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Can Over Six Months of Teriparatide Treatment Prevent the Progression of Osteoporotic Thoracolumbar Compression Fracture?

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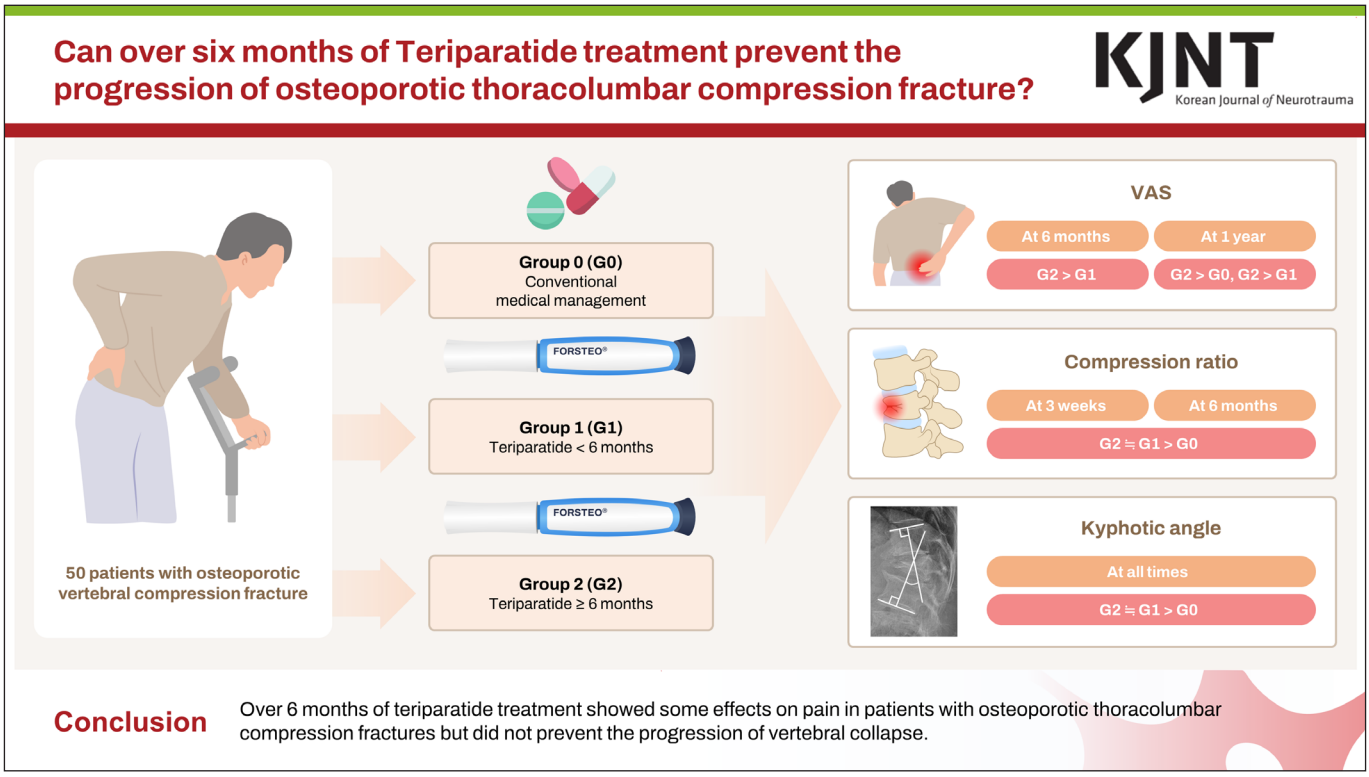
ABSTRACT

Objective: Osteoporosis is one of the most common causes of thoracolumbar compression fractures. Teriparatide is an anabolic agent used to treat osteoporosis. This study aimed to determine whether teriparatide treatment for over 6 months could be effective in patients with osteoporotic thoracolumbar compression fractures.
Methods: Between July 2012 and June 2020, we reviewed 50 patients with thoracolumbar osteoporotic compression fractures who could be followed up for more than 1 year. Patients were divided into 3 groups: 11 patients who did not receive teriparatide (Group 0), 19 patients who received teriparatide for less than 5 months (Group 1), and 20 patients who received teriparatide for over 6 months (Group 2). Demographic data, visual analog scale (VAS) scores, and medical histories were reviewed. Radiographs were reviewed to evaluate the vertebral body compression ratio and kyphotic angles.
Results: VAS scores improved in all groups at each time point after injury. Score improvements at 6 months and 1 year between Group 0 and Groups 1 or 2 were significantly different. The compression ratio in all groups increased at each time point after injury, but the differences between Groups 0, 1, and 2 were statistically significant at 3 weeks and 6 months. While the kyphotic angle significantly increased at 1 year in all groups, the differences between the groups at each time point did not reach statistical significance.
Conclusion: Over 6 months of teriparatide treatment had some effects on pain in patients with osteoporotic thoracolumbar compression fractures, but did not prevent the progression of vertebral collapse.

Keywords: Fractures, compression; Osteoporotic fractures; Teriparatide; Thoracic vertebrae; Treatment outcome

GRAPHICAL ABSTRACT



Conflict of Interest
Je Hoon Jeong serves as an Editor-in-Chief of the *Korean Journal of Neurotrauma*, but has no role in the decision to publish this article. Except for that, no potential conflict of interest relevant to this article was reported.

Informed Consent
This study had Institutional Review Board approval, and the need to obtain informed patient consent was waived.

Ethics Approval
The study was approved by the Institutional Review Board (IRB) of Soonchunhyang University Bucheon Hospital on June 16, 2022 (IRB file Number: SCHBC 2024-01-009).

INTRODUCTION

Osteoporosis, a systemic skeletal disorder characterized by reduced bone mass, is an important risk factor for fractures.[18] Especially, thoracolumbar compression fracture is a common consequence of osteoporosis, leading to significant morbidity, decreased quality of life, and increased mortality in affected individuals.[11] The pathophysiology of osteoporotic fractures encompasses decrease in bone strength, which predisposes the vertebrae to fail under physiological loads.[23] As global population ages, the incidence of osteoporotic thoracolumbar compression fractures is rising, underscoring the need for effective prevention and treatment strategies.[6]

Teriparatide, a recombinant form of human parathyroid hormone, has emerged as a useful anabolic agent for treatment of osteoporosis. By stimulating bone formation, increasing bone mass, and improving bone architecture, teriparatide offers a therapeutic advantage, especially when combined with subsequent usage of antiresorptive agent.[3,16] Clinical trials have already demonstrated the efficacy of teriparatide in increasing bone mineral density and reducing the risk of fractures in patients with osteoporosis.[10] However, despite the known benefits of teriparatide in the treatment of osteoporosis, there needs to be more data specifically addressing its effectiveness in the healing process of thoracolumbar compression fractures. Thus, the treatment effect of teriparatide in the management of osteoporotic thoracolumbar spine fractures remains to be a promising area of investigation.

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This study focuses on the application of teriparatide for more than 6 months to patients with osteoporotic thoracolumbar compression fractures. In this research, we evaluated the clinical and radiological outcomes of teriparatide treatment in this patient population. The results of this study could potentially refine treatment protocols and care strategy for this debilitating condition.

MATERIALS AND METHODS

Study design and patients

We reviewed medical records of patients with thoracolumbar osteoporotic compression fractures of a tertiary referral hospital between July 2012 and June 2020. The inclusion criteria were as follows: 1) only one level of osteoporotic vertebral fracture without spinal cord compression, 2) bone mineral density (BMD) T-score less than −2.5, and 3) follow-up period of more than one year. The exclusion criteria were: 1) presence of neurological deficits, 2) pathological fracture, 3) unstable vertebral fracture involving the posterior column of the spine, and 4) any spinal procedure such as vertebroplasty.

We divided the patients who were included in our research into 3 groups depending on the usage status of teriparatide: Group 0 who did not receive teriparatide, Group 1 who did receive subcutaneous teriparatide injection on daily basis but did not proceed the treatment for more than 6 months, and Group 2 who proceeded the teriparatide treatment for more than 6 months.

Patients in Group 0 received other osteoporotic drugs, such as selective estrogen receptor modulators (SERMs), bisphosphonates, or calcium and vitamin D supplements, depending on their individual circumstances. After the teriparatide treatment, patients in Groups 1 and 2 were given SERM, bisphosphonate, or denosumab. The decision as to choosing the type of therapy was primarily made by the patients, after informed of estimated effect teriparatide injection therapy.

Analgesic medications were given to all patients, including non-steroidal anti-inflammatory drugs, acetaminophen, opiate derivatives, et cetera. Regardless of their groups, the patients had bed rest for at least 1 week, after which they began to ambulate with thoracolumbosacral orthosis from 6 to 12 weeks.

Clinical and radiological data

We reviewed the patients' demographic data, length of hospitalization, body mass index (BMI), visual analog scale (VAS) score, and medical history such as diabetes and usage of tobacco, alcohol, or steroid. BMD was measured at the initial phase of treatment.

To assess the vertebral integrity and postural deformity after injury, we measured vertebral body compression ratio and kyphotic angle on plain lateral radiography of the spines. The compression ratio was defined by, first calculating the ratio of the anterior height of compromised vertebra ($V_{injured}$) divided by the mean anterior height of superiorly ($V_{superior}$) and inferiorly ($V_{inferior}$) adjacent vertebrae, then subtracting this ratio from one then multiplying it by 100 percent (**FIGURE 1A & B**).

The kyphotic angle was defined as the angle subtended by the superior endplate of the vertebral body directly above and by the inferior endplate of the vertebral body directly below

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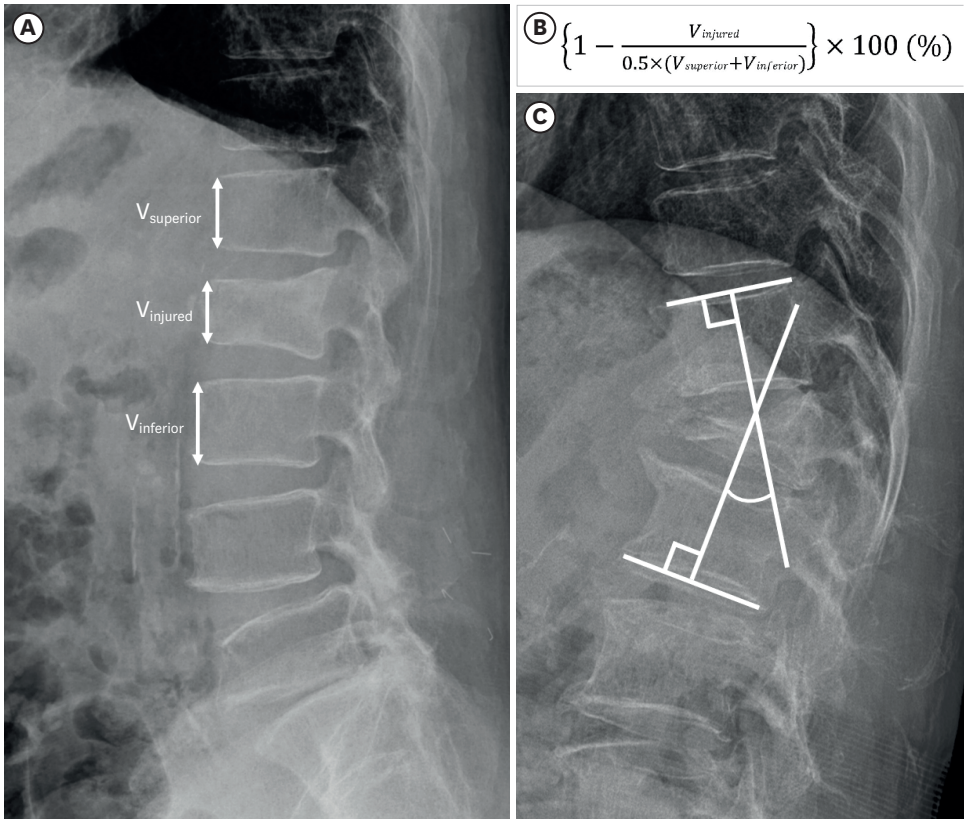

FIGURE 1. Measurement of radiologic variables in three groups of different teriparatide treatment.
(A) Depictions of anterior height of each vertebral body. (B) Calculation formula of compression ratio. (C) Definition of kyphotic angle.

the fractured vertebra (**FIGURE 1C**). Sequential radiographic evaluations were instituted at baseline, followed by 2 weeks, 3 months, 6 months, and 12 months subsequent to the initial fracture diagnosis in all groups.

Statistical analysis

Continuous variables are shown as (median, 75 percentile), except for patient age which was written as (mean ± standard deviation). Fisher's exact test was executed to compare categorical variables. A 2-tailed *p*-value of <0.05 was considered statistically significant. One-way analysis of variance or Kruskal-Wallis test was executed to compare continuous variables between groups. Mann-Whitney U test was performed to compare VAS score, vertebral compression ratio, and kyphotic angle between groups at each time point. Wilcoxon signed-rank test was used to notice any difference in the 3 aforementioned variables at each time point compared to the baseline in each group. We used Friedman test to analyze the overall tendency of VAS score, compression ratio and kyphotic angle across the whole study period. Dunn's test was applied to make multiple comparisons. All statistical analyses were performed by Rex (version 3.0.3; RexSoft Inc., Seoul, Korea).

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RESULTS

Fifty patients met the criteria and thus included in this study. Of these 50 patients, 11 patients (22.0%) who did not take teriparatide were assigned to the Group 0, 19 patients (38.0%) with less than six months of teriparatide therapy were allocated to the Group 1, and remaining 20 patients (40.0%) with more than six months of teriparatide treatment were classified as Group 2.

The male-to-female patient ratio was 9:41. Mean age of patients was 69.4±10.87 years. Location and number of the injured vertebrae were as follows: T6 (n=1), T10 (n=1), T11 (n=1), T12 (n=10), L1 (n=16), L2 (n=8), L3 (n=7), and L4 (n=6). Initial BMD T-scores were −3.03±1 points. **TABLE 1** summarizes the demographic data and their statistical comparisons between 3 groups. In short, the baseline characteristics of patients did not show any statistically significant difference between groups, except for follow-up duration.

Median VAS scores of Groups 0, 1 and 2 were 5 (4.5–6.0), 5 (3.5–6.0), and 3 (3–4.25) at injury, 4 (3–4), 2 (1.25–3.5), and 3 (2–3) at 1 week post-injury, 3 (2–3), 5 (1–2), and 2 (1–2) at 2 weeks post-injury, 2 (1–3), 1 (1–2), and 2 (1–2) at 3 weeks post-injury, 1 (1–4), 1 (1–2) and 1 (0.75–1) at 6 months post-injury, and 1 (1–2), 1.5 (1–3.25) and 1 (0.25–1) at 1 year post-injury, respectively (**TABLE 2**, **FIGURE 2**). The VAS scores improved significantly in all groups at any given time point after injury (**TABLE 3**), and Friedman test showed the *p*-value for trend was 0.0003, 0.0013, and <0.0001 for each group. Between Groups 0 and 1, the VAS scores were different at 1, 2, and 3 weeks after injury. At 6 months and 1 year after injury, the VAS score difference reached statistical significance between Groups 0 and 2, and Groups 1 and 2, respectively (**TABLE 2**).

TABLE 1. Demographics and clinical data for osteoporotic vertebral compression fracture patients with different usage status of teriparatide

Parameter	Total (n=50)	Group 0 (n=11)	Group 1 (n=19)	Group 2 (n=20)	*p*-value
Age (years)	60±10.87	61.45±13.69	71.53±10.28	71.75±7.68	0.0901
BMD (points)	−3.03±1	−3.11±1.07	−3.08±1.09	−2.94±0.92	0.8861
Admission period* (days)	3 (2, 3)	3 (2.5, 3)	2 (1, 3)	3 (2, 3)	0.3795
Follow-up duration* (months)	20.5 (11, 25.5)	22 (17, 29)	10 (7, 24)	22.5 (13.75, 27.75)	0.0113
Sex					0.4624
Female	41 (82.0)	8 (72.7)	17 (89.5)	16 (80.0)	
Male	9 (18.0)	3 (27.3)	2 (10.5)	4 (20.0)	
Refracture					0.1299
No	42 (84.0)	7 (63.6)	17 (89.5)	18 (90.0)	
Yes	8 (16.0)	4 (36.4)	2 (10.5)	2 (10.0)	

Group 0 with no teriparatide treatment, Group 1 with less than 6 months, and Group 2 with more than 6 months of teriparatide injection. Values are presented as mean ± standard deviation or number (%).
BMD: bone mineral density.
*Admission period and follow-up duration are shown as median (interquartile range).

TABLE 2. Comparisons of VAS score at each time point between groups with different usage status of teriparatide

Time*	Group 0	Group 1	Group 2	Raw *p*-value		
				Group 0 vs. Group 1	Group 0 vs. Group 2	Group 1 vs. Group 2
T0	5 (4.5–6.0)	5 (3.5–6.0)	3 (3–4.25)	0.4683	0.0223	0.0688
T1	4 (3–4)	2 (1.25–3.5)	3 (2–3)	0.0299	0.1470	0.3759
T2	3 (2–3)	5 (1–2)	2 (1–2)	0.0283	0.0779	0.5707
T3	2 (1–3)	1 (1–2)	2 (1–2)	0.0484	0.3231	0.2364
T4	1 (1–4)	1 (1–2)	1 (0.75–1)	0.5206	0.0222	0.0773
T5	1 (1–2)	1.5 (1–3.25)	1 (0.25–1)	0.5068	0.0311	0.0079

Group 0 with osteoporotic vertebral compression fracture patients with no teriparatide treatment, Group 1 with less than 6 months, and Group 2 with more than 6 months of teriparatide injection.
VAS: visual analog scale.
*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

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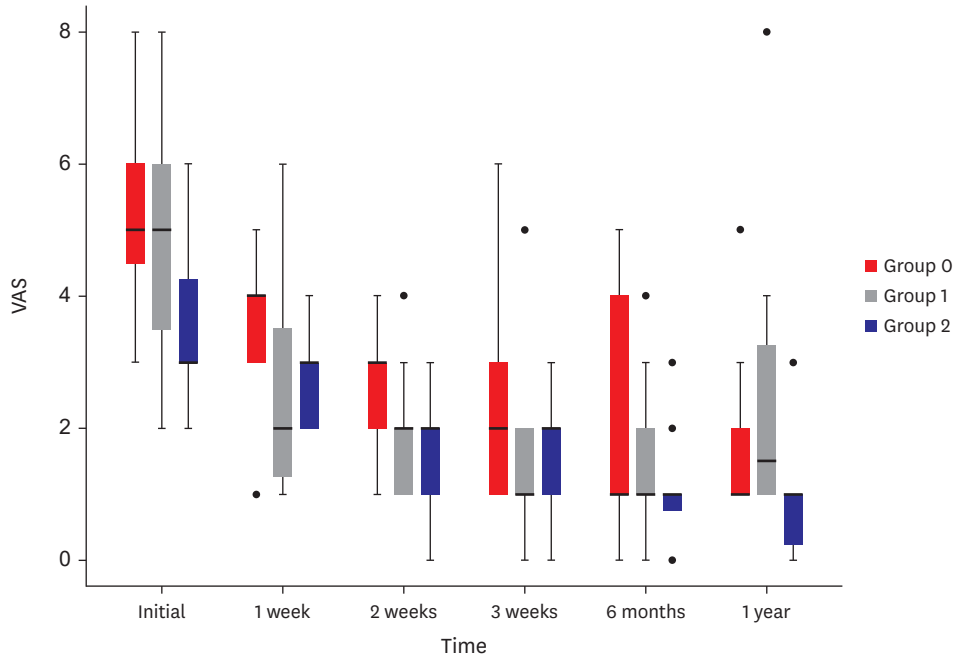

FIGURE 2. Change of VAS scores after osteoporotic compression fracture of 3 groups over time. Group 0 with no teriparatide treatment, Group 1 with less than 6 months of teriparatide treatment, and Group 2 with more than 6 months of teriparatide treatment. Data are shown in median values and interquartile range, with outliers dotted outside each plot.
VAS: visual analog scale.

TABLE 3. VAS score of each group compared to the baseline

Time*	Raw *p*-value		
	Group 0	Group 1	Group 2
T1 vs. T0	0.0196	0.0003	0.0005
T2 vs. T0	<0.0001	<0.0001	<0.0001
T3 vs. T0	<0.0001	<0.0001	<0.0001
T4 vs. T0	<0.0001	<0.0001	<0.0001
T5 vs. T0	<0.0001	0.0042	<0.0001

VAS: visual analog scale.
*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

The vertebral compression ratios of Groups 0, 1, and 2 were 22.8 (21.2–31.45), 17.8 (9.74–24.6), and 22.95 (13.33–27.33) at injury, 34.6 (25.8–38.85), 22.55 (17.7–26), and 23.17 (16.62–27.47) at 2 weeks post-injury, 40.1 (38.7–57.4), 27.02 (16.88–35.51), and 27.92 (22.12–34.41) at 3 weeks post-injury, 48.55 (41.6–60.85), 24.87 (16.21– 37.7), and 31.18 (20.67–36.43) at 6 months post-injury, and 50 (32.2–63.55), 33(18.12–45.65), and 33.65(23.45–37.37) at 1 year post-injury, respectively (**TABLE 4**, **FIGURE 3**). Overall tendency for increase in compression ratio was confirmed by Friedman test, with *p*-value for trend of <0.0001 in Groups 0 and 2, and 0.0013 for Group 1. The compression ratios in all groups were significantly increased starting from 2 weeks after injury, except for Group 1 at 1 week post-injury, when the change in compression ratio did not reach statistical significance (**TABLE 5**). The compression ratio of Group 0 differed significantly from its counterparts at 3 weeks and 6 months post-injury.

Mean kyphotic angles of Groups 0, 1, and 2 were 10.1 (5–16.25), 12 (8.1–18.25), and 9 (6.82–14.22) at injury, 10 (4.5–16.35), 13 (9.5–20.15), and 7.5 (5.08–15.28) at 2 weeks post-injury, 13 (5–19.25), 12.9 (6.9–22.48), and 12.3 (2.3–17.9) at 3 weeks post-injury, 14.7 (7.75–22.35), 8

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TABLE 4. Comparisons of compression ratio at each time point between groups with different usage status of teriparatide

Time*	Group 0	Group 1	Group 2	Raw *p*-value		
				Group 0 vs. Group 1	Group 0 vs. Group 2	Group 1 vs. Group 2
T0	22.8 (21.2, 31.45)	17.8 (9.74, 24.6)	22.95 (13.33, 27.33)	0.1633	0.4979	0.3929
T1	34.6 (25.8, 38.85)	22.55 (17.7, 26)	23.17 (16.62, 27.47)	0.0698	0.0681	0.9780
T2	40.1 (38.7, 57.4)	27.02 (16.88, 35.51)	27.92 (22.12, 34.41)	0.0134	0.0325	0.6259
T3	48.55 (41.6, 60.85)	24.87 (16.21, 37.7)	31.18 (20.67, 36.43)	0.0321	0.0476	0.7054
T4	50 (32.2, 63.55)	33 (18.12, 45.65)	33.65 (23.45, 37.37)	0.1241	0.0998	0.9153

Group 0 with osteoporotic vertebral compression fracture patients with no teriparatide treatment, Group 1 with less than 6 months, and Group 2 with more than 6 months of teriparatide injection. Data are written as ratio (interquartile range).
*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

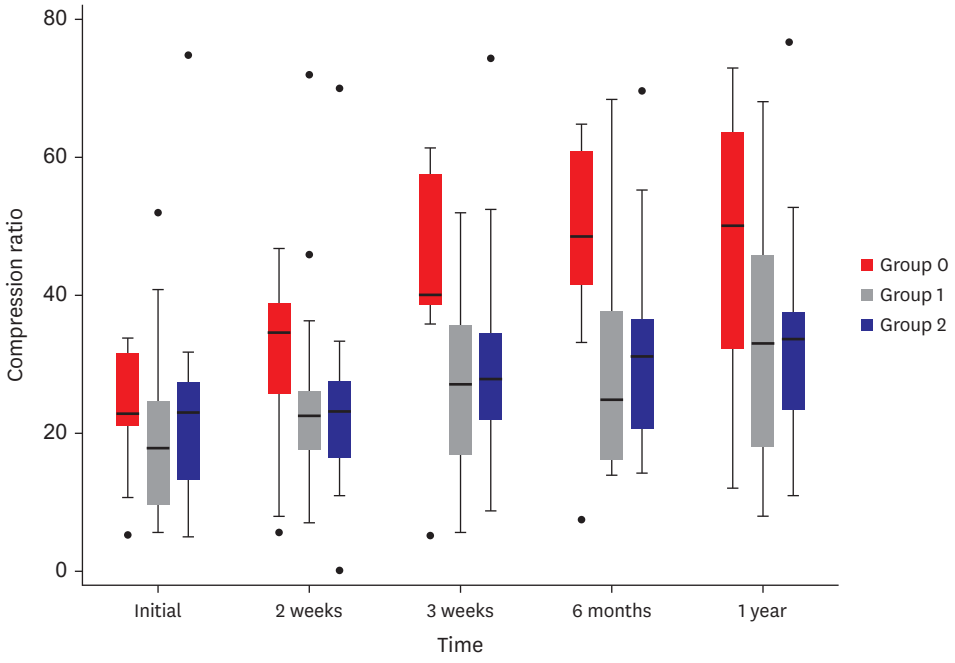

FIGURE 3. Change of compression ratio after osteoporotic compression fracture of 3 groups over time. Group 0 with no teriparatide treatment, group 1 with less than 6 months of teriparatide treatment, and Group 2 with more than 6 months of teriparatide treatment. Data are shown in median values and interquartile range, with outliers dotted outside each plot.

TABLE 5. Compression ratio of each group compared to the baseline

Time*	Raw *p*-value		
	Group 0	Group 1	Group 2
T1 vs. T0	0.0479	0.0623	<0.0001
T2 vs. T0	<0.0001	0.0047	<0.0001
T3 vs. T0	<0.0001	<0.0001	<0.0001
T4 vs. T0	<0.0001	<0.0001	<0.0001

*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

(7–19.2), and 12.55 (8.25–19.55) at 6 months post-injury, and 20 (11–23.85), 14 (8.07–23.85), and 11.2 (5.3–18.3) at 1 year post-injury, respectively (**TABLE 6**, **FIGURE 4**). From 6 months after injury, the kyphotic angle showed noticeable progression from baseline, except for the sixth-month data in Group 1, which did not reach statistical significance (**TABLE 7**). However, when it comes to comparing the kyphotic angles between the 3 groups, no cases showed admissible difference at any given time point (**TABLE 6**). In Friedman test, only

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TABLE 6. Comparisons of kyphotic angle at each time point between groups with different usage status of teriparatide

Time*	Group 0	Group 1	Group 2	Raw *p*-value		
				Group 0 vs. Group 1	Group 0 vs. Group 2	Group 1 vs. Group 2
T0	10.1 (5, 16.25)	12 (8.1, 18.25)	9 (6.82, 14.22)	0.4980	0.9219	0.4924
T1	10 (4.5, 16.35)	13 (9.5, 20.15)	7.5 (5.08, 15.28)	0.2128	0.8109	0.0794
T2	13 (5, 19.25)	12.9 (6.9, 22.48)	12.3 (2.3, 17.9)	0.5904	0.6240	0.2425
T3	14.7 (7.75, 22.35)	8 (7, 19.2)	12.55 (8.25, 19.55)	0.5323	0.7213	0.7214
T4	20 (11, 23.85)	14 (8.07, 23.85)	11.2 (5.3, 18.3)	0.6276	0.1265	0.2319

Group 0 with osteoporotic vertebral compression fracture patients with no teriparatide treatment, Group 1 with less than 6 months, and Group 2 with more than 6 months of teriparatide injection. Data are written as degree (interquartile range).
*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

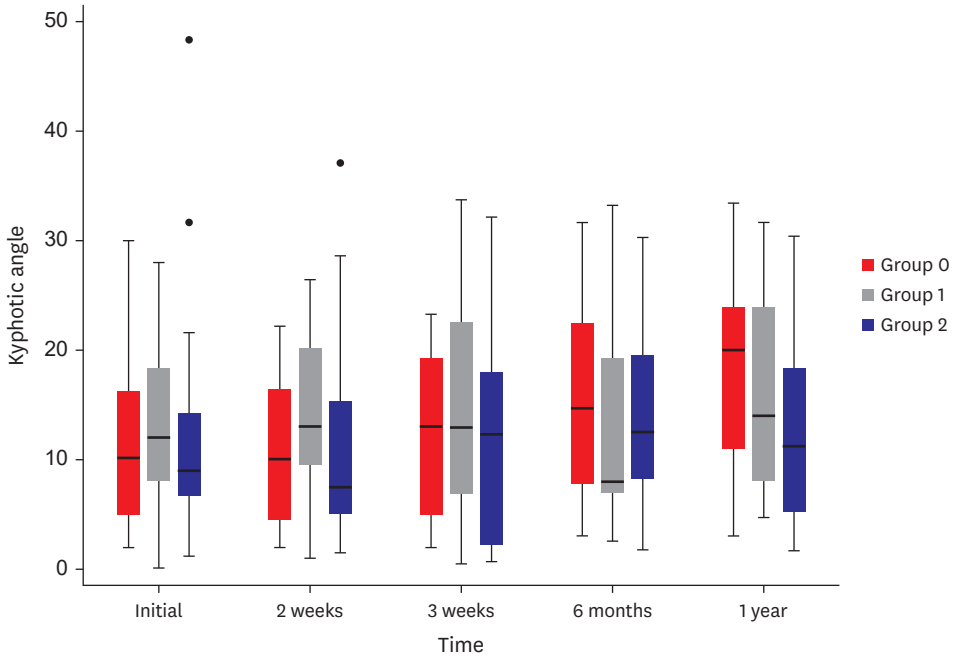

FIGURE 4. Change of kyphotic angle (in degrees) after osteoporotic compression fracture of three groups over time. Group 0 with no teriparatide treatment, Group 1 with less than 6 months of teriparatide treatment, and Group 2 with more than 6 months of teriparatide treatment. Data are shown in median values and interquartile range, with outliers dotted outside each plot.

TABLE 7. Kyphotic angle of each group compared to the baseline

Time*	Raw *p*-value		
	Group 0	Group 1	Group 2
T1 vs T0	0.6743	0.4240	0.9193
T2 vs T0	0.0763	0.2732	0.9193
T3 vs T0	<0.0001	0.9201	0.0018
T4 vs T0	<0.0001	0.0154	0.0013

*T0: initial, T1: 1 week post-injury, T2: 2 weeks post-injury, T3:3 weeks post-injury, T4: 6 months post-injury, and T5: 1 year post-injury.

Group 0 showed tendency for increase in kyphotic angle across the whole study period (p for trend=0.001), while teriparatide groups did not show such result (p=0.4756 for Group 1, and p=0.132 for Group 2).

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DISCUSSION

Osteoporosis is a chronic condition characterized by loss of skeletal integrity and increased susceptibility to fracture. Currently, there are several medications approved for osteoporosis, but they are generally unable to restore the bone strength in most osteoporosis patients, which leads to prolonged management over many years. In treating[21] osteoporosis, continuous usage of single drug has limitations, both in terms of efficacy and safety, making sequential therapy commonly necessary. Therefore, careful consideration for drug choice is mandatory, as to which drugs to use and in what sequence.

Teriparatide, a recombinant human parathyroid hormone, promotes bone formation through stimulating the maturation of osteoblast precursor,[7] prevention of osteoblast apoptosis,[22] and increasing osteoblast activity.[2] The resultant improvement in new bone formation ensures a positive bone balance at the individual bone multicellular unit level,[14] thereby enhancing bone microarchitecture and quality.[20]

Previous randomized controlled trials have substantiated that teriparatide can expedite fracture healing. Aspenberg et al.[1] demonstrated, through a prospective, randomized, double-blind study involving 102 postmenopausal women with distal radius fractures, the potential of teriparatide to augment fracture repair. Similarly, Peichl et al.,[17] in a randomized controlled trial of 65 patients with osteoporotic pubic bone fractures, confirmed that daily injections of PTH 1–84 could significantly improve healing outcomes compared to treatments centered on vitamin D and calcium. These studies suggest that teriparatide could enhance fracture healing and strengthen bone strength and quality in osteoporotic vertebral compression fracture (VCF) treatment, thereby preventing vertebral body collapse and kyphosis while enhancing pain management in patients with osteoporosis.

In line with these evidences, the American Association of Clinical Endocrinologists/American College of Endocrinology guideline of 2020 supports the use of teriparatide as one of the first line drugs in patients who had osteoporotic fracture within 12 months,[4] which is the same indication for the subjects in this study.

The main symptom in patients with osteoporotic VCF is pain, especially motion-induced. Previous studies have reported analgesic properties of teriparatide,[9,15,21] which are thought be caused by its preventive effects against further micro- or macro-fractures.[8,12] This mechanism represents the indirect aspect of teriparatide-induced analgesia. In this study, while VAS scores improved in all 3 groups, patients with teriparatide treatment had greater pain suppression from six months after injury, compared to those who did not inject the drug (**TABLE 2**). Therefore, the teriparatide demonstrated a more enduring effect on pain control, aligning with previous findings of other authors.[5,8,19]

According to the aforementioned guideline,[4] maximum duration of teriparatide treatment is limited to 2 years. However, to the best of our knowledge, there have been no studies regarding the optimal duration of teriparatide treatment for osteoporotic VCF patients. Knowing that our previous report[13] did not show protective effects of three months of teriparatide treatment in progression of thoracolumbar VCF, we decided to elucidate whether more than six months of teriparatide treatment is effective for similar group of patients. And in this study, we observed protective effect of teriparatide against progression of compression at 3 weeks and 6 months, although at 1 year post-injury this effect did not reach the statistical significance

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(TABLE 4). Similarly, when we look at the overall tendency for kyphotic angle progression across the whole study period with Friedman test, only Group 0 showed such tendency for progression. While this may suggest some protective effect of teriparatide against kyphotic consequences after compression fracture, results from group comparisons at each time point were equivocal (TABLE 6). These results highlight the challenges in preventing the progression of vertebral collapse and kyphotic deformity in osteoporotic patients.

This study is subject to certain limitations, primarily owing to its nature as a non-randomized retrospective study. This study focuses solely on pain and radiological outcomes, without considering economic implications of this drug on patients' quality of life for the long haul. Another weakness of this article comes from its relatively small cohort size of 50 patients. This is because exclusion of patients who received vertebroplasty or kyphoplasty yielded a great decrease in the total patient cohort. Since the majority of osteoporosis patients is first diagnosed in outside private clinics and secondary care hospitals, the portion of patients who were newly-diagnosed, had not been treated otherwise, and hence were enrolled in this study is relatively small. A long-term follow-up involving a larger cohort would robustly elucidate the positive effects of teriparatide in the conservative treatment of osteoporotic VCF.

CONCLUSION

Over 6 months of teriparatide treatment in osteoporotic thoracolumbar compression fracture showed some protective effects on pain and progression of collapse of the fractured vertebrae.

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