

Guide to Percutaneous Vertebroplasty



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GUIDE TO PERCUTANEOUS VERTEBROPLASTY

NOTICE

This guide is intended solely as an introduction to Percutaneous Vertebroplasty (PV) technical aspects. By no means it has to be considered as a medical publication. PV must be performed by Physicians adequately trained in such procedures.

What is Percutaneous Vertebroplasty?

Percutaneous Vertebroplasty is a procedure intended for the treatment of focal vertebral lesions.

The purpose of this technique is to provide an “internal cast” to the affected vertebral body.

History

First experiences were published in 1987 by Galibert et al⁽¹⁾ for the treatment of aggressive hemangiomas (vascular malformations).

Today, PV is used in the treatment of many other conditions affecting the spine, like benign and malign tumors (Metastasis, Lymphomas, Myelomas) as well as vertebral body compression fractures due to Osteoporosis.⁽²⁻³⁾

In Osteoporosis, main indication for PV is severe pain not responding to conservative treatment.⁽²⁻³⁻⁵⁾

Population

Post-menopausal women are the population under higher risk of suffering fractures due to osteoporosis (life-time risk is 16%). Incidence in men is much lower: 5%.⁽⁶⁾ Patients undergoing immunosuppressive, treatment dialysis and steroids also are under risk of presenting osteoporotic fractures.

Incidence

In the United States, 700,000 osteoporotic vertebral compression fractures occur every year, causing 115,000 hospital admissions/year.⁽⁶⁾

Indications

Patients who underwent different treatment alternatives due to intense pain or show a progression in the collapse of one or more vertebrae or have a vertebral tumor which may cause vertebral instability are cases which may benefit from Percutaneous Vertebroplasty.

Special Features

The most important feature of this procedure is a mayor and persistent pain relief.

Impact on Patients Life

After VP, patients usually have a rapid return to activities of daily life (ADL), speedily becoming more independent from external help. Overall quality of life (QOL) improves significantly.⁽⁶⁻⁷⁾

Impact on Health Care System

As Percutaneous Vertebroplasty can be performed as an Outpatient Procedure(*) under Local Anesthesia and low complexity postoperative cares are usually required, overall cost of VP (compared to former alternatives) is negligible.

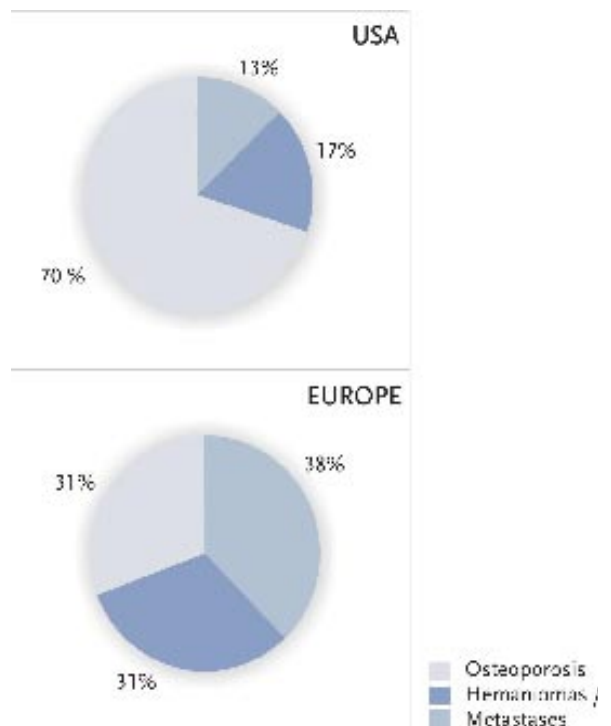
(*) In selected cases a short hospital stay (< 24 hrs) is necessary.

Medical Costs also decrease significantly after VP due to the dramatic reduction of pain (decrease in pain medication and anti depressives intake) also lessening other medical expenses (Rehabilitation, Daycare Institutions, Nursing, Bracings, Wheelchairs, etc)

Percutaneous Vertebroplasty is considered a Minimally Invasive procedure.

COMPARATIVE CHART:

INDICATIONS FOR PERCUTANEOUS VERTEBROPLASTY



Indications
Relative Contraindications
Absolute Contraindications.
Materials
Equipment
Technique
Procedure Images

Indications

1. Painful osteoporotic vertebral compression fracture(s) refractory to medical therapy.
2. Painful vertebral fracture or osteolysis related to benign or malignant tumor, such as hemangioma, myeloma, or metastasis.
3. Osteonecrotic painful vertebral fracture.
4. Unstable compression fracture.
5. Chronic traumatic fractures in normal bone with nonunion of fracture fragments.

Relative Contraindications

1. Radicular pain or radiculopathy, caused by a compressive syndrome unrelated to vertebral body collapse.
2. Retropulsion of fracture fragment causing spinal canal compromise.
3. Tumor extension into the epidural space with spinal canal compromise.
4. Severe vertebral body collapse.
5. Stable fracture without pain, known to be more than 2 years old.

Absolute Contraindications

1. Asymptomatic stable fracture.
2. Patient of collapse improving on medical therapy.
3. Prophylaxis in osteopenic patients with no evidence of acute fracture.
4. Osteomyelitis of target vertebra.
5. Acute traumatic fracture of nonosteoporotic vertebra.
6. Uncorrectable coagulopathy.
7. Allergy to any component required for the procedure.

Materials

Synicem VTP **Vertebroplasty System**

Main features

Synicem VTP Percutaneous Vertebroplasty System was developed to provide a cost – effective alternative to current totally disposable VP systems.

Synicem VTP Percutaneous Vertebroplasty System consists of:

- Reusable Application Gun
- Disposable Application System
- Synicem VP cement.

Synicem VTP Cement

1 poche containing (each) 25 gr of Polymer.
1 ampoule containing (each) 10 ml of Monomer.

Synicem VTP Disposable Application Set

1 Mixing Bowl
1 Mixing Spatula
1 Surgical Hammer
1 Cement Aspiration Cannula.
1 Connecting tube
1 Syringe
1 Vertebral Access Needle

Reusable Application Gun is sold separately.

Equipment

It is highly recommended to perform PV under continuous real time fluoroscopy. Depending on the Surgeons preferences and / or experience a Mobile or Fixed “C” arm can be used.



Fixed “C” Arm



Mobile “C” Arm

Technique

PV must be performed conditions in a adequate environment such as a Operating Suite or Procedure Room under sterile.

Vital parameters (O₂ Saturation, BP, Heart Rate) of the patient must be monitored throughout the procedure.

Despite the low incidence of complications, immediate access to ICU and / or Operating Suite are mandatory.

- Depending on the Surgeons preferences, patient can be placed laterally or ventrally.
- Procedure is performed under Local Anesthesia with / without IV conscious sedation.



Skin antisepsis is performed according to institutional standards



Injection of Local Anesthesia.



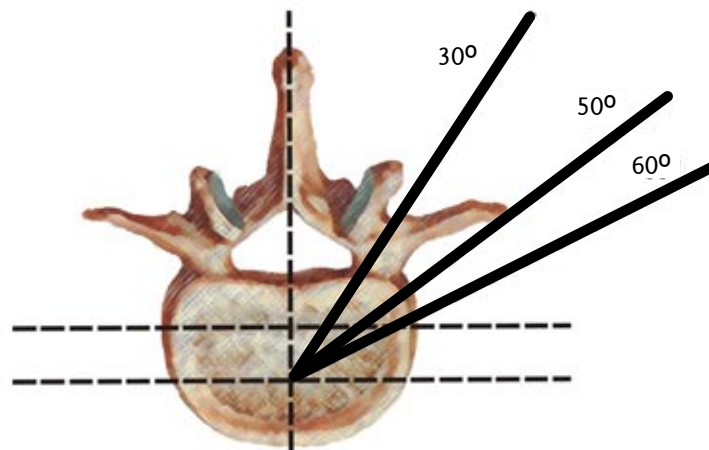
Location of pedicle.



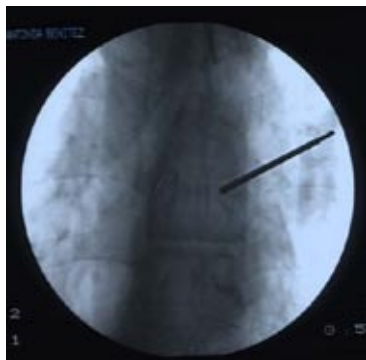
Control of needle placement

Procedure Images

APPROACH ANGLES TO LUMBAR VERTEBRAE



Target:
anterior 1/3 of Vertebral Body



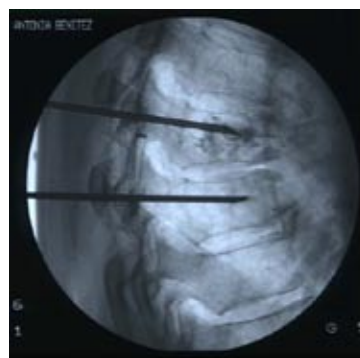
AP View: Search for the Pedicle



Lat View: Transpedicular progress into Vertebra



Ideal Placing of needle (anterior 1/3 of the vertebra)



Bi Vertebral approach. (Vertebrography is performed in the upper)



Lateral control of Vertebral Filling

Post Procedural Care

- After the procedure, patients should be observed for about one hour while resting in supine position.
- Later on, they may sit up or stand, under proper supervision.
- After controlling vital signs and neurological status, patients may be discharged on the day of the procedure.
- Analgesics may be taken as needed. Follow up should be done within 48 hours.

References:

1. **Galibert P, Deramond H, Rosat P, Le Gars D.** Note préliminaire sur le traitement des angiomes vertébraux par vertébroplastie acrylique percutanée. *Neurochirurgie* 1987;33:166-168
2. **Depriester C, Deramond H, Toussaint P, Jhaveri H. S. Galibert P.** Percutaneous vertebroplasty: indications, technique and complications. In: Connors W, ed. *Interventional Neuroradiology Strategies and Practical Techniques*. Philadelphia: Saunders; 1999:246-257.
3. **Gangi A, Kastler BA, Dietmann JL.** Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. *AJNR Am J Neuroradiol* 1994;15:83-86
4. **Cotten A, Dewatre F, Cortet B, et al.** Percutaneous vertebroplasty for osteolytic metastasis and myeloma: effects of the percentage of the lesion filling and the leakage of methyl methacrylate at clinical follow-up. *Radiology* 1996;200:525-530
5. **Cotten A, Boutry N, Cortet B, et al.** Percutaneous vertebroplasty: state of the art. *Radiographics* 1998;18:311-320
6. **Weill A, Chiras J, Simon JM, Rose M, Sola-Martinez T, Enkaoua E.** Spinal metastasis: indications and results of percutaneous injection of acrylic surgical cement. *Radiology* 1996;199:241-247.
7. **McGraw JK, Lippert JA, et al.** Prospective Evaluation of Pain Relief in 100 Patients Undergoing Percutaneous Vertebroplasty: Results and Follow-up. *J Vasc Interv Radiol* 2002 Sep;13(9):883-6
8. Collaborative panel of the American College of Radiology, the American Society of Neuroradiology, the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Spine Radiology. 2000 **Standard for the Performance of Percutaneous Vertebroplasty.**

WARNING:

Some of the above mentioned authors describe the injection of a generic PMMA cement during VP by altering the original manufacturer's formula.

Synimed strongly discourages this practice due to unpredictable quality and behavior of final product.

On July 29 2003, Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom, issued a Warning which reported: "Inappropriate use or modifications of composition leading to serious consequences."

Further information available at: <http://www.mhra.gov.uk>