SIOG 2017 - Abstract Submission

Track 4: Modern diagnostics & therapeutic areas

Clinical trials for elderly cancer patients

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FEASIBILITY OF ENROLLING VULNERABLE OLDER ADULTS WITH CANCER IN A GERIATRIC ASSESSMENT MODEL OF CARE CLUSTER RANDOMIZED TRIAL

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I submit my abstract to be considered for the following award: None

Introduction: Older adults represent the majority of patients with cancer, yet they are under-represented in cancer clinical trials. COACH, the Improving Communication in Older Cancer Patients and Their Caregivers study (NCT02107443), compared whether a geriatric assessment (GA)-based model of care vs. usual care for vulnerable older adults with cancer will improve patient and caregiver satisfaction regarding communication about aging-related issues. This nationwide cluster randomized trial funded by the Patient-Centered Outcome Research Institute (PCORI) included 68 community-based oncology practices affiliated with the University of Rochester NCI Community Oncology Research Program (NCORP). Patients were age ≥70 years and had ≥1 baseline GA impairment excluding polypharmacy.

Objectives: To assess the feasibility of enrolling vulnerable older patients onto this trial.

Methods: This study is a descriptive analysis of procedures and metrics related enrollment onto a recently completed multi-center, community-based clinical trial. We reviewed screening logs from the study opening April 3, 2014 through March 15, 2017, which was the last data extraction for interim analyses. Screening log information reflects patients who were approached prior to informed consent. Our analysis focused on patient retention after informed consent. After consent, patients who chose not to remain in the study due to volitional reasons or extenuating circumstances were labeled “screening withdrawal” (SW). On the other hand, patients not meeting study inclusion criteria were labeled “screening failure” (SF). We also examined the differences in demographic, clinical, and baseline GA measures between enrolled and SF/SW patients.

Results: The study successfully completed accrual during the funding period. Over 32 months, 547 patients were accrued to the study. Peak enrollment was 34 patients/month. As of March 15 ,2017, 1438 [MM1] patients were identified as being approached about the study as per screening log review. Of these, 472 (33%) were deemed ineligible by research staff; 15 (1%) declined and were ineligible; 389 (27%) declined prior to consent.; 215 (15%) had missing data. After pre-screening, 349 (24%) patients enrolled. However, 59 (4%) patients consented but ultimately did not proceed on study. Of these, 23 (39%) patients were SF. Six SF patients (26%) did not have ≥1 GA impairment beyond polypharmacy. However, more non-enrolled patients were SW (N=36, 61%), mostly due to supervening health problems such as being too ill, going on hospice, or having died (N=17; 47%). Of the SF/SW patients, 37 (63%) had some baseline information available; 92% completed ≥1 GA domain measure. Among demographic/clinical characteristics, the only significant difference was in cancer types between the 2 groups (P<0.05). However, among baseline GA measures, a higher mean number of impairments was seen in the enrolled group (4.50 vs. 3.78, P<0.05). Moreover, among specific GA measures, there were more patients with nutritional and physical performance impairment in the enrolled group (See Table).

Image:

Table. Comparison of Geriatric Assessment Impairments between Enrolled vs. Non-Enrolled Study Patients

Study Enrollment Status	N	Geriatric Assessment Domain Impaired															
		Cognitive Function		Functional Status		Mental Health		Comorbidity		Social Support		Nutritional Status		Physical Performance		Polypharmacy	
		N (%)	*P*	N (%)	*P*	N (%)	*P*	N (%)	*P*	N (%)	*P*	N (%)	*P*	N (%)	*P*	N (%)	*P*
Enrolled	349	123 (35)	0.73	208 (60)	0.28	90 (26)	0.12	218 (64)	0.45	82 (23)	1.0						
SF/SW*	34	13 (38)		17 (50)		13 (38)		19 (56)		8 (23)							
Enrolled	349											223 (64)	<0.05				
SF/SW	35											12 (34)					
Enrolled	349													331 (95)	<0.05		
SF/SW	36													27 (75)			
Enrolled	349															294 (84)	0.62
SF/SW	37															30 (81)	

Abbreviations: SF/SW: Screening Failure/Screening Withdrawal
*SW/SF subtotals may not be consistent across domains due to patients not completing some or all of the assessment.

Conclusion: Our study showed that it was feasible to enroll vulnerable older adults onto a cancer clinical trial by using a GA as part of routine study screening. Additional studies analyzing enrollment facilitators/barriers will better inform the design and conduct of future cancer studies targeting older adults.

Disclosure of Interest: None Declared

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