SREE CHITRA TIRUNAL INSTITUTE
FOR
MEDICAL SCIENCES AND TECHNOLOGY
THIRUVANANTHAPURAM

PROJECT REPORT

NAME : SUKALYAN PURKAYASTHA

PROGRAMME : D.M. NEURORADIOLOGY

MONTH & YEAR OF SUBMISSION : NOVEMBER 2003

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Title of the Project:

'Role of Percutaneous Vertebroplasty in the Management of Debilitating Backache'

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CERTIFICATE

I, Dr. Sukalyan Purkayastha hereby declare that I have actually carried out the project 'Role of Percutaneous Vertebroplasty in the Management of Debilitating Backache' independently under supervision and guidance in the institution.

Thiruvananthapuram

Signature ....

November 2003

Sukalyan Purkayastha

Forwarded.

Dr. Sukalyan Purkayastha carried out the above-mentioned project in the Department of Radiology, SCTIMST, Thiruvananthapuram.

Signature ....

Prof. A.K. Gupta
Head of the Department of Radiology
SCTIMST, Thiruvananthapuram.

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Sukalyan Purkayastha

CONTENTS

INTRODUCTION

Percutaneous vertebroplasty (PV) was described in 1987(1) for the treatment of aggressive vertebral hemangioma. It was later applied to osteolytic metastasis and osteoporotic compression fractures (2-10). The goal of percutaneous vertebroplasty is to alleviate spinal pain by stabilizing the fracture and strengthening the bone of vertebrae through the percutaneous injection of cement in to the vertebral body.

In 80-90% of cases vertebroplasty procedure leads to a durable partial or complete pain reduction. Pain relief is usually observed within the first 72 hours after treatment (5,11). Destruction of the posterior vertebral wall, with or without compression of the spinal canal, complete loss of vertebral body height, and presence of osteoblastic metastatic lesion were considered as relative contraindications (5,11).

Procedural complications like extravasation of cement into the spinal canal, neural foramen, paraspinal veins, or disc space has been reported in 11 to 73% of the procedures (2,3,5,9,11,12). Venous leaks caused compression of spinal cord or nerves or could also cause pulmonary embolism (3,5,13). Risk of damaging nerve roots or the spinal cord was mostly considered due to compression or by damage due to exothermic effect (5,14). The overall complication rate was reported to range from 1–10% with a higher incidence of complications in cases with metastatic lesions (15). Mortality was observed rarely with periprocedural complications including bronchoaspiration and pneumonia or complications related to advanced cancer stage (5,16).

The treatment involves percutaneous access and advancement of vertebroplasty needle under fluoroscopy, CT or both and injection of bone cement into the affected vertebra. It gives durable pain relief in hemangioma and osteoporotic collapse; however, vertebroplasty can be combined with surgery or with radiotherapy for the management of metastatic lesions.

This study was undertaken to assess the therapeutic benefit of percutaneous vertebroplasty in treating painful vertebral lesions.

REVIEW OF LITERATURE

The technique of percutaneous minimal invasive vertebroplasty was introduced a little over decade ago (1) and has found increasing recognition. The current indication for this treatment is in management of pain, likely to be caused by structural instability of the vertebral body. This condition is encountered in degenerated vertebral hemangioma (20,21,22,23), vertebral osteoporotic fracture (6,14,18,19) and the presence of vertebral metastatic disease (4,5,14,18,20).

Galibert et al introduced percutaneous vertebroplasty in 1987 to manage mainly vertebral angioma. Since then many reports have come regarding polymethylmethacrylate (PMMA) assisted vertebroplasty (1,3,17,24,25,26).

CEMENTS USED IN VERTEBROPLASTY:

Currently, vertebroplasty is performed with some type of PMMA, such as simplex P (Stryker – Howmedica-Osteonics, Rutherford, NJ), Osteobond (Zimmer Warsaw, In), Cranioplastic (CMW, Blackpool, England) and DePuy CMW bone cement (DePuy CMW, Jhonson & Jhonson, Blackpool, UK). Only simplex P is approved by the Food and Drug Administration (FDA) in United States for use in pathologic fractures, including those in the spine (10). Simplex P and Osteobond contain 10% wt/vol of barium sulfate for opacification, however, this amount is insufficient for easy visualization during fluoroscopically guided PV (14). Cranioplastic contains no barium sulfate and is not intrinsically radio-opaque. Therefore, all PMMA cements that are currently available commercially require the addition of opacifier in sufficient quantity to ensure visualization and safe injection under fluoroscopy. In Europe, tungsten and tantalum powder are commonly used opacifiers (14) but these substances are difficult to obtain in sterile, medical grade in the United States and the FDA does not approve them as opacifiers for PMMA cement. Therefore, in the United States, sterile barium sulfate has been the predominant choice as a cement opacifier. Approximately 30% wt/vol of barium sulfate must be added to PMMA powder to provide sufficient opacification for fluoroscopic monitoring (27). The barium sulfate must be pure, as defined by the United States Pharmacopoeia and must not contain additives such as those commonly present in barium used for gastrointestinal evaluations. Barium sulfate requires sterilization by dry heat or radiation, Ethylene oxide and steam are not acceptable methods of sterilization (10).

Biomechanical tests have shown that the addition of barium sulfate powder to the cement changes its strength; however the strength of the cement with barium sulfate added to produce a 30% wt/vol mixture produces no practical change in the compressive strength of PMMA (28), and it is doubtful that this change is clinically significant, because no mechanical failures of vertebrae treated by vertebroplasty have been reported.

Masato et al. (29) used calcium phosphate cement (CPC) for osteoporotic compression instead of PMMA. They think it is as effective as PMMA as published in other literature (6,9,19). They performed 4 CPC-assisted vertebroplasty without complication.

In the bioceramics laboratory of the Biomedical Technology wing of our institute (SCTIMST) we have developed CPC formulations of two types: apatitic cement and injectable cement. Injectable cement is obtained as a viscous paste and can be injected using a syringe and needle. This type of cement is highly useful in vertebroplasty and endodontic sealing. CPCs contain calcium phosphate based inorganic ingredients, which undergo cementing reaction in presence of aqueous solvent. During setting, the cement mass gets converted to hydroxyapatite, the mineral part of bone and teeth. CPCs show remarkable biocompatibility and fast osteointegration and later complete resorption, giving way to the growing new bone. This property called 'osteotransduction' is absent in other bone repair materials. The Chitra-formulation of CPC contains two component cements- a dry powder of combination of calcium phosphate minerals and an aqueous solvent of phosphate solution. The cement setting time is 10-2- minutes and gives a compressible strength of 10-12 Mpa, compared to that of trabecular bone.

TECHNIQUE OF VERTEBROPLASTY:

Many authors in detail in their articles described the technique of vertebroplasty. Deramond et al. (14) described the procedure in 4 steps as vertebral puncture, spinal biopsy, venography and then injection of bone cement. They prefer anterolateral puncture for the cervical level, posterolateral transpedicular puncture for the thoracic and lumbar region. The authors recommend biopsy for hemangioma. Biopsy can be taken for suspected mass lesion. According to them, venography can only be done in suspected hemangioma.

Mathis et al. (10) also described the technique of vertebroplasty in detail. They prefer biplane fluoroscopy for vertebroplasty. They add prophylactic antibiotic 30minute before the procedure and also tobramycin along with the cement only in immunocompromised patients.

Gangi et al. (25) described the technique under CT and fluoroscopy.

Jensen et al. (6) also gave an excellent description of the technique of vertebroplasty. They emphasized the importance of vital monitoring and also described the procedural pitfalls and some helpful hints for carrying out a safe procedure.

Lin et al. (30) also described the vertebroplasty procedure in detail. They clearly emphasized the need of various preoperative investigations after proper patient selection. Vital monitoring and oxygen administration via a facemask should be a routine. They prescribe transoral route for first and second cervical vertebra. They used Cook needle of cement injection. The authors prefer unilateral approach and they observed that bilateral route was only required in 35-40% of cases. Jensen et al. (6) used Jamshidi needle for cement injection.

ROUTE OF VERTEBROPLASTY:

Vertebroplasty is usually done via bipedicular approach for better lesion filling. But unipedicular approach has several advantages. It is less time consuming, associated with less complication. Kim et al. (31) described a modified unipedicular approach with more lateral angulation of the needle. They compared the technique with bipedicular approach. Lesion filling across midline was achieved in 96% of cases. Mean opacification of vertebral body halves was 83%±19(SD) and 77%±16 for bipediculate and unipediculate approaches respectively (p=0.19). Mean decrease in pain severity of 7.3±3.1 and 6.6±2.9 respectively. There was no statistically significant difference in clinical outcome from that of bipediculate route.

For cement injection, Jensen et al. (6) recommends 1 mm Luer-Lock syringes, which they fill from back end from 10ml syringe. 0.5-0.7ml cement is usually taken into it for easy injection. Deramond et al. (14) used 2-3ml Luer-Lock syringes for cement injection.

Although it easy to inject with 1ml syringe, it is some time costly and cement solidification is a potential disadvantage. Standard 20 or 10 ml push-plunger syringes cannot produce adequate pressure to smoothly inject the volume required. Moreover, the flanges of 10ml syringes bend readily during injection and may result in premature injection failure.

Schallen et al. (32) described a reusable flange converter with hub lock for injection of cement with screw-plunger syringe. They used the device in 172 vertebroplasties and achieved more volume of cement that can be injected. It reduces the cost of multiple 1 ml syringes.

ANESTHESIA FOR VERTEBROPLASTY:

Sensitizations of neural elements by direct pressure or by heat generated during cement polymerization are plausible mechanisms of cause of pain in vertebroplasty (93,32). Sesay et al. (34) showed that trocar insertion was more painful than cement injection and suggest the need for more effective strategies towards this target. They recommend intraosseous lidocaine for effective analgesia.

Different anesthetic techniques have been proposed to control pain during vertebroplasty, but all have important limitations. On the one hand, general anesthesia adds its own risks (26) and prevents clinical assessment of the patient during the procedure. Sedative analgesia with opioids and benzodiazepines, which is currently the main analgesic technique for PV (19) can be hazardous, specially with the patient in the prone position, as conventional systemic opioid administration entails the potential risk of respiratory depression. The rationale behind the intraosseous injection of a local anesthetic involves a regional blockade of the bone nociceptive fibers, thereby avoiding the major complications of sedation or general anesthesia.

Deramond et al. (14) recommend general anesthesia, diazanalgesia or local anesthesia for vertebroplasty; general anesthesia with propofol, fentanyl; diazanalgesia with fentanyl and midazolam and local anesthesia with 1% lidocaine. Lin et al. (30) used both local anesthesia with a buffered lidocaine solution and intravenous sedation during vertebroplasty. Mathis et al. (10) recommend fentanyl and midazolam to provide conscious sedation along with local anesthesia for the procedure under fluoroscopy, but general anesthesia for CT guidance alone as it need proper immobility. Gangi et al. (25) recommend neuroleptanalgesia and local anesthesia for vertebroplasty guided by a combination of CT and fluoroscopy. Jensen et al. (6) also recommend fentanyl and midazolam along with local anesthesia for the procedure. It takes approximately 30-40 minutes to treat a compression fracture including patient positioning and skin preparation. Each additional level increases the procedure time by 15 minutes to 20 minutes (30).

RELEVANCE OF VENOGRAPHY IN PERCUTANEOUS VERTEBROPLASTY:

Among the increasing number of articles about the various aspects of percutaneous vertebroplasty, some authors have discussed using intraosseous venography (35,36), whereas others do not favor its use. (8,13,14,18).

Jensen et al. (6) recommend venography to exclude needle placement within the basivertebral venous complex and to ensure continuity the posterior vertebral wall as evidenced by containment of contrast material within the bony trabeculae.

In a recent review article, Mathis et al (10) remarked that venography is not commonly used in Europe. Some of the leading proponents of vertebroplasty form Europe do not appear to advocate its routine use (13,14,18). Infact, Cotton et al (13) in a response to an invited commentary by Barr and Barr (37), stated that they do not perform intraosseous venography. These authors mentioned that they did the procedure earlier in their experience, particularly in patients with aggressive vertebral hemangiomas. Deramond et al (14) reported that they perform venography only for managing angioma.

The major goals of intraosseous venography are to determine whether the needle is positioned in a direct venous anastomosis to the central or epidural veins, observe the venous structures that are filled first and gain information to anticipate the preferential pathway of cement passage during subsequent injection (35). However, the technical details and additional potential usefulness of routine intraosseous venography during this procedure have not been described in detail. Jenson and Dion (35) have described the technique of intraosseous venography in their review article. They use 3-5 ml of iohexol for venography during vertebroplasty. These authors stated that in addition to showing needle placement directly in the basivertebral venous plexus and outlining the trabecular venous drainage, vertebrography allowed easy identification of the junction between the basivertebral venous plexus and the anterior epidural venous plexus, giving the operator a reference point to watch during PMMA injection. Maynard et al (36) recommended using

3-5 ml of contrast medium and performed intraossous venography using a biplane digital subtraction angiography unit at a framing rate of 2 frames per second.

Mathis et al (10) emphasized some limitation of intraosseous venography – namely different flow characteristics between contrast medium and PMMA and questioned whether the depiction of extra corporeal venous filling actually led to modification of the injection technique. In addition, they stated that contrast filling of fracture clefts might preclude early detection of PMMA leakage at the same site. Deramond et al. (14) mentioned that when performing vertebroplasty for malignant spinal tumors, contrast material that has been injected in to the tumor may diffusely stain the tumor tissue and may nor be washed out. This staining may interfere with the fluoroscopic evaluation during PMMA injection. Although intraosseous venography has been reported to obscure bone detail so much that vertebroplasty cannot be performed.

Wilfred et al. (38) described a modified method of venography using 0.5-2ml of iohexol and saw the passage of contrast, amount of bone vascularity and the site of draining veins. Then a wash out venogram was performed by injecting 20 ml of saline through the needle. According to them this method can obviate the disadvantages of usual method.

Gaughen et al. (39) studied the relevance of antecedent venography in vertebroplasty for the treatment of osteoporotic compression fracture. They divided the patients into two groups: group1 with venography and group 2 without venography. Relief of pain was seen in 19 of 20 group1 patients, compared with 21 of 22 in group 2 patients. Mean postoperative pain levels were 1.3 and 1.8 respectively (p=0.5). Twenty-two of 42 vertebrae treated in group1 demonstrated extravasation, compared to 28 of 42 in group 2. Of 22 procedures with extravasation in group 1, venogram in 14 showed correlative extravasation. They found no significance of the same as far as the effectiveness and complication is concerned.

Christina et al. (40) evaluated the safety of vertebroplasty without venography in 205 consecutive patients including hemangioma, myeloma, metastasis and benign compression fractures and concluded that the procedure can be performed safely without prior angiographic evaluation of the vertebral venous system.

Indications of vertebroplasty are straightforward (4). It is indicated for the treatment of destabilizing and painful vertebral lesions.

VERTEBROPLASTY IN THE TREATMENT OF VERTEBRAL HEMANGIOMA:

Hemangiomas are found in 10-12% of all autopsies, making vertebral hemangioma (VH) the most common benign spinal lesion (41). The peak incidence is in the sixth decade of life. Asymptomatic hemangiomas occur equally in men and women but there is a female predominance with symptomatic lesion (42). Lower thoracic and lumbar regions are the most common sites. Multiple lesions are seen in 25-30% of cases (42,43).

Cervical VH are rare, most being between T_8 and L_4. Schmorl and Junghans (44) reported 5.5% of cervical lesions in a post mortem series of 579 VH and Laredo et al (45) observed radiographically 6.5% of cervical VH in 58 cases. It is uncommon in younger age and only 3.5 – 3.8 % incidence is reported in patients younger than 30 (21).

The aggressiveness of the vertebral angioma may be identified by clinical symptoms like severe back pain or radiological signs of aggressiveness as described by Laredo et al (45). Radiological signs are location between T-3 and T-9, involvement of entire vertebral body, involvement of neural arch, irregular trabeculation, expanded and poorly defined cortex and soft tissue swelling. In asymptomatic patients radiological criteria of aggressiveness estimates risk to the patients.

Dousset et al (21) reports a 17-year-old asymptomatic patient with partially collapsed seventh cervical vertebra due to a hemangioma revealed by conventional radiographs performed for army enrolment. According to radiological criteria proposed by Laredo et al (45), four of six indicating aggressiveness were present: involvement of the entire vertebral body, extension to the pedicles and posterior arch, irregular honeycomb appearance and expanded anterior cortical bone. Further more, the MR signal was taken to indicate aggressiveness (46,47). Non-aggressive fatty hemangiomas usually give high signal on T1 Weighted images, slightly high signal on T2 weighting and show no contrast enhancement. Given radiological evidence of aggressiveness, percutaneous vertebroplasty by injection of methylmethacrylate cement was performed to prevent complications. CT a year later showed no progression of the lesion. The patient remains asymptomatic.

Deramond et al. (14) classified vertebral hemangioma into 4 groups according to their clinical and radiological manifestations: (1) painful VH without radiological signs of aggressiveness; (2) asymptomatic VH with radiological signs of aggressiveness; (3) symptomatic VH with radiological signs of aggressiveness; (4) VH with radiological signs of aggressiveness, epidural component, and acute symptomatic compression of spinal cord or nerve roots. PV is the treatment of choice in-group 1 and Deramond et al. treated 38 such patients with disappearance of pain in more than 90% of patients. They prefer to follow up group 2 patients without treatment and they saw no secondary evolution of these patients. Group 3 patients need alcohol injection along with vertebroplasty in the same sitting. Deramond et al. treated 12 such patients with slow disappearance of neurological signs in all patients. Epidural component also disappeared in 2 patients on follow-up. Group 4 patients need laminectomy and Deramond et al. treated 3 such patients. In all patients neurological symptoms improved and there was no change in clinical status through out the follow-up period of 8 years.

Cotton et al. (20) treated 4 patients presented with complicated vertebral hemangioma (spinal cord compression in three cases, intermittent spinal claudication in one case). A three-part treatment was performed: initially, arterial embolization in three cases; 1 day later, percutaneous injections of methyl methacrylate into the vertebral body to strengthen it and of N-butyl cyanoacrylate into the posterior arch to optimize hemostasis during surgery; finally, the day after percutaneous injections, decompressive laminectomy and epidural hemangioma excision. The follow-up (average, 20 months) showed no evidence of vertebral collapse.

VERTEBROPLASTY IN THE TREATMENT OF VERTEBRAL COMPRESSION FRACTURES:

Vertebral compression fractures (VCF) occur when the combined axial and bending loads on the spine exceeds the strength of the vertebral body (48). It may result from infiltrative processes or loss of bone mineral from osteoporosis (49,50,51). VCF may be defined as either a radiographic or symptomatic clinical event (52). Melton et al. (53) reported its prevalence to be as high as 26% in women more than 50 years. Osteolytic metastasis and myeloma are the most frequent malignant lesions of the spine resulting in VCFs (54).

Several bench-top studies have been conducted to gain a better understanding of the underlying mechanics responsible for the success of vertebroplasty in VCFs. Factors responsible for pain relief are thermal necrosis, chemotoxicity of intraosseous pain receptors as well as mechanical stabilization (55). It has been seen that monomer liquid may be neurotoxic (55,56,57,58). Such toxicity may also account for necrotic zone around the injected tumor (59). Temperature reaching 122° during polymerization are also responsible for neural damage and tumor necrosis, but a recent in vitro study suggested the temperature may not be sufficient for thermal necrosis of osteoblast (60) or neural tissue (62). Tumor tissue may be more sensitive to the thermal effect and thus exothermic reaction may still play a role in vertebroplasty for treatment of tumors. Most likely mechanism of pain relief is mechanical stabilization (28,63,64,65).

The various cements used in vertebroplasty posses different material properties. Simplex P exhibited strongest and stiffest repair of in vitro specimens (28) where as Cranioplastic has the lowest, yet results a good clinical outcome (19,26).

Primary indication of PVP in VCFs either from osteoporosis or tumor infiltration is debilitating severe pain (3,13,14,18,19,20,24,26,66). Currently the role of prophylactic intervention is still not justified (67). However, early intervention may be indicated because of low procedure related complication and progression of collapse during the lengthy period of conservative therapy (3,13,14,18,19,20,24,26,68).

Vertebroplasty effectively treats most vertebral compression fractures. Durable complete or significant pain relief is achieved in 80-90% of patients (9,20,22,69) usually within 72 hours of the procedures (18,22,69). At John Hopkins, Lin et al. (30) reviewed 112 vertebroplasties in 97 treatment sessions done for compression fractures of 6 weeks to 10 years duration. Complete or major pain relief was obtained in 91 of 97 treatment sessions with no complications. Published frequency of complications is 1.3% in osteoporosis and 10% for metastatic disease (6). Major complications include venous leak with spinal cord, nerve root compression or pulmonary embolism (2,3,17,65,69).

VERTEBROPLASTY IN THE TREATMENT OF OSTEOPOROTIC COLLAPSE:

This is most frequently seen in women more than 60 yrs of age, either after minimal trauma or spontaneously. Vertebroplasty is indicated in patients with incapacitating and persistent severe back pain (14).

Deramond et al. (14) treated 80 patients with a follow-up of 1 month to 10 years. Immediate pain relief was seen in more than 90% of patients. Only 1 patient suffered intercostal neuralgia.

Jensen et al. (26) treated 29 patients with 47 painful vertebral fractures. 26 patients (90%) reported pain relief immediately after treatment. Only 2 complications were met (nondisplaced rib fractures).

Wilfred et al. (70) reports 48 vertebroplasties in 37 patients for severe osteoporotic collapse (height reduced less than 1/3rd of their originals height). Mean volume of cement injection was 6ml. Complete pain relief was seen in 47%, partial in 50% and no change in 3% of patients. Cement leak into adjacent disc was noted in 35% and in paravertebral soft tissue in 8% of patients.

Anita et al. (71) reported the incidence of new fractures after vertebroplasty. Of 117 patients treated by them, 22 developed a total of 36 new vertebral body fractures following treatment. Twenty-four involved vertebrae adjacent to the previously treated levels. They relate it to the altered stiffness of the treated vertebrae and altered distribution of force to near by vertebrae (7,8).

Masato et al. (29) reports vertebroplasty for osteoporotic fractures with calcium phosphate cement. They did 17 vertebroplasties in 16 patients and all patients had pain relief till last follow-up.

VERTEBROPLASTY IN METASTASIS AND NEOPLASM:

Osteolytic metastasis and myeloma are the most frequent malignant lesions of spine. Approximately 30% of patients with various neoplastic conditions develop symptomatic spinal metastases during the course of their illness, and pain is the presenting complaint in the majority of cases. Radiation therapy gives partial or complete pain relief in more than 90% of patients. However strengthening of the vertebra is minimal and there is a risk of collapse. So, vertebroplasty is indicated to prevent collapse (18).

Neoplasms are not innervated and therefore are not directly painful. Tumors and metastasis lead to pain due to bone fracture and reaction of the nervous structures of the remnant normal bone to the mass effect of the foreign tissue. Vertebroplasty reduces pain due to fracture stabilization and the cytotoxic effect of PMMA in the cement (18).

Alain et al. (18) did 52 vertebroplasties in 37 patients of spinal metastasis. Improvement was stable in 73% of patients. 2 patients showed no improvements. Dose of analgesics could be reduced by 50%.

Deramond et al. (14) treated 101 patients of metastasis and myeloma with significant analgesic effect and improved quality of life. More than 80% of patients could walk again. Complications were observed in 10% of patients.

Cotton et al. (3) treated 37 patients for metastasis (30 cases) and myeloma (10 cases). Pain relief was obtained in 36 of 37 patients. Most of the complications were of no clinical importance, but 2 foraminal leaks required decompressive surgery. Lesion filling was more than 75% in 14 cases, 25-49% in 13 cases, less than 25% in 8 cases. No statistical relationships were seen between the percentage of lesion filling and the reduction of pain.

Deryl et al. (72) did 65 vertebroplasties and 32 kyphoplasties in 56 patients of myeloma and other primary vertebral malignancies. Statistically significant analgesic intake reduction was achieved. In only 9.2% of vertebroplasties there were asymptomatic cement leakage.

Hiwatashi et al. (73) showed vertebral body height increase after vertebroplasty for painful compression fractures. The average increase in vertebral body height was 2.5 mm anteriorly, 2.7 mm centrally and 1.4 mm posteriorly.

Recurrent pain after vertebroplasty is relatively common, usually representing a new fracture at a different vertebral level. Gaughen et al. (39) demonstrate that repeat percutaneous vertebroplasty performed within the same fractured vertebra can offer therapeutic benefit for patients with recurrent pain after initial treatment in 6 patients.

After repeat vertebroplasty, five of the six patients reported a reduction of at least 3 points in their rating of pain, with a mean reduction of 6.5 points and a mean postoperative pain level of 3.5 points (11-point scale). Four of six patients reported impaired mobility before repeat vertebroplasty, and all four demonstrated a postoperative improvement in mobility. Mean increase in mobility was 1.50 points, and the mean postoperative mobility impairment was 0.25 points (5-point scale).

COMPLICATIONS IN VERTEBROPLASTY:

Clinical complications reported after vertebroplasty include transitory fever, transient worsening of pain, rediculopathy, rib fractures, cement pulmonary embolism, infection and spinal cord compression.

Complication rate of vertebroplasty varies with the underlying bone lesion (30). The published frequency of complications is 1.3% in osteoporosis, 2.5% in spine hemangiomas and 10% in metastatic disease (66). With osteoporotic fractures, complications most often are non-neurologic and transient (6,9,18,68). Transient rediculopathy has been reported in3-6% of cases and has been successfully treated with steroids and anti-inflammatory drugs (3,13,14,66). Lin et al. (30) achieved 0% complication rate in vertebroplasty in 200 patients. Complications are almost invariably related to leakage of cement. Venous leak may cause compression of spinal cord or nerves and can also result in pulmonary embolism (3,14,69,65). Chiras (66), Cotton (13) and Deramond (14) have stated that clinically significant complications with vertebroplasties occur predominantly in patients with spinal metastatic disease, but they are usually medically manageable.

Chiras et al. (66) related the extravasation to the way the needle is positioned or to the presence of cortical destruction, which is more in metastatic disease.

Although there is only one report of infection after vertebroplasty (66), few authors (26) prefer to add antibiotics in immunocompromised patients along with the cement to reduce the rate of infection as based on surgical reports (74,75). One series reported a decrease in infection from 5% to 1% when tobramycin impregnated PMMA was used for cranioplasty, vertebral body replacement and spinal fusion (74).

Deramond et al. (14) reports two deaths few days after vertebroplasty related to the preexisting bad systemic condition secondary to cancer and extensive metastasis. They report rediculopathy in 4% of their patients. Only one patient needed surgical decompression after vertebroplasty with preexistent spinal cord compression.

Kyung et al. (76) evaluated the incidence of dose dependent epidural leakage of PMMA after vertebroplasty in osteoporotic compression fractures. They did 347 vertebroplasties and saw the epidural leak was more above level of T-7 than below. They found the larger volume of PMMA injected the higher incidence of epidural leakage ($p=0.03$).

Venous leak and distal embolization is a potential risk for vertebroplasty. Most pulmonary emboli form PMMA is asymptomatic, clinically significant disease has been reported (77). Cerebral emboli have been reported to occur after PMMA assisted arthroplasty and have been attributed to fat emboli from raised intramedullary pressure during reaming and cementation (78). Rebecca et al. (77) reported a case of paradoxical cerebral arterial embolization of cement during intraoperative vertebroplasty via a patent foramen ovale. Although that was an open procedure, the technical aspects were the same as for vertebroplasty and the precautions should be applied to percutaneous vertebroplasty.

Many authors have described an association between the use of PMMA in human hip arthroplasty and cardiovascular derangement such as hypotension, bradycardia, asystole and bronchospasm. The etiology of these effects in uncertain, but mechanisms such as fat embolism associated with increased intramedullary pressure, air embolism, a neurogenic reflex, the release of vasoactive mediators such as histamine, direct depressive effects on the myocardium, peripheral vasodilatation, and activation of the coagulation cascade within the lungs have been proposed (79). There have been two case reports of an association between the injection of PMMA during percutaneous vertebroplasty and untoward cardiovascular or pulmonary effects: report of the symptomatic pulmonary embolism (14), and a report of transient arterial hypotension (80). Kaufmann et al. (79) evaluated the effects of PMMA injection on patient vital signs during percutaneous vertebroplasty and found no generalized association between PMMA injection and systemic cardiovascular derangement.

Occupational exposure of medical personnel PMMA vapor is a potential hazard during vertebroplasty. Dental students who were exposed to methacrylate vapor while preparing dentures complained nausea and lack of appetite. It is also known to be a potential pulmonary toxin. Acute exposure to extremely high levels of MMA vapor can cause liver necrosis, pulmonary edema and pulmonary emphysema (10). Cloft et al. (81) measured the level of exposure of medical personnel to methacrylate vapor during percutaneous vertebroplasty and found the level to be less than 5 ppm and is well below the published recommended standard of 100ppm.

Finally Kallmes et al. (82) measured the radiation dose to the operator during vertebroplasty with a prospective comparison of the use of 1-cc syringe versus an injectable device. Radiation dosimeters were worn on the left wrist during 39 vertebroplasty injection procedures in 25 patients. Cases were alternated between the use of 1-cc syringes (19 procedures) and the use of an injectable device (20 procedures). Mean whole case radiation dose was 128 ± 161 mrem for 1-cc syringe group versus 98 ± 90 mrem for injection device group ($p=0.23$). Mean dose during injection was 100 ± 145 mrem for 1-cc syringe group versus 55 ± 43 mrem for injection device group ($p=0.09$). Duration of injection was markedly different between groups, with mean injection times of 4.2 and 7.5 minutes for 1-cc syringe and injection device cases ($p< 0.0002$). The authors concluded that injection device significantly decreased the radiation dose to the operator's extremity pre unit time of injection.

This study is being conducted to enhance our knowledge regarding various aspects of percutaneous vertebroplasty in treatment of back pain.

OBJECTIVE

The primary objective of this study is to assess the therapeutic benefit of percutaneous vertebroplasty in alleviating back pain and comparing the morphologic & functional status of painful pathologic vertebrae in pre and post procedural states.

The secondary objectives are to study the different technical aspects of the procedure and their relation to outcome and complications.

MATERIAL & METHODS

From January 2001 to September 2003, 29 patients were included in the study.

In our study, 7 (31.6%) were male and 22 (68.4%) were female patients. 38 vertebroplasties were done in 29 patients. Fifteen (39.47%) procedures were done for osteoporotic compression collapse, 17 (44.73%) for hemangioma and 6 (15.78%) for vertebral body tumors and metastasis.

Table I: **Summary of patient demography, type and location of lesion, level of VP.**

Sl No	Age	Sex	Presentation	Levels of Vertebroplasty	Diagnosis
1	68	F	a,e	L1, L3	1
2	77	F	a,e	D12	1
3	30	M	a,b,d,e	D5	2
4	76	F	a,b,d,e	D12	1
5	36	M	a	D10, D11, D12, L1	2
6	65	F	a,e	L1, L3	1
7	56	F	a,e	D12	1
8	53	F	a,b,c,d,e,f,g	D12	1
9	53	F	a	D11, D12	1
10	27	F	a	D7	1
11	13	F	a,b,d,e	D6	3
12	45	F	a	L1	2
13	28	M	a	D4	2
14	55	F	a,e	D9	1
15	30	F	a,b,c,d,e,f,g	D3	2
16	26	F	a,b,c,d,e	D4	2
17	60	F	a,b,c,d,e	D12, L4	2
18	42	M	a,e	D5	3
19	65	F	a,b,d,e	D10	1
20	43	M	a	D21	3
21	71	F	a,b,c,d,e,g	D21	1
22	69	F	a,e	D11	1
23	27	F	a	L1	2
24	32	M	a,b,c,d,e,f,g	D7	2
25	47	F	a,c	L4	2
26	47	F	a	D10	2
27	45	F	a	L3	2
28	22	F	a,b,c,d,e,g	D6	2
29	36	M	a	L1,L2,L3	3

Diagnosis: 1=Osteoporotic collapse; 2=Hemangioma; 3=Tumor

Presentation: a= low backache
b= motor deficit
c= sensory deficit

d= difficulty in walking
e= difficulty in climbing stairs
f= bladder involvement
g= paresthesia.

Presenting symptoms of the patient:

Low Backache (LBA): All patients presented with moderate to severe backache.

In 9 (60%) out of 15 osteoporotic fractures, the back pain was of less than 6 months whereas in 58.9%(10 out of 17) of hemangioma back pain was of more than 6 months duration. In 83.4% of tumors back pain was of less than 6 months duration. Over all in 55.3% of lesions back pain was of less than 6 months duration and in 36.8% of lesions back pain was of more than 1year duration, which consisted of only hemangioma and osteoporotic fracture. No statistical correlation was seen between the duration of backache and the lesion type (p=0.197).

Table II: **The incidence of duration of low backache in different lesion type**:

LBA Duration		Osteoporotic fracture	Hemangioma	Tumor	Total	p-value
<6wks	Count	5	3	1	9	0.197
	%	33.3	17.6	16.7	23.7	
>6wks	Count	4	4	4	12	
	%	26.7	23.5	66.7	31.6	
>6mnths	Count		2	1	3	
	%		11.8	16.7	7.9	
>1 year	Count	6	8		14	
	%	40.0	47.1		36.8	

No statistically significant correlation was seen in duration of low backache in different lesion type (p=0.197).

Local Tenderness: In 23 (3 male, 11 female) lesions local tenderness was noted.

Motor deficit: 11 out of 19 patients presented with lower limb weakness. In 34.2% of lesions lower limb weakness was the presenting symptom. In 41.2% of hemangiomas motor deficit was seen as compared to 33.3% of osteoporotic collapses and 16.7% of tumors because 7 out of 17 hemangiomas had epidural element and cord compression.

Table III: **Incidence of motor deficit (lower limb weakness) in different lesion type:**

Motor deficit		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	10	10	5	25	0.551
	%	66.7	58.8	83.3	65.8	
Present	Count	5	7	1	13	
	%	33.3	41.2	16.7	34.2	

No statistically significant correlation was in the incidence of motor deficit (lower limb weakness) in different lesion type (p=0.551)

Difficulty in walking:

11 out of 29 patients presented with difficulty in walking. It was seen in 33.3% of osteoporotic collapses and 35.3% of hemangiomas. It was observed in lesions where epidural component and cord compression was seen or in lesions, which were severely painful.

Table IV: **Incidence of difficulty in walking in different lesion type:**

Walking difficulty		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	10	11	5	25	0.688
	%	66.7	64.7	83.3	68.4	
Present	Count	5	6	1	13	
	%	33.3	35.3	16.7	31.6	

No statistically significant correlation was in the incidence of difficulty in walking in different lesion type (p=0.668).

Difficulty in climbing stairs:

18 out of 29 patients presented with difficulty in climbing stairs. It was seen 66.6% of tumors, 60% of osteoporotic collapses and 52.9% of hemangiomas. It was seen 6.7% of osteoporotic collapses and 11.8% of hemangiomas.

Table V: **Incidence of difficulty in climbing in different lesion type:**

Difficulty in climbing stairs		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	6	8	2	16	0.824
	%	40.0	47.1	33.3	42.1	
Present	Count	9	9	4	22	
	%	60.0	52.9	66.7	57.9	

No statistically significant correlation was in the incidence of difficulty in climbing stairs in different lesion type (p=0.668).

Sensory deficit and paresthesia: 7 patients had sensory dulling of varying severity. It was seen in 18.4% of lesions of lesions. Paresthesia was seen in 13.2% of lesions. 6.7% of osteoporotic collapses and 23.5% of hemangiomas paresthesia was seen

Table VI**: Incidence sensory deficit in different lesion type:**

Sensory deficit		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	13	12	6	31	0.225
	%	86.7	70.6	100.0	81.6	
Present	Count	2	5		7	
	%	13.3	29.4		18.4	

Table VII: **Incidence of paresthesia in different lesion type:**

Paresthesia		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	14	13	6	33	0.216
	%	93.3	76.5	100.0	86.8	
Present	Count	1	4		5	
	%	6.7	23.5		13.2	

No statistically significant correlation was in the incidence of sensory deficit and paresthesia in different lesion type.

Bladder involvement: 3 patients presented with difficulty in urination and urinary retention. These were seen in lesions at lower thoracic level with cord compression. No statistically significant correlation was in the incidence of bladder involvement in different lesion type ($p = 0.216$).

Tables VIII: **Incidence of bladder involvement in different lesion type:**

Bladder involvement		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Absent	Count	14	15	6	33	0.216
	%	93.3	88.2	100.0	86.8	
Present	Count	1	2		3	
	%	6.7	11.8		7.9	

Bowel involvement: No patients presented with bowel involvement in this series.

In our series, lesions were classified into 3 pathological categories:

1. Symptomatic VB hemangioma.
2. Osteoporotic collapse causing backache.
3. Other tumors involving the vertebral body resulting in back pain.

For result analysis the lesions were grouped under 3 levels:

Level 1: D1-D6 (First to sixth thoracic vertebra)

Level 2: D7-D12 (Seventh to twelfth thoracic vertebra)

Level 3: L1-L5 (Lumbar vertebrae)

Imaging characteristics of the lesions were based on the findings of preprocedure X-ray/CT/ MRI scans. Voluntary full informed consent was obtained from all patients after explaining the details of disease & the procedure. Neurology consultation was taken in all cases to document the clinical findings. Neurosurgery consultation was also taken in all patients to assess the need of any surgical decompression, if necessity arises after the procedure. A detailed history was taken regarding present and past illness.

The clinical severity of pain was documented in a 10 – point ordinal scale before and after the procedure as well as on follow-up visits. The patients were asked to rate their pain according to the severity.

Pain severity score: 0 = No pain

10 = Most severe pain.

Activity score and intake of analgesics were documented in a 5 point scores respectively before and after the procedure as well as on follow-up visits.

Activity score: 0 = Independent

1 = Walking with assistance

2 = Wheel chair bound

3 = Sitting in bed

4 = Lying in bed.

Medication score: 0 = None

1 = NSAIDs

2 = Non-narcotic opoids

3 = Narcotic drugs

4 = I.V narcotic drugs.

The patient was examined and all the systemic & neurological findings were noted appropriately in the proforma.

Pre-procedure laboratory investigations & cardiological work up were done routinely.

Laboratory investigations: Blood RE, Urine RE, PT, PRT etc.

Cardiological work up: Chest X-ray, ECG, echocardiography and clinical cardiac evaluation.

Imaging: Pre procedure X-ray – AP, lateral spine

CT Spine

MRI Spine

Post procedure X-ray / CT.

Cement and needle used in our procedures:

Needle:

Osteosite bone biopsy needle (Cook, Bloomington, USA)

Types: Murphy side bevel M1

Murphy diamond bevel M2

Size: 11-G and 13-G

Length: 10cms, 15cms.

Bone cement: DePuy CMW bone cement (DePuy CMW, Jhonson & Jhonson, Blackpool, UK)

Table IX: **Constituent of different bone cements**:

	CMW1 ORIGINAL	CMW1 RADIOPAQUE	CMW2	CMW3
Bone cement powder:				
Polymethyl Methacrylate (%w/w)	97.75	88.85	86.70	88.00
BenzoylPeroxide (%w/w)	2.25	2.05	2.00	2.00
BariumSulphate (%w/w)	*	9.10	11.30	10.00
Bone Cement Liquid:				
MethylMethacrylate (%w/w)	99.18	99.18	98.75	97.50
N,N-Dimethyl-p-toluidine (%w/w)	≤0.82	≤0.82	≤1.25	≤2.50
Hydroquinone (ppm)	25	25	25	25

Two polyethylene bags each containing 2.5gm barium sulphate are included With CMW1 original Bone Cement.

Preparation of the cement: 10 ml of bone cement and 3 ml of barium was mixed properly and then bone cement liquid was added to that to get a consistency of toothpaste. The cement paste was then passed to 10 ml syringe and subsequently multiple 1 ml syringes were filled for injecting via vertebroplasty needle.

Vertebroplasty procedure:

Vertebropalsty was done under fluoroscopic guidance under LA in all cases except in one patient where GA was given. Patient was kept fasting from the morning and was premedicated from the ward with intravenous injection of Pethidine 50mg and Phenargan 25mg and shifted to Radiology cathlab. Patient was positioned prone on the table. Anticeptic cleaning of the back was performed properly. Infiltration of local back skin and periosteum was done by 1% lidocaine.

Vertebroplasty:

The procedure was done with following steps:

The needle was advanced through transpedicular or paravertebral route and placed into the anterior third of vertebral body. Venography and biopsy was done in desired cases. Then bone cement was injected under fluoroscopic control till proper filling was achieved. Then needle was taken out under fluoroscopic control. Anticeptic bandage of puncture site was done after the procedure was over. The patients were kept prone for 1/2hour and then made supine.

All vitals parameters were strictly monitored during & after the procedure. The details of procedure were noted down in the patient proforma. Biopsy specimen was taken and sent to histopathology in all tumor cases and suspected osteoporotic collapse. No biopsy was taken in hemangiomas. After the procedure the patient was shifted to the ward/ICU as required & was observed to 12-24hours or as required. Alcohol injection was performed in posterior elements in relevant cases under CT guidance.

Post procedure neurological examination was carried out & details noted meticulously.Before discharge, routinely X-ray/CT scan of the spine was done to assess the result of the procedure.On follow-up visits detailed history of progress taken, neurological examination performed. In relevant cases required radiological examinations performed.

Statistical analysis was done with:

i) Chi-Square test

ii) Wilcoxon Signed Rank test

iii) Mann-Whitney test.

p-value was calculated in relevant areas for statistical significance.

Fig 1: Bone cement CMWI RADIOPAQUE Powder, monomer liquid and Barium sulphate.

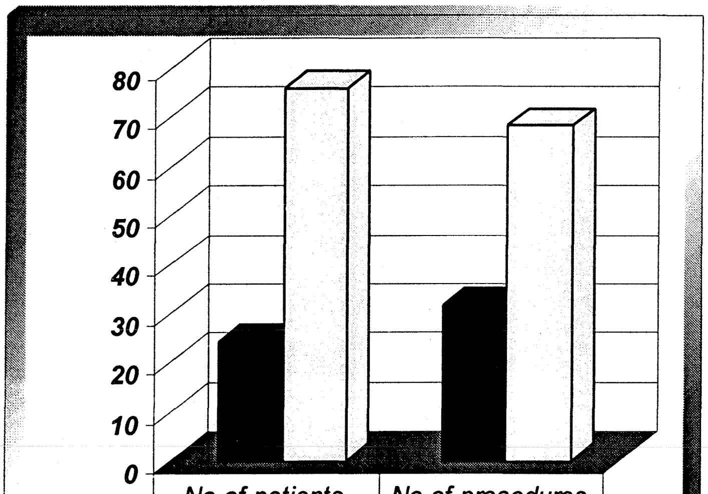
Fig 2: Cook Bone Biopsy Needle (11G, 10cm); 18G Spinal needle.

RESULTS

In our study, 38 vertebroplasties were done in 29 patients. 7 (31.6%) were male and 22 (68.4%) were female patients. The lesions were divided in three levels. Proper clinical examinations were done in all cases. Pre and post procedure activity level, analgesic intake and pain level were noted meticulously. Imaging diagnoses were made from preprocedure X-ray, CT scan and MRI scans. Fifteen (39.47%) procedures were done for osteoporotic compression collapse, 17 (44.73%) for hemangioma and 6 (15.78%) for vertebral body tumors and metastasis. Vertebroplasty were done under fluoroscopic guidance with a single plane facility. Transpedicular route were preferred for the procedure. Venography and biopsy were done in relevant cases. Amount of cement injected, percentage of filling and complications were noted properly for statistical analysis.

Total no of procedures: 38
Male: 12(31.6%)
Female: 26(68.4%)

Chart I: Sex distribution in the total number of patients and procedures:
(in percentages)



	No of patients	No of procedures
Male	24.13	31.6
Female	75.86	68.4

Type of Lesion:

Osteoporotic compression fracture: 15
Hemangioma: 17
Tumor: 6
Osteoclastoma - 4
Multiple myeloma – 1
Metastasis (unknown primary) – 1.

Percentages of different lesions:

1. Osteoporotic collapse – 39.47%
2. Hemangioma – 44.83%
3. Tumor – 15.78%

Table X: **Sex incidence in different pathologies in total procedures**

Diagnosis	Male	Female
Compression fracture	0%	100%
Hemangioma	41.2%	58.8%
Tumor	83.3%	16.7%

Statistically significant correlation was seen in sex incidence of different pathologies (p=0.001).

Percentages of lesion presented with epidural component and cord compression:

1.Osteoporotic collapse – 5 of 15(33.33%)
2.Hemangioma – 8 of 17(47.05%)
3.Tumor – 5 of 6(83.33%)

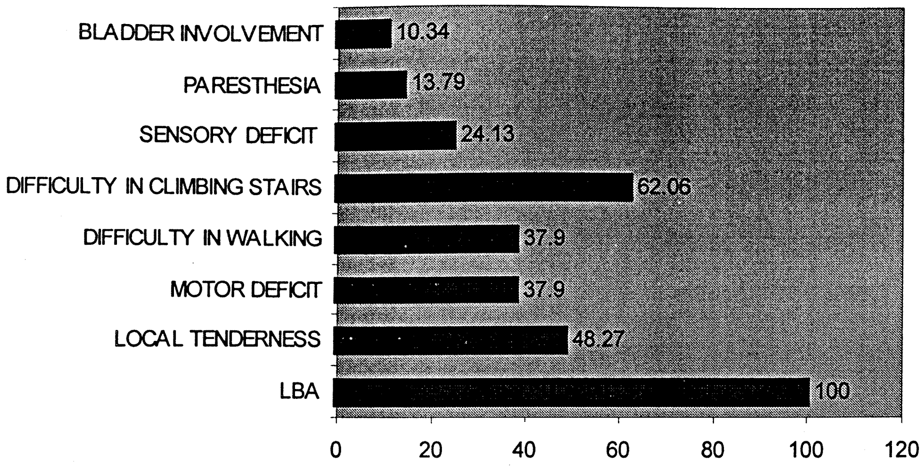
Incidence of lesion according to location:

Level 1 = 5 procedures (13.15%)
level 2 = 20 procedures (52.63%)
level 3 = 13 procedures (34.21%)

Table XI: **Incidence of lesion according to level:**

Level	Osteoporotic collapse	Hemangioma	Tumor
1		4	1
2	11	7	2
3	4	6	3

Chart II: Incidence of different complaints in patient population (In percentages):



Comparison of pre and post procedure pain severity, activity level and analgesic intake:

1. Pain severity score:

   Positive response: 3 points gain
   Pre procedure range: 5- 9
   Post procedure (1st visit 1 month post): 0-1
   p= <0.001

2. Activity score:

   Positive response: 1point gain
   Pre procedure range: 0-4
   Post procedure (1st visit 1 month post): 0-2
   p= <0.001

3. Analgesic usage: 5-point score

   Positive response: 1point gain
   Pre procedure range: 0-2
   Post procedure: 0 (1st visit 1 month post)
   p=<0.001

Table XII: **The scores of pain severity, activity level and analgesic intake calculated in total procedures:**

	Minimum	Maximum	Mean	Std. deviation	p-value
Prevertebroplasty pain severity score	5	9	6.74	1.427	<0.001
Postvertebroplasty pain severity score	0	1	0.05	0.226	
Prevertebroplasty activity score	0	4	0.84	1.053	<0.001
Postvertebroplasty activity score	0	2	0.11	0.388	
Prevertebroplasty medication score	0	2	1.00	0.465	
Postvertebroplasty medication score	0	0	0.00	0.000	<0.001

The decrease in the scores of pain severity, activity level and analgesic intake after the procedure was statistically significant ($p<0.0001$). Analysis was done with Wilcoxon Signed Rank Test.

Procedure:

Route: Transpedicular -

Left: 24 procedures (63.2%)

Right: 7 procedures (18.4%)

Both: 4 procedures (10.5%)

Para vertebral -

Right: 2 procedures (5.3%)

Left: 1 procedure (2.6%)

Route used in different pathology types:

Left transpedicular route was used in 53% (8) of osteoporotic fractures, 82.4% (14) of hemangiomas and 33.3% (2) of tumors. Right transpedicular route was used in 26.7% (4) of osteoporotic fractures, 11.8% (2) of hemangiomas and 16.7% (1) of tumors. Paravertebral route was used only in tumors and in 7.9% of all procedures.

Bilateral transpedicular route was used in only 4(10.5%) procedures out of which 20% was used for osteoporotic fractures.

Table XIII: **Route of vertebroplasty in different pathologies**:

Vertebroplasty route		Osteoporotic collapse	Hemangioma	Tumor	Total	p-value
Right transpedicular	Count	4	2	1	7	0.006
	%	26.7	11.8	16.7	18.4	
Left transpedicular	Count	8	14	2	24	
	%	53.3	82.4	33.3	63.2	
Bipedicular	Count	3	1		4	
	%	20.0	5.9		10.5	
Right paravertebral	Count			2	2	
	%			33.3	5.3	
Right paravertebral	Count			1	1	
	%			16.7	2.6	

Anesthesia:

Table XIV: **Correlation of type of anesthesia with preprocedure pain score in total procedures:**

Anesthesia	Mean preprocedure pain severity score	No of procedure	Std. Deviation
Local	6.94	34	1.369
General	5	4	0.000

No correlation with pain severity and pathology was noted with the types of anesthesia induced.

Mean duration of procedure = 50.13 mts.

Table XV: **Correlation between duration of procedure, amount of cement injected and % of filling in different lesion types:**

Diagnosis	Duration of procedure of procedure in minute (mean)	Amount of cement injected (mean)	% of filling of vertebral bodies (mean)
Osteoporotic collapse	52.67	5.6	85.33
Hemangioma	48.82	5.35	84.82
Tumor	47.50	8	88.67

Mean duration of total procedure: 50.13 mts (SD 8.095)

Mean amount of cement injected in total procedures: 5.87 ml (SD 2.362)

Mean % of vertebral filling in total procedures: 85.63 (SD 10.143)

No statistically significant correlation was noted between the groups.

Size of needle: 13G needle was used in 10 procedures

11G needle was used in 28 procedures.

13G needle was mostly used in thoracic level except in 2 lumbar levels where there was severe compression of vertebral bodies.

Table XVI: **Correlation between the size of need used, amount of cement injected, % of filling and duration of procedure**:

	Size of the needle	No of procedure	Mean	Std. deviation
Duration	11G	28	50.71	9.201
	13G	10	48.50	3.375
% of filling	11G	28	86.57	9.747
	13G	10	83.00	11.294
Cement injected	11G	28	6.07	2.478
	13G	10	5.30	2.003

No statistically significant correlation was seen between these groups.

Table XVII: **Correlation between volume of cement injected and % of filling in different levels:**

Level	Mean volume of cement injected in ml	Mean % of filling	p-value	Overall p-value
D1-D6	4.4	77.6	0.123	
D7-D12	5.1	92.2	0.182	<0.001
L1-L5	7.62	87.64	0.002	

Overall correlation between volume of cement injected and % of filling irrespective of levels was significant (p=<0.001).

Table XVIII: **Correlation between the duration of the procedure, mean % of filling and the amount of cement injected in different levels:**

Level	Mean amount of cement injected	Mean % of filling	Mean duration of procedure in minutes
D1-D6	4.4±2.07	77.6±14.1	51.0±4.18
D7-D12	5.1±1.25	85.7±9.53	51.0±10.46
L1-L3	7.6±2.84	88.6±8.39	48.4±4.27

No statistical correlation was noted between these groups.

Increase in height of compressed vertebra after PV:

Total number of procedures done in compressed vertebra: 22 (57.89%)

Increase in height observed in vertebra – 59.09% (13 out of 22)

Table XIX: **Correlation between amount of cement injected and % of filling in these groups:**

	Height	Total no	mean	Std. deviation	p-value
Amount of cement injected	Increased	13	5.69	1.653	0.514
	No change	9	5.44	1.81	
% of filling	Increased	13	85.69	10.633	0.323
	No change	9	85.11	9.44	

No statistically significant correlation was noted between the increase in height of the vertebra and the amount of cement injected (p=0.514) and the % of filling of the vertebra (p=0.323).

Venography:

Total procedures done: 3 (7.89)

Table XX: **Correlation between the amount of cement injected and % of filling of the vertebra where venography was done:**

	Venography	Total no	mean	Std. deviation	p-value
Amount of cement injected	Done	35	5.94	2.400	0.514
	Not done	3	5.00	2.000	
% of filling	Done	35	86.11	10.151	0.323
	Not done	3	80.00	10.000	

No statistically significant correlation was found between the amount of cement injected and % of filling of the vertebra where venography was done to that where it was not done. P-values were respectively 0.514 and 0.323.

Table XXI: **The number of laminectomy, pre-vertebroplasty embolization and posterior element alcohol injection:**

	Total	Percentage
Laminectomy	6	15.8
Pre vertebroplasty embolization	3	7.9
Posterior element alcohol injection	5	13.2

Pre procedure embolization was done to reduce the vascularity in aggressive hemangiomas with posterior element involvement and where the lesions looked very vascular on cross-sectional imaging to reduce the vascularity. Post vertebroplasty alcohol injection was done in posterior elements in five procedures where hemangioma involved posterior elements.

Laminectomy was done in 3 patients at 6 levels. Out of these 2 were done after vertebroplasty in 2 patients of hemangioma and osteoporotic collapse respectively. Rest 3 laminectomy was done before vertebroplasty in a single patient where osteoclastoma involved L1-L3 vertebral bodies with cord compression.

Intraprocedure Pain:

In 5 (13.15%) procedures patients complained of intraprocedure pain despite routine premeditation. In these patients preprocedure pain score was >5. These patients consisted of 3 aggressive hemangioma, one osteoporotic collapse with cord compression and one patient with vertebral body metastsis.

Table XXII: **Intraprocedure analgesic usage and its relation to pain severity score in pre and post vertebroplasty period:**

Intraprocedure medication	No of procedures	Mean prevertebroplasty pain severity score	Mean postvertebroplasty pain severity score
Analgesics	5	1.225+6.00	0.00
No medication	33	1.439+6.85	0.06

No statistically significant correlation was noted between the preprocedure pain score and analgesic usage during the procedure.

Table XXIII: **The incidence of intraprocedure vital change:**

Intraprocedure vitals	No of procedures	Percentage
Tachycardia	1	2.6%
Bradycardia	-	-
Respiration	-	-
% of saturation	-	-
ECG Changes	-	-
Blood pressure	-	-

Only one patient had intraprocedure tachycardia that had no clinical implication.

Table XXIV: **The incidence of post procedure vital change:**

Intraprocedure vitals	No of procedures	Percentage
Tachycardia	-	-
Bradycardia	1	2.6%
Respiration	-	-
% of saturation	-	-
ECG Changes	-	-
Blood pressure	-	-

Only one patient had postprocedure bradycardia, which was managed with atropine.

Table XXV: **Post procedure medication usage:**

Medication	No of procedures	Percentage
Analgesics	7	24.13
Calcium preparation	15	51.72
Others	1	3.4

In 24.13% of procedures analgesics were continued for 3-5 days for minimal residual pain. Out of them only one patient had moderate postprocedre pain for which she required intravenous analgesics. All the patients were off analgesics at one month of follow-up.

We prescribed calcium preparation to all patients of osteoporotic fracture in postprocedural period.

Table XXVI: **The duration of hospital stay of the patients:**

Hospital stay	Minimum	Maximum	Mean	SD
Days	1	8	3.24	1.403

Table XXVII: **The incidence of complications:**

Overall complications	No of proceduers	Percentage
Present	11	28.9
Absent	27	71.1

In 11 (28.9%) of procedures minor complications were seen. All the complications were clinically silent and required no surgical intervention for the complication. No patient deteriorated because of any procedure related event.

Table XXVIII: **The incidence of individual complication:**

Individual complications	No of procedures	Percentage
Preverterbal venous filling	3	7.89
Paraverterbal venous filling	3	7.89
Preverterbal soft tissue extravasation	0	0
Paraverterbal soft tissue extravasation	4	10.52
Epidural leak	2	5.26
Disc space filling	3	7.89
Injury to cord	0	0
Pain during injection	1	
Needle track and subcutaneous hematoma	0	0
Local infection	0	0
Pulmonary embolism	0	0
Systemic embolism	0	0

Table XXIX: **The percentage of complication in different levels:**

Level		No of procedures		Total
		With complication	Without complication	
D1-D6	No	2	3	5
	%	40	60	100
D7-D12	No	6	14	20
	%	70	30	100
L1-L5	NO	3	10	13
	%	23.1	76.9	100

No statistically significant correlation was noted between the levels and the percentage of complications (p=0.769)

Table XXX: **The incidence of complications in different pathologic groups**:

Lesion type		No of procedures		Total
		With complication	Without complication	
Osteoporotic collapse	No	10	5	15
	%	66.7	33.3	100
Hemangioma	No	11	6	17
	%	64.7	35.3	100
Tumor	N0	6	0	6
	%	100	0	100

No statistically significant correlation was noted between the levels and the percentage of complications (p=0.233)

Table XXXI: **Correlation of incidence of complication with volume of cement injected:**

	Complication	No of procedures	Mean	SD	Std. error mean
Amount of cement injected	Nil	27	6.07	2.571	0.495
	Present	11	5.36	1.748	0.527
% of filling of vertebrae	Nil	27	86.33	9.668	1.861
	Present	11	83.91	11.537	3.478

No statistically significant correlation was noted between the volume of cement injected, percentage of filling of the vertebrae and the percentage of complications (p=0.408,0.512).

Table XXXII: **Correlation of complications with venography:**

Venography		Complications		Total
		Absent	Present	
Not done	Total no.	25	10	35
	%	71.4	28.6	100
Done	Total no.	2	1	3
	%	66.7	33.3	100

No statistically significant correlation was noted between the with and without vertebral phlebographic evaluation and the percentage of complications (p=0.861).

Follow up:

Duration: 4 months – 33 months.

Table XXXIII: **Follow-up result at 1 month:**

Clinical status	No of patients	Percentage
Asymptomatic	23	79.31
Improved	6	20.68
Static	0	0
Deteriorated	0	0

Table XXXIV: **Result of 1-month follow-up with respect to total no of procedures:**

Clinical status	No of procedures	Percentage
Asymptomatic	27	71.1
Improved	11	28.9
Static	0	0
Deteriorated	0	0

Table XXXV: **Follow-up result according to the level of treatment (at 1 month):**

Follow-up		Level			p-value
		D1- D6	D7- 12	L1- L3	
Asymptomatic	No of procedures	3	13	11	0.403
	%	11.1	48.1	40.7	
Improved	No of procedures	2	7	2	
	%	18.2	63.3	18.2	
Static	No of procedures	-	-	-	
	%	-	-	-	
Deteriorated	No of procedures	-	-	-	
	%	-	-	-	

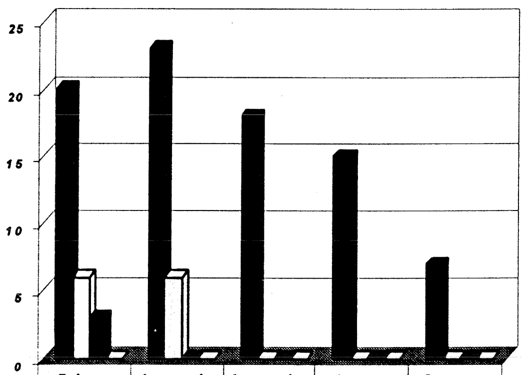
No significant difference in follow-up status is noted in this different level of procedures.

Table XXXVI: **Follow-up result according to lesion type (at 1 month):**

Follow-up		Osteoporotic collapse	Hemangioma	Tumor	p-value
Asymptomatic	No of procedures	10	11	6	
	%	37.0	40.7	22.2	
Improved	No of procedures	5	6	-	
	%	45.5	54.5	-	0.233
Static	No of procedures	-	-	-	
	%	-	-	-	
Deteriorated	No of procedures	-	-	-	
	%	-	-	-	

No statistically significant correlation was noted between the different pathology type treated and their response to treatment.

Chart III: **Follow-up results of the patients:**



	7 days	1-month	6-months	1-year	2-years
■ Asymptomatic	20	23	18	15	7
□ Improved	6	6	0	0	0
■ Static	3	0	0	0	0
□ Deteriorated	0	0	0	0	0

At 7-days after treatment 20 patients were pain free and asymptomatic, 6 patient showed improvement, 3 patients were static. Out of the 3 static patients 2 underwent laminectomy and they showed improvement. After 1-months 23 patients were asymptomatic and 6 showed clear improvement. At 6-months, 1-year and 2-year period we have the follow-up 18,15 and 7 patients respectively and all were asymptomatic and independent. None of the patients due to procedure related events.

DISCUSSION

Developed in France in the late 1980s, minimally invasive vertebroplasty involves the percutaneous injection of PMMA into fractured vertebral body. Although this does not reexpand the collapsed vertebra, reinforcing and stabilizing the vertebra seems to alleviate pain (72). The procedure was first used to treat aggressive vertebral hemangiomas (1) and was later applied to other lesions that weaken the vertebral body, including osteolytic metastasis (3,18,82) and osteoporotic vertebral body collapse (45,82,83). Although the European experience with vertebroplasty in the setting of spinal metastasis and myeloma is more extensive, (3,14,82,83) the indication of treatment among most North American series is currently heavily weighted toward osteoporotic bone disease (9,45,83).

In our study, 31.6% were male and 68.4% were female patients. Thirty-eight vertebroplasties were done in 29 patients and 39.47% of procedures were done for osteoporotic compression collapse, 44.73% for hemangioma, 15.78% for vertebral body tumors and metastasis. All the patients prescribed with moderate to severe backache. Local tenderness was present in 14 patients. Motor deficit and difficulty in walking was seen in 37.9% patients. Motor deficits were seen in 41.2% of hemangiomas, 33.3% of osteoporotic collapse and 16.7% of tumor. Difficulty in walking was noted in 35.3% of hemangiomas and 33.3% of osteoporotic collapses. Sensory deficit and bladder involvement was noted in 24.13% and 10.34% of patients respectively. Deficits were more in hemangioma group. Epidural component and cord compression in our series was noted in 33.33% of osteoporotic collapse, 47.05% of hemangioma and 83.33% of vertebral tumors. Rest of the lesion was confined to the vertebral body only.

Vertebroplasty is performed with some type of PMMA, such as simplex P, Osteobond or Cranioplastic. Simplex P and Osteobond contain 10% wt/vol of barium sulfate for opacification; however, this amount is insufficient for easy visualization during fluoroscopically guided PVP (14). All PMMA cements that are currently available commercially require the addition of opacifier in sufficient quantity to ensure visualization and safe injection under fluoroscopy.

We used bone cement from DePuy (Jhonson & Jhonson, Blackpool, England). We used CMW1 ORIGINAL, CMW1 RADIOPAQUE and CMW2 types. CMW1 RADIOPAQUE and CMW2 donot need extra barium for their radioopacity. In CMW1 ORIGINAL, we usually add 3-4 ml of barium with 10 ml of bone cement powder for adequate radio opacity. Then bone cement liquid is added till we get a toothpaste consistency of the whole mixture.

In Europe, tungsten and tantalum powder are commonly used opacifiers (14). In the United States, sterile barium sulfate has been the predominant choice as a cement opacifier. Approximately 30% wt/vol of barium sulfate must be added to PMMA powder to provide sufficient opacification for fluoroscopic monitoring (27).

We never used tungsten and tantalum powder for opacifying the bone cement. Barium usually provides adequate radio opacity for fluoroscopic visualization. We never encountered any difficulty in injection related to cement opacity. We could see properly the cement progression while injection and stopped when any leak was encountered. So, we recommend barium for opacification, as it is cheap, easily available and easy to use.

Biomechanical tests have shown that the addition of barium sulfate powder to the cement changes its strength; however the strength of the cement with barium sulfate added to produce a 30% wt/vol mixture produces no practical change in the compressive strength of PMMA (28), and it is doubtful that this change is clinically significant, because no mechanical failures of vertebrae treated by PVP have been reported (10).

We performed 38 procedures over this study period and never came across any mechanical failure in our patients. So, we recommend addition of required amount of barium to bone cement for adequate visualization change its strength to a clinically unacceptable level.

Many authors in detail described the technique of vertebroplasty. Deramond et al. (14) described the procedure in 4 steps as vertebral puncture, spinal biopsy, venography and then injection of bone cement. They prefer anterolateral puncture for the cervical level, posterolateral transpedicular puncture for the thoracic and lumbar region. Mathis et al. (10) prefer biplane fluoroscopy and Gangi et al. (25) described the technique of vertebroplasty under combined CT and fluoroscopy.

We performed all our cases under single plane fluoroscopy. The advancement of needle and injection needs continuous visualization for better control of injection. We did not try combined CT and fluoroscopy approach as described by Gangi et al. (25) However, we did alcohol injection into posterior element in five cases of aggressive hemangioma under CT-guidance only. Although, we did all the procedures under single plane fluoroscopy, biplane facility is preferred as it reduces the procedure time substantially because of simultaneous orthogonal visualization.

We performed the procedures via transpedicular route in all except 3 procedures. These 3 procedures were done in a patient who had laminectomy before vertebroplasty for osteoclastoma at L1-L3 level. Plate and screw was fitted, so paravertebral route was preferred.

We prefer the steps as was suggested by Deramond et al (4). Biopsy was taken in all tumor and osteoporotic collapse cases for histopathological diagnosis. We donot prefer biopsy in cases of hemangioma. Deramond et al. (4) also donot recommend biopsy for hemangioma.

Many authors routine used antibiotics with the bone cement (73). Mathis et al. (10) recommended prophylactic intravenous antibiotic 30minute before the procedure and also tobramycin along with the cement in immunocompromised patients. Jensen et al. (6) also prefer adding antibiotics to PMMA only in immunocompromised patients.

We did not use antibiotics in bone cement mixture in any of our patients. Neither we prefer to give intravenous antibiotic before the procedure. We did not encounter any osteomyelitis or local soft tissue infection related to the procedure. Proper maintenance of sterility during the procedure is enough to avoid infections. However, antibiotics can be used in immunocompromised cases. Gangi et al. (25) also reported of successful procedures without any antibiotics.

Among the increasing number of articles about the various aspects of percutaneous vertebroplasty, some authors have discussed using intraosseous venography (35,36), whereas others do not favor its use. (8,13,14,18).

Jensen et al. recommend venography to exclude needle placement within the basivertebral venous complex. Deramond et al. (4) reported that they perform venography only for managing angioma. Gaughen et al. (39) studied the relevance of antecedent venography in vertebroplasty for the treatment of osteoporotic compression fracture and found no significance of the same as far as the effectiveness and complication is concerned. Christina et al. (40) evaluated 205 vertebroplasty procedures without pretreatment venography and found no major difference of cement leak was seen between the benign and malignant diseases in their series.

We performed venography in only during 3 procedures. Two were aggressive hemangiomas and one osteoporotic collapse. In three procedures, the mean amount of cement injected and % of filling of the vertebrae were 5ml and 80%. In the procedures done without venography it was 5.94ml and 86.11%. We have achieved better filling even without assistance of preprocedure venography; however, small number of patients in the study group may not have significant influence in the statistical analysis. No statistically significant correlation was found between the amount of cement injected and % of filling of the vertebra where venography was done to that where it was not done. P-value was respectively 0.514 and 0.323.

Indications of vertebroplasty are straightforward (4). It is indicated for the treatment of destabilizing and painful vertebral lesions.

We used this procedure in three major indications:

a) Vertebral angiomas

b) Osteoporotic vertebral collapse syndrome

c) Painful vertebral tumors.

Vertebral angioma and vertebroplasty:

The aggressiveness of the vertebral angioma may be identified by clinical symptoms like severe back pain or radiological signs of aggressiveness as described by Lordeo et al. (45). In asymptomatic patients radiological criteria of aggressiveness estimates risk to the patients. Deramond et al. (4) classified vertebral hemangioma into 4 groups according to their clinical and radiological manifestations and found disappearance of pain in more than 90% of treated patients.

We treated 17 vertebral body hemangiomas. Out of these, 8 were aggressive hemangiomas with epidural component and cord compression of varying severity. In three of these 8 lesions, we did hemangioma embolization before vertebroplasty. Only one aggressive lesion required post vertebroplasty laminectomy for reduction of cord compression. We also did post procedure alcohol injection in to the posterior elements. At one month of follow-up all the patients were independent.

In most of the aggressive hemangiomas there is no fat and the whole of the tumor is composed of vascular soft tissue (84). The degree and extent of vascularity may be appreciated on selective spinal angiography. Though this technique is essentially used to identify the feeding arteries and the origin of the anterior spinal artery prior to surgery, embolization can be performed during the examination (43).

Vertebral tumor, metastasis and vertebroplasty:

Destructive vertebral lesion is a common source of morbidity in patient with metastatic disease and multiple myeloma. Approximately 30% of patients with various neoplastic conditions develop symptomatic spinal metastases during the course of their illness, and pain is the presenting complaint in the majority of cases. Nonoperative treatments include analgesic medication and radiotherapy. Although this does not reexpand a collapsed vertebra, reinforcing and stabilizing the fracture seems to alleviate pain.

Weill et al. (18) reported 24 (73%) of 33 treatment sessions performed for pain relief resulted in clear improvement for spinal metastases. Three patients had transient rediculopathy due to cement extrusion; surgical removal of epidural cement in the neural foramen was required in one patient. Cotton et al. (3) reported partial or complete pain relief was sustained in 36 of 37 of their patients. Deramond et al. (14) treated 101 patients of metastasis and myeloma and saw significant improvement of quality of life in more than 80% of patients.

We had 6 (15.78%) procedures in 4 patients done for tumors. Out of these 4 were osteoclastoma, 1 metastasis and 1 multiple myeloma. No complications were seen in these procedures. Pain reduction was achieved in 3 patients within 24 hours. One patient with osteoclastoma had to continue analgesic for one week and she was asymptomatic at 1-month follow up. Two patients had laminectomy before vertebroplasty for cord compression. One patient having minimal preprocedure motor deficit recovered full lower limb strength within a month.

Osteoporotic collapse and vertebroplasty:

Deramond et al. (14) treated 80 patients of osteoporotic collapse with a follow-up of 1month to 10 years. Immediate pain relief was seen in more than 90% of patients. Only 1 patient suffered intercostals neuralgia. Jensen et al. (6) treated 29 patients with 47 painful vertebral fractures. 26 patients (90%) reported pain relief immediately after treatment. Only 2 complications were met (non-displaced rib fractures).

We treated 15 vertebrae in 12 patients for osteoporotic collapse. All were female patients. Pain reduction was achieved in all the cases within 24 hours of the procedures. No analgesics were prescribed for them. Only one patient had minor pain on prolonged standing but she did not require any analgesics for that. Mean amount of cement injected was 5.6ml and mean percentage of filling was 85.33%. Extravasation of cement was noted in 33.3% of procedures in osteoporotic collapse. All were minor and did not require any decompression.

Both Cotton at al. (3) and Deramond et al. (14) agreed that the reduction to one third of vertebral body height constituted severe vertebral compression and was considered a relative contraindication to the procedure. Wilfred et al. (38) reports 48 vertebroplasties in 37 patients for severe osteoporotic collapse (height reduced less than 1/3rd of their originals height). They have shown that it was feasible to perform vertebroplasty in patients with severe compression. Technically it is more difficult and more caution has to be taken in these patients.

Out of 15 procedures on osteoporotic vertebrae in our series, we performed 8 vertebroplasties for severe collapse. The mean volume of cement injected was 4.2ml and percentage of filling was 77.5. There were no major complications. Pain reduction was achieved in all the cases within 24 hours of the procedures.

In cases of involvement of posterior arch, local injection of ethibloc at the end of vertebroplasty has been suggested to reduce the bleeding during laminectomy; injection of histoacryl into the epidural component has also been suggested. We injected alcohol into the posterior elements in 5 procedure (13.2%). Out of them, 4 were hemangioma and one osteoclastoma. All the injections were done with 18-20G spinal needle with local anesthesia and under CT guidance. No patient required pre procedure medication. No procedure related complication was seen in this. Average volume of injection was 6ml per half of posterior element of vertebrae.

Great care must be taken in case of posterior wall rupture. Vertebral venography is recommended prior to acrylic cement injection to indicate the risk of intravenous embolization of cement or its diffusion in to the spinal canal (83). Ide et al. (84) reports vertebroplasty of 3 hemangiomas with epidural component with no such complication. Risk of epidural overflow can also be avoided by injecting the cement during its fast polymerization phase and by monitoring vertebral filling by lateral fluoroscopy (83).

Our series include 8 hemangioma, 4 osteoclastoma, 1metastasis and 5 osteoporotic collapses where breach was noted in posterior wall with epidural component and cord compression. Posterior wall breach was not considered a contraindication of vertebroplasty in our series but the procedure was performed with great care to avoid catastrophic leakage of cement into unwanted areas. We met minimal complication in two of these procedures, one hemangioma and one osteoporotic collapse. They were disc space filling and paravertebral vein filling which were clinically silent. No epidural spillage was seen in these procedures.

Vertebroplasty is usually done via bipedicular approach for better lesion filling. But unipedicular approach has several advantages. It is less time consuming, associated with less complication. But, it is slightly more difficult to use the unipediculate approach than the bipediculate in the thoracic spine, given the relatively small size of pedicles in the thoracic region (31).

We did 4 (10.5%) procedures via bipediculate approach out of which 3 were osteoporotic collapses and 1 hemangioma. We prefer to do unipediculate approach because it is less time consuming and there are less chances of complication. In lateral view it sometimes difficult to trace cement progression in the second injection because previously injected cement obstruct view. Bipediculate injection was made when satisfactory filling was not achieved after first injection that were mostly seen in cases of osteoporotic collapse. We donot find any statistically significant difference in the amount of cement injected in unipediculate versus bipediculate procedures. 2(50%) minor complications were seen in bipediculate approach.

Kim et al. (31) described a modified unipedicular approach with more lateral angulation of the needle. They compared the technique with bipedicular approach. Lesion filling across midline was achieved in 96% of cases with mean filling of 77% in both vertebral halves. There was no statistically significant difference in clinical outcome from that of bipediculate route. Authors consider this lateral approach is considerably safe with little risk of neural injury.

We found satisfactory cement filling via unipediculate approach in almost all our procedures especially in hemangiomas. In three osteoporotic collapse (20%), we had to do second injection and we think it may be because of internal organization of compressed vertebra in these cases, which hindered the cement percolation and filling. Out of 17 hemangiomas only 1(5.9%) needed bipediculate injection.

Complications:

The principal radiographic complication PMMA leakage is epidural and foraminal extravasation. Any resultant spinal cord or nerve root damage may require emergency surgical decompression. Neurologic complications, however, are uncommon. Perivertebral venous, paravertebral soft tissue and intradiscal leakages are of no clinical importance in the short and midterm.

Extravasation of fractures in more than canal, neural foramen, and paraspinal veins or disc space has been reported in 11 to 73 % of the PTPV procedures (2,3,5,11,72).

In the series reported by Weill et al. (18) one patient with foraminal extravasation required decompressive surgery. Kaemmerlen et al. (4) described one case of intraforaminal extravasation and one of spinal cord compression that required surgical removal of the cement. Deramond et al. (14) reported three cases of foraminal extravasation (1%) that required surgery and one case involving spinal cord compression that required surgery. Rafliff et al. (85) reported a case of both intraforaminal and canal extravasation in which decompressive surgery was performed. Of four patients in whom PTPV was undertaken by Wenger and Markwalder (86) canal extravasation occurred on one and required surgery.

In our series, extravasation of cement was observed in 28.9% of procedures. In 2(5.26%) procedures only minor epidural leak was seen which was clinically unapparent and required no decompressive surgery. Disc space filling and paravertebral soft tissue extravasation were seen in 7.89% and 10.52% respectively. Venous extravasation and filling of adjacent pre and paravertebral veins were seen in 7.89% of procedures each. However, no distal embolization was seen.

Cyteveal et al. (8) found disc leakage in five (25%) of 20 patients, none of whom had complication. In the series by Weill et al, slight PMM leaks toward the disc epidural fat, perivertebral veins were observed in 20 (38%) of 52 vertebroplasties; leaks were symptomatic in only five vertebroplasties. These authors suggest that slight PMM leaks, when not symptomatic, should not be considered as complication. Deramond et al. (14) and Cotton et al. (3) indicate that leakage in to intervertebral discs and paravertebral soft tissues was frequent and almost always asymptomatic. Wilfred et al. (38) concluded that there is no direct relationship between the rate of PMM leakage and the severity of vertebral body compression. Deramond et al. (14) recommended placement of the needle in the lateral part of the vertebra to decrease the risk of cement leakage.

In our series, cement leak was observed in 28.9% of procedures. Leak was observed in 40% of total procedures done at level 1(D1-D6), 30% and 23.1% for level 2(D7-D11) and level 3(L1-L3) respectively. Leak was observed in 33.3% of osteoporotic fractures and 35.3% of hemangiomas. No leak was observed in procedures done for tumors. All the leaks were clinically silent and required no decompressive surgery. No statistically significant correlation was noted between the volume of cement injected, percentage of filling of the vertebrae and the incidence of cement leak ($p=0.408, 0.512$).

The rate of cement leak in the published series went up to 73% of vertebroplasties. In some series it was very low (3,25). Many authors advocate vertebral phlebogram prior to cement injection to identify potential sites of cement leak (14), but it has some disadvantages also.

In our series, we did not find any significant correlation between the amount of cement leak and the group of procedures done with or without preprocedure assessment by venography (p=0.861). Percentages of leak were 33.3 and 28.6 in these two groups respectively.

Factors, which can keep low rate of cement leak, are discussed by Fourney et al. (72). Usage of PMMA, which polymerizes rapidly, can reduce extravasation (72). Liquid consistency of PMMA increases extravasation (5). Insufficient polymerization has been implicated as a major risk factor for pulmonary embolization, which is some series, had been fatal (87). Second important factor if volume of cement injection. Few authors (69) have correlated complications with excessive PMMA injection where as others found no correlation. Kyung et al. (76) evaluated the incidence of dose dependent PMMA leak in osteoporotic fractures and found larger the volume of PMMA injected the higher the incidence of epidural leakage (p=0.03). Weill et al. (18) in their study of vertebroplasty for spinal metastasis observed that despite posterior wall breach there was no major complication and they consider posterior wall destruction no more a contraindication for vertebroplasty.

A transient decrease in blood pressure and HR is generally observed during the injection of cement (89). Hypotension has been attributed to vasodilatation as a result of histamine liberation or to myocardial depression, which are supposed consequences of methylmethacrylate toxicity (90). Gaughen et al. (39) studied the vital parameters in treating osteoporotic compression fracture with and without antecedent venography. No patient in either group had any clinical apparent complications as a result of cement deposition. Cardiovascular and respiratory parameters, including oxygen saturation, blood pressure and heart rate, remained within normal limits throughout each procedure in every patient in both groups. We also found no significant correlation between these parameters.

Only one patient in our series had intraprocedure tachycardia that was clinically non-significant. We never came across any other ominous vital change in patients related to the procedure. Another patient had bradycardia 2-3 hours after the procedure, which was managed by atropine.

Sensitizations of neural elements by direct pressure or by heat generated during cement polymerization are plausible mechanisms of pain during vertebroplasty. Different anesthetic techniques have been proposed to control pain during vertebroplasty, but all have important limitations.

In 28 patients, 34 vertebroplasty were performed under local anesthesia and sedation in our series. In 5 (14.7%) out of these 34 procedures, patient needed intraprocedure analgesics for pain. There was no statistical correlation between these medication usage and preprocedure pain score of the patient. In two of the procedures 11G and in rest 3 procedures 13G needles were used. Pain was observed during needle passage in 4 procedures and during venography and injection of cement in one case. In 4 procedures GA was given with fentanyl, propofol and midazolam. These 4 procedures were done in a single patient of D10-L1 hemangioma. We had to use GA because the patient was very comprehensive.

Pain relief after vertebroplasty:

Pain relief is expected after a mean of 24 hours after the procedure. Marked or complete pain relief was demonstrated in 70% of patients of vertebral metastasis or myeloma and in 90% of patients with osteoporotic compression fracture and hemangioma in different series. In the series of 29 patients with osteoporotic compression fractures, Jensen et al. (6) found marked pain relief in 90% patients within 24 hours. Cyteval et al. (8) reported complete pain relief in 75% of 23 patients with osteoporotic fractures.

In our series, pain reduction was achieved in 75.87% of cases within 24 hours. 7 (24.13%) patients needed analgesics for 3-5 days for minimal residual pain. One patient had persistent pain after the procedure and the patient was taken for second sitting at the same level. Total cement injected was 5 ml after two sitting and after that pain reduction was achieved. All patients were free of backache at one month of follow-up.

Kallmes et al. (61) performed 63 vertebroplasties with osteoporotic compressions ranging from 15-70%(mean 44%) at T4-T8 level. Bipediculate injections were used in 19% of procedures only at T6-T8 level. Eleven-gauge needle were used in 73% and 13G in 27% of procedures irrespective of the levels. Mean volume of cement injection was 3.2±2ml. The mean volume of cement injected at T4-T6 was less than that at T7-T8 level (2.4+1.5 versus 3.6+2.1ml,p=0.01). No correlation existed between the volume of cement injected and the percentage of compression.

We performed 15 vertebroplasties for osteoporotic compression fractures ranging from 30-80% (mean 60%) at D7-L3 level. Mean volume of cement injected was 5.6ml and mean % of filling was 85.33. 20% of cases bipediculate route was used. 11G needle was used in 53.33% and 13G in 46.67% of procedures. No statistically significant correlation existed between % of compression and the volume of cement injected.

We did 28 procedures with 11G needle and 10 procedures with 13G needle. The mean duration of procedure with these needles were 50.71 minutes and 48.50 minutes respectively. The mean % of filling and mean amount of cement injected via 11G & 13G needle were 86.57%, 83.0% and 6.07ml and 5.3 ml respectively. No statistical correlation was noted amongst them.

Kallmes et al. (61) in their study did preoperative assessment in the following clinical parameters: 1) pain severity, using an eleven point scale (0=no pain, 10=most sever pain); 2) analgesic requirement, using a six-point scale (0=no analgesic use, 5= parenteral narcotic administration and mobility using a five-point scale (0=full activity, 4=bedridden). They compared pre and postoperative scores with 'paired t-test'. At 28 days, Mean pre – and post operative pain intensity was 9.7 ± 1.0 and 1.7 ± 1.9 respectively (p< .0001). Mean pre and postoperative medication scores were 3.4 ± 0.7 and 1.7 ± 1.7 respectively (p=. 075). Mean pre and postoperative mobility scores were 1.5 ± 1.5 and 0.4 ± 0.5 respectively (p = .17).

In our study, we compared pre and post procedure scores with Wilcoxon signed rank test. Mean pre and post procedure pain intensity was 6.7 (SD 1.427) and 0.05 (SD 0.226) respectively *(p< .001)*. Mean pre and post procedure activity scores were 0.84 (SD 1.053) and 0.11(SD 0.388) respectively *p< .001)*. Mean pre and post procedure analgesic intake scores were 1.0 (SD 0.465) and 0 respectively (*p*< .001). Statistically significant reduction of pain and analgesic intake was achieved after the procedure. Activity levels of the patients were also increased which was also statistically significant at 1 month of follow up.

Cotton et al. (3) in their 40 vertebroplasties in 37 patients for metastasis and myeloma achieved lesion filling in more than 75% in 5 cases, more than 50% in 14 cases, 25-49% in 13 cases and less than 25% in 18 cases. They noted no significant relation between percentage of lesion filling and the reduction of pain. We did not found any correlation between the volume of cement injected, % of lesion filling and pain reduction.

Cotton et al (3) clearly showed that pain relief is not related to the amount of cement injected but to the distribution of cement in the vertebral body. In our series, the mean amount of cement injected and % of filling is osteoporotic collapses, hemangioma and tumor are 5.6ml, 5.35ml, 8 ml and 85.33%, 84.82%, 88.67% respectively. No statistically significant correlation or differences were noted in this group.

Hiwatashi et al (73) observed increase in vertebral body height after vertebroplasty. They measured the height of 85 vertebral bodies in 37 patients before & after vertebroplasty in pre operative MR images & post OP CT sagittal reformation. Height increased was noted in 72 of 85 treated vertebral bodies. Average increase in height was 2.2 mm.

In out series, 57.89% (22) of procedures were done in compressed vertebrae. In 13 out of 22 (59.09%) procedures, increase in height was observed. In rest & vertebrae, no height change was noted after vertebroplasty. We did not seen any statistically significant difference in those two groups with respect to the mean amount of cement injected and % of filling of the vertebrae.

We had regular follow up for our patients. Our protocol for follow up is at 1 month, 6 months and then yearly. At every follow up visit, we do routine neurological check up, assess score for pain and activity as well as for medication. We do imaging if necessary usually with plain picture of spine and in some cases with CT scan.

The duration of follow up is from 4-33 months. After seven days, 20 patients were completely asymptomatic. Six patients improved with respect of pain and activity scoring & these patients showed at least 2 points gain for pain and 1-point gain in activity status. Other 3 patients were static. They had features of cord compression on imaging. Out of them two patients were sent for laminectomy & decompression and they improved after that. One patient was showing gradual improvement in his power of lower limb and we followed him up. At one month of follow up 23 patients were asymptomatic and the rest 6 showed clear improvement. No patient deteriorated. We had 2 year, 1 year and 6 months follow up for 7,15, and 18 patients respectively. All were asymptomatic. No new symptoms were seen in the patient population. One patient with cord compression because of aggressive hemangioma who showed slow improvement after treatment. We preferred to follow up. At 1 month she showed mild improvement and after 1 year her power was normal in lower limbs save some mild sensory disturbance. Deramond et al. (14) also treated 12 such cases (five with complementary injection of ethanol). In all cases, neurological signs slowly disappeared & reinforcement was obtained. Epidural component also disappeared progressively.

RECOMMENDATIONS FOR SUCCESSFUL PROCEDURE:

(a) It is helpful to have the patient attempt the prone position on a firm table before beginning the procedure to check for tolerance.

(b) A thorough clinical examination before the procedure is always helpful to anticipate the difficulties likely to be met during the procedure.

(c) Cardiological and neurological checkup is mandatory for older patients with cardiovascular compromise.

(d) A dedicated nurse or other qualified person must be responsible for monitoring the patient, as respiratory distress or depression may occur quickly in older patients with osteoporotic fracture and metastasis.

(e) Patients who experience difficulty with ventilation or who are unable to tolerate the prone position may require general anesthesia or deep sedation.

(f) The needle position should be checked frequently in both planes to avoid exiting through the endplate. One end plate penetration occurs, the needle may have to be removed and repositioned.

(g) If the venogram shows rapid, direct filling of the basivertebral complex, the tip should be advanced in to the bone instead of withdrawn. With severe osteopenia, there may be rapid flow of contrast material through the bone in to the veins, which is misinterpreted as positioning within the vein. The PMMA used in this situation should be of a slighter thicker in consistency than usual and the injection needs to be slower to avoid complications.

(h) The powdered material should be mixed thoroughly to avoid clumping of barium. Powdered barium preparations designed for gastrointestinal work contain gums and flavors that may act as nutrients for bacteria, and should not be used in vertebroplasty.

(i) Pure barium sulfate powder is available, but needs to be sterilized by using dry heat before vertebroplasty.

(j) The liquid agent is extremely volatile and should be opened only when needed. Inhalation of the fumes should be avoided.

(k) After mixing for approximately 1 minute, the material is relatively thin. At this point it is loaded in to the 10 ml syringe. Further mixing seems to speed the polymerization and if one waits until the material appears to be of correct consistency in the bowl, it will be too thick to inject by the time the syringe is loaded.

(l) Owing to the viscosity of the material, injection may be difficult and the best results are obtained by using small amounts (0.5 to 0.7 ml) with the force of the injection applied parallel to the syringe cylinder. Injection is best done using 1 ml syringes for proper filling of the vertebrae.

(m) Injection is performed under fluoroscopic control, paying particular attention to the epidural space, the spinal canal, and the perivertebral veins visible on the venogram. The lateral projection is best but may be useful for only the initial vertebral hemisphere when bipedicular injection is sought. Since the opaque cement from the first hemivertebral injection obscures the entire vertebral body in the lateral view.

(n) When leakage occurs, delaying further injection for a minute allows the material to thicken and form a plug before proceeding. This technique is also useful when material enters the paravertebral veins. If continued injection shows filling only of the disk space or veins, the procedure is terminated in that hemisphere.

(o) After the procedure, the patient should always be monitored in the ward for any delayed vital changes.

CONCLUSION

Percutaneous vertebroplasty is safe and effective treatment of non-infective, painful, destructive vertebral lesions, whether benign or malignant, as well as osteoporotic vertebral fractures in which conservative therapy fails.

We believe, in patient selection, there is no minimum requirement of vertebral height for the patient to be benefited and cortical disruption does not constitute a contraindication for the procedure.

Vertebroplasty is a very safe procedure when performed on high quality imaging equipment and when properly opacified and proper consistency cement is used. We think the procedure can be performed safely without pretreatment venography and the occurrence of clinically significant complication can be avoided with adequate precautions and expertise. The consistency of the cement should be toothpaste like for proper percolation and at the same time preventing inadvertent leak. The procedure should be carried out swiftly before the cement gets hardened. The injection should be stopped if any ominous leak is detected and can be restarted when the cement settles there. Most of the leaks are clinically silent. Epidural symptomatic leaks needs surgical decompression.

Vertebroplasty strengthens & stabilizes the diseased vertebral body, gives relief from incapacitating pain and thus enhances the activity level of the patient. A multi disciplinary team should ideally make the decision of treatment because at times decompressive surgery or radiotherapy should be combined with vertebroplasty for better outcome.

The cements and the devices used are evolving and improving, making the procedure safer day by day.

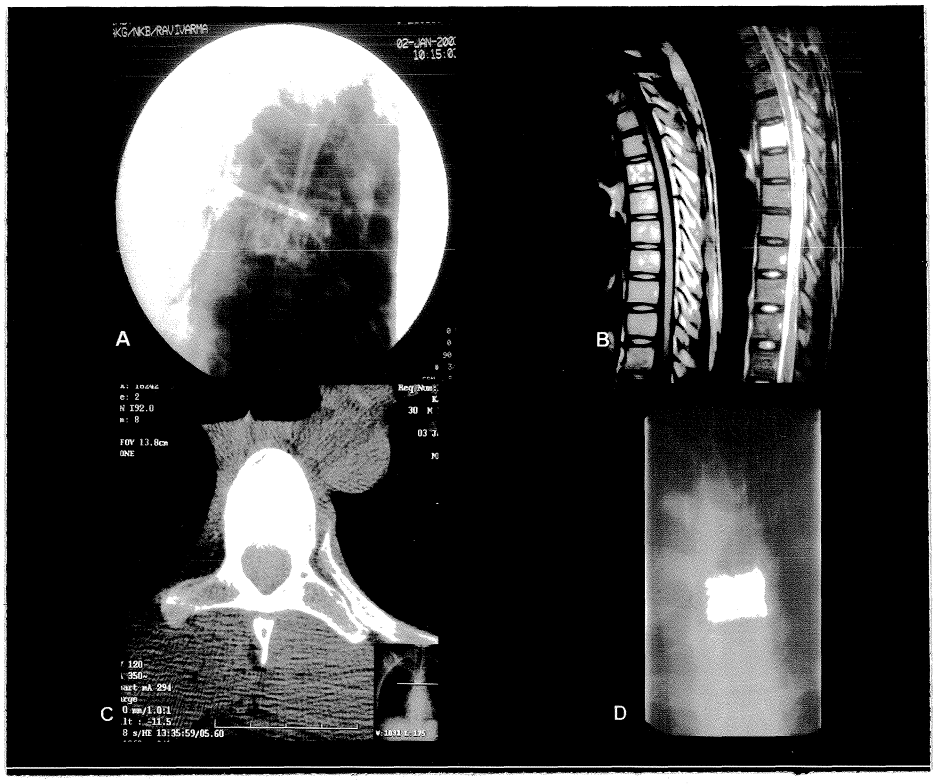


Fig 3: Lateral fluoroscopic image shows D6 hemangioma with vertebroplasty needle in situ. (b) T1 & T2 weighted sagittal MRI scan shows hemangioma with involvement of whole vertebral body. No thecal sac compression. (c) Post vertebroplasty axial CT scan shows complete filling of vertebra. (d) Follow – up X-ray anteroposterior view shows good result.

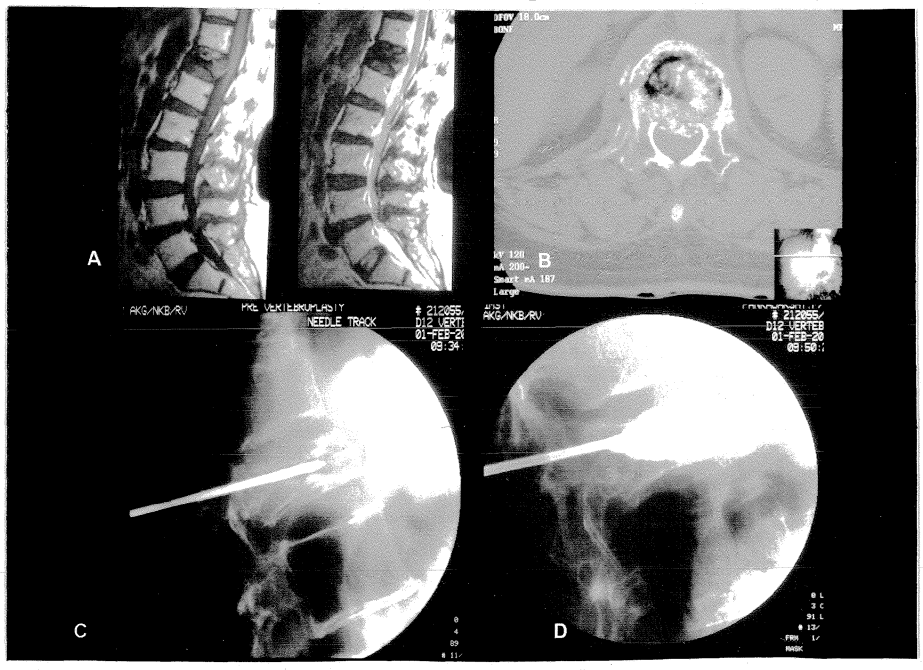


Fig 4: (a) T1 & T2 weighted sagittal MRI scan shows D12 osteoporotic collapse with thecal sac compression. (b) Axial CT scan shows vacuum phenomenon in the fractured vertebra. (c) Lateral fluoroscopic image shows vertebroplasty needle in the compressed vertebra. (d) Post vertebroplasty lateral fluoroscopic image shows good filling of vertebrae.

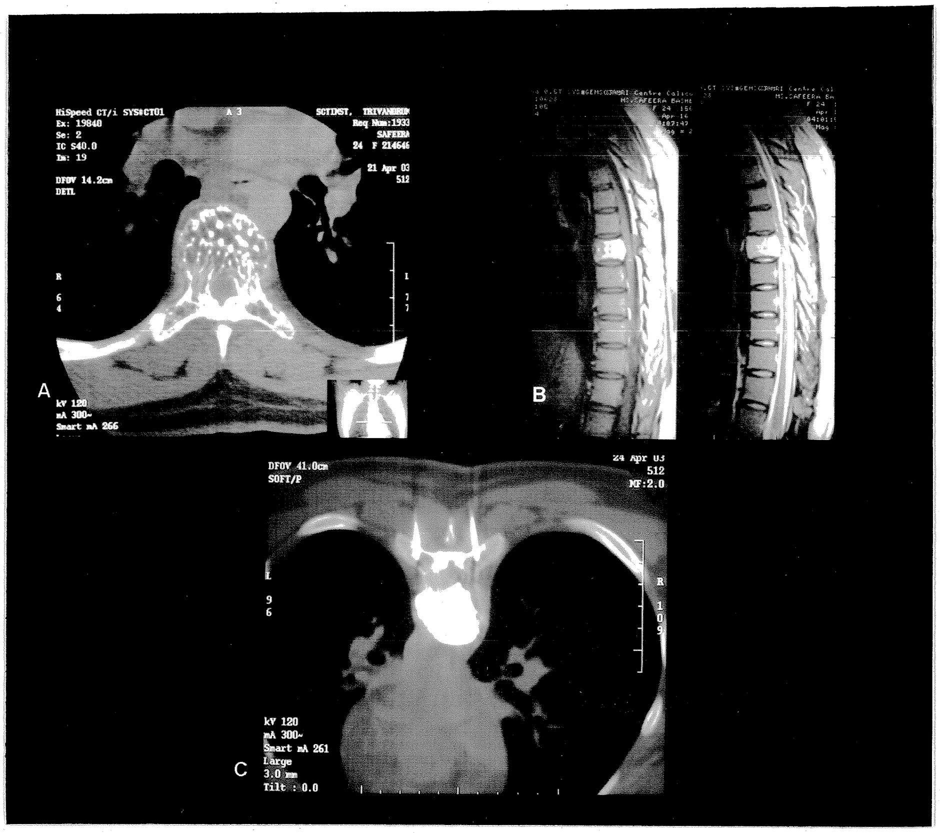


Fig 5: (a) Axial CT scan shows vertebral body hemangioma. (b) T1 & T2 weighted sagittal MRI shows fat containing hemangioma with mild thecal sac compression. (c) Axial CT scan shows post vertebroplasty bilateral posterior element alcohol injection.

Fig 6: Complication: (a) Post vertebroplasty axial CT scan shows pre and paravertebral venous filling. (b) Lateral fluoroscopic image shows disc space filling.

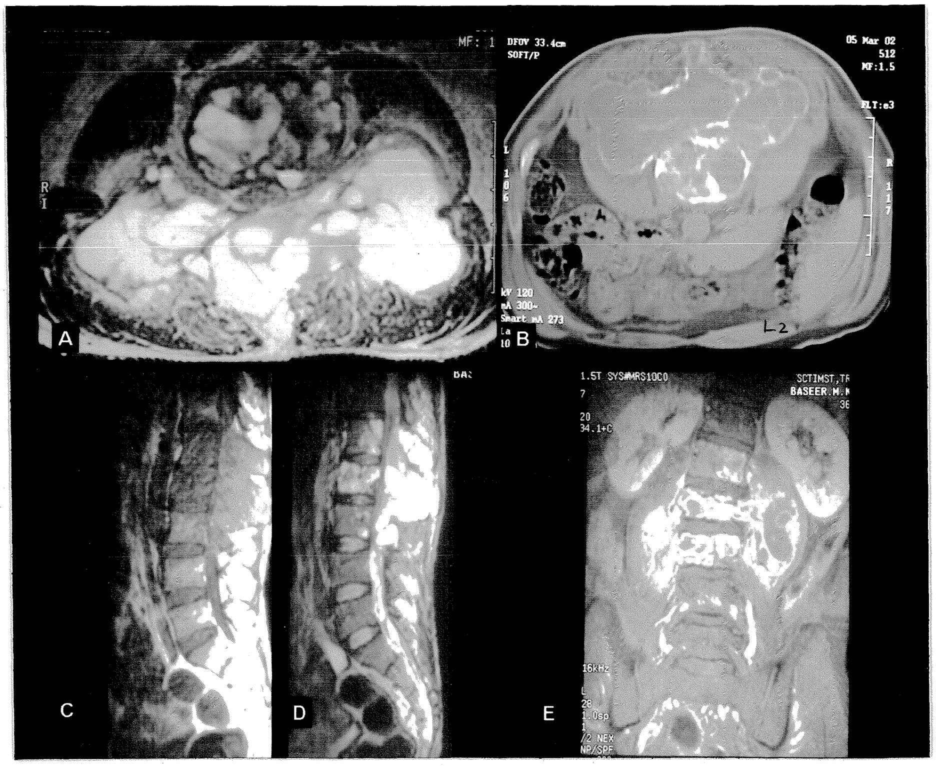


Fig 7: (a) T2 weighted axial image, (B) Axial CT scan, (c)(d)T1 & T2 weighted sagittal MRI scan and (e) Post contrast coronal T1 weighted image show osteoclastoma at L1-L3 level.

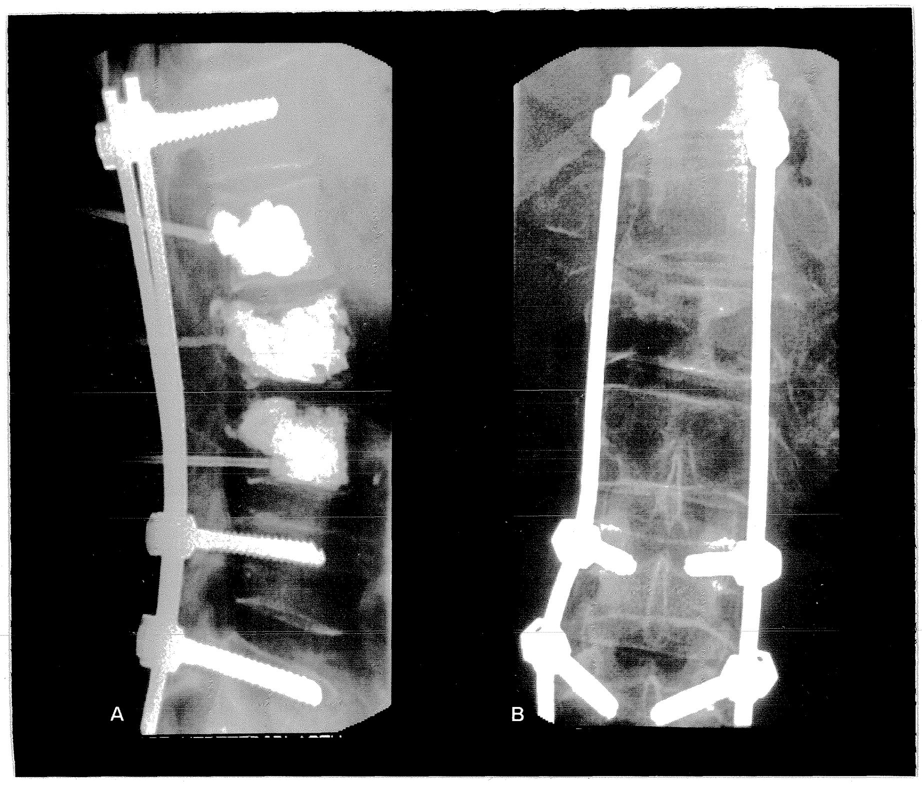


Fig 8: (a) Post vertebroplasty and (b) Pre vertebroplasty lateral fluoroscopic image show good cement filling of the vertebrae (L1-L3). Fixation rod in situ.

Fig 9: Example of preprocedure venography shows contrast filling of vertebral body affected by hemangioma.

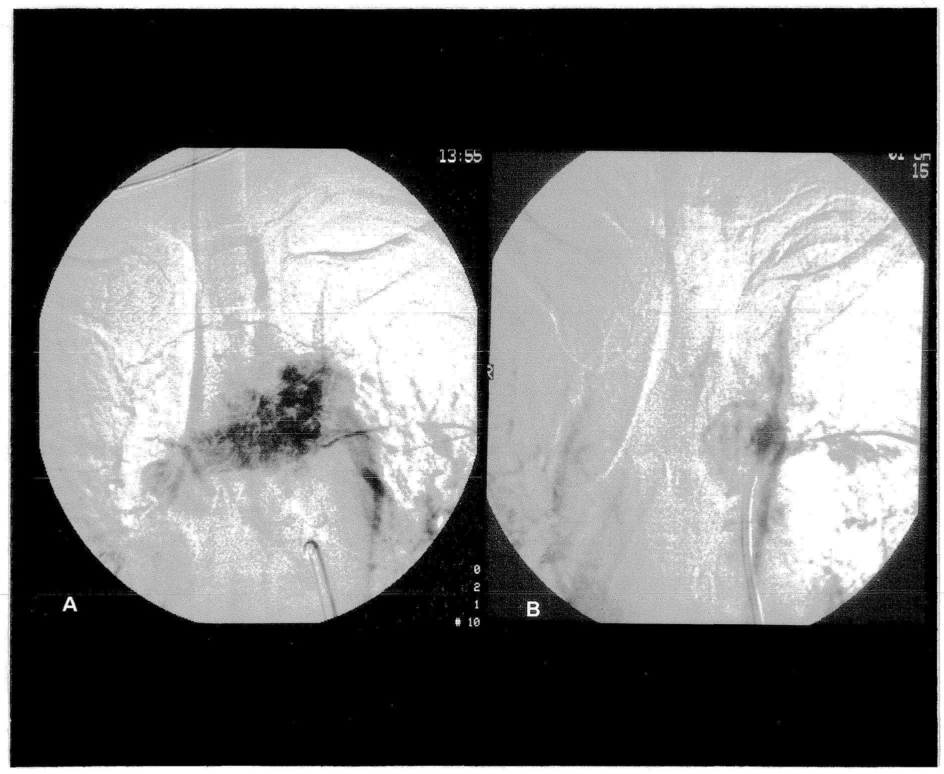


Fig 10: Example of pre vertebroplasty hemangioma embolization with PVA particles. (a) Pre and (b) Post embolization fluoroscopic images.

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PROFORMA

Proforma – Percutaneous Vertebroplasty

Name: Age: Sex: Hosp. no
Referred by:
Diagnosis :

DO Adm DO Dis

Pre Procedure evaluation

History: Date

Pain: site
duration
nature
radiation
aggravating factor
relieveing factor

Clinical severity:
11-point ordinal scale
* no pain 0
* most severe 10

Local tenderness: yes/no site:

Focal deficits: motor: weakness
spasticity
progressive
permanent

sensory:paresthesia
sensory loss
progressive
permanent

Difficulty in walking
Difficulty in forward bending
Difficulty in climbing stairs
Difficulty in lying straight
} DURATION:

Bladder / bowel involvement:

Activity score: Points: 0-4 0-walking without assistance
1-walking with assistance
2-wheel chair bound
3-sitting in bed
4-lying in bed

Others:

Other systemic diseases :
Hypertension y / n diabetes y / n
Systemic malignancy:

Body weight: Addiction:

Present medication:

For pain - 5-point score

0-none
1-nsaids
2-non-narcotic opoids
3-narcotic opoids
4-iv narcotic deugs

Other medication:

General examination:

Baseline pulse rate: others:
Baseline b.p.:
Local deformity / skin changes:

CNS examination :

Handedness: rt / lt / ambi
Orientation:
Preprocedural deficits
CN:

Motor -	rt	lt
bulk		
power		
tone		
reflexes		

Sensory:

Gait:

Cerebellar signs:

Pre procedure lab ix : TC DLC ESR
sugar Hb%
PT/PRT platelet count
urea creat HIV/HBV

Cardiological work up :
EGC:
Echocardiography:

Preprocedure imaging:

1. X-ray date:
   - part –
   - finding -

2. CT scan date:
   - part –
   - finding

     type of lesion
     calcification
     involvement of epidural space
     % of reduction of vb height

3. MRI scan date:

type of lesion

1.compression fracture - osteoporotic post-infectious

2.tumor
benign hemangioma others
malignant primary mets
location

vertebral body

whole
partial
right left midline
site cervical thoracic lumbar
involvement of posterior element
lamina
transverse process
spine

morphology of lesion: compressive expansile
% reduction in height: axial coronal sagittal
border regular irregular

hemorrhage in lesion (if any)
location
size
approximate age

3. State of spinal canal
    compression   anterior   posterior

    lateral   rt   lt

4. State of spinal cord
    compression   yes / no
    signal change
        t1-wi mri

        t2-wi mri

        contrast enhancement

5. State of paravertebral / prevertebral soft tissue

    final imaging diagnosis:

Dagnostic spinal angiogram if any : yes / no   date:

part:
findings :
abnormal blush :
arterial :
    feeding arteries
draining vein :

embolization of lesion done if any before vertebroplasty:

anesthesia: GA   sedation   LA
    Material used:
    result:
    complication:

Vertebroplasty: date:
preprocedure medication: pethidine / phenergan
location
image guidance: fluoroscopy   ct guided
anaesthesia   la   ga
route: transpedicular   rt   left   both
others:
final location of needle :   anterior1/3   middle1/3   posterior1/3
needle used   gauge   length

diamond bevle

Preprocedure vertebral venography:

amount of constrast used: type:

fillinf of vertebral body partial total

filling of epidural veins

filling of paravertebral veins

filling of disc spac

technical complication

Biopsy taken: yes / no

amount of cement injected: ml

consistency of cement

amount of different ingredient in total cement volume made:

PMMA monomer

pmma dimer

barium

tantalum

antiobiotics

intraprocedural medication, if any:

intraprocedural vitals monitoring:

pulse rate:

bp:

spo2:

neurological exam:

motor system-

sensory system-

intraprocedural pain monitoring:

local pain-

refered pain-

end point of vertebroplasty :

good percolation of entire vertebral body

filling of epidural / paravertebral veins

reflux into epidural space

solisifying of cement

pulmonary embolism

paradoxical systemic embolism

Technical complications :

filling of epidural veins

filling of paravertebral veins
filling of disc space
reflux in to epidural space
prematuere solidifying of cement leading inadequate filling
pulmonary embolism
paradoxical systemic embolism

End of procedure :
extubation, if done under GA:
post procedural vitals
pulse BP
post procedural neurological status
motor system: right left
power
tone
reflexes
sensory system

Traetment of posterior elements, if involved:
Image guidance: ct / fluoroscopy ga / la

PMMA injection: amount:
Alcohol injection: amount:
route:
needle used:
result:
complication, if any:

Result

Imaging - fluoroscopy (on table on completion of procedure)
% of filling of vertebra:
filling of disc space:
filling of veins:
% of gain in height of treated vertebra:
epidural spilling:

Other procedural data :
duration of procedure: fluoroscopy time:
other drugs:

Post procedural orders:
analgesics
other drugs

Post procedure CTscan
- % of filling of vertebra
- filling of disc space
- filling of veins
- filling of epidural space
- % of gain in height of treated vertebra

Post prcedure MRI:
Overall result: satisfactory others

Post vertebroplasty surgical decompression, if any:
- laminectomy: yes / no
- site:
- reason for laminectomy:

Details of hospital stay
- ICU stay
- ward stay
- days of stay

Review 1 month 3 months others
Imaging
- X-ray
- CT scan
  - % of filling
  - % of height gain
  - disc spaces
  - new fracture
  - cord status (MRI)

Clinical -
- pain score:
- analgesic score:
- activity level:

Motor status
- power
- tone
- reflexes

Sensory status
Condition of bladder
Condition of bowel
Others: