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The Association of Polypharmacy with Functional Status Impairments, Frailty, and Health-Related Quality of Life in Older Adults with Gastrointestinal Malignancy - Results from the Cancer and Aging Resilience Evaluation (CARE) Registry

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Abstract

Objectives: Polypharmacy is a common problem among older adults that can complicate cancer care and outcomes. Our objective was to examine the prevalence of polypharmacy and its potential association with functional status impairments, frailty, and health-related quality of life (HRQoL) in older adults with gastrointestinal (GI) malignancy.

Methods: The Cancer and Aging Resilience Evaluation (CARE) registry is an ongoing prospective cohort study that uses a patient-reported geriatric assessment (GA) in older adults with cancer. For this cross-sectional analysis, we focused on older adults with GI malignancy that completed the GA prior to starting systemic cancer therapy. Polypharmacy was defined as patients reporting the use of ≥9 daily medications at their first visit to the medical oncology clinic. Using multivariable analyses, we examined the association of polypharmacy with functional status limitations, frailty, and HRQoL.

Results: 357 patients were included in our analysis, with a mean age of 70.1 years. 24.1% of patients reported taking with ≥ 9 medications. In multivariable analyses adjusted for age, sex, race, cancer type, cancer stage, and medical comorbid conditions, patients taking ≥ 9 medications were more likely to report limitations in activities of daily living (adjusted odds ratio [aOR] 3.29, 95% CI 1.72-6.29) and instrumental activities of daily living (aOR 2.86, 95% CI 1.59-5.14), have

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a higher prevalence of frailty (aOR 3.06, 95% CI 1.73-5.41), and report lower physical HRQoL (aOR 2.82, 95% CI 1.70-4.69) and mental HRQoL (aOR 1.73, 95% CI 1.03-2.91).

Conclusions: Older adults with GI malignancy taking ≥ 9 medications prior to cancer therapy were more likely to report functional status limitations, frailty, and reduced HRQoL, independent of the presence of medical comorbid conditions.

Keywords

Polypharmacy; Geriatric Assessment; Cancer; Aging; Geriatric Oncology

INTRODUCTION

Cancer disproportionately affects older adults. The median age at cancer diagnosis is now greater than 65 years, and the burden of cancer diagnoses and deaths is expected to only further increase over upcoming years [1–3]. As the complexity of cancer diagnoses, evaluation, trials, and therapeutics continues to rapidly increase, there is a constantly growing need to adapt all aspects of cancer care to the older adult population. Breakthroughs in cancer research must be carefully considered with comorbid medical conditions, functional status limitations, frailty, quality of life, and goals of care in cancer therapy decision making for older adults [4]. For example, the presence of frailty has been independently associated with adverse outcomes in older adults with cancer, including fatigue, depression, and all-cause mortality [5, 6].

To assist with the goal of providing evidence-based, objective care for older adults with cancer, the geriatric assessment (GA) is now recommended for all older adults with a new diagnosis of malignancy [7–10]. The GA is a broad, multi-disciplinary evaluation and intervention tool that seeks to address multiple aspects of care for older adults, with the purpose of maximizing all aspects of health in the aging process [11]. Specific components of the GA, pertinent to older adults with cancer, include evaluation of functional status, medical comorbid conditions, nutrition, psychosocial health and support, cognition, polypharmacy, and the presence of other geriatric syndromes [12, 13].

Polypharmacy is a key element of the GA, and it remains a common and potentially devastating challenge for older adults [14]. Polypharmacy can be particularly problematic among older adults with cancer, as up to 50-80% of older adults with cancer have been found to take at least five medications [15]. Polypharmacy can also be worsened during the treatment of cancer, as medications may be added for the management of cancer-related symptoms or treatment-related symptoms. A recent meta-analysis by Mohamed et al. suggested an association between polypharmacy and negative consequences in older adults with cancer, including an increased incidence of chemotherapy toxicity, functional decline, and post-surgical complications [16]. The National Comprehensive Cancer Network (NCCN) now recommends medication screening for polypharmacy as part of the routine evaluation and surveillance for all older adults with a diagnosis of cancer [3]. Unfortunately, the prevalence of polypharmacy and its impact on older adults with gastrointestinal (GI) malignancies is poorly understood.

Through analysis of data collected from the Cancer and Aging Resilience Evaluation (CARE) registry at the University of Alabama at Birmingham (UAB), our objective was to (1) assess the prevalence of polypharmacy and (2) examine the potential association between polypharmacy and functional status impairments, frailty, and health-related quality of life (HRQoL) in older adults with newly diagnosed GI malignancies.

METHODS

Study Population

The CARE registry at UAB is an ongoing prospective cohort study, with a brief, patient-reported GA completed at the initial patient visit to the UAB oncology team [17]. The CARE tool is based upon the Cancer and Aging Research Group (CARG) GA developed under the visionary leadership of Dr. Arti Hurria [13, 18] with modifications to be completed entirely by patient report [17]. We evaluated older adults (defined as ≥ 60 years of age) with a new diagnosis of GI malignancy, who presented for an initial evaluation at UAB prior to receiving systemic cancer therapy, from September 2017 through March 2020. The focus of this report is older adults with GI malignancies, as the concomitant problems of sarcopenia, malnutrition, and alterations in GI tract motility and absorption accompanying these cancer diagnoses may further augment the negative consequences of polypharmacy and highlight the lack of data specifically in this population [17]. The CARE Registry was approved by the Institutional Review Board at UAB in September 2017 (IRB-300000092).

Polypharmacy Assessment

Based on a review of the medical literature, many different medication thresholds have been proposed to define polypharmacy. This includes a number of daily medications taken by older adults, commonly ranging from ≥5 to ≥10 medications [16, 19]. For example, a review by Williams et al. in 2015 showed that older adults with cancer taking 9 or more medications reported increased falls over the previous 6 months [20]. During the completion of the CARE GA, patients are asked to record “How many medications do you take on a daily basis?” This includes prescription medications, as well as over-the-counter medications and supplements. Based on previous literature, we defined the presence of polypharmacy as patients reporting the use of ≥ 9 medications on a daily basis [19–21]. We also performed a sensitivity analysis, using polypharmacy as continuous variable, to assess the potential relationship between the number of self-reported medications and the same variables of functional limitations, frailty, and reduced HRQoL. This analysis is shown in the supplemental material.

Comorbidity Assessment

During the completion of the CARE GA, patients are also asked to record the presence of medical comorbid conditions and then grade how the condition impacts their activity level. For statistical analysis, the presence of medical comorbid conditions was determined using patient-reported answers to the presence of 13 medical conditions, as modified from the OARS Physical Health scale [22, 23]. These 13 medical conditions, as listed in the survey, are included in the supplemental material. Patients were dichotomized into having <3 or ≥3

comorbid conditions based on prior work demonstrating that ≥3 patient-reported comorbid conditions was associated with increased mortality [22].

Functional Status Impairments

The presence of functional status impairments was assessed by a patient report of dependency in activities of daily living (ADL) or instrumental activities of daily living (IADL), as demonstrated in the Older Americans Resources and Services (OARS) methodology [23, 24]. The CARE registry specially asks about select ADL, including the ability to manage bathing, dressing, and transferring, as well as select IADL, including the ability to manage housework, finances, meal preparation, medications, shopping, and transportation. A patient-reported dependency in any of the aforementioned ADL and IADL items was scored as a functional status impairment.

Frailty

The presence of frailty was determined by creation of a CARE frailty index, derived from the deficit accumulation method, based upon 44 items in the CARE GA [5, 25, 26]. Health deficits were identified and scored from patient responses to specific questions, including recent falls, dependency in ADL and IADL, global health concerns, reduced nutrition or weight, anxiety, depression, cognitive changes, social activity impairments, and medical comorbid conditions. A frailty index was then calculated as the fraction of reported deficits, ranging from 0 (no deficits) to 1 (all deficits reported). For purposes of this analysis, patients were dichotomized as being frail (frailty index > 0.35) or not frail (frailty index ≤ 0.35). Of note, the development and use of similar frailty indices in older adults with cancer have been found to be predictive of cancer treatment toxicity, overall survival, and HRQoL [5, 6, 27].

Health-related quality of life

The presence of impairments in HRQoL, in both physical and mental domains, was determined using previously validated scales included in the CARE GA [17]. HRQoL was calculated from the Patient-Reported Outcomes Measurement Information System (PROMIS) 10 Global Health questionnaire of the National Institutes of Health [28–30]. Patient responses were translated into t-scores, set to a standardized mean. Impairment in physical and mental HRQoL was then set at t-scores less than one standard deviation below the mean, as recommended by the PROMIS scoring manual [31].

Statistical Analysis

We used descriptive statistics to characterize the patient population, the number of reported daily medications, and the prevalence of polypharmacy. Group differences in demographic, clinical, and geriatric assessment domains between those with and without polypharmacy were initially examined using Student’s t-tests for continuous variables, and Chi-square tests or Fisher’s exact tests; the latter was used when expected cell size were small (<5) for categorical variables. We used separate multivariable logistic regression analyses to assess the potential association between polypharmacy and functional status impairments, frailty, and HRQoL, in separate models, adjusted a priori for age, sex, race, cancer type, cancer stage, and medical comorbid conditions, based on prior literature and clinical

judgment. These a priori adjustments were made similar to previous work involving the CARE registry, with the aim of reducing the potential confounding influence between medical comorbid conditions and polypharmacy [32–34]. Statistical tests were two-sided; statistical significance was set at a p-value ≤0.05. Statistical analysis was performed with SAS Statistical Software, Version 9.4, SAS Institute, Cary, North Carolina, USA.

RESULTS

Overall, 357 older adults who enrolled in the CARE registry at UAB met the eligibility criteria for inclusion in our study (see Table 1 below). The mean age was 70.1 years, 43.4% of patients were female, and 56.6% were male. 23.5% of patients were Black, 2.2% were Hispanic, and 75.1% were white. More than 70% of patients were retired or disabled and more than 60% were married. There was also a broad spectrum of GI malignancies included in the study, with colorectal cancer and pancreatic cancer as the most common subtypes of GI malignancy, although patients with hepatobiliary cancer, gastroesophageal cancer, neuroendocrine tumors, gastrointestinal stromal tumors, and anal cancers were also included. 26.1% of patients had stage III disease and 44.3% of patients had stage IV disease at diagnosis.

Patients reported a median of 6 medications (range 0-30; standard deviation 4.2). 27.7% of adults reported taking 0-3 medications, 48.2% reported taking 4-8 medications, and 24.1% reported taking with ≥ 9 medications per day. Of note, there was no significant difference regarding age, sex, race, ethnicity, and cancer type or stage between patients with or without polypharmacy.

When compared to patients taking <9 medications, older adults with polypharmacy (taking ≥ 9 medications) were more likely to report falls within the past six months (39.0% vs. 14.7%, $p < 0.0001$), self-reported eastern cooperative oncology group performance status scores of ≥ 2 (45.2% vs. 29.6%, p 0.008), and limitations in walking one block (76.5% vs. 45.7%, $p < 0.0001$). Additionally, older adults taking ≥ 9 medications were more likely to report limitations in ADL (32.5% vs. 13.2%, $p < 0.0001$) and IADL (71.8% vs. 44.1%, $p < 0.0001$), have a higher prevalence of frailty (57.5% vs. 27.8%, $p < 0.0001$), and report lower HRQoL physical (37.9 vs. 44.6, $p < 0.0001$) and mental (44.4 vs. 48.9, p 0.0001) scores (see Table 2 below).

When adjusted for age, race, cancer type, cancer stage, and the presence of medical comorbid conditions, these statistically significant associations remained. Older adults taking ≥ 9 medications were more likely to report limitations in ADL (adjusted odds ratio [aOR] 3.29, 95% CI 1.72-6.29) and IADL (aOR 2.86, 95% CI 1.59-5.14), frailty (aOR 3.06, 95% CI 1.73-5.41), and lower physical HRQoL (aOR 2.82, 95% CI 1.70-4.69) and mental HRQoL (aOR 1.73, 95% CI 1.03-2.91) (see Table 3 below).

DISCUSSION

In this study, we found that polypharmacy is common in older adults with recently diagnosed GI malignancy, as almost 75% of patients were taking ≥ 4 medications and approximately one fourth of patients were taking ≥ 9 medications prior to initiation of

systemic cancer therapy. We also found that older adults with cancer and polypharmacy, as defined by the use of ≥ 9 medications on a daily basis, reported a higher prevalence of functional status limitations, frailty, and reduced HRQoL.

Traditionally, some have viewed polypharmacy as a consequence of the management of medical comorbid conditions. Therefore, it could be theorized that medical comorbid conditions, such as cardiovascular disease, diabetes mellitus, and chronic obstructive pulmonary disease, are driving adverse measures in patients taking more medications, leaving polypharmacy as a mere association, but not a contributive agent. However, we found that when multivariable analysis controlled for the presence of medical comorbid conditions, polypharmacy remained a strong, independent, predictor of age-related impairments in older adults with recently diagnosed GI malignancy. This is consistent with years of well-validated data from the field of geriatric medicine, where screening tools such as the American Geriatrics Society (AGS) Beers Criteria, have been used to help identify and classify medications that have independently been associated with adverse outcomes in older adults [35]. Therefore, polypharmacy should be considered a primary problem for older adults with cancer, and it has appropriately been included as a key screening component of a comprehensive GA.

Our findings of the presence of polypharmacy and the potential association with reduced health status in older adults with malignancy are supported by the medical literature, although we have explored new avenues with the focus on GI malignancy and the measures of functional limitations, frailty, and HRQoL. In a study by Lu-Yao et al. of older adults with prostate, breast, or lung cancer, they found a statistically significant association between number of medications taken before initiation of chemotherapy and subsequent hospitalization rates after completion of chemotherapy [36]. In this review, patients taking 5-9 medications had 17-42% higher rates of hospitalization and patients taking 10-14 medications had 49-75% higher rates of hospitalization, compared to patients taking less than 5 medications.

Another recent article by Mohamed et al. reviewed the prevalence of polypharmacy and the association with functional limitations in 439 older adults with cancer treated in community practice; 34% of the patients had GI malignancies [37]. In this study, they found that the mean number of medications taken by patients was 7.1. Patients taking ≥ 8 medications were found to have statistically significant impairments in ADL, but not IADL, compared to those taking < 8 medications.

Our study is not without limitations. First, this review results from a single institution, cross-sectional analysis, and therefore, no causality between polypharmacy and these outcomes can be inferred. Our study also does not account for changes in prescribing practices during or after cancer therapy, as medications were reported at the time of the patient's first visit to the oncology team. Additionally, the measure of polypharmacy is determined by patient or caregiver reported numbers of medications, and does not account for differences in the prescription, over-the-counter, and supplemental medications. Our study is also currently limited to patients with GI malignancy located from the Southeastern United States and may not be applicable to other populations of older adults with cancer. Finally, it should be noted

that there are limitations to defining polypharmacy by a simple number of medications, as certain medications are clearly more potentially problematic than others for older adults. This has led to the identification and classification of “potential inappropriate medications” for older adults, such as in the aforementioned AGS Beers Criteria [35]. However, even the inclusion of these validated and updated criteria in the assessment of polypharmacy and cancer-related outcomes has limitations, as these tools were developed in the general older adult population. There is an ongoing need to develop polypharmacy tools specific to older adults with cancer.

Currently, there is much ongoing work in the field of geriatric oncology and polypharmacy. A recent review by Barlow et al. highlighted key areas for improvement in the care of older adults with cancer [38]. This includes using clear and concise definitions of polypharmacy, utilizing a multidisciplinary approach to polypharmacy assessment including the performance of comprehensive medication reviews and comprehensive GA, and using evidence-based deprescribing practices to reduce the polypharmacy burden in older adults. The review also points out the ongoing need for interventional research, particularly in outcomes that matter most to older adults with cancer [38]. There is a significant need to perform prospective studies to evaluate the pattern, changes, and influence of polypharmacy on cancer care and outcomes for older adults, throughout the course of cancer therapy.

In the future we plan to continue our work elucidating these adverse associations of polypharmacy in older adults with cancer. In particular, further work is critically needed to identify which medications are particularly problematic in older adults with cancer and to improve our understanding of how polypharmacy changes during cancer therapy. This work will be instrumental to providing meaningful screening and interventional tools to help prevent and reduce the adverse consequences of polypharmacy in the growing number of older adults with cancer.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Demographic and Cancer Characteristics for the Study Population

	All	Polypharmacy (≥9 medications)		*p*-value*
		No	Yes	
Total Patients	**N= 357**	**N= 270**	**N= 87**	
Age, mean (SD)	70.1 (7.3)	69.9 (7.4)	70.6 (7.1)	0.3847
Age, n (%)				
60-64	97 (27.2)	78 (28.9)	19 (21.8)	0.6901
65-69	84 (23.5)	63 (23.3)	21 (24.1)	
70-74	78 (21.8)	56 (20.7)	22 (25.3)	
75-79	54 (15.1)	39 (14.4)	15 (17.2)	
80+	44 (12.3)	34 (12.6)	10 (11.5)	
Sex, n (%)				
male	202 (56.6)	160 (59.3)	42 (48.3)	0.0723
female	155 (43.4)	110 (40.7)	45 (51.7)	
Race, n (%)				
white	268 (75.1)	201 (74.4)	67 (77.0)	0.8828
Black	84 (23.5)	65 (24.1)	19 (21.8)	
Ethnicity, n (%)				
Hispanic	8 (2.2)	7 (2.6)	1 (1.1)	0.4290
Educational Level, n (%)				
less than high school	63 (17.6)	47 (17.4)	16 (18.4)	0.3177
high school graduate	97 (27.2)	71 (26.3)	26 (29.9)	
some college	64 (17.9)	47 (17.4)	17 (19.5)	
associate / bachelor's degree	100 (28.0)	75 (27.8)	25 (28.7)	
advanced degree	33 (9.2)	30 (11.1)	3 (3.4)	
Employment, n (%)				
retired	216 (60.5)	162 (60.0)	54 (62.1)	0.0211
disabled	47 (13.2)	28 (10.4)	19 (21.8)	
part-time (<32hr/week)	10 (2.8)	9 (3.3)	1 (1.1)	
full-time (>32hr/week)	38 (10.6)	33 (12.2)	5 (5.7)	
other	46 (2.9)	38 (14.1)	8 (9.2)	
Marital Status, n (%)				
single	26 (7.3)	18 (6.7)	8 (9.2)	0.5857
widowed / divorced	103 (28.9)	76 (28.1)	27 (31.0)	
married	228 (63.9)	176 (65.2)	52 (59.8)	
Cancer Type, n (%)				
Colorectal	120 (33.6)	87 (32.2)	33 (37.9)	0.6045
Pancreatic	88 (24.6)	66 (24.4)	22 (25.3)	

	All	Polypharmacy (≥9 medications)		*p*-value*
		No	Yes	
Total Patients	**N= 357**	**N= 270**	**N= 87**	
Hepatobiliary	58 (16.2)	43 (15.9)	15 (17.2)	
Gastroesophageal	39 (10.9)	33 (12.2)	6 (6.9)	
Other (NEC, GIST, Anal)	52 (14.6)	41 (15.2)	11 (12.6)	
Cancer Stage, n (%)				
0-II	106 (29.7)	75 (27.8)	31 (35.6)	0.2665
III	93 (26.1)	75 (27.8)	18 (20.7)	
IV	158 (44.3)	120 (44.4)	38 (43.7)	

*based on comparison between patients with polypharmacy and patients without polypharmacy

Table 2:

Differences in Geriatric Assessment and Health-Related Quality of Life by Report of Polypharmacy

	Polypharmacy (≥9 medications)		
	No	**Yes**	***p*-value**
Geriatric Assessment Domains			
≥1 falls, n (%)	38 (14.7)	32 (39.0)	**<.0001**
Impaired (≥2) ECOG performance status, n (%)	79 (29.6)	38 (45.2)	**0.0080**
Reported limitations in walking one block, n (%)	121 (45.7)	65 (76.5)	**<.0001**
Any IADL dependence, n (%)	115 (44.1)	61 (71.8)	**<.0001**
Any ADL dependence, n (%)	35 (13.2)	27 (32.5)	**<.0001**
Frail, n (%)	75 (27.8)	50 (57.5)	**<.0001**
Health-Related Quality of Life			
Physical health score, mean (SD)	44.6 (10.8)	37.9 (9.4)	**<.0001**
Mental health score, mean (SD)	48.9 (9.7)	44.4 (9.0)	**0.0001**

Abbreviations: IADL, Instrumental Activities of Daily Living; ADL, Activities of Daily Living; SD, standard deviation.

Table 3:

Unadjusted and Adjusted Odds Ratios of Polypharmacy (≥9 medications per day) with Geriatric Assessment and Health-Related Quality of Life

Geriatric Assessment Domains	Unadjusted Odds, 95% CI	Adjusted Odds*, 95% CI
≥1 fall	**3.71 (2.11-6.50)**	**3.34 (1.80-6.22)**
Impaired (≥2) ECOG performance status	**1.97 (1.19-3.25)**	**1.91 (1.09-3.32)**
Reported limitations in walking one block	**3.87 (2.22-6.75)**	**3.40 (1.82-6.33)**
Any IADL dependence	**3.23 (1.90-5.49)**	**2.86 (1.59-5.14)**
Any ADL dependence	**3.18 (1.78-5.69)**	**3.29 (1.72-6.29)**
Frail	**3.51 (2.13-5.80)**	**3.06 (1.73-5.41)**
Health-Related Quality of Life		
Physical health score, ≤40	**2.82 (1.70-4.69)**	**2.82 (1.70-4.69)**
Mental health score, ≤40	**1.73 (1.03-2.91)**	**1.73 (1.03-2.91)**

*Adjusted for age, sex, race, cancer type, cancer stage, and comorbid medical conditions