Cancer Clinical Trials in Older Adults:

Lessons Learned

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November 14, 2019

- Shifting/shifted demographics
- Chemotherapy adverse event profiles carry age-based differences
- Efforts to enroll more older cancer patients to trials
- Working to define future research questions

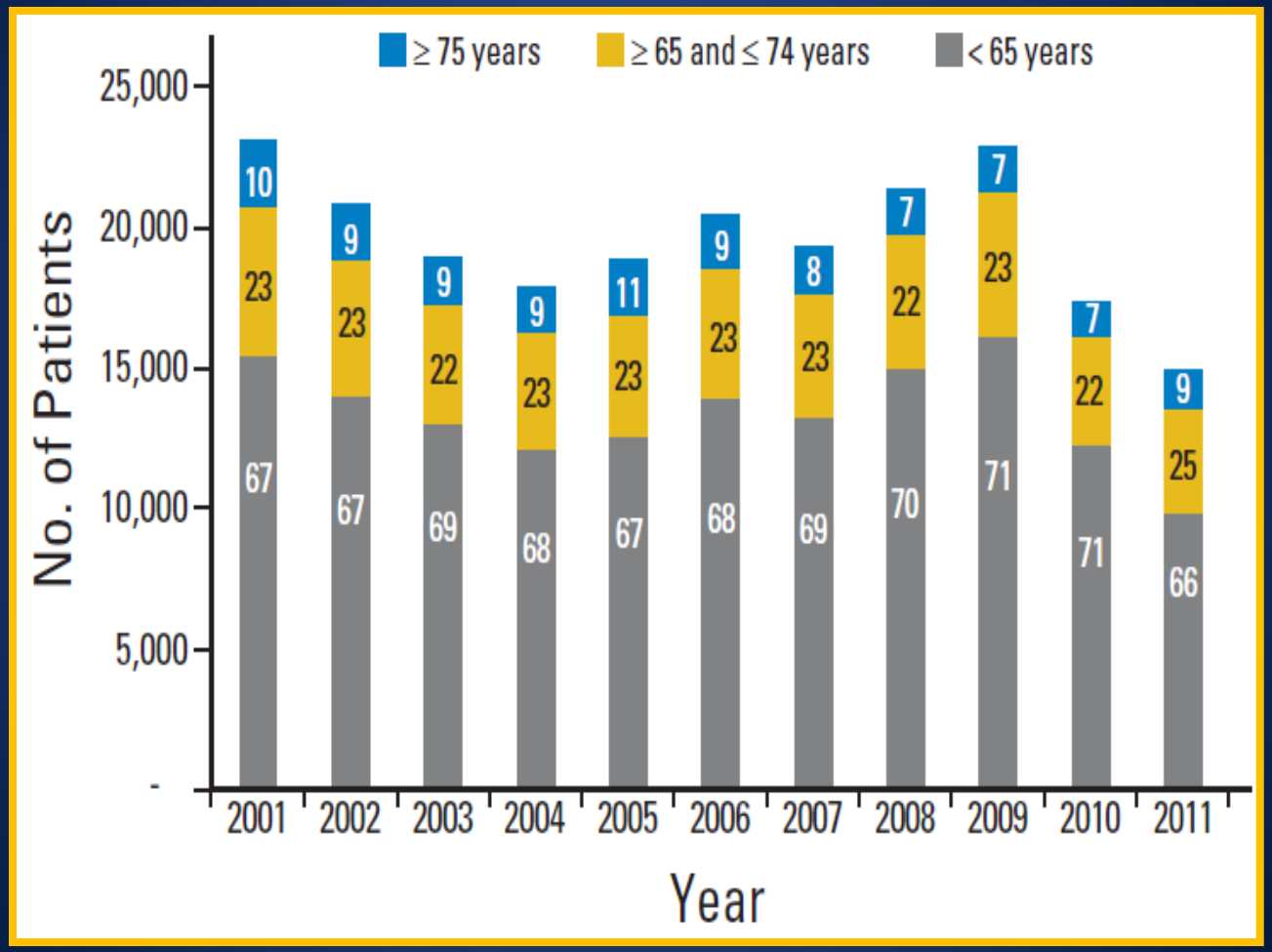
Trial Results and Contemporaneous Age-Based Demographics are Nonaligned……

Older Patients are Under-represented in FDA Registration Trials

And Worst in Patients >/= 75 Years of Age

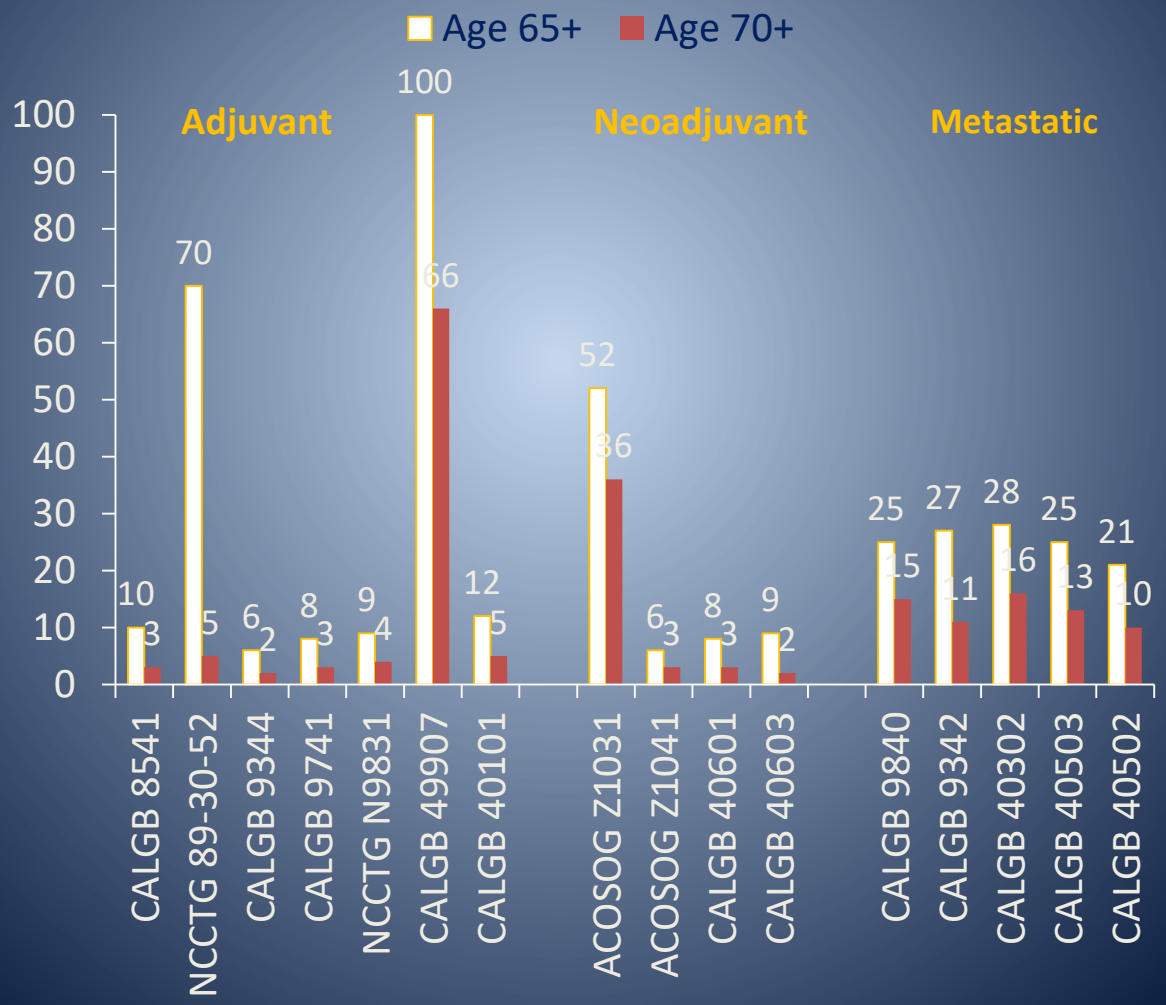
(graph courtesy of Harpreet Singh, M.D. from the FDA)

Accrual of Older Patients to NCI-Funded, Cooperative Group Trials is Poor and Not Improving



Hurria et al JCO 2014

The Alliance Experience in Breast Cancer: Accrual of Older Patients is Poor -- with the Exception of Trials Designed for Older Patients



Freedman et al JCO 2017

- Shifting/shifted demographics
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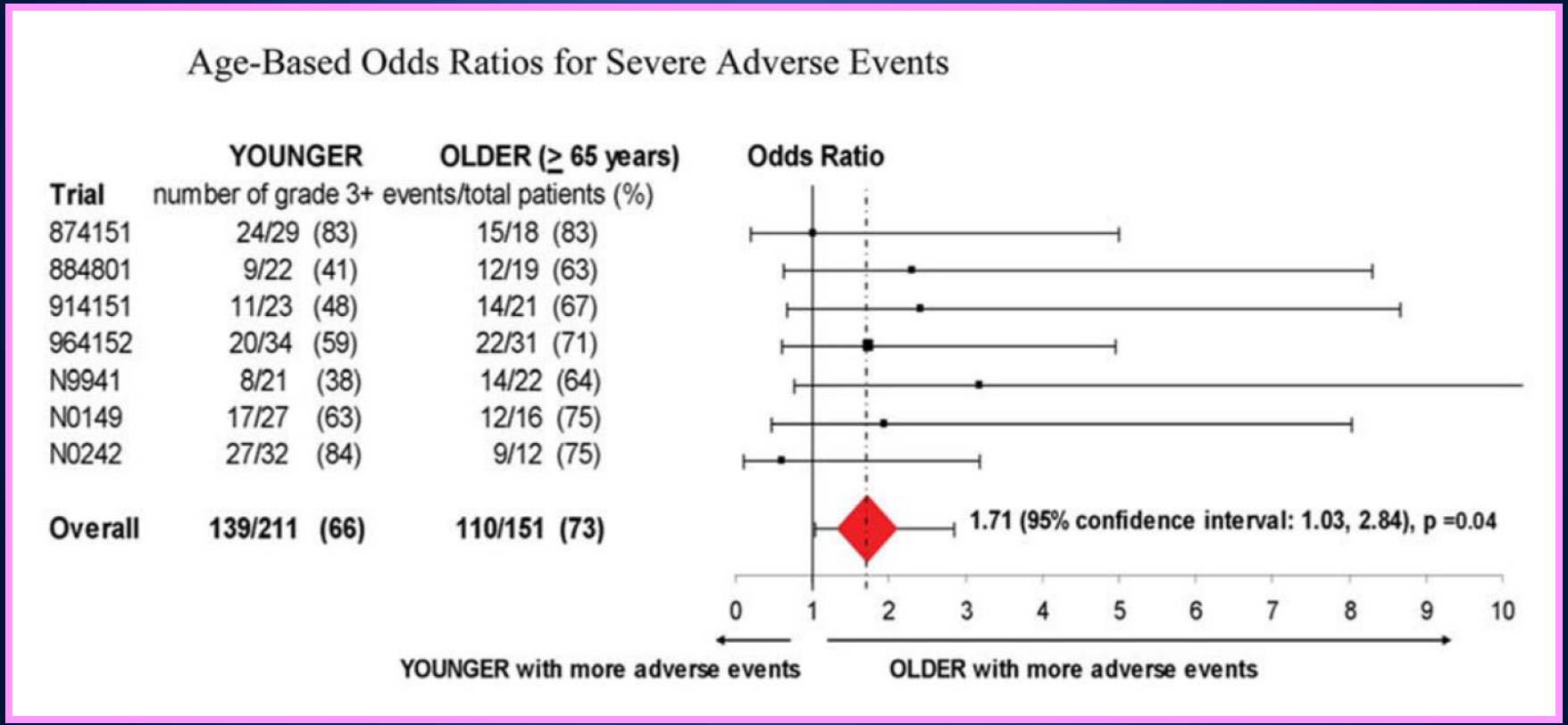
Adverse Events Tend to Be Worse in Older Patients Even with Chemotherapy

(Jatoi, et al, 2010)



Adverse Events Tend to Be Worse in Older Patients Even with Radiation (Schild et al, 2005)

Toxicity for Patients Treated with EP + Either BID-RT or QD-RT Based on Age Group[a]

Characteristics	Age < 70 (yrs) (n = 209) (%)	Age ≥ 70 (yrs) (n = 54) (%)	P value
Grade ≥ 3 toxicity			
All toxicity	190 (90.9)	51 (94.4)	0.58
Hematologic toxicity	186 (89)	49 (90.7)	0.81
Leukopenia	179 (85.6)	48 (88.9)	0.66
Thrombocytopenia	111 (53.1)	25 (46.3)	0.45
Anemia	13 (6.2)	6 (11.1)	0.24
Non-hematologic toxicity	95 (45.5)	28 (51.9)	0.45
Nausea	37 (17.7)	7 (13)	0.54
Emesis	30 (14.4)	5 (9.3)	0.38
Esophagitis	20 (9.6)	3 (5.6)	0.43
Pneumonitis	11 (5.3)	3 (5.6)	1.0
Renal	3 (1.4)	0 (0)	1.0
Grade ≥ 4 toxicity			
All toxicity	96 (45.9)	27 (50)	0.65
Hematologic toxicity	86 (41.1)	27 (50)	0.28
Leukopenia	71 (34)	23 (42.6)	0.27
Thrombocytopenia	43 (20.6)	14 (25.9)	0.46
Anemia	0 (0)	1 (1.9)	0.21
Non-hematologic toxicity	24 (11.5)	6 (11.1)	1.0
Nausea	1 (0.5)	0 (0)	1.0
Emesis	14 (6.7)	2 (3.7)	0.54
Esophagitis	0	0	1.0
Pneumonitis	0 (0)	3 (5.6)	0.008
Renal	1 (0.5)	0 (0)	1.0

Adverse Events Tend to Be Worse in Older Patients Even with Novel Agents

(Tallarico, et al, 2016)

"Among CLL pts (259 pts ³ 65), the effect of age on the probability of experiencing a grade 3 hematologic toxicity differed by treatment type (age-by-treatment interaction p = 0.047). Specifically, the adjusted odds ratio (OR) (age ³ 65 vs. < 65) for pts receiving only biologic therapy was 3.075 (95% CI: 1,15-8.25), and that for pts receiving biologic + chemotherapy was 1.044 (95% CI: 0.69 - 1.57). Similar results were seen in CLL pts for grade 4 hematologic toxicities (age-by-treatment interaction p = 0.033; biologic OR 6.937, 95% CI: 1.76-27.35; biologic + chemo OR 1.484, 95% CI: 1.04-2.13)."

Breast Cancer Research and Treatment (2018) 171:325–334
https://doi.org/10.1007/s10549-018-4828-5

CLINICAL TRIAL

Identification of risk factors for toxicity in patients with hormone receptor-positive advanced breast cancer treated with bevacizumab plus letrozole: a CALGB 40503 (alliance) correlative study

Daneng Li[1] · Linda M. McCall[2] · Olwen M. Hahn[3] · Clifford A. Hudis[4] · Harvey J. Cohen[5] · Hyman B. Muss[6] · Aminah Jatoi[7] · Jacqueline M. Lafky[7] · Karla V. Ballman[8] · Eric P. Winer[9] · Debu Tripathy[10] · Bryan Schneider[11] · William Barry[9] · Maura N. Dickler[4] · Arti Hurria[1]

Risk factors	*p* value
Age	<0.01
Decreased vision	0.04
Lower instrumental activities of daily living scores (OARS IADL[a])	0.02
Lower activities of daily living scores (MOS[b])	0.02
Needing help getting to places out of walking distance[c]	0.02
Limitation in climbing flights of stairs[d]	0.02
Limitation climbing one flight of stairs[d]	0.04
Limitation walking more than one mile[d]	0.04

Do these differences have consequences?

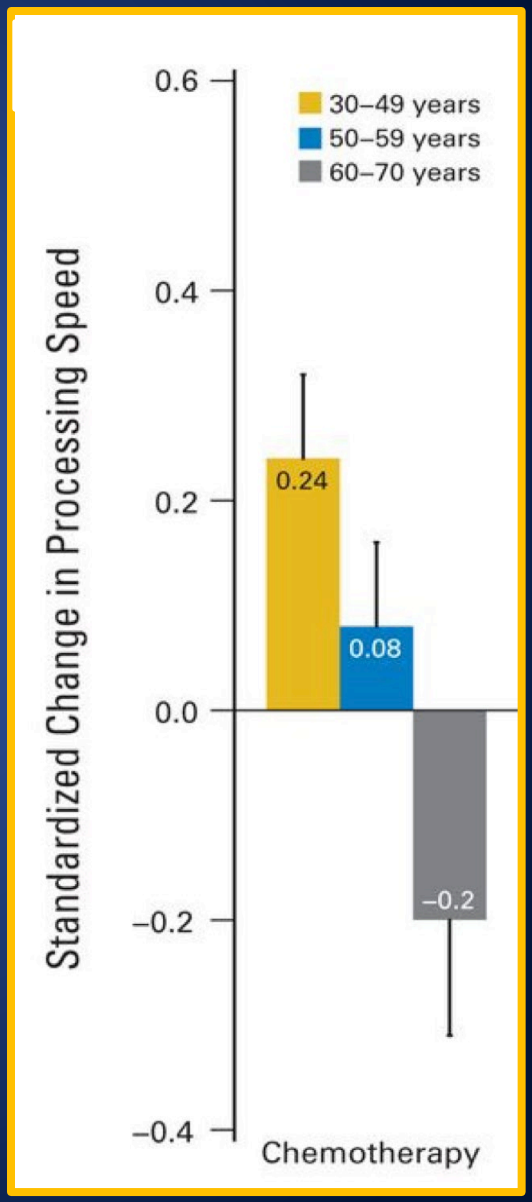
Yes.

Long-term toxicity
can compromise outcomes in
older patients…..

Cancer therapy has a negative impact on cognition in older patients

Pre- and post-treatment change in processing speed in patients with low cognitive reserve:

Mandelblatt *JCO* 2014



N=150,000+ patients (SEER database):

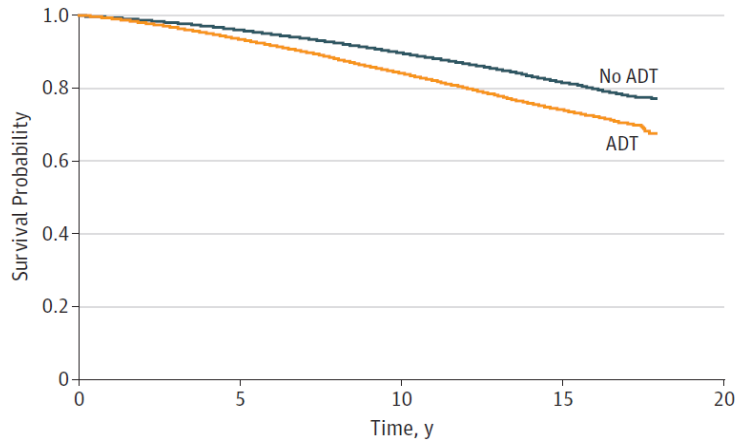
Table 2. Association Between ADT and Diagnosis of Alzheimer Disease or Dementia

Model	Hazard Ratio (95% CI)	
	Alzheimer Disease	Dementia
Association Between ADT and Diagnosis of Alzheimer Disease or Dementia		
Unadjusted	1.56 (1.51-1.60)	1.61 (1.57-1.65)
Propensity score-adjusted[a,b]	1.14 (1.10-1.18)	1.20 (1.17-1.24)
Association Between ADT Dose and Diagnosis of Alzheimer Disease or Dementia[c]		
Unadjusted		
1-4 ADT doses	1.41 (1.36-1.46)	1.40 (1.37-1.44)
5-8 ADT doses	2.03 (1.94-2.12)	1.99 (1.93-2.07)
>8 ADT doses	1.94 (1.82-2.08)	1.96 (1.86-2.08)
No ADT	1 [Reference]	1 [Reference]
Propensity score-adjusted[a,b]		
1-4 ADT doses	1.19 (1.15-1.24)	1.19 (1.15-1.23)
5-8 ADT doses	1.28 (1.22-1.35)	1.24 (1.19-1.29)
>8 ADT doses	1.24 (1.16-1.34)	1.21 (1.15-1.28)
No ADT	1 [Reference]	1 [Reference]

Jayadevappa R, et al. 2019

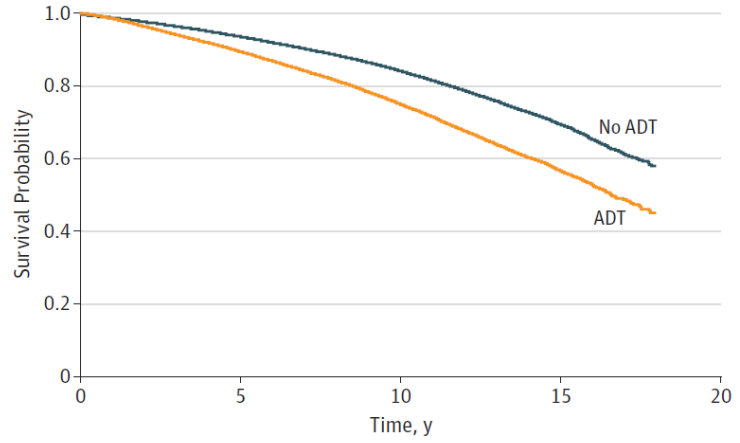
The time to diagnosis of Alzheimer's/ dementia was shorter with androgen deprivation therapy (ADT).

Figure 2. Survival Curve for Alzheimer Disease



No. at risk									
No ADT	91507	78405	67952	58583	50438	43293	23678	9123	3370
ADT	62330	53787	44727	37075	30229	24328	12108	3835	1257

Figure 3. Survival Curve for Dementia



No. at risk									
No ADT	35071	34969	34802	34529	34120	33309	18875	7329	2838
ADT	18832	18709	18508	18229	17805	17108	9046	2892	1027

The ASCO Post

Falls in Older Patients With Cancer: Recognizing and Reducing the Risk

"… a fall occurs in 30% to 50% of cancer patients 65 years of age or older."

By Aminah Jatoi, MD
January 25, 2017

Guest Editor

Stuart M. Lichtman, MD

Geriatrics for the Oncologist is guest edited by **Stuart M. Lichtman, MD**, and developed in collaboration with the International Society of Geriatric Oncology (SIOG). Dr. Lichtman is an Attending Physician at Memorial Sloan Kettering Cancer Center, Commack, New York, and Professor of Medicine at Weill Cornell Medical College, New York. He is also President of SIOG. For more information about geriatric oncology, visit www.siog.org and the new ASCO Geriatric Oncology website (www.asco.org/practice-guidelines/cancer-care-initiatives/geriatric-

In older patients, a current or previous cancer diagnosis confers a 15% to 20% greater risk of suffering a fall.[1] Defined as an "unexpected event in which the participant comes to rest on the ground, floor, or lower level," a fall occurs in 30% to 50% of cancer patients 65 years of age or older.[2-4] Because of suboptimal reporting, the actual rate may, in fact, be even higher.[5]

Falls can be catastrophically injurious, resulting, for example, in bone fractures, head trauma, and erosion of self-confidence, detracting from a patient's ability to live independently.[6] Curiously, among older patients, progressively advancing age does not appear to increase the risk of falling, but it does increase the risk of injury from a fall. Indeed, older patients run a greater risk of hospitalization and long-term institutional confinement after a fall; and falls rank as the sixth leading cause of death in older people.[3,7]

Risk Factors

Why are falls so common in older patients with cancer? As oncologists, many of our well-intentioned efforts to treat cancer increase the risk for falling. Neuropathy-inducing chemotherapy agents make patients less sure-footed, thus predisposing them to falls. Vision changes from chemotherapy

Motor neuropathy increases fall risk….
(Gewandter JS, et al. 2013 University of Rochester CCOP).

Predictor	Adjusted odds ratio estimate			
	Odds ratio	95 % confidence interval		*p*
Age	1.019	0.983	1.057	0.32
Gender (female vs. male)	1.019	0.466	2.267	0.96
Race (white vs. non-white)	0.501	0.204	1.304	0.15
Marital status				
Married vs. widowed	0.672	0.233	2.165	0.49
Married vs. other	1.094	0.488	2.646	0.83
Education (≥partial college vs. HS or less)	1.449	0.714	3.072	0.310
Previous surgery (yes vs. no)	0.602	0.241	1.571	0.29
Previous RT (yes vs. no)	1.379	0.680	2.828	0.37
Cancer type				
Breast vs. other	0.506	0.197	1.298	0.16
Alimentary vs. other	1.089	0.446	2.673	0.85
Sensory neuropathy	1.036	0.946	1.34	0.45
Motor neuropathy	1.127	1.029	1.238	0.01*
Any functional impairment (yes vs. no)	1.110	0.498	2.396	0.80

- Shifting/shifted demographics
- Chemotherapy adverse event profiles carry age-based differences.
- Efforts to enroll more older cancer patients to trials
- Working to define future research questions.

Strategies to Improve Accrual

(Alliance Survey with Responses from 1,146 Members)

Strategy	Frequency Ranked	Ranking 1	Ranking 2
Create more dedicated trials	**416/1146**	**N=173**	**N=139**
Minimize exclusion criteria focused on comorbidity	**407/1146**	**N=189**	**N=79**
Distinct strategies for 65+ and 70+	**380/1146**	**N=79**	**N=112**
Require all trials to have an expansion dedicated endpts for older pts	**344/1146**	**N=97**	**N=113**
Create standardized educational intervention for family/caregivers	256/1146	N=41	N=69
Provide extra credits to sites when they enroll older pt	252/1146	N=63	N=77
Create standardized educational intervention for older pts	235/1146	N=57	N=66
Ensure inclusion of sites who treat high proportions of older pts	205/1146	N=36	N=54
Require sites to capture why a patient declines enrollment	195/1146	N=21	N=61
Create standardized educational intervention for providers	157/1146	N=30	N=43
Require that all trial concepts be discussed and approved by Cancer in the Elderly Committee as part of approvals process	151/1146	N=76	N=32
Require sites to screen and record all older pts, who is approached, and they decline/accept	128/1146	N=21	N=40
Require trials to have specific target number of older pts	116/1146	N=27	N=28
I have other ideas or I don't like these options	48/1146	N=21	N=12

Freedman et al. the Oncologist, 2018

- Shifting/shifted demographics
- Chemotherapy adverse event profiles carry age-based differences.
- Efforts to enroll more older cancer patients to trials
- And such differences should help define future research questions.

Should the answer just be,
“Enroll more older patients on trials”?

World Health Organization

HelpAge International/C. Canham

Fact 4: When it comes to health, there is no 'typical' older person

Biological ageing is only loosely associated with person age in years. Some 80 year-olds have physical and mental capacities similar to many 20 year-olds. Other people experience declines in physical and mental capacities at much younger ages.

World Health Organization

What is old?

65

Courtesy of Arti Hurria, M.D.

Acknowledging the "Gray"

Factors other than chronological age that predict morbidity & mortality in older adults

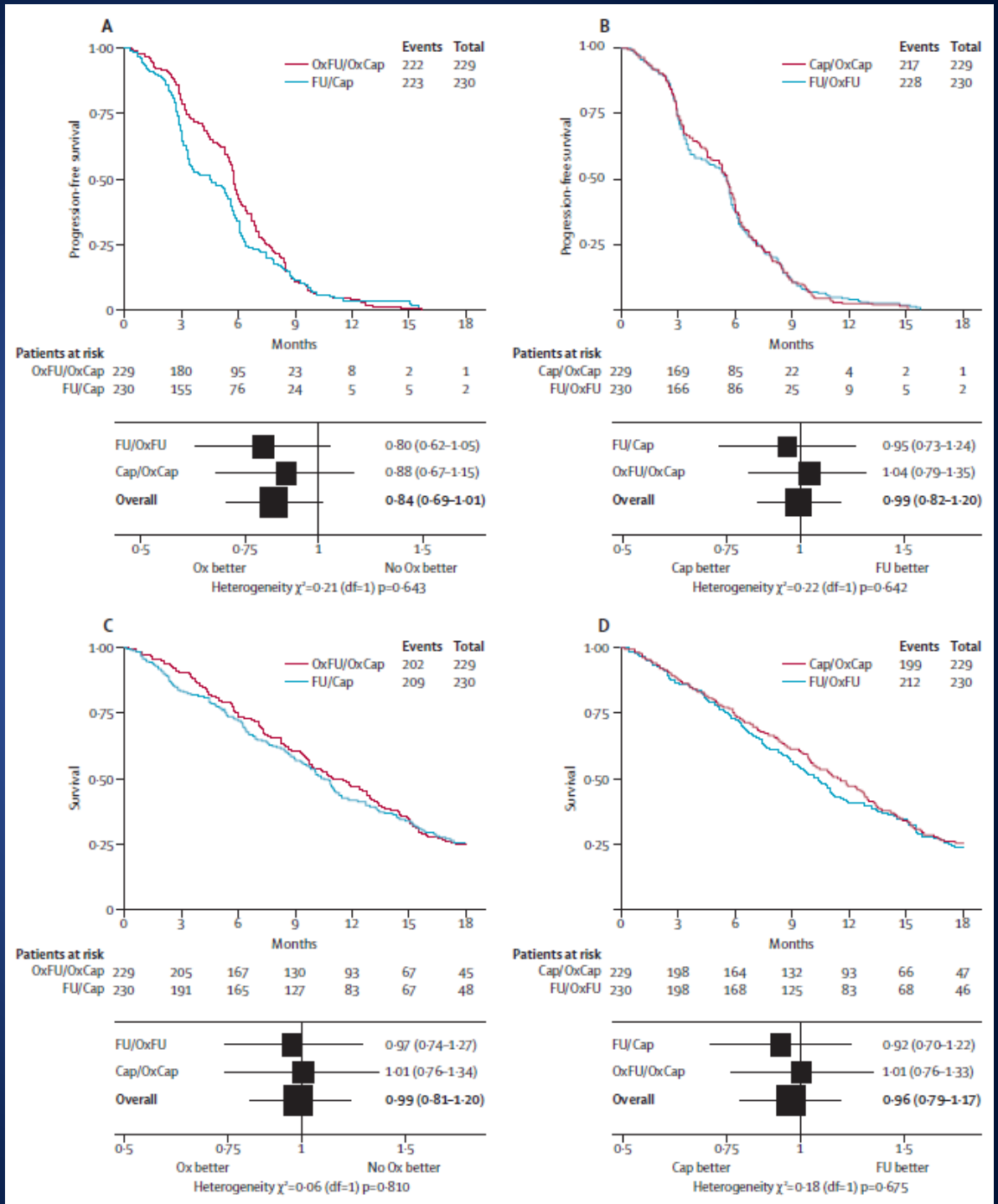
- Function
- Comorbid medical conditions
- Cognition
- Nutritional status
- Psychological state
- Social support
- Medications (polypharmacy)

Should the answer just be,
"Enroll more older patients on trials"?

Or maybe the answer should be,
"Design more trials to for older patients."

AN EXAMPLE:

FOCUS 2



Comments on Trials Designed for Older Patients

The Oncologist®

Geriatric Oncology

Older-Patient-Specific Cancer Trials: A Pooled Analysis of 2,277 Patients (A151715)

Dyda Dao,[a] Tyler Zemla,[b] Aminah Jatoi,[a] Rachel A. Freedman,[c] Arti Hurria,[d,†] Hyman Muss,[e] Harvey Jay Cohen,[f] Lawrence N. Shulman,[g] Marc Citron,[h] Daniel Budman,[i] Ryan McMurray,[b] Ann Partridge,[c] Lisa Carey,[e] Mina S. Sedrak,[d] Jacqueline M. Lafky,[a] Jennifer G. Le-Rademacher[b]

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[†]Deceased.

Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Older patients • Clinical trials • Accrual • Breast cancer • Adjuvant

Trials included in the pooled analysis:

Trial	Trial type	Dates of accrual	Treatment arms
CALGB 49907 [11]	Older-patient-specific	June 2002–December 2006	Standard therapy vs. capecitabine
NCCTG 89-30-52 [12]	Older-patient specific	January 1991–April 1995	Tamoxifen alone vs. tamoxifen combined with fluoxymesterone
CALGB 40101 [13, 14]	Age-unspecified	June 2002–July 2010	Cyclophosphamide and doxorubicin vs. paclitaxel
NCCTG N9831 [15]	Age-unspecified	May 2000–April 2005	Sequential vs. concurrent therapy with doxorubicin, cyclophosphamide paclitaxel and trastuzumab
CALGB 9741 [16]	Age-unspecified	October 1997–March 1999	Sequential vs. concurrent therapy with doxorubicin, cyclophosphamide and paclitaxel
CALGB 9344 [17]	Age-unspecified	May 1994–April 1997	4 cycles of doxorubicin/cyclophosphamide vs. doxorubicin/cyclophosphamide followed by 4 cycles of paclitaxel
CALGB 8541 [18]	Age-unspecified	January 1985–March 1991	Low vs. standard vs. high-dose cyclophosphamide/doxorubicin/5-fluorouracil

Abbreviations: CALGB, Cancer and Leukemia Group B; NCCTG, North Central Cancer Treatment Group.

Dyda Dao et al. The Oncologist 2019;24:e284-e291

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Characteristics of cohorts in older-patient-specific and age-unspecified trials

Characteristics	Older-patient-specific trials (*n* = 1,014), *n* (%)	Age-unspecified trials (*n* = 1,263), *n* (%)	*p* value
Median age at trial entry (range), yr	72 (65–89)	68 (65–84)	<.0001
Age at enrollment (percentage of cohort)			
≥70 years	567 (56)	369 (30)	<.0001
≥75 years	260 (26)	77 (6)	<.0001
ECOG performance[a]			<.0001
0	457 (72)	394 (84)	
1	161 (25)	74 (16)	
2	15 (2)	0	
Missing	381	795	
Hispanic			.89
No	908 (97)	1,172 (97)	
Yes	30 (3)	40 (3)	
Missing	76	51	
Tumor size, cm			.80
<3	707 (70)	870 (69)	
≥3	305 (30)	384 (31)	
Missing	2	9	
Number of positive lymph nodes[b]			<.0001
0	367 (37)	324 (28)	
1–3	471 (47)	423 (36)	
4–9	124 (12)	266 (23)	
10+	44 (4)	163 (14)	
Missing	8	87	
Estrogen receptor status[a]			.06
Positive	418 (66)	774 (62)	
Negative	214 (34)	481 (38)	
Missing	382	8	
Progesterone receptor status[a]			.14
Positive	333 (53)	707 (57)	
Negative	297 (47)	545 (43)	
Missing	384	11	

[a]Performance score was not available for trials NCCTG 89-30-52, NCCTG 9831, CALGB 9741, CALGB 9344, or CALGB 8541, leaving 381 and 795 patients with missing data in older-age-specific and age-unspecified trials, respectively. Missing data with respect to ER status also occurred in 382 patients in older-patient-specific trials and 8 patients in age-unspecified trials and with respect to PR in 384 older age-specific trials and 11 age-unspecified trials.
[b]Numbers in parentheses refer to percentages within the cohort and may not sum to 100% because of rounding.

Dyda Dao et al. The Oncologist 2019;24:e284-e291

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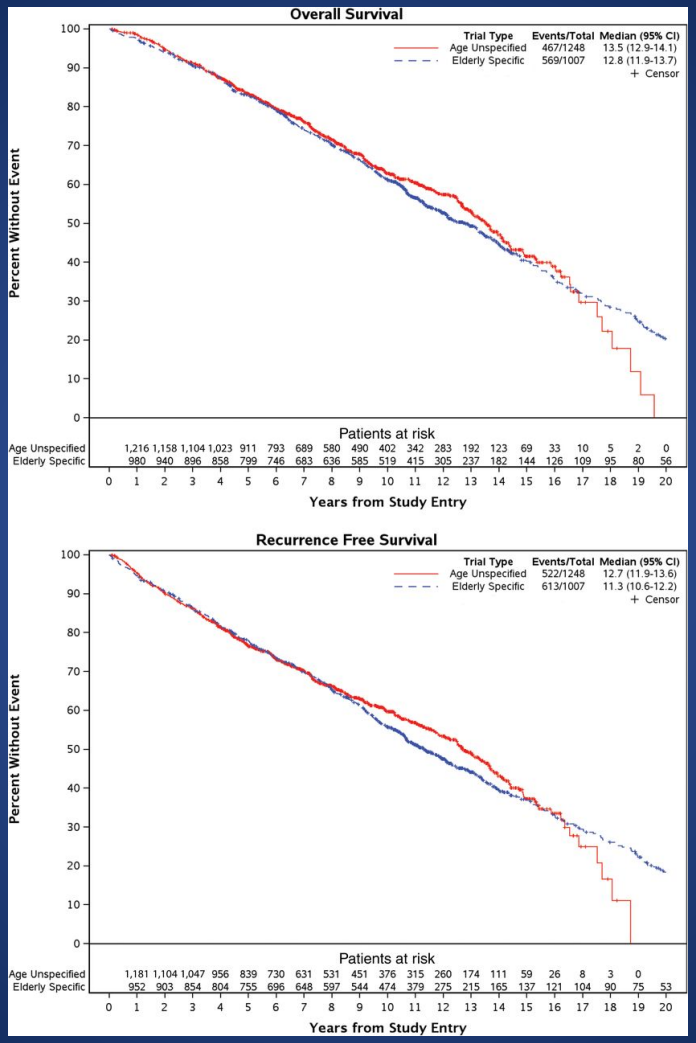
Survival outcomes based on trial type.



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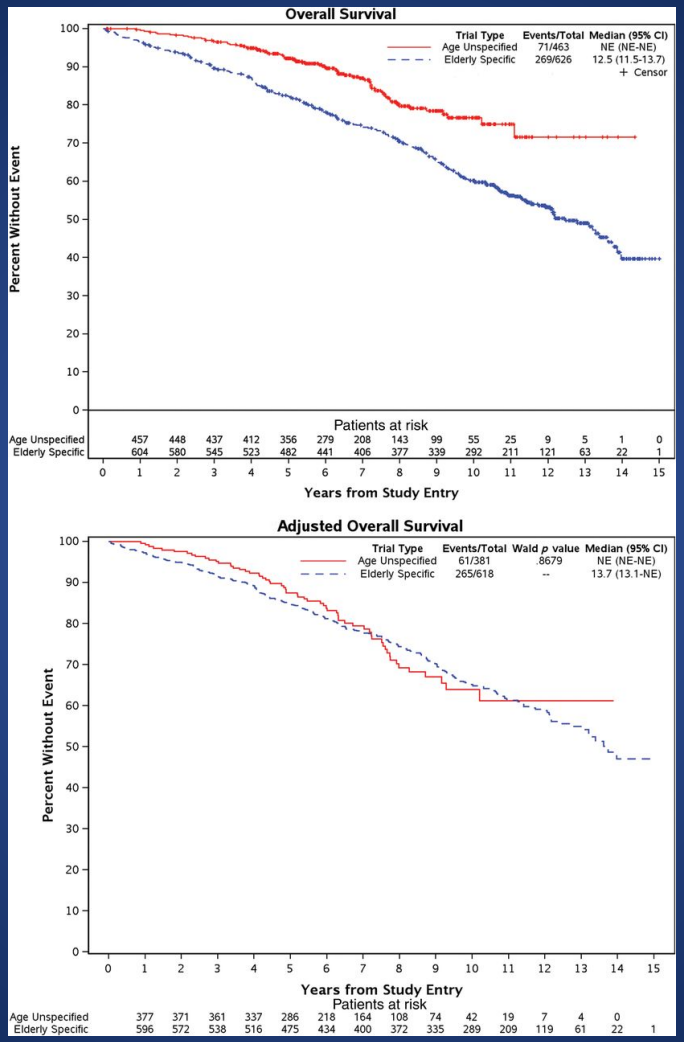
Subgroup analysis of overall survival based on trial type but with adjustment for performance score.



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Multivariate analysis of overall survival (OS) and recurrence-free survival (RFS)

Variable[a]	Hazard ratio, (95% confidence interval)	*p* value
OS		
Trial type (referent age-unspecified)	1.08 (0.92–1.28)	.34
Age, yr		<.0001[b]
<70	1	
70–75	1.29 (1.12–1.49)	.0004
>75	2.35(1.98–2.78)	<.0001
Tumor size, cm		
<3	1	
≥3	1.38 (1.21–1.57)	<.0001
Number of positive lymph nodes[c]		<.0001[b]
0	1	
1–3	1.40 (1.19–1.65)	<.0001
4–9	2.04 (1.69–2.46)	<.0001
10+	2.75 (2.21–3.45)	<.0001
Estrogen receptor status[b]		
Negative	1	
Positive	0.81 (0.69–0.94)	.0045
RFS[d]		
Trial type (referent age-unspecified)	1.10 (0.94–1.29)	.24
Age		<.0001[b]
<70 years	1	
70–75 years	1.23 (1.07–1.41)	.0028
>75 years	2.04 (1.73–2.41)	<.0001
Hispanic		
No	1	
Yes	1.67 (1.15–2.43)	.0072
Estrogen receptor status		
Negative	1	
Positive	0.80 (0.70–0.93)	.0025

[a]Select variables are shown.
[b]Overall *p* value.
[c]Missing data (*n* = 88 for lymph node status and *n* = 384 for estrogen receptor status) were included in the model.
[d]Model was stratified by tumor size and number of positive nodes.
Abbreviations: OS, overall survival; RFS, regression-free survival.

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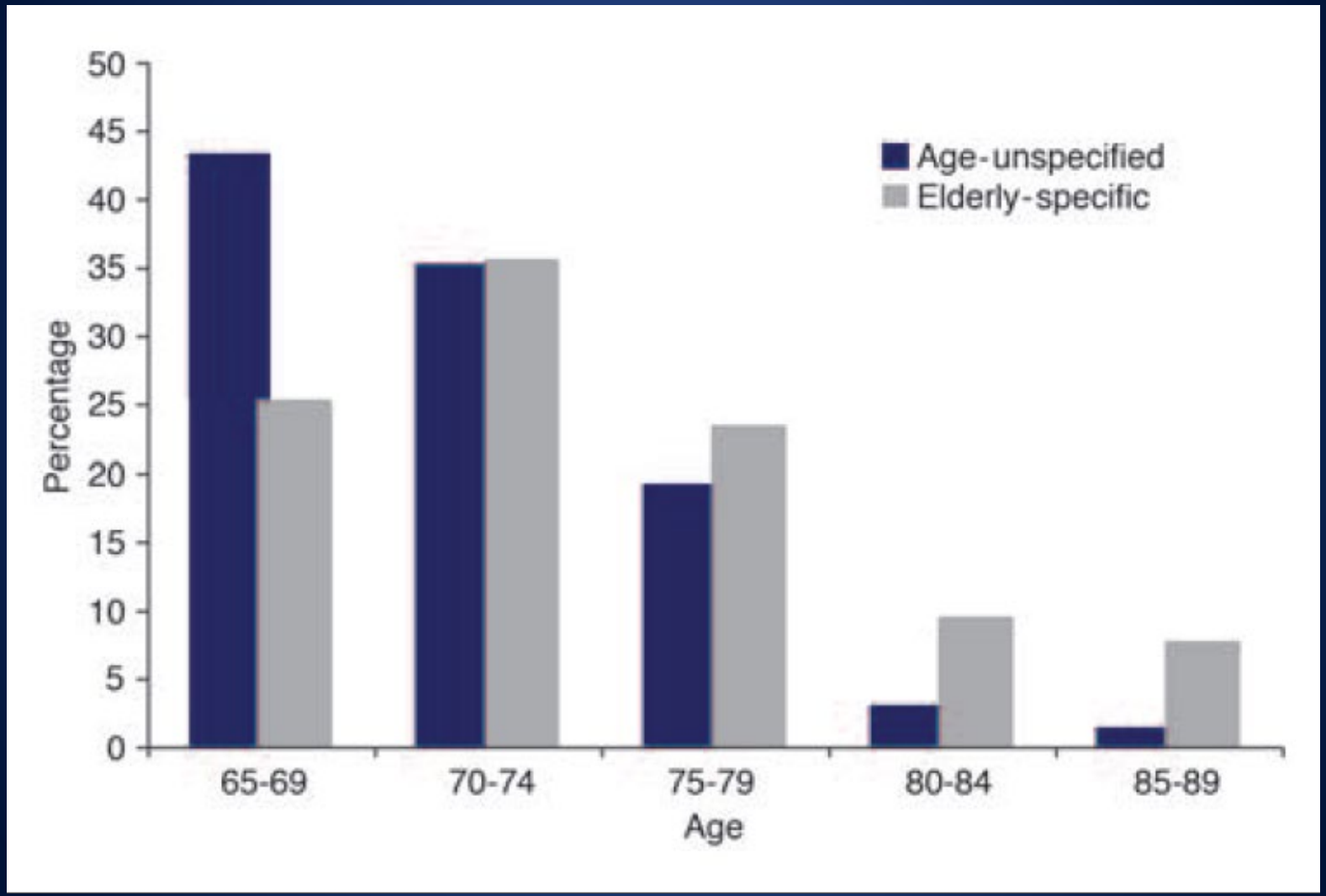
The Oncologist

Similar findings in lung cancer trials…..



Jatoi , et al. J Clin Oncol, 2005

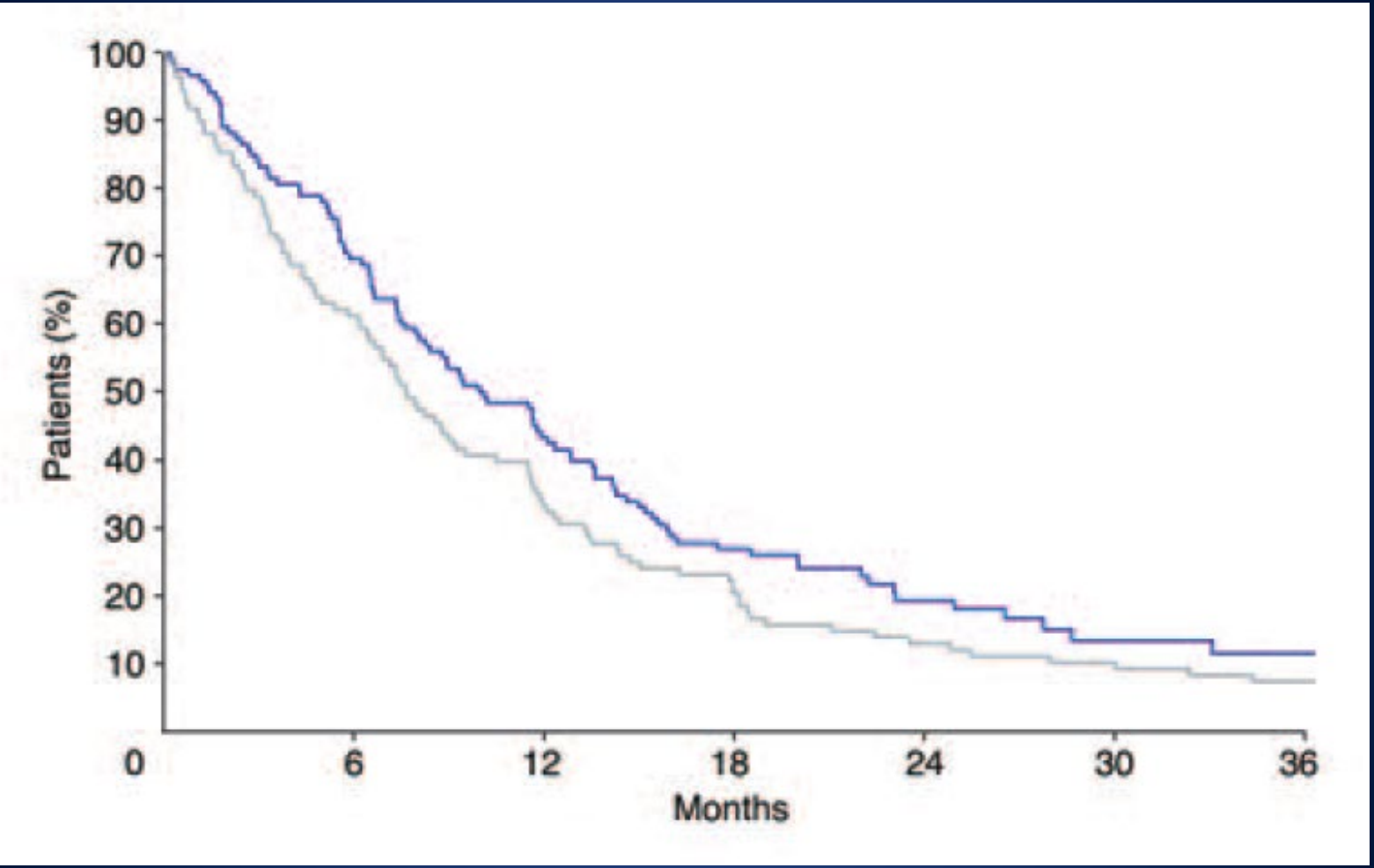

100
90
80
70
60
50
40
30
20
10
0
Patients (%)
6
12
18
24
30
36
Months

Table 4. Adverse Events

	Age-Unspecified (n = 118)		Elderly-Specific (n = 104)		
	No.	%	No.	%	*P*
Patients with any grade 3+ event	112	95	63	61	< .001
Patients with any grade 3+ hematologic event	80	68	10	10	< .001
Patients with any grade 3+ nonhematologic event	95	81	59	57	< .001
Patients with grade 3+ neutropenia	66	56	9	9	< .001
Patients with grade 3+ dyspnea	21	18	20	19	.78
Patients with grade 3+ fatigue	30	25	9	9	.001
Patients with grade 3+ leukopenia	47	40	2	2	< .001
Patients with grade 3+ thrombocytopenia	16	14	1	1	< .001
Patients with grade 3+ febrile neutropenia	15	13	1	1	< .001

NOTE. Throughout Table, adverse events are included only if their frequency was ≥ 10% in either group.

Should the answer just be,
"Enroll more older patients on trials"?

Or maybe the answer should be,
"Make use of the data we have on older patients."

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JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Effect of Pretreatment Renal Function on Treatment and Clinical Outcomes in the Adjuvant Treatment of Older Women With Breast Cancer: Alliance A171201, an Ancillary Study of CALGB/CTSU 49907

Stuart M. Lichtman, Constance T. Cirrincione, Arti Hurria, Aminah Jatoi, Maria Theodoulou, Antonio C. Wolff, Julie Gralow, Daniel E. Morganstern, Gustav Magrinat, Harvey Jay Cohen, and Hyman B. Muss

Older patients who had renal insufficiency and who received chemotherapy dose modifications were <u>not</u> at increased risk for complications.

Contents lists available at ScienceDirect

Journal of Geriatric Oncology

Do older patients with non-small cell lung cancer also benefit from first-line platinum-based doublet chemotherapy? Observations from a pooled analysis of 730 prospectively-treated patients (Alliance Study A151622)☆

Josephine L. Feliciano [a], Jennifer G. Le-Rademacher [b,c], Ajeet Gajra [d], Martin J. Edelman [e], Tyler Zemla [b], Ryan McMurray [b], Hongbin Chen [f], Arti Hurria [g], Hyman Muss [h], Harvey J. Cohen [i], Rogerio Lilenbaum [j], Aminah Jatoi [c,*]

Yes.

ORIGINAL ARTICLE

IASLC

Time-to-Treatment-Failure and Related Outcomes Among 1000+ Advanced Non-Small Cell Lung Cancer Patients: Comparisons Between Older Versus Younger Patients (Alliance A151711)

Check for updates

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Older patients are more likely to discontinue chemotherapy because of cancer progression and more likely to discontinue because of toxicity or choice.

Breast Cancer Res Treat (2017) 166:793–808
DOI 10.1007/s10549-017-4454-7

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CLINICAL TRIAL

Lymphedema, musculoskeletal events and arm function in older patients receiving adjuvant chemotherapy for breast cancer (Alliance A171302)

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75% of older, curatively treated breast cancer patients develop debilitating musculoskeletal events.

Breast Cancer Res Treat (2017) 163:391–398
DOI 10.1007/s10549-017-4188-6

BRIEF REPORT

Using ePrognosis to estimate 2-year all-cause mortality in older women with breast cancer: Cancer and Leukemia Group B (CALGB) 49907 and 369901 (Alliance A151503)

Gretchen G. Kimmick[1] · Brittny Major[2] · Jonathan Clapp[3,4] · Jeff Sloan[2] · Brandelyn Pitcher[1,5] · Karla Ballman[6] · Myra Barginear[7] · Rachel A. Freedman[8] · Andrew Artz[9] · Heidi D. Klepin[10] · Jacqueline M. Lafky[2] · Judith Hopkins[11] · Eric Winer[8] · Clifford Hudis[12] · Hyman Muss[13] · Harvey Cohen[1] · Aminah Jatoi[14] · Arti Hurria[15] · Jeanne Mandelblatt[16]

E-Prognosis can be used to estimate age-based prognosis when discussing whether or not to pursue adjuvant chemotherapy for early-stage breast cancer in older patients.

Limitations of “Database” Studies

- Heavy reliance on patients who had been enrolled on clinical trials.
- Full profile of health and morbidity sometimes lacking.
- Sometimes no age-based comparison.

CONCLUSIONS

- Older patients are underrepresented on cancer clinical trials.
- Specific research initiatives – designing trials for older patients and relying on data bases -- will help us better under issues these patients face.
- Now is the time to study older cancer patients.

The time is **now** for determining how **best** to treat older patients with cancer.