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ORIGINAL INVESTIGATION / ÖZGÜN ARAŞTIRMA

Comparison of the Cement Volume Delivered During Percutaneous Vertebroplasty/Kyphoplasty Interventions with Volumes Calculated on Postoperative Radiological Images: A Clinical Experience

Perkütan Vertebroplasti/Kifoplasti Girişimleri Sırasında İletilen Çimento Hacimlerinin Postoperatif Radyolojik Görüntülere Göre Hesaplanan Hacimlerle Karşılaştırılması: 67 Müdahalede Klinik Deneyim

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ABSTRACT

Objective: Although many researchers have investigated the cement volume delivered during vertebroplasty (VP) and kyphoplasty (KP) as a factor affecting outcomes, to the best of our knowledge, none of these investigations compared this cement volume with those of postoperative radiological images. This study aims to compare the cement volume delivered during VP and KP with the volumes calculated on postoperative radiological images to assess their level of compatibility and reflection for the actual quantity of cement.

Method: In a single-center, retrospective observational study, clinical data and radiological images of a total of 49 patients, among whom 28 and 21 underwent VP and KP, respectively, for a total of 67 vertebral levels, were examined. The median age (interquartile range) was 70 (17) years; 39 (79.6%) patients were females and 10 (20.4%) patients were males. Data were analyzed and differences in the volumes were assessed.

Results: For the overall volume, there was no statistically significant difference (One sample t-test, $p > 0.05$). The KP interventions had a significantly higher mean volume difference when compared to the VP interventions (Two samples t-test, $p < 0.01$, $d = 0.785$).

Conclusion: Our results showed consistency in the overall volumes of cement; however, KP interventions had a significantly higher mean volume difference.

Keywords: Kyphoplasty, polymethyl methacrylate, spontaneous fractures, vertebroplasty, volume

ÖZ

Amaç: Birçok araştırmacı vertebroplasti (VP) ve kifoplasti (KP) müdahaleleri sırasında verilen sement hacmini sonuçları etkileyen bir faktör olarak incelemiş olsa da, bilgimiz dahilinde hiçbiri postoperatif radyolojik görüntülerle karşılaştırmamıştır. Bu çalışmada, gerçek çimento miktarı için uyumluluk derecelerini değerlendirmek amacıyla bu hacimleri karşılaştırmak amaçlanmıştır.

Yöntem: Tek merkezli, retrospektif ve gözlemsel olan çalışmada, 67 omurga seviyesine 28'ine VP ve 21'ine KP prosedürü uygulanan toplam 49 hastaya ait klinik veriler ve radyolojik görüntüler incelendi. Ortanca yaş (çeyrekler arası aralık) 70 (17) yıl idi. Otuz dokuz (%79,6) hasta kadın, 10 (%20,4) hasta erkekti. Veriler istatistiksel olarak analiz edildi ve hacim farklılıkları değerlendirildi.

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Bulgular: Toplam hacim farklılıkları için istatistiksel fark yoktu (tek örneklem t-testi, $p > 0.05$). KP müdahalelerinin ise VP müdahalelerine kıyasla ortalama hacim farkı daha yüksekti (İki örneklem t-testi, $p < 0.01$, $d = 0.785$).

Sonuç: Sonuçlarımız toplam çimento hacimleri arasında tutarlılık gösterdi; bununla birlikte, KP müdahalelerinin hacim farkı anlamlı olarak daha yüksekti.

Anahtar kelimeler: Kifoplasti, polimetil metakrilat, spontan kırıklar, vertebroplasti, hacim

INTRODUCTION

In 27 countries of the European Union, 27 million people were estimated to have osteoporosis, which gave rise to 3.5 million new fractures, including 520,000 vertebral fractures [1]. In Europe, the total economic burden of these fragility fractures was estimated to be 37 billion euros and, in the United States, the annual cost of osteoporosis and fractures was estimated to be 16-22 billion dollars [1,2]. Vertebral compression fractures (VCF) form the leading fracture type caused by osteoporosis, with a 27% ratio, apart from the unclassified "other" fractures, which constitute 33% [3].

Percutaneous vertebroplasty (VP) and kyphoplasty (KP) are two common minimally invasive procedures performed, which provide significant pain relief for VCFs [4]. VP is an intervention that involves the injection of cement percutaneously into the body of the fractured vertebrae through its pedicle. KP is a similar intervention, in which, prior to cement injection, a balloon is introduced and inflated to restore the vertebral height and create a cavity [5].

The most common type of cement used for VP and KP is polymethyl methacrylate (PMMA) [6]. The volume and distribution of the cement affect the outcomes significantly [7].

There are several reasons suggesting a difference between the cement volumes delivered during VP and KP interventions and those of radiological images. The first and most obvious one is the cement leakage. Although PMMA leakage was reported in 30%-80% of the cases, with the paravertebral soft tissue being the most frequent location, a clinical manifestation was rarely present [8-10]. Another reason for the volume difference, which has not been comprehensively investigated, is the volumetric shrinkage of PMMA during the curation. The net volumetric shrinkage ratio of PMMA is reported within the range of 3%-21% [11-13]. Furthermore, the calculations for the volumes also have an error margin.

Although many studies included the volume of cement delivered during VP or KP interventions as a factor affecting outcomes, none of these studies compared it with the volumes calculated via postoperative radiological images [14-17]. Even if one makes an assumption that the volumes of cement delivered would match those derived from postoperative radiological images for reasons, such as cement leakage, shrinkage, and calculation errors, the volumes of cement delivered during the interventions might differ from the postoperative volumes calculated from radiological images.

In this study, we compared the volumes of cement delivered during VP and KP interventions in our institution with the volumes calculated on radiological images after the procedure and assessed its level of reflection for the actual quantity of cement occupying the vertebral body.

METHOD

This study was planned as a single-center, retrospective observational study. The study was conducted at the Research and Application Centre of Trakya University, Edirne, Turkey.

Study Population

Data on patients who underwent VP or KP in our institution between January 01, 2010, and December 31, 2019, were reviewed retrospectively. Radiological images of the patients were gathered via Picture Archiving and Communication System workstation (Sectra ©2018 PACS IDS7 20.2, Linköping, Sweden).

Inclusion Criteria

The predefined inclusion criteria were: 1) Acute VCF confirmed by bone marrow edema on magnetic resonance imaging; 2) Back pain related to the location of the fracture; 3) VP or KP intervention; 4) Complete documentation on patient's data.

The predefined exclusion criteria were: 1) Chronic VCF; 2) Open surgery interventions; 3) Missing or incomplete documentation.

Data Acquirement

We recorded the data extracted from the patients' written and electronic medical records in a digital database. We recorded the patients' age, gender, trauma history, time to the intervention, level of the involved vertebra, the volume of PMMA cement delivered, the volume of PMMA cement calculated from radiological images, operation duration, and length of stay at the hospital.

Definitions

To extract demographic, clinical, and outcome data, patients' electronic and written records were screened. We divided the patients into three groups according to their trauma history: No history of trauma such as simple trauma, including falling and high energy trauma, including traffic accidents was noted. The time of the intervention was recorded in minutes and the length of stay in the hospital in days. We interpreted each level of vertebrae intervened by either VP or KP as a separate event for volume calculations. Volumes of PMMA delivered were recorded as noted in the patient records. Volumes of PMMA were calculated on two planned postoperative radiographs using the coronal, axial, and sagittal measurements of cement according to the ABC/2 formula (Figure 1) [18]. The volume differences were calculated by subtracting the latter.

Operative Technique

Local anesthetic infiltration combined with conscious sedation was the primary choice for pain relief during the procedures. When indicated, deep sedation or general anesthesia was administered. A unilateral transpedicular approach was used when applicable. Patients were placed in a prone position, and under C-arm guidance, a working cannula was placed using a Kirschner wire through the pedicle, trespassing up to three-quarters of the vertebral body. For the VP procedures, after confirmation of the correct position of the working cannula, PMMA was prepared and injected using bone filler cannulas of 1.5 mL [19].

For the KP procedures, prior to the cement injection, a balloon was inserted and filled with 3-5 mL of contrast agent under C-arm guidance and pressure monitoring with an in-built manometer. The amount of cement injected was decided by the surgeon on a case-by-case basis. The basic steps of a KP procedure are summarized in C-arm images in Figure 2.

Statistical Analysis

Shapiro-Wilk test was used to assess the normality of the continuous variables. Descriptive statistics for the continuous variables were expressed as mean ± standard deviation or median (interquartile range), depending on the normality of the distribution. T-tests, Mann-Whitney U test, and chi-square tests were performed where appropriate. A p-value less than 0.05 was considered statistically significant. Statistical analyses were conducted using Jamovi software version 1.2 [20].

A priori power analysis was done using the parameters α = 0.05, power (1-β) = 0.80, and effect size = 0.5 (medium) and the sample size was determined as 34. Moreover, a post hoc power analysis was done using the parameters α = 0.05 and effect size = 0. 5 (medium) and, sample size = 67, and the post hoc power (1-β) was calculated as 0.98. G*Power software version 3.1 was used for power analysis [21].

Ethics and Informed Consent

All procedures performed in this study were done according to the ethical standards of the institutional research committee and the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All patients had provided written informed consent for the anonymous publication of their medical information. The Ethics Committee of Trakya University approved the study (decision number: TUTF-BAEK 2020/172).

RESULTS

We identified a total of 49 patients who were intervened on 67 levels whose records met the inclusion criteria. The median age (interquartile range) was 70 (17) years; 39

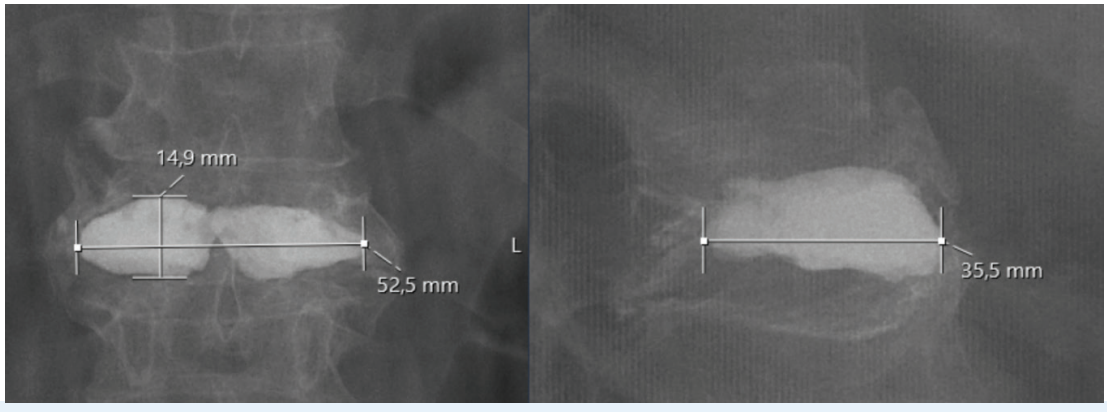

Figure 1. Measurements on postoperative images

(79.6%) patients were females, while 10 (20.4%) patients were males. Thirty-one (63.3%) patients had no trauma history, 11 (22.4%) had simple traumas, such as falling, and 7 (14.3) had high energy traumas, such as traffic accidents.

The median time to the intervention was 21 (30) days and the median length of stay in the hospital was 4 (4) days. The median intervention time was 60 (15) minutes. The descriptive statistics are summarized in Table 1. The most frequently intervened levels were L1 (25.4%), L2 (19.4%), and Th12 (16.4%); other levels altogether constitute 39% of the interventions (Table 2).

Shapiro-Wilk test and descriptive plots showed that the volume differences were distributed normally ($p > 0.05$). For the overall volume differences, there was no statistical difference (One sample t-test, $p > 0.05$). The mean volume difference for KP interventions was 1.41 ± 2.4 cc and the mean volume difference for VP interventions was -0.29 ± 2.0 cc. There was a statistical difference between these intervention groups, with KP interventions having a significantly higher mean volume difference (Two samples t-test, $p < 0.01$, $d = 0.785$).

DISCUSSION

Our findings showed no significant difference between the cement volumes delivered and calculated via radiological images ($p > 0.05$). However, further investigation depicted that the KP interventions had a significantly higher mean

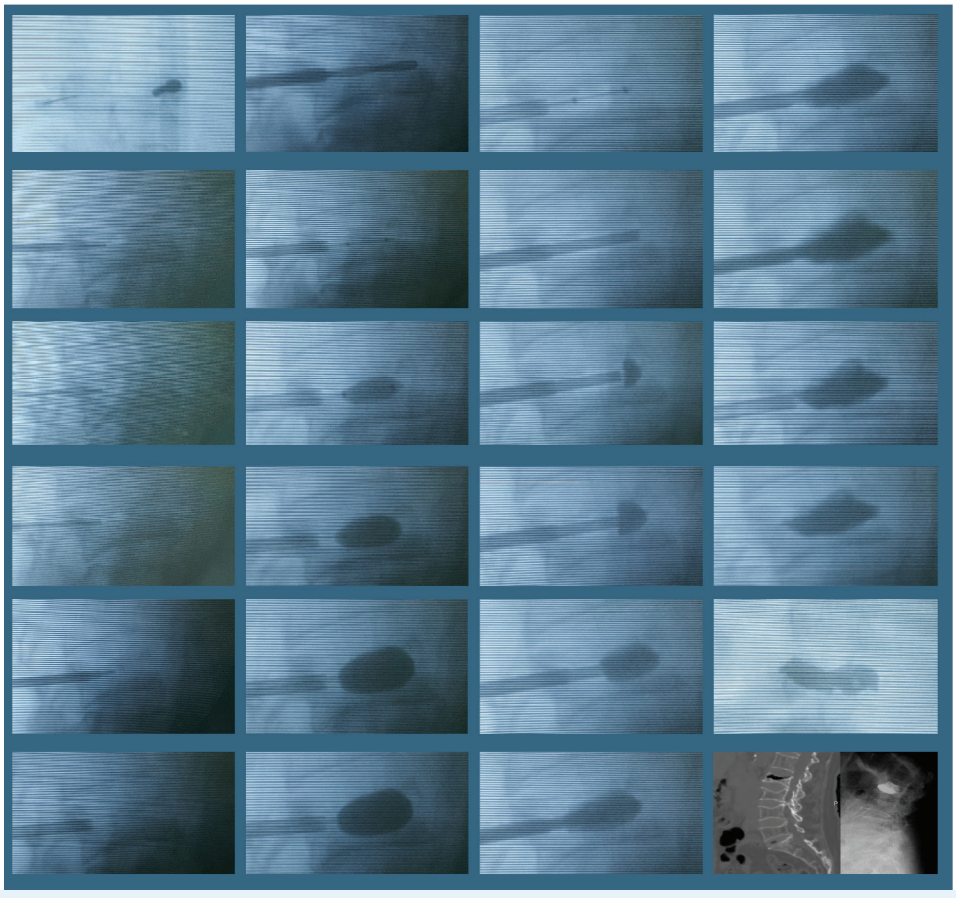

Figure 2. Basic steps of a kyphoplasty procedure

Table 1. Descriptive statistics

	Age	Time (onset-intervention)	Operation duration (minutes)	Hospital stay (days)
Median (25th percentile-75th percentile)	70 (61.0 - 78.0)	21 (10.0 - 40.0)	60 (60.0 - 75.0)	4 (3.0 - 7.0)
Skewness	-1.23	1.56	2.44	2.34
Shapiro-Wilk p value	**< 0.01**	**< 0.001**	**< 0.001**	**< 0.001**

Table 2. Frequencies of intervened levels			
Levels	**Counts**	**% of total**	**Cumulative %**
T4	1	1.5	1.5
T5	1	1.5	3.0
T6	1	1.5	4.5
T7	1	1.5	6.0
T9	1	1.5	7,5
T10	2	3.0	10,4
T11	4	6.0	16,4
T12	11	16.4	32,8
L1	17	25.4	58,2
L2	13	19.4	77,6
L3	9	13.4	91,0
L4	4	6.0	97,0
L5	2	3.0	100,0

volume difference when compared with the VP interventions. We suppose that the main reason for this deviation was the more ellipsoid spread of the cement in KP due to the cavity-forming structure of the process.

Due to the high comorbidity frequency in the risky population in VCFs, surgical intervention was not the treatment of choice, since it is reserved only for patients with neurological deficits or severe deformities [5]. Due to its first description by Galibert and Déramond as a treatment option for vertebral angioma, minimally invasive procedures, such as VP and KP, had been increasingly used as interventions for VCFs [22-24].

In 2009, two randomized controlled trials advocating that there was no significant difference between the outcomes of these interventions compared to sham surgery had a remarkable negative impact on the trend [25,26]. However, many researchers criticized these trials for their methodological flaws, such as the inclusion of chronic fracture cases of up to 12 months, the underpowered nature of the study, and the discrepancy of sample size [27-29]. Numerous studies questioned various aspects of the topic, reporting mixed results [30].

PMMA, also known as acrylic glass, is the most frequently used cement type for VP and KP procedures; other types are composite bone cement, biodegradable bone cement, and calcium phosphate cement [6]. The volume and distribution of the cement have a substantial impact on the outcomes, such as stiffening of the fractured vertebrae, stabilization, and pain reduction [7]. In a retrospective study, which includes the data of a total of 220 KP procedures, He et al. [31] evaluated the effects of the volume and distribution of bone cement on pain relief of the patients. They emphasized the necessity of exploring a new way to measure the cement distribution using X-rays [31]. Although some studies investigated the effects of volume and distribution pattern of the cement, none have focused on the accuracy of the volume of the cement injected by comparing it with the calculations on postoperative radiological images [31-34].

The volumes of the cement delivered during VP or KP interventions were investigated as a factor affecting outcomes [14-17]. Nevertheless, no study among them questioned their relations with postoperative cement volumes. In this study, we compared the overall volumes of cement delivered during the procedures with postoperative volumes and further assessed them for each type of intervention.

Study Limitations

There are several limitations to our study. Despite the high level of power evaluated by our power analysis, the sample size and number of measurements were small. Additionally, for more accurate and fast measurement of volume, an automated software-assisted method could be used.

CONCLUSION

Our findings showed consistency between the overall volumes of cement delivered and calculated via radiological images; nonetheless, KP interventions had a significantly higher mean volume difference compared with VP interventions. Larger sample-sized repeated measurement by multiple raters and the utility of more sophisticated volume calculation methods, such as software-assisted ones, may provide more insight on the topic.

Ethics

Ethics Committee Approval: The Ethics Committee of Trakya University approved the study (decision number: TUTF-BAEK 2020/172).

Informed Consent: All patients had provided written informed consent for the anonymous publication of their medical information.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: A.T.A., B.A., Design: A.T.A., B.A., Data Collection or Processing: A.T.A., B.A., Analysis or Interpretation: A.T.A., B.A.,Literature Search: A.T.A., B.A., Writing: A.T.A., B.A.

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REFERENCES

1. Hernlund E, Svedbom A, Ivergård M, et al. Osteoporosis in the European Union: medical management, epidemiology and economic burden. A report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA). Arch Osteoporos. 2013;8:136. doi:10.1007/s11657-013-0136-1.
2. Blume SW, Curtis JR. Medical costs of osteoporosis in the elderly Medicare population. Osteoporos Int. 2011;22:1835-44. doi:10.1007/s00198-010-1419-7.
3. 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;22:465-75. doi:10.1359/jbmr.061113.
4. Burton AW, Mendoza T, Gebhardt R, et al. Vertebral compression fracture treatment with vertebroplasty and kyphoplasty: experience in 407 patients with 1,156 fractures in a tertiary cancer center. Pain Med. 2011;12:1750-7. doi:10.1111/j.1526-4637.2011.01278.x.
5. Goldstein CL, Chutkan NB, Choma TJ, Orr RD. Management of the Elderly With Vertebral Compression Fractures. Neurosurgery. 2015;77 (Suppl 4):S33-45. doi:10.1227/NEU.0000000000000947.
6. Yang H, Zou J. Filling materials used in kyphoplasty and vertebroplasty for vertebral compression fracture: a literature review. Artif Cells Blood Substit Immobil Biotechnol. 2011;39:87-91. doi:10.3109/10731199.2010.503319.
7. Liebschner MA, Rosenberg WS, Keaveny TM. Effects of bone cement volume and distribution on vertebral stiffness after vertebroplasty. Spine. 2001;26:1547-54. doi:10.1097/00007632-200107150-00009.
8. Jay B, Ahn SH. Vertebroplasty. Semin Intervent Radiol. 2013;30:297-306. doi:10.1055/s-0033-1353483.
9. Padovani B, Kasriel O, Brunner P, Peretti-Viton P. Pulmonary embolism caused by acrylic cement: a rare complication of percutaneous vertebroplasty. AJNR Am J Neuroradiol. 1999;20:375-7.
10. Cotten A, Dewatre F, Cortet B, et al. Percutaneous vertebroplasty for osteolytic metastases and myeloma: effects of the percentage of lesion filling and the leakage of methyl methacrylate at clinical follow-up. Radiology. 1996;200(2):525-530. doi:10.1148/radiology.200.2.8685351.
11. Darvell BW. Chapter 5 - Acrylic. In: Darvell BW, editor. Materials science for dentistry. Tenth edition. Oxford: Woodhead Publishing; 2018. p. 121-42.
12. Turagam N, Mudrakola DP. Effect of micro-additions of carbon nanotubes to polymethylmethacrylate on reduction in polymerization shrinkage. J Prosthodont. 2013;22:105-11. doi:10.1111/j.1532-849X.2012.00917.x.
13. Hill RG. 10 - Biomedical polymers. In: Hench LL, Jones JR, editors. Biomaterials, artificial organs and tissue engineering. Boca Raton, Cambridge: CRC Press; Woodhead; 2005. p. 97-106.
14. Zhou X, Meng X, Zhu H, Zhu Y, Yuan W. Early versus late percutaneous kyphoplasty for treating osteoporotic vertebral compression fracture: a retrospective study. Clin Neurol Neurosurg. 2019;180:101-5. doi:10.1016/j.clineuro.2019.03.029.
15. Zhan Y, Jiang J, Liao H, Tan H, Yang K. Risk factors for cement leakage after vertebroplasty or kyphoplasty: a meta-analysis of published evidence. World Neurosurg. 2017;101:633-42. doi:10.1016/j.wneu.2017.01.124.
16. Yin P, Ji Q, Wang Y, et al. Percutaneous kyphoplasty for osteoporotic vertebral compression fractures via unilateral versus bilateral approach: a meta-analysis. J Clin Neurosci. 2019;59:146-54. doi:10.1016/j.jocn.2018.10.112.
17. Wang P, Li J, Song Z, Peng Z, Wang G. Utilization of the directional balloon technique to improve the effectiveness of percutaneous kyphoplasty in the treatment of osteoporotic vertebral compression fractures and reduction of bone cement leakage. Medicine (Baltimore). 2019;98:e15272. doi:10.1097/MD.0000000000015272.
18. Leary OP, Merck LH, Yeatts SD, Pan I, Liu DD, Harder TJ, et al. Computer-assisted measurement of traumatic brain hemorrhage volume is more predictive of functional outcome and mortality than standard ABC/2 method: an analysis of CT imaging data from the ProTECTIII trial. J Neurotrauma. 2020. doi:10.1089/neu.2020.7209.
19. Becker S, Ogon M, eds. Balloon Kyphoplasty. Vienna: Springer-Verlag/Wien; 2008. Interventional procedure guidance. https://books.google.com.tr/books?id=gV41cKBzpRkC.
20. jamovi - Stats. Open. Now. Last Accessed Date: 04.02.2020. Available from: https://www.jamovi.org/. Updated February 4, 2020..
21. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods. 2007;39:175-91. doi:10.3758/BF03193146.
22. Galibert P, Déramond H. La vertébroplastie acrylique percutanée comme traitement des angiomes vertébraux et des affections dolorigènes et fragilisantes du rachis. Chirurgie. 1990;116:326-34; discussion 335.
23. 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;95:1729-36. doi:10.2106/JBJS.K.01649.
24. Cheng J, Muheremu A, Zeng X, Liu L, Liu Y, Chen Y. Percutaneous vertebroplasty vs balloon kyphoplasty in the treatment of newly onset osteoporotic vertebral compression fractures: A retrospective cohort study. Medicine (Baltimore). 2019;98:e14793. doi:10.1097/MD.0000000000014793.
25. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med. 2009;361:557-68. doi:10.1056/NEJMoa0900429.
26. 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. doi:10.1056/NEJMoa0900563.
27. Noonan P. Randomized vertebroplasty trials: bad news or sham news? Am J Neuroradiol. 2009;30:1808-9. doi:10.3174/ajnr.A1875.
28. Bono CM, Heggeness M, Mick C, Resnick D, Watters WC. North American Spine Society: Newly released vertebroplasty randomized controlled trials: a tale of two trials. Spine J. 2010;10:238-40. doi:10.1016/j.spinee.2009.09.007.
29. Clark WA, Diamond TH, McNeil HP, Gonski PN, Schlaphoff GP, Rouse JC. Vertebroplasty for painful acute osteoporotic vertebral fractures: recent Medical Journal of Australia editorial is not relevant to the patient group that we treat with vertebroplasty. Med J Aust. 2010;192:334-7. doi:10.5694/j.1326-5377.2010.tb03533.x.
30. Chandra RV, Maingard J, Asadi H, et al. Vertebroplasty and Kyphoplasty for Osteoporotic Vertebral Fractures: What Are the Latest Data? Am J Neuroradiol. 2018;39:798-806. doi:10.3174/ajnr.A5458.
31. He X, Li H, Meng Y, et al. Percutaneous kyphoplasty evaluated by cement volume and distribution: an analysis of clinical data. Pain Physician. 2016;19:495-506.
32. Liu H, Zhang J, Liang X, et al. Distribution pattern making sense: patients achieve rapider pain relief with confluent rather than separated bilateral cement in percutaneous kyphoplasty for osteoporotic

vertebral compression fractures. World Neurosurg. 2019;126:e1190-6. doi:10.1016/j.wneu.2019.03.063.

33. Niu J, Zhou H, Meng Q, Shi J, Meng B, Yang H. Factors affecting recompression of augmented vertebrae after successful percutaneous balloon kyphoplasty: a retrospective analysis. Acta Radiol. 2015;56:1380-7. doi:10.1177/0284185114556016.

34. Tanigawa N, Komemushi A, Kariya S, et al. Relationship between cement distribution pattern and new compression fracture after percutaneous vertebroplasty. AJR Am J Roentgenol. 2007;189:W348-52. doi:10.2214/AJR.07.2186.