Vertebral Body Stenting: Early Results with a New Technique for the Treatment of Vertebral Compression Fractures

ESLAM E. ALY, M.Sc.* and MOKHTAR E. ABDEL AZEEM, M.D.**

The Department of Orthopedic Surgery, Faculty of Medicine, Ain Shams* and Al-Azhar** Universities and A l-Razi Orthopedic Hospital – Kuwait*, **

Abstract

**Background:** Balloon kyphoplasty is an established minimally invasive procedure to restore vertebral body height, and internally stabilize osteoporotic and/or cancer related vertebral compression fractures. In the same time there is a technique inherent problem with the amount of reduction; when filling the kyphoplasty balloons, an acceptable reduction is achieved in many patients. However, the resulting final reduction after cementing is about 25% lower due to the partial collapse after balloons deflation. In order to avoid this loss of reduction, a newer alternative technique has been introduced, based on the principles of balloon kyphoplasty and vascular stenting.

**Study Design:** A prospective consecutive cohort study of clinical and radiographic results after vertebral body stenting for treatment of vertebral compression fractures.

**Objectives:** To evaluate the safety and effectiveness of Vertebral body stenting as a new technique to treat symptomatic vertebral compression fractures.

**Methods:** A total of 33 elderly patients with 52 symptomatic vertebral compression fractures were enrolled in a prospective study of Vertebral body stenting. Clinical outcomes were measured pre- and postoperatively using the visual analogue scale (VAS), Oswestry Disability Index (ODI) and ambulatory status (AS). All outcomes were assessed before the procedure, and at 1, 12, 24, and 36 weeks after the procedure.

**Results:** The median VAS scores went from 10.0 preoperatively to 6 at one week post-operatively, to 5 at 12 weeks following the procedure and to 2 and 1 at 24 weeks and last follow-up, respectively. The pre-operative ODI score was 80 before the operation, improved to 45 at one week postoperatively, decreased to 35 at 12 weeks and to 22 and 18 at 24 weeks and last follow up, respectively. The ability to move independently and ease of ambulation significantly improved after the procedure (p<0.001). The median kyphosis angle was 15.0 degrees before the procedure and decreased by a median of 4.5 degrees after the operation.

**Conclusions:** Elderly patients with symptomatic vertebral compression fractures had rapid, significant, and sustained improvements in back pain, back function, and quality of life following Vertebral body stenting.

**Key Words:** Vertebral body stenting (Vbs) – Balloon kyphoplasty – Vertebral compression fractures (VCFs) – Loss of reduction – Back pain.

Introduction

**VERTEBRAL** compression fractures are frequent and constitute a common and often debilitating feature of osteoporosis. The incidence of vertebral compression fractures rises with increasing age [1,2]. Due to increasing elderly population, the treatment of vertebral compression fractures becomes more and more important [3-7]. The objective target in treating VCFs is a relief of pain and the restoration of spinal function with a minimal invasive therapy. The ideal treatment should result in an immediate relief of fracture-related pain and a satisfying restoration of vertebral body height and correction of angular deformity [8,9,10]. Both vertebroplasty and kyphoplasty lead to immediate pain relief because the broken vertebra is stabilized and further deformity prevented [9,11,12]. Characteristic complications, such as cement extrusion and pulmonary embolism, are less likely to appear in kyphoplasty due to lower pressure when injecting the cement [13]. In addition, a restoration of height and correction of kyphosis is achieved by filling the kyphoplasty balloons. There are reports of relative restoration of vertebral body height between 0 and 90% and correction in kyphotic angle up to 8.8 in kyphoplasty treated patients [8,14-19]. At the same time, there is a device related problem with the amount of reduction; when filling the kyphoplasty balloons a satisfying reduction is achieved in many patients. However, the resulting reduction after cementing is about 25% lower due to the partial collapse after balloon deflation [13]. In order to avoid this loss of height, a newer alternative has
been developed, based on the principles of balloon kyphoplasty and vascular stenting. Using VBS, the stent remains within the newly created vertebral cavity, so the balloons can be removed after deflation while preventing the vertebral body from collapsing, so that, in an ideal scenario, a virtually physiological vertebral body height and shape can be restored and preserved. The cavity is then filled with PMMA (Poly-methylmethacrylate) bone cement [20]. We performed a prospective analysis of the first 33 patients treated with VBS at our hospital. They had VCFs at levels T5 to L5 due to osteoporosis. There were 52 VCFs in these 33 patients. The goals of this study were to determine the safety and effectiveness of VBS in improving vertebral body height, decreasing pain, and improving function.

**Patients and Methods**

The study included 33 patients (9 male, 24 female) with a follow-up of nine months. The median age was 67 years (range 49-89 years) (Table 1). Subjects were excluded if they had associated spinal stenosis, pedicle fracture, neurologic deficit, an active infection, and severe comorbidities, such as uncorrected coagulopathy. The date of the fracture was determined by a retrospective chart review. During the preoperative visit, the patient was subjectively asked to recall a traumatic event or sudden onset of pain. The interval between date of fracture and the date of surgery determined the age of the fracture. The age of the fracture could be determined for 41 of the 52 fractures based on this method of data collection. Informed consent was obtained from all patients. Physical examination combined with lateral radiographs, magnetic resonance imaging and computerized tomography were used to diagnose vertebral body compression fractures.

**Surgical technique:**

A radiolucent table (TruSystem 7500, Trumpf Medizin Systeme GmbH, Puchheim, Germany), and two C-arm fluoroscopy machines (Fluorostar 7900 Mobile Digital C-Arm, GE OEC Medical Systems GmbH, Wendelstein, Germany) were requested for every Vertebral body stenting procedure at our hospital. The two fluoroscopy machines placed orthogonally across the radiolucent table allowed simultaneous viewing of antero-posterior and lateral projections of the spine. This process helped to accelerate the operation and minimize contamination risk during the operation. The patient was then taken to the operating room, where general anaesthesia was used in 29 procedures and local anaesthesia with heavy sedation in five interventions. The patient was carefully turned prone onto the Wilson frame and all bony prominences were protected. To prevent infection, a pre-operative single shot I.V dose of a third generation cephalosporins was administered. Two fluoroscopy machines were then wheeled into position, and the fractured level was centered in both the antero-posterior and lateral projections before the skin was prepared and the patient draped. The fluoroscopy machines were also covered with appropriate sterile covers. A 1-cm incision was made just lateral and superior to both pedicles. Under continuous fluoroscopic guidance, the guide wires were inserted to the superior outer pedicle quadrant using slight manual pressure and controlled blows from a hammer (Fig. 1). The working sleeves over a side-opening cannulae were applied and guide wires removed. At this stage, any bone fragment that was extracted through the cannulae, was taken as a biobsy and sent for histopathological examination. A drill was manually twisted in the vertebral body to create a tract for the stents. The vertebral body stents are available in two sizes, {Vertebral body stent (Ø17mm [diameter] x 15mm [length]) or (Ø17mm [diameter] x 20mm [length]), Synthes GmbH, Solothurn, Switzerland}. The stent implants consist of strong cobalt-chromium alloy that is extensively used in coronary and peripheral artery stenting. The balloon catheters with the attached stents were inserted bilaterally, and this was continued until the white indicator on the catheter shaft aligned with the top of the working sleeves. Then the packaging wires were removed. The prepared VBS inflation systems were connected bilaterally, and the air bubbles were evacuated out of the catheters using visual (fluoroscopic) and manometric parameters. Criteria for stopping the balloons inflation are the fracture being reduced, the balloon violating the confines of the bone, the inflation pressure reaching 440 psi, or maximum balloon volume being reached (5ml for 15mm stent & 5.5ml for 20mm stent). The balloons were gradually deflated to maintain maximum stent expansion and removed through the working sleeves leaving the stents behind. PMMA cement (Vertecem, Synthes) corresponding to the combined volume of the inflated balloons was inserted bilaterally, using the side-opening cannulae by Synthes. Cement viscosity was measured by a viscometer (Viscosafe, Synthes) before and during the injection. Each step was performed under fluoroscopic control. The cement was inserted until it infiltrated the surrounding bone around the stent then, the cannulae were pulled back slightly but kept in until the cement hardened, and then twisted to break off any connected cement from being left in the pedicles.
Radiographic evaluation:

Standing films were used to measure kyphosis of the fracture vertebral body as the angulation between both endplates. In some patients, pre-op standing films could not be obtained due to their pain. In these cases, measurements were taken from the available supine films. Kyphotic angles were analysed from these radiographs using a special software (Centricity PACS-IW 3.7.3.3; GE Healthcare, United Kingdom). Sagittal alignment across the fractured level was calculated using the Cobb technique. Measurements were taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebral body one level below the treated vertebra. When non-adjacent levels were treated in a patient, separate Cobb angles were measured for each treated level. If adjacent level vertebral fractures were treated, a single Cobb angle measurement across the treated levels was performed. Thoracic and lumbar fractures were analysed for alterations in angles of kyphosis and lordosis, respectively. All symptomatic patients underwent magnetic resonance imaging. The fractured levels requiring augmentation showed evidence of edema on T2-weighted images and magnetic resonance imaging short TI inversion recovery sequences, hence the cause of pain. These were considered for treatment. Computed tomography scans were not done as a routine study in every patient as we thought that in most cases enough information could be obtained about the integrity of the posterior wall from the magnetic resonance imaging studies. Fluoroscopic and radiographic images were used to monitor extra-vasation from all treated vertebral levels.

Clinical outcome measurements:

Clinical outcomes were measured pre- and postoperatively using the visual analogue scale (VAS), Oswestry Disability Index (ODI) and ambulatory status (AS). All outcomes were assessed before the procedure and at 1, 12, 24, and 36 weeks after the procedure.

VAS Patients were asked to mark their pain on a scale of 0 to 10.0cm with 0.0cm being no pain at all and 10.0cm being the worst pain imaginable.

ODI The ODI is a low back pain-specific questionnaire that assesses the ability of the patient to perform various activities of daily living. The questionnaire consists of 10 categories (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, changing degree of pain, and traveling). Each category includes 6 options, ranked from 0 to 5, representing no limitation to severe limitation. The ODI score is calculated by using the following formula: Total score/(5 x number of questions answered) x 100.21 A lower percentage indicates a better health status.

Ambulatory status Ambulatory status was categorized as “fully ambulatory” for patients who could ambulate independently without assistance, “assisted ambulation” for patients who required a brace, cane, or walker to maintain mobility, and “not ambulatory” for wheelchair bound or bedridden patients.

Statistical analysis:

Statistical analysis was performed using SPSS V17.0 (SPSS Inc, Chicago, Illinois). The data for clinical scores were checked for normality and found to be not normal. Hence, we used Wilcoxon paired rank test to compare two related groups, and Friedman test was used to compare more than two related samples. A p-value of 0.001 was considered as a cut-off for statistical significance. Median and interquartile range were used as descriptive statistics.

Results

A total of 33 patients with 52 VCFs underwent cement augmentation at our hospital from April 2009 to June 2010. Two or more fractures were treated in 15 (46%) subjects. Of the 33 subjects enrolled, 3 (9%) did not complete the 9 months of follow-up. Causes for study withdrawal included 1 (3%) subjects refusing to return for follow-up clinic visits, 1 (3%) having more than subsequent medical comorbidities making them unable to comply, and 1 (3%) moved out of the area. This article reports clinical effectiveness measures for the subjects (30), who completed the 9 months follow-up. This group included 21 females and 9 males with a median age of 67 years. Of the patients, 7 (21%) had back pain lasting more than 60 days before the procedure. Of the 52 fractures treated, 2 (4%) were at the thoracic levels and 14 (27%) were at the lumbar levels. The largest concentration compression fractures was in the thoracic-lumbar spine. All patients could be mobilised within the first 48 hours after surgery. Twenty-nine patients were hospitalised for 1-3 days. Due to additional injuries, four (12%) patients stayed for a maximum of 10 days. In 22 (67%) cases, VBS was performed as an isolated procedure, whereas in 11 (33%) patients the adjacent levels above and below the treated level were reinforced with vertebroplasty or kyphoplasty during the same surgery. Indications for a combined procedure were an advanced stage of osteoporosis as well as significant overall kyphosis of the segments to be treated.
The clinical outcomes:

The median VAS scores (Fig. 2) went from 10.0 preoperatively to 6 at one week postoperatively, to 5 at 12 weeks following the procedure, and to 2 and 1 at 24 weeks and last follow-up, respectively. The pre-operative ODI score was 80 before the operation, improved to 45 at one week post-operatively, decreased to 35 at 12 weeks and to 22 and 18 at 24 weeks and last follow-up respectively. The ability to move independently and ease of ambulation significantly improved after the procedure ($p<0.001$). The proportion of patients fully ambulatory increased from 24% before surgery to 82% at 1-week postoperatively and to 95% at 9 months follow-up. The median kyphosis angle was 15.0 degrees before the procedure and decreased by a median of 4.5 degrees after the operation. 76% of patients experienced a reduction in kyphosis of more than 4 degrees (Interquartile range 8.8 degrees). In an analysis of this subgroup of patients, faster pain relief was achieved compared with patients who showed minimal to no reduction in kyphotic angle.
Complications:

There were two medical complications reported. Seven days after VBS, a pulmonary embolism was diagnosed in a patient with a history of deep vein thrombosis (no evidence of PMMA leakage to the lungs by (CT angiography). The second patient had peri-operative confusion and generalized weakness that gradually resolved (negative brain CT and neurologic workup). Evaluation of intra- and postoperative radiographs revealed extra-vertebral cement leaks in 13 (25%) of 52 vertebral fractures treated. In three cases, cement leaked into the adjacent intervertebral disc. In four cases, leakage occurred anterior to the vertebral body, and in one patient, cement leaked both into the adjacent intervertebral disc and anterior to the vertebra. All polymethylmethacrylate extravasations were asymptomatic. The cement remained in the immediate area of the treated vertebrae, and no medical or surgical intervention was required to remove the
extravasated polymethylmethacrylate (Table 1). The clinical results of the group with polymethylmethacrylate extravasation did not differ from those subjects in whom it was not observed. The overall reoccurrence rate was 3 out of 30 patients who completed the 9 months follow-up. At 24 weeks following initial fixation, one patient was treated for multilevel fractures, two of these fractures were adjacent to the initial Level. The others were remote (Fig. 3). The remaining two patients refused any further interference. At the operative level, no subsequent treatment was warranted, and no additional fractures occurred.

Table (1): Study demographics.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjects:</strong></td>
<td></td>
</tr>
<tr>
<td>Number of females</td>
<td>24</td>
</tr>
<tr>
<td>Number of males</td>
<td>9</td>
</tr>
<tr>
<td>Total number</td>
<td>33</td>
</tr>
<tr>
<td><strong>Index of fracture treated:</strong></td>
<td></td>
</tr>
<tr>
<td>One level</td>
<td>18</td>
</tr>
<tr>
<td>Two levels</td>
<td>11</td>
</tr>
<tr>
<td>Three levels</td>
<td>4</td>
</tr>
<tr>
<td>Four levels</td>
<td>0</td>
</tr>
<tr>
<td>Cement extra-vasation</td>
<td>13</td>
</tr>
<tr>
<td>Location of leaks:</td>
<td></td>
</tr>
<tr>
<td>Posterior</td>
<td>3</td>
</tr>
<tr>
<td>Anterior</td>
<td>4</td>
</tr>
<tr>
<td>Superior/inferior</td>
<td>2</td>
</tr>
<tr>
<td>Lateral</td>
<td>3</td>
</tr>
<tr>
<td>Anterior and superior</td>
<td>1</td>
</tr>
</tbody>
</table>

**Discussion**

Osteoporotic VBCFs are a major cause of back pain in the elderly. Even though only about one third of all fractures come to clinical attention, the sequelae of VCFs represent a major impact on patients’ physical function, quality of life, and survival. As our population ages, the rate of osteoporotic fractures is expected to triple over the next 30 years [22]. An ideal treatment for VBCFs should relieve fracture related pain and durably correct the kyphotic deformity of the spinal segment. In most cases, conservative measures are effective; however, one third of vertebral compression fractures become chronically painful [23,24] and percutaneous stabilization methods, such as vertebroplasty and kyphoplasty, have been developed to address these painful fractures. Vertebroplasty in its proper sense is not able to restore a kyphotic deformity; however, in fresh fractures, positioning of the patient can reduce the deformity to a certain extent and this reduction can be preserved by cementing the VB. Kyphoplasty, which was designed to address the kyphotic deformity and help to realign the spine [8,19,26]. It has been reported that kyphoplasty can improve the kyphotic angle in the range of 3.4 to 8.8° degrees. However, clinically, 34% of kyphoplasties do not result in a demonstrable reduction in kyphotic angle or restoration of vertebral body height [27]. Dudeney et al. [14] report on the treatment of VB fractures in metastatic lesions in 18 patients. They performed 55 kyphoplasty procedures. Of height loss, 34% was restored. Weisskopf et al. [18] show the experience on the treatment of 22 patients with 37VB treated. Kyphosis reduction was achieved in only 4 cases with 8.5° in average. One reason for inadequate height preservation in kyphoplasty is the loss of vertebral body height after balloon tamp deflation prior to cement injection [28,29]. This is the inherent problem related to the technique of kyphoplasty. Stenting of a VB in order to correct a deformed VB has been introduced as a practical solution to maintain the initially gained height, as well as kyphotic angular changes of the vertebrae. Moreover, the stent maintains the size of the created cavity inside the vertebra after balloon removal. However, it could not yet be established that VB height reconstruction and correction of kyphosis are clinically relevant. McKiernan et al. [30] found the quality of life significantly improved in 46 patients following vertebroplasty. Garfin et al. [8] gave an overview on the treatment of the first 340 patients treated. Six hundred three fractures were reduced and reinforced. Of patients, 90% did show a functional and symptomatic improvement. On the other hand, Markus et al. [31] found that there was no correlation between the height reconstruction in the vertebral body affected and quality of life. This finding underlines the fact that the degree of height reconstruction might not have significant influence on the quality of life after cement augmentation procedures. In our study, we found that 76% of patients experienced a reduction in kyphosis of more than 4 degrees. In an analysis of this subgroup of patients, faster pain relief was achieved compared with patients who showed minimal to no reduction in kyphotic angle. Furthermore, at last the follow-up, these patients were shown to do better in the areas of pain relief and functional capacity. To our knowledge, this is the first report of 9 months follow-up of VBS treated fractures. The clinical and radiographic results showed that the effects of VBS are immediate and dramatic, and showed no evidence of deterioration with time. Alleviation of pain, reduction in the use of pain medications, and improved mobility occurred within the first few postoperative days to weeks and remained stable.
for the entire length of study. This effect was shown by at least a 4-point decrease in the VAS pain score in 75% of patients at 1 week, 85% by 1 month, and 96% at 9 months. This result supports the earlier findings of rapid pain relief, as well as quality of life (odi score & ambulatory status). In addition, it is noteworthy that clinical outcomes were nearly identical for subjects with age of fractures of more than 60 days, suggesting that older fractures can be successfully treated with Vertebral Body Stenting. Subsequent fractures occurred in 10% of subjects by 9 months of follow-up. The majority were adjacent level fractures. The exact cause for subsequent adjacent-level VCFs following cement augmentation procedures is still not fully explained. Some investigators [32] have suggested that vertebral body augmentation may alter stiffness, leading to an increased risk of subsequent adjacent-level VCFs. However, the biomechanical basis for this theory is poorly documented. Mechanically, the response of the functional spinal unit (2 vertebral bodies with an intervening disc) to a load is driven by its least stiff component. Because the disc 33 is 5-10 times less stiff than bone, load transfer to adjacent vertebrae is related to the stiffness of the disc, not the bone. Whether cement augmentation leads to an elevated incidence of new adjacent-level fractures is the subject of ongoing discussion [29,30,32,34]. As our patient population was so small and the duration period of follow-up was relatively short, we were not able to conclude anything definite about the problem of adjacent level fractures. In our study, all polymethylmethacrylate extravasations were asymptomatic. The cement remained in the immediate area of the treated vertebrae. The last odd thing that must be discussed is that the device is not able to conclude anything definite about the exact cause for subsequent adjacent-level VCFs. However, the incidence of new adjacent-level fractures is the subject of ongoing discussion [29,30,32,34]. As our patient population was so small and the duration period of follow-up was relatively short, we were not able to conclude anything definite about the problem of adjacent level fractures. In our study, all polymethylmethacrylate extravasations were asymptomatic. The cement remained in the immediate area of the treated vertebrae. The last odd thing that must be discussed is that the device is not able to conclude anything definite about the exact cause for subsequent adjacent-level VCFs. However, the biomechanical basis for this theory is poorly documented. Mechanically, the response of the functional spinal unit (2 vertebral bodies with an intervening disc) to a load is driven by its least stiff component. Because the disc 33 is 5-10 times less stiff than bone, load transfer to adjacent vertebrae is related to the stiffness of the disc, not the bone. Whether cement augmentation leads to an elevated incidence of new adjacent-level fractures is the subject of ongoing discussion [29,30,32,34].

Key points:

- One reason for inadequate height preservation in kyphoplasty is the loss of vertebral body height after balloon tamp deflation, prior to cement augmentation. Stenting of a VB in order to correct a deformed VB has been introduced as a practical solution to maintain the initially gained height.
- This study supports VBS as a safe and effective way of improving vertebral height and improving overall sagittal alignment.
- Future studies will need to address the efficiency of VBS as a valuable alternative to balloon kyphoplasty. The ideal study should be a direct in vivo comparison between kyphoplasty and VBS.

References

14- DUDENSEY S., LIEBERMAN I.H., REINHARDT M.K. and HUSSEIN M.: Kyphoplasty in the treatment of os-
Vertebral Body Stenting


