VERTEBROPLASTY AS TREATMENT OF SYMPTOMATIC VERTEBRAL HEMANGIOMAS

Thesis submitted in fulfilment of the rules and regulations for DM Degree Examination of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram

By

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DECLARATION

I hereby declare that the dissertation titled ***"Vertebroplasty as treatment of symptomatic Vertebral hemangiomas"*** *has been prepared by me under guidance* ***of Dr. A.K, Gupta,*** *professor, Department of Imaging sciences and Intervention Radiology, SCTIMST, Trivandrum and is submitted in partial fulfillment of the regulations for the award of DM Degree.*

I have not submitted this work previously to any university for the award of any degree.

Place

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CERTIFICATE

This is to certify that the dissertation titled ***"Vertebroplasty as treatment of symptomatic Vertebral hemangiomas"*** *is a record of work done by* ***Dr. Pranjal Phukan****, during the period January 2009- September 2011 at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram under my guidance and supervision, in partial fulfillment of the regulations governing DM degree Examination of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram to be held in December 2011.*

Place

Date *Dr A K Gupta.*

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Introduction

Vertebral hemangioma is a common benign lesion of the spine that is often asymptomatic and discovered incidentally during evaluation of neck or back pain. Rarely VH may be painful and/or aggressive resulting in nerve root or spinal cord compression. The treatment of choice for such complications has been surgical decompression; however surgical intervention may be associated with profuse intraoperative bleeding and post operative epidural hematoma. To decrease this complications surgery may be preceded by percutaneous vertebroplasty.

PVP is a therapeutic, interventional radiologic procedure that involves injection of an acrylic polymer into a partially collapsed vertebral body in an effort to relieve pain and provide stability. This procedure was initially described by French radiologists for the treatment of painful VH, myeloma, and metastatic lesions, and is now also being used in patients with osteoporotic compression fractures. These vertebral fractures may cause persistent often excruciating pain, which impairs mobility and reduces the patient's quality of life.

The primary goal of treatment is to alleviate pain, with a secondary goal of vertebral body stabilization. PVP is indicated in the following situations:

- Painful osteoporotic vertebral compression fracture refractory to medical therapy. Failure of medical therapy is considered to be no, or minimal, pain relief with the administration

of physician-prescribed analgesics. Associated major disability such as inability to walk, transfer or perform ADLs is almost always present.

- Painful vertebral fracture related to benign or malignant tumor, such as hemangioma, myeloma or metastatic lesion.
- Painful vertebral fracture associated with osteonecrosis (Kummell's disease).
- Unstable compression fracture that demonstrates movement at the wedge deformity.
- Conditions where reinforcement of the vertebral body or pedicle prior to a posterior surgical stabilization procedure is desired in patients with osteoporosis, or vertebral tumor resulting in bone loss/destruction.
- Patients with multiple compression deformities resulting from osteoporotic collapse where further collapse would result in pulmonary compromise as a result of deformity of the spine.

Contraindications to vertebroplasty are occasionally encountered, and may be summarized as follows:

Absolute contraindications

- Tumor extension into the adjacent epidural space.
- Patient clearly improving on medical therapy.
- Prophylaxis in osteopenic patients with no evidence of fracture and no planned spinal destabilization procedure.

Relative contraindications

- Radicular pain or radiculopathy caused by a compressive syndrome unrelated to vertebral body collapse; pre-operative vertebroplasty may be indicated if spinal destabilization procedure is planned.
- Spinal canal compromise of greater that 20% by retropulsed fragment.
- Vertebral body collapse of greater than 90% (vertebra plana).
- Long-standing back pain of duration greater than one year

Aims of the study

The aim of this work is to illustrate the efficacy of vertebroplasty in the treatment of patient with aggressive symptomatic VH even with epidural extension resistant to conservative medical management.

Review of literature

Percutaneous vertebroplasty (PVP) is a treatment procedure involving the injection of bone cement (eg, polymethyl methacrylate) into a painful osteoporotic compression fracture (8), or painful pathologic vertebral body (eg, multiple myeloma (69) metastatic disease (69), and hemangioma (1)) under fluoroscopic guidance.

Galibert et al introduced PVP in 1987 to manage mainly VH (1). Since then many reports have come regarding vertebroplasty polymethylmethacrylate (PMMA) assisted vertebroplasty.

CEMENT USED IN VERTEBROPLASTY:-

Various types of cements are commercially available for orthopedic interventions. 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 (2). 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 (3).

Physical properties of bone cements:-

Many reports have compared the physical properties (strength and stiffness) of some of the cements commonly used for PVP when they are prepared according to the manufacturer's instructions. One such study found that molded cylinders of Simplex P were stronger and stiffer than those made of Osteobond (4). However, because cement injected into the vertebral body

may behave differently than that in molded cylinders and because the direct injection of cement into a vertebral body could alter the cement's performance, biomechanical testing of cadaveric osteoporotic vertebral bodies has been conducted. In one test, such vertebral bodies were compressed to determine their initial strength and stiffness and then mechanically crushed posterior to the anterior wall to simulate compression fractures (3). After vertebroplasty with Simplex P, Osteobond, or Cranioplastic containing additional barium (per the current standard of practice in off-label use), the vertebral bodies were retested. All three cements resulted in increased strength (beyond precrush levels), but only Simplex P and Osteobond restored initial stiffness (5).

S. No	**Cement**	**Manufacturer**
1.	Allegiance	Cardinal Health, McGaw Park, IL
2.	BoneSource	Stryker Leibinger, Kalamazoo, MI
3.	Cranioplastic	(DePuy CMW, Johnson & Johnson, Blackpool, UK)
4.	Orthocomp	Orthovita, Malvern, PA
5.	Osteobond	Zimmer, Warsaw, IN
6.	Palacos	E. Merck, Darmstadt, Germany or Biomet, Inc, Warsaw, IN
7.	Palacos E-Flow	Essex Chemie AG, Lucerne, Switzerland
8.	Simplex P	Stryker-Howmedica-Osteonics, Mahwah, NJ
9.	Sucour	Arthro Care (formally Parallax), Sunnyvale, CA
10.	Vertifix (US, Osteofirm in Europe)	WE Cook, Bloomington, IN William Cook Europe Cook Australia

Liquid Polymer:-

PMMA-based cements are prepared by mixing a powdered polymer and a liquid monomer. Each cement manufacturer recommends a specific monomer-to- polymer ratio, expressed as grams per milliliter. Changing the monomer-to-polymer ratio (i.e. increasing the amount of liquid polymer) dilutes the cement, which increases the handling and injection times. However, doing so can affect the cement's properties, specifically strength and polymerization temperature, and it may affect monomer-induced neural toxicity (one of the proposed pain relief mechanisms for PVP). To our knowledge, the latter claim is as yet unsupported by data.

In one study, cylindrical specimens of Cranioplastic were prepared by using various monomer-to-powder ratios (0.40 to 1.07 mL/g) and tested to determine ultimate strength, compressive strength, and the ability to withstand mechanical stress (0.40 to 1.07 mL/g) (6). Results showed that all three measurements were highest at a mixture of 0.53 mL/g, close to the manufacturer's recommended ratio of 0.57 mL/g, and diminished when the ratio deviated in either direction. The study's authors estimated that the actual mixture ratio used in PVP is between 0.60 and 0.74 mL/g, resulting in a reduction in strength of 16% for this range of ratios (6).

Radiopaque Compounds:-

Radiopaque substances, such as tantalum powder, tungsten, barium sulfate, or zirconium dioxide, have been added to bone cements before injection to facilitate visualization under fluoroscopy and monitoring for possible cement extravasations (7). Although tungsten and

tantalum powder have been added to bone cement in PVP (8), little is known concerning their effect on the cement's physical and mechanical properties. Studies on the addition of barium sulfate have produced conflicting reports: it has been reported to decrease the ability to withstand deformation under a load or fracture (11), to diminish some physical properties (tensile, compressive, and transverse bending strengths) (9), not to affect the ability to withstand shearing forces until it exceeded 50% of the total dry powder weight of the cement (surpassing the amounted added during PVP) (10), and to increase compressive strength. Barium sulfate affects not only mechanical strength but also polymerization temperature. One study showed that the maximum polymerization temperatures for Simplex P with 30% and 60% barium sulfate by weight had maximum polymerization temperatures of 60°C and 44°C, respectively (10). Other work has shown no significant difference in peak polymerization temperature between PMMA cement with 10% and 0% barium sulfate (9). Although Haas et al (9) did not observe statistically significant temperature changes, they found that dough time, handling, and setting times all significantly increased with the addition of 10% barium sulfate.

The addition of barium sulfate to PMMA also has been associated with significantly increased bone resorption (12, 13), which if occurring within the vertebral body, could negate the strengthening features of the cement and reduce the effectiveness of PVP. These findings led to the hypothesis that the increased bone resorption is caused by barium sulfate– enhanced macrophage-osteoclast differentiation (13). The addition of zirconium dioxide to PMMA cements also has produced mixed results. The addition caused a significant increase in bone resorption, although that increase was 50% less than that of cement-containing barium sulfate

(12). Another study of PMMA with zirconium dioxide did not show a significant increase in bone resorption (13).

Pain Relief:-

Thermal necrosis of surrounding nerves has been postulated as a mechanism of pain relief in vertebroplasty. Research indicates that thermal necrosis of bone tissue occurs when temperatures surpass 50°C for more than 1 minute (15).

Deramond et al measured temperatures at the anterior cortices, centers, and spinal canals of cadaveric vertebral bodies after bipedicular injections of Simplex P or Orthocomp (Bis-phenol glycidyl dimethacrylate / Bis-phenol ethoxy dimethacrylate/triethyleneglycol dimethacrylate, a matrix composite cement reinforced with glass-ceramic), both of which were prepared according to the manufacturer's specifications. They found that, at the central location, Simplex P injection was associated with significantly higher temperatures and with temperatures exceeding 50°C for significantly longer times (61.8°C 12.7, 3.6 minutes±2.1) than Orthocomp injection (51.2°C ±6.2; 1.3 minutes ±1.4). However, measurements at the anterior cortex and spinal canal locations showed no significant difference between the two cements. In fact, at the latter location, the temperature of cement did not exceed 41°C in either cement. The authors hypothesized that, given their results; it was unlikely the pain relief from vertebroplasty was caused by intraosseous neural tissue damage (14).

Bone Formation and Other New Developments:-

Although research has shown that PMMA cements cannot induce new bone formation (16), some new bone cements show promise not only in terms of bone growth but also in terms

of improved physical and mechanical properties, which could be beneficial for percutaneous vertebroplasty. . One recently developed cement consists of bioactive glass beads and a novel organic matrix of PMMA, which resulted in new bone formation around the beads and a significant increase in bending strength compared with PMMA cement without the beads (17). Curing time and polymerization temperatures were not reported. Adding a glass-ceramic powder and bisphenol-a-glycidyl methacrylate (Bis-GMA) resin to a PMMA-based cement has produced a bioactive acrylic bone cement that bonds directly to the bone after 4–8 weeks in vivo and has faster hardening times, lower curing temperatures, and significantly better physical properties (18)

TECHNIQUE OF VERTEBROPLASTY:

Many authors describe the technique of PVP in detail. Deramond et al described the procedure in 4 steps

1. Vertebral puncture.
2. Spinal biopsy.
3. Venography.
4. Injection of bone cement.

They prefer anterolateral puncture for the cervical level, postterolateral 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. (3)

Mathis et al. also described the technique of vertebroplasty in detail. They prefer biplane fluoroscopy for vertebroplasty. They add prophylactic antibiotic 30 minutes before the procedure and also tobramycin along with the cement only in immunocompromised patients. (2)

Gangi et al described the technique under CT and fluoroscopy. (19)

Jensen et al 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. (20)

Lin et al 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 1^{st} and 2^{nd} cervical vertebra. They used Cook needle for cement injection. The authors prefer unilateral approach and they observed that bilateral route was only required in 35-40% of cases. (21). Jensen et al used Jamshidi needle for cement injection. (20)

Route of vertebroplasty:

Vertebroplasty can be done via unipedicular or bipedicular approach. Bipedicular approach may be required for better lesion filling. But unipedicular approach has several advantages. It is less time consuming, associated with lesser chance of complication. Kim et al.

described a modified unipedicular approach with more lateral angulation of the needle (22). 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 difference in clinical outcome from that of bipediculate route.

Needles:-

Needle selection is operator dependent. To our knowledge, there are no studies on comparison of performance among needle types that might guide selection. Multiple needles are available that are excellent for vertebroplasty. Important attributes include the shape of the tip of the stylet as well as the type of handle. Needles suitable for vertebroplasty are supplied with a variety of stylets. Needles are available which are suitable for vertebroplasty with a variety of stylets like single bevel; multibevel point; diamond point; threaded stylet.

Also available is a coaxial system with a curved nitinol cannula (Cook, Bloomington, Ind, Australia) for facilitating cross-midline access or specific placement. With this device, care should be used to avoid puncture of the lateral wall of the vertebral body. While most needle cannulas have a square distal shape, one available cannula has a beveled distal end (Cook) that may allow one to direct cement in a given direction. Multiple handle shapes are available, including standard grip designs (Cook; Manan Medical Products, Wheeling, Ill), whereas other manufacturers offer novel designs such as an awl handle (Parallax Medical, Scotts Valley,

California**,** U.S.A.). Last, we use 10-cm-long needles in most patients but favor 15-cm-long needles when treating lower lumbar vertebrae in larger patients.

Injection Devices

For cement injection, Jensen et. al recommended 1 mm Luer-lock syringes, which they fill from back end from 10 ml syringe. Around 0.5- 0.7 ml cement is usually taken in to it for easy injection. Deramond et. al used 2 – 3 ml Luer-lock syringes for cement injection. (8)

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

Schallen et al described a reusable flange converter with hub lock for injection of cement with screw-plunger syringe (23). They used the device in 172 vertbroplasties and achieved more volume of cement that can be injected. It reduces the cost of multiple 1 ml syringes.

Anesthesia for Vertebroplasty

Sensitization of neural elements by direct pressure or by heat generated during cement polymerization is plausible mechanisms of cause of pain in vertebroplasty. Sesay et al. 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 and prevents clinical assessment of the patient during the procedure (25). Sedative analgesia with opioids and benzodiazepines, which is currently the main analgesic technique for PV can be hazardous, especially 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. recommend general anesthesia, diazanalgesia (a general anesthetic technic with spontaneous ventilation) or local anesthesia for vertebroplasty; general anesthesia with propofol, fentanyl; diazanalgesia with fentanyl and midazolam and local anesthesia with 1 % lidocaine (3). Lin et al used both local anesthesia with a buffered lidocaine solution and intravenous sedation during vertebroplasty (21). Mathis et at 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(2). Gangi et al recommend neuroleptanalgesia and local anesthesia for vertebroplasty guided by a combination of CT and fluoroscopy (19). Jensen et al. also recommend fentanyl and midazolam along with local anesthesia for the procedure (8). 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.

VERTEBROPLASTY IN THE TREATMENT OF VERTEBRAL HEMANGIOMA:-

Vertebral body hemangiomas are the most common slow-growing, benign tumors of the spine (26). They represent about 2–3% of all spinal tumors and they are usually found in about 11% of all vertebral autopsies (27).

Pathological classification of vertebral hemangioma:-

From a histological point of view, hemangiomas are subdivided into capillary, cavernous and mixed. (89)

1. Capillary hemangiomas.
2. Cavernous hemangioma
3. Mixed pattern of vertebral hemangiomas.

The most common variety that occurs in the vertebral bodies is the cavernous variety, characterized by large sinusoid spaces of venous engorgement and a single stratified epithelium (36).

Capillary angiomas are formed of thin-walled capillary vessels of various sizes separated by normal bone tissue or stromal tissue. There were two main microscopic types of vertebral hemangiomas which frequently coexisted (mixed type)

Clinical classification of vertebral hemangioma:-

VH are clinically subdivided into three main categories: the most common asymptomatic hemangioma, the compressive vertebral hemangioma and the rare symptomatic hemangioma (29).

Most of the hemangioma remains clinically silent, in about 0.9 to 1.2% of patients they are presented with pain symptomatology (26, 27). Asymptomatic hemangiomas occur equally in man and women. But there is a female predominance with symptomatic lesion. Lower thoracic and lumber regions are the most common site. Multiple regions are seen in 25-30 % of cases. Asymptomatic VH remaining in the vertebral body are not considered to progress or to need treatment, but treatment becomes necessary if they develop posteriorly beyond the vertebral cortex and cause myelopathy or radiculopathy (which is generally considered to occur in 1% or less of cases) (34).

As the lesion grows in the vertebral body or arch or when it determines the compression of the dural sac or of the nerve root due to presence of epidural tissue or to the occurrence of intralesional bleeding, hemangiomas become symptomatic with onset of critical neurological deficit. Venous congestion impairs the trabecular architecture of the vertebral bone leading to fractures (37).

In symptomatic VH the most common symptom is pain, rarely they are presented with neurological deficit due to hypertrophy of the posterior cortex of the vertebral body. Compression fractures or hemorrhages are very rare. They are usually detected at the fourth or fifth life decade and are twice more often in women than in men (26, 28).

Aggressiveness of the vertebral hemangioma 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: 4 of 6 indicating aggressiveness were present:

1. Location between T3 and T9
2. Involvement of entire vertebral body.
3. Involvement of neural arch.
4. Irregular trabeculation.
5. Expanded and poorly defined cortex
6. Presence of epidural or paravertebral components of tumor

Furthermore, the MR signal was taken to indicate aggressiveness. Non-aggressive fatty hemangiomas usually give high signal on T1 Weighted images, slightly high signal on T2 weighted images and show no contrast enhancement. Given the radiological evidence of aggressiveness PVP by injection of methylmethacrylate cement was performed to prevent complications. CT, a year later, showed no progression of the lesion. The patient remains asymptomatic

Treatment of vertebral hemangioma:-

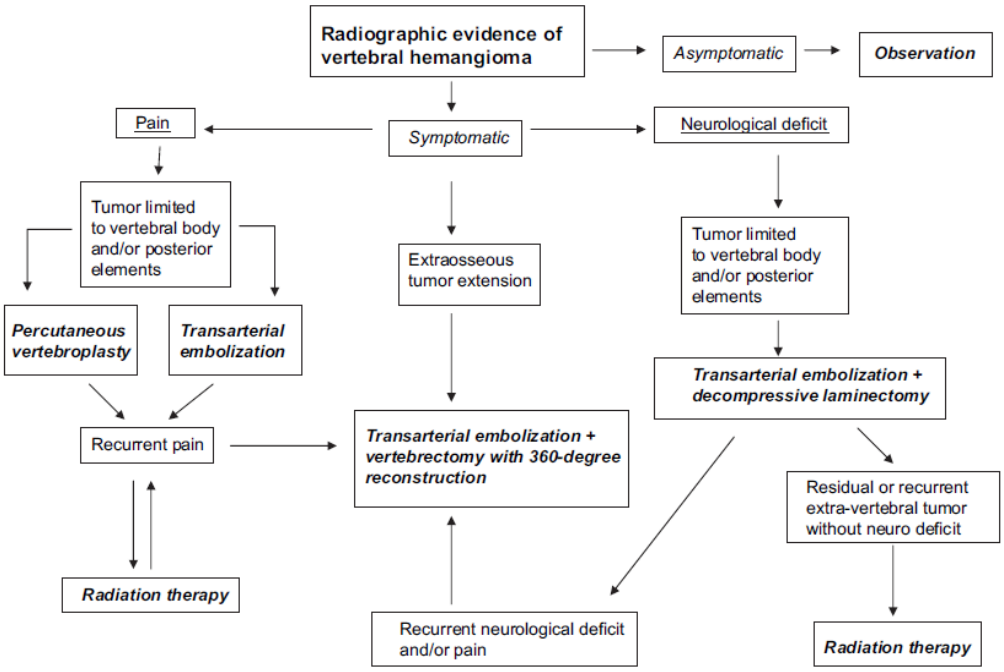
VH can be treated by methods that include direct resection and fixation, embolization, irradiation, and ethanol sclerotherapy. (39- 42)

Deramond et al. classified symptomatic VH in to 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, acute symptomatic compression of spinal cord or nerve roots.

PVP is the treatment of choice in group-I. Deramond et al. treated 38 patients with disappearance of pain in more than 90% of patients. They prefer to follow up group-II patients without treatment and they show no secondary evolution of these patients. Group-III 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 two patients on follow-up. Group –IV patients need laminectomy. Deramond et al. treated 3 such patients. In all patients neurological symptoms improved and there was no change in clinical status throughout the follow-up period of 8 years.



Flow chart:- Treatment algorithm for symptomatic vertebral hemangiomas

Radiotherapy or surgical therapy has been for many years the treatment of choice for symptomatic or aggressive vertebral hemangiomas. Both of these therapeutic solutions have been burdened with many complications related to intraoperative or postoperative bleeding, anticipated by selective arterial embolization. Decompression by surgical resection has been reported to produce quick effects but to cause massive intraoperative hemorrhage occasionally because of the nature of the lesion, resulting in insufficient resection and palliative procedures such as laminectomy (44, 45). In this setting, the treatment with VP finds its strong indications.

Concerning embolization, many hemangiomas are located in the thoracic vertebrae, and the radiculomedullary artery and the vessel supplying the tumor often originate from the same vessel, making selective embolization using a liquid embolizing agent difficult. (44). Also, the effect of embolization is temporary, (46) and it is presently performed before surgery for reducing hemorrhage (39).

The absolute ethanol injection therapy for VH performed in a study has been used since 1994, and it has been reported to be effective. As for the long-term prognosis, symptomatic improvements were observed without complications in 9 of the 11 patients followed up for a mean period of 40 months (maximum of 76 months) as reported by Doppman et al (44).

Advantages of this therapy include the simplicity of the procedure, which is less invasive than surgical treatment, and no need for postoperative rest; it is also effective for lesions compressing the spinal cord, it has rapid effects, and therapy can be repeated. (47)

Because ethanol dehydrates and fixes cells, ethanol injection is considered to alleviate spinal cord compression symptoms within a few days by causing thrombus formation, destroying

the tunica intima, and reducing the tumor size. Although absolute ethanol has neurotoxicity, it is usually reported not to cause nerve damage because of the presence of the periosteum as a barrier between the dura mater and the hemangioma (44).

Injection of a large volume of ethanol into the vertebral body may cause pathologic fracture, which has been reported in 2 of the 13 patients of Gobal et al (47) and in 2 of the 11 patients of Doppman et al (44). In Doppman et al patients who suffered fracture, ethanol was injected at a total volume of 42 mL and 50 mL, and the authors recommended that the volume of each ethanol injection should be 15 mL or less.

Because the maximum tolerated dose of ethanol is considered to be 1 mL/kg body weight (49), an ordinary dose administered by means of intravertebral injection is not expected to cause problems. Nevertheless, because death has been reported after injection at 0.52 ml/kg as a result of cardiotoxicity (50), a recommended injection volume per treatment is considered to be 15 mL or less

Pregnancy-related hemangioma

Pregnancy is a recognized risk factor for developing a rapid onset of symptoms from these normally silent lesions. The first case of pregnancy related VH was reported in 1927 by Balado (90).

There are few cases of pregnancy related VH in literature. Majority of them presented during the third trimester and the rest during the second trimester. Contrary to their usual location in the lower thoracic and lumbar vertebrae in non-pregnant patients, pregnancy related VH occur more frequently in the upper thoracic levels.

It is postulated that neurological symptoms may be produced by one or more of the following mechanisms:

(a) Expansion of an involved vertebrae leading to narrowing of the spinal canal.

(b) Compression fracture of involved vertebrae

(c) Acute hemorrhage into the epidural space

(d) Sub-periosteal growth of tumor creating an extradural mass producing compression

(e) Spinal cord ischemia caused by ‘‘steal’

Physiological changes that occur during pregnancy tend to stress the growing tendency of VH, especially during the first trimester of gestation. In fact, the venous occlusion, the increased intra-abdominal pressure, and the vascular redistribution of flow in the vertebral venous plexus due to uterine enlargement are all predisposing factors to hemangioma growth and to the related onset of compression fractures (38).

The treatment of spinal cord compression due to VH during pregnancy is undoubtedly surgical. Pregnancy is a relative contraindication to radiotherapy. Embolization is not risk free especially during pregnancy, and complications include vascular injury and radiation exposure to the fetus during fluoroscopy. No cases of antepartum embolization or vertebroplasty for vertebral hemangioma have been reported.

The treatment algorithm proposed by Chi et al. based on the duration of pregnancy and status of neurology is useful in planning treatment in these cases. Patients at 36 weeks of gestation or later, are observed, if neurological function deteriorates, one can consider induction of delivery followed by appropriate management of the tumor. Between 32 and 36 weeks of gestation, expectant observation is considered; surgery is reserved for severe cases of paraplegia.

For patients in whom gestation is earlier than 32 weeks prepartum surgical treatment should be considered for those who are severely symptomatic (92).

A review of literature showed that eight patients underwent surgery antepartum. Six patients had a laminectomy and two had a vertebrectomy and fusion. Except two all the patients treated with laminectomy had a good to excellent outcome. The two patients who underwent vertebrectomy also had an excellent outcome (93).

PERCUTANEOUS VERTEBROPLASTY OF VERTEBRAL BODY COMPRESSION FRACTURES:

Vertebral body compression fractures (VCF) are a common cause of back pain and subsequent functional impairment. Percutaneous vertebroplasty is an image-guided, minimally invasive technique used for the treatment of VCFs whereby polymethylmethacrylate (PMMA) is injected into the vertebral body, typically through a transpedicular approach. Vertebroplasty has been used to provide pain relief and structural stability for patients with VCFs.

Although there is some recent controversy related to treatment of nonsevere VCF, typically accepted indications include osteoporotic fractures, myeloma, and metastasis. However, there has been little published on vertebroplasty treatment of severe VCFs classified as vertebral body collapsed to less than one-third of original height (99). In fact, many reports cite severe VCFs as a relative contraindication to vertebroplasty treatment (100).

Factor responsible for pain relief are thermal necrosis, chemotoxcity of intraossious pain receptors as well as mechanical stabilization. (101)

PERCUTANEOUS VERTEBROPLASTY OF OSTEOPOROTIC COLLAPSE:

Vertebral fractures are the most common complication of osteopenia. One-third of all over 65 year-old women experience at least one vertebral compression fracture (VCF), representing the most common fracture type in this population.

Vertebral fractures in osteoporotic patients may be of minimal degree and therefore go unnoticed, or they can cause acute and intense lumbar back pain, compromising quality of life (102). In most cases, conservative treatment based on bed rest, bracing, physical therapy and pharmacological treatment may reduce pain intensity within a few weeks. Generally, this treatment allows a gradual recovery process within 2 or 3 months.

Although conservative treatment offers satisfactory clinical results in most of the cases, it is not riskless, especially in elderly people. A considerable number of patients do not respond successfully to conservative treatment and chronic pain may result from (103):

(a) Incomplete vertebral healing due to further bone collapse

(b) Altered vertebral column kinematics subsequent to spinal deformity

(c) Pseudoarthrosis of the fractured vertebral body

PVP provides the possibility to stabilize vertebral fractures by injecting a small quantity of bone cement into the collapsed vertebral body

Deramond et al treated 80 patients with follow up of 1 month to 10 years. Immediate pain relief was seen in more than 90% of patients. Only 1 patient suffered intercostals neuralgia (33).

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

PERCUTANEOUS VERTEBROPLASTY IN NEOPLASTIC LESION METASTATIC LESION

Bone is one of the most frequent sites of metastasis and the spine is the most common of painful skeletal sites (94). Spinal metastases are found in more than 2/3rd of patients who die of cancer (95). Vertebrae are therefore frequently affected by pathologic fractures, in 10% to 20% of cases bone is one of the most frequent sites of metastasis and the spine is the most common of painful skeletal sites. Vertebrae are therefore frequently affected by pathologic fractures, in 10% to 20% of cases involving the posterior wall of the vertebral body, which can protrude posteriorly and cause spinal canal compromise and neurologic injury (96). Thoracic vertebrae are the most common sites of disease (60%–80%), followed by lumbar (20%) and cervical spine (10%) (95)

Harrington classified patients with spinal metastases into the following five categories (96), according to the extent of neurologic compromise and bone destruction:

Class 1: No major neurologic involvement

Class 2: Involvement of bone without collapse or instability

Class 3: Major neurologic impairment (sensory or motor) without major involvement of bone.

Class 4: Vertebral collapse with pain due to mechanical causes or instability but without major neurologic compromise.

Class 5: Vertebral collapse or instability combined with major neurologic impairment.

Treatment is palliative and aims to relieve pain, prevent development of any pathologic fracture, improve mobility and function, and, if possible, prolong survival. The initial therapeutic option (Classes 1 and 2) is a nonoperative treatment based on rest, bracing, chemotherapy/hormonal treatment, and analgesics, but in the presence of refractory pain, spinal instability or neurologic deficit from cord compression (Classes 4 and 5), surgical stabilization is necessary. Patients in Class 3 are initially treated with radiotherapy alone, but similar to those in Classes 4 and 5, they do not always respond.

Furthermore, life expectancy is an important factor to justify surgical treatment, and generally, indications include a life expectancy of greater than 6 months and isolated metastasis (97).

Radiation therapy provides local pain control in a high percentage of cases and works best if combined with chemotherapy. The aim of radiotherapy for patients with a short life expectancy may be different from that for those who have a better prognosis and require not only pain relief but also spinal function (98). Since its efficacy is dose-dependent, to obtain longerlasting results, a high dose of irradiation may be required and the adverse effects of radiation therapy (eg, radiation myelitis) must be considered. Furthermore, the painrelieving effect of radiation therapy is gradual and local response rates after repeated radiotherapy due to recurrent pain symptoms at the same port drastically decrease after the first course.

PVP is currently considered a reasonable alternative for treating vertebral fractures of the thoracic and lumbar spine since polymethylmethacrylate (PMMA) injection inside the vertebral body provides both pain control in approximately 97% of patients and vertebral stabilization (78).

COMPLICATIONS IN VERTEBROPLASTY:

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

The major complications of vertebroplasty include epidural hematomas caused by medial pedicle wall breach or by cement via needle malposition, leakage of bone cement into the epidural and neural foraminal areas, pulmonary embolization caused by polymethylmethacrylate, arterial injury, and death.

Published frequency of complications is 1.3% in osteoporosis, 2.5% in spinal hemangiomas and 10% in metastatic disease. With osteoporotic fractures, complications most often are non-neurologic and transient. Transient radiculopathy has been reported in 3-6% of cases and has been successfully treated with steroids and anti-inflalnmatory drugs. Lin et al. achieved 10% 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 Chiras, Cotton and Deramond have stated that clinically significant complications with vertebroplasties occur predominantly in patients with spinal metastatic disease, but they are usually medically manageable. (60, 63 &71)

Leakage of cement after vertebroplasty has been reported in between 38% and 72.5% of cases (1). It may cause pulmonary embolism and neurological complications including myelopathy and radiculopathy.

Yeom et al analyzed the 76 vertebrae in 49 patients who underwent vertebroplasty for painful osteoporotic compression fractures. They classified the leaks of cement into three types: those via the basivertebral vein (type B), via the segmental vein (type S), and through a cortical defect (type C). Most common was type-B (93%) and type-S was found in (86%) cases (79).

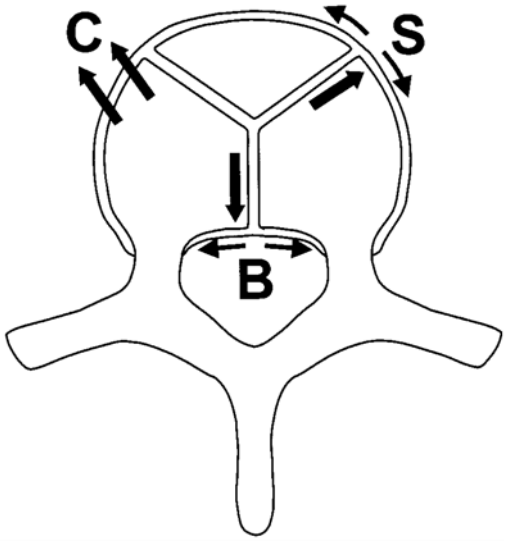


Fig: - The classification of patterns of cement leakage.

Type B: Leakage via the basivertebral vein.

Type S: Leakage via the segmental vein.

Type C: Leakage through a cortical defect.

The percutaneous injection of liquid acrylic bone cement may increase intramedullary pressure, and thereby, marrow contents may be forced into the paravertebral venous circulation (70).

Although there is only one report of infection after vertebroplasty (71), few authors (72) prefer to add antibiotics in immunocompromised patients along with the cement to reduce the

rate of infection as based on surgical reports. One series reported a decrease in infection from 1 % to 0.5 % when tobramycin impregnated. PMMA was used for cranioplasty, vertebral body replacement and spinal fusion (73).

Derarmond et al reports two deaths few days after vertebroplasty related to the preexisting bad systemic condition secondary to cancer and extensive metastasis. They report radiculopathy in 4% of their patients. Only one patient needed surgical decompression after vertebroplasty with preexistent spinal cord compression. Kyung et al 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 (60).

Most pulmonary emboli form PMMA is asymptomatic, clinically significant disease has been reported. 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 (74).

Rebecca et al 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 PVP (75).

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 is uncertain, but mechanisms such as fat embolism associated with increased intramedullary pressure, air embolism and 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. There have been two case reports of an association between the injection of PMMA during percutaneous vertebroplasty and untowards cardiovascular or pulmonary effects: report of the symptomatic pulmonary embolism (80), and a report of transient arterial hypotension (80). Kaufmann et al evaluate the effects of PMMA injection on patient vital sign during PVP and found no generalized association between PMMA injection and systemic cardiovascular derangement (76).

Occupational exposure of medical personnel to PMMA is a potential hazard during vertebroplasty. It is known to be a potential pulmonary toxin. Acute exposure to extremely high level of MMA vapor can causes liver necrosis, pulmonary edema and pulmonary emphysema. Cloft et al measured the level of exposure of medical personnel to methacrylate vapor during percutaneous vertebroplasty and found the level to be less than 5ppm and is well below the published recommended standard of 100 ppm (87).

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Kallmes et al measured the radiation dose to the operator's hands during vertebroplasty when using 1-cc syringes versus that when using an injection 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 injection device (20

procedures). Mean while case dose was 128 ± 161 mrem (range, 0–660 mrem) for the 1-cc syringe group versus 98 ± 90 mrem (range, 0–340 mrem) for the injection device group. Mean dose during injection was 100 ± 145 mrem (range, 0–660 mrem) for the 1-cc syringe group versus 55 ± 43 mrem (range, 0–130 mrem) for the injection device group ($P = .09$). Three of 19 1-cc syringe cases yielded zero dose, compared with four of 20 injection device cases. Duration of injection was markedly different between groups, with mean injection times of 4.2 and 7.5 min for 1-cc syringe and injection device cases, respectively ($P < .00002$). Mean injection dose per minute of lateral fluoroscopy was 23.6 and 7.3 mrem for the 1-cc syringe and injection device groups, respectively ($P<.002$). (88)

Materials and methods

Thirty four consecutive patients underwent PVP for VH between January 2001 and December 2010. Sixteen (47.1%) of these were males and 18 (52.9 %) were females with an age range of 20-60 years (mean 66 ± 9 years). A total 38 vertebroplasties were performed in 34 patients.

Patient selection:

***Inclusion criteria*:-**

All patients affected by VH who were symptomatic and resistant to conservative medical management.

***Exclusion criteria*:-**

1. Asymptomatic / incidentally detected VH
2. Presence of systemic or local infections
3. Patients with uncorrectable coagulation disorder

Clinical Assessment

A general physical, neurological as well as systemic examination was performed before taking up the patient for PVP. The clinical severity of pain was documented in a 10 -point ordinal scale (Visual Analog Scale) pre and post procedure and also 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 score respectively before and after the procedure as well as on folIow up.

***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 opioids

3 = Narcotic drugs

4 = IV narcotic drugs.

The score ranged from a minimum of zero to a maximum of 18. The patients were examined and all the systemic & neurological findings were noted appropriately in the proforma attached.

Pre procedure investigations -

Laboratory investigations:-

- Routine haemogram
- Routine urine examination
- Coagulation profile

Cardiology work- up was done with chest radiograph, ECG, echocardiography and clinical cardiac evaluation.

Imaging:-

1. Anterior and lateral radiographs of the spine.
2. All the patients have been studied with MR examination with and without IV gadolinium chelate in order to correctly depict the aggressiveness of the hemangiomatous lesion, as assessed by
    - Bone involvement
    - Evidence of epidural soft tissue
    - Cord compression.
3. For a proper evaluation of integrity of the posterior vertebral wall and the trabecular microarchitecture, CT was performed (Single slice spiral CT).

Vertebroplasty hardware:

***Needle*:**

Osteosite bone biopsy needle (Cook, Bloomington, USA)

Types:

a. Murphy side bevel M1
b. Murphy diamond bevel M2

Size: 11G and 13 G

Length: 10 cm and 15 cm. (Majority of the times 10 cm needle was used)

In addition, small needles for local anaesthesia, two nos of 10 ml syringes, and 6 nos of 1 ml leuer lock syringes are also required.

Bone cement:

We used DePuy CMW bone cement (DePuy CMW, Johnson & Johnson, Blackpool, UK) in 30 procedures and Simplex P (Stryker-Howmedica-Osteonics, Mahwah, NJ) in 8 procedures.

Constituent of different bone cements:-

DePuy CMW bone cement:-

	CMW1 Original	**CMW1 Radiopaque**	**CMW2**	**CMW3**
Bone cement powder:-				
Polymethyl Methacrylate (%w/w)	97.7	88.8	86.7	88.0
Benzoyl Peroxide (%w/w)	2.3	2.0	2.0	2.0
Barium Sulphate (%w/w)		9.2	11.3	10.0
Bone cement Liquid:-				
Methyl Methacrylate (%w/w)	99. 2	99.2	98.7	97.5
N,N-Dimethyl-p-toluidine (%w/w)	< 0.8	< 0.8	<1.3	<2.5
Hydroquinone (ppm)	25	25	25	25

Two polyethylene bags each containing 2.5gm barium sulphate are included with CMW1 original bone cement.

Simplex P bone cement:-

Ingredients (75% Methylmethacrylate-styrene copolymer for strength; 15% Polymethylmethacrylate (PMMA) for handling; 10% Barium Sulfate for radiopaqueness. Benzoyl Peroxide, formulated in every bead, is crucial for determining the mixing, handling, and setting characteristics of bone cement.

Preparation of the cement:-

PMMA was prepared by adding liquid methylmethacrylate monomer to the powder (per vertebra 8 parts of cement and two parts of Barium). The quantity of liquid monomer was just adequate to blend the mixture in toothpaste like consistency. It was kept on ice to prolong the solidifying time.

Procedure-

We performed all the procedures in the angiographic unit. Twenty-five patients in GE ADVANTEX LCV single plane C arm DSA fluoroscopy system was used in 25 patients and GE INNOVA 3131 biplane system in 9 patients.

Patients were kept fasting for 6 hours before the procedure. Premedication with injection Tramadol 50mg and Phenargan 25 mg was administered just before shifting the patient to the DSA lab.

The patient was kept in a prone position and all the procedures were performed under strict sterile conditions.

One of the pedicle of the involved vertebra was identified with the use of a metallic marker. A 25-gauge needle was used to infiltrate the skin overlying the pedicle, and a 23-gauge

needle was used to infiltrate the periosteum of the posterior lamina. An incision was made in the skin, and a 11/13-gauge needle was placed posterolaterally relative to the eye of the pedicle. Gentle tapping guided the needle through the pedicle into the anterior two thirds of the involved vertebral body. Frontal and lateral images were recorded with the needle in the correct position.

Prepared PMMA was slowly injected into the vertebral body, and satisfactory infiltration of the vertebral body was confirmed radiographically. The amount of cement injected was variable depending on the vertebral level that had to be treated and size of the lesion: larger for dorsal and lumbar bodies and smaller for cervical bodies. The cement introduction was always performed under fluoroscopic guidance with a slow and careful injection of high viscosity material. The filling of the vertebra was aimed to obtain as complete and homogenous as possible without causing intraspinal leakage of bone cement. In case the unipedicular approach did not give the desired or aimed result, the other pedicle was also used (bipedicular approach)

Injection was stopped when substantial resistance was met or when the cement reached the posterior quarter of the vertebral body; injection was also stopped if cement leaked into extra osseous structures or veins. The needle was then removed, and all patients were observed in the supine position for 6 hours after the procedure.

All participants in the vertebroplasty group received an IV antibiotic for five days.

Biopsy was done before injecting the cement during the treatment.

Outcome Evaluation

Pain level was evaluated with a visual analog scale (VAS) of 0–10 performed between 1 and 3 days after the procedure

Frontal and lateral radiography and CT of the spine was performed before discharged. The patients were followed-up at 1, 3, 12 months postoperatively, and then examined once a year. Patients were evaluated by X-ray, CT-scan or MRI immediately, and three years and 5 years after the procedure.

Results

In our study 38 vertebroplasties were performed in 34 patients, 18(53%) were female and 16 (47%) were male.

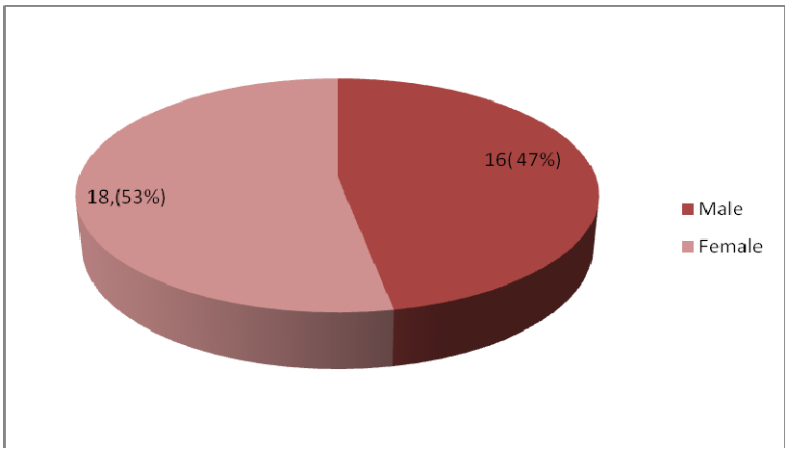

Fig 1- Sex distribution

The mean age was 36.791 ± 16.13 (range: 20–69 years.)

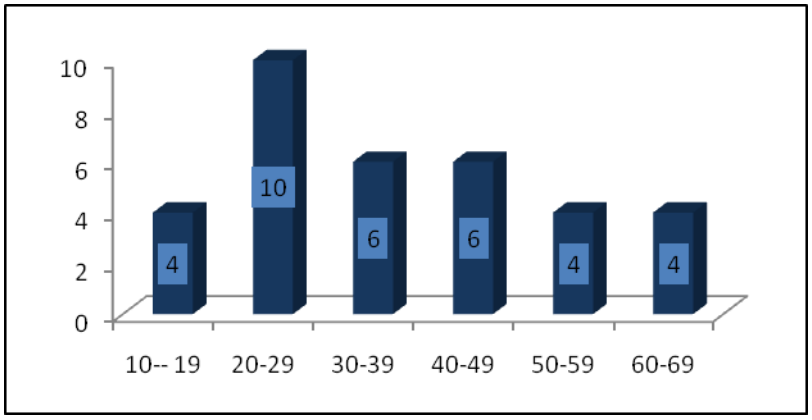

Fig 2 – Age distribution

The treated vertebrae were distributed between T1 and L4 vertebrae, in which the most common treated vertebrae were D12 (21.05%), D6 (10.53%) followed by D5, D8, D10, L1 and L3 (7.89%)

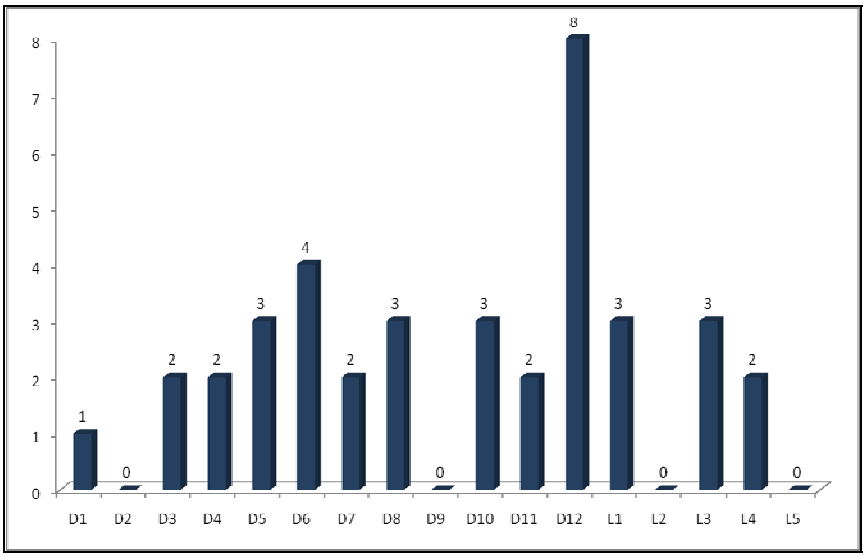

Fig 3:- Distribution of vertebral hemangioma and treatment levels.

Incidence of different symptoms in patient population

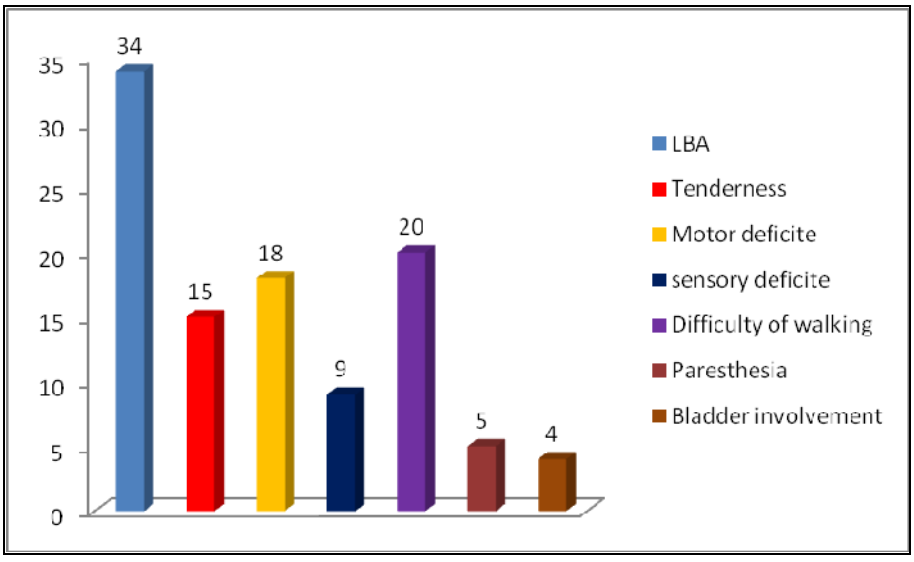

Fig 4: - Different symptoms in patient population

The pain score, activity level, analgesic intake -

	Prevertebroplasty	
	Mean	Standard deviation
Pain	6.26	1.75
Activity score	1.38	1.41
Medication Score	1.15	0.99

Table: - The pain score, activity level, analgesic intake

Mean preoperative VAS score was 6.26 ± 1.75 (SD) and activity score was 1.38. ± 1.41. The analgesic intake was 1.15 ± 0.99

Route:-

Left transpedicular route was used in 47.3 %(n= 18) followed by bipedicular route used in36.8% (n= 14). Right transpedicular route was used 13.1 %(5). Paravertebral route was used only in 1 patient (2.7%) who had recurrent lesion after laminectomy.

Vertebroplasty route	**No of case**	**Percentage**
Right transpedicular	5	13.1
Left transpedicular	18	47.4
Bipedicular	14	36.8
Para vertebral	1	2.7

Table: - Different route used for vertebroplasty

Anesthesia-

Anaesthesia	**No of vertebroplasties**
GA	2
LA	36

Table: - Anesthesia used for vertebroplasty

Correlation between duration of procedure, amount of cement injected and filling of the lesions-

Mean duration of total procedure- 53.7 mts

Mean amount of cement injected in total procedures: 6.24 ml

Mean vertebral filling in total procedures: 84.03 %

Size of needle:

13 G needle was used in 8 procedures mostly in thoracic vertebrae.

11G needle was used in 30 procedures.

Correlation between the sizes of the needle used, amount of cement injected and % of filling and duration of procedure:

	Size of the needle	No of procedures	mean	std. deviation	P value
Duration (min)	11G	30	60.62	13.93	0.6552
	13G	8	58.13	12.67	
% of filling	11G	30	82.08	12.57	0.1965
	13G	8	74.88	16.42	
Cement injected (ml)	11G	30	7.242	3.176	0.5632
	13G	8	6.500	3.024	

Table: - Correlation between the sizes of the needle used, amount of cement injected and % of filling and duration of procedure

No statistically significant correlation between the sizes of the needle used, amount of cement injected and % of filling and duration of procedure.

Correlation between volume of cement injected and % of filling in different level

Level	Mean volume of filling cement injected (ml)	Mean % of filling	p-value
D1-D6	6.617	79.083	0.0001
D7-D12	6.588	79.750	0.0001
L1-L5	6.938	84.750	0.0001

Table: - Correlation between volume of cement injected and % of filling in different level

Overall correlation between volume of cement injected and filling irrespective of levels was significant.

The number of laminectomy, prevertebral embolization and posterior element alcohol injection

	Total no of case	Percentage
Laminectomy	5	13.13
Prevertebral embolization	18	52.94
Alcohol injection	9	26.47

Table: - The number of laminectomy, prevertebral embolization and posterior element alcohol injection

Pre procedure embolization was done in aggressive hemangiomas with posterior element involvement and where the lesions appeared very vascular on cross sectional imaging to reduce the vascularity.

Post PVP alcohol injection was done in posterior elements in patients where hemangioma involved posterior elements.

Laminectomy was done in 5 patients; one of them before the PVP. PVP of this patient was done for recurrence of hemangioma. Of the 4 patients wherein laminectomy followed PVP, three patients were

operated electively after PVP; however 1 patient needed laminectomy immediately after vertebroplasty because of contrast leak in to spinal canal with rapid detoriation of symptoms.

Intraprocedure pain-

In 4 (10.52%) procedures patients complained of intraprocedural pain despite routine premedications. In these patients procedure pain was more than 4. Intraprocedural analgesic was supplemented in these patients.

Incidence of intraprocedure vital changes:-

Intraprocedure vital	**Total no of procedure**	**Precentage**
Trachycardia	2	5.26
Bradycardia	-	-
Respiration	-	-
% of saturation	-	-
ECG changes	-	-
Blood pressure	-	-

Table: - Incidence of intraprocedure vital changes

Only two patients had intraprocedure tachycardia that had no clinical implication.

Post procedure pain medication:-

In 9 patients analgesic were required to be continued for 5-7 days for residual pain. Out of these 1 patient had post procedure pain for which she required intravenous analgesia. All the patients were off analgesia at one month of follow up.

Duration of hospital Stay of the patients:-

The hospital stay of the patients of PVP ranged from 3-12 days (Mean 6.62, SD 2.42)

Complications:-

We encountered 10 (26.3%) patients who had complication after vertebroplasty. One patient deteriorated after vertebroplasty. CT showed mild extension of bone cement posteriorly. Patient was taken for emergency decompression and underwent laminectomy. Rests of the 9 patients were clinically silent and required no surgical intervention.

The incidence of complications:-

Complication	Number	Percentage
Venous filling	2	5.26
Soft tissue extravasations	2	5.26
Epidural leak	4	10.53
Disc space filling	1	2.63
Pulmonary embolism	0	

Table: - The incidence of complications:-

Most of the vertebrae had no visible cement leakage at all. The epidural space was the primary site of cement leakage (10.53 %). Venous filling and paraspinal soft tissue extravasations accounted for 5.26%in each.

Follow up-
Duration – 3months to – 60 months

Immediate post-procedure result.

Clinical Status	No of patients	Percentage
Asymptomatic	15	44.12
Improved	13	38.24
Static	5	14.71
Detoriated	1	2.94

Table: - Immediate post-procedure result.

At immediate post procedure period 15 patients were pain free and asymptomatic, 13 patients showed improvement. Five patients were static. Out of these 5, 2 patients underwent laminectomy and they show improvement. One patient detoriated because of cement leak in to the spinal canal causing compression of spinal cord for which he underwent emergency laminectomy.

The pain score, activity level, analgesic intake

	Prevertebroplasty		**Post vertebroplasty**		
	Mean	**Standard deviation**	**Mean**	**Slandered deviation**	**p-value**
Pain	6.26	1.75	1.59	1.99	0.0001
Activity score	1.38	1.41	0.53	1.23	0.0187
Medication Score	1.15	0.99	0.41	0.56	0.0003

Table: - The pain score, activity level, analgesic intake Immediately after vertebroplasty

Mean preoperative VAS score was 5.91 ± 2.07 (SD), and their mean postoperative VAS scores were 3.5 ± 2.22(SD). Paired-samples t testing of preoperative versus postoperative VAS scores were significantly different ($P<0.001$). The analgesic intake after the procedure was statistically significant ($p < 0.001$).

Follow up result at 3 months

Clinical Status	**No of patients**	**Percentage**
Asymptomatic	26	76.47
Improved	6	17.65
Static	2	5.88
Detoriated	0	0

Table: - Three months post-procedure result

At three months 26 patients were asymptomatic and 6 patients show clear improvement. Two patients had static course.

The pain score, activity level, analgesic intake

	Prevertebroplasty		**Post vertebroplasty**		
	Mean	**Standard deviation**	**Mean**	**Standard deviation**	**p-value**
Pain	6.26	1.75	0.24	0.99	0.0001
Activity score	1.38	1.41	0.26	0.79	0.0002
Medication Score	1.15	0.99	0.06	0.24	0.0001

Table: - The pain score, activity level, analgesic intake three month after vertebroplasty.

There is significant improvement of pain activity, physical activity and medication score at 3 month follow-up.

Follow up result at 12 months

Clinical Status	**No of patients**	**Percentage**
Asymptomatic	30	90.91
Improved	2	6.06
Static	1	3.30
Detoriated	0	

Table: - Twelve months post-procedure result

At 12 months 30 patients were asymptomatic, 6 patients showed improvement, 1 patient had a static course. The patient who had static course underwent embolization of feeders of the residual lesion from the intercostals arteries.

Follow up result at 60 months

Seventeen patients had 60 months follow-up.

Clinical Status	No of patients	Percentage
Asymptomatic	14	87.6
Improved	1	6.2
Static	0	0
Detoriated	1	6.2

Table: - Sixty months post-procedure result

Sixteen patients had 60 months follow up. Out of these, 14 patients were asymptomatic, The patient who underwent embolization of intercostal arterial feeders of the residual lesion at 12 months follow up, show significant improvement at 5years followup. One patient had recurrent symptoms for which underwent laminectomy.

Discussion

Vertebroplasty was first introduced in 1987 by Galimbert and Deramond, French neurosurgeon and radiologist, respectively, as “alternative” treatment for vertebral hemangiomas (1). The technique consists of injection of an acrylic material, polymethylmethacrylate (PMMA), in the pathological vertebral body. Since then, when the great potential of this procedure became evident, its indications were extended to vertebral collapses of osteoporotic or different etiology and to primary and repetitive vertebral neoplasm. Today it has become an essential technical tool with the interventional neuroradiologist for the treatment of vertebral painful syndromes.

Currently, the treatment of vertebral hemangiomas is the less common indication for vertebroplasty due to the low incidence of this disease among the population.

In our study, 16.47% were male and 18.53% were female patients with mean age was 36.791 ± 16.13 (range: 20–69 years). All the patients presented with moderate to severe backache. Local tenderness was present in15 (44.13%) patients. Difficulty in walking was noted in 58.8 % (20) of patients. Sensory deficit and bladder involvement was noted in 26.4 % (9) and 11.7% of patients respectively.

On preprocedure imaging, only vertebral body involvement was seen in 55.8%, posterior elements involved in 44.1%. Epidural component and cord compression in our series was noted in 58.23% of patients.

Bone Cement:-

Currently, percutaneous vertebroplasty is performed with some type of PMMA, such as Simplex P (Stryker-Howmedica- Osteonics, Rutherford, NJ), Osteobond (Zimmer, Warsaw, IN), or Cranioplastic (CMW, Blackpool, England). 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. 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 (8).

We used bone cement from Simplex P (Stryker-Howmedica- Osteonics, Rutherford, NJ) and DePuy (Johnson & Johnson, Blackpool, England). We also used CMWI ORIGINAL, CMWI RADIOPAQUE and CMW2 -types. CMWI RADIOPAQUE and CMW2 do not need extra barium for their radio-opacity. In CMWI ORIGINAL, we usually add 3-4 ml of barium with 10 ml 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 (3). Approximately 30% wt/vol of barium sulfate must be added to PMMA powder to provide sufficient opacification for fluoroscopic monitoring (8).

We never used tungsten and tantalum powder for opacifying the bone cement. Barium usually provides adequate radioopacity 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.

Technique:-

Many authors in detail described the technique of vertebroplasty. Deramond et al described the procedure in 4 steps (33) as follows-

1. Vertebral puncture
2. Spinal biopsy
3. Venography
4. Injection of bone cement.

They prefer anterior- lateral puncture for the cervical level, postero-lateral trans pedicular puncture for the thoracic and lumbar region. Mathis et al prefer biplane fluoroscopy (2) and Gangi et al described the technique of vertebroplasty under combined CT and fluoroscopy (19).

More details technical aspect was described by Mubin et al where they described 10 steps (35):

Step 1: Anatomic orientation

Step 2: Center the pedicle within the vertebral body, cephalocaudal

Step 3: Offsetting the trocar so that the needle tip is not obscured by the hub of the trocar

Step 4: Trocar advancement through the pedicle

Step 5: Check lateral projection

Step 6: Continued trocar advancement through the pedicle

Step 7: Check lateral projection

Step 8: Turn the bevel 180°

Step 9: Check lateral projection

Step 10: Inject cement in the lateral projection with continuous fluoroscopic monitoring

We performed 30 cases in our cases single plane fluoroscopy and rests were in biplane fluoroscopy. Biplane fluoroscopy allows simultaneous imaging of the stylet tip position in two planes, thus decreasing the overall procedure time.

We did not try combined CT and fluoroscopy approach as described by Gangi et aI. However, we did alcohol injection into posterior element in nine cases of aggressive hemangioma under CT -guidance only. Biplane facility reduces the procedure time substantially because of simultaneous orthogonal visualization

Many authors' routine used antibiotics with the bone cement. Mathis et al recommended prophylactic intravenous antibiotic 30 minute before the procedure and also tobramycin along with the cement in immunocompromised patients (2). Jensen et al also prefer adding antibiotics to PMMA only in immunocompromised patients (8)

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.

Route:-

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. (22)

We performed the 37 procedures via transpedicular route and 1 procedure via paravertebral approach. We did 14 (34.8%) procedures via bipediculate approach. We prefer to do unipedicular approach because it is less time consuming and there are less chances of complication. In lateral view it is 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. We do not find any statistically significant difference in the amount of cement injected in unipediculate versus bipediculate procedures.

Kim et al described a modified unipedicular approach with more lateral angulation of the needle. They compared the technique with bipedicular approach. Lesions filling across midline were 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 bipedicular route. Author considers this lateral approach is considerably safe with little risk of neural injury (22).

Needle:-

Ten to 15 G needle frequently used, with the diameter and the length of the needles chosen depends on spinal level involvement (83). The low invasivity is related to the use of an 11- or 13- gauge needle with a length of 10–15 cm through the vertebral pedicle, with no need to perform cutaneous and muscular traumatic incisions, as is done in the surgical approach. This kind of procedure makes it possible to reduce the time of hospitalization and it offers to the patient a faster and less painful postoperative recovery (51)

We did 30 (78.95 %) procedures with 11G needle and 8 (21.05 %) procedures with 13G needle. The mean duration of procedure with these needles were 60.62 minutes and 58.13 minutes respectively. The mean % of filling and mean amount of cement

injected via 11 G & 13G needle were 82.08 %, 74.88 % and 7.24 ml and 6.5 ml respectively. No statistical correlation was noted amongst them.

Complications;-

The main risk of vertebroplasty is related to the possibility of cement leak during the extravertebral intraspinal injection, in the prevertebral and paravertebral venous plexus with risk of spinal cord compression or pulmonary embolism. (53-58). The rate of thromboembolic complications has been reduced considerably by the increased operator skill and the use of denser cements and it is now set on 0.5–1% (59)

In the treatment of the vertebral hemangiomas, this risk is increased due to the presence of an anarchic intravertebral vascularization, proper aggressive lesions, or of the presence of wide high-flow blood ectasias (expansive angiomas) or of the formation of intravertebral and paravertebral venous neo-anastomosis related to the tumor extension (51).

In our series, extravasations of cement as observed in 26.32 % of procedures. In 4 patients epidural leak was seen, three were clinically unapparent and required no decompressive surgery. One patient developed rapid detoriation of clinical symptoms and underwent emergency surgery. Disc space filling and paravertebral soft tissue extravasations were seen in 2.63 % and 5.26 % respectively. Venous extravasation and

filling of adjacent pre and paravertebral veins were seen in 5.26% of procedures each. However no distal embolization was seen.

Cyteveal et al. found disc leakage in 5 (25%) of 20 patients, none of whom had complication (8). In the series by Weill et al slight PMMA leaks towards the disc, epidural fat, perivertebral veins were observed in 20 (38%) of 52 vertebroplasties; leaks were symptomatic in only 5 vertebroplasties (25). These authors suggest that slight PMMA leaks, when not symptomatic, should not be considered as complications. Deramond et al (14) and Cotton et al(3) indicate that leakage in to intravertebral discs and paravertebral soft tissues were frequent and almost always asymptomatic. Wilfred et al concluded that there is no direct relationship between the rate of PMMA leakage and the severity of vertebral body compression (81). Deramond et al recommended placement of the needle in the lateral part of the vertebra to decrease the risk of cement leakage (14).

Factors, which can keep low rate of cement leak, are discussed by Forney et al. (82). Usage of PMMA, which polymerizes rapidly, can reduce extravasation. Liquid consistency of PMMA increases extravasation (83). Insufficient polymerization has been implicated as a major risk factor for pulmonary embolization, which is some series, had been fatal. Second important factor is volume of cement injection. Few authors have correlated complications with excessive PMMA injection where as others found no correlation (84). Kyung et al. 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) (85).

A transient decrease in blood pressure and HR is generally observed during the injection of cement (76). Hypotension has been attributed to vasodilatation as a result of liberation or to myocardial depression, which are supposed consequences of methylmethacrylate toxicity (86).

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 and myeloma and in 90% of patients with osteoporotic compression fracture and hemangioma in different series.

In the series of 24 patients with VH, Boschi et al found marked pain relief in 8 patients within 24 hours. In 10 patients the pain disappeared 5–6 days after operation and at 6 patients after 2 weeks (thoracic spine localization). Following the postoperative period of the next 4–9 years we did not record the pain recurrence in the level of hemangioma. The average extent of pain severity decreased from 8.40 preoperatively to 0.85 one month postoperatively ($P < 0.001$). (52)

In 20 patients of our series, there was no longer any pain corresponding to the haemangioma in the immediate post procedure (within 3 days) period. Thirteen patients had persistent pain with partial improvement. Analgesic was given to all these patients with decreased dose and showed improvement after 1month. Two patients had no improvement of back pain.

Following this, patient had no pain recurrence as recorded at 3 month and 1 year follow up. The average extent of pain severity decreased from 6.26 to 0.24 three months postoperatively ($P < 0.001$)

Sixteen patients have a 5 year follow-up. Of these 16 patients, 14 were asymptomatic. One patient who underwent PVP of D4 haemangioma had involvement of the body and the posterior elements with epidural component. She was asymptomatic at 3 months and 1 year follow up. Three years after procedure she developed backache and underwent ethanol injection in to the lesion at posterior elements. After this she was symptom free. Two year after alcohol embolization she developed ascending weakness of both lower limbs and sensory loss below the nipple bilaterally for two and half months duration which gradually progressed to grade 0 power with urinary and fecal incontinence. She underwent elective LSCS for her first child at this stage. After this she underwent D2-D5 laminectomy and total excision of extradural component. Following surgery, patient had progressive improvement in her paraplegia.

The other patient had hemangioma at D8 vertebra. She underwent embolisation of feeders from intercostals arteries followed by laminectomy and excision of extradural component. She had an uneventful recovery and was ambulant with a brace, on regular follow-up. She developed recurrent symptoms and found to have recurrent hemangioma extending into spinal canal. She underwent D8 vertebroplasty. Post procedure her power gradually improved and she was able to walk without support. On 5 year post vertebroplasty patient had minimal back pain and can walk with support.

Pain regression was accompanied by complete recovery of motor activity and better tolerance of static physical loads in 13cases (72.2 %) in 3 month follow-up and asymptomatic in 1year follow up. Four patients had significant improvement at 3 month follow up.

Thirteen patients (38.2%) continued to take non-steroid anti-inflammatory drugs episodically; 11 cases gave up taking analgesics and 2 patients needed them constantly.

Deramond depicted a successful outcome of vertebroplasty in the treatment of symptomatic and/or with neurological deficit VH in more than 80% of patients, even if the lesions showed aggressive features at imaging studies.(3)

Brunot S. et al. in the short-term and long-term follow-up for the treatment with VP of symptomatic vertebral angiomas found an efficacy of the treatment in 90% of cases and, in the long run, three patients preemptively treated for aggressive VH stayed

asymptomatic. None of the treated patients showed a clinical worsening during the follow-up (61).

In our study, we compared pre and post procedure scores with paired t-test. Mean pre and post procedure pain intensity was 6.24 (SD 1.75) and 1.59(SD 1.99) respectively ($p<.001$). Mean pre and post procedure activity scores were 1.38 (SD 11.41) and 0.53 (SD1.23) respectively ($p < .001$). Mean pre and post procedure analgesic intake scores were 1.15 (SD 0.99) and 0.41 (SD 0. 0.56) 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.

Alcohol injection-

The technique of percutaneous alcohol ablation first was described by Heiss et al (21). They injected 10 mL of alcohol in increments of 2 mL every 10–15 minutes.

In our study, 9 patients were treated with alcohol injection to the lesion via transpedicular route. In all patients hemangioma involved the posterior elements. We injected 3–16 mL of absolute alcohol. All patients showed transient deterioration of neurologic status after alcohol ablation. Subsequently, excellent results were seen with significant symptomatic improvement.

Mayank et al described treatment of fourteen patients with symptomatic VH by injection of absolute alcohol into the lesion via the percutaneous transpedicular route. All patients showed transient deterioration of neurologic status after alcohol ablation. Subsequently, excellent results were seen in 85% patients (62).

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Abbreviation

BP- Blood Pressure

CN- Cranial Nerve

HMF- Higher Mental Function

HR- Heart rate

PMMA- Poly methyl methacrylate

PR- Pulse rate

PVP- Percutaneous vertebroplasty

VAS - Visual analog scale

VCF - vertebral compression fracture

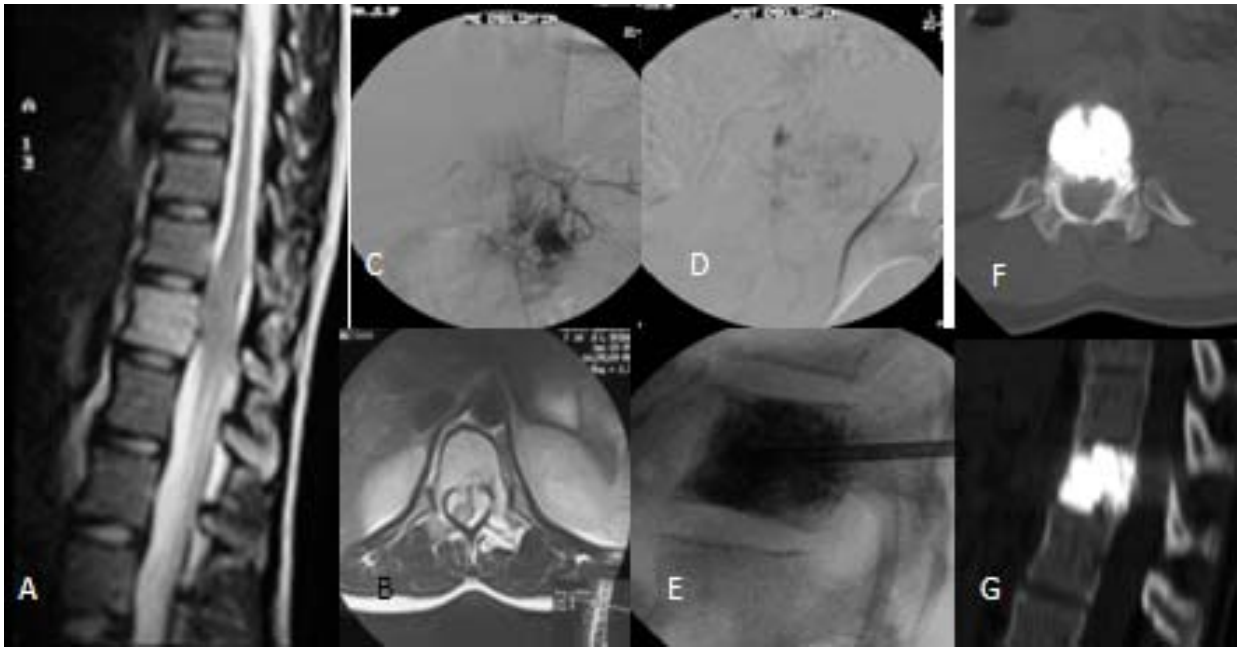
VH - Vertebral hemangioma

Conclusions

PVP represents a therapeutical option available for the neuroradiologist and for the interventional radiologist for the treatment of vertebral angiomas. The accurate and correct selection of the patients is mandatory. In fact, this treatment must be reserved only to vertebral hemangiomas which are symptomatic and resistant to common conservative treatments, with radiological evidences of aggressiveness and/or epidural extension. This way, PVP joins the antalgic effect with the vertebral stabilization reducing the risk of secondary vertebral collapse, without major or minor complications.

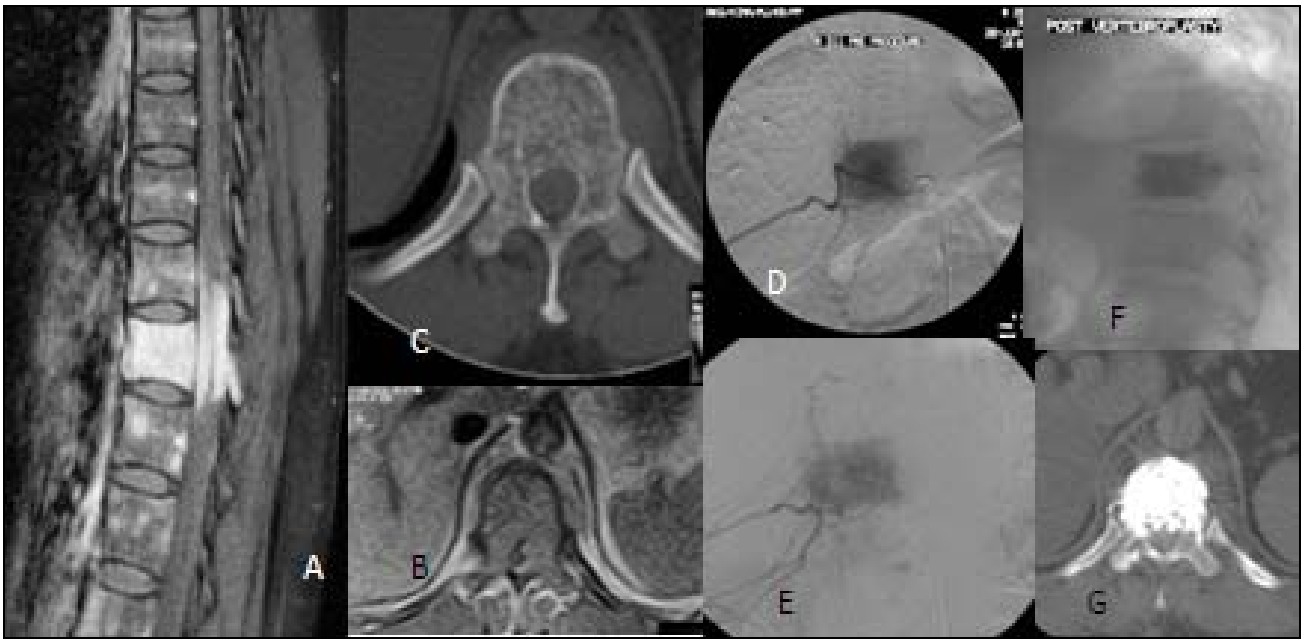
Photographic section

Case 1. This 15 year old girl presented with back pain and difficulty in walking.



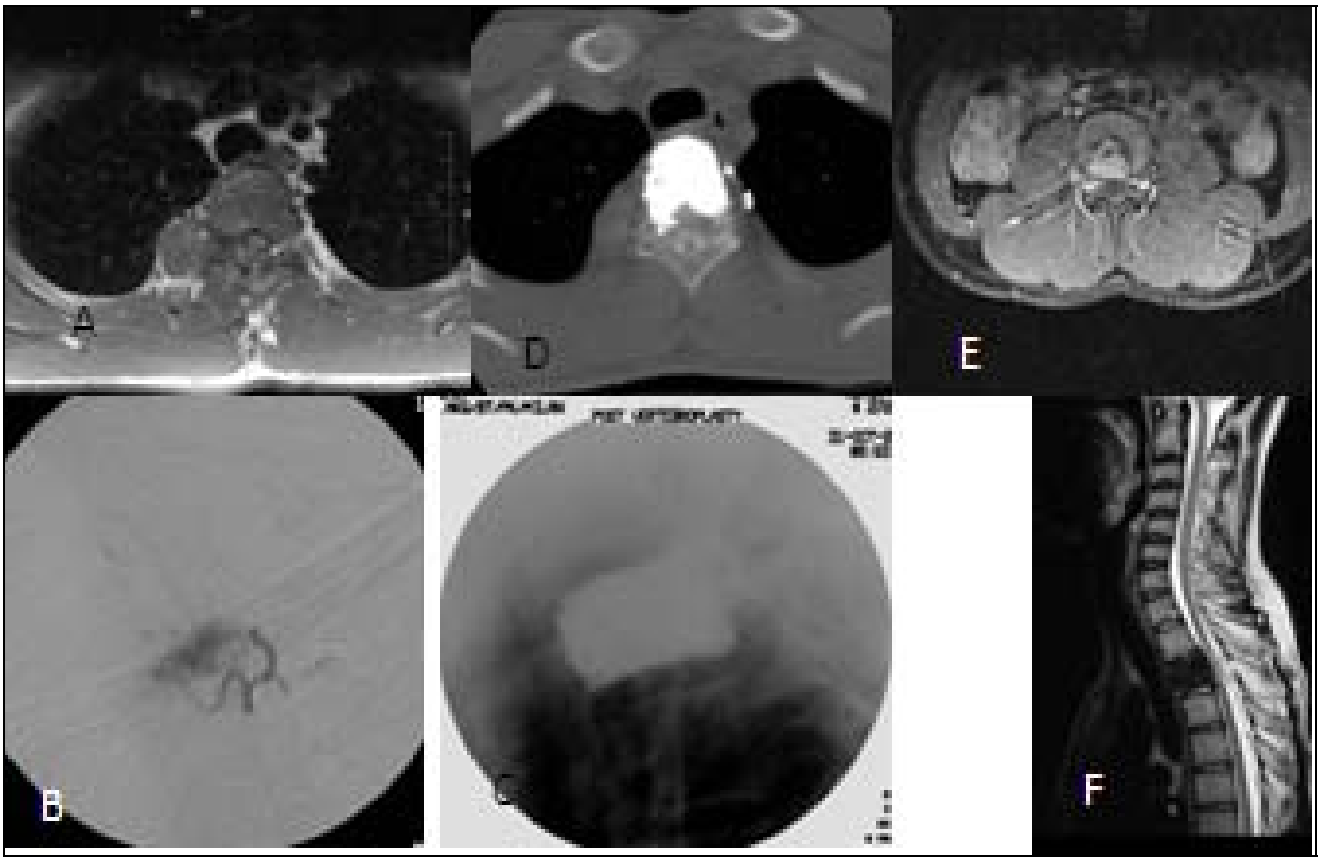
A. MRI T2WI shows a vertebral hemangioma in D 12 vertebral body.
B. Axial T2WI shows D12 VH involving the left pedicle of D12 vertebra with minimal epidural and paraspinal soft tissue component with cord compression
C. Tumor blush in D12 vertebral body fed by branches from left D12, D11 intercostal artery
D. Arterial feeders were embolized with PVA particles with good reduction of the tumor blush
E. Postvertebroplasty image shows good filling of bone cement in the body of D12 vertebra. After vertebroplasty, 10 ml of ethanol was injected to the left pedicle and adjacent soft tissue lesion
F. CT scan 3 days after vertebroplasty shows good filling of bone cement in to the D12 vertebra.
G. One year follow-up MRI shows no residual lesion

Case 2. This 40 year old man presented with back pain since 3 months duration



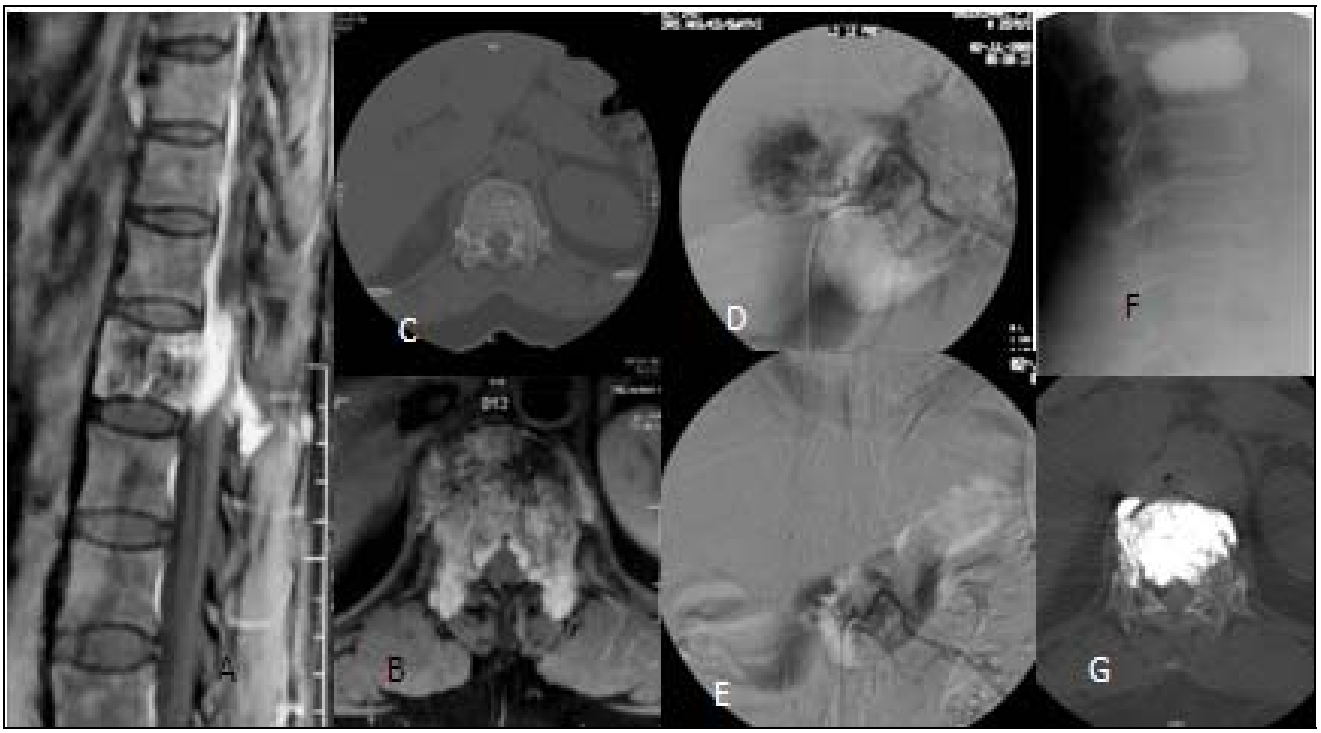
A. MRI T1 postcontrast images show an enhancing vertebral hemangioma in D 11 vertebral body with enhancing softissue component.
B. Axial T12WI shows D11 VH with minimal epidural and paraspinal soft tissue component with cord compression.
C. CT axial section show prominent trabeculation at D11 vertebra. No evidence of cortical break
D. Preprocedure DAS show tumor blush at D11 vertebral body
E. Arterial feeder was embolized with PVA particles with good reduction of the tumor blush
F. Lateral fluoroscopic image show good filling of cement in to D11 vertebra.
G. Post procedure CT scan show homogenous cement filling of the D11 vertebra.

Case 3. 17 year old college student presented back pain with difficulty in walking



A. Axial T1WI MRI show hemangioma in body and posterior element at D3 vertebral with extra and intraspinal extension.
B. DSA image show tumor blush at D3 vertebral body. Feeders were embolized
C. Lateral fluoroscopic image show good filling of cement in to D11 vertebra.
D. Post procedure CT scan show homogenous cement filling of the D11 vertebra.
E. & F. One year follow up MRI showed no residual lesion

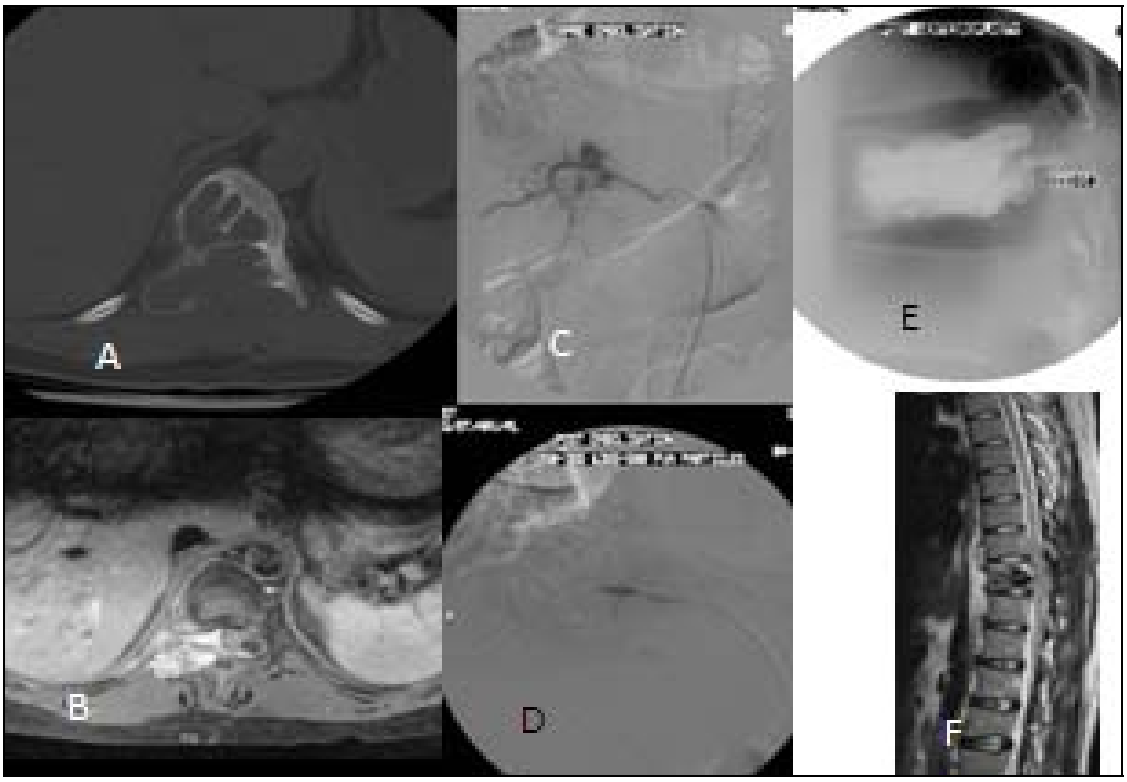
Case 4. This 52 years old lady presented with backache for 4 years duration.



A. MRI T1 postcontrast images show a enhancing vertebral hemangioma in D 12 vertebral body with enhancing epidural component.
B. Axial T12WI shows D12 VH involving the vertebral body and bilateral pedicle with minimal epidural causing cord compression.
C. CT axial section show prominent trabeculation at D11 vertebra. No evidence of cortical break
D. Preprocedure DAS show tumor blush at D12 vertebral body
E. Arterial feeder was embolized with PVA particles with good reduction of the tumor blush
F. Lateral fluoroscopic image show good filling of cement in to D11 vertebra.
G. Post procedure CT scan show homogenous cement filling of the D11 vertebraa.

Case 5.

Case of D10 vertebral hemangioma underwent laminectiomy. Patient complaints of backache for 6 months duration with paresthesias for past 3 months duration.



A. Axial CT scan: Laminectimy defect with lytic lesion in body and pedicle of D10 vertebra.
B. MRI : Residual expansile hemangioma involving body of D10 vertebra with epidural component on right side with cord compression
C. Tumor blush involving the body of D10 vertebra with feeders from right D10 intercostal artery.
D. Arterial feeder was embolized with PVA particles with good reduction of the tumor blush
E. Postvertebroplasty image shows good filling of bone cement in the body of D10 vertebra. Minimal extravasation of the cement into spinal canal noted. (Under CT guidance, 2.5 ml of ethanol was injected to the right pedicule and adjacent soft tissue lesion)
F. One year follow-up MRI shows no residual lesion.