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Incidence and Predictors of All and Preventable Adverse Drug Reactions in Frail Elderly Persons After Hospital Stay

Joseph T. Hanlon,[1,2] Carl F. Pieper,[3,4] Emily R. Hajjar,[5] Richard J. Sloane,[3] Catherine I. Lindblad,[6,7] Christine M. Ruby,[1] and Kenneth E. Schmader[3,8,10]

[1]Department of Medicine (Geriatrics), School of Medicine, and Department of Pharmacy and Therapeutics, School of Pharmacy, University Pittsburgh, Pennsylvania.
[2]Center for Health Equity Research, Veterans Affairs Pittsburgh Healthcare System, Pennsylvania.
[3]Aging Center and [4]Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina.
[5]Philadelphia College of Pharmacy, University of the Sciences in Philadelphia, Pennsylvania.
[6]College of Pharmacy, University of Minnesota, Minneapolis.
[7]Veterans Affairs Medical Center, Minneapolis, Minnesota.
[8]Geriatric Research Education and Clinical Center, Veterans Affairs Medical Center, Durham, North Carolina.
[9]School of Pharmacy, University of North Carolina, Chapel Hill.
[10]School of Medicine, Duke University Medical Center, Durham, North Carolina.

Background. Adverse drug reactions (ADR) negatively impact life quality and are sometimes fatal. This study examines the incidence and predictors of all and preventable ADRs in frail elderly persons after hospital discharge, a highly vulnerable but rarely studied population.

Methods. The design was a prospective cohort study involving 808 frail elderly persons who were discharged from 11 Veteran Affairs hospitals to outpatient care. The main outcome measure was number of ADRs per patient as determined by blinded geriatrician and geropharmacist pairs using Naranjo's ADR algorithm. For all ADRs (possible, probable, or definite), preventability was assessed. Discordances were resolved by consensus conferences.

Results. Overall, 33% of patients had one or more ADRs for a rate of 1.92 per 1000 person-days of follow-up. The rate for preventable ADRs was 0.71 per 1000 person-days of follow-up. Independent risk factors for all ADRs were number of medications (adjusted [Adj.] hazard ratio [HR], 1.07; 95% confidence interval [CI], 1.05–1.10 per medication), use of warfarin (Adj. HR, 1.51; 95% CI, 1.22–1.87), and (marginally) the use of benzodiazepines (Adj. HR, 1.23; 95% CI, 0.95–1.58). Counterintuitively, use of sedatives and/or hypnotics was inversely related to ADR risk (Adj. HR, 0.14; 95% CI, 0.04–0.57). Similar trends were seen for number of medications and warfarin use as predictors of preventable ADRs.

Conclusions. ADRs are very common in frail elderly persons after hospital stay, and polypharmacy and warfarin use consistently increase the risk of ADRs.

IT is estimated that 10%–25% of older adults are frail. The majority of frail older adults live in the community (1). Frail older adults have clinical manifestations that include weakness, anorexia, weight loss, sarcopenia, osteopenia, undernutrition, deconditioning, decreased mobility, and impaired activities of daily living (1). Frail elderly persons are at high risk for serious morbidity and mortality. The goal of caring for this vulnerable population is to optimize their health-related quality of life (1).

A major threat to the health-related quality of life of frail elderly persons is adverse drug reactions (ADRs) (2). As outlined in an Institute of Medicine report (3), ADRs are a major patient-safety problem. Specifically, ADRs in older adults can decrease functional status and increase health services use and costs and death (2). Of major concern is that these consequences of ADRs are likely to be more pronounced in frail elderly persons. There are limited data regarding the incidence of ADRs in elderly outpatients. Previously reported annual ADR rates ranged from 5% to 35% in community dwelling and outpatient older adults (4–7). Of note, none of these studies focused on frail elderly persons recently discharged from hospital or found consistent ADR risk factors. The objectives of this study are to determine the incidence and predictors of all and preventable ADRs in frail elderly persons after hospital stay.

Methods

Study Setting, Sample, and Design

This investigation was part of a randomized controlled health services trial examining the impact of specialized geriatric evaluation and management care on drug-related problems (GEM Drug Study) (8). The intervention was conducted at 11 Veterans Affairs Medical Centers (VAMCs) and randomized 1388 patients overall. Patients were eligible if they were: (a) age >65 years, (b) hospitalized on a medical or surgical ward for >48 hours, and (c) met 2 or more of 10 criteria for frailty (dependence in at least one activity of daily living [ADL], stroke within 3 months, previous falls, difficulty ambulating, malnutrition, dementia, depression, unplanned admission in the last 3 months, prolonged bed rest, or incontinence). Patients were excluded if they were admitted from a nursing home, cared for by a geriatric clinic, previously hospitalized in a geriatric

unit, were currently enrolled in another clinical trial, had a severe disabling disease or terminal condition, had severe dementia, did not speak English, lacked access to a telephone for follow-up, or were unwilling and/or unable to return for follow-up clinic visits. Patients were enrolled between August 31, 1995 and January 31, 1999 and followed for a 1-year period. Due to the time requirements for ADR evaluations, a computer program generated a random sample of 864 patients from the parent study. The current study sample included 808 GEM Drug Study participants who were discharged from hospital and had complete data for ADR evaluations. There were no significant differences between the characteristics of the original 1388 patients enrolled and these 808 patients from the GEM Drug Study (8). All patients received outpatient care in VAMC clinics. The design of the study was a prospective cohort study. The study was approved by the VAMC Research and Human Subjects Committees at each study site and the Institutional Review Boards of Duke University and the University of Minnesota.

Data Collection and Self-Report of Potential Drug-Related Adverse Events

A trained research assistant at each site prepared an abstract of each patient's VAMC inpatient and outpatient medical chart that included problem lists, progress notes for all clinic appointments, laboratory results, medications, procedures, and discharge summaries from emergency room visits and hospitalizations from the year prior to randomization and for the year of the study. Closeout telephone interviews, 1 year after the original randomization, were conducted by a trained research clinical pharmacist who queried for self-reports of potential drug-related adverse events. Specifically, patients were asked whether in the past year they had experienced any side effects, unwanted reactions, or other problems with their medications (9). For those participants answering ''yes,'' the pharmacist used a semi-structured questionnaire to determine the name of the medication involved, to obtain a full description of the problem, and to find out whether the patient talked to a doctor about the event and what was advised (e.g., medication modification, emergency room visit, hospitalization) or whether the patients, on their own, modified the use of the medication in question. A previously published study that we conducted showed that only 56% of a random sample of 25 participants that self-reported potential drug-related adverse events had information also reported in their medical record (9).

Chart Review and Abstracting of Potential Drug-Related Adverse Events

A trained research nurse reviewed the abstracted charts and applied each of five standardized drug-related adverse event screens: tracer drugs (e.g., vitamin K to treat bleeding due to warfarin); elevated serum levels for narrow therapeutic range drugs (e.g., theophylline); medications discontinued without replacement, diagnosed drug-related adverse events; electronic medical record notation of drug allergy/ADR) (9).

For each potential drug-related adverse event identified by chart review and/or patient interview, trained clinical pharmacists created a detailed narrative. This narrative, based on reporting methods by the Food and Drug Administration, included a description of the adverse event; the implicated medication, its purpose, and start and stop date; previous ADR history with similar drugs; severity of the potential drug-related event; effects of medication withdrawal (dechallenge) or rechallenge; and treatment for the potential drug-related adverse event (10). It is important to note that we had detailed information about the medications taken at the time of the drug-related adverse event because of a complete listing of medication refills that appeared on patients' VA ''Action Profile.''

Outcome Measures

Blinded geriatrician and geropharmacist pairs evaluated ADR causality using the narrative and the reliable and valid algorithm by Naranjo and colleagues (11). The algorithm classifies ADRs as doubtful, possible, probable or definite; the latter three categories were considered ADRs. These ADRs were also assessed for preventability (i.e., prescribing, monitoring, dispensing, or adherence errors; 12). Any discordances among evaluators were resolved by clinical consensus conference. ADRs were categorized by COSTART body system and VA Medication Class codes (13,14). For descriptive purposes, the percentage with one or more ADRs and the ADR incidence rate per 1000 days were calculated. For analysis purposes, the number of ADRs was calculated.

Independent Variables

We examined 17 potential risk factors for ADRs in older adults as determined by expert panel consensus (7). Briefly, the process of achieving consensus was achieved through a modified two-stage Delphi survey of 10 physicians and pharmacists. Using a 5-point Likert scale, the panel rated the probability that 50 potential factors could independently place ambulatory elderly persons at high risk for experiencing an ADR. After the survey responses were received, means and 95% confidence intervals (CIs) were calculated. Consensus was defined as a mean of 4.0 or greater with a lower 95% CI greater than 4.0. Patient characteristics were represented by dichotomous variables for dementia, advanced age, multiple prescribers, history of prior ADR, and severe renal insufficiency. Severe renal insufficiency was defined as being currently on dialysis, admitted for dialysis initiation or graft placement, or having a creatinine level of 5.0 or greater. Continuous measures were created for the number of medications and comorbidities (defined by Charlson index). Medication characteristics were represented by dichotomous variables for use of anticholinergics, benzodiazepines, antipsychotics, sedatives and/or hypnotics, theophylline, warfarin, nonsteroidal anti-inflammatory drugs, tricyclic antidepressants, opioid analgesics, and corticosteroids. All risk factors were measured at the time of hospital discharge.

Statistical Analysis

Descriptive statistics were calculated for all dichotomous and continuous variables. To analyze number of ADRs, we used Poisson regression using PROC GENMOD in SAS (Cary, NC; 15). To derive a final multivariable model, we

Table 1. Selected Characteristics of Frail Elderly Patients After Hospital Stay ($N = 808$)

Variables	%	Mean (*SD*)
Patient characteristics		
Female	2.0	
Advanced age (>75 y)	46.4	
Dementia	10.3	
Severe renal insufficiency	5.2	
Prior adverse drug reaction	18.9	
Multiple prescribers (≥2)	4.0	
No. of medications		8.7 (4.2)
No. of comorbidities		2.5 (1.9)
Limitations in basic activities of daily living		2.8 (2.0)
Fair or poor self-rated health	61.7	
Depression	9.32	
History of multiple falls (≥2)	17.6	
Malnutrition	32.5	
Use of specific medications or classes of medications		
Anticoagulants (i.e., warfarin)	14.6	
Theophylline	4.1	
Anticholinergics	13.1	
Opioid analgesics	24.4	
Antipsychotics	2.2	
Benzodiazepines	10.8	
Nonsteroidal anti-inflammatory drugs	14.1	
Tricyclic antidepressants	6.4	
Corticosteroids	9.4	
Sedatives and/or hypnotics	2.0	

Note: *SD* = standard deviation.

used stepwise procedures ($p < .10$ to stay) using all candidate variables listed above. The model fit was assessed by the ratio between the deviance statistic and its degrees of freedom. Those models with a ratio close to 1.00 demonstrate adequate fit.

Results

Table 1 presents some of the characteristics of the 808 frail elderly outpatients. Most were men and less than 75 years old. Many patients had multiple comorbidities and took multiple medications. The most common drugs taken were warfarin and opioid analgesics.

Overall, 497 ADRs (possible = 298; probable = 183; definite = 16) were determined of which 13.7% were self-reported by patients. Thirty three percent of patients had one or more ADRs during follow-up for an incident rate of 1.92 events per 1000 person-days of follow-up. Table 2 shows the most common medication classes causing an ADR. The most common ADRs involved the digestive (e.g., diarrhea), nervous (e.g., somnolence), cardiovascular (e.g., dizziness), and metabolic (e.g., kidney function abnormality) systems.

One hundred eighty-seven preventable ADRs (possible = 82; probable = 95; definite = 10) were determined of which 11.54% were self-reported by patients. Sixteen percent of patients had one or more preventable ADRs for an incident rate of 0.71 events per 1000 person-days of follow-up. Table 2 shows the most common medication classes causing a preventable ADR. The most common reactions involved the nervous (e.g., somnolence), metabolic (e.g., hypoglycemia), digestive (e.g., constipation, diarrhea, and dyspepsia),

Table 2. Most Common Drugs Involved With Adverse Drug Reactions (ADRs) in Frail Elderly Persons After Hospital Stay

Drugs	%
All ADR ($N = 497$)	
Anticoagulants (i.e., warfarin)	8.6
Diuretics	8.5
Angiotensin-converting enzyme inhibitors	6.2
Antidiabetics	6.2
Anticholinergics	6.2
Anti-infectives	5.4
Nonsteroidal anti-inflammatory drugs	5.4
Nontricyclic antidepressants	4.8
Digoxin	4.4
Beta blockers	4.2
Calcium channel blockers	3.8
Opioid analgesics	2.8
Antiepileptic drugs	2.4
Others	33.8
Preventable ADRs ($N = 187$)	
Antidiabetics	11.8
Anticholinergics	11.2
Anticoagulants (i.e., warfarin)	10.7
Diuretics	9.6
Nonsteroidal anti-inflammatory drugs	7.0
Digoxin	5.8
Opioid analgesics	5.3
Calcium channel blockers	4.8
Antiepileptic drugs	4.3
Angiotensin-converting enzyme inhibitors	3.2
Anti-infectives	3.2
Beta blockers	2.1
Benzodiazepines	2.1
Others	17.8

and cardiovascular (e.g., bradycardia) systems. Figure 1 shows that the majority of both all and preventable ADRs occurred within 4 months of hospital discharge.

Tables 3 and 4 shows the results of our bivariate and multivariable analyses. Multivariable models showed that those persons who took warfarin and multiple medications had an increased incidence rate of all and preventable ADRs. The use of sedatives and/or hypnotics was protective for all ADRs but not for preventable ones. However, this finding may be spurious as there were only 16 users of sedatives and/or hypnotics with two ADRs. No demographic or health status variables contributed to the final multi-

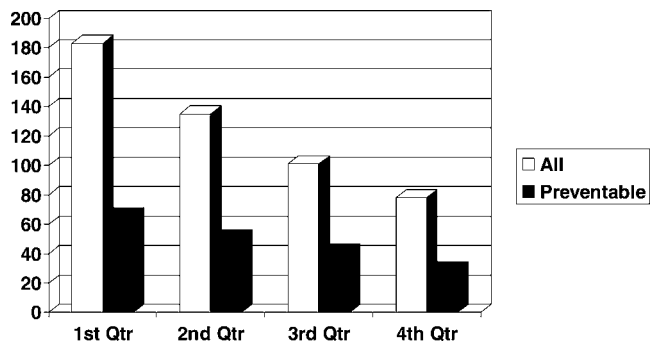

Figure 1. Time to all and preventable adverse drug reaction (ADR) occurrence.

Table 3. Bivariate Association Between Potential Risk Factors and Any and Preventable Adverse Drug Reactions (ADRs) in Frail Elderly Persons After Hospital Stay ($N = 808$)

Risk Factors	Any ADRs Crude HR	Any ADRs 95% CI	Preventable ADRs Crude HR	Preventable ADRs 95% CI
Patient characteristics				
Age >75 y	0.55	0.30, 1.00	0.81	0.36, 1.83
Dementia	1.07	0.80, 1.43	1.04	0.65, 1.68
Multiple prescribers	1.87	1.30, 2.67	2.21	1.28, 3.81
No. of medications	1.08	1.06, 1.10	1.11	1.08, 1.15
Multiple comorbidities (Charlson index)	1.03	0.98, 1.07	1.03	0.95, 1.11
Severe renal insufficiency	1.16	.79, 1.71	1.27	0.69, 2.34
Prior ADR	1.15	0.93, 1.44	0.99	0.68, 1.44
Specific medications or classes of medication				
Anticoagulants (i.e., warfarin)	1.67	1.35, 2.06	1.71	1.21, 2.40
Theophylline	1.29	0.86, 1.95	1.15	0.56, 2.33
Anticholinergics	1.11	0.86, 1.43	0.92	0.59, 1.44
Opioid analgesics	0.86	0.69, 1.06	0.78	0.54, 1.11
Antipsychotics	1.18	0.66, 2.08	1.86	0.87, 3.96
Benzodiazepines	1.63	1.28, 2.06	1.87	1.29, 2.71
Nonaspirin, nonsteroidal anti-inflammatory drugs	1.26	1.00, 1.59	1.58	1.11, 2.25
Tricyclic antidepressants	1.44	1.05, 1.97	1.43	0.86, 2.39
Corticosteroids	1.18	0.88, 1.57	1.10	0.68, 1.79
Sedatives and/or hypnotics	0.19	0.05, 0.76	0.25	0.04, 1.80

Note: HR = hazard ratio; CI = confidence interval.

Table 4. Multivariable Model of Risk Factors for All and Preventable Adverse Drug Reactions (ADRs) in Frail Elderly Persons After Hospital Stay ($N = 808$)*

	All ADRs†			Preventable ADRs‡		
Risk Factor	Adj. HR	95% CI	p	Adj. HR	95% CI	p
Anticoagulants (i.e., warfarin)	1.51	1.22, 1.87	<.001	1.50	1.08, 2.11	.021
Benzodiazepines	1.23	0.95, 1.58	.119	—	—	—
Sedatives and/or hypnotics	0.14	0.04, 0.57	.006	0.16	0.02, 1.18	.072
No. of medications	1.07§	1.05, 1.10	<.001	1.11§	1.08, 1.15	<.001

Notes: *Hazard ratio (HR) and 95% confidence interval (CI) were determined by stepwise multivariable analyses ($p < .10$) using Poisson regression to allow for multiple ADRs per patient and to determine the impact of 17 potential risk factors.

†Deviance/degrees of freedom = 1.50.

‡Deviance/degrees of freedom = .86.

§Hazard ratio increases per number of medications.

variable models. Our multivariable models demonstrated adequate fit (i.e., deviance and/or degrees of freedom ratios were 1.50 and 0.86).

Discussion

To our knowledge, this is the first study documenting all and preventable ADRs in frail elderly patients recently discharged from hospital and followed as outpatients for up to 1 year. We found that one third of patients had at least one ADR. Moreover, more than one third of the 497 total ADRs were judged to be preventable. It is interesting to note that the majority of ADRs occurred in the first few months after discharge. This finding suggests that better in-hospital review and short-term review after discharge might be especially needed to prevent and/or manage ADRs. Few studies have investigated the epidemiology of ADRs in elderly outpatients after hospital discharge. A study by Forster and colleagues (16) examined adverse events (including some involving medications) in 400 adult patients (mean age 57 years) recently discharged from a tertiary care hospital. Overall, the researchers determined by medical record review and patient interview in the 1-month follow-up period that 50 of the patients (12.5%) experienced an ADR. A study by Gray and colleagues (17) examined 256 elderly patients discharged from hospital to receive home health care. They found that 20% self-reported an ADR over a 1-month period. The difference between our results and the results from these two studies may in part be due to our sample (frail older outpatients) and our longer follow-up period.

This study also found that only two variables (warfarin and multiple medication use) were consistent risk factors for both all and preventable ADRs. It is important to note that the incidence rate of an ADR increases with each additional medication used. For example, the incident rate of an ADR is 30% greater for those elderly persons taking nine medications. Multiple medication use was identified as a significant ADR risk factor in ambulatory care, long-term care facilities, and hospital settings (2,4,6,18). This finding is important because multiple medication use is potentially modifiable, unlike some other risk factors. The most common ADRs with anticoagulants (i.e., warfarin) were gastrointestinal bleeding, epistaxis, and hematuria. The study by Gurwitz and colleagues (6) also found that anticoagulant (i.e., warfarin) users were at increased risk for all and preventable ADRs. It is also of interest to discuss the negative findings for age and comorbidity. The study by Gurwitz (6) showed a relationship between ADRs and the Charlson comorbidity index. It is possible, because all patients in our study were frail, that there was less heterogeneity in this potential risk factor. Most studies that controlled for the number of medications taken, comorbidities, and other potential health status risk factors have not found an association between age and the occurrence of ADRs (2).

How can health care professionals taking care of older frail adults use the results of this study? Clinicians who care for frail older patients taking warfarin or those with polypharmacy should (a) consider these individuals at high risk for ADRs and (b) critically review their medication regimens during hospitalization and in the outpatient setting (e.g., at least every 6 months). Clinical pharmacists are particularly well trained and situated to help conduct these medication reviews (19). They can identify for prescribers and patients unnecessary medications that may be discontinued and inappropriate medications that can be optimized. In addition, specialized outpatient geriatric care may reduce the risk of serious ADRs (8).

There are several potential limitations worth noting. We used retrospective detection methods which could have led to an underestimate of the true ADR incidence. Our chart-based screens could have also resulted in surveillance bias for some particular types of ADRs. For example, the drug

level screen may have been very sensitive for identifying high Prothrombin Time–International Normalized Ratio warfarin ADRs whereas some other ADRs had no such relevant screen. Moreover, we could not evaluate some potential medication-related ADR risk factors as no patients were taking these drugs (i.e., lithium, chlorpropamide) during this study. Finally, the generalizability of our findings is unknown as it involved mostly male frail elderly veteran outpatients recently hospitalized and thus may differ from other ADR studies of older outpatients who were not hospitalized.

Conclusion

Despite these potential limitations, we conclude that ADRs are common in frail elderly persons after hospital stay and that polypharmacy and the use of warfarin consistently increase the risk of ADRs. Additional studies are needed in non-VAMC settings to a priori identify and intervene upon elderly persons after hospital stay at risk of ADRs.

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Address correspondence to Joseph T. Hanlon, PharmD, MS, Department of Medicine (Geriatrics), University of Pittsburgh, Kaufman Medical Building, Suite 514, 3471 5th Avenue, Pittsburgh, PA 15213. E-mail: hanlonj@dom.pitt.edu

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