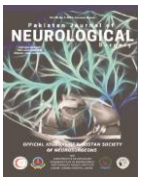

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Original Article

Efficacy of Balloon Kyphoplasty in Compression Fractures of the Thoracolumbar Spine

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ABSTRACT

Objective: To study the Efficacy of Balloon Kyphoplasty in compression fractures of the thoracolumbar spine.

Material and Methods: This study was conducted on 95 patients with thoracolumbar wedge fractures from 2017 to 2022. Complete neurological examination and CT and MRI scans of the spine of all patients were done. All patients have been treated with a balloon kyphoplasty procedure. Data was collected on VAS score, SF-36 score, kyphotic angle and percentage of vertebral body destruction both preoperatively and post-operatively. Statistical analysis was done by using paired sample t-test.

Results: The mean age was 57 years. Males were 58.9% and females 41.0%. Osteoporosis was the cause of fracture in 90.5% and trauma in 9.4% of patients. VAS improved from 7.42 ± 1.24 to post-procedure 3.24 ± 1.51, P < 0.0001. SF-36 improved from 35.31 ± 17.4 to post-procedure 49.23 ± 19.2, P < 0.0001. Kyphosis angle restoration from 18.42 ± 7.41 to post-procedure 10.61 ± 6.32, P value < 0.0001. Percentage loss of vertebral height from 32.91% to postoperatively 17.64% (SD-17.2 and P < 0.0001). 10.5% of patients developed cement leakage and there is no leakage in 89.4%. The adjacent level fracture occurred in 4 patients.

Conclusion: Balloon Kyphoplasty is an effective procedure for thoracolumbar wedge fractures. It improves pain, activities of daily living, kyphosis angle improvement, and restoration of vertebral height.

Keywords: Balloon Kyphoplasty, Vertebral Compression Fractures (VCF), Visual analog score (VAS), SF-36 (short form score-36), PMMA (Poly methyl methacrylate) bone cement.

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INTRODUCTION

Osteoporotic compression fractures of the spine are a common problem that we encounter in our clinical practice. It is common in elderly patients because of osteoporosis of bones. Pain and spinal deformity are important symptoms of these patients which affects the quality of life these

patients.[1] Conservative management includes analgesics, bed rest, and bone strengthening medication.[16] The thoracolumbar orthosis can be used for initial pain relief but its prolonged use is not well tolerated by old age patients with impaired lung functions and muscle atrophy. This leads to further bone loss and osteoporosis.[4,7] Operative management via open fixation is required in cases where there is neurological compromise or delayed kyphotic deformity correction. Historically vertebroplasty was first started for treatment of vertebral hemangiomas by injecting PMMA (Poly methyl methacrylate) cement. Later on, the same treatment was used to treat myelomas and metastasis. In 1993 this technique was used for the treatment of osteoporotic fractures pain management. In 1999 new technique kyphoplasty was introduced in which a balloon was inflated into the fractured vertebral body with the restoration of vertebral endplates. Later bone cement was injected into the fractured vertebral body.[10,13] A study was conducted by Ledlie et al[7] in which 155 patients were operated on for kyphoplasty and this showed significant improvement in VAS of 4.5 out of 10.[7] Theodorou et al, found improvement in kyphotic angle from 26 to 16 degrees in 24 patients post kyphoplasty.[1]

Vertebroplasty and kyphoplasty procedures continue to evolve with time. There are innovations in cannula systems, cement systems, and multiple systems to improve vertebral height. There are specially designed curettes that help in the restoration of vertebral body height. There are alternatives to balloon inflation. These include the permanently implanted stacks and wafers that are implanted into the fractured vertebral body. Nowadays there is continuous interest in the development of bone cement. One approach is extracorporeal radiofrequency heating of bone cement and slow injection of bone cement. PMMA bone cement can be mixed with a radioisotope and injected into the metastatic vertebrae. Bioactive materials are becoming popular because their properties match the native bone.[4,7,15]

The rationale of this study is to determine clinical and radiological outcomes after balloon kyphoplasty after VCF in our hospital setup. No local study is available in our setups of this new technique. We have included both traumatic and osteoporotic fractures in our study as compared to previous national studies where only osteoporotic fractures were treated with kyphoplasty.

MATERIAL AND METHOD

Study Design and Setting

A prospective case study was conducted in the Neurosurgery department of Bakhtawar Amin medical college and hospital Multan from December 2017 to May 2020.

Inclusion Criteria

95 patients having VCF were included in our study. These were admitted from OPD and emergency. These patients had severe back pain due to VCF with intact neurological status. All patients were having osteoporotic or traumatic wedge fractures. These patients had intact posterior vertebral walls without a breach in the cortex.

Exclusion Criteria

Patients having unstable fractures, complete vertebral collapse, fractures with breach of posterior cortex, fractures with neurological compromise, spinal tumors, signs of infection, history of spine surgeries, allergic to polymethylmethacrylate bone cement, patients having previous kyphoplasty procedure, patients having more than three levels involved and coagulopathies were excluded from the study.

Sampling Technique and Sample Size

95 patients were included by simple random sampling technique in our study. The sample size was calculated using the software G Power version 3.1.9.4. Considering the values of effect size as 0.3, alpha as 0.05, and power of the test as 80% a sample size of 104 was calculated. However, we took a sample size of 95 patients.

Clinical Management

All patients were admitted to the hospital. All patients were evaluated by a team of surgeons, anesthetists, and medical specialists. Complete history, physical examination, and baseline tests were done. Intravenous analgesics and bone strengthening medications were started and they were advised to complete bed rest. A thoracolumbar orthotic brace was applied to all patients initially for pain relief. Radiological evaluation was done by X-ray of spine AP and lateral views.[4] CT (Computerized tomography) and MRI (Magnetic resonance imaging) of the spine were done on all patients. In MRI there should be no spinal cord compression with intact intervertebral discs. CT scan was mandatory to evaluate the morphology of the fracture, the status of end plates, and the breach of the posterior vertebral cortex.[4,13]

Data Collection

Data were collected from these patients. Parameters that were evaluated for pain improvement and quality of life post-procedure were VAS (Visual analog scale), and SF-36 (short form -36 score) respectively.[9,17]

VAS was evaluated on a paper with a horizontal line of 100 mm drawn on paper. 10 points from left to right were written on that line and the patient had to choose the status of pain pre-procedure and post-procedure. SF-36 is a health score that is evaluated by an eight-scaled score (vitality, physical functioning, body pain, general health perceptions, emotional role function, social role function, mental health, and physical role function).[8] Each question carried equal weight and the scale was transformed to a 0-100 score. The higher the score, the less will the disability be.

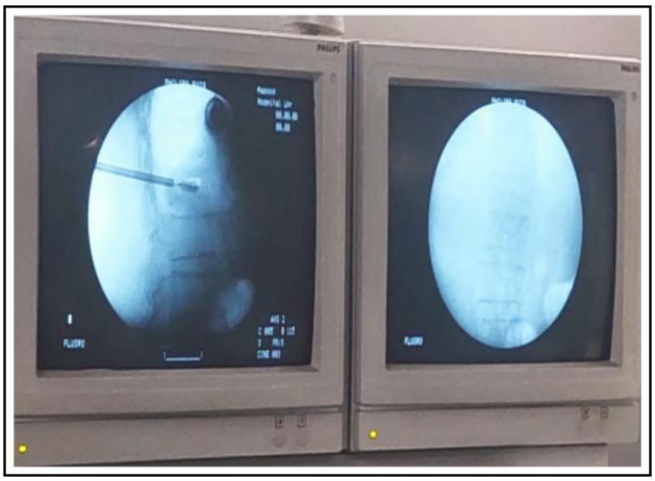
The kyphotic angle of the spine was calculated by lateral x-ray of the spine using a method by Raja Sekeran.[10] In this technique, one line was drawn on the upper endplate of the upper intact vertebra and another line was drawn along the lower endplate of vertebrae below the VCF. This kyphotic angle was calculated pre and post-procedure to evaluate the improvement of kyphosis.[17] The percentage of vertebral body height loss was evaluated by CT scans of the spine which were evaluated both pre-procedure and post-procedure.[11,19] All the pros and cons of the technique were explained to patients and detailed informed consent was taken. Intraoperative pictures and preoperative and postoperative radiographs of patients were taken with the permission and consent of the patients.

Surgical Management

The procedure was done by the consultant surgeon under local anesthesia with monitoring by a consultant anesthetist. Patients were positioned prone on a radiolucent operation table with C-arm guidance. Pressure points were secured with gel pads. Preoperative antibiotic injection ceftriaxone 1.0 gm was given after checking sensitivity. Sterile draping was done after disinfection with pyodine solution. First, the surgical level was marked under C –arm both AP and lateral views. The local anesthetic 1% lignocaine (diluted) was applied.[12,15,6] Under C-arm guidance, the fractured vertebral body was entered by transpedicular route using the Jamshidi needle. The stylet of the needle was removed and the guide wire was passed through the sheath and the needle was removed. Cannulas were used to dilate the track of the pedicle (Figure 1-a) Kyphoplasty balloon was inserted into the working channel and was

advanced to the anterior 3/4 of the vertebral body and its position was confirmed by C-arm AP and lateral view. The balloon was inflated with radiopaque dye keeping an eye on the pressure gauge which should not be more than 280 psi (Figure 1-b). The size of the balloon, restoration of body height, and elevation of endplates were confirmed by C-arm.[16,7] The polymethylmethacrylate bone cement was slowly mixed until it started hardening. The balloon was slowly deflated and removed. Cement filling devices were filled with bone cement and then put in the working channel and cement was put with a pusher into the space of the vertebral body (Figure 1-c). Regular radiological evaluation with C-arm was done to determine the distribution of cement in the body.

During the cement filling the working channel was rotated periodically to prevent the adherence of the channel to the cement. The working channel was removed slowly to prevent leakage of cement into the pedicle. Multiple precautionary measures were taken during the procedure to prevent cement leakage. The procedure was being carried out in local anesthesia so cement leakage into the spinal canal was hazardous. These include thorough preoperative evaluation of the status of posterior vertebral cortex breach, placement of kyphoplasty balloon in the anterior 3/ 4 of VCF, continuous radiological evaluation by C-arm, and making the correct viscosity of the bone cement.[1,8,16,20]



a: Cannula inserted in vertebrae.

b: Kyphoplasty balloon inflation with pressure gauge and radiopaque contrast. (picture included with patient' consent)

C: cement injected into vertebrae.
Figure 1: the intraoperative technique of balloon kyphoplasty. (pictures included with consent)

Post-procedure Management

Patients have managed post-procedure in high dependency units for 24 hours. Neurological monitoring including sensory and motor evaluation in lower limbs was done for 1 hour along with monitoring of vitals and intake output record for any complication. After 24 hours patients were shifted to the ward and slowly mobilized and physiotherapy started. Postoperative radiographs were taken to determine the status of VCF, kyphotic angle correction, vertebral body height restoration, and cement distribution.[9,15] Postoperative VAS and SF 36 scores were also taken to determine the improvement in pain and quality of life. Patients were discharged 2 to 3 days after surgery.[8,20]

Follow up

Follow-up was done initially after 2 weeks then 1, 2, 6, 12, 15, and 24 months. On every visit, the radiological evaluation was done by x-ray of spine AP and lateral views including vertebral body height and kyphotic angle.

The data were analyzed by SPSS version 21. Descriptive analysis was done of age, the number of vertebral levels involved, etiology of fracture, gender of patients, complications, and cement leakage.[7,19]

Analytical analysis was done by paired sample t-test with a p-value < 0.05 was taken as significant. This was done to determine the level of significance between pre-procedure and post-procedure variables including loss of vertebral body height, kyphotic angle, VAS score, and SF-36 scores.[6,11,16]

RESULTS

Age and Gender Distribution

95 patients were operated on for kyphoplasty. The mean age was 57 years (range from 29 to 72). Male to female distribution is male 56 (58.9%) and females 39 (41.0%).

Clinical Information

As far etiology of fracture cases was concerned osteoporosis was the cause of fracture in 86 patients (90.5%) and trauma in 9 (9.47%) patients. A single level was involved in 88 patients (92.6%), two levels were involved in 4 patients (4.21%) and three levels were involved in 3 patients (3.15%). 65 patients have a fracture at the thoracic level (68.4%) and 30 patients have a fracture at the lumbar level (31.5%). In the thoracic spine, upper thoracic (T1 to T4) fracture in 10 patients (15.3%), mid-thoracic level (T5 to T8) fracture in 15 patients (23.0%) and lower thoracic (T9 to T12) fracture occurs in 40 patients (61.5%). The mean follow-up of patients was 16 months (range is 13 to 18 months).

Analytical Analysis

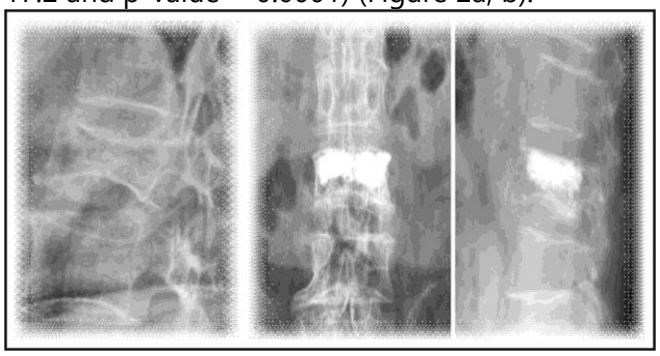
Pain improvement in VAS score after surgery was analyzed, there was a significant improvement in pain VAS from a pre-procedure mean of 7.42 ± 1.24 to a post-procedure VAS mean of 3.24 ± 1.51 with a p-value < 0.0001 (Table 1).

Table 1: Analysis of VAS score, SF-36, and kyphotic angle by paired sample t-test.

	Pre-operative Mean ± SD	Post-operative Mean ± SD	P-value
VAS scale	7.42 ± 1.24	3.24 ± 1.51	< 0.0001
SF-36 score	35.31 ± 17.4	49.23 ± 19.2	< 0.0001
Kyphosis angle	18.42 ± 7.41	10.61 ± 6.32	< 0.0001

As far as SF-36 score improvement was studied, there was a significant improvement in SF-36 from a pre-procedure mean of 35.31 ± to 17.4 to post-procedure 49.23 ± 19.2 with a p-value < 0.0001.

Kyphotic angle improvement postoperatively as compared to pre-operatively was analyzed. The results showed that the pre-procedure mean angle was 18.42 ± 7.41 and post-procedure mean angle was 10.61 ± 6.32 with a p-value < 0.0001.
The percentage of vertebral body loss of height both pre and post-operatively was assessed. The mean percentage loss of vertebral height pre-operatively was 32.91% and post-operatively to 17.64% with a mean improvement of 15.27% (SD-17.2 and p-value < 0.0001) (Figure 2a, b).



a. Preoperative x-ray b. Postoperative x-ray.

Figure 2: preoperative and postoperative radiographs of kyphoplasty technique of osteoporotic fracture. (Image used with consent)

Complications

The first complication was noted as cement leakage. Cement leakage occurred in 10 patients (10.5%) and there was no leakage in 85 patients (89.4 %). In those patients in whom cement leakage occurred, there was leakage in superior disc space in 1 patient (14.2 %), inferior disc space in 2 patients (28.5%), anterolateral leakage of cement in 4 patients (57.1%), and posterolateral leakage occurred in 3 patients (42.8%). The second complication was of adjacent level fracture which occurred in 4 patients. Three patients had an upper vertebral level fracture and one patient had a lower vertebral level fracture. Three patients did not improve after kyphoplasty and they require open fixation with pedicle screws. One patient developed pulmonary embolism due to venous leakage of cement. He remained admitted to ICU under the care of a cardiologist and pulmonologist. His pulmonary angiography was also done. Ultimately he recovered and was discharged. There was no wound complication except for 3 cases of minor superficial infection which were healed with dressing and oral antibiotics.

DISCUSSION

There are multiple causes of compression fractures of the thoracolumbar spine. Osteoporosis, trauma, and metastatic collapse are the most common causes of fracture. In our study, we include both osteoporotic and traumatic wedge fractures for the treatment of kyphoplasty. Osteoporotic fractures are an important cause of disability and morbidity in elderly patients. This causes pain, disability, and decreased quality of life and there is an impairment of physical wellbeing and self-image.[2,5,17,19] One fracture increases the risk of a second osteoporotic fracture four times. Respiratory function is also affected. Osteoporosis is a progressive systemic skeletal disease that increases the fragility of bones and makes them susceptible to fracture.[6,21]

Vertebroplasty and kyphoplasty both are percutaneous techniques in which an early setting bone cement is injected into the fractured vertebral body to relieve pain and disability.[1,6,8]

These techniques have been used in painful osteoporotic vertebral compression fractures (VCF), trauma, and tumor compression fractures. The key differences between kyphoplasty and vertebroplasty are the specialized cannula system, the balloon and pressure monitoring gauge system, and the technique of cement injection. These specialized features increase the time and complexity of the technique but decrease the chance of cement leakage. In kyphoplasty, we introduce inflating balloon into the vertebral body under fluoroscopic guidance. By inflating a balloon a space is created in the vertebral body in which bone cement can be filled it also restores the height of vertebrae[6,20] (Figure 2).

As far as improvement in post-procedure pain was concerned, the primary aim of both vertebroplasty and kyphoplasty is analgesia. Most patients got pain relief immediately after the procedure but some continue to take analgesics for a short period. About 90% of patients' pain improved. A multicenteric study was conducted by Ledlie et al.[7] in which 155 patients were operated on for kyphoplasty and these show significant improvement in VAS of 4.5 out of 10. Another study by Hodler et al, and Evans et al, was done which also showed significant improvement in VAS post-operatively. Our study results pre-procedure mean of VAS 7.42 ± 1.24 to post-procedure VAS mean of 3.24 ± 1.51 with p-value < 0.0001 matched with the international literature and we found significant improvement in VAS post kyphoplasty procedure.

Improvement in SF-36 was assessed in patients with kyphoplasty. These patients were usually bedridden with pain. With kyphoplasty, their activities of daily living resumed significantly and there was a functional improvement in rehabilitation. Couman et al. conducted a study on 300 patients.[20] This was a randomized control trial in which patients were managed by kyphoplasty or medical management. SF 36 was assessed after 1 month and it showed significantly greater improvement in kyphoplasty patients and no clinical adverse outcome was found. In our study, we found the same results with mean SF-36 35.31 ± to 17.4 to post-procedure 49.23 ± 19.2 with p-value <0.0001 which showed significant improvement in short form 36 score post kyphoplasty.

Kyphoplasty had an additional benefit of improvement in mechanical stability and sagittal balance improvement of fracture kyphotic angle. Kyphosis leads to decreased lung function, quality of life, and chronic back pain. By improving kyphotic angle with kyphoplasty, there is an improvement in pulmonary function and deformity correction. Philips et al worked on improvement in kyphotic angle in 52 patients treated with kyphoplasty.[16] He found 58% fracture reducible with kyphoplasty with a mean angle improvement of 14 degrees. Theodorou et al, found improvement in kyphotic angle from 26 to 16 degrees in 24 patients post kyphoplasty.[1] Our study results showed that the pre-procedure mean angle was 18.42 ± 7.41 and the post-procedure mean angle was 10.61 ± 6.32 with a p-value < 0.0001 which significant improvement in kyphotic angle post kyphoplasty.

Height restoration after kyphoplasty had been studied in multiple case series. Height restoration to complete or near complete was achieved in 10 to 20% of patients and some degree is achieved in 80% of patients. Garfin et al did work on patients' vertebral body height restoration after kyphoplasty.[19] According to his study, 95% of patients achieved body height if kyphoplasty was done within 3 months of osteoporotic fracture. Lieberman et al did a multicenter US study on kyphoplasty patients.[11] He found a 35% improvement in vertebral body height after kyphoplasty to its native height which achieved normal sagittal balance. Our results in which mean percentage loss of vertebral height preoperatively was 32.91% and post-operatively to 17.64% with a mean improvement of 15.27% (SD-17.2 and p-value < 0.0001). This correlates with international literature and in significant

improvement in vertebral body height.

The most common complication that is encountered with kyphoplasty is rib fracture. This results from even minor trauma, transfer of patient, or needle placement. The reported incidence is about 3%. Another common complication is cement leakage. The cement spreads along paths of least resistance like fracture clefts and venous clefts. Cement leaks into the anterolateral and posterolateral surfaces of vertebral bodies and intervertebral discs. Cement leakage into the nerve root foramen causing significant symptomatic nerve root compressions and radicular symptoms is also reported which may require local steroid injection blocks or decompressions. Cement leakage into the spinal canal causing cauda equina or spinal cord compressions requires urgent decompression. Sometimes extraosseous spread also occurs which remained asymptomatic. The risk of cement leakage is less in kyphoplasty because a cavity is created and the cement is more viscous and the reported evidence is 14%. In our study cement leakage occurred in 10 patients (10.5%) and there is no leakage in 85 patients (89.4%). In those patients in whom cement leakage occurred, there was leakage in superior disc space in 1 patient (14.2%), inferior disc space in 2 patients (28.5%), anterolateral leakage of cement in 4 patients (57.1%), and posterolateral leakage occurred in 3 patients (42.8%).

LIMITATIONS

One limitation was that our study was non-randomized, so further randomized trials should be needed to check the efficacy of our results. The second limitation was the high cost of kyphoplasty equipment so further research should be required to decrease the health resources with kyphoplasty. The third limitation was that no correlation was checked between different variables of fractured vertebra like restoration of the height of vertebra and VAS score. The fourth limitation was that kyphoplasty and vertebroplasty efficacy was not checked. Vertebroplasty had the advantage of simplicity, low cost, and time-saving. The fifth limitation was medical vs surgical management of fractures with orthotic bracing. This requires further research.

CONCLUSION

In this prospective case study, we concluded that with kyphoplasty in patients with thoracolumbar wedge fractures, there was a significant improvement in post-procedure pain scores, kyphotic angle deformity, activities of daily living, and vertebral height restoration. So kyphoplasty had an added benefit in the management of fractured patients in addition to medical management. Patients needed short hospital stays and morbidity post-procedure. However further randomized trials are required to conclude.

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Additional Information

Disclosures: Authors report no conflict of interest.
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Human Subjects: Consent was obtained by all patients/participants in this study.
Conflicts of Interest:
In compliance with the ICMJE uniform disclosure form, all authors declare the following:

Financial Relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.
Other Relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

AUTHORS CONTRIBUTIONS

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Waqas Noor Chughtai	1. Study design and methodology.
2.	Muhammad Adeel Razzaque	2. Paper writing.
3.	Tanveer Ahmad	3. Data collection and calculations.
4.	Muhammad Tahir	4. Analysis of data and interpretation of results.
5.	Shakeel Ahmad	5. Literature review and referencing.
6.	Shahzeb Nasir	6. Editing and quality insurer.