

Research Article

Percutaneous mesh-container-plasty for osteoporotic thoracolumbar burst fractures: A prospective, nonrandomized comparative study

Chengxuan Tang 🗅, Xiaojun Tang 🕒, Weihao Zhang 🕩, Minghai Dai 🕩, Maoxiu Peng 🕒, Shaoqi He 🕩

Department of Orthopedic Surgery, Third Affiliated Hospital of Wenzhou Medical University, Wenzhou, Zhejiang, China

ARTICLE INFO

Article history: Submitted January 25, 2020 Received in revised form March 13, 2020 Last revision received July 18, 2020 Accepted August 16, 2020

Keywords: Spinal fracture Minimally invasive surgery Osteoporosis Percutaneous kyphoplasty Mesh container

ORCID iDs of the authors: C.T. 0000-0002-7803-3959; X.T. 0000-0002-3188-3665; W.Z. 0000-0001-9285-2902; M.D. 0000-0002-7961-3453; M.P. 0000-0003-3279-8232; S.H. 0000-0002-9368-2228.

Corresponding Author:

Content of this journal is

licensed under a Creative

Commons Attribution

NonCommercial 4.0

International License

heshaoqi@126.com

Shaoqi He

© () (S

ABSTRACT

Objective: This study aimed to compare the clinical and radiological results of percutaneous mesh-container-plasty (PMCP) versus percutaneous kyphoplasty (PKP) in the treatment of osteoporotic thoracolumbar burst fractures.

Methods: A prospective study of 122 patients with osteoporotic thoracolumbar burst fractures was conducted. The patients were nonrandomly assigned to receive PKP (62; 16 men, 46 women) and PMCP (60; 14 men, 46 women). The epidemiological data, surgical outcomes, and clinical and radiological features were compared between the 2 groups. Cement leakage, height restoration, deformity correction, canal compromise, and cement distribution were calculated from the radiographs. Visual pain analog scale (VAS), the Oswestry disability index (ODI), and short-form 36 health survey domains role physical (SF-36 rp) and bodily pain (SF-36 bp) were calculated before surgery and immediately and 2 years after surgery.

Results: Although VAS, ODI, SF-36 bp, and SF-36 rp scores improved from 7 (6-9), 71.28 \pm 16.38, 22 (0-32), and 25 (0-50) preoperatively to 2 (1-3), 20.02 \pm 8.97, 84 (84-84), and 75 (75-100) immediately postoperatively in the PMCP group (p<0.05) and from 7 (6-8), 71.40 \pm 13.52, 22 (10.5-31.75), and 25 (0-50) preoperatively to 2 (1-3), 21.78 \pm 11.21, 84 (84–84), and 75 (75-100) immediately postoperatively in the PKC group (p<0.05), there was no difference between the 2 groups. The mean cost in the PKP group was less than that in the PMCP group ($\$5109\pm$ 231 vs. $\$6699\pm$ 201, p<0.05). Anterior, middle, and posterior vertebral body height ratios in the PMCP group were greater than those in the PKP group postoperatively (88.44 \pm 3.76% vs. $\$1.10\%\pm$ 11.78%, $\$6.15\%\pm$ 3.50% vs. $\$2.30\%\pm$ 11.02%, and $93.91\%\pm$ 3.01% vs. $\$1.43\%\pm$ 6.71%, respectively, p<0.05). The Cobb angle in the PMCP group was lower than that in the PKP group postoperatively ($6.67\pm$ 4.39° vs. $\$9.9^{\circ}\pm$ 4.06°, p<0.05). Cement distribution in the PMCP group was higher than that in the PKP group (30.48 \pm 5.62% vs. 27.18 \pm 4.87%, p<0.05). Cement leakage was observed to be lesser in the PMCP group (2/60) than in the PKP group (10 vs. 62, p<0.05).

Conclusion: Both PKP and PMCP treatments seem to have significant ability in pain relief and functional recovery. Despite its higher cost, PMCP treatment may have a better inhibition ability of cement leakage, cement distribution, height restoration, and improvement in segmental kyphosis than PKP treatment for osteoporotic thoracolumbar burst fractures.

Level of Evidence: Level II, Therapeutic Study

Introduction

Because of the demographic development toward an older society, the annual incidence of osteoporosis and its associated fractures is prevalent. Osteoporotic vertebral fractures (OVFs) can affect the patient's quality of life, including chronic back pain, functional limitations, depression, and disability, which have grown to be an important health issue (1).

Osteoporotic thoracolumbar burst fractures are severe type of OVFs. The management of osteoporotic thoracolumbar burst fractures has not been properly coded to date. However, the surgical treatment of these fractures seems to reduce pain and mobilize the patients more quickly; therefore, the hospital stay is shorter in this case. Many patients with osteoporotic thoracolumbar burst fractures without neurologic deficit have recently undergone kyphoplasty with good clinical and radiological results (2, 3). However, there have been some complications, including cement leakage, loss of the restored height, and kyphotic alignment after balloon deflation before cement injection (4-6). The risk of cement leaking into the spinal canal is greater when the posterior wall has been damaged.

To avoid these complications, a mesh container was developed with advantages of cement leakage, height restoration, and kyphotic angle reduction (7). During the cement injection process, continuous cement injection makes the mesh container produce a pressure; thereafter, the cement leaks outside of the mesh container and enters the bone trabeculae. Therefore, better inhibition ability of cement leakage can be achieved. The mesh container remains within the newly created vertebral cavity, and the balloon can be removed after deflation while preventing the vertebral body from collapsing. Thus, virtually, the physiological vertebral body height and shape might be restored and preserved.

On the basis of these previous studies, we hypothesize that there will be differences in the clinical efficacy and safety of percutaneous mesh-container-plasty (PMCP) and percutaneous kyphoplasty (PKP) for treatment of osteoporotic thoracolumbar burst fractures. To test this hypothesis, we compared the clinical and radiological results of PMCP and PKP for treatment of osteoporotic thoracolumbar burst fractures.

Cite this article as: Tang C, Tang X, Zhang W, Dai M, Peng M, He S. Percutaneous mesh-container-plasty for osteoporotic thoracolumbar burst fractures: A prospective, nonrandomized comparative study. Acta Orthop Traumatol Turc 2021; 55(1): 22-7.

DOI: 10.5152/j.aott.2021.20045

Materials and Methods

Study design

Ethical approval for this prospective, nonrandomized study was provided by the ethics committee of the authors' institute. The patients were given sufficient explanation of the study goals, and they signed a consent form. The inclusion criteria were as follows: 1) elderly (≥ 60 years), 2) thoracolumbar (T10 to L2) single fresh burst fractures (type A3 or A4 according to the AOSpine thoracolumbar spine injury classification system) (8), 3) minor injury or no history of trauma without neurological deficit, 4) constant ache and fatigue in the thoracolumbar vertebrae that can significantly affect daily life, and 5) diagnosed with osteoporosis according to the T value of dual-energy X-ray absorptiometry (DXA) less than -2.5. The exclusion criteria were as follows: 1) symptoms of neurological deficits, 2) polytraumatized patients, 3) patients with pre-existing spinal deformity or previous spinal operation, 4) clinical or imaging evidence of the metastatic bone tumor or multiple myeloma, 5) asymptomatic fractures, 6) systemic or local infections and severe bleeding disorders, and 7) other OVF types.

From January 2016 to December 2017, 170 consecutive patients who sustained the osteoporotic thoracolumbar burst fractures without neurologic deficit were included in this study. After a comprehensive explanation of this study and expected benefits and risks, 32 patients refused to participate in the study. After applying the exclusion criteria, we analyzed 122 patients who underwent PKP (PKP group, n=62) and PMCP (PMCP group, n=60). The differences between PKP and PMCP were explained to all the patients before surgery, and the surgical methods were selected according to patient preference.

Preoperatively, standard clinical examination and evaluation, including the medical history, physical examination of percussion pain, assessment of the pain intensity (visual pain analog scale [VAS]) and activity level (Oswestry disability index [ODI]) (9), and short-form 36 health survey domains role physical (SF-36 rp) and bodily pain (SF-36 bp) (10) were evaluated. X-rays of the relevant spinal region in 2 planes, computed tomography (CT) scan, magnetic resonance imaging (MRI) (T1-weighted and T2-weighted sequences including short tau inversion recovery sequences), and DXA were performed.

All the patients underwent operations within 4 days of admission to relieve pain, restore the vertebral body height, and correct the segmental kyphosis. All patients received a calcium supplementation (1,000 mg of elemental calcium daily), vitamin D (600 UI daily), and alendronate (70 mg weekly).

Surgical technique

All surgical procedures were performed under local anesthesia. The patients were positioned in a prone position on 4 bolsters placed on a radiolucent operating table with the abdomen freely suspended.

A 1-cm skin incision was made lateral to the desired entry point of the pedicle percutaneously. A trocar (Shandong Guanlong Medical Utensils Co., Ltd., Jinan City, Shandong Province, China) in a can-

HIGHLIGHTS

- Both PKP and PMCP treatments seems to have significant ability in pain relief and functional recovery.
- PMCP treatment may have a better inhibition ability of cement leakage, cement distribution, height restoration, improvement in segmental kyphosis than PKP treatments for osteoporotic thoracolumbar burst fractures.
- The cost of PMCP treatment is higher than that of PKP treatment.

nula was inserted into the pedicle at the fractured vertebra through pedicular approach as a working channel. After removing the trocar, a balloon was placed into the working channel and slowly inflated to create a low-pressure cavity for cement injection. Inflation continued until the balloon pressure reached 300 psi. The anteroposterior radiograph showed that the balloon size exceeded the midline of the vertebra. Then, the balloon was deflated and removed. If the balloon does not exceed the midline of the vertebra, a bilateral puncture is required.

In the PKP group, poly-(methyl methacrylate) (PMMA) cement was injected into the defect of the fractured body through the cannula under continuous fluoroscopic monitoring. The PMMA insertion was considered complete when it reached the posterior third of the vertebral body or had a potential tendency of cortical, epidural, and anterior venous cement leakage. In the PMCP group, a mesh container (Shandong Guanlong Medical Utensils Co., Ltd.) was advanced into the cavity. The mesh container was made of polyethylene terephthalate. Thereafter, the PMMA cement was manually injected into the mesh container within the treated vertebral body by applying a cement perfusion apparatus under fluoroscopic guidance. With the continuous injection of PMMA, the mesh container was inflated, and the height of the fractured vertebra was restored. At a certain injection amount, the PMMA cement leaked outside of the mesh container from the meshes and entered the bone trabeculae (Figure 1 and Supplementary figure 1).

A neurologic examination was performed soon after the operation. The patients were encouraged to walk while wearing a 3-point fixation brace after surgery. Radiographs and CT images were obtained to evaluate the reduction of the fracture, improvement in the segmen-



Figure 1. a-i. Percutaneous mesh-container-plasty surgical procedure for the treatment of a 75-year-old female patient with a single osteoporotic thoracolumbar burst fracture in the L1 vertebra. (a) Lateral radiograph showing a burst fracture of L1. (b, c) Preoperative computed tomography (CT) images (plain and sagittal reconstruction) showing the burst fracture with spinal canal compromise. (d) Preoperative magnetic resonance image (T2-weighted sequences) showing the burst fracture with spinal canal compromise. (e) Intraoperative view. (f) Postoperative lateral radiograph showing better alignment after cement injection and adequate vertebral body reduction. (g, h) Postoperative CT images (plain and sagittal reconstruction) showing no worse spinal canal compromise and better alignment and adequate vertebral body reduction. (i) Lateral radiograph 2 years after surgery showing reduced spinal canal compromise, excellent alignment, and adequate vertebral body reduction



Supplementary figure 1. a-c. Intraoperative view of percutaneous mesh-container-plasty for the treatment of a 69-year-old male patient with a single osteoporotic thoracolumbar burst fracture in the L1 vertebra. (a) Intraoperative lateral radiograph showing collapse of the superior endplate of L1. (b) Intraoperative lateral radiograph showing reduction of the collapsed superior endplate of L1. (c) Intraoperative lateral radiograph showing that the mesh cage has remained in shape and restored the collapsed superior endplate of L1 after the balloon deflation



Figure 2. a-c. Methods of measurements on images. (a) Lateral radiograph showing evaluation of the Cobb angle, anterior vertebral body height ratio (AVBHr), middle vertebral body height ratio (MVBHr), and posterior vertebral body height ratio (PVBHr), The Cobb angle= α , AVBHr=2×A_2/(A_i+A_j), MVBHr=2×M_2/(M_i+M_j), and PVBHr=2×P_2/(P_i+P_j). (b) Computed tomography (CT) plain image showing the evaluation of cement distribution. Cement distribution of a single CT section=a/(a+b). Cement distribution was calculated as the mean of all CT sections of the fractured vertebra. (c) CT plain image showing the evaluation of canal compromise. Canal compromise=1-2×d_2/(d_i+d_3)

tal kyphosis, and distribution of the cement. Operation time, estimated blood loss, cost, hospital stay, cement volume, and complications (cement leakage, cerebrospinal fluid leakage, and infection) were also noted. Back pain intensity was recorded on VAS (0=no pain, 10=worst pain). Functional outcome was evaluated using ODI, SF-36 rp, and SF-36 bp. All the patients were postoperatively followed up clinically and radiologically immediately; at 1, 3, and 6 months; and at 1 and 2 years.

The Cobb angle and the anterior, middle, and posterior vertebral body height ratios (AVBHr, MVBHr, and PVBHr, respectively) were measured using the lateral radiograph as described in a previous study (11, 12) Cement distribution and canal compromise were calculated using the CT images (Figure 2). Cement leakage was determined using the CT images of all the sections of the fractured vertebra.

Furthermore, 2 independent blinded spine surgeons performed the clinical evaluation of patients. Additionally, 3 other independent blinded spine surgeons assessed the radiographs.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 18.0 software IBM SPSS Corp.; Armonk, NY, USA). The numerical variables were presented as means±standard deviation or median (interquartile range). The Student's *t* or Wilcoxon signed-rank test was used to compare the measurements between the 2 groups. Repeated measures analysis of variance was used to compare the measurements of VAS, ODI, SF-36, AVBHr, MVBHr, PVBHr, and the Cobb angle preoperatively, postoperatively, and 2 years postoperatively. The nominal variables (sex, distribution of the fractured vertebra, fracture type, and cement leakages) were presented as numbers (percentages) and compared using the chi-square test. A two-sided p-value of <0.05 was considered statistically significant.

Results

The clinical characteristics of the 122 patients are summarized in Table 1. There were no statistical differences in the demographic data including age, sex, distribution of the fractured vertebra, fracture type, T-score, body mass index, and injury time between the 2 groups. The mean cost in the PKP group was less than that in the PMCP group ($$5109\pm231$ vs. $$6699\pm201$, p<0.05). There were no significant differences in the blood loss, operation time, and hospital stay between the 2 groups. The details are shown in Table 2.

Clinical evaluation

The VAS scores decreased from preoperative 7 (6-9) to postoperative 2 (1-3) in the PMCP group (p<0.05) and from preoperative 7 (6-8) to postoperative 2 (1-3) in the PKP group (p<0.05). The ODI scores decreased from preoperative 71.28 ± 16.38 to postoperative 20.02 ± 8.97

Table 1. Basic characteristics and comparative analysis between PKP and PMCP for the treatment of the 122 patients with osteoporotic thoracolumbar burst fractures in this study $(x\pm s)$

PMCP (n=60) PKP (n=62) t (χ2) р 71 37+7 04 Age (years) 71 18+6 63 0 151 0.88 0 101 Male/female 16/4614/460.835 Distribution 1.839 0.765 T10 5 5 T11 6 8 T12 17 12 L1 20 24 L2 14 11 Fracture type 0.141 0.721 A3 30 27 A4 32 33 T-score -2.96 ± 0.38 -3.04 ± 0.46 1.09 0 278 BMI 23 77+4 25 23 51+3 71 0.357 0.722 Injury time (days) 4 ± 2.31 4.30 ± 2.21 -0.7330.465 PKP: percutaneous kyphoplasty; PMCP: percutaneous mesh-container-plasty; BMI: body mass index

Table 2. Comparison of perioperative parameters between the PKP and PMCP groups for the treatment of the 122 patients with osteoporotic thoracolumbar burst fractures in this study[5+s or median [interrouatile range]]

	PKP (n=62)	PMCP (n=60)	t (χ²/Ζ)	р
Operation time (min)	31.71±4.23	32.47±5.57	<i>t</i> =-0.843	0.401
Blood loss (mL)	6.34 ± 1.87	$6.20 {\pm} 2.1$	t=0.386	0.700
Hospital stay (days)	$4.24{\pm}1.51$	$4.37 {\pm} 1.83$	t=-0.411	0.682
Cost (dollar)	5109 ± 231	6699 ± 201	t=-40.477	< 0.001
Cement leakage	10/62	2/60	$\chi^2 = 6.629$	0.018
Cement volume (mL)	7.5 (4.5–8.63)	7.5 (4.5–7.5)	Z=-0.348	0.727

PKP: percutaneous kyphoplasty; PMCP: percutaneous mesh-container-plasty

Table 3. Clinical comparisons between the PKP and PMCP groups for the treatment of the 122 patients with osteoporotic thoracolumbar burst fractures in this study (x+s or median [interguartile range])

	0			
	PKP (n=62)	PMCP (n=60)	t (Z)	Р
VAS				
Preoperative	7 (6-8)	7 (6-9)	Z=-0.547	0.584
Postoperative	2 (1-3)*	2 (1-3)*	Z=-0.451	0.652
2 years postoperative	2 (1-2)*	2 (1-2)*	Z=-3.05	0.652
ODI				
Preoperative	$71.40{\pm}13.52$	$71.28{\pm}16.38$	t=0.043	0.996
Postoperative	21.78±11.21*	$20.02 \pm 8.97*$	t=0.953	0.342
2 years postoperative	$16.02 \pm 7.76^*$	$16.13 \pm 7.27^*$	t=-0.085	0.932
SF-36 bp				
Preoperative	22 (10.5-31.75)	22 (0-32)	Z=-0.547	0.584
Postoperative	84 (84-84)*	84 (84-84)*	Z=-1.580	0.114
2 years postoperative	84 (84-91.5)*	84 (84-94)*	Z=-0.109	0.913
SF-36 rp				
Preoperative	25 (0-50)	25 (0-50)	Z=-0.045	0.964
Postoperative	75 (75–100)*	75 (75–100)*	Z=-0.159	0.874
2 year postoperative	75 (75-100)*	75 (75–100)*	Z=-0.012	0.99
*Repeated measures variance anal	veie was used for the statisti	cal analysis. There y	vere simificant	differenc

(p=0.05) between the postoperative or 2 years postoperative and preoperative values of these 2 groups PKP: percutaneous kryphoplasty; PMCP: percutaneous mesh-container-plasty; VAS: visual pain analog scale; ODI: Oswestry disability index; SF-36 pr: short-form 36 health survey domains role physical; SF-36 bp: shortform 36 health survey domains bodily pain

in the PMCP group (p<0.05) and from preoperative 71.40 ± 13.52 to postoperative 21.78 ± 11.21 in the PKP group (p<0.05). The SF-36 bp scores improved from preoperative 22 (0-32) to postoperative 84 (84-84) in the PMCP group (p<0.05) and from preoperative 22 (10.5-31.75) to postoperative 84 (84-84) in the PKP group (p<0.05). The SF-36 rp scores improved from preoperative 25 (0-50) to postoperative 75 (75-100) in the PMCP group (p<0.05) and from preoperative 25 (0-50) to postoperative 75 (75-100) in the PKP group (p<0.05). Moreover, follow-up results showed that the VAS, ODI, and SF-36 scores Table 4. Radiologic comparisons between the PKP and PMCP groups for treatment of the 122 patients with osteoporotic thoracolumbar burst fractures in this study (

(A±0)				
	PKP (n=62)	PMCP (n=60)	t	р
AVBHr (%)				
Preoperative	$65.69{\pm}10.51$	66.72 ± 5.35	-0.678	0.499
Postoperative	$81.10 \pm 11.78^*$	$88.44 \pm 3.76^*$	-4.597	< 0.001
2 years postoperative	$79.08 \pm 11.26^{*}$	$87.10 \pm 4.16^*$	-5.171	< 0.001
MVBHr (%)				
Preoperative	$68.34{\pm}12.74$	$67.81 {\pm} 5.04$	0.298	0.766
Postoperative	82.30±11.02*	$86.15 \pm 3.5^*$	-2.58	0.012
2 years postoperative	78.70±11.76*	84.75±3.78*	-3.793	< 0.001
PVBHr (%)				
Preoperative	$86.69{\pm}6.78$	87.31±3.30	-0.635	0.527
postoperative	$91.43{\pm}6.71{*}$	93.91±3.01*	-2.607	0.011
2 years postoperative	$89.04{\pm}6.92*$	$93.11 \pm 2.85^*$	-4.215	< 0.001
The Cobb angle (°)				
Preoperative	11.88 ± 4.28	13.31 ± 6.46	-1.439	0.153
Postoperative	$8.99{\pm}4.06*$	$6.67 \pm 4.39^{*}$	3.007	0.003
2 years postoperative	$9.52 \pm 4.07^{*}$	7.35±4.41*	2.82	0.006
Canal compromise (%)				
Preoperative	$20.70{\pm}6.38$	$19.44{\pm}5.33$	2.855	0.230
Postoperative	20.65 ± 6.58	$19.70 {\pm} 5.23$	1.396	0.373
2 years postoperative	$20.55 {\pm} 6.3$	19.52 ± 5.44	1.074	0.325
Cement distribution (%)	$27.18 {\pm} 4.87$	$30.48 {\pm} 5.62$	-3.477	0.001

Repeated measures variance analysis was used for the statistical analysis. There were significant differences (p=0.05) between postoperative or 2 years postoperative and preoperative values of these 2 groups. PKP: percutaneous kyphoplast; PMCP: percutaneous mesh-container-plast; AVEH: anterior vertebral body height ratio; NVBHr: middle vertebral body height ratio; PVBHr: posterior vertebral body height ratio.

Table 5. Comparison of cement leakage between PKP and PMCP groups with respect to the fracture type				
	PKP (n=62)	PMCP (n=60)	χ^2	Р
Fracture type				
A3	2/30	1/27	0.256	0.613
A4	8/32	1/33	4.861	0.027

did not obviously change at 2 years postoperatively. There were no significant differences in the VAS, ODI, and SF-36 scores between the 2 groups both postoperatively and at 2 years postoperatively. The details are shown in Table 3.

Therefore, although both PKP and PMCP treatments had a significant ability for pain relief and functional recovery postoperatively and at 2 years postoperatively, there was no difference between the 2 groups.

Radiologic evaluation

The AVBHr, MVBHr, PVBHr, and Cobb angle scores improved from preoperative (66.72%±5.35%, 67.81%±5.04%, 87.31%±3.30%, and 13.31%±6.46%, respectively) to postoperative (88.44%±3.76%, 86.15%±3.50%, 93.91%±3.01%, and 6.67%±4.39%, respectively) in the PMCP group (p<0.05) and from preoperative (65.69%±10.51%, 68.34%±12.74%, 86.69%±6.78%, and 11.88%±4.28%, respectively) to postoperative (81.10%±11.78%, 82.30%±11.02%, 91.43%±6.71%, and 8.99%±4.06%, respectively) in the PKP group (p<0.05). Moreover, long-term follow-up results showed that AVBHr, MVBHr, PVBHr, and the Cobb angle did not obviously change even after 2 years postoperatively. AVBHr, MVBHr, and PVBHr in the PMCP group were greater than those in the PKP group postoperatively (p<0.05). The Cobb angle in the PMCP group was lower than that in the PKP group postoperatively (p<0.05). The CT images demonstrated that cement distribution in the PMCP group was higher than that in the PKP group (30.48%±5.62% vs. 27.18%±4.87%, p<0.05). There were no significant differences in the canal compromise both postoperatively and at 2 years postoperatively between the 2 groups. All the radiographic results are shown in Table 4.

Therefore, PKP and PMCP treatments could significantly restore the height and improve the segmental kyphosis of the fractured vertebral body. The PMCP group had significantly higher height restoration, improvement in the segmental kyphosis, and cement distribution than the PKP group, which indicated that PMCP treatment had a better ability to treat the vertebral body than PKP treatment.

Surgical complications

After the surgeries, CT was performed immediately to assess PMMA cement leakage. PMMA cement leakage was observed in 16% (10/62) patients of the PKP group (2 anterior to the vertebral body, 1 lateral to the vertebral body, and 7 into the disk without sequelae) and in 3.33% (2/60) of patients in the PMCP group (1 anterior to the vertebral body and 1 into the disk without sequelae) (p<0.05) (Table 2). Furthermore, cement leakage was observed in 6.67% (2/30) patients of the PKP group and 3.70% (1/27) patients of the PMCP group of fracture type A3 (p>0.05) and 25% (8/32) patients of the PKP group and 3.03% (1/33) patients of the PMCP group of fracture type A4 (p<0.05) (Table 5). All the cement leakages were asymptomatic, and no surgical intervention was required to remove the extravasated cement. Postoperative complications, such as neurological functional aggravation, hemorrhage, wound healing abnormalities, infection, and pulmonary embolism, were not observed during the 2-year follow-up period. These analyses indicate that PMCP treatment had better safety than PKP treatment for A4 fractures.

Discussion

Osteoporosis and associated fractures are prevalent in clinics. A standardized treatment strategy for osteoporotic thoracolumbar burst fractures does not exist at present (2, 13-16). PKP has been increasingly used in older people currently because it is a minimally invasive treatment. However, the major disadvantages of PKP are cement leakage and loss of the restored height and kyphotic alignment after balloon deflation before cement injection. Therefore, the mesh container was developed (7).

This research showed that PMCP treatment had better safety than PKP treatment in terms of cement leakage, ability in cement distribution, height restoration, and improvement in the segmental kyphosis. Cementoplasty involves risks of complications, including pulmonary embolism, intradiscal cement leakage, neurological deficit, and even paraplegia (4, 6, 17). The cavity created in PKP treatment may decrease the cement perfusion pressure as well as the possibility of cement leakage. A4 fractures are complete burst fractures involving the posterior wall with an increased risk of cement leakage into the vertebral canal during the classical vertebroplasty and kyphoplasty interventions. The mesh container in PMCP treatment keeps the PMMA cement inside the container, and only partial cement leaks outside from the mesh to the bone trabeculae. In this study, cement leakage was observed in 6.67% (2/30) patients of the PKP group and 3.70% (1/27) patients of the PMCP group of fracture type A3 (p>0.05) and 25% (8/32) patients of the PKP group and 3.03% (1/33) patients of the PMCP group of fracture type A4 (p<0.05). The difference might be as a result of the mechanical difference of these 2 treatments. Therefore, PMCP treatment had a better inhibition ability of cement leakage than PKP treatment for A4 fractures.

Height restoration and improvement in the segmental kyphosis of the treated fractured vertebral body might be the important parameters to evaluate the clinical efficacy of minimally invasive techniques. However, previous studies found no correlation between the reconstitution of the vertebral body and the clinical outcome (pain reduction) (18, 19). In this study, height restoration and improvement in the segmental kyphosis in the PMCP group were both higher than those in the PKP Supplementary Table 1. Comparison of the Cobb angle (°) between the PKP and PMCP groups with respect to the fracture type

	PKP (n=62)	PMCP (n=60)	t	р
Fracture type				
A3				
Preoperative	11.45 ± 4.37	$13.98{\pm}6.07$	-1.823	0.074
Postoperative	8.88 ± 4.13	$6.89{\pm}4.43$	1.756	0.085
% Changes	23.66 ± 12.73	$52.59{\pm}21.17$	-6.168	< 0.001
2 years postoperative	9.2 ± 4.19	$7.77 {\pm} 4.24$	1.272	0.209
% Changes	20.95 ± 12.7	40.53 ± 28.81	-3.259	0.002
A4				
Preoperative	$12.27{\pm}4.08$	$12.77{\pm}6.81$	-0.358	0.722
Postoperative	$8.92{\pm}3.98$	$6.49 {\pm} 4.41$	2.331	0.023
% Changes	28.22 ± 15.98	$50.68{\pm}16.76$	-5.527	< 0.001
2 years postoperative	9.81 ± 4	7 ± 4.58	2.634	0.011
% Changes	20.68 ± 13.69	$44.04{\pm}22.15$	-5.132	< 0.001
PKP: percutaneous kyphoplasty; PMCP: percutaneous mesh-container-plasty				

group. However, the clinical outcome was not significantly different between these 2 groups. Previous studies indicated that PKP was not useful for height restoration and improvement in the segmental kyphosis. The improvement in segmental kyphosis was attributed to postural reduction with cement strengthening. The most significant factors affecting the improvement in segmental kyphosis were the fracture type and the volume of cement injected (11, 20, 21). This study showed that improvement in the segmental kyphosis in the PMCP group was higher than that in the PKP group with respect to both A3 and A4 fractures (Supplementary Table 1). The possible mechanism for height restoration and kyphosis correlation is the inflation of the mesh container.

Cement is the key factor for stabilizing the injured vertebrae by filling the bone cavity. When the cement volume (22) remains constant, the more extensive cement distribution leads to better surgical outcomes (23-25). In this study, cement distribution in the PMCP group was higher than that in the PKP group. An extensive cement distribution can improve the kyphotic angle and vertebral height effectively, without causing cement leakage or adjacent vertebral fractures (25). High distribution of the cement in the vertebral body in the PMCP group could possibly affect height restoration and improvement in the segmental kyphosis of the treated fractured vertebral body and the rate of new fracture.

In this study, although both PKP and PMCP treatments had significant ability in pain relief and functional recovery for the treatment of osteoporotic thoracolumbar burst fractures, there was no difference between the 2 groups. Previous studies also found that there was no significant difference of clinical outcome between shield kyphoplasty, vertebroplasty, and balloon kyphoplasty (26).

For patients using PMCP as our preceding operative method, the average cost is relatively higher than that for patients using PKP.

The major shortcomings of this study are that the results were available from a small patient population and a short follow-up duration. Another limitation of this study is its nonrandom nature. Prospective, randomized controlled studies enrolling more patients with longterm follow-ups are needed to evaluate the clinical and radiographic efficiency of PMCP more reliably and objectively.

In conclusion, both PKP and PMCP treatments seem to have significant ability in pain relief and functional recovery. Despite higher cost, PMCP treatment may have a better inhibition ability of cement leakage, cement distribution, height restoration, and improvement in the segmental kyphosis than PKP treatment for osteoporotic thoracolumbar burst fractures. Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Third Affiliated Hospital of Wenzhou Medical University (YJ2020006).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Author Contributions: Concept - S.H.; Design - W.Z., S.H.; Supervision - S.H.; Materials - X.T.; Data Collection and/or Processing - C.T., W.Z., M.P.; Analysis and/or Interpretation - C.T., W.Z., M.D., M.P.; Literature Review - X.T., S.H.; Writing - C.T.; Critical Review - C.T., X.T., S.H.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

References

- Fehlings MG, Tetreault L, Nater A, et al. The aging of the global population: the changing epidemiology of disease and spinal disorders. Neurosurgery 2015; 77 Suppl 4: S1-5. [Crossref]
- Krüger A, Zettl R, Ziring E, Mann D, Schnabel M, Ruchholtz S. Kyphoplasty for the treatment of incomplete osteoporotic burst fractures. Eur Spine J 2010; 19: 893-900. [Crossref]
- 3. Gan M, Yang H, Zhou F, et al. Kyphoplasty for the treatment of painful osteoporotic thoracolumbar burst fractures. Orthopedics 2010; 33: 88-92.
- Kim YJ, Lee JW, Park KW, et al. Pulmonary cement embolism after percutaneous vertebroplasty in osteoporotic vertebral compression fractures: Incidence, characteristics, and risk factors. Radiology 2009; 251: 250-9. [Crossref]
- 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. [Crossref]
- Nieuwenhuijse MJ, Van Erkel AR, Dijkstra PD. Cement leakage in percutaneous vertebroplasty for osteoporotic vertebral compression fractures: Identification of risk factors. Spine J 2011; 11: 839-48. [Crossref]
- Chen C, Li D, Wang Z, Li T, Liu X, Zhong J. Safety and efficacy studies of vertebroplasty, kyphoplasty, and mesh-container-plasty for the treatment of vertebral compression fractures: Preliminary report. PLoS One 2016; 11: e0151492. [Crossref]
- Vaccaro AR, Oner C, Kepler CK, et al. AOSpine thoracolumbar spine injury classification system: fracture description, neurological status, and key modifiers. Spine (Phila Pa 1976) 2013; 38: 2028-37. [Crossref]
- Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. Physiotherapy 1980; 66: 271-3. [Crossref]
- Vaidya A, Kleinegris MC, Severens JL, et al. Comparison of EQ-5D and SF-36 in untreated patients with symptoms of intermittent claudication. J Comp Eff Res 2018; 7: 535-48. [Crossref]
- 11. Xu C, Liu HX, Xu HZ. Analysis of related factors on the deformity correction of balloon kyphoplasty. AJNR Am J Neuroradiol 2014; 35: 202-6. [Crossref]

- Thaler M, Lechner R, Nogler M, Gstöttner M, Bach C. Surgical procedure and initial radiographic results of a new augmentation technique for vertebral compression fractures. Eur Spine J 2013; 22: 1608-16. [Crossref]
- Ender SA, Eschler A, Ender M, Merk HR, Kayser R. Fracture care using percutaneously applied titanium mesh cages (OsseoFix®) for unstable osteoporotic thoracolumbar burst fractures is able to reduce cement-associated complications-results after 12 months. J Orthop Surg Res 2015; 10: 175. doi: 10.1186/s13018-015-0322-5. [Crossref]
- Bakhsheshian J, Dahdaleh NS, Fakurnejad S, Scheer JK, Smith ZA. Evidence-based management of traumatic thoracolumbar burst fractures: a systematic review of nonoperative management. Neurosurg Focus 2014; 37: E1. [Crossref]
- Song X, Wang W, Yan Y, Zuo J, Yao N, Lin H. Clinical effect evaluation of percutaneous vertebroplasty combined with the spinal external fixator for the treatment of osteoporotic compressive fractures with posterior vertebral defect. Eur Spine J 2014; 23: 2711-7. [Crossref]
- He S, Lin L, Tang X, et al. The treatment of osteoporotic thoracolumbar severe burst fractures with short pedicle screw fixation and vertebroplasty. Acta Orthop Belg 2014; 80: 493-500.
- Hong SJ, Lee S, Yoon JS, Kim JH, Park YK. Analysis of intradiscal cement leakage during percutaneous vertebroplasty: multivariate study of risk factors emphasizing preoperative MR findings. J Neuroradiol 2014; 41: 195-201. [Crossref]
- Feltes C, Fountas KN, Machinis T, et al. Immediate and early postoperative pain relief after kyphoplasty without significant restoration of vertebral body height in acute osteoporotic vertebral fractures. Neurosurg Focus 2005; 18: e5. [Crossref]
- McKiernan F, Faciszewski T, Jensen R. Does vertebral height restoration achieved at vertebroplasty matter. J Vasc Interv Radiol 2005; 16: 973-9. [Crossref]
- Hiwatashi A, Westesson PL, Yoshiura T, et al. Kyphoplasty and vertebroplasty produce the same degree of height restoration. AJNR Am J Neuroradiol 2009; 30: 669-73. [Crossref]
- Kanayama M, Oha F, Iwata A, Hashimoto T. Does balloon kyphoplasty improve the global spinal alignment in osteoporotic vertebral fracture. Int Orthop 2015; 39: 1137-43. [Crossref]
- Nieuwenhuijse MJ, Bollen L, van Erkel AR, Dijkstra PD. Optimal intravertebral cement volume in percutaneous vertebroplasty for painful osteoporotic vertebral compression fractures. Spine (Phila Pa 1976) 2012; 37: 1747-55. [Crossref]
- Liang D, Ye LQ, Jiang XB, et al. Biomechanical effects of cement distribution in the fractured area on osteoporotic vertebral compression fractures: a three-dimensional finite element analysis. J Surg Res 2015; 195: 246-56. [Crossref]
- Zhang L, Wang Q, Wang L, Shen J, Zhang Q, Sun C. Bone cement distribution in the vertebral body affects chances of recompression after percutaneous vertebroplasty treatment in elderly patients with osteoporotic vertebral compression fractures. Clin Interv Aging 2017; 12: 431-6. [Crossref]
- 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.
- Endres S, Badura A. Shield kyphoplasty through a unipedicular approach compared to vertebroplasty and balloon kyphoplasty in osteoporotic thoracolumbar fracture: A prospective randomized study. Orthop Traumatol Surg Res 2012; 98: 334-340. [Crossref]