Retrospective Study

A Single-Center Retrospective Analysis Investigating the Effect of Timing of Vertebral Augmentation on Pain Outcomes

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Background: Approximately 700,000 individuals experience osteoporotic vertebral compression fractures (OVCF) every year in the United States. Chronic complications from patients and increasing economic burdens continue to be major problems with OVCFs. Multiple treatment options for OVCF are available, including conservative management, surgical intervention, and minimally invasive vertebral augmentation. Prior studies have investigated the utility of vertebral augmentation techniques such as percutaneous vertebroplasty (PVP), balloon vertebroplasty (BVP), and vertebral augmentation with the Kiva™ implant on patient mortality with favorable results. The optimal time from OVCF occurrence to vertebral augmentation continues to be a topic of investigation.

Objectives: To further investigate the effect of the timing of vertebral augmentation on pain outcomes.

Study Design: A retrospective cohort chart review study.

Setting: A single academic center in Albuquerque, New Mexico.

Methods: One hundred twenty-six consecutive patient encounters with OVCF diagnosed on imaging and treated with PVP, BVP, or vertebral augmentation with a Kiva™ implant between 01/01/2004 and 11/28/2016 were analyzed. The time between fracture and intervention was categorized into < 6 weeks, 6-12 weeks, and ≥ 12 weeks. Pain scores were measured before and after treatment using the numeric pain rating scale. Statistical analysis using Wilcoxon-Mann-Whitney and Kruskal-Wallis tests were used as appropriate, and effect sizes were described with the Hodges-Lehmann estimates of difference.

Results: The 3 vertebral augmentation procedures compared in this study did not demonstrate statistically significant differences in pain score reduction ($P = 0.949$). The < 12 weeks group had a median and interquartile range (IQR) pain improvement of 3 (IQR 1,6) versus 1 (IQR 0,4) in the ≥ 12 weeks group ($P = 0.018$). Further analysis showed that the median and IQR pain improvement for the < 6 weeks group was 3 (IQR 1,7), for the 6-12 weeks group was 3 (IQR 1,4), and for the ≥ 12 weeks group was 1 (IQR 0,4). The overall effect of the time category on pain improvement was statistically significant for these groups ($P = 0.040$). Comparisons between groups only showed differences between the < 6 weeks and ≥ 12 weeks groups ($P = 0.013$), with an estimated median difference of 2 (95% CI 0,3). There was no statistically significant relationship between fill percentage and pain relief ($P = 0.291$).

Limitations: This is a retrospective cohort study from a single academic center with a limited sample size that lacked a control group and procedural blinding. There was also substantial heterogeneity among patients, fractures, operators, and techniques. Pain relief outcomes are subjective and can be biased by patients as well as physician reporting.

Conclusions: Early intervention (< 12 weeks) with vertebral augmentation in patients with OVCF is associated with improved pain scores when compared to later intervention (> 12 weeks). Very early intervention (< 6 weeks) confers a greater advantage when compared to later intervention (> 12 weeks).

Key words: Osteoporotic vertebral compression fracture, vertebral augmentation, vertebroplasty, pain outcomes

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Vertebral compression fractures (VCF), typically osteoporotic or pathologic, are common. One and a half million individuals in the United States experience osteoporotic fractures each year (1). Osteoporotic vertebral compression fractures (OVCF) comprise approximately 700,000 of those fractures (2). OVCFs are a significant source of disability and lost wages. OVCFs account for approximately 1.1 billion dollars in economic burden annually and will continue to rise (3,4). A multitude of complications can arise for individuals with OVCF, including chronic back pain, kyphosis, susceptibility to future vertebral fractures, and death (5). In a study of risk of mortality following fractures, the age-adjusted relative risk of dying following a fracture was 2.15 (1.36, 3.42), with vertebral fracture having a relative risk of 8.64 (4.45, 16.74) (6). OVCF has been shown to contribute to decreased health-related quality of life for patients, most likely secondary to the morbidity associated with the pathology (7).

Treatment options for OVCF range from conservative management to surgery. Surgical intervention is the preferred option for OVCF with neurological compromise or associated spinal instability (8). Open reduction or short segment fixation have shown to be effective treatments for continually or progressively painful OVCFs but can result in blood loss, operative complications, particularly related to poor bone quality, and prolonged time under anesthesia (9). Conservative management includes physical therapy, patient-specific analgesia, osteoporosis medication, relative rest, and bracing. Though recovery from OVCF has a generally favorable natural history, many patients have severe pain that prevents them from taking care of themselves, and some have persistent disabling pain. There are also limitations to conservative management; braces are not always well-tolerated, opioid analgesics can cause sedation as well as constipation, and osteoporosis medications can cause other adverse effects (10,11). The OVCF-related deformity can alter biomechanics and generate new secondary pain generation (12).

For those with severe pain and functional loss from OVCF, vertebral augmentation leads to greater improvement in pain and quality of life when compared to conservative management of severely painful or functionally limiting OVCF (13-15). While there are randomized controlled trials that failed to show the benefit of vertebroplasty (16), percutaneous vertebral compression fracture treatment has consistently shown safety and efficacy and remains a mainstay of clinical practice (17). Vertebral augmentation may also improve the mortality of patients with OVCF. A meta-analysis of 2 million people with OVCFs that underwent vertebral augmentation had a 22% reduction in mortality at up to 10 years after treatment compared to those who received conservative treatment (18).

Percutaneous vertebroplasty (PVP) involves the injection of polymethylmethacrylate (PMMA) or newer cement agents into vertebral bodies using imaging guidance, while balloon vertebroplasty (BVP) uses an inflatable device to create a void in vertebral bodies that is then filled with PMMA to induce stabilization (19). In recent years, another novel vertebral augmentation implant called the Kiva™ system was developed (20,21). For detailed comparative reporting of outcomes for PVP, BVP and Kiva™, see the reviews from Chang et al and Ebeling et al (22,23). Altogether, these minimally invasive vertebral augmentation techniques appear to be equivalent in efficacy (24-26).

The optimal timeframe of OVCF treatment with vertebral augmentation continues to be a topic of investigation. Patients who undergo BVP less than 4 weeks after vertebral fracture have shown better low back pain (LBP) scores and reduced rates of subsequent fracture (27). Early PVP within 3 weeks of fracture has also been reported to show clinical benefits (28). In this study, we investigated the effect of vertebral augmentation timing and vertebral body fill amount on pain outcomes at a single academic institution.

Methods

Study Design

This was a retrospective chart review of 126 consecutive patient encounters receiving care at the University of New Mexico Hospital (UNMH) for OVCF between 01/01/2004 and 11/28/2016. Inclusion criteria consisted of patients with thoracic or lumbar vertebral compression fractures diagnosed on imaging that were treated with vertebroplasty, balloon vertebroplasty, or Kiva™. Patients who were pregnant, prisoners, and individuals under the age of 18 were excluded from data collection. Records reviewed included operative and imaging reports, radiographs, CT scans, and MRIs in the UNMH picture archiving and communication system (PACS) system and clinical documentation in the UNMH electronic medical record. The numeric pain rating scale (NRS) pain scores were used to determine pain relief. Institutional review board (IRB) approval was obtained prior to the initiation of the study (20-503).

Surgical Procedure

Vertebroplasty Procedure

The vertebroplasty procedure was consistent with other reported protocols (29-31). The procedure was performed using biplane or uniplanar fluoroscopy. Unipedicular or bipedicular access was selected. A trocar was introduced and guided to the dorsal pedicle. For transpedicular access, the trocar was malleted through the cortex to access trabecular bone, then advanced using mallet and bevel changes to steer the tip through the pedicle without breaching the cortical margins of the pedicle until the vertebral body was accessed. For extrapedicular access, the trocar was introduced and guided to the superolateral aspect of the root of the pedicle, then malleted through the cortex to access the trabecular bone of the vertebral body. Multiple projections were used to confirm trocar position and safe advancement, with ideal needle tip placement being the anterior third of the vertebral body close to the midline. Radio-opaque PMMA was then injected. If PMMA was noted to flow intravascularly or out of the vertebral body, the injection was immediately halted, the PMMA allowed to cure, then injection was reattempted. The ventral vertebral body was filled, then the cannula was withdrawn in steps to sequentially fill the vertebral body from ventral to dorsal. The injection was halted if cement approached the dorsal vertebral body wall or other undesirable procedural events occurred. The stylet was placed back within the cannula before withdrawal of the cannula (Fig. 1, A1-A4).

Balloon Vertebroplasty Procedure

The balloon vertebroplasty procedure was consistent with other published protocols (32-35). The approach was identical to the vertebroplasty description in the previous section until the cannula and trocar accessed the target in the vertebral body. The trocar was removed from the cannula; then a manual drill was used to create a cavity distal to the tip of the cannula. In some cases, the curette was used to direct the balloon more medially when appropriate. An inflatable balloon(s) was inserted into the cavity and ensured to be fully within the anterior two-thirds of the vertebral body using radio-opaque markers. The balloon was then inflated under intermittent fluoroscopic visualization until balloons were observed to touch the cortical bone anteriorly at the end plates or on the lateral side, or when the inflation pressure reached approximately 200-300 PSI. The operator ensured either no contact or only minimal contact of the balloon with endplates or vertebral body walls on lateral or anteroposterior (AP) views. Thereafter, the balloon was deflated and withdrawn. PMMA was injected into the vertebral body in an intermittent fashion using delivery cannulas with manual plungers under direct fluoroscopic guidance (Fig. 1, B1-B4).

Kiva™ Procedure

For the Kiva™ implant, initial access was identical to the vertebroplasty description in the previous section until the trocar was placed into the targeted area of the vertebral body and the stylet withdrawn. Then a coiling nitinol guidewire was placed through the cannula into the cancellous bone of the vertebral body, and the Kiva™ implant was advanced over the guidewire to form a coil within the vertebral body. Once the implant was fully deployed, the guidewire was removed. PMMA cement was then injected into the vertebral body (Fig. 1, C1-C4).

Statistical and Image Analysis

Analyses included Wilcoxon-Mann-Whitney and Kruskal-Wallis tests as appropriate and least-squares multiple regression in order to allow adjustment for potential confounding factors. The magnitude of treatment effects among the subgroups was described with the Hodges-Lehmann estimate of the difference between medians. Percent fill was estimated based on an imaging review by a neuroradiologist, consistent with other studies (36,37). The effect of fill percentage on the primary outcome while adjusting for time to treatment was also analyzed with least-squares multiple regression.

Results

Patient Characteristics

A total of 126 consecutive patient encounters met the inclusion criteria, with a median patient age of 69 years (IQR 63, 78) (Table 1). The majority of patients (69%) were female (Table 1). Four fracture types were defined and identified: osteoporotic, osteoporotic and traumatic, traumatic, and pathologic. Osteoporotic fractures encompassed the majority of pathology (62 patient encounters, 50%) (Table 1). The median time from fracture to the procedure was 7.0 weeks (IQR 3.8, 14.8) (Table 1). The median pain level among our patient population before treatment was 7 (6, 8) (Table 1).

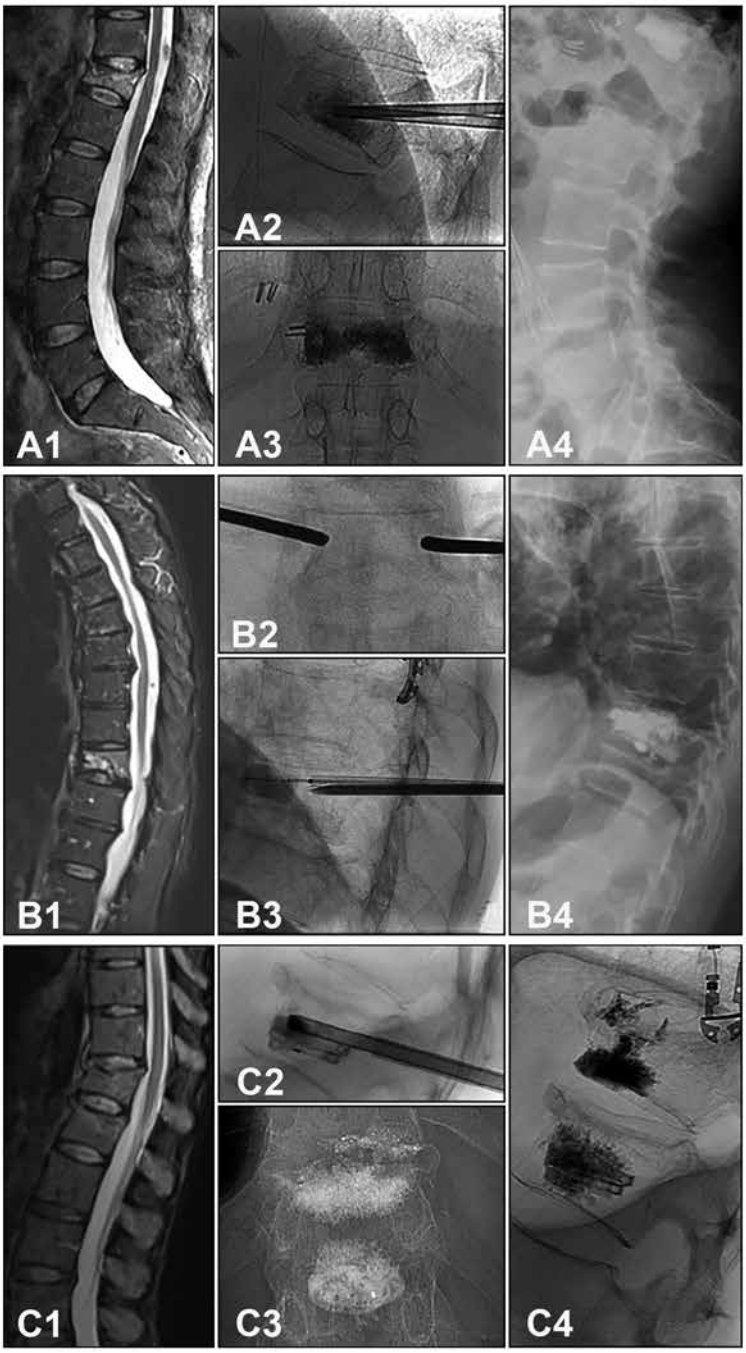

Fig. 1. *Images of Vertebral Augmentation Procedures. Images (A1-A4) are of patient undergoing vertebroplasty procedure: (A1) Sagittal STIR MRI showing bone marrow edema and vertebral compression fracture at T12; (A2) Procedural lateral fluoroscopic image with vertebroplasty needles in position (A3) Anterior-Posterior fluoroscopic image after needle removal showing bilateral cement distribution; (A4) Lateral radiograph showing vertebroplasty at T12. Note cholecystectomy clips and partially visualized inferior vena cava filter. Images (B1-B4) are of patient undergoing balloon vertebroplasty procedure: (B1) Sagittal Short Tau Inversion Recovery magnetic resonance imaging displaying T10 pathologic fracture; (B2) Anterior-Posterior fluoroscopic image showing transpedicular needle placement; (B3) Lateral fluoroscopic image with balloon inflated (B4) Lateral radiograph with T10 cement and small volume cement extension along pedicle needle tracks. Images (C1-C4) are of patient undergoing Kiva procedure: (C1) Sagittal Short Tau Inversion Recovery magnetic resonance imaging displaying T12 and L1 vertebral compression fracture; (C2) Lateral fluoroscopic image with PEEK Kiva coil partially deployed; (C3) Anterior-Posterior fluoroscopic image showing KIVA and cement at L1 and vertebroplasty cement at T12; (C4) Lateral fluoroscopic image showing vertebroplasty cement at T12 with small volume intradiscal leakage and L1 Kiva implant and cement.*

Procedures and Complications

Out of the 3 vertebral augmentation procedures that were analyzed, balloon vertebroplasty was the most frequent procedure at 59 patient encounters (47%) (Table 2). The majority of patient encounters analyzed had one vertebra treated (73 patient encounters, 58%), with the rest of the patients having multiple vertebrae treated (Table 2). Seventy (56%) underwent a bipedicular approach to vertebral augmentation, and 56 (44%) were unipedicular (Table 2). The majority of patients (96, 76%) did not have a complication (Table 2). Complications from the vertebral augmentation

procedures included leakage of cement into the disc, leakage of cement into the venous system outside of the vertebral bodies, violation of the endplate with a manual drill, new fracture, and pulmonary embolization (Table 2). The most common complication in the patient cohort was leakage of cement into the disc (23 patients, 18%, Table 2). The majority of these complications are technical or observed on imaging with uncertain clinical impact.

Pain Improvement Based on Percutaneous Vertebroplasty, Balloon Vertebroplasty, or Kiva™

The 3 procedures compared in this study did not display statistically significant differences in pain score reduction (P = 0.949). The median and interquartile range (IQR) for pain score reduction with balloon vertebroplasty was 3 (IQR 0,5) (n = 59), with percutaneous vertebroplasty was 3 (IQR 1,5) (n = 42), and with Kiva™ was 2 (IQR 1,6) (n = 25).

Pain Improvement Based on Time to Percutaneous Vertebroplasty, Balloon Vertebroplasty, or Kiva™

There were 88 encounters in the less than 12-week group (Group 1) and 37 encounters in the 12-week or more group (Group 2). The median and IQR for Group 1 was 3 (IQR 1, 6) versus 1 (IQR 0, 4) for Group 2 (Table 3), and this difference was statistically significant (P = 0.018; Fig. 2). The Hodges-Lehmann estimate of the difference between these medians is 1 point on the 0 - 10 scale (95% CI: 0, 2) (Table 4).

We analyzed the response to vertebral augmentation for a fracture to procedure time of less than 6 weeks (Group 1a, n = 50), 6 weeks to less than 12 weeks (Group 1b, n = 38), and 12 weeks or more (Group 2, n = 37). The median and IQR for a decrease in pain score in Group 1a was 3 (IQR 1, 7), in Group 1b was 3 (IQR 1, 4), and in Group 2 was 1 (IQR 0, 4) (Table 5). The overall effect of the time category on pain improvement

Table 1. *Patient characteristics.*

Patient Characteristics	Median (IQR) or n (%)
Age (years), 126	69 (63, 78)
Female gender, 126	87 (69%)
Fracture type(s), 125	
Osteoporotic	62 (50%)
Osteoporotic and traumatic	33 (26%)
Traumatic	12 (10%)
Pathologic	18 (14%)
Weeks since fracture, 125	7.0 (3.8, 14.8)
Pain level before treatment, 126	7 (6, 8)

Table 2. *Procedures and complications.*

Treatment type	n (%)
Balloon Vertebroplasty	59 (47%)
Percutaneous Vertebroplasty	42 (33%)
Kiva™	25 (20%)
Number of treated vertebrae	n (%)
1	73 (58%)
2	37 (29%)
≥ 3	16 (13%)
Approach	n (%)
Bipedicular	70 (56%)
Unipedicular	56 (44%)
Complications*	n (%)
None	96 (76%)
Disc extravasation	23 (18%)
Venous extravasation	4 (3%)
Trans-endplate drill	1 (1%)
New fracture	1 (1%)
Pulmonary cement embolization	2 (2%)

Table 3. *Group 1 and Group 2 pain improvement.*

Group	Median (IQR) Pain Improvement
Group 1 (< 12 weeks), n = 88	3 (1, 6)
Group 2 (≥ 12 weeks), n = 37	1 (0, 4)

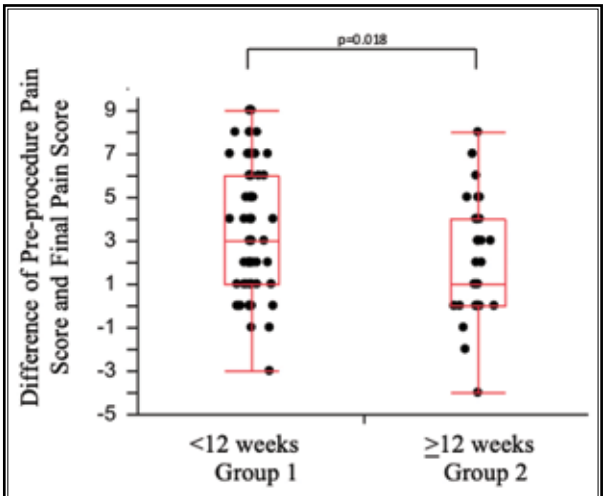

Fig. 2. *Difference in pain improvement for Group 1 versus Group 2.*

Table 4. *Hodges-Lehmann differences between group medians.*

	Hodges-Lehmann (95% CI)
Group 1 vs Group 2	1 (0,2)
Group 1a vs Group 1b	1 (-1,2)
Group 1a vs Group 2	2 (0,3)
Group 1b vs Group 2	1 (0,2)

was significant at $P = 0.040$. Since the effect of time to vertebral augmentation was statistically significant, we conducted pairwise Wilcoxon-Mann-Whitney comparisons between pairs of groups. It appears that the main driver of the difference between Groups 1 and 2 may derive from greater improvement in Group 1a. The only statistically significant difference among the 3 groups was between Groups 1a and 2 ($P = 0.013$; Fig. 3); Groups 1a and 1b were not statistically significantly different ($P = 0.359$), and neither were Groups 1b and 2 ($P = 0.114$). Hodges-Lehmann estimates of differences between medians are 1 (95% CI -1,2) for Group 1a versus Group 1b; 2 (95% CI 0,3) for Group 1a versus Group 2; and 1 (95% CI 0,2) for Group 1b versus Group 2 (Table 4).

Fill Percentage vs Pain relief, Considering Time Categories

Given that increasing fill percentage may correlate with more severe vertebral damage and nerve impingement, we also analyzed the relationship of fill percentage with pain relief. This relationship was not statistically significant, however; $P = 0.291$. Pain score reductions broken down by time category and fill percentage category are presented in Tables 6 and 7. Since fill percentage alone did not show a significant association with pain relief, a least-squares multiple regression model was used to permit simultaneous control of the effects of fill percentage and the time category. When controlling for fill percentage, time remains a statistically-significant factor in comparisons of Group 1 and Group 2 ($P = 0.008$) and also for Group 1a, Group 1b, and Group 2 ($P = 0.011$). However, fill percentage does not significantly affect pain reduction when controlling for time, whether dividing time categories into binary Group 1 and Group 2 ($P = 0.189$) or for the more granular comparison of Group 1a, Group 1b, and Group 2 ($P = 0.131$).

Table 5. *Group 1a, Group 1b, and Group 2 pain improvement.*

Group	Median (IQR) Pain Improvement
Group 1a (< 6 weeks), n = 50	3 (1, 7)
Group 1b (6 to < 12 weeks), n = 38	3 (1, 4)
Group 2 (≥ 12 weeks), n = 37	1 (0, 4)

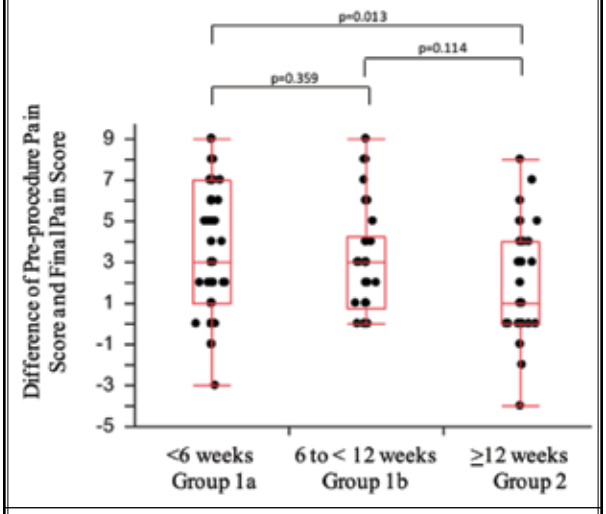

Fig. 3. *Difference in pain improvement for Group 1a versus Group 1b versus Group 2.*

Discussion

Vertebral augmentation procedures are commonly performed to treat painful OVCFs. The aim of our paper is to present our institution's experience with vertebral augmentation, specifically investigating the association

Table 6. *Time category and fill category for Group 1 and Group 2.*

Time Category and Fill Category	Median (IQR) Pain Improvement
Group 1 (< 12 weeks)	
1: 0-25%, n = 4	4 (1, 6)
2: 26-50%, n = 20	2 (0, 7)
3: 51-75%, n = 40	3 (0, 6)
4: 76-100%, n = 24	4 (2, 7)
Group 2 (≥ 12 weeks)	
1: 0-25%, n = 4	4 (1, 5)
2: 26-50%, n = 9	1 (0, 5)
3: 51-75%, n = 13	0 (0, 3)
4: 76-100%, n = 11	3 (0, 4)

Table 7. *Time category and fill category for Group 1a versus Group 1b versus Group 2.*

Time Category and Fill Category	Median (IQR) Pain Improvement
Group 1a (< 6 weeks)	
1: 0-25%, n = 1	5 (5, 5)
2: 26-50%, n = 15	2 (0, 7)
3: 51-75%, n = 23	3 (1, 6)
4: 76-100%, n = 11	5 (2, 7)
Group 1b (6 to < 12 weeks)	
1: 0-25%, n = 3	2 (0, 6)
2: 26-50%, n = 5	1 (0, 5)
3: 51-75%, n = 17	3 (0, 4)
4: 76-100%, n = 13	3 (2, 7)
Group 2 (≥ 12 weeks)	
1: 0-25%, n = 4	4 (1, 5)
2: 26-50%, n = 9	1 (0, 5)
3: 51-75%, n = 13	0 (0, 3)
4: 76-100%, n = 11	3 (0, 4)

between the timing of the procedure and vertebral body filling on pain relief. Our results demonstrated no difference between the 3 interventions, consistent with previous reviews reporting that PVP, BVP, as well as Kiva™ had similar effects on pain and quality of life outcomes (24-26). Given their comparable efficacy, rather than analyzing each technique individually, we grouped the vertebral augmentation procedures in our analysis.

Although the clinical efficacy of percutaneous vertebral augmentation and balloon vertebroplasty has been extensively studied, there are relatively few studies investigating the effect of timing of intervention to pain response. Previous investigations have shown that early intervention resulted in better clinical outcomes. Yang et al exhibited that vertebroplasty at a mean of 8.4 ± 4.6 days (range, 2-21 days) after onset resulted in greater pain relief than conservative treatment (e.g., bed rest, analgesics, anti-inflammatory drugs, brace, physical therapy) (38). Other studies, including the VAPOUR trial illustrated that early intervention with vertebral augmentation within 4 weeks of presentation correlates with better pain relief, greater long-term vertebral alignment, reduced rates of subsequent fractures, and improved vertebral body height restoration (28,39,40). Our results build upon these studies and demonstrate that early intervention with vertebral augmentation is associated with better outcomes than delayed intervention. Our initial analysis between < 12 weeks (Groups 1) and > 12 weeks (Group 2) demonstrated that intervention at < 12 weeks resulted in better pain relief outcomes when compared to > 12 weeks. We expanded our analysis of Group 1 to investigate if there were differences in pain relief outcomes of interventions < 6 weeks (Group 1a) versus 6 weeks to < 12 weeks (Group 1b); there was a progressive decline in the outcome as the time from fracture increased.

It is interesting to note that the difference between the Group 1 and Group 2 was driven by the subgroup Group 1a. When we compare the findings of the 2-way split (Group 1 versus Group 2) with those of the 3-way split (Group 1a versus Group 1b versus Group 2), we see that the results in the 2-way split are largely driven by outcome differences between patients at the extremes of the time-to-procedure spectrum, i.e., those treated < 6 weeks (Group 1a) versus those treated ≥ 12 weeks (Group 2). Those treated between 6 and 12 weeks (Group 1b) are not significantly different, clinically or statistically, from Group 1a or Group 2; however, we must note that the results of this pilot study need to be confirmed by a larger study. To our knowledge, no other studies have analyzed these timeframes.

We must also make a strong qualification to the statement that patients did not respond as well when treated more than 12 weeks after a diagnosis of OVCF. Although our data suggest earlier treatment may have a larger treatment effect, intervention after 12 weeks was still beneficial in a subset of patients. We note that 16 of 37 Group 2 patients reported an improvement in pain that was greater than or equal to 3 points of improvement on the pain scale. Clinically, this is a meaningful response. Though this magnitude of response occurs with greater frequency among patients with OVCF treated before 12 weeks, the treatment should not be withheld solely because of the diminished rate of effectiveness. Rather, risks and potential benefits should be carefully considered and discussed with the patient, weighing the probability of success when accounting for time elapsed after OVCF.

Our study also analyzed the correlation between the percentage of vertebral body filling and pain relief among the different time categories. Previous studies in a nonclinical setting showed that approximately 15% of bone cement fill through vertebroplasty is the ideal amount where vertebral stiffness starts to resemble pre-damage levels (41,42). To our knowledge, there have been no studies documenting the effect of the percentage of vertebral body filling on pain relief. Our study demonstrates that the overall pattern of percentage filling proportions appears to be a less significant factor than time to intervention, with the possible exception of 0 to 25% filling showing moderate levels of pain relief. Our findings indicate that any relationship between percent filling and pain relief is a relatively minor element of the treatment picture.

The complication rate from vertebral augmentation in our study was lower when compared to previous studies. One study investigating the outcome of BVP showed 65 out of 135 patients (48.14%) encountered cement leakage (43). This differs from our study, which showed cement leakage in 21% of patients. Another study analyzing complications of PVP reported 23.3% of patients having disk space leakage and 6.7% of patients having venous leakages (44). In our study, 18% of patients had disc leakage, while 3% of patients had venous leakage. The incorporation of multiple techniques in our dataset may have had an impact on the rates and categories of complications reported.

Limitations

This study has several limitations. One limitation is that this is a retrospective cohort study at a single academic center, and consequently, we were reliant on the data collected in the medical record. We recognize that the potential of this study having selection and indication bias both in terms of individuals selected for vertebral augmentation as well as timing for the procedures. Another limitation is that there was a great deal of heterogeneity among patients, fractures, operators, and techniques. We also understand that pain relief is subjective that can be biased by the patient as well as the physician reporting. Functional outcomes, morbidity, mortality, and hospital discharge are more objective measures and may be better measures of procedure efficacy, although such studies require large data sets and have been assessed elsewhere (18,45,46). Our study also has limitations in sample size, making it difficult to detect and characterize the effect of confounding factors within our population.

Conclusion

Our study is consistent with current literature suggesting that early vertebral augmentation in patients with OVCF is associated with higher chances of pain relief compared to delayed intervention. There are still a substantial number of patients who demonstrate clinically meaningful improvement on the pain scale when treated after 12 weeks, but the proportion achieving this result declines as time passes between diagnosis and vertebral augmentation. Vertebral body cement fill percentage does not appear to be associated with the clinical outcome. Further testing in a larger and more diverse population of patients will be required to address generalizability.

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