Retrospective Study

Minimally Invasive Percutaneous Vertebroplasty for Thoracolumbar Instrumented Vertebral Fracture in Patients With Posterior Instrumentation

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Background: The traditional treatment for an instrumented vertebral fracture involves removing the loosened pedicle screws and extending the posterior instrumentation cephaladly or caudally. There has been a recent trend of performing minimally invasive fluoroscopy-guided percutaneous vertebroplasty as a salvage procedure.

Objective: The aim of this study was to compare the outcomes of surgical interventions for instrumented vertebral fracture.

Study Design: Retrospective assessment.

Setting: All data came from Chang Gung Memorial Hospital, Taiwan.

Methods: We retrospectively reviewed 35 patients with an instrumented vertebral fracture who underwent fluoroscopy-guided percutaneous vertebroplasty (Group I, n = 16) or extension of the posterior instrumentation (Group II, n = 19). Demographic data were recorded. The operating time, amount of intraoperative blood loss, time to postoperative ambulation, and duration of hospital stay were also evaluated. The visual analog scale (VAS) score, kyphotic angle on radiological images, Kirkaldy-Willis functional score, complications, and revision surgery were evaluated at one week and one, 3, 6, and 12 months postoperatively.

Results: Group I had a shorter operating time ($P < 0.001$), less intraoperative blood loss ($P < 0.001$), earlier postoperative ambulation ($P < 0.001$), and a shorter hospital stay ($P < 0.001$). The mean VAS score improved significantly after surgery in both groups ($P = 0.001$). The postoperative kyphotic angle was better in Group II ($P < 0.05$). There was no significant between-group difference in the Kirkaldy-Willis functional score at the last follow-up ($P = 0.91$). There was no significant between-group difference in the need for revision surgery (Group I, n = 4; Group II, n = 5; $P = 0.93$).

Limitation: This study is a retrospective cohort.

Conclusions: Minimally invasive fluoroscopy-guided percutaneous vertebroplasty can be used as an alternative to extension of posterior instrumentation for instrumented vertebral fracture. It has several advantages, including a shorter operating time, earlier postoperative ambulation, less blood loss, and a shorter hospital stay. The clinical outcomes of these 2 treatment approaches were similar.

Key words: Minimally invasive, instrumented vertebral fracture, extension of posterior instrumentation, fluoroscopy-guided percutaneous vertebroplasty, osteoporosis, percutaneous cement augmentation

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Pedicle screw fixation is a method used to stabilize the thoracolumbar spine. It has many benefits, including promotion of bony fusion, correction of deformity, and stabilization of a vertebral fracture (1-4). However, there are some potential complications with posterior instrumentation using pedicle screws, including instrumented vertebral fractures at the level of the screws or an adjacent level, and pedicle screw loosening (5-8). The incidence of instrumented fracture is estimated to be 2% – 27% (5). Several studies have identified the risk factors for instrumented fractures to include low bone mineral density, older age, obesity, women, long instrumentation fusion, and sagittal imbalance (6-12). With the continuing growth of geriatric populations (13), elderly patients with spinal osteoporosis are becoming more common (14), as are instrumented fractures (7).

The traditional treatment for instrumented vertebral fracture is open revision surgery to remove the loosening pedicle screws and extend the posterior instrumentation cranially cephaladly or caudally. Recently, there has been a trend of performing minimally invasive surgery with salvage cement augmentation (1,8,11,15-18). However, there are no reports in the literature on whether a minimally invasive procedure or open surgery is the optimal treatment for instrumented fractures. The goal of this study was to compare the surgical outcomes of these 2 interventions in patients with instrumented vertebral fractures.

Methods

Patient Selection

We retrospectively reviewed 56 patients with upper or lower instrumented vertebral fractures of the thoracolumbar spine treated at Chang Gung Memorial Hospital from January 2013 through December 2018. Patients with an instrumented vertebral fracture associated with spondylodiscitis (n = 5), spinal metastasis (n = 1), or screw backout (n = 13) and those who were lost to follow-up within one year (n = 2) were excluded. The final study population included 35 patients who had undergone posterior instrumentation with pedicle screws for degenerative spine disease and developed an upper or lower instrumented vertebral fracture (Fig. 1). The typical clinical presentations were back pain and soreness with or without an episode of trauma. The findings on plain films or computed tomography scans showed a decrease in vertebral body height with or without an intervertebral cleft sign at the instrumented vertebrae. Conservative treatments for intractable back pain were limited to medication, physical therapy, and wearing of a protective brace.

Surgical Technique

Fluoroscopy-guided Percutaneous Vertebroplasty

The procedure was performed in an operating room with the patient under intravenous sedation and prone on the operating table. A standard sterile preparation was used for the surgical field. Local anesthesia with 1% lidocaine was injected through the planned trajectory under fluoroscopic guidance. Because the standard trajectory was blocked by the existing pedicle screw, a 12.7-cm trochar (Stryker Corp., Kalamazoo, MI) was adjusted via a lateropedicular approach. Under the anteroposterior view of the fluoroscope, the trochar tip was located lateral on the 2 o'clock or 10 o'clock position of the pedicle screw head. Along the trajectory direction of the pedicle screw, the trochar was inserted into the pedicle to avoid dural injury on the medial side. Turning to a lateral view, the depth of the bilateral trochar inserted into the anterior aspect of the vertebral body was visualized. The trochar position was checked on an anteroposterior view, lateral view, and an additional oblique view for better visualization. A probe was placed in contact with the anterior cortex of the vertebral body through the trajectory of the trochar to determine the precise position of the trochar tip. The same steps for insertion of the trochar were used for the contralateral screws. After aspiration of blood and gas around the vertebral defect, the cement (Confidence, DePuy Synthes, West Chester, PA) was carefully injected bilaterally under lateral fluoroscopic guidance (Figs. 2e, 2f). The injection was considered complete when the cement filled the vertebral defect without extravasation to the spinal canal or neuroforamen (Fig. 2).

Extension of instrumentation

The patient was placed prone on a radiolucent table under general anesthesia. After standard sterile preparation of the surgical field, a single posterior midline incision was made along the scar from the previous spine surgery. The loosening pedicle screws were found at the upper or lower instrumented fracture and carefully removed. The new pedicle screws were then inserted into the adjacent level of the vertebra of the instrumented fracture. The upper and lower instruments were connected by dominos. Posterolateral

bone grafting was performed to create circumferential fusion in patients with nonunion after initial pedicle screw fixation (Fig. 3).

Evaluation of Outcomes

The demographic data and perioperative data were analyzed (Table 1). The patients were followed up in an outpatient clinic at one week and one, 3, 6, and 12 months postoperatively. Clinical outcomes were evaluated by comparing preoperative and postoperative visual analog scale (VAS) scores, correction of kyphotic angles on plain films, and Kirkaldy-Willis functional scores (19). The kyphotic (Cobb) angle was measured as the angle between the superior endplate of the superior vertebra and the inferior endplate of the inferior vertebra (Fig. 4). We defined the kyphotic angle as a positive value and the lordotic angle as a negative value. Surgical correction

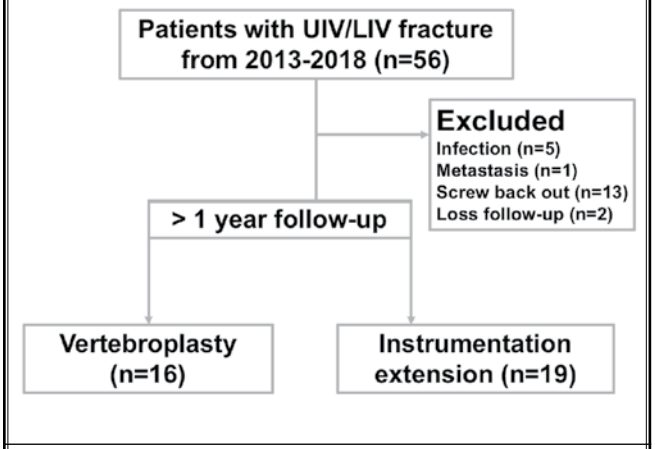

Fig 1. *Flow chart describing the study population. LIV, lower instrumented vertebral fracture; UIV, upper instrumented vertebral fracture.*

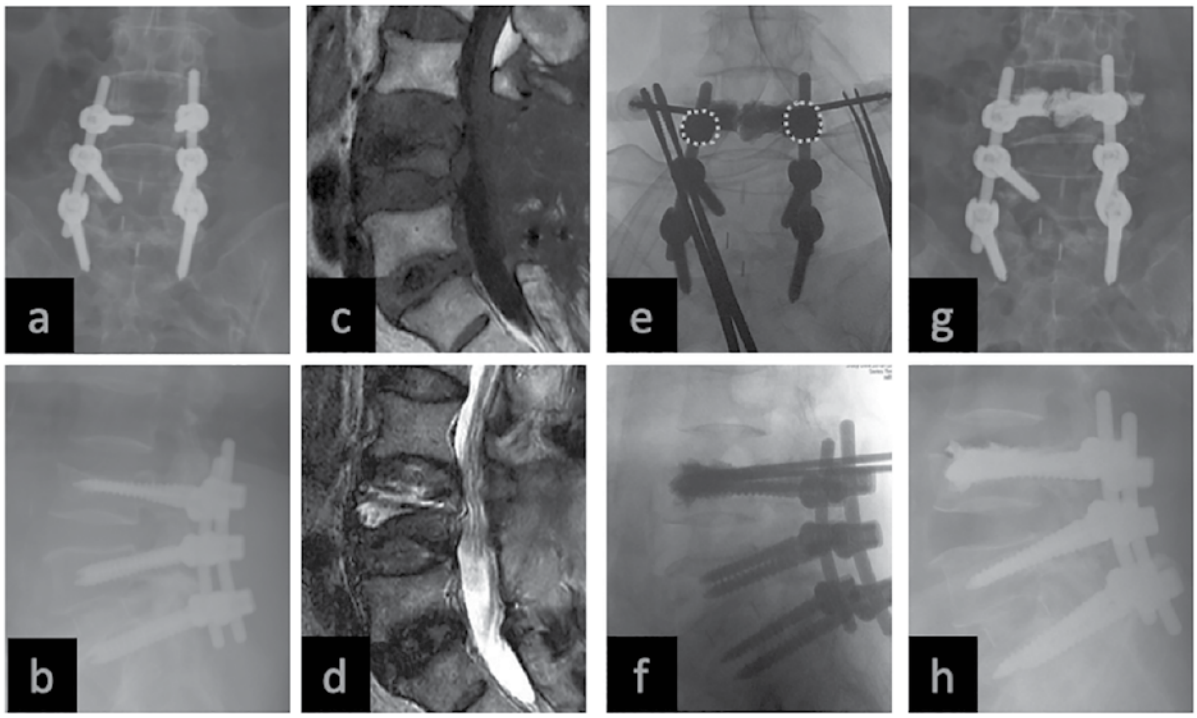

Fig 2. *(a, b) Preoperative plain films show an instrumented vertebral fracture at L4 with a decrease in vertebral body height. (c, d) Preoperative sagittal T1-weighted and T2-weighted images showing the intervertebral cleft sign with air and fluid in parallel with the instrumented fracture at L4. (e, f) Intraoperative anteroposterior and lateral images showing good cement augmentation via a lateropedicular approach. The ideal trochar insertion was identified as 2 o'clock or 10 o'clock lateral to the dotted screw head in anteroposterior view. (g, h) Plain films obtained immediately after surgery showing good cement filling within the L4 vertebral body. Note the small round density around the L4 upper endplate. This was the extravasated cement after removal of the 12.7cm trochar; the patient did not have any postoperative cement-induced neurological deterioration or complication.*

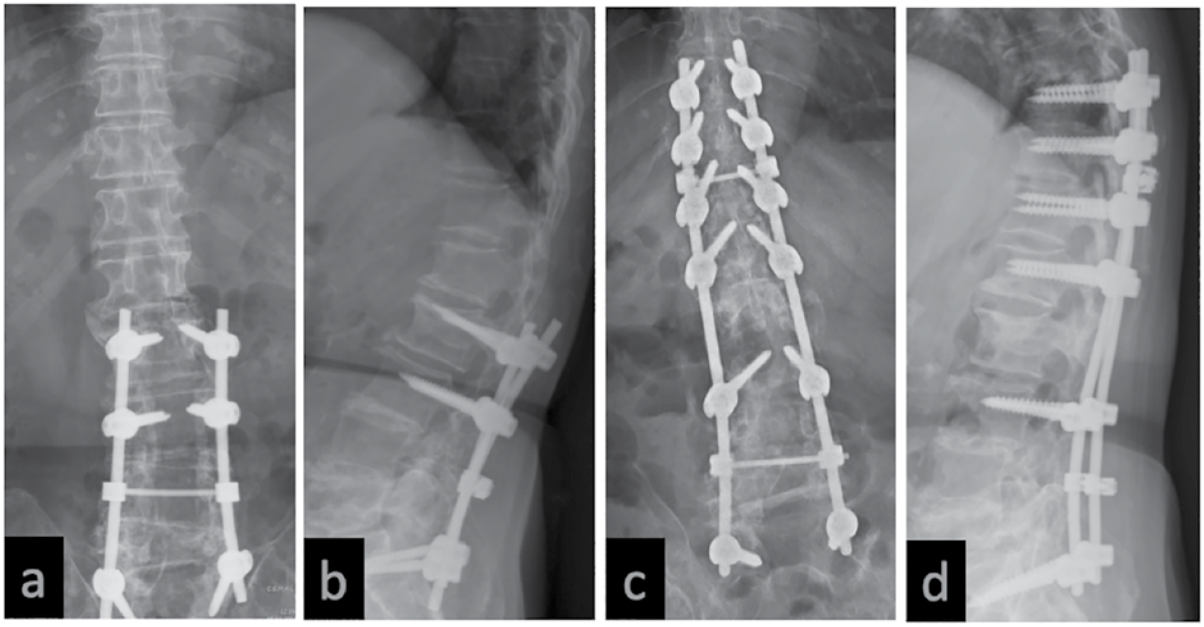

Fig 3. *(a, b) Preoperative anteroposterior and lateral radiographs showing an instrumented fracture at L2 and an adjacent vertebral fracture at L1. (c, d) Plain films obtained postoperatively showing extension instrumentation to T11.*

of the kyphotic angle was calculated on lateral plain films by the first author using the following equation: postoperative kyphotic angle – preoperative kyphotic angle ($\theta_2 - \theta_1$, Fig. 4). Any intraoperative or postoperative complications were also reviewed.

Statistical Analysis

Continuous variables were compared between the 2 groups using the independent t-test and categorical variables using the χ^2 test. All statistical analyses were performed using IBM SPSS version 20.0 software (IBM Corp., Armonk, NY). A P value < 0.05 was considered statistically significant.

Results

The 16 patients in Group I comprised 4 men and 12 women with a mean age of 72.3 ± 8.8 years; the 19 patients in Group II included 3 men and 16 women with a mean age of 70.6 ± 8.6 years. The mean interval between the initial surgery and instrumented fracture was 154.9 ± 38.7 days in Group I and 139.1 ± 25.0 days in Group II; the mean interval between the instrumented fracture and revision surgery was 120.8 ± 30.5 days in Group I and 114.7 ± 15.4 days in Group II. Sixteen upper instrumented vertebral fractures and 7 lower instrumented vertebral fractures were treated in group I and 14 upper instrumented vertebral fractures and 6 lower instrumented vertebral fractures in Group II. The mean follow-up duration was 14.6 ± 5.3 months in group I and 16.8 ± 5.5 months in Group II. There were no significant between-group differences in the demographic data (Table 1).

The average operating time was significantly shorter in Group I (79.7 ± 32.3 minutes vs 199.0 ± 70.1 minutes, $P < 0.001$) and the mean amount of intraoperative blood loss was also significantly less in Group I (1.6 ± 0.8 mL vs 629.0 ± 400.5 mL, $P < 0.001$). The mean time to postoperative ambulation was significantly shorter in Group I (day 0.1 vs day 1.8, $P < 0.001$). The mean postoperative hospital stay was significantly shorter in Group I (3 [range 2–5] days vs 8 [range 4–19] days, $P < 0.001$; Table 2). No perioperative or postoperative cement-induced neurological deterioration occurred in Group I and there was no uncontrolled perioperative or postoperative bleeding or cases of incidental durotomy in Group II. There were no major perioperative respiratory, gastrointestinal, or genitourinary complications in either study group.

The mean VAS score improved significantly by one week after surgery in both groups (from 6.0 ± 0.7 to 3.3 ± 2.0 in Group I and from 5.4 ± 1.8 to 2.8 ± 1.8 in Group II; both $P = 0.001$; Table 3). There was no significant

Table 1. *Patient demographic data*

	Group I (n = 16)	Group II (n = 19)	*P* value
Age (years)	72.3 ± 8.8 (range, 45 - 85)	70.6 ± 8.6 (range, 53 - 89)	0.55
Gender (M/W)	4/12	3/16	0.51
BMD (T-score)	-2.7 ± 0.6	-2.8 ± 0.9	0.78
Time of instrumented fracture after initial surgery (days)	154.9 ± 38.7 (range, 134 - 175)	139.1 ± 25.0 (range, 127 - 151)	0.15
Time between revision OP and instrumented fracture (days)	120.8 ± 30.5 (range, 104 - 137)	114.7 ± 15.4 (range, 107 - 122)	0.45
Previous level of fused (No.)	5.1 ± 1.1 (range, 3 - 8)	6.2 ± 2.4 (range, 4 - 13)	0.32
UIV/LIV fracture (No.)	16/7	14/6	0.58
UIV fracture			
T9	0	1	
T10	0	2	
T11	1	2	
T12	1	1	
L1	7	3	
L2	5	5	
L3	1	0	
L4	1	0	
LIV fracture			
L4	0	4	
L5	2	2	
S1	5	0	
Follow-up time (months)	14.6 ± 5.3 (range, 12 - 25)	16.8 ± 5.5 (range, 12 - 32)	0.42

Group I: fluoroscopy-guided percutaneous vertebroplasty; Group II: extension of the instrumentation; M: men; W: women; BMD: bone mineral density; OP: operation; UIV/LIV: upper instrumented vertebra/ lower instrumented vertebra

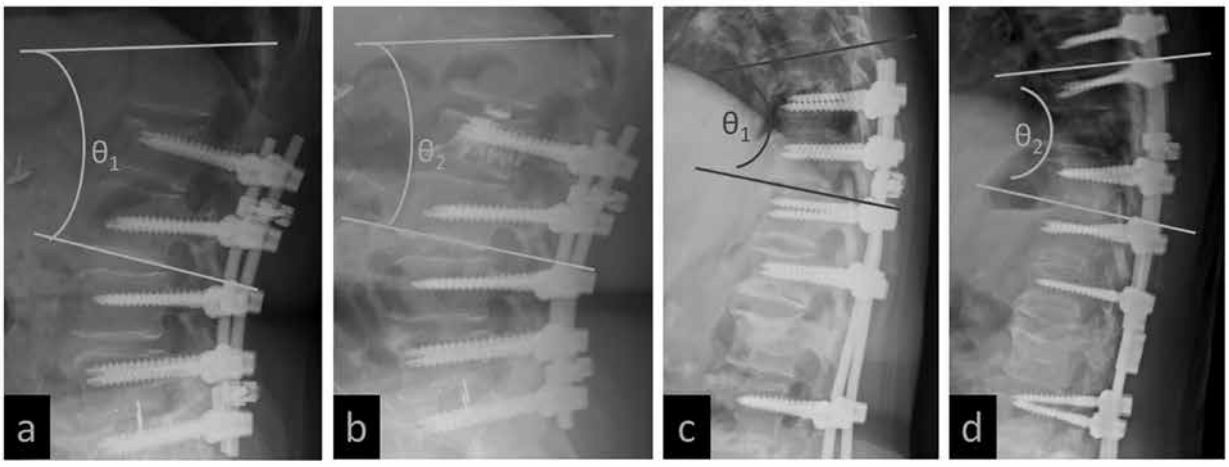

Fig 4. *The Cobb angle was measured as the angle between the superior endplate of the superior vertebra and the inferior endplate of the vertebra inferior to the fractured vertebra on lateral plain films. (a, c) Preoperative kyphotic angle (θ1). (b, d) Postoperative kyphotic angle (θ2). The kyphotic angle was calculated using the following equation: postoperative kyphotic angle – preoperative kyphotic angle, (θ2 – θ1).*

Table 2. *Clinical outcomes and complications.*

	Group I (n = 16)	Group II (n = 19)	*P* value
OP time (min)	79.7 ± 32.3 (range, 62 - 97)	199.0 ± 70.1 (range, 165 - 233)	< 0.001*
Blood loss (mL)	1.6 ± 0.8 (range, 1.1 - 2.0)	629.0 ± 400.5 (range, 436 - 822)	< 0.001*
Ambulation time (postoperative d)	0.1 (range, 0 - 1)	1.8 (range, 1-5)	< 0.001*
Hospital stay (d)	3 (range, 2 - 5)	8 (range, 4 - 19)	< 0.001*
Kirkaldy-Willis functional score (No.)			0.91
Excellent	4	5	
Good	5	4	
Fair	3	5	
Poor	4	5	
Re-operation (No.)			
Rod broken	1	1	
Adjacent fracture	3	1	
New UIV/LIV fracture	0	1	
Reinserted screw loosening	0	1	
Poor wound healing	0	1	
Total	4	5	0.93

Group I: fluoroscopy-guided percutaneous vertebroplasty; Group II: extension of the instrumentation; OP: operation; UIV/LIV: upper instrumented vertebra/ lower instrumented vertebra, *$P < 0.05$

between-group difference in the preoperative and postoperative VAS scores. The preoperative kyphotic (θ_1) angle was not significantly different between Group I and Group II (-9.2° ± 18.0° vs -9.5° ± 18.8°, P = 0.96); however, the respective mean correction of the kyphotic angle ($\theta_2 - \theta_1$) was 2.9° ± 8.5° in Group I and 11.2° ± 14.6° in Group II (P = 0.04) at one week, 2.7° ± 9.1° and 9.7° ± 11.7°, respectively, at one month (P = 0.05), 2.4° ± 9.2° and 9.8° ± 11.2° at 3 months (P = 0.03), 1.6° ± 9.2° and 9.1° ± 10.5° at 6 months (P = 0.03), and 1.2° ± 9.5° and 10.4° ± 12.6° at 12 months (P = 0.01). All correction values were significantly more effective in Group II than in Group I (Table 3).

At the last follow-up visit, there was no significant difference in the Kirkaldy-Willis functional score for return to activity between groups (P = 0.91). Four patients in Group I needed revision surgery: one for the rods breaking on both sides after an accidental fall (n = 1) and 3 for an adjacent vertebral compression fracture. Three patients underwent open revision surgery to extend the instrumentation and one underwent repeat fluoroscopy-guided percutaneous vertebroplasty for an adjacent fracture. Four patients in Group II required revision surgery: one for rod breakage after a fall, one for an adjacent compression fracture, one for an instrumented fracture at the level of extension, and one for pedicle screw loosening. All 4 patients underwent revision open extension surgery. One other patient with poor surgical wound healing and tissue necrosis underwent debridement. There was no significant difference in the reoperation rate between the 2 groups (P = 0.93; Table 2).

Discussion

The traditional treatment for an instrumented vertebral fracture is open surgery to remove the loosening pedicle screws, extend the posterior instrumentation, and reinsert more pedicle screws. O'Leary et al (11) reported improvement in clinical symptoms in 31 patients who underwent revision extension surgery. However, open surgery entails significant blood loss, which may lead to hypovolemic shock, and a more extensive operative field that may lead to long operating and anesthesia times and a prolonged hospital stay and recovery time. Therefore, this option may be contraindicated in patients who are elderly, medically complex, and fragile and in those for whom the risks of general anesthesia are higher.

Another concern is for the complications which can occur with extension of the posterior instrumentation. In a study by Yagi et al (15), 23 (1.4%) of 1,668 patients developed junctional failure after posterior spinal fusion and instrumentation. After revision extension spinal fusion to a more proximal level was performed, 9 of these 23 patients still needed additional revision extension surgery because of new proximal junctional failure at the upper instrumented vertebra. Furthermore, revision extension surgery was required in 2 of the 9 patients due to further proximal junctional failure during follow-up. Further proximal junctional failure is reportedly common after traditional open revision surgery. Repeated rounds of extension surgery to treat ongoing instrumented failure is not only a catastrophic experience for patients but also an economic burden (20).

Minimally invasive cement augmentation reduces the likelihood of perioperative complications, resolves symptoms, and improves quality of life. However, this

technique was only recently developed and only a few case series have been reported. The technical challenge during the procedure is the existing implants, including the pedicle screws and connecting rods, which are also an obstacle to the trajectory of the trochar into the vertebral body. In a series reported by Fu and Li (8), 10 patients were treated with percutaneous cement augmentation for loosened pedicle screws and instrumented fracture via a lateropedicular approach under fluoroscopic guidance only to avoid a high radiation dose. Cianfoni et al (17) described 31 patients with instrumentation failure whom they treated with fluoroscopy-guided cement augmentation under moderate sedation and local anesthesia. In that series, transpedicular and extrapedicular approaches were used for trochar insertion to overcome the access constraints imposed by the implants. In all the abovementioned reports, the VAS scores improved during at least 6 months of follow-up, and no patient experienced cement augmentation-related complications or a neurologic deficit.

In our study, patients undergoing fluoroscopy-guided percutaneous vertebroplasty had a shorter operating time, less blood loss, earlier recovery, and a shorter hospital stay. Furthermore, these patients did not have any immediate or postoperative complications of cement leakage into the posterior spinal canal or neural foramina. The postoperative VAS score improved significantly during at least one year of follow-up in both our study groups, with no significant between-group difference in the amount of improvement. Similar improvement was noted in the Kirkaldy-Willis functional score, again with no significant difference between the groups. We suggest that this minimally invasive procedure is an effective, feasible, and alternative treatment for patients with instrumented fracture.

The postoperative kyphotic angle correction was more effective in Group II than in Group I, which is consistent with the finding in previous studies that vertebroplasty for osteoporotic compression fracture could reduce pain effectively but without adequate restoration of height or correction of the kyphotic angle following cement augmentation (21-23). With abnormal or excessive mechanical stress on the spine, increasing the kyphotic angle may induce adjacent fracture and retropulsion of bony fragments into the spinal canal, causing progressive kyphosis and neurological complications (24,25). Although posterior spinal instrumentation has the advantage of being able to correct localized kyphosis and achieve long-term stabilization, successful long-term durable fixation on osteoporotic bone without instrumentation failure remains challenging (26,27). In our study, there was no progressive postvertebroplasty kyphosis-related neuropathy or refracture in Group I and the complication rate was similar in the 2 groups. Therefore, we believe that percutaneous vertebroplasty resulted in good clinical outcomes despite inadequate correction of the kyphotic angle.

Four patients in Group I and 4 in Group II needed additional surgery due to screw loosening, fracture within or adjacent to the instrumented segment, or broken rods. In a study by Cianfoni et al (17), 5 of 28 patients required additional extension instrumentation for failure of access during the procedure, refracture, kyphosis despite cement augmentation, or instrumentation failure. Xu et al (21) reported that one of 11 patients required additional revision surgery due to a

Table 3. *Preoperative and postoperative parameters.*

	Group I (n = 16)	Group II (n = 19)	P value
VAS score			
Preoperative	6.0 ± 0.7	5.4 ± 1.8	0.29
Postoperative			
One week	3.3 ± 2.0	2.8 ± 1.8	0.46
One month	2.9 ± 1.8	2.4 ± 1.2	0.37
3 months	2.8 ± 1.5	2.2 ± 1.4	0.16
6 months	2.5 ± 1.9	2.2 ± 2.0	0.63
12 months	2.5 ± 2.5	2.1 ± 2.1	0.53
P value	*< 0.001	*0.001	
Kyphosis angle (°)			
Pre-op (θ1)	-9.2 ± 18.0	-9.5 ± 18.8	0.96
Postoperative (θ2)			
One week	-6.3 ± 14.0	1.7 ± 19.0	0.16
One month	-6.5 ± 15.5	0.2 ± 17.0	0.21
3 months	-6.8 ± 15.7	0.2 ± 17.2	0.20
6 months	-7.6 ± 17.1	-0.4 ± 16.5	0.20
12 months	-6.4 ± 16.0	0.9 ± 18.3	0.21
Correction of kyphosis angle (°) (θ2-θ1)			
One week	2.9 ± 8.5	11.2 ± 14.6	0.04*
One month	2.7 ± 9.1	9.7 ± 11.7	0.05*
3 months	2.4 ± 9.2	9.8 ± 11.2	0.03*
6 months	1.6 ± 9.2	9.1 ± 10.5	0.03*
12 months	1.2 ± 9.5	10.4 ± 12.6	0.01*

Group I: fluoroscopy-guided percutaneous vertebroplasty; Group II: extension of the instrumentation; VAS: visual analog scale; OP: operation; *: $P < 0.05$

unilateral rod fracture after the procedure. Moreover, Fu and Li (8) reported a 20% additional revision rate due to symptomatic pedicle loosening and instrumentation-associated vertebral fracture. We believe that the major cause of implant failure and repeat instrumented fracture was poor bone quality despite a successful procedure (the T-score for bone mineral density was 3.0 in Group I and 3.2 in Group II). Therefore, treatment for osteoporosis, including modification of activity, wearing of a protective brace, and medication, is extremely important in this patient population (28).

Limitations

Our study has several limitations. First, it had a retrospective design, which introduced a degree of selection bias. Second, given the rarity of instrumented fractures, the patient sample was relatively small with limited power for statistical analysis. A larger prospective cohort with long-term follow-up is needed. Finally, in some cases of major instrumented failure, such as backout screws, disassembly of implants, and progressive kyphotic deformity, traditional open surgery seems necessary. Whether fluoroscopy-guided percutaneous cement augmentation or another feasible, safe, and effective minimally invasive surgery can be combined with traditional open surgery in such situations should be evaluated. The main strength of our study is that it compares the recent trend of minimally invasive surgery and traditional treatment for instrumented fracture. Furthermore, it provides more generalizable outcomes data than the previous studies, which only compared the preoperative and postoperative pain scores as the surgical outcome.

Conclusion

In conclusion, fluoroscopy-guided percutaneous vertebroplasty has several advantages over traditional open revision surgery, including a shorter operating time, a shorter hospital stay, and less blood loss. Although open surgery still provides adequate correction of kyphotic angle, the clinical outcomes and complication rates between the 2 groups in our study are similar despite the commonality of junctional failure requiring extension surgery as reported in the literature regarding traditional surgery. We recommend this minimally invasive procedure as an alternative treatment for patients with instrumented fractures.

Ethical Approval

This study was approved by the institutional review board of Chang Gung Medical Foundation (No. 201901635B0, approved on 2019/11/11).

Author Contributions

Chang. Acquisition of data: Chang. Analysis and interpretation of data: all authors. Drafting the article: Huang. Critically revising the article: Chang. Approved the final version of the manuscript: all authors. Study supervision: Chang.

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