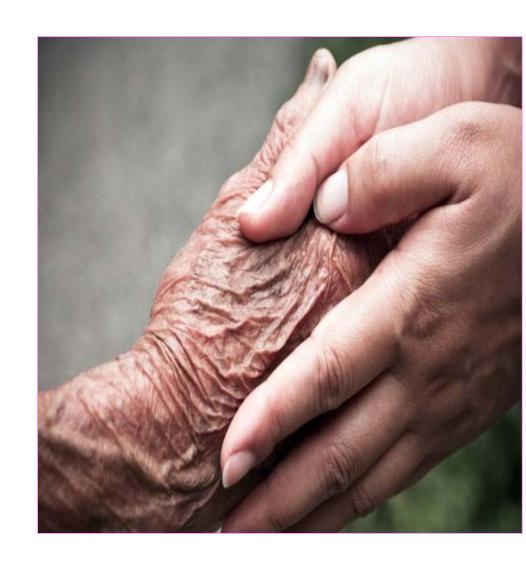


"All oncologists are geriatric oncologists...
they just don't know it yet."

Stu Lichtman, M.D.



What is the geriatric assessment (GA) and why use it?

(HINT: To make cancer therapy more tolerable).

- Has it always achieved its "goals" of making cancer therapy more tolerable?
- Have recent studies provided insights on how to make cancer therapy more tolerable (fewer side effects)?



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)



Performance score under-represents the <u>tolerability</u> of chemotherapy in older patients.

Older Patients with Cancer Experience More and More Severe Side Effects from Cancer Treatment.

Multiple studies with

- chemotherapy
- radiation
- biological agents (some)
- targeted agents

What is a Geriatric Assessment?

Parameter	Assessment/Measure		
Physical Function	 Self reported—ADLs, IADLs, mobility Objectively measured—walking speed, grip strength Performance status 		
Cognitive Function	Four cardinal domains: 1. Functional status		
Comorbidity	2. Physical health3. Socio-environmental4. Psychological health		
Socioeconomic issues	Social support (caregivers, transportation)Income/ financial challenges		
Psychological state	Depression, distress, anxiety		
Geriatric Syndromes	Dementia, delirium, falls, failure to thrive		
Polypharmacy	Number of medications, high risk meds		
Nutrition	Weight loss, BMI, access to nutritional support		

What are realistic goals of a geriatric assessment?

 It goes beyond the history and physical to find issues germane to patients and their anticipated cancer therapy.

For example, it detects baseline neuropathy that would preclude oxaliplatin....

(10+ papers support this statement.)

• It <u>predicts severe adverse events</u> and survival in older cancer patients.

(15+ papers support this statement.)

60%

of oncologists

<u>do not</u>

use a formal GA

Gajra A, Jeune-Smith Y, Fortier S, Feinberg B, Phillips E Jr, Balanean A, Klepin HD. The Use and Knowledge of Validated Geriatric Assessment Instruments Among US Community Oncologists. JCO Oncol Pract. 2022 Jul;18(7):e1081-e1090. doi: 10.1200/OP.21.00743. Epub 2022 Mar 9. PMID: 35263162.



+ limited resources

What is the Practical Geriatric Assessment? (JCO Oncol Pract 00:1-6)

Domain	Measure	Items	Definition of Impairments	Recommendation if Patient Meets Threshold for Impairment
Physical function/	Falls	Single item of falls in past 6 months	≥1 falls ^{13,22}	(For falls specifically)—check orthostatic blood pressure and adjust blood
performance	Physical function	Walking one block and climbing one flight of stairs	Any limitation (a little or lot)13	pressure medications if blood pressure is low or low normal. Offer falls prevention handout
	4-meter gait speed	Time in seconds	Time ≥4 s (or gait speed ≤1.0 m/s²².²⁴) Weigh risks and benefits of cancer treatment option information about physical performance Consider physical therapy (outpatient or home-based for home care): request gait/assistive device evalu strength, and balance training Consider occupational therapy (if eligible for home of safety evaluation): request evaluation and treatment	
Functional status	OARS IADL	6 IADL items (walking, transportation, meals, housework, medicines, money)	Any IADL items with some help or unable 13,25,26	Consider the following potential cancer treatment modifications, particularly in the noncurative treatment setting: (1) consider single agent rather than
	OARS activities of daily living (IADL)	3 ADL items (in/out of bed, dressing, bath/shower)	Any ADL items with some help or unable	doublet therapy; (2) modify dosage (eg., 20% dose reduction with escalation as tolerated); (3) modify treatment schedule if appropriate Consider more frequent toxicity checks (weekly or every other week) Consider physical therapy (outpatient or home-based depending on eligibility for home care): request gait/assistive device evaluation, strength, and balance training Consider occupational therapy (outpatient or home-based depending on eligibility for home care): request evaluation and treatment for functional impairment
Nutrition/weight loss	Single item from the G8 and MNA	Weight loss during the past 3 months? 0 = weight loss >3 kg (6.6 lbs) 1 = does not know 2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs) 3 = no weight loss (range 0-3)	Score of 0 ^{27,28}	Discuss concerns related to nutrition and how potential treatment may impact nutrition Consider recommendations and/or handouts for nutritional supplements, liberalize calorie-restricted diets; small frequent meals, and/or high protein/ high calorie snacks Consider referral to (1) nutritionist/dietician: (2) dentist if poor dentition or denture issues: (3) speech therapy if difficulty with swallowing; (4) meals-on-wheels Use caution with highly emetogenic regimens and use aggressive antiemetic therapy Refer to physical therapy/occupational therapy for functional impairments affecting food intake Consider medications for loss of appetite
Social support	MOS social support, 8-item	Instrumental items 1-4 Emotional items 5-8	Any instrumental item with none, a little, or some of the time ^{29,30} Any emotional item with none, a little, or some of the time ^{29,30}	Discuss adequacy and availability of social support at home Discuss who the patient can contact in case of an emergency Confirm documented health care proxy is in the medical record Consider referral or information on (1) social worker (2) visiting nurse service or home health aide (if meets criteria) Order on-person lifeline emergency service
Psychological	PROMIS anxiety, 4-item	Summed 4-20 raw score	Raw score: ≥1131,32	Discuss history of mood issues and treatment history Consider referral to (1) psycho-oncology (social work, clinical psychology) for
	GDS 5	Sum of 1 point for no answer to item 1 and 1 point for yes answers to items 2-5 (range, 0-5)	Score: 22 ^{33,34}	counseling; (2) psychiatry if severe symptoms or if already on medications which are inadequate, (3) spiritual counseling or Chaplaincy services, (4) palliative care if other physical and/or cancer symptoms present Consider initiating pharmacologic therapy if appropriate in conjunction with PCP Provide linkage to community resources (such as support groups and local/national buddy or volunteer programs) Assess suicide risk and/or elder abuse if appropriate

Domain	Measure	Items	Definition of Impairments	Recommendation if Patient Meets Threshold for Impairment
Comorbidity	OARS comorbidity	No/yes summed (0-13) Interference for each	≥3 conditions 25,36 Or any condition with a great deal of interference Specific for any history of diabetes, heart disease, or liver/kidney disease	Initiate direct communication (written, electronic, or phone) with patient's PCP about the plan for the patient's cancer Discuss how comorbidities affect risks and benefits of treatments choices Modify dosage or schedule if there is concern about treatment tolerability or if there is a concern about worsening of comorbidities If history of diabetes (of any level)—avoid neurotoxic agents if another option is equivalent If history of heart disease (of any level)—consider minimizing volume of agents and/or administer at slower infusion rate If history of chronic liver or kidney disease (of any level)—adjust medication dose as appropriate to avoid accumulation
	Hearing	Single item	Fair/poor/deaf	Ensure wearing hearing aids if indicated and consider hearing specialist referral Pocket talker available for office visits
	Vision	Single item	Fair/poor/blind	Ensure wearing glasses if indicated Test for glaucoma (esp with steroid use) Consider vision specialist referral
Cognitive function	Mini-cog	1 point for each word recall 2 points for clock draw if normal, 0 if abnormal Total of 5 points (range, 0-5)	Score: 0-2 high likelihood of cognitive impairment ^{37,38}	Provide explicit and written instruction for appointments, medications, and treatments Elicit input from trusted confidant or caregiver about patient's cognition Assess decision-making capacity and elicit health care proxy information and input if the patient lacks decision-making capacity Consider referral to cognitive specialist (eg, neurologist or geriatrician) Consider occupational therapy referral for cognitive rehabilitation If dementia is suspected, consider neuropsychological testing
Geriatric assessment screening tool ^a	G-8	items (food intake, weight loss, mobility, neuropsychological problem, body mass index, prescription drug, self-perception of health, and age)	Score: 0-14 recommend completing a full GA evaluation ^{30,40}	Administer the full PGA and implement the recommendations noted above on the basis of the patient-reported results
Risk of chemotherapy toxicity ^b	CARG toxicity tool	11 items (sociodemographics, tumor/treatment variables, laboratory test results [hemoglobin, creatinine clearance], and GA variables)	Score: 0-5 low risk 6-9 intermediate risk 10-23 high risk ^{11,41}	For intermediate- and high-risk patients, consider administering the full PGA and implement the recommendations noted above on the basis of the patient-reported results Consider the following potential cancer treatment modifications, particularly for intermediate- and high-risk patients and taking into consideration noncurative treatment settings: (1) consider single agent rather than doublet therapy; (2) modify dosage (eg, 20% dose reduction with escalation as tolerated); (3) modify treatment schedule if appropriate Consider more frequent toxicity checks (weekly or every other week)

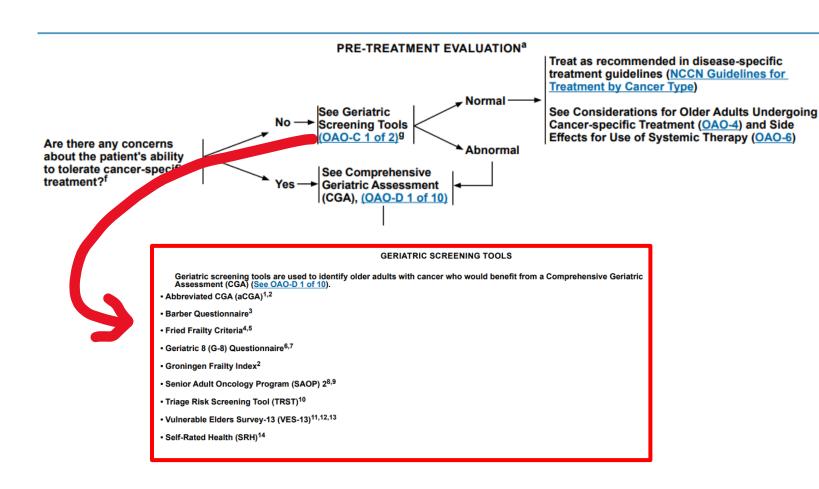
NOTE. These recommendations are based on the intervention material from the GAP708 and GAIN6 studies.

Abbreviations: ADL, activities of daily living; CARG, Cancer and Aging Research Group; GA, geriatric assessment; GDS, Geriatric Depression Scale; IADL, instrumental activities of daily living; MOS, Medical Outcomes Survey; PGA, Practical Geriatric Assessment.

[&]quot;The Vulnerable Elders Survey-13 (VES-13) is an alternative geriatric assessment screening tool. 16,42

^bChemotherapy Risk Assessment Scale for High-Age Patients (CRASH) Score is an alternative tool that can be used to calculate risk of chemotherapy toxicity.⁴³

NCCN GUIDELINE



Is it time to integrate the GA – in some form — into the care of all older patients with cancer?



"The updated guideline recommends that GA **CON** be used to identify aging-associated vulnerabilities or impairments that are not routinely captured in oncology assessments for all patients older than 65 years with cancer."

What is the geriatric assessment (GA) and why use it?

(HINT: To make cancer therapy more tolerable).

- Has it always achieved its "goals" of making cancer therapy more tolerable?
- Have recent studies provided insights on how to make cancer therapy more tolerable (fewer side effects)?



STUDY #1

Research

JAMA Oncology | Original Investigation

Communication With Older Patients With Cancer Using Geriatric Assessment A Cluster-Randomized Clinical Trial From the National Cancer Institute Community Oncology Research Program

Supriya G. Mohile, MD, MS; Ronald M. Epstein, MD; Arti Hurria, MD; Charles E. Heckler, PhD, MS; Beverly Canin; Eva Culakova, PhD, MS; Paul Duberstein, PhD; Nikesha Gilmore, PhD; Huiwen Xu, MHA; Sandy Plumb, BS; Megan Wells, MPH; Lisa M. Lowenstein, PhD; Marie A. Flannery, PhD; Michelle Janelsins, PhD, MPH; Allison Magnuson, DO; Kah Poh Loh, MB, BCh, BAO; Amber S. Kleckner, PhD; Karen M. Mustian, PhD, MPH; Judith O. Hopkins, MD; Jane Jijun Liu, MD; Jodi Geer; Rita Gorawara-Bhat, PhD; Gary R. Morrow, PhD, MS; William Dale, MD, PhD

31 Practice site clusters randomized (546 patients, 417 caregivers, 132 physicians)

17 Practice sites allocated to intervention

296 Patients

233 Caregivers

64 Physicians

14 Practice sites allocated to usual care

250 Patients

184 Caregivers

68 Physicians

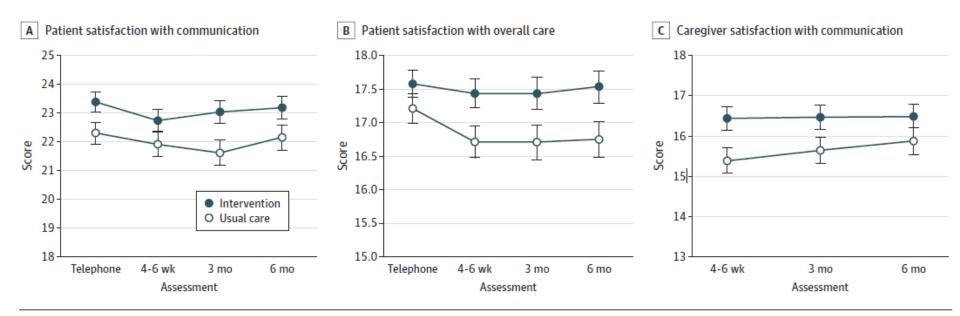
<u>Intervention</u>:

GA summary and GA-guided recommendations

Primary Endpoint:

patient satisfaction with communication about aging-related concerns

Patient Satisfaction with a Geriatric Assessment



A, Patient satisfaction with communication about aging-related concerns. B, Patient satisfaction with overall care. C, Caregiver satisfaction with communication about the patient's age-related conditions. Scores were derived using modified versions of the Health Care Climate Questionnaire. The telephone assessment was 7 to 14 days after the audio-recorded clinic visit.

However, no improvement in quality of life between arms.

****secondary endpoint****

STUDY #2

JOURNAL OF CLINICAL ONCOLOGY

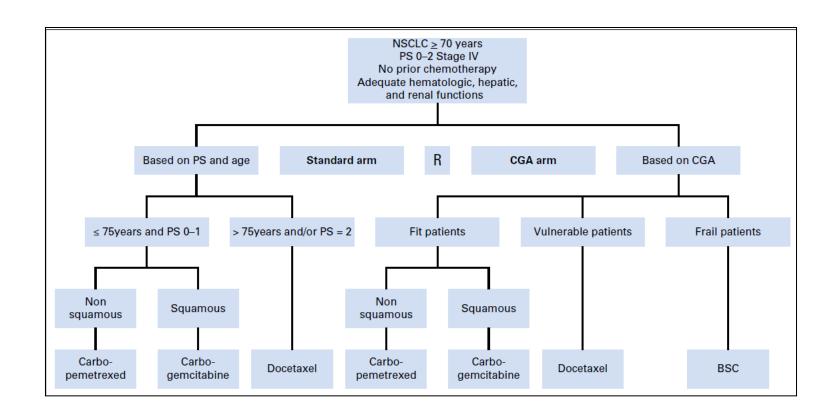
ORIGINAL REPORT

Use of a Comprehensive Geriatric Assessment for the Management of Elderly Patients With Advanced Non–Small-Cell Lung Cancer: The Phase III Randomized ESOGIA-GFPC-GECP 08-02 Study

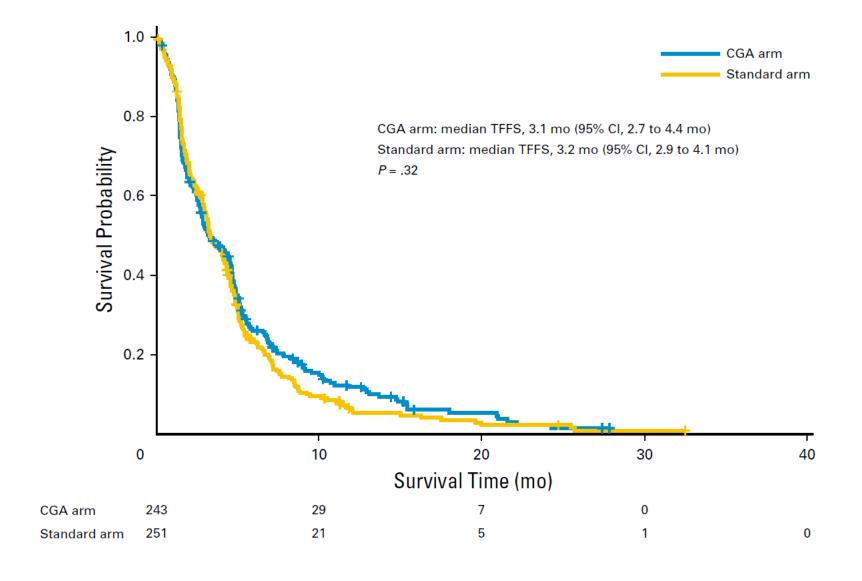
Romain Corre, Laurent Greillier, Hervé Le Caër, Clarisse Audigier-Valette, Nathalie Baize, Henri Bérard, Lionel Falchero, Isabelle Monnet, Eric Dansin, Alain Vergnenègre, Marie Marcq, Chantal Decroisette, Jean-Bernard Auliac, Suzanna Bota, Régine Lamy, Bartomeu Massuti, Cécile Dujon, Maurice Pérol, Jean-Pierre Daurès, Renaud Descourt, Hervé Léna, Carine Plassot, and Christos Chouaïd

STUDY DESIGN: Randomized, Multi-site Trial

Primary Endpoint: <u>treatment failure-free survival</u>
N=494

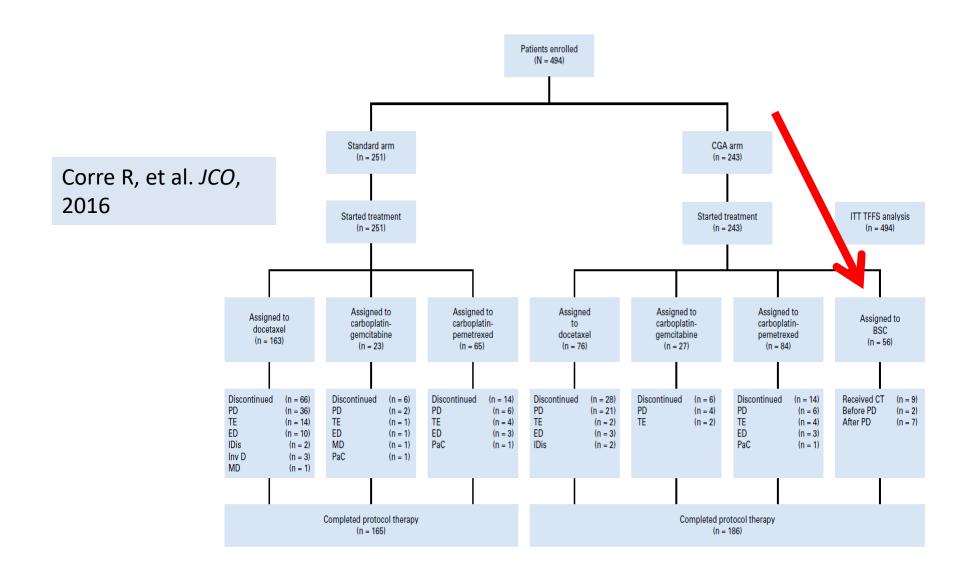


The Primary Endpoint Was Not Met



	% of Patients		
Toxicity	Standard Am (n = 251)	CGA Am (n = 243)	F
All grades	93.4	85.6	.0
Grade 3-4	71.3	67.9	.4
Grade 3-4 neutropenia			.4
All	11.1	13.2	
Doublet	16.0	25.2	
Monotherapy	8.0	5.3	
BSC	_	0	
Grade 3-4 febrile neutropenia			.2:
All	5.6	3.3	
Doublet	11.0	5.4	
Monotherapy	2.4	2.6	
BSC	_	0	
Grade 3-4 anemia			.8
All	11.2	10.7	
Doublet	21.6	16.2	
Monotherapy	5.5	6.6	
BSC	_	5.3	
Grade 3-4 thrombocytopenia			.04
All	3.6	7.8	
Doublet	7.9	17.1	
Monotherapy	1.2	0	
BSC	_	0	
Grades 3-4 asthenia			.34
All	10.8	13.6	
Doublet	7.9	14.4	
Monotherapy	12.3	15.8	
BSC	_	8.9	
Grade 3-4 anorexia			.2
All	4.0	6.2	
Doublet	0	10	
Monotherapy	6.0	5.3	
BSC	_	0	
Grade 3-4 nausea/vomiting			.4
All	3.6	4.9	
Doublet	1.1	8.1	
Monotherapy	4.9	2.6	
BSC	_	1.8	
Grade 3-4 peripheral sensory neuropathy			.6:
All	1.2	0.4	
Doublet	0	0	
Monotherapy	1.8	1.3	
BSC	_	0	

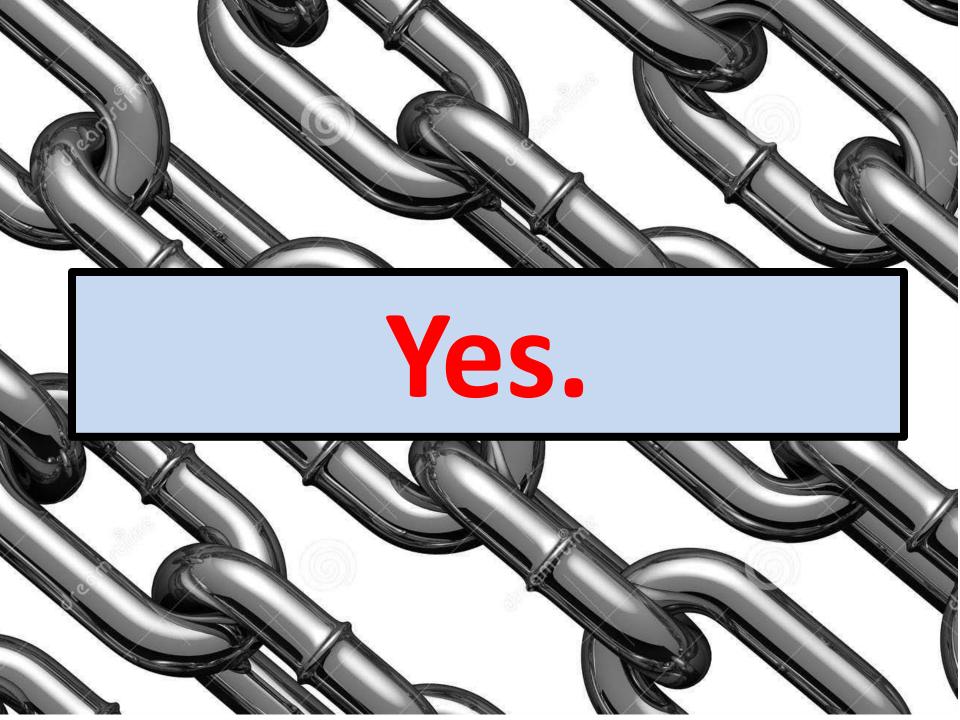
Grade 3 and 4 adverse events were more common in the standard arm; higher toxicity was hematologic.



What is the geriatric assessment (GA) and why use it?

(HINT: To make cancer therapy more tolerable).

- Has it always achieved its "goals" of making cancer therapy more tolerable?
- Have recent studies provided insights on how to make cancer therapy more tolerable (fewer side effects)?



Geriatric Assessment-driven INtervention (GAIN) on chemotherapy toxicity in older adults with cancer: a randomized controlled trial

Daneng Li, Can-Lan Sun, Heeyoung Kim, Vincent Chung, Marianna Koczywas, Marwan Fakih, Joseph Chao, Leana Chien, Kemeberly Charles, Simone Fernandes Dos Santos Hughes, Monica Trent, Elsa Roberts, Enrique Soto Perez De Celis, Reena Jayani, Vani Katheria, Jeanine Moreno, Cindy Kelly, Mina Sedrak, Arti Hurria, William Dale

City of Hope, Duarte, CA

This work was supported by the Unihealth Foundation, the Hearst Foundation, and City of Hope's Center for Cancer and Aging.



Study Design

GAIN ARM City of Hope **Usual Care** Followed until End of Chemotherapy or Eligibility 6 mo Post Initiation of Chemotherapy • Age ≥65 Geriatric RANDOMIZATION (2:1) (whichever comes first) Solid tumor Assessment-Driven Baseline Interventions All stages Geriatric n = 398 Starting a new Assessment chemotherapy (Pre-Chemotherapy) **Geriatric Assessment SOC** ARM • English, Spanish or Chinese speakers Standard of Care n = 202

- Primary endpoints:
 - Incidence of grade 3-5 chemo toxicity (NCI CTCAE 4.0)
- Secondary endpoints:
 - Advance directive completion
 - Unplanned hospitalizations
- Emergency room visits
- Average length of stay (ALOS)

NCT02517034

Methods: GAIN Arm vs. Standard of Care (SOC) Arm

GAIN ARM

Completion Baseline GA

GA reviewed by multidisciplinary (MDT) study team

Interventions and referrals finalized by MDT study team based on pre-defined GA triggers

GA and intervention plan reviewed with treating oncologist and patient

Chemotherapy treatment proceeded at discretion of oncologist

Ongoing care coordination by study NP with the patient & oncologist to implement recommendations from the intervention plan

Completion of End of Study GA

MDT Study Team

- Oncologist
- Geriatric NP
- Pharmacist
- Physical Therapist
- Occupational Therapist
- Social Worker
- Nutritionist

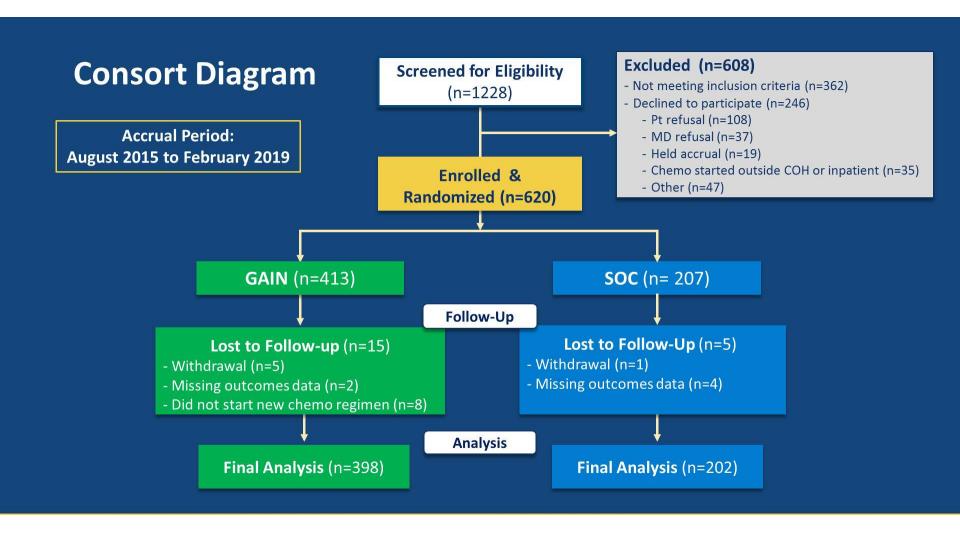
SOCARM

Completion Baseline GA

GA sent to treating oncologist for review

Chemotherapy treatment proceeded at discretion of oncologist

Completion of End of Study GA



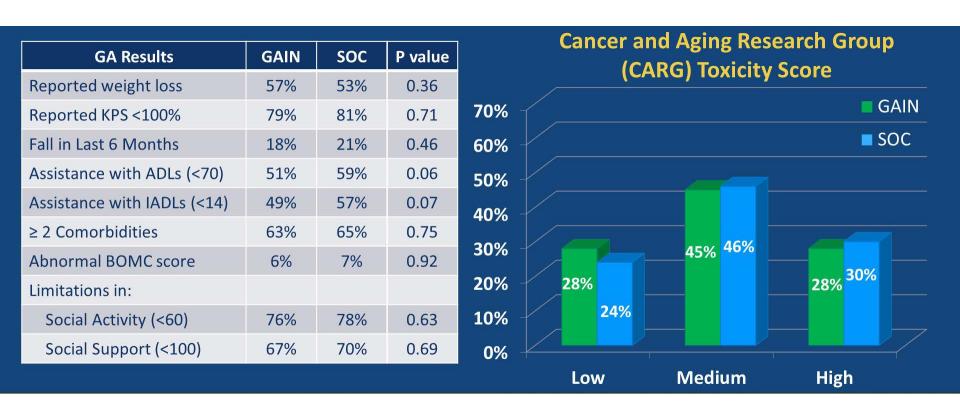
Note that about half of screened patients were enrolled.

Results: Patient Characteristics

Demographics	Overall % (n)	GAIN % (n)	SOC % (n)
Age (median, range)	71 (65-91)	71 (65-91)	72 (65-88)
Female	59% (355)	59% (233)	60% (122)
Race			
Caucasian	79% (471)	78% (312)	79% (159)
Asian	15% (90)	15% (58)	16% (32)
African American	6% (36)	7% (27)	5% (9)
Ethnicity			
Hispanic	20% (117)	19% (74)	21% (43)
Non-Hispanic	80% (480)	81% (323)	78% (157)

Disease Characteristics	Overall % (n)	GAIN % (n)	SOC % (n)
Cancer Type			
GI	34% (201)	34% (134)	33% (67)
Breast	23% (135)	23% (92)	21% (43)
Lung	16% (95)	14% (59)	18% (36)
GU	15% (90)	15% (63)	13% (27)
Other	13% (79)	13% (50)	14% (29)
Cancer Stage IV	71% (428)	71% (284)	71% (144)

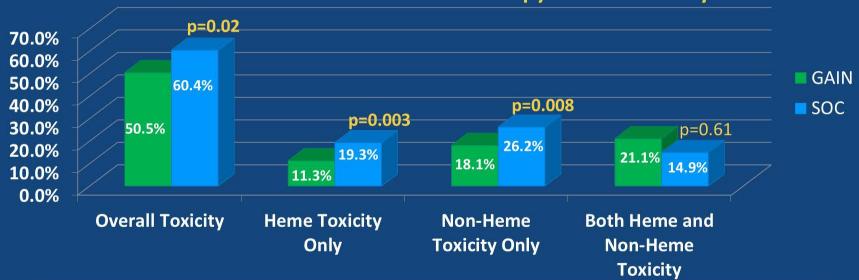
There were no significant differences in patient characteristics between arms.



GA SCORES WERE NOT STATISTICALLY DIFFERENT BETWEEN GROUPS.

Results: Primary Endpoint





The GAIN arm had a statistically significant reduction of 9.9% (95% CI: 1.6-18.2%, p=0.02) in chemo-related toxicity compared to the SOC arm

Results: Secondary Endpoints

	GAIN Arm N (%)	SOC Arm N (%)	P-value
Advanced directive completion	278 (70%)	119 (59%)	<0.01
ER visits due to chemo tox	109 (27%)	62 (31%)	0.40
Hospitalizations due to grade 3+ chemo tox	88 (22%)	39 (19%)	0.43
Hospitalizations due to grade 4+ chemo tox	19 (22%)	14 (36%)	0.09
Average Length of Stay [median (range)]	4.8 (1-23)	5 (1.7-26)	0.60

COMMENTS

This was a well-planned, well-conducted trial, although selection bias noted.

We already know that if we provide patients with resources, they will do better (the palliative care literature supports this).

We do not know if the GA improved outcomes, or if everything else that went with the GA improved outcomes.

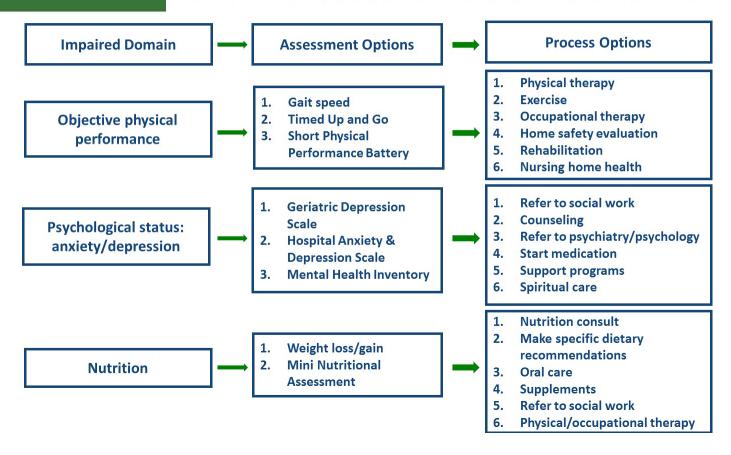




A Geriatric Assessment (GA) intervention to reduce treatment toxicity in older patients with advanced cancer: A University of Rochester Cancer Center NCI Community Oncology Research Program cluster randomized controlled trial (CRCT)

Supriya G. Mohile, Mostafa Mohamed, Eva Culakova, Huiwen Xu, Kah Poh Loh, Allison Magnuson, Marie Flannery, Erika Ramsdale, Richard Dunne, Nikesha Gilmore, Spencer Obrecht, Amita Patil, Sandy Plumb, Lisa M. Lowenstein, Michelle Janelsins, Karen Mustian, Judy Hopkins, Rakesh Gaur, Jeffrey Berenberg, William Dale

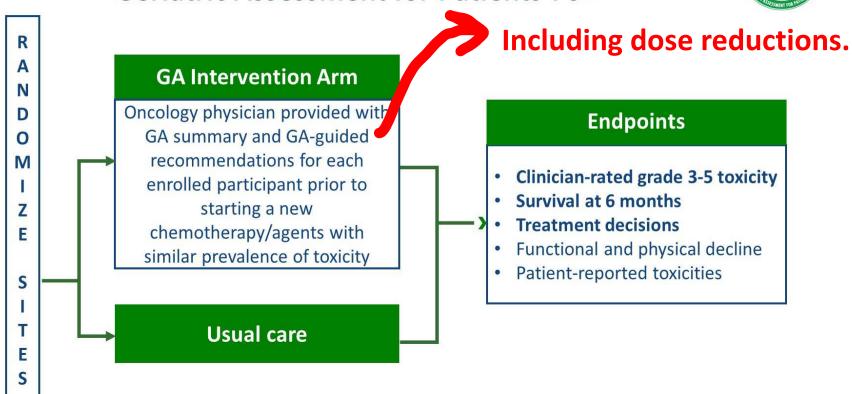
GA Intervention Care Processes for Older Adults with Cancer

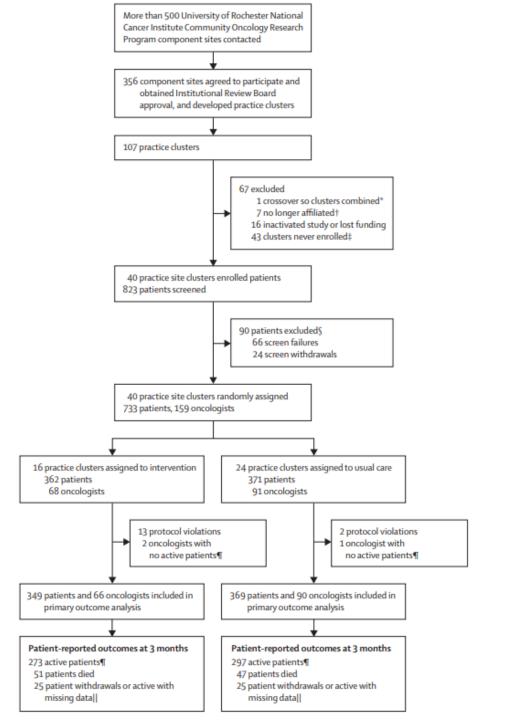


And chemotherapy dose reductions.....

Study Schema Geriatric Assessment for Patients 70+







N = 823N = 570

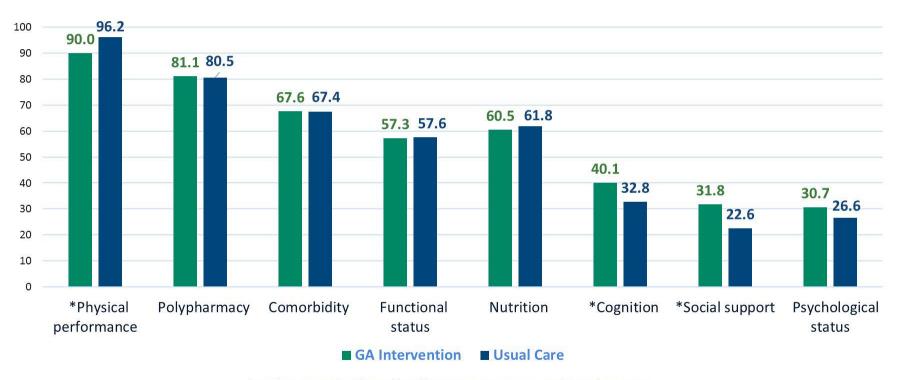
Patient Eligibility

- Aged 70+
- Incurable stage III or IV cancer
- >1 GA domain impaired other than polypharmacy
- Starting a new regimen chemotherapy or other agents with similar prevalence of toxicity
- Not on 'best supportive care' or hospice

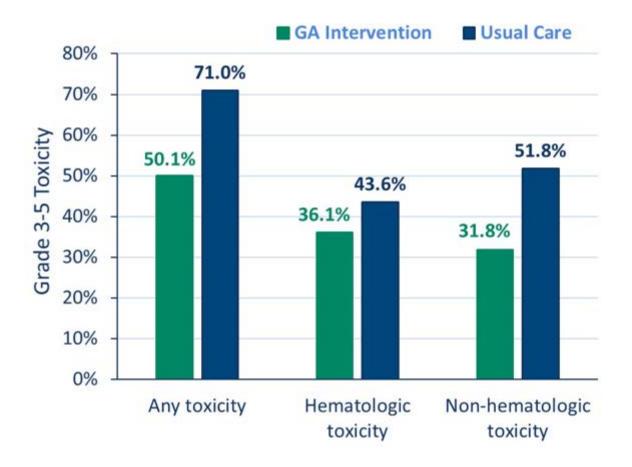
	GA Intervention	Usual Care	
	N or Mean (% or SD)	N or Mean (% or SD)	P value
Age	77.2 (5.7)	77.2 (5.2)	0.98
Female	145 (41.5%)	166 (45.0%)	0.35
Race/Ethnicity			<0.01
Non-Hispanic White	281(80.5%)	347 (94.0%)	
African American	40 (11.5%)	12 (3.3%)	
Cancer Type			<0.01
Gastrointestinal	133 (38.1%)	114 (30.9%)	
Genitourinary	56 (16.0%)	53.0 (14.4%)	
Lung	63 (18.1%)	116 (31.4%)	
Stage IV	304 (87.1%)	324 (87.8%)	0.11
Cancer Treatments			0.53
Chemotherapy	305(87.4%)	328 (88.1%)	
Non-chemotherapy	44(12.6)	41(11.1%)	
Prior chemotherapy	104 (30.8%)	81 (22.7%)	0.02

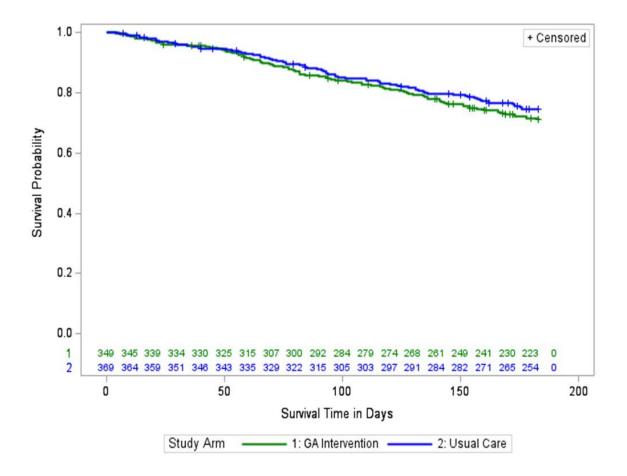
RESULTS:

Prevalence of GA Domain Impairments by Study Arm

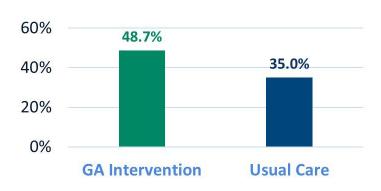


^{*}P value <0.05 for Physical performance, Cognition, and Social Support.

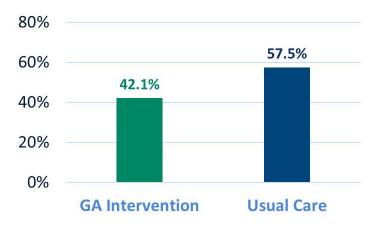




Reduced Dose Intensity at Cycle 1



Dose modification at 3 months Related to Toxicity



COMMENTS

Some selection bias is noted.

Was it the GA or the interventions that went with it— for example, the dose reduction — that improved outcomes?

Why not consider an initial dose-reduction of chemotherapy in older or low PS patients (for example, FOCUS-2 trial)?





Cost-utility of geriatric assessment in older adults with cancer: Results from the 5C trial

Trial registration number NCT03154671

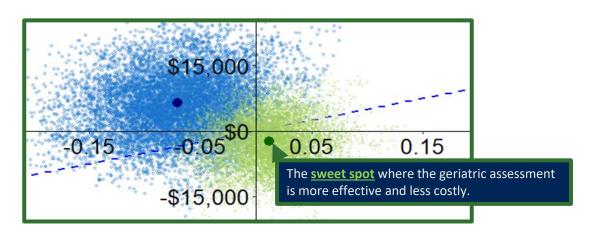
This study is funded by the Canadian Cancer Society (grant #705046)

Dr. Shabbir M.H. Alibhai on behalf of the 5C investigators



BASED ON ALIBHAI AND OTHERS....

Based on ASCO 2023 data, preliminarily, the GA appears <u>cost-effective</u> for older patients with potentially curable cancers:



COMMENTS

 FAVORABLE: This work is innovative because it examines cost-effectiveness – and it suggests that, if cost effectiveness is proven – the GA might become more pervasive.



OTHER COMMENTS:

- These are non-US data.
- Cost-effectiveness appears restricted to a small subset of patients with curable malignancies.

THOUGHTS and CONCLUSIONS

- Most oncologists are not performing the GA and seem to ignore its intended role of making cancer therapy more tolerable for older patients.
- Previous studies have not definitively shown that the GA itself drives better outcomes.

Practical approaches:

- To the extent possible, spend time with older patients to assess their needs.
- Try to garner appropriate resources to meet these needs.
- Try to provide closer follow up.
- Perhaps <u>consider a dose reduction</u> of cancer therapy upfront with the possibility of escalation later.
- Further evidence of cost-effectiveness might drive the more widespread implementation of the GA.

THANK YOU!