

Clinical Studies

Time to revisit contraindications of vertebroplasty- A retrospective study of osteoporotic burst fracture operated with vertebroplasty and short segment fixation

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ABSTRACT

Background: To evaluate the safety and efficacy of vertebroplasty with short segmented cement augmented pedicle screws fixation for severe osteoporotic vertebral compression fractures (OVCF) with posterior/anterior wall fracture patients.

Methods: A retrospective study of 48 patients of DGOU type-4 (vertebra plana) OVCF with posterior/anterior wall fracture, were treated by vertebroplasty and short segment PMMA cement augmented pedicle screws fixation. Radiological parameters (kyphosis angle and compression ratio) and clinical parameters Visual analogue scale (VAS) and Oswestry disability index (ODI) were analysed.

Results: A significant improvement was noted in VAS (preoperative, 7.90 ± 0.60 ; final follow-up 2.90 ± 0.54) and ODI (77.10 ± 6.96 to 21.30 ± 6.70), ($P < 0.05$). Neurological improvement was noted in all patients. Kyphosis corrected significantly from preoperative 23.20 ± 5.90 to 5.30 ± 1.40 postoperative with 5% (3.30 ± 2.95) loss of correction at final follow-up. Anterior vertebral height restored significantly from $55.80 \pm 11.9\%$ to $87.6 \pm 13.1\%$ postoperative with $4.5 \pm 4.0\%$ loss at final follow-up. Two cases of cement leakage were found, but both patients were asymptomatic. One patient had implant backout, one had Screw breakage and two had proximal junction kyphosis at final follow-up. No iatrogenic dural or nerve injury.

Conclusions: Treatment with vertebroplasty with cement augmented screw fixation and direct decompression is a great option in treating such a complex situation in fragile age with fragile bones because. Vertebroplasty is a viable option for restoring vertebral anterior columns in patients who are considered as contraindications for vertebroplasty, like DGOU-4. It provides anterior support avoiding corpectomy, minimise blood loss, and also the duration of surgery. The addition of short segment fixation gives adequate support with less stress risers at the junctional area.

INTRODUCTION

The incidence of osteoporotic vertebral compression fractures (OVCF) is gradually increasing with the increasing life expectancy of the population [1,2]. Most OVCFs are well managed conservatively [3]. German Society for Orthopaedics and Trauma (DGOU) classified OVCFs according to the morphological patterns and the biomechanical stability of the fractures. According to the DGOU treatment algorithm was introduced for different types of OVCFs, type 1 and type 2 fractures were only recommended for vertebroplasty followed by failed conservative treatment, and the other three types OVCFs need to be fixed [13]. (Fig. 1).

These severe OVCFs (type-4) can lead to delayed union or non-union (13% and lead to progressive collapse (30%) that can result in kyphosis

with the possibility of neurological deficit (3%) [4]. The principles of OVCF treatment are fixing instability, anterior support, and decompression. There is a paucity of literature regarding ideal surgical procedures [5]. The ideal procedure for OVCF should be the least invasive, smaller surgery duration, minimal blood loss, without implant-related complications, faster recovery, and provide a good neurological and functional outcome. The efficacy of various approaches is well documented in the literature. Anterior approach has high morbidity and mortality in these fragile elderly patients [6]. Posterior long extensive fusion operations have morbidities and complications associated with surgical procedures and long surgical time. Fixation of the osteoporotic vertebra is challenging due to weak and rarefied trabeculae, and weak pedicles which provide poor bone screw interface and it may lead to implant loosening and adjacent segment kyphosis [7–9]. Vertebroplasty in patients with a complete collapse of the vertebra (vertebra plana) is generally avoided due to the risk of cement leakage from the posterior or anterior wall

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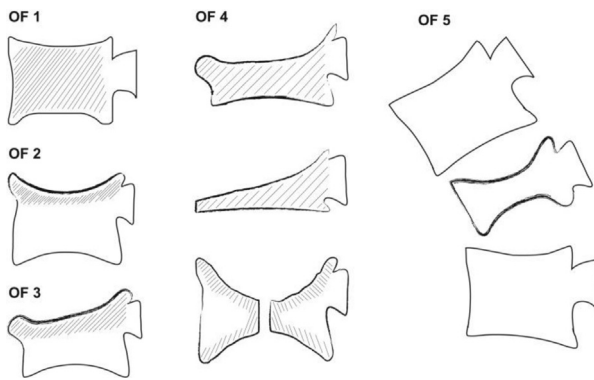


Fig. 1. Schematic representation of the German Society for Orthopaedics and Trauma (DGOU) Osteoporotic vertebral compression fracture subtypes (OF 1-5).

breach, and that lack of anterior height restoration and lack of kyphosis correction [6,10-12]. The study aim was to assess clinical and radiologic outcomes of the vertebroplasty with short-segment PMMA augmented pedicle screw fixation to treat severe OVCFs with anterior-posterior wall fracture patients.

Material and methods

This was a retrospective study including 48 severe OVCF patients who were operated on between 2017 to 2019 with vertebroplasty and short segmented PMMA augmented pedicle screws fixation. Institutional ethics committee approval was taken before conducting this study. All patients were operated by a single surgeon. Inclusion criteria were Age 60-85 years, DEXA scan T score <-2.5, Single level vertebral fracture, DGOU Type-4 OVCF, CT-scan shows Posterior/ Anterior wall fracture and Minimum 18-months follow-up. Exclusion criteria were other pathological fractures, Previously operated spine patients, Uncontrolled diabetes patients and, highly comorbid patients

Surgical procedure

A standard midline posterior approach was used. All pedicle screws were inserted in one level above and below to fractured levels. Vertebroplasty was done for fractured levels. Transpedicular fluid from the non-union site was aspirated. The cement was injected only after it had attained paste form. The cement introducing needle was placed initially at the anterior 1/4th of the body till the anterior wall was sealed with the cement paste after that cement introducer was withdrawn till the middle of the body in the lateral image and more cement paste was injected and withdrawn till posterior 3/4th and cement injected. At the end of the procedure, the whole vertebral body was filled with cement and reasonable body height was achieved. Pedicle screws augmented with PMMA cement. Laminectomy and decompression were done where indicated. Pedicle screws connected with a connecting rod. Posterolateral fusion

with morselized cancellous autograft was performed in all patients. Local vancomycin powder was added to the wound. The closure was done in layers over the surgical negative drain. All patients were started on standard anti-osteoporotic medications as per endocrinologist advice. Surgical parameters including operative time, intraoperative blood loss, and intraoperative complications were noted.

Clinical Assessment

Demographic data (Age, Sex, Mode of injury, Duration of injury to clinical presentation, duration of neurological deficit, Bone Density), Back Pain score – (Visual Analog Score [VAS], Oswestry Disability Index [ODI]), Frankel Neurology Grading and Activity of Daily Living (ADL) Evaluation (Fig. 2).

Radiological assessment

Spine radiographs, Magnetic Resonance Imaging, and computed tomograms (CT) scan, DEXA scan. Radiological parameters–Vertebral body height, local kyphosis angle measured from the superior endplate of immediate, intact cephalic vertebrae, and the inferior endplate of intact caudal vertebrae [9]. Fusion status was assessed by thoracolumbar radiographs and dedicated CT scan of the surgical area after 9-months of the surgery. Implant failure, pull out and adjacent level fractures were noted during the follow-up.

Statistical analysis

Preoperative and postoperative follow-up data of all patients were collected. Statistical analysis was performed using SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA) and paired Student’s t-test. Data were presented as the means ± standard deviations A value of less than 0.05 was considered statistical significance.

Results

A total of 48 OVCF patients (Male: Female= 16:32) underwent surgery with a mean age of 79.19 years. The mean follow-up was 19.2 ± 6.7 months (range 15–32). The average surgical duration was 150.7±21.5 min. The mean blood loss was 130.5 ± 50.6 ml (range 95–180), the mean injected cement volume was 4.5 ± 1.9 ml (range 2.6–7) for vertebroplasty. The mean hospitalization stay days was 6.2 ± 2.8 (range 4–9). The mean duration of delay in the presentation (time from injury to surgery) was 14.31 ± 2.90 weeks (12–24 weeks). The mean T score was -3.79 ± 1.12 (-2.6 to- 5.4). Fractured vertebral levels are mentioned in the table (Table 1).

VAS was significantly improved from a mean value of 7.90 ± 0.60 preoperatively to 4.0 ± 0.54 at one month postoperatively and 2.90 ± 0.54 at final follow-up. ODI was significantly improved from a mean value of 77.10±6.90 preoperatively to 30.50 ± 6.50 at one month postoperatively and 21.30 ± 6.70 at final follow-up. ADL was significantly

Category	ADL Status	Score
C2 (bedbound)	Unable to roll over in bed independently	0
C1 (bedbound)	Able to roll over in bed independently	1
B2 (chair bound)	Able to transfer to wheelchair independently	2
B1 (chair bound)	unable to transfer to wheelchair independently	3
A2 (housebound)	Goes out rarely, with assistance	4
A1 (housebound)	Goes out frequently, with assistance	5
J2 (able to go out independently)	Goes around the neighbourhood	6
J1 (able to go out independently)	Goes out using public transport and goes long way away from home	7
The independence level of person regarding ADL (C2-J1) was determined by a algorithm from the ministry of Health, Welfare and Labour of Japan ADL Activities of daily living		

Fig. 2. Activity of Daily living (ADL) Evaluation.

Table 1
Patient demographic data (n=48).

Variables	Value
Age	79.19
Male: Female Ratio	16:32
Delay in presentation (weeks)	14.31 ± 2.90
DEXA scan T score (mean)	-3.79 ± 1.12
S. Vitamin-D3 (ng/ml)	24.41 ± 8.80
Fracture level	
T10	2
T11	6
T12	20
L1	18
L2	2
Surgical Data	
Duration of Surgery (min)	150.7±21.5
Intraoperative blood loss(ml)	130.5 ± 50.6
Hospital stay (Days)	6.2 ± 2.8
injected cement volume (ml)	4.5 ± 1.9

Table 2
Functional results of patients.

	Mean	SD	p value
VAS			
Preoperative	7.90	0.60	<0.05
Postoperative 1 month	4.00	0.54	
Final follow-up	2.90	0.54	
ODI			
Preoperative	77.10	6.90	<0.05
Postoperative 1 month	30.50	6.50	
Final follow-up	21.30	6.70	
ADL			
Preoperative	2.5	0.44	<0.05
Postoperative	6.0	0.50	

VAS: Visual Analog Score; ODI: Oswestry Disability Index; ADL: Activity of Daily living; SD: Standard deviation

Table 3
Pre- and post-operative neurological status using Frankel grading.

Pre-operative No of patients	Post-operative				
	A	B	C	D	E
C	16			02	14
D	28			02	26
E	4				04

improved from 2.5.5± 0.44 preoperative to 6.0±0.50 postoperatively (p <0.05) (Table 2).

Preoperative neurological status was assessed using Frankel grade (Grade C=16, Grade D=28, Grade-E= four patients). At the final follow-up, all patients showed significant neurological recovery post-operatively (Table 3).

The mean preoperative local kyphotic angle was 23.20°±5.90° and that was improved to 5.30°±3.9° immediately postoperatively and 8.60°±4.60° local kyphosis at final follow-up (p<0.05). The correction of the local kyphotic angle was 18.20°±5.3° (p < 0.05), and the loss of correction was 3.30°± 2.50° (p > 0.05). The mean preoperative anterior body height was 55.80 ± 11.9% that was restored to a mean of 87.6±13.1 and 83.1±12.6 at the final follow-up. The correction of anterior vertebral height was 31.80±8.6 (p < 0.05), and the loss of correction was 4.5± 4.0% (p > 0.05) (Table 4).

All patients showed healing of fractures by six to nine months follow-up as demonstrated on radiographs and CT scans (Fig. 3).

Following surgery, two patients had intradiscal cement leakage but both patients were asymptomatic and managed conservatively. No patient developed an intra-operative dural injury or nerve root injury. One patient had a caudal screw pulled out, one had Screw breakage and two patients had proximal junction failure, all presented with increas-

Table 4
Radiological parameters.

Variables	Value (Mean ±SD)	Anterior height (%)
Pre-Operative	23.20°±5.90°	55.80±11.9
Immediate postoperative	5.30°±3.9°	87.6±13.1
Final follow-up	8.60°±4.60°	83.1±12.6
Correction	18.20°±5.3°	31.80±8.6
Loss of correction	3.30°± 2.50°	4.5±4.0

All data is given is mean with standard deviation (SD).

Table 5
Complications.

Complications	Number
Cement leakage	2
Infection	0
Proximal junctional failure	2
Screw Pull-out	1
Screw breakage	1

ing back pain which required revision surgery in the form of implant removal and extension of the level of fixation. There was no surgical site infection during follow-up in any patients (Table 5).

Discussion

Vertebral compression fractures are common sequelae of osteoporosis and it comprises approximately 40% of osteoporotic fractures annually [14]. There is controversy regarding the optimal treatment of OVCFs. There is poor pedicle screw hold between screw thread and trabeculae of osteoporotic vertebral bone, PMMA cement strengthens this bone/metal interface. Cement augmented pedicle screws increase primary stability, the fatigue resistance of the implants [15,16], and stresses pull-out stresses [17–21]. Long segment fixation is a superior and rigid fixation but is associated with great physiological challenges (sacrificed spine motion and adjustment segment disease) and high perioperative morbidities in these elderly fragile patients [22] (Fig. 4).

Short segmented cement augmented fixation is more reliable because it improves the rigidity and stiffness of pedicle screws. In the literature, some authors reported the success of short segmented instrumentation to manage thoracolumbar burst fracture, but the study population was young adult patients with relatively good bone quality [23]. Posterior short-segment fixation including the fractured vertebral has been widely applied for thoracolumbar fractures, this method can reduce the operation time and blood loss, preserve motion segments compared to long-segment posterior fixation, and provide greater mechanical strength to prevent early implant failure compared with traditional 4-screws short-segment posterior fixation [27]. There is diminished bone quality in the osteoporotic bone that impairs primary screw purchase and increased implant loosening chances, PMMA cement augmented pedicle screw fixation may reduce implant-related complications [24]. Weiser et al [9], Wuisman et al.[15], Ozdemir et al.[25] advocated cement augmentation of pedicle screws to increase the success rate of instrumentation. However, Ryu et al noted in their study that there is a significant risk with the exothermic effect of PMMA cement on nerve roots [26].

Literature suggested that osteoporotic burst fracture with anterior or posterior wall breach is contraindicated for vertebroplasty. Treatment options for acute OVCF have been extensively discussed in the literature but there is a paucity of literature defining the best surgical technique for patients with subacute or chronic OVCF with vertebra plana or other contraindications for vertebroplasty [5,8,19]. In this study, we try to extend the limitation of vertebroplasty to manage the challenging situation of unstable OVCF with Vertebra plana.

In our study, there was significant pain control, functional improvement, and acceptable deformity correction in OVCF patients. DGOU introduced treatment algorithms for OVCFs, type-1 and type-2 fractures

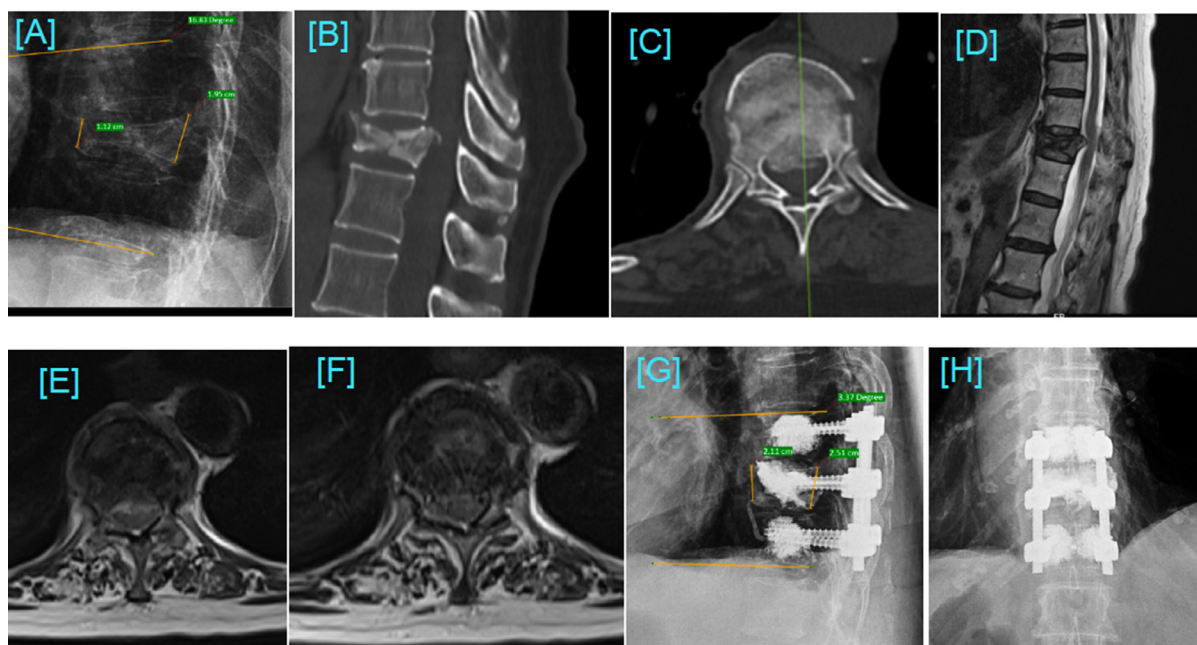


Fig. 3. 80-year-old Female patient with D11 osteoporotic burst fracture underwent Vertebroplasty with cement augmented pedicle screws short segment fixation. [A,B] The preoperative lateral radiograph, sagittal CT scan showed D11 fracture, the kyphosis angle was 16.81° , anterior vertebral height was 57.43%. [C] Axial CT Scan shows retro-pulse posterior wall fragment. [D,E,F] MRI was suggested of D11 vertebral fresh fracture with canal stenosis. [G,H] Postoperative final follow-up radiographs showed the fractured vertebra was restored with local kyphotic angle was 3.37° degree, and the anterior vertebral height was almost normal (84.06%).

were recommended for vertebroplasty if conservative management fails, and the rest of the other types of OVCFs required fixation [13].

Our results demonstrated satisfactory clinical application of this method in severe OVCF patients, effective pain control and improved outcomes were obtained in our series. In this study, all neurological deficit patients improved significantly in follow-ups. In our study, the VAS score improved from 7.90 ± 0.60 to 4.00 ± 0.54 at four weeks postoperative and 2.90 ± 0.54 on final follow-up ($p < 0.05$). ODI scores also significantly improved ($p < 0.05$) from 77.10 ± 6.90 preoperative to 30.50 ± 6.50 one-month postoperative and 21.30 ± 6.70 at final follow-up. Jensen et al [9] found marked pain relief in 90% of the patients within 24-hours. Deramond et al [28] in their study of acute 80 OVCF patients found that more than 90% of the patients had rapid and complete pain relief within 24-hours. However, Cotten et al [29] found that pain relief was not proportional to the degree of lesion filling by PMMA cement during vertebroplasty. Hentschel et al [33] also found significant pain relief with percutaneous vertebroplasty and kyphoplasty in a patient with vertebral fracture with bony metastasis. In our study patients experienced improved mobility within 24-hours, and the majority could bear weight soon after the next day of the surgery, though in our study we had patients with only subacute or chronic OVCF. The pain amount and pain medication could either be reduced or stopped in these patients. In some of our patients, especially those who were bedridden for a long period, pain relief sometimes occurred gradually over a few days.

Uchida et al. had conducted a study in osteoporotic vertebral collapse with neurological deficit in the thoracolumbar spine and found that mean loss of kyphosis correction $4.60 \pm 4.50^\circ$ after posterior surgery (Vertebroplasty-cement augmented short-segment posterior fixation) group and mean loss of $4.50^\circ \pm 5.90^\circ$ in the anterior surgery group, but at final follow-up kyphosis angle was not significantly different between two groups [30]. Kim et al. demonstrated cement augmented six screw fixation including the fractured vertebral is satisfactory in maintaining the deformity correction for the patients with severe osteoporotic unstable burst fractures, the average amount of correction loss of the kyphotic was 2.0 degrees 15-months post-operation, and there were no signs of hardware pull-out, however, the reconstruction of the

fractured vertebral was unacceptable, the height of the vertebral just increased from 35 and 40% to 70% in the anterior and middle portion [31]. In our study, there was a significant improvement in kyphotic angle immediate postoperative and at final follow-up ($p < 0.05$). There was a $2.50 \pm 0.5^\circ$ loss of kyphosis correction at the final follow-up. The anterior vertebral height was reconstructed from 55.8 ± 12.2 to 86.6 ± 13.1 and it was more important than the correction of the Cobb angle. The vertebral height loss of reduction was minimal at the final follow-up.

In our study, initial fracture reduction was achieved by patient prone position on the operation table and we injected cement in a thicker consistency and slowly during vertebroplasty slowly raising the vertebral height in a controlled manner by injecting cement. that further correct kyphosis and maintained that vertebral body height. We performed additional posterolateral fusion in all patients. There was minimal sagittal plane correction loss at final follow-up and minimal loss of anterior body height correction. Cyteval et al [32] found disc leakage in five (25%) of 20 patients, none of whom had complications. Slight PMMA leaks toward the disc, epidural fat, paravertebral soft tissue, epidural veins, and paravertebral veins were observed in 20 (38%) of 52 vertebroplasties; leaks were symptomatic in only five vertebroplasties. These authors suggest that slight cement leaks, when not symptomatic, should not be considered as complications. Deramond et al [28] and Cotten et al [29] indicate that leakage into intervertebral discs and paravertebral soft tissues was frequent and almost always asymptomatic. In our study, only two patients had intradiscal cement leakage found. We were able to extend the limitations of vertebroplasty without significant cement leakage due to the following explanation. Hyperintense intravertebral signal changes are seen on T2-weighted MRI image in non-united OVCFs that is suggested of intravertebral fluid collection. In our belief, this fluid of non-union is contained by a pseudo-membrane within the boundaries of the vertebra which does not allow the fluid to flow out. As we inject cement of thicker consistency in a cavity that already had fluid of less viscosity, the likelihood of cement leakage from that membranous boundary is practically nil. The mean amount of PMMA injected was 6.0 ml (from 5.5 to 7.1 mL), and it was comparable with that used in other series [22,23,26,27]. Our all patients were started with anti-osteoporotic

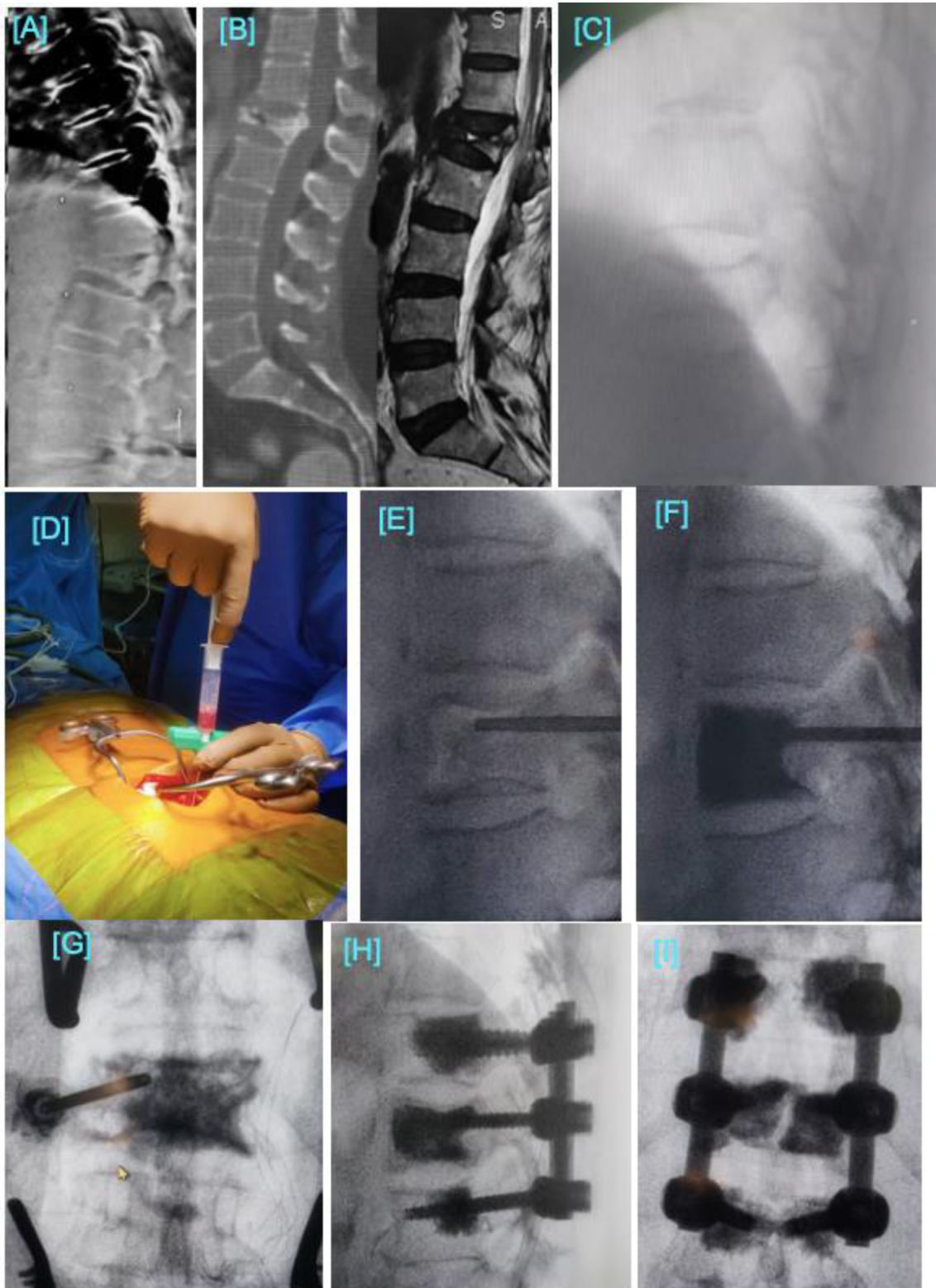


Fig. 4. 72-year-old female patient with D12 osteoporotic burst fracture underwent vertebroplasty with cement augmented pedicle screws short segment fixation. [A,B] The preoperative lateral radiograph, sagittal CT scan showed L1 osteoporotic vertebral fracture with fluid collection on MRI. [C] Radiograph showing correction and partial restoration of vertebral height after prone position on operation table. [D] intraoperative aspiration on fluid from non-united osteoporotic vertebral fracture. [E] Radiograph after aspiration of fluid. [F,G] Vertebrogram. [H,I] Postoperative radiogram showing vertebroplasty with short segment fixation with restoration of vertebral height.

therapy as per the endocrinologist, which increased both bone quality. There are some limitations concerning our study. It is a retrospective study, the number of patients is limited, the follow-up time is short, and there is a lack of control group comparing other possible surgical approaches. Future prospective comparative studies with a larger patient number and longer follow-up are required for confirmation of our results.

Conclusions

Vertebroplasty and short segment fixation a safe and reliable surgical management for severe OVCF, because of the following advances: Early pain relief and early mobility, kyphosis correction and maintenance of correction, decreased Surgical morbidity and, rigid enough biomechanical construct.

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Authors' contributions: Ghanshyam Kakadiya: Writing Original Draft, writing reviewing and editing

Deepak Joshi: Conceptualization, Methodology, Supervision

Mohammad Umair Attar: Writing- Original draft preparation, Writing - reviewing and Editing

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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