ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 02 | February - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

TRANSPEDICULAR AUGMENTATION WITH BETA- TRICALCIUM PHOSPHATE AND CALCIUM SULFATE AND SHORT SEGMENT FIXATION IN TRAUMATIC THORACOLUMBAR BURST FRACTURE-A PROSPECTIVE STUDY

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ABSTRACT

Study Design: A prospective study was conducted from November 2021 to March 2024. Purpose: Posterior short-segment stabilization for thoracolumbar burst fractures is recognized for its high incidence of implant failure caused by inadequate anterior support. This research aimed to examine the effectiveness of short-segment transpedicular fixation combined with anterior augmentation using tricalcium phosphate and calcium sulfate hemihydrate grafting. **Overview of Literature:** Thoracolumbar Burst fractures were treated by distraction and ligamentotaxis with traditional pedicle screw instrumentation allowed indirect reduction and kyphosis correction. However, there is a chance of frequent failure to support the anterior spinal column, which ultimately causes loss of correction. Transpedicular intracorporeal grafting with autogenous bone graft and artificial graft substitutes has been used to promote vertebral fracture healing and maintain vertebral height, **Methods:** Patients with single-level thoracolumbar burst fractures undergoing short-segment fixation and completed at least one year of follow-up were included. Thirty-one patients with single-level thoracolumbar fracture underwent posterior short-segment pedicle screws fixation and transpedicular tricalcium phosphate and calcium sulfate hemihydrate grafting. The anterior vertebral height ratio, anterior vertebral height compression ratio of the fractured vertebra, vertebral wedge angle, and canal encroachment ratio were recorded during the follow-up period. **Results:** Thirty-one patients were followed up for at least 12 months. The kyphotic angle improved from an average of 10.7° to -3.59°. Anterior vertebral height was corrected from a preoperative average of 42.3% to 64%. One patient experienced a loss of correction exceeding 10°. **Conclusions:** The results' analysis indicated that this technique effectively corrects deformities, restores vertebral height, prevents early implant failure, and provides satisfactory results.

KEYWORDS

Thoracolumbar, Burst fractures, Short segment fixation, anterior augmentation

INTRODUCTION

Thoracolumbar fractures are the most common type of spine fracture, and they are caused primarily by high- energy events such as falls from heights or motor vehicle accidents[1]. These fractures can result in loss of function, pain, deformity, and paralysis. Burst fractures are the most common type of thoracolumbar fracture.

Burst fracture results from failure of the anterior and middle columns caused by axial loading. Surgery is indicated in burst fractures if the anterior vertebral body height is lost by more than 50%, the canal is compromised by more than 50%, or the angulation is greater than 20 degrees[2].

By using distraction and ligamentotaxis, traditional pedicle screw instrumentation can indirectly reduce and correct kyphosis in thoracolumbar bursts[3], However, because the anterior spinal column is frequently unsupported, loss of correction linked to a high failure rate is not uncommon.

Transpedicular intracorporeal cancellous bone grafting has been used to promote vertebral fracture healing and maintain vertebral height[4], and found effective in maintaining the fractured vertebral height[5]. The primary concern about autogenous cancellous bone grafts harvested from iliac crest ,is donor site complications[6], including infections, pain, and hematoma formation,herniation of abdominal contents,iliac bone fracture[7].Iliac crest bone graft versus autograft laminectomy bone with calcium sulfate has been found equally effective and safe for fusion in treating thoracolumbar burst fracture[8].

Burst fractures have been effectively treated using transpedicular intracorporeal hydroxyapatite stick grafting in conjunction with short pedicle screw fixation [9]. However, there are significant disadvantages to kyphoplasty using polymethylmethacrylate [PMMA][10,11], and thus does not appear to be a suitable cement for patients. The perfect type of bone cement would be a suitable, osteoconductive, slowly biodegradable (resorbable) augmentation substance that can be replaced by freshly created bone.

A biomechanical study evaluated injectable calcium sulfate cement compared with PMMA for kyphoplasty in a simulated cadaverous vertebral compression fracture model. The results suggest that the vertebral strength of calcium sulfate grafting is comparable to that of PMMA grafting[12], so calcium sulfate cement can provide adequate structural support after Surgery.

We hypothesize that posterior short-segment fixation followed by beta-tricalcium phosphate and Calcium sulfate hemihydrate grafting to the fractured vertebra for patients with thoracolumbar burst fractures could provide strength to the anterior spinal column and improve healing of fractured vertebra by enhancing intracorporeal osteoconductive ability and could sufficiently and permanently reduce lost fractured body height, segmental kyphosis and decrease spinal canal encroachment in patients.

MATERIALS AND METHODS

A prospective study was conducted from November 2021 to March 2024. Those who had completed at least one year of follow-up were included in this study. The ethics committee of Nil Ratan Sircar Medical College and Hospital approved the study (NRSMC/IEC/188/2022).

Patients in this prospective study were enrolled based on the following inclusion criteria:
a] single level fracture, b] fracture level at T11-L4, c] unstable burst fracture (a local kyphotic angle >20, or anterior vertebral height collapse >50%, or spinal canal encroachment >50%), f] with at least 1 year of follow up with radiographic and clinical data. Patients with polytrauma, significant osteoporosis, or a prior spinal deformity were excluded from the study.

All patients underwent X-ray, magnetic resonance imaging [MRI], and computed tomography scan [CT]of the thoracolumbar spine preoperatively. The preoperative local kyphotic Cobb angle [LKA], vertebral wedge angle [VWA], anterior vertebral height [AVH], anterior vertebral height ratio [AVHR], anterior vertebral height compressive ratio [AVHC], and canal encroachment ratio of the fractured vertebra were calculated.

The results was declared unsuccessful if radiographs obtained at the follow-up showed an increase of 10° or more in sagittal kyphosis or there is an implant failure[13]compared to the local kyphosis angle measured immediately after Surgery in postoperative radiographs.

Surgical Procedure

The skin over the back of the posterior aspect of the trunk overlaying the thoracolumbar spine was sterilely prepared and draped. The posterior thoracolumbar spine was approached through a midline skin incision based on the fracture site. The subcutaneous tissues and deep fascial layer were split so the paravertebral muscles could be elevated off the posterior elements. The subperiosteal exposure extended laterally until the facet joints and the transverse processes of the segments of interest were fully exposed in preparation for an instrumented spinal arthrodesis. Transpedicular screws were fixed into one level above, one level below the fracture level, and one screw was inserted at the level of the fractured vertebra. Connecting rods were inserted, and a distraction force was applied using a distractor to restore lordosis. A trocar in the cannula was inserted in the pedicle of the fractured vertebra under fluoroscopic guidance until it reached the optimal position. The beta-tricalcium phosphate and calcium sulfate hemihydrate(Genex® Biocomposite, USA) were prepared and introduced to the fractured vertebra after removing the trocar under fluoroscopic guidance(Fig 1).

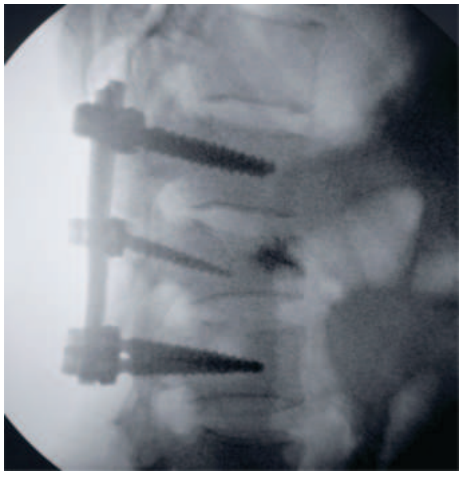

Figure 1: Intraoperative Fluoroscopic Images Of Vertebral Augmentation

A drain was given, and local ropivacaine was injected into subcutaneous tissue for postoperative pain relief. After Surgery, the drainage tube was taken out 24 hours later.

Follow-up x-rays were performed during postoperative day 1 and after 6 months and 12 months follow-up. A postoperative CT scan of the thoracolumbar spine was performed during the follow-up at 12 months. The perioperative blood loss, duration of the operation, and postoperative complications were recorded. The preoperative, postoperative, and final AVH, VWA, LKA, and canal encroachment ratios were measured. The neurological assessment with an ASIA impairment scale was done during the postoperative and final follow-up periods.

RESULTS

The preoperative, postoperative, and final follow-up AVHR, AVHC, VWA, LKA, and canal encroachment ratio were compared using the paired data t-test. A value of $P < 0.001$ denoted statistical significance in all tests.

We enrolled 31 patients in this study,20 were men and 11 were women. Based on the ASIA neurological grading system, three patients had Grade A, 4 had Grade B, 15 had Grade D, 1 had Grade C, and 8 had Grade E on admission. Twenty patients with incomplete neurological impairment and two patients with complete neurological impairment had at least one ASIA-grade neurological improvement on the final follow-up observation.1 patient with incomplete neurological impairment had no improvement in ASIA grade on the final follow-up observation.

The information was gathered in a Microsoft Excel spreadsheet, and statistical analysis was performed. (Microsoft Corporation, Washington, USA). The mean preoperative kyphotic cobb angle was 11.4 ± 11.8, which was statistically significantly decreased at postoperative to -9.19 ± 7.7 ($P<0.001$). From the postoperative to the final follow-up period, the local kyphotic angle increased to a mean -5.34±7.79, which was statistically significant ($P<0.001$ (Fig 2).

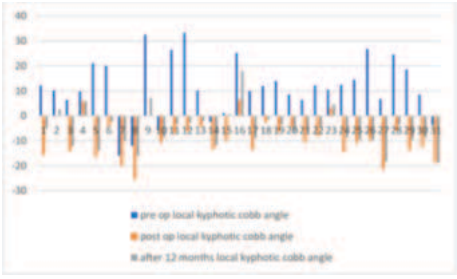

Figure 2: Graphical Comparison Of Pre-op, Immediate Postop, And One- Year Follow-up Of Local Kyphotic Cobb Angle

The mean preoperative canal encroachment ratio was 48.2% ± 26.6%, which was statistically significantly reduced to a mean of 26.9% ± 22.1% on the final follow-up ($P<0.001$) (Fig 3).

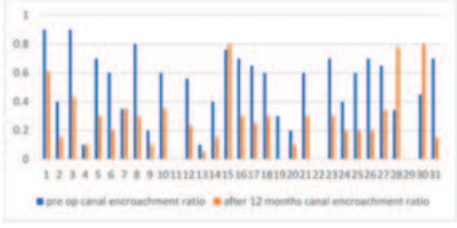

Figure 3: Graphical Comparison Of Pre-op, Immediate Postop, And One- Year Follow-up Of The Canal Encroachment Ratio

The mean preoperative anterior vertebral height ratio was 45.9% ± 18.1%, statistically significantly increasing to 73.8% ± 16.8% postoperatively($P<0.001$). There is a statistically significant increase in the anterior vertebral height ratio from the preoperative period to the final follow-up period to 66%±16% ($P<0.001$) (Fig 4).

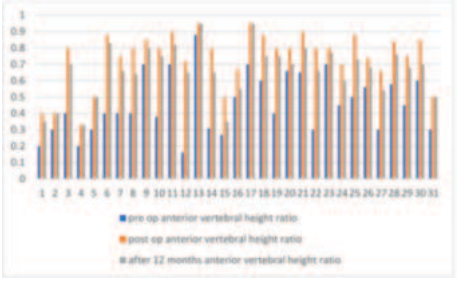

Figure 4: Graphical Comparison Of Pre-op, Immediate Postop, And One- Year Follow-up Of Anterior Vertebral Height Ratio

The preoperative vertebral wedge angle mean was 17.27± 7.3, significantly decreasing postoperatively to a mean of 7.59 ±5.8($P<0.001$). The final follow-up mean of vertebral wedge angle was 9.16 ± 5.680, which was significantly increased compared to the postoperative period($P<0.001$) (Fig5).

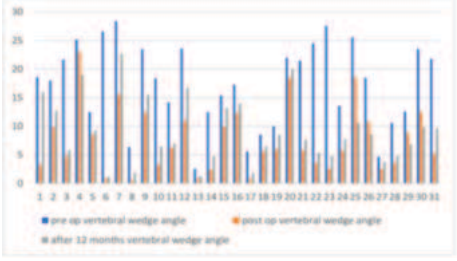

Figure 5: Graphical Comparison Of Pre-op, Immediate Postop, And One- Year Follow-up Of Vertebral Wedge Angle

The mean preoperative AVHC was 54%±17%which, which

statistically considerably decreased to 27%+16% (P,.001). From the preoperative to the final follow-up, the AVHC decreased to 33%±16%(P<.001), which was statistically significant. (Fig6).

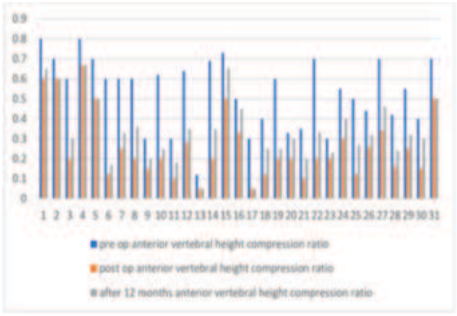

Figure 6: Graphical Comparison Of Pre-op, Immediate Postop, And One- Year Follow-up Of Anterior Vertebral Compression Ratio.

At the last follow-up 12 months after surgery, no significant bone defect, no fracture line was seen, and the bone healed well compared to the preoperative status (Fig7a,b).

Figure 7: Imaging Of A Typical Patient Who Underwent The Transpedicular Short Segment Fixation With Anterior Augmentation By Beta-tricalcium Phosphate And Calcium Sulfate A: Preoperative Anteroposterior And Lateral X-ray Demonstrating Burst Fracture Of The Vertebral Body

Figure 8: B: Follow-up X-ray Showing Correction Of Kyphosis With Gain Of Height

A CT scan at 1 year showed complete assimilation of graft. (Fig8).

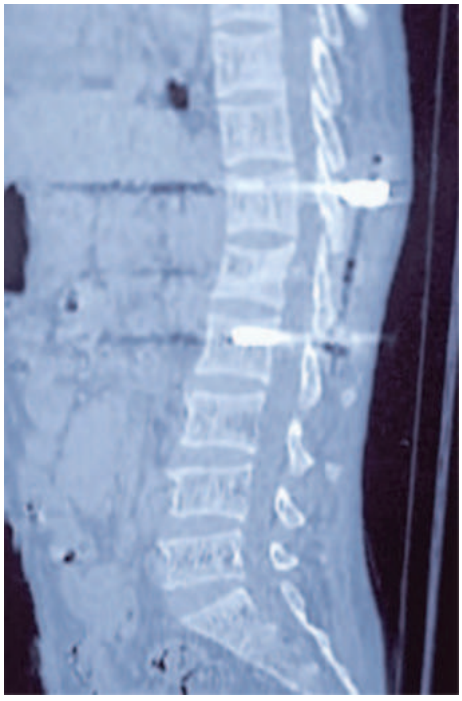

Figure 9: Sagittal CT 12 Months After Operation. The Augmentation Material That Filled The Anterior And Middle Columns Was Absorbed

Complications included one penetration of the pedicle screw through the lateral cortex and one loss of kyphosis >10 on the last follow-up. However, no neurological deterioration was noted, so no further interventions were performed.

DISCUSSION

Thoracolumbar Burst Fractures are clinically common spinal fractures. The most common location for spinal fractures is the thoracolumbar region. The transition from the less mobile thoracic spine to the more mobile lumbar spine turns the thoracolumbar junction into a large area of biomechanical stress. The imaging features include rupture of the vertebral body's posterior wall, retropulsion of the posterior edge of the vertebral body into the lumen, a decrease in the height of the vertebral body, and an increase in the interpedicular distance. Holdsworth [14] believes that burst fractures cause damage to the anterior and middle columns and that the posterior column is often intact, corresponding to a stable fracture. Denis [15] proposed that damage to the middle column is a vital stability factor. All thoracolumbar burst fractures have 2 out of 3 column damage; the middle column is the most important, corresponding to an unstable fracture. Orthotics and bed rest are examples of conservative management that can provide weeks or months of pain relief.

Most stable fractures can benefit from conservative therapy [16], but extended bed rest raises the risk of bedsores, pneumonia, venous thrombosis, and even mortality [17]. Surgical treatment of thoracolumbar fractures, compared with conservative treatment, does provide some advantages, especially for patients who cannot tolerate orthotics for several months, such as patients with polytrauma, dermatology conditions, and high BMI [18]. Additionally, surgical decompression has the potential to be more dependable and successful in eliminating the bone block extending into the spinal canals, regaining neurological function, and enhancing recovery.

In 1984, Denis et al. conducted a retrospective comparison between the surgical and nonsurgical treatment in 52 cases of blowout fractures without neurological defects. They concluded that all patients treated with surgery had no relevant disability and returned to full-time work, whereas 25% of patients without surgery could not return to full-time work [15]. Furthermore, 17% of patients who did not undergo surgery experienced neurological issues. Siebenga et al. found that surgical treatment not only yielded better clinical results but also proved to be more cost-effective compared to conservative management. [19].

Surgical treatment of thoracolumbar burst fractures depends on

various factors, including the patient's neurological status, fracture pattern, and surgeon preference[20]. Short-segment pedicle screw fixation is now used widely, but the acknowledged complications include early reduction failure and loss of sagittal balance leading to recurrent kyphosis. In thoracolumbar burst fractures, the cancellous bone of the vertebral body is compressed, with often endplate collapses, only indirectly restoring the vertebra height by distraction[21]. The bone trabeculae are not wholly reset, leading to incomplete recovery of the depressed end plate. Due to bone defects and voids, the vertebral body forms an eggshell-like configuration. This eggshell-like vertebral body cannot provide sufficient support strength to the anterior and middle columns of the vertebral body[22]. There is further reduced vertebral height and eventual internal fixation failure under slight external forces on the eggshell-like vertebral body.

Several studies have shown that reinforcing fractured vertebrae with bone cement such as polymethacrylate can enhance healing and prevent implant failure. However, Eck et al reported[23],PMMA has complications like a high-temperature setting, possible damage to local nerve and vascular structure, inadequate bone fusion, and a severe stiffness mismatch with bone, which results in subsequent adjacent fractures and even vertebral restenosis.Commonest complication of PMMA augmentation is leakage[24], and the distal cement emboli enter the cardiac cavity and pulmonary system[25].

Yang HL et al[26] observed in their experimental study that β - tricalcium phosphate and calcium sulfate hemihydrate(Genex® Biocomposite, USA), has regenerative capacity, in addition to resorption and incorporation into new bone tissue.

The composition includes β-tricalcium phosphate and calcium sulfate in the same ratio. According to Giannoudis PV [27], β-TCP possesses porosity, when bone tissue adheres to it, osteoid develops, becomes mineralized, and ultimately transforms into bone tissue before resorption.

In a study by Funayama et al. [28] on artificial bone grafting for acute vertebral burst fractures in elderly patients, including patients with osteoporosis, porous ß-tricalcium phosphate shows good clinical potential as a bone-graft substitute.

In a study by Cai et al. [22] the novel transpedicular reducer and bone grafting combined with pedicle screw fixation have a good therapeutic effect in patients with Thoracolumbar burst fractures, which can effectively restore the injured vertebra and reduce complications and postoperative pain, thereby improving quality of life.

Therefore, we applied beta-tricalcium phosphate and calcium sulfate hemihydrate as augmentation material to fill the bone defect in the vertebral body. This augmentation procedure effectively restores vertebral body height and avoids the complications of bone cement.

CONCLUSIONS

Anterior augmentation by calcium composite grafting (beta-tricalcium phosphate and calcium sulfate hemihydrate) is a safe adjunct to short-segment pedicle screw fixation for the treatment of traumatic thoracolumbar burst fractures. Evaluation of the outcomes showed that this method successfully addresses deformities, reinstates vertebral height, prevents implant failure, and yields favorable results.

Additional Information

Disclosures

Human subjects: Institutional Ethics Committee Nil Ratan sircar Meedical College & Hospital issued approval NRSMC IEC 188/2022. **Animal Subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: Nil

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