd zijn op basis van 1p/19q-status van het anaplastische glioom. Ten tijde van rapportage waren de resultaten voor overleving nog immatuur. In het licht van de nagekomen rapportages bij studies EORTC 26951, RTOG 9402 en RTOG 8502 waarbij pas op lange follow-up algemene overleving significante verschillen ten voordele van toevoeging PCV kuren liet zien, dienen we mogelijk bedacht te zijn op een dergelijk nakomend bericht in deze studie.

Er is nog een retrospectieve studie met 109 patiënten [Brandes 2006^a²⁹] met een anaplastisch astrocytoom beschikbaar die achteraf het verschil tussen PCV (49 patiënten) en TMZ (60 patiënten) heeft geanalyseerd. Ook in deze analyse werd geen verschil in behandeluitkomst tussen de twee chemotherapieregimes gevonden.

In 2014 loopteen grote gerandomiseerde fase III-trial voor anaplastische glioompatiënten zonder 1p/19q deletie (CATNON, EORTC-26053). Dit is een 4-armige studie: RT alleen vs. RT plus concomitant temozolamide vs. RT plus adjuvant temozolamide vs. RT plus concomitant en adjuvant temozolamide. Aanvankelijk liep ook een gerandomiseerde fase III-trial voor patienten met 1p/19q-deletie (CO_DEL, EORTC-26081). Dit was een 3-armige studie waarbij een van de armen radiotherapie alleen was. Na het beschikbaar komen van de lange termijndata van zowel de EORTC-26951 als de RTOG-9402, werd RT alleen echter als onderbehandeling gezien en is de studie gesloten.

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chemotherapie recidief anaplastisch glioom

Uitgangsvraag

Wat is de indicatie voor chemotherapie bij een patiënt met een recidief anaplastisch glioom?

Aanbeveling

Patiënten met een recidief hooggradig glioom dienen in een multidisciplinair neuro-oncologisch overleg besproken te worden. In de recidiefsetting dienen andere palliatieve behandelingen, zoals radiotherapie en chirurgie, telkens mede in overweging genomen te worden.

De werkgroep is van mening dat patiënten met een recidief anaplastisch glioom bij voorkeur in studieverband behandeld moeten worden.

Indien er geen studie beschikbaar is, wordt geadviseerd behandeling met twaalf kuren temozolamide te overwegen. Vervolgbehandeling met PCV lijkt vooral voor tumoren met een 1p/19q-deletie voor de hand te liggen.

Overwegingen

In de recidiefsetting dienen alle palliatieve behandelingen waaronder radiotherapie en chirurgie telkens mede in overweging genomen te worden.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat zowel PCV als temozolamide effectief kan zijn in zowel eerste als tweedelijnsbehandeling van het recidief anaplastisch glioom.

Yung 1999⁴⁰⁷, Brandes 2006²⁹, Van den Bent 2003³⁵⁸, Van den Bent 1998³⁵⁶, Brandes 2004³¹, Kouwenhoven 2006¹⁸²

Samenvatting literatuur

Er zijn meerdere studies die de waarde van chemotherapie bij het recidief anaplastisch glioom ondersteunen, zowel in de eerste als in de tweede lijn. Deze data zijn er voor zowel temozolamide [Yung 1999⁴⁰⁷, Brandes 2006²⁹, van den Bent 2003³⁵⁸] als PCV [van den Bent 1998³⁵⁶, Brandes 2004³¹, Kouwenhoven 2006¹⁸²] in verscheidende fase II-studies met patiënten aantal variërend van 18-97. Prognose en respons op chemotherapie is afhankelijk van de tijd tot recidief, histologie, moleculaire achtergrond en eerdere behandeling. Bij ongeveer de helft van deze patiënten wordt een objectieve response rate gezien met een progressievrije overleving na zes maanden van rond de 60% en na twaalf maanden van ongeveer 50%. In een tweedelijnsbehandeling liggen deze getallen lager [Yung 1999⁴⁰⁷, van den Bent 2003³⁵⁸, van den Bent 2001³⁵⁵, Triebels 2004³⁴⁴, Chinot 2001⁵⁷].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chemotherapie nieuw gediagnostiseerd glioblastoom

Uitgangsvraag

Wat is de indicatie voor chemotherapie bij een patiënt met een nieuw gediagnostiseerd glioblastoom?

Aanbeveling

Bij patiënten met een glioblastoom in goede conditie tot 60 jaar dient postoperatief radiotherapie gegeven te worden, gecombineerd met concomitant en adjuvant temozolomide.

Voor de behandeling van patiënten met een glioblastoom ouder dan 60 jaar die niet fit genoeg zijn om deze behandeling te ondergaan wordt verwezen naar de module Behandeling van ouderen.

De chemotherapie dient gegeven te worden, door middel van temozolomide 75 mg/m²/d gedurende zes weken, gecombineerd met radiotherapie tot een totale dosis van 60 Gy in 30 fracties, gevolgd door een rustperiode van vier weken en daarna zes postradiatielijken temozolomide 200 mg/m²/d dag 1-5 elke vier weken. De eerste postradiatielukuur wordt gedoseerd op 150 mg/m²/d en opeenvolgende kuren worden vervolgens op 200 mg/m²/d gedoseerd indien goed verdragen. Dose-dense schema's van temozolomide hebben geen toegevoegde waarde voor het glioblastoom. Ook het toevoegen van bevacizumab aan het Stupp-schema laat geen toename in overleving zien.

De werkgroep is van mening dat bij goede en voortgaande tumorrespons overwogen kan worden het aantal postradiatielijken uit te breiden van zes naar twaalf.

Overwegingen

Op farmacologische gronden kan getwijfeld worden aan de noodzaak tot reduceren van de dosis van de eerste postradiatielukuur. Overwogen kan worden om de eerste postradiatielukuur ook op de dosis 200 mg/m²/d toe te dienen. In uitzonderlijke gevallen (enkel bij goede tolerantie en voortdurende tumorrespons met in achtneming dat het wetenschappelijk bewijs zeer beperkt is) kan de behandelaar overwegen het aantal postradiatielijken op te hogen tot maximaal twaalf. Er is een risico op pneumocystis jirovecii pneumonie tijdens de chemoradiatie. Overweeg profylaxe [De Vos 2013⁷⁵]. Bij 20-30% patiënten behandelde met chemoradiatie wordt pseudoprogressie waargenomen [Wen 2010³⁸²].

Onderbouwing

Conclusies

Er is aangetoond dat bij patiënten met een nieuw gediagnostiseerd glioblastoom en in een goede conditie chemoradiatie door middel van temozolomide resulteert in een langere overleving dan radiotherapie alleen. Stupp 2005³³¹, Stupp 2009³³⁰

De werkgroep is van mening dat het veilig is om het aantal postradiatielijken bij zeer goede tumorrespons uit te breiden. Door de opzet van de studies kan echter geen uitspraak worden gedaan over een mogelijk overlevingsvoordeel.

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Hau 2007¹³⁰, Roldan 2012²⁸¹

Het is aangetoond dat toevoeging van bevacizumab aan het Stupp-schema niet leidt tot verlenging van de totale overleving.

Chinot 2014⁵⁸, Gilbert 2014¹⁰⁹

Samenvatting literatuur

In 2005 werd een open gerandomiseerde fase III-onderzoek gepubliceerd verricht bij patiënten met een nieuw-gediagnostiseerd glioblastoom waarmee de aanvullende waarde van temozolamide aan (postoperatieve) radiotherapie werd aangetoond [Stupp 2005³³¹]. In de studie werden 573 volwassen patiënten tot 70 jaar (84% voorafgaande resectie, 16% alleen biopsie) gerandomiseerd tussen radiotherapie alleen of een gecombineerde behandeling met tegelijkertijd radiotherapie en temozolamide gevolgd door een behandeling met alleen temozolamide [Stupp 2005³³¹]. Het primaire eindpunt was overleving en dit werd geanalyseerd volgens het intention-to-treat-principe. De mediane overleving was 14,6 maanden in de gecombineerde radio- en chemotherapiegroep en 12,1 maanden in de groep die alleen werd behandeld met radiotherapie. Dit is een significant verschil, maar de grootte van het effect is gering. Na twee jaar waren echter 30 (10,4%) patiënten in de radiotherapiegroep en 76 (26,5%) patiënten in de combinatiegroep in leven, ook een significant verschil [Stupp 2005³³¹]. Na vijf jaar waren respectievelijk 5 (1,9%) en 28 (9,8%) patiënten in de radiotherapie- en combinatiegroep nog in leven [Stupp 2009³³⁰]. Een post-hoc analyse van 206 patiënten suggereerde dat patiënten met een gemethyleerd DNA-herstelenzym O6-methylguanine-DNA methyltransferase (MGMT) (aanwezig bij 45% van de onderzochte patiënten) een groter voordeel bij de toevoeging van temozolamide aan radiotherapie hebben [Hegi 2005¹³²]. De methyleringsstatus van MGMT heeft zowel een prognostische als predictieve waarde (Hegi 2005; Wick 2012). Bij chemoradiatie bleek het overlevingsvoordeel beduidend groter te zijn dan monotherapie radiotherapie bij patiënten met een gemethyleerde MGMT promotor. Dit voordeel is veel kleiner bij patiënten met een ongemethyleerde MGMT promotor. In geval dat de patiënt onvoldoende conditie heeft tot het verkrijgen van chemoradiatie, kan op basis van deze methyleringsstatus geopteerd worden tussen een van beide monotherapiën (dus ofwel radiotherapie ofwel chemotherapie). Of het uitbreiden van het aantal postradiatiekuren zinvol is, is niet bekend; het is vooral retrospectief beschreven. De enige prospectieve studie waarin een uitgebreid Stupp-schema (meer dan zes postradiatiekuren temozolamide) wordt onderzocht, bevatte ook graad III gliomen waardoor de mediane overleving van 58 maanden beïnvloed werd [Hau 2007¹³⁰].

Retrospectief Canadees onderzoek bij 52 patiënten laat zien dat 29 patiënten die met meer dan zes postradiatiekuren werden behandeld een mediane overleving van 24,6 maanden hadden versus 16,5 maanden bij een behandeling van zes postradiatiekuren. Doordat dit een retrospectieve studieopzet was, is er dan ook sprake van enige patiëntselectie-bias, aangezien zij met een betere respons op temozolamide ook langer overleven [Roldan 2012²⁸¹]. MGMT-status was geen doorslaggevende factor bij het besluit al dan niet te continueren na zes postradiatiekuren. Er moet wel gewezen worden op de beperkingen van deze studie: retrospectief, niet gekeken naar impact van type neurochirurgische ingreep of MGMT-status.

Daarnaast is er onderzoek verricht naar de dosis temozolamide, waarbij de gedachte is dat een hogere dosis leidt tot het teniet doen van de MGMT-gemedieerde resistentie. In een fasellII-studie werden 833 patiënten gerandomiseerd in een arm met postradiatie temozolamide standaarddosering 200 mg/m2/d d1-5 versus dose-dense schema 75 mg/m2/d d1-21 elke 4 weken in 6-12 cycli [Gilbert 2013¹¹⁰]. Deze studie liet geen significante verbetering van totale overleving (OS) zien (16,6 versus 14,9 maanden), noch van mediane

progressie vrije overleving (PFS) (5,5 versus 6,7 maanden). Echter, bij de MGMT-gemethyleerde groep werd wel significant verbeterde OS en PFS gezien, ongeacht het regimen temozolomide (algemene overleving: 21,2 versus 14 maanden voor de standaarddosering temozolomidegroep versus dose-dense temozolomidegroep, en progressievrije overleving: 8,7 versus 5,7 maanden voor de standaarddosering temozolomidegroep versus dose-dense temozolomidegroep). Per behandelarm werd in de MGMT-gemethyleerde groep geen significant verschil gevonden: OS 20,2 vs. 21,4 maanden en PFS van 6,5 vs. 10,1 maanden, respectievelijk in de standaard behandelarm en in de dose-dense behandelarm. Daarnaast werd een forse toename aan graad 3 toxiciteit gezien met name lymfocytopenie en vermoeidheid in de dose-dense arm ten opzichte van de standaardarm (53% versus 34%).

In een volgende studie werd gekeken naar de waarde van het postoperatief plaatsen van gliadel rasters (ook carmustine implants genoemd) in de resectieholte [Bock 2010²¹]. Bij 44 patiënten met nieuw gediagnostiseerd glioblastoom werden na het verwijderen van de tumor biologisch afbreekbare rasters geïmpregneerd met carmustine in het tumorbed geïmplanteerd. Hierna volgde chemoradiatie met temozolomide. Er werd geen beduidende overlevingswinst gezien met een mediane progressievrije overleving van 7 maanden en een mediane overleving van 12,7 maanden en daarbij werd een toename in toxiciteit gerapporteerd [Sabel 2008²⁸]. In een systematische review, die 19 studies met 795 patiënten samenvat, is de eventuele toegevoegde waarde van carmustine implants onderzocht. Hieruit bleek dat de overlevingswinst marginaal was, terwijl er een hoog risico op postoperatieve complicaties van 42,7% werd beschreven [Bregy 2013³²]. Gerandomiseerd fase III-onderzoek over de toevoeging van carmustine implants bij patiënten tijdens het Stupp-protocol ontbreekt.

Er is veel belangstelling voor de behandeling van glioblastomen met geneesmiddelen die de signaaltransductie via VEGF remmen, zoals bevacizumab, een monoklonaal antilichaam tegen VEGF. In een gerandomiseerde studie waarin de toevoeging van bevacizumab aan het Stupp-protocol werd onderzocht, werd bij 921 patiënten een mediane PFS van 10,6 maanden in de bevacizumabgroep versus 6,2 maanden in de placebogroep waargenomen. Deze significante verbetering vertaalde zich echter niet in overlevingswinst (resp. 16,8 versus 16,7 maanden). Een kwaliteit van leven-analyse toonde voorts dat het langer duurde voordat een toename in klachten optrad in de bevacizumabgroep (hazard ratio 0,64; 95%CI 0,56-0,74). Ook bleek er een grotere groep patiënten die de deelname startten met corticosteroïden-gebruik deze tijdens behandeling te kunnen staken indien ze behandeld werden met bevacizumab (66,3% versus 47,1%) [Chinot 2014[239]]. In een gelijkwaardige Amerikaanse studie met 978 patiënten, vertaalde een significant voordeel in PFS voor patiënten die met bevacizumab behandeld werden (10,7 versus 7,3 maanden) [Gilbert 2014¹⁰⁹]. Daarnaast liet deze studie een snellere achteruitgang in neurocognitie zien in de bevacizumabgroep. De onderzoekers duiden dit als vroegtijdige tumorprogressie dan wel bevacizumab-gerelateerde neurotoxiciteit.

Blokkade van integrines $\alpha\beta 3$ en $\alpha\beta 5$ door cilengitide werd onderzocht bij patiënten met glioblastomen in een fase III-onderzoek [Reardon 2008²⁷³], Stupp 2013³³³]. In deze gerandomiseerde studie werd de toevoeging van cilengitide aan het Stupp-protocol onderzocht bij 272 patiënten met nieuw gediagnostiseerde glioblastoom en gemethyleerde MGMT status. De mediane overleving was 26,3 maanden in beide armen met hazard ratio 1,02 (95%CI; 0,81-1,29). Mediane PFS was niet significant verschillend (13,5 maanden in de cilengitidearm en 10,7 maanden in de controle-arm). Enkelarmige fase II-studies waarbij nieuwe medicijnen aan het Stupp-protocol werden toegevoegd, melden een mediane overleving tussen 17 en 25 maanden, vergeleken met historische controles [Grossman 2009¹¹⁷], Butowski 2009³⁹], Soffietti

2014³²¹]. Hier kunnen echter, gezien het gebrek aan sluitend fase III-gerandomiseerd onderzoek, nog geen conclusies aan verbonden worden.

ICT-107 is een autologe dendritische cel vaccin met klasse I peptiden afkomstig van tumor-geassocieerde antigenen met overexpressie op gliomen [Phuphanich 2013²⁶⁰]. Een placebo-gecontroleerde, gerandomiseerde fase II- studie heeft het beoogde patiëntenaantal voor inclusie in 2013 bereikt.

Rindopepimut (CDX-110) induceert tumorspecifieke immuunrespons in tumoren met een epidermale groeifactor receptor vIII (EGFRvIII) mutatie [Babu 2012⁶]. In 2013 is een gerandomiseerde fase III-studie (ACT-IV/EORTC-26112) geopend met het streven 700 patiënten te includeren met een nieuwe gediagnostiseerde glioblastoom met EGFRvIII mutatie. Tot slot, NovoTTF-100A is een op de behaarde hoofdhuid draagbaar toedieningstoestel dat met afwisselende electrogebieden door middel van lage intensiteit tumorceldeling onderbreekt [Davies 2013⁶⁹]. Dit toestel is door de Food and Drug Administration (FDA) goedgekeurd. Deze goedkeuring slaat op de veiligheidsaspecten in kader van de toepasbaarheid van het toestel en niet de effectiviteit van de behandeling d.m.v. het toestel welke tot op heden niet is aangetoond bij het nieuw gediagnostiseerde glioblastoom [Salzberg 2008²⁹⁰]. In 2013 is er een studie gestart (Effect of NovoTTF-100A together with temozolamide in newly diagnosed glioblastoma multiforme (GBM). ClinicalTrials.gov Identifier NTC00916409).

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Chemotherapie recidief glioblastoom

Uitgangsvraag

Wat is de rol van chemotherapie bij een patiënt met een recidief glioblastoom?

Aanbeveling

Bij een patiënt met een recidief glioblastoom in een goede conditie dient in eerste instantie een behandeling in studieverband te worden overwogen. Bij het niet beschikbaar of geschikt zijn voor een studie, dient in multidisciplinaire bespreking de verschillende behandelopties te worden besproken.

Als chemotherapeutische behandeling het advies is bij een aangetoond recidief glioblastoom zes maanden of meer na beëindigen van het Stupp-schema, kan temozolamide 200 mg/m²/d op dagen 1-5 elke vier weken overwogen worden.

Indien patiënten eerder behandeld zijn geweest met chemotherapie, wordt de eerste kuur gedoseerd op 150 mg/m²/d en worden opeenvolgende kuren vervolgens hoger gedoseerd, indien het goed wordt verdragen.

In het licht van de RESCUE studie kan dose dense temozolamide overwogen worden bij geselecteerde patiënten met een vroeg recidief glioblastoom en weinig doorgemaakte toxiciteit tijdens Stupp-schema.

Indien het recidief al tijdens of binnen zes maanden na staken Stupp-schema wordt aangetoond, is afhankelijk van de conditie van de patiënt PCV-kuren dan wel lomustine monotherapie een optie.

Behandeling met biologicals gebeurt in studieverband.

Overwegingen

Bij 20-30% van de patiënten behandeld met chemoradiatie wordt pseudoprogressie waargenomen [Wen 2010³⁸²]. Dit kan een rol spelen in de beoordeling van het effect van een vervolgbehandeling en benadrukt de noodzaak van een ervaren neuro-radioloog binnen het multidisciplinaire team.

Nadat er een recidief is vastgesteld, is de eerste keuze voor patiënten met een recidief glioblastoom een behandeling binnen studieverband. Er is geen gerandomiseerde studie die de verschillende behandelingsmodaliteiten (her-operatie, her-bestraling of tweedelijnschemotherapie/andere systeemtherapie) naast elkaar heeft bestudeerd en heeft vergeleken. Voor een adequate palliatieve behandeling buiten studieverband voor patiënten met een recidief glioblastoom is het belangrijk verschillende individuele patiëntgebonden factoren, zoals leeftijd, klinische conditie, mate van initiële resectie, respons op eerdere therapie, tijd sinds diagnose, of het een lokaal of diffuus recidief betreft, in acht te nemen. Gezien de beschikbaarheid van meerdere behandelingsmodaliteiten, dient bespreking in een neuro-oncologisch MDO plaats te vinden.

Onderbouwing

Conclusies

Het is aangetoond dat monotherapie temozolomide bij recidief glioblastoom effectief kan zijn, maar de kans op en de duur van het effect zijn niet zo groot (ca. 20% progressievrij na zes maanden wanneer geen eerdere behandeling met temozolomide is gegeven).

Er zijn (beperkte) aanwijzingen dat, in geval van een recidief na eerstelijns behandeling met (radiotherapie en) temozolomide, temozolomide opnieuw effectief kan zijn; de kans op effect lijkt groter wanneer het behandelings-vrije interval groter is.

Brada 2010²⁶, Wick 2009³⁸⁶, Perry 2008²⁵⁸, Perry 2010²⁵⁵

Er zijn aanwijzingen dat op nitrosurea gebaseerde therapie als tweedelijnstherapie bij recidief glioblastoom in geselecteerde patiëntengroepen een behandeloptie kan zijn.

Kuhnhenn 2012¹⁸⁵, Schmidt 2006³⁰⁰, Wick 2010³⁸⁸

Er zijn aanwijzingen dat bevacizumab gecombineerd met lomustine bij recidief glioblastoom een aanvulling in het behandelplan zou kunnen zijn. Bevestiging is nodig in een gerandomiseerde fase-III studie.

Taal 2014³³⁵

Samenvatting literatuur

Cytostatica

Temozolomide

In een niet-geblindeerd, gerandomiseerd fase II onderzoek werd temozolomide vergeleken met procarbazine bij 225 patiënten met een eerste recidief glioblastoom na operatie en radiotherapie [Yung 2000⁴⁰⁶]. De progressievrije overleving na zes maanden was significant hoger met temozolomide dan procarbazine (21% versus 8%). Een niet-geblindeerd, gerandomiseerd fase III-onderzoek waarbij temozolomide of PCV (procarbazine-lomustine-vincristine) werd gegeven aan patiënten met recidief graad III en IV glioom (n=447), die niet eerder met chemotherapie waren behandeld, liet geen verschil zien in mediane progressievrije overleving en algemene overleving (respectievelijk, 3,6 versus 4,7 maanden en 6,7 versus 7,2 maanden) [Brada 2010²⁶].

Dose-dense schema's temozolomide

In een fase III-studie werden twee doseringen van temozolomide gebruikt: een geregistreerde dosering temozolomide (200 mg/m² dag 1-5 elke vier weken) of een off-label intensieve dosering (100 mg/m² dag 1-21 elke 4 weken) [Brada 2010²⁶]. Hierbij bleek er een duidelijk voordeel in kwaliteit van leven voor patiënten behandeld met standaarddosering temozolomide ten opzichte van dose-dense therapie. Daarnaast werd er ook minder toxiciteit in de vijfdaagse temozolomide behandelde groep vermeld. Echter, hierbij moet in acht genomen worden dat de patiënten chemotherapie-naïef waren, omdat de studie plaatsvond voordat het Stupp-protocol standaardbehandeling voor nieuw gedagnosticeerde glioblastomen werd. Retrospectieve studies naar verscheidende rechallenge doseringsschema's met temozolomide bij recidief gliomen lieten een bescheiden winst voor dose-dense schema's zien met een 6 maanden progressievrije overleving variërend van 28 - 57% [Wick 2009³⁸⁶, Perry 2008²⁵⁸]. De uitkomst van de rechallenge behandeling werd gunstig beïnvloed naarmate de tijd tussen eerstelijnsbehandeling en vaststellen tumorprogressie groter werd.

Dit resulteerde in de Fase II RESCUE-studie waarbij recidief glioblastoom progressief na temozolomide monotherapie behandeld werd met een continuumschema [Perry 2010²⁵⁵]. Dit leidde tot 24% 6-maanden PFS bij

91 patiënten. Interessant is dat bij de groep met een vroegtijdig recidief (PD tijdens de eerste zes postradiatierecuren) vergelijkbare overlevingsresultaten behaald werden ten opzichte van de groep met laattijdig recidief (PD tijdens de zevende tot twaalfde postradiatierecuren) in vergelijking met de groep die recidiveerde na meer dan twee maanden na staken postradiatierecuren. Er was verschil in 6-maanden PFS (respectievelijk, 27,3 versus 7,4 versus 35,7%, p=0,0027) en in 1-jaars overleving (27,3 versus 14,8 versus 28,6%, niet significant). Hierbij werd rekening gehouden met de mogelijke invloed van pseudoprogressie, door patiënten met PD binnen twaalf weken na beëindigen chemoradiatie te excluderen. De onderzoekers konden geen verklaring vinden voor het verschil in overlevingsdata en vermoedden depletie van MGMT of een antiangiogenetisch effect van het dose-dense toedieningsschema. In een gelijkwaardige studie werd een 6-maanden PFS van 19% met een totale overleving van 7 maanden bij 37 patiënten waargenomen. Eerdere behandeling met bevacizumab leidde tot een lagere totale overleving (4 versus 13 maanden), maar dit kwam doordat de bevacizumab voorbehandelde patiëntengroep meerdere behandellijnen voorafgaand aan de behandeling met dose-dense temozolamide hadden gekregen. [Omuro 2013²³⁸]. Deze fase II-studie waarin een dose-dense schema temozolamide bij recidief glioblastoma werd onderzocht in het bevacizumab-tijdperk toonde aan dat de mediane overleving na recidief bij eerdere bevacizumab behandeling significant minder is dan bij bevacizumab-naïeve patiënten (13 versus 4,3 maanden met hazard ratio 3,1). Hierbij werd een objectiveerbare respons bij twee patiënten gezien met een 6-PFS van 29%. Echter, een review over dose-dens temozolamide schema's duidt op de verhoogde kans op lymfocytopenie gerelateerde *Pneumocystis jirovecii* pneumonie in vergelijking met standaarddosering [Neyns 2010²²⁷].

Combinatiebehandelingen met temozolamide

Een review toonde aan dat combinaties van temozolamide met cisplatine, fotemustine, interferon, sorafenib, celecoxib, irinotecan of PCV kuren geen verbetering in overleving gaf ten opzichte van standaard temozolamide monotherapie [Weller 2013³⁷⁸]. De toevoeging van tamoxifen 80 mg/m2/d aan temozolamide 75-150 mg/m2 op dagen 1-7 elke 2 weken werd in een fase II-studie bij 32 patiënten als tweedelinsttherapie geëvalueerd [Di Cristofori 2013⁸⁰]. De mediane totale overleving en progressie vrije overleving waren respectievelijk 17,5 en 7 maanden. Aangetoond is dat mismatch mutaties of hypermethylation van de promotor regio van MSH6, een DNA-herstelmechanisme, frequent voorkomt bij recidief glioblastoom [Yip 2009⁴⁰¹]. Hierdoor komen vaker DNA-fouten voor, die niet hersteld worden en hangt de overleving van de cel meer af van het PARP-herstelmechanisme. Vandaar dat PARP-inhibitoren als nieuwe behandelstrategie worden onderzocht om de efficiëntie van temozolamide te verhogen.

Nitrosurea (carmustine of lomustine)

Nitrosurea-gebaseerde kuren bij recidief glioblastoom na eerdere temozolamide behandeling toonde bij 69 patiënten een beperkte mediane progressie vrije overleving van 15 weken aan, met een partiële remissie bij 1 patiënt [Kuhnhenn 2012¹⁸⁵]. Bij 86 patiënten met een recidief glioblastoom werden drie partiële remissies en een mediane progressie vrije overleving gezien van 17,1 weken na PCV-kuren [Schmidt 2006³⁰⁰]. Lomustine monotherapie bij 92 patiënten met een, met temozolamide behandeld, recidief glioblastoom, toonde in een fase III-studie een 19% 6-PFS en een mediane totale overleving van 7 maanden [Wick 2010³⁸⁸].

Irinotecan

Irinotecan in recidiefsetting bij patiënten met een glioblastoom toonde geen respons bij alle 40 onderzochte patiënten en is dus geen alternatieve behandeling bij een recidief [Chamberlain 2002⁴⁹].

Nieuwe middelen

Bevacizumab

Op grond van een gerandomiseerd fase II onderzoek bij 170 patiënten, waarin bevacizumab werd vergeleken met de combinatie bevacizumab en irinotecan, is bevacizumab in de VS geregistreerd (conditional approval) voor gebruik bij glioblastoom recidieven [Friedman 2009¹⁰³]. De respons ratio was hoger dan verwacht: 53% in de combinatie-arm, 43% in de bevacizumab-arm versus 10% bij historische controles. Echter, overlevingsvoordeel was minder duidelijk met een mediane overleving van acht maanden, vergeleken met zes maanden bij historische controles. Het ontbreken van een controlegroep zonder bevacizumab was voor de European Medicines Agency reden om dezelfde registratieaanvraag af te wijzen. Een bijkomende complicerende factor is dat bevacizumab pseudorespons in de hand werkt, door een effectieve therapie tegen hersenoedeem te zijn en de bloedhersenbarriëre te sluiten waardoor aankleuring afneemt [Omuro 2007²⁴⁰]. In de gerandomiseerde Nederlandse fase II-studie BELOB [acroniem: Bevacizumab vs. bevacizumab plus lomustine vs. lomustine bij recidief GBM] werden drie behandelarmen met elkaar vergeleken: bevacizumab, lomustine en lomustine in combinatie met bevacizumab bij 148 patiënten met recidief glioblastoom [Taal 2014³³⁵]. In de combinatie-arm werd de dosering lomustine verlaagd van 110 naar 90 mg/m² op dag 1 elke 6 weken, wegens beenmergsuppressie. Na 9 maanden was de OS 38% in de bevacizumab-arm, 43% in de lomustine-arm, 59% in de combinatie-arm met lomustine 90 mg/m² en 88% in de combinatie-arm met lomustine 110 mg/m². Op deze bevinding is de studie EORTC- 26101 aangepast naar een fase IIItwee-arms-studie waarin lomustine monotherapie vergeleken wordt met de combinatie lomustine en bevacizumab bij eerste recidief na Stupp-protocol.

Tot nu toe is er enkel retrospectief onderzocht of het zinvol is bevacizumab te continueren bij progressie onder bevacizumab [Reardon 2012²⁷²]. Toevoeging van fotemustine, sorafenib, temsirolimus, combinatie carboplatine-irinotecan, dose-dense schema temozolamide, interferon- en combinatie cetuximab-irinotecan aan bevacizumab in de recidiefsetting gaf geen verbeterde overleving [Soffieti 2014³²¹, Galanis 2013¹⁰⁴, Lassen 2013¹⁹³, Desjardins 2012⁷⁸, Groves 2009¹¹⁸, Hasselbach 2010¹²⁹].

Enzastaurine en cediranib

In een gerandomiseerde fase III-studie werd lomustine monotherapie vergeleken met enzastaurine bij 266 patiënten met recidief glioblastoom na eerdere temozolamide behandeling [Wick 2010³⁸⁸]. Het onderzoek werd voortijdig stopgezet bij een geprotocolleerde interim-analyse vanwege onvoldoende werkzaamheid. Op dat moment was er geen significant verschil in het primaire eindpunt: het percentage patiënten dat progressievrij was na zes maanden (11 versus 19%, respectievelijk enzastaurine en lomustine). Onderzoekers verklaarden het niet aantonen van effectiviteit door een te vroeg opstarten van de fase III-studie zonder de definitieve resultaten van de fase II-studie te hebben afgewacht. In een drie-arms fase III REGAL-studie werd cediranib, een VEGF-receptor inhibitor, onderzocht ten opzichte van lomustine en de combinatie van beide agentia [Batchelor 2013¹¹]. Bij 325 patiënten met een glioblastoom die vooraf met het Stupp-protocol behandeld waren, werd geen significant verschil gezien in PFS tussen de drie behandelarmen, waarbij de hazard ratio bij de combinatie-arm 0,76 met 95%CI 0,53-1,08 bedroeg. Mogelijk ligt nog onvoldoende kennis van predictieve factoren aan de grondslag van het falen van deze studie.

Nieuwe toedieningswegen: NovoTTF-100A, CED en gliadel rasters

NovoTTF-100A werd in een gerandomiseerde fase III-studie onderzocht bij 237 patiënten in vergelijking met

een behandeling naar keuze van de behandelaar. Na een mediaan van twee lijnen therapie voorbehandeling werd een mediane overleving van 6.6 versus 6 maanden waargenomen [Butowski 2013⁴⁰, Stupp 2012³³³]. Toevoeging van gliadel rasters in een recidiefsetting geeft geen noemenswaardige overlevingswinst [De Bonis 2012⁷³]. Een systematische review liet slechts bij een selecte groep patiënten in recidiefsetting, waarbij een haast complete resectie van het recidief werd verkregen, enige overlevingswinst zien [Perry 2007²⁵⁶]. De PRECISE-studie was een fase III-studie die convection-enhanced delivery (CED) van cintredekin besudotox vergeleek met gliadel rasters [Kunwar 2010¹⁸⁶]. Dit toeleveringssysteem omzeilt de bloed-hersenbarrièrè via een druk-gedreven infusieflow, waarbij een recombinant eiwit bestaande uit interleukine-13 en een gemuteerde vorm van Pseudomonas toxine werd toegediend. Ondanks het feit dat IL-13-receptoren overvloedig in glioblastoom aanwezig zijn, werd geen significante overlevingswinst aangetoond. Of CED met andere middelen effectief kan zijn, is onvoldoende bekend; het wordt in diverse studies onderzocht.

Noodzaak voor verder onderzoek

Het niet kunnen aantonen van effectiviteit bij verschillende fase III-studies bij recidief (en nieuw gediagnostiseerd) glioblastoom heeft geleid tot hernieuwd preklinisch en translationeel onderzoek [Yin 2013³⁹⁸]. Het glioblastoom wordt onderverdeeld in verschillende histologische subklassen op basis van genetisch profiel en moleculaire diagnostiek [Colman 2008⁶³, Verhaak 2010³⁶⁵]. Epidermale groeifactor (EGF) en de receptor EGFR, platelet-derived groeifactor (PDGF) A en B en de receptoren PDGFR α en β, vasculair endotheliale groeifactor (VEGF) en de receptor VEGFR, insuline-like groeifactor-1 (IGF-1) en de receptor (IGFR), transforming groeifactor-α (TGF-α), fibroblast groeifactor (FGF) en hepatocytair groeifactor (HGF) spelen een grote rol binnen het tumorproces bij het glioblastoom. Stimulering van deze receptoren stuurt drie grote cascadeprocessen aan: mitogen-activated proteïne kinase (MAPK); fosfoïnositide 3 kinase (PI3K/Akt); en fosfolipase Cγ (PLCγ) en proteïne kinase C (PKC). Deze processen reguleren celdeling, differentiatie en voorkomen apoptose. Hierop richt zich het klinisch onderzoek naar de ontwikkeling van doelgerichte therapie. Dit heeft geleid tot een reeks fase II-studies waarin verschillende klassen 'biologicals', tyrosine kinase remmers en antilichamen zijn en worden onderzocht [Weller 2013³⁷⁸, Quant 2010²⁶⁷]. Het falen van een fase III-studie waarin imatinib, een PDGFR inhibitor, gecombineerd met hydroxyurea, een ribonucleotide reductase remmer, werd onderzocht in vergelijking met hydroxyurea alleen, werd door onderzoekers verklaard vanwege een gebrek aan kennis van moleculaire en genetische karakteristieken [Dreseman 2010⁸³]. Hoewel beide agentia in monotherapie geen effect lieten zien, leek een eerdere fase II-studie met combinatiebehandeling overlevingswinst aan te tonen [Reardon 2005²⁷¹].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Behandeling van ouderen bij glioblastoom

Uitgangsvraag

Wat is de beste behandeling voor oudere patiënten met een glioblastoom?

Aanbeveling

Bij oudere patiënten (> 60 jaar) in slechte conditie (KPS < 70 ;) en met cognitieve functiestoornissen (MMSE $< 27/30$) is de levensverwachting $\leq 4-5$ maanden en lijkt de beperkte potentiële overlevingswinst van behandeling niet op te wegen tegen de belasting van de behandeling. De werkgroep is van mening dat in deze groep afzien van behandeling een realistische optie is.

Bij patiënten van 60-70 jaar, bij wie het behandelteam verwacht dat chemoradiatie volgens het Stupp-protocol te zwaar uitvalt (bijvoorbeeld door comorbiditeit, minder goede conditie en/of afwijkende MMSE), is de werkgroep van mening dat MGMT-promotoranalyse ingezet kan worden. Bij gemethyleerde promotor wordt de patiënt dan monotherapie met temozolamide aangeraden, bij een niet gemethyleerde promotor een kort schema radiotherapie. Er is een risico op een foutpositieve uitslag van de MGMT-promotormethylering waardoor voor een individuele patiënt het weglaten van radiotherapie zou kunnen betekenen dat hem/haar een effectieve behandeling wordt onthouden.

Bij patiënten ouder dan 70 jaar wordt geadviseerd MGMT-promotoranalyse in te zetten. Bij een gemethyleerde promotor wordt de patiënt dan monotherapie met temozolamide aangeraden, bij een niet gemethyleerde promotor een kort schema radiotherapie. Slechts in uitzonderlijke gevallen (zeer goede conditie en MMSE én resectie ondergaan én geen comorbiditeit) kan het behandelteam overwegen om in overleg met de patiënt alsnog chemoradiatie volgens het Stupp-protocol toe te dienen.

Overwegingen

In het algemeen leidt behandeling van het glioblastoom met radiotherapie en/of chemotherapie niet tot verbetering van de klinische toestand, wel mogelijk tot verlenging van de overleving. De klinische conditie en levenskwaliteit van de patiënt op het moment van aanvang van de behandeling bepalen daarom in sterke mate of en op welke manier de patiënt behandeld dient te worden. Diverse geriatrische beoordelingsschalen zijn onderzocht in de oncologie en kunnen wellicht aanvullende informatie geven betreffende prognose, maar de toegevoegde waarde hiervan staat niet vast [Puts 2014²⁶⁶. Leeftijd is een belangrijke prognostische factor en gemiddeld hebben oudere patiënten een slechtere prognose dan jongere patiënten, hoewel oudere patiënten met overigens gunstige prognostische factoren ook baat kunnen hebben van intensieve behandeling. Over de leeftijd waarop een patiënt oud of ouder is, bestaat geen consensus en ook in studies worden verschillende leeftijden aangehouden. Doorgaans wordt met 'ouder' een leeftijd bedoeld vanaf 60 tot 70 jaar.

Bij patiënten tot 70 jaar is de meerwaarde van gecombineerde bestraling en temozolamide chemotherapie aangetoond. Bij oudere patiënten is alleen monotherapie bestraling vergeleken met monotherapie temozolamide. Combinatiebehandeling bij ouderen, met een kort schema radiotherapie gecombineerd met

temozolomide, is onderzocht in de EORTC/NCIC-ouderenstudie maar hiervan zijn de resultaten nog niet bekend. Eventueel kan in afwachting van de resultaten van deze studie bij oudere patiënten met een gemethyleerde MGMT promotor ook temozolomide met een kort schema radiotherapie worden overwogen.

Onderbouwing

Conclusies

Het is aangetoond dat bij oudere patiënten (> 60 jaar) in slechte conditie (KPS < 70) en/of met cognitieve functiestoornissen (MMSE $< 27/30$) de levensverwachting kort is ($\leq 4-5$ maanden).

Curran 1993⁶⁵, Mirimanoff 2006²²⁰, Stupp 2009³³⁰

Het is aannemelijk dat bij oudere patiënten (> 60 jaar) in slechte conditie (KPS < 70) en/of met cognitieve functiestoornissen (MMSE $< 27/30$) de beperkte potentiële overlevingswinst van de behandeling niet opweegt tegen de belasting van de behandeling.

Roa 2004²⁷⁹, Slotman 1996³¹⁷, McAleese 2003²¹²

Het is aannemelijk dat voor patiënten van 60-70 jaar met gunstige prognostische factoren (goede performance status, KPS > 70 én MMSE $\geq 27/30$ én resectie ondergaan) behandeling met standaard 60 Gy radiotherapie met gelijktijdig en adjuvant temozolomide zinvol kan zijn. Voor deze groep geldt dat de mediane overleving langer is dan 12 maanden en dat bij hen, evenals bij jongere patiënten, de kans op levensverlenging met standaard 60Gy gecombineerde chemoradiotherapie groter is dan bij radiotherapie alleen.

Stupp 2009³³⁰, Stupp 2005³³¹, Yin 2013³⁹⁸

Het is aangetoond dat de methyleringsstatus van de MGMT-promotor bij oudere patiënten ($> 60-65$ jaar) predictieve waarde heeft ten aanzien van behandeling met temozolomide.

Malmstrom 2012²⁰⁸, Yin 2014a/b³⁹⁷ 400

Het is aannemelijk dat een lang schema radiotherapie geen voordeel biedt boven een kort schema bij oudere patiënten.

Roa 2004²⁷⁹, Malmstrom 2012²⁰⁸

Het is aannemelijk dat bij patiënten vanaf 60-65 jaar, in geval van een gemethyleerde promotor, temozolomide chemotherapie tenminste gelijkwaardig is aan bestraling.

Malmstrom 2012²⁰⁸, Wick 2012³⁸⁷, Yin 2014³⁹⁷

Het is aannemelijk dat ook oudere patiënten in een suboptimale conditie temozolomide chemotherapie kunnen verdragen.

Gallego Perez-Larraya 2011¹⁰⁵

Het is aangetoond dat de bepaling van de methyleringsstatus van de MGMT-promotor geen volmaakte sensitiviteit en specificiteit heeft. Er is een risico op een foutpositieve uitslag van de MGMT-

promotormethylering waardoor voor een individuele patiënt het weglaten van radiotherapie zou kunnen betekenen dat hem/haar een effectieve behandeling wordt onthouden.

Quillien 2012²⁶⁸, Vlassenbroeck 2008³⁶⁷

Samenvatting literatuur

De prognose voor oudere patiënten met een glioblastoom is slechter dan voor jonge patiënten, zeker wanneer de algehele conditie of mentale status verminderd is. Het is de vraag of standaardbehandeling met radiotherapie en gelijktijdig en adjuvant temozolamide haalbaar en zinvol is bij deze patiëntenpopulatie [Curran 1993⁶⁵, Mirimanoff 2006²²⁰, Stupp 2009³³⁰]. Bij aanwezigheid van de volgende prognostisch ongunstige variabelen; leeftijd > 60 jaar, Karnofsky performance status (KPS) < 70, MMSE < 27/30, niet hebben ondergaan van een resectie, wordt de prognose slechter en neemt de winst van aanvullende behandelingen af [Mirimanoff 2006²²⁰, Stupp 2009³³⁰]. Subgroepanalyses van de gerandomiseerde fase III-EORTC/NCIC-studie 26981, waarin behandeling met 60 Gy radiotherapie vergeleken werd met gecombineerd 60 Gy radiotherapie en temozolamide, laten echter zien dat ook bij oudere patiënten (60-70 jaar) met gunstige prognostische factoren (ruime resectie, goede performance status en MMSE > 27/30) de mediane overleving meer dan twaalf maanden is [Stupp 2009³³⁰, Stupp 2005³³¹]. In een prospectieve serie van 42 opeenvolgende patiënten ouder dan 65 jaar (mediaan 71,3 jaar) bleek deze behandeling haalbaar bij 70% van de patiënten, zonder behandelinggeïnduceerde toxiciteit, en was de prognose significant beter bij patiënten met een KPS ≥ 80% [Fiorica 2010⁹⁹]. Hoewel er geen andere gerandomiseerde studies beschikbaar zijn, ondersteunt een recente meta-analyse van niet gerandomiseerde studies overlevingswinst met deze behandeling ook voor patiënten ouder dan 65 jaar. In deze meta-analyse zijn ook patiënten boven de 80 jaar geïncludeerd en, overeenkomstig de subgroepanalyse van de EORTC-26981-studie, was de winst van de gecombineerde behandeling het grootste bij de patiënten met een goede performance status die een resectie hadden ondergaan [Yin 2013³⁹⁸]. Veel oudere patiënten zijn echter in een minder goede conditie of hebben geen resectie ondergaan, waardoor de prognose beduidend slechter is [Curran 1993⁶⁵, Chaichana 2011⁴⁷].

Om deze patiënten een acceptabele maar minder belastende behandeling te kunnen aanbieden is een aantal studies verricht. Behandeling met een kort schema radiotherapie is vergeleken met een lang schema (standaard, 60 Gy) in een gerandomiseerde studie bij 100 patiënten van 60 jaar of ouder. Er werd geen verschil gevonden in overleving na behandeling met 40 Gy in 15 fracties in vergelijking met 60 Gy in 30 fracties [Roa 2004²⁷⁹]. Enkele niet-gerandomiseerde studies toonden een vergelijkbaar resultaat met een mediane overleving van 4-6 maanden [Roa 2004²⁸⁰, Slotman 1996³¹⁷, McAleese 2003²¹²]. Behandeling met radiotherapie werd vergeleken met alleen ondersteunende therapie in een gerandomiseerde studie bij 85 patiënten van ≥ 70 jaar met een KPS van ≥ 70. Na alleen ondersteunende therapie werd een mediane overleving gevonden van 16,9 weken en na 50 Gy gefractioneerde radiotherapie was de mediane overleving 29,3 weken [Keime-Guibert 2007¹⁶⁶]. Oudere patiënten in een minder goede conditie (KPS < 70) zijn in deze studies niet geïncludeerd; wel bleek uit een fase II-studie met 70 patiënten dat deze populatie behandeling met temozolamide kan verdragen (13-14% neutro- en thrombopenie) en dat dit leidt tot een mediane overleving van 25 weken (95%CI 19 tot 28 weken) [Gallego Perez-Larraya 2011¹⁰⁵].

Of radiotherapie of temozolamide de voorkeur verdient bij oudere patiënten met een glioblastoom werd onderzocht in twee gerandomiseerde fase III-studies. In de Nordic-studie werden 342 patiënten van 60 jaar of

ouder gerandomiseerd voor behandeling met een kort schema radiotherapie (10 x 3.4 Gy), TMZ chemotherapie (tot 6 kuren, 200 mg/d op dag 1-5/28) of een standaardschema radiotherapie (30 x 2 Gy) [Malmstrom 2012²⁰⁸]. De overleving was langer voor patiënten die met temozolomide werden behandeld, dan met een lang schema radiotherapie (8,5 vs. 6 mnd.; hazard ratio [HR] 0·70; 95%CI 0·52-0·93, p=0·01). Bij patiënten boven de 70 jaar leidde bovendien een kort schema radiotherapie tot een langere overleving dan een lang schema radiotherapie. Van de patiënten die werden behandeld met temozolomide hadden degenen met een gemethyleerde MGMT-promotor een langere overleving dan die met een niet-gemethyleerde MGMT-promotor (9,7 maanden [95%CI 8,0-11,4] vs. 6,8 maanden [5,9-7,7]; HR 0,56 [95%CI 0,34-0,93], p=0·02) [Malmstrom 2012²⁰⁸]. In de NOA 08-studie werden 373 patiënten van 65 jaar of ouder gerandomiseerd tussen standaard radiotherapie (30 x 2 Gy) en dose-dense temozolomide (100 mg/m²/d op dag 1-7 en 15-21/28) [Wick 2012³⁸⁷]. Er was geen verschil in mediane overleving tussen de twee groepen, getest volgens non-inferiority principe: 8,6 mnd. (95%CI 7,3-10,2) in de TMZ-groep versus 9,6 mnd. (95%CI 8,2-10,8) in de radiotherapiegroep (hazard ratio [HR] 1,09; 95%CI 0,84-1,42, p-non-inferiority=0,033). Hoewel deze twee studies een verschillende dosering temozolomide gebruikten, is het niet waarschijnlijk dat dat de resultaten heeft beïnvloed: een gerandomiseerde fase III-studie toonde geen verschil in effectiviteit aan tussen adjuvant dose-dense temozolomide en adjuvante standaard dosering bij patiënten met een glioblastoom [Gilbert 2013¹¹⁰].

In deze studies is de combinatie van een kort schema radiotherapie met chemotherapie niet onderzocht; hiertoe is de EORTC/NCI-ouderenstudie (clinicaltrials.gov NCT00482677) opgezet, waarvan de inclusie compleet is maar de resultaten nog niet bekend zijn.

In een meta-analyses van studies naar radiotherapie en temozolomide bij oudere glioblastoompatiënten blijkt dat bij patiënten met gemethyleerde MGMT-promotor in hun tumor temozolomide effectiever was dan radiotherapie voor verbetering van de overleving (temozolomide vs. radiotherapie: HR 0,66; 95%CI 0,47-0,93) terwijl het tegenovergestelde gold voor patiënten met niet-gemethyleerde tumoren (HR 1,32; 95%CI 1,00-1,76) [Yin AA 2014a/b^{397 400}].

Hoewel in diverse studies MGMT-promotormethylering voorspellend was voor effectiviteit van temozolomide is de praktijk van de bepaling niet eenvoudig. Diverse methodes voor het onderzoeken van de methyleringsstatus zijn in gebruik en de uitslagen van de verschillende methodes voor individuele patiënten zijn lang niet altijd in overeenstemming met elkaar [Quillien 2012²⁶⁸]. Bovendien bepaalt de keuze van het afkappunt of de test een hogere sensitiviteit of specificiteit zal hebben [Vlassenbroeck 2008³⁶⁷].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Indicatie geriatrisch assessment

Uitgangsvraag

Bij welke patiënten met een middels pathologie bevestigd glioom en een indicatie voor behandeling is een geriatrisch assessment geïndiceerd?

Aanbeveling

Verzamel zoveel mogelijk informatie die relevant is om de winst en risico's van de verschillende behandel mogelijkheden op korte en lange termijn zo goed mogelijk in te schatten evenals de levensverwachting en kwaliteit van leven met en zonder behandeling. Betrek hierbij eventueel de huisarts. Inventariseer aanvullend samen met de patiënt en/of naaste(n) de levensvisie, beleving en persoonlijke behandel doelen van de patiënt met een middels pathologie bewezen glioom.

Overweeg een geriater, of verpleegkundig specialist geriatrie te betrekken indien er sprake is van één of meerdere van onderstaande factoren:

- aanwijzingen voor kwetsbaarheid, aan de hand van een screeningsinstrument (bijvoorbeeld de 'geriatric 8' aangevuld met MMSE of 6CIT voor het in kaart brengen van cognitief functioneren),
- uitgebreide comorbiditeit met het risico op behandelcomplicaties (bijv. meer toxiciteit),
- polyfarmacie met risico van interacties met bijvoorbeeld chemotherapie,
- KPS tussen 60 en 70,
- twijfel bij behandelteam en/of patiënt/naasten over meest geschikte behandeling,
- twijfel over de wilsbekwaamheid van de patiënt.

Maak de definitieve behandelkeuze in samenspraak met patiënt en diens naaste(n).

Overwegingen

Het doel van deze uitgangsvraag was om te achterhalen of het uitvoeren van een geriatrisch assessment bij oudere (kwetsbare) patiënten tot betere uitkomsten leidt, dan wanneer een geriatrisch assessment niet is uitgevoerd. Hiervoor is geen literatuur gevonden. Daarom kunnen er op basis van systematisch gevonden literatuur geen conclusies getrokken worden, en worden de aanbevelingen onderbouwd in de overwegingen.

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Het IDH wildtype glioblastoom, WHO graad 4, is de meest voorkomende primaire hersentumor bij volwassenen, zeker bij ouderen. Hogere leeftijd is zowel een negatieve prognostische factor als ook een risicofactor voor het optreden van bijwerkingen/toxiciteit van behandeling. Dit kan een nadelige invloed hebben op de kwaliteit van leven. De groep oudere patiënten is meer heterogeen dan de jongere patiëntengroep, waarbij rekening gehouden moet worden met comorbiditeit, fysiek en cognitief functioneren en mate van zelfredzaamheid. Derhalve zijn de biologische leeftijd en fitheid belangrijker gebleken dan kalenderleeftijd. (Balducci, 2005; Colloca, 2020) Indien de fitheid van de oudere patiënt niet correct wordt ingeschat, bestaat het risico van onder- of overbehandeling, met als gevolg afname van kwaliteit van leven.

In diverse studies wordt gerefereerd aan Balducci (Balducci, 2005), die oudere oncologische patiënten indeelt

in 3 categorieën: de zogenoemde Balducci 1 zijn de fitte ouderen die volledig zelfredzaam zijn zonder comorbiditeit. Deze groep kan meestal dezelfde behandeling ondergaan als jongere patiënten. De tweede categorie (Balducci 2) is de 'kwetsbare oudere', met 1-2 comorbiditeiten en/of beperkingen in ADL. Bij deze groep patiënten zal de (standaard)behandeling moeten worden aangepast. De derde groep (Balducci 3) of "unfit elderly", betreft patiënten die 3 of meer comorbiditeiten hebben, ADL afhankelijk zijn, of een progressief geriatrisch syndroom hebben. Bij deze groep lijkt de beperkte potentiële overlevingswinst van behandeling niet op te wegen tegen de belasting van de behandeling.

Momenteel wordt fitheid – naast anamnese van patiënt en naaste(n) – vastgesteld met behulp van de Karnofsky Performance Scale (KPS), European Organization for Research and Treatment of Cancer (EORTC) classificatie van de WHO en Mini-Mental State Examination (MMSE). Dit zijn echter breed screenende instrumenten die niet specifiek ontwikkeld zijn voor de neuro-oncologische patiënt.

Bij neuro-oncologische patiënten is het belangrijk de beoordeling van de cognitie mee te nemen in het vaststellen van eventuele behandelopties. Cognitieve stoornissen hebben namelijk invloed op de therapietrouw en de toxiciteit gerelateerd aan behandeling en daardoor op het vroegtijdig staken van behandeling (Colloca, 2020). Cognitieve stoornissen kunnen derhalve als negatieve prognostische factor worden beschouwd. Cognitieve stoornissen kunnen ook van invloed zijn op de wilsbekwaamheid van een patiënt (kan de patiënt zelf een adequate beslissing nemen ten aanzien van wel/geen behandeling en begrijpt hij/zij de consequenties van zijn/haar keuze).

De gouden standaard om fitheid en kwetsbaarheid te beoordelen is een geriatrisch assessment, ook wel 'Comprehensive Geriatric Assessment' (CGA) genoemd. Het belangrijkste doel van zo'n CGA is het voorkomen of vertragen van functionele achteruitgang. In de Nederlandse richtlijn 'Comprehensive Geriatric Assessment 2021' wordt aanbevolen om een risico-inschatting te maken op het risico op negatieve uitkomsten als er behandeling wordt overwogen met een hoog risico op complicaties en/of functionele achteruitgang, er potentieel beperkte opbrengst te verwachten is of wanneer er twijfel is over de belastbaarheid van de patiënt. Omdat het uitvoeren van een CGA door een klinisch geriater arbeidsintensief is, is het raadzaam om de patiënten te selecteren die baat kunnen hebben bij een CGA. Dit kan gebeuren aan de hand van meetinstrumenten, waaronder de VMS-vragen (veiligheidsmanagementsysteem) of de G8 ('Geriatric 8') vragenlijst. Deze laatste vragenlijst is het meest gevalideerde screeningsinstrument binnen de oncologische populatie. De G8 vragenlijst is speciaal ontwikkeld voor de oudere kankerpatiënt en heeft een sensitiviteit van > 80% in 6 studies en een specificiteit van > 60% in 4 studies (Bruijnen, 2020). De vragenlijst bestaat uit 8 vragen: afname van voedingsinname, gewichtsverlies, mobiliteit, neuropsychologische problemen, BMI, polyfarmacie, inschatting eigen gezondheidstoestand en leeftijd (Bruijnen, 2020). De totale score bedraagt 17 en de score is afwijkend indien deze ≤ 14 is. De afname duurt ongeveer 2 minuten. Een beperking van de vragenlijst is de beperkte aandacht voor cognitieve problemen, welke – zoals hierboven reeds vermeld – een belangrijk aspect zijn voor de prognose van de neuro-oncologische patiënt. Er wordt derhalve geadviseerd om additioneel een MMSE of 6CIT af te nemen (richtlijn CGA).

Wanneer een patiënt vanuit de G8 mogelijk kwetsbaar is gebleken, kan worden overwogen een patiënt naar de geriater of internist ouderengeneeskunde te verwijzen voor een uitgebreidere beoordeling. Deze uitgebreidere beoordeling bestaat uit tenminste de volgende onderdelen : anamnese en hetero-anamnese

ten aanzien van mate van zelfredzaamheid, voedingsstatus, vallen en mobiliteit, sociale omstandigheden, steunsysteem, cognitieve en wel stemmingsstoornissen en eerder doorgemaakt delier. Naast voorgenomen aspecten moet er aandacht zijn voor de wensen en verwachtingen van de patiënt zelf. Het doel van de beoordeling wordt omschreven als: het formuleren van een conclusie met betrekking tot geriatrische kwetsbaarheid en de invloed daarvan op beleid/behandeltraject.

Hamaker (2018) verrichtte een systematische review naar het effect van een geriatrisch evaluatie op de oncologische en niet-oncologische behandeling van ouderen (> 70 jaar) met kanker en is dus niet specifiek gericht op onze populatie. Daarbij werden 36 publicaties uit 35 studies geïncludeerd. Bij mediaan 28% (spreiding 8 tot 45%) van de oudere patiënten met kanker werd op basis van de gegevens van de geriatrische evaluatie het oncologische behandelplan aangepast. Daarnaast werd in mediaan 72% van de patiënten (spreiding 26 tot 100%) één of meer niet-oncologische interventies ingezet gericht op het verbeteren van de uitgangspositie van de patiënt. Het uiteindelijke effect op de behandeluitkomsten was wisselend, waarbij vaker de ingestelde behandeling kon worden gegeven (positief effect in 75% van de studies) en er minder behandelings-gerelateerde complicaties of toxiciteit optrad (positief effect in 55% van de studies).

Hoewel er geen vergelijkende studies zijn gevonden over de meerwaarde van geriatrische assessments bij oudere patiënten met een glioblastoom zijn er in de afgelopen jaren wel diverse studies gedaan naar de inzetbaarheid en het effect van screeningslijsten en assessments bij deze patiënten. Dit vanuit een behoefte aan verbetering van de wijze waarop voor oudere patiënten de behandelkeuze wordt gemaakt. Het geriatrische assessment (CGA) is in deze studies het meest onderzochte/gebruikte en (waarschijnlijk) het meest aanbevolen instrument. Ook in neuro-oncologische centra waar geriatrische beoordeling wordt ingezet bij glioblastoom patiënten bij wie er twijfel is over de optimale behandeling blijkt dat een geriatrisch assessment kan bijdragen om tot een weloverwogen behandelkeuze te komen.

Waarden en voorkeuren van patiënten (en evt. hun naasten/ mantelzorgers)

Patiënten met een behandelwens hebben vaak tot doel om tijd van leven te verlengen met behoud van kwaliteit van leven, zodat ze de dingen kunnen blijven doen die voor hen belangrijk zijn. Hiervoor is een zo passend mogelijke behandelkeuze van belang. Een extra consult bij een geriater (assessment) kost tijd en energie voor patiënt en naasten, maar kan wel helpend zijn in het behalen van het doel. Daarnaast kan dit consult aandachtspunten naar voren halen die bij de neurologische beoordeling onderbelicht zijn gebleven. Om te beoordelen of een patiënt gebaat kan zijn bij een dergelijke beoordeling kan gebruik gemaakt worden van een screeningsinstrument zoals de G8. Bij een vitale oudere patiënt zonder risicofactoren voor functionele achteruitgang heeft een uitgebreide geriatrische beoordeling geen meerwaarde, dit zal ook gelden voor een terminale patiënt.

Kosten (middelenbeslag)

Het inzetten van uitgebreide geriatrische assessments is arbeidsintensief en kost tijd. Hamaker et al (2018) hebben in hun systematische review laten zien dat een geriatrisch assessment wel inzichten ten aanzien van optimale behandel mogelijkheden kan opleveren, echter is er hierbij niet gekeken naar kosteneffectiviteit. De werkgroep acht het mogelijk dat door het voorkomen van overbehandeling extra consulten en ziekenhuisopnames beperkt worden.

Aanvaardbaarheid, haalbaarheid en implementatie

Het inzetten van arbeidsintensieve uitgebreide geriatrische assessments vraagt om voldoende capaciteit bij de afdeling geriatrie (geriater of verpleegkundig specialist) of de interne geneeskunde (met name internist ouderengeneeskunde) en het is de vraag of dat dit haalbaar is gezien de sterke vergrijzing en de daarmee toenemende incidentie van gliomen. Het is derhalve van groot belang de juiste groep patiënten te selecteren waarbij deze interventie meerwaarde zal hebben. Gezien de bevindingen uit de systematische review van Hamaker et al (2018) zal het bij vermoedelijk een kwart van de patiënten een verandering in behandelplan teweegbrengen en zit de grootste winst in het verbeteren van de uitgangspositie van de patiënt door niet-oncologische interventies.

Onderbouwing

Achtergrond

Vanwege toenemende vergrijzing zal de incidentie van gliomen de komende decennia verder stijgen, met name in de hogere leeftijdsgroepen. Patiënten met een hogere leeftijd zijn vaak ondervertegenwoordigd in wetenschappelijke studies en een optimale behandelstrategie ontbreekt derhalve in deze groep. Kalenderleeftijd komt vaak niet overeen met de biologische leeftijd van patiënten, waarbij kwetsbaarheid een belangrijke parameter is. Behoud van kwaliteit van leven en autonomie zijn belangrijk, vaak belangrijker dan verlengen van levensduur. In het algemeen leidt behandeling van het glioblastoom met radiotherapie en/of chemotherapie niet tot verbetering van de klinische toestand, wel mogelijk tot verlenging van de overleving. Het is derhalve belangrijk met de individuele patiënt te bespreken wat de wensen of behandeldoelen zijn. De klinische conditie en levenskwaliteit van de patiënt op het moment van aanvang van de behandeling bepalen daarom in sterke mate of en op welke manier de patiënt behandeld dient te worden. Het is onduidelijk of het zinvol is om een geriatrische evaluatie uit te voeren bij oudere patiënten die potentieel in aanmerking komen voor behandeling. Sommige instituten doen het wel, andere niet. Ook de aanpak en bij wie deze evaluatie wordt uitgevoerd verschilt.

Voor de tekst in deze module geldt dat waar 'geriater' geschreven staat, ook een verpleegkundig specialist geriatrie of internist ouderengeneeskunde gelezen kan worden.

Conclusies

All outcomes

No GRADE	No evidence was found regarding the effect of geriatric assessment on any outcome when compared with no geriatric assessment in elderly (frail) patients with glioma who are potentially eligible for treatment.
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Zoeken en selecteren

A systematic review of the literature was performed to answer the following question: Does a geriatric assessment in elderly (frail) patients with glioma lead to different outcomes?

Patients: Elderly (frail) patients (over 60 years old) with pathology confirmed glioma who are potentially

eligible for treatment

Intervention: Geriatric evaluation

Control: No geriatric evaluation

Outcomes: Treatment options, treatment related complications, complete treatment, survival, quality of life, patient satisfaction

Relevant outcome measures

The guideline development group considered quality of life and overall survival as a critical outcome measure for decision making; and treatment related complications, complete treatment, patient satisfaction, number of treatment options as an important outcome measure for decision making.

Treatment options: eligible for systemic therapy, radiotherapy and/or resection.

For the other outcomes, the working group did not define the outcome measures listed above but used the definitions used in the studies.

Per outcome, the working group defined the following differences as a minimal clinically (patient) important differences:

Overall survival: Benefit > 12 weeks or hazard ratio < 0.7

Quality of life: The minimum important difference (MID) has been estimated to be a difference of 0.08 or more points for the EQ-5D utility index, seven or more points for the EQ-5D VAS (Pickard, 2007), or ≥ 10 points on the Karnofsky Performance Score (KPS).

Cognitive functioning: MMSE ≥ 3 points, EORTC cognitive functioning subscale ≥ 10 points.

Adverse events: lethal < 5% (absolute difference), acute or severe < 25%.

Treatment options/treatment completemet: RR ≤ 0.8 or ≥ 1.25

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until December 2nd 2021. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 52 hits. Studies were selected based on the following criteria:

- Systematic reviews (searched in at least two databases, and detailed search strategy, risk of bias assessment and results of individual studies available), randomized controlled trials, or observational comparative studies;
- Full-text English language publication;
- Studies including ≥ 20 (ten in each study arm) patients; and
- Studies according to the PICO

Five studies were initially selected based on title and abstract screening. After reading the full text, all studies were excluded (see the table with reasons for exclusion under the tab Methods), and no studies were included.

Results

No studies were included in the analysis of the literature.

Level of evidence of the literature

No studies were included in the analysis of the literature.

Verantwoording

Laatst beoordeeld : 11-07-2023

Laatst geautoriseerd : 11-07-2023

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

Referenties

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Behandeling ouderen/kwetsbaren

Uitgangsvraag

Met welke aandachtspunten dient rekening gehouden te worden specifiek in de behandeling van ouderen/kwetsbare patiënten met een glioblastoom?

Aanbeveling

Zie bij patiënten af van behandeling indien er sprake is van een Karnofsky performance status (KPS) < 70 of ernstige cognitieve functiestoornissen.

Bespreek de wensen en verwachtingen van de patiënt, de te verwachten therapeutische winst en de mogelijke nadelen van de behandelingen. Raadpleeg bij twijfel een geriater/verpleegkundig specialist geriatrie/internist ouderengeneeskunde conform de aanbevelingen in module 'Indicatie geriatrisch assessment'.

Bij patiënten met een behandelindicatie en wens tot behandeling:

- Bied bij patiënten boven 60 jaar ook chemoradiatie volgens het Perry protocol als alternatief voor het standaard Stupp protocol aan in afwezigheid van comorbiditeit/polyfarmacie met risico op behandelcomplicaties.
- Bied bij patiënten boven 60 jaar monotherapie op basis van MGMT-status aan (monotherapie temozolamide bij gemethyleerde MGMT-tumor en radiotherapie bij ongemethyleerde tumor) indien ze geen gecombineerde behandeling aankunnen door comorbiditeit of verhoogd risico op behandelcomplicaties.

Overwegingen

Het doel van deze uitgangsvraag was om te achterhalen wat de waarde van oncologische behandeling is bij oudere patiënten met een nieuw gediagnosticeerd glioblastoom is. Er is één Cochrane systematische review met netwerk meta-analyse gevonden die oncologische behandeling vergeleek met ondersteunende (palliatieve) zorg (Hanna, 2020). Naast enkele methodologische beperkingen waren de studiepopulaties relatief klein. Bewijskracht voor de kritieke uitkomstmaten (progressievrije overleving, totaaloverleving en kwaliteit van leven) was laag tot zeer laag. Dit betekent dat andere studies kunnen leiden tot nieuwe inzichten. Er kunnen op basis van de literatuur alleen geen sterke aanbevelingen geformuleerd worden over de toegevoegde waarde van oncologische behandeling voor oudere patiënten met nieuw gediagnosticeerde glioblastoom.

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Op basis van de studies door Mirimanoff (2006) en Stupp (2009) concludeert de werkgroep dat de prognose voor patiënten met een glioblastoom slechter is bij aanwezigheid van de volgende prognostisch ongunstige variabelen: leeftijd > 60 jaar, Karnofsky performance status (KPS) < 70, MMSE < 27/30, niet hebben

ondergaan van een resectie en afwezigheid van MGMT promotor hypermethyleatie. Met aanwezigheid van deze ongunstige variabelen wordt de prognose slechter en neemt de winst van aanvullende behandelingen af (Mirimanoff, 2006; Stupp, 2009).

In de beschreven meta-analyse van Hanna (2020) wordt een winst op overall survival (OS) beschreven bij het toedienen van chemoradiatie bij ouderen van 70 jaar. Subgroepanalyse naar leeftijdsgroepen of MGMT status was helaas niet mogelijk wegens onvoldoende beschikbare geaccumuleerde data (Hanna, 2020). In de studies waar wel MGMT data beschikbaar was, ziet de werkgroep een overlevingsvoordeel (Minniti, 2012; Perry, 2017). In de studie van Perry (2017) werden 562 patiënten gerandomiseerd tussen chemoradiatie of radiotherapie, 281 per behandelarm. De mediane totale overleving was langer met chemoradiatie dan met radiotherapie alleen (9,3 maanden vs. 7,6 maanden; hazard ratio (HR) voor overlijden, 0,67; 95% betrouwbaarheidsinterval (CI), 0,56 tot 0,80; $P<0,001$), evenals de mediane progressievrije overleving (5,3 maanden versus 3,9 maanden; hazard ratio voor ziekteprogressie of overlijden, 0,50; 95% BI, 0,41 tot 0,60; $P<0,001$). Bij 165 patiënten met MGMT gemethyleerde glioblastoom was de mediane totale overleving 13,5 maanden met chemoradiatie en 7,7 maanden met alleen radiotherapie (hazard ratio voor overlijden, 0,53; 95% BI: 0,38 tot 0,73; p -waarde $<0,001$). Kwaliteit van leven bleef onveranderd tussen beide groepen.

In de Nordic-studie werden 342 patiënten van 60 jaar of ouder gerandomiseerd voor behandeling met een kort schema radiotherapie ($10 \times 3,4$ Gy), temozolamide chemotherapy (tot 6 kuren, 200 mg/d op dag 1-5/28) of een standaardschema radiotherapie (30×2 Gy) (Malmstrom, 2012). De overleving was langer voor patiënten die met temozolamide werden behandeld, dan met een lang schema radiotherapie (8,5 vs. 6 mnd; hazard ratio [HR] 0,70; 95%BI: 0,52 tot 0,93, $p=0,01$). Bij patiënten boven de 70 jaar leidde bovendien een kort schema radiotherapie tot een langere overleving dan een lang schema radiotherapie. Van de patiënten die werden behandeld met temozolamide hadden degenen met een gemethyleerde MGMT- promotor een langere overleving dan die met een niet-gemethyleerde MGMT-promotor (9,7 maanden (95% BI: 8,0 tot 11,4) versus 6,8 maanden (5,9 tot 7,7); HR 0,56 (95%BI: 0,34 tot 0,93), p -waarde=0,02) (Malmstrom, 2012). In de NOA 08-studie werden 373 patiënten van 65 jaar of ouder gerandomiseerd tussen standaard radiotherapie (30×2 Gy) en dose-dense temozolamide (100 mg/m²/d op dag 1-7 en 15-21/28) (Wick, 2012). Er was geen verschil in mediane overleving tussen de twee groepen, getest volgens non-inferiority principe: 8,6 mnd. (95% BI: 7,3 to 10,2) in de TMZ-groep versus 9,6 mnd. (95%BI: 8,2 tot 10,8) in de radiotherapiegroep (HR 1,09; 95% BI: 0,84 tot 1,42, p -non-inferiority= 0,033). Zowel de NOA-08 als de Nordic studie zijn opgenomen in de meta-analyse door Hanna (2020), echter niet individueel uitgelicht. Hoewel deze twee studies een verschillende dosering temozolamide gebruikten, acht de werkgroep het niet waarschijnlijk dat dit de resultaten heeft beïnvloed: een gerandomiseerde fase III-studie toonde geen verschil in effectiviteit aan tussen adjuvant dose-dense temozolamide en adjuvante standaard dosering bij patiënten met een glioblastoom (Gilbert, 2013). Hypofractioneerde schema's zijn niet inferieur aan standaard bestralingsschema's volgens deze review (de Melo, 2020). De verminderde belasting in tijd en verminderd risico op bijwerkingen zijn argumenten ten voordele van hypofractionering.

In een meta-analyse van studies naar radiotherapie en temozolamide bij oudere glioblastoompatiënten blijkt dat bij patiënten met gemethyleerde MGMT-promotor in hun tumor temozolamide effectiever was dan radiotherapie voor verbetering van de overleving (temozolamide versus. radiotherapie: HR 0,66; 95%BI: 0,47

tot 0,93) terwijl het tegenovergestelde gold voor patiënten met niet-gemethyleerde tumoren (HR 1,32; 95%BI 1,00 tot 1,76) (Yin, 2014).

Mits goede selectie op basis van patiënt- en tumorkarakteristieken acht de werkgroep dat therapievoordelen (overleving en kwaliteit van leven) kunnen worden behaald zoals beschreven in meta-analyse (Nassiri, 2020).

Waarden en voorkeuren van patiënten (en evt. hun naasten/ mantelzorgers)

In de beslissing omtrent het te voeren beleid bij de oudere (>65 jaar), kwetsbare patiënt met een nieuw gediagnosticeerd glioblastoom, zal te allen tijde de waarden en voorkeuren van de patiënt worden meegenomen. Een belangrijk doel van een interventie is overlevingswinst met een acceptabele kwaliteit van leven. Kwaliteit van leven zal voor de individuele patiënt verschillende waarden omvatten. Interventie kan er echter ook voor zorgen dat de kwaliteit van leven achteruit gaat, bij de patiënt met een slechte initiële uitgangssituatie, op basis van bijvoorbeeld de klinische conditie. Ook kan de keuze voor een interventie zorgen voor frequente ziekenhuisbezoeken en dus extra belasting voor de patiënt opleveren. Dezen en andere voor- en nadelen van een bepaalde interventie zullen door de behandelaar met de patiënt besproken moeten worden waardoor er een weloverwogen afweging gemaakt kan worden of de belasting en impact van een interventie voldoende meerwaarde voor hen heeft, afgewogen tegen de te verwachten overlevingswinst en kwaliteit van leven (gedeelde besluitvorming).

Kosten (middelenbeslag)

Door patiënten beter te selecteren op behandelingen die haalbaar zijn op grond van objectieve parameters kunnen best mogelijk behandeling leiden tot minder zorgbelasting (minder bezoeken aan het ziekenhuis, minder bijwerkingen, kortere behandeltijd). Volgens de Dutch Brain Tumor Registry (DBTR) hebben 35% van de glioblastoompatiënten ouder dan 70 jaar in de periode 2014 – 2017 geen nabehandeling na operatie gehad. 25% had enkel radiotherapie, 10% enkel temozolamide monotherapie en 30% een vorm van gecombineerd schema. In dit rapport wordt geen gewag gemaakt over de overleving of levenskwaliteit per behandeltype in deze categorie patiënten. Het is dus realistisch aan te nemen dat 65% van de oudere patiënten na de diagnose een vorm van nabehandeling krijgt. Aangezien MGMT bepaling al standaard in het diagnose pakket zit voor deze leeftijdscategorie, kan in het multidisciplinair overleg beter worden ingespeeld op het type patiënt en tumor met een op maat gemaakte behandeling, leidend tot minder afgebroken behandelingen door bijwerkingen of progressie. Uitgaande van 40% kans op aantreffen MGMT gemethyleerde tumor, verwacht de werkgroep dat het aandeel nabehandelde patiënten met chemotherapie alleen zal stijgen naar 15 – 26%. Als we uitgaan dat de helft van de resterende patiënten chemoradiatie krijgt en de andere helft radiotherapie, komen beide groepen rond 20 – 25% aandeel uit. Een kleinere groep zal de gecombineerde behandeling krijgen, waarbij met een gehypofractioneerde schema men minder vaak naar het ziekenhuis zal hoeven komen en men meer patiënten met dezelfde middelen kan behandelen. Minder blootstelling aan zware behandelingsschema's leidt tot minder bijwerkingen en ziekenhuisopname. Kosten zullen volgens de werkgroep enigszins gereduceerd worden, maar omdat deze behandelvormen naast radiotherapie geen dure medicatie bevatten zal het qua besparing beperkt zijn.

Aanvaardbaarheid, haalbaarheid en implementatie

De randvoorwaarde is om leeftijd niet als een beperking te beschouwen, maar als een gegeven naast de overige prognostische factoren. Op basis van een volledig beeld gebaseerd op patiënt en tumorkarakteristieken kan een arts het gesprek met de patiënt starten waarin de mogelijkheden en uitdagingen liggen per behandeloptie in een proces van gedeelde besluitvoering. Gezien de soms beperkte winst in prognose is het van belang om altijd de optie symptoomgericht in plaats van tumorgericht handelen te bespreken. Bij twijfel kan de hulp van de huisarts voor context bepaling en van de geriater voor ondersteunende maatregelen tijdens behandelen ingeroepen worden.

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies

Over de leeftijd waarop een patiënt oud of ouder is, bestaat geen consensus en ook in studies worden verschillende leeftijden gehouden. Doorgaans wordt in de internationale literatuur met 'ouder' een leeftijd bedoeld vanaf 60 of 70 jaar.

Aan oudere patiënten met goede Karnofsky performance status (KPS) ≥ 70 , MMSE $\geq 27/30$ (indien verricht bij verdenking op cognitieve stoornissen), status na resectie en in aanwezigheid van MGMT-promotor hypermethylatie kan volgens de werkgroep een chemoradiatie schema volgens de studie van Perry (2017) worden aangeboden. Het betreft hypogefractioneerde bestraling van 15 sessies tot 40 Gy met gelijktijdig temozolamide 75 mg/m² gevolgd door zes postradiatiekuren temozolamide 200 mg/m² dagen 1-5 elke 4 weken. Voor oudere patiënten met een of meer ongunstige prognostische factoren, maar die volgens de eigen behandelaar wel nog in aanmerking voor aanvullende behandeling komen, kan op basis van MGMT-status monotherapie hypogefractioneerde radiotherapie (ongemethyleerde tumoren) of monotherapie temozolamide (gemethyleerde tumoren) met de patiënt en zijn naasten worden besproken. Naar analogie met de NOA-08 studie zou een maximale behandelduur met TMZ van één jaar een overweging kunnen zijn.

Onderbouwing

Achtergrond

In de huidige situatie zijn er nog onvoldoende handvatten over welke overwegingen leiden tot de keuze van het behandelbeleid bij de oudere (> 65 jaar oud) kwetsbare patiënt met een nieuw gediagnosticeerd glioblastoom, welke in voldoende conditie verkeert om potentieel in aanmerking te komen voor een behandeling. In verband met de vergrijzing van de bevolking zal deze vraag in de klinische praktijk steeds vaker aan de orde zijn. De werkgroep heeft een advies geformuleerd over de overwegingen die een rol kunnen spelen bij de keuze voor oncologische behandeling (bijvoorbeeld neurochirurgie, radiotherapie, chemoradiotherapie, systemische therapie (inclusief chemotherapy)) dan wel best supportive care in deze populatie.

Verdiepende informatie over de specifieke therapieën kunt u vinden in de betreffende modules, dat wil zeggen de informatie over resectie, chemotherapy en radiotherapie wordt beschreven in de modules behandeling hooggradig glioom, respectievelijk over neurochirurgie, radiotherapie en chemotherapy/systeemtherapie.

Conclusies

1.1 Progression free survival (critical)

Low GRADE	The evidence suggests radiotherapy increases progression free survival when compared with no treatment (supportive care) in elderly people with newly diagnosed glioblastoma. <i>Source: Hanna, 2020</i>
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1.2 Overall survival (critical)

Very low GRADE	The evidence is very uncertain about the effect of RT40, RT60, CRT, RT40+BEV-CRT, BEV-CRT, or TMZ on overall survival compared with no treatment (supportive care) in elderly people with newly diagnosed glioblastoma. <i>Sources: Hanna, 2020</i>
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2. Quality of life, any length of follow-up (critical)

Very low GRADE	The evidence is very uncertain about the effect of radiotherapy on quality of life, compared with no treatment (supportive care) in elderly people with newly diagnosed glioblastoma. <i>Sources: Hanna, 2020</i>
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3. Adverse events (critical); 4. Objective response (important)

No GRADE	No information was found regarding the effect of oncological treatment on adverse events or objective response when compared with no treatment (best supportive care) in patients with newly diagnosed glioblastoma. <i>Source: -</i>
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5. Cognitive functioning, any length of follow-up (important)

Very low GRADE	The evidence is very uncertain about the effect of radiotherapy on cognitive functioning compared with no treatment (supportive care) in elderly people with newly diagnosed glioblastoma. <i>Sources: Hanna, 2020</i>
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Comparison with neurosurgery

No GRADE	No information was found regarding the effect of neurosurgery on any outcome when compared with no treatment (best supportive care) in elderly patients with newly diagnosed glioblastoma. <i>Source: -</i>
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Samenvatting literatuur

Description of studies

The selection of Hanna (2020) was performed in April 2019. Twelve studies were included in the review. Studies either included only elderly (65+ years) or performed separate analyses on an elderly subgroup of patients. Participants had newly diagnosed glioblastoma, receiving interventions including best supportive care, hypofractionated radiotherapy, standard radiotherapy, temozolamide, chemoradiotherapy, bevacizumab with chemotherapy, and bevacizumab with radiotherapy. A network meta-analysis was performed for overall survival, using six studies. Other outcomes (progression free survival, health related quality of life and cognition) were reported for the comparison between radiotherapy (50 Gy) and supportive care, by Keime-Guibert (2007).

Table 1. Study characteristics

Study ID	Intervention (n)	RT EQD2 ab2/ab10	Control (n)	Age	Baseline KPS
Wirsching, 2018	RT 40.0 Gy (25)	48Gy/43Gy	BEV_RT 40.0 Gy (50)	Median 70 (range 65-87)	90-100: 41 (55%) 70-80: 27 (36%) ≥60: 7 (9%)
Saran, 2016	CRT (33)	60Gy/60Gy	BEV_CRT (39)	NR for subgroup	NR for subgroup
Keime-Guibert, 2007	RT 50 Gy with supportive care (39)	51Gy/53Gy	Supportive care only (42)	RT 50: median 73 (range 70-85) Supp care: median 75 (range 70-84)	70: 43 (53%) 80: 29 (36%) 90: 7 (9%) 100: 2 (2%)
Malmstrom, 2012	TMZ (42)	60Gy/60Gy	RT 60.0 Gy (41)	Approx. median age: 70 (range 60-88)	NR for subgroups
		46Gy/38Gy	RT 34 Gy (40)		
Perry, 2017	RT 40.05 Gy (281)	48Gy/43Gy	CRT (281)	Approx. median age: 73 (range 65 to 90)	NR
Roa, 2004	RT 60.0 Gy (47)	60Gy/60Gy 48Gy/43Gy	RT 40.0 Gy (48)	RT 60: mean age 72.4 (SD: 5.4) RT 40: mean age 71.0 (SD: 5.5)	median 70 (IQR: 60-80)
Wick, 2012	RT 60.0 Gy (178)	60Gy/60Gy	TMZ (195)	RT 60: median 72 (range 66-84) TMZ: median 71 (range 66-82)	Median 80 (range 60-100)

Abbreviations: ab2: alpha/beta ratio for central nervous system tissue; ab10: alpha/beta ratio for tumor; BEV_(C)RT, bevacizumab (chemo)radiotherapy; CRT, Chemoradiotherapy; EQD2, equivalent dose in 2Gy based on the Linear Quadratic Model; KPS, Karnofsky Performance Score; NR, Not Reported; RT, Radiotherapy; TMZ, temozolomide IQR:

Results

1. Survival (critical)

1.1 Progression free survival - radiotherapy 50 Gy versus supportive care

The outcome progression free survival was analyzed by Keime-Guibert (2007). Median time to progression was 14.9 weeks (95% CI 10.9 to 22.1) in participants receiving radiotherapy with supportive care, and 5.4 weeks (95% CI 4.4 to 7.6) in participants receiving supportive care only. The corresponding hazard ratio for disease progression was 0.28 (95% CI 0.17 to 0.46). This difference was clinically relevant, favoring the group receiving radiotherapy with supportive care.

1.2 Overall survival – network meta-analysis

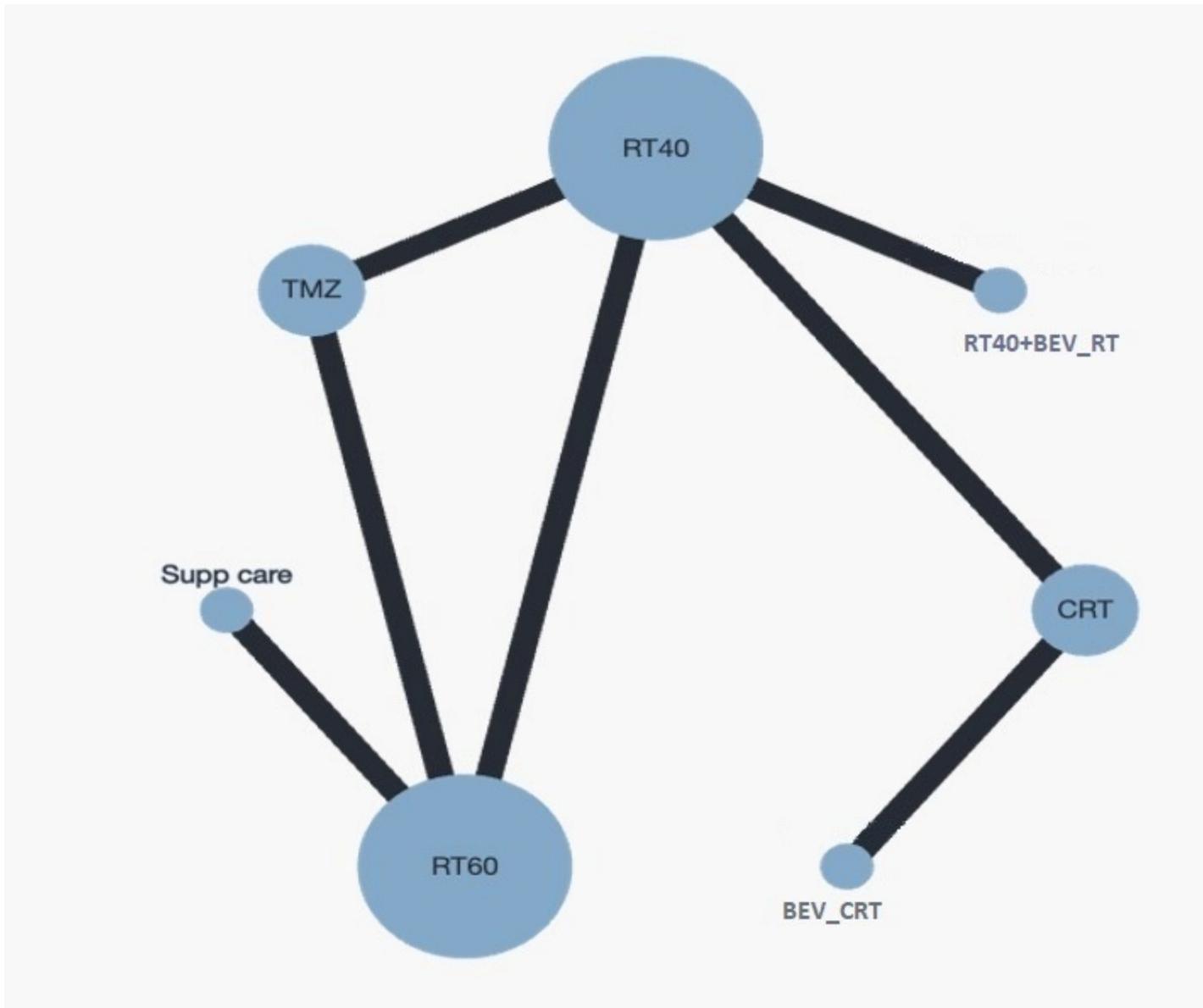
The outcome overall survival was analyzed in a network using a total of seven RCTs (Wirsching, 2018; Saran, 2016, Keime-Guibert, 2007; Malmstrom, 2012; Perry, 2017; Roa, 2004; and Wick, 2012). Network estimates for hazard ratios for overall survival are shown in table 2. The network is shown in figure 1.

Table 2. Network estimates for overall survival, reference supportive care only

Intervention (n)	Relative effect network meta-analysis, HR (95% CI)
Supportive care only (81)	1.0
RT 60.0 Gy (713)	0.47 (0.29 to 0.76)
BEV_RT (75)	0.48 (0.23 to 1.00)
RT 40.0 Gy (930)	0.44 (0.25 to 0.77)
TMZ (538)	0.42 (0.25 to 0.71)
CRT (635)	0.30 (0.17 to 0.53)
BEV_CRT (73)	0.25 (0.11 to 0.54)

Abbreviations: BEV_(C)RT, bevacizumab (chemo)radiotherapy; CRT, Chemoradiotherapy; RT, Radiotherapy; TMZ, temozolomide

Figure 1. Network plot for overall survival



2. Quality of life (critical) - radiotherapy 50 Gy versus supportive care

Health related quality of life was measured by Keime-Guibert (2007) at 30, 60, 90 and 135 days, using the European Organization for Research and Treatment of Cancer Quality of life Questionnaire (EORTC QLQ-C30) summary score (0-100), with higher scores indicating higher quality of life.

Quality of life (30 days)

At 30 days, mean quality of life in the group receiving radiotherapy with supportive care (n= 31) was 57.6 (SD 3.5). Mean quality of life in the group receiving supportive care (n= 28) was 61.8 (SD 4.7). This resulted in a mean difference of -4.2 (95% CI -6.33 to -2.07). This difference was not clinically relevant.

Quality of life (60 days)

At 60 days, mean quality of life in the group receiving radiotherapy with supportive care (n= 23) was 56.6 (SD 3.9). Mean quality of life in the group receiving supportive care (n= 22) was 60.3 (SD 5). This resulted in a mean difference of -4.7 (95% CI -7.33 to -2.07). This difference was not clinically relevant.

Quality of life (90 days)

At 90 days, mean quality of life in the group receiving radiotherapy with supportive care (n= 22) was 49.1 (SD 4). Mean quality of life in the group receiving supportive care (n= 17) was 56.7 (SD 6.3). This resulted in a mean difference of -7.6 (95% CI -11.03 to -4.17). This difference was not clinically relevant.

Quality of life (135 days)

At 135 days, mean quality of life in the group receiving radiotherapy with supportive care (n= 16) was 58.4 (SD 4.5). Mean quality of life in the group receiving supportive care (n= 10) was 48.1 (SD 6.7). This resulted in a mean difference of 10.7 (95% CI 6.01 to 15.39). This difference was clinically relevant.

3. Adverse events (critical)

None of the RCTs assessed the effect of oncological treatment compared with no treatment (best supportive care) in patients with newly diagnosed glioblastoma on adverse events.

4. Objective response (important)

None of the RCTs assessed the effect of oncological treatment compared with no treatment (best supportive care) in patients with newly diagnosed glioblastoma on objective response.

5. Cognitive functioning (important) - radiotherapy 50 Gy versus supportive care

Cognition was measured by Keime-Guibert (2007) at 30, 60, 90 and 135 days, using the cognitive functioning scale of the EORTC QLQ-C30 (0-100), with higher score indicating higher level of functioning.

Cognitive functioning (30 days)

At 30 days, the mean score for cognitive functioning in the group receiving radiotherapy with supportive care (n= 31) was 59.6 (SD 4.9). The mean score in the group receiving supportive care (n= 28) was 60 (SD 6.1). This resulted in a mean difference of -0.4 (95% CI -3.24 to 2.44). This difference was not clinically relevant.

Cognitive functioning (60 days)

At 60 days, the mean score for cognitive functioning in the group receiving radiotherapy with supportive care (n= 23) was 57.4 (SD 6.7). The mean score in the group receiving supportive care (n= 22) was 63 (SD 5.6). This resulted in a mean difference of -5.6 (95% CI -9.2 to -2). This difference was not clinically relevant.

Cognitive functioning (90 days)

At 90 days, the mean score for cognitive functioning in the group receiving radiotherapy with supportive care (n= 22) was 42.8 (SD 7.1). The mean score in the group receiving supportive care (n= 17) was 63.8 (SD 6.2). This resulted in a mean difference of -21 (95% CI -25.18 to -16.82). This difference was clinically relevant.

Cognitive functioning (135 days)

At 135 days, the mean score for cognitive functioning in the group receiving radiotherapy with supportive care (n= 16) was 43.8 (SD 6.7). The mean score in the group receiving supportive care (n= 10) was 56.8 (SD 7.8). This resulted in a mean difference of -13 (95% CI -18.84 to -7.16). This difference was clinically relevant.

Level of evidence of the literature

1. Survival (critical)

1.1 Progression free survival

The level of evidence regarding the outcome measure progression free survival started as high because it was based on an RCT and was downgraded by two levels to low because of 19/39 participants in the supportive care only group underwent partial- or complete resection of the tumor (-1, bias due to indirectness) and a low number of included patients (n= 81) (-1, imprecision). Because survival is an objective outcome and allocation was centrally performed, the level of evidence was not downgraded for risk of bias.

1.2 Overall survival

RT40 & TMZ: The level of evidence regarding the outcome overall survival started as high because it was based on RCT's and was downgraded by three levels to very low because the confidence interval crosses both boundaries of clinical important difference (-3 imprecision).

RT60: The level of evidence regarding the outcome overall survival was downgraded by three levels to very low because the confidence interval crosses a boundary of clinical important difference (-1 imprecision), heterogeneity (-1, inconsistency) and 19/39 participants in the supportive care only group underwent partial- or complete resection of the tumor (-1, indirectness).

CRT, RT40+BEV-CRT, BEV-CRT: The level of evidence regarding the outcome overall survival was downgraded by three levels to very low because of study limitations (-1, risk of bias) and the confidence interval crosses both boundaries of clinical important difference (-2, imprecision).

2. Quality of life (critical)

The level of evidence regarding the outcome measure quality of life started as high because it was based on an RCT and was downgraded by three levels to very low because of lack of blinding and high attrition rates (-2, risk of bias); and 19/39 participants in the supportive care only group underwent partial- or complete resection of the tumor (-1, bias due to indirectness).

3. Adverse events (critical); 4. Objective response (important)

The level of evidence regarding the outcome measures adverse events and objective response was not graded because of lack of data.

5. Cognitive functioning

The level of evidence regarding the outcome measure cognitive functioning started as high because it was based on an RCT and was downgraded by three levels to very low because of lack of blinding and high attrition rates (-2, risk of bias); and 19/39 participants in the supportive care only group underwent partial- or complete resection of the tumor (-1, bias due to indirectness).

Zoeken en selecteren

The character of the clinical question was broad in order to meet the whole spectrum of potential treatment paths a clinician considers when treating elderly (frail) patients. However, a more focused search question was defined.

A systematic review of the literature was performed to answer the following question: What are the favorable and unfavorable effects of oncologic treatment (i.e. neurosurgery, radiotherapy, systemic therapy (including

chemotherapy) compared to no treatment in elderly (frail) patients with new diagnosed glioblastoma, who qualify for treatment?

Patients: Elderly (frail) patients (over 65 years old) with pathology confirmed glioblastoma who are potentially eligible for treatment

Intervention: Oncological treatment (including neurosurgery (resection/debulking), radiotherapy, chemotherapy, chemoradiation, or systemic therapy)

Control: No treatment after pathology confirmation (best supportive care)

Outcomes: Objective Response, survival (progression-free, or overall), quality of life, cognitive functioning, adverse events.

Relevant outcome measures

The guideline development group considered survival, quality of life and adverse events as a critical outcome measure for decision making; and objective response and cognitive functioning as an important outcome measure for decision making.

A priori, the working group did not define the outcome measures listed above but used the definitions used in the studies.

Per outcome, the working group defined the following differences as a minimal clinically (patient) important differences:

Survival (progression-free, or overall): hazard ratio < 0.7

Quality of life: The minimum important difference (MID) has been estimated to be a difference of 0.08 or more points for the EQ-5D utility index, seven or more points for the EQ-5D VAS (Pickard, 2007), or ≥ 10 points on the Karnofsky Performance Score (KPS).

Cognitive functioning: EORTC cognitive functioning subscale ≥ 10 points.

Adverse events: lethal < 5% (absolute difference), acute or severe < 25%.

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until December 13nd 2021. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 109 hits. Studies were selected based on the following criteria:

- Systematic reviews (searched in at least two databases, and detailed search strategy, risk of bias assessment and results of individual studies available), randomized controlled trials;
- Full-text English language publication;
- Studies including ≥ 20 (ten in each study arm) patients; and
- Studies according to the PICO

Nineteen studies were initially selected based on title and abstract screening. After reading full texts, one systematic review with network meta-analysis was included (Hanna, 2020).

Results

One study was included in the analysis of the literature. Important study characteristics and results are

summarized in tables (see Table 1). The assessment of the risk of bias is summarized in the risk of bias tables.

Verantwoording

Laatst beoordeeld : 11-07-2023

Laatst geautoriseerd : 11-07-2023

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Behandeling Gliomatosis cerebri

Uitgangsvraag

Wat is het beleid bij gliomatosis cerebri?

Aanbeveling

Voor een patiënt met gliomatosis cerebri dienen de risico's en de voordelen van de verschillende behandelstrategieën, waaronder chemotherapie en radiotherapie, afgewogen te worden in een multidisciplinaire hersentumorwerkgroep. In de overweging voor de keuze van de primaire behandeling moeten de volgende factoren meegenomen worden: grootte van het gebied van tumorinfiltratie, histologische classificatie en gradering en moleculaire diagnostiek.

De werkgroep is van mening dat voor patiënten met gliomatosis cerebri:

- chirurgische interventie niet geïndiceerd is, behoudens het verrichten van een biopt voor het stellen van de pathologische diagnose. Daarnaast kan in uitzonderlijke gevallen een debulking worden overwogen bij massawerking uitgaande van het tumorproces.
- chemotherapie de eerste keus primaire behandeling is. Gekozen kan worden voor combinatie procarbazine en lomustine of temozolamide.
- radiotherapie kan worden overwogen als eerste en tweedelijnsbehandeling, maar bij de afweging dient rekening te worden gehouden met het aanzienlijke risico op neurotoxiciteit.

Overwegingen

Gliomatosis cerebri is een zeldzame heterogene tumor. De heterogeniteit betreft zowel de histologische classificatie als het klinisch beloop van de ziekte. Dit laatste kan variëren van snel progressief met neurologische uitvalsverschijnselen tot een meer indolent beloop met weinig of geen klinische verschijnselen behoudens epilepsie. Palliatieve therapeutische mogelijkheden zijn vooralsnog chemotherapie of radiotherapie. Gezien de diffuse verspreiding van gliomatosis cerebri (over drie kwabben) zal bij radiotherapie het bestralingsvolume groot zijn, waarbij de kans op vroege en late neurotoxiciteit aanzienlijk wordt geacht. Mede hierdoor wordt bij patiënten met gliomatosis cerebri chemotherapie veelal als primaire behandeling gekozen.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat chemotherapie een effectieve behandeling is voor een deel van de patiënten met gliomatosis cerebri.

Chen 2013⁵³, Rudà 2014²⁸⁴, Glas 2011¹¹²

Er zijn aanwijzingen dat temozolamide even effectief is als de combinatie chemotherapie procarbazine en lomustine / CCNU (PC), maar alleen PC is in prospectieve setting onderzocht.

Glas 2011¹¹², Mattox 2012²¹¹

De resultaten van radiotherapie uit verschillende retrospectieve studies laten onderling grote verschillen zien.

Samenvatting literatuur

Volgens de World Health Organization wordt gliomatosis cerebri gedefinieerd als een diffuus groeiend glioom met uitbreiding in drie of meer hersenkwabben, meestal bilateraal voorkomend en met frequente betrokkenheid van infratentoriële structuren. Gliomatosis cerebri wordt geklassificeerd als een WHO graad III glioom, waarbij radiologische kenmerken worden gecombineerd met histologische kenmerken. De histologische typering en gradering van gliomatosis cerebri door de patholoog is echter zeer variabel. Ofschoon gliomatosis cerebri meestal bestaat uit astrocytaire cellen, kan er ook een oligodendroglial fenotype zijn en is er in een minderheid van de gevallen sprake van glioblastoma multiforme. Er is geen standaardbehandeling voor gliomatosis cerebri. Mede door de zeldzaamheid en de heterogeniteit van deze tumorsoort zijn er geen vergelijkende studies verricht. Behandelkeuzes worden gemaakt aan de hand van één fase II-studie, veelal kleine retrospectieve series, case reports en expert opinions. Zowel bestraling als chemotherapie komen als behandelingsmodaliteit in aanmerking. Heel zelden is er een plaats voor decompressiechirurgie.

In een retrospectieve analyse van 105 patiënten met de diagnose gliomatosis (die tussen 1955 en 1998 werden onderzocht in het MD Anderson Cancer Center), werden 30 patiënten geïdentificeerd van wie follow-up data na bestraling beschikbaar waren [Perkins 2003²⁵⁴]. Binnen deze geselecteerde groep patiënten werd geen verschil in totale overleving (OS) of progressie vrije overleving (PFS) gevonden tussen de groep die alleen een biopsie ondervond en de groep die partiële resectie ondervond. 21/30 patiënten kregen een vorm van chemotherapie verdeeld over 9 regimes en ook hier werd geen verschil waargenomen tussen de wel of niet met chemotherapie behandelde patiënten voor wat betreft PFS en OS. Alle patiënten kregen dus radiotherapie, maar er werd geen verschil gevonden in PFS of OS tussen lokaal, versus whole brain RT (al dan niet in combinatie met chemotherapie).

Chirurgie

Gezien de diffuse verspreiding van de ziekte komen patiënten met gliomatosis cerebri zelden in aanmerking voor chirurgische interventie. Een biopsie wordt verricht voor het stellen van de pathologische diagnose en in geval van ernstige massawerking kan in uitzonderlijke gevallen debulking zinvol zijn. Er zijn geen data beschikbaar die het effect van een operatie ondersteunen.

Radiotherapie

Er zijn alleen retrospectieve data over de effectiviteit van radiotherapie bij patiënten met gliomatosis cerebri op PFS en OS. Bij al deze studies lijkt selectiebias een rol te spelen. De uitkomsten van de diverse studies laten grote verschillen zien. Taillibert analyseerde retrospectief 296 patiënten met gliomatosis cerebri gediagnostiseerd tussen 1993 en 2004, waarbij de OS van patiënten die radiotherapie ondervonden niet verlengd werd in vergelijking met de groep die geen tumorremmende behandeling ondervond [Taillibert 2006³³⁶]. Chen daarentegen beschreef een serie van 54 opeenvolgende patiënten waarbij radiotherapie (als eerste behandeling) sterk geassocieerd was met een betere prognose (PFS 16,5 versus 4,5 mnd., p < 0,01; OS 27,5 vs. 6,5 maanden, p < 0,01) [Chen 2013⁵³]. De studie van Mattox pleit voor combinatie radiotherapie en chemotherapie (temozolamide), gebaseerd op een casus en literatuuronderzoek [Mattox 2012²¹¹].

Chemotherapie

Er is één prospectieve studie betreffende chemotherapie bij gliomatosis cerebri. Glas onderzocht in een fase II-studie de effectiviteit van combinatie chemotherapie procarbazine en lomustine / CCNU (PC) bij 35 onbehandelde patiënten met gliomatosis cerebri [Glas 2011¹¹²]. Het percentage patiënten zonder ziekteprogressie op 8 maanden betrof 50,3%. De mediane progressievrije overleving was 14 maanden (95%CI 6,4-21,6 maanden). De mediane overleving was 30 maanden (95%CI 14,0-45,9 maanden). Sanson beschrijft een retrospectieve serie van 63 patiënten met gliomatosis cerebri die initieel behandeld werden met chemotherapie [Sanson 2004²⁹³]. Zeventien patiënten werden behandeld met combinatie chemotherapie procarbazine, lomustine (CCNU) en vincristine (PCV) en 46 patiënten werden behandeld met monotherapie temozolamide (TMZ). De PFS voor de gehele groep bedroeg 16 maanden en de OS bedroeg 28,8 maanden. Er was geen significant verschil in PFS en OS tussen de met PCV behandelde groep en de met TMZ behandelde groep. Oligodendrogliale tumoren hadden een betere PFS en OS dan astrocytaire en oligoastrocytaire tumoren. In deze studie waren geen data over 1p/19q-status aanwezig. Levin beschreef een serie van 11 patiënten die behandeld werd met TMZ waarbij 45% een objectieve respons optrad en een PFS van 13 maanden werd gerapporteerd [Levin 2004²⁰⁰]. De PFS op 12 maanden was 55%. Louis beschreef in een kleine groep patiënten een zeer goede response na TMZ bij gliomatosis cerebri van het oligodendrogliale subtype [Louis 2003²⁰⁶].

Post-radiatie chemotherapie

Er is één studie die een aanwijzing vond voor voordeel van chemotherapie na radiotherapie [Kong 2010¹⁷⁹]. Binnen deze retrospectieve analyse werd bij 19 patiënten alleen RT gegeven en bij 18 patiënten adjuvante chemotherapie bestaande uit TMZ of lomustine. De mediane overleving voor de patiënten die niet met adjuvante chemotherapie behandeld werden was 13,1 maanden versus 24 maanden voor de patiënten die chemotherapie kregen.

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Behandeling Recidief gliomen

De behandeling van recidief gliomen wordt beschreven in de volgende modules:

Systemische therapie

Chemotherapie recidief laaggradig glioom

Chemotherapie recidief anaplastisch glioom

Chemotherapie recidief glioblastoom

Neurochirurgie

Waarde en mate van re-resectie glioblastoom

Radiotherapie

Radiotherapie bij progressie hooggradig glioom/recidief

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Medicamenteuze symptoombestrijding bij gliomen

Deze module is onderverdeeld in de volgende submodules en sub-submodules:

- Corticosteroïden
- Anti-epileptica
 - Rol van anti-epileptica bij de behandeling
 - Invloed van anti-epileptica op de behandeling
- Medicatie in de terminale fase

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Corticosteroïden bij gliomen

Uitgangsvraag

Wat is de rol van corticosteroïden bij de behandeling van patiënten met gliomen?

Aanbeveling

Corticosteroïden zijn effectief in het bestrijden van symptomen ten gevolge van vasogenen oedeem bij met name hooggradige gliomen en vroege complicaties van radiotherapie. Gezien de mogelijke invloed op tumorgroei, betrouwbaarheid van beeldvormend onderzoek, interacties met anti-epileptica en chemotherapeutica en potentieel ernstige bijwerkingen op lange termijn, is de werkgroep van mening dat:

- gestreefd moet worden naar een zo kort mogelijke toediening van corticosteroïden, in een zo laag mogelijke dosering.
- dexamethason als protocollaire medicatie rondom een operatie niet onderzocht is en wellicht achterwege kan blijven, indien dexamethason nog niet gegeven werd.
- dexamethason postoperatief zo snel als op klinische gronden mogelijk is, dient te worden afgebouwd.
- de dosering van corticosteroïden bij klinische verslechtering tijdens radiotherapie tijdelijk verhoogd kan worden; nadien moet opnieuw geprobeerd worden de medicatie af te bouwen.
- gezien de verbeterende overleving, bij langdurig gebruik van corticosteroïden osteoporose-profilaxe overwogen moet worden.

Overwegingen

Hoewel osteoporotische fracturen weinig voorkomen bij gliompatiënten, hebben ze een belangrijke invloed op de kwaliteit van leven. Bij langdurig gebruik (>2,25 mg dexamethason en (verwachte) behandelduur van > 3 maanden) wordt geadviseerd osteoporose profilaxe toe te passen conform de CBO-richtlijn osteoporose. Hoewel het perioperatief gebruik van corticosteroïden in veel klinieken gebruikelijk is voor reduceren van postoperatief oedeem, ontbreekt hiervoor enige wetenschappelijke onderbouwing. In klinieken waar geen corticosteroïden perioperatief worden gegeven per protocol, maar op indicatie voor symptoomreductie, wordt geen toename van postoperatief oedeem waargenomen.

Onderbouwing

Conclusies

Corticosteroïden bestrijden tumor-geassocieerd vasogenen oedeem, met name bij hooggradige gliomen [Dietrich 2011⁸¹]. Het gebruik van corticosteroïden kan gepaard gaan met vele ongewenste bijwerkingen. Er zijn geen vergelijkende studies verricht naar optimale dosering of afbouwschema's.

Samenvatting literatuur

Corticosteroïden verminderen tumor-geassocieerd vasogenen oedeem, hetgeen leidt tot afname van symptomen. Dexamethason is het middel van voorkeur gezien de lange halfwaardetijd en geringe mineralocorticoïde werking [Dietrich 2011⁸¹, Ryan 2012²⁸⁵]. De halfwaardetijd rechtvaardigt een dosering van eenmaal daags.

Er zijn geen wetenschappelijk onderbouwde data met betrekking tot een gestandaardiseerde dosering of afbouwschema's. Aanvangsdoses van 4-16 mg per dag zijn gebruikelijk [Ryan 2012²⁸⁵].

Bij (verdenking op) hooggradige gliomen wordt vaak snel gestart met corticosteroïden. Laaggradige gliomen gaan gepaard met weinig oedeem, de rol van corticosteroïden is initieel meestal beperkt. Rondom een biops of resectie reduceren corticosteroïden het postoperatief oedeem gemeten met beeldvorming, maar klinische uitkomstmaten, zoals postoperatieve complicaties, werden niet onderzocht [Dietrich 2011⁸¹, Kotsarini 2010¹⁸¹, Deutsch 2013⁷⁹]

Corticosteroïden zijn effectief bij de behandeling van vroege complicaties van radiotherapie. Een prospectieve studie naar het gebruik van corticosteroïden tijdens radiotherapie voor hooggradige gliomen, toont dat 87% van de patiënten tijdens radiotherapie behandeld wordt met corticosteroïden. Voor start van radiotherapie was dit 70%. Bij 55% van de patiënten vond tijdens radiotherapie verhoging van de dosis plaats, gemiddeld na 8 dagen. Drie maanden na bestraling was 29% van de patiënten zonder corticosteroïden. Een initiële Karnofsky Performance Score van ≤80 was geassocieerd met een hogere steroïdbehoefte tijdens en na radiotherapie. Een partiële resectie (vs. biops) was geassocieerd met een lagere steroïdbehoefte tijdens, maar niet na radiotherapie [Marantidou 2010²¹⁰].

Er zijn - met name in vitro - aanwijzingen dat corticosteroïden de proliferatie van tumorcellen kunnen remmen of juist stimuleren [Dietrich 2011⁸¹].

Corticosteroïden beïnvloeden de mate waarin contrastvloeistof de bloed-hersenbarrière passeert, hetgeen radiologisch afname van aankleuring kan geven, zonder dat er daadwerkelijk sprake hoeft te zijn van tumorrespons [Dietrich 2011⁸¹, Kotsarini 2010¹⁸¹].

Bij gelijktijdig gebruik van enzym-inducerende anti-epileptica, met name fenytoïne, kan er sprake zijn van interactie: enerzijds kan het effect van dexamethason hierdoor afnemen, anderzijds kunnen de spiegels van anti-epileptica sterker fluctueren. Tevens kan interactie met chemotherapeutica optreden. Er zijn aanwijzingen dat dexamethason cellen kan beschermen tegen temozolamide geïnduceerde apoptose [Dietrich 2011⁸¹]. Bijwerkingen zijn onder andere hyperglycaemie, osteoporose, gewichtstoename, bijnierschors insufficiëntie, myopathie, slapeloosheid, ontremming, psychotische ontregeling, tremor, visusklachten, een verhoogd risico op opportunistische infecties en incidenteel cognitieve stoornissen [Dietrich 2011⁸¹, Ryan 2012²⁸⁵].

Een associatie tussen het gebruik van corticosteroïden en gastro-intestinale bloedingen kon bij retrospectieve analyse van klinische studies niet worden aangetoond. Het standaard voorschrijven van een maagbeschermer is dan ook niet geïndiceerd.

Vanwege het risico op bijwerkingen, dat samen lijkt te hangen met zowel de cumulatieve dosis als behandelduur, moet herhaaldelijk getracht worden de corticosteroïden af te bouwen. Hiervoor bestaan geen standaard schema's. Bij kort gebruik van corticosteroïden (korter dan 10 dagen) is een snelle afbouw gerechtvaardigd, bij langer gebruik moet de dosis langzamer verlaagd worden, met name als fysiologische doseringen bereikt worden om herstel van het adrenerge systeem te bevorderen en het risico op een steroïd onhoudingssyndroom te verkleinen [Ryan 2012²⁸⁵].

Verantwoording

Laatst beoordeeld : 15-04-2015

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Anti-epileptica bij gliomen

Deze submodule is onderverdeeld in de volgende sub-submodules:

- Rol van anti-epileptica bij de behandeling
- Invloed van anti-epileptica op de behandeling

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Rol van anti-epileptica bij de behandeling van gliomen

Uitgangsvraag

Wat is de (profylactische) rol van anti-epileptica bij de behandeling van patiënten met gliomen?

Aanbeveling

Bij patiënten met een glioom zonder epileptische aanvallen dienen geen profylactische anti-epileptica voorgeschreven te worden.

De werkgroep is van mening dat perioperatief profylactisch gebruik van anti-epileptica bij patiënten met een glioom niet gerechtvaardigd is.

De werkgroep is van mening dat bij patiënten met een glioom met epileptische aanvallen gekozen dient te worden voor onderhoudsbehandeling met niet-enzym-inducerende anti-epileptica.

Overwegingen

Er zijn geen studies die het gebruik van een specifiek anti-epilepticum ondersteunen. Het frequent gebruik van comedicatie met potentieel interactie met anti-epileptica door patiënten met een glioom, is een reden om bij voorkeur te kiezen voor niet-enzym-inducerende anti-epileptica.

Onderbouwing

Conclusies

Hoewel epileptische insulten frequent voorkomen bij patiënten met een glioom, zijn er geen gerandomiseerde studies die de keuze voor een bepaald anti-epilepticum ondersteunen.

Het is aannemelijk dat profylactisch gebruik van fenytoïne bij patiënten die niet eerder een insult gehad hebben, niet tot significante risico-reductie leidt, wel tot ongewenste bijwerkingen.

Tremont-Lukats 2008³⁴³

Samenvatting literatuur

Het optreden van epileptische insulten bij patiënten met een glioom kan leiden tot toename van uitvalsverschijnselen en ziekenhuisopname. De incidentie van insulten bij patiënten met een laaggradig glioom varieert tussen 65-85% en bij patiënten met een hooggradig glioom tussen 30-62% in verschillende series [Van Breemen 2007³⁴⁹]

Onderhoudstherapie wordt gestart bij klinisch manifeste insulten. Er zijn geen vergelijkende onderzoeken naar effectiviteit en bijwerkingen van verschillende anti-epileptica bij gliomen [Kerrigan 2011¹⁷⁰]. In kleine studies naar met name het effect van de nieuwere anti-epileptica worden vaak zeer heterogene patiëntengroepen beschreven. Bij de behandeling van epilepsie bij patiënten met een hersentumor hebben anti-epileptica die het cytochrome P450-co-enzymsysteem induceren (carbamazepine, fenobarbital, fenytoïne, oxcarbazepine en topiramaat) niet de voorkeur vanwege de interactie tussen anti-epileptica,

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chemotherapeutica en andere comedicatie, bijvoorbeeld dexamethason [Brodie 2013³³]. Het ligt daarnaast voor de hand te kiezen voor een eerste-keus middel bij de behandeling van partiële epilepsie [Vecht 2014³⁶³].

Voor een beschrijving van de beschikbare literatuur ten aanzien van individuele anti-epileptica bij neuro-oncologische patiënten wordt verwezen naar de Richtlijn Epilepsie.

De beschikbare literatuur geeft geen ondersteuning voor het profylactisch gebruik van anti-epileptica bij gliomen, terwijl er wel een verhoogd risico bestaat op het optreden van bijwerkingen [Tremont-Lukats 2008³⁴³].

Een prospectieve gerandomiseerde trial naar het gebruik van perioperatieve profylaxe met fenytoïne toont geen significante risico-reductie door het profylactisch gebruik van een adequate dosering fenytoïne in de postoperatieve periode bij patiënten met een supratentoriaal glioom of metastase [Wu 2013³⁹¹]. De algehele incidentie van insulten - ook in de controlegroep - was 8% in de eerste 30 dagen na operatie. De studie bleek van onvoldoende power om een significant verschil tussen de groepen te kunnen aantonen.

Verantwoording

Laatst beoordeeld : 15-04-2015

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Invloed van anti-epileptica op de behandeling van gliomen

Uitgangsvraag

Wat is de invloed van anti-epileptica op de (chemotherapeutische) behandeling?

Aanbeveling

De werkgroep is van mening dat het voorschrijven van enzym-inducerende anti-epileptica als fenytoïne, carbamazepine, oxcarbazepine en topiramaat niet gewenst is bij patiënten die worden behandeld voor een glioom.

De werkgroep is van mening dat er nog onvoldoende data zijn om een behandeladvies te baseren op de aanwijzingen dat het gebruik van valproaat in combinatie met temozolamide de overleving positief zou kunnen beïnvloeden.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat valproaat de overleving van patiënten met een glioblastoom positief zou kunnen beïnvloeden.

Weller 2011³⁸⁰, Simo 2013³¹³, Tsai 2012³⁴⁵, Guthrie 2013¹²¹, Kerkhof 2013¹⁶⁹

Er zijn geen prospectieve gerandomiseerde onderzoeken die de invloed van specifieke anti-epileptica op de chemotherapeutische behandeling beschrijven.

Samenvatting literatuur

Er zijn interacties beschreven tussen anti-epileptica en chemotherapeutica, gebaseerd op het gedeelde cytochrome P450-metabolisme. Enzym-inducerende anti-epileptica als fenobarbital, fenytoïne en carbamazepine geven verlaging van de spiegels van sommige chemotherapeutica en tevens een verhoogd metabolisme van corticosteroïden en verdienen dus niet de voorkeur tijdens chemotherapeutische behandeling [Brodie 2013³³, Oberndorfer 2005²³³].

Valproaat heeft een complexe invloed op de tumorcelproliferatie, waarbij theoretisch zowel stopzetten van de celcyclus als tumorproliferatie kan optreden. Preklinisch onderzoek toont een remmend effect van valproaat aan op DNA-repair mechanismen. Hierdoor kan het cytotoxische effect van chemotherapie of radiotherapie versterkt worden. Er worden *in vitro* geen aanwijzingen gevonden voor een remmend effect van valproaat op het cytotoxisch effect van temozolamide [Chen 2012⁵⁵, Ryu 2012²⁸⁶, Van Nifterik 2012³⁶¹, Berendsen 2012¹⁵].

In een retrospectieve analyse naar het gebruik van anti-epileptica bij patiënten met een glioblastoom die tussen 2000 en 2002 deelnamen aan een studie waarin radiotherapie werd vergeleken met chemoradiotherapie, hadden patiënten in de chemoradiatie-groep die werden behandeld met valproaat monotherapie een significant betere mediane overleving (17 maanden, versus 14 maanden bij patiënten zonder anti-epileptica of alleen enzym inducerende anti-epileptica) [Weller 2011³⁸⁰]. In de groep die alleen behandeld werd met radiotherapie werd geen significant verschil gevonden in overleving. Wel trad bij het

gebruik van valproaat in combinatie met temozolamide vaker trombocytopenie, neutropenie en leukopenie op [Weller 2011³⁸⁰, Simo 2012³¹³].

Ook in andere retrospectieve studies zijn er aanwijzingen dat valproaat de overleving positief zou kunnen beïnvloeden. Er zijn echter geen gerandomiseerde trials die deze bevindingen bevestigen [Tsai 2012³⁴⁵, Guthrie 2013¹²¹, Kerkhof 2013¹⁶⁹].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Medicatie in de terminale fase bij gliomen

Uitgangsvraag

Wat zijn effectieve medicamenteuze interventies om bij een patiënt met een glioom in de terminale fase (met tekenen van intracraniële drukverhoging), de volgende klachten te verminderen:

- hoofdpijnklachten
- onrust
- insulten

Aanbeveling

De werkgroep is van mening dat bij patiënten in de terminale fase:

- hoofdpijnklachten behandeld kunnen worden met een combinatie van corticosteroïden (bij voorkeur eenmaal daags gedoseerd) en opioïden. Als er sprake is van een gedaald bewustzijn kan overwogen worden de toediening van corticosteroïden te staken.
- onrust en agitatie bestreden kunnen worden met neuroleptica en sedativa.
- de behandeling met anti-epileptica zo lang als mogelijk gecontinueerd dient te worden, zo nodig in rectale, buccale, subcutane of intranasale toedieningsvorm. Clonazepam subcutaan (m.b.v. een pompje of in bolussen) sublinguaal of buccaal in doseringen van 2-4 mg per dag lijkt een bruikbaar alternatief als de reguliere anti-epileptica ten gevolge van slikstoornissen niet meer ingenomen kunnen worden.
- het vroegtijdig starten van begeleiding en het geven van voorlichting over het palliatieve traject raadzaam is om de beslissingen ten aanzien van het levenseinde te vergemakkelijken voor zowel patiënt als naasten.

Onderbouwing

Conclusies

Er zijn geen prospectieve gerandomiseerde onderzoeken naar de beste behandeling van de frequent voorkomende symptomen hoofdpijn, onrust en insulten in de terminale fase.

Het is aannemelijk dat corticosteroïden hoofdpijn en symptomen veroorzaakt door oedeem verminderen.
Ryan 2012²⁸⁵

De werkgroep is van mening dat opioïden geschikte analgetica zijn in de terminale fase mede vanwege de mogelijkheid tot subcutane toediening.

De werkgroep is van mening dat onrust en agitatie in de terminale fase bestreden kan worden met neuroleptica of sedativa.

Er zijn aanwijzingen dat een aanzienlijk deel van de patiënten in de laatste week van het leven een epileptisch insult doormaakt, daarom lijkt doorbehandelen met anti-epileptica ook bij dysfagie en bewustzijnsdaling zinvol.

Sizoo 2010³¹⁴, Walbert 2014³⁷²

Het is aannemelijk dat het vroegtijdig starten van begeleiding en het geven van voorlichting over het palliatieve traject de beslissingen ten aanzien van het levens einde kunnen vergemakkelijken en de kwaliteit van leven kunnen vergroten.

Sizoo 2012³¹⁵, Walbert 2014³⁷²

Samenvatting literatuur

Uit enkele retrospectieve studies blijkt dat de meest voorkomende symptomen bij patiënten in de terminale fase bewustzijnsdaling, dysfagie, toenam van focale uitvalsverschijnselen, communicatieve problemen, insulten, incontinentie, hoofdpijn, progressieve cognitieve stoornissen en onrust of verwardheid zijn.

Bewustzijnsdaling en dysfagie gaan vaak samen en treden met name in de laatste week voor overlijden op. Hierdoor wordt de inname van medicatie bemoeilijkt [Sizoo 2010³¹⁴, Walbert 2014³⁷², Sizoo 2014³¹⁶].

Corticosteroïden verminderen klachten van hoofdpijn en de symptomen veroorzaakt door oedeem [Ryan 2012²⁸⁵]. Er zijn geen onderbouwde richtlijnen ten aanzien van de dosering en de behandelduur in de terminale fase. Als het ophogen van de dosis dexamethason niet binnen enkele dagen effectief is, dan is continueren van een hogere dosis niet zinvol en wordt teruggegaan naar de eerdere dosering. Bij slikstoornissen kan dexamethason in gelijke dosering subcutaan worden toegediend. Het continueren van corticosteroïden wanneer inname niet meer mogelijk is door gedaald bewustzijn, lijkt niet zinvol.

Er zijn geen prospectieve studies naar het gebruik van analgetica bij patiënten met een glioom in de terminale fase. Opioïden worden in de terminale fase het meest frequent toegepast en kunnen subcutaan worden toegediend. Terughoudendheid ten aanzien van het gelijktijdig gebruik van corticosteroïden en NSAID's is op zijn plaats vanwege het risico op darmperforaties.

Onrust en agitatie in de terminale fase komen frequent voor bij patiënten met een glioom. Dit wordt behandeld met neuroleptica of sedativa, er zijn geen prospectieve studies naar het effect van deze behandelingen.

Er zijn geen prospectieve studies naar het gebruik van anti-epileptica in de terminale fase. Omdat ruim een derde van de glioompatiënten in de laatste week insulten doormaakt, lijkt het waardevol de behandeling met anti-epileptica ook bij slikstoornissen of bewustzijnsdaling te continueren [Sizoo 2010³¹⁴, Walbert 2014³⁷²]. In de thuissituatie wordt bij voorkeur gekozen voor non-invasieve toediening. Rectale toediening van carbamazepine, levetiracetam, natriumvalproaat en fenobarbital is mogelijk, maar preparaten moeten soms door de apotheker speciaal bereid worden. Clonazepam buccal of sublinguaal is een goed alternatief. Vaak wordt gestart met een dosis van 1-2 mg en een onderhoudsdosering van 2-4 mg per dag. Insulten kunnen gecoupeerd worden met diazepam rectioles, midazolam intranasal of subcutaan of clonazepam buccal.

In de terminale fase zijn patiënten door cognitieve stoornissen, fatische stoornissen of bewustzijnsstoornissen vaak niet meer actief betrokken in de beslissingen rondom het levens einde. Het is aannemelijk dat het vroegtijdig starten van begeleiding en het geven van voorlichting over het palliatieve traject de beslissingen ten aanzien van het levens einde kunnen vergemakkelijken en de kwaliteit van leven kunnen vergroten [Sizoo 2012³¹⁵, Walbert 2014³⁷²].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Cognitie, revalidatie en begeleiding bij gliomen

Deze module is onderverdeeld in de volgende submodules:

- Revalidatie en begeleiding
- Signaleren en behandeling cognitieve en emotionele gevolgen
- Voorlichting
- Rol verpleegkundige/verpleegkundig specialist

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Revalidatie en begeleiding bij gliomen

Uitgangsvraag

Welke vormen van revalidatie en begeleiding zijn effectief om cognitieve klachten, vermoeidheid en stemmingsstoornissen te voorkomen/verminderen bij patiënten met een glioom?

Aanbeveling

Overweeg om patiënten met een laaggradig en anaplastisch glioom een revalidatieprogramma aan te bieden, dat erop is gericht de cognitieve klachten en symptomen te verbeteren.

Onderbouwing

Conclusies

Voor patiënten met een laaggradig en anaplastisch glioom is er bewijs van lage kwaliteit dat direct na het volgen van een revalidatieprogramma de cognitieve klachten verminderen.

Gehring 2009¹⁰⁸

Voor patiënten met een laaggradig en anaplastisch glioom is er bewijs van lage kwaliteit dat zes maanden na het volgen van een revalidatieprogramma de aandacht, verbaal geheugen en vermoeidheid verbeteren.

Gehring 2009¹⁰⁸

Samenvatting literatuur

Ten aanzien van de beantwoording van bovenstaande uitgangsvraag zijn gerandomiseerde gecontroleerde trials (RCT's) of gecontroleerde klinische trials schaars. Een Cochrane review [Khan 2013¹⁷¹] vond op grond van 12 observationele studies 'very low level' evidentiële voor de effectiviteit van een multidisciplinair revalidatieprogramma op de verbetering van de functionele status en kwaliteit van leven van patiënten met primaire hersentumoren. Hoewel recent de effectiviteit van cognitieve revalidatie bij een heterogene groep patiënten (gliomen en meningeomen) met primaire hersentumoren binnen een RCT is aangetoond [Zucchella 2013⁴⁰⁹], evalueerde slechts één RCT de effecten van een revalidatieprogramma op het cognitief functioneren van gliompatiënten [Gehring 2009¹⁰⁸]. Binnen dit onderzoek werden 140 patiënten met een laaggradig of anaplastisch glioom gerandomiseerd in een cognitief revalidatieprogramma of een wachtlijstgroep. De interventie bestond uit een computertraining gericht op herstellen van cognitieve vaardigheden gecombineerd met een face-to-face training gericht op compensatoire vaardigheden voor beperkingen in aandachts-, geheugen- en executieve functies. De compensatietraining bestond uit zes sessies psycho-educatie, met zowel didactische als praktische elementen. Deelnemers kregen een neuropsychologisch onderzoek en vulden vragenlijsten in bij de start van de studie, na voltooiing van de interventie en na 6 maanden.

Direct na de interventie hadden de patiënten in de interventiegroep minder cognitieve klachten dan de patiënten in de controlegroep ($p = 0,001$), maar werd er geen verschil gevonden in cognitieve prestaties. Zes maanden na de interventie waren de aandachtsfuncties en het verbaal geheugen beter in de experimentele groep dan in de controlegroep (respectievelijk $p = 0,004$, $p = 0,009$), maar er werd geen verschil meer gevonden in cognitieve klachten. De interventie had geen significant effect op de kwaliteit van leven, wel

rapporteerden patiënten in de experimentele groep na zes maanden minder vermoeidheidsklachten ($p = 0,044$).

Kwaliteit van het bewijs

Het risico op bias is hoog. Er is vooral een hoog risico op bias door de (onvermijdelijke) afwezigheid van blinding van de patiënten, terwijl de uitkomsten van het vragenlijsonderzoek subjectief zijn. Er is ook geen vermelding van allocation concealment. Hierdoor zijn de effecten van de zelf-gerapporteerde uitkomstmaten weinig betrouwbaar.

Zoeken en selecteren

In de evidence tabellen vindt u de uitkomsten van het literatuuronderzoek voor de vraag: 'Welke vormen van revalidatie en begeleiding zijn effectief om cognitieve klachten, vermoeidheid en stemmingstoornissen te voorkomen/verminderen bij patiënten met een glioom?'

1. Welke diagnostische techniek (MRI, PET, CT perfusie, SPECT) is het beste in staat om bij patiënten met gliomen tumorprogressie en therapie-effect (radionecrose en pseudoprogressie) van elkaar te onderscheiden ten einde een optimale behandelingsstrategie te kunnen kiezen?

P: Patiënten met een glioom die zijn behandeld met radiotherapie waarbij sprake is van een groeiende aankleurende laesie bij wie de differentiaal diagnose tumorprogressie dan wel therapie-effect (radionecrose/pseudoprogressie) is

I: MRI (aankleuring), MRI anatomie, MRI perfusie, MRI diffusie, MRI spectroscopie, PET (MET en FET tracers), CT perfusie, SPECT

C: bevestiging tumorprogressie danwel therapie-effect met PA of klinische follow-up diagnose

O: tumorprogressie of therapie-effect (radionecrose/pseudoprogressie)

Search strategy

Searches were run on October 28, 2013 for systematic reviews and on November 19, 2013 for primary studies. OVID Medline, Embase and the Cochrane Library were searched using a search strings provided in the appendix. The search limits were:

- 2004-2013 for systematic reviews and 2009-2013 for primary studies;
- English and Dutch only;
- At least 30 patients included.

Search results

Systematic reviews

After merging the search files into 1 file and removal of the duplicates, 262 hits were screened on title and abstract. Of these, 245 were excluded. The most important reasons for exclusion were:

1. Other population: patients with other cancer types
2. Other intervention: interventions other than those specified
3. Wrong study design: narrative reviews, observational studies

4. Wrong language: N=32

Of the remaining 17 papers, the full-text was retrieved. Based on the full-text, an additional 12 studies were excluded. Exclusion Table 1 provides an overview of these excluded studies.

Exclusion Table 1. overview of excluded reviews based on full-text evaluation.

Author	Reference	Title	Reason
	Health Technology Assessment Database 2008 3):	PET for glioma and sarcoma (Project record)	No full-text, not published yet
Alexiou GA	J Neurooncol 2009 95(1):1-11	Glioma recurrence versus radiation necrosis: accuracy of current imaging modalities	Narrative review
Brandsma D	Curr Opin Neurol 2009 22(6):633-8	Pseudoprogression and pseudoresponse in the treatment of gliomas	Narrative review
Caroline I	J Clin Neurosci 2012 19(5):633-7	Imaging modalities in high-grade gliomas: pseudoprogression, recurrence, or necrosis?	No quality assessment
Chen W	Semin Nucl Med 2008 38(4):240-50	Advances in evaluation of primary brain tumors	Narrative review
IqwiG	Health Technology Assessment Database 2010 3):	Positron emission tomography (PET) in high-grade malignant glioma (grades III and IV) (Structured abstract)	German
Javier CJ	Health Technology Assessment Database 2008 3):	Perfusion MR Imaging in differentiating brain gliomas. Meta-analysis and economic assessment (Structured abstract)	Only executive summary
Mertens K	Eur J Nucl Med Mol Imaging 2010 37(11):2188-93	PET with (18)F-labelled choline-based tracers for tumour imaging: a review of the literature	Narrative review
Shah AH	Neurosurg 2011 31(6):E12	The management of incidental low-grade gliomas using magnetic resonance imaging: systematic review and optimal treatment paradigm	On management of glioma
Shah AH	J Neurooncol 2013 112(2):141-52	Discriminating radiation necrosis from tumor progression in gliomas: a systematic review what is the best imaging modality?	No quality assessment
Treglia G	Ann Nucl Med 2012 26(6):451-61	The role of positron emission tomography using carbon-11 and fluorine-18 choline in tumors other than prostate cancer: a systematic review	No quality assessment
van den Bent MJ	Lancet Oncol 2011 12(6):583-93	Response assessment in neuro-oncology (a report of the RANO group): assessment of outcome in trials of diffuse low-grade gliomas	Narrative review

Primary studies

After merging the search files into 1 file and removal of the duplicates, 2502 hits were screened on title and abstract. Of these, 2479 were excluded. The most important reasons for exclusion were:

1. Other population: patients with other cancer types
2. Other intervention: interventions other than those specified
3. Wrong study design: case reports, reviews, less than 30 patients
4. Wrong language: N=72

Of the remaining 23 papers, the full-text was retrieved. Based on the full-text, an additional 6 studies were excluded. Exclusion Table 2 provides an overview of these excluded studies.

Exclusion Table 2. overview of excluded primary studies based on full-text evaluation.

Author	Reference	Title	Reason
Agarwal A	J. Neuro-Oncol. 2013 112(3):413-420	Morphologic MRI features, diffusion tensor imaging and radiation dosimetric analysis to differentiate pseudo-progression from early tumor progression	Only MRI used as reference standard
Constantin A	Artif. Intell. Med. 2012 55(1):61-70	Identifying malignant transformations in recurrent low grade gliomas using high resolution magic angle spinning spectroscopy	Not on distinguishing progression from necrosis
Hu X	J. Magn. Reson. Imaging 2011 33(2):296-305	Support vector machine multiparametric MRI identification of pseudoprogression from tumor recurrence in patients with resected glioblastoma	Only MRI used as reference standard
Matsunaga S	Int. J. Radiat. Oncol. Biol. Phys. 2013 85(1):47-52	Semiquantitative analysis using thallium-201 SPECT for differential diagnosis between tumor recurrence and radiation necrosis after gamma knife surgery for malignant brain tumors	27 patients with glioma and 48 patients with brain metastases
Narang J	Neuro-Oncology 2011 13(9):1037-1046	Differentiating treatment-induced necrosis from recurrent/progressive brain tumor using nonmodel-based semiquantitative indices derived from dynamic contrast-enhanced T1-weighted MR perfusion	29 patients with treated gliomas and 8 patients with treatment-naïve gliomas
Xu JL	Chin. J. Med. Imaging Technol. 2010 26(4):639-642	Differentiation of postoperative recurrent glioma and radiation injury with two-dimensional proton MR spectroscopy	Chinese

2. *Wat is de beste behandelingsmethode bij een patiënt met een laaggradig glioom op beeldvorming in termen van kwaliteit van leven, symptom free survival, progression free survival, morbiditeit, mortaliteit en overall survival: resectie versus watchful waiting?*

P: patiënten met een laaggradig glioom op beeldvorming

I: resectie

C: watchful waiting

O: kwaliteit van leven, symptom free survival, progression free survival, morbiditeit, mortaliteit, overal survival

Search strategy

Searches were run on October 23, 2013.

OVID Medline, Embase and the Cochrane Library were searched using a search strings provided in the appendix. The search limits were:

- 2004-2013;
- English and Dutch only;
- At least 30 patients included.

Search results

After merging the search files into 1 file and removal of the duplicates, 1515 hits were screened on title and abstract. Of these, 245 were excluded. The most important reasons for exclusion were:

1. Other population: patients with other cancer types
2. Other intervention: interventions other than those specified
3. Wrong study design: narrative reviews, editorial, etc
4. Wrong language or publication date: N=101

Of the remaining 38 papers, the full-text was retrieved. Based on the full-text, an additional 31 studies were excluded. Exclusion Table 3 provides an overview of these excluded studies.

Exclusion table 3. overview of excluded papers based on full-text evaluation.

Author	Reference	Title	Reason
Abeloos L	Neurochirurgie 2007 53(4):277-283	Management of low-grade glioma: a retrospective study concerning 201 patients	No full-text
Creach KM	J Neurooncol 2012 106(2):377-82	Oligodendrogiomas in children	Biopsy not separately analysed
El-Hateer H	J Neurosurg 2009 111(2):265-71	Low-grade oligodendrogloma: an indolent but incurable disease? Clinical article	Biopsy not separately analysed
Fisher PG	Pediatr Blood Cancer 2008 51(2):245-50	Outcome analysis of childhood low-grade astrocytomas	Biopsy not separately analysed
Horowitz PM	Neurosurgery 2013 72(2):N19	Adult low-grade gliomas: surgery vs biopsy?	Editorial
Klomo P, Jr.	J Neurosurg Pediatrics 2013 Pediatrics.. 11(3):274-81	Management and outcome of focal low-grade brainstem tumors in pediatric patients: the St. Jude experience	Children with brainstem tumors
Li F	Chin. J. Clin. Oncol. 2009 36(1):5-8	Predictive factors for postoperative survival of glioma patients: A report of 56 cases	Chinese

Author	Reference	Title	Reason
Markert JM	JAMA 2012 308(18):1918-9	The role of early resection vs biopsy in the management of low-grade gliomas	Editorial
Martino J	Neurocirugia 2012 23(3):104-111	WHO grade II gliomas: Review of the current management	Spanish
Park K-J	J Neurooncol 2011 103(3):523-32	Early or delayed radiosurgery for WHO grade II astrocytomas	Radiosurgery
Perkins SM	Int. J. Radiat. Oncol. Biol. Phys. 2011 80(4):1117-1121	Glioblastoma in children: A single-institution experience	Glioblastoma
Peters O	Pediatr. Blood Cancer 2004 43(3):250-256	Impact of location on outcome in children with low-grade oligodendrogloma	Biopsy not separately analysed
Potts MB	J Neurosurg 2012 116(2):365-72	Natural history and surgical management of incidentally discovered low-grade gliomas	Biopsy not separately analysed
Pouratian N	Nat. Clin. Pract. Neurol. 2007 3(11):628-639	Surgery Insight: The role of surgery in the management of low-grade gliomas	No quality appraisal of included studies
Rogne SG	Acta Neurol Scand 2009 120(5):288-94	Intracranial tumor surgery in patients >70 years of age: is clinical practice worthwhile or futile? [Erratum appears in Acta Neurol Scand. 2009 Dec;120(6):453]	82/87 had grade IV astrocytoma
Schomas DA	Neuro-oncol 2009 11(4):437-45	Intracranial low-grade gliomas in adults: 30-year experience with long-term follow-up at Mayo Clinic	Biopsy not separately analysed
Smith SF	J. Clin. Neurosci. 2005 12(8):915-920	What progress has been made in surgical management of patients with astrocytoma and oligodendrogloma in Australia over the last two decades?	No quantified results about comparison
Stummer W	Curr. Opin. Neurol. 2009 22(6):645-649	The importance of surgical resection in malignant glioma	Narrative review
Taylor M	Curr. Oncol. 2004 11(2):53-62	Evidence-based review of the role of surgery for malignant glioma	Malignant glioma
Tsitolakidis A	J Neurosurg 2010 112(5):1020-32	Biopsy versus resection in the management of malignant gliomas: a systematic review and meta-analysis	High-grade glioma
Ushio Y	Neurol Med Chir (Tokyo) 2005 45(9):454-60; discussion 460-1	Effect of surgical removal on survival and quality of life in patients with supratentorial glioblastoma	Glioblastoma

Author	Reference	Title	Reason
Uzuka T	Neurol. Med.-Chir. 2012 52(8):570-576	Effectiveness of maximal safe resection for glioblastoma including elderly and low Karnofsky performance status patients: Retrospective review at a single institute	Glioblastoma
Youland RS	Am. J. Clin. Oncol. Cancer Clin. Trials 2012	Adult low-grade glioma: 19-year experience at a single institution	Biopsy not separately analysed
Compton JJ	J. Neurosurg. 2012 117(5):825-830	Long-term outcomes for low-grade intracranial ganglioglioma: 30-Year experience from the Mayo Clinic	Biopsy not separately analysed
Lebrun C	Neurology 2004 62(10):1783-7	Long-term outcome of oligodendrogiomas	No quantified results about comparison
Martinez R	Zentralbl. Neurochir. 2007 68(4):176-181	Gross-total resection of malignant gliomas in elderly patients: Implications in survival	Malignant glioma
Pontes LDB	J. Geriatr. Oncol. 2013 4(4):388-393	Patterns of care and outcomes in elderly patients with glioblastoma in Sao Paulo, Brazil: A retrospective study	Glioblastoma
Robinson CG	Int J Radiat Oncol Biol Phys 2005 63(1):91-100	Long-term survival and functional status of patients with low-grade astrocytoma of spinal cord	Some pts in WW group received radiotherapy
Tait MJ	Br. J. Neurosurg. 2007 21(5):496-500	Survival of patients with glioblastoma multiforme has not improved between 1993 and 2004: Analysis of 625 cases	Glioblastoma
Walker DA	Neuro-oncol 2013 15(4):462-8	A multi-disciplinary consensus statement concerning surgical approaches to low-grade, high-grade astrocytomas and diffuse intrinsic pontine gliomas in childhood (CPN Paris 2011) using the Delphi method	No methodological information
Yamini B	Expert Rev. Neurother. 2005 5(6 SUPPL.):S13-S19	Surgery for low-grade gliomas: Current evidence and controversies	Narrative review

3. Welke vormen van revalidatie en begeleiding zijn effectief om cognitieve klachten, vermoeidheid en stemmingsstoornissen te voorkomen/verminderen bij patiënten met een glioom?

P: patiënten met een glioom die zijn/worden behandeld, met neurochirurgie, radiotherapie e/o chemotherapie

I: revalidatie, (neuro)psychologische begeleiding, zijdende (inspanningstherapie, progressieve spierkracht training, cognitieve gedragstherapie, problem solving therapie, cognitieve revalidatie)

C: geen revalidatie en (neuro)psychologische begeleiding

O: kwaliteit van leven, (neuro)psychologisch functioneren (cognitief, emotioneel (angst-depressie), vermoeidheid)

Search strategy

PubMed, Embase, PsychInfo en CINAHL were searched. The search strategies can be found in the appendix. Articles published before 2009 and not written in English or Dutch were excluded.

Search results

The PubMed search yielded 209 hits (9-1'14), the Embase search 143 hits (24-1'14), the PsychInfo search yielded 57 hits (23-1'14) and the CINAHL search yielded 18 hits (27-1'14).

Studies were selected if a comparison was made between a control group and an intervention group receiving care to reduce cognitive and emotional functioning and fatigue.

Studies were not selected in case a pharmacological intervention was investigated.

After merging all search files into 1 file (410) and removal of the duplicates, 387 hits were screened on title and abstract. Of these, 375 were excluded. The most important reasons for exclusion were:

- Studies were not on patient with gliomas
- Studies did not make a comparison between interventions

Of the remaining 12 studies the full-text was retrieved. Based on the full-text, an additional 11 studies were excluded. ExclusionTable 4 provides an overview the reason of exclusion of studies.

Exclusion Table 4. overview of excluded studies based on full-text evaluation.

Referentie	Reden exclusie
Ford, E., Catt, S., Chalmers, A., & Fallowfield, L. (2012). Systematic review of supportive care needs in patients with primary malignant brain tumors. <i>Neuro-Oncology, 14</i> (4), 392-404.	No comparison between intervention
Gehring, K., Aaronson, N. K., Gundy, C. M., Taphoorn, M. J. B., & Sitskoorn, M. M. (Mar 2011). Predictors of neuropsychological improvement following cognitive rehabilitation in patients with gliomas. <i>Journal of the International Neuropsychological Society, 17</i> (2), 256-266.	No comparison between intervention
Gehrke, A. K., Baisley, M. C., Sonck, A. L. B., Wronski, S. L., & Feuerstein, M. (2013). Neurocognitive deficits following primary brain tumor treatment: Systematic review of a decade of comparative studies. <i>Journal of Neuro-Oncology, 115</i> (2), 135-142.	No comparison between intervention
Henriksson, R., Asklund, T., & Poulsen, H. S. (2011). Impact of therapy on quality of life, neurocognitive function and their correlates in glioblastoma multiforme: A review. <i>Journal of Neuro-Oncology, 104</i> (3), 639-646.	No comparison between intervention
Keilani, M., Krall, C., Marosi, C., Flechl, B., Dieckmann, K., Widhalm, G., et al. (2012). Strength of skeletal muscle and self-reported physical performance in austrian glioblastoma-patients. <i>Wiener Klinische Wochenschrift, 124</i> (11-12), 377-383.	No comparison between intervention
Physical function and fatigue outcomes in patients with high-grade glioma undergoing concurrent chemo-radiation and outpatient physical therapy: A pilot study.(2012). <i>Rehabilitation Oncology, 30</i> (1), 25-25.	No comparison between intervention
Boele, F. W., Hoeben, W., Hilverda, K., Lenting, J., Calis, A. --, Sizoo, E. M., et al. (2013). Enhancing quality of life and mastery of informal caregivers of high-grade glioma patients: A randomized controlled trial. <i>Journal of Neuro-Oncology, 111</i> (3), 303-311.	Effect on informal caregivers

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Signalering en behandeling cognitieve en emotionele gevolgen na glioom

Uitgangsvraag

Op welke wijze dienen de cognitieve en emotionele gevolgen van de tumor en/of behandeling te worden gesignaliseerd en behandeld?

Aanbeveling

- Alle gliompatiënten en directe naasten dienen standaard en structureel gescreend te worden op lichamelijke, cognitieve, emotionele en gedragsmatige beperkingen.
- Alle gliompatiënten en directe naasten dienen standaard en structureel gescreend te worden op de behoefte aan psychosociale zorg en zo nodig worden doorverwezen.
- De werkgroep adviseert om bij het in kaart brengen van de gevolgen van de tumor en/of behandeling gebruik te maken van de Signaleringslijst Volwassenen met Niet-Aangeboren Hersenletsel en de Richtlijn Detecteren behoefte psychosociale zorg.
- De werkgroep adviseert om voor het maken van een eerste inschatting van de belasting van de mantelzorger de screeningsvragenlijst 'Ervaren druk door informele zorg' (EDIZ) te gebruiken die is opgenomen in de richtlijn mantelzorg op <http://www.oncoline.nl/>. De werkgroep is van mening dat verwijzen naar een revalidatiearts, psycholoog of klinisch neuropsycholoog zinvol is voor gliompatiënten die hinder ervaren van fysieke en/of cognitieve en emotionele veranderingen waardoor zij beperkt worden in hun dagelijks leven of bij hun maatschappelijke participatie. Voor de behandeling wordt verwezen naar de volgende richtlijnen:
 - Richtlijn Neuropsychiatrische gevolgen van niet-aangeboren hersenletsel
 - Richtlijn Niet-aangeboren Hersenletsel en arbeidsparticipatie
- Er wordt geadviseerd bij de behandeling van vermoeidheidsklachten non-farmacologische interventies toe te passen, zoals deze onder meer beschreven staan in de Richtlijn Vermoeidheid bij kanker.
- Er wordt geadviseerd om bij de behandeling van angststoornissen en depressie gebruik te maken van de multidisciplinaire evidence-based GGZ-richtlijnen voor de diagnostiek en behandeling van patiënten met psychische stoornissen.
- Er wordt geadviseerd bij overbelasting van de informele zorgverleners van hooggradig gliompatiënten, psychologische interventies toe te passen die het mentaal functioneren en gevoelens van controle van informele zorgverleners stabiliseert of verbetert.

Onderbouwing

Conclusies

Cognitieve beperkingen

- Cognitieve revalidatieprogramma's ontwikkeld voor patiënten met niet-aangeboren hersenletsel, lijken ook bruikbaar voor gliompatiënten [Cicerone 2011].
- De werkgroep is van mening dat instrumenten ontwikkeld om veranderingen in emotie, cognitie en gedrag in kaart te brengen bij patiënten met niet-aangeboren hersenletsel, mogelijk ook bruikbaar zijn bij gliompatiënten.
- De werkgroep is van mening dat de verschillende digitaal beschikbare evidence-based

behandelprotocollen voor cognitieve stoornissen bij patiënten met niet-aangeboren hersenletsel, zinvol kunnen zijn voor gliompatiënten.

Cognitieve klachten

- Er is vaak een beperkte samenhang tussen cognitieve klachten en cognitieve beperkingen zoals deze gevonden worden in het neuropsychologisch onderzoek [Aaronson 2011, Boele 2014, Klein 2011].
- Klachten over vermoeidheid en klachten van depressieve aard kunnen cognitieve klachten versterken [Cull 1996].
- De werkgroep is van mening dat instrumenten ontwikkeld om bovengenoemde klachten in kaart te brengen bij patiënten met niet-aangeboren hersenletsel bruikbaar zijn bij gliompatiënten.

Vermoeidheid

- Vermoeidheid is één van de meest voorkomende en meest ingrijpende symptomen bij gliompatiënten [Lovely 1999].
- Farmacologische behandeling van vermoeidheid met modafinil is niet effectiever dan een placebo [Boele 2013²³].

Stemmingsstoornissen

- Van alle oncologische patiënten hebben patiënten met een glioom de grootste kans op psychiatrische symptomen [Rooney 2011²⁸²].
- Er is vaak sprake van een multifactorieel beeld, waarbij bij één patiënt sprake is van zowel depressie als van vermoeidheid en cognitieve beperkingen [Taphoorn 2004³⁴¹].
- De werkgroep is van mening dat verschillende digitaal beschikbare evidence-based behandelprotocollen voor patiënten met psychische stoornissen zinvol kunnen zijn voor gliompatiënten.

Partners

- De begeleiding van en zorg voor gliompatiënten heeft, in vergelijking met de begeleiding van en zorg voor andere kankerpatiënten, door de veranderingen van gedrag en cognitie een grotere invloed op het welbevinden van een informele zorgverlener [Boele 2013²³, Schubart 2008³⁰³].
- Er zijn aanwijzingen dat psychologische interventies het mentaal functioneren en de gevoelens van controle van informele zorgverleners van patiënten met hooggradig gliomen stabiliseren of verbeteren [Boele 2013²³].

Samenvatting literatuur

Cognitieve beperkingen

Gliompatiënten worden geconfronteerd met serieuze bedreigingen voor hun kwaliteit van leven [Liu 2009²⁰³]. De draaglast is hoog en het gevoel van onvermogen is aanzienlijk, vooral bij patiënten met hooggradige gliomen of bij een recidief van de tumor.

Ongeveer 80% van de gliompatiënten heeft cognitieve beperkingen [Giordana 2006¹¹¹]. Deze beperkingen kunnen veroorzaakt worden door de tumor zelf of samenhangen met de medische behandeling, waaronder

radiotherapie, chirurgie, en anti-epileptica [Taphoorn 2004³⁴¹]. De cognitieve beperkingen kunnen veroorzaakt worden door corticale laesies, maar kunnen door de vele corticaal-subcorticale verbindingen ook de oorzaak zijn van subcorticale schade of schade aan cerebellaire structuren. Patiënten met een tumor in de dominante (linker) hemisfeer, hebben vaak meer in het oog springende cognitieve stoornissen dan patiënten met een tumor in de niet-dominante hemisfeer.

Beperkingen komen voor in verschillende cognitieve domeinen, maar voornamelijk in de aandachts- en concentratiefuncties, het geheugen en de executieve functies [Taphoorn 2004³⁴¹]. Hoewel deze beperkingen relatief mild kunnen zijn, kunnen cognitieve beperkingen wel interfereren met het dagelijks leven, zoals werk, sociale- en gezinssituaties.

Relevant voor de screening van gliompatiënten is de [Signaleringslijst Volwassenen met Niet-Aangeboren Hersenletsel](#). Aan de hand van deze vragenlijst, die is ontwikkeld voor patiënten met cerebrale schade die niet veroorzaakt is door hersentumoren, kunnen veranderingen in emotie, cognitie en gedrag in kaart worden gebracht. Deze signaleringslijst kan ook gebruikt worden ter signalering van dergelijke veranderingen bij gliompatiënten. Een geschikt moment voor afname ligt in de subacute fase binnen drie maanden na de diagnose en/of behandeling. Een aanvullend neuropsychologisch onderzoek is zinvol, indien sprake is van een onduidelijk beeld of om onderscheid te maken tussen een depressie en cognitieve problematiek.

Voor wat betreft cognitieve revalidatiemogelijkheden, lijken programma's, die overwegend zijn ontwikkeld voor patiënten met traumatisch hersenletsel en cerebrovasculaire schade, ook bruikbaar te zijn voor neuro-oncologische patiënten [Formica 2011¹⁰²]. Ten aanzien van de mogelijkheden om cognitieve beperkingen te behandelen is het onderzoek van het door [ZonMw](#) gefinancierde consortium Cognitieve Revalidatie relevant. Dit consortium heeft in een aantal onderzoeksprojecten behandelingen van cognitieve stoornissen op effectiviteit geëvalueerd en dit heeft geresulteerd in de [Richtlijn Cognitieve revalidatie bij Niet-Aangeboren Hersenletsel](#). De richtlijnen, ontwikkeld voor verschillende cognitieve stoornissen en gebaseerd zijn op de resultaten van onderzoek van dit consortium, zijn vooral toepasbaar in de settings die hebben deelgenomen aan de effectevaluaties (dit zijn revalidatieafdelingen, zowel binnen de revalidatiecentra als binnen het verpleeghuis en het ziekenhuis). Echter, ook andere settings waar patiënten met niet-aangeboren hersenletsel behandeld worden, kunnen baat hebben bij deze richtlijnen. Verschillende [evidence-based behandelprotocollen](#) zijn digitaal beschikbaar en kunnen worden gedownload. Hierbij is het nadrukkelijk van belang dat de deskundigheid van de zorgverlener van dien aard moet zijn, dat toepassing van de richtlijnen en gebruik van de protocollen verantwoord kan gebeuren.

Cognitieve klachten

De cognitieve klachten die patiënten rapporteren komen vaak niet overeen met de resultaten van het neuropsychologische onderzoek [Janda 2007¹⁵³]. Patiënten met een depressieve stemming kunnen hun cognitieve mogelijkheden onderschatten en de cognitieve klachten die zij uiten zijn vaak een weergave van angstige of depressieve gevoelens of worden veroorzaakt door vermoeidheidsklachten in plaats van cognitieve beperkingen [Hermelink 2010¹³⁴, Taphoorn 2004³⁴¹]. Het hebben van vermoeidheidsklachten en/of een depressie kunnen cognitieve klachten dus versterken.

Om te kunnen beoordelen of verwijzing naar een revalidatiearts, psycholoog of klinisch neuropsycholoog zinvol is voor een individuele patiënt, is het van belang dat de gevolgen van het glioom en/of de behandeling goed in kaart worden gebracht.

In aanvulling op de [Signaleringslijst Volwassenen met Niet-Aangeboren Hersenletsel](#) dienen volgens de [Kwaliteitscriteria neuro-oncologie](#), patiënten standaard gescreend te worden op de behoefte aan

psychosociale zorg en zo nodig te worden doorverwezen. Screening vindt op meerdere ziekte- of behandelingsrelevante momenten in het zorgproces bij voorkeur plaats met de Lastmeter. De patiënt wordt geïnformeerd over de mogelijkheid voor psychosociale ondersteuning in het ziekenhuis of in de eigen omgeving van de patiënt en deze wordt op indicatie en in overleg doorverwezen naar gespecialiseerde aanbieders van psychosociale zorg. De follow-up frequentie wordt bepaald in overleg en op indicatie en is bekend bij patiënt en naasten. De werkwijze en frequentie van de follow-up staan beschreven in het dossier. Bij het inschatten van de aard van de eventuele doorverwijzing kunnen onderstaande richtlijnen met betrekking tot neuropsychiatrische symptomen en gevolgen van hersenletsel voor de arbeidsparticipatie, die verschenen zijn voor patiënten met hersenletsel, ook voor gliompatiënten bruikbaar zijn.

Richtlijn Neuropsychiatrische gevolgen van niet-aangeboren hersenletsel, CBO en Nederlandse Vereniging voor Revalidatieartsen, 2007.

Richtlijn Niet-aangeboren Hersenletsel en arbeidsparticipatie, CBO 2012.

Vermoeidheid

Vermoeidheid is één van de meest voorkomende en meest ingrijpende symptomen bij gliompatiënten [Lovely 1999]. Het is het symptoom met de grootste invloed op de kwaliteit van leven en het dagelijks functioneren van patiënten en hun naasten [Wefel 2008]. Uit resultaten van een kleine studie bleek dat van alle geteste variabelen vermoedheid de sterkste relatie had met kwaliteit van leven bij patiënten met een laaggradig glioom [Gustafsson 2006¹²⁰]. De meest gerapporteerde klachten zijn overmatige slaperigheid, lethargie, concentratieproblemen en onhandigheid [Pelletier 2002²⁵³]. Bij 80% van de gliompatiënten die behandeld worden met radiotherapie is er sprake van vermoedheid. Vermoeidheid blijkt echter ook na behandeling, waarbij geen radiotherapie is gebruikt, te blijven bestaan, naar schatting bij 40% van de gliompatiënten [Struik 2008].

De behandeling van vermoedheid bij gliomen is moeilijk, omdat er nog weinig bekend is over de pathofysiologie en er vaak meerdere factoren tegelijkertijd een rol spelen. De enige dubbelblinde RCT waarbinnen onderzocht werd of een farmacologische behandeling met modafinil beter was dan placebo in de behandeling van vermoedheid, cognitief functioneren en kwaliteit van leven liet zien dat modafinil niet effectiever was dan placebo [Boele 2013²²]. Een wegens moeizame inclusie voortijdig beëindigde open-label RCT [Gehring 2012¹⁰⁷] vond naast inconsistent effecten van methylfenidaat en modafinil op cognitie enige gunstige effecten op zelf-gerapporteerde vermoedheid, stemming en kwaliteit van leven. Voor wat betreft de zelf-gerapporteerde uitkomsten waren er geen verschillen in de tijd tussen de condities.

Gezien het ontbreken van consistent effecten en de beperkte bereidheid van patiënten om medicatie te gebruiken voor vermoedheidsklachten dienen non-farmacologische interventies overwogen te worden.

Binnen de oncologische zorg is de Richtlijn Vermoeidheid bij kanker verschenen. Hierin wordt ook aandacht besteed aan non-farmacologische interventies gericht op onder meer het helpen vinden van een balans tussen inspanning en rust, het aanbieden van fysieke trainingsprogramma's, ontspanningstherapie en psychosociale ondersteuning.

Stemmingsstoornissen

Neuropsychiatrische problemen kunnen ontstaan door het ziekteproces zelf en door de behandeling van neurologische symptomen; zo kan het gebruik van hoge doses corticosteroïden resulteren in restverschijnselen zoals een labiel affect of gedragsveranderingen [Pelletier 2002²⁵³]. De primaire symptomen

van een depressie zijn bij gliompatiënten moeilijk te onderscheiden van de gevolgen van de tumor of de medische behandeling [Rooney 2011²⁸²]. Daadwerkelijke klinische depressie komt echter regelmatig voor wanneer de gezondheidstoestand vermindert. Van alle kankerpatiënten hebben patiënten met een glioom de grootste kans op psychiatrische symptomen, waarbij de prevalentie van depressie bij gliompatiënten wordt geschat op 6-28% [Rooney 2011²⁸²]. De negatieve gemoedstoestand is geassocieerd met de neurologische uitval en wordt versterkt door comorbid psychosociale problemen zoals reactieve depressie, verlies van werk, financiële problemen en echtelijke conflicten [Pelletier 2002²⁵³].

Cognitieve beperkingen en vermoeidheidsklachten kunnen het beroepsmatig- en sociaal functioneren verder beperken en leiden tot gevoelens van frustratie en controleverlies, die een voedingsbodem zijn voor depressieve klachten [Sohlberg 2001]. Een groot deel van de patiënten spreekt hierover niet met zijn of haar behandelend arts, omdat ze deze te druk of onvoldoende toegerust achten om hierin begeleiding te bieden [Wefel 2011³⁷⁶].

Het cognitief functioneren is gecorreleerd met toenemende vermoeidheid en depressie [Liu 2009²⁰³]. Er is dan ook vaak sprake van een multifactorieel beeld, waarbij bij één patiënt sprake is van zowel depressie als van vermoeidheid en cognitieve beperkingen. Bij onderzoek naar specifieke symptoomclusters bij gliompatiënten vormen depressie, vermoeidheid, verstoring van de slaap en cognitieve beperkingen een cluster dat 29% van de variantie van kwaliteit van leven verklaart. Daarnaast vormen depressie, vermoeidheid, verstoring van slaap, cognitieve beperkingen en pijn een cluster dat 62% van de functionele status van de patiënt verklaart [Liu 2009²⁰³].

Bij de behandeling van angststoornissen en depressie kan gebruik worden gemaakt van de multidisciplinaire evidence-based richtlijnen voor de diagnostiek en behandeling van patiënten met psychische stoornissen. Deze richtlijnen zijn ontwikkeld onder auspiciën van de Landelijke Stuurgroep Multidisciplinaire Richtlijnontwikkeling in de GGZ en/of het Trimbos-instituut.

Partners

Net als bij andere ziektes heeft de diagnose van een glioom grote impact op het leven van de patiënt [Gupta 2011¹¹⁹]. Aangezien gliompatiënten naast fysieke symptomen ook worden geconfronteerd met veranderingen in cognitie, stemming en persoonlijkheid hebben zij meer ondersteuning nodig van hun omgeving dan patiënten met een tumor waarbij de hersenen niet zijn betrokken. Inherent aan de problematiek van gliompatiënten is de mogelijkheid dat door de ernst van de cognitieve stoornissen niet de patiënt degene is die de hulpvraag uit, maar zijn omgeving. In de meeste gevallen is de partner de primaire informele zorgverlener [Boele 2013²³]. Het verzorgen van een gliompatiënt heeft, in vergelijking met de verzorging van andere kankerpatiënten, door de veranderingen van gedrag en cognitie een grotere invloed op het welbevinden van een informele zorgverlener [Boele 2013²³, Schubart 2008³⁰³].

Patiënten en hun zorgverleners worden geconfronteerd met de taak de diagnose en behandeling te begrijpen en veranderingen bij de patiënt te identificeren en hiermee om te leren gaan [Gupta 2011¹¹⁹]. Sommige patiënten zullen na behandeling al snel compleet hersteld zijn; er is echter een groot deel van de patiënten dat steun en zorg nodig heeft in de jaren die daarop volgen [Janda 2007¹⁵³]. Deze zorg wordt over het algemeen gegeven door partners en naaste familie. De stress die met de verzorging gepaard gaat, is aanzienlijk en heeft een significant negatieve invloed op het welzijn van de informele zorgverlener zelf [Janda 2007¹⁵³]. Bij 10% van de informele zorgverleners is sprake van een depressieve stemming [Janda 2006¹⁵²] en met name informele zorgverleners van hooggradig gliompatiënten lijken in de acute fase van de ziekte het meeste risico te lopen [Boele 2013²³]. Daarnaast is er sowieso sprake van toenemende symptomen van angst,

psychosomatische problemen, beperkingen van activiteiten, huwelijksproblemen en slechtere fysieke gezondheid bij informele zorgverleners van kankerpatiënten [Weitzner 1999³⁷⁷. Een recente RCT [Boele 2013²³] laat zien dat psychologische interventies het mentaal functioneren en gevoelens van controle van informele zorgverleners van patiënten met hooggradig gliomen kan stabiliseren of verbeteren. Voor het maken van een eerste inschatting van de belasting van de mantelzorger is de screeningsvragenlijst 'Ervaren druk door informele zorg' (EDIZ) ontwikkeld die is opgenomen in de [richtlijn mantelzorg](#) op www.oncoline.nl/.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Voorlichting bij gliomen

Uitgangsvraag

Welke voorlichting dienen de patiënt met gliomen en zijn naasten/omgeving (inclusief huisarts) te ontvangen?

Aanbeveling

De werkgroep is van mening dat de Kwaliteitscriteria neuro-oncologie gevolgd dienen te worden:

- De patiënt ontvangt de PA-diagnose van de hoofdbehandelaar volgens de richtlijn slechtnieuwsgesprek.
- Door de hoofdbehandelaar en/of verpleegkundige/verpleegkundig specialist neuro-oncologie wordt uitleg gegeven over: de ziekte/behandeling, de mogelijke gevolgen hiervan op cognitief, lichamelijk en sociaal gebied en de laatste levensfase.
- In de dialoog tussen hulpverlener en patiënt moeten alle facetten van de mogelijke behandelingsopties, zoals de te verwachten uitkomsten en lasten voor de patiënt, aan de orde komen. Daarnaast is het raadzaam dat de hulpverlener zich op de hoogte stelt van de angsten, visie en prioriteiten van de patiënt.
- De huisarts is op de hoogte van de diagnose en het behandelplan.
- De hoofdbehandelaar draagt zorg voor een schriftelijk overdracht naar de huisarts in alle fasen van het behandelproces. Indien er geen behandeling (meer) aan de patiënt gegeven kan worden en de zorg overgaat op het bestrijden van symptomen in de laatste levensfase, draagt de hoofdbehandelaar de zorg over aan de huisarts.
- Met patiënten worden eventuele alternatieve therapieën besproken. Zorgverleners dienen hier specifiek naar te vragen.
- Mondelinge voorlichting wordt ondersteund door schriftelijk of online voorlichtingsmateriaal (bijvoorbeeld van <http://hersentumor.nl/>).

Overwegingen

Er is geen literatuur beschikbaar van waaruit een uitspraak gedaan kan worden over specifieke behoeften van patiënten met een kwaadaardige hersentumor ten aanzien van communicatie, informatie en begeleiding. De literatuur die vorhanden is niet van recente data. De studies zijn vooral in de Verenigde Staten en Engeland verricht. De laatste tien jaar is er in de Nederlandse ziekenhuizen veel veranderd aan de zorg voor patiënten met hersentumoren. Vrijwel alle academische ziekenhuis en de grote perifere ziekenhuizen in Nederland waar neuro-oncologie een aandachtsgebied is, hebben een gespecialiseerd verpleegkundige/verpleegkundig specialist binnen de keten, die op basis van specifieke deskundigheid betrokken is bij de zorg voor deze complexe patiëntengroep. Daarnaast vervult de verpleegkundige de functie van casemanager en is zij mede verantwoordelijk voor de juiste logistiek in het gehele ziekteproces van de patiënt.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat patiënten vooral behoefte hebben aan gesprekken met arts en gespecialiseerd verpleegkundige waarin aandacht is voor de individuele patiënt en van diens naasten.

Davies 2002⁷¹, Madsen 2011²⁰⁷

Er zijn aanwijzingen dat patiënten behoefte hebben aan zorg op maat, aangepast aan zijn of haar copingstijl.
Davies 1997⁷²

Er zijn aanwijzingen dat naasten van patiënten de zorg voor hun zieke partner met een hersentumor als bijzonder zwaar ervaren. De gedragsverandering die met de ziekte gepaard gaat is hierbij van grote invloed.
Salander 1996²⁸⁹

Er zijn aanwijzingen dat patiënten en naastenbehoefte hebben aan begeleiding in het ziekenhuis van artsen en verpleegkundigen. Tevens zoeken ze steun bij lotgenoten.

Horowitz 1996¹⁴²

Samenvatting literatuur

Het doel van het geven van voorlichting is het informeren van de patiënt en zijn naasten over de diagnose en de gevolgen die dit heeft op het dagelijks leven van zowel de patiënt als zijn omgeving. Deze voorlichting moet opzettelijk en doelbewust gegeven worden. De kennis kan de patiënt en naasten helpen om zelfstandig en bewust, zoveel mogelijk overeenkomstig zijn eigen belang en welzijn, beslissingen te nemen [Van den Ban 1985⁷]. Er is beperkte literatuur beschikbaar waaruit een uitspraak gedaan kan worden over specifieke behoeften van patiënten met een kwaadaardige hersentumor ten aanzien van communicatie, informatie en begeleiding. De beschikbare data zijn verkregen uit observationele studies met kleine aantallen patiënten met een hersentumor. Veelal zijn het ook patiënten met de meest maligne hersentumoren. Deze vooral kwalitatieve studies dateren van (ver) voor 2000 en zijn veelal uitgevoerd in de Verenigde Staten of Engeland. Een systematische review uit 2003 [Davies⁷¹] en uit 2011 [Madsen²⁰⁷] bevat aanwijzingen dat patiënten vooral behoeftte hebben aan gesprekken met een arts en een gespecialiseerd verpleegkundige waarin aandacht is voor de individuele patiënt en van diens naasten. De zorgverleners moeten de tijd nemen voor een zorgvuldig voorbereid gesprek. Patiënten vragen om informatie op maat, aangepast aan de eigen copingstijl [Davies 1997⁷²]. Ten aanzien van de diagnose benoemen patiënten dat de hoop ze niet ontnomen mag worden. Patiënten zijn zich ervan bewust dat de prognose somber is maar dat dit niet steeds benadrukt hoeft te worden. Patiënten zijn kritisch of het ziekenhuis deze ondersteuning wel kan bieden [Davies 1997⁷²].

Patiënten, maar vooral ook naasten, zoeken contact binnen lotgenotengroepen om ervaringen te delen en om te leren omgaan met de zielteklast en met veranderingen binnen het gezin [Leavitt 1996]. Vooral naasten ervaren de zorglast als erg zwaar. De mantelzorgers worden extra belast als de patiënt te maken krijgt met persoonlijkheidsveranderingen. Er ontstaat afstand tussen partners en het verdriet neemt toe [Salander 1996²⁸⁹]. In de lotgenotengroepen wordt door de naasten openlijk gesproken over het omgaan met gedragsveranderingen zonder dat de patiënt hierbij aanwezig is. Ze vinden hierbij duidelijk steun van de lotgenoten [Horowitz 1996¹⁴²].

Een inventarisatie onder patiënten in Nederland beschrijft dat, indien de diagnose hersentumor wordt gesteld, de behandelend arts met de patiënt het behandelplan bespreekt en de vervolgstappen in de behandeling en begeleiding. 'Shared decision making' is hierbij het uitgangspunt [Kwaliteitscriteria cerebraal 2011¹⁸⁹]. In het gehele zorgtraject geven patiënten aan dat ze niet zozeer behoeft te hebben aan standaard

routinecontroles, maar dat de behoefte groter is aan meer individueel gefocuste zorg. Qua medische behandeling heeft een groot deel van de patiënten voldoende aan advies van het multidisciplinaire behandelteam; maar een deel van de patiënten zoekt naar alternatieve genezingen [Verhoef 1999³⁶⁶]. Niet altijd wordt dit met de behandelend arts in het ziekenhuis besproken. Het is niet aangetoond welke wijze van informatie het meest ondersteunend is voor patiënten maar het is aannemelijk dat de spanning van, en tijdens een slechtnieuwsgesprek ertoe bijdraagt dat niet alle informatie wordt opgenomen(zie Richtlijn Handreiking slecht-nieuws gesprek). Het is daarom belangrijk dat de mondelinge informatie ondersteund wordt met schriftelijk informatie. Patiëntenfolders zijn hierbij belangrijk, maar uiteraard ook informatie op het internet, zoals op www.hersentumor.nl. Er is tevens uitgebreide informatie beschikbaar van de diverse ziekenhuizen, maar ook van patiëntenverenigingen. Hiermee kunnen patiënten worden geïnformeerd over de operatie, de bestraling of de behandeling met chemotherapie. Voor lotgenotencontact, informatie en belangenbehartiging kunnen patiënten terecht bij een patiëntenvereniging. Voor patiënten met hersentumoren is dat Vereniging Cerebraal, een patiëntenvereniging voor mensen die getroffen zijn door hersenletsel.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Rol verpleegkundige/verpleegkundig specialist bij gliomen

Uitgangsvraag

Wat is de rol van de verpleegkundige/verpleegkundig specialist bij de behandeling van patiënten met gliomen?

Aanbeveling

De werkgroep is van mening dat de kwaliteitscriteria neuro-oncologie gevolgd dienen te worden:

- Patiënten met een glioom weten wie de inhoudelijk eindverantwoordelijke (hoofdbehandelaar) is, wie het aanspreekpunt en wie de zorgcoördinator is, tijdens alle fasen van de ziekte (diagnose-, behandeltraject, follow-up en palliatieve/ terminale fase).
- Binnen het behandelteam is er een gespecialiseerd verpleegkundige/verpleegkundig specialist neuro-oncologie.
- De verpleegkundige/verpleegkundig specialist neuro-oncologie of de hoofdbehandelaar is het aanspreekpunt voor patiënten en zijn/haar naasten in alle fasen van de ziekte.
- De verpleegkundige/verpleegkundig specialist neuro-oncologie kan vragen van de patiënt over behandeling/ ziekte/problemen adequaat beantwoorden, hetzij op basis van eigen kennis, hetzij door de benodigde informatie bij anderen na te vragen.
- Patiënten ontvangen schriftelijk gegevens over bereikbaarheid van de verpleegkundige/verpleegkundig specialist neuro-oncologie.
- Patiënten weten bij wie ze terecht kunnen met (acute) problemen, binnen en buiten kantooruren.
- De verpleegkundige/verpleegkundig specialist neuro-oncologie heeft structureel een eigen spreekuur op de polikliniek, waar patiënten/naasten terecht kunnen voor advies/informatie aangaande hun ziekte.
- Follow-up frequentie indien medische behandeling afgesloten is, wordt bepaald in overleg met patiënt en naasten.

Overwegingen

In 2012 is het Beroepsprofiel voor de verpleegkundig specialist vastgesteld [Beroepsprofiel verpleegkundig specialist V&V 2020, 2012¹⁶]. Hierin staat nauwkeurig beschreven wat de functie inhoudt en waar de taken uit kunnen bestaan. De inhoud sluit goed aan bij de wensen van patiënten en hun naasten ten aanzien van de zorg en begeleiding in het zorg- en behandelproces. Kernprincipes zijn:

- De verpleegkundig specialist gaat eigen behandelrelaties aan binnen het aandachtsgebied waarin zij deskundig is.
- Vanuit de zorgvraag van de patiënt integreert de verpleegkundig specialist 'cure en care' met als doel de bevordering van de continuïteit en kwaliteit van de verpleegkundige zorg en de medische behandeling, het vermogen tot zelfmanagement van de patiënt en de kwaliteit van leven

Vrijwel alle academische ziekenhuizen en de grote perifere ziekenhuizen in Nederland waar neuro-oncologie een aandachtsgebied is, hebben een gespecialiseerd verpleegkundige/ verpleegkundig specialist binnen de keten die op basis van specifieke deskundigheid betrokken is bij de zorg voor deze complexe patiënten

groep. Daarnaast vervult de verpleegkundige de functie van casemanager en is zij mede verantwoordelijk voor de juiste logistiek in het gehele ziekteproces van de patiënt.

Onderbouwing

Conclusies

Er zijn aanwijzingen dat de gespecialiseerde verpleegkundige zorg een belangrijke rol heeft in de neuro-oncologische keten. De gespecialiseerde verpleegkundige richt zich in de zorg en begeleiding op de patiënt met een hersentumor maar ook op de naasten.

Laurant 2009¹⁹⁴, James 1994¹⁵¹, Leavitt 1996¹⁹⁸, Sardell 2001²⁹⁷, Davies 1996⁷⁰, Spetz 2005³²⁵, Clarke 2003⁶¹

Samenvatting literatuur

Voorlichting en begeleiding over de gevolgen van de ziekte en behandeling is bij uitstek het terrein van een gespecialiseerd verpleegkundige of verpleegkundig specialist met neuro-oncologie als aandachtsgebied. Voor patiënten is het niet noodzakelijk dat alleen de arts de rol van voorlichter op zich neemt. Mits duidelijk is wie welke rol vervuld is hier een grote ruimte voor een gespecialiseerd verpleegkundige [Laurant 2009¹⁹⁴].

Binnen de neuro-oncologie wordt de rol van een gespecialiseerd verpleegkundige aanbevolen [James 1994¹⁵¹, Leavitt 1996¹⁹⁸]. Een telefonisch spreekuur heeft zijn dienst al bewezen [Sardell 2001²⁹⁷].

Mantelzorgers maken ruim twee keer zoveel gebruik van telefonische zorg als patiënten zelf. De vragen betreffen vooral het opnieuw informatie verstrekken, vragen over symptomen van de ziekte, en emotionele ondersteuning [Curren 2001⁶⁶]. De beste de zorg lijkt echter een combinatie van medisch en (gespecialiseerde) verpleegkundige zorg [Davies 1996⁷⁰]. Patiënten en naasten beschrijven de rol van de verpleegkundige als een actief kameraadschap door het gehele ziekteproces. Belangrijke pijlers zijn bereikbaarheid, een proactieve rol, flexibele ondersteuning en professionaliteit en tevens een persoonlijke benadering [Spetz 2005³²⁵, Clarke 2003⁶¹].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Follow-up na gliomen

Deze module is onderverdeeld in de volgende submodules:

- Onderscheiden tumorprogressie en therapie-effect
- Radiologische follow-up tijdens behandeling
- Postoperatieve scan
- Radiologische follow-up na afronden behandeling

Verantwoording

Laatst beoordeeld : 15-04-2015

Laatst geautoriseerd : 15-04-2015

Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Onderscheiden tumorprogressie en therapie-effect bij gliomen

Uitgangsvraag

Welke diagnostische techniek (MRI, PET, CT perfusie, SPECT) is het beste in staat om bij patiënten met gliomen tumorprogressie en therapie-effect (pseudoprogressie danwel radionecrose) van elkaar te onderscheiden teneinde een optimale behandelingsstrategie te kunnen kiezen?

Aanbeveling

De werkgroep is van mening dat patiënten vervolgd dienen te worden met T1 MRI zonder en met contrast in drie richtingen, aangevuld met T2/FLAIR beeldvorming. Indien hiermee in de follow-up twijfel ontstaat over tumorprogressie of therapie-effect (pseudoprogressie dan wel radionecrose), kan worden overwogen de specificiteit voor het aantonen van tumorprogressie te verhogen middels aanvullende MRI-series (zoals perfusie-MRI-wegingen of spectroscopie), Tc-MIBI-, Thallium-, of GBA-SPECT en of C-MET-, F-DOPA-, of FET-PET. Het beloop in de tijd, beoordeeld middels normale follow-up of eventueel met een vervroegde controle-MRI-scan, kan ook waardevolle informatie verschaffen. Gezien het beperkt beschikbare bewijs, is zowel het vervolgen als de aanvullende diagnostiek een keuze die per patiënt gemaakt kan worden. Bij blijvende twijfel met name bij een symptomatische patiënt valt reoperatie te overwegen voor diagnostiek en eventueel symptoombestrijding.

Overwegingen

Bij een aanzienlijk deel (30-50%) van de patiënten die met radiotherapie, eventueel gecombineerd met chemotherapie, behandeld wordt voor een primaire hersentumor, zal vroeg of laat in het follow-up traject, op beeldvorming onzekerheid optreden of er sprake is van tumorprogressie of therapie-effect (pseudoprogressie dan wel radionecrose) [Taal 2008³³⁴, Brandes 2008²⁸, Fink 2011⁹⁷]. In de literatuur wordt de term pseudoprogressie meestal gereserveerd voor de initiële post-behandeling scans; de term radionecrose wordt vaak later in de follow-up gebruikt. Meestal zal deze twijfel ontstaan door toename in volume van de laesie, nieuwe en/of toegenomen aankleuring zichtbaar na toediening van contrast op de follow-up-MRI binnen het volume van de hersenen dat tot hoge dosis bestraald is. Het huidige literatuuronderzoek laat zien dat een eerste post-behandeling-MRI vaak niet conclusieve beelden laat zien met aankleuring die meer oorzaken kan hebben (sensitiviteit hoog, specificiteit laag). In de praktijk wordt de eerste MRI na behandeling dan ook gebruikt als een uitgangsscan, en wordt een al dan niet versnelde opvolgende MRI scan gebruikt om meer duidelijkheid te verkrijgen. Bij blijvende twijfel staat een scala aan aanvullende technieken, zoals aanvullende MRI-technieken (perfusie, spectroscopie), PET (C-MET-PET, F-DOPA-PET, FET-PET) en SPECT (Tc-MIBI, TI, GBA-SPECT) ter beschikking. Gezien echter de matige kwaliteit van de beschikbare literatuur en de overlap in specificiteit van de verschillende methodes kan geen voorkeur uitgesproken worden voor een daarvan. Een belangrijke overweging in de keuze voor aanvullende beeldvorming is de ervaring met een van deze specifieke onderzoeken binnen het centrum. Ook bij deze aanvullende onderzoeken zal echter enige onzekerheid blijven bestaan over de aard van de progressieve afwijkingen. Men moet zich realiseren dat de kans op pseudoprogressie het grootste is in de eerste drie maanden na de bestraling en afname in de tijd nadien, past derhalve bij pseudoprogressie. Indien twijfel blijft bestaan kan, met name in geval van klinische verschijnselen van de aankleurende laesie, besloten worden tot reoperatie voor een definitieve diagnose en

tevens symptoombestrijding. De a-priori kans op pseudoprogressie/radionecrose, die het grootste is in de eerste drie maanden na de bestraling of chemoradiatie en na hogere bestralingsdoses (>50 Gy), dient te worden meegenomen in deze overweging.

Onderbouwing

Conclusies

Het is aannemelijk dat contrast-enhanced-MR een sensitiviteit van 71-97% en een specificiteit van 24-90% heeft voor de detectie van tumorprogressie (versus radionecrose/pseudoprogressie).

Niveau 2: B Karunanthi 2013¹⁶⁴, Khangembam 2013¹⁷², Santra 2011b²⁹⁵, Santra 2012²⁹⁶, Ozsunar 2010²⁴², Barajas 2009⁸, Chung 2013⁵⁹, Fink 2012⁹⁷, Xu 2010³⁹⁴, Xu 2011³⁹⁵

Het is aannemelijk dat perfusie-MR een sensitiviteit van 88% en een specificiteit van 85% heeft.

Niveau 2: B Deng 2013⁷⁷

Het is aannemelijk dat MR-spectroscopie een sensitiviteit van 64-89% en een specificiteit van 82-89% heeft.

Niveau 2: : B Hollingworth 2006¹³⁹

Er zijn aanwijzingen dat perfusie-CT een sensitiviteit van 82% en een specificiteit van 82-90% heeft.

Niveau 3: B Jain 2011¹⁴⁸

Het is aannemelijk dat Tc-MIBI-SPECT een sensitiviteit van 90% en een specificiteit van 92% heeft.

Niveau 2: B Cheng 2011⁵⁶

Het is aannemelijk dat ²⁰¹Tl-SPECT een sensitiviteit van 40-100% en een specificiteit van 25-100% heeft.

Niveau 2: B Vos 2007³⁷⁰

Er zijn aanwijzingen dat SPECT/CT een sensitiviteit van 86% en een specificiteit van 63% heeft.

Niveau 3: B Karunanthi 2013a¹⁶⁴

Het is aannemelijk dat GHA-SPECT een sensitiviteit van 85-86% en een specificiteit van 97% heeft.

Niveau 2: B Santra 2011a/b^{294 295}

Het is aannemelijk dat C-MET-PET een sensitiviteit van 55-87% en een specificiteit van 70-100% heeft.

Niveau 2: : B Deng 2013⁷⁷, Nihashi 2013²²⁹

Het is aannemelijk dat FDG-PET een sensitiviteit van 77% en een specificiteit van 78% heeft op basis van een meta-analyse [Nihashi] en een sensitiviteit van 81% en een specificiteit van 90% op basis van een bijkomende oorspronkelijke studie [Ozsunar].

Niveau 2: B Nihashi 2013²²⁹, Ozsunar 2010²⁴²

Er zijn aanwijzingen dat FLT/FET-PET een sensitiviteit van 82-91% en een specificiteit van 88-100% heeft.

Niveau 3: B Jeong 2010¹⁵⁸

Het is aannemelijk dat F-DOPA-PET/CT een sensitiviteit van 100% en een specificiteit van 88-89% heeft.

Niveau 2: B Kanunanihi 2013a/b^{164 165}

Er zijn aanwijzingen dat N-ammonia-PET/CT een sensitiviteit van 83% en een specificiteit van 86% heeft.

Niveau 3: B Khangembam 2013¹⁷²

Er zijn aanwijzingen dat C-MET PET/CT een sensitiviteit van 96% en een specificiteit van 88% heeft.

Niveau 3: B Li 2012²⁰²

Het is aannemelijk dat FDG-PET/CT een sensitiviteit van 40-70% en een specificiteit van 97-100% heeft.

Niveau 2: B Li 2012²⁰², Santra 2011a²⁹⁴, Santra 2012²⁹⁶

Bovenstaande conclusies zijn in onderstaande tabel 1 schematisch weergegeven.

Tabel 1. Differentiëren tussen tumorprogressie en therapie-effect

Voor de diagnose van recurrence	Test	Sens (%)	Spec (%)	Studies
Het is aannemelijk dat de sensitiviteit en de specificiteit.... <u>(Niveau 2)</u>	Tc-MIBI-SPECT	90	92	Cheng 2011 ⁵⁶
	201TI-SPECT	40-100	25-100	Vos 2007 ³⁷⁰
	GHA-SPECT	85-86	97	Santra 2011a/b ^{294 295}
	C-MET PET/CT	55-96	70-100	Deng 2013 ⁷⁷ , Nihashi 2013 ²²⁹ , Li 2012 ²⁰²
	FDG PET/CT	40-81	78-100	Nihashi 2013 ²²⁹ , Ozsunar 2010 ²⁴² , Li 2012 ²⁰² , Santra 2011a ²⁹⁴ , Santra 2012 ²⁹⁶
	F-DOPA PET/CT	100	88-89	Kanunanihi 2013a/b ^{164 165}
	Contrast-enhanced MR	71-97	24-90	Karunanihi 2013 ¹⁶⁴ , Khangembam 2013 ¹⁷² , Santra 2011b ²⁹⁵ , Santra 2012 ²⁹⁶ , Ozsunar 2010 ²⁴² , Barajas 2009 ⁸ , Chung 2013 ⁵⁹ , Fink 2012 ⁹⁷ , Xu 2010/2011 ^{394 395}
	Perfusie MR	88	85	Deng 2013 ⁷⁷
Er zijn aanwijzingen dat dat de sensitiviteit en de specificiteit..... <u>(Niveau 3)</u>	MR spectroscopie	64-89	82-89	Hollingworth 2006 ¹³⁹
	SPECT/CT	86	63	Karunanihi 2013a ¹⁶⁴
	FLT/FET PET	82-91	88-100	Jeong 2010 ¹⁵⁸
	N-ammonia PET/CT	83	86	Khangembam 2013 ¹⁷²
	Perfusie CT	82	82-90	Jain 2011 ¹⁴⁸

Samenvatting literatuur

We selecteerden vijf systematische reviews, welke in totaal 62 studies includeerden. Bijkomend werden 17 artikelen (16 studies) geselecteerd. Van deze 16 studies is er nog mogelijke overlap tussen de twee studies van Karunanihi en tussen de drie studies van Santra. Het is om die reden onmogelijk het totaal aantal patiënten correct te berekenen, maar uitgaande van de gerapporteerde patiëntenaantallen werden in de oorspronkelijke studies maximaal 831 patiënten ingesloten (mediaan 40, minimum 30, maximum 93). In de volgende studies werden ook patiënten met graad I-gliomen opgenomen: [Karunanihi 2013a¹⁶⁴] (3,7% van de populatie), [Karunanihi 2013b¹⁶⁵] (6%), [Khangembam 2013¹⁷²] (1,9%), [Santra 2011a²⁹⁴] (9%), [Santra 2011b²⁹⁵] (4,8%), [Santra 2012²⁹⁶] (10%).

De studies die in de systematische reviews werden geïncludeerd en de bijkomende oorspronkelijke studies die door ons werden geïdentificeerd hadden allemaal belangrijke methodologische tekortkomingen. Slechts een studie kreeg een A2-niveau van evidence [Chung 2013⁵⁹], alle andere studies kregen een B. De belangrijkste redenen voor dit lage niveau van evidence zijn de kleine patiëntpopulaties en het gebruik van

meerdere referentiestandaarden waarbij in vele gevallen ook de indextest werd gebruikt als referentiestandaard tijdens follow-up (incorporation bias).

MRI (Magnetic Resonance Imaging)

De sensitiviteit van contrast-enhanced-MRI was 92,3-96,7% en de specificiteit 24,1-48,3% in vier studies [Karunanithi 2013b¹⁶⁵, Khangembam 2013¹⁷², Santra 2011b²⁹⁵ en Santra 2012²⁹⁶]. In de studies van Khangembam en Santra werd de accuratesse ook berekend voor subgroepen naar gliomtype. Er werden geen duidelijke verschillen teruggevonden op basis van de 95%-betrouwbaarheidsintervallen. Arterial spin-labeled beelden hadden een sensitiviteit van 88% en een specificiteit van 89%, en dynamic susceptibility contrast-enhanced cerebral bloodvolume beelden een sensitiviteit van 86% en specificiteit van 70% [Ozsunar 2010²⁴²]. Daarnaast kunnen Dynamic Contrast-Enhanced Magnetic Resonance (DCE MR) (T1) perfusie opnames worden gebruikt [Chung 2013⁵⁹].

Vijf studies evalueerden de accuratesse van verschillende afkappunten voor MRI-beelden [Barajas 2009⁸, Chung 2013⁵⁹, Fink 2012⁹⁷, Ozsunar 2010²⁴², Xu 2010³⁹⁴/2011³⁹⁵]. De afwezigheid van 95%-betrouwbaarheidsintervallen of statistische toetsing maakt dat we geen duidelijke uitspraken kunnen doen over eventuele verschillen; de sensitiviteit varieert van 71%-95,7% en de specificiteit van 40%-90,0%. Een bepaald MRI-patroon suggestief voor recurrence (solid enhancement with distinct margins or focally enhancing nodules) had een sensitiviteit van 85% en een specificiteit van 33% [Reddy 2013²⁷⁵]. Tenslotte kwam in een studie alleen subependymale aankleuring naar voren als significant teken van progressie, sensitiviteit was 38,1% en de specificiteit 93,3% [Young 2011⁴⁰⁵].

De systematische review van Deng includeerde zeven studies voor perfusie-MRI en vond een sensitiviteit van 88% en een specificiteit van 85%.

Hollingworth includeerde vier studies voor MRI-spectroscopie en rapporteerde een sensitiviteit tussen 64-89% en een specificiteit tussen 82-89%.

CT (Computed Tomography)

Er was een studie beschikbaar naar de accuratesse van perfusie-CT, met een sensitiviteit van 81,5% en een specificiteit van 81,8-90% voor twee verschillende parameters (rCBV 1,5 en PS 2,5) [Jain 2011¹⁴⁸].

SPECT (Single-Photon Emission Computed Tomography)

De diagnostische accuratesse van SPECT werd gerapporteerd in twee systematische reviews [Cheng 2011⁵⁶, Vos 2007³⁷⁰] en in drie oorspronkelijke studies [Karunanithi 2013a¹⁶⁴, Santra 2011a²⁹⁴, Santra 2011b²⁹⁵].

De sensitiviteit en specificiteit van Tc-MIBI-SPECT (Technetium Methoxyisobutylisonitrile SPECT) was respectievelijk 89,8% en 91,9% op basis van een meta-analyse van zes studies [Cheng 2011⁵⁶].

De systematische review van Vos voerde geen meta-analyse uit omwille van de belangrijke heterogeniteit, en rapporteerde voor ²⁰¹Tl (Thallium)-SPECT een sensitiviteit tussen 43-100% en een specificiteit tussen 25-100%.

Een primaire prospectieve studie vond voor SPECT-CT een sensitiviteit van 86,4% en een specificiteit van 62,5% [Karunanithi 2013a¹⁶⁴]. Het hanteren van verschillende afkapwaarden resulteerde in lagere sensitiviteit en hogere specificiteit: T/S (tumour/striatum) ratio van 0,83 sensitiviteit 75%, specificiteit 86%; T/NP (tumour/nasopharynx) ratio 0,2 sensitiviteit 50%, specificiteit 95%.

Tenslotte werd GHA (glucoheptonate)-SPECT geëvalueerd in twee studies met een sterk vermoeden van gedeeltelijke overlap in de patiëntenpopulatie [Santra 2011a²⁹⁴, Santra 2011b²⁹⁵]. In deze studies werd een

sensitiviteit van 84,7%-86,5% en specificiteit van 96,8-96,5% gerapporteerd.

PET (Positron Emission Tomography)

Er waren twee systematische reviews met resultaten over PET [Deng 2013⁷⁷, Nihashi 2013²²⁹]. Deng vond voor C-MET (Methionine)-PET een gepoolde sensitiviteit en specificiteit van 87% en 81,3% op basis van elf studies, Nihashi heeft voor C-MET-PET geen meta-analyse uitgevoerd en vond een sensitiviteit van 55-80% en een specificiteit van 70-100% op basis van zeven studies. Voor enkel hooggradige gliomen leek de sensitiviteit iets hoger (70%).

Nihashi vond voor FDG-PET een gepoolde sensitiviteit van 77% en een gepoolde specificiteit van 78%, met vergelijkbare accuratesse bij enkel hooggradige gliomen. Bijkomend werd voor FDG-PET een sensitiviteit van 81% en een specificiteit van 90% gevonden in een primaire diagnostische studie [Ozsunar 2010²⁴²].

FLT/FET-PET werd gerapporteerd in een oorspronkelijke studie [Jeong 2010¹⁵⁸] voor verschillende afkapwaarden, variërend met een sensitiviteit van 81,8-91,3% en een specificiteit van 87,5-100%.

PET/CT

Twee studies evalueerden F-DOPA (Fluorodopa) PET/CT [Karunanithi 2013a¹⁶⁴, Karunanithi 2013b¹⁶⁵], waarbij er mogelijke een overlap is tussen deze studies. De sensitiviteit was 100% in beide studies, de specificiteit 87,5% en 88,9% respectievelijk. In de eerste studie werden ook nog verschillende afkappunten geanalyseerd, resulterend in een onveranderde sensitiviteit (87,5%) en een specificiteit variërend tussen 95,4-100%.

N-ammonia-PET/CT had in een studie een sensitiviteit van 82,6% en een specificiteit van 86,2%; verschillende afkapwaarden resulteerden in een sensitiviteit variërend tussen 65,2-73,9% en een specificiteit tussen 82,8-89,7% [Khangembam 2013¹⁷²].

Er was een oorspronkelijke studie voor C-MET-PET/CT welke een sensitiviteit van 96,4% en een specificiteit van 87,5% rapporteerde [Li 2012²⁰²].

Voor FDG (Fludeoxyglucose)-PET/CT waren drie studies beschikbaar [Li 2012²⁰², Santra 2011a²⁹⁴, Santra 2012²⁹⁶], maar deze twee rapporteren identieke resultaten en zijn vermoedelijk gebaseerd op dezelfde patiënten [Santra 2011a, Santra 2012]. Hierdoor zijn er slechts twee in plaats van drie sets van resultaten beschikbaar: de sensitiviteit is 46,4% en 69,5%, de specificiteit is 100% en 96,8%.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Radiologische follow-up tijdens behandeling bij het glioblastoom

Uitgangsvraag

Met welke frequentie dient radiologische follow-up plaats te vinden tijdens behandeling bij het glioblastoom?

Aanbeveling

De werkgroep is van mening dat, zeker indien een (experimentele) vervolgbehandeling tot de mogelijkheden behoort, MRI-beeldvorming op gezette tijden de meest voor de hand liggende strategie is. In overleg met de patiënt kan hier van worden afgezien en op klinische indicatie beeldvorming worden verricht.

Overwegingen

Omdat MRI-beeldvorming tijdens chemoradiotherapie behandeling verwarringende uitkomsten kan opleveren, zal voorafgaand aan het verrichten van deze beeldvorming het doel en de consequentie hiervan bij de behandelaren alsmede de patiënt en diens naasten duidelijk moeten zijn. Een MRI-scan met moeilijk te interpreteren beelden kan onrust veroorzaken bij patiënt en familie. Echter, wanneer de eerste scan pas na de zesde adjuvante kuur gemaakt wordt, worden patiënten potentieel langer dan nodig blootgesteld aan ineffectieve chemotherapie.

Steeds zal de onrust, veroorzaakt door een potentieel moeilijk interpreteerbare MRI kort na de bestraling, moeten worden afgewogen tegen het voordeel van op een vroeger tijdstip vaststellen van een recidief met potentieel een betere uitgangssituatie voor (experimentele) vervolgbehandeling evenals het tijdig staken van ineffectieve chemotherapie.

Onderbouwing

Conclusies

De werkgroep is van mening dat er geen bewijs is voor een specifieke strategie ten aanzien van het maken van vervolgsans tijdens gecombineerde chemoradiatiabehandeling, maar dat de enige onderzochte strategie MRI-beeldvorming is vier weken na (chemo-)radiotherapie en na de derde en zesde adjuvante kuur. Stupp 2005³³²

Samenvatting literatuur

De direct postoperatieve MRI wordt in de module Postoperatieve scan besproken. In deze module zal alleen worden ingegaan op de MRI-beeldvorming tijdens chemo-radiotherapie behandeling. Er zijn geen publicaties gevonden waarin de invloed van het moment en de frequentie van MRI-beeldvorming tijdens de behandeling op het ziektebeloop of de prognose wordt onderzocht.

In de oorspronkelijke studie waarin de toegevoegde waarde van gelijktijdig en adjuvant temozolomide chemotherapie bij het glioblastoom werd aangetoond, EORTC-studie-26981, werd MRI-beeldvorming verricht vier weken na de radiotherapie, evenals na de derde en na de zesde adjuvante kuur [Stupp 2005³³¹]. Een MRI met name in de eerste drie maanden na de (chemo)radiotherapie levert vaak moeilijk interpreteerbare beelden op met 20-30% pseudoprogressie als gevolg van de behandeling [Wen 2010³⁸², Van den Bent 2011³⁵⁹, Vogelbaum 2012³⁶⁸]. Zie ook de evidence based module Onderscheiden tumorprogressie.

en therapie-effect. Deze pseudoprogressie is zichtbaar als aankleuring op een T1-gewogen opname na contrast en is moeilijk met zekerheid te onderscheiden van werkelijke tumorprogressie. Alleen wanneer er binnen de eerste drie maanden na bestraling een nieuwe aankleurende laesie is *buiten* het bestralingsveld kan met zekerheid gesteld worden dat er sprake is van progressie. Het doel van de MRI vier weken na de radiotherapie is dan ook voornamelijk om een uitgangswaarde te hebben waarmee vervolgscans kunnen worden vergeleken. Een andere mogelijkheid is om de eerste MRI na de chemoradiotherapie behandeling pas laat te maken bijvoorbeeld na drie adjuvante kuren of zelfs na beëindiging van de gehele behandeling. Het risico van deze strategie is dat een recidief pas wordt vastgesteld wanneer klinische achteruitgang is opgetreden met verslechtering van de conditie en daarmee een slechtere uitgangssituatie voor (experimentele) vervolgbehandeling. Net als bij het nieuw gediagnosteerd glioom is ook bij patiënten met een recidief glioom een slechtere performancestatus bij aanvang van de recidiefbehandeling een prognostisch ongunstige factor [Wong 1999³⁹⁰, Park 2010²⁴⁹].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Postoperatieve scan bij gliomen

Uitgangsvraag

Wat is het moment waarop de eerste postoperatieve scan moet worden gemaakt bij patiënten met een laaggradig/anaplastisch/glioblastoom?

Aanbeveling

De werkgroep is van mening dat een vroege postoperatieve MRI (<72uur) voor zowel laag- als hooggradige tumoren zinvol kan zijn. Er is echter geen bewijs dat het weglaten van deze vroege postoperatieve MRI nadelige prognostische consequenties heeft. Daarom is het wel of niet maken van een direct postoperatieve MRI een keuze die in samenspraak tussen de verschillende behandelaars gemaakt dient te worden.

Onderbouwing

Conclusies

Het is aannemelijk dat op een vroege postoperatieve MRI-scan de mate van tumorresectie kan worden vastgesteld bij aankleurende gliomen.

Van den Bent 2013³⁵⁴, Cairncross 2013⁴¹, Zaidi 2014⁴⁰⁸, Smets 2013³¹⁸, Albert 1994⁴, Ekinci 2003⁹⁰

Het is aannemelijk dat een vroege postoperatieve MRI-scan als uitgangsscan kan dienen voor verdere follow-up MRI's bij aankleurende gliomen.

Van den Bent 2013³⁵⁴, Cairncross 2013⁴¹, Zaidi 2014⁴⁰⁸, Smets 2013³¹⁸, Albert 1994⁴, Ekinci 2003⁹⁰

Er zijn aanwijzingen dat een vroege postoperatieve MRI het meest betrouwbaar is zo vroeg mogelijk na de operatie en in ieder geval binnen 72 uur.

Zaidi 2014⁴⁰⁸, Smets 2013³¹⁸, Albert 1994⁴, Ekinci 2003⁹⁰

Het is niet bekend of het wel of niet maken van een direct postoperatieve MRI tot verschillen leidt in behandeling en/of overleving.

Zaidi 2014⁴⁰⁸, Smets 2013³¹⁸, Albert 1994⁴, Ekinci 2003⁹⁰

Samenvatting literatuur

In de RANO-richtlijnen [Wen 2010³⁸², Van den Bent 2011³⁵⁹, Vogelbaum 2012³⁶⁸] wordt aangeraden de eerste postoperatieve scan bij laag- en hooggradige gliomen zo vroeg mogelijk en in ieder geval binnen 72 uur na de operatie te maken om resttumor en operatie-effecten zoals ischemie (zichtbaar als diffusierestrictie) en contusie vast te kunnen stellen. Als de MRI-scan later wordt gemaakt kunnen postoperatieve effecten zorgen voor aankleuring op T1-gewogen MRI-opnames na contrast die niet te onderscheiden is van rest- of recidiettumor [Cairncross 2013⁴¹, Zaidi 2014⁴⁰⁸]. Voor glioblastoom en anaplastisch glioom (met aankleuring) kan deze MRI tevens dienen als uitgangs-MRI voor de mate van resttumor. Bij laaggradige tumoren en anaplastisch glioom zonder aankleuring is het volgens de RANO-richtlijn raadzaam de uitgangs-MRI voor T2-gewogen beelden later dan twaalf weken na de operatie plaats te laten vinden [Wen 2010³⁸², Van den Bent 2011³⁵⁹, Vogelbaum 2012³⁶⁸]. Bij een eerdere MRI-scan kan er nog postoperatief oedeem aanwezig zijn die

niet te onderscheiden is van resttumor. Echter ook voor laaggradige tumoren kan worden overwogen om een vroege MRI te maken korter dan 72 uur na de operatie. Het eventuele effect van een vroege postoperatieve MRI op behandelkeuzes en patiënten-uitkomstmaten is niet bekend. Voor de interpretatie van veranderingen op MRI bij verdere follow-up met MRI-beeldvorming is de uitgangs-MRI-scan wel van belang.

Gezien de rol van de (rest)aankleuring bij de afweging om een MRI-scan vroeg (<48-72uur) of laat (>12 weken) na de operatie te maken zal bij hooggradige gliomen het moment van de MRI-scan afhangen van de wel/niet aanwezige aankleuring. Als er aankleuring aanwezig is, lijkt het het meest logisch om ook bij deze hooggradige gliomen de postoperatieve MRI binnen 48-72uur na de operatie te maken [Van den Bent 2013³⁵⁴, Cairncross 2013⁴¹]. Er is discussie over de waarde van deze direct postoperatieve MRI omdat er ook al vroeg aankleuring aanwezig kan zijn, bijvoorbeeld door operatieve manipulatie en bloed-hersenbarrière verstoring [Zaidi 2014⁴⁰⁸]. Wel is de aanwezigheid van aankleuring op een vroege postoperatieve scan een prognostische factor [Smets 2013³¹⁸, Albert 1994⁴, Ekinci 2003⁹⁰]. Er zijn geen vergelijkende studies gedaan waarbij de prognostische waarde is vergeleken tussen de vaak gehanteerde <48uur of <72uur postoperatieve MRI's [Albert 1994⁴, Ekinci 2003⁹⁰].

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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Radiologische follow-up na afronden behandeling bij glioblastoom

Uitgangsvraag

Met welke frequentie dient radiologische follow-up plaats te vinden na afronden van de behandeling bij het laaggradig/anaplastisch/glioblastoom?

Aanbeveling

De werkgroep is van mening dat radiologische follow-up bij patiënten met een glioom alleen moet worden verricht wanneer er klinische en/of therapeutische consequenties zijn.

Het doel van radiologische follow-up is het in een vroeg stadium opsporen van tumorgroei en daarmee de mogelijkheid voor en de slagingskans van vervolgbehandeling al dan niet in studieverband te optimaliseren.

De werkgroep is van mening dat de volgende radiologische follow-up frequentie gehanteerd kan worden:

- patiënten met een glioblastoom (WHO graad IV): drie tot zes maanden
- patiënten met een anaplastisch glioom (WHO graad III): drie tot zes maanden
- patiënten met een laaggradig glioom (WHO graad II): zes tot twaalf maanden

De werkgroep is van mening dat mede gezien het ontbreken van wetenschappelijk bewijs, tumorfactoren en patiëntgerelateerde factoren een rol spelen in het komen tot een optimale follow-up frequentie voor de individuele patiënt binnen de hierboven genoemde grenzen.

Overwegingen

De optimale radiologische follow-up frequentie bij patiënten met een laag- of hooggradig glioom zal van verschillende factoren afhankelijk zijn. Bij het ontbreken van vergelijkende studies of series in de literatuur zullen klinische en/of patiëntgerelateerde argumenten een grote rol spelen. Zo kan grootte en lokatie van (rest)tumor belangrijk zijn en kan ook de wens van de patiënt meegewogen worden. Daarnaast kan kosteneffectiviteit een argument zijn in de besluitvorming over follow-up frequentie.

Geplande follow-up zal in het algemeen alleen plaatsvinden als er behandelbaarheden of klinische consequenties bestaan bij aantonen van recidief tumor, tumorgroei of radiologische kenmerken van dedifferentiatie naar hogere gradering. Het doel van de follow-up is om voorgenomen events in een vroeg stadium op te sporen, vóór de patiënt (ernstige) neurologische uitvalsverschijnselen vertoont. De mogelijkheid voor en de slagingskans van een vervolgbehandeling of behandeling in studieverband is namelijk sterk afhankelijk van de performance status van de patiënt.

In hoeverre de hoge follow-up frequentie in de studies van Stupp en Van den Bent daadwerkelijk heeft bijgedragen aan de overlevingswinst van respectievelijk patiënten met een glioblastoom en een AO is niet duidelijk. Het vroeg opsporen van recidiettumor of tumorgroei heeft mogelijk wel geleid tot het eerder of vaker starten van een vervolgbehandeling.

Onderbouwing

Conclusies

De werkgroep is van mening dat op basis van de literatuur geen uitspraak kan worden gedaan over de optimale frequentie van radiologische follow-up voor patiënten met hoog- en laaggradige gliomen. In een aantal klinische trials is de methode en frequentie van follow-up duidelijk beschreven [Stupp 2005³³¹, Van den Bent 2013³⁵⁴]. In de overige trials is de frequentie van follow-up variabel óf niet beschreven.

Samenvatting literatuur

Er zijn voor zowel laag- als hooggradige gliomen geen studies waarin verschillende frequenties van radiologische follow-up worden vergeleken.

In de studie van Stupp [Stupp 2005³³¹], die de standaardbehandeling van het glioblastoom herdefinieerde, werd een follow-up frequentie van drie maanden aangehouden. Twee trials bij anaplastische oligodendrogliomen [Van den Bent 2013³⁵¹, Cairncross 2013⁴¹] hanteerden verschillende follow-up frequenties. In de studie van Van den Bent werd elke drie maanden een MRI of CT verricht. In de studie van Cairncross wordt geen precieze follow-up frequentie genoemd, maar beschreven als variabel en oplopend qua interval, naarmate de overleving langer werd. Na vijf jaar werd een MRI of CT jaarlijks gemaakt of alleen 'wanneer nodig'. Bij deze twee studies waren de progressie vrije overleving (PFS) en de totale overleving (OS) vergelijkbaar. Wick onderzocht bij patiënten met een anaplastische astrocytoom de volgorde van behandeling (radiotherapie gevolgd door chemotherapie en andersom) daarbij werd de frequentie en methode van follow-up niet beschreven [Wick 2009³⁸⁶, Wick 2012³⁸⁷]. Bij laaggradige tumoren is in studies en beschreven series de gehanteerde follow-up frequentie variabel (zes tot twaalf maanden) óf niet gerapporteerd.

Verantwoording

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Voor de volledige verantwoording, evidence tabellen en eventuele aanverwante producten raadpleegt u de Richtlijnendatabase.

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