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Radiofrequency Kyphoplasty – An Innovative Method of Treating Osteoporotic Vertebral Body Compression Fractures

P. Drees, K. Kafchitsas, S. Mattyasovszky, S. Juri, N. Breijawi

Abstract: Osteoporotic vertebral body fractures are encountered increasingly often. Cement augmentation using vertebroplasty or balloon kyphoplasty are standardised and established procedures. However, the optimal cement viscosity at the time of cement augmentation has not yet been satisfactory resolved for either method. In other words, the time point of cement application is left to the surgeon's subjective estimation. Early application of cement may cause cement leakage whereas late application may cause incomplete filling of the vertebral body. Radiofrequency kyphoplasty is a recently developed augmentation system that enables the surgeon to exert control when creating the cavity, as well as aids him in the placement and application of cement. Cement is applied by remote control and thus uniformly retains its properties. The method is presented in the following. **J Miner Stoffwechs 2011; 18 (Supplement 1): 13–7.**

Introduction

Increasing numbers of patients experience an osteoporotic vertebral body fracture [1, 2]. In the USA the incidence is about 700,000 vertebral body fractures per year. Only about 35 % of these patients [1] are diagnosed with this condition and undergo treatment for it because of severe back pain. A similar incidence is found in Europe: About 23,000,000 symptomatic vertebral body fractures were registered in the year 2000, whereas about 37,300,000 are predicted for the year 2050 [3]. Approximately 85 % of these may be classified as osteoporotic fractures [4]. The patients' quality of life is limited because they become less mobile due to massive pain. This increases the rate of cardiovascular diseases [5–7] and, as a result, mortality rates are 23 % higher than those in compared groups [8, 9].

In order to accelerate the rehabilitation of these patients who frequently present with multiple morbidities and have to undergo unsuccessful or very prolonged conservative treatment, and simultaneously stabilize the vertebral body, minimally invasive procedures for augmentation of the vertebral body with the use of cement have been developed.

Evolution of augmentation techniques

Vertebroplasty – a minimally invasive augmentation procedure as an alternative to the open surgical approach – was first reported in France in 1987 [10]. Polymethylmethacrylate (PMMA) cement in liquid form is injected into the vertebral body under very high pressure and the vertebral body is thus stabilized. A procedure that was initially used exclusively for the treatment of vertebral body hemangioma began to be increasingly employed for the treatment of osteoporotic vertebral body fractures [11, 12].

However, the combination of very high injection pressure and low-viscosity cement bears the risk of extravasation from the vertebral body, especially at fracture gaps. Complication rates range between 20 % and 70 % of operated patients [13, 14]. Leakage of cement dorsally into the spinal canal or segmental vessels with potential injury to the spinal cord and subsequent lung embolism are especially hazardous [15].

Balloon kyphoplasty, approved in the USA in 1998, signifies an advancement in the field of safe cement application and re-straightening of the vertebral body [16, 17]. In addition to simple stabilization of the fracture, the purpose of balloon kyphoplasty is to achieve straightening and restoration of the previous profile of the vertebral body [18, 19]. Other methods that employ aids introduced into the vertebral body usually in bipedicular fashion, such as intravertebral stents, bags, plates or meshes, are also based on this principle. The still existing structures of cancellous bone are largely destroyed, displaced and compressed by these procedures. The aim is to limit the cavity created by the technique and prevent the outflow of low-viscosity bone cement [20, 21].

The long-term sequelae of residual and usually poorly fixed cement and other foreign bodies that may remain in the vertebral body have not yet been sufficiently investigated. Compression and the consequent destruction of the remaining microarchitecture, however, have been criticized by many osteologists.

On the other hand, the authors agree about the lower rate of risk-laden cement leakage [21–28]. It has not been conclusively established yet whether the rates of subsequent fractures after balloon kyphoplasty are lower than those after vertebroplasty [21, 25–30].

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Radiofrequency kyphoplasty

In the USA, radiofrequency kyphoplasty was approved by the FDA in 2007 for controlled treatment of symptomatic vertebral body compression fractures. This was followed by approval in Germany in January 2009. This new procedure is the answer to the frequently voiced criticism of the destruction of microarchitecture by conventional procedures. The basic principle is transformation of the PMMA cement ex vivo by means of radiofrequency into a semisolid mass of ultra-high viscosity. The inactivated cement can be applied in controlled fashion for up to 35 minutes – its properties remain constant during this time – without destroying the still existing cancellous bone.

Following approval, more than 2300 vertebral body compression fractures have been treated by this procedure. As the procedure is a promising approach, it will be described in detail as a complement to conventional balloon kyphoplasty.

Radiofrequency kyphoplasty is an advancement of conventional kyphoplasty techniques by the use of balloons, stents and other aids. This minimally invasive procedure employs the StabiliT® radiofrequency kyphoplasty system of DFine Company, and can be performed under local or general anesthesia.

Like conventional techniques, radiofrequency kyphoplasty is performed with the patient in prone position. Cushions are placed below the chest and both pelvic crests. The abdomen is not compressed in order to avoid venous congestion or hindrance to breathing. Lordosis of the lumbar spine is desirable and may assist straightening. Therefore, especially in cases of fractures at the junction between the thoracic and the lumbar spine, the positioning alone straightens the vertebral body to a certain extent [29].

The fact that this new method minimizes irradiation for the patient (by the unipedicular access) and especially for the surgeon (by remote operation of the application unit) is of notable significance.

Indications and contraindications

Hass et al. 2008 [20] have adequately described the potential indications and contraindications of conventional augmentation techniques. As these apply in equal measure to radiofrequency kyphoplasty, they will be briefly mentioned here:

1. Painful osteoporotic sintering fracture(s) in the absence of adequate trauma
2. Painful traumatic compression fracture(s) that are stable according to the AO criteria, in the presence of osteoporosis
3. Painful and/or fracture-prone osteolyses with or without sintering in the presence of systemic or disseminated malignant tumors (e.g. those of the spinal cord, or vertebral body metastases)
4. Adjuvant peri- or intraoperative radiofrequency kyphoplasty in the course of surgery for stabilization

Contraindications for radiofrequency kyphoplasty include the presence of coagulation disorders or infections, partial or complete loss of the posterior margin of the vertebral body, tumor invasion into the epidural space with constriction of the spinal canal, and known allergies to any element required for the procedure.

Steps of surgery

Using an image converter, the desired level of the vertebral body is marked. At approximately 3-o'clock or 9-o'clock-position at the level of the corresponding pedicle, a small skin incision of about 0.5 to 1 cm is made in unipedicular fashion. A so-called VertecoR® Introducer (working cannula with stylet) is introduced under anteroposterior and lateral radioscopy into the posterior to middle third of the vertebral body. The 3.6-mm-thick access instrument serves as the subsequent working cannula after removal of the introducer stylet. It should be ensured that the distal end of the working cannula is located in the posterior to middle third of the vertebral body. Once the final position has been achieved, the introducer stylet is removed and the working cannula left *in situ*.

Under radioscopic control, first of all a small cavity is created in the vertebral body in controlled and targeted fashion. A straight hollow osteotome is introduced into the anterior third of the vertebral body through the working cannula for the purpose of drilling. The osteotome is pushed forward in controlled fashion for the purpose of drilling, rotated several times, and re-positioned as required. The bone material obtained by the creation of the cavity in the vertebral body – as in conventional augmentation techniques – can be used to perform a biopsy.

As the next step, a so-called VertecoR® MidLine osteotome which is a larger osteotome with a flexible shaft at its distal end, is introduced through the working cannula. It is then pushed outward through the mid-line or into the region of the vertebral body in which the cavity is to be created. The MidLine Osteotome thus permits targeted placement of small pathways in the vertebral body beyond the midline. This ensures that the ultra-high viscosity bone cement is applied in a controlled manner at the desired site and is very well fixed in the surrounding cancellous bone. Additionally, it creates an abutment for straightening. By rotating the tip of the flexible MidLine Osteotome, a pedestal can be created in targeted fashion and, if required, enlarged in a controlled manner. In order to create further pathways for the cement at a different plane or in a different region of the vertebral body, the instrument can be withdrawn several times in the working cannula, turned, re-introduced, and the flexible tip of the osteotome can be bent in different directions.

Before the actual application of cement the so-called MultiPlex controller, a radiofrequency generator with a hydraulic regulator, is switched on. The activation element, cable and a special hydraulic assembly are connected to the controller. A cement cartridge is filled with liquid monomer, fixed to the hydraulic assembly, and connected to the activation element. After removing the introducer stylet the locking delivery cannula is fixed to the activation element and introduced into the working cannula such that the end of the delivery cannula is located in the prepared intravertebral space created in the anterior third of the vertebral body. The delivery cannula which is coated on the inside with Teflon is locked in the working cannula such that it is fixed during application of the semi-solid ultra-high viscosity cement and cannot slip. The bone cement is directly

activated *ex vivo* into an ultra-thick (rubbery) mass by means of the radiofrequency waves of the activation element. This activated cement is then directly introduced into the created cavity by means of the locking delivery cannula. The mass of the ultra-high viscosity cement increases by 1.3 ml every minute and is thus distributed in the vertebral body. This process can be interrupted and resumed at any time. The cement is applied under radiographic control and can be performed at any time outside the source of radiation as well, by remote control, in order to reduce the radiation exposure. If necessary – for instance if more cement is needed or the cement has not been applied in the correct region – the locking delivery cannula can be removed at any time before cement application is continued.

This is rendered possible by the cement's very long processing time of 35 minutes in its inactivated state, during which its properties remain constant. The extremely high viscosity of the cement markedly reduces the possibility of extravasation and cement particles being washed away (as is well known with conventional procedures using balloons, meshes, etc.). Thus, one of the principal procedure-specific complications of conventional augmentation techniques [24] seems to have been resolved.

The injection of cement is concluded once the cement mass has led to adequate straightening of the vertebral body or the operator believes that appropriate filling of cement has been achieved. The locking delivery cannula is removed and the stylet re-introduced into the working cannula. Straightening and filling are checked on a final intraoperative image. After removing the working cannula the incisions are closed and covered with sterile plaster.

Patients and Method

Between May and December 2009, 33 patients (23 women and 10 men) aged on average 71 years (range, 48 to 87 years) who had experienced a vertebral body fracture with no trauma or as a result of minimal trauma were treated by radiofrequency kyphoplasty after attempted conservative treatment at the Orthopedic Department of the University Medicine in Mainz.

An MRT investigation of the corresponding vertebral body provided evidence of a recent fracture. If the symptoms persisted under appropriate analgesia and the patients had clinical symptoms of a fracture in the region, we established the indication for radiofrequency kyphoplasty with due regard to contraindications of the procedure.

The pain score was determined on a visual analog scale (VAS 0–10) immediately preoperatively and on the second postoperative day. Cement leakage was identified on postoperative radiographs and was classified according to Yeom et al's description [31]. A distinction was made between three types: Type B was defined as cement leakage through the basic vertebral veins into the spinal canal. Type S was defined as cement leakage through the segmental veins and type C as those through the fracture gap [32]. Additionally, the respective operating times required for the procedures were documented.

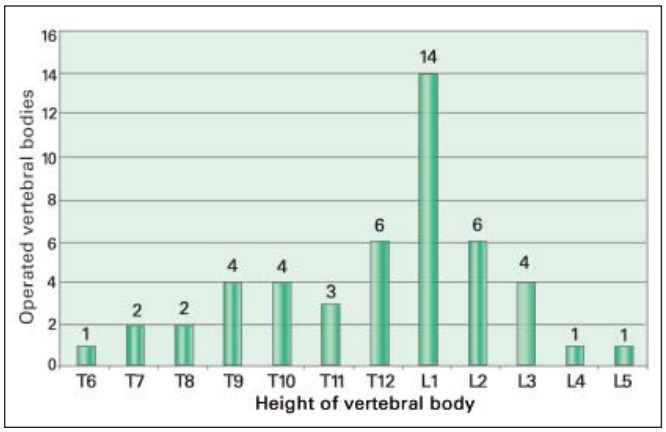

Figure 1: Distribution of the operated vertebral bodies

Statistics

Data were evaluated using the SPSS statistical program packet 16. The following statistical measures were used to demonstrate values: number (N), means (MW), standard deviation (SD), minimum (Min) and maximum (Max). As a non-parametric test for paired random samples, the signed-rank test was used to evaluate the results. The level of significance was set to $p < 0.005$

Clinical results

A total of 48 vertebral bodies were augmented in 33 patients. One segment was treated in 22 patients, two segments in 6 patients, three segments in 3 patients, and four segments in one patient. The distribution of vertebral body heights is shown in Figure 1.

The mean operating time was 31.7 minutes per augmented vertebral body. Independent of the number of treated segments, the mean operating time was 35.9 minutes (range, 15 to 67 minutes). For single-segment augmentation the mean operating time was 31.7 min (range, 15 to 67 minutes). Bi-segmental augmentation was performed in 6 cases, and required a mean operating time of 41 minutes (range, 31 to 56 minutes). Three segments were treated in 3 patients, requiring an operating time of 50 minutes (range, 24 to 65 minutes). Four segments were kyphoplastied in one patient, and the operating time was 64 minutes.

Twenty-eight patients with 39 treated vertebral bodies could be evaluated clinically. The mean preoperative pain score on VAS was 8.1 (range, 4 to 10; SD 1.5) (Figure 2). Postoperatively a mean score of 2.8 (range, 0 to 7; SD 1.6) was registered. Thus, significant pain relief ($p<0.005$) was achieved (Figure 3).

Postoperative complications

Cement leakages occurred in 13 (27.1 %) of 48 augmented vertebral bodies. Type C leakages occurred in 11 cases. Only in two cases did cement leak through the basal vertebral veins. No cement leakage required revision.

No further complications were encountered. One woman died postoperatively due to previously known COPD; the death was not related to the intervention.

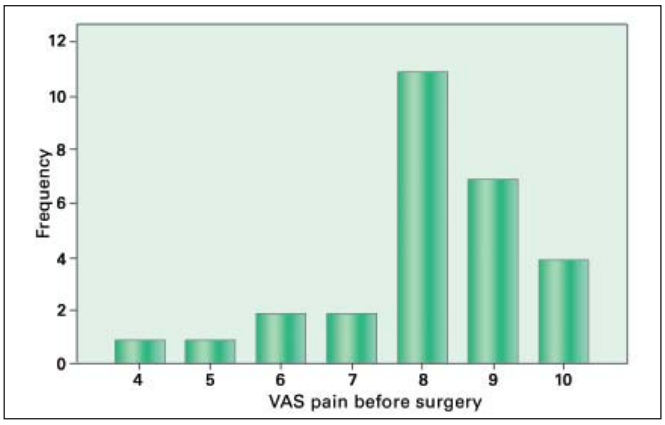

Figure 2: Preoperative pain rating on VAS (0–10). VAS = Visual Analog Scale

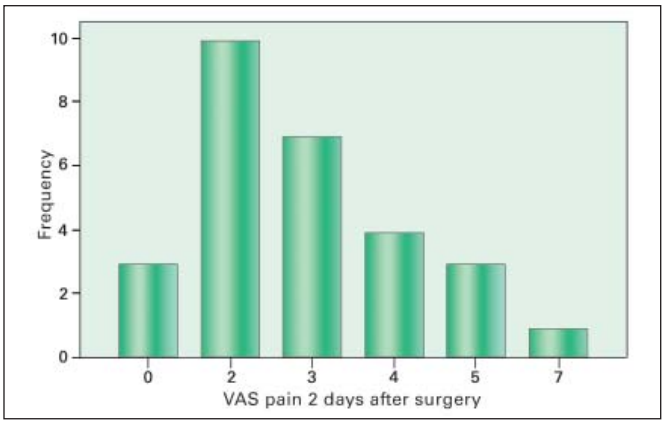

Figure 3: Postoperative pain rating on VAS (0–10). VAS = Visual Analog Scale

Discussion

Clinical results of radiofrequency kyphoplasty using the StabiliT® Vertebral Augmentation System of DFine achieves a similar degree of pain relief immediately post-surgery as that achieved by the well known procedure of balloon kyphoplasty [33–35].

Evaluation of the 183 studies showed that a kyphoplasty is able to reduce pain on average from 7.15 to 3.4 points on the VAS [35]. In our current group, the patients reported an even lower mean VAS score of 2.8 on the second postoperative day.

The number of cement leakages may be viewed with some criticism, although none of these necessitated a renewed operation. A large proportion of the leakages occurred through the fracture gap of the base and upper plates in the intervertebral space. In the published literature, balloon kyphoplasty was reported to be associated with cement leakage in 8.6 to 57.9 % of cases [34, 36–38] without taking clinical symptoms or the need for revision into account. Controlled cement application in radiofrequency kyphoplasty is believed to cause less cement leakage than balloon kyphoplasty. However, the rate of 27.1 % observed in the present study does not justify the anticipation of a lower rate of cement leakage. We draw attention to the small sample size and the learning curve during initial application of the surgical method. Also, the patients had conditions which were not treatable with conventional kyphoplasty via balloon due to technical limitations of the system and would have eventually caused the patients to undergo a rather large surgical intervention. Thus, the first 10 patients with 13 segments that required treatment experienced cement extravasations in 6 cases.

The duration of the intervention can be markedly reduced by the unipedicular access and the use of previously prepared cement. Besides, the long processing time of the cement enables the surgeon to treat several segments. A mean intervention time of 53.7 minutes has been reported for balloon kyphoplasty [33]. Without considering the learning curve and the number of augmented segments, the mean operating time in the current study was 31.7 minutes – i.e. it was reduced by nearly a half. This is not merely advantageous for the patient, but has financial implications for the institution as well.

Conclusion and Future perspectives

The new StabiliT® radiofrequency kyphoplasty system in combination with the MidLine Osteotome permits targeted and controlled application of ultra-high viscosity cement with uniform properties over a processing period of up to 35 minutes.

In addition to the primary goal of fracture stabilization, radiofrequency kyphoplasty offers the possibility of straightening and consequent restoration of the original profile of the vertebral body [32]. These two factors in unison cause significant pain relief – as in conventional balloon kyphoplasty – and a concomitant enhancement of quality of life while the duration of the intervention is reduced nearly by a half.

Further investigations on radiofrequency kyphoplasty are needed to confirm the experience described above. However, it now appears possible to preserve the existing microarchitecture by controlled cement application, and simultaneously straighten the vertebral body. Biocompatible absorbable bone cements are currently being developed and will be available in the future for specific indications.

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