Systematic Review

Is Osteoporotic Thoracolumbar Burst Fracture a Contraindication to Percutaneous Kyphoplasty? A Systematic Review

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Background: The management of pain after osteoporotic thoracolumbar burst fracture has not reached a treatment consensus. Percutaneous kyphoplasty has been shown to be efficient in reducing acute pain after burst fracture, although the topic remains highly controversial in this field.

Objective: This study aimed to conduct a systematic review of the current literature to evaluate the effectiveness and safety of percutaneous kyphoplasty on the treatment of osteoporotic thoracolumbar burst fracture.

Study Design: A systematic review.

Setting: University hospital.

Methods: A comprehensive literature search was performed through PubMed, EMBASE, Web of Science, and Cochrane library without time restriction. Among the studies meeting the eligible criteria, any study in which percutaneous kyphoplasty was utilized alone in the treatment of osteoporotic thoracolumbar burst fracture was included in the current review. For radiographic outcome evaluation, vertebral height and kyphotic angle were analyzed. VAS (Visual Analog Scale) and ODI (Oswestry Disability Index) were utilized for clinical outcome evaluation. Complications such as cement leakage and adjacent vertebral fracture or relapse were also analyzed.

Results: In total, 289 patients (338 vertebral bodies) were included in the 8 studies. Clinical outcomes indicated that patients achieved pain relief (VAS) from 6.8 preoperatively to 1.1 postoperatively, and improvement of quality of life (ODI) ranged from 87.0 ± 6.0% to 23.9 ± 4.4%. The radiological outcome indicated that anterior vertebral height restoration ranged from 20.1 ± 2.3 to 85.3 ± 10.6, and posterior vertebral height restoration ranged from 27.3 ± 1.7 to 83.3 ± 7.4. Kyphotic angle achieved correction ranged from 21.7 ± 7.8° preoperatively to 3.17° postoperatively. The main complications after PKP were cement leakage and adjacent vertebral fracture or relapse, which had an incidence of 7.7% -45.4% and 4.3% -74.1%, respectively.

Limitations: Due to the good quality of the English publications, only English-language research searches were conducted, but they do not unduly affect our aggregate results impact. More prospective randomized controlled trials are needed to provide higher evidence for clinical practice.

Conclusions: To osteoporotic thoracolumbar burst fracture is absolutely not a contraindication to percutaneous kyphoplasty. Percutaneous kyphoplasty can obtain satisfactory effectiveness for the treatment of osteoporotic thoracolumbar burst fractures. Complications can be effectively decreased by meticulous evaluation, careful manipulation, and appropriate precautionary measures.

Key words: Percutaneous kyphoplasty, osteoporosis, burst fracture, cement leakage, adjacent fracture

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With the aggravation of population aging, osteoporotic fractures have become a serious problem. Spinal fractures are a common type of osteoporotic fractures, which seriously affect the quality of life of the elderly. Thoracolumbar fractures, which account for 5%-6% of full-body fractures (1,2), are the most common spinal injuries, occurring in the area considered to be biomechanically the weakest point in the spine: about 90% of spinal fractures occur in the thoracolumbar area, and thoracolumbar burst fractures account for 21%-58% of all thoracolumbar spinal fractures. The definition of burst fracture, according to the three-column theory raised by Dennis in 1983, refers to the fracture of anterior and middle columns of the spine where involved under axial load, result in vertebral collapse (3,4). It is mainly caused by high-energy impacts such as trauma or accident, or low-energy impacts such as falls and collisions.

The ideal management for osteoporotic thoracolumbar burst fracture without neurological deficit has not been properly organized. Due to pain limiting mobilization and the high risk of secondary nerve injury caused by local instability, conservative treatment is often not available (5). Traditional open surgery, such as short- or long-segment pedicle screw fixation, has yielded satisfactory results in non-osteoporosis patients with high-energy traumatic injuries (6), but in patients with osteoporosis, it is usually accompanied by a relatively high incidence of complications such as screw loosening, backout, migration, or postoperative system comorbidities (7,8). Recently, percutaneous kyphoplasty has been widely used to treat osteoporotic vertebral compression fractures and has shown good clinical effects (9,10). Previous studies reported that, in osteoporotic thoracolumbar burst fracture, the decrease in the height of the anterior and posterior edges of the vertebral body, fractures of different degrees in the posterior wall of the vertebral body, and vertebral cortical defect, all appeared to be risk factors of cement leakage (11). Additionally, some scholars consider that it is easy to make fracture segments shift into the spinal canal and leak cement along the cortex behind the ruptured vertebral body by percutaneous kyphoplasty (12-14). Hence, osteoporotic patients with thoracolumbar burst fractures have been regarded as a contraindication for the treatment of percutaneous kyphoplasty.

Recently some clinical studies (15-17) demonstrated that percutaneous kyphoplasty can achieve satisfactory results in patients with osteoporotic thoracolumbar burst fractures without any complications, which is also in line with the authors' experience. Given the previously demonstrated success of treating thoracolumbar burst fractures with kyphoplasty, we conducted a systematic review of the scientific literature to present the current evidence in a way that could provide additional perspective to improve the current treatment of patients with this condition.

Methods

Search Strategy

A systematic search was conducted of PubMed, EMBASE, Web of Science, and Cochrane Library, according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for published studies evaluating percutaneous kyphoplasty in patients with osteoporotic thoracolumbar burst fractures. Keywords used to identify relevant articles were osteoporosis or osteoporotic, vertebral fracture or spinal fracture or burst fracture, percutaneous kyphoplasty or balloon kyphoplasty. Google Scholar was also used to screen relevant literature, and the reference list was manually searched from all the relevant original research and review articles to identify additional potentially eligible studies.

Inclusion and Exclusion

The inclusion criteria were: (1) patients with osteoporotic burst fracture who were only undergoing percutaneous kyphoplasty; (2) Fractures are Dennis type II; (3) low-energy injury mechanism such as falls and collision, not trauma or accident; (4) no neurologic deficits; (5) no signs of active infection; (6) no neoplastic etiology (metastasis or myeloma). Studies were excluded according to the following criteria: (1) patients with neurological symptoms or those with posterior column invasion; (2) duplicate or multiple publications of the same study; (3) reviews, commentaries, case reports, and biomechanical studies in cadaveric or animals.

Data Extraction

All relevant data that met the eligibility criteria were independently and separately extracted by 2 authors (YXC, PY). Discrepancies were resolved by discussion with each other. The following data were extracted from each included study: first author, region, study design, number of patients, mean age, mean length of follow-up, vertebral height, kyphotic angle, Visual Analog Scale (VAS), Oswestry Disability Index (ODI), cement leakage, and adjacent vertebral fracture or relapse.

Quality Assessment

The methodological quality of all included studies was assessed with the Cochrane collaboration's tool for assessing the risk of bias and the Newcastle–Ottawa scale (NOS). The randomized controlled trial (RCT) was evaluated with the Cochrane collaboration's tool which included the following aspects: (1) random sequence generation (selection bias); (2) allocation concealment (selection bias); (3) blinding of participants and personnel (performance bias); (4) blinding of outcome assessment (detection bias); (5) incomplete outcome data (attrition bias); (6) selective reporting (reporting bias); (7) other bias (18). The cohort studies were evaluated by the NOS, which is one of the most useful for assessing the methodological quality of non-randomized studies (19). The NOS consists of 3 quality parameters for cohort studies: selection, comparability, and outcome, which are assigned with a maximum of 4, 2, and 3 stars, respectively. Studies with more than 6 stars are considered high quality; therefore, 9 stars reflects the highest quality.

Results

Search Results

We identified 309 relevant studies. After 44 duplicates were removed, the titles and abstracts of 265 studies were reviewed; 227 did not meet the inclusion criteria and were excluded. Next, 38 full-text articles were carefully assessed and reviewed, of which 30 studies were excluded. Finally, 8 differentiated studies were found to be eligible and included in the systematic review (17,20-26). The study selection process is shown in Fig. 1.

Study Characteristics

A total of 289 individuals and 338 vertebral bodies were identified in the 8 studies. All the 8 studies included 5 prospective and 3 retrospective studies, which consisted of one randomized control trial (21), 4 prospectively design cohort studies (20,23,24,26), and 3 retrospectively design cohort studies (17,22,25). Characteristics of these 8 studies are summarized in Table 1 and Table 2.

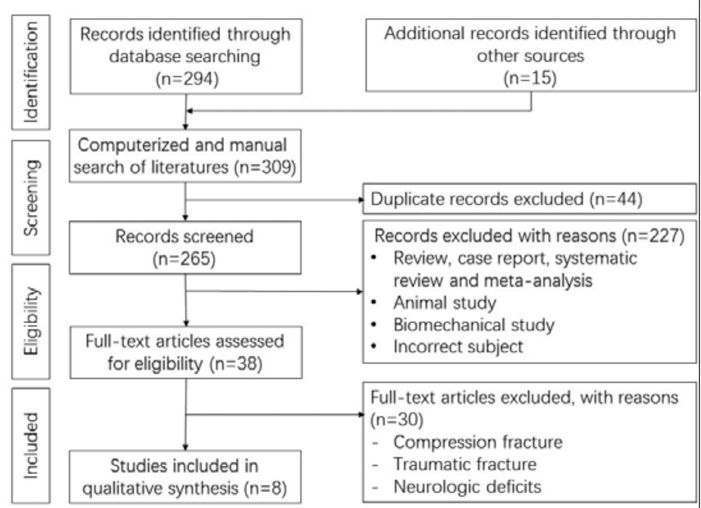

Fig.1. *PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram showing the process of literature selection.*

Table 1. *Summary of study characteristics of included trials.*

Studies	Region	Study Design	Number of Patients	Age (years)	Gender M/F	Follow-Up (months)
He D (22)	China	Prospective RCT	22	73.18 ± 4.90 (65-82)	11/11	34.00 ± 9.41 (24-59)
Kruger A (21)	Germany	Retrospective Cohort	97	76.1 ± 12.36 (59-98)	29/68	20.2 ± 9.79 (5-48)
An KC (18)	Korean	Retrospective Cohort	12	78 (66-84)	0/12	≥ 12
Stoffel M (17)	Germany	Prospective Cohort	74	72 (34-95)	22/52	15 (8-32)
Fuentes S (19)	France	Prospective Cohort	18	53 (22-78)	12/6	26 (17-30)
Zhang L (16)	China	Retrospective Cohort	23	63.7 ± 5.8 (58-72)	7/16	24
Yin P (23)	China	Prospective Cohort	46	75.9 ± 7.6 (55-88)	18/28	28.8 ± 7.0
Gan M (20)	China	Prospective Cohort	25	69 (56-82)	7/18	≥ 6

Table 2. *Clinical and radiological outcomes and complications of percutaneous kyphoplasty.*

Results		He D (22)	Kruger A (21)	An KC (18)	Stoffel M (17)	Fuentes S (19)	Zhang L (16)	Yin P (23)	Gan M (20)
Number of vertebrae		22	110	13	81	18	23	46	25
VAS	pre-	8	8.1 ±0 .815	8.3 ± 0.4	7.0 ± 0.3	6.8 (4-8)	8.0 ± 1.0	8.2 ± 0.7	8.2 ± 1.3
	post-	3	/	3.9 ± 0.2	2.3 ± 0.2	1.1 (0-2)	2.8 ± 0.7	1.8 ± 0.7	2.8 ± 0.8
	final	2	1.6 ± 1.02	3.1 ± 0.17	/	1.1 (0-2)	2.3 ± 0.6	0.7 ± 0.7	2.9 ± 1.1
ODI	pre-	/	/	/	/	/	68.4 ± 8.9%	87.0 ± 6.0%	68.2 ± 6.6%
	post-	/	/	/	/	/	34.2 ± 3.2%	23.9 ± 4.4%	35. 3± 2.8%
	final	/	/	/	/	/	33.9 ± 5.1%	19.1 ± 3.8%	34.5 ± 1.8%
Complications	cement leakage	10	46	1	17	2	4	8	4
	adjacent fracture	3	5	/	6	/	/	2	/
Kyphotic angle (KA)	pre-	11°	8.53° ± 6.3° (-5 to 27°)	15.9 ± 2.4°	10 ± 1°	14.44° (5 to 35°)	16.9 ± 9.1°	17.9 ± 1.4	21.7 ± 7.8
	post-	7°	4.77° ± 3.97° (-2 to 14°)	6.2 ± 1.6°	5 ± 1°	3.17° (-5 to 10°)	11.9 ± 7.9°	14.2 ± 1.9	8.6 ± 6.6
Height of anterior vertebra (Ha)	pre-	/	/	/	/	65% (36-83%)	64.1 ± 14.8%	20.1 ± 2.3	61.5 ± 13.9
	post-	/	/	/	/	89% (67-100%)	80.7 ± 12%	22.9 ± 2.4	85.3 ± 10.6
Height of posterior vertebra (Hp)	pre-	/	0.808 ± 0.182	/	/	65% (40-83%)	87 ± 8.7%	27.3 ± 1.7	73.0 ± 9.3
	post-	/	0.875 ± 0.118	/	/	92% (82-100%)	92.2 ± 6.0%	28.1 ± 1.7	83.3 ± 7.4

VAS, Visual Analog Scale; ODI, Oswestry Disability Index.

Risk of Bias Assessment

In the RCT enrolled, the value of low risk was 85.7% (6/7). After assessment of the NOS, all 7 cohort studies were assigned 6 or more stars. Therefore, we thought enrolled RCT and cohort studies had high quality. Assessment of risk bias in the 8 studies is shown in Table 3 and Table 4.

Clinical Outcome

VAS and ODI were utilized for clinical outcome evaluation. All of the included studies reported the VAS, and 3 studies evaluated ODI. The patients' pain and quality of life were significantly relieved after percutaneous kyphoplasty, from preoperative VAS score 6.8 to postoperative 1.1, and preoperative ODI scores 87.0 ± 6.0% to postoperative 23.9 ± 4.4% in cohort studies (20,22,23,26). Short-segment pedicle instrumentation can provide pain relief from pre-VAS 7.8 ± 0.9 to post-VAS 5.8 ± 1.2, pre-ODI 66.1 ± 9% to post-ODI 58.2 ± 5.9%, compared to short-segment pedicle instrumentation, percutaneous kyphoplasty can provide quick pain relief from pre-VAS 8.0 ± 1.0 to post-VAS 2.8 ± 0.7, pre-ODI 68.4 ± 8.9% to post-ODI 34.2 ± 3.2% mentioned by Zhang L (17). He D and colleagues (21) reported that VAS improved from 8 to 3 in the percutaneous kyphoplasty alone group compared with that from 8 to 4 in the internal fixation group. Fuentes and colleagues (24) observed that VAS dropped to 1.1 in the isolated percutaneous kyphoplasty group compared with 1.6 in the percutaneous osteosynthesis group.

Radiological Outcome

The radiological outcome was evaluated via vertebral height and kyphotic angle correction. Four studies assessed the vertebral height correction through both Ha (height of anterior vertebrae) and Hp (height of posterior vertebrae), and all of the 8 studies observed the outcome of kyphotic angle perioperatively. Kyphotic angle received an ideal correction range from 21.7 ± 7.8° preoperatively to 3.17° postoperatively(17,20-26). Ha increased from 20.1 ± 2.3 preoperatively to 85.3 ± 10.6 postoperatively reported by Yin P (20) and Gan M (23). They also mentioned that Hp increased from 27.3 ± 1.7 to 83.3 ± 7.4. Similarly, Lei Zhang (17) and Fuentes S (24) received significant improvement of the vertebral height (Ha ranged from

64.1 ± 14.8% to 80.7 ± 12%, and Hp ranged from 87 ± 8.7% to 92.2 ± 6.0%).

Complications

All of the included studies described the outcome of complications. Cement leakage, the most common complication, had a wide incidence range from 7.7% to 45.4% in 8 studies, although without any neurological symptoms or other clinical consequences. Adjacent vertebral fracture or relapse was another complication described from 4.3% to 74.1% in 4 studies.

Discussion

To our knowledge, this is the first systematic review of osteoporotic thoracolumbar burst fracture treated by percutaneous kyphoplasty. The main outcome variables and postoperative complications were recorded in our study. Generally, the results presented showed that PKP is effective and safe for the treatment of osteoporotic burst fractures, so there is a good possibility that this is an effective treatment for patients with osteoporotic burst fractures without neurological deficit.

The ideal management of osteoporotic thoracolumbar burst fractures is still controversial. Conservative treatment usually leads to various complications, such as secondary nerve injury, aggravation of kyphotic deformity, pseudarthrosis, and so on (27-30). Traditional surgical technique, for instance, pedicle instrumentation, has been reported successfully performed in previous studies on the treatment of burst fractures (31-34). However, the high rate of failures, such as internal fixation loosening and loss of reduction, is not scarce with pedicle instrumentation in osteoporotic patients (20,35). Moreover, the osteoporotic aging population with ongoing pain or chronic diseases may not endure this surgery at all.

Typical of minimally invasive procedures, including smaller blood loss and shorter bed-rest time, percutaneous kyphoplasty may be much more suitable for osteoporotic patients with ongoing pain or chronic diseases. Isolated kyphoplasty treatment has been proposed in A3.1 fracture with good clinical results and kyphosis correction that was stable over time (20). Schofer and his colleagues (36) found that percutaneous kyphoplasty can lead to a significant reduction in fracture pain. It has also been shown that the angle of kyphosis is successfully and significantly improved, especially following kyphoplasty. Gan and colleagues (23) explored the feasibility and clinical outcome of percutaneous kyphoplasty for the treatment of painful osteoporotic thoracolumbar burst fractures without neurological deficit. They concluded that this technique can reduce pain, increase vertebral body height, and decrease wedge angle without worsening of retropulsion. Zhang and his colleagues (17) compared the clinical efficacy of percutaneous kyphoplasty and short-segment pedicle instrumentation. Results showed that both approaches appeared to be effective and reliable operative techniques for selected thoracolumbar fractures in the short term. Percutaneous kyphoplasty had a significantly smaller blood loss and shorter bed-rest time. Fuentes and their colleagues (24) conducted a prospective evaluation to assess percutaneous kyphoplasty and pedicle screw fixation for the management of thoracolumbar burst fractures. The conclusion showed that this approach gives similar vertebral height recovery and kyphosis correction rates to those obtained with open surgery. It provides a short hospital stay and might, therefore, constitute a useful alternative to open surgical methods. In the authors' experience, traditional open surgery is suitable for young patients with high energy injury and spinal canal injury, while percutaneous kyphoplasty is more suitable for the osteoporotic aging population with ongoing pain or chronic diseases, and those who cannot endure open surgery.

Table 3. *The bias of risk of a randomized controlled trial*

Items	He D
Random sequence generation	Low risk
Allocation concealment	Low risk
Blinding of participants and personnel	Low risk
Blinding of outcome assessment	Low risk
Incomplete outcome data	Low risk
Selective reporting	Low risk
Other bias	Unclear risk

Table 4. *Quality assessment of cohort studies according to Newcastle-Ottawa Scale*

Study ID	Selection	Comparability	Exposure	Total Score
Kruger A	4	2	2	8
An KC	4	2	3	9
Stoffel M	4	2	2	8
Fuentes S	3	1	3	7
Zhang L	4	2	3	9
Yin P	3	1	3	7
Gan M	3	1	3	7

Many studies have reported that percutaneous kyphoplasty can achieve better effectiveness and a lower rate (9%) of cement leakage compared with 38% of PVP (percutaneous vertebroplasty), which is another minimally invasive approach (20,23,25,37). Cement leakage is one of the major complications, which may cause severe consequences such as remote organ embolism (38) or local chemical or compress symptoms (39,40). Stoffel and his colleagues (26) considered that the potential complication of procedure-related secondary narrowing of the spinal canal by the retropulsion posterior wall in burst fractures appeard to be a theoretical risk rather than an actual one. Walter and colleagues (41) conducted a meta-analysis to assess the frequency and pattern of cement leakages in spinal burst fracture compared with osteoporotic compression fractures. Their conclusion demonstrated that percutaneous kyphoplasty can be considered a safe procedure in burst fracture. Lei Zhang and his colleagues (17) considered that inflation of the balloon may be beneficial to reduce the cement leakage due to compressing the cancellous bone around the defects; moreover, the longitudinal ligament and soft tissue around the vertebrae would also have the potential to prevent cement leakage. Peng Yin and his colleagues (20) mentioned that cement leakage can be prevented by meticulous evaluation, careful manipulation, and appropriate precautionary measures. The authors believe that cement leakage can be effectively decreased by a meticulous surgical plan.

Among the studies about cement leakage, the lower rate always comes from a unilateral approach rather than a bilateral approach. It showed that different procedure approaches may also affect the rate of cement leakage. In the early stage, percutaneous kyphoplasty was performed with a bilateral approach using 2 balloon tamps. However, due to the advantages of simple surgery and short operative time, the unilateral approach has also been widely accepted (42). Several studies compared these 2 approaches to explore which is better (20,43,44). Some of these studies found that the unilateral approach may be the better choice when operative time, cement volume, cement leakage, radiation dose, and hospitalization costs were taken into consideration (20). Other studies considered that no apparent differences between the 2 approaches in the short- and long-term clinical outcomes and complications (45). Based on the authors' experience and opinion, they considered that the unilateral procedure is more suitable for elderly patients with osteoporotic thoracolumbar burst fractures without nerve injury.

Complications regarding new-level fractures have also been reported in many previous studies (46-48), raising concern over whether percutaneous kyphoplasty may increase the incidence of new fractures, especially in adjacent vertebrae. Weibo Yu and his colleagues (48) conducted a meta-analysis to assess significant potential risk factors for relapse of the augmented vertebrae. They found 5 major factors were associated with relapse of the augmented vertebrae, including preoperative intravertebral cleft, the affected vertebrae in the thoracolumbar region, preoperative severe kyphotic deformity, solid lump cement distribution pattern, and higher vertebral height restoration. They concluded that careful observation of patients with these risk factors and reasonable intervention could be useful to prevent deterioration of their clinical course. Zhang H and colleagues (49) evaluated the new-level fracture risk after percutaneous kyphoplasty. Their analysis did not reveal evidence of an increased risk of fracture of vertebral bodies, especially those adjacent to the treated vertebrae following augmentation. Oishi Y and colleagues (50) investigated the correlation of the incidence of adjacent vertebral fracture with the loss of global alignment correction after percutaneous kyphoplasty. They found that the presence or absence of adjacent vertebral fractures did not affect long-term global alignment and patient quality of life.

Limitations

There are still some limitations in this systematic review. The authors did the English language study restriction due to a better quality of English publications, which could have resulted in missing data but would not unduly affect our pooled results. The number of included studies was small; more prospective randomized controlled trials are needed to provide higher evidence for clinical practice.

Conclusion

In conclusion, the results of this systematic review showed that percutaneous kyphoplasty could obtain satisfactory pain relief with optimal safety in the treatment of osteoporotic thoracolumbar burst fractures. The complications, which appear to be a theoretical risk rather than an actual one, can be prevented through meticulous evaluation, careful manipulation, and appropriate precautionary measures. An osteoporotic thoracolumbar burst fracture is absolutely not a contraindication to percutaneous kyphoplasty.

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