Percutaneous vertebroplasty set for easier and safer glue injection (RSNA 2001, ECR 2002)

A. GANGI MD, PHD, S. GUTH MD, J.P. IMBERT MD, X. BUY MD, J.L. DIETEMANN MD, C. ROY MD.

Department of Radiology, University Louis Pasteur Strasbourg

Any questions or to submit cases please send us the mail at following addresses

E-mail : Afshin Gangi - E-mail : Stephane Guth

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1) Introduction and principle

Percutaneous Cementoplasty (PC, vertebral packing, vertebroplasty) with acrylic glue (polymethylmethacrylate: PMMA) is a procedure aimed at preventing vertebral body collapse and pain in patients with pathological vertebral bodies. The temperature during polymerization is high enough to produce coagulation of the tumoral cells. Therefore, good pain relief can be obtained with a low volume of glue. Percutaneous cementoplasty ia a promising therapeutic technique for pain control in patients with bone failure.

Fig 1: principle

Principle

The analgesic effect of cement cannot be explained by the consolidation of the pathological bone alone. In fact, good pain relief is obtained after injection of only 2 ml of methyl methacrylate in metastasis. In these cases the consolidation effect is minimal. The methyl methacrylate is cytotoxic due to its chemical and thermal effect during polymerization. The temperature during polymerization is high enough to produce coagulation of the tumoral cells. Therefore, good pain relief can be obtained with a low volume of glue.

2) Indications & Contraindications

Indications

Percutaneous injection of acrylic glue is indicated in cases of :

- Symptomatic vertebral angioma.
- Painful vertebral body tumors (particularly metastasis and myeloma). The best indications are painful vertebral body tumors, when there is a risk of compression fracture.
- Severe painful osteoporosis with loss of height and/or with compression fractures of the vertebral body.

Contraindications

- Hemorrhagic diathesis
- Infection
- Lesions with epidural extension require careful injection to prevent epidural overflow and spinal cord compression by the cement or displaced epidural tissue.

3) Material

Material for vertebroplasty

- Sterile drapes, towels
- 22-gauge needle for anesthesia, scalpel
- Iodine, 1% lidocaine
- Surgical hammer

The optimed (Optimed®) vertebroplasty set

- 10-gauge vertebroplasty bevelled needle (Optimed®) for thoracic and lumbar spine and a 15-gauge needle for cervical spine
- Acrylic glue (methyl methacrylate Howmedica®, Microlok®, Simplex® or Palacos® low viscosity)
- Pressure syringe (Optimed®) to facilitate the injection of this viscous glue
- and 3g tantalum or tungsten (acrylic cement is not sufficiently radio-opaque)

Fig 1a: PC material 10-g needle Cemento®

Fig 1b: PC material Cemento® acrylic glue, pressure gun, 3g tantalum, 10-g needle

Fig 1c: PC material Cemento®, surgical hammer, pressure gun, 10-g needle

Fig 1d: Cement mixture

Fig 1e: cement aspiration cannula

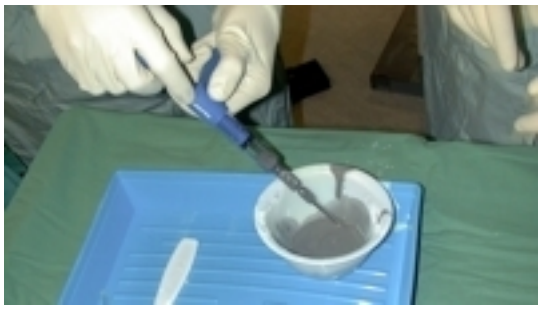


Fig 1f: Cement aspiration directly inside the Cemento® gun

Fig 1g: Cement aspiration inside the Cemento® gun

Material : The Cemento® (Optimed®) vertebroplasty set

The Cemento® set (Optimed®) contains

Needle :

- A 10- or 15-gauge. Special beveled edge needle with large metal wings for an easy insertion / removal and easy rotation of the needle
- Special needle alloy with reduction of artifacts under CT and excellent cement visibility in the cannula
- Highly polished inner cannula for less cement friction, less exertion during injection, and faster and easier injection of the viscous glue
- Shock resistant stylet

Aspiration Cannula :

- Extra large inner diameter for efficient and fast cement aspiration

Cementogun :

- Screw applicator, pressure resistant. Fast pressure buildup with precise speed control of the injection
- Consistent cement delivery
- Quick release lever. Ensures immediate stopping of the injection
- Allows Easy and fast cement aspiration directly in the syringe with the aspiration cannula o Special luer-Lock, extra large caliber for efficient aspiration and injection of the cement

Connecting tube :

- Reduction of radiation for the physician

The PC set Cemento®

1. Cement aspiration cannula
2. Connecting screw
3. Cemento gun
4. Screw applicator, pressure resistant
5. Connecting flexible
6. quick release lever (immediate stopping of the injection), Easy and fast cement aspiration directly in the syringe
7. Needle
8. Head
9. Wings : handy metal wings for an easy insertion / removal and easy rotation of the needle
10. Needle
11. Special beveled edge

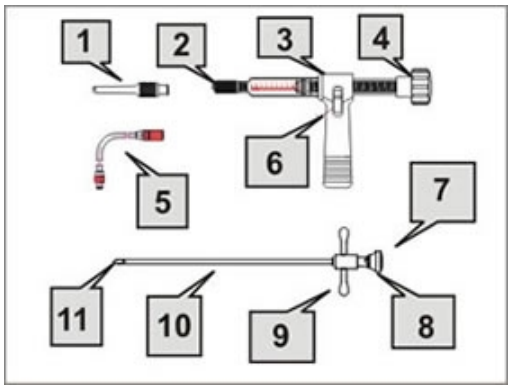


Fig 1g : PC Cemento® set composition

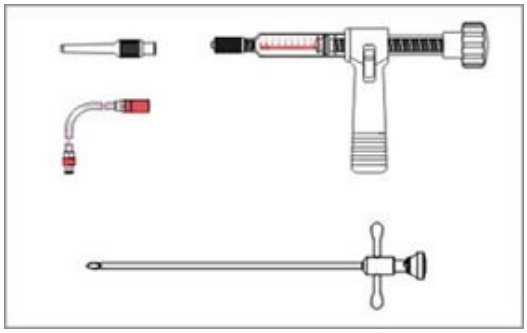


Fig 1f : PC Cemento® set composition

Fig 1h: PC Cemento® set pressure gun

Fig 1i: PC Cemento® set connecting flexible

Fig1j: PC Cemento® set , 10-g needle

Fig 1k: PC Cemento® set , 10-g needle, handy metal wings for an easy insertion / removal and easy rotation of the needle

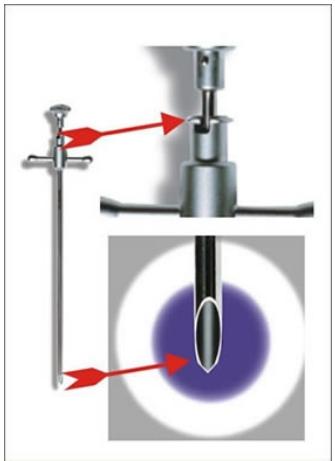


Fig 1l: PC PC Cemento® set , 10-g needle, handy metal wings for an easy insertion / removal and easy rotation of the needle, special beveled edge

Fig 1m: PC Cemento® set pressure gun 1-quick release lever (immediate stopping of the injection) 2- Screw applicator, pressure resistant

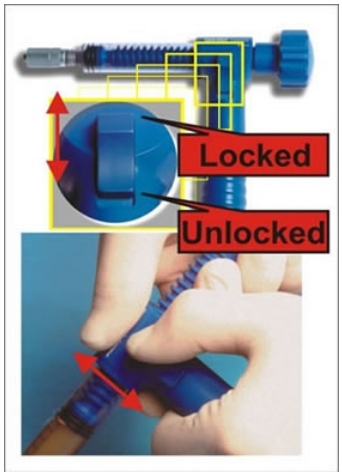


Fig 1o: PC Cemento® set, quick release lever (immediate stopping of the injection), Easy and fast cement aspiration directly in the syringe

Fig 1p: PC Cemento® set 10-g needle, shock resistant stylet

Fig 1q:PC Cemento® set 10-g needle, shock resistant stylet

Fig 1r: Cemento® gun direct aspiration and injection of the cement

Fig 1t: Cemento® gun Screw applicator, pressure resistant, consistent cement delivery, quick release lever , easy and fast cement aspiration directly in the syringe

4) Technique

Technique overview

The procedure is performed under local anesthesia usually combined with neuroleptanalgesia. The patient is placed in the prone position for lumbar and thoracic level and in the supine position for cervical level. A 15-gauge needle is used for cervical vertebral bodies, a 10-gauge needle for thoracic and lombar vertebrae. We always use dual guidance : CT and C-arm fluoroscopy. The entry point and the pathway are determined by CT, avoiding the nerve root and visceral structures.The needle is safely guided under CT.

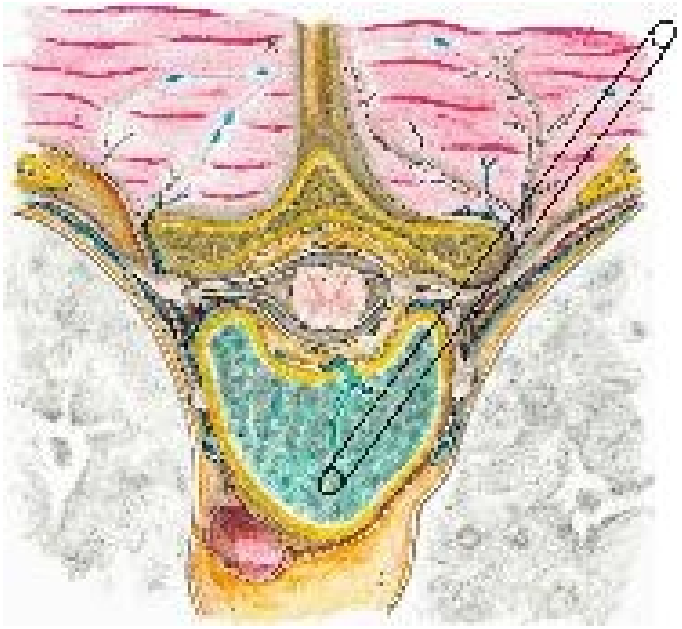


Fig 2 : PC axial plane

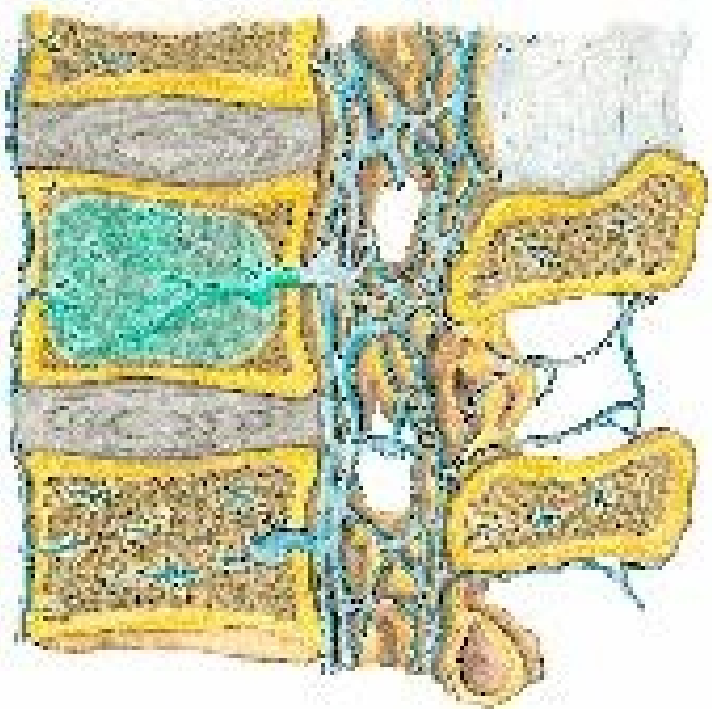


Fig 3: PC sagittal plane

Once the needle is in the optimal position, the imaging mode is switched to fluoroscopy. The acrylic cement mixed with tantalum (to increase radio-opacity) has to be injected

during its pasty polymerization phase to prevent distal venous migration. The injection of glue is carefully controlled under strict lateral fluoroscopy. The injection of glue is stopped whenever an epidural or paravertebral opacification is observed or when the glue reaches the posterior quarter of the vertebral body.

Guidance Focus on dual guidance

Percutaneous cementoplasty, like other interventional procedures, is usually performed with a single imaging technique : fluoroscopy or CT, both of which have advantages and drawbacks. Fluoroscopy offers multiple planes and direct imaging with the disadvantages of poor soft-tissue contrast and non-negligible radiation exposure for both patient and operator. CT is well-suited for precise interventional needle guidance because it provides good visualization of both bone and surrounding soft tissues. It also avoids damage to adjacent vascular, neurological, and visceral structures. The disadvantages of are restriction to the axial plane and delayed imaging.

Fig 6: dual guidance CT and fluoroscopy

Fig 7: dual guidance fluoroscopy and CT

To address these concerns on a routine basis, a combination of CT and fluoroscopy for interventional procedures has been recommended. For fluoroscopy, a mobile C-arm is used, positioned in front of the CT-gantry. By using a rotating fluoroscope and CT, the structure to be punctured can be visualized three dimensionally and with exact differentiation of anatomic structures, which in many cases is not possible with fluoroscopy alone. Two mobile monitors are placed in front of the physician, displaying the last stored image and the fluoroscopic image. The operator can switch from CT to fluoroscopy and vice versa at any time as shown in the dual guidance movie (go to movie page).

Fig 8: CT pathway

Fig 9: CT control

In percutaneous vertebroplasty, the intervention begins with CT and is followed by fluoroscopy. The needle is placed precisely and safely under CT guidance. The injection of the methyl methacrylate requires real-time imaging and is therefore performed under fluoroscopic control as shown in the cement injection movie cases (go to movie page). This combination has many advantages. The possibilities of the simultaneous combination of the two imaging methods are almost unlimited and other applications in interventional radiology are possible .

Local anesthesia

The procedure is performed under local anesthesia usually combined with neuroleptanalgesia. The skin, subcutaneous layers, muscles and the periosteum are infiltrated by local anethesia (1% lidocaine) with a 22-gauge needle, 9 cm long.

Illustration is provided in the local anesthesia movie

Fig 10: Local anesthesia

Puncture

After positioning the patient, under neuroleptanalgesia and local anesthesia, a 10- to 15-gauge trocar needle is introduced into the vertebral body. Different approach routes can be selected : the anterior route for cervical level, the transpedicular and intercostovertebral route for the thoracic level, the transpedicular route for the lumbar level.

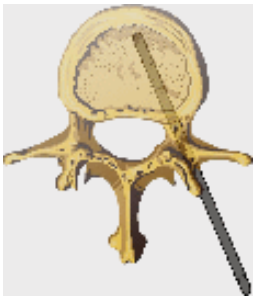


Fig 11: Transpedicular

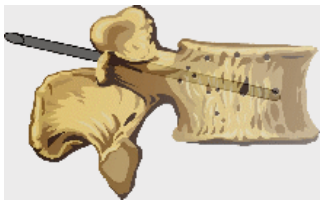


Fig 12: Transpedicular route

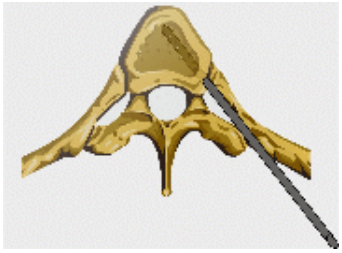


Fig 13: Intercostovertebral route

The needle is guided safely under CT. Precise controlled cortical perforation requires the aid of a surgical hammer. When the needle is in the optimal position (needle tip in the

anterior third of the vertebral body), the imaging mode is switched to fluoroscopy (illustration is provided in the puncture movie cases).

Fig 14: puncture ; surgical hammer

Preparation of the cement

A package of methyl methacrylate (Howmedica®, Microlok®, Palacos or Simplex®) low viscosity is composed of a packet of 20 g powder and a tube of 20 ml fluid monomer. The acrylic glue is prepared by mixing 20 g of powder and 20 ml of fluid monomer.Then half of the glue is discarded and because the cement is not sufficiently radiopaque, 3 g of tantalum is added to the mixture. Illustration is provided in the cement preparation movie cases

Fig 16: PMM powder + monomer

Fig 17: PMM + tantalum powder

Fig 18: End product after mixing

Fig 19: Syringe filling

During the first 30-50 seconds after mixing, the glue is thin but then becomes pasty. The acrylic cement has to be injected during its pasty polymerization phase to prevent distal venous migration. Between two to eight milliliters of acrylic glue are injected using a pressure syringe (Optimed®) to facilitate the injection of this viscous mixture. This stage of the procedure must be performed quickly because the glue begins to thicken after three minutes and any further injections become impossible.

This phase of the procedure is controlled under strict lateral fluoroscopy. The injection of acrylic glue is stopped immediately whenever an epidural or paravertebral opacification is observed in order to prevent spinal cord compression. When vertebral filling is insufficient, a contra-lateral injection is suggested in order to complete the filling. After the vertebral filling, the mandrin of the needle is replaced again under fluoroscopic control before the cement begins to set (because the needle itself contains about 1 ml glue). Then the needle is removed carefully . Six to seven minutes after mixing, the methyl methacrylate begins to harden. During this hardening time, the methyl methacrylate becomes hot (+/- 90 °C). The patient should be under neureuleptanalgesia to control pain. Monitoring of the arterial pressure is necessary during the procedure because methyl methacrylate injections can induce transient hypotension. Total procedure time ranges from 20 to 50 minutes. In patients with osteoporosis and symptomatic hemangioma, an optimal filling (2.5 - 4 ml) of the vertebral body is required to obtain both effects of percutaneous vertebroplasty : consolidation and pain relief. In patients with tumoral pathologies, percutaneous cementoplasty is usually performed for excruciating pain. In these cases, a low volume

(1.5 - 2.5 ml) of acrylic glue provides good pain relief. Illustration is provided in the cement injection movie cases

Fig 20: Injection of the cement

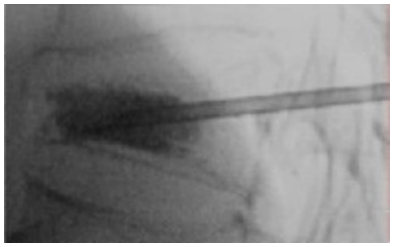


Fig 21: Injection of the cement under fluoroscopy

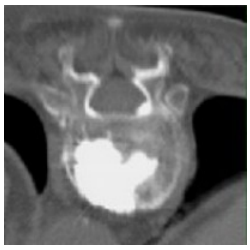


Fig 22: CT control

5) Complications

- The major complications are cement leaks.
- The second complication is infection. To avoid this complication, strict sterility during the intervention is mandatory.
- Temporary pain can be observed after the procedure. The patients are usually free of symptoms after 24 hours. Post-procedural pain is usually proportional to the

volume of glue injected. The majority of these patients had good packing of the vertebral body with more than 4 ml of acrylic glue injected

- The risk of allergic accidents and hypertension is limited in these procedures, because the quantities of acrylic glue injected in percutaneous cementoplasty are far less than those used in orthopedic surgery.

Cement leaks

Cement leaks toward epidural veins, epidural space and neural foramina : the major complication during acrylic glue injection is epidural overflow of methyl methacrylate with spinal cord compression : this risk is minimized by monitoring the bone filling with a high-quality fluoroscopy unit, and by adequate radiopacity (tantalum) of acrylic glue. Radiculopathy is the major risk with neural foramina leaks. In our series, three complications occurred immediately after cementoplasty with the filling of an epidural vein and neural foramina causing intercostal neuralgia. This complication can be successfully treated by a series of intercostal steroid infiltrations. In case of severe complication, orthopedic or neurosurgical support should be available. Epidural vein filling does not systematically cause neuralgia.

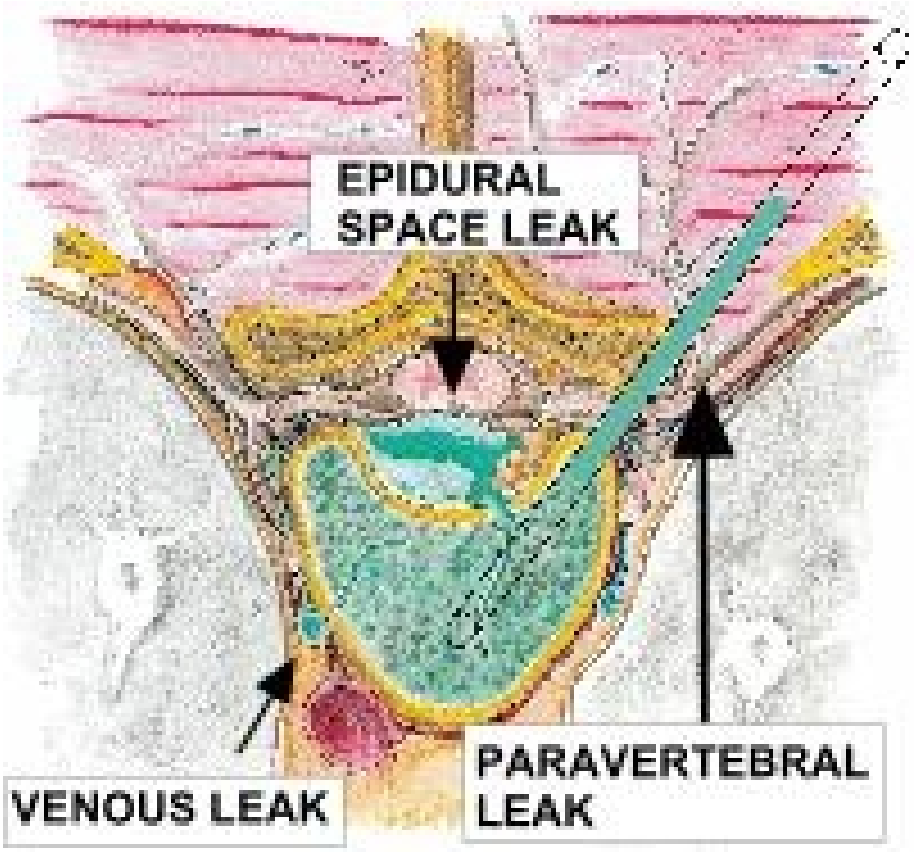


Fig 21: axial plane, leaks

- Cement leaks towards the disk. These leaks are usually without clinical consequence, however these leaks may increase the risk of adjacent vertebrae collapse.
- Leak into perivertebral veins can lead to pulmonary cement embolism. In our series, an asymptomatic pulmonary embolism was detected in two cases. In both cases, paravertebral venous opacification was observed. To avoid major pulmonary infarction, the glue should be injected slowly during its pasty polymerization phase under fluoroscopy control, and the injection should immediately be stopped if a venous leak is observed.
- Cement leaks into paravertebral soft tissues have no clinical significance.
- In one case, the control CT scan showed a leak of acrylic cement into an intercostal artery. This leak was asymptomatic.

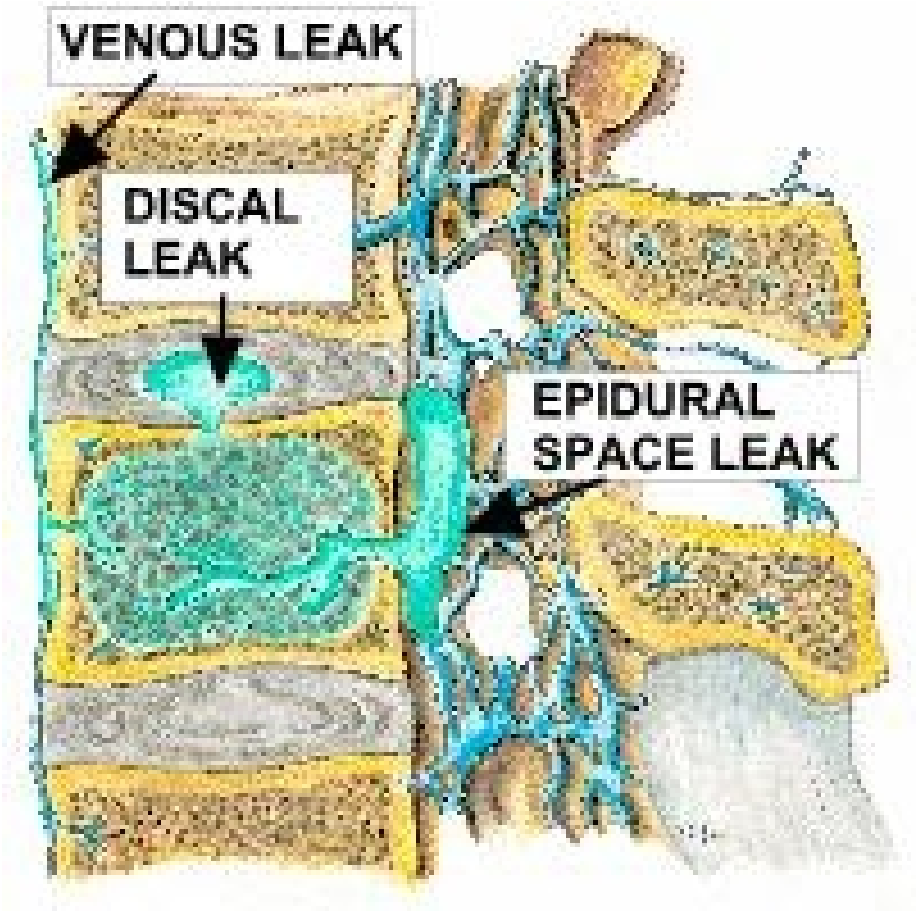


Fig 22: sagittal plane, leaks

Leaks toward the disk

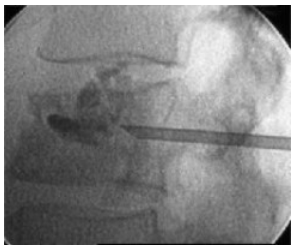


Fig 23: fluoroscopy leak toward the disk

Fig 24: CT leak toward the disk

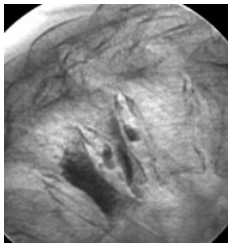


Fig 25: fluoroscopy leak toward the disk

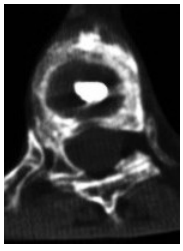


Fig 26: CT leak toward the disk

Venous leak

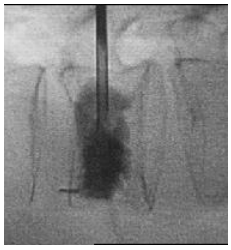


Fig 27: fluoroscopy venous leak

Fig 28: CT venous leak

Pulmonary cement embolism secondary to venous leak

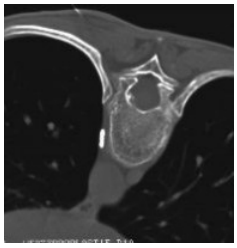


Fig 29: CT venous leak

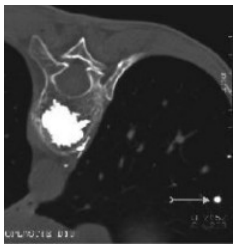


Fig 30: CT pulmonary cement embolism (arrow)

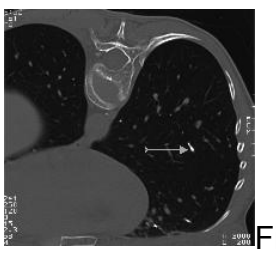


Fig 31: CT pulmonary cement embolism (arrow)

Cement leaks toward epidural space : Cement leaks toward epidural space causing intercostal neuralgia

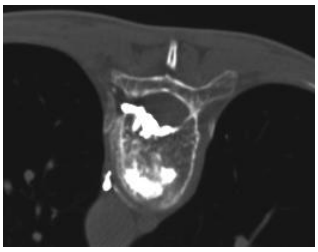


Fig 32: CT anterior epidural space leak

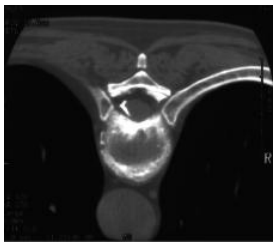


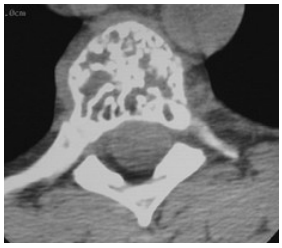
Fig 33: CT epidural space leak

6) Conclusion

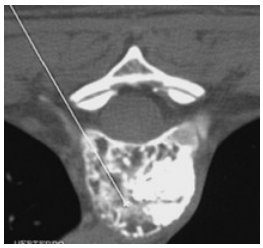
Percutaneous vertebroplasty is safe and effective, and has a useful role in the treatment of painful vertebral compression fractures that do not respond to conventional treatments. Short-term complications, mainly the result of extravasation of cement, include increased pain and damage from heat or pressure to the spinal cord or nerve roots. Proper patient selection and good technique with adapted material is mandatory to minimize complications. Methyl methacrylate is too viscous to be handled without difficulty with normal syringe in the conventional way because injection time is short. With the conventional technique the glue was prepared than 3 to 4 two ml luer lock syringes were filled with the glue. The operator is left with little time and must handle with multiple syringes. To allow the injection with this technique the glue should be very fluid with higher risk of leak. Another disadvantage of this conventional technique is the manipulation of the glue, which increases the risk of infection. We describe a special screw-system syringe (Cemento® Optimed/Germany) that decreases the effort needed to aspirate and to inject the cement with increase of the injection time. In addition, it can standardize the injection pressures and control the injected volume because the screw applicator affords greater control of injection pressure and volume delivered than does the conventional method with reduction of complication particularly leak due to fluid glue.

7) Cases

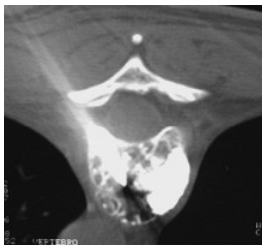
Case 1 : Percutaneous cementoplasty. Intercostovertebral route. Indication: aggressive vertebral angioma. Bilateral approach. No complications.



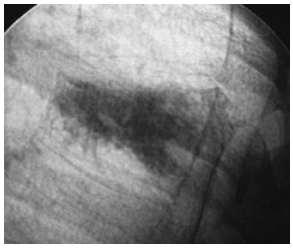
CT : Vertebral angioma



PC : CT pathway



PC : Puncture CT control

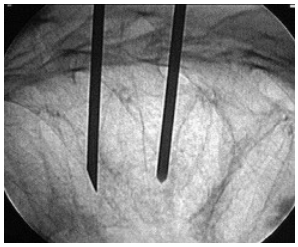


PC : Fluoroscopy control

PC : CT control

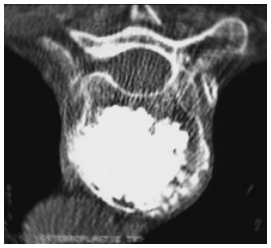
Case 2 : Percutaneous cementoplasty at five levels. Intercostovertebral route. Indication : severe osteoporosis with loss of height and with several compression fractures of vertebral bodies. No complications.

PC : Puncture CT control



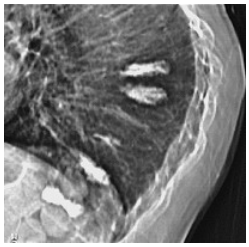
PC : Puncture fluoroscopy control

PC : Cement injection fluoroscopy control



PC : CT control

PC : CT control

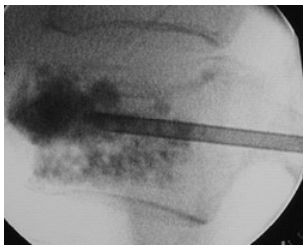


PC : Fluoroscopy control

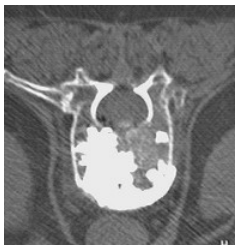
Case 3 : Percutaneous cementoplasty. Intercostovertebral route. Indication : severe osteoporosis. No complications.

Fluoroscopy : severe osteoporosis

PC : vertebral puncture CT control

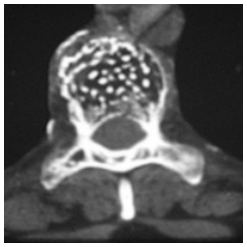


PC : Cement injection fluoroscopy control

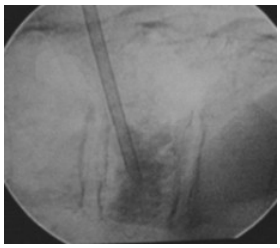


PC : CT control

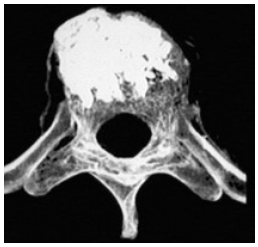
Case 4 : Percutaneous cementoplasty. Transpedicular route. Indication : vertebral angioma.



CT vertebral angioma

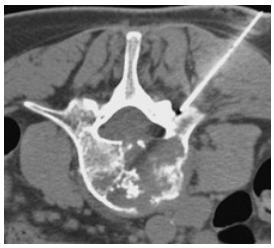


PC: Cement injection fluoroscopy control



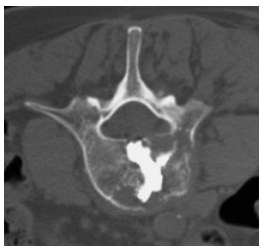
PC : CT 3D reconstruction

Case 5 : Percutaneous cementoplasty : injection of 3.5 ml of glue. Transpedicular route. Indication : painful metastases. Good pain relief, no complications.



PC : Local anesthesia CT control

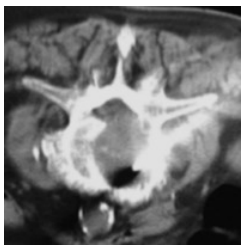
PC : Puncture CT control



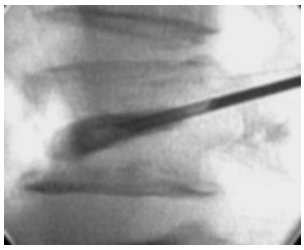
PC : CT control

Case 6 : Vertebroplasty : injection of 2.5 ml of glue. Posterolateral route. Indication : painful metastases. No complications.

CT Osteolytic metastasis

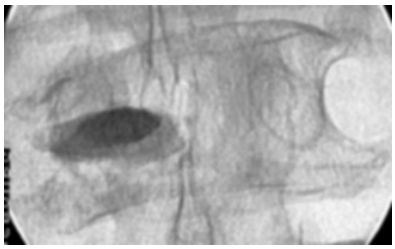


PC : Puncture CT control



PC: Cement injection fluoroscopy control

PC : CT control

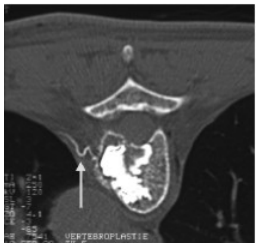


PC: Cement injection fluoroscopy control

Case 7 : Percutaneous cementoplasty. Transpedicular route. Indications : osteolytic hypervascular breast cancer metastasis. Cement leak in the intercostal artery

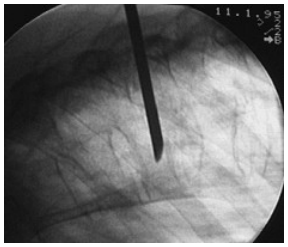
PC : Local anesthesia CT control

PC : Puncture CT control

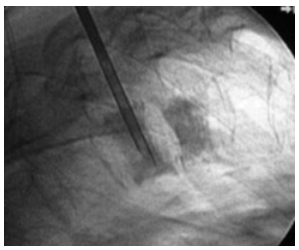


PC : CT control, intercostal artery leak (arrow)

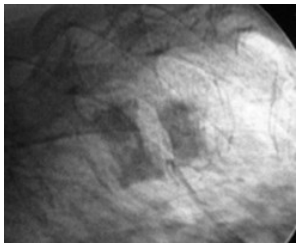
Case 8 : Percutaneous cementoplasty at two levels. Intercostovertebral route. Indication : severe osteoporosis. Minimal veinous leak.



PC : Puncture fluoroscopy control



PC : Cement injection under fluoroscopy

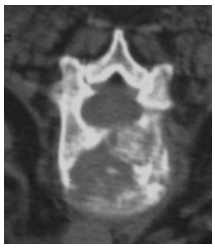


PC : Fluoroscopy control

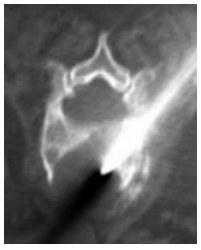
 PC : CT control veinous leak

PC : CT control minimal veinous leak (arrow)

Case 9 : Percutaneous cementoplasty : injection of 3.5 ml of glue. Intercostovertebral route. Indication : painful metastases. Good pain relief, no complications.

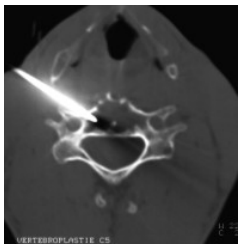


CT osteolytic metastasis

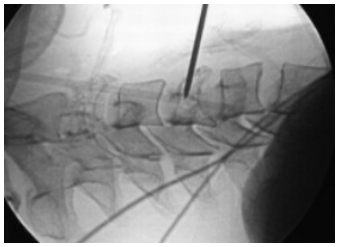

PC : Puncture CT control

PC : CT control

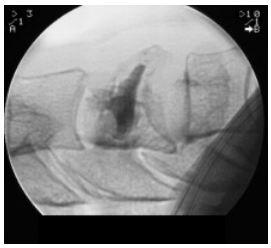
Case 10 : Percutaneous cementoplasty at C4 level, anterior route. Indication : myeloma. Minimal discal leak C3-C4.



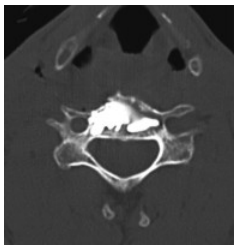
PC : Puncture CT control



PC : Puncture fluoroscopy control

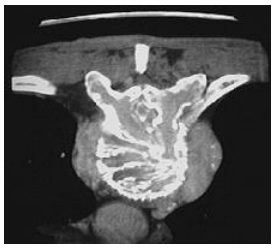


PC : Fluoroscopy control, discal leak

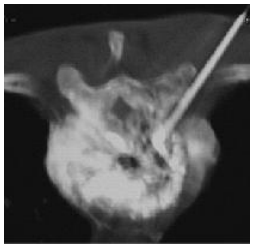


PC : CT control

Case 11 Percutaneous cementoplasty. Indication : aggressive vertebral angioma. Intercostovertebral pathway. First percutaneous vertebroplasty was performed and the surgical intervention was carried out for epidural decompression in a second phase.



CT : aggressive angioma

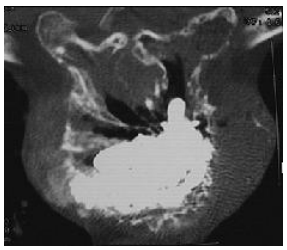


CT : venography

MRI : aggressive angioma with spinal cord compression

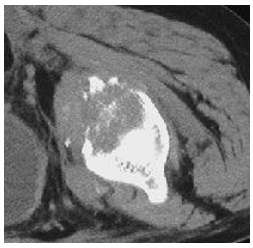
CT : aggressive angioma, puncture

PC : CT control



PC : CT control

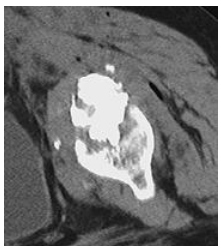
Case 12 : Percutaneous acetabular cementoplasty. Same technique as vertebroplasty. Indication : painful metastases. Good pain relief, no complications.



CT : osteolytic metastasis of acetabulum

Fluoroscopy : osteolytic metastasis of acetabulum

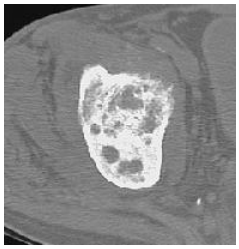
CT : acetabular cementoplasty



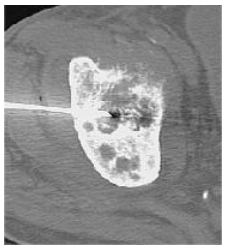
CT control : acetabular cementoplasty

Fluoroscopy : acetabular cementoplasty

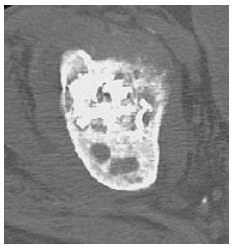
Case 13 : Percutaneous acetabular cementoplasty. Same technique as vertebroplasty. Indication : painful metastases. Good pain relief, no complications.



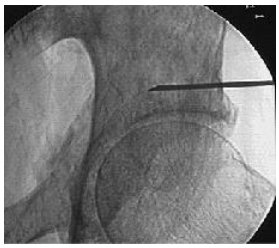
CT : osteolytic acetabular metastasis



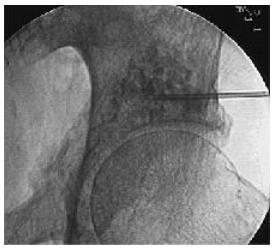
Puncture : CT control



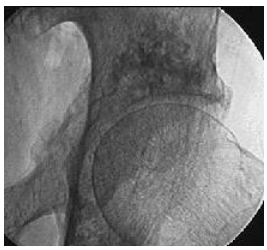
Acetabular cementoplasty : CT control



Puncture : fluoroscopy control



Injection : fluoroscopy control



Acetabular cementoplasty : fluoroscopy control

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