Original Research Article

Low Rate of Teriparatide Supplementation for the Treatment of Osteoporotic Pelvic Fractures in Elderly Females

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Abstract

Background: Osteoporotic pelvic fractures in the elderly lead to pain and immobility resulting in decreased quality of life and worsening frailty. Teriparatide has been shown to shorten time to fracture union, diminish pain, and improve mobilization. At our hospital, this medication is prescribed by an outpatient endocrinologist or geriatrician. We hypothesize that elderly female patients sustaining low energy lateral compression (LC) pelvic fractures are not given Teriparatide. This study reports rates of successful Teriparatide initiation and looks for areas of improvement. **Materials and Methods:** A retrospective chart review of stable LC pelvic fractures admitted to a single urban academic level 1 trauma center from January 2012 to February 2021 was conducted. Females over 60 years old with stable LC pelvic fractures were included. Males and those aged less than 60 were excluded. **Results:** 118 females with mean age of 79.1 ± 10.5 were included. Fourteen patients were not eligible for Teriparatide due to medical history, leaving 104 eligible patients. Twenty-eight patients (23.7%) had previous dual energy X-ray absorptiometry (DEXA) scans with mean T-scores of −3.14 ± 1.1 and 61% had Medicare insurance. Orthopaedic services recommended Teriparatide in 100% of cases. Geriatricians or endocrinologists documented evaluations for Teriparatide in 18 (17%), prescribed in 10 (9.6%), and initiated in 7 (6.7%) patients. Insurance type did not significantly differ among those that initiated Teriparatide and those that did not (p-0.10). Insurance did not approve the medication in 2 instances and in 1 instance it was discontinued at follow-up. **Conclusion:** Despite level 1 evidence of Teriparatide's benefit for elderly osteoporotic women with low energy LC pelvic fractures, we failed to initiate treatment in 93% of eligible patients. Barriers to initiation included low rates of medical evaluation for its use and failure of insurance coverage. There are opportunities for multidisciplinary collaboration to increase evaluation for and initiation of Teriparatide. **Level of Evidence:** Cohort Retrospective (level III evidence).

Keywords

osteoporosis, teriparatide, orthopedics, geriatric assessment, fracture healing

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Introduction

Low energy pelvic fractures in the elderly are classified as fragility fractures that indicate the presence of underlying osteopenia. These fractures lead to pain and immobility, a decreased quality of life, and an increased individual frailty. The lateral compression fracture type 1 (LC-1) is

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the most common injury pattern and is identified as a unilateral anterior impaction fracture of the sacrum with an anterior transverse pubic rami fracture (either unilateral or bilateral).[1] These injuries are vertically stable with intact posterior pelvic ligaments, and are most often treated nonoperatively with immediate weightbearing yielding acceptable functional outcomes.[2,3] Recent reports have demonstrated that 5%–20% of pelvic fractures in this population experience delayed healing.[4] The injury is not without its morbidity as patients often spend multiple days in the hospital and demonstrate persistent disability at long-term follow-up.[5]

Parathyroid hormone (PTH) is an important hormone that regulates the concentration of calcium, phosphate, and active vitamin D in the blood and is involved in bone remodeling. It is a peptide composed of 84 amino acids (1-84). The first 34 amino acids (N terminal fragment or PTH 1-34) have been shown to produce the anabolic effects of bone formation.[6] The synthetic form of the N terminal fragment (PTH 1-34), or Teriparatide, is currently approved for the medical treatment of osteoporosis in the United States (US) and works similarly to endogenous PTH.[7,8] Teriparatide is an anabolic medication that increases both osteoblastic and osteoclastic activity, in contrast to anti-resorptive medication, such as bisphosphonates, that only inhibit osteoclastic activity.[9]

Preclinical studies have demonstrated that supplementation of Teriparatide can accelerate fracture healing through its effects on callus formation, bone repair, and bone mineralization.[8,10,11] Additionally, it has been shown to improve healing in cases of delayed union, nonunion, and spinal fusion.[9,12,13] A pivotal RCT out of Austria by Peichl et al, in 2011 demonstrated that elderly osteoporotic women with LC-1 pelvic fractures who received recombinant PTH 1-84 supplementation had a shorter mean time to computed tomography (CT) evidence of fracture healing (7.8 weeks vs 12.6 weeks) and had improvements in both the visual analog scale score (VAS) for pain, and faster Timed "Up and Go" tests 12 weeks (22.9 vs 54.3 seconds) following injury when compared to those that did not receive PTH 1-84.[14] The authors concluded that PTH 1-84 supplementation may improve outcomes and decrease the morbidity associated with immobilization in this patient population.

With level 1 evidence from a RCT supporting the use of this medication for this specific patient population, our department adopted the practice of recommending the use of Teriparatide in elderly osteoporotic women with LC-1 pelvic fractures. At our institution, these patients are typically seen by the orthopaedic service as a consultation in the emergency room at presentation. A recommendation for Teriparatide supplementation is then documented with the intent to accelerate fracture healing time and reduce pain. They are then seen by physical therapy and are only discharged home if deemed safe by that service. Otherwise, they are admitted for further pain control and re-evaluation by physical therapy.

At our institution, Teriparatide is not easily obtained in the inpatient setting, therefore our pharmacy has created a system requiring a referral to endocrinology, geriatrics, or family medicine to assess any contraindications for use of Teriparatide as a supplemental treatment. The dose and route of administration is also determined at that time by the medical specialist. Ultimately, the entire evaluation, including a serum and urine laboratory work-up, is performed by the medical specialist in the outpatient setting. Unfortunately, this process puts these patients at risk for never receiving Teriparatide treatment, as many of them have difficulty making follow-up appointments immediately following their injury. We hypothesize that a large proportion of this patient population neither undergo an assessment for Teriparatide supplementation nor receive Teriparatide treatment, despite existing level 1 evidence. Therefore, the purpose of this study is to evaluate the rate of successful Teriparatide evaluation and initiation in this patient population.

Methods

Study Patients

A retrospective inpatient and outpatient chart review of all consecutive stable LC-1 pelvic ring fractures at a single urban academic level 1 trauma center from January 2012 to February 2021 was conducted. Patients were identified by a prospective fracture database. Inclusion of female patients over 60 years of age required radiographic review by 2 fellowship trained orthopaedic traumatologists (PTIII and MSHK) to confirm the diagnosis of an LC-1 type pelvic ring fracture. Exclusion criteria included males and those aged less than 60 years old. This study was approved by our hospital's Institutional Review Board (IRB), number H-44501, and given the retrospective nature of the study, informed consent was not required.

Outcome Measures

The primary outcome measure was the rate of Teriparatide supplementation following injury. Secondarily, we evaluated the rate of outpatient evaluation for the initiation of therapy as well as reasons for failure of its initiation. Additional variables were collected including baseline demographics such as age, gender, body mass index (BMI), race, smoking status, comorbidities, payor type, documented history of osteoporosis, bone mineral density (BMD) using the lowest T score at any site as measured by

a documented dual X-ray absorptiometry (DEXA) scan, and osteoporosis medications prior to injury (Table 1). Patients with contraindications to Teriparatide were identified and the reason for why they could not be prescribed the medication was documented. An extensive chart review was conducted utilizing our institutions electronic medical record as well as electronic medical records that share information with our institution. This includes outpatient office notes by orthopaedic surgeons and other providers. Records were carefully reviewed to identify whether the use of Teriparatide was appropriately recommended in the consultation note following evaluation by the orthopaedic service. Following patient discharge and through the latest documented follow-up, information was collected on the number of patients that received a medical evaluation for Teriparatide, whether patients who were eligible were prescribed the medication, and of those, which patients started the medication. If there was missing data, a separate category labeled "unknown" was created. For example, insurance status on every patient was not known, there a category of "unknown" was created.

Table 1. Patient Characteristics.

	n = 118 (%)
Age (yrs.) (mean ± SD [range])	79.1 ± 10.5 [60-100]
BMI (kg/m^2) (mean ± SD [range])	24.1 ± 4.8 [14.1-39.7]
Race	
Caucasian	61 (51.7)
African American	27 (22.9)
Hispanic/Latino	19 (16.1)
Asian	6 (5.1)
Other	1 (0.8)
Unknown	4 (3.4)
Smoking	
Current	8 (6.8)
Former	36 (30.5)
Never	74 (62.7)
Payor type	
Medicare	72 (61)
Medicaid	12 (10.2)
Commercial	3 (2.5)
Uninsured	6 (5.1)
Self-pay	5 (4.3)
Unknown	20 (16.9)
History of osteoporosis (yes)	60 (50.8)
Bone mineral density (mean ± SD [range])	−3.1 ± 1.1 [−5.4 to −0.43]
Prior bone health medical treatment	27 (22.9)
Bisphosphonate	25 (21.2)
Denosumab	1 (0.8)
Raloxifene	1 (0.8)
Prior fracture (yes)	48 (40.7)
Osteoporotic (hip, vertebral, distal radius)	31 (64.6)
Comorbidities	
Renal failure	8 (6.8)
Neurodegenerative disorder	28 (23.7)
Chronic pulmonary disease	20 (16.9)
Cardiac arrhythmia	23 (19.5)
Congestive heart failure	23 (19.5)
Diabetes	23 (19.5)
Liver disease	2 (1.7)
Alcohol abuse	4 (3.4)
Depression	11 (9.3)
Elixhauser comorbidity index (mean ± SD [range])	5.6 ± 6.2 [−3 to 22]

Statistical Analysis

Data were collected, de-identified, and stored in a password protected Microsoft Excel file version 1710 (Microsoft Corporation, Redmond, WA). Chart review was performed and aforementioned variables were collected and analyzed. Means, standard deviations, and ranges were calculated using Microsoft Excel. χ^2-Square tests were conducted for categorical variables. Fisher's exact test was used for categorical variables with events less than 5. Analyses were conducted using SPSS v29 (International Business Machines, Armonk, NY). A *P*-value of <0.05 was deemed significant.

Results

Patient Demographics

A total of 163 consecutive stable LC-1 pelvic ring fractures were initially reviewed. Of those, 45 were males and were therefore excluded. This left 118 female patients who form the basis of the study. The mean age at the time of injury was 79.1 ± 10.5 years (range 60 to 100). Mean BMI was 24.1 ± 4.8 kg/m^2 (range 14.1 to 39.7). The majority of patients were Caucasian (n = 61, 51.7%) and the majority had Medicare insurance (n = 72, 61%). Six patients (5.1%) were uninsured. The majority were never smokers (n = 74, 62.7%) whereas 8 patients (6.8%) were current cigarette smokers. Sixty (50.8%) had a documented history of osteoporosis. DEXA scan information was available on 28 (23.7%) patients, and of these the lowest T-score at any site was recorded. This resulted in a mean T-score of −3.14 ± 1.1 (range −5.35 to −0.43). Twenty-seven (22.9%) patients had a documented history of taking medications for bone health at some point prior to their injury. Of those, 25 were on bisphosphonates, 1 was on a selective estrogen receptor modulator (raloxifene), and 1 was on denosumab. Fifteen (55.5%) of the 27 were taking 1 of these medications at the time of their pelvic fracture. Forty-eight

patients had a prior fracture. Of these, 31 were classified as having osteoporotic fractures, specifically in the hip, vertebrae, or distal radius – the 3 most common sites for osteoporotic fractures.[15] The mean Elixhauser comorbidity index was 5.6 ± 6.2 with a range from −3 to 22 across the entire cohort. A more detailed list of comorbidities is included in Table 1.

Based on review of medical charts and past medical history, 14 (11.8%) patients had known contraindications for Teriparatide use at the time of admission, leaving 104 patients who were eligible to receive the medication following their injury. The most common contraindication was renal disease in 13 (92.8%) patients as Teriparatide is not recommended for patients with a creatinine clearance (CrCl) <30 mL/min.[16,17] Renal disease was determined by CrCl calculated on admission or from previous diagnosis ascertained via chart review. Eight of the 13 patients with renal disease had end stage renal disease, 6 of whom were receiving hemodialysis. Three patients had chronic kidney disease stage IV and 2 patients had acute on chronic kidney disease. One patient had a history of Raynaud's disease and had a prior adverse reaction to Teriparatide where her fingers turned black.

Teriparatide Supplementation

During hospitalization, Teriparatide use was recommended by the orthopaedic service in 100% of patients. The recommendation for Teriparatide was documented as early as the initial consultation note in 73.9% of encounters.

Geriatric, endocrine, family medicine or medicine physicians documented an evaluation for potential use of Teriparatide in 18 (17%) patients, it was prescribed for 10 (9.6%), and started in only 7 (6.7%) patients (Figure 1). One patient was prescribed the medication by the general surgery trauma team on discharge without a medical evaluation. Of the 27 patients that were on medications for bone health at any time prior to their injury, 15 patients were taking bone health medications at the time of their injury. Of the 15 patients on bone health medications at the time of injury, 10 patients were taking alendronate, 2 patients were on zoledronic acid, 1 was on raloxifene, 1 was on risedronate, and 1 was on denosumab. There were 3 patients who were transitioned from a different bone health medication (2 patients were on alendronate and 1 was on zoledronic acid) to Teriparatide following their injury (Figure 1).

Of the 18 patients who were evaluated for supplementation, 16 patients were evaluated in the outpatient setting. Thirteen of which were evaluated by an endocrinologist specifically for osteoporosis, 2 patients followed up with their established rheumatologist with documented discussion of Teriparatide supplementation, and 1 patient was evaluated by geriatrics. Two patients were evaluated by inpatient internal medicine providers. Nine patients were not prescribed the medication following documented evaluation. Three were deemed inappropriate due to renal disease, 4 did not have appropriate follow-up in the chart and therefore it is unknown if they started the medication, 1 patient did not want a daily injection, and 1 was deemed inappropriate due to being 96 years old and concern for orthostatic hypotension in the setting of previous falls due to orthostatic hypotension.

In the 10 patients that were initially prescribed Teriparatide, 3 were unable to start taking the medication. Insurance did not approve the medication in 2 instances and in 1 instance the outpatient geriatrician discontinued it at follow-up after deeming it unnecessary for bone healing or pain reduction. Of the 7 patients that started Teriparatide, 3 had Medicare (42.9%), 3 had Medicaid (42.9%), and 1 patient's insurance status was unknown (14.2%). There was no statistically significant difference among insurance status with respect to those that were able to initiate Teriparatide and those that did not ($P = 0.10$). Additionally, the majority of patients started on Teriparatide had a documented history of osteoporosis, however this did not reach statistical significance ($P = 0.44$). Ultimately, 7 patients successfully initiated treatment of Teriparatide supplementation (Table 2).

Six patients who underwent an outpatient evaluation for Teriparatide supplementation by endocrinology were started on different bone health medications including 3 that were started on zoledronic acid, 2 on alendronate, and 1 on denosumab. Additionally, patients who were not evaluated specifically for Teriparatide, initiated bone health medications following their injury in 6 cases, including 1 patient starting denosumab and 5 patients starting alendronate. Lastly, of the 15 patients who were already taking bone health medication at the time of their fracture, 12 were continued on their current regimes, while 3 patients were transitioned from their bone health medication at the time of injury to Teriparatide following their injury. Annual trends of Teriparatide supplementation is included in Figure 2.

Discussion

Osteoporotic pelvic ring fractures can result in substantial morbidity in the elderly population due to decreased mobilization. Any treatment that can promote early mobilization should be considered. Reports have demonstrated 1-year mortality rates as high as 16.3% following these injuries.[18] This is comparable to 1-year mortality rates associated with hip fractures (15% to 20%).[19,20] Morbidity and potentially mortality in these patients may be related to immobility that can lead to medical complications such as pneumonia, delirium, urinary tract infections, and venous thromboembolism.[2,21] Moreover,

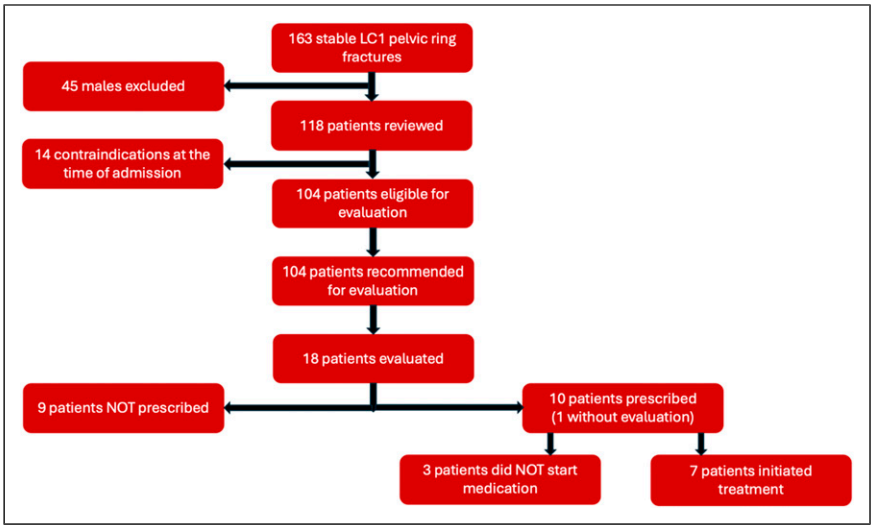

Figure 1. Patient selection for Teriparatide Supplementation.

Table 2. Teriparatide Initiation by Insurance Payor Type.

	Teriparatide Initiated n = 7 (%)	Teriparatide Not Initiated n = 111 (%)
Payor Type		
Medicare	3 (42.9)	69 (62.2)
Medicaid	3 (42.9)	9 (8.1)
Commercial	0	3 (2.7)
Uninsured	0	6 (5.4)
Self-pay	0	5 (4.5)
Unknown	1 (14.2)	19 (17.1)
History of osteoporosis (yes)	5 (71.4)	2 (28.6)

patients often do not return to pre-injury independence, thus requiring increased use of ambulatory aids and exhibit decreased quality of life and physical function.[18,22] It is therefore essential to apply a multidisciplinary approach to the treatment of this patient population, similar to the approach used for the management of geriatric hip fractures. Despite level 1 evidence supporting the use of Teriparatide in this patient population, only 17% of patients were actually screened for the use of Teriparatide, and an even lower 7% of patients received it as supplementation. Prescriber awareness of Teriparatide's potential benefits did not seem to play a role as there did not seem to be any increase in prescription since the publication of Peichl et al.[14]'s study in 2011 as there was a consistent number of evaluations performed from 2011 until latest follow-up.[14] This demonstrates an inability to successfully implement evidence-based medicine into clinical practice and emphasizes the importance of organizing a multidisciplinary approach to patient care.

A collaborative approach that combines treatment strategies from the orthopaedic and medical fields has been previously studied. The elderly hip fracture population has benefited from the multidisciplinary effort of these specialists by implementing various models of orthogeriatric care. A study out of Australia by Fisher et al assessed the impact of combined orthopaedic and geriatric medical management on outcomes of elderly hip fractures. Additionally, they evaluated the rate and adequacy of anti-osteoporotic prescriptions at the time of discharge. They defined adequate prescription as patients receiving a bisphosphonate, calcium, and vitamin D for future fracture prevention. Prior to the introduction of the orthogeriatric model, 11.8% of patients received an anti-osteoporotic treatment, and in all cases, it was deemed inadequate. This increased to 68.9% of patients receiving anti-osteoporotic treatment upon discharge following implementation of a combined orthogeriatric care model, increasing their rates for adequate treatment to 43.7%.[23] While this study had a different patient population, and medical treatment with anti-resorptive medications as opposed to anabolic medications, the results demonstrated an improved rate of osteoporotic medical treatment achieved through a collaborative effort. This highlights the opportunity to develop a more cohesive system with the goal of increasing the number of patients who receive supplementation of Teriparatide for their osteoporotic pelvic fracture.

It is important to note that while Peichl et al demonstrated the benefits of using Teriparatide supplementation in fracture healing, governing bodies such as the Food and Drug Administration (FDA) do not approve its use in

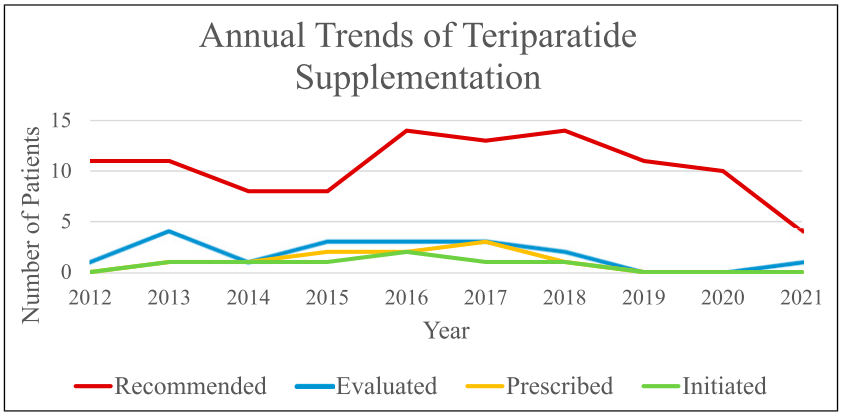

Figure 2. Annual trends of teriparatide supplementation.

accelerating fracture healing. Additionally, Peichl et al utilized 100 μg PTH 1-84, whereas Teriparatide is a synthetic form of 1-34 PTH. Currently, in the US, PTH 1-84 is only approved for the treatment of hypocalcemia in patients with hypoparathyroidism, whereas Teriparatide is approved as an anabolic treatment for postmenopausal women with osteoporosis at risk for fracture.[24,25] Studies have shown dose-dependent differences in the anabolic effects of Teriparatide.[7,11] An apparent accelerated time to radiographic evidence of cortical bridging in distal radius fractures was seen when patients were given 20 μg Teriparatide per day, as opposed to no difference seen when comparing groups given 40 μg per day vs placebo.[26] A 2022 study by Nieves et al investigated the benefits of Teriparatide 20ug/day for a duration of 3 months following pelvic fractures and found that those supplemented with Teriparatide had significantly improved physical performance at 3 months. Despite no evidence of increased fracture healing time or pain reduction, the improvement of physical performance may prove essential to reducing disability in elderly patients following pelvic fractures.[27] Considering there is no current study that exists on the use of Teriparatide in the treatment of elderly female LC-1 pelvic fractures, the optimal dose is unknown. Additionally, while patients in the Peichl study received PTH 1-84 for 24 months following their injury, there is no clear consensus as to whether patients should receive Teriparatide supplementation for the FDA approved maximum allowed duration of 2 years, or until the fracture has healed.[25] For example, Nieves et al recommended treatment for 3 months following pelvic fractures and Yang et al recommended treatment for 6 months following sacral insufficiency fractures.[27,28] The paucity of data surrounding the optimal dosage and duration of treatment for the use of Teriparatide in elderly female patients with LC-1 pelvic fractures suggests the need for further studies.

Side effects of Teriparatide use include vomiting, nausea, headaches, transient orthostatic hypotension, elevations in serum calcium and/or uric acid, and sequalae of hypercalcemia, including constipation, low energy, and muscle weakness.[16] Additionally, Teriparatide has been shown to increase the risk for bone cancers, such as osteosarcoma, in rats treated with doses 200 times over the recommended human dose (20-40 μg).[29] As a result, Teriparatide is contraindicated in patients who have a history of bone tumors, Paget's disease, prior adverse reactions to Teriparatide, unexplained high levels of serum alkaline phosphatase, hyperparathyroidism, hypercalcemia, digoxin co-administration, hyperuricemia, hypercalciuria, history of targeted radiation therapy to bone, or metabolic bone disease other than osteoporosis.[9] There is hesitation to prescribe Teriparatide in patients with renal disease, specifically, CrCl less than 30 mL/min, as PTH is already upregulated due to the renal pathology and the elimination of the drug can be prolonged.[17,30]

Lastly, the high cost of Teriparatide supplementation can influence the ability for a patient to receive it. Although our study failed to find a statistical difference with respect to insurance status and the initiation of Teriparatide, it is important to point out that the median inflation adjusted out of pocket monthly cost of the medication has been estimated to be $50 for patients with insurance, in those without insurance, the price can range from $500 to $5000 per month.[31,32] The large discount afforded by having the medication covered by insurance emphasizes that those without coverage are unlikely to be able to afford the drug. Our study demonstrated that 23.7% of patients had a documented BMD in their chart. This rate is far lower than expected in our patient population with a mean age of 79.1 years, given that the current US preventative services task force guidelines recommend BMD testing for all women aged > 65.[33] This highlights the need for an evaluation of our current practices as there is an opportunity to improve our delivery of care for this patient population. Considering that Teriparatide is only approved for the treatment of osteoporosis in elderly female patients,

by identifying these patients following a fragility pelvic fracture, and screening them for osteoporosis, we would be able to justify the use of Teriparatide.

Limitations

There are several limitations of our study. As we had access only to our institution's data and other select nearby institutions, it is possible that we failed to capture those patients who were evaluated and prescribed Teriparatide at an outside hospital or by a physician outside our institution's medical record. It is also possible that the ability to evaluate and prescribe Teriparatide solely in the outpatient setting is unique to our institution, therefore limiting the generalizability of our study. Lastly, the study was limited to data from only 1 institution therefore limiting the sample size. Additionally, a power analysis was not conducted, and therefore it is not known if the study was powered enough to reach any statistical conclusions. It is possible that the small number of patients started on Teriparatide is unique to only our institution and may not be generalizable to the general population.

Conclusions

Despite strong level 1 evidence that Teriparatide is beneficial for elderly osteoporotic women with low energy LC pelvic fractures, we failed to institute it in 93% of eligible patients. There is an opportunity for a multidisciplinary collaborative effort to increase the rate at which this patient population is evaluated for and receives this effective treatment. We were surprised to see our low rate of Teriparatide evaluation and treatment. We hope this study may prompt others to review their own system's practices and delivery of care models. Future direction and research should be conducted looking at this patient population's ability to receive this type of medication and whether they have improved outcomes.

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Author Contributions

D.N., P.T.III, and M.S.H.K. contributed to the conception and design of the study. D.N. and M.G.K. conducted data collection, data analysis, and data interpretation. D.N. and M.G.K. wrote the manuscript and prepared figures with input from all co-authors. All authors reviewed, provided feedback and approved the final version of the manuscript.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Statement

Ethical Approval

Our study was approved by Boston Medical Center Institution Review Board (approval no. H-44501) on January 07, 2024. This is a retrospective study and does not require informed consent. Patient data will not be shared with outside parties.

Informed Consent

There was no need for informed consent for this study given the retrospective nature of the study. This study was granted IRB exemption.

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