Vertebroplasty and kyphoplasty

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Summary

Vertebral fractures are a major health care problem in Western countries. Pain and deformity are the major problems related to these fractures, with an enormous impact on the quality of life. Surgery is indicated in patients with concurrent spinal instability or neurologic deficit. The cornerstone of management for vertebral body fractures without neurological impairment is medical therapy, which include analgesics, bed rest, orthoses and rehabilitation. In the majority of patients such treatment modalities are effective. However, conservative management measures are not indicated for every type of fracture. Two different percutaneous minimally invasive vertebral augmentation methods for cement application into the vertebral body in the management of symptomatic fractures without neurological impairment have been developed, namely vertebroplasty and kyphoplasty. Aim of this paper is to give an overview of the state of the art about vertebroplasty and kyphoplasty, discussing the indications, techniques, results and pitfalls.

KEY WORDS: vertebral fractures, minimally invasive, spine, surgery, vertebroplasty, kyphoplasty.

Introduction

Vertebral fractures are a major health care problem in western countries. They are a common cause of severe debilitating pain, with consequent deteriorated quality of life, physical function and psychosocial performance (1, 2).
Osteoporotic vertebral fractures are the most common complication of osteoporosis, accounting for about 50% of the osteoporotic fractures. Pain and deformity are the major problems related to these fractures, with an enormous impact on the quality of life (3, 4). A critical evaluation of the patient and the systematic use of computed tomography with sagittal and coronal reconstructions are necessary to avoid pitfalls in the diagnosis and successive management of patients with vertebral fracture (5-8).
Surgery is indicated in patients with vertebral fracture, and concurrent spinal instability or neurologic deficit (1, 2). The cornerstone of management for vertebral fractures without neurological impairment is medical therapy, which include analgesics, bed rest, orthoses and rehabilitation. External immobilization (bracing or casting) remains the most important non-operative management for vertebral fracture, and most patients will heal with non-operative management in brace. In the majority of patients such treatment modalities are effective. However, conservative management measures are not indicated for every type of fracture. For example, in older patients with vertebral fractures and cardio-respiratory disease it is not possible to prescribe bedrest for long period and sometimes it is not possible to apply bracing or casting. Respiratory function may be significantly impaired in older patients. Thoracic vertebral fractures may cause further loss of respiratory function in these patients, and bed rest and orthoses may not be the best treatment option. Moreover, sometimes anti-inflammatory drugs are poorly tolerated by older patients, and bed rest can lead to further demineralization of the vertebrae, predisposing to future fractures (1, 2).
Percutaneous minimally invasive vertebral augmentation methods for cement application into the vertebral body are a useful tool for the management of symptomatic fractures without neurological impairment when conventional measures of treatment can not be adopted.
Two different percutaneous minimally invasive vertebral augmentation methods for cement application into the vertebral body for the management of symptomatic compression fractures without neurological impairment have been developed, namely vertebroplasty and kyphoplasty.
Vertebroplasty, first reported in literature in 1987 for the management of a painful aggressive haemangioma of a vertebral body (9), is a minimally invasive percutaneous procedure which aims to percutaneously inject polymethylmethacrylate cement into a collapsed vertebral body, under imaging guidance, to strengthen it.
Kyphoplasty was introduced to manage the kyphotic deformity and help to realign the spine (10). Kyphoplasty involves to place percutaneously into a vertebral body an inflatable balloon device (bone tamp), approved by the US Food and Drug Administration (FDA) since 1998. The inflation of the bone tamp with liquid allows restoration of vertebral height and correction of the kyphosis. After deflation, the cavity which has been produced is filled by injection of polymethylmethacrylate (PMMA).
Kyphoplasty and vertebroplasty have gained wide acceptance worldwide to manage patients without neurological impairment suffering with otherwise unmanageable pain caused by vertebral compression fractures secondary to osteoporosis (5-7) or osteolytic lesions (11) within a vertebral body. Both procedures depend on mechanical stabilization of the fracture produced by PMMA cement injection into the fractured vertebra (12-15).

The exact mechanism of the analgesic effect of vertebral augmentation remains under debate. Pain reduction with the use of these percutaneous vertebral augmentation techniques has been attributed to the mechanical effects of the reconstruction and stabilization of the endplates and vertebral body segment by stiffening of the cement, and to the therapeutic effect of the exothermic reaction of the cement, assuming that the pain originates from intraosseous nerve endings (16). The mainstay of the controversy between kyphoplasty and vertebroplasty are height restoration, whether or not this height restoration is clinically significant, and the risks related to height restoration (17-20).
Specific concerns of kiphoplasty include that the endplates are not rigid structures. When the ballon is inflated, fissurations of the endplate may be produced, with consequent extravasation in the intervertebral space. Moreover, when the fracture presents posterior fissuration, cement may invade the cord space, with dramatic neurological damages. Absolute contraindication to the use of cementoplasty techniques include neurological damage, and fracture of the posterior wall of the vertebra (with potential extravasation of cement and neurological damage).
Cementoplasty techniques require good skills with the use of cement, as its use in a liquid phase may determine embolism.
Another reason of concern is the presence, after the procedure, of a cement “stone” in the bone. Necessarily, the cement has a different mechanical properties than vertebral bone. If this can be a minor problem in the surgery of the limbs, this is of great concern in spinal surgery for the neighbouring anatomical structures. This is the main reason because we never perform vertebral augmentation as prophylaxis in patients with osteoporosis.
Aim of this paper is to give an overview of the state of the art about vertebroplasty and kyphoplasty, discussing the indications, techniques, results and pitfalls. We recommend to limit the use of cementoplasty to patient with symptomatic fractures without neurological impairment in whom a classical conservative management with brace is not possible for impairment of the general conditions. We prompt not to forget that for many years successful conservative management of vertebral fractures has been the standard of care.

Indications

Continuous developments are evolving in the field of vertebroplasty and kyphoplasty. For this reason, we recommend to follow the guidelines of national and international societies (21).
The main indication for vertebroplasty and kyphoplasty are:

1. Intractable, intense pain adjacent to the level of the fracture (6, 7) in patients with osteoporotic fractures, diagnosed by radiographs, CT or MRI. Conservative management for at least 3-4 weeks (22) should have failed in these patients for the procedure to produce clinically relevant pain relief, in the absence of need for surgical stabilization.
2. Pain of the affected segment in patients with osteolytic lesions of vertebral bodies from bony metastases (21).

Absolute contraindications to vertebroplasty and kyphoplasty are:

1. Unmanageable bleeding disorder
2. Improvement of the symptoms of the patient with conservative management
3. Asymptomatic vertebral body fracture,
4. Local or generalized infection
5. Allergy to bone cement
6. Tumour mass with involvement of the spinal canal.

Vertebral augmentation as prophylaxis in patients with osteoporosis is debated. It is regarded as a contraindication in some guidelines (23). On the other hand, it has been advocated by other authors for patients at very high risk for fracture (24).
The Consensus Guidelines for Vertebroplasty developed by the Standards of Practice Committee of the Society of Interventional Radiology are (25, 26):

1) painful primary and secondary osteoporotic vertebral compression fracture(s) refractory to medical therapy;
2) painful vertebrae with extensive osteolysis or invasion secondary to benign or malignant tumor; and
3) painful vertebral fracture associated with osteonecrosis.

Techniques

Vertebroplasty

To achieve a low complication rate, the most important factor which influences the result of the vertebroplasty is the visualization of needle placement and cement application (27). Vertebroplasty may be performed using both biplanar fluoroscopy, and CT scanning (28) to obtain an accurate visualization of needle position and cement distribution (Figure 1-4). The monitoring of the distribution of the cement under direct fluoroscopic control is another crucial aspect of the procedure, independently from the technique used for needle placement.

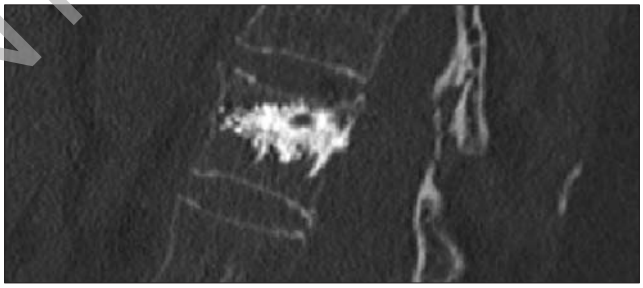

Figure 1 - Sagittal CT view in a 71-year-old female patient with back pain showing a vertebral fracture of the body of D11. She had a symptomatic vertebral fractures without neurological impairment. A classical conservative management with brace was not possible for impairment of the general conditions.

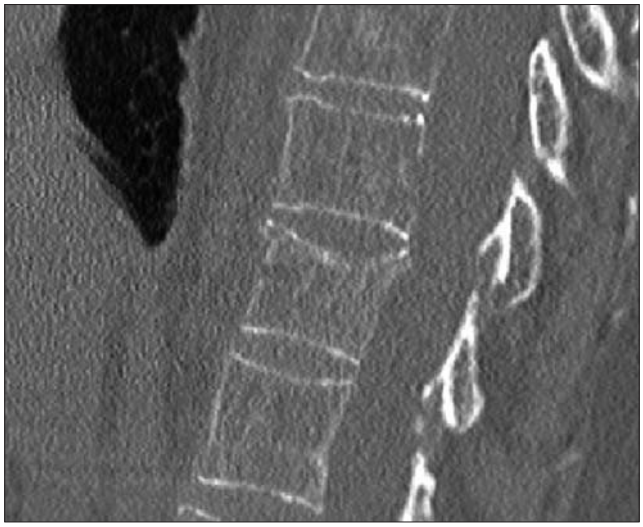

Figure 2 - Sagittal CT view showing the transpedicular route.

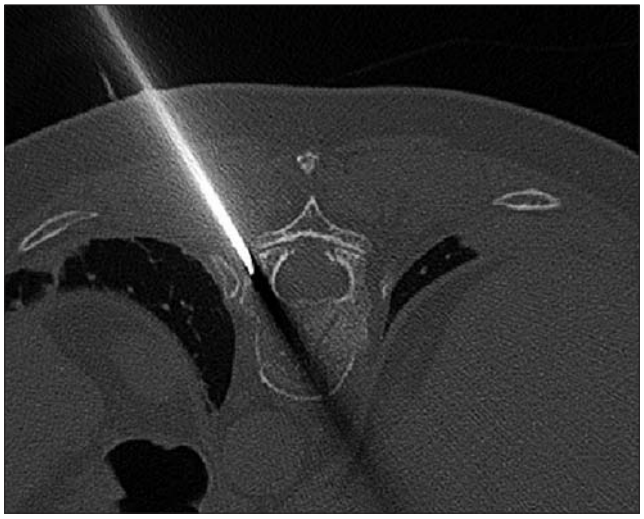

Figure 3 - Axial CT view of the vertebra after PMMA injection.

Figure 4 - Axial CT view of the vertebra after PMMA injection.

Vertebroplasty can be performed under local anaesthesia or a combination of conscious sedation (29) in most patients, and is therefore particularly useful in patients with risk factors for general anaesthesia. General anaesthesia is required only in patients unable to cooperate due to pain or in very agitated patients (30).
The access path depends on the level of the vertebral segment to be injected. In the lumbar spine, a transpedicular route is preferred. In the thoracic vertebrae, an intercostovertebral access is recommended. In the cervical vertebrae, an anterolateral approach is used.
To identify potential routes of venous cement extravasation, an angiographic evaluation of the vertebral venous system (venography) has been suggested prior to cement injection, but its utility is still debated (31-33). The cement should be injected while in its tooth-paste like phase to minimize complications from extravasation in the surrounding tissues, as the flow characteristics of the cement change over the time.
Cement injection may be stopped when the anterior two thirds of the vertebral body are filled and the cement is homogenously distributed between both endplates (34). During cement injection, continuous fluoroscopic monitoring is performed to immediately detect extravasations of cement. In case of extravasation, the procedure must be interrupted.

A direct correlation between the risk of extraosseous extravasation and the amount of cement injection has been proposed, but, to date, no studies have addressed the specific issue of the volume of cement needed during vertebroplasty. Normally, 2.5-4 mL of cement should provide good filling of the vertebra and achieve both consolidation and pain relief in patients with osteoporotic fractures. The material cost of a single-level vertebroplasty is approximately 200 Euros (35).

Kyphoplasty

Kyphoplasty is normally performed under general anaesthesia in some patients as proper placement of the balloons is mandatory, and several steps need to be taken before cement can be injected.
A mono- or bilateral trans- or para-pedicular approach is used to insert a working cannula into the posterior aspect of the vertebral body. The procedure is performed under biplanar fluoroscopy or CT scan control. With reaming tools, two working channels within the anterior aspect of the vertebral body are produced, and the appropriate balloon is inserted. To reduce the fractured vertebra and to produce a cavity, the balloon is inflated using visual volume and pressure controls. The behaviour of the vertebral body is monitored under fluoroscopic control. Inflation is stopped when a pressure above 250 psi is obtained, when the balloon contacts the cortical surface of the vertebral body, or if the balloon expands beyond the border of the vertebral body, and if the height of the vertebra is restored. Successively, the balloons are retracted and cement polymethylmetacrylate (PMMA) is injected using a blunt cannula under continuous fluoroscopic control. The material cost of a single-level kyphoplasty is approximately 3,000 Euros (35).

Pitfalls

The procedures have a low rate of clinical complications, but potential complications can be devastating. The possibility of complications should be discussed with the patient and family before the procedure. Cement extravasation is one of the possible complications of vertebroplasty. The reported incidence is up to 40% in patients with osteoporotic fractures. Paravertebral soft tissue, intervertebral disc, needle tract, epidural and paravertebral veins, the spinal canal and the neuroforamen can be invaded. Obviously, the clinical relevance of this complication will be different in relation to the anatomical structure which is invaded from the cement. Cement invasion into the vena cava, lungs, heart and even the kidneys have been described (36-40). These major adverse events only occur in less than 1% of the patients (41), and require immediate management.
Cement embolization may be responsible of pulmonary embolism.
In patients with osteoporosis, new fractures of neighbouring vertebrae can be caused by cement leakage within the intervertebral disc (42). The pathogenesis of these new fractures is still under debate, and probably resides in the difference between the stiffness of the vertebra undergoing the procedure and the adjacent vertebral body (39). Moreover, the high temperature of the cement during polymerization (85°C) (43) may be responsible of possible thermal damage to the surrounding tissues.
Mechanical stabilization of the fractured vertebral body, chemical toxicity, and thermal necrosis of surrounding tissues and nerve endings have been indicated as the main reasons for pain relief after vertebroplasty (13).
Vertebroplasty and kyphoplasty in most patients produce improvement in the quality of life because of pain relief, marked

reduction of the amount of analgesics needed for pain control, and improvement in physical mobility.
Advantages of vertebroplasty over kyphoplasty are the possibility to perform the management under local anaesthesia or a combination of conscious sedation (29) in most patients. For this reason, vertebroplasty is particularly useful in patients with risk factors for general anaesthesia. General anaesthesia is required only in patients unable to cooperate due to pain or in very agitated patients (30).
The rate of success in restoration of vertebral body height after kyphoplasty ranges between 0 and 90%. The incidence of leakage during kyphoplasty is reported ranging from 0 to 13.5% (11, 44), and in vertebroplasty from 2 to 67% (45-47). In addition to providing rapid pain relief, balloon tamp kyphoplasty has the advantage to reduce acute fractures, allowing controlled cement placement under lower pressure, and to improve deformity. Obviously, elderly patient with a vertebral compression fracture benefit from restoration of normal overall spinal sagittal alignment and kyphotic deformity.
Several authors have reported its effectiveness in relief pain and in preservation of posture (48, 49). Despite the high success of outcome reported with vertebroplasty, this procedure does not restore the height of the vertebral body and does not correct kyphosis. Moreover, a low viscous cement injection technique is used, with a higher reported incidence of cement leakage when compared with kyphoplasty (19, 47, 50, 51).
Cotton et al (52) performed a study to determine whether the percentage of vertebral lesion filling and the leakage of methyl methacrylate have any clinical significance at follow-up. Forty percutaneous vertebroplasties were performed. 15 epidural leaks, 8 intradiskal leaks, and 2 venous leaks of methyl methacrylate occurred. Two of 8 foraminal leaks produced nerve root compression that required decompressive surgery.
Moreland et al. (53) in a study on 53 levels of vertebroplasty performed on 35 patients stated that the overall complication rate was 6% per treated vertebral level. They concluded that although vertebroplasty is considered a minimally invasive procedure, it can result in serious complications even without technical misadventures
Complications reported with kyphoplasty include cement extravasation as well as rib fractures, which in one study occurred in 2 of 30 patients secondary to patient positioning (12).
Garfin et al. (10) reported two cases of neurologic injury secondary to problems with needle insertion and positioning of the cement filling tube with epidural cement extravasation. Intraoperative balloon rupture occurred 14 times, manly at the end of inflation. All broken bone tamps were removed, and in three patients reinsertion of a new balloon was required to complete the inflation.
Grados et al. (54) reported on 34 vertebrae treated by PV in 25 patients. There was a slight but significantly increased risk of vertebral fracture in the vicinity of a cemented vertebra.

Vertebroplasty versus kyphoplasty

Despite the good clinical outcomes reported with both vertebroplasty and kyphoplasty, and the fact that percutaneous vertebroplasty has been performed for more than 30 years, there is a lack of well-conducted randomized control trials on the subject. The evidence to support these techniques in the management of patients with symptomatic osteoporotic vertebral compression fractures refractory to conventional medical therapy is, at best, a level III based (55, 56).
Three systematic reviews evaluated the efficacy and safety of vertebroplasty and kyphoplasty for the management of vertebral compression fractures.
Hulme et al. (57) performed a systematic literature review to evaluate the safety and efficacy of vertebroplasty and kyphoplasty, with respect to patient pain relief, restoration of mobility and vertebral body height, complication rate, and incidence of new adjacent vertebral fractures. A large proportion of subjects had some pain relief, respectively 87% with vertebroplasty and 92% with kyphoplasty. Vertebral height restoration was possible using kyphoplasty and for a subset of patients using vertebroplasty. Cement leaks occurred for 41% and 9% of treated vertebrae for vertebroplasty and kyphoplasty, respectively. New fractures of adjacent vertebrae occurred for both procedures at rates that are higher than the general osteoporotic population but approximately equivalent to the general osteoporotic population that had a previous vertebral fracture.
Taylor et al. (55, 56) conducted a comparative systematic review of efficacy and safety of balloon kyphoplasty and vertebroplasty for the management of patients with vertebral compression fractures.
They concluded that to date, there is no good quality direct comparative evidence of balloon kyphoplasty versus vertebroplasty. From indirect comparison of case series evidence, the techniques appeared to provide similar gains in pain relief, while for balloon kyphoplasty there is better documentation of gains in patient functionality and quality of life. The rates of adverse events (pulmonary embolism, neurologic complications, and perioperative mortality) are low with both procedures, although poorly reported across studies (55, 56).
Ploeg et al. (20) undertook a systematic review to assess the efficacy and safety of percutaneous vertebroplasty in osteoporotic vertebral compression fractures. Totally, the authors reported on 1,136 interventions performed on 793 patients. The short-term complication rate varied between 0.4 and 75.6%. Leakage of cement outside the vertebral body was markedly common, ranging from 3.3 to 75.6%. Although the majority was asymptomatic, a few devastating clinical adverse effects were reported. Percutaneous vertebroplasty is a widely accepted treatment for osteoporotic vertebral fractures, but the authors identified only one controlled trial. They concluded that there are insufficient data available to reliably assess efficacy of percutaneous vertebroplasty.

Costs

Kyphoplasty is 10 to 20 times more expensive than a vertebroplasty performed with conscious sedation on an outpatient basis (28, 31, 58, 59). Additional costs of a kyphoplasty include the device itself, the cost of the anaesthesia, duration of the procedure, and inpatient hospitalization (60).

Conclusions

In our clinical practice, we limit the use of cementoplasty to patient with symptomatic fractures without neurological impairment in whom a classical conservative management with brace is not possible for impairment of the general conditions. We prompt not to forget that for many years successful conservative management of vertebral fractures has been the standard of care!

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