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Evaluation of Medication Risks for Falls on an Inpatient Medical/Surgical Unit

A Thesis

Presented to the Department of Pharmacy

College of Pharmacy and Health Sciences

and

The Honors Program

of

Butler University

In Partial Fulfillment

of the Requirements for Graduation Honors

Joseph Albert Zegar III

May 12th, 2018

Abstract

Purpose: Patient falls during hospitalization can delay discharge and decrease quality of life. Medications are one factor that can impact fall risk. This study examines patients who fell while admitted to a cardiac surgery unit to identify which high-risk medications are most prevalent to promote patient safety.

Methods: This was a retrospective case control study. Adult patients over the age of 18 were included. Exclusion criteria included pediatric patients and those with an intentional fall event. A total of 39 falls and 78 controls were analyzed in the study. The primary outcome was a fall event during hospitalization. Other variables included medications, time of medication administration, and risk factors.

Results: The medications significantly more common in patients who fell include morphine (31% vs. 6%, p=0.001), insulin glargine (28% vs. 12%, p=0.011), amlodipine (23% vs. 10%, p=0.0495), hydralazine (23% vs. 8%, p=0.036), isosorbide mononitrate (21% vs. 5%, p=0.02), lorazepam (21% vs. 1%, p<0.001), and levothyroxine (21% vs. 5%, p=0.02). Furthermore, 56% of patients who fell received two or more medications an hour before the event. Patients who fell were significantly more unsteady (41% vs. 5%, p<0.001), impulsive (21% vs. 1%, p=0.001) and classified as having an altered mental status (33% vs. 6%, p<0.001). After performing a binomial logistic regression, significant medications included morphine (OR 10.56, 95% Cl 2.704-41.248, p=0.001), lorazepam (OR 31.987, 95% Cl 3.179-321.798, p=0.003), and levothyroxine (OR 7.641, 95% Cl 1.816-32.146, p=0.006).

Conclusion: Cardiac surgery patients are exposed to multiple high-risk medications. Benzodiazepines and potent analgesics may increase fall risk and should be closely monitored. Further work is warranted to examine the clinical impact of these results in larger patient populations.

Background

Although much work has already been done to prevent patients from falling during hospitalization, it is still a major concern due to the wide array of potential complications. The challenge with preventing falls is largely associated with the numerous risk factors that are at play (1–3). Additionally, while falls have been well-characterized, they can vary greatly and each event may be due to unique problems, making it hard to accurately predict which patients will fall for one reason or another (1,2).

Although some risk factors are generally unalterable, a patient's medications are one risk that can be impacted through deprescribing or changes in therapy. Also, while there are multiple screening tools available to assess a patient's fall risk, it is unclear if they are sufficient when attempting to identify patients most likely to fall (4,5). Therefore, it may be beneficial to focus on various risk factors to mitigate individual concerns relevant to each patient. There are multiple resources that highlight the various risks of medication use. One example is the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative through the CDC and American Pharmacist Association. There are resources for fall assessment and information on how medications may contribute to fall risk based on available literature (6). Additionally, the Beers Criteria includes information on potentially inappropriate medications in geriatric patients (7). This information can be helpful in all patients, even those that are not classified as geriatric (8). Therefore, there is already some information available to identify high-risk medications being used during a patient's hospitalization and their role in fall risk.

Previous studies have contributed a large amount of information regarding how medications can affect fall risk. Many of these studies agree with respect to the generally accepted classes of high risk medications, including anticonvulsants, antipsychotics, benzodiazepines, non-benzodiazepine hypnotics, tricyclic antidepressants (TCAs), selective serotonin receptor inhibitors (SSRIs), and opioids (7,9– 11). While each of these medications can impact fall risk in different ways, the Beers Criteria recommends avoiding them due to potential for various side effects such as dizziness, sedation, and syncope (7). However, many of these medications are often necessary, which complicates balancing of fall risk and treatment of conditions. These risks can be further increased when patients are in the hospital for surgery, as they are often receiving multiple high-risk medications in the perioperative period. Previous work has characterized perioperative falls as a significant issue that can persist up to a year after discharge (12).

When attempting to quantify or assess a patient's fall risk, screening tools can be helpful (4,5,13). One such example is the John Hopkins Fall Risk Assessment Tool (14). The validity and predictive value of this tool has previously been studied in home healthcare and in the inpatient setting (5,13). This assessment is typically completed by a registered nurse and can be repeated throughout a patient's admission as fall risk may change over time. Multiple categories determine how high a patient's fall risk may be. These include age, fall history, incontinence, urinary urgency or frequency, presence of high risk medications, patient care equipment, mobility, and cognition are assessed. Each risk factor has an assigned value between 1 and 7 points. If the total score is

between 6 and 13, the patient has a moderate fall risk. If the score is >13, the patient has a high fall risk. In the case of the hospital included in this study, the assessment was typically performed upon admission and at least once daily throughout the patient's stay.

It is crucial to continue studying fall risk during hospitalization since patients are at higher risk for complications due to acute illnesses. While high-risk patients can typically be identified, this alone has not proven effective at reducing inpatient falls (15). Therefore, the purpose of this study is to focus on patients in cardiac surgery units and determine if risk factors are varied in this setting. Some previous studies have used a case control design to assess fall risk, but these patients were not specifically hospitalized for cardiac-related issues (16). Furthermore, initiation of new medications may also contribute to increase in fall risk, especially when the medications contribute to orthostatic hypertension or confusion (17). This study intends to identify if timing of administration is a potential risk factor for patients who fall. Examining temporal relationships may also help determine if chronic or acute medications are stronger contributors. Additionally, such relationships can identify when increased monitoring by nursing staff following medication administration may be beneficial. Information from this study will ideally add to the general knowledge of medication risk and potentially identify safer medications to use when fall risk is already elevated for other reasons.

Methods

This study was a retrospective case-control study designed to identify medications that increase fall risk for hospitalized patients. The study was conducted at a large academic center. The hospital units examined included the cardiovascular surgery step-down units, made up of 51 beds total. This was done due to the perceived increase in falls for patients in these two units over the period of time included in this study. While the patient population in these units is largely post-surgical, some general medicine patients were periodically admitted to the unit based on hospital demands and availability of beds. Patients with a fall event between January 1, 2015 and June 30, 2016 were eligible for inclusion in the study. Falls were identified from the adverse event reports used within the hospital to report various events during hospitalization, such as a patient fall. These reports were completed by the nurse supervisor upon discovery of the event. If a patient fell multiple times during an admission while on either unit, each event was included in the study as a separate fall. Patients were excluded if they were under the age of 18 or if the fall event was deemed to be intentional. There were some patients who attempted to feign a fall to receive medication. As such, they were excluded as it is unlikely that medications played a role in their fall. For each fall event, two control patients were matched in order to compare risk factors and medications. The control patients were from the same unit and had to be hospitalized during the same time period as the study. Additionally, the patients were matched by age (±1 year), sex, and length of stay (±24 hours).

Information on each patient was obtained from the electronic medical record. Only information from the time of hospitalization was utilized. Age, sex, race, length of stay, ICU length of stay, admitting diagnosis, John Hopkins fall risk scores, contributing factors, and medication list at the time of falling were collected. Additionally, it was noted if a patient received surgery or had a known history of falling. Contributing factors were obtained from the John Hopkins Fall Risk Assessment Tool (JH-FRAT), and could include advanced age, incontinence, urgency or frequency, presence of high-risk medications, lack of independent mobility, unsteady gait, visual or auditory impairments, altered awareness, impulsiveness, and lack of understanding (14). These assessments were completed by nursing staff at admission and periodically throughout a patient's stay in the hospital. Fall risk scores were calculated using JH-FRAT and were placed into three groups: <6 or low risk, 6-13 or moderate risk, and >13 or high risk. For patients who fell, the risk score closest to the time of fall was used. For those that did not fall, an average score from their stay was calculated. The timing of medications was also examined to determine if starting new medications or receiving multiple medications at once had an impact on falling. For patients who fell, it was noted if they started a new medication within 24 hours of the fall and if they received 2 or more medications within an hour of the fall. The same information was collected for each control patient, except for information regarding medication initiation or administration around time of fall, as this was not applicable. For control patients, the medication list was evaluated at 3 days prior to their discharge. This is different from patients who fell,

where the medication list reflects what they received immediately around the time of their fall.

Due to the small sample size expected for this study, statistical analysis was performed on the assumption of a non-normal distribution to minimize bias. The Fishers Exact Test was used to compare presence of surgery, fall risk score, previous fall, contributing factors, and presence of each medication, while the Mann-Whitney U Test was used for number of medications and ICU length of stay. A z score for difference of proportions was used to compare the prevalence of various medication classes between the two groups. In all cases, results with *p* less than 0.05 were deemed to be statistically significant for the purposes of this study. In addition, a binary logistic regression was performed to compare medications to each other and determine odds ratios. Medications with a p value less than 0.2 after analysis with the Fishers Exact Test were included in this analysis.

After a formal review by the institutional review boards at Indiana University Health and Butler University, this study was granted exemption based on study design.

Results

A total of 44 falls occurred within the specified date range. After excluding any falls that were later determined to be incorrectly classified or intentional, a total of 39 falls remained for analysis. Therefore, 78 control patients were matched in a 2:1 ratio with the fall patients.

Baseline characteristics for the two groups are noted in Table 1. Of the patients who fell, 62% were male and 38% female. Additionally, 74% were white, 26% were African American, and no patients in the fall group were Asian, while 6% of control patients were. For patients who fell, the median length of stay was 13 days (IQR 19) and the median age was 58 (IQR 15). It is also important to note that while this was a cardiac surgery unit, only 62% of patients were admitted for a cardiac-related issue. Finally, within this study ICU length of stay, rate of surgery, and history of a previous fall were not significantly higher in the fall group compared to the control patients.

After accounting for the prevalence of various risk factors recorded by the nursing staff, the following traits were documented enough for comparisons to be made: unsteady, impulsive, altered mental status, incontinence, presence of one high risk medication, and presence of two or more high risk medications (Table 2). The definition of "high risk" was left to the nurse's discretion, but were typically classified based on the Beers Criteria (7). Of note, 56% of patients who fell received two or more medications within one hour of their fall. However, patients receiving at least one high risk medication regardless of time were not significantly more likely to fall. Of patients that fell, 44% had one high risk medication and 36% had two or more high risk medications compared to 60% and 27% in the control group respectively. Of those who did fall, 36% did begin a new medication within 24 hours of the fall, however it is not known if these new medications increase fall risk. Finally, patients who fell were noted to be significantly more unsteady (41% vs. 5%, p<0.001) and impulsive (21% vs. 1%,

p=0.001). They were also more likely to be classified as having an altered mental status (33% vs. 6%, p<0.001).

Johns Hopkins Fall Risk Scores were also compared between the two groups. For a score to be used, it must have been recorded around the time of fall, as the score can change throughout hospitalization. Of those recorded prior to the fall, 15% of falls and 33% of controls were <6, indicating a low risk (p=0.049). Additionally, 51% of falls and 60% of controls were moderate risk with a score of 6-13 (p=0.43), and 10% of falls were high risk, with a score >13, compared to none of the control patients (p=0.011).

Within the fall group, a total of 139 different medications were administered during hospitalization. These medications were initially classified into various classes, including alpha-1 blockers, anticholinergics, anticonvulsants, antidepressants, cardiovascular, anti-infectives, antithrombotics, benzodiazepines, endocrine, gastrointestinal, muscle relaxants, non-benzodiazepine hypnotics, analgesics, and other. The medication classes were selected based on high risk medication classes as noted by the Beers Criteria, with additional classifications added based on common groups of medications (7). There was no significant difference in prevalence of medication classes between the two groups. Overall, patients who fell were on a larger number of medications, with a median total of 15 compared to 12 in patients who did not fall (p=0.015). Additionally, the twenty-five most common medications within the fall group were compared with their prevalence in the control group. Table 4 includes the full list of medications. Of note, 16 of the 25 medications are known to be high-risk for falls based on previous studies. Even though many of the medications were previously

shown to be high-risk for contributing to a fall, only morphine (31% vs. 6%, p=0.001), insulin glargine (28% vs. 12%, p=0.011), amlodipine (23% vs. 10%, p=0.0495), hydralazine (23% vs. 8%, p=0.036), isosorbide mononitrate (21% vs. 5%, p=0.02), lorazepam (21% vs. 1%, p<0.001), and levothyroxine (21% vs. 5%, p=0.02) were significantly more common among patients who fell. Of these 25 medications, those with p<0.2 were included in the binary logistic regression. The binary logistic regression was statistically significant ($\chi^2(8)$ =44.67, p<0.001). The model was able to explain 44.1% (Nagelkerke R²) of the variance in falling and correctly classified 82.1% of cases. However, only three medications were determined to be statistically significant in this model. They included morphine (OR 10.56, 95% CI 2.704-41.248, p=0.001), lorazepam (OR 31.987, 95% CI 3.179-321.798, p=0.003), and levothyroxine (OR 7.641, 95% CI 1.816-32.146, p=0.006).

Discussion

Although hospitalized patients are subject to increased monitoring in order to promote safety, this does not seem to completely counteract the potential harm from medications being administered. While the fall and control groups were controlled based on age, sex, and length of stay, it was surprising to see that the percentage of cardiac-related diagnoses was also equivalent between groups. However, this may be due to length of stay unintentionally correlating with admitting diagnosis. Also, while ICU length of stay, surgery, and history of falling have all been established as potential risk factors, they did not appear relevant for this patient population. However, the large

number of post-surgical patients on the units may create a culture of increased monitoring due to known fall risk after surgery.

When considering the fall risk score, it appeared to be predictive of a patient's fall outcome when at either extreme of the scale (<6 or >13). In both cases, a significant majority of patients who fell had a high score and a significant majority of control patients had a low score. However, with more than half of fall patients receiving a moderate score, which is similar to the control group, the fall risk score may not be entirely predictive of which patients will fall. While precious research has confirmed the score's benefit in multiple settings including home health care, many hospitalized patients receive a low or moderate risk score which makes it challenging to justify interventions (5, 13). Additionally, in this hospital, the score was not often used to guide treatment or patient management.

Many risk factors known to impact falling were noted to be more common in the patients within this study who had a fall event, confirming that having an altered mental status, being unsteady, or impulsive are all reasons to increase patient monitoring. Of note, being unsteady can often be due to medications that are commonly used in cardiac patients, such as beta blockers and other antihypertensives. This may provide an important area for more intentional prescribing and seeking out safer alternatives.

Interestingly, 56% of the patients who fell received two or more medications within an hour of their fall and 36% had started a new medication within the last 24 hours. Although this study was unable to detect a clear association between timing of

medication administration and fall risk, this suggests the need for further exploration of the ways medication administration can impact fall risk. For example, separating the administration of multiple high-risk medications may minimize side effects if given at one time. It is also important to note that while receiving one or more high risk medications was not significantly more likely in patients who fell, this is likely due to the ubiquitous administration of such medications to all patients on a routine basis and the small size of this study. Therefore, it is difficult to use presence of high risk medications as a concern, although the risk likely increases as the number of medications increases beyond one or two. The confirmation of more medications being received by the patients who fell highlights the importance of removing unnecessary medications or changing the patient to safer alternatives when appropriate. It is much more difficult to predict how multiple medications will interact within the patient, so limiting medicines to only those that are necessary can prove to be critical.

While no medication class was found to be significantly more common among patients who fell, this is likely due to patients being admitted for similar diagnoses and the hospital formulary limiting the treatment options for these patients. Previous literature has already well-establish that many of these drug classes are high risk, and this study should not change that view (7). Of the most commonly used medications among the patients, only morphine, insulin glargine, amlodipine, hydralazine, isosorbide mononitrate, lorazepam, and levothyroxine were significantly more common among those who fell. While multiple other medications have already been implicated in fall risk, they did not appear to be significantly more common among fall patients within

this sample. Part of this may be due to these medications being used too often to detect a difference between patients. However, they were also typically less potent and therefore may have been less impactful with respect to fall risk. For example, morphine was nearly 5 times more prevalent in patients who fell, but hydrocodoneacetaminophen was nearly equivalent. While it is unclear if the patients receiving morphine had acute post-surgical pain or another valid indication, it confirms the need to assess pain management and consider a mild analgesic as soon as it is appropriate.

Furthermore, the use of long-acting insulin highlights the potential benefit of carefully watching a patient's blood glucose during admission. In particular, it is important to consider baseline levels and how decreasing glucose dramatically, albeit to recommended ranges, may impact their coordination and awareness. This point is also valid when considering the three anti-hypertensive medications that were significantly more prevalent among fall patients. While amlodipine and isosorbide mononitrate are not particularly potent, hydralazine has strong vasodilatory effects that can cause dramatic orthostatic hypotension for patients not used to a lower blood pressure. Finally, lorazepam use was drastically higher among patients who fell. The use of benzodiazepines during hospitalization has severe effects on mental status, indicating they should only be used when necessary (10). While levothyroxine was also noted to be more common among patients who fell, there is no clear mechanism for why this would be at this time. Additional research may be warranted, but this is likely not a true association.

While the binary logistic regression was significant, the wide ranges for each confidence interval may indicate inaccurate results due to the small sample size. The confirmation of morphine and lorazepam as having significant results may help to confirm the need for decreasing their use when not truly indicated. However, it is again unclear if levothyroxine is truly increasing risk of falls, as previous literature has not confirmed this.

There are several limitations that must be considered when interpreting results from this study. First, the sample size was rather small, which may account for differences between this study and previous studies. Additionally, while it was intended to study a cardiac population, only about 60% of patients were admitted for a cardiacrelated diagnosis. Hospital formularies can impact prescribing and therefore may unintentionally guide medication selection despite known dangers. Finally, it is difficult to determine exact timing of when to record the control patients' medication lists, as they often change throughout admission. Despite these limitations, this study does attempt to further characterize hospital falls and can serve as further evidence for the need to avoid well-established medications with known risks.

Conclusion

Overall, these results help to shed additional light on medications that may be of increased risk for hospitalized patients. This study attempted to focus on a population that was significantly cardiac-related in order to determine how their risk may differ from other patients. However, the study also demonstrates the challenges in seeking

meaningful data to use as part of quality improvement. This hospital correctly identified increased falls within this unit, but there are still no clear answers as to what caused this change. The study was able to highlight several high-risk medications that are still prevalent within the units, but further work is needed to confirm if limiting use of such agents can effectively decrease fall risk (18). Pharmacists can help impact fall risk by monitoring patients for high-risk medications and intervene when changes may help improve patient safety (19). However, due to the multifactorial nature of a fall event, multidisciplinary approaches with considerations for numerous factors are critical in order to meaningfully decrease a patient's risk of falling and increase their likelihood of leaving the hospital without unnecessary and preventable complications.

Tables and Figures

Characteristic	Fall, n (%n)	Control, n (%n)	p
Male	24 (62)	48 (62)	1
Female	15 (38)	30 (38)	1
White	29 (74)	51 (65)	0.4
Black	10 (26)	22 (28)	0.83
Asian	0 (0)	5 (6)	0.17
Age	58 (15)^	58 (15)^	0.99
LOS	13 (19)^	12 (15)^	0.81
ICU LOS	2 (6)^	2 (5)^	0.86
Surgery	24 (62)	47 (60)	1
Previous Fall	11 (28)	12 (15)	0.14
Cardiac Diagnosis	24 (62)	48 (62)	1

Table 1: Baseline Characteristics. LOS, length of stay; ICU LOS, intensive care unit length of stay. ^ denotes data reported as median (interquartile range).

Contributing Factors:	Fall, n(%)	Control, n(%)	р
2+ High Risk Meds	14 (36)	21 (27)	0.39
1 High Risk Med	15 (38)	47 (60)	0.03*
Incontinence	7 (18)	7 (9)	0.23
AMS	6 (15)	5 (6)	0.18
Impulsive	7 (18)	1 (1)	0.002*
Unsteady	15 (38)	4 (5)	<0.001*
Total Medications	15 (5)^	12 (8)^	0.015*

Table 2: Contributing Factors. ^ denotes data reported as median (interquartile range). * denotes statistical significance (p<0.05).

Fall Risk Score	Fall, n(%)	Control, n(%)	р
None	9 (23)	5 (6)	0.043
<6	6 (15)	26 (33)	0.049*
6-13 (Moderate)	20 (51)	47 (60)	0.43
>13 (High)	4 (10)	0 (0)	0.011*

Table 3: Fall Risk Scores. * denotes statistical significance (p<0.05).

Medication Class	Fall, n	Control, n	р
Alpha-1 Blockers	5	7	0.726
Anticholinergics	11	22	0.674
Anticonvulsants	10	14	0.617
Antidepressants	25	34	0.368
Anti-HTN/CV	92	157	0.968
Anti-Infectives	28	53	0.667
Antipsychotics	6	12	0.757
Antithrombotics	70	153	0.069
BZDs	11	12	0.271
Endocrine	38	50	0.204
GI	67	144	0.099
Muscle Relaxant	2	1	0.285
Non-BZD Hypnotics	5	2	0.057
Pain	61	96	0.575
Other	128	202	0.401

Table 4: Prevalence of Medications by Class.

Medication	Fall, n	Control, n	p
Aspirin	26	59	0.38
Metoprolol	21	36	0.44
Docusate-Senna	20	43	0.7
Atorvastatin	17	29	0.55
Polyethylene Glycol 3350	16	24	0.41
Pantoprazole	16	24	0.3
Hydrocodone/Acetaminophen	14	39	0.17
Enoxaparin	12	27	0.84
Heparin	12	30	0.54
Morphine	12	5	0.0013*
Clopidogrel	11	15	0.35
Insulin (short acting)	18	24	0.11
Insulin (long acting)	11	9	0.011*
Famotidine	11	0	< 0.001*
Amlodipine	9	8	0.0495*
Furosemide	9	18	1
Hydralazine	9	6	0.036*
Hydromorphone	9	11	0.3
Amiodarone	8	17	1
Isosorbide Mononitrate	8	4	0.02*
Lorazepam	8	1	< 0.001*
Levothyroxine	8	4	0.02
Acetaminophen	8	12	0.6
Nicotine Patch	8	11	0.43
Pravastatin	8	8	0.16

Table 5: Most commonly used medications in patients who fell. * denotes statistical significance (p<0.05).

Medication	OR	95% CI	Р
Amlodipine	2.668	0.729-9.772	0.138
Hydralazine	4.022	0.945-17.119	0.06
Hydrocodone-acetaminophen	0.661	0.241-1.814	0.422
Insulin (short acting)	2.441	0.896-6.647	0.081
Isosorbide Mononitrate	1.063	0.202-5.607	0.943
Levothyroxine	7.641	1.816-32.146	0.006*
Lorazepam	31.987	3.179-321.798	0.003*
Morphine	10.56	2.704-41.248	0.001*

Table 6: Results from a binary logistic regression. * denotes statistical significance (p<0.05).

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