



Patient Experience Following Kyphoplasty: Safety, Efficacy, and Patient Satisfaction

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Authors' contributions

This work was carried out in collaboration between all authors. Author KPK contributed to study design, data, analysis, and manuscript preparation. Authors PRP and HR were responsible for patient recruitment and data collection. Author DMP assisted with data analysis and manuscript preparation.

Author FJC assisted in data entry and collection. Author RST contributed to manuscript preparation and revision as well as study design. Author MRC was responsible for study design, patient recruitment, data entry, data analysis, and manuscript preparation. All authors read and approved the final manuscript.

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ABSTRACT

Aims: Kyphoplasty is a minimally invasive treatment used to reduce pain, restore vertebral height and improve mobility in patients with painful spinal VCF. Pain from vertebral compression fractures (VCF) comprises an important health issue with significant social and economic impact, particularly in elderly patients with osteoporosis where treatment options are limited. We assessed outcomes

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in patients with VCF who failed conservative management and underwent kyphoplasty.

Study Design: Prospective and retrospective case series.

Place and Duration of Study: At a single neurosurgical practice February 2003 and September 2012.

Methodology: A total of 203 patients with 288 treated vertebral body fractures treated with kyphoplasty were enrolled. The Visual Analog Scale (VAS) was used to prospectively measure back pain before and after surgery. Pre and post operative disability and quality of life were retrospectively measured with the Roland Morris Disability Index (RMDI) and EuroQol 5-Domain scale (EQ5D), respectively, via patient survey. Pre and post-operative narcotic analgesic usage and incidence of subsequent fractures were recorded.

Results: There was a statistically significant improvement ($P < .001$) in each of the assessed measures following surgery. The post-operative rate of narcotic use was reduced from 63% to 17%. Eight patients (4.2%) developed and underwent repair of an adjacent fracture with a mean time between surgeries of 461 days.

Conclusion: Following kyphoplasty, patients experienced significant, rapid, and sustained reduction of back pain, improved quality of life, and reduced disability with a low complication rate. Timely repair of VCF is indicated, not only to prevent complications associated with prolonged inactivity but also for effective treatment of severe pain in the acute setting.

Keywords: Kyphoplasty; vertebral body compression fracture; quality of life; elderly; osteoporosis.

1. INTRODUCTION

Pain from vertebral body compression fractures (VCF) is an important health issue with significant social and economic impact, particularly in elderly patients with osteoporosis. The consequences of inactivity in this population are significant. Quality of life is threatened and mortality rates increase following osteoporotic fragility fractures [1]. Kyphoplasty is a minimally invasive treatment aimed at reducing pain, restoring vertebral height and improving mobility in a timely manner in patients with vertebral body compression fractures.

Two percutaneous options exist for treatment of VCF: vertebroplasty involves the high pressure injection of cement into the vertebral body, while kyphoplasty involves a lower pressure cement injection following intravertebral balloon inflation to restore vertebral height. Two papers published in the New England Journal of Medicine in 2009 found no benefit to vertebroplasty [2,3]. Kyphoplasty has the advantage of restoration of vertebral body height by balloon inflation, and lower pressure injection of cement leading to increased control and less cement leakage compared to vertebroplasty [4]. However, a shift in practice pattern away from all percutaneous treatments for VCF followed the publication of these studies. The utility of kyphoplasty for pain relief in VCF remains controversial among neurosurgeons as well as primary care physicians first evaluating and referring these patients. Our patients showed an overwhelming

improvement in pain and quality of life after kyphoplasty, and this study was undertaken to more rigorously examine and quantify our experience in support of kyphoplasty in this otherwise orphan condition.

In the presented case series, we assessed outcomes following kyphoplasty in 203 patients over a 9-year period.

2. PATIENTS AND METHODS

In this case series, patients undergoing kyphoplasty for vertebral body compression fractures between February 2003 and September 2012 were queried.

The diagnosis of a compression fracture was made by preoperative history and physical examination followed by radiographs, CT, MR and/or nuclear bone scan imaging studies. All patients had persistent, life-altering pain and were classified as failures to respond to at least four weeks of preoperative conservative management including rest, orthotic immobilization and support, and analgesic medications. Patients underwent kyphoplasty in the standard fashion according to manufacturer instructions (Kyphon™, Medtronic, Memphis, Tennessee). Following Institutional Review Board approval, eligible patients were contacted by mail, telephone, or personal interview to complete assessments of their pain, disability and quality of life relative to their vertebral fractures and kyphoplasty. The Visual Analog

Scale (VAS, range: 0(none) - 10(worst)) was used to prospectively measure back pain preoperatively in all patients. Additionally, the patients participating in the study assessed their back pain post operatively with the VAS. Pre and post operative measurements of disability and quality of life were retrospectively collected using the Roland Morris Disability Questionnaire (RMDI, range: 0(no disability) -24(high disability)) and EuroQol 5-Domain scale (EQ5D, range: -0.11 (poor quality of life) - 1.0 (perfect health)), respectively. Demographic data, fracture aetiology, pre and postoperative narcotic analgesic usage, and the postoperative incidence of subsequent fractures were collected by chart review. Following the procedure, new compression fractures at levels adjacent to those treated were identified as a result of a symptom burden necessitating imaging and additional intervention.

The diagnosis of osteoporosis was made by dual axial absorptiometry (DXA, Hologic and GE Lunar) scanning. Osteoporosis was defined as a value of bone mineral density (BMD) 2.5 standard deviations or more below the young adult mean (T score < -2.5) [5]. Osteopenia (decreased bone mass) was defined as a value of BMD of more than one standard deviation below the mean for a young adult, but less than 2.5 standard deviations below this value (T- score < -1 and > -2.5).

Pre- and post-operative pain, function, quality of life and narcotic usage were analyzed using paired t-tests.

3. RESULTS

Of 304 eligible patients having undergone kyphoplasty during the designated period, 203 completed assessments (response rate: 64%). The mean age was 75±11 years (median: 77 years, range: 37-94 years). There were 161 (79%) females and 42 (21%) males. A total of 288 fractures were treated with 203 procedures (128 single-level, 40 two-level, 24 three-level, and 2 four-level procedures). The aetiology of vertebral body compression fractures treated included osteoporosis (n=105, 52%), non-osteoporotic trauma (n=40, 20%), multiple myeloma and vertebral metastatic disease (n=9, 4%) (Table 1). Confirmation of aetiology was unavailable for the remainder of patients (n=49, 24%). 79 patients (39%) had lumbar vertebral fractures, 85 (42%) had thoracic vertebral fractures and 23 (11%) had both lumbar

and thoracic vertebral fractures (Table 1). The mean follow-up period was 730±401 days, (median: 715 days, range: 17-1,472 days).

Table 1. Demographic information on patient cohort

Sex		
Female	161 (79%)	
Male	42 (21%)	
Type of fracture		
Osteoporosis	105 (52%)	
Non-osteoporotic	40 (20%)	
Trauma	9 (4%)	
Cancer	49 (24%)	
Unknown		
Mean age at surgery	75±11 years	
Age range	37-94 years	
Mean follow up	730±401 days	
Narcotic use		
Pre Op	121 (63%)	
Post Op	32 (17%)*	* <i>P</i> < .001
Number of levels treated		
1	128 (62%)	
2	40 (20%)	
3	24 (12%)	
4	2 (1%)	
Unavailable	9 (4%)	
Anatomic levels treated		
Thoracic	85 (42%)	
Lumbar	79 (39%)	
Thoracic and lumbar	23 (11%)	
Unavailable	16 (8%)	

The prospectively collected mean pre-operative VAS was 9.0±1.3 (median: 10, range: 5-10), while the post-operative mean was 2.4±2.6 (median: 2, range: 0-10) (*P* < 0.0001) (Fig. 1).

The mean pre-operative RMDI was 13.3±7.0 (median: 13, range: 1-48) while post-operative mean was 4.8±5.6 (median: 3, range: 0-23) (*P* < .0001) (Fig. 2).

The mean pre-operative EQ5D was 0.308±0.233 (median: 0.312, range: -0.109-0.854). The post-operative mean EQ5D was 0.797±0.0.186 (median: 0.816, range: 0.030-1.000) (*P* < .0001) (Fig. 3).

Results of the evaluations were analyzed by aetiology subgroup, and found to be identical to the overall trend in improvement found in the group as a whole (Fig. 4).

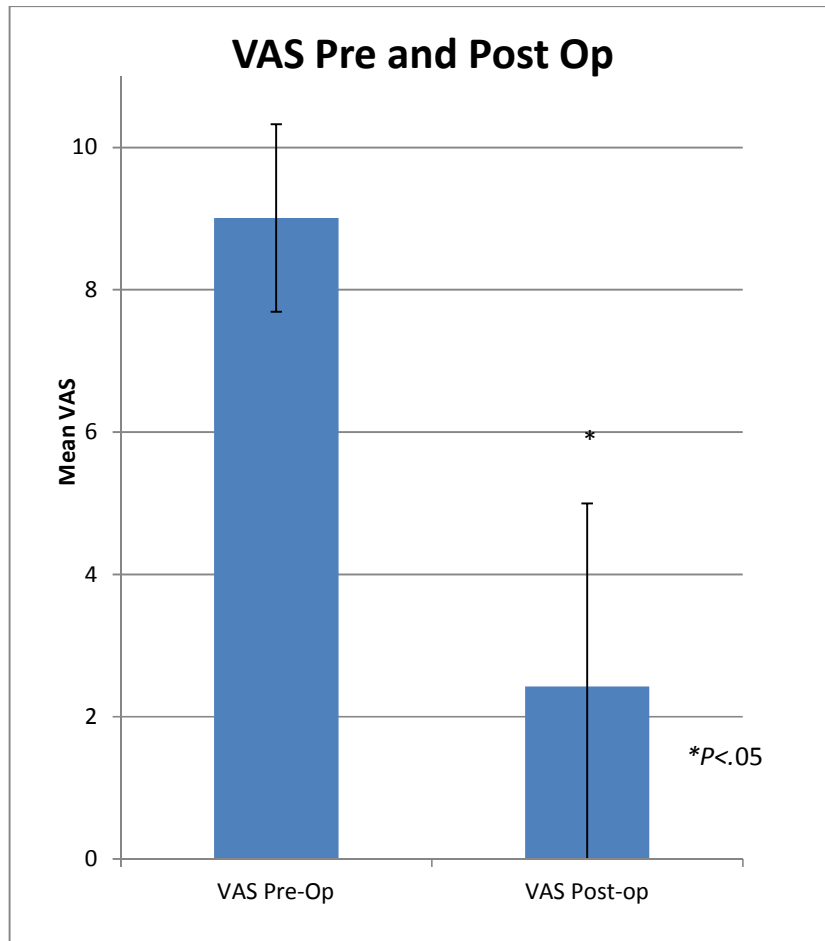


Fig. 1. Mean VAS Pre and post operatively with error bars depicting standard deviation

Narcotic usage information was available for 190 patients included in the study (94%). The pre-operative rate of narcotic use was 63% (n = 121). Post-operative use of narcotics at last follow-up was 17% (n = 32) ($P < .001$) (Fig. 5).

The complication rate was 1.6% for all eligible procedures performed during the assessment time. Cement extravasation represented the sole complication and occurred in five patients. One patient required reoperation in a delayed fashion for removal of cement and neural decompression; pain was relieved following surgery. There were no procedure related infections, cardiac complications, or pneumothoraces.

Thirteen patients (6.8%) were treated for subsequent fractures, eight of which were at levels adjacent to those initially treated (4.2%). The mean time between surgeries was 461 ± 691 days (median: 91 days, range: 21-2,156 days).

4. DISCUSSION

The worldwide incidence of VCF is 1 in 3 women and 1 in 8 men over 50 years of age [1]. Osteoporosis is the most common condition associated with painful vertebral body compression fractures, resulting in over 500,000 fractures in the United States in 2005 [6]. According to the report of the U.S. Surgeon General, in 2004, osteoporosis-related fractures resulted in more than 432,000 hospital admissions, almost 2.5 million medical office visits, and about 180,000 nursing home admissions [5]. The mean length of stay for management of a VCF was 10.1 days with an average hospital charge of \$12,300 [1]. The total United States health care bill associated with lumbar spine fractures in 2007 exceeded 1 billion dollars [6] and it is projected that by 2025, there will be over 3 million osteoporosis-related fractures, with health-related costs of \$25.3 billion per year [7]. Our patients treated with

kyphoplasty were discharged the same day or the following day. Any reduction in length of hospital stay offers significant healthcare cost savings.

In addition to pain, there are many factors associated with osteoporotic vertebral body compression fractures that threaten quality of life. Compression of the thoracic spine reduces thoracic volume and can inhibit pulmonary function and compression of the abdomen may lead to decreased appetite and bladder incontinence [8]. Chronic pain and dysfunction can lead to sleep disorders and depression, and decreased activity fosters additional bone loss [9,10]. Increased mortality has been described following osteoporotic fragility fractures [11]. The mortality rate following a VCF increases 23-34%

[7,11,12]. In a review, Mc Girt et al. found level II and III evidence that kyphoplasty resulted in greater improvement of daily activities, physical function and pain relief when compared to optimal medical management for osteoporotic VCF by six months after intervention [13]. Our patients experienced a sustained reduction in pain with a mean pre-operative VAS of 9.0 and a mean postoperative VAS of 2.4; the mean disability index (RMDI) was reduced from a mean of 13.3 pre-operatively to 4.8 following kyphoplasty, and the mean pre-operative EQ5D was 0.308, improved to 0.797 post-operatively. The reduction in narcotic usage alone would be expected to improve quality of life. Pharmacodynamic changes occur and comorbidities often result in polypharmacy in the elderly; they are at a greater risk for opioid side effects [14].

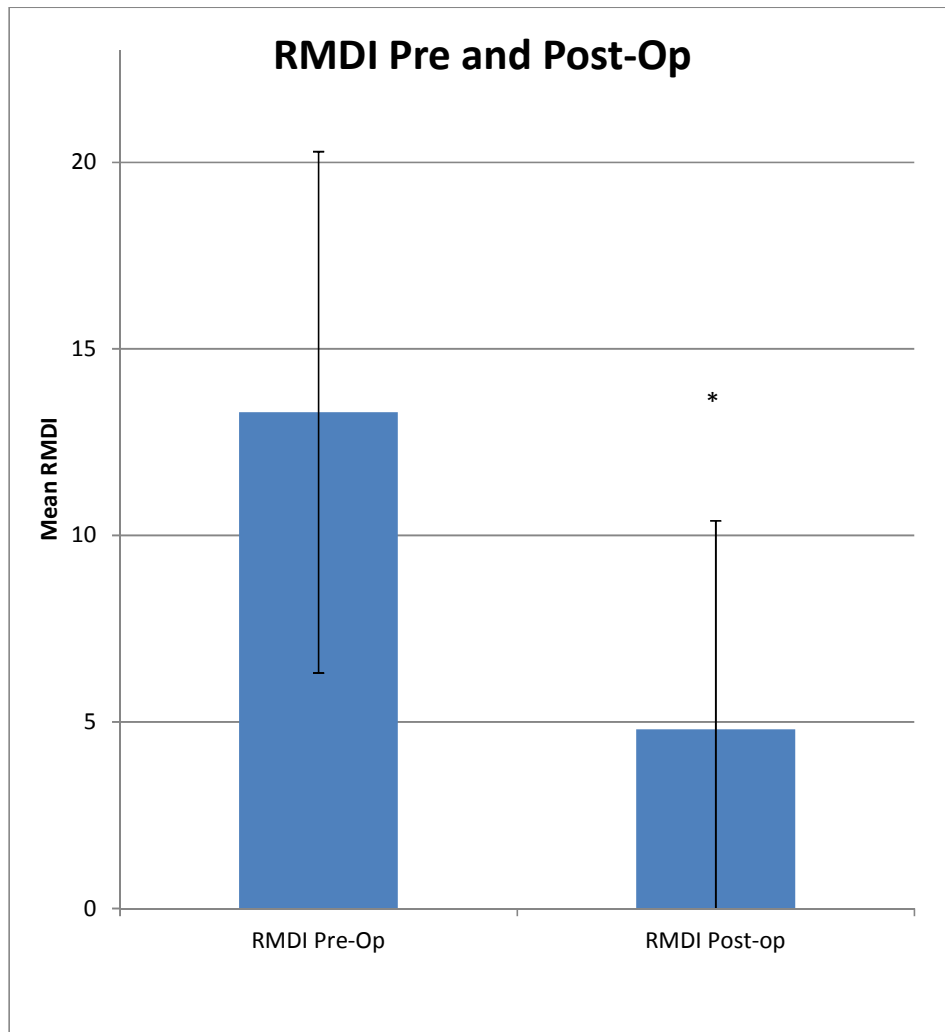


Fig. 2. Mean RMDI Pre and post operatively with error bars depicting standard deviation

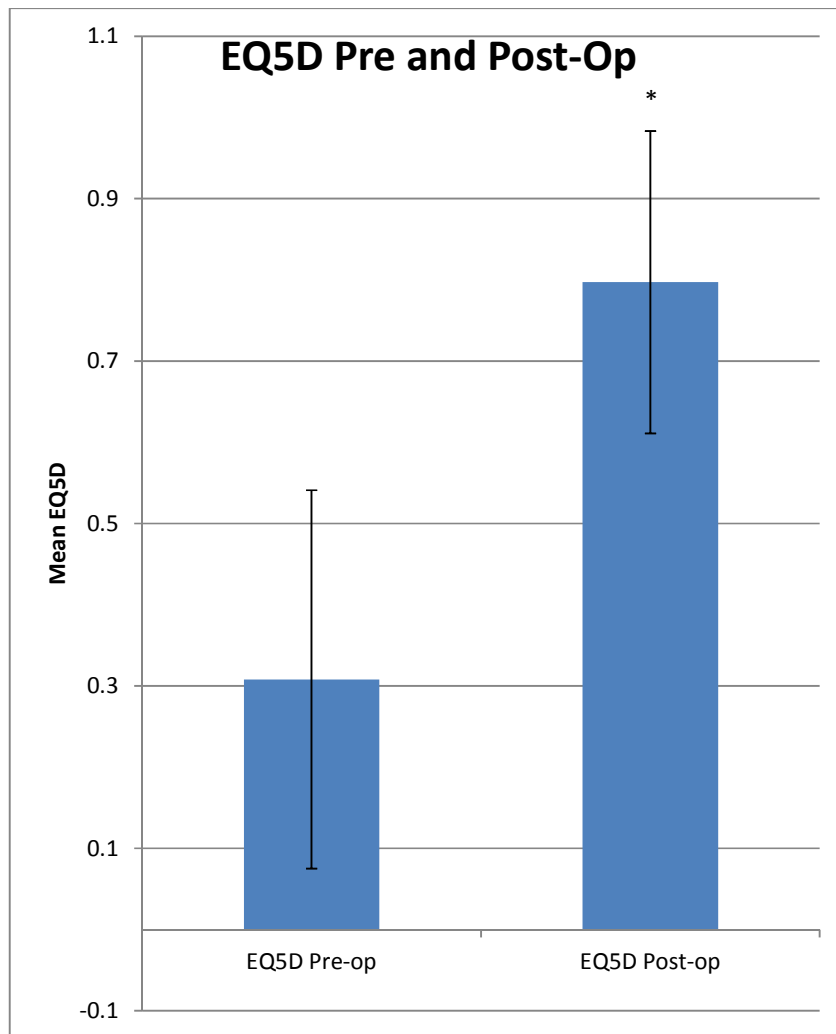


Fig. 3. Mean EQ5D Pre and post operatively with error bars depicting standard deviation

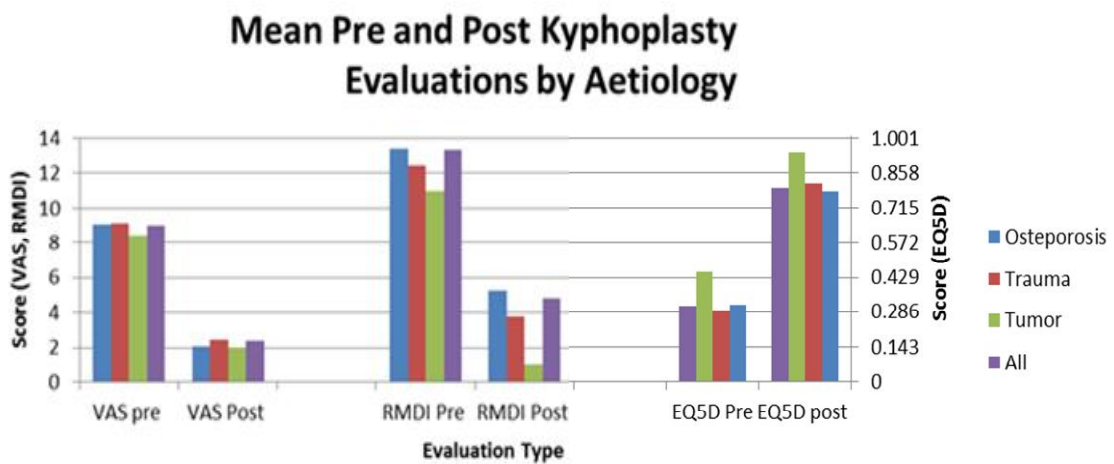


Fig. 4. Mean pre and post kyphoplasty evaluations by aetiology

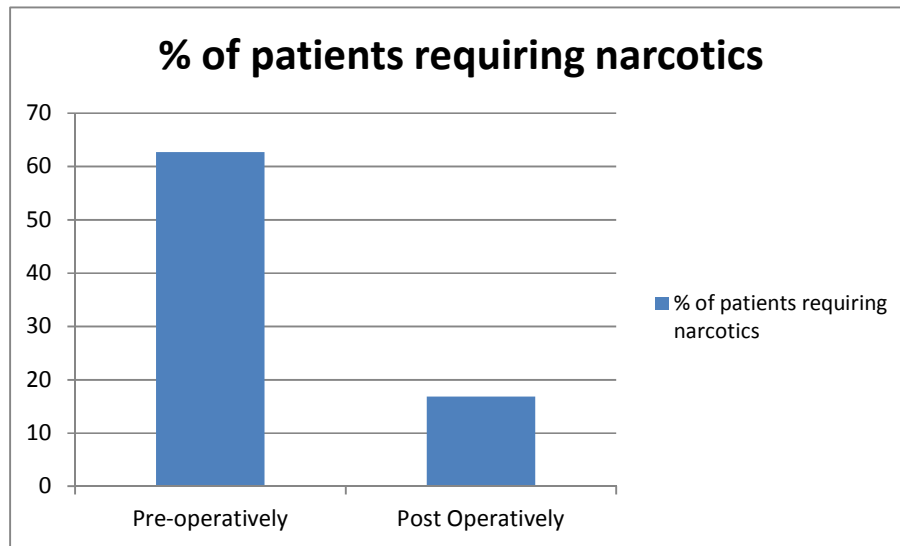


Fig. 5. Percentage of patients receiving narcotics pre and post-operatively

A patient with a thoracic compression fracture typically develops kyphosis. The anterior vertebral body compression shifts the center of gravity forward creating a large bending moment. Increased forces on the posterior musculature and ligaments then result in compressive stress. Adjacent vertebral fractures may follow with further kyphosis and increased pain [15,16]. As with the treatment of any fracture, four general principles of treatment are applied: reduction of the fracture to restore anatomic alignment, stabilization by fixation, preservation of blood supply, and early and safe mobilization [17].

Conservative measures such as bed rest, analgesics and bracing do not restore anatomic alignment nor do they improve long term function. Timely repair of these fractures is indicated for effective treatment and to prevent complications associated with inactivity in the elderly. The consequences of inactivity in this population may be devastating and include deconditioning with loss of bone, muscle and body mass; orthostatic intolerance with an increased risk of falls [9]; increased risk of deep venous thrombosis, reduced calorie intake; depressed mood and social isolation [18]. Bed rest will lead to continued, if not accelerated bone loss at a rate of up to 2% per week and weight bearing is an important step toward halting or slowing progressive bone loss [16,19-22].

Surgical management may include instrumented fusion, vertebroplasty, or balloon kyphoplasty. Open surgical procedures, including decompression and instrumented fusions, are invasive,

painful, and require hospitalization, postoperative rehabilitation, and osteopenic bone leads to poor outcomes [23]. First introduced in the U.S. in 1993, vertebroplasty uses a high-pressure percutaneous injection of polymethyl methacrylate for stabilizing a painful VCF [24,25]. Balloon kyphoplasty was introduced in 1997 and uses a low pressure injection, thereby reducing the risk of cement leakage [26]. Balloon inflation is intended to restore vertebral height and allow for the low pressure injection. Both kyphoplasty and vertebroplasty can provide immediate pain relief and allow for an early return to activity. Both procedures allow for bone biopsies for pathological analysis. Additionally, kyphoplasty has been shown to be safe and effective in the correction of non-osteoporotic fractures of the thoracolumbar junction in young patients, with long-term stability [27].

Potential complications of vertebroplasty and kyphoplasty include extravasation of cement resulting in neural compression, pulmonary embolization, infection, bleeding, and pneumothorax [28]. The reported rate of cement extravasation remains lower for kyphoplasty (7-33%) when compared with vertebroplasty (9-47%) [29]. Our procedure-related complication rate was 1.6% with cement extravasation occurring in five patients, one of whom required surgical decompression (open re-operation rate of 0.3%).

Additional fractures have been reported following vertebral augmentation procedures but the causal relationship between the procedure and

subsequent adjacent vertebral fractures remains unproven as patients with osteoporosis who do not undergo surgery can also develop additional fractures [15,18,30-38]. Following percutaneous procedures, an increased rate of fracture above that of the natural history of the disease has not been demonstrated [1,39,40]. The incidence of fracture following vertebroplasty has been reported to be about 20% within 1 year [32]. This may represent the natural history of subsequent fracture in untreated osteopenic patients. Following an initial fracture, osteoporotic patients not treated with systemic osteoporotic therapy develop an additional fracture at twice the rate (20%) of those on anti-resorptive medication. [18,21,40].

Regardless of bone mineral density, age and other clinical risk factors, vertebral fractures confirmed radiographically, even if they are completely asymptomatic, signal impaired bone quality and strongly predict new vertebral and other fractures. The presence of a single vertebral fracture increases the risk of subsequent vertebral fractures 5-fold and the risk of hip and other fractures 2 to 3 fold [9].

In a matched prospective study, Komp et al. reported a six-month adjacent fracture rate of 37% in patients treated with balloon kyphoplasty and 65% in conservatively treated patients [16].

In cadaveric studies, Berlemann et al. described a “stress riser” effect weakening a functional spinal unit (2 vertebral bodies and the intervening disc), whereby increased stiffness of the treated vertebra alters the load transfer to the non-cemented adjacent level [39]. Although increased stiffness may theoretically increase the risk of an adjacent fracture by creating a “stress riser”, the kyphotic deformity itself contributes to the compressive effects. Correction of the kyphosis reduces the compressive forces by reducing the bending moment [41]. Our results demonstrate a lower incidence of adjacent fractures in patients treated with kyphoplasty (4.2%), compared to published rates in untreated patients with osteoporotic fractures (20%). In the current case series, complication rates were low, as were adjacent fracture rates. This may result from a reduction in bending moment, primarily through restoration of anterior vertebral body height, resulting in the lower incidence of adjacent fractures when compared to published rates in untreated patients with osteoporotic fractures. While we do not provide radiological confirmation of vertebral body height restoration in this series,

it has been demonstrated in previous kyphoplasty series [42].

Another clinically relevant finding is the striking 46% reduction in narcotic usage after kyphoplasty. The typical kyphoplasty candidate is elderly, making narcotic reduction and freedom important for improving mental status, limiting adverse side effects, and reducing polypharmacy in these often complex patients.

There are several limitations to our study. While the VAS was collected prospectively, the RMDI and EQ5D were collected retrospectively, introducing the possibility of recall bias. However, the rate of improvement in RMDI and EQ5D after kyphoplasty follows the same trend as the VAS results, which were collected prospectively. Furthermore, no patient had a worse score post-operatively in any of the three domains, supporting the strength of this trend. Although some of the data were collected retrospectively, they still capture patients’ perception of pre-operative functioning and assess their satisfaction with the procedure, a key consideration in patient-centered outcomes. Despite the retrospective collection, the data accurately reflect patients’ improvement in quality of life and functional outcome following kyphoplasty. Multiple VCF aetiologies were included in this group, creating a heterogeneous group. However, the results were identical when evaluated as subgroups by aetiology, supporting the efficacy of kyphoplasty across a wide range of pathologies. Additionally, the adjacent fractures captured represent only those leading to symptoms warranting further evaluation. This may have resulted in an underestimate of fractures. However, this estimate was low (4.1%) and represents the clinically relevant fractures sustained by patients. As this was a cross-sectional study, patient follow up was completed at specific catchment points, March, 2007 and September, 2012, rather than at a standard time period post-procedure and a wide range of follow up was represented (17-1,472 days). While this may limit reproducibility, it enhances generalizability and demonstrates that the results found in kyphoplasty are rapidly effective and also durable. The follow up range confirms both immediate and sustained pain relief. Although a well-designed blinded randomized prospective placebo-controlled trial would provide the highest quality of evidence available, it is not necessary nor ethical to further withhold treatment from a patient in severe pain who fails conservative therapy.

5. CONCLUSION

Our patients undergoing kyphoplasty during this nearly ten-year period experienced significant reduction of pain, improved quality of life, and reduced disability. Benefits were rapid and sustained. Postoperative pain relief was substantial and narcotic usage was drastically reduced, especially important in the elderly population. Complication rates were low and the incidence of adjacent fractures was lower than published rates in untreated patients with osteoporotic fractures, presumably because of the reduced bending moment resulting from reduction of the fractures. We believe that timely repair of these fractures is indicated, not only to prevent complications associated with inactivity but also for effective treatment of severe pain in the acute setting. Our results strongly support the use of kyphoplasty as a safe, effective and durable treatment for immediate and lasting benefits to patients with back pain resulting from VCF.

CONSENT

All authors declare that 'written informed consent was obtained from the approved parties for publication of this case report and accompanying images.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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