Journal of Korean Society of
Spine Surgery

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J Korean Soc Spine Surg 2022 Sep;29(3):52-61.
Originally published online September 30, 2022;
https://doi.org/10.4184/jkss.2022.29.3.52

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pISSN 2093-4378 eISSN 2093-4386

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://www.krspine.org/DOIx.php?id=10.4184/jkss.2022.29.3.52

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Original Article

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Parathyroid Hormone Injection Versus Vertebroplasty in the Treatment of Osteoporotic Vertebral Fracture in Old Age: A Retrospective Study of 49 Patients

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Study Design: Case-control retrospective study.
Objectives: To compare the effects of percutaneous vertebroplasty (VP) and parathyroid hormone (PTH) administration in patients with osteoporotic vertebral fracture (OVF), as well as to investigate the optimal duration of PTH injections.
Summary of literature review: Although the indications of PTH for osteoporosis prevention and management have been established, its indications for the treatment of OVF remain unknown.
Materials and Methods: We retrospectively studied elderly patients with OVF between 2015 and 2019. Treatment was selected based on the patient's modified frailty index (mFI), preference, and severity of osteoporosis. Group C was administered PTH once weekly, whereas group I underwent VP. Both groups then received anti-resorptive agent administration. Radiological parameters (e.g., local kyphotic angle, vertebral height, and height loss ratio), clinical parameters such as VAS, and complications were analyzed between the two groups.
Results: Forty-nine female patients were included. Group C included 18 patients with a mean age of 78.2 years (range, 65–85 years), while group I included 31 patients with a mean age of 77.4 years (range, 65–92 years). There was no significant difference between the two groups in initial demographic, clinical, and radiographic parameters, except for a higher mFI in group C ($p<0.01$). Group I showed significantly better clinical and radiological outcome at the last follow-up. Regarding side effects in group C, two cases of dizziness (11.1%) and nausea and vomiting (11.1%) were reported. In group I, cement leakage was found in 20 vertebrae (64.5%), and related complications were observed in four patients (12.9%).
Conclusions: Conservative treatment using PTH demonstrated inferior clinical and radiological outcomes compared to vertebroplasty. However, PTH injections demonstrated a lower risk of procedure-related complications. The patient's frailty and preferences with respect to the severity of osteoporosis should be considered when determining treatment options for OVF in old age.

Key words: Parathyroid hormone, Osteoporotic vertebral fracture, Vertebroplasty

Introduction

Osteoporotic vertebral fracture (OVF) is a typical fracture type caused by osteoporosis, with an incidence of 7.6 – 14% in women in their 60s and 30 – 45% in women in their 70s.[1,2] OVF increase fracture risks in other vertebral bodies, and both repeated fractures and deformity progression at the fracture site can cause persistent pain and reduce the quality of life significantly.[3–5] An intermittent injection of parathyroid hormone (PTH) promotes the new bone formation, and is thus commonly used to treat patients who are at a high risk

Received: March 10, 2021
Revised: March 24, 2021
Accepted: September 20, 2022
Published Online: September 30, 2022
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Journal of Korean Society of Spine Surgery. www.krspine.org. pISSN 2093-4378 eISSN 2093-4386
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of osteoporotic fractures.[6] The use of PTH as a treatment for OVF has been suggested relatively recently.[7] Short-term follow-up studies have reported that PTH improves bony union rate, reduces the time to union more significantly than anti-resorptive agents (i.e., bisphosphonates) as a conservative treatment of OVCF.[7,8] In addition, PTH obtained similar clinical effects including pain level and quality of life with those of percutaneous vertebroplasty (VP) within the short term follow up.[9] Therefore, PTH may be clinically effective and useful in treating OVF. However, while the indications of PTH in osteoporosis prevention and management have been well established, its indications in the treatment of OVF are unknown. Thus, this study aimed to compare the effects of an existing treatment method (percutaneous VP followed by the anti-resorptive agents) and PTH injection in patients with OVF. Furthermore, we investigated the optimal duration of PTH injection based on clinical and radiological parameters.

Materials and Methods

The institutional review board of our institution approved this study (IRB No: 2020-06-044). Written informed consents were obtained from all patients. We retrospectively reviewed the patients aged ≥65 years hospitalized for OVF from January 2015 to November 2019, with follow-up period ≥3 months. Plain radiograph and physical examination were performed to the patients visiting for acute lower back pain. Those with suspected OVF were hospitalized for further evaluation.

Lumbar magnetic resonance imaging (MRI) was taken to identify the acuteness (acute or chronic), type (compression or stable burst fracture), and site (thoracolumbar: T9-L2, lumbar: L3-L5) of fracture. The bone mineral density (BMD) of the L1 to L4 vertebrae was measured. The average value of the T-score of the two lowest segments were defined as lumbar BMD. Osteoporosis was defined as a T-score ≤-2.5. Patients confirmed with OVF were treated conservatively with weekly administration of teriparatide (PTH) 56.5 μg (Teribone®, Asahi Kasei Pharma Corporation, Tokyo, Japan) (Group C), or by an intervention (percutaneous VP) followed by anti-resorptive agents (denosumab, Prolia®, Amgen Inc., Thousand Oaks, CA, USA) (Group I).

An appropriate treatment method was chosen for each patient considering their frailty, T-score and preference. A modified frailty index (mFI) score which was created using standard demographic variables such as underlying disease and systemic condition, has been used for measure of frailty of surgical populations.[10] And it could also predict the postoperative morbidity and mortality for patients undergoing spine procedure.[11] A modified frailty index (mFI) score (range 0-1.0) was calculated by identifying the patient's underlying disease and systemic condition. Perioperative risk was assessed by mFI. In determining the treatment method, the reference mFI value was set at 0.27, which was based on the result of previous study.[11] When mFI was ≥ 0.27, the risk was considered high, thus conservative treatment was recommended. When mFI was<0.27, VP was recommended. If the patient's preferred treatment and the recommendation were different, it was determined through sufficient discussion with the patient.

In Group C, PTH administration was ceased when clinically pain turned to mild (visual analog scale [VAS] score ≤ 3)[13], and radiologically no signs of fracture progression on follow-up plain radiographs shown, along with radiological parameters had stabilized. Anti-resorptive agents (denosumab, Prolia®, Amgen Inc., Thousand Oaks, CA, USA) were then subcutaneously injected. The patients were monitored for any side effects of PTH both admission and follow up period.

In the intervention treatment group (Group I), VP was performed for the fracture level with following indication. (1) Acute fracture which could be confirmed on MRI finding and vertebral body height loss is more than 30% (2) Specific pathology with high risk of collapse such as Kummell's disease. Anti-resorptive agents (Prolia®) was administered following VP. Percutaneous VP was performed under general anesthesia with the patient in the prone position. Fracture site was checked, and the cannula was placed into the vertebral body using fluoroscopy with bipedicular method. Polymethylmethacrylate (PMMA) cement (CMW3®, DePuy, Warsaw, IN, USA) was used. PMMA cement was injected slowly through a cannula in the dough phase, and the injection was monitored under fluoroscopy. The amount of injection was 3cc per pedicle. If cement leakage was found during injection, procedure was immediately stopped. All VP procedures were performed by a single operator (YSP). The operator checked the patient's neurological status before and after the procedure, any cement leakage on plain radiographs,

as well as any complications associated with cement leakage.

All patients underwent pain control with oral analgesics (paracetamol 650 mg, Tylenol® ER Tab, Janssen Korea Ltd. Seoul, Korea) from the day of admission, and the medication was continued for 2 weeks after the PTH injection or VP. All patients were discharged 2 weeks after the start of treatment, and additional analgesics were prescribed if desired. For Group C, TLSO braces were applied for 3 months from the date of admission. After discharge, patients visited the outpatient clinic 1 month after treatment. They visited the clinic monthly until 3 months, after which they visited the clinic every 3 months. Pain levels were measured using the VAS at the time of admission and outpatient follow-up period. For radiological parameters, local kyphotic angle, vertebral height and rate of height loss were measured. The local kyphotic angle was defined as the angle between the upper and lower endplates of the fractured vertebra. The vertebral height was defined as the anterior height of the fractured vertebra. The rate of height loss was calculated using Mumford's method: anterior height of the fractured vertebrae divided by the average of the anterior height of the upper and lower segments.[14] Theses radiologic parameters were measured on plain radiographs during admission and outpatient follow-up. Also, time for the radiologic parameters to stabilize was measured.

Two examiners (ICK and BJK) independently measured radiological parameters. Interobserver reliability was measured to evaluate the degree of agreement between observers. The measurement was repeated after 1 month to assess the intraobserver reliability.

When comparing the demographic, radiological, and clinical characteristics between two groups, independent t-test, chi-square test or Fisher's exact test was used. A paired t-test or Wilcoxon signed-rank test was used to examine the changes in follow-up period. Intraclass correlation coefficients were used to measure the degree of agreement. All statistical analyses were performed using IBM SPSS Statistics ver. 20.0 software (IBM Corp., Armonk, NY, USA). The level of statistical significance was set at $p<0.05$.

The exclusion criteria were multilevel vertebral fractures, follow-up period <3 months, neurologic deficits at admission, tumor or infection at the fracture site, proof of secondary osteoporosis based on medical records or medication, and history of osteoporosis treatment before visiting our institution.

Results

49 female patients were analyzed. Only 5 male patients were treated for OVF during the study period, and none of them met the inclusion criteria, mainly due to early follow-up loss. Group C included 18 patients and Group I included 31 patients. The average duration from initial trauma to VP was 21.89±8.05 days (range 14-46). No significant differences in age, fracture type, fracture level, BMD and initial VAS were found between the two groups. However, mFI (Group C: 0.277 ±0.11 vs. Group I: 0.120±0.79; $p<0.05$) showed a significant difference between the two groups (Table 1). While there was no difference in the mean follow-up period between the two groups, Group C showed a significantly longer time to achieve mild (VAS ≤3) pain as compared to Group I (Table 2). In Group C, there were significant differences between the initial and final local kyphotic angle (7.42±10.03° vs. 11.08±11.83°; $p<0.05$), vertebra height (19.3±4.68 mm vs. 15.39±4.38 mm; $p<0.05$), and height loss rate (24.4±14.78% vs. 39.16± 16.18%; $p<0.05$). Group I did not show significant differences between the initial and final local kyphotic angle (12.67± 8.00° vs. 11.71±8.14°; $p=0.448$), vertebra height (20.21± 5.25 mm vs. 20.76±4.07 mm; $p=0.301$), and height loss rate (26.44±15.50% vs. 24.40±13.32%; $p=0.420$). There were no significant differences in the initial kyphotic angle, vertebra height, and height loss rate between groups. Furthermore, no significant differences were found in the final VAS score

Table 1. Demographic and initial clinical data of the participants*

	Group C	Group I	p-value
Age (years)	78.2±7.37	77.4±7.52	0.689
BMD	-3.4±0.95	-3.35±0.91	0.860
Initial VAS	7.94±1.11	7.9±1.14	0.902
Fracture type (Burst:Compression)	14:4	17:14	0.427
Fracture level (TL:Lower lumbar)	16:2	26:5	0.637
mFI	0.275±0.11	0.113±0.69	0.000†

*Data are presented as mean±standard deviation, †Statistically significant.
Group C: conservative group, Group I: intervention group, BMD: bone mineral density, VAS: visual analog scale, TL: thoracolumbar, mFI: modified frailty index.

Table 2. Comparisons of clinical and radiological outcomes between the two groups*

	Group C	Group I	p-value
Initial-VAS	7.94±1.11	7.9±1.14	0.902
Final-VAS	1.78±0.81	1.94±0.89	0.540
Time to acceptable VAS score ≤3 (weeks)	9.1±5.43	1.53±0.66	0.001†
Initial kyphotic angle (°)	7.42±10.03	12.67±8.00	0.079
Final kyphotic angle (°)	11.08±11.83	11.71±8.14	0.830
Initial vertebral height (mm)	19.3±4.68	20.21±5.25	0.549
Final vertebral height (mm)	15.39±4.38	20.76±4.07	0.000†
Initial height loss (%)	24.4±14.78	26.44±15.50	0.654
Final height loss (%)	39.16±16.18	24.40±13.32	0.001†
Change of height loss (%)	14.76±11.36	-2.04±15.31	0.000†
Time to kyphotic angle plateau (weeks)	15.79±7.11		
Time to vertebral height plateau (weeks)	24.38±9.23		
Time to height loss plateau (weeks)	24.38±9.23		

*Data are presented as mean±standard deviation, †Statistically significant.
Group C: conservative group, Group I: intervention group, VAS: visual analog scale.

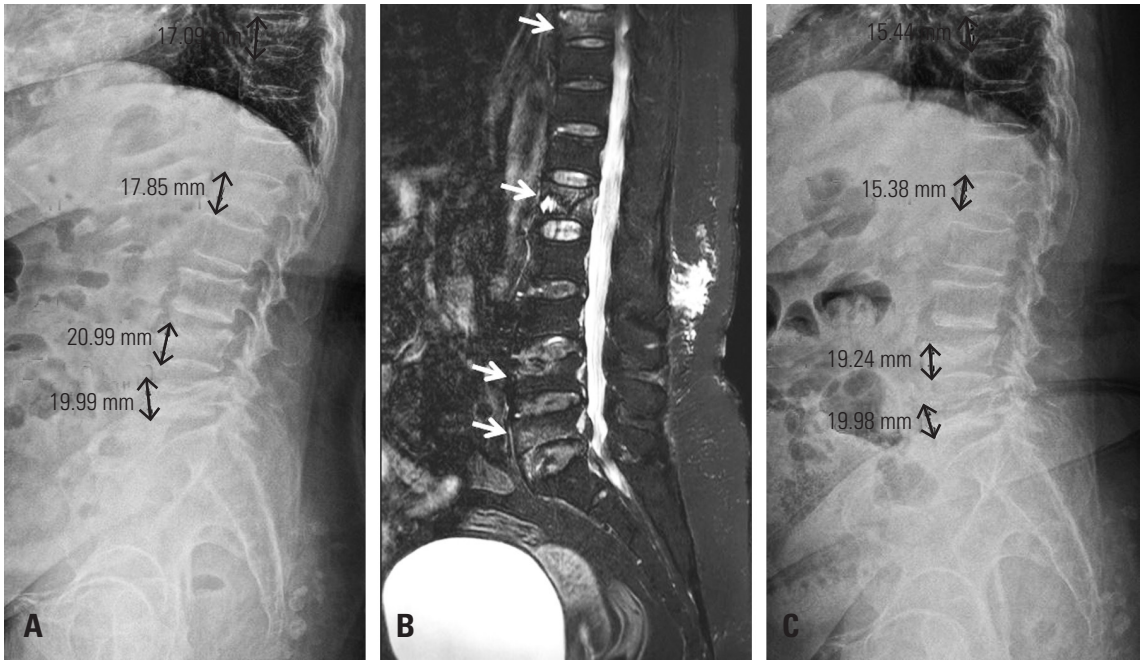

Fig. 1. (A) Initial radiograph of a 77-year-old woman showing height loss at T9, L1, L4, and L5 (double-headed arrows). **(B)** T2-weighted magnetic resonance imaging shows acute fracture (arrows). **(C)** After 6 months of parathyroid hormone injections, a plain radiograph shows minimal height loss progression (double-headed arrows).

and local kyphotic angle. However, there were significant differences in the final vertebra height, height loss rate, and changes in height loss rate between groups (Fig. 1, 2, Table 2).

In Group C, the time to radiological parameters be stabilized was 15.79±7.11weeks (range, 8–36 weeks) for the local kyphotic angle and height loss rate, and 24.38±9.23 weeks (range, 18–38 weeks) for the vertebra height (Table 2).

The measurements for the local kyphotic angle had an excellent interobserver reliability of 0.846. Vertebra height and height loss rate also showed excellent interobserver reliability. The intraobserver reliability was rated as "excellent" to "very good" (Table 3).

Table 3. Interobserver and intraobserver reliability of radiologic parameters

	Interobserver	Intraobserver (ICK/BJK)
Initial kyphotic angle (°)	0.846	0.784/0.805
Final kyphotic angle (°)	0.875	0.794/0.871
Initial vertebral height (mm)	0.808	0.859/0.789
Final vertebral height (mm)	0.845	0.802/0.794
Initial height loss (%)	0.828	0.851/0.823
Final height loss (%)	0.837	0.823/0.830

ICK/BJK: two examiners independently measuring the radiological parameters.

Regarding complications and side effects, there were two cases (11.1%) of dizziness and two (11.1%) of nausea in Group C. Dizziness, nausea, and vomiting were all transient symptoms that improved without treatment and were not severe enough to cease treatment. In Group I, 20 of the 31 vertebral bodies (64.5%) showed cement leakage on plain radiographs, and four of these vertebral bodies had severe complications. In one case, the leaked cement entered the heart and formed foreign body, which was removed under general anesthesia[15]. In another case, the leaked cement caused pulmonary thromboembolism, and two cases showed neurologic deficit (Table 4). Both neurologic deficit cases showed transient motor weakness and paresthesia that resolved within a few weeks (Fig. 3).

There was no significant difference in the initial and final VAS score, kyphotic angle, vertebral height, and height loss rate according to the duration of PTH administration.

Discussion

PTH is a bone forming agent that significantly reduces the

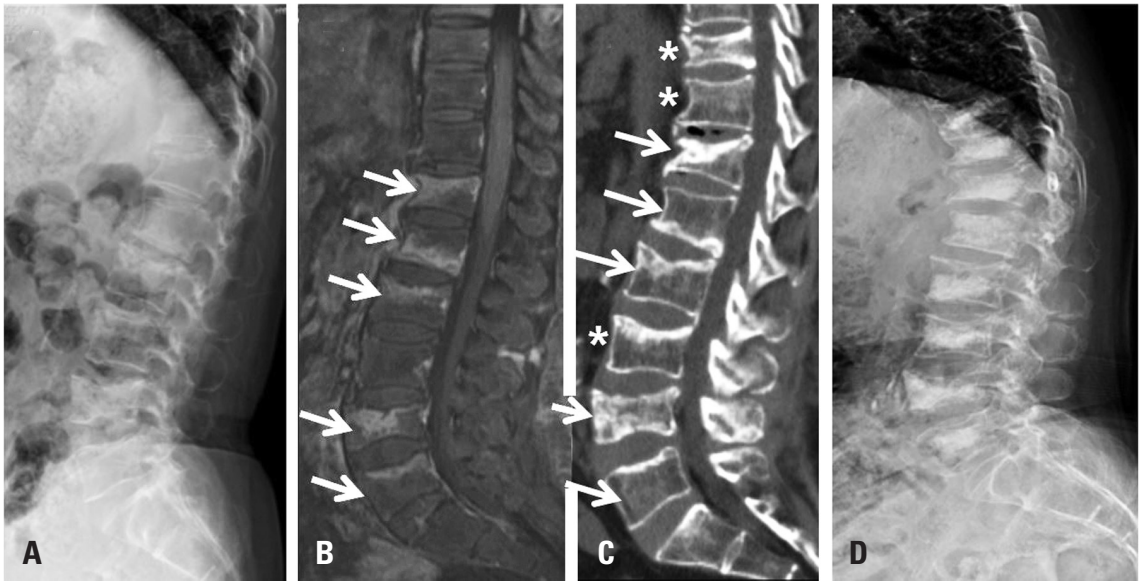

Fig. 2. (A) Initial radiograph of a 68-year-old woman. **(B)** T2-weighted magnetic resonance imaging shows acute fractures at T12, L1, L2, L4 and L5 (arrows). **(C)** Computed tomography (CT) taken 1 month after admission shows newly developed fractures at T10, T11, and L3 (asterisk) with the progression of the fractures (arrows). **(D)** Plain radiograph showing vertebroplasty done from T10 to L5.

Table 4. Complications reported in both groups

	Group C (n = 18)	Group I (n = 31)
Cardiovascular (%)	0 (0%)	1* (3.22%)
Respiratory (%)	0 (0%)	1† (3.22%)
Neurology (%)	0 (0%)	2 (6.45%)
Dizziness (%)	2 (11.11%)	0 (0%)
Nausea or Vomiting (%)	2 (11.11%)	0 (0%)

*cardiac foreign body; †pulmonary thromboembolism.

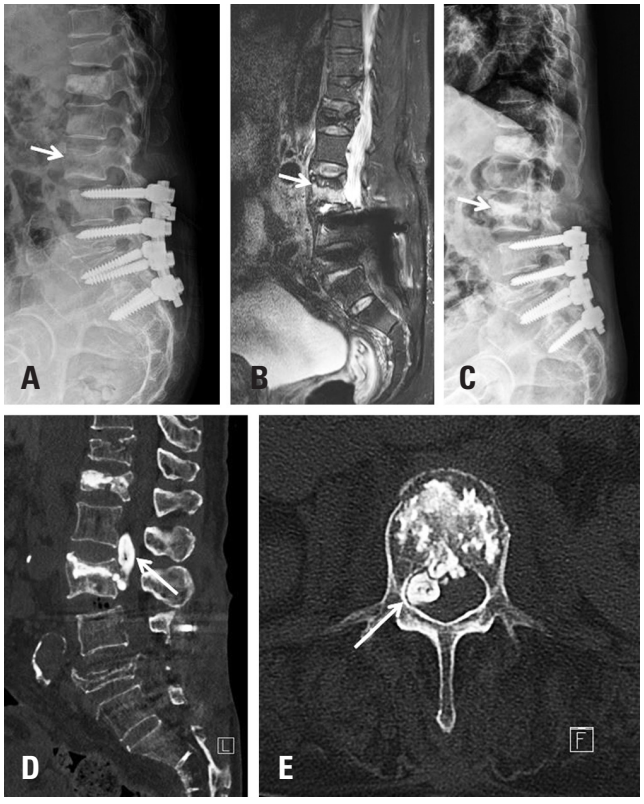

Fig. 3. (A) Initial radiograph of a 79-year-old woman showing height loss at L2 (arrow). The patient had undergone vertebroplasty and spinal fusion 15 years ago due to a car accident. She had osteopenia (T-score: -1.4) at that time. **(B)** T2-weighted magnetic resonance imaging showing an acute fracture at L2 (arrow). **(C)** Postoperative radiograph shows cement injected at the L2 vertebral body (arrow). **(D)** Postoperative computed tomography shows cement leakage through the spinal canal at L1-L2 (arrow). **(E)** Axial image of leaked cement on the right side of spinal canal (arrow). The patient showed transient motor weakness of the right hip flexor with hypoesthesia of the right thigh. The symptom improved within a week, and the patient was discharged with an independent ambulatory status.

risk of OVF.[5,12] While previous studies reported that conversion to anti-resorptive agents is necessary after 2 years of PTH administration for the treatment of osteoporosis, there is no standard duration of PTH administration established for acute OVF.[16,17] This study compared the PTH-used conservative group (Group C) and the VP-implemented intervention group (Group I).

Although percutaneous VP is commonly used to treat OVF and is effective in relieving acute pain, studies have reported that patients still experience difficulty in returning to a daily routine after this procedure.[18,19] Also, other studies showed no significant difference in symptom relief when compared to conservative treatment at 12 months after the fracture, no evident symptom relief compared to a sham procedure[20,21], as well as interruption of bony union and occurrence of re-fracture.[22]

Ma et al.[9] compared the outcomes from a 3-month follow-up of patients undergoing PTH treatment and percutaneous VP. VP significantly relieved pain in the first week and increased the vertebra height. However, VP did not show a significant difference in the pain level and the social function after 3 months when compared to PTH treatment. Moreover, there were lower medical expenditures reported in the PTH group as compared to the VP group.

Previous studies on PTH examined patients with OVF without dividing them according to the severity of osteoporosis, and these studies only included patients with relatively good general condition. In such cases, a sample population may predominantly consist of patients with mild to moderate OVF. Hence, it may appear as if the patients responded well to conservative palliative treatments, such as simple bed rest, thus limiting an accurate assessment of the effects of different treatments. In the present study, treatment plan was selected considering patients' general condition by mFI, bone density by T-score. The current study setting reflects real-world patients more closely.

It took an average of 9.1 weeks for the pain to subside to mild in PTH group. However, it took 4–6 months (15.79–24.38 weeks) until the radiological parameters stabilized. A study investigated time to union by cancellous bone continuity in OVF patients using the weekly PTH showed mean 2.8 months.[8] In our study, different radiologic parameters were used to assess bony union, and the time to achieve bony union differed from the previous study. The results of this study suggest that it is advisable to continue the use of

PTH in patients with OVF even after their pain improved, necessarily maintaining PTH for 3–6 months after the initial administration for stable healing of fracture.

While VP is an effective treatment option for acute OVF, its use is limited in patients with multiple level fractures or severe comorbidities, and when patients do not consent to the operation. Also, cement leakage and the resulting complications have been considered severe problems of VP.[23] Cement leakage may be asymptomatic, but it can cause complications such as pulmonary thromboembolism or nerve root and cord compression.[23,24] Cement-related complications would most likely require additional procedures or operations, placing a physical burden on elderly patients and increasing the hospital stay and medical expenditures. Cement leakage was observed in this study as well. The viscosity and the amount of cement have an effect on the risk of leakage.[25] Even the cement was injected in the dough phase, CMW3® PMMA has medium viscosity, this may have an effect on the leakage. Injecting 3cc of cement per cannula is supposed to be a large amount, and it should be necessary to reduce the amount of injection to reduce leakage.[25] Although several protocols have been proposed to prevent cement leakage, extra caution is required when injecting cement to patients with severe OVF, as the injection amount and level increases, the risk of cement leakage increases significantly.[25-27] Therefore, different treatment approach would be considered in terms of osteoporosis severity. Different approaches are also required depending on patient's general condition. Present study assessed the patient's frailty and perioperative risk by mFI, and the treatment policy was classified. Through this, relatively few complications and appropriate treatment results were obtained in Group C with significantly higher mFI. These findings suggest that PTH is a good treatment option in elderly patients of high frailty with severe or multiple OVF.

In this study, two cases of dizziness and two nausea or vomiting were reported in the Group C. However, these symptoms were not severe enough to cease treatment and were relieved through conservative treatment. The two most common side effects of PTH are dizziness and lower leg cramps, others as nausea, arthralgia, fatigue, headache, and hypertension.[28,29] Previous study reported side effects usually occur at the beginning of PTH and rarely occur after 3 months.[16] It is consistent with the present study in which side effects occurred in the early treatment period and were relieved with conservative treatment. Hence, it is necessary to inform patients that the aforementioned symptoms, albeit mild, may occur in the early period before injection in order to form a therapeutic relationship.

The limitations of this study include the single-center retrospective design, small sample size and relatively short follow-up period. We used prolia after administration of PTH or VP in accordance with HIRA guideline, which may cause drug-drug interactions (especially additive effect) between PTH and prolia. However, we administered prolia to both groups to minimize confounding of prolia. A prospective randomized controlled trial is warranted. Due to small sample size of group C, clinical and radiological differences between administration periods could not be confirmed. Further studies with large samples are necessary

Conclusions

Conservative treatment using PTH in OVF relieved pain more slowly and was inferior in aspect of preventing progressive collapse compared to VP. However, PTH showed evident symptom relief and less side effects. Therefore, conservative treatment using PTH may be a new and effective treatment method in severe OVF patients with poor general conditions, recommended to use over 6 months. When choosing treatment method for OVF, it is recommended to consider the patient's frailty and severity of osteoporosis.

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J Korean Soc Spine Surg. 2022 Sep;29(3):52-61

고령의 골다공증성 척추 골절 치료에서 부갑상선 호르몬 주사와 척추 성형술 비교

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목적: 골다공증성 척추 골절(OVF) 환자에서 경피적 척추 성형술(VP)과 부갑상선 호르몬(PTH) 투여의 효과를 비교하고, 최적의 PTH 기간을 조사하고자 하였다.

선행 연구문헌의 요약: 골다공증 예방 및 관리에서 PTH의 적응증은 확립되었으나, OVF 치료에서의 PTH 적응증은 아직 알려지지 않았다.

대상 및 방법: 2015년과 2019년 사이에 OVF가 있는 고령 환자를 대상으로 후향적 분석을 시행하였다. 환자의 modified Frailty Index (mFI), 선호도 및 골다공증의 중증도를 기준으로 치료 방법을 선택하였다. 그룹 C는 주 단위 PTH를 투여받았으며, 그룹 I는 VP를 시행받았다. 두 그룹 모두 골흡수 억제제 투여가 뒤따랐다. 두 그룹간에 국소 후만각, 추체 높이, 추체 높이 감소율과 같은 영상의학적 지표, 시각통증척도(VAS) 및 합병증과 같은 임상적 지표를 비교, 분석하였다.

결과: 49명의 여성 환자를 대상으로 연구가 시행되었다. 그룹 C에는 평균 78.2세(범위, 65~85 세)의 환자 18명이 포함되었으며, 그룹 I에는 평균 연령 77.4세(범위, 65~92세)의 31명 가 포함되었다. mFI ($p<0.01$)를 제외한 초기 인구 통계학적, 임상적 및 방사선학적 지표에서 두 그룹간에 유의한 차이는 없었다. 그룹 I는 최종 추시 상 유의미하게 더 나은 임상 및 방사선학적 결과를 보였다. 그룹 C의 부작용으로는 어지럼증(11.11%) 및 메스꺼움, 구토(11.11%) 각 2예가 있었다. 그룹 I에서는 20 개의 추체(64.5 %)에서 시멘트 누출이 확인되었으며, 4 명의 환자(12.9%)에서 관련 합병증이 관찰되었다.

결론: PTH를 사용한 보존적 치료는 척추 성형술보다 임상적 및 방사선학적 결과가 열등한 것으로 나타났다. 그러나 PTH는 시술 관련 합병증의 위험이 낮은 것으로 나타났다. 고령의 OVF에서 치료 방침의 결정 시 환자의 선호와 더불어 전신상태, 골다공증의 중증도 또한 고려되어야 한다.

색인 단어: 부갑상선 호르몬, 골다공증성 척추 골절, 척추 성형술

약칭 제목: 골다공증성 척추골절의 치료법 비교

접수일: 2021년 3월 10일 **수정일:** 2021년 3월 24일 **게재확정일:** 2022년 9월 20일

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Journal of Korean Society of Spine Surgery. www.krspine.org. pISSN 2093-4378 eISSN 2093-4386

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