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Percutaneous Kyphoplasty: New Treatment for Painful Vertebral Body Fractures

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Abstract. *Aims and Background: The purpose of this study was to assess the effectiveness and safety of Percutaneous Kyphoplasty as a new method of treatment for pain deriving from vertebral compression fractures (VCF). Patients and Methods: We treated sixteen patients with unremitting pain over spine, which increased particularly when pressure was applied over the spinous process, in absence of neurological signs and refractory to conventional medical therapy. Results: The method demonstrated swift pain relief associated with an evident augmentation in the resistance and restoration of the vertebral body's physiological shape. Polymethylmethacrylate (PMMA) leakages were not observed in the epidural space or foraminal area. The presence of complications such as pulmonary embolism involving the venous plexus, toxicity due to PMMA and infection due the procedure did not occur. Conclusion: Kyphoplasty is an effective, alternative, simple and safe treatment of vertebral collapse consequent to osteoporosis, aggressive haemangiomas, myelomas and metastases.*

Kyphoplasty is a recent treatment for vertebral compression fractures (VCF), first employed by M. A. Reiley in 1997 that, through the swelling of an inflatable bone tamp (IBT) into the collapsed vertebral body, elevates the endplates, thereby restoring the vertebral body height and creating a void to be filled with cement. Kyphoplasty can be performed in the thoracic portion from T5 to T12 and in all lumbar levels (1, 2). The importance of early diagnosis is shown from the increased probability of a favourable prognosis if this procedure is executed within three months from the occurrence of the fracture (3). Although the mechanism of polymethylmethacrylate (PMMA) analgesic effect remains unknown, the key element may be the stabilization of microfractural fragments. In addition to this thermal and chemical mechanisms have been proposed.

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Patients and Methods

Indications. Kyphoplasty is a technique increasingly utilized in the field of VCF based on primary and secondary osteoporosis (approximately 20% of women and more than 50% of men with osteoporosis have a secondary cause of bone loss) (4). Further, it is extremely useful in the treatment of aggressive vertebral hemangiomas and in the bone osteolytic metastases that complicate 30% of the underlying primitive neoplasies.

Additionally, kyphoplasty is indicated in the treatment of destructive multiple myeloma that is associated with VCF in 55-70% of the cases.

Contraindications. The contraindications of kyphoplasty are divided into absolute and relative. The former consist of fractures with retropulsion of the fragments within neural foramen, local infection (osteomyelitis, discitis or epidural abscess), coagulative disorders, pain not related to vertebral collapse, steady asymptomatic fractures, effective medical therapy and pregnancy. The latter are due to the inability of the patient to stay in the prone position during the procedure, the severe compression of the vertebral body, the missing integrity of pedicles or joint facets, the spread of tumor within the epidural space and, finally, an allergy connected to the medium contrast agents (5-7).

Technique. All the patients were subjected to a thorough clinical examination in order to determine the symptomatic vertebral level, which is revealed by acute pain and tenderness over the spine at or near the level of radiographic compression deformity (4).

Radiographic examinations (Figure 1) and CT were preliminarily performed to evaluate the location, severity and the extension of the collapsed vertebra, as well as to ascertain the visibility of the vertebral pedicles and the integrity of the posterior wall . Magnetic resonance is fundamental in the pre-treatment diagnosis and in the follow-up to evaluate the success of the procedure; the presence of intraspongious edema, particularly in fat suppression sequences, testifies to a recent fracture.

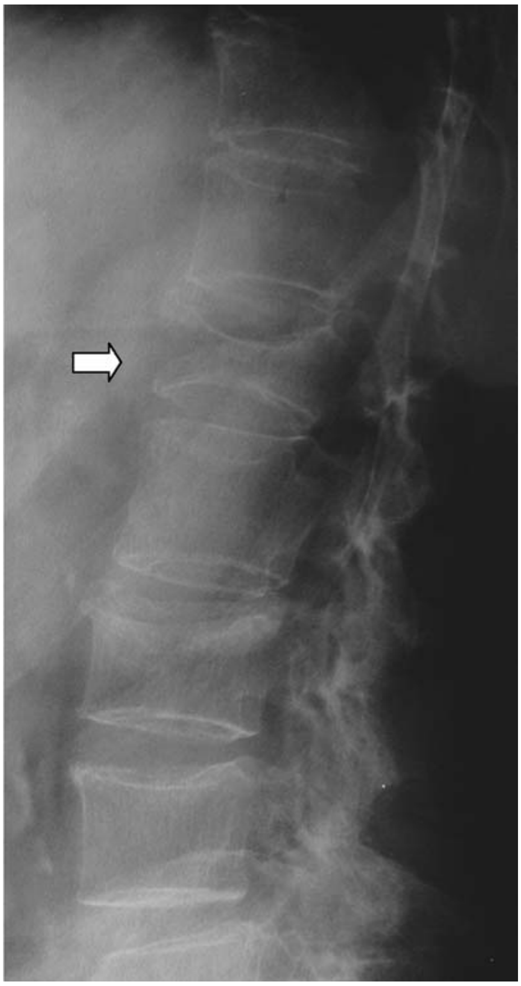

Figure1. *Preoperative radiograph, lateral view, vertebral collapse on L1 level.*

Written informed consent was obtained from the patients. Given the suffering connected to the inflation of the tamp, the procedure is carried out under general anaesthesia (1).

The patient is placed in prone position on the angiographic table; to obtain the maximum extension of the spine, two rolls of soft material are inserted transversally, respectively under the chest and the pelvis (1-5). After confining the vertebra and its corresponding pedicles to be treated with the radiologic tube in antero-posterior projection, a small cutaneous incision is made in the dorsal or lumbar area. Then a bone biopsy needle of 11/13 gauge is introduced through the posterior portion of the pedicles, sloping anteriorly, medially and caudally (1-5) (Figure 2A 1,2,3).

The access to the vertebral body is normally transpedicular, however eventually one can opt for an inter-costo-vertebral entrance into the thoracic levels or posterolateral for lumbar levels (8). To achieve a better restoration of vertebral body morphology, we prefer to treat levels bilaterally. Once the exact position of the needle has been verified, a Kirshner wire is introduced coaxially. The biopsy device is then extracted and replaced by a working cannula (outer diameter (OD) 4.2 mm; inner diameter (ID) 3.6 mm) with the edge positioned 3mm beyond the posterior wall. For the successive passage of the IBT an intravertebral bone channel is created a few millimetres from the anterior cortex margin using a drill tip (3.3 mm in diameter).

Under fluoroscopic guidance in lateral projection the IBT is pushed forward carefully and placed, checking with the auxilium of two radiopaque markers, the exact positioning of the balloon, in the anterior 2/3 of the vertebra. The IBT can have a length of 15 or 20 mm with a maximum volume respectively of 4 and 6 ml. The tamps in the two hemivertebrae are stretched simultaneously with a mixture of contrast medium to 60% (9). Through circumferential impaction of the cancellous bone at the periphery, additional support is provided to the cortical shell and a void is created internally. The inflation is stopped when one of the following conditions occur: a reduction of the fracture, achievement of maximum pressure (20 atm), complete dilatation of the balloon or, lastly, if the tamp abuts the cortical somatic surface (1-9) (Figure 2B 1,2,3).

Meanwhile the cement is prepared by combining liquid monomer and powder cement polymer; everything is amalgamated until it forms into a paste with high viscosity. The PMMA is charged into dedicated cannulas (OD 3.4 mm; 1.5 ml) and moved forward through the working cannula until the correspondence of the third anterior of the void. Immediately after the acrylic cement is pushed with low pressure utilizing a blunt plunger stylet under continuous fluoroscopic guidance. The filling volume is usually 1-2 ml greater than that which is obtained with the balloon, which allows the cement to distribute itself effectively inside the cancellous bone (10) (Figure 2C 1,2,3). To complete the procedure all cannulas are extracted, the cutaneous incisions are sutured and the patient is instructed to remain in bed for the next four hours (10) (Figure 2D 1,2,3).

The most commonly encountered complication is localized pain and tenderness at the needle sites in the first 72 hours after the procedure, usually caused by local bruising or hematoma, which can be resolved with mild analgesics (4). The length of the process for each vertebra is around 35-45 minutes. A traditional radiographic and CT inspection is performed after the procedure to evaluate the results obtained (Figure 3). The release is generally the following day.

Results

From January to July 2003, we treated 16 patients (F=9, M=7; ages ranged from 63 to 82 years, mean age 72.3) with vertebral collapse. Respectively 12 (F=8, M=4) had fractures consequent to osteoporosis and 4 (F=1, M=3) due to primary and metastatic osteolityc neoplasms (3 myelomas and 1 lung metastasis). All patients underwent a single level treatment (Dorsal 8 number of patients 2, D11 n= 1, D12 n=3, Lumbar 1 n=1, L2 n=5, L3 n= 3 L4 n=1).

The procedure was successfully performed on our patients, whose improvements were swift and persistent in reducing all symptoms, decreasing from an average of 8.2 points of VAS to 2.4 (VAS of Huskisson = Visual analog scale, pain score with points assigned subjectively from patient pre- and post-procedure in a range between 0 absence of grief and 10 maximum pain). Resistance was considerably increased and normal vertebral body morphology was restored. A reduction of the kyphosis angle

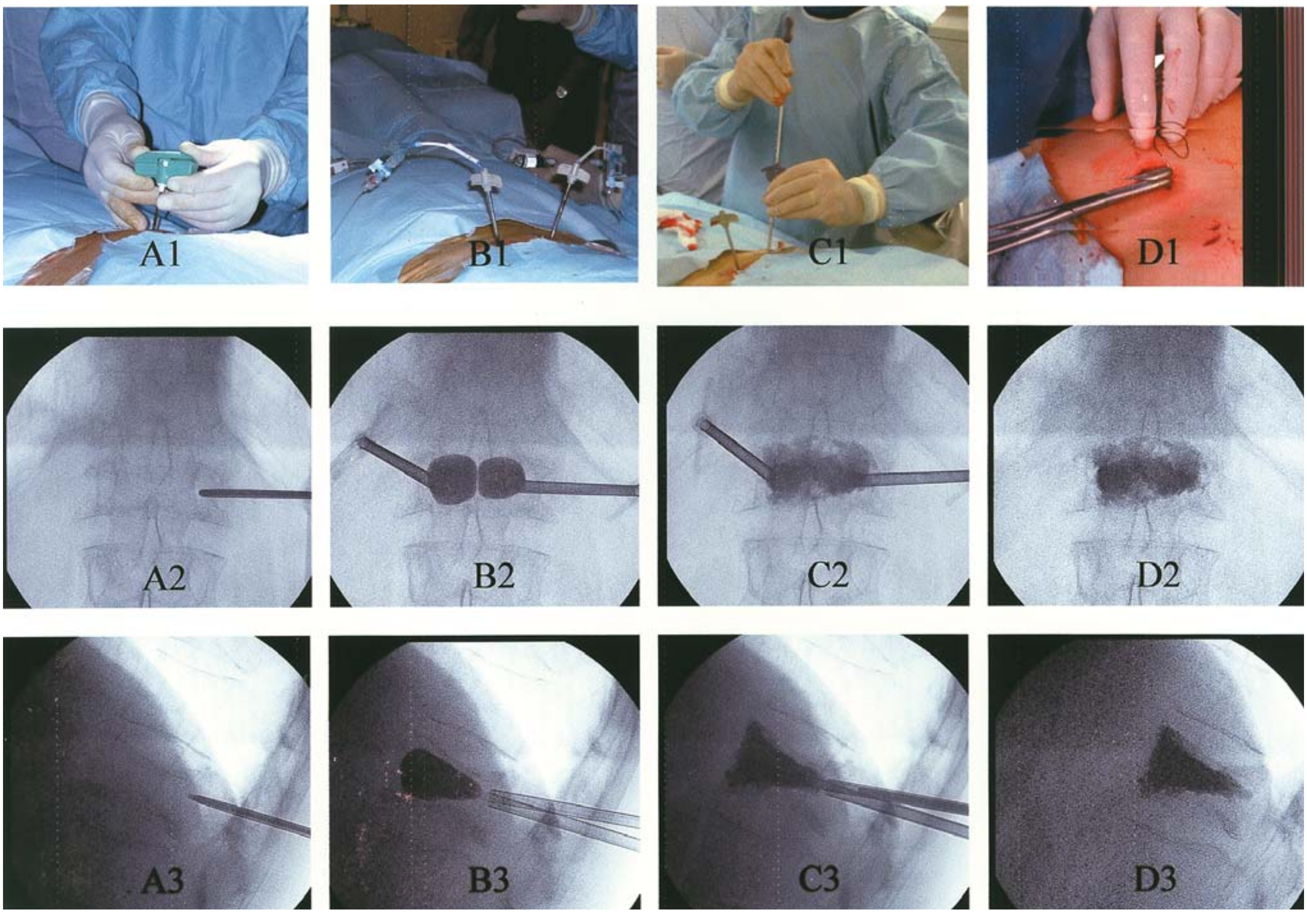

Figure 2. *Kyphoplasty treatment performed at L1 level. Sequential intraoperative and fluoroscopic images: A) 11 G needle placed with transpedicular approach; B) inflation of the balloon catheters; C) filling of the performed cavity with PMMA; D) post-procedure control.*

was noted both clinically and radiologically with a positive effect on the lumbar compensatory hyperlordosis (5) (Figure 4). We did not find any conditions where there were extravasations of PMMA in the epidural or foraminal sites with marrow or radicular compression (11-17).

Discussion

Percutaneous injection of PMMA bone cement into the vertebral body, described for the first time by Galibert *et al.* in 1984 (18) as " Vertebroplasty ", and succesfully applied to the treatment of C2 aggressive hemangiomas, is also used on VCF secondary to osteolytic tumors and osteoporosis.

The vertebral fractures are generated when the combination of the axial and rotational charges on the spine exceed the resistance offered by the vertebral body (12). The VCF is defined as a reduction in height, which must be at least 20% beyond its initial dimensions. In relation to its severity, it is distinguished as mild 20-25%, moderate 25-40%, or severe>40% (2). The most frequent locations are the third inferior of the thorax and the superior lumbar levels, correlated to different kinetics of the two segments, and followed by the thoracic third medium and inferior lumbar. The cervical vertebrae and the third superior of thorax are rarely involved (19,20). Primary osteoporosis is responsible for about 85% of VCF, while secondary osteoporosis and neoplasty determine the remaining 15% (1). The presence of a vertebral fracture puts the individual in the following years at a 5 times greater risk of having a second VCF, which in almost 20% of the cases occurs within a one-year period (21-23).

Acute complications of VCF include urinary retention, transient ileus and eventually a painful symptomatology; the long-term complications, in more than a third of these patients, are chronic pain, depression, insomnia, low quality of life and finally a progressive kyphosis of the spine. The sagittal deformity of the spine is without a doubt one of the most grave consequences of VCF. It is associated with a loss of height and

Figure 3. *Postoperative radiograph, lateral view, vertebral collapse on L1 level.*

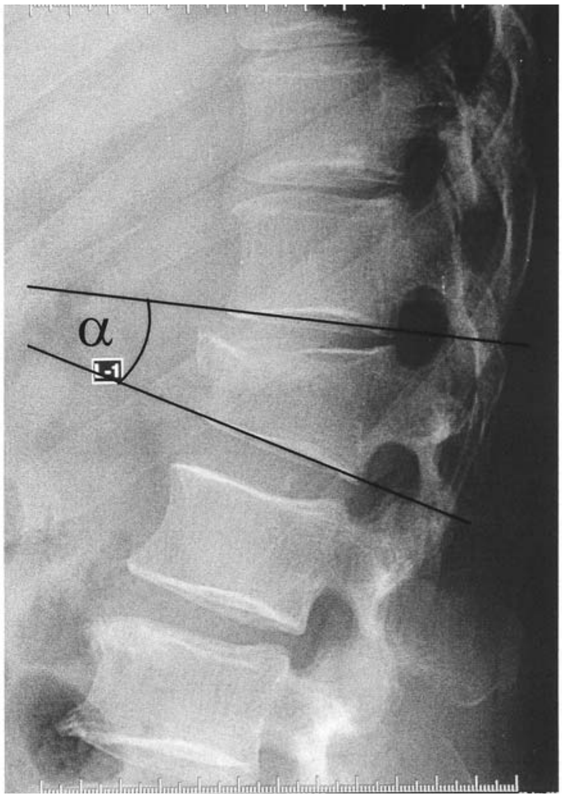

Figure 4. *Local Kyphosis angle (assessed on the lateral radiograph by measuring the angle obtained by a line parallel to the inferior endplate of the fractured vertebra and that of the vertebra one level above)*

a reduction of volumes in the thoracic and abdominal cavities. In consequence to this it generates pulmonary compression, with a reduction of vital capacity (VC) to 9% for each level fractured and of "forced expiratory volume to 1 second" (FEV1), as well as gastrointestinal dysfunction. Moreover, there is a major risk of death compared to the age-matched controls (adjusted mortality risk 1.6) (1,16,21,24,25).

Percutaneous kyphoplasty is similar to vertebroplasty in that it involves the introduction of bone cement into the vertebral body but also attempts to restore the vertebral body height (97% *vs.* 30%) (23), to minimize spinal deformity (reduction angle of kyphosis) and its clinical sequelae.

Vertebroplasty's reported rates of complications are 1.3% in osteoporosis, 2.5% in spinal angiomas and 10% in metastatic disease (26). Because it is necessary for the injection of PMMA in the cancellous bone to have a high pressure and a low viscosity for filling, there is an elevated confirmation of cement extravasations. They are present in 65% of the treatments of VCF due to metastases in multiple areas, in 30-60% of the fractures from myeloma and in 30% of osteoporotic fractures mainly in the intervertebral space (10,27,28). Pulmonary embolism and spinal compressions can derive from the extrusion of cement, although they are rare potential complications.

The reduction/injection procedure of kyphoplasty decreases the risk of leakage of cement thanks to the contained effect of the void created from the tamp in the vertebral body (29). In the cavity the injection of PMMA is performed at low pressure and with a highly viscous cement. Moreover, the quantitative composition of volume to be injected is preventively determined evaluating that which is utilized by the contrast agent during the inflation of the tamp (22).

In our experience, kyphoplasty has demonstrated itself to be an effective method, both simple and safe, for the treatment of vertebral compression fractures. The combination of the balloon and the cement provides a precocious and long lasting pain relief, associated with an evident increase in the resistance and restoration of the normal shape of the vertebral body.

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