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Efficacy and safety of vertebral augmentation techniques in patients with osteoporotic vertebral compression fractures: A single center, retrospective, observational study

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ABSTRACT

Background: Back pain secondary to osteoporotic vertebral compression fractures (OVCF) is a common global health problem that is frequently overlooked. For some patients, conservative management (CM) is inadequate to treat the pain associated with OVCF. This subset of patients are often candidates for interventional vertebral augmentation techniques (VAT). Multiple studies have shown significant pain reduction, height restoration, reduction in hospitalization time, morbidity and mortality in patients treated with VAT as compared with those patients treated with CM. This study examines if the previously published trials are consistent with outcomes in a real-world cohort of patients in interventional pain practices following VAT.
Objectives: The purpose of this retrospective databased analysis was to further investigate the efficacy and safety of percutaneous vertebral augmentation techniques in patients suffering from osteoporotic vertebral compression fractures in our center.
Study design: Retrospective study.
Setting: A single-center study.
Patients and methods: We have included data from a total of 42 patients (26 females, 16 males) with diagnosis of OVCF that received VAT at our center between January 2023 and June 2024. Efficacy data included pre-procedure, 2-week, 1-month and 3-month follow-up numerical rating scale (NRS) pain scores when available.
Results: The mean pain score using NRS was 7.5 (n = 45), 3.24 (n = 44), 3.65 (n = 21) and 2.7 (n = 15) at pre-procedure, 2-week, 1-month and 3-month follow-up ($P < 0.001$), respectively. At the 2-week follow up, 44 %, 16 %, 20 % and 13 % of patients (n = 45) had NRS pain score reduction between 76 and 100 %, 51–75 %, 26–50 % and 0–25 % ($P \leq 0.05$), respectively. At the 1-month follow-up visit, 24 %, 33 %, 14.3 % and 24 % of patients (n = 21) had NRS pain score reduction between 76 and 100 %, 51–75 %, 26–50 % and 0–25 % ($P \leq 0.05$), respectively. At the 3-month follow-up visit, 60 %, 6.7 %, 6.7 % and 20 % of patients (n = 15) had NRS pain score reduction between 76 and 100 %, 51–75 %, 26–50 % and 0–25 % ($P \leq 0.05$), respectively. This indicates significant differences in NRS pain scores across the different time points. There was a high dropout rate at the 3-month follow up visit most likely due to patient's pain improving post procedure.
Limitations: This was a single-center retrospective study with a small sample size and relatively short follow-up time.
Conclusion: VAT are effective and safe procedures for patients suffering from OCVF. However, proceduralists must be aware of patient-specific risk factors to prevent possible complications.

1. Introduction

Back pain secondary to osteoporotic vertebral compression fractures (OVCF) is a common global health problem that is frequently overlooked. OVCF is the most common form of osteoporotic fracture affecting 30 % of men and women over 50 years of age in Western countries and has a prevalence of 12–25 % in Asia. In Europe, there is incidence of 10.7 per 1000 person-years in women and 5.7 per 1000

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persons-years in men. Approximately 700,000 cases of VCF are reported yearly in the United States [1,2]. For some patients, conservative management (CM) is adequate to treat the pain associated with OVCF, but for others, untreated fractures may lead to chronic pain in the affected area, increased disability and mortality, decreased functional capacity and quality of life [3].

Clinically, patients present with a sudden onset of mid- or low-back pain with or without history trauma. Nonetheless, they can be diagnosed as incidental findings while performing routine imaging. While plain radiographs, computed tomography and magnetic resonance imaging (MRI) are required to evaluate for non-osteoporotic causes, MRI is the diagnostic test of choice to distinguish between acute and non-acute fractures. Patients can be managed with a combination of nonsurgical modalities including medications, bracing, and physical therapy, and interventional vertebral augmentation techniques (VAT) such as balloon kyphoplasty (BK) or vertebroplasty (VP) [4].

Complex fractures may require neurosurgical intervention for stabilization. Placement of polymethylmethacrylate (PMMA) within the vertebral body has been described in the literature since 1980s. The most common indications for VAT include painful acute stable OVCF, osteolytic processes, sub-acute/chronic fractures with non-union, and post trauma. Cementoplasty could also be done in combination with surgical stabilization if there is a need to reinforce the vertebral body or pedicle. Multiple studies have shown significant pain reduction and height restoration when comparing VAT to CM.[5–9]. Other studies have demonstrated significant reductions in hospitalization time, morbidity and mortality in patients treated with VAT as compared with those patients treated with CM [10,11]. However, previous large randomized controlled trials had failed to show improvement in pain or functional capacity when compared to facet injections with local anesthetics, which caused a significant division among the spine community [12,13].

The purpose of this retrospective databased analysis was to further investigate the efficacy and safety of percutaneous VAT in patients suffering from OVCF in our center. This study examines if the previously published negative trials are consistent with outcomes in a real-world cohort of patients in interventional pain practices following VAT.

2. Methods

WCG Western IRB approval was obtained. All patients provided informed consent, in accordance with the Declaration of Helsinki. All patient data were kept deidentified for confidentiality. The study is exempt under 45 CFR § 46.104(d), because the research involves the use of identifiable private information/biospecimens; and information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily by ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Data were retrospectively analyzed from January 2023 to June 2024 on patients that had undergone percutaneous VAT, VP or BK by experienced interventional physicians in a single center. Data was collected from electronic medical records and entered into a spreadsheet. Data included patient demographics, pre and post-procedure pain scores and adverse events. The statistical analysis was performed using descriptive statistics and paired t-tests for comparing pre- and post-procedure numerical rating scale (NRS) pain scores at 2-weeks, 1- and 3-month follow ups; the p-value was considered significant if ≤ 0.05. The analysis of variance (ANOVA) was conducted to examine the differences in pain scores across different time points. Each procedure was counted once, regardless of whether multiple levels had been treated during the same date of service. There were missing follow-ups at different durations, and the mean scores were adjusted accordingly to reflect only pain scores for patients with complete follow-ups.

2.1. Procedure methods

The Medtronic Balloon Kyphoplasty Essentials™ Kit and KYPHON® Xpede™ and Mixer Pack were used for the majority of cases, except the tumor-related lesion and sacroplasty for which the OsteoCool™ and KYPHON V ™ Premium Vertebroplasty Kits were used, respectively (Fig. 1). All the procedures were performed in an office setting using oral sedatives. Neither conscious sedation nor MAC anesthesia was utilized.

The procedure area was prepped and draped in the usual sterile fashion. The skin and subcutaneous area over the affected fracture site pedicle was marked and anesthetized with a combination of 1 % lidocaine and bupivacaine 0.25 %. After a small incision was made, an 11-gauge trocar was passed through the subcutaneous tissues towards the target pedicle. The trocar was advanced under direct fluoroscopic guidance using anteroposterior (AP) and lateral (LAT) views to guide the trocar into the vertebral body thru a transpedicular approach. Under the lateral view, the tip of the trocar or curved needle was seen in the anterior portion of the vertebral body. A cavity was created with the balloon device for fracture augmentation. The balloon was inflated until reaching approximately 250psi and/or 4 mL. In instances where a curved introducer was used, the approach was unilateral, otherwise the balloons were placed bilaterally. The monomer and polymer were mixed according to protocol. The cement delivery system device was filled with PMMA and injected into the vertebral body using AP and LAT fluoroscopic views to monitor the spread of the cement mixture and avoid extravasation. The amount of PMMA injected varied based on level of fracture and percentage of compression. After the filling was complete, the trocars were removed from the pedicles with the utmost care to prevent any posterior migration of the PMMA. Pressure dressings and Steri-Strips™ were applied to the sites. The patients were contacted within 24 h to inquire about their condition.

3. Results

This retrospective study included data from a total of 42 patients (26 females, 16 males) with diagnosis of OVCF that received VAT at our center between January 2023 and June 2024 (Fig. 2). Efficacy data included pre-procedure, 2-week, 1-month and 3-month follow-up NRS pain scores when available. There was a significant drop out rate at the 3-month follow up visit with data included from only 36 % of patients. The average age was 77 and 78.3 for female and men, respectively. A total of 36 patients carried the diagnoses of osteoporosis-related fractures, however, patients with history of multiple myeloma, tumor-related, Schmorl's node related acute endplate fractures and insufficiency fractures were also included. Only 41 % of patients had confirmed history of osteopenia/osteoporosis or had a bone density scan at the time of the initial consult (average T-score −2.33). Patient with history of trauma, falls and lifting incidents were also included in the analysis. Vertebral fractures from T4 to sacrum were included with a total of 59 vertebral levels treated and 13 patients receiving multilevel procedures with a maximum of 3 levels. The most common vertebral fracture location was T12 (n = 13, 22 %), followed by T11, L4 and L5 (n = 7, 12 %). Most patient were evaluated within 3 months of their initial diagnosis (n = 32, 76 %) with the most common pain location being low back without radicular symptoms, (n = 17, 40 %). All patients were receiving medications during their evaluation and treatment period, including simple analgesics (n = 8), NSAIDS (n = 13), anticonvulsants (n = 13), muscle relaxants (n = 12) and opioids (n = 29). Eighty-six percent of the patients on opioids had MME <50, with an average of 23.5, and 14 % with MME of 60 (Table 1).

The efficacy of VAT was measure with pre and post procedure NRS pain scores (Fig. 3). The mean NRS pain score was 7.5 (n = 45), 3.24 (n = 44), 3.65 (n = 21) and 2.7 (n = 15) at pre-procedure, 2-week, 1-month and 3-month follow-up ($P < 0.001$), respectively. Data was missing at the 1- and 3-month follow-up visits. At the 2-week follow up, 44 %, 16 %, 20 % and 13 % of patients (n = 45) had NRS pain score reduction

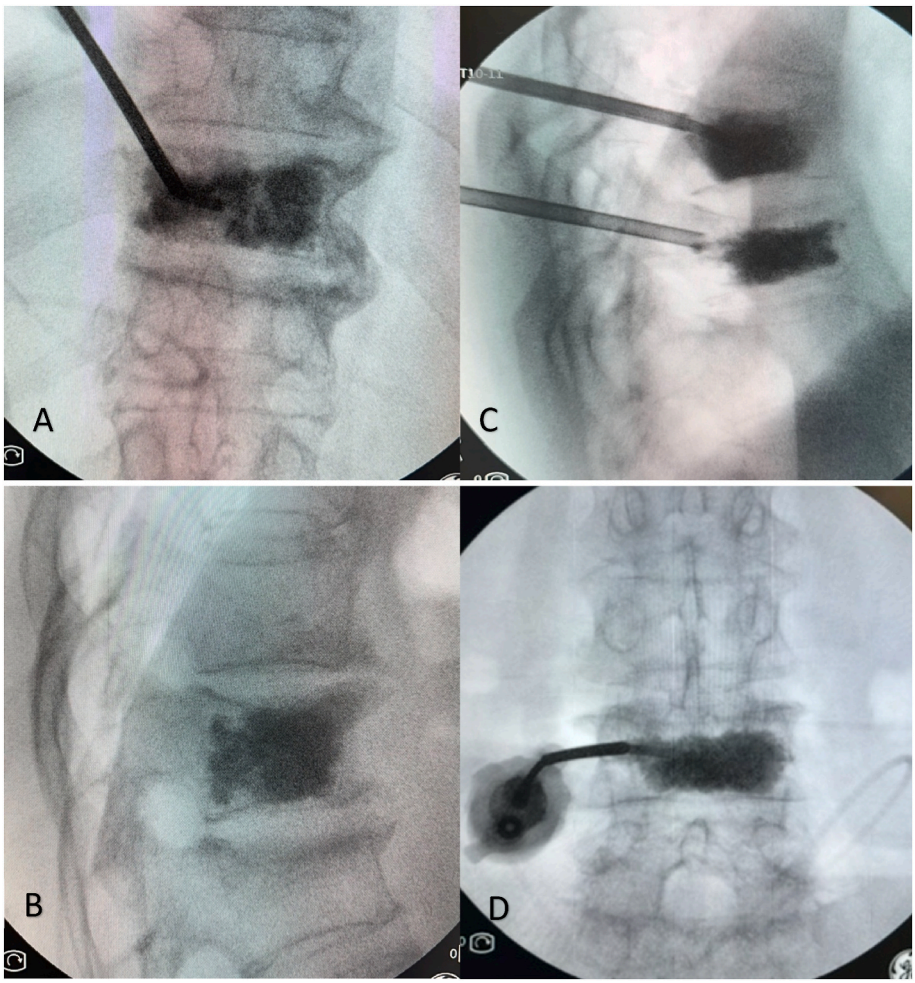

Fig. 1. (A) AP and (B) Lateral fluoroscopic view of PMMA at T10 vertebral body, unipedicular approach; (C) Lateral fluoroscopic view of PMMA at T10 and T11 vertebral bodies; (D) AP fluoroscopic view of PMMA at L4 vertebral body
Abbreviations: PMMA = polymethyl methacrylate, AP = anterior-posterior.

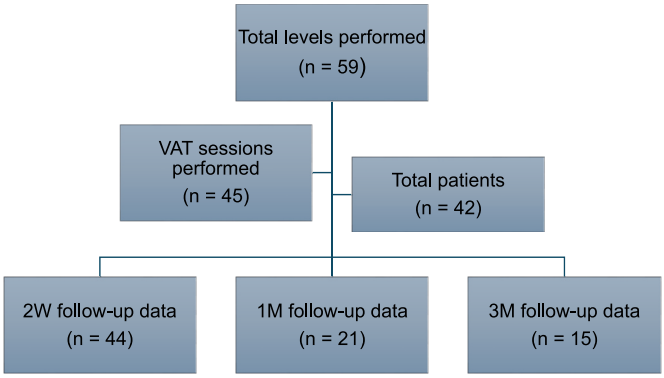

Fig. 2. Flowchart for retrospective data review
Abbreviations: VAT = vertebral augmentation technique, W = week, M = month.

between 76 and 100 %, 51–75 %, 26–50 % and 0–25 % ($P \leq 0.05$), respectively. Two patients experienced an increase in pain and 1 patient was lost to follow up. At the 1-month follow-up visit, 24 %, 33 %, 14.3 % and 24 % of patients (n = 21) had NRS pain score reduction between 76 and 100 %, 51–75 %, 26–50 % and 0–25 %, respectively. One patient had increased pain post procedure. At the 3-month follow-up visit, 60 %, 6.7 %, 6.7 % and 20 % of patients (n = 15) had NRS pain score reduction between 76 and 100 %, 51–75 %, 26–50 % and 0–25 % ($P \leq 0.05$), respectively. One patient had increased pain post procedure.

This analysis suggests that the treatment is effective across both genders, with some variation in individual outcomes, especially among male patients. Both genders started with similar pain levels, male; 7.4 SD $\pm$ 2.03, female; 7.55 SD $\pm$ 1.82 and experienced significant pain reduction post-procedure. However, the T-tests showed no significant differences in pain reduction between males and females at any time point ($P > 0.05$), indicating that gender does not appear to play a significant role in the effectiveness of the treatment in this sample.

There were no reported complications on the day of the procedure, immediate post-procedure period or during the 3-month follow-up visits.

4. Discussion

Back pain secondary to OVCF continues to be a significant global health care problem and a contributor to disability, morbidity and reduction in quality of life [1]. As treating physicians, it is crucial to identify those patients early in their disease process to establish the appropriate symptomatic treatment and to prevent recurrent pathological fractures. CM is still considered first line in the OVCF treatment algorithm, however, for those with refractory pain, prompt interventions such as VAT could potentially lead to complete pain resolution in the target area. Minimally invasive vertebral augmentation procedures have been widely used to treat vertebral compression

Table 1
Patient characteristics and procedures conditions.

Characteristics	All (n = 42)	Vertebral Augmentation (n = 59)
Male sex	16 (38)	21 (35.6)
Female sex	26 (62)	38 (64)
Age, years	77.5	
Male	78.25	
Female	77	
Diagnosis		
Osteoporosis-related fracture	36 (86)	51 (86)
Multiple Myeloma	2 (4.8)	3 (5)
Schmorl node with fracture	2 (4.8)	2 (3.4)
Tumor involvement	1 (2.4)	1 (1.7)
Insufficiency fracture	1 (2.4)	1 (1.7)
Cause of Fracture		
Osteopenia/Osteoporosis	17 (41)	26 (44)
T-score	7 (−2.33)[a]	
Trauma	18 (43)	24 (40)
Lifting	2 (4.8)	2 (3.4)
Unknown	8 (19)	11 (18.6)
Fracture location		
T4		2 (3.4)
T5		1 (1.7)
T6		2 (3.4)
T7		3 (5)
T8		3 (5)
T9		1 (1.7)
T10		1 (1.7)
T11		7 (11.9)
T12		13 (22)
L1		4 (6.8)
L2		4 (6.8)
L3		3 (5)
L4		7 (11.9)
L5		7 (11.9)
Sacrum		1 (1.7)
Pain duration		
≤ 3 months	32 (76)	
3–6 months	5 (11.9)	
≥ 6 months	5 (11.9)	
Pain location		
Mid back	13 (31)	
Low back w radicular symptoms	13 (31)	
Low back wo radicular symptoms	17 (40)	
Medications	42 (100)	
Simple analgesics	8 (19)	
NSAIDS	13 (31)	
Anticonvulsants	13 (31)	
Muscle Relaxant	12 (28.6)	
Opioids	29 (69)	
MME <50	25 (86)	
MME 50-100	4 (14)	

Abbreviations: NSAIDS = nonsteroidal anti-inflammatory drugs, MME = morphine milligram equivalents.
[a] Average T-Score.

fractures caused by osteoporosis [9].

The EVOLVE trial led by Beall et al. was a large prospective and multicenter evaluation designed to investigate 12-mo disability, quality of life, and safety outcomes for BK in the treatment of OVCFs and cancer-related fractures, specifically in a Medicare-eligible population [14]. A total of 354 patients were enrolled at 24 US sites with 350 undergoing BK. At the 3-month primary endpoint, the numerical rating scale improved from 8.7 to 2.7 and Oswestry Disability Index improved from 63.4 to 27.1; Short Form-36 Questionnaire Physical Component Summary (SF-36 PCS) was 24.2 at baseline improving to 36.6, and EuroQol-5-Domain improved from 0.383 to 0.746 ($P < 0.001$ each). These outcomes were statistically significant at every follow-up time point. Only five device-/procedure-related adverse events were reported including: intraoperative asymptomatic balloon rupture, rib pain, aspiration pneumonia, a new VCF post-procedure, and myocardial infarction (105 days post-procedure) [14].

A multicenter randomized controlled trial led by Meirhaeghe et al. compared the efficacy and safety of BK with CM during 24 months in patients with OVCFs [15]. Three hundred patients suffering OVCFs were randomized to undergo BK (n = 149) or CM (n = 151). The BK group had greater improvements in SF-36 physical component summary (PCS) scores at 1 month ($P < 0.0001$) and across the 24 months ($P = 0.0001$). In terms of functionality, the BK group had greater functionality by assessing timed up and go ($P = 0.0036$). At 24 months, the change in index fracture kyphotic angulation was statistically significantly improved in the BK group ($P = 0.003$). In the BK group, the highest quart for kyphotic angulation correction had higher PCS improvement than the quart having lowest correction of angulation, 13.4 versus 7.40 points, respectively ($P = 0.0146$).

A long-term follow up study published by Liu et al. determined if the clinical outcomes from VAT persist in the long term [16]. In the original study, a total of 100 patients were randomly assigned to VP or BK groups. At 5 years, there were no evident changes in vertebral body height, VAS score and kyphotic wedge angle. However, 15 patients (8 for BK, 7 for VP) developed adjacent fractures within one year of the procedure. Seven patients (3 for VP, 4 for BK) had nonadjacent fractures. There was a statistically significant correlation between angular correction and the occurrence of adjacent fractures in the VP group.

Several negative randomized controlled published more than a decade ago, led to the recommendation against VAT by the American Academy of Orthopedic Surgeons [12,17]. Subsequent data had shown the efficacy and safety of VAT in this patient population. Nonetheless, data showed continued downtrend in VP and increased utilization of BK among Medicare beneficiaries. A study conducted by Lindquester et al. studied the utilization, trends in volume and reimbursement of VAT among Medicare beneficiaries by physician specialty and practice from 2010 to 2018 [18]. The total volume of VP decreased by 61.2 % whereas the volume of BK increased by 14.4 % in this period. Total payment for VP decreased by 74.3 %; whereas it increased by 235.3 % for BK procedures. There was a 6833 % increase in office-based BK which bill at the higher non-facility rate.

For decades, the word VAT has served as a general term for a variety of techniques involving the injection of PMMA after a cavity creation by a balloon or with the insertion of an implant to prevent cement leakage. The literature has had mixed results when compared BK to implant-assisted VAT procedures[19–22]. Regardless of the technique used, for decades, VAT has been found to be effective and safe for the treatment of OVCF, leading to a rapid and marked improvement in clinical signs; however, some of them provide better vertebral height restoration than others [23–26].

It is always recommended to review the patient-specific risk factors to avoid possible adverse effects and re-admission rates regardless of the place of service. Toy et al. published a retrospective study in which identified risk factors for poor short-term outcomes after VAT. A total of 850 patients were included in the analysis. The average age was 78.9 ± 11.7 years with 70.8 % females. Approximately, 9.5 % had any adverse event (AAE), and 6.6 % had a serious adverse event (SAE), both significantly associated with American Society of Anesthesiologists (ASA) class 4 ($P = 0.013$, $P = 0.040$) and inpatient status before procedure (AAE: $P < 0.001$, SAE: $P = 0.003$). Increased postoperative mortality rate was associated with ASA class 4 ($P = 0.024$) and the use of non-general anesthesia ($P = 0.022$). Readmission was associated with history of pulmonary disease ($P = 0.005$) and inpatient status before procedure ($P = 0.005$). We must take these factors into consideration when engaging in preoperative discussions and counseling [27]. Another study by Beall et al. showed lower risk of readmissions when an implant was used [28]. In our study, no AAE nor SAE were reported which emphasizes on the safety if this procedure when performed by expert hands. In addition, all procedures were performed using oral sedatives instead of intravenous sedation or general anesthesia at a surgery center or hospital.

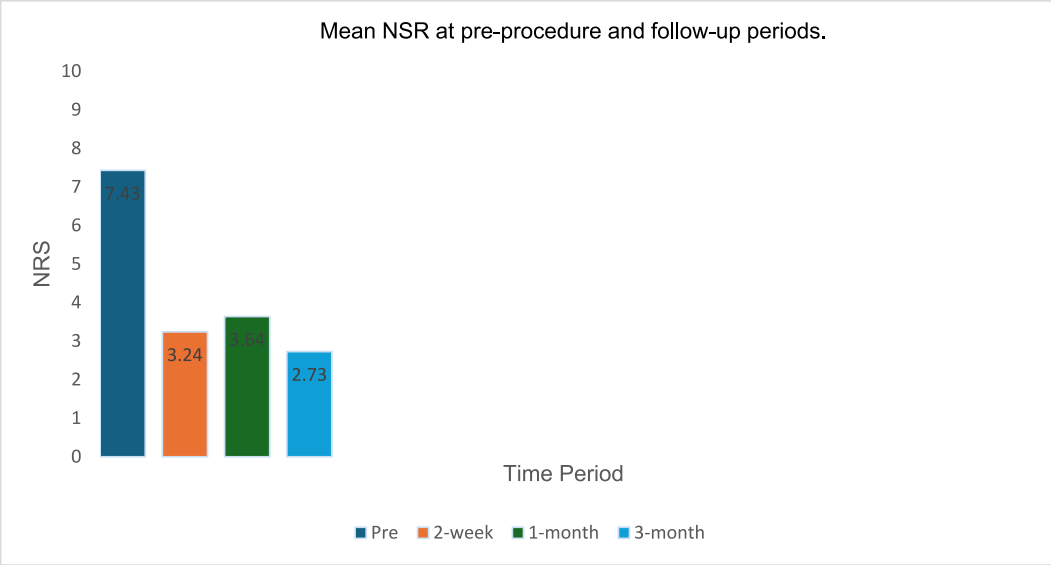

Fig. 3. Mean NSR at pre-procedure and follow-up periods
Abbreviations: NRS = numerical rating scale.

Osteoporosis is not the only scenario where this treatment could be implemented. Patient suffering from metastatic disease, tumor infiltration, multiple myeloma [29], acute Schmorl's nodes or insufficiency fractures could also benefit from this treatment. It is important to reiterate that not all fracture types are amenable to VAT. For example, burst fractures may require surgical instrumentation with or without VAT. The efficacy of cement augmentation in mitigating pain and screw loosening following PSF surgery in low-density bones has been proven to be comparable to that of normal-density bone [30,31].

In this article, we discussed the results of 42 patients who underwent VAT in our outpatient clinic. We have analyzed data retrospectively to include the pre-op NRS pain scores as well as 2-week, 1-month, 3-month follow ups, however, significant follow up data was missing past the two-week follow-up appointment. Patients treated with VAT oftentimes improve in several days to weeks post treatment and do not return to clinic unless they develop pain in other areas or subsequent fractures. Only 2 patients, had increased pain at their 2-week follow-up visit.

Several studies have analyzed the impact of VAT in subsequent adjacent fractures [32,33]. Nieuwenhuijse et al. performed a clustered analysis of fracture-free probabilities of intact nontreated vertebrae after VP OVCFs to determine risk factors for new vertebral fractures and estimate fracture-free probabilities of multiple intact nontreated vertebrae [34]. A total of 115 patients who underwent VP for OVCFs were prospectively followed up to detect new OVCFs during the 1st postoperative year. Three- and 12-month vertebral fracture-free probability was 97.0 % and 94.5 %, respectively. Patient-specific risk factors included low bone mineral density, high spinal deformity index and low fracture age. Strong vertebra-specific risk factors were thoracolumbar localization, vicinity to the treated level, and presence of intradiscal cement leakage [34].

A recent study by Yu et al. studied the recompression of augmented/cemented vertebrae after VAT, to develop and validate a risk prediction model [35]. The study also evaluated the efficacy of a modified puncture technique for recompression prevention after VAT for OVCFs. A total of 394 patients were included in the analysis with 29.4 % sustaining a recompression. The independent risk factors were similar to the ones mentioned above. They included decreased bone mineral density, lower level of serum 25-hydroxy vitamin D3, larger C7-S1 sagittal vertical axis, preoperative intravertebral cleft, and solid-lump cement distribution. Those patients at high risk of postoperative recompression might benefit from the target puncture technique and vitamin D supplementation as well as effective anti-osteoporotic therapies [35].

It is also part of our assessment and due diligence as pain physicians to identify osteoporosis risk factors and/or underlying pathology that could trigger an initial fracture, recompression or fractures at the adjacent levels. Patients with osteoporotic compression fractures must be treated for the underlying osteoporosis to reduce the risks of additional fractures in the future. In our study, only three patients had recompressions, two at distant and one at the adjacent level. No recompressions at the same level were observed.

The study has limitations as this was a retrospective analysis with some missing follow up pain scores. As any other retrospective study, it is not possible to adjust for all confounders.

5. Conclusion

The use of VAT for patient suffering from OVFCs is a well-established interventional procedure that have shown significant pain reduction and height restoration when comparing to CM. Even though former several randomized controlled trials failed to show improvement in pain and functional capacity, subsequent studies and real word data have demonstrated otherwise. The results of this single center, retrospective, observational study is consistent with the results of larger prospective studies which have demonstrated efficacy of VAT in this patient population [14,19,20]. In terms of safety, it is always important to identify patient-specific risk factors to minimize AEE/SAE.

Patient Consent Statement

Not applicable.

Author Contribution statement

All listed authors have contributed to the manuscript substantially in the following areas: concept of the article; analysis, and interpretation of data for the article; and have agreed to the final submitted version.

Ethical approval statement

WCG Western IRB approval was obtained.

Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

[1] Salari N, Ghasemi H, Mohammadi L, et al. The global prevalence of osteoporosis in the world: a comprehensive systematic review and meta-analysis. J Orthop Surg 2021;16:609.
[2] Ensrud KE, Schousboe JT. Clinical practice. Vertebral fractures. N Engl J Med 2011;364(17):1634–42. https://doi.org/10.1056/NEJMcp1009697.
[3] Hallberg I, Rosenqvist AM, Kartous L, Löfman O, Wahlström O, Toss G. Health-related quality of life after osteoporotic fractures. Osteoporos Int 2004;15(10):834–41. https://doi.org/10.1007/s00198-004-1622-5.
[4] Dohm M, Black CM, Dacre A, Tillman JB, Fueredi G, KAVIAR investigators. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. AJNR Am J Neuroradiol 2014 Dec;35(12):2227–36. https://doi.org/10.3174/ajnr.A4127. Epub 2014 Oct 9. PMID: 25300981; PMCID: PMC7965303.
[5] Farrokhi MR, Alibai E, Maghami Z. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. J Neurosurg Spine 2011;14(5):561–9.
[6] Li Y, Zhu J, Xie C. A comparative study of percutaneous kyphoplasty and conservative therapy on vertebral osteoporotic compression fractures in elderly patients. Int J Clin Exp Med 2017;10(5):8139–45.
[7] Jin C, Xu G, Weng D, Xie M, Qian Y. Impact of magnetic resonance imaging on treatment-related decision making for osteoporotic vertebral compression fracture: a prospective randomized trial. Med Sci Monit 2018;24:50–7. https://doi.org/10.12659/MSM.905729.
[8] Carli D, Venmans A, Lodder P, et al. Vertebroplasty versus Active control intervention for chronic osteoporotic vertebral compression fractures: the VERTOS V randomized controlled trial. Radiology 2023 Jul;308(1):e222535. https://doi.org/10.1148/radiol.222535.
[9] Klazen CAH, Lohle PNM, DeVries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (VERTOS II): an open-label randomised trial. Lancet 2010;376:1085–92.
[10] Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the Medicare population. J Bone Joint Surg Am 2013;95(19):1729–36.
[11] Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials? Osteoporos Int 2018;29(2):375–83.
[12] Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med 2009;361(6):557–68. https://doi.org/10.1056/NEJMoa0900429.
[13] Comstock BA, Sitlani CM, Jarvik JG, Heagerty PJ, Turner JA, Kallmes DF. Investigational vertebroplasty safety and efficacy trial (INVEST): patient-reported outcomes through 1 year. Radiology 2013;269(1):224–31. https://doi.org/10.1148/radiol.13120821.
[14] Beall DP, Chambers MR, Thomas S, et al. Prospective and multicenter evaluation of outcomes for quality of life and activities of daily living for balloon kyphoplasty in the treatment of vertebral compression fractures: the EVOLVE trial. Neurosurgery 2019 Jan 1;84(1):169–78. https://doi.org/10.1093/neuros/nyy017. PMID: 29547939; PMCID: PMC6354561.
[15] Meirhaeghe JV, Bastian L, Boonen S. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine 2013 May 20;38(12):971–83. https://doi.org/10.1097/BRS.0b013e31828e8e22.
[16] Liu JT, Li CS, Chang CS, Liao WJ. Long-term follow-up study of osteoporotic vertebral compression fracture treated using balloon kyphoplasty and vertebroplasty. J Neurosurg Spine 2015 Jul;23(1):94–8. https://doi.org/10.3171/2014.11.SPINE14579. Epub 2015 Apr 17.
[17] Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med 2009;361:569–79.
[18] Lindquester WS, Warhadpande S, Dhangana R. Trends of utilization and physician payments for vertebroplasty and kyphoplasty procedures by physician specialty and practice setting: 2010 to 2018. Spine J 2020 Oct;20(10):1659–65. https://doi.org/10.1016/j.spinee.2020.05.002. Epub 2020 May 14.
[19] Korovessis P, Vardakastanis K, Repantis T, Vitsas V. Balloon kyphoplasty versus KIVA vertebral augmentation–comparison of 2 techniques for osteoporotic vertebral body fractures: a prospective randomized study. Spine 2013 Feb 15;38(4):292–9. https://doi.org/10.1097/BRS.0b013e31826b3aef.
[20] Noriega DC, Marcia S, Theumann N, et al. A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study). Spine J 2019 Nov;19(11):1782–95. https://doi.org/10.1016/j.spinee.2019.07.009. Epub 2019 Jul 17.
[21] Bornemann R, Roessler PP, Rommelspacher Y, Strauss A, Koch EMW, Pflugmacher R. The Vertect Jack Device: a new method for augmentation of vertebral fractures. Clinical study with comparisons to kyphoplasty. Technol Health Care 2017 Aug 9;25(4):739–47. https://doi.org/10.3233/THC-160714.
[22] Ould-Slimane M, Petit A, Gille O, et al. A prospective multicenter randomized study comparing the SpineJack system and nonsurgical management with a brace in acute traumatic vertebral fractures: the SPICO study. J Neurosurg Spine 2024 Mar 1;40(6):790–800. https://doi.org/10.3171/2023.12.SPINE23824. Print 2024 Jun 1.
[23] Macciacchera M, McDonnell JM, Amir A, et al. Mechanical vertebral body augmentation versus conventional balloon kyphoplasty for osteoporotic thoracolumbar compression fractures: a systematic review and meta-analysis of outcomes. Glob Spine J 2024 Jun 18:21925682241261988. https://doi.org/10.1177/21925682241261988. Epub ahead of print. PMID: 38889443.
[24] Noriega DC, Ramajo RH, Lite IS, et al. Safety and clinical performance of kyphoplasty and SpineJack(®) procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study. Osteoporos Int 2016 Jun;27(6):2047–55. https://doi.org/10.1007/s00198-016-3494-x. Epub 2016 Feb 8.
[25] Noriega DC, Rodríguez-Monsalve F, Ramajo R, Sánchez-Lite I, Toribio B, Ardura F. Long-term safety and clinical performance of kyphoplasty and SpineJack® procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study. Osteoporos Int 2019 Mar;30(3):637–45. https://doi.org/10.1007/s00198-018-4773-5. Epub 2018 Nov 28.
[26] Tutton SM, Pflugmacher R, Davidian M, Beall DP, Facchini FR, Garfin SR. KAST study: the kiva system as a vertebral augmentation treatment-A safety and effectiveness trial: a randomized, noninferiority trial comparing the kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. Spine 2015 Jun 15;40(12):865–75. https://doi.org/10.1097/BRS.0000000000000906.
[27] Toy JO, Basques BA, Grauer JN. Morbidity, mortality, and readmission after vertebral augmentation: analysis of 850 patients from the American college of Surgeons national surgical quality improvement program database. Spine 2014 Nov 1;39(23):1943–9. https://doi.org/10.1097/BRS.0000000000000563.
[28] Beall DP, Coe JD, McIlduff M, et al. Serious adverse events associated with readmission through one year after vertebral augmentation with either a polyetheretherketone implant or balloon kyphoplasty. Pain Physician 2017 Sep;20(6):521–8.
[29] Alkhatatba M, Alma'aiteh A, Audat Z. Clinical outcome of chemotherapy and radiation therapy versus chemotherapy, radiation therapy, and multilevel vertebroplasty or kyphoplasty for multiple myeloma. Orthopedics 2024 Jul-Aug;47(4):225–31. https://doi.org/10.3928/01477447-20240325-06. Epub 2024 Apr 4. PMID: 38568002.
[30] Shafiekhani P, Darabi M, Jajin EA, Shahmohammadi M. Pedicle screw fixation with cement augmentation versus without in the treatment of spinal stenosis following posterior spinal fusion surgery, superiority according to bone mineral density: a three-arm randomized clinical trial. World Neurosurg 2023 Dec;180:e266–73. https://doi.org/10.1016/j.wneu.2023.09.050. Epub 2023 Sep. 21.
[31] Yan H, Ni M, Zhai W, et al. Balloon kyphoplasty combined with posterior pedicle screw fixation for the treatment of osteoporotic thoracolumbar burst fractures. Ann Palliat Med 2021 Jul;10(7):7514–24. https://doi.org/10.21037/apm-21-665.
[32] Staples MP, Howe BM, Ringler MD, et al. New vertebral fractures after vertebroplasty: 2-year results from a randomised controlled trial. Arch Osteoporos 2015;10:229. https://doi.org/10.1007/s11657-015-0229-0. Epub 2015 Aug 14.
[33] Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. Arch Orthop Trauma Surg 2014 Jan;134(1):21–30. https://doi.org/10.1007/s00402-013-1886-3. Epub 2013 Nov 28.
[34] Nieuwenhuijse MJ, Putter H, van Erkel AR, Dijkstra PDS. New vertebral fractures after percutaneous vertebroplasty for painful osteoporotic vertebral compression fractures: a clustered analysis and the relevance of intradiskal cement leakage. Radiology 2013 Mar;266(3):862–70. https://doi.org/10.1148/radiol.12120751. Epub 2012 Nov 30.
[35] Yu W, Jiang X, Zhang H, et al. Establishment of a novel risk prediction model for recompression of augmented vertebrae at the thoracolumbar junction and modified puncture technique for prevention: a multicenter retrospective study. J Neurosurg Spine 2023 Apr 28;39(2):238–46. https://doi.org/10.3171/2023.3.SPINE2312. Print 2023 Aug 1.