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EVALUATION OF SHORT AND LONG TERM BENEFITS/SIDE EFFECTS OF CEMENT AUGMENTATION IN PATIENTS WITH NON INFECTIVE PATHOLOGICAL OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES

Neurosurgery

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ABSTRACT

BACKGROUND: Vertebral compression fracture usually occurs in old age population with osteoporosis. Due to severity of pain, quality of life becomes very poor. **METHODS:** During the study period 67 patients fulfilling the eligibility criteria underwent vertebroplasty/ kyphoplasty/ cement augmented screw fixation/ hybrid procedures were included. Short term and long term benefits /side effects were evaluated in all patients. Patients were evaluated on visual analogue score and modified ranking scale. **RESULTS:** Vertebroplasty was performed in 26(38.8%) whereas kyphoplasty, cement augmented screw fixation and hybrid procedure were performed in 18(26.8%), 17(25.4%) and 6(9.0%) respectively. Significant pain relief occurred in all patients which were evaluated by Visual Analogue Scale. Quality of life also improved which was evaluated with Modified Rankin Scale. In our study, complications which occurred were local cement leak, hematoma formation, infection in 8 (11.9%), 3(4.5%) and 2(3.0%) patients respectively. **CONCLUSION:** Use of biological cement has revolutionized the management of vertebral compression fracture. Both vertebroplasty and kyphoplasty procedures which are minimal invasive, almost cure the non infective pathological fractures with instant pain relief and very low procedure related morbidity. In cases requiring fixation, cement augmentation significantly improves the purchase of the screw and makes the construct more reliable. Hybrid technique helps to prevent extensive long level fixation.

KEYWORDS

Osteoporosis, Vertebroplasty, Kyphoplasty, Cement augmented screw fixation, Hybrid technique

INTRODUCTION

Vertebral compression fracture usually occurs in old age population with osteoporosis.[1] Due to severity of pain, quality of life becomes very poor. Both vertebroplasty and kyphoplasty have gained popularity in recent times. They have overcome the disadvantages of non surgical management i.e. absolute bed rest, brace application and analgesics but still have different complications.[1,2,3] Surgical decompression and instrumentation (Cement augmented screw fixation) is required for patients in which there is neurological deficit and spinal canal compromise by the fracture segment. Evaluation of short term and long term benefits /side effects of cement augmentation in patients with non infective pathological osteoporotic vertebral compression fractures are the aim of our study.

METHODS

This study included patients from June 2012 to May 2016. It was a both retrospective (June 2012 to May 2015) and prospective observational study (June 2015 to May 2016). Informed consent was taken from all the patients who were included in the study. Data was collected on printed PROFORMA.

INCLUSION CRITERIA

All patients with osteoporotic vertebral compression fracture between 40 to 90 years of age and above said procedure were performed. Patients willing to undergo vertebroplasty/ kyphoplasty/cement augmented screw fixation/hybrid procedure.

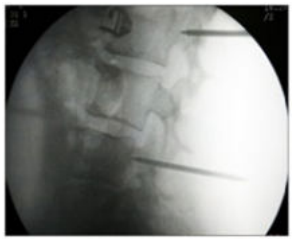
EXCLUSION CRITERIA

Exclusion criteria included the following: spine fracture due to infective pathology, coagulopathy and patients who did not give consent. SPSS (Statistical Package for social sciences) version 21.0 and Epi - info version 3.0 software were used for statistical analysis.

Osteoporosis was diagnosed by qualitative method via spinal radiographs which shows thinned cortices and decreased number of trabeculae. A normal standing radiograph of the painful spine region was requested. CT scan and MRI were done to evaluate further if situation cannot be assessed sufficiently. The clinical presentation and the imaging studies allowed for a decision to be made about the best treatment modality. Vertebroplasty and kyphoplasty were performed by senior neurosurgeon according to the standard method. (Plate no.1 & 2) We also used cement augmented screw fixation and combined procedure (Hybrid) when required. (Plate No. 3)

Plate No. 1: Vertebroplasty 1(a): Jamshedi Needle Insertion; 1(b): Working Channel With Cement Insertion.

1(A)



1(B)

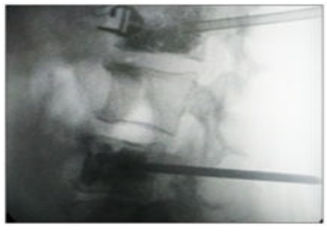


Plate No.2: Kyphoplasty 2(a): Balloon Tamp In Situ; 2(b): Inflated Balloon Tamp In Situ.

2(a)

2(B)

Plate No.3: Hybrid procedure (Cement augmented screw fixation for L3 fracture with vertebroplasty at D11, D12 and L1) for vertebral compression fractures at D11, D12, L1 and L3. 3(A): Sagittal MRI T2WI; 3(B): X – ray AP view; 3(C): Sutured wound with drain.

3(A)

3(B)

3(C)

The outcomes were scored on the Visual analogue scale and Modified Rankin scale for patients enrolled in prospective study. These scores were also used for evaluating patients in retrospective study group by retrieving information from hospital IPD records and follow up OPD consultation sheets. The patients were followed up subsequently during admission, at 1 month, at 3 month and at ≥6 month with X- ray spine prospectively. Post operatively patients were given calcium supplementation and Vitamin D. Patients also received teriparatide (20 Ω gm s/c OD) or bisphosphonates.

RESULTS

During this study period 67 patients fulfilling the eligibility criteria underwent vertebroplasty / kyphoplasty/cement augmented screw fixation/hybrid procedures were enrolled in the study. All patients tolerated surgical procedure well. The patient ranged from 47 years of age to 84 years with mean age of 64.48. In our study, 40 were female and 27 were male patients. Female to male ratio was of 1.48:1. Localized back ache was the main clinical feature present in 65(97%) patients. (Figure No. 1). In half of the patients 35(52.2%) there was history of trivial trauma. In our study, most common affected vertebrae were L1 followed by D12 and L2. (Figure No. 2) These fractures involved multiple vertebrae levels i.e. 1 level in 52(77.6%), 2 levels in 9(13.4%), 3 levels in 3(4.5%), 4 levels in 2(3.0%) and ≥ 5 in 1(1.5%) patients.

Figure No. 1: Clinical Presentation

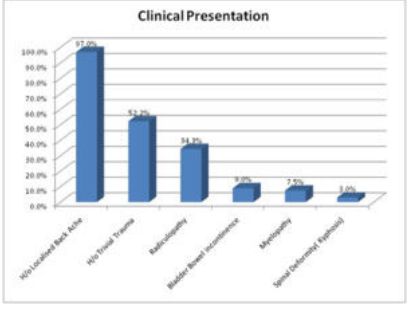
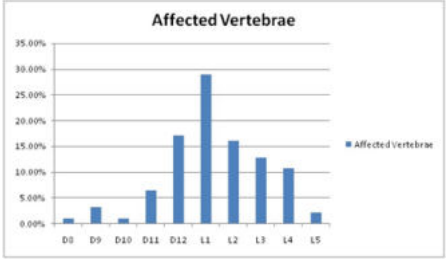


Figure No. 2: Distribution of affected vertebrae



Out of 67 patients enrolled in our study, vertebroplasty, kyphoplasty, cement augmented screw fixation and hybrid procedure were performed in 26(38.8%), 18(26.8%), 17(25.4%) and 6(9.0%) patients respectively depending upon clinical and radiological findings.(Table 1)

TABLE: 1 - Type of Procedures

Sr. No.	Procedure	No. of patient (n)	Percentage (%)
1	Vertebroplasty	26	38.8
2	Kyphoplasty	18	26.8
3	Cement Augmented Screw Fixation	17	25.4
4	Hybrid Technique	06	9.0
	Total	67	100.0

There was a significant difference in mean VAS score and mean MRS score between all groups. The mean VAS score were significantly more among cement augmented screw fixation and hybrid group in comparison to vertebroplasty and kyphoplasty groups. (Table 2) The mean MRS score was significantly more among cement augmented screw fixation and hybrid in comparison to vertebroplasty and kyphoplasty groups. (Table 3)

Table: 2 - Mean VAS score

VAS	Procedure	Number	Mean	Std. Deviation	F -value	p -value
Pre-operatively	Vertebroplasty	26	8.69	0.88	1.951	0.151
	Kyphoplasty	18	8.89	0.90		
	Cement augmented screw fixation	17	8.28	0.57		
	Hybrid	6	8.80	0.84		
Immediately	Vertebroplasty	26	4.42	0.70	7.635	0.001*
	Kyphoplasty	18	4.72	0.83		
	Cement augmented screw fixation	17	5.33	0.69		
	Hybrid	6	5.00	1.00		
At discharge	Vertebroplasty	26	2.88	0.71	13.309	< 0.001*
	Kyphoplasty	18	2.72	0.75		
	Cement augmented screw fixation	17	3.94	0.80		
	Hybrid	6	3.40	0.89		
At 1 month	Vertebroplasty	26	1.92	0.74	18.465	< 0.001*
	Kyphoplasty	18	1.61	0.85		
	Cement augmented screw fixation	17	3.06	0.73		
	Hybrid	6	2.60	0.55		
At 3 months	Vertebroplasty	26	1.54	0.90	14.565	< 0.001*
	Kyphoplasty	18	1.28	0.89		
	Cement augmented screw fixation	17	2.61	0.85		
	Hybrid	6	2.60	0.55		
At ≥ 6 months	Vertebroplasty	26	1.38	0.75	9.259	< 0.001*
	Kyphoplasty	18	1.22	0.88		
	Cement augmented screw fixation	17	2.28	0.89		
	Hybrid	6	2.00	0.71		

One-way ANOVA test *** Significant difference**

Table: 3 - Mean Mrs Score

MRS	Procedure	Number	Mean	Std. Deviation	F -value	p -value
Pre-operatively	Vertebroplasty	26	3.50	0.51	6.350	0.001*
	Kyphoplasty	18	3.44	0.51		
	Cement augmented screw fixation	17	4.11	0.76		
	Hybrid	6	4.20	0.45		
At discharge	Vertebroplasty	26	1.65	0.80	12.538	< 0.001*
	Kyphoplasty	18	1.67	0.69		

	Cement augmented screw fixation	17	3.11	1.23		
	Hybrid	6	3.00	0.71		
At 1 month	Vertebroplasty	26	0.62	0.75	20.913	< 0.001*
	Kyphoplasty	18	0.61	0.70		
	Cement augmented screw fixation	17	2.33	1.08		
	Hybrid	6	2.40	0.89		
At 3 months	Vertebroplasty	26	0.19	0.40	23.027	< 0.001*
	Kyphoplasty	18	0.39	0.70		
	Cement augmented screw fixation	17	1.83	1.04		
	Hybrid	6	1.80	0.84		
At ≥ 6 months	Vertebroplasty	26	0.04	0.20	13.358	< 0.001*
	Kyphoplasty	18	0.17	0.38		
	Cement augmented screw fixation	17	1.33	1.24		
	Hybrid	6	1.00	1.00		

One-way ANOVA test *** Significant difference**

There was a significant difference in mean cement volume / vertebrae between groups. (Table 4) (Figure No. 3). There were no obvious changes on follow up of patients in the morphology and position of bone cement also in upper and lower end plates of the fractured vertebrae. In kyphoplasty group and vertebroplasty group, there was increase in mean vertebral height (middle) of 3.5 mm and 1.3 mm centrally on follow up respectively.

Figure No. 3: Mean Cement Volume (ml) Per Vertebrae

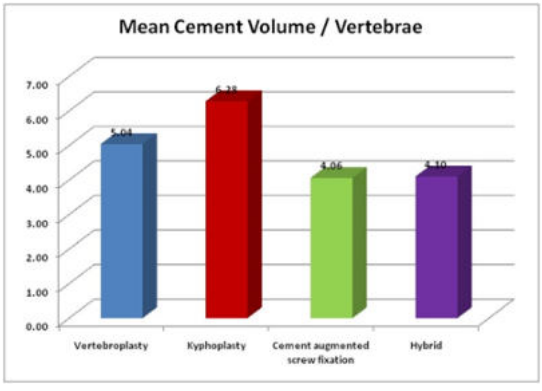


Table: 4 - Mean cement volume (ml) per vertebrae

		Cement Volume (ml)/ Vertebrae				
Sr. No		**Number**	**Mean**	**Std. Deviation**	**F -value**	**p -value**
1	Vertebroplasty	26	5.04	0.37	143.857	< 0.001*
2	Kyphoplasty	18	6.28	0.39		
3	Cement augmented screw fixation	17	4.06	0.24		
4	Hybrid	6	4.10	0.22		

One-way ANOVA test *** Significant difference**

In our study, complications which occurred were local cement leaks, subcutaneous hematoma formation, infection in 8 (11.9%), 3(4.5%) and 2(3.0%) patients respectively among vertebroplasty, kyphoplasty, cement augmented screw fixation and hybrid groups. (Table 5)

Table: 5- Complications

Sr. No.	Complications	No. of patient (n)	Percentage (%)
1	Local cement leaks	08	11.9
2	Subcutaneous hematoma formation	03	4.5
3	Infection	02	3.0

The intradiscal, needle tract and paravertebral cement leaks were significantly more among vertebroplasty group. (Plate No. 4) No epidural and foraminal cement leaks observed. All local cement leaks were asymptomatic. There was no significant difference in the distribution of both subcutaneous hematoma and infection. No death, pulmonary cement embolism, new vertebral compression fracture, increase in back pain, neurological complication and any complication requiring surgery was reported.

Plate No. 4: Radiograph of PMMA cement leakage from the broken endplate in to the intervertebral disc 4(A): X-ray Lateral view; 4(B): C-arm guided AP view.

4(A)

4(B)

DISCUSSION

After age of 50 year, almost 50% of women and 20% of will have an osteoporotic fracture.[4] The most commonly affected vertebrae with osteoporotic vertebral fracture is L1.[5] Similarly in our study, we also observed that commonly affected vertebrae was L1 in 27(29.0%). Compression fractures, most commonly occurred in T8-L4 vertebrae. In our study, patients with both vertebroplasty and kyphoplasty procedures showed significant reduction on VAS Score scale. In cement augmented screw fixation and hybrid group, pain also gets reduced. Vertebroplasty and kyphoplasty effectively stabilize the vertebrae and relive pain in 75-92% of patient.[6,7&8] Chang et al evaluated cannulated cement augmented screw fixation found that pain decreased significantly.[9]

Over all there was significant improvement in disability on MRS in our study. Similarly Blasco and colleagues reported significant improvement of quality of life in Qualeffo total score in vertebroplasty group.[10] Boonen and colleagues found that without additional risk of adjacent vertebral fractures, kyphoplasty rapidly decreases pain and improves quality of life (SF -36 PCS scores).[11] Chang et al evaluated cannulated cement augmented screw fixation found that the functional Oswestry disability index score improved significantly.[9] Hybrid procedure was performed by freud et al in a 97 year old male with lumbar vertebrae burst fracture and showed improvement.[12]

In our study, kyphoplasty group has significantly more mean cement per vertebrae (6.28 ± 0.37). Kruger et al reported that average cement volume used was 6.7 ± 1.9 ml for balloon kyphoplasty. According to Hitawashi et al, average of 7 ml bone cement was required for vertebroplasty.[13] There are reports that when mean cement volume of more than 4 ml used, there was increase in complications rate during procedures.[14] Usually it is 1-4 ml bone cement per screw is required for improving stability. High viscosity bone cement is the important factor for preventing cement leakage. The amount of cement is variable; at the thoracic spine, the volume is about 2 to 5 ml, and at the lumbar spine, it is up to 10 ml. The volume needed is determined by both the degree of porosity and the amount of decrease in height. When an experienced surgeon is conducting the procedure, bone cement can be injected up to three fractured vertebra in one session.[15] In our study we have injected maximum up to three level only. The factor which can limit the number of vertebrae can be treated is the maximum amount of cement which can be safely injected in one session is approximately 25 ml. According to belkoff et al, 2 ml of bone cement is required to gain the strength of vertebral body and 4-8 ml of bone cement needed for restoring stiffness.[16]

In inter-interval comparison of mean vertebral heights anterior, middle and posterior the results for kyphoplasty group were significantly better. In kyphoplasty group, there was increase in mean middle vertebral height 3.5 mm centrally on follow up. Gaitanis et al have reported that the mean central height increment was 4.8 mm after kyphoplasty. [19] In vertebroplasty group, there was increase in mean middle vertebral height 1.3mm centrally on follow up. Hivatashi et al reported that there was an increase of 2.7 mm central vertebral height in 28 patients.[13] Increase in height may be related to injection of high viscosity bone cement under pressure. Kyphoplasty achieve better restoration of height in fractured vertebrae then vertebroplasty because of use of inflatable bone tamp which elevates the end plate. There were no obvious changes in the morphology and position of bone cement during the follow up in fractured vertebrae. Also there were no obvious changes in upper and lower end plate.

In our study, complications which occurred were local cement leak, subcutaneous hematoma formation, infection in 8 (11.9%), 3(4.5%) and 2(3.0%) patients respectively. No death, pulmonary cement embolism, new vertebral compression fracture, increase in back pain, neurological complication and any complication requiring surgery occurred.

There were total 8 local cement leaks (vertebroplasty 6 & kyphoplasty 2) which were visible on x rays but are asymptomatic. Vertebroplasty group had more cement leak as compared to kyphoplasty group where as no cement leak was seen in cement augmented screw fixation and hybrid groups. The intradiscal, needle tract and paravertebral leaks were significantly more among vertebroplasty group where as no leak were present in 59 (88.1%) patients. There was no foraminal and epidural leak in our study. Bregmann et al reported cement leakage in 129 (40.06 %) patients in their study which occurred in intervertebral disc spaces, pedicle, paravertebral, basivertebral plexus, renal vein and cement embolization in to the lungs. These cement leaks were clinically unremarkable.[5] Cement embolization to the lungs leading to death and cement leakage causing canal compromise and paraplegia also been reported.[2,20-21] Other complications include adjacent level vertebrae fracture, increase in pain, rib fractures, venous thromboembolism, bleeding and infection.[3] There is almost no difference in clinical outcome after both vertebroplasty and kyphoplasty.[22]

In vertebroplasty, high bone cement perfusion pressure may cause cement leakage through the cleft in the fractured vertebra body where as cavity created in kyphoplasty decreases the bone cement perfusion pressure which may decrease the bone cement leakage.[23] Main factors for leakage in kyphoplasty may be large amount of bone cement injected and peripheral wall damage. Yang et al also reported that there are less chances of bone cement leak in kyphoplasty as compared to vertebroplasty.[24] Chen et al in their study showed that vertebroplasty and kyphoplasty had bone cement leak 6.67% and 3.33% respectively.[25] Risk of bone cement embolization after cement augmented pedicle screw placement is 0.8% where as in vertebroplasty and kyphoplasty it ranges from 3% to 23%. Treatment options for symptomatic cement embolization include surgical removal of embolism, heparin or warfarin administration for 3 to 6 months.[26]

In our study subcutaneous hematoma formation occurred in 3 (4.5%) patients. Subcutaneous hematoma resolved spontaneously did not required evacuation. Bergmann et al reported in their study that 3 patients required evacuation of subcutaneous hematoma out of 372 patients. [5]

Antibiotics are mixed with bone cement before injecting bone cement by some clinicians to decrease infection.[27] Mechanical strength of the bone cement is not affected by small quantity (< 2 gm of per standard cement pocket) of antibiotics (gentamicin, cefazolin, oxacillin). [28] There are few conflicting reports which showed that when 250-500 mg of gentamicin is used with bone cement it substantially decreases the mechanical strength.[29] Other alternative method, we can give intravenous antibiotics to prevent infection without hampering the mechanical strength of bone cement.[30] In our study, we administered the antibiotics intravenously before the procedure, we had two cases of superficial wound infection in cement augmented screw fixation and hybrid group each managed by local debridement, dressings and culture specific antibiotics.

According to review in 2004 by US FDA of MAUDE (Manufacturer and User Facility Device experience) data base of medical complications, there were 7 deaths caused by vertebroplasty because of (1) anaphylactic reactions to the cement in patients who had preexisting cardiopulmonary disease (2) extravasation of the cement in to spinal canal resulting in cord compression (3) too many vertebral levels being treated at once. [31] There were 21 cases of neurological deficit related to cement extravasation into spinal canal or epidural hematoma, 3 combined episodes of blood pressure drop, 2 pulmonary embolisms, 2 infections (1 osteomyelitis and 1 discitis) and 1 pneuomothorax. Bone cement embolizations into pulmonary and cardiac system were asymptomatic. There were no mortality and neurological complication in our study. There was also no worsening of back pain and any complication which required surgery.

Klazen and colleagues reported that fracture risk for adjacent versus distant vertebrae was not higher and incidence of new vertebral compression fracture was similar after vertebroplasty as compared with the conservative treatment after 11.4 month follow up.[32] According to Lindsay and colleagues, there is 19.2% of relative risk of having another fracture after the initial vertebrae fracture in the first year. [33] In our study there was no incidence of adjacent level vertebral compression fractures. Prophylactic reinforcement with bone cement can be performed on vertebrae next to the fixation level. [34]

In osteoporotic spine, failure rate of spine fixation range from 0.6% to 11%, main reasons for these failures were pedicle screw loosening and pull out. [35]No instrument failure occurred in our study. In our study, symptoms were relieved to various degrees in all patients. Cement augmentation of pedicle screw in osteoporotic bone may be necessary to improve rigidity of the construct.

In our study, six patients underwent hybrid procedure which includes cement augmented screw fixation and vertebroplasty in single stage with good results. Bruval et al reported that kyphoplasty provide more resistant to screw avulsion as compared to vertebroplasty. However both kyphoplasty and vertebroplasty were superior to control group.[38]Chroma et al found that partially fenestrated PMMA augmented screws have improved fixation in osteoporotic spine.[39]There may be risk of cement leakage in these types of screws if the screw is too short and the fenestrated portion is too close to foramen.[40]

CONCLUSION

Benefits of cement augmented procedures can be divided into short term which includes excellent pain relief and long term which includes prevention of recurrent pain, limitation or restoration of height loss, improvement in spinal deformity and improved functional ability. Side effects can be short term i.e. cement extravasations which can cause compression of spinal cord or nerve root, pulmonary embolism, subcutaneous hematoma, infection or even death and long term side effect i.e. new adjacent vertebral fractures, construct failure.

Use of biological cement has revolutionized non infective pathological osteoporotic vertebral compression fracture. Both vertebroplasty and kyphoplasty are minimal invasive method to almost cure non infective pathological fractures with instant pain relief and very low procedure related morbidity. In cases requiring fixation, cement augmentation significantly improves the purchase of the screw and makes the construct more reliable. Hybrid technique helps to prevent extensive long level fixation.

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