Observational Study

Office-Based Kyphoplasty: A Viable Option Using Local Anesthesia with Oral Sedation

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Background: Vertebral compression fractures (VCFs) can be conservatively treated with pain management, bracing, and bed rest, or treated surgically with a kyphoplasty or vertebroplasty procedure.

Objectives: The objective of this retrospective review was to assess the viability, safety, and efficacy of using local anesthesia with oral sedation for an office-based kyphoplasty procedure.

Study Design: A retrospective review.

Setting: Private orthopedic clinic.

Methods: Ninety-nine consecutive patients (9 office-based and 90 ambulatory surgical centers [ASC]) between January 2015 to May 2017 receiving their first percutaneous balloon kyphoplasty (PBK) with our physician in an office-based setting or at an ASC. Clinical outcomes observed were rates of surgical complications, 6-month re-fracture rates, adjacent fracture rates, and postprocedure medical management.

Results: No intraoperative complications were observed during the PBK procedure. No re-fractures occurred during the 6-month follow-up window. A total of 6% of the patients experienced an adjacent vertebral compression fracture, but there were no significant differences between facility type. Level-specific verbal pain score at the postoperative follow-up visit was significantly lower than at the preoperative visit for the cohort (5.3 ± 3.1 vs.7.5 ± 2.0) ($P = 0.001$) and the ASC group (5.5 ± 3.1 vs. 7.5 ± 2.0) ($P = 0.002$).

Limitations: Only 9 single-level office-based PBKs were performed by a single physician and followed for at least 6 months suggesting these findings cannot be generalized to all patients, practitioners, facilities, or vertebral augmentation procedures (VAPs).

Conclusions: To the best of our knowledge, this study of a continuous series of primary PBKs was the first to report the safety of an office-based procedure. The cohort reported significantly lower pain at their first postoperative follow-up visit when compared to their preoperative visit, adding to the body of evidence that PBKs are an effective treatment for pain associated with VCFs. The overall adjacent fracture rate in this series (6%) was slightly lower than previously reported for VAPs performed in a hospital under local anesthesia (7%-13%).

Key words: Osteoporosis, vertebral compression fracture, kyphoplasty, local anesthesia, office-based, oral sedation**:**

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Vertebral compression fractures (VCFs) are likely to occur in individuals > 50 years, with low bone mass, participating in low levels of physical activity, with inadequate nutrition and coupled with a fall or traumatic event (1,2). A review of the National Inpatient Sample for the years of

2008 to 2014, aggregate yearly national charges for kyphoplasty procedures ranged from $800 million and $1.4 billion dollars, respectively (3). Researchers have estimated that by 2025, there will be >3 million VCFs occurring annually in the United States, resulting in $25 billion in related health care costs (4). VCFs are conservatively treated with pain management, bed rest, and bracing; however increased pain, altered activities of daily living (ADL), increased morbidity and mortality, and a decreased quality of life may persist for months following the injury (5,6). For injuries that fail to respond to conservative management (i.e., refractory VCFs), vertebral augmentation procedures (VAPs) such as percutaneous balloon kyphoplasty (PBK) or percutaneous vertebroplasty (PV) provide pain relief and improvement of disability (7,8). In fact, a VCF cohort of over one million Medicare patients, conservatively treated patients experienced a 55% and 25% higher 4-year mortality risk when compared to PBK and PV, respectively (9).

Interestingly, roughly 70% of the PBKs were performed in an inpatient setting. Determination of where VAPs are performed and patient selection depends on several factors and is still a topic for debate (10).

Inpatient PBK procedures are likely more appropriate for patients with multiple comorbidities, whereas outpatient procedures appear to be a viable option for select patients who can tolerate the procedure well. Furthermore, patients with minimal to no comorbidities may also do well with an office-based procedure under local anesthesia. It appears that local anesthesia for VAPs is a viable technique that may have a better risk-to-benefit ratio in appropriately selected patients. For example, elderly patients, who are at risk for intraoperative and postoperative complications, may benefit from an office-based procedure (11). Previous studies have demonstrated that hospital-based VAPs can be performed safely without the need for general anesthesia, and recent scrutiny of the location of services provided prompted the authors to explore the feasibility and safety of office-based PBKs (11-15).

To the best of our knowledge, there were no published cases of PBKs using oral sedation and local anesthesia at an office-based facility available in the literature at the time of submission. Therefore, the purpose of this retrospective review was to assess the viability, safety, and efficacy of using local anesthesia with oral sedation for an office-based PBK by comparing rates of surgical complications, 6-month re-fracture rates, adjacent fracture rates, and postprocedure medical management with PBKs performed at ambulatory surgical centers (ASCs).

Methods

All methods were approved by the Florida State University institutional review board.

Data Aggregation

A computer-based review of patients between the dates of January 2015 and May 2017 with the associated Current Procedural Terminology (CPT) codes 22513 (thoracic percutaneous vertebral augmentation) and 22514 (lumbar percutaneous vertebral augmentation) was completed by the orthopedic clinic's billing department. These dates correspond with the first case performed in an office-based setting. All patients included were treated at one of 3 different ASCs or in the fluoroscopy suite of the orthopedic clinic by a single pain management physician. Of the 149 cases evaluated during the time window, 50 cases were excluded because the procedure was performed at a hospital or the procedure was not the initial PBK for that patient. Of the 99 patients treated, one patient moved away, and 3 patients did not show up for their visit and did not schedule a follow-up appointment. The remaining 95 patients were followed for at least 6 months postsurgery to determine re-fracture and adjacent fracture rates, complication rates, and postoperative medication management. Patients that required a multilevel augmentation during a single procedure were included in the retrospective review.

Evaluation of Clinical Data

To determine the presurgical state of the included cases, the last clinical examination note before the PBK was reviewed to assess comorbidities, patient demographics, reported verbal pain, and medication management. Morphine milligram equivalents (MME) were calculated when measurable dosing was provided (e.g., 5 mg 3 times a day) and a morphine conversion could be made. The maximum mg/day was reported when a range was provided in the dosing (e.g., 1-2 tablets per day). All operation notes were reviewed for the following complications: blood transfusion needed; resuscitation required; organ failure; neurologic impairment; vascular complications; and discharge status. Additionally, the vertebral level and the number of vertebral levels repaired during the procedures were also documented. To determine the postsurgical status, the first clinical follow-up examination note after the

PBK was reviewed to determine if any additional treatments were required, reported verbal pain, medication management, or if any postsurgical complications presented after discharge. The average time from surgery to follow-up was 36.2 ± 46.6 days.

Clinical Logistics

As part of a typical pain management visit, patients were asked to provide a verbal pain score from 0 to 10; complete a Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) form; complete a standard medical history form; and complete a controlled-medication agreement (if warranted). However, because of the nature and timing of kyphoplasty referrals, not all assessments were included preoperatively and therefore not included in our pre- and postoperative comparisons.

Criteria for Office-Based Procedure Consideration

For a patient to be considered for an office-based PBK, the following criteria were developed with guidance from the practice's compliance committee: patient must choose an office-based facility; no history of anxiety; patient must tolerate the prone position; be classified by the American Society of Anesthesiologists score level 3 or below (16); no pathological fractures; body mass index $\leq$ 40 kg/m^2; able to discontinue anticoagulants and/or no coagulopathy; lack of local anesthetic allergies; no greater than 2 fracture repairs per procedure; and meet the requirements of a level-one office-based surgery according to Florida statute. In addition to this criteria, the physician would also consider the physical limitations of the patient, such as the ability to safely ambulate or transition from the operating table, to minimize the risk of perioperative falls.

Office-Based PBK Surgical Procedure

Thirty minutes before the office-based PBK procedure, patients were provided oral syrup Midazolam HCL (up to 0.25 mg/kg with a maximum dose of 20 mg) (17). Patients were reassessed prior to the procedure to evaluate if additional dosing was needed. An intravenous (IV) line was started for hydration and emergency access. Standard patient monitoring was used. Staffing for the procedure included an advanced cardiorespiratory life support (ACLS)-trained physician, a registered nurse, and a radiologic technologist. Patients were then moved into the prone position, where meticulous preparation and draping was performed after the targeted vertebral level was identified. A skin wheal was created. Next, subcutaneous infiltration of the soft tissues were accomplished down to the pedicle used a 22-gauge Quincke tip needle (BD 405181, Becton Dickinson, Franklin Lakes, NJ). This allowed not only adequate local anesthetic infiltration with 0.5% lidocaine, but also assisted with planning optimal trocar trajectory in both the anterior-posterior and lateral fluoroscopic views. The average volume used was approximately 10 mLs of 0.5% lidocaine. The trocar (Kyphon Express Osteo Introducer System, Medtronic Sofamor Danek, Memphis, TN) was then introduced after a small stab incision was made for the trocar introduction at the skin. Once the trocar was advanced down the pedicle, it was gently advanced to "dock" into the pedicle. Advancing the trocar with a rotational technique is better tolerated than the significant stimulation associated with using a mallet. Multiplanar fluoroscopic views allowed optimal passage through the pedicle and prevented complications from either too medial or lateral needle placement. As the trocar was gently advanced, a 22-gauge 7-inch needle was placed through the trocar and small aliquots of 2% lidocaine were injected in front of the trocar insertion. Once the cortical bone was injected, several minutes were allowed to pass, the stylet was reintroduced, and the trocar was manually rotated and advanced. This was repeated several times until the trocar passed through the pedicle into the vertebral body. This technique soaks the cortical bone and appears to provide enough anesthesia to permit trocar rotational advancement. Approximately 2-5 ccs of 2% lidocaine seemed to reduce the noxious stimulation, much like the periarticular infiltration analgesia used for the total knee arthroplasties (18). Next, the bone drill was inserted to create a cortical window in the vertebral body. The bone drill was then withdrawn, and the balloon was inserted and inflated to a pressure that was appropriate to safely create a cement cavity and potentially restore the vertebral body height (Fig. 1). Once the cavity was identified, the balloon was deflated and withdrawn. This was followed by incremental injection of the polymethylmethacrylate into the vertebral body cavity. The vertebral filling was confirmed with multiple, multiplanar views to demonstrate vertebral spreading without vascular uptake or epidural spread (Figs. 2 and 3). The trocar was cleared of cement and withdrawn. The open incision was closed using steri-strips. When warranted, intramuscular or IV ketorolac tromethamine (30-60 mg) was used for post-procedural tolerance. Patients were monitored for 20 minutes in the prone position and then discharged to the recovery area where they were monitored for an ad-

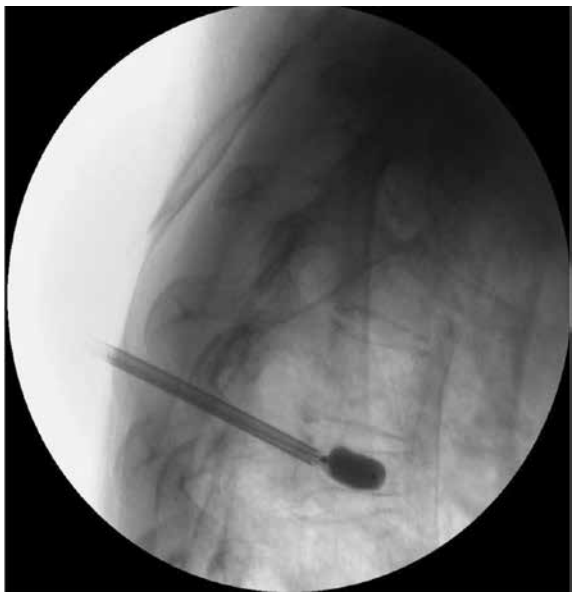

Fig. 1. *Lateral radiograph during ballon inflation.*

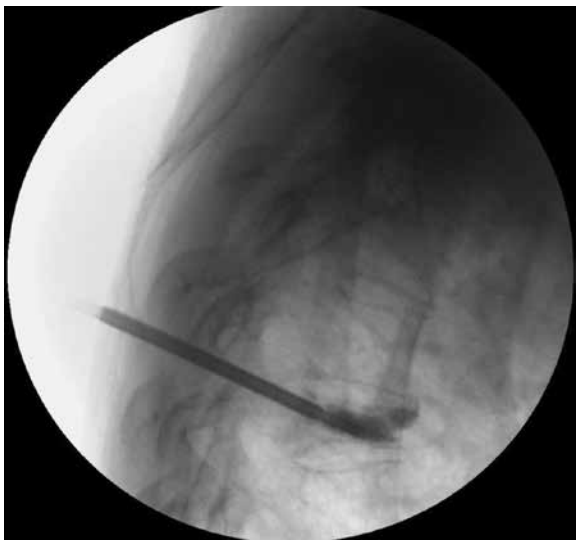

Fig. 2. *Lateral radiograph with torcar, during PMMA injectate.*

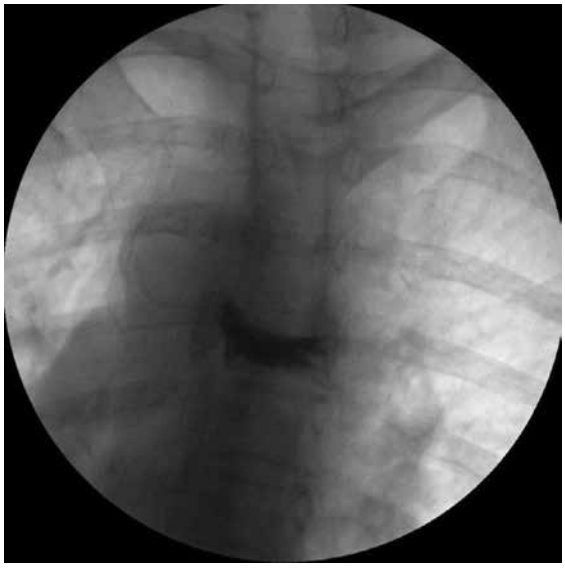

Fig. 3. *AP radiograph fter PMMA injectate.*

ditional 30 minutes. Patients were demonstrated to be neurovascularly intact before discharge.

Emergency Preparation

Although an unexpected, life-threatening event was unlikely, the facility and staff took specific precautions to minimize catastrophic complications. Items available in the fluoroscopy suite were standard resuscitative equipment with oxygen; airway management supplies (e.g., suction, laryngoscope, endotracheal tubes); ACLS drugs, including those for allergic reactions; IV fluids; and defibrillator. If emergency medical services are required, patient preference would generally guide which hospital the patient is transported to. One hospital was 0.4 miles and the other was 2.7 miles. Both facilities could be reached in < 10 minutes. Although neurosurgery or spine surgery support does not have to be present, it is prudent to have them available by phone for emergency treatment of cement migration.

Statistical Analysis

Descriptive statistics were performed using Microsoft Excel (Microsoft Corp., Redmond, WA). Group comparisons for continuous variables by facility type were performed using independent samples t tests, and group comparisons for dichotomous variables were performed using the Fisher exact test in SPSS Version 22 (IBM Corporation, Armonk, NY). Paired samples t tests were performed for verbal pain score and MME.

Results

Ninety-nine consecutive patients (9 office-based and 90 ASC) that underwent a PBK procedure at an ASC

or in an office-based setting were included in the retrospective review. Presurgical patient status is listed in Table 1. There were no significant differences between facilities for any of the presurgical patient characteristics (Table 1). There were no significant differences in age, individual comorbidities, or total morbidities (Table 2), however, diabetes was trending toward significance (P = 0.066). All cases for office-based PBK involved only single-level augmentations, whereas approximately 23% of the cases at ASCs were multilevel procedures (Table 3).

All 99 patients were deemed to be neurologically intact and discharged the same day the procedure was performed (Table 4). Only one of the 95 followed patients were subsequently admitted to a hospital. This patient sought medical attention 36 hours postoperative for chronic gastritis with ulcers. This was known to be a preexisting condition, and the patient was receiving treatment for the condition when they sustained the compression fracture. The augmentation was radiologically confirmed as intact at the next orthopedic visit. Across both facilities, there were no re-fractures reported (Table 4). Six adjacent fractures were reported; 2 occurring in the office-based group and 4 in the ASC group, although there were no significant differences between groups (P = 0.098). Of the 6

Table 1. *Pre-Surgical Patient Status.*

	Total Cohort	ASC	Office-Based	*P* Value
Age (years)	74.7 ± 12.5	74.5 ± 12.9	76.5 ± 6.5	0.648
Sex (M / F)	19 / 80	17 / 73	2 / 7	0.682
BMI (kg / m2)	26.6 ± 6.4	27.0 ± 5.4	26.5 ± 7.4	0.823
SOAPP-R Score	10.3 ± 6.4	10.7 ± 6.8	9.0 ± 4.5	0.610
Pre-surgical Opioid Use	71%	73%	56%	0.272
Prescribed Pre-Surgical Physical Therapy	61%	58%	78%	0.463

M ± SD; ASC = Ambulatory Surgical Center; BMI = Body Mass Index; BMI was included if it was recorded within 1 month of surgery (n = 69); Opioid Use Recorded (n = 87); SOAPP-R = Screener and Opioid Assessment for Patients with Pain-Revised (n = 22);

Table 2. *Comorbidities and demographics.*

	Total Cohort n = 99	ASC n = 90	Office-Based n = 9	*P* Value
Diabetes	17/88 (19%)	13/79 (16%)	4/9 (44%)	0.066
Hypertension	47/88 (53%)	41/79 (52%)	6/9 (67%)	0.494
Abnormal Blood Lipids	22/88 (25%)	20/79 (25%)	2/9 (22%)	1.000
Heart Disease	10/88 (11%)	8/79 (10%)	2/9 (22%)	0.270
Chronic Obstructive Pulmonary Disease	11/88 (13%)	9/79 (11%)	2/9 (22%)	0.313
Depression/Anxiety/Bi-polar Disorder	14/88 (16%)	14/79 (18%)	0/9 (0%)	0.344
Neurodegenerative Diseases	5/89 (6%)	5/81 (6%)	0/9 (0%)	1.000
Seizure Disorders	1/90 (1%)	1/81 (1%)	0/9 (0%)	1.000
Cardiovascular Disease/Disorder	18/86(21%)	16/81 (20%)	2/9 (22%)	1.000
Osteoporosis	35/99 (36%)	31/90 (34%)	4/9 (44%)	0.720
Obesity Classification (I,II,III) on BMI	21/69 (30%)	18/61 (30%)	3/7 (43%)	0.668
Previous or Current Tobacco User	36/65 (55%)	31/58 (53%)	5/7 (71%)	0.447
Previous or Current Alcohol User	22/66 (33%)	20/58 (34%)	2/8 (25%)	0.709
Previous or Current Alcohol Recreational Drug User	7/67 (10%)	6/59 (10%)	1/8 (13%)	1.000
Participated in Regular Exercise	14/67 (21%)	14/60 (23%)	0/7 (0%)	0.330
Total Comorbidities	4.2 ± 3.0	4.1 ± 3.1	4.8 ± 2.1	0.548

(Reported / available); BMI = Body Mass Index

adjacent fractures, one patient's preoperative dual-energy x-ray absorptiometry (DXA) scan reported a lumbar T-score of –2.9, one patient's preoperative computed tomography report revealed multiple VCFs, and one patient had multiple VCFs identified using radiographs preoperatively, with the most acute facture addressed during PBK. One patient's one-week postoperative DXA revealed a femoral neck and hip T-score of –2.5, one patient's 3-month postoperative DXA revealed a lumbar T-score of –1.6, and one patient's 3-month postoperative DXA revealed a total hip T-score of –0.4. The bone mineral density results were not comprehensive, and thus, limited the assessment of the adjacent fracture subgroup. An additional 3 VCFs occurred that were not a re-fracture or adjacent fracture; 2 occurred in the ASC group and one in the office-based group. There were no significant differences in group proportions between facilities for postoperative treatment rates. Postoperative verbal pain score was significantly lower than at preoperative for the cohort (5.3 ± 3.1 vs. 7.5 ± 2.0) (P = 0.001) (n = 37) and the ASC group (5.5 ± 3.1 vs. 7.5 ± 2.0) (P = 0.002) (n = 35). MME was trending but not significantly different between pre- and postoperative visits for the cohort (28.0 ± 31.6 vs. 30.0 ± 34.7) (P= 0.061) (n = 82). Failure to meet the required assumptions for a mixed analysis of variance (ANOVA) prohibited the authors from comparing facility differences for verbal pain score and MME without the increased the risk of type I errors from unadjusted multiple comparisons.

Overall, the presurgical patient status was poor, with patients reporting 4.2 ± 3.0 comorbidities (range: 0-15), verbal pain score of 7.5 ± 2.0 (range: 3-10), MME of 28.0 ± 31.6 mg/day (range: 0-180), and a SOAPP-R score of 10.3 ± 6.4 (range: 2-30). Post-surgically, 11 of the 95 followed patients verbalized complete resolution of their fracture pain as was documented in their clinical note. Eight patients verbalized specific improvements following their procedure; 2 stopped their analgesic medications completely; 2 reported noticeable improvements in function; and 3 patients reported noticeable improvements in their ADLs. Treatment performed during their first postop-

Table 3. *Percutaneous balloon kyphoplasty (PBK) surgical details.*

	Total Cohort	ASC	Office-Based
	n = 99	n = 90	n = 9
Thoracic PBK			
1 Level	29%	30%	22%
2 Levels	6%	7%	0%
3+ Levels	1%	1%	0%
Lumbar PBK			
1 Level	51%	47%	78%
2 Levels	9%	10%	0%
3+ Levels	2%	2%	0%
Multi-Region PBK			
2 Levels	2%	2%	0%
3+ Levels	1%	1%	0%

Percentages may equal greater that 100% as they were rounded to the nearest whole number

Table 4. *Clinical outcomes across facility type.*

	Total Cohort	ASC	Office-Based
Surgical Complications	0% (0/99)	0% (0/90)	0% (0/9)
6-month Re-fracture	0% (0/95)	0% (0/86)	0% (0/9)
6-month Adjacent Fracture	6% (6/95)	5% (4/86)	22% (2/9)
Requiring Additional Post-op Treatment	92% (65/71)	92% (58/63)	88% (7/8)
Pre-op Prescribed Morphine Equivalents (mg/day)	28.0 ± 31.6 (82/95)	28.1 ± 33.4 (73/86)	26.3 ± 10.9 (9/9)
Post-op Prescribed Morphine Equivalents (mg/day)	30.0 ± 34.7 (82/95)	30.5 ± 36.4 (73/86)	24.0 ± 7.9 (9/9)
Pre-op Verbal Pain Score (# /10)	7.5 ± 2.0 (37/95)	7.5 ± 2.0 (35/86)	8.0 ± 0.0 (2/9)
Post-op Verbal Pain Score (# / 10)	5.3 ± 3.1(37/95)†	5.5 ± 3.1 (35/86)*	3.0 ± 2.9 (2/9)

Percentages may equal greater that 100% as they were rounded to the nearest whole number; values are listed as M ± SD;
†Post-op was significantly lower than Pre-op (P = 0.001)
* Post-op was significantly lower than Pre-op (P = 0.002)

erative visit was documented. Six patients required no additional treatment, 4 patients were referred only for physical therapy, 38 patients only received alterations to their medication regimen, 3 patients received initial antiresorptive treatment for osteoporosis, 3 patients only received follow-up imaging for new or persistent pain, one patient was re-admitted 36 hours postoperative, one patient received bracing, and 18 patients received multiple treatments. Of the 18 patients that received multiple treatments, 18 patients received medication alterations, 13 patients were referred for physical therapy, 4 patients received follow-up imaging, one patient received psychological counseling, and one patient received bracing. Myofascial pain (20%), sacroiliac pain (12%), other existing fractures (5%), musculoskeletal deconditioning (4%), osteoporosis therapeutics (3%), and a recent fall (4%) were the most common reasons for additional treatments. Of the 7 patients to receive follow-up imaging, 4 patients were part of the adjacent level fracture subgroup. The remaining 3 patients' imaging studies were unremarkable or reported chronic VCFs identified on previous imaging studies.

Discussion

To the best of our knowledge, this study of a continuous series of primary PBKs was the first to report the safety and efficacy of an office-based procedure using local anesthesia with oral sedation. A primary finding was from our review were procedures performed in either facility type reported zero operative complications and only a single hospital admission that was unrelated to surgery, demonstrating that PBKs can be safely performed by a trained physician in either facility. Patients reported significantly lower pain at their first postoperative follow-up visit when compared to their preoperative visit, adding to the body of evidence that PBKs are an effective treatment for pain associated with VCFs. However, although not significantly different, patients at follow-up were prescribed a slightly higher dose of their opioid analgesics (28.0 ± 31.6 vs. 30.0 ± 34.7) (P = 0.06), which may have contributed to the improvement in verbal pain score. It is also important to emphasize that PBKs only address the pain related to the fractured vertebral bodies. Typically, these patients have other spine conditions that contribute to their disability and pain. It is important to set realistic patient expectations, as many of the patients will return with myofascial pain secondary to chronic deconditioning. Returning with persistent pain requires further imaging to rule out any additional fractures. If the earlier mentioned films are negative, the other spine structures are targeted as indicated based on clinical exam. No patients experienced a re-fracture of the augmented vertebrae(s), and 6 of the 95 patients (6%) followed experienced an adjacent VCF within 6 months of the procedure; 4 patients in the ASC group and 2 patients in the office-based group. Although not statistically different, a larger proportion of adjacent fractures occurred in the office-based group than the ASC group (22% vs. 5%) (P = 0.098). Interestingly, all patients that experienced an adjacent fracture and reported their physical activity status considered themselves sedentary (n = 5), which may have played a role in bone demineralization. The natural progression of osteoporosis or a patient's nutrition status may have also influenced these outcomes. The adjacent fracture rates in this series (6%) were slightly lower than previously reported for VAPs performed in a hospital under local anesthesia (7%-13%) (11,13-15,19).

This study was not without limitation or bias. The authors were limited in the pre- and postoperative comparisons across facilities as the number of complete cases available for analyses varied widely. A sample size of 9, single-level office-based PBKs performed by a single physician and followed for at least 6 months suggest that these findings cannot be generalized to all patients, practitioners, facilities, long-term outcomes, or VAPs. The drastic group imbalance between facilities were because of the surgeon recently initiating the office-based procedure and the desire to review the program's viability. Opioid medication use before and after surgery, although not significantly different, may have affected the reported improvement in pain following the procedure. Likewise, the reported comorbidities may have also affected the postsurgical therapeutics needed. Our patient search may have been restricted by the limitations of our billing software, as such, patients may have been missed in our billing code search. Recording bias may have limited the relevant medical information obtained by the clinician and information may have been missed when trying to fully understand the patient condition. Attrition bias may have affected our findings, as patients that did not follow-up may have experienced an adverse event outside of Tallahassee or not reported the event to the clinical staff. Although the patient grouping may have been exposed to selection bias by the physician because of the compliance committee's predetermined eligibility criteria, whereas the healthier patients could have been more likely referred for an office-based procedure, patient demographics and comorbidities did not significantly

differ across facilities. Only single-level PBKs were performed in an office-based setting, which creates an opportunity for future research on multilevel PBKs in an office-based setting. However, Wiles et al. (20) suggested that local anesthesia is not preferable for multilevel procedures due to patient discomfort from prolonged prone positioning and the need for large volumes of local anesthetics to adequately provide relief. Clinicians should consider this, along with other factors, when determining which patients are ideal candidates for an office-based procedure. Osborn and Sandler (21) reported that patients with a high level of anxiety required greater amounts of propofol to maintain clinically acceptable levels of sedation during dental surgery. Based on this information and clinical experience, it is the operating physician's opinion that one of the greatest predictors of procedural tolerance can be determined by the patient's preoccupation with procedural pain, and whether it outweighs the desire for postprocedural pain relief. Interestingly, recent work suggests that preoperative extended periods of prone positioning may help identify which patients would tolerate the procedure and not require IV sedation (22).

Conclusions

The presurgical patient condition may be somewhat alarming to practitioners outside of pain management (Table 1). This consecutive series of patients demonstrated that mostly sedentary, osteoporotic, opioid-using, hypertensive patients with a history of tobacco use can undergo a single-level PBK safely, regardless of facility type and will likely experience a decrease in level-specific pain following the procedure. {AU: Please clarify the sentence beginning, "Although this consecutive series of patients …} The PBK procedures did not ameliorate all disabilities or pain that the patient was experiencing at the time of surgery, but rather addressed the level-specific dysfunction, which explains why many patients required additional treatment (92%) after the VCF was repaired. Future research is warranted to determine the use of office-based PBKs and examine which patient profile might be best suited for an office-based procedure.

References

1. Cauley JA. Osteoporosis: Fracture epidemiology update 2016. *Curr Opin Rheumatol* 2017; 29:150-156.
2. Cosman F, Lindsay R, LeBoff MS, Jan de Beur S, Tanner B. Clinician's guide to prevention and treatment of osteoporosis. *Natl Osteoporos Found* 2014; 1-55.
3. Laratta JL, Shillingford JN, Lombardi JM, Mueller JD, Reddy H, Saifi C, Fischer CR, Ludwig SC, Lenke LG, Lehman RA. Utilization of vertebroplasty and kyphoplasty procedures throughout the United States over a recent decade: An analysis of the nationwide inpatient sample. *J Spine Surg* 2017; 3:364-370.
4. Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A, Tosteson A. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005-2025. *J Bone Miner Res* 2007; 22:465-475.
5. Xie L, Zhao Z-G, Zhang S-J, Hu Y-B. Percutaneous vertebroplasty versus conservative treatment for osteoporotic vertebral compression fractures: An updated meta-analysis of prospective randomized controlled trials. *Int J Surg* 2017; 47:25-32.
6. Chandra RV, Maingard J, Asadi H, Slater LA, Mazwi TL, Marcia S, Barr J, Hirsch JA. Vertebroplasty and kyphoplasty for osteoporotic vertebral fractures: What are the latest data? *Am J Neuroradiol* 2018; 39:798-806.
7. Goz V, Errico TJ, Weinreb JH, Koehler SM, Hecht AC, Lafage V, Qureshi SA. Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010. *Spine J* 2015; 15:959-965.
8. Lee HM, Park SY, Lee SH, Suh SW, Hong JY. Comparative analysis of clinical outcomes in patients with osteoporotic vertebral compression fractures (OVCFs): conservative treatment versus balloon kyphoplasty. *Spine J* 2012; 12:998-1005.
9. Edidin AA, Ong KL, Lau E, Kurtz SM. Morbidity and mortality after vertebral fractures. *Spine (Phila Pa 1976)* 2015; 40:1228-1241.
10. Filippiadis DK, Marcia S, Masala S, Deschamps F, Kelekis A. Percutaneous vertebroplasty and kyphoplasty: Current status, new developments and old controversies. *Cardiovasc Intervent Radiol* 2017; 40:1-9.
11. Cagli S, Isik HS, Zileli M. Vertebroplasty and kyphoplasty under local anesthesia: Review of 91 patients. *Turk Neurosurg* 2010; 20:464-469.
12. Department of Justice O of PA. Fifty-five hospitals to pay U.S. more than $34 million to resolve false claims act allegations related to kyphoplasty [press release]. *Justice News* 2013.{AU: Please verify that reference 12 is set correctly}
13. Yaltirik K, Ashour A, Reis C, Ozdogan S, Atalay B. Vertebral augmentation by kyphoplasty and vertebroplasty: 8 years experience outcomes and complications. *J Craniovertebr Junction Spine* 2016; 7:153-160.

14. Sesay M, Dousset V, Liguoro D, Péhourcq F, Caillé JM, Maurette P. Intraosseous lidocaine provides effective analgesia for percutaneous vertebroplasty of osteoporotic fractures. *Can J Anesth* 2002; 49:137-143.
15. Lee JK, Jeong H, Joo I-H, Ko Y-I, Kang C-N. Percutaneous balloon kyphoplasty for treatment of very severe osteoporotic vertebral compression fractures: A case-controlled study. *Spine J* 2017; 1-8. {AU: Please provide volume number and check page range for reference 15}
16. Owens WD, Felts JA, Spitznagel EL. ASA physical status classifications: A study of consistency of ratings. *Anesthesiology* 1978; 49:239-243.
17. Donaldson M, Gizzarelli G, Chanpong B. Oral sedation: A primer on anxiolysis for the adult patient. *Anesth Prog* 2007; 54:118-128.
18. Perret M, Fletcher P, Firth L, Yates P. Comparison of patient outcomes in periarticular and intraarticular local anaesthetic infiltration techniques in total knee arthroplasty. *J Orthop Surg Res* 2015; 10:1-7.
19. Liu L, Cheng S, Lu R, Zhou Q. Extrapedicular infiltration anesthesia as an improved method of local anesthesia for unipedicular percutaneous vertebroplasty or percutaneous kyphoplasty. *Biomed Res Int* 2016; 2016:1-4.
20. Wiles MD, Nowicki RWA, Hancock SM, Boszczyk B. Anaesthesia for vertebroplasty and kyphoplasty. *Curr Anaesth Crit Care* 2009; 20:38-41.
21. Osborn TM, Sandler NA. The effects of preoperative anxiety on intravenous sedation. *Anesth Prog* 2004; 51:46-51.
22. Li G, Liu H, Wang Q, Zhong D. Preoperative prone position exercises: A simple and novel method to improve tolerance to kyphoplasty for treatment of single level osteoporotic vertebral compression fractures. *BMC Musculoskelet Disord* 2017; 18:1-5.