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NYU, Winthrop Hospital, Mineola, NY, USA

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Original Article

Analysis of injected cement volume and clinical outcomes following kyphoplasty for vertebral compression fractures

Mitchell Self[1], James Mooney[2], John Amburgy[2], Bonita Agee[2], Leah Schoel[1], Patrick Pritchard[2], Melissa Chambers[2]

[1]Department of Neurosurgery, School of Medicine, The University of Alabama at Birmingham, [2]Department of Neurosurgery, University of Alabama at Birmingham, Birmingham, Alabama, United States.

E-mail: Mitchell Self - dmself@uab.edu; *James Mooney - jamesmooney@uabmc.edu; John Amburgy - jamburgy@uabmc.edu; Bonita Agee - bagee@uabmc.edu; Leah Schoel - leahschoel@uabmc.edu; Patrick Pritchard - ppritchard@uabmc.edu; Melissa Chambers - mrchambers@uabmc.edu

***Corresponding author:**
James Mooney,
Department of Neurosurgery,
University of Alabama at
Birmingham, Birmingham,
Alabama, United States.

jamesmooney@uabmc.edu

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ABSTRACT

Background: It has been suggested that greater volumes of cement injected during kyphoplasty correlate with improved vertebral body height restoration and kyphotic angulation correction. However, there is little evidence tying cement volume to patient outcomes. Here, we analyzed the association between cement volume and outcome utilizing indices of pain, disability, and quality of life.

Methods: One hundred and thirty-six patients undergoing kyphoplasty were analyzed retrospectively. The total volume of bone cement injected was recorded intraoperatively for each patient; the average total cement volume was 5.44 cc. Pre- and postoperative outcome indices were documented, using the visual analog scale (VAS), Roland-Morris disability index (RMDI), and the EuroQol 5 Dimension instrument (EQ5D). Pearson's correlations and linear regression models were derived for the association of total cement volume with each of the patient outcome measures. This was a retrospective cohort study.

Results: The average change in VAS, RMDI, and EQ5D scores for all patients was −6.8, +8.3, and +0.41, respectively. For VAS, RMDI, and EQ5D improvements, neither Pearson's correlations nor multiple linear regression models revealed a correlation or an association with total cement volume.

Conclusion: For patients undergoing kyphoplasty, outcomes were not associated with the total injected cement volume; all had a significant reduction in pain and most exhibited decreased disability with improved quality of life.

Keywords: Cement volume, Kyphoplasty, Vertebral compression fracture

INTRODUCTION

Many studies have shown the effectiveness of kyphoplasty in restoring vertebral height and relieving pain.[4-6,8] Kyphoplasty involves placing a balloon into the vertebral body and creating a void within that body that can then be filled cement injected under lower pressures, to reduce the risk of cement leakage.[7]

Here, we uniquely correlated cement volumes injected with pain, disability, and quality of life indices in those undergoing percutaneous kyphoplasty for the treatment of vertebral compression fractures.

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MATERIALS AND METHODS

Patient selection

This retrospective series of 136 consecutive patients undergoing kyphoplasty for vertebral compression fractures was approved by an IRB. Two neurosurgeons treated 230 vertebral fractures with kyphoplasty in these 136 patients [Table 1]. All had cement injected bilaterally utilizing an average total cement injected volume of 5.44 cc ± 1.35 cc (range 2–9 cc), and these injection volumes were correlated with outcomes.

Assessment of outcomes

Pain was measured prospectively before and after surgery with the visual analog scale (VAS, range: 0 (none)–10 [worst]), the Roland-Morris disability index (RMDI, range: 0 [no disability]–24 [high disability]), and EuroQol 5 Dimension instrument (EQ5D, range: −0.11 [poor quality of life]–1.0 [perfect health]), respectively. Postoperative evaluations were completed at 2 and 6 weeks after surgery and at specific catchment points: March 2007 and September 2012.

Narcotic use

Pre- and postoperative narcotic usage was recorded from medical records and correlated with total cement volume injected.

Diagnosis compression fractures

The diagnosis of compression fractures was made by preoperative history, physical examination, and correlated with radiographs, computed tomography (CT), magnetic resonance, and/or nuclear bone scan imaging studies. All patients had failed conservative treatment for 4 prior weeks.

Documentation of osteoporosis

The diagnosis of osteoporosis was confirmed on dual axial absorptiometry (DXA, Hologic, and GE Lunar) scanning.

Surgical technique

Kyphoplasty was performed under fluoroscopic guidance and utilized semi-solid polymethylmethacrylate cement mixed with radiopaque contrast injected under low pressure; its location was confirmed using anteroposterior and lateral fluoroscopic imaging.[7]

Statistical analysis

Mean pain VAS, EQ5D scores, and RMDI scores were recorded preoperatively and postoperatively. Pearson's correlations and linear regression models were derived for the association of total cement volume and vertebral height restoration with patient outcomes [Tables 2-5]. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

All patients had reduced pain (n = 136; 100.0%), most had reduced disability (n = 134; 98.5%), and most exhibited an improved quality of life (n = 135; 99.3%). The average improvement in VAS, RMDI, and EQ5D scores for all patients was −6.8, +8.3, and +0.41, respectively [Table 2]. Eighty-eight (64.7%) patients reported preoperative narcotic use**;** this decreased to 24 (17.6%) postoperatively. No correlations or associations were found between total cement

Table 1: Demographics by cancer status, n=136.

	Total, n=136	No cancer, n=127	Cancer, n=9	P value
Gender				0.40
Male	29 (21.3)	26 (20.5)	3 (33.3)	
Female	107 (78.7)	101 (79.5)	6 (66.7)	
Age in years, mean±SD	74.7±11.3	75.1±11.5	69.6±5.2	0.02*
Age in years, median (range)	76.0 (37.0–93.0)	77.5 (37.0–93.0)	71.0 (60.0–78.0)	0.02*
BMI, mean±SD	26.5±6.3	26.5±6.2	26.8±7.3	0.89
BMI, median (range)	25.8 (14.1–43.6)	25.9 (14.1–43.6)	24.4 (18.0–40.4)	0.73
VAS improvement, mean±SD	6.8±2.6	7.0±2.6	5.1±3.1	0.04*
VAS improvement, median(range)	7.0 (0.0–10.0)	7.0 (0.0–10.0)	5.0 (0.0–10.0)	0.14
RMDI improvement, mean±SD	8.3±6.4	8.4±6.4	6.1±6.5	0.30
RMDI improvement, median (range)	7.0 (−4.0–44.0)	7.0 (−4.0–44.0)	4.0 (0.0–20.0)	0.29
EQ-5D improvement, mean±SD	0.41±0.40	0.42±0.40	0.30±0.29	0.42
EQ-5D improvement, median (range)	0.31 (0.0–0.99)	0.32 (0.0–0.99)	0.14 (0.0–0.89)	0.30

*Statistically significant at P<0.05. VAS: Visual analog scale, RMDI: Roland-Morris disability index, EQ-5D: EuroQol-5D, BMI: Body mass index, SD: Standard deviation

volume injected and outcomes utilizing VAS, RMDI, and EQ5D scores [Table 2]. There was little relationship between total cement volume injected and outcome measures using the Pearson's correlation [Table 2]. Linear regression models also revealed little evidence for age, gender, body mass index, or total cement volume as predictors of clinical improvement [Tables 3-5].

DISCUSSION

The biomechanical literature suggests that cement-filling volumes may play an important role in vertebral augmentation and its effectiveness in relieving pain.[1-3] However, adequate clinical data regarding optimal filling volumes are scarce, as most series are small, and results are mixed. Röder *et al.*, in a study of 276 patients, found that cement volume was a significant predictor for pain relief in kyphoplasty and recommended utilizing cement volumes of >4.5 cc.[2] In a biomechanical analysis, Rotter *et al.* reported that injecting only 10% of the vertebral volume when performing bilateral kyphoplasty was insufficient in stabilized fractured vertebra/relieving pain.[3] Rather, Molloy *et al.* found that kyphoplasty injected cement volumes of 16–30% were warranted.[1,3] Notably, neither study correlated the volume of injected cement during kyphoplasty with quality of life metrics.

Table 2: Pearson's correlations for VAS, RMDI, and EQ-5D improvement.

	Total cement	95% CI	*P* value
VAS improvement	*r*=0.042	−0.216, 0.294	0.79
RMDI improvement	*r*=−0.167	−0.405, 0.093	0.29
EQ-5D improvement	*r*=−0.091	−0.169, 0.339	0.57

*Statistically significant at *P*<0.05. VAS: Visual analog scale, RMDI: Roland-Morris disability index, EQ-5D: EuroQol-5D, *r*: Pearson's rho, CI: Confidence interval

No optimal kyphoplasty cement volume to relieve pain

No optimal volume of injected cement during kyphoplasty relieves pain and/or optimizes function and quality of life. Although our results demonstrated no significant relationships between injected cement volume and outcomes, all patients improved on VAS, RMDI, and EQ-5D outcome measures.

Future directions

In future studies, CT volumetric analysis would more accurately define injected cement volumes and cement

Table 3: Multiple linear regression modeling VAS improvement as outcome, *n*=136.

	Parameter estimate (β)	Standard error	95% confidence interval for β	R-square	F-statistic	*P* value
Overall				0.002	F(3,37)=0.03	0.99
Total cement	0.0792	0.3646	−0.6595, 0.8180			0.83
Age	0.0072	0.0430	−0.0799, 0.0943			0.87
BMI	−0.0101	0.0771	−0.1664, 0.1462			0.90

*Statistically significant at *P*<0.05. VAS: Visual analog scale, BMI: Body mass index

Table 4: Multiple linear regression modeling RMDI improvement as outcome, *n*=136.

	Parameter estimate	Standard error	95% confidence interval for β	R-square	F-statistic	*P* value
Overall				0.029	F(3.35)=0.35	0.79
Total cement	−0.6215	1.0013	−2.6542, 1.4112			0.54
Age	0.0366	0.1168	−0.2005, 0.2738			0.76
BMI	−0.0601	0.2080	−0.4824, 0.3622			0.77

*Statistically significant at *P*<0.05. RMDI: Roland-Morris disability index, BMI: Body mass index

Table 5: Multiple linear regression modeling EQ-5D improvement as outcome, *n*=136.

	Parameter estimate	Standard error	95% confidence interval for β	R-square	F-statistic	*P* value
Overall				0.023	F(3.35)=0.27	0.84
Total cement	−1.1198	5.8696	−13.0358, 10.7962			0.85
Age	0.4764	0.6848	−0.9136, 1.8666			0.49
BMI	−0.2173	1.2193	−2.6926, 2.2581			0.86

*Statistically significant at *P*<0.05. EQ-5D: EuroQol-5D, BMI: Body mass index

leakage and could be better correlated with quality of life measures, adjacent vertebral body fractures, postinjection vertebral body height restoration, and resultant kyphotic angle reduction.

CONCLUSION

All patients improved on all outcome scales (e.g., VAS, RMDI, and EQ5D) regardless of the injected cement volume following kyphoplasty.

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Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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