

Original Article

Experience of Percutaneous Balloon Kyphoplasty under Local Anesthesia for Multilevel Osteoporotic Vertebral Fracture

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ARTICLE INFO

Accepted 31 July 2018

Keywords:

multilevel,
osteoporotic vertebral fracture,
percutaneous balloon kyphoplasty,
adjacent segment fracture

SUMMARY

Background: Osteoporotic vertebral fracture (OVF) is a main cause of disability for the elderly. For intractable back pain after medical therapy, cement augmentation is an option. We report our results of multilevel percutaneous balloon kyphoplasty (PBK) for OVF.

Methods: This is a retrospective study. Patients receiving PBK for multilevel (at least two continuous segments) OVF from Jan. 2011 to Jan. 2017 were included. Their clinical and image results were analyzed at 6 months. The cement distribution was classified into three filling types: glandular, trabecular, and mix type. Patients were divided into two groups according to the presence of subsequent adjacent segment fracture (ASF). The clinical characters were analyzed between two groups.

Results: A total of 18 patients underwent multilevel PBK were enrolled. The mean age was 77.4 years. Fifteen of the patients were female. Sixteen patients underwent two levels PBK and two for three levels, resulting in a total of 38 levels. Twenty-one ASF occurred during follow-up period. Patients with ASF had lower body mass index (BMI) values than those without fracture ($p < 0.05$). More vertebral fractures at pre-operative magnetic resonance image (MRI) had higher incidence for ASF ($p < 0.05$). The glandular pattern of cement had higher risk in ASF ($p < 0.05$).

Conclusion: In our experience, lower BMI values, more vertebral fractures before operation, and glandular pattern of bone cement were associated with higher risk of ASF. For the higher incidence of ASF after PBK for multilevel of OVF, long term follow-up and medical therapy for osteoporosis are suggested.

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1. Introduction

Osteoporosis is a major public health problem and affects more than thirty percent of the elderly in the world, according to current studies.^{1–4} In Taiwan, from the 2005 to 2008, National Nutrition Survey reported that the prevalence of osteoporosis for men and women over the age of 50 was 23.9% and 38.3%.^{5,6} It is also an important issue in our country. There are many strategies for osteoporosis treatment, such as sunlight, nutrition supplement, medical therapy, physical therapy, and surgical intervention. Vertebral fracture is a common complication for osteoporosis, leading to disability sometimes. For intractable back pain after conservative treatments, patients may need surgical intervention, such as cement augmentation and/or fusion by internal fixation.⁷ Galibert et al. in 1987 first performed the vertebral cement augmentation procedures for osteoporosis.⁸ They report it quick and safe in comparison to internal fixation and fusion. Current studies prefer the PBK for lower risk of cement extravasation and greater kyphotic angle correction.^{9–13} Our study reports our experience in PBK for multilevel OVF.

2. Materials and methods

This is a retrospective study for patients with multilevel OVF (at

least two continuous) underwent PBK. The data were collected from Jan. 2011 to Jan. 2017. Osteoporosis conforms to the WHO diagnostic criteria (BMD of T score < -2.5 , spine and/or hip). Spinal osteoporosis caused by trauma, tumors, or vascular lesions are excluded. All patients have preoperative magnetic resonance imaging (MRI) and postoperative plain films for evaluation at six months after initial intervention. The MRI before operation showed evidence of bone marrow edema and/or necrotic cavity in all patients. The grading of vertebral fracture was according to the Genant classification (grade 0: no compression, grade 1: 20–25%, grade 2: 25–40%, grade 3: $> 40%$). The type of osteoporotic compression was according to the Genant classification (w: wedge, b: biconcave, c: crush). We classified the distribution of cement into three filling types according to postoperative plain films (Fig. 1): glandular pattern dominant which means compact and solid distribution of the cement (g type), trabecular pattern dominant which means diffuse and sponge-like distribution (t type), and mix type which means similar percentage for glandular and trabecular distribution (m type). The body mass index (BMI), body bone density (BMD), the number of vertebral fractures on pre-operative MRI, the grading of fracture, the presence of bone cement leak, and occurrence of ASF were reviewed and recorded. The functional outcome is evaluated by back pain visual Analogue scale (VAS). This study was approved by institutional review board of MacKay Memorial Hospital with informed consent (18MMHIS055e).

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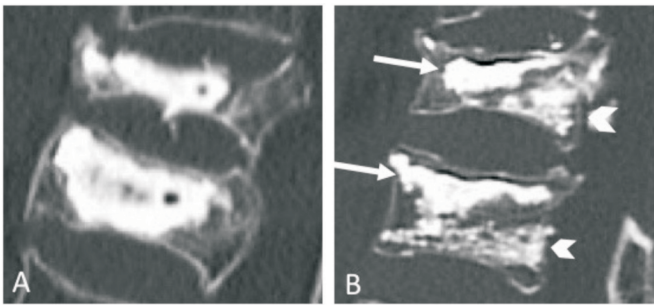


Fig. 1. Demonstration of cement distribution by computer tomography scan: (A) G-type: glandular pattern which means compact and solid distribution of cement within the vertebra; (B) M-type: Both trabecular pattern (arrow head) and glandular pattern (arrow) are seen in the same vertebra.

2.1. Technique

We used the Kyphon TM Balloon Kyphoplasty set (Medtronic Inc.) for vertebral augmentation. Patients were prone position. The procedure was performed under local anesthesia (1% xylocaine) with the aid of C-arm fluoroscope at operative room. Approximately 4 ml bone cement with material of polymethyl-methacrylate (PMMA) was slowly injected into the fractured body after balloon dilatation. Patients tolerated the procedure well and no symptomatic cement leakage occurred during the operation. A case demonstration was shown in Fig. 2.

2.2. Statistics

We compared the clinical characteristics between patients with and without adjacent level fracture by student t-test for continuous variables or by Fisher’s exact test for categorical variables. We further performed group difference in proportions using Bonferroni multiple (post hoc) comparisons if the number of category was equal or greater than 3. To investigate the potentially predictive factor of adjacent segment fracture, we introduced significant variables in previous univariate analyses into the multivariable logistic regression model with a stepwise selection. $P < 0.05$ was considered to be statistically significant. Data analyses were conducted using SPSS 22 (IBM SPSS, Armonk, NY: IBM Corp).

3. Result

A total of 18 patients were enrolled in our study. The mean age

was 77.4 years (SD = 8.7 years) with a range of 63 to 91. Fifteen (83%) of the patients were female. Sixteen of the patients underwent two continuous segments and the others had three segments (two continuous) of PBK, resulting in a total of 38 segments. All patient had pain relief after the operation. Adjacent segment fracture was noted in 9 patients. The level was between the PKB segment in 2, below the PKB segment in 2, and above the PKB segment in 5. Five patients had significant recurred back pain due to ASF and the others 4 were regarded as asymptomatic. In patients without subsequent fracture, the improvement lasted till 6 months. In the ASF group, the back-pain VAS increased at 3 months without significant difference than the no ASF group. All the ASF was treated by conservative treatment and got good pain control at 6 months (Fig. 3). Though continuous two-level spine fracture tends to have instability, only two patients converted to open surgery in our series. One was in the non-fractured group and the other was in the fractured group (Fig. 4). Both reoperation was due to re-collapse of the cemented vertebra. Table 1 lists the clinical characters in patients with and without adjacent level fracture. There was no significant difference for age, sex, level, pre-operative MRI type, grade of fracture, and cement leak. For BMD, there is no statistically difference between two groups. According to our results, BMD did not influence the incidence of subsequent ASF. Patients with ASF had lower BMI values than those without (24.1 vs. 28.3 kg/m²; $p < 0.05$). The number of pre-operative existing fractures was higher in patients with ASF (4.5 vs. 1.9; $p < 0.05$). The distribution of cement significantly differed

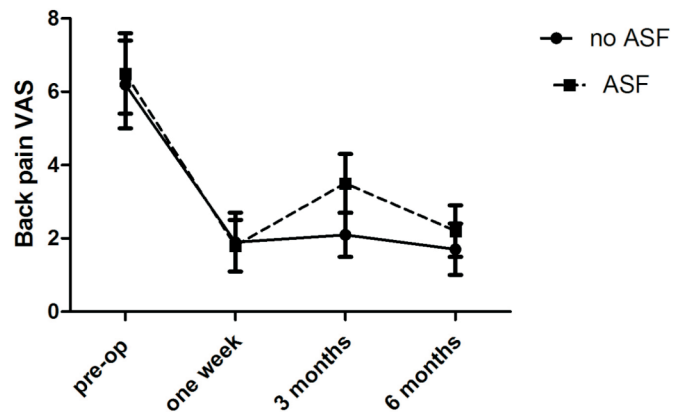


Fig. 3. Back pain VAS between two groups. The pain increased at 3 months in the ASF group without significant difference.

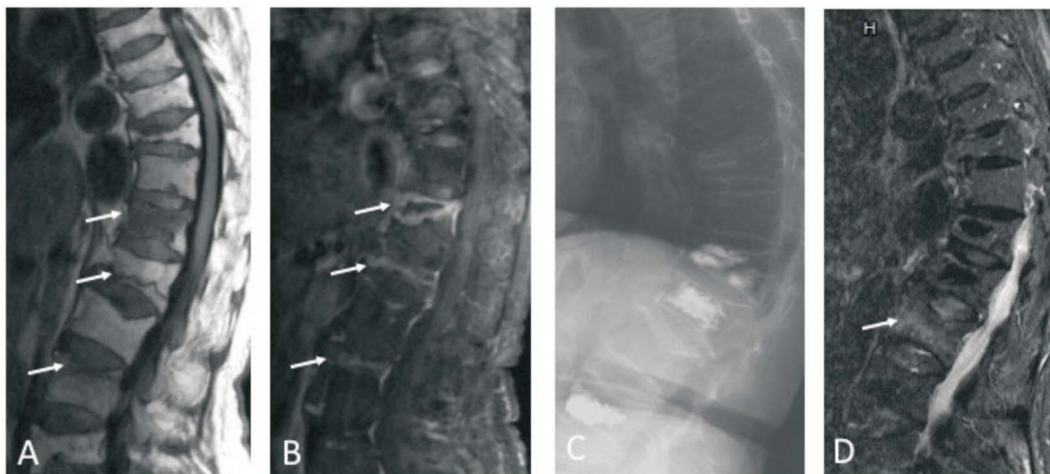


Fig. 2. A 70-year-old female had a BMI of 22.1. She suffered from medical intractable back pain. (A) T1 weighted image MRI revealed bone marrow edema in T12, L3 and a cleft in L1 (arrows), another 5 old fractures were noted also. (B) A contrast enhanced MRI revealed new fracture in T12, L1 and L3 (arrows). (C) She underwent 3 segments percutaneous balloon kyphoplasty. (D) Back pain occurred 1 months later and a follow-up MRI revealed bone marrow edema in L2 (arrow), which indicated adjacent segment fracture.

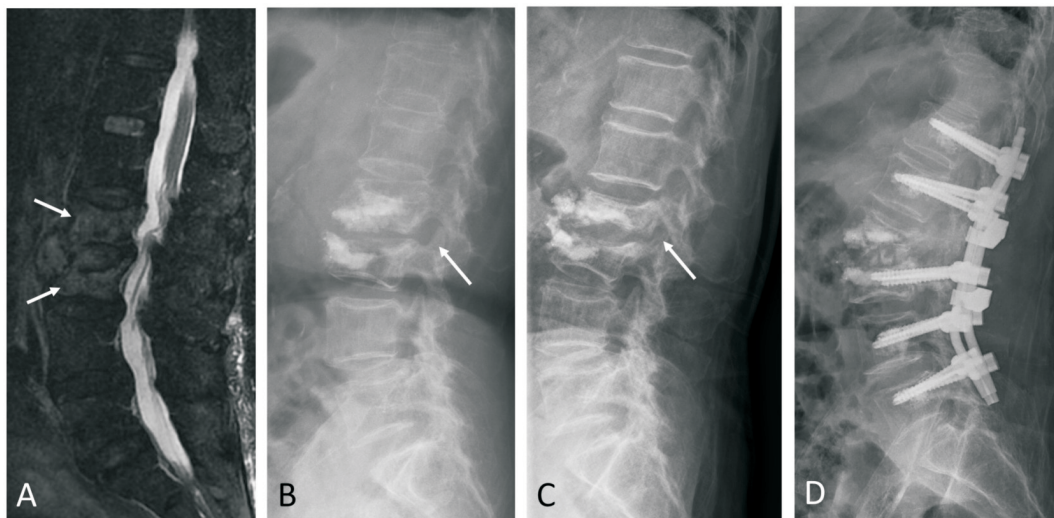


Fig. 4. A 75-year-old female patient sustained motion related low back pain for one month. (A) MRI T2WI showed bone marrow edema in L2 and L3 (white arrow). (B) A lumbar spine lateral view one week after L2, 3 PKB. The size of L23 foramen was wide (white arrow). (C) Back pain recurred 6 months after the operation. A follow-up X-ray revealed re-collapse of the L23 cemented vertebra. The L23 foramen became narrowed (white arrow). (D) She underwent internal fixation finally.

Table 1

	Total	Adjacent segment fracture		p value
		Yes	No	
Patient number	18	9	9	
Segment of vertebra	38	21	17	
Age, years	77.2 ± 8.4	76.3 ± 7.4	78.2 ± 9.5	0.496
Male sex, n (%)	6 (15.8)	2 (10.0)	4 (22.2)	0.395
Body mass index, kg/m ²	26.1 ± 4.8	24.1 ± 2.2	28.3 ± 5.9	0.006
Bone mineral density, g/cm ²	0.56 ± 0.09	0.54 ± 0.09	0.58 ± 0.10	0.178
Bone mineral density, T score	-3.3 ± 0.7	-3.5 ± 0.7	-3.2 ± 0.6	0.133
Level, n (%)				
L1	9 (23.7)	5 (23.8)	4 (23.5)	
L2	5 (13.2)	3 (14.3)	2 (11.8)	
L3	8 (21.1)	5 (23.8)	3 (17.6)	
L4	2 (5.3)	1 (4.8)	1 (5.9)	
L5	2 (5.3)	0 (0.0)	2 (11.8)	
T8	1 (2.6)	0 (0.0)	1 (5.9)	
T9	1 (2.6)	0 (0.0)	1 (5.9)	
T11	1 (2.6)	1 (4.8)	0 (0.0)	
T12	9 (23.7)	6 (28.6)	3 (17.6)	
Pre-OP MRI type, n (%)				0.705
0	2 (5.3)	1 (4.8)	1 (5.9)	
b	20 (52.6)	12 (57.1)	8 (47.1)	
c	2 (5.3)	0 (0.0)	2 (11.8)	
w	14 (36.8)	8 (38.1)	6 (35.3)	
Grade, n (%)				0.956
0	2 (5.3)	1 (4.8)	1 (5.9)	
1	12 (31.6)	7 (33.3)	5 (29.4)	
2	13 (34.2)	7 (33.3)	6 (35.3)	
3	11 (28.9)	6 (28.6)	5 (29.4)	
Number of pre-operative fractures on MRI	3.3 ± 2.2	4.5 ± 2.4	1.9 ± 0.8	< 0.001
Leak, n (%)	8 (21.1)	3 (15.0)	5 (27.8)	0.438
Cement, n (%)				0.022
t	6 (15.8)	3 (14.3)	3 (17.6)	
g	16 (42.1)	14 (66.7)	2 (11.8) [‡]	
m	16 (42.1)	4 (19.0)	12 (70.6) [‡]	

[‡] Indicates column proportions differed significantly in patients with and without adjacent level fracture in the Bonferroni multiple (*post hoc*) comparisons.

between patients with and without adjacent level fracture ($p < 0.05$). Patients with adjacent fracture were more likely to be in g type (66.7% vs. 11.8%) but less likely to be in m type (19.0% vs. 70.6%).

Table 2 displays the associated factors of ASF. After introducing those significant variables in previous univariate analyses (BMI, MRI existing fractures and cement distribution) into a stepwise selection logistic regression model, two variables were identified as potentially predictive factors. A higher number of existing fracture seen on pre-operative MRI was associated with a higher risk of ASF (odds

ratio [OR], 3.01; 95% confidence interval [CI], 1.29–7.01; $p < 0.05$). The risk of ASF in g type was greater than that in m type (OR, 21.00; 95% CI, 1.78–248.1; $p < 0.05$).

4. Discussion

Percutaneous vertebral body cement augmentation for OVF was performed for decades. Current studies showed that low BMI will be related to high risk of osteoporosis.^{14–17} In our study, patients with

Table 2
Associated factors of adjacent segment fracture.

Predictor	Odds ratio (OR)	95% CI of OR	p value
Number of pre-operative fractures on MRI	3.01	1.29–7.01	0.011
Cement type			
t	3.00	0.75–18.64	0.106
g	21.00	1.78–248.1	0.016
m	1	Reference	–

CI, confidence interval.

lower BMI undergoing PBK had higher risk of ASF. The explanation was that higher BMI indicated much more adipose tissue, which converted androgen into estrogen and resulted in improving bone mass. Currently, some studies demonstrated awful complications during cement augmentation, such as cement leakage and nerve root injury. Zhan Y et al. showed that patients with intra-vertebral cleft, cortical disruption, low cement viscosity, and high volume of injected cement resulted in high risk of cement leakage.¹⁸ In our study, cement leak occurred in 8 patients (21.1%) and all are asymptomatic.

Papanastassiou ID et al. stated that balloon kyphoplasty provided fewer subsequent fractures.⁹ However, the incidence of ASF in our multilevel patients was higher than other reports (21/38, 55% per segment). This may be the tendency of ongoing fracture in these patients with existing two or more vertebral fracture. We found a higher number of fractures before operation was associated with a higher risk of adjacent level fracture. In addition, the distribution of bone cement in glandular type had higher risk of ASF than that of mix type. Lin Liang et al. stated that better pain relief and greater quality of life following balloon kyphoplasty.¹² In our study, all patient had pain relief immediately after percutaneous balloon kyphoplasty. Recurrent back pain was noted as subsequent fractures occurred but finally got good control at 6 months. In our series, glandular type cement distribution had higher incidence of subsequent ASF than trabecular type. It was because that the glandular type cemented vertebra had greater volume of PMMA injection than the trabecular type. The more bone cement injected, the higher the change of vertebral body height restored. Body height restoration further added soft tissue tension and lead to an increased load on the adjacent vertebra. The above mechanism explained why ASF occurred more frequently in the glandular type cemented vertebra.⁷

5. Conclusion

Percutaneous vertebral body augmentation for osteoporotic vertebral fractures is safe and quick. However, subsequent fractures happened frequently and often resulted in recurrent back pain. According to our experience, lower BMI values, a more number of existing fractures seen on pre-operative MRI, and a glandular (solid) distribution of bone cement were associated with a higher risk of adjacent segment fracture. It should be kept in mind the higher incidence of this complication after PBK for patients with multilevel vertebral fracture. Long term follow-up and medical treatment for osteoporosis is suggested for these patients.

Highlight

1. Percutaneous balloon kyphoplasty is safe and effective for pain control in osteoporotic vertebral fracture patients
2. The incidence of subsequent Adjacent segment fracture is high for patients with multilevel fractures.
3. More preexisting fracture numbers on MRI, lower BMI, and glandular pattern of cement distribution were risk factors for

adjacent segment fracture.

Abbreviations and units

MRI, magnetic resonance image; OVF, osteoporotic vertebral fracture; ASF, adjacent segment fracture; BMI, body mass index; BMD, bone marrow index; CI, confidence interval; g type, glandular type; t type, trabecular type; m type, mix type; SD, standard deviation.

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