

# Thrombectomy in ischemic stroke patients with alberta stroke program early computed tomography score 4-5 and 0-3: Factors associated with favorable outcome

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**Objectives:** Recently published results of the ANGEL-ASPECT and SELECT2 trials suggest that stroke patients presenting with low Alberta Stroke Program Early Computed Tomography Score (ASPECTS) benefit from mechanical thrombectomy. Purpose of this retrospective study was to identify factors that are associated with a favorable outcome in patients with low ASPECTS of 4-5 and 0-3 undergoing mechanical thrombectomy. **Material and methods:** All patients reported in the quality registry of the German Society for Neuroradiology that were treated between 2018 and 2020 were analyzed. Favorable outcome was defined as a National Institute of Health Stroke Scale (NIHSS) score of less than 9 at dismissal. Successful recanalization was defined as Thrombolysis in Cerebral Infarction (mTICI)  $\geq 2$ . Multivariable logistic regression analyses were performed to assess the association of baseline and treatment variables with favorable outcome. **Results:** 621 patients were included in the analysis, thereof 495 with ASPECTS 4-5 and 126 with ASPECTS 0-3. In patients with ASPECTS 4-5 patients with favorable outcome had less severe neurological symptoms at admission with median NIHSS of 15 vs. 18 ( $p < 0.001$ ), had less often wake-up strokes (44% vs. 81%,  $p < 0.001$ ), received more often iv-lysis (37% vs. 30%,  $p < 0.001$ ), had more often conscious sedation (29% vs. 16%,  $p < 0.001$ ), had a higher rate of successful recanalization (94% vs. 66% and lower times from groin puncture to recanalization. In multivariate regression analysis lower NIHSS at admission (aOR 0.87, CI 0.89-0.91) and successful recanalization (aOR 3.96, CI 2-8.56) were associated with favorable outcome. For ASPECTS 0-3, patients with favorable outcome had lower median NIHSS at admission (16 vs. 18 ( $p < 0.001$ ), lower number of passes (1 vs. 3,  $p = 0.003$ ) and a higher rate of successful recanalization (94% vs. 66%,  $p < 0.001$ ) and lower times from groin puncture to recanalization. In multivariate regression analysis lower NIHSS at admission (aOR 0.87, CI 0.81-0.94) and successful recanalization, (aOR 11.19, CI 3.19-55.53), were associated with favorable outcome. **Conclusion:** Full recanalization with low groin puncture to

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recanalization times and low number of passes were associated with favorable outcome in patients with low ASPECTS.

**Keywords:** Ischemic stroke—Anterior circulation—ASPECTS—Thrombectomy

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## Introduction

Mechanical Thrombectomy has become the standard of care for acute large vessel occlusions of the anterior circulation.<sup>1,2</sup> Due to narrow inclusion criteria, several subgroups of patients with acute ischemic stroke potentially eligible for thrombectomy were excluded in the underlying studies<sup>3–6</sup> and are therefore not treated with mechanical thrombectomy in clinical practice, according to current guidelines.<sup>7,8</sup> These borderline indications include patients with progressed radiological signs of brain infarction defined by low Alberta Stroke Program Early CT Score (ASPECTS). The proportion of salvageable tissue becomes smaller with larger infarct cores, resulting in less favorable functional outcomes in these patients. Whether patients with large infarct core should be treated with thrombectomy is subject of an ongoing debate. However, recently published results of the RESCUE-Japan Limit, ANGEL-ASPECT and SELECT2 trials suggest that stroke patients presenting with ASPECTS 3–5 or an infarct core volume of at least 50ml benefit from mechanical thrombectomy.<sup>9–11</sup> Numerous previous studies suggested a beneficial effect of endovascular therapy of patients with MRI and CT based ASPECTS 0–5.<sup>12–17</sup> In contrast, an analysis of patients with ASPECTS 0–4 from the MR CLEAN cohort concluded, that for these patients, endovascular treatment might yield only marginal absolute benefit.<sup>18,19</sup>

To the best of our knowledge, no study to date has performed a dedicated analysis of a patient cohort that includes patients with an unclear time window with a very large infarct core (ASPECTS 0–3).

The aim of the present study was to identify factors that are associated with favorable outcome (FO) at dismissal in patients undergoing mechanical thrombectomy with a very large infarct core as defined by ASPECTS 0–3 and in patients with a large infarct core as defined by ASPECTS 4–5.

## Methods

### *Study sample and data collection*

The presented retrospective study is based on the nationwide quality registry of the German Society for Neuroradiology (DGNR) and of the German Society for Interventional Radiology and Minimally Invasive Therapy (DEGIR).<sup>20</sup> The registry database contains clinical and procedural data of patients with ischemic stroke that were treated with mechanical thrombectomy between 2018 and 2020. Large vessel occlusion was diagnosed by

CT-angiography or MR-angiography prior treatment. The recanalization technique used was selected on discretion of the interventionalists. Iv-lysis was administered to the patients if eligible according to the national guidelines. Neither approval of the institutional review board nor patient informed consent were required according to the local ethics committee due to the retrospective character of the analysis of anonymized patient records and imaging. All study protocols and procedures were conducted in accordance with the Declaration of Helsinki.

### *Variable and image analysis*

Large vessel occlusion of the anterior circulation was defined as occlusion of the distal internal carotid artery, and M1 segment of the middle cerebral artery and proximal anterior cerebral artery.

The grade of reperfusion was measured with the mTICI scale. mTICI grade 1 was defined as antegrade reperfusion past the initial occlusion, but limited distal branch filling with little or slow distal reperfusion, mTICI grade 2a was defined as antegrade reperfusion of less than half of the occluded target artery. mTICI 2b was rated of as reperfusion of at least 50% of the previously occluded target territory and TICI 2c was defined as near complete reperfusion except for slow flow or distal emboli in a few distal cortical vessels.<sup>21,22</sup>

In contrast to previous studies, FO in our study was defined as an NIHSS  $\leq 8$  at discharge rather than mRS  $\leq 2$  three months after onset<sup>12,13</sup> because three months follow-ups are not reported in the underlying registry data. However, a previous study indicated a very good correlation of a NIHSS  $\leq 8$  at an early timepoint for anterior circulation stroke with functional outcome at 90 days as measured by a mRS  $\leq 2$ .<sup>23</sup>

ASPECTS was evaluated at each site and was based on admission CT in 556 (89%) and based on MRI in 65 (11%) patients.

### *Statistical analysis*

Univariate comparisons were made using standard statistical measures (Fisher exact test for categorical variables, Mann–Whitney U test for nonnormally continuous, or ordinally scaled variables). Association of favorable outcome with all other parameters was assessed using multivariable logistic regression adjusting for the following prespecified variables: age, sex, NIHSS on admission, the presence of wake-up stroke, the administration of iv-lysis and a recanalization result of mTICI  $\geq 2b$ .

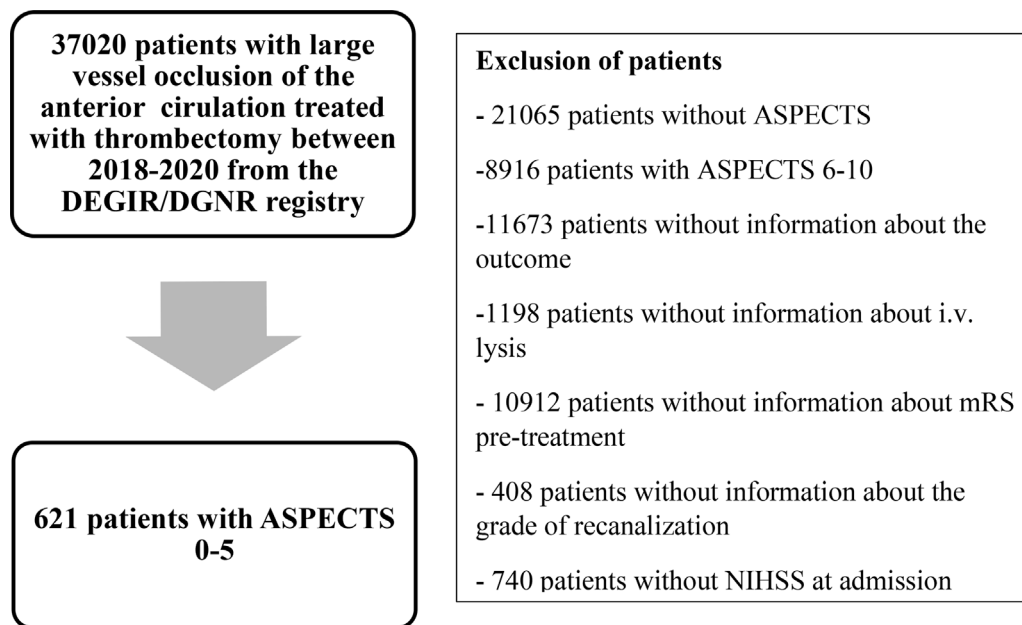


Fig 1. Flowchart of the formation of the study cohort analyzed in the present study.

## Results

### Study cohort

Of 37020 patients from the DGNR registry that were treated between 2018 and 2020, 621 complete cases presented with ASPECTS 0-5. Fig. 1 shows a flowchart of the patient selection. Mean age of these patients was 71 years (median 75, IQR 65 -85) and 54% were female. 49 % patients suffered from stroke with unknown onset. Patients presented with a mean NIHSS score of 17 (median 17, IQR 14-20) and a median mRS score of 5 (IQR 4-5). 21% of the patients were treated in conscious sedation and mean time from groin puncture to recanalization was 64 minutes (median 48 minutes, IQR 22-74 minutes). Successful reperfusion defined as mTICI  $\geq$  2b was achieved in 83% of the patients. Complete recanalization was achieved in 46% of the patients. Mean number of passes was 3 (median 2, IQR 1-3). FO was achieved in 35% of the patients.

### Differences between patients with favorable and unfavorable outcome

#### ASPECTS 4-5

FO was achieved in 35% of the patients with ASPECTS 4-5 in this study. Mortality was 17%. Patients with favorable outcome in this subgroup were more often treated with iv-lysis (FO:37%, unfavorable outcome (UO): 30%,  $p<0.001$ ) and in conscious sedation (FO: 29%, UO: 16%,  $p<0.001$ ). NIHSS at admission was lower (FO: median 15 (IQR 7), UO: median 18 (IQR6),  $p<0.001$ ) and mRS at admission was lower (FO: median 5 (IQR1), UO: 5 (IQR

0),  $p<0.001$ ) in patients with favorable outcome. A highly significant higher grade of recanalization (FO: mTICI  $\geq$  2b: 94%, UO: 81%,  $p<0.001$ ) was achieved with a fewer number of passes (FO: median 2 (IQR 2), UO: median 2 (IQR 1-4),  $p=0.003$ ) in a highly significant shorter time interval between groin puncture and recanalization (FO: median 40 min (IQR 36 min), UO: median 57 min (IQR 59 min),  $p<0.001$ ). Table 1 provides an overview of the patients with favorable and unfavorable outcome with ASPECTS 4-5.

In the logistic regression analysis, highly significant lower NIHSS at admission (adjusted OR: 0.87 (IQR 0.84-0.91),  $p<0.001$ ) was noted for patients with a favorable outcome, and a recanalization result of mTICI  $\geq$  2b was highly significantly more often achieved in patients with a favorable outcome (adjusted OR: 3.96, (IQR 2.0-8.56),  $p<0.001$ ). Fig. 2 provides a more detailed overview of the results of the logistic regression analysis.

#### ASPECTS 0-3

Favorable outcome was achieved in 44 (35%) of the 126 patients with ASPECTS 0-3 in this study. Mortality was 21.4%. Patients with favorable outcome in this subgroup received significantly more MRI imaging at admission (FO: 17%, UO: 6%,  $p=0.038$ ), initial mRS was highly significant lower (FO:4 (IQR 3-5), UO: 5 (IQR 5),  $p>0.001$ ) and NIHSS at admission was highly significant lower (FO: 16 (IQR 9-18), UO: 18 (IQR 15-21),  $p<0.001$ ). A highly significant higher grade of recanalization (FO: mTICI  $\geq$  2b: 94%, UO: 66%,  $p<0.001$ ) was achieved with a fewer number of passes (FO: median 1 (IQR 1-3), UO: median 3 (IQR 1-4),  $p=0.003$ ) in a highly significant shorter time

**Table 1.** Comparison of patients with favorable and unfavorable outcome with ASPECTS 4-5.

	Favorable	Unfavorable	P value
<b>N</b>	172	323	
<b>Female (%)</b>	92 (54)	178 (55)	0.02
<b>Age, median, (IQR)</b>	72 (19)	76 (19)	0.232
<b>MRI, n (%)</b>	22 (13)	30 (9)	0.214
<b>NECT+CTA, n (%)</b>	152 (88)	299 (93)	0.041
<b>CTP, n (%)</b>	93 (54)	167 (52)	0.832
<b>Iv-lysis, n (%)</b>	63 (37)	97 (30)	<0.001
<b>MRS score pre-treatment, median (IQR)</b>	5 (1)	5 (0)	<0.001
<b>NIHSS, median (IQR)</b>	15 (7)	18 (6)	<0.001
<b>Wake-up stroke, n (%)</b>	75 (44)	170 (53)	<0.001
<b>Conscious sedation, n (%)</b>	50 (29)	51 (16)	<0.001
<b>Number of passes, n (IQR)</b>	2 (2)	2 (3)	<0.001
<b>mTICI</b>			
<b>0</b>	3 (2)	28 (9)	0.001
<b>1</b>	1 (1)	3 (1)	1
<b>2a</b>	7 (4)	31 (10)	0.032
<b>2b</b>	57 (33)	120 (37)	0.377
<b>2c</b>	8 (5)	14 (4)	1
<b>3</b>	96 (56)	127 (39)	<0.001
<b>mTICI <math>\geq</math> 2b, n (%)</b>	161 (94)	261 (81)	<0.001
<b>Time interval from groin puncture to recanalization, median (IQR)</b>	40 (36)	57 (59)	<0.001
<b>Dead, n</b>		85	
<b>NIHSS at dismissal, median (IQR)</b>	4 (4)	18 (19)	

Depiction of baseline and procedural data of patients with favorable and unfavorable outcome of patients with ASPECTS 4-5. MRI: magnetic resonance imaging, NECT+CTA: non enhanced computed tomography and CT-angiography, CTP: CT-perfusion, iv-lysis: intravenous thrombolysis, MRS: modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, mTICI: modified treatment in cerebral ischemia score. The\* indicates a significance level of  $p < 0.05$  and the \*\*indicates a significance level of  $p < 0.001$ .

interval between groin puncture and recanalization (FO: median 31 min (IQR 13-77 min), UO: median 55 min (IQR 35-81 min),  $p < 0.001$ ). Table 2 provides an overview of the differences between the patient groups with ASPECTS 0-3.

In the logistic regression analysis, highly significant lower NIHSS at admission (adjusted OR: 0.87 (IQR 0.81-0.94),  $p < 0.001$ ) was noted for patients with a favorable outcome, and a recanalization result of mTICI  $\geq$  2b was significantly more often achieved in patients with a favorable outcome (adjusted OR: 11.19 (IQR 3.19-55.53),  $p = 0.001$ ). Fig. 3 provides a more detailed overview of the results of the logistic regression analysis.

## Discussion

This retrospective study investigating factors that are associated with functional outcome at dismissal in patients with large (ASPECTS 4-5) and very large infarct core (ASPECTS 0-3) revealed several findings.

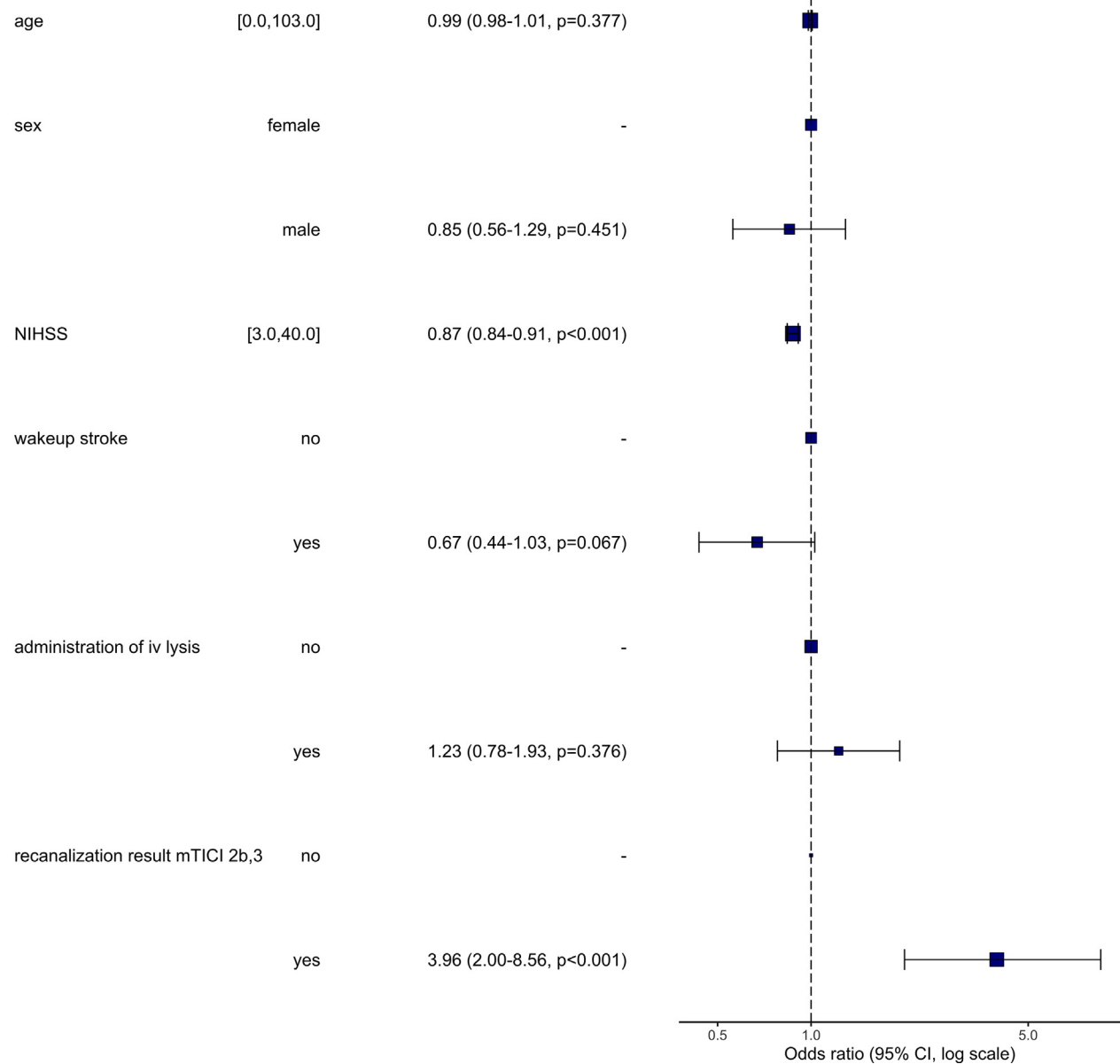
Successful endovascular recanalization therapy was highly associated with a favorable outcome in patients with a very large infarct core (ASPECTS 0-3) and with a large infarct core. (ASPECTS 4-5). Only six percent of these patients achieved a favorable outcome despite a

recanalization result of mTICI 2a or worse. Our study complements previous studies with shorter onset to recanalization times and without patients with wake-up stroke.<sup>12,24,25</sup> In concordance with previous studies about 35% of the patients with ASPECTS 4-5 and as a new finding, a similar percentage of patients with ASPECTS 0-3 achieved a favorable outcome in our study.<sup>12,24,26</sup>

A significant association between thrombectomy and positive clinical outcome was observed in the RESCUE-Japan Limit study in patients with ASPECTS 3-5.<sup>11</sup> In this study, patients were treated with a median time interval of 3 hours between stroke and admission, and only 30% of patients presented with a time interval greater than 6 hours. In contrast, about half of the patients with ASPECTS 0-3 in our study presented with wake-up stroke. The vast majority of patients in the RESCUE-Japan Limit study received MRI imaging which is more problematic in critical ill patients, whereas CT-based imaging was the primary modality in our study. Overall, the inclusion criteria of our study appear less strict and perhaps closer to daily reality.

Results from the recent ANGEL-ASPECT and SELECT 2 trials also suggest, that stroke patients presenting with large infarct core benefit from mechanical thrombectomy. Similar to our study, these studies included patients in an

## ASPECTS 4-5 odds for a favorable outcome: OR (95% CI, p-value)



**Fig 2.** Depiction of the adjusted odds ratios for favorable outcome for patients (n=495) with ASPECTS 4-5.

extended time window of up to 24 hours. In the ANGEL-ASPECT study, patients with ASPECTS 3-5 or an infarct core volume of 70-100ml whereas in the SELECT 2 trial patients with ASPECTS 3-5 or an infarct core volume of at least 50ml with no upper limit were included in the analysis. A small number of patients that were treated with thrombectomy in the SELECT 2 trial presented with ASPECT 0-2 and these patients showed similar odds for a favorable outcome as patients with ASPECTS 3-5. In the study by Almallouhi et al, a potential benefit of endovascular recanalization in a patient cohort that included patients with an unclear time window with a large infarct

core with the exclusion of patients with ASPECTS 0-2 was reported.<sup>17</sup>

The dedicated analysis of patients with ASPECTS 0-3 performed in our study augments these previous studies. In line with the results of the SELECT 2 trial, the results of our study indicate, that patients with ASPECTS 0-2 can benefit from thrombectomy in a similar way as patients with ASPECTS 3-5. Furthermore, the results from our regression analysis suggest, that favorable outcome in this highly selected patient group is primarily associated with successful recanalization and factors like sex, age, the presence of wake-up stroke and the administration of iv-



**Table 2.** Comparison of patients with favorable and unfavorable outcome with ASPECTS 0-3.

	Favorable	Unfavorable	P value
<b>N</b>	44	82	
<b>Female (%)</b>	22 (48)	46 (55)	0.506
<b>Age, median, (IQR)</b>	77 (60-84)	76 (60-82)	0.990
<b>MRI, n (%)</b>	8 (17)	5 (6)	0.038*
<b>NECT+CTA, n (%)</b>	39 (85)	79 (94)	0.063
<b>CTP, n (%)</b>	24 (52.2)	47 (56)	0.404
<b>Iv-lysis, n (%)</b>	18 (39)	19 (23)	0.106
<b>MRS score pre-treatment, median (IQR)</b>	4 (3-5)	5 (5)	<0.001**
<b>NIHSS, median (IQR)</b>	16 (9-18)	18 (15-21)	<0.001**
<b>Wake-up stroke, n (%)</b>	18 (39)	44 (52)	0.508
<b>Conscious sedation, n (%)</b>	9 (20)	21 (25)	0.251
<b>Number of passes, n (IQR)</b>	1 (1-3)	3 (1-4)	0.003*
<b>mTICI</b>			
<b>0</b>	1 (2.2)	11 (13)	0.054
<b>1</b>	0	4 (4.8)	0.299
<b>2a</b>	2 (4.3)	14 (16.7)	0.049
<b>2b</b>	11 (23.9)	22 (26.2)	0.834
<b>2c</b>	0	1 (1.2)	1
<b>3</b>	32 (69.6)	32 (38.1)	<0.001**
<b>mTICI <math>\geq</math> 2b, n (%)</b>	43 (94)	55 (66)	<0.001**
<b>Time interval from groin puncture to recanalization, median (IQR)</b>	31 (13-77)	55 (35-81)	<0.001**
<b>Dead, n</b>		27	
<b>NIHSS at dismissal, median (IQR)</b>	4 (2-6)	19 (14-42)	

Depiction of baseline and procedural data of patients with favorable and unfavorable outcome of patients with ASPECTS 0-3. MRI: magnetic resonance imaging, NECT+CTA: non enhanced computed tomography and CT-angiography, CTP: CT-perfusion, iv-lysis: intravenous thrombolysis, MRS: modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, mTICI: modified treatment in cerebral ischemia score. The\* indicates a significance level of  $p < 0.05$  and the \*\*indicates a significance level of  $p < 0.001$ .

lysis might not substantially affect the functional outcome. In addition to a previous study from the anterior circulation, a shorter groin puncture to recanalization time and lower number of passes were significantly associated with a favorable outcome in our study in patients with ASPECTS 0-3 and 4-5.<sup>27</sup>

Despite the observed positive association of successful endovascular reperfusion with favorable results, patients with ASPECTS 4-5 and in particular ASPECTS 0-3 exhibited an increased risk of death of up to 21%. This severe prognosis should be taken into account in pre-treatment discussions with relatives and patients.

In general, the odds for poor outcome are higher in older patients due to more comorbidities and decreased functional reserve.<sup>28</sup> Two previous studies suggested, that the odds for a favorable outcome was higher for patients younger than 70 years and 65 years respectively that were treated with thrombectomy when presenting with ASPECTS 0-5.<sup>13,29</sup> Zaidat et al reported a low clinical benefit of endovascular treatment for patients older than 75 years in these patients.<sup>29</sup> We did not find significant age differences between patients with favorable and unfavorable outcome in our patient groups with ASPECTS 0-5 and 0-3. These differences could be related to the different recanalization rates. In the study by Zaidat et al, no

patient with ASPECTS 0-5 exhibited a recanalization rate of mTICI 3 and in 85% of the patients a recanalization rate of mTICI 2b was achieved.<sup>29</sup> In the study by Kaesmacher et al, recanalization rates of mTICI  $\geq$  2b of 70% were observed in patients with ASPECTS 0-5.<sup>12</sup> We observed a recanalization rate of mTICI 3 in 47% of the patients and of mTICI  $\geq$  2b in 85.5%. In the more frequent incomplete recanalization rates in these previous studies the mentioned cognitive reserve capacity and comorbidities might play a bigger role. In concordance with a previous study, the results of our study suggest, that endovascular treatment might be associated with a favorable outcome regardless of patient age.<sup>12</sup>

### Limitations

In the database on which our analysis is based, some data, especially the ASPECTS, have to be encoded optionally.<sup>20</sup> This results in a large number of data sets, but unfortunately also in a relatively large number of missing values which constitutes an important limitation of our study. The ASPECTS in the present study was evaluated at each site of our multicentric study which makes our study susceptible to interrater inaccuracies. A recent study on this topic concluded that interrater agreement

## ASPECTS 0-3 odds for a favorable outcome: OR (95% CI, p-value)

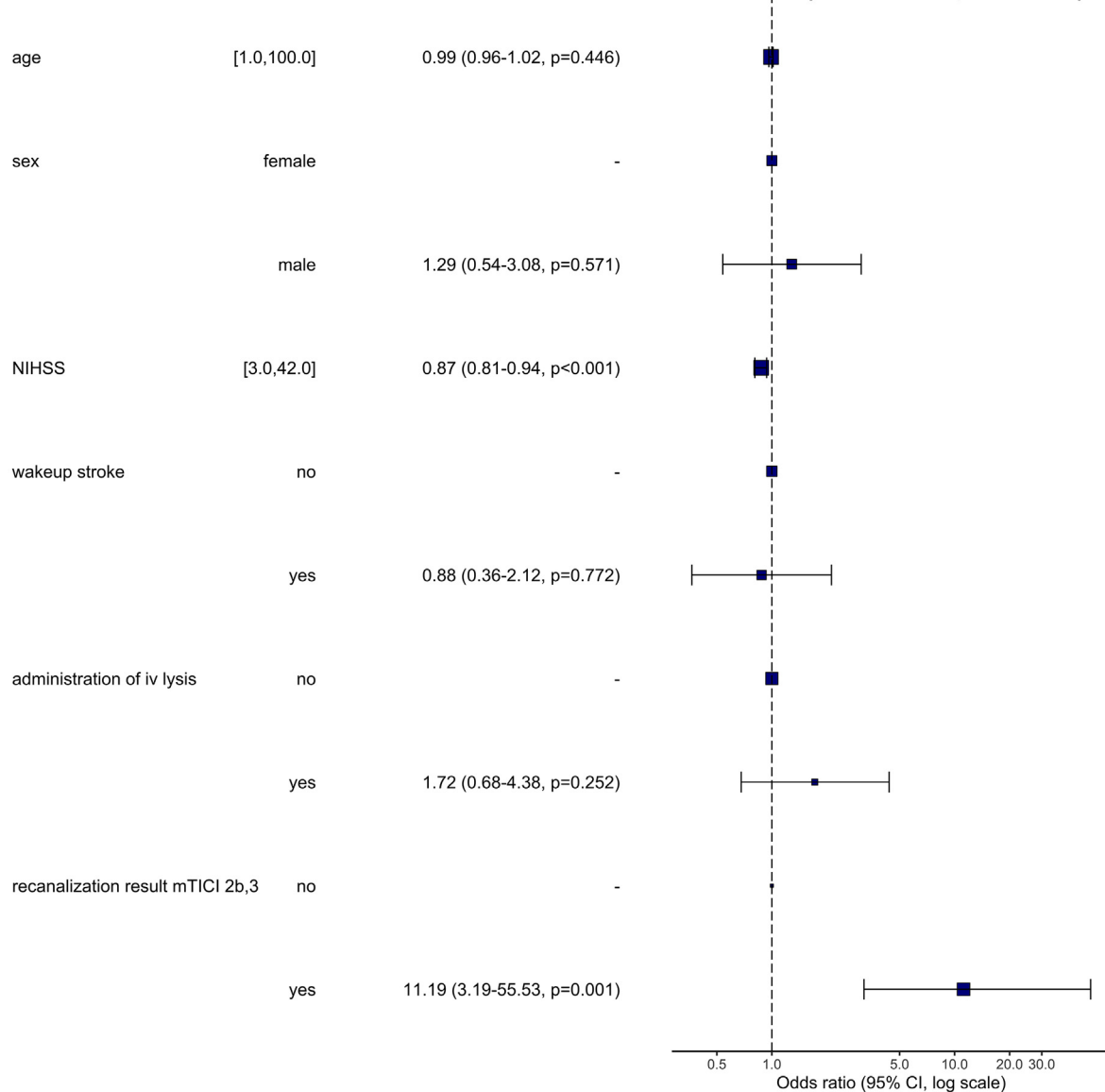


Fig 3. Depiction of the adjusted odds ratios for favorable outcome for patients (n=126) with ASPECTS 0-3.

reliability for total ASPECTS was relatively low but seemed sufficient for practical application.<sup>30</sup> The ASPECTS constitutes an estimation of the volume of the infarct core and just like the simple infarct volume neglects the functional eloquence of the different tissue areas.<sup>31,32</sup> The dichotomization of the score (infarcted vs non infarcted) neglects the intermediate stages of the gradually developing infarct core. The inclusion of these intermediate stages or the application of additional techniques such as the lesion water uptake in the analysis of the infarct core might provide additional valuable prognostic information.<sup>33</sup> Because we analyzed self-reported data, overestimation of recanalization results cannot be excluded. The achieved recanalization results in our study

however are comparable to the reported recanalization rates of the EXTEND-IA trial of 86% which makes a systematic overestimation of the recanalization results unlikely.<sup>34</sup> Further randomized controlled trials such as the ongoing TENSION trial will hopefully provide additional insight into the efficacy and safety of thrombectomy in stroke with extended lesion as defined by ASPECTS 0-5.<sup>35</sup>

## Conclusion

Full recanalization with low groin puncture to recanalization times and low number of passes were associated with favorable outcome in patients with low ASPECTS in our large multicentric study.

## Ethics approval for retrospective studies, Consent

Neither approval of the institutional review board nor patient informed consent were required according to the local ethics committee due to the retrospective character of the analysis of anonymized patient records and imaging. All study protocols and procedures were conducted in accordance with the Declaration of Helsinki.

## Author contributions

All authors contributed to the study conception and design. The first draft of the manuscript was written by Ludger Feyen. All authors read and approved the final manuscript.

## Funding

None.

## Data availability

The deidentified data can be requested from the corresponding author after necessary consultation with the professional society which provided the data.

## Declaration of Competing Interest

The authors have no competing interests to declare that are relevant to the content of this article.

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