PAIN RELIEF AFTER VERTEBROPLASTY FOR OSTEOPOROTIC AND OSTEOLYTIC COMPRESSION FRACTURES

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ABSTRACT

Objective: To find out the role of percutaneous cement vertebroplasty (PCV) in osteoporotic and osteolytic compression fractures of the vertebral bodies using polymethyl methacrylate (PMMA) bone cement in early pain relief.

Design: Quasi-experimental study.

Place and Duration of Study: This study was conducted in Spinal Unit, Orthopaedic Department, Combined Military Hospital, Rawalpindi, Pakistan from Nov 2005 to May 2007.

Patients and Methods: Ten patients with sixteen osteoporotic and osteolytic fractures were treated with PCV using PMMA. Seven patients out of these had osteoporotic vertebral compression fractures (OVCF) and three had compression fractures secondary to spinal metastases (SM). Six patients were males and four were females. Average age among OVCF was 66 years and among SM was 54 years. Patients were followed up on 1st post op day, two weeks and six weeks after PCV. Patient satisfaction, relief in pain, early mobilization, restoration of vertebral height and complications were noted.

Results: Nine out of ten patients were fully satisfied with PCV. Eight patients had excellent pain relief (p value < 0.001). Eight patients were mobilized within two hours of the procedure. There was one major cement leak inside spinal canal causing paraparesis. In this patient immediate exploration, decompression and pedicle screw fixation was done. He had complete neurological recovery post-operatively. Three patients had minor asymptomatic cement leaks. One patient had prolonged ileus, which settled ultimately.

Conclusion: In carefully selected cases, PCV is shown to be very efficacious in relieving the pain associated with both osteoporotic and osteolytic compression fractures. It is a minimally invasive procedure that has gained widespread acceptance as the standard of care for compression fractures unresponsive to traditional forms of treatment.

Key Words: Vertebroplasty; PMMA; Osteoporotic compression fracture; Osteolytic compression fracture; Osteoporosis; Spinal metastases.

INTRODUCTION

With increase in aging population all over the world, low energy spinal fractures due to osteoporosis

and osteolysis have become common problems. The number of osteoporotic compression fractures of spine per year far exceed the number of osteoporotic hip fractures and Colle's fractures combined in United States and they are associated with 30% ageadjusted increase in mortality(1).

Vertebroplasty has become a gold standard in the recent past for treatment of acute osteoporotic and osteolytic compression fractures. This has dramatically improved the outcome in old patients who had to stay in bed for prolonged times after these

fractures. This has also decreased the incidence of

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associated complications of bed rest in the old age population(2).

Vertebroplasty is a procedure in which ultra thin bone cement (Polymethyl methacrylate PMMA) mixed with radio-opaque substance (like sterile barium sulphate) is injected percutaneously in the body of a collapsed vertebra. The injected bone cement gives immediate structural support to the collapsed vertebral body and relieves pain, allowing patient to mobilize within two hours of the procedure. Furthermore this procedure is done under local anaesthesia and can be performed as an outpatient procedure. This procedure, though safe and effective can have serious complications and needs to be learned carefully. There is a steep learning curve and with experience one can perform it safely on a routine basis where indicated(3).

Vertebroplasty was first reported by Galibert et al from France in 1987(4). In USA it was first reported by Jensen et al in 1997(5). In Pakistan Army hospitals, we performed the first case in 2005. This is a relatively new procedure in Pakistan. There is a need for increasing general awareness about this useful procedure.

PATIENTS AND METHODS

This was a quasi-experimental study, carried out at Spinal Unit, Orthopaedic Department, Combined Military Hospital, Rawalpindi, Pakistan. Between Nov 2005 and May 2007, ten patients with sixteen vertebral fractures were treated by percutaneous cement vertebroplasty.

Patient selection was purposive. Inclusion criteria included osteoporotic and osteolytic compression fractures which failed to respond to conservative therapy for at least one month. Patients with fracture duration of over one year, with neurological deficit, bleeding disorders and active infections or skin pathology at the puncture site were excluded. All patients had MRI. Cases with obvious damage to posterior vertebral wall or retropulsion of bone fragments in spinal canal were also excluded.

Procedure was performed under local anaesthesia and mild sedation. Single dose broad spectrum peri-operative IV third generation

cephalosporin antibiotic was used. V-MAX Mixing & Delivery System® (DePuy Spine, Johnson & Johnson) was used to deliver VERTEBROPLASTIC® Radiopaque PMMA (Fig. 1).

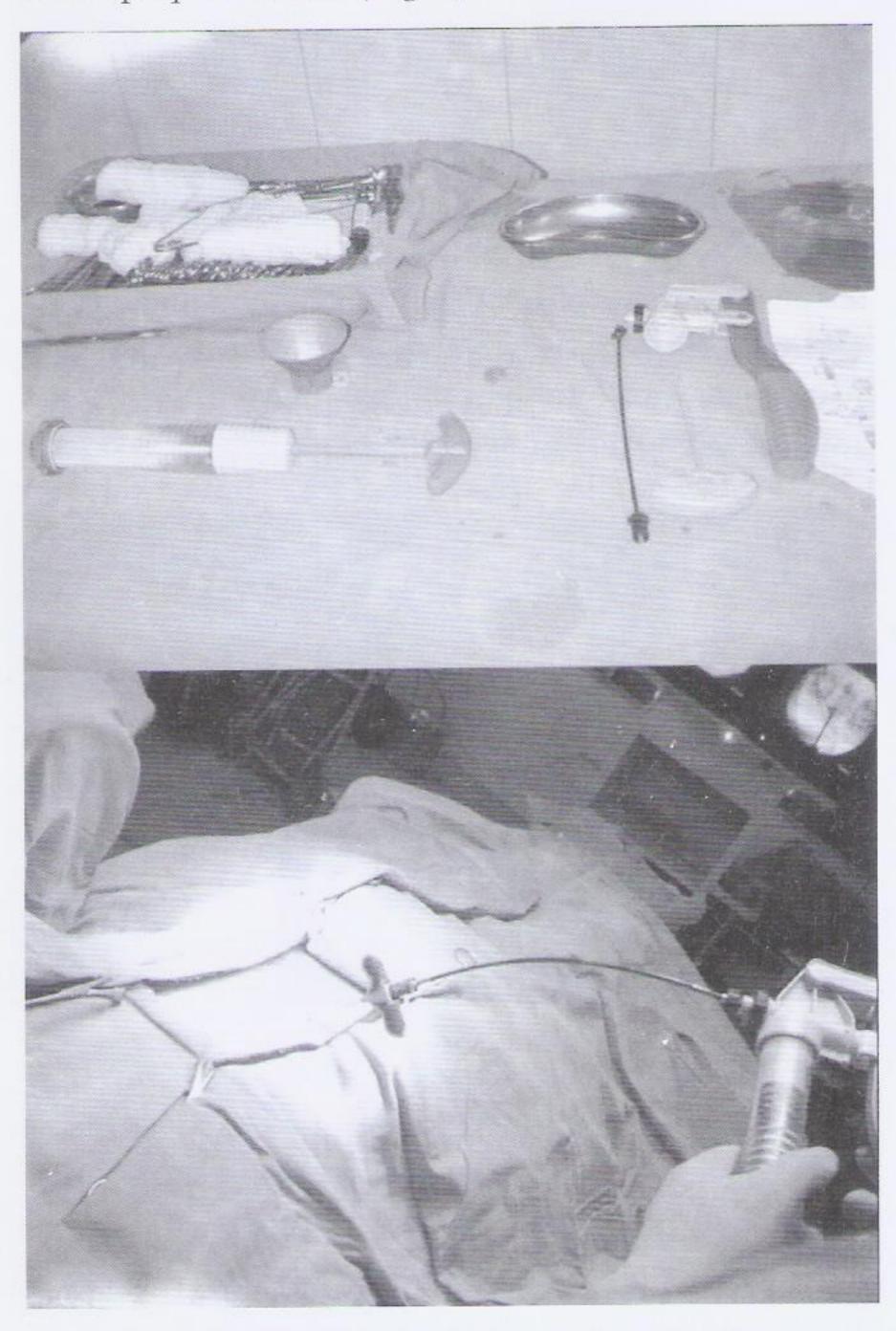


Fig: 1. V-MAX Mixing & Delivery System.

Patients were placed prone on radiolucent table with provision for image intensification in two planes. Single needle technique was used for each vertebral level. Pedicles were identified under image intensifier and spinal needle was used to anaesthetize tract with local anaesthetic. Stab incision was made at place of entry of 11 gauge needle. Needle with obturator was maneuvered in the anterior half of vertebral body, entering from the side of maximal compression, trans-pedicularly. Position of needle was checked under image in two planes. PMMA was injected using special gun under image control till adequate fill was achieved. (Figs: 2 & 3).

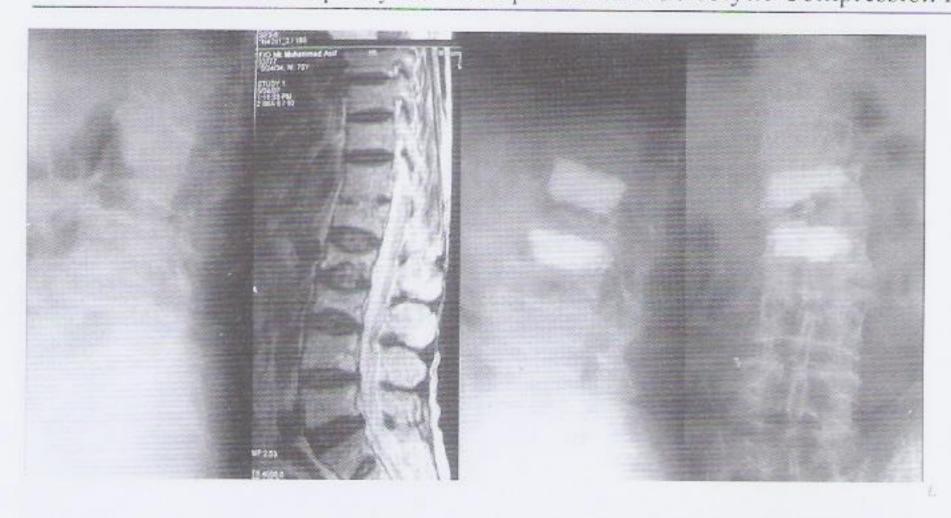


Fig: 2. 73 years old male with osteoporotic vertebral compression fractures L2/3 treated with percutaneous cement vertebroplasty. Old healed fracture at L1 level is also visible on MRI.

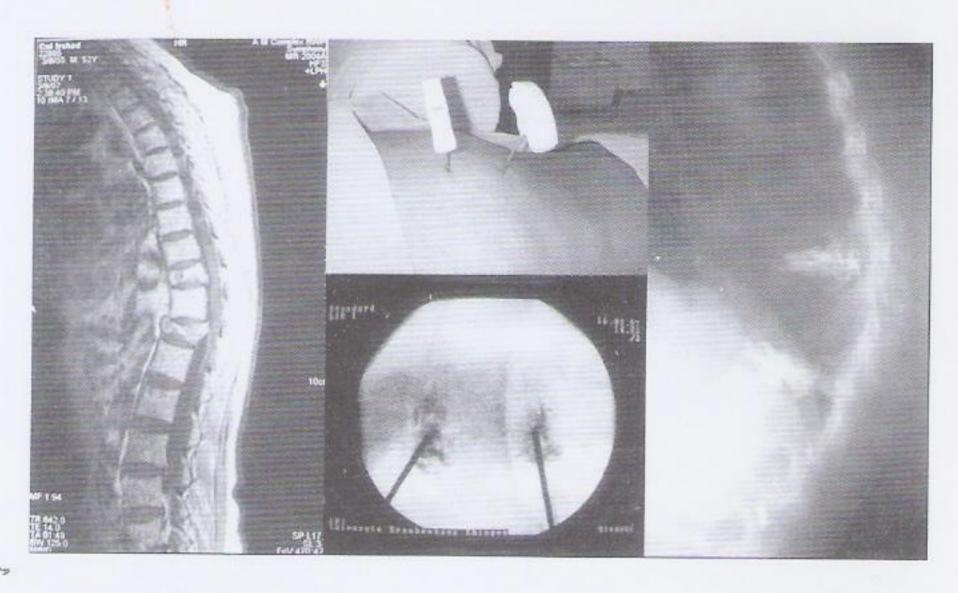


Fig: 3. 52 years old male with multiple myeloma vertebral compression fractures T11/ L1 visible on MRI. Needle placement, cement injection under image control and post op x-ray is shown.

During the procedure patients were monitored for increase in pain, allergic reactions to PMMA, neurological deficit, radicular pain, cement leakage and embolization. Patients were kept under observation for two hours after the procedure and discharged on remaining complication free and having adequate pain relief. Free mobilization was allowed on discharge and long term anti-resorptive therapy in form of a combination of bisphosphonates, calcium and vitamin D₃ was started in all patients. Patients were followed up after one day, two weeks and six weeks.

On follow up patient satisfaction, reduction in pain, early mobilization, restoration of vertebral body height and complications were noted. Patient satisfaction was defined on a three point scale as fully

satisfied, partially satisfied and not satisfied. Pain was measured pre and post operatively using visual analogue scale (VAS), zero was defined as no pain and ten was defined as maximum possible pain.

Data was kept in a custom built Microsoft Access database and analyzed using SPSS version 10. Paired sample T-test was applied to assess post operative change in VAS.

RESULTS

We had ten patients in our study and in these sixteen fractured vertebrae were injected with PMMA per-cutaneously. Seven patients had osteoporotic vertebral compression fractures (OVCF) and three had osteolytic compression fractures due to spinal metastases (SM). One patient had metastases from transitional cell carcinoma of kidney, for which he had nephrectomy earlier. Other patient had multiple myeloma. In third patient the primary source was not known. All patients with SM had radiotherapy initially without worthwhile pain relief, necessitating vertebroplasty. There were six males and four females. Average age among OVCF was 66 years and among SM was 54 years. Five fractures involved thoracic spine and eleven involved lumbar spine (Table: 1).

TABLE: 1. Patient Demography

SNO	IDPT	SEX	AGE	DIAGNOSIS	LEVEL	DATE OP
1	4401	F	50	OVCF	L2	08/11/05
2	4485	M	85	OVCF	L1	03/01/06
3	4484	M	60	SM	T12	06/01/06
4	4531	F	65	OVCF	T4/T5	05/02/06
5	4683	F	70	OVCF	T11/L2	27/06/06
6	4975	F	68	OVCF	LV1	15/12/06
7	5095	M	52	SM - MM*	T11/L1	16/03/07
8	5111	M	49	SM - TCC	L1/2	30/03/07
9	5158	М	54	OVCF	L1/3	18/05/07
10	5175	M	73	OVCF	L1/3	25/05/07

* Multiple Myeloma

Nine out of ten patients were fully satisfied with the procedure. Eight patients had immediate and excellent pain relief which was maintained till last follow up (p value < 0.001). Pain relief was better in OVCF than SM patients. Eight patients were mobilized within two hours of the procedure. There was no appreciable height restoration on post op x-rays in most of the patients (Table: 2).

TABLE: 2. Patient Follow up

SNO	IDPT	SATISFACTION	PREOP-VAS	POSTOP-VAS	MOBILITY
1	4401	FULL	9	3	2HR
2	4485	FULL	7	3	2HR
3	4484	PARTIAL	9	7	2Wks
4	4531	FULL	8	3	2HR
5	4683	FULL	8	3	2HR
6	4975	FULL	7	3	2HR
7	5095	FULL	10	7	2HR
8	5111	FULL	9	7	2HR
9	5158	FULL	7	3	2HR
10	5175	FULL	7	4	5 Days

One patient with spinal metastasis had leakage of bone cement into spinal canal resulting in weakness in lower limbs. In this patient immediate exploration was done under general anaesthesia. Laminectomy was done and the cement was removed from spinal canal by trans-pedicular approach on one side assisted with laminectomy. Pedicle screw fixation was done one level above and below and collapsed vertebral body was reconstructed with more bone cement through the sacrificed pedicle. Post operatively patient regained full neurological recovery. Three patients had asymptomatic extraosseous cement leak which did not merit active intervention. One patient had prolonged ileus post op. There were no other complications.

DISCUSSION

There have been many clinical trials and many review articles show significant pain relief after vertebroplasty as compared to conventional treatment of rest and symptomatic pain management(6-14). Our small study shows comparable pain relief with this procedure.

This procedure is quick and effective for pain relief in vertebral insufficiency fractures but it has many inherent complications and risks like asymptomatic cement leakage, cardiovascular effects, embolism with lethal outcome as well as severe neurological deficits(15). We had neurological deficit in one patient which was immediately addressed and patient recovered fully. There were some asymptomatic extracorporeal cement leakages. There were no adjacent level new fractures after the procedure and no known significant embolization.

Cement leakage and embolization can be reduced by a newer modification of vertebroplasty,

which is called kyphoplasty. It is also claimed that kyphoplasty gives better restoration of vertebral body height. In this procedure first a balloon tamp is inflated inside fractured vertebral body to create a space and then that space is filled with PMMA under low pressure. However, most of the studies fail to show a significant advantage of kyphoplasty over vertebroplasty except in some selected cases (16).

The future advances in vertebroplasty will probably come from improvements in biomaterials. Although PMMA is widely used in vertebroplasty with good clinical results, it lacks many desirable properties of ideal cement. It is not bio-absorbable and biocompatible, and cannot participate in any bone healing. Exothermic reaction of PMMA can cause thermal damage to surrounding soft tissues. Any significant cement leakage can have deleterious clinical consequences. Monomer toxicity is also an issue that the physician has to contend with.

Newer substitutes are currently being under trial and may offer viable alternatives to PMMA in the future. Examples are calcium sulfate cement (CSC) and calcium phosphate cement (CPC). These cements are biocompatible, osteoconductive, euthermic, and are bio-absorbable.

One study recently examined vertebral augmentation with CSC in osteoporotic compression fractures(17). They found similar strength and stiffness between the use of calcium sulfate and PMMA. The degree of restoration of strength and stiffness was greater than expected. They concluded that the lower potential stiffness of calcium sulfate may reduce the complications of adjacent level fractures. They may also be suitable agents for the incorporation of growth factors that facilitate bony ingrowth.

Other studies evaluated the use of CPC in vertebroplasty(18,19). They found reliable early relief of pain with this procedure. However, maintenance of pain relief and correction of kyphosis are not encouraging.

CONCLUSION

In carefully selected cases, percutaneous vertebroplasty has been shown to be very efficacious in relieving the pain associated with both

osteoporotic and osteolytic compression fractures. It is a minimally invasive procedure that has gained widespread acceptance as the standard of care for compression fractures unresponsive to traditional forms of treatment. Considerable expertise is required to perform it safely.

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