Do Outpatient Podiatry Evaluations Reduce the Risk of Falls in Elderly Patients With Diabetes Mellitus?

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Abstract

Background: Elderly patients with diabetes mellitus (DM) are faced with potential changes in their lower extremities, such as peripheral neuropathy and peripheral arterial disease, making them vulnerable to falls. We hypothesized that evaluations by podiatrists would lower the events of falls.

Methods: A retrospective chart review of a cohort of patients with DM, 65 years or older, was performed, who visited our primary care office between January 1, 2019 and June 30, 2019. Patients were divided into those who had podiatrist evaluations (PODEVAL), and those who did not (no PODEVAL). Events of falls and comorbid medical conditions were compared between the two groups. We also compared the associations of risk factors between the patients who had falls and those who did not.

Results: Among 197 patients (PODEVAL = 92; no PODEVAL = 105), the mean ages of the two groups were comparable (76.9 years for PODEVAL, 75.5 years for no PODEVAL; P = 0.151). There was no significant difference in the events of falls in a 6-month follow-up period between PODEVAL and no PODEVAL groups (35.9% vs. 32.4%; P = 0.606). We found significantly higher frequencies of association of several disorders of the lower extremities in PODEVAL group compared to no PODEVAL group, such as bunions and calluses (48.9% vs. 27.6%; P = 0.002), peripheral arterial disease (50.0% vs. 26.7%; P < 0.001), and peripheral neuropathy (75.0% vs. 47.6%; P < 0.001). Patients with falls had higher frequencies of associations of some comorbidities compared to the patients without reported falls, such as coronary artery disease, peripheral arterial disease, dementia, congestive heart failure, carotid stenosis, and syncope.

Conclusions: Among elderly patients with DM, there is no significant difference in the events of falls between the groups of patients who had podiatrist evaluations and who did not.

Keywords: Diabetes mellitus; Elderly; Fall; Podiatrist evaluations

Introduction

In the last three decades, the mortality due to diabetes mellitus (DM) has doubled in the United States of America (USA), especially among individuals who are 65 years of age and older [1]. It is now ranked as the sixth leading cause of death among the elderly population in the USA [1], affecting about 10.5% (34.2 million) of the US population [2]. Current estimates also indicate that 26.8% (14.3 million) Americans aged 65 years and older suffer from diagnosed and undiagnosed DM [2]. DM is a known independent risk factor for cardiovascular disease and a major risk factor for peripheral arterial disease (PAD) and peripheral neuropathy; it especially affects the lower extremities, which can eventually lead to decrease in sensation and concomitant ulceration of the feet [3]. The sequelae of decreased sensation, decreased position sense, ulceration, and infection include falls, amputations, and systemic infections in elderly patients with DM [4]. In addition to increased risk of falls, the outcomes of falls in patients with DM are worse when compared to the non-diabetic population, such as increased rates of fractures, poorer rehabilitation outcomes, increased occurrence of future falls, etc. [5].

In the USA, the number of individuals who are 65 years and older is expected to reach approximately 88.5 million by the year 2050 [6]. The annual incidence of falls for patients with DM over the age of 65 is estimated to be 39%. A simple computation elucidates that an exorbitant number of elderly patients with DM will experience falls every year. The burden placed on the healthcare system as a result of these falls is expected to be significant. For example, in the year 2000, there were 10,300 fatal falls among elderly Americans and an additional 2.6 million non-fatal falls resulting in direct medical costs upwards of $19.2 billion [7].

The United States Preventive Services Task Force (USPSTF) grade B recommendation to prevent falls in the community dwelling adults of ages 65 and over, who are at increased risk for falls, suggests exercise interventions [8]. The USPSTF grade C recommendation suggests clinicians to offer multi-
factorial interventions based on the circumstances of prior falls, presence of comorbid medical conditions, and patients’ values and preferences [8]. While many national associations delineate standard practice guidelines to decrease the risk of diabetic foot ulcers caused by PAD, there are fewer objective guidelines for podiatric foot care for the prevention of falls in this population despite a high annual incidence of falls in this population [4]. A multidisciplinary approach includes referrals to podiatrists for all patients with DM, especially for those who are 65 years and older, to undergo evaluations and frequent follow-ups. The aims and objectives of our study were to investigate whether the evaluations by podiatrists would lower the events of falls in elderly patients with DM, or not. We hypothesized that the evaluations by podiatrists would lower the events of falls.

**Materials and Methods**

**Study selection**

Our study was a retrospective chart review study of a cohort of patients with DM type 1 or 2, aged 65 years or older, who had an office visit in our internal medicine - primary care office between January 1, 2019 and June 30, 2019. The study was reviewed and approved by the Institutional Review Board of Cooper University Health Care (CUHC), Camden, New Jersey, USA and was fully compliant with the ethical standards set forth by the CUHC Institutional Review Board. Patients younger than 65 years, patients aged 65 years or older without a diagnosis of DM, or patients who were non-ambulatory, were excluded from the study.

**Data collection**

We collected the following data for each patient: age, gender, race, smoking history, alcohol use, recreation drug use, history of Charcot joints, bunions, callouses, hammer toes, ulcers, coronary artery disease (CAD), stroke, PAD, dementia, Alzheimer’s disease, seizures, osteoarthritis, congestive heart failure, dizziness, anemia, chronic kidney disease, chronic obstructive pulmonary disease, carotid stenosis, syncope, peripheral neuropathy, and Parkinson disease. Documentation of vitamin D levels, vitamin B12 levels, glycosylated hemoglobin (HbA1c) level, statin use, aspirin use, insulin use, oral hypoglycemic agent (OHA) use, angiotensin-converting enzyme inhibitor (ACE-I) use, and angiotensin II receptor blocker (ARB) use was also gathered. Vital signs including systolic and diastolic blood pressure, pulse, and body mass index (BMI) from the visit were also collected. We reviewed the electronic medical records for referral to and evaluation by podiatry specialists as documented by either a signed note by a doctor of podiatric medicine (DPM) or documentation by a primary care physician that the patient was evaluated by a podiatrist and they were up-to-date with their examination of their feet. Photocopyied notes from podiatrists also qualified individuals as having visited podiatry. These individuals’ records were then searched for documentation of falls within 6 months of podiatric intervention. Falls were defined using a widely accepted definition, which included any unintentional change in body position resulting in contact with the ground, or lower level. Additionally, we searched each electronic medical record using search terms “fall”, “falls”, and “fell”. Progress notes, emergency department notes, problem lists, telephone encounter notes, and indications of the imaging studies were reviewed for the mention of these terms. To overcome the potential sources of bias, patient records were first searched for documentation of falls, and then searched for podiatry interventions within the 6-month period prior to the documentation of falls.

**Statistical analysis**

We entered the collected data into a Microsoft Excel (2016, Redmond, Washington, USA) spreadsheet. Statistical analysis was done by using SPSS (Statistical Package for the Social Sciences, version 15.01, IBM, Armonk, New York, USA). The study was approved for a sample size of 786 records. This assumed that there would be a small effect size between the study groups along with the following values: 80% power, 5% alpha error, and 20% effect size. There were only 197 records included in the final analysis as this was the number of patient encounters that met inclusion criteria between the approved dates.

The cohort of patients were divided into two groups; the first group was comprised of patients who had podiatrist evaluations (PODEVAL), and the second group was represented by the patients who did not have podiatrist evaluation (no PODEVAL). The documentation of podiatry referral was based on the criteria that followed the standard of care guidelines from the American Diabetes Association (ADA), which included patients with histories of cigarette smoking, patients who had histories of prior lower-extremity complications, patients who had documented loss of protective sensation in their feet, or had other structural abnormalities, or PAD. Evaluations by the podiatrists included, assessment of neuropathy in the form of sensory loss, current or prior ulceration or amputation, pain, burning, numbness, and Charcot foot; assessment of vascular disease based on symptoms of leg fatigue, claudication, decreased walking speed, evaluation of the pedal pulses, Ankle-brachial index testing in patients who had symptoms or signs of PAD, history of angioplasty or other vascular surgery; inspection of the skin, and assessment of foot deformities. All patients were provided with the general preventive foot self-care education which highlighted the importance of daily foot monitoring, including nail and skin care. Family members and caregivers were also educated for the patients who had cognitive impairment, or visual difficulties, or who had mobility constraints. Specialized therapeutic footwear, such as well-fitted walking shoes or athletic shoes that cushion the feet and redistribute pressure, or custom-molded shoes, were provided to the high-risk patients, such as patients with severe neuropathy, foot deformities, or history of amputation. Surgical care, including would care, were provided to the patients who had evidence of severe vascular disease, foot deformities, foot ulcerations, or other disorders of skin.
We compared the data between the two groups and studied their association with falls within a 6-month follow-up period. We also compared the comorbid medical conditions and other variables between the two groups. We also conducted a secondary case-control study in which the patients were stratified based on falls, or no falls, in order to assess whether there were statistically significant differences in the rates of exposures to one or more risk factors between the two groups. Independent t-tests were used to compare the means of continuous variables between the study groups. Chi-square tests were used to compare the proportions of categorical variables. Multivariable logistic regression analysis was carried out to evaluate for potential risk factors (independent variables) that were predictive of falls (dependent variable). Age, gender, cigarette smoking, alcohol use, anemia, BMI, HbA1c, and podiatrist evaluation were included as the independent variables in the multivariable regression analysis. This model also provided a 95% confidence interval (CI) for the comparisons. The odds ratios (ORs) were evaluated within the model for each term assumed that all other items were stable. In the model, the main variable of interest was “podiatry consult”. We wanted to examine whether all other factors being stable, that a consultation to podiatry was a “podiatry consult”. We wanted to examine whether with all other factors being stable, that a consultation to podiatry was a factor in falls. All other factors were used in the model to see if after all were considered, that podiatry was a factor in falls, or not. The significance in our study was defined as a P < 0.05.

Results

A total of 197 patients were included in this study. Ninety-two (46.7%) patients received evaluations by podiatrists (PODEV AL group), and the remaining 105 (53.3%) patients were not evaluated by a podiatrist (no PODEV AL group). There was no significant difference in the mean ages of patients in both groups (PODEV AL = 76.9 years vs. no PODEV AL = 75.5 years; P = 0.151) (Table 1). There was a significantly greater number of men in the POEVAL group compared to the no PODEV AL group (55.4% vs. 41.0%), and a significantly lesser number of women in the POEVAL group compared to the no PODEV AL group (44.0% vs. 59.0%) (P = 0.042) (Table 1). The majority of patients in the POEVAL group were Caucasian (63.0%), followed by African-American (20.7%), and other races (16.3%), which included Hispanics, Asians, and others. There was no significant difference in the age distribution among the two groups. The differences in cigarette smoking, and alcohol use were not statistically significant between the two groups (Table 1).

We found significantly higher frequencies of association of several comorbid medical conditions in patients in the POEVAL group compared to the patients in the no POEVAL group. These included PAD, peripheral neuropathy, bunions and callouses (Table 1). There were no significant differences in the frequencies of associations of other comorbid medical conditions between the two groups, such as CAD, cerebrovascular accidents (CVAs), dementia, osteoarthritis, carotid artery stenosis (CAS), congestive heart failure (CHF), dizziness, anemia, chronic kidney disease (CKD), chronic obstructive pulmonary disease (COPD), syncope, and hammer toes (Table 1).

Among other parameters, there was no significant difference in the mean systolic and diastolic blood pressures and pulse rate between the POEVAL group and the no POEVAL group. Similarly, there was no significant difference in the mean BMI, mean serum vitamin D levels, and mean serum vitamin B12 levels between the two groups (Table 1). Analysis of the mean HbA1c level revealed that the patients in the POEVAL group had significantly higher level than those in the no POEVAL group (7.3% vs. 6.9%; P = 0.038) (Table 1). We found no significant difference in the frequencies of use of statin, aspirin, OHA, ACE-I, and ARB between the two groups (Table 1). We did find that significantly more patients in the POEVAL group were treated with insulin compared to the patients in the no POEVAL group (34.8% vs. 18.1%; P = 0.008) (Table 1). Analysis of fall events showed that there was not a significant difference in the events of falls in a 6-month follow-up period since their last visit to the podiatrist among patients in the POEVAL group compared to the patients in the no POEVAL group (35.9% vs. 32.4%, P = 0.606) (Table 1).

A secondary analysis was conducted which stratified subjects based on documentation of falls rather than podiatry evaluation. Thus, the two groups in this section of the results were classified based on documentation of falls, and no documentation of falls. There were 69 patients who had an incident of fall and 130 patients who did not experience falls. There were no significant differences in the age, gender, race, cigarette smoking or recreational drug use between the two groups (Table 2). The frequency of alcohol use was significantly lower in the group with documentation of falls compared to the group with no documentation of falls (22.4% vs. 36.9%; P = 0.038) (Table 2). There were significantly higher frequencies of association of many comorbid medical conditions in the group of patients with documentation of falls compared to the group of patients without documentation of falls, such as CAD, PAD, dementia, CAS, CHF, and syncope (Table 2).

Multivariable logistic regression analysis which included age, gender, cigarette smoking, alcohol use, anemia, BMI, HbA1c, and podiatrist evaluation as independent variables showed that the patients with history of alcohol use had lower odds of having documentation of falls compared to those who did not (OR: 0.141, 95% CI: 0.022 - 0.906; P = 0.025). Patients with anemia had 4.9 times greater odds of having a fall (95% CI: 1.282 - 18.485; P = 0.021) (Table 2). The model also showed that as the HbA1c level increased by a percentage point, the odds of falls dropped by 0.45 (95% CI: 0.022 - 0.906; P = 0.025). Age, gender, cigarette smoking, BMI, and podiatrist evaluation did not make significant differences in the odds of having, or not having a fall (Table 3).

Discussion

The major finding of our study was that the evaluations by the podiatrists did not lower the events of falls in our elderly patients with DM. The events of falls in the POEVAL group and in the no POEVAL group were 35.9% and 32.4%, respectively, which happens to be greater than the reported prevalence in a meta-analysis conducted by Yang and associates.
Table 1. Baseline Characteristics Based on Podiatry Evaluation Status

| Variable                     | PODEVAL (N = 92) | No PODEVAL (N = 105) | P   |
|------------------------------|------------------|----------------------|-----|
| Age mean (SD)                | 76.9 (6.9)       | 75.5 (6.9)           | 0.151 |
| Gender                       |                  |                      |     |
| Male (n, %)                  | 51 (55.4)        | 43 (41.0)            | 0.042 |
| Female (n, %)                | 41 (44.6)        | 62 (59.0)            |      |
| Race                         |                  |                      |     |
| Caucasian (n, %)             | 58 (63.0)        | 68 (64.8)            | 0.682 |
| African-American (n, %)      | 19 (20.7)        | 17 (16.2)            |      |
| Other (n, %)                 | 15 (16.3)        | 20 (19.0)            |      |
| Social factors               |                  |                      |     |
| Cigarettes (n, %)            | 18 (19.6)        | 20 (19.0)            | 0.927 |
| Alcohol (n, %)               | 29 (31.5)        | 34 (32.4)            | 0.897 |
| Comorbidities                |                  |                      |     |
| CAD (n, %)                   | 52 (56.5)        | 47 (44.8)            | 0.100 |
| CVA (n, %)                   | 11 (12.0)        | 10 (9.5)             | 0.581 |
| PAD (n, %)                   | 46 (50.0)        | 28 (26.7)            | < 0.001 |
| Dementia (n, %)              | 17 (18.5)        | 18 (17.1)            | 0.598 |
| Osteoarthritis (n, %)        | 58 (63.0)        | 77 (73.1)            | 0.121 |
| CAS (n, %)                   | 17 (18.5)        | 12 (11.4)            | 0.164 |
| CHF (n, %)                   | 20 (21.7)        | 14 (13.3)            | 0.119 |
| Dizziness (n, %)             | 33 (35.9)        | 42 (40.0)            | 0.551 |
| Anemia (n, %)                | 44 (47.8)        | 54 (51.4)            | 0.614 |
| CKD (n, %)                   | 53 (57.6)        | 60 (57.1)            | 0.947 |
| COPD (n, %)                  | 19 (20.7)        | 22 (21.0)            | 0.959 |
| Syncope (n, %)               | 13 (14.1)        | 16 (15.2)            | 0.827 |
| Peripheral neuropathy (n, %) | 69 (75.0)        | 50 (47.6)            | < 0.001 |
| Bunions and callouses (n, %) | 45 (48.9)        | 29 (27.6)            | 0.002 |
| Hammertoe (n, %)             | 23 (25.0)        | 16 (15.2)            | 0.086 |
| Vitals                       |                  |                      |     |
| SBP (mm Hg), mean (SD)       | 128 (12.6)       | 131 (13.7)           | 0.178 |
| DBP (mm Hg), mean (SD)       | 72 (10.4)        | 75 (9.4)             | 0.077 |
| Pulse (BPM), mean (SD)       | 74 (11.2)        | 76 (12.2)            | 0.213 |
| Other parameters             |                  |                      |     |
| BMI, mean (SD)               | 30.3 (5.9)       | 31.7 (7.5)           | 0.145 |
| HbA1c, mean (SD)             | 7.3 (1.2)        | 6.9 (1.1)            | 0.038 |
| Vitamin D (ng/mL), mean (SD) | 34.1 (17.2)      | 34.5 (12.9)          | 0.861 |
| Vitamin B12 (µg/mL), mean (SD)| 860.8 (695.3)  | 856.8 (706.6)        | 0.974 |
| Medication                   |                  |                      |     |
| Statin (n, %)                | 76 (82.6)        | 84 (80.0)            | 0.640 |
| Aspirin (n, %)               | 61 (66.3)        | 62 (59.0)            | 0.294 |
| Insulin (n, %)               | 32 (34.8)        | 18 (18.1)            | 0.008 |
| OHA (n, %)                   | 68 (73.9)        | 84 (80.0)            | 0.310 |
| ACE-I (n, %)                 | 25 (27.2)        | 25 (23.8)            | 0.588 |
| ARB (n, %)                   | 31 (33.7)        | 49 (46.7)            | 0.064 |
| Outcome                      |                  |                      |     |
| Fall (n, %)                  | 33 (35.9)        | 34 (32.4)            | 0.606 |

PODEVAL: Had an evaluation by a podiatrist; No PODEVAL: Did not have a podiatrist evaluation; SD: standard deviation; CAD: coronary artery disease; CVA: cerebrovascular accident; PAD: peripheral artery disease; CAS: carotid artery stenosis; CHF: congestive heart failure; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; SBP: systolic blood pressure; DBP: diastolic blood pressure; BPM: beats per minute; BMI: body mass index; HbA1c: glycosylated hemoglobin; OHA: oral hypoglycemic agent; ACE-I: angiotensin-converting enzyme inhibitor; ARB: angiotensin II receptor blocker.
### Table 2. Baseline Characteristics Based on the Status of Falls

| Variable                  | Fall (N = 67) | No fall (N = 130) | P   |
|---------------------------|---------------|-------------------|-----|
| Age mean (SD)             | 77.5 (6.3)    | 75.5 (7.3)        | 0.053 |
| Gender                    |               |                   |     |
| Male (n, %)               | 30 (44.8)     | 64 (49.2)         | 0.553 |
| Female (n, %)             | 37 (55.2)     | 66 (50.8)         |     |
| Race                      |               |                   |     |
| Caucasian (n, %)          | 47 (70.2)     | 79 (60.8)         | 0.365 |
| African-American (n, %)   | 9 (13.4)      | 27 (20.7)         |     |
| Other (n, %)              | 11 (16.4)     | 24 (18.5)         |     |
| Social factors            |               |                   |     |
| Cigarettes (n, %)         | 14 (20.9)     | 24 (18.5)         | 0.682 |
| Alcohol (n, %)            | 15 (22.4)     | 48 (36.9)         | 0.038 |
| Comorbidities             |               |                   |     |
| CAD (n, %)                | 44 (65.7)     | 55 (42.3)         | 0.002 |
| CVA (n, %)                | 11 (16.4)     | 10 (7.7)          | 0.060 |
| PAD (n, %)                | 32 (47.8)     | 42 (32.3)         | 0.034 |
| Dementia (n, %)           | 19 (28.4)     | 16 (12.3)         | 0.026 |
| Osteoarthritis (n, %)     | 46 (68.7)     | 89 (68.5)         | 0.978 |
| CAS (n, %)                | 15 (22.4)     | 14 (10.8)         | 0.029 |
| CHF (n, %)                | 17 (25.4)     | 17 (13.1)         | 0.030 |
| Dizziness (n, %)          | 30 (44.8)     | 45 (34.6)         | 0.164 |
| Anemia (n, %)             | 39 (58.2)     | 59 (45.4)         | 0.088 |
| CKD (n, %)                | 38 (56.7)     | 75 (57.7)         | 0.896 |
| COPD (n, %)               | 17 (25.4)     | 24 (18.5)         | 0.258 |
| Syncope (n, %)            | 19 (28.4)     | 10 (7.7)          | < 0.001 |
| Peripheral neuropathy (n, %) | 42 (62.7)   | 77 (59.2)         | 0.639 |
| Bunions and callouses (n, %) | 28 (41.8)   | 46 (35.4)         | 0.379 |
| Hammertoe (n, %)          | 13 (19.4)     | 26 (20.0)         | 0.921 |
| Vitals                    |               |                   |     |
| SBP (mm Hg), mean (SD)    | 129 (13.7)    | 130 (13.0)        | 0.780 |
| DBP (mm Hg), mean (SD)    | 73 (9.8)      | 73 (10.0)         | 0.560 |
| Pulse (BPM), mean (SD)    | 75 (11.5)     | 75 (11.9)         | 0.560 |
| Other parameters          |               |                   |     |
| BMI, mean (SD)            | 30.7 (6.5)    | 31.2 (6.9)        | 0.612 |
| HbA1c, mean (SD)          | 7.1 (1.1)     | 7.2 (1.2)         | 0.419 |
| Vitamin D (ng/mL), mean (SD) | 37.1 (17.6) | 32.8 (13.2)       | 0.097 |
| Vitamin B12 (µg/mL), mean (SD) | 798.7 (520.3) | 894.6 (787.4) | 0.409 |
| Medication                |               |                   |     |
| Statin (n, %)             | 55 (82.1)     | 105 (80.8)        | 0.822 |
| Aspirin (n, %)            | 46 (68.7)     | 77 (59.2)         | 0.196 |
| Insulin (n, %)            | 17 (25.4)     | 34 (26.2)         | 0.908 |
| OHA (n, %)                | 51 (76.1)     | 101 (77.7)        | 0.803 |
| ACE-I (n, %)              | 20 (29.9)     | 30 (23.1)         | 0.301 |
| ARB (n, %)                | 27 (40.3)     | 53 (40.8)         | 0.949 |

SD: standard deviation; CAD: coronary artery disease; CVA: cerebrovascular accident; PAD: peripheral artery disease; CAS: carotid artery stenosis; CHF: congestive heart failure; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; SBP: systolic blood pressure; DBP: diastolic blood pressure; BPM: beats per minute; BMI: body mass index; HbA1c: glycosylated hemoglobin; OHA: oral hypoglycemic agent; ACE-I: angiotensin-converting enzyme inhibitor; ARB: angiotensin II receptor blocker.
They reported that out of 14,685 participants, the prevalence of falls in the elderly diabetic and non-diabetic individuals was 25.0% and 18.2%, respectively [9]. Although, there have been reports of reduction in fall events in the community dwelling elderly patients who received podiatrist evaluation and interventional [10], there is a lack of research with respect to falls in elderly patients with DM. Spink and associates conducted a parallel group randomized controlled trial in 296 community dwelling older patients with disabling foot pain, in which 153 patients (15% had DM) were allocated to a multifaceted podiatry intervention group, and 152 patients (20% had DM) received routine care. The intervention group received foot orthoses, advice on shoes, instructions for home-based rehabilitation exercises, and podiatry care for a year. Patients in the intervention group experienced 36% fewer falls than the control group over a 12-month period [10].

Our findings differ from the findings of Spink and associates. We believe that our findings reflect mitigation of fall events in the no PODEV AL group by periodic, timely, and effective foot care assessments and interventions by the primary care physicians. All of our patients had documentations of comprehensive foot examination during their office visits as per the ADA standard of care guidelines, which include inspection of the skin, assessment of foot deformities, neurological assessment (10-g monofilament test and test of vibration), and vascular assessment including pulses in the legs and feet. Our patients who had histories of cigarette smoking, or who had histories of prior lower-extremity complications, loss of protective sensation, structural abnormalities, or PAD, were given referral orders to podiatrists for evaluations and management, as per the ADA’s recommendations [11]. We believe that comprehensive foot examination by the primary care physicians of the elderly patients with DM during their office visits was a key factor in identification and management of early changes in feet due to diabetic microvascular and macrovascular disorders.

The association of several disorders of foot including bunions, callouses, PAD, and peripheral neuropathy, were all significantly higher in our group of patients who had been evaluated by the podiatrists. We believe that this group of patients were the ones who received referrals to the podiatrists by their primary care physicians as per the ADA guidelines [11], due to the identification of clinical abnormalities and foot-related risks associated with increased risk of amputations, imbalance, or falls, such as peripheral neuropathy, altered biomechanics, evidence of increased pressure, bony deformity, peripheral vascular disease, history of ulcers or amputation, and severe nail pathology.

Many elderly patients with DM wear suboptimal shoes. Several studies conducted in elderly patients under test environments and gait-laboratories, which involve walking with obstacles and on surfaces with low friction, have reported that soft soled footwear creates side-to-side imbalance, while high-heeled hard sole footwear promotes anteroposterior sway [12-16]. Some patients tend to go barefoot, or wear slippers, in order to mitigate early changes of alterations in the joint-position sense. Robbins and associates reported that sensitivity to foot position declined with age, being barefoot created a substantial diminution in joint position awareness, and loss of foot position awareness contributed to falls in later life [17].

Diabetic shoes, which include shoes with stiff outsoles, or athletic shoes, have shown best performance in the parameters reported by the gait-laboratories, which include timed navigation, sway, and stop start initiation [12-16]. In our study, the primary care physicians were authorized to provide orders for customized diabetic footwear, early on, in patients who had even mild dermatological, neurological, vascular or joint changes in their feet, considered to be associated with DM, without a need for an evaluation and authorization by the podiatrists. We believe that early recognition of foot involvement in our elderly patients with DM by their primary care physicians, and incorporation of fall mitigation efforts by providing diabetic shoes, had been a factor behind the comparable frequency of fall events in the no PODEV AL group compared to the PODEV AL group.

We found that having a diagnosis of anemia was a major risk factor for fall among elderly patients with DM. Duh and associates completed a retrospective open-cohort study of 47,350 individuals over 65 years and found that association of anemia increased the risk of injurious falls by 1.66 times compared to participants without anemia (CI: 1.41 - 1.95) [18]. Additionally, they found that lower hemoglobin levels were

### Table 3. Multivariable Logistic Regression Analysis

| Variable                  | B     | P     | Exp(B) | Lower CI | Upper CI |
|---------------------------|-------|-------|--------|----------|----------|
| Age                       | -0.070 | 0.262 | 0.933  | 0.826    | 1.053    |
| Gender male               | -1.001 | 0.297 | 0.368  | 0.056    | 2.412    |
| Cigarette smoking         | 1.111  | 0.242 | 3.036  | 0.473    | 19.478   |
| Alcohol                   | -1.959 | 0.044 | 0.141  | 0.021    | 0.949    |
| Anemia                    | 1.583  | 0.020 | 4.868  | 1.282    | 18.485   |
| BMI                       | 0.046  | 0.394 | 1.047  | 0.942    | 1.185    |
| HbA1c                     | -0.800 | 0.025 | 0.450  | 0.223    | 0.906    |
| Podiatrist evaluation     | -0.087 | 0.900 | 0.917  | 0.235    | 3.573    |

Multivariable logistic regression analysis showing association between the independent variables and falls. B: beta weight; P: significance; Exp(B): odds ratio; CI: confidence interval; BMI: body mass index; HbA1c: glycosylated hemoglobin.
significantly associated with higher risk of falls; as for hemoglobin levels of less than 10 g/dL, 10 - 11.9 g/dL, and 12 - 12.9 g/dL, the rates of falls were 1.47, 1.39, and 1.14, respectively (P < 0.001) [18]. Dharmarajan and associates conducted a retrospective study on nursing home and community dwelling older adults aged 60 - 97 years and found that falls were more common in anemic individuals compared to those without anemia (30% vs. 13%; P = 0.028) [19]. After they controlled for age, gender, place of residence, and arthritis, they found by using a linear regression model that anemia predicted a three-fold increased risk of falls (P = 0.041), and that as hemoglobin levels rose in increments of 1.0 g/dL the risk of falls decreased by 45% [19]. There are some studies that suggest that anemia, by itself, may not be a predictor of falls in people over the age of 65 years, rather, a more specific predictor may be the delta, or rate of change of hemoglobin levels, or general disability of the individual. This is supported by the KORA-Age study conducted by Thaler-Kall and associates, who enrolled 967 community-dwelling people over 65 who were questioned about history of falls and had non-fasting venous blood samples obtained to assess their hemoglobin levels. Anemia was defined as a hemoglobin level below 12 g/dL in women and below 13 g/dL in men [20]. There was no significant association between anemia and falls in their unadjusted and multivariable adjusted models; however, they found a two-fold increased risk of falls after joint analysis of individuals with anemia and disability in comparison to persons without anemia and disability (OR: 2.10; 95% CI: 1.12 - 3.93) [20]. Our finding of anemia contributing 4.9 times greater odds of having a falls (95% CI: 1.282 - 18.485; P = 0.020) in our elderly patients with DM aligns with the findings of the reported studies.

The association of several comorbid medical conditions including CAD, PAD, dementia, CHF, CAS, and syncope was significantly higher in our patients with documentation of falls compared to the group of patients without any documented falls. It is well known that each of these medical conditions carry their own morbidities; they also have implications related to falls. Pijpers and associates conducted a prospective cohort study to identify the predictors and consequences of aging in The Netherlands. A subset of their data was risk factors associated with falls in older adults with diabetes. They used Cox-proportion hazard regression models to account for confounding data and found that in their fully adjusted model, polypharmacy, increased pain, poorer self-perceived health, lower physical activity, decreased grip strength, limited activities of daily living, and cognitive impairment accounted for 47% increased risk of recurrent falls in diabetic patients over the age of 65 [21]. Each of the associated comorbid conditions found in our study can be categorized into the risk factors identified by Pijpers and associates. Additionally, medications, musculoskeletal weakness, neurological factors, pain, cognitive decline, and general health deterioration, all contribute to falls in this population.

Interestingly, we found that documentation of alcohol use was associated with decreased odds of falls by 0.141 (0.021 - 0.949; P = 0.044). Being a retrospective study, we could only collect the data that were documented in two categories: self-reported abstainers, and self-reported current alcohol use; hence we could not quantify the alcohol use in order to stratify the level of alcohol consumption. It is conceivable that with the relatively small sample size, the rates of accurate reporting of falls were not consistent with actual fall rates. Other larger studies have encountered similar obstacles. Chen and associates pooled 289,187 samples of the adults over 18 years of age from the United States National of Health Interview Surveys between 2004 and 2013 which asked questions on alcohol consumption and incidence of falls [22]. They found 3,579 fall episodes among the participants and then conducted analysis using cubic regression splines to determine age cutoffs for the subsequent analysis of differential risks for falls. They determined an age cutoff of 50 years and over and then used a regression model for incidence rate ratios and stratified these individuals into five categories: lifetime abstainer, former drinker, low-risk drinker, increased-risk drinker, and highest-risk drinker and found that there was no statistically significant increase in incident risk of falls among all categories of drinkers both male and female over the age of 50. They concluded that falls in older individuals more likely are the result of an interplay between demographic, behavioral, biological, and environmental risk factors rather than alcohol use alone [22]. The Centers for Disease Control and Prevention (CDC) estimates that one in six of the US adults binge drink about once a week [23]. Fortunately, the Substance Abuse and Mental Health Services Administration found a significantly lower prevalence in the elderly population and estimated that nearly 3% of adults aged 65 and older drank heavily within the previous month [24]. Overall, it is believed that the rates of heavy alcohol consumption are low among elderly individuals; hence we believe that our sample size may be too small to detect significant effects of alcohol use on falls. Other studies, such as the one from Mukamal and associates, have reported that older adults who engage in heavy drinking tend to avoid enrolling in cohort studies resulting in selection bias [25]. The same group also tends to underreport alcohol use during clinical encounters, which could have influenced our findings, as well.

We also found that with each unit percentage increase in the HbA1c, there was a decrease in the odds of falls (OR: 0.450, 95% CI: 0.223 - 0.906; P = 0.025). In the PODEVAL group, there were significantly more patients using insulin compared to the no PODEV AL group (34.8% vs. 18.1%; P = 0.008). This finding is not unusual. Episodic hypoglycemia is a known risk factor for falls in older individuals with DM. Although there is a delicate balance in managing blood glucose levels in patients with diabetes, there are deleterious sequelae at both ends of the spectrum. Schwartz and associates conducted a prospective cohort study of older adults with DM to determine if DM-related complications and treatments were associated with increased risk of falls [26]. Using ORs, they found that there were increased odds of falls in individuals using insulin with low HbA1c levels (OR: 4.36; 95% CI: 1.32 - 14.46, HbA1c < 6% vs. > 8%). Interestingly, they also found that patients using only OHA did not have increased odds of falls with lower HbA1c levels. Likewise, a meta-analysis completed by Yang and associates found that there was an increased risk of falls among those patients with DM who were treated with insulin therapy compared to the patients treated without insulin (risk ratio (RR): 1.94; 95% CI: 1.42 - 2.63 vs. RR: 1.27; 95% CI: 1.06 - 1.52) [9]. Preventing falls related to hypoglycemia must
be balanced with achieving goal HbA1c values. We believe that the chronic maladies caused by DM by themselves contribute as the major causes of falls with the passage of time, and as the condition worsens, acute hypoglycemic episodes could contribute to falls, as well.

There were a few limitations in our study. Being a retrospective chart review study, we had to rely on the data and documentations entered in the electronic medical record by the patient care teams, which could have influenced the reliable ascertainment of medical histories. Much of the data were self-reported to the patient care teams; information such as smoking status, alcohol use status, and even some falls could only be obtained through accurate and honest reporting by the patients to their physicians. Information that was not documented, but could have been useful for better classification of falls, such as the environment of the fall, surface, footwear, timing of the fall, association of hypoglycemia, etc. The major strength of our study was that all of the patients were followed by their specific physicians for a long period. The documentation, surveillance, and management of many of their chronic medical conditions and comorbidities were accurately, comprehensively, and carefully overseen from a standpoint of continuity.

Conclusion

We conclude that among elderly patients with DM, there is no significant difference in the events of falls between the groups of patients who undergo podiatrist evaluations, and those who do not. Patients with a diagnosis of anemia, lower HbA1c levels, and history of lesser alcohol use have increased odds of falls.

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Financial Disclosure

None to declare.

Conflict of Interest

None to declare.

Informed Consent

Not applicable. Being a retrospective chart review study, the Institutional Review Board waived the need for informed consent.

Author Contributions

AM and SR made substantial contributions to the study design, drafting, data acquisition and analysis, and manuscript writing. All authors contributed in data collection and manuscript writing. KH analyzed the data. SR contributed in revising the manuscript critically for improved intellectual content, and final approval for the version to be published.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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