

Personalized Medicine: Identification and Treatment of Fragile Patients

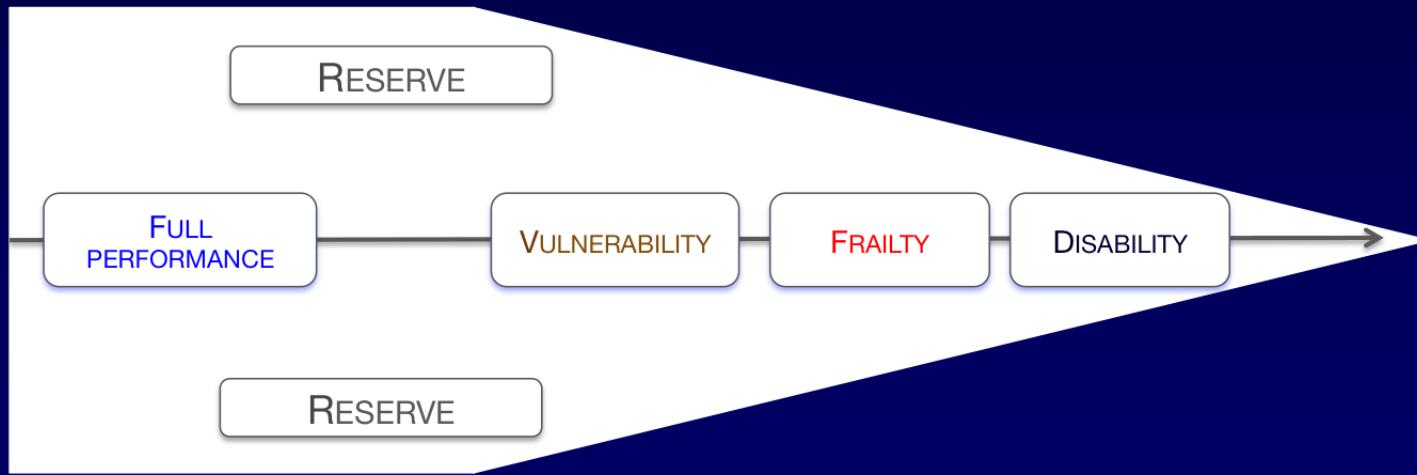
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The Context

Vulnerability/Fragility

Less functional reserve predisposing patients to rapid deterioration of health and functional decline.



OVARIAN CANCER STRESSORS

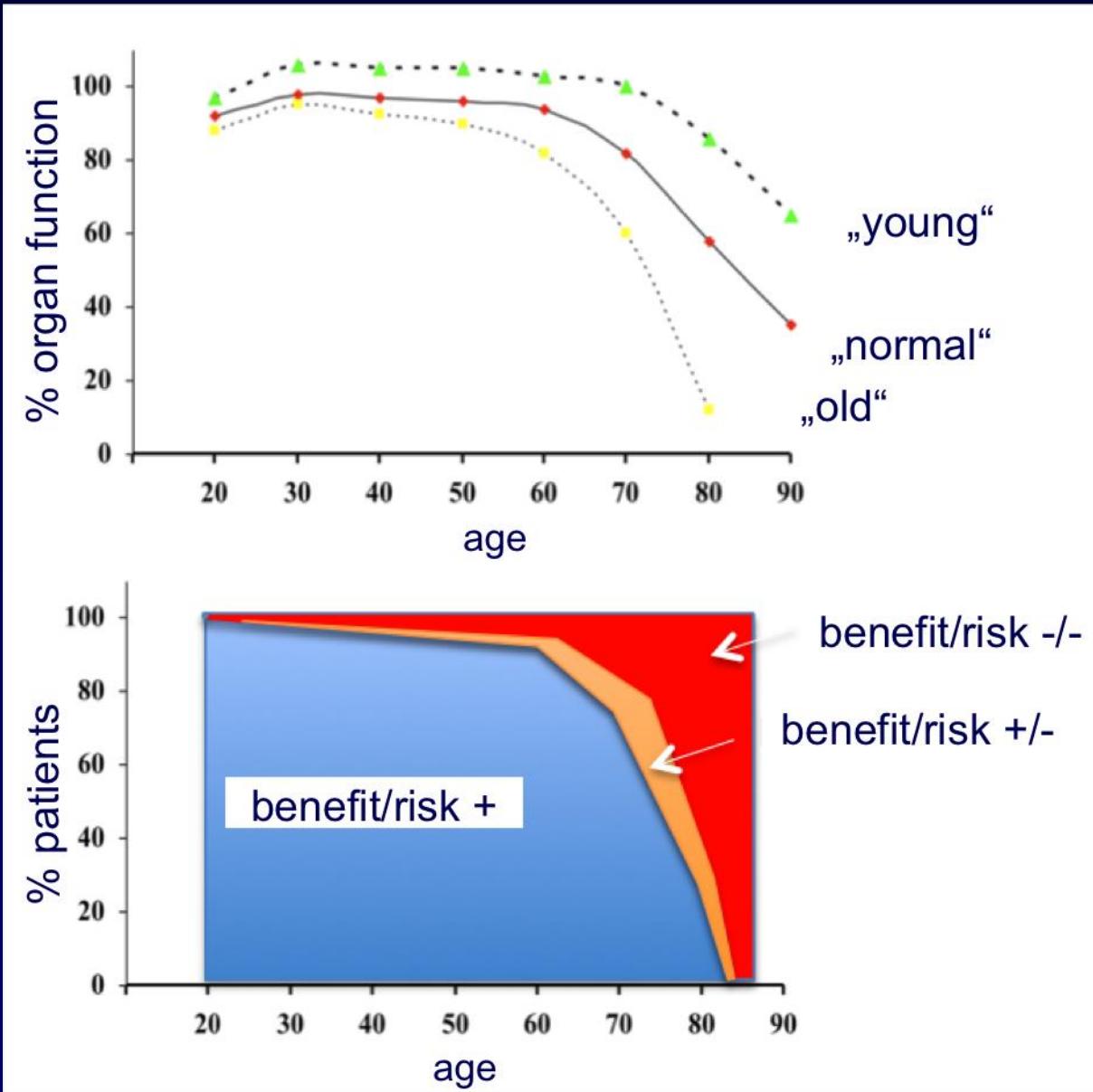
Disease-related symptoms

Mental burden

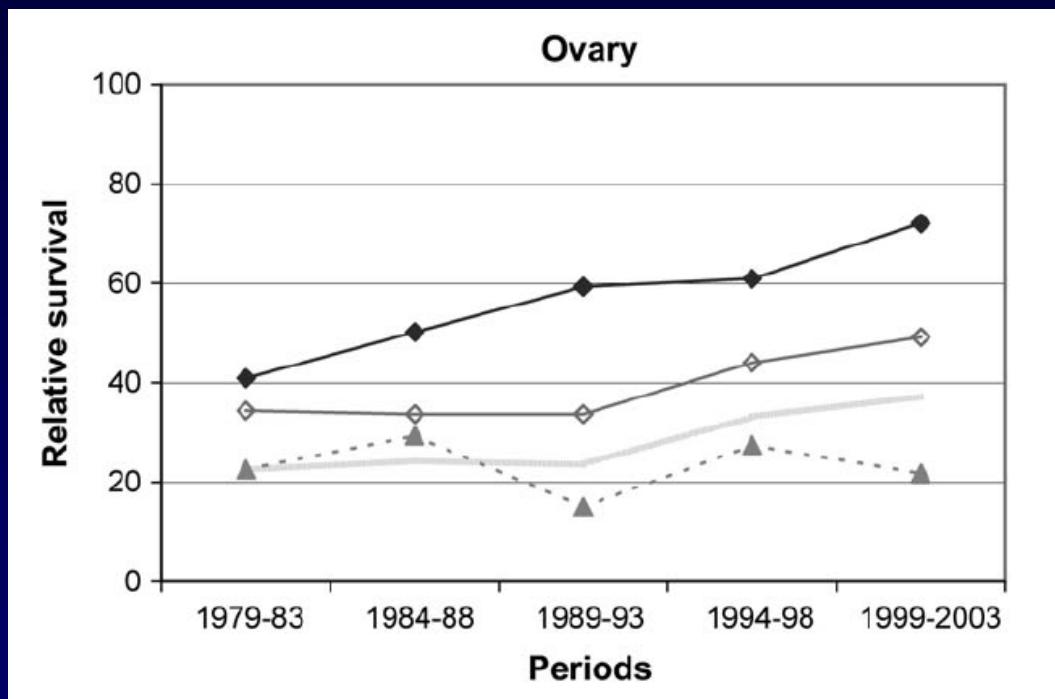
Chemotherapy +/- antiangiogenesis

Cytoreductive surgery

Thoughts



Results: Age-Specific Survival

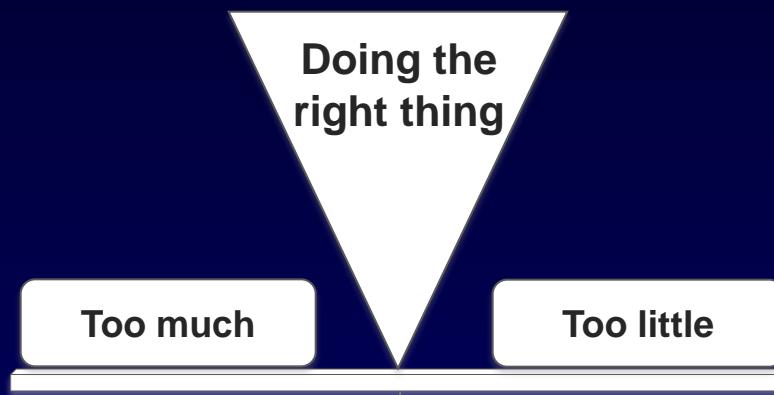


Highest age gradient
among all tumors!

Age Groups



The Dilemma: The Thin Line



Risk to increase

- Treatment-related frailty/disability
- Morbidity and mortality
- QoL deterioration
- Latrogenic worsening of prognosis

Miss the opportunity to improve:

- QoL
- Symptoms
- Prognosis

Sequence OP→ CTX

Aletti, et al (2010)¹

Aim: Definition of high-risk subgroups after standard sequence OP>CTX

- 4 spec. centers
- 1999-2006
- 576 pts

High-Risk 6.6%:

High and severe postoperative morbidity (up to 64%)
17 months OS
18.4% 3-months-mortality

High tumor dissemination or FIGO IV
poor performance (ASA) or
Poor nutrition (preop albumin <3.0 g/dL),
age ≥ 75 yrs

Thrall, et al (2011)²

Aim: Identification of factors associated with increased 30 day-mortality after cytoreductive surgery among elderly

- SEER-data
- 1995-2005
- 5457 pts ≥ 65 LJ

30-day mortality (8.2 %)

High-risk (30-day mortality: 12.7%)
age ≥ 75 yrs and FIGO IV or
age ≥ 75 yrs with comorbidities and FIGO III

1. Aletti GD, et al. *Gynecol Oncol.* 2011;120(1):23-28. 2. Thrall MM, et al. *Gynecol Oncol.* 2011;118(3):537-547.

The German Reality

Quality Assurance Program: QS-OVAR 2001, 2004, and 2008: OS for Patients With Intended Standard Strategy OP→CTX

	FIGO I-IV	FIGO IIIB-IV	FIGO IIIB-IV		
	(n = 2116)	(n = 1436)	(N = 289)	(N = 436)	(N = 166)
	(E = 1041)	(E = 896)	(E = 243)	(E = 333)	(E = 146)
OS in months					
median	43.5	30.3	14.1	17.3	10.6
95% CI	40.8 – 46.6	28.1 – 32.8	11.9 – 16.4	15.2 – 20.6	7.6 – 14.0
OS-rates in %					
3 months	92.7	90.2	80.0	78.4	72.3
6 months	89.1	85.5	69.1	71.6	60.0
9 months	86.2	81.7	61.6	67.6	53.8
12 months	82.3	76.9	55.2	61.0	46.4

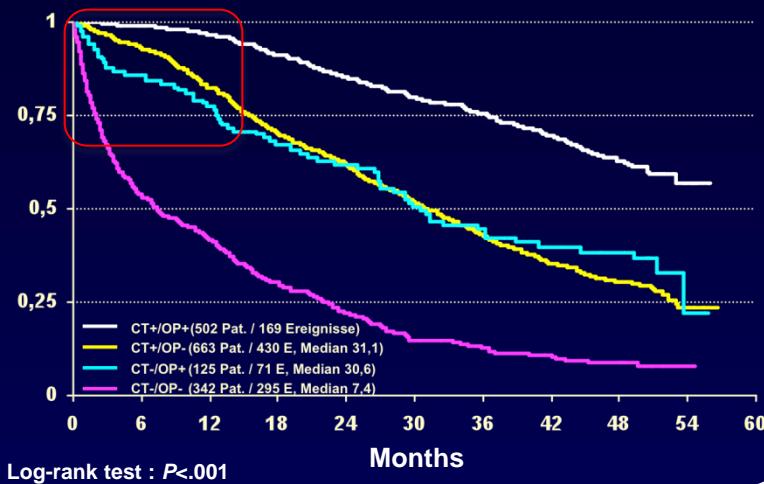
≈12% of all pts

Standard strategy
fails too often in
“vulnerable”
patients!!!

3-month mortality rate:
27.7%
6-month mortality rate:
40.0%

Basic Considerations

QS-OVAR 2001, 2004, 2008
Treatment quality and survival (IIB-IV)
(with "OP+" = complete CR)

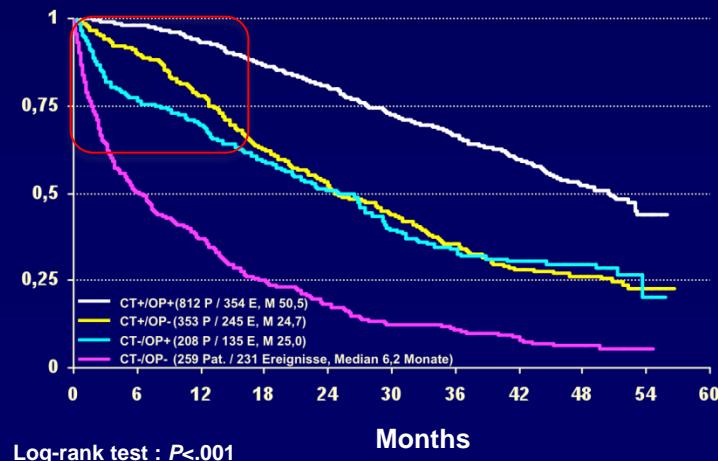


Ideally: optimal surgery and CTX

Limitations of surgery or CTX have a comparable longitudinal effect

But: limitations of CTX seem to have a stronger negative impact on short-term survival

QS-OVAR 2001, 2004, 2008
Treatment quality and survival (IIB-IV)
(with "OP+" = max 10 mm residuals)

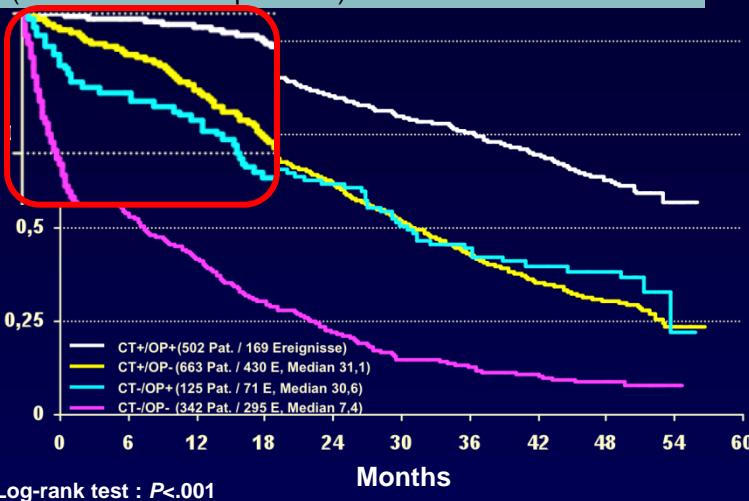


Basic Considerations

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Treatment quality and survival (IIB-IV)

(with "OP+" = complete CR)



Ideally: optimal surgery and CTX

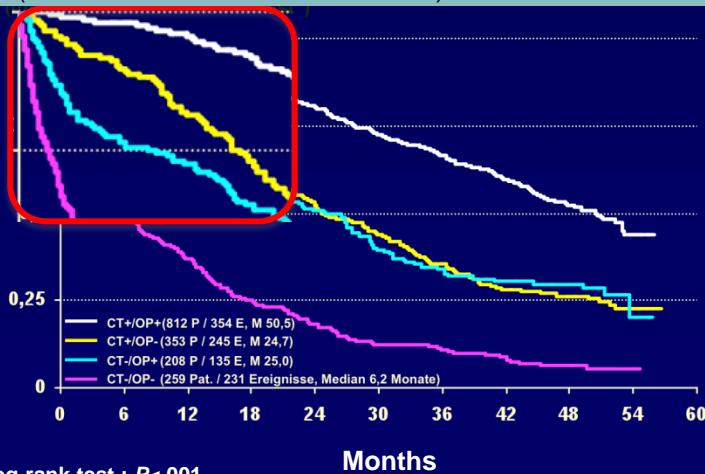
Limitations of surgery or CTX have a comparable longitudinal effect

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QS-OVAR 2001, 2004, 2008

Treatment quality and survival (IIB-IV)

(with "OP+" = max 10 mm residuals)



CT+/OP-

better than

CT-/OP+

?

Ovarian cancer in the octogenarian: Does the paradigm of aggressive cytoreductive surgery and chemotherapy still apply? [☆]

Kathleen N. Moore ^{*}, Monica S. Reid, Daniel N. Fong, Tashanna K.N. Myers, Lisa M. Landrum, Katherine M. Moxley, Joan L. Walker, D. Scott McMeekin, Robert S. Mannel

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Received 19 February 2008

Available online 20 May 2008

85 pts.

Median age: 83 (80 yrs - 93 yrs)

70% ≥1 comorbidity

72% FIGO III-IV

Primary treatment:

Only CTX (18%)

NACT (2%)

PDS+ CTX (80%)

Surgical outcome (n=61)

optimal CR: 74%

Multivisceral surgery: 41%

Two-Year Survival for Stage III & IV: Primary Surgery vs. Primary Chemo

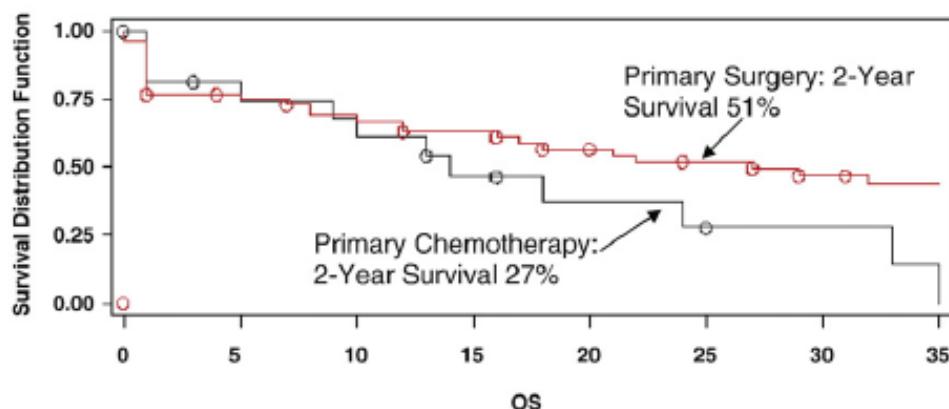


Table 2

Post-operative complications for the 70 patients who underwent primary surgical evaluation or surgery after 3–4 cycles of chemotherapy

n=70

Cardiac

Arrhythmias	10 (14%)
CHF	2 (3%)
MI	1 (1%)

Pulmonary

Pleural effusions	9 (13%)
Aspiration pneumonia	2 (3%)
Prolonged ventilatory requirement [□]	6 (9%)
Pulmonary embolus	1 (1%)

Gastrointestinal

Ileus > 6 days	8 (11%)
TPN requirement	8 (11%)

Hematologic/infectious

Transfusion	23 (33%)
Antibiotic use	20 (29%)
Mental status changes	7 (10%)

Surgical site complications

Wound infections	6 (9%)
Dehiscence	1 (1%)
Bowel anastomotic leak*	2 (9%)
Return to OR	3 (4%)

Length of hospital stay

Mean	12 days
Median	8 days
Range	2–54 days

Disposition[○]

Home	19 (50%)
Nursing facility	19 (50%)
Died prior to discharge	9 (13%)



US-QS-data (NIS)

1998-2007

N = 28,651 (7878 ≥ 70 yrs)

Defining the limits of radical cytoreductive surgery for ovarian cancer

Jason D. Wright^{a, e}, , Sharyn N. Lewin^{a, e}, Israel Deutsch^{b, e}, William M. Burke^a, Xuming Sun^a, Alfred I. Neugut^{c, d, e}, Thomas J. Herzog^{a, e}, Dawn L. Hershman^{c, d, e}

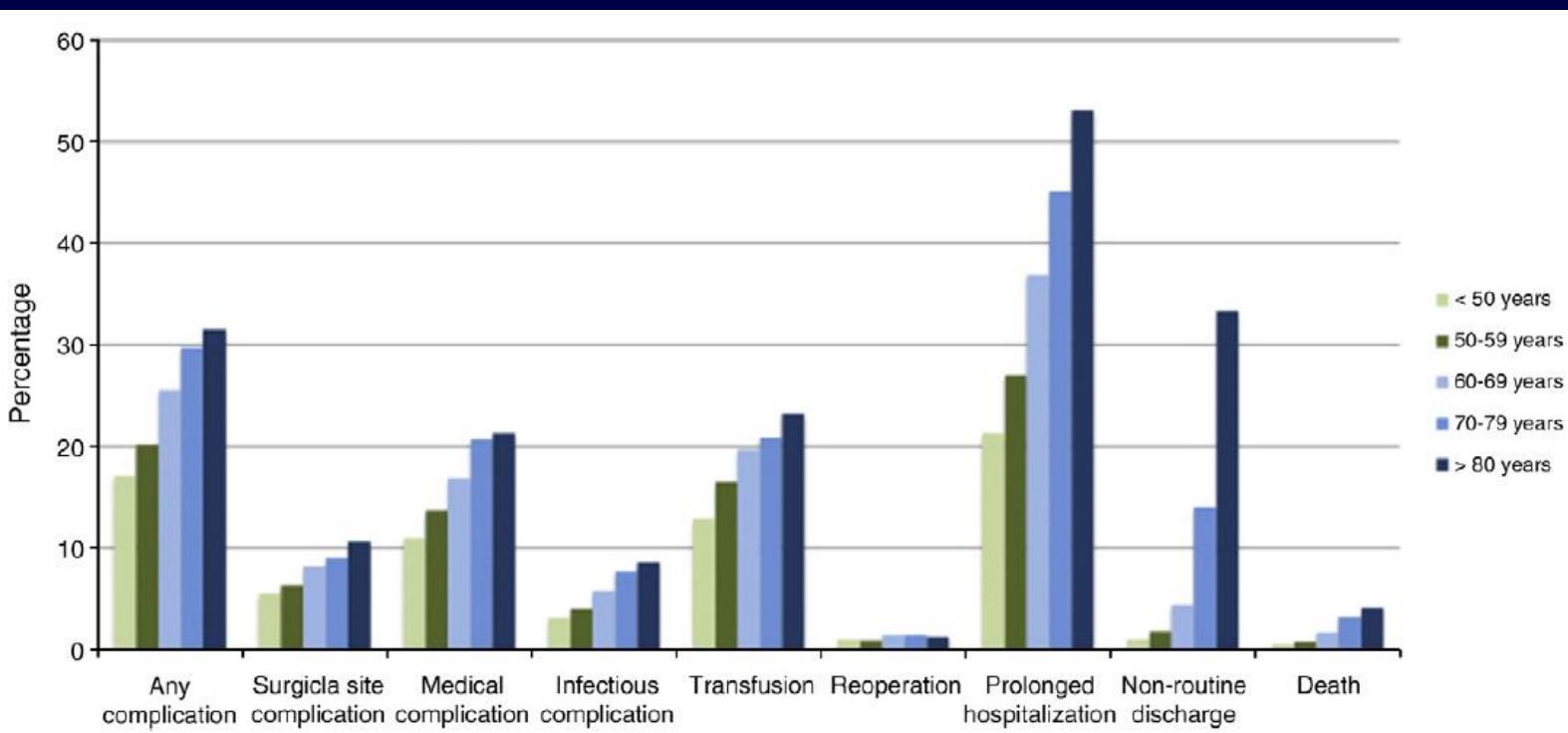


Fig. 1. Morbidity and mortality associated with cytoreductive surgery in women with ovarian cancer stratified by age at diagnosis (n = 28,651).



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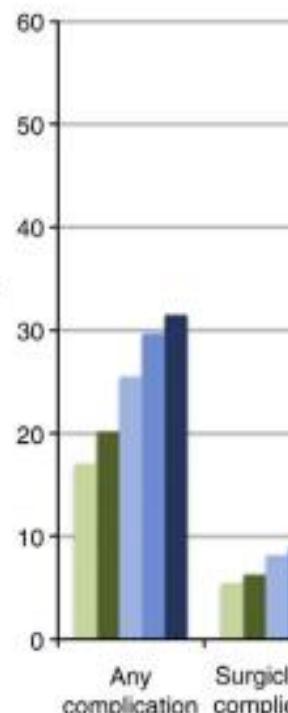


Fig. 1. Morbidity and mort

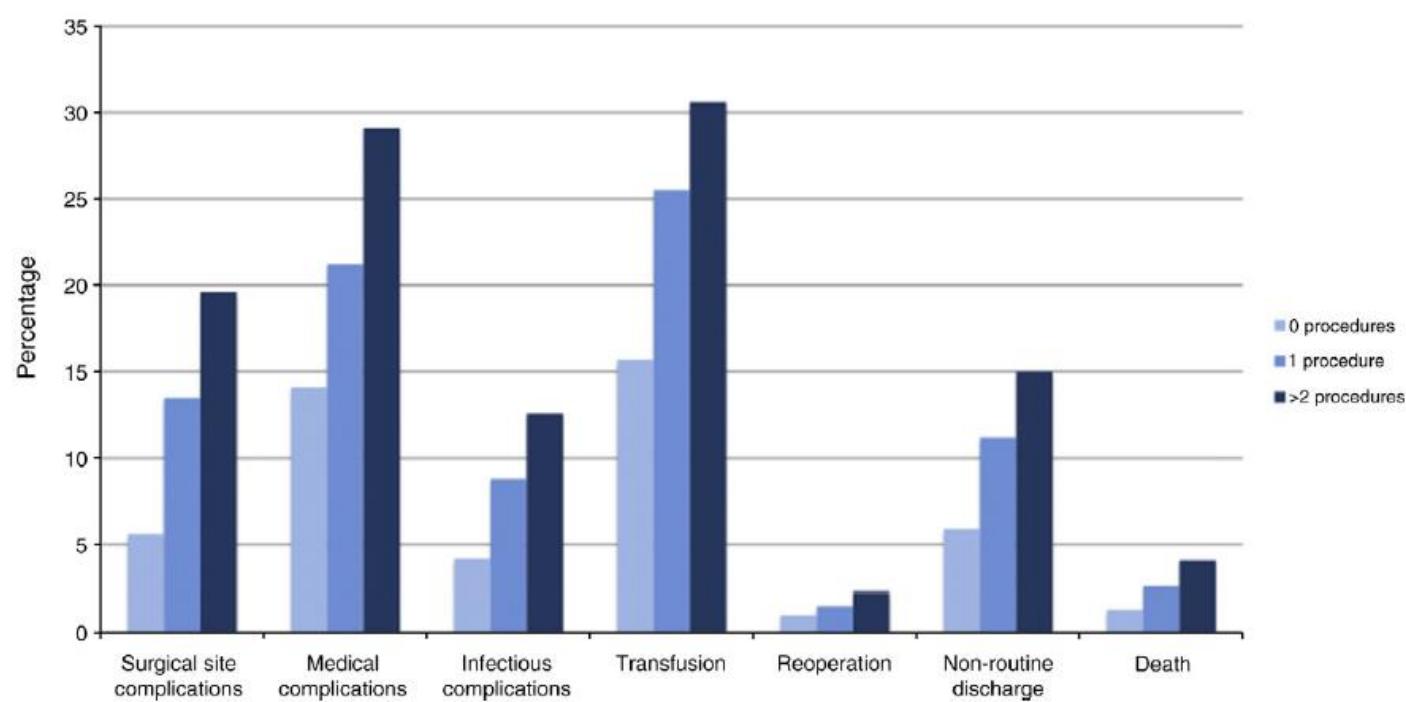


Fig. 2. Morbidity and mortality associated with cytoreductive surgery in women with ovarian cancer stratified by the number of extended procedures performed (n = 28,651).



US-QS-data (NIS)

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Table 4.

Morbidity of cytoreductive surgery stratified into age strata by the number of extended procedures performed.

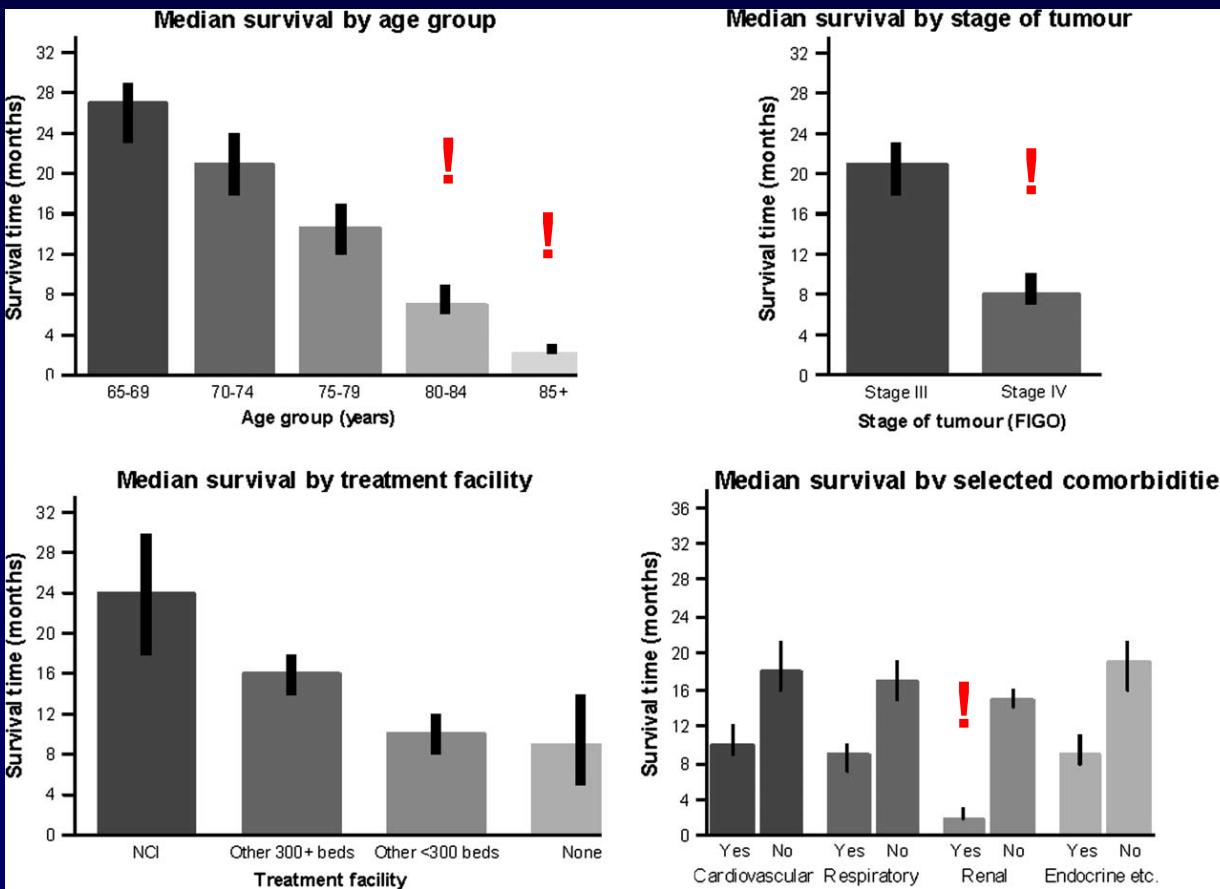
Procedures	< 50		50–59		60–69		70–79		≥ 80	
	(%)	OR	(%)	OR	(%)	OR	(%)	OR	(%)	OR
<u>Surgical site complications</u>										
0	(4.7)	Referent	(4.9)	Referent	(5.8)	Referent	(6.7)	Referent	(7.9)	Referent
1	(9.9)	1.96 (1.42– 2.70)*	(11.7)	2.60 (2.05– 3.30)*	(14.7)	2.64 (2.14– 3.25)*	(14.1)	2.36 (1.85– 3.00)*	(18.1)	2.40 (1.78– 3.24)*
≥ 2	(16.5)	3.45 (2.23– 5.35)*	(17.7)	4.22 (3.00– 5.92)*	(22.0)	4.31 (3.21– 5.79)*	(19.7)	3.36 (2.47– 4.56)*	(20.0)	2.73 (1.69– 4.42)*
<u>Medical complications</u>										
0	(10.2)	Referent	(12.2)	Referent	(15.6)	Referent	(18.5)	Referent	(18.3)	Referent
1	(15.7)	1.28 (1.01– 1.64)*	(18.4)	1.35 (1.13– 1.62)*	(20.2)	1.21 (1.03– 1.43)*	(24.9)	1.29 (1.10– 1.52)*	(28.9)	1.70 (1.33– 2.17)*
≥ 2	(23.7)	2.06 (1.41– 3.03)*	(29.7)	2.37 (1.82– 3.09)*	(25.7)	1.62 (1.24– 2.11)*	(33.1)	1.82 (1.43– 2.31)*	(33.3)	2.00 (1.32– 3.02)*

Postop
morbidity
Age and
extent of
surgical
procedures

Elderly patients with stage III or IV ovarian cancer: should they receive standard care?

JANDA, M.*; YOULDEN, D. R.†; BAADE, P. D.†; JACKSON, D.‡; OBERMAIR, A.‡

Population based
(SEER)
 $n= 3994 \geq 65$ yrs
FIGO III-IV
No data on surgical
outcome



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Population based
 (SEER)
 n= 3994 ≥ 65 yrs
 FIGO III-IV
 No data on surgical outcome

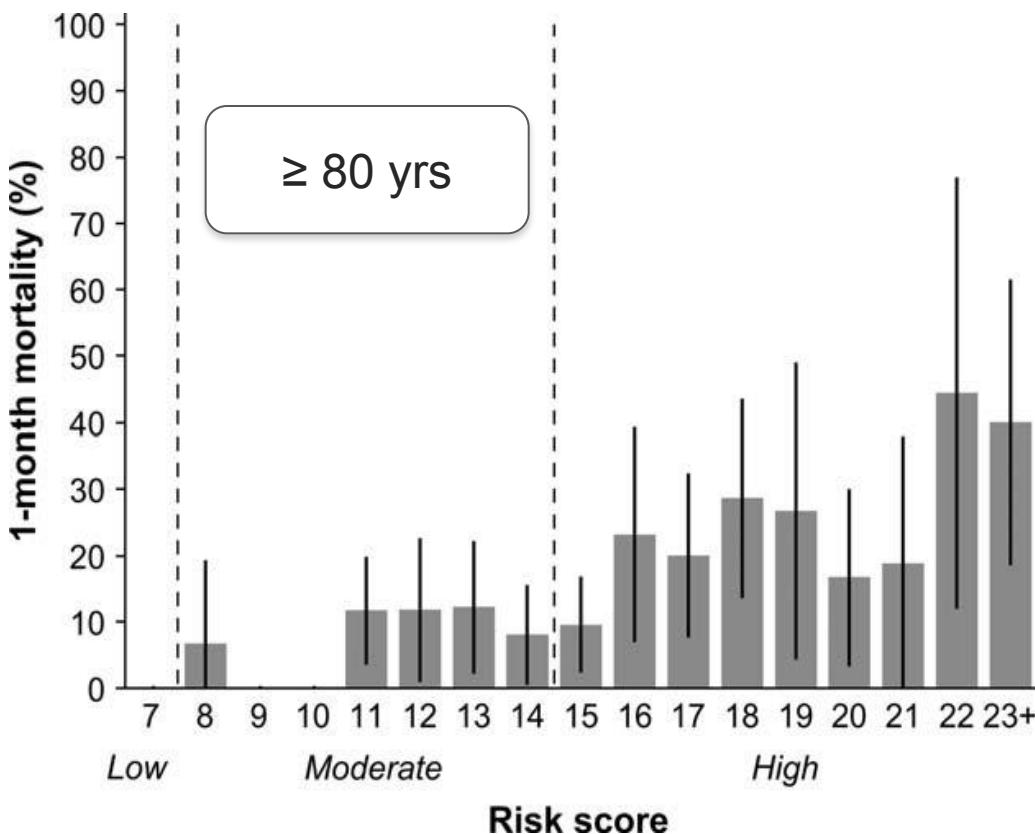
Table 3. Multivariate accelerated failure-time model to develop risk scores associated with 1-year survival (derivation cohort, n = 1,998)

Covariates ^a	1-year survival			
	Adjusted Hazard Ratios	95% CI	P-value	Risk Score ^b
Risk Factors				
Age group (yrs)		Wald chi-square = 266.68; df = 4; P < 0.001		
65–69	1.00			0
70–74	1.53	(1.20–1.94)	0.001	3
75–79	2.24	(1.77–2.82)	<0.001	5
80–84	3.18	(2.51–4.05)	<0.001	7
85 years and older	5.91	(4.63–7.55)	<0.001	11
Stage of tumor (FIGO)		Wald chi-square = 80.47; df = 1; P < 0.001		
Stage III	1.00			0
Stage IV	1.87	(1.63–2.14)	<0.001	4
Treatment facility ^c		Wald chi-square = 19.04; df = 3; P < 0.001		
NCI-Comprehensive Cancer Center	1.00			0
Other hospital/facility with 300 + beds	1.24	(0.90–1.71)	0.19	0
Other hospital/facility with <300 beds	1.59	(1.14–2.21)	0.006	3
Facility unknown/no facility recorded	1.71	(1.16–2.52)	0.007	3
Cardiovascular diseases		Wald chi-square = 5.36; df = 1; P = 0.021		
No	1.00			0
Yes	1.18	(1.03–1.36)	0.02	1
Respiratory diseases		Wald chi-square = 35.93; df = 1; P < 0.001		
No	1.00			0
Yes	1.51	(1.32–1.73)	<0.001	2
Renal diseases		Wald chi-square = 64.16; df = 1; P < 0.001		
No	1.00			0
Yes	2.63	(2.08–3.33)	<0.001	6
Endocrine, nutritional or metabolic diseases or immunity disorders		Wald chi-square = 38.34; df = 1; P < 0.001		
No	1.00			0
Yes	1.56	(1.36–1.80)	<0.001	3

Risk Score

Elderly patients with stage III or IV ovarian cancer: should they receive standard care?

JANDA, M.*; YOULDEN, D. R.†; BAADE, P. D.†; JACKSON, D.‡; OBERMAIR, A.‡



Risk group	n	1-month
		mortality*
Low-risk	19	0.0 (0.0-11.5)
Moderate-risk	235	8.9 (5.3-12.6)
High-risk	254	21.3 (16.2-26.3)

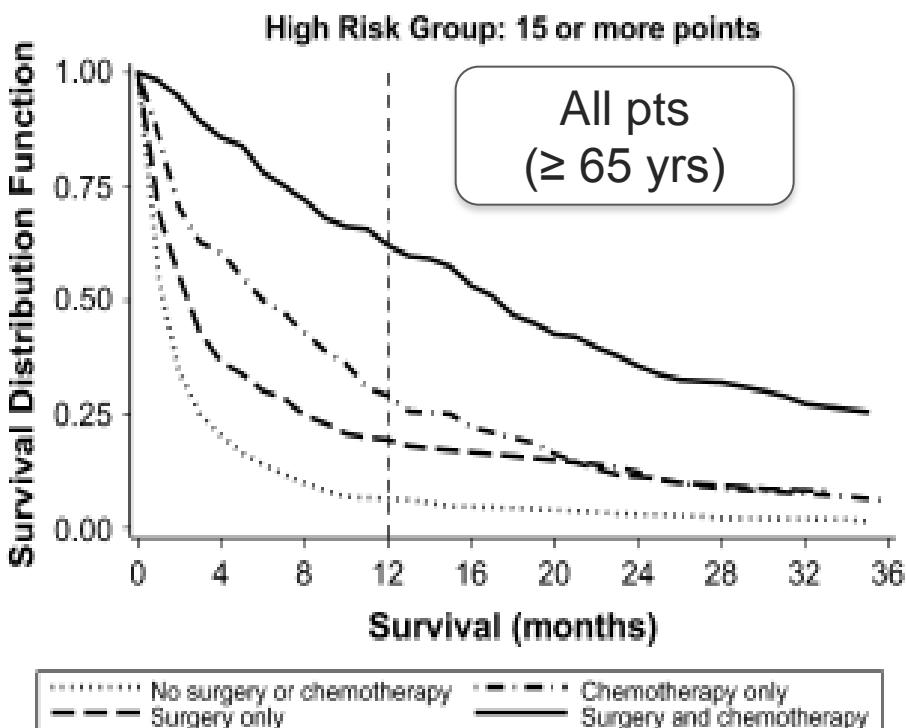
* 95% confidence intervals shown in italicised brackets

Cochrane-Armitage chi-square test for trend:
 $Z = 4.25, p < 0.001$

Elderly patients with stage III or IV ovarian cancer: should they receive standard care?

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Score-based decisions:
?



Treatment group	n	1-year survival* (%)	Median survival* (months)
No surgery or chemotherapy	367	13.6 (10.3-17.3)	2 (2-3)
Chemotherapy only	288	52.4 (46.5-58.0)	13 (12-15)
Surgery only	427	48.9 (44.1-53.6)	12 (8-15)
Surgery and chemotherapy	830	78.2 (75.2-80.9)	26 (24-28)

* 95% confidence intervals shown in italicised brackets

Log rank test for 1-year survival:

Chi-square = 689.55; df = 3; p < 0.001

!



Ovarian cancer in the elderly: Outcomes with neoadjuvant chemotherapy or primary cytoreduction [☆]

Kate A. McLean ^{*}, Chirag A. Shah, Sara A. Thompson, Heidi J. Gray, Ron E. Swensen, Barbara A. Goff

Department of Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, Washington, USA

- 175 pts
- Med age: 73 yrs (> 80 yrs 35%)
- >50% ≥1 comorbidity
- 83% FIGO III-IV
- 93% Carbo/Pac (med 6 cycles) prior or after surgery

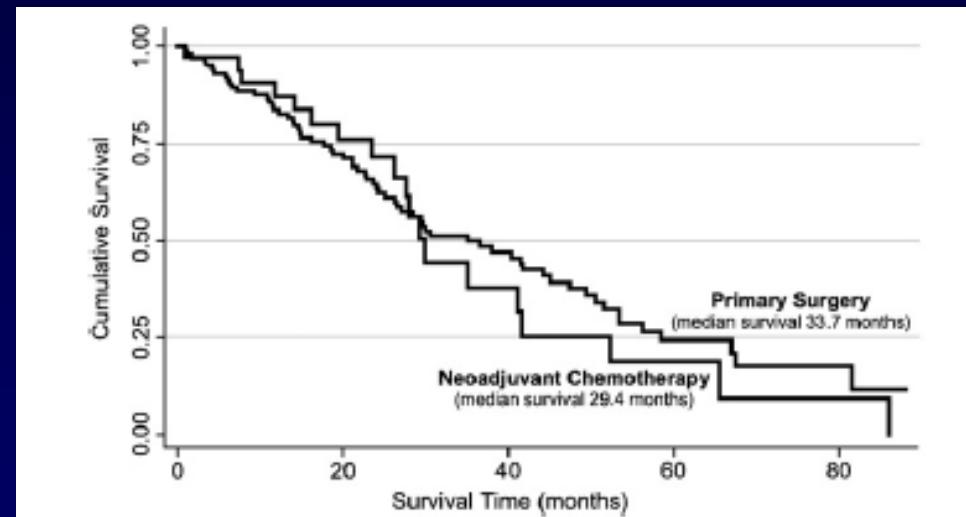


Fig. 1. Kaplan Meier survival curves for neoadjuvant chemotherapy vs. primary surgery.

Table 3

Complication rates and survival information.

Outcomes	Primary surgery	Neoadjuvant	OR	65-79	80+	OR
Surgical complications	87 (64.0)	20 (58.8)	0.80 (0.37–1.75)	89 (63.1)	18 (52.9)	1.01 (0.79–1.18)
Chemotherapy complications	47 (60.3)	16 (55.2)	0.79 (0.33–1.90)	52 (57.1)	11 (32.2)	1.04 (0.82–1.27)
Optimal cytoreduction	80 (65.6)	24 (77.4)	1.8 (0.72–4.52)	85 (67.5)	19 (55.8)	1.33 (0.54–3.23)
# Post-op deaths	3 (2.1)	0 (0.0)	^a	3 (2.1)	0 (0.0)	^a

^a Not applicable.

Comparative Effectiveness of Upfront Treatment Strategies in Elderly Women With Ovarian Cancer

Jason D. Wright, MD^{1,2}; Cande V. Ananth, PhD, MPH^{1,3}; Jennifer Tsui, PhD³; Sherry A. Glied, PhD⁴; William M. Burke, MD¹; Yu-Shiang Lu, MS¹; Alfred I. Neugut, MD, PhD^{2,3,5}; Thomas J. Herzog, MD^{1,2}; and Dawn L. Hershman, MD, MS^{2,3,5}

TABLE 1. Characteristics of Observational, Propensity Score Matched, Propensity Score IPTW, and Patients Grouped by Median Value of Instrumental Variable Cohort Grouped by Median Value of the Instrument^a

	Observational			Propensity Score Matched			Propensity Score IPTW			Instrumental Variable		
	Surgery	CT	P	Surgery	CT	P	Surgery	CT	P	Below	Above	P
Age, y	5346	2238	<.0001	1442	1442	.91	7356	7967	.41	21.4	22.0	.72
65-69	23.3	17.6		20.3	20.6		21.9	22.7		21.4	22.0	
70-74	29.1	24.9		27.1	27.4		28.4	28.5		28.2	27.3	
75-79	26.4	26.3		27.8	26.6		27.0	27.1		26.5	26.1	
≥80	21.2	31.1		24.8	25.4		22.7	21.7		23.9	24.6	
Year of diagnosis			<.0001			<.0001			<.0001			<.0001
1991-1996	33.8	23.4		34.3	24.9		34.2	24.2		26.8	21.1	
1997-2002	34.1	35.1		33.6	34.3		34.3	35.8		34.0	35.1	
2003-2007	32.1	41.5		32.1	40.8		31.6	40.0		29.2	43.9	
Race			.02			.73			.81			<.0001
White	90.9	88.7		89.5	89.7		89.9	89.8		91.0	89.0	
Black	4.1	5.5		5.3	4.8		4.7	4.6		4.5	4.5	
Hispanic	1.2	1.2		1.1	0.8		1.2	1.3		1.3	1.1	
Missing/other	3.8	4.6		4.2	4.7		4.2	4.3		3.2	5.4	
Marital status			<.0001			.87			.53			.17
Married	46.8	41.7		44.2	45.2		45.7	46.3		45.3	45.3	
Unmarried	50.5	56.1		53.7	52.8		51.7	51.3		52.4	51.7	
Unknown	2.8	2.2		2.2	2.1		2.7	2.4		2.3	3.0	
Socioeconomic status			.67			.99			.20			<.0001
Lowest (first) quintile	10.5	10.0		8.5	9.2		10.2	9.3		9.6	11.6	
Second quintile	17.6	19.0		17.6	17.7		18.0	17.7		17.5	18.9	
Third quintile	22.9	22.2		23.4	23.0		22.8	23.8		23.5	21.4	
Fourth quintile	23.1	23.2		23.7	23.7		23.2	22.5		24.7	20.8	
Highest (fifth) quintile	24.9	24.8		25.7	25.5		24.8	25.6		2.3	25.8	
Unknown	1.0	0.8		1.2	1.0		1.0	1.1		0.5	1.6	
Area of residence			.09			.07			.0009			.57
Metropolitan	92.1	93.2		94.8	93.2		92.6	93.9		92.5	92.2	
Nonmetropolitan	7.9	6.8		5.2	6.8		7.4	6.1		7.5	7.8	
SEER Registry			<.0001			.98			.02			<.0001
Atlanta	4.6	5.2		5.8	5.1		5.0	6.2		-	12.3	
Connecticut	10.1	11.3		12.2	11.7		10.7	11.2		7.0	16.0	
Detroit	12.0	11.9		11.4	10.3		12.0	12.7		19.5	-	
Greater California	10.0	13.8		12.5	12.7		10.6	10.8		2.2	25.4	
Hawaii	1.3	1.6		1.3	1.4		1.3	1.2		-	3.6	
Iowa	11.2	9.6		8.1	9.8		10.5	9.2		14.9	4.1	
Kentucky	4.0	3.6		4.0	3.7		4.1	3.8		1.3	8.1	
Los Angeles	11.4	8.9		9.5	9.5		10.7	10.9		17.3	-	
Louisiana	0.8	1.1		0.8	1.0		0.9	0.8		-	2.3	
New Jersey	10.5	12.3		11.8	11.9		10.6	10.3		10.0	12.6	
New Mexico	3.1	3.1		3.2	3.1		3.0	2.9		0.7	6.9	
Rural Georgia	0.1	0.2		0.2	0.3		0.2	0.1		-	0.4	
San Francisco	5.5	5.1		5.3	5.9		5.8	5.5		6.3	4.0	
San Jose	3.9	2.4		3.5	3.0		3.6	3.5		4.0	2.5	
Seattle	7.3	6.3		6.8	7.1		7.1	7.5		10.8	0.9	
Utah	4.3	3.7		3.5	3.6		4.0	3.4		6.0	1.0	
Grade			<.0001			.78			<.0001			.87
1	3.7	0.9		1.1	1.5		2.9	1.6		3.0	2.7	
2	17.5	7.9		11.5	12.0		15.1	15.2		14.5	14.8	
3	62.9	32.4		51.4	50.1		56.2	57.2		54.0	53.9	
Unknown	15.8	58.8		36.0	36.4		25.8	26.0		28.5	28.6	
Histology			<.0001			.70			.90			.02
Serous	66.7	34.3		54.3	52.2		59.5	59.1		58.0	55.8	
Mucinous	4.9	3.5		4.7	5.3		4.6	4.4		4.7	4.2	
Endometrioid	9.2	1.7		2.4	2.7		7.2	7.5		7.1	6.9	
Clear cell	2.5	1.0		1.8	1.5		2.1	2.1		2.3	1.8	
Other/not otherwise specified	16.7	59.5		36.8	38.4		26.6	26.9		28.1	31.4	
Comorbidity score			<.0001			.22			.23			.97
0	68.1	58.7		63.8	61.4		66.2	67.1		65.5	65.2	
1	21.1	25.0		23.9	24.1		22.1	22.0		22.2	22.4	
≥2	10.8	16.3		12.3	14.4		11.7	10.8		12.3	12.5	
grade												
I	34.5	26.3		48.2	49.3		38.8	37.4		40.4	37.4	
II	24.8	38.4		42.8	37.9		41.0	37.8		39.0	37.8	
III	11.0	2.8		3.9	3.9		1.2	0.8		0.8	0.8	
IV												

1000
800
600
400
200
000

1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0

Population-based (SEER)

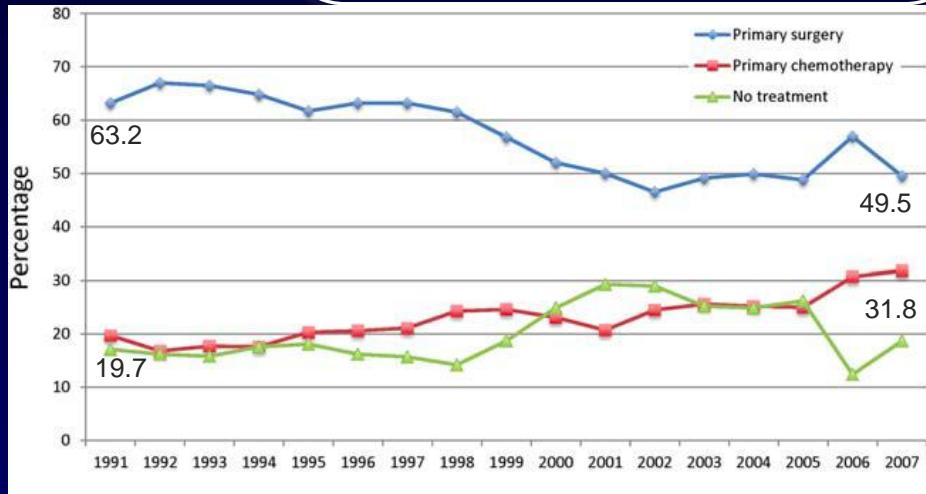
1991-2007

n = 9587 ≥65 yrs

FIGO II-IV

min 6 months OS

No data on surgical outcome



Upfront treatment for women with ovarian cancer (stratified by year of diagnosis)

Problem: strong selection bias

NACT more often when:

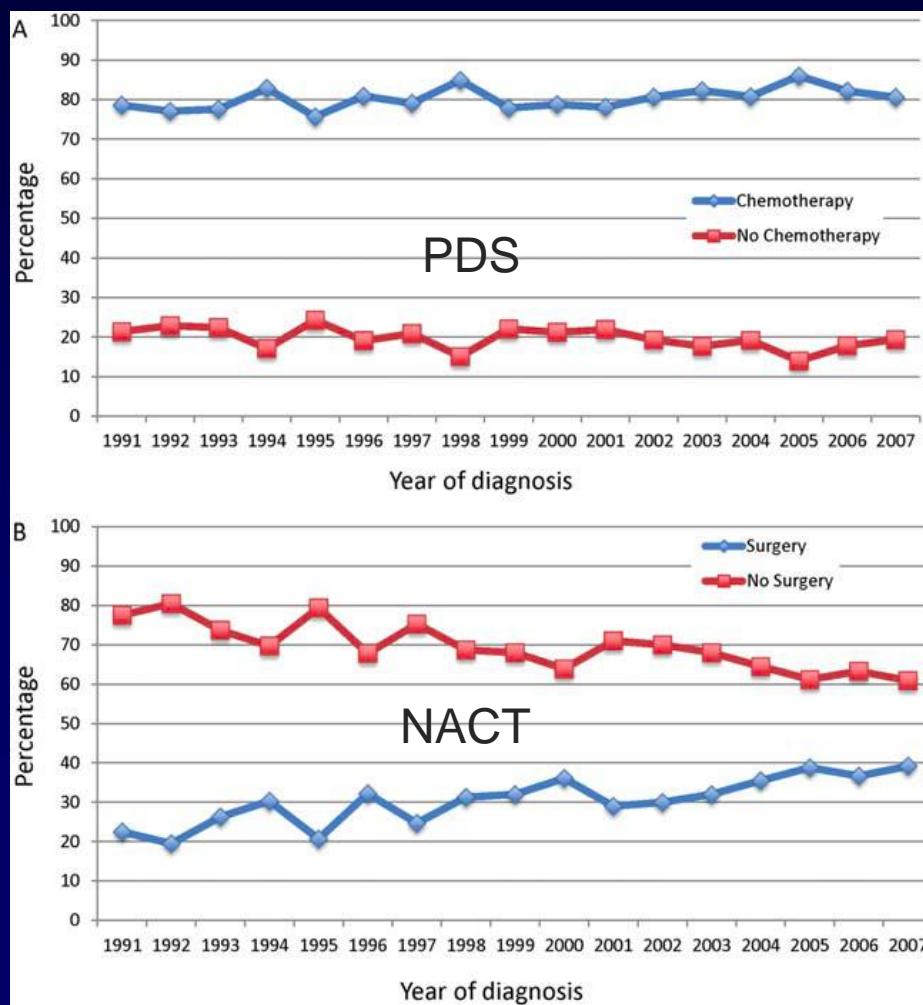
stage ↑, grade ↑, comorbidity↑, serous, metropolitan area

Under consideration of methodical aspects:

Only year of diagnosis (in favor of NACT)

Comparative Effectiveness of Upfront Treatment Strategies in Elderly Women With Ovarian Cancer

Jason D. Wright, MD^{1,2}; Cande V. Ananth, PhD, MPH^{1,3}; Jennifer Tsui, PhD³; Sherry A. Glied, PhD⁴; William M. Burke, MD¹; Yu-Shiang Lu, MS¹; Alfred I. Neugut, MD, PhD^{2,3,5}; Thomas J. Herzog, MD^{1,2}; and Dawn L. Hershman, MD, MS^{2,3,5}



OS-Outcome : PDS vs NACT

Observation:
28.8 vs 15.8, HR 1.26 (1.17-1.35)

Modell (IVA): HR 0.94 (0.58-1.52)

So far only
limited data

How do we proceed?

Detection of Frailty and Pre-Frailty

Comprehensive Geriatric Assessment (CGA)

A systematic procedure to detect disabilities and geriatric conditions that can contribute to frailty

Main domains:

- Somatic (nutritional status, comorbidity, polypharmacy...)
- Functional (ADL, IADL, mobility, falls...)
- Psychosocial (cognitive function, mood and depression, social support...)

Phenotype Model Standardized Definition For Frailty In Older Adults

Frailty as a clinical syndrome in which three or more of the following criteria were present:

- unintentional weight loss (10 lbs in past yr)
- self-reported exhaustion
- weakness (grip strength)
- slow walking speed
- low physical activity

Fried LP, et al. J Gerontol A Biol Sci Med Sci. 2001;56(3):46-56.

So far, no consensus on the definition and measurement of frailty

Prevalence and Outcomes of Frailty in Older Cancer Patients

Systematic Review

- Observational studies on prevalence/outcomes of frailty
- Solid or hematologic malignancy in older patients
- Identification of frailty by phenotype model or CGA
- 20 studies, with 2916 patients

RESULTS

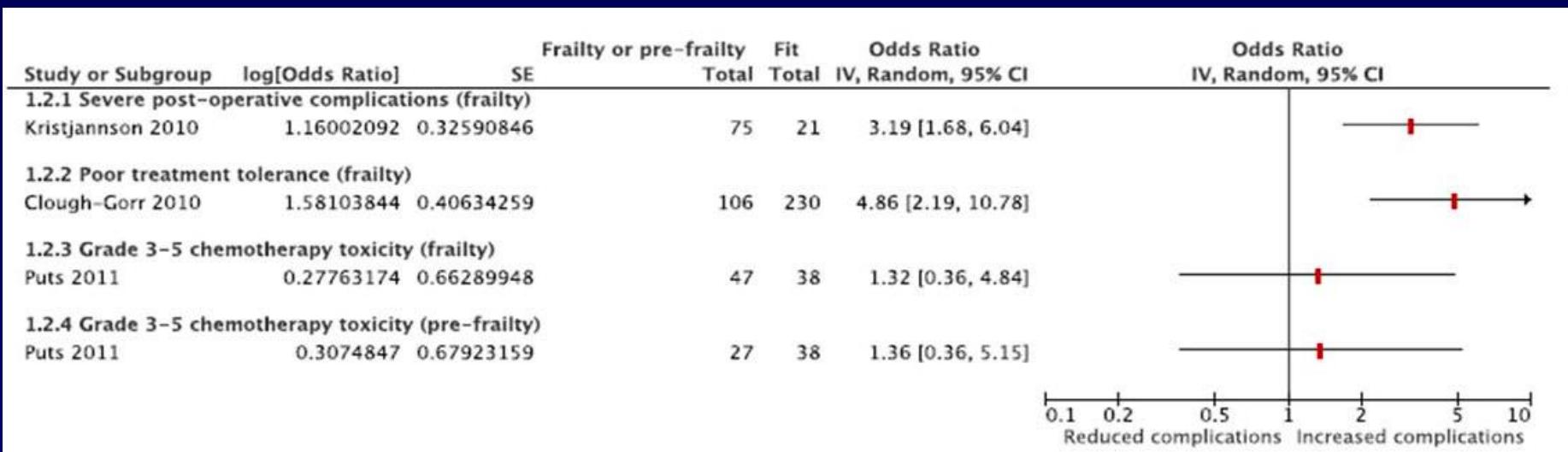
Prevalence

Frailty: 42% (6-86%)

Pre-frailty: 43% (13-79%)

Fit: 32% (11-78%)

RESULTS: Outcomes



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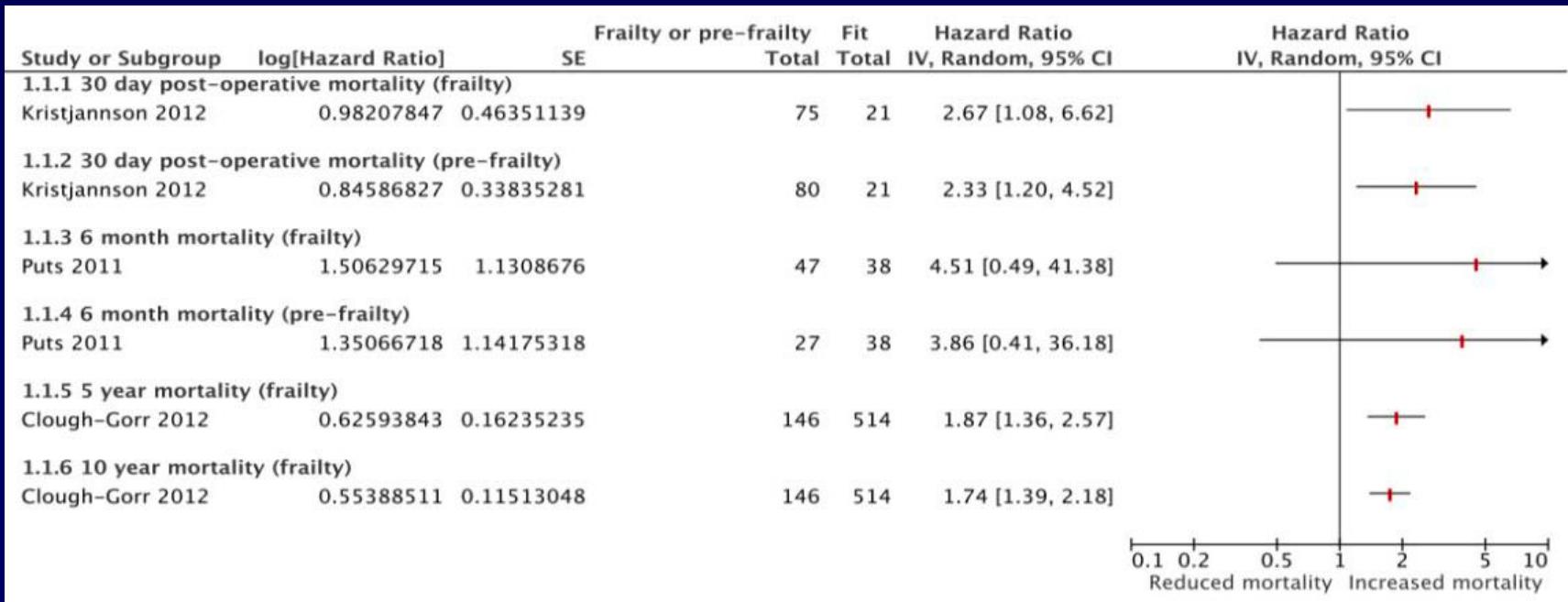
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RESULTS: Outcomes



Screening for Frailty

Screening methods to identify fit elderly patients who should receive standard cancer treatment based on vulnerable patients who should subsequently receive a CGA to guide tailoring of their treatment

Crucial:

High sensitivity to ensure identification of frail patients

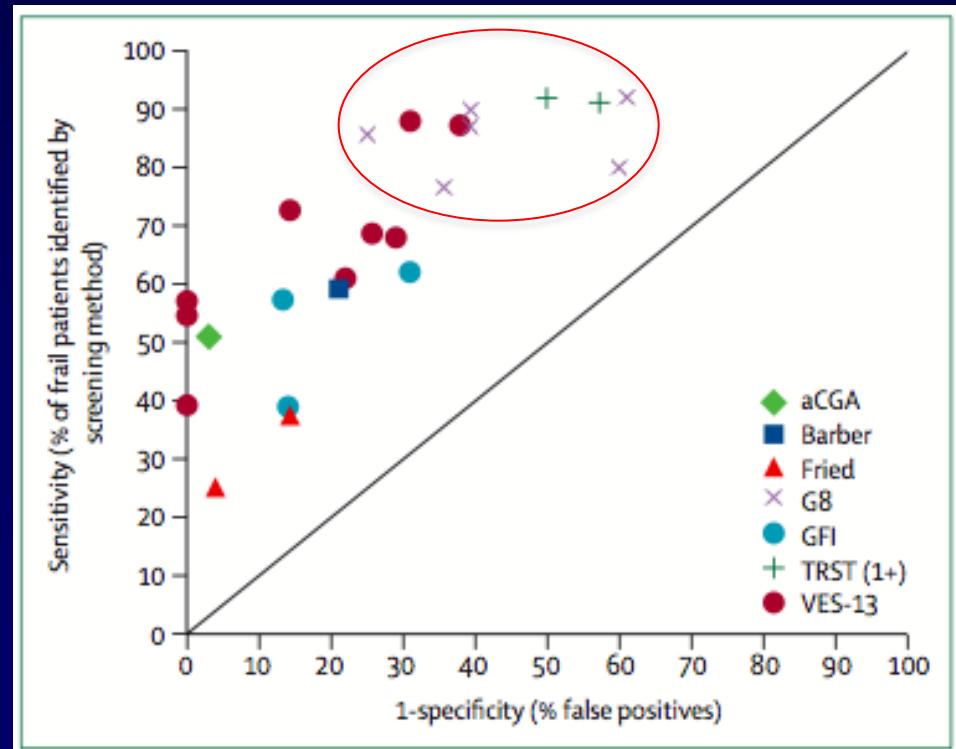
High specificity to optimize the time-saving potential of a two-stepped approach

Systematic Review

Studies on the association between frailty screening outcome and results of CGA in elderly patients with cancer

22 publications from 14 studies
Seven frailty screening methods

Screening Tool (no. of studies)	Sensitivity, %	Specificity, %
VES-13 (9)	68	78
G8 (6)	87	61
GFI (3)	57	86
TRST (2)	92	47
Fried criteria (2)	31	91
aCGA (1)	51	97
Barber (1)	59	79



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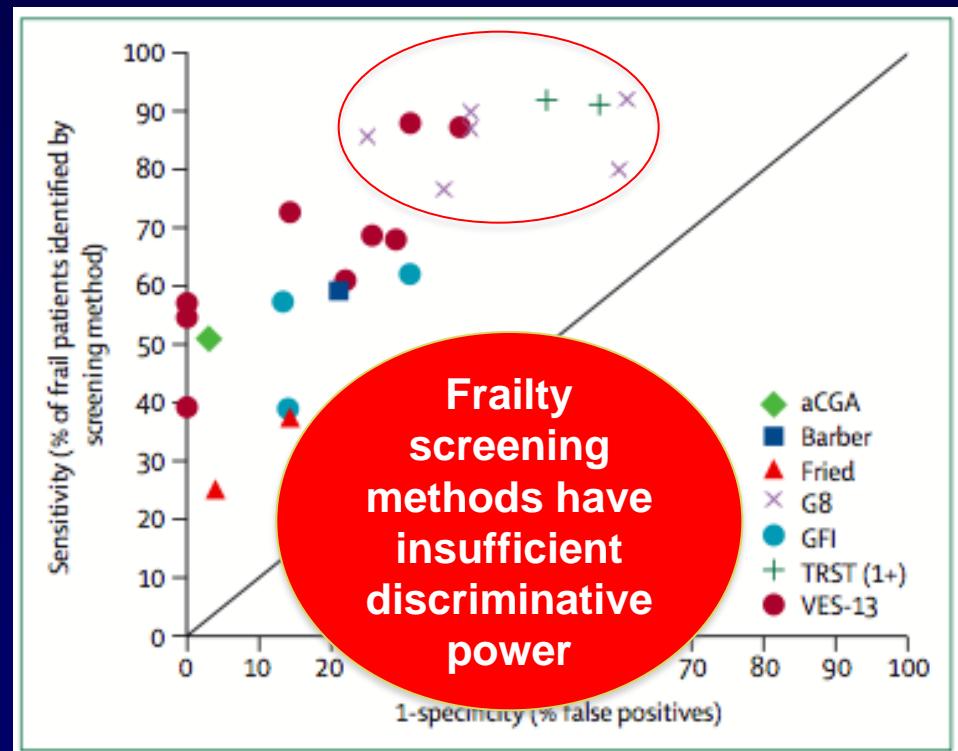
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Geriatric Vulnerability Score in AOC

The GINECO Experience

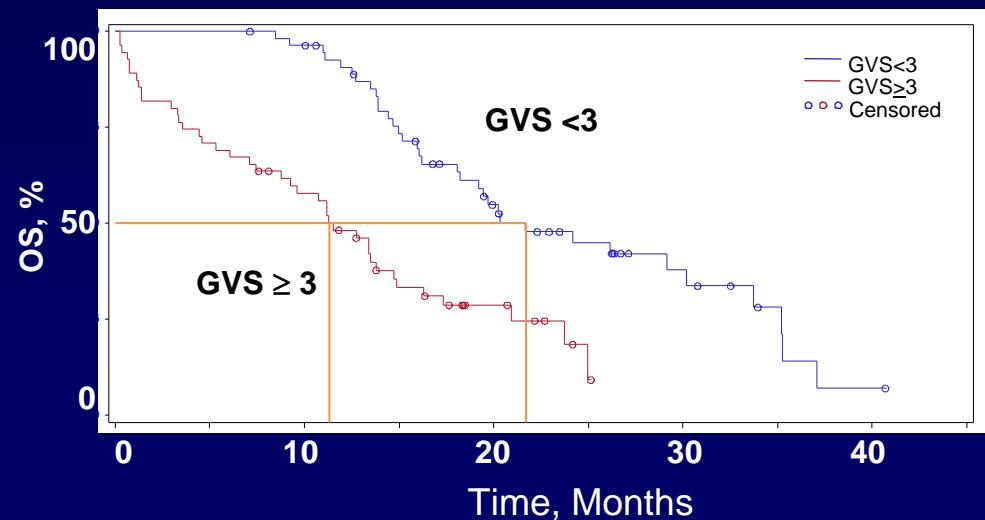
Open-label phase II multicenter trial

111 pts FIGO III-IV, ≥ 70 yrs of age, no planned IDS

Carboplatin AUC 5 q21x6

- 1° endpoint: confirm impact of psychogeriatric covariates on OS.
- 2° objectives: assessment of CTX feasibility and toxicity; PFS and response; impact of psychogeriatric covariates on treatment tolerance
- Median age 79 yrs
- PS/ECOG ≥ 2 : 47%
- PDS: 75% (16% CRR)

Overall Survival	Univariate (Log-rank)	
	HR	P
Geriatric vulnerability score (GVS) criteria :	1.41	<.0001
- ADL score <6		
- IADL score <25		
- Albuminemia <35 g/L		
- Lymphocytes <1 g/L		
- HADS score >14		
0 criterion	1	-
1 criterion	1.319	.57
2 criteria	1.297	.55
3 criteria	3.369	.008
4 criteria	3.771	.005
5 criteria	4.092	.01
GVS ≥ 3	2.939	<.0001



HR = 2.94 [1.79-4.84]; $P<.0001$
median 11.5 vs 21.7 months

Identifying the Optimal CTX for Vulnerable Patients



EWOC



Elderly Women Ovarian Cancer

Multicenter, randomized trial of carboplatin +/- paclitaxel in vulnerable elderly patients with stage IIB-IV advanced ovarian cancer

First ENGOT-GCIG international study of elderly patients in Ovarian Cancer

Potential participating Groups

GINECO, AGO, MITO, ANZGOG, Canada, JGOG, GOTIC, NSGO



**≥ 70 years old
GVS* ≥ 3**

R

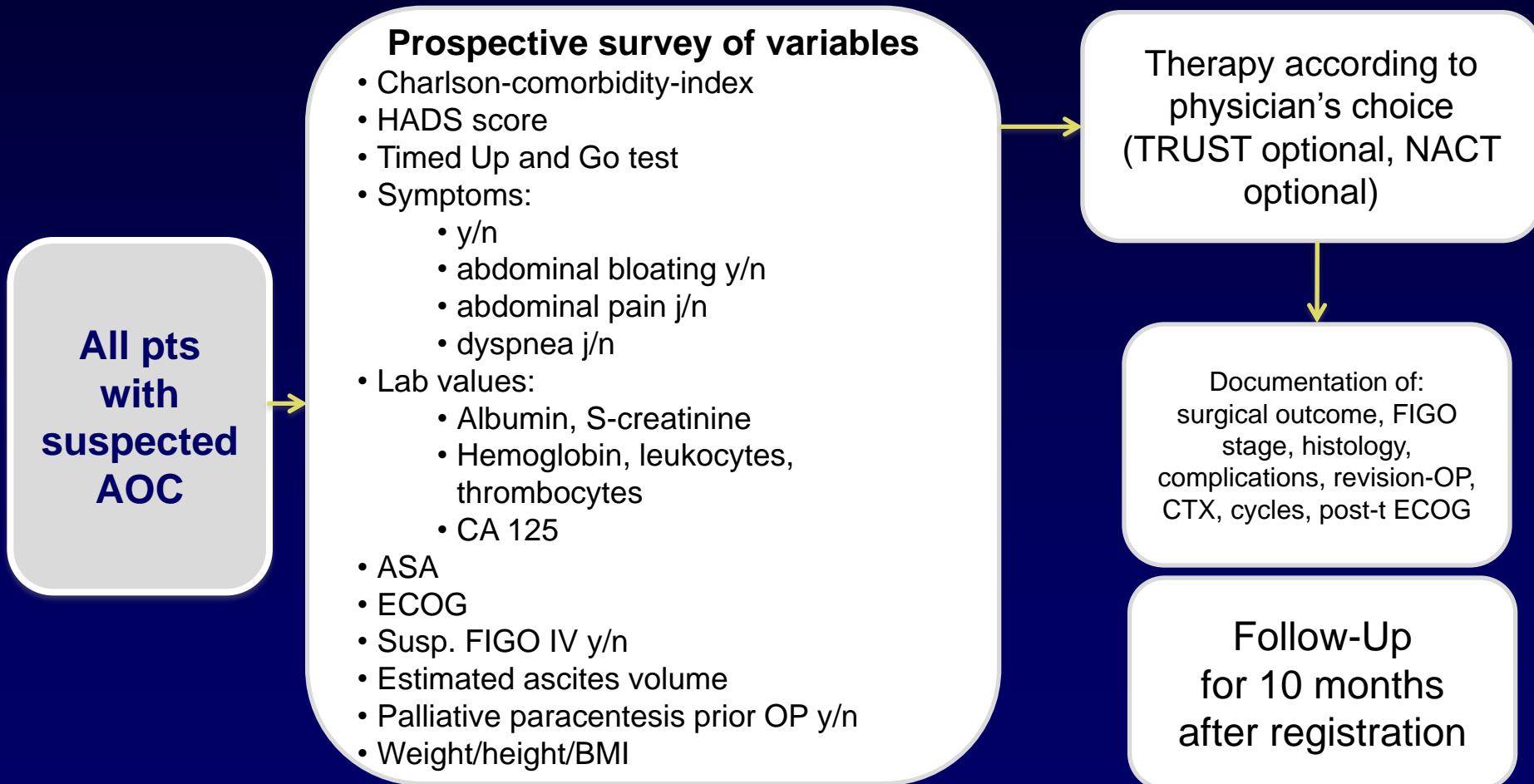
Arm A : carboplatin AUC 5 + paclitaxel 175mg/m² q21 X 6 cycles

Arm B: carboplatin AUC 5-6 q21 X 6 cycles

Arm C : carboplatin AUC 2 + paclitaxel 60 mg/m² weekly d1, d8, d15 q28x 6 cycles

Identifying Patients Without Benefit From Standard OP→CTX

AGO OVAR 19/FRAGILE



Primary endpoint: identification of fragile pts without benefit from standard OP→CTX (= progression/death within 10 months)

Secondary endpoint: 3-month survival, feasibility (time to 1st cycle, cycles, residual tumor, FIGO stage, ECOG after 6 months, 6-month PFS, revision surgery)

Conclusions

- There is a population of vulnerable and frail patients who do not benefit from our treatment
 - Potentially: we harm
- Cytoreductive surgery is critical
 - When it has negative impact on subsequent CTX
 - In patients 75+ yrs plus comorbidity and large tumor burden
- No consensus on the definition and measurement of frailty
- Future research should focus on:
 - Identification of vulnerable ovarian cancer patients
 - Tailored strategies: PDS, NACT, CTX-only

2015

Progress and Controversies in Gynecologic Oncology Conference

