Vesselplasty: A New Technical Approach to Treat Symptomatic Vertebral Compression Fractures

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OBJECTIVE. The objective of our study was to evaluate the effectiveness and safety of vesselplasty to treat symptomatic vertebral compression fractures (VCFs).

SUBJECTS AND METHODS. Twenty-nine patients undergoing vesselplasty at our institution between April 2006 and February 2008 were enrolled in the study. All patients had been undergoing medical therapy for one or more painful VCFs. Pain, mobility, and analgesic use scores were obtained, and restoration of vertebral body height was evaluated. A two-tailed paired Student's *t* test was used to compare differences in the mean scores for levels of pain, mobility, and analgesic use before and after the procedure and to evaluate changes in vertebral body height. We analyzed the influence of the age of the fracture and its cause in the variations in the pain, mobility, and analgesic use scores.

RESULTS. Seven of the 29 patients had fractures in more than one level, for a total of 37 procedures. The cause of the vertebral collapse was osteoporosis in 27 (73%), high-impact trauma in five (13.5%), myeloma in three (8%), and metastatic fracture in two (5.4%). The average pain score before treatment was 8.72 ± 1.25 (SD), whereas the average pain score after treatment was 3.38 ± 2.35. The average mobility score before treatment was 2.31 ± 1.94, whereas the average mobility score after treatment was 0.59 ± 1.05 ($p < 0.001$). The average analgesic use score before treatment was 3.07 ± 1.46, whereas it was 1.86 ± 1.90 after treatment ($p < 0.001$). There was no evidence of clinical complications.

CONCLUSION. Vesselplasty offers statistically significant benefits in improvements of pain, mobility, and the need for analgesia in patients with symptomatic VCFs, thus providing a safe alternative in the treatment of these fractures.

Keywords: balloon kyphoplasty, osteoporosis, spine fracture, vesselplasty, vertebral compression fracture, vertebroplasty

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Vertebral compression fractures (VCFs) are a major health care burden because of their high incidence, deleterious effects on quality of life, and high cost [1].

VCFs are caused by a combination of axial and bending loads on the spine that exceed the strength of the vertebral body. Fracture occurs as a result of either high-impact trauma on normal bone or minor trauma on a vertebral body that has been weakened by osteoporosis or an infiltrative process [2].

Osteoporosis is the most common cause of VCFs and can be primary (age-related or postmenopausal) or secondary (due to numerous diseases and medications) [3]. It is characterized by fragility fractures that most commonly occur as a result of a fall from standing height or less [4].

Tumor infiltration, primarily by metastasis or myeloma, is another important cause of VCF [5]. The increase in overall survival of oncologic patients has subsequently increased the incidence of pathologic vertebral collapse. Furthermore, because the treatment of oncologic patients requires the use of corticosteroids, secondary osteoporosis may develop and result in additional VCFs [2].

The sequelae of VCFs are diverse yet uniformly onerous: They can result in severe and prolonged pain, kyphotic angulation of the spine that can diminish forced vital capacity [6–8], and multiple comorbidities such as weight loss due to early satiety and poor psychologic well being [9–12]. The 5-year survival of a patient who sustains a VCF is lower than that of a similar patient who sustains a hip fracture [4, 10].

The conventional management of symptomatic VCFs is medical therapy, which includes analgesics, bed rest, external bracing, and rehabilitation [13, 14]. These treatments are only partially effective and do not prevent kyphotic deformity [14]. Moreover, bed

rest accelerates bone resorption and leads to an increased risk of future fractures. Surgery is generally limited to cases of spinal instability or neurologic deficit [15–17]. However, surgical fixation often fails because of the poor quality of osteoporotic bone [15]. For these reasons, physicians have become interested in new methods for pain relief and functional restoration with the goal that patients may return to their activities of daily living [4].

Vertebroplasty and balloon kyphoplasty are two minimally invasive percutaneous approaches developed for the treatment of symptomatic VCFs.

Percutaneous vertebroplasty was first performed in 1984 [18]. It is an imaging-guided procedure in which polymethylmethacrylate (PMMA) is percutaneously injected into the vertebral body with the fracture. Although not well established, the most likely mechanism for pain relief after vertebroplasty treatment appears to be mechanical stabilization of the vertebral body. In most ex vivo studies, injection of cement into the vertebral body restored its stiffness and increased its strength [2]. The main risk of this technique is leakage of PMMA into the venous system, with the possibility of pulmonary embolism, and into the spinal canal or neural foramina, precipitating neurologic disorders.

Percutaneous balloon kyphoplasty, a modification of vertebroplasty, involves inflation of a high-pressure balloon (KyphX Inflatable Bone Tamps, Kyphon) within the collapsed vertebral body followed by percutaneous injection of bone cement into the cavity created by the balloon [19]. This procedure was devised and first performed in 1998 [20, 21]. The risk of cement extravasation is reduced with balloon kyphoplasty because of the lower-pressure injection of high-viscosity cement into a previously formed cavity [22], with new bone margins created by the compressed trabeculae.

Vesselplasty is a new intriguing alternative to vertebroplasty and kyphoplasty. It was devised to obtain control of the volume of void created in the vertebral body, prevent the leakage of bone filler material, and restore vertebral body height. Designed by Jerry Lin, the chairman of A-Spine Holding Group Corporation (Taipei, Taiwan), vesselplasty was first performed in 2004 by Darwono (Darwono B, presented at the 2004 Triennial Asia Pacific Orthopedic meeting, Kuala Lumpur, Malaysia). Instead of using a balloon to create a cavity, vesselplasty uses a polyethylene terephthalate (PET) balloon container (Vessel-X, A-Spine Holding Group Corporation) to restore the height of the vertebral body. This receptacle serves as both a vertebral body expander and a bone cement container. It is introduced into the vertebra in its reduced configuration and, once positioned within the vertebra, is expanded by the injection of PMMA. Then, owing to the porous structure comprising the fibers of the PET vessel, a small amount of bone cement permeates through its wall and interdigitates within the vertebral body to increase its stability. Theoretically, this technique solves the problem of leakage of cement from the vertebral body because most of the cement is contained by the expandable artificial vessel, providing a safe method to treat VCFs.

This study was designed to evaluate the effectiveness and safety of vesselplasty to treat symptomatic VCFs.

Subjects and Methods

Patient Selection

All patients undergoing vesselplasty at our institution between April 2006 and February 2008 were enrolled in the study after informed consent from patients and approval from the institutional review board were obtained. All patients had one or more painful VCFs currently being treated with medical therapy—that is, bed rest, analgesics and muscle relaxant medication, external braces, or a combination of these therapies. Our disqualifying criteria were the following: pain thought to be due to a herniated disk or disks, spinal stenosis, or other spine abnormality not associated with the fracture; fractures responsive to medical therapy; VCF with a retropulsed bone fragment resulting in myelopathy; existence of an uncorrectable coagulopathy; and the presence of any systemic or spinal infection. None of our patients presented with a condition excluding them from treatment.

The following causes of VCFs were included in our study cohort: osteoporosis (primary or secondary), multiple myeloma, metastatic disease, and high-impact trauma. All the patients with osteoporosis had a positive diagnosis based on standard criteria with dual-energy x-ray absorptiometry.

All patients had imaging evidence of a VCF or VCFs on radiography, CT, or MRI and pain localized to the fracture level or levels. The time from fracture to vesselplasty was categorized as acute, 0–15 days; subacute, 16–60 days; or chronic, 61 days or more. The procedure was performed in acute fractures and in only those subacute and chronic fractures exhibiting edema on MRI, as assessed on sagittal spin-echo T1 and STIR images.

Procedure

Vesselplasty procedures were performed at our institution using the Vessel-X Bone Filling Container System (A-Spine Holding Group Corporation) with CE mark (certifying product has met European Union consumer requirements) and current good manufacturing practice approval. The system consists of the following items (Fig. 1): bone access needle (10-gauge), composed of a cannula tube and stylet, used for initial access into the vertebra; precision drill, used to create a working channel; controllable cement delivery system with an extension tube, available to

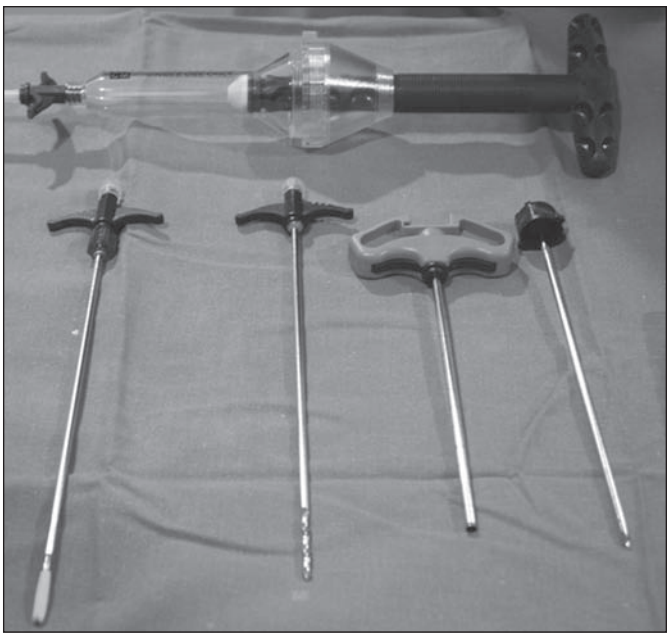


Fig. 1—Photograph shows Vessel-X Bone Filling Container System (A-Spine Holding Group Corporation). From right to left: stylet, cannula tube, precision drill, and Vessel-X bone filling container; Vessel-X introducer and pushing rod are inside bone filling container. Controllable cement delivery device is on top.

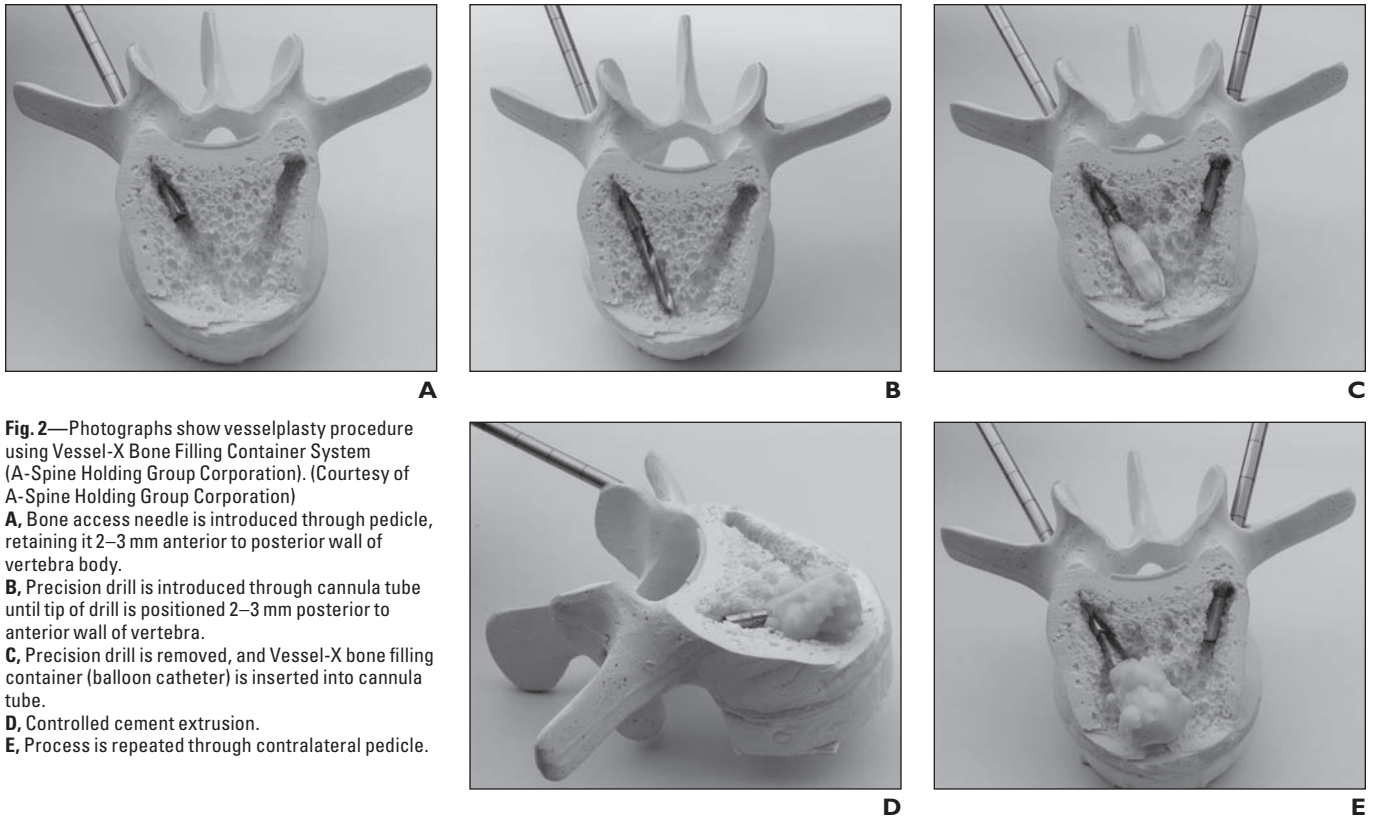


Fig. 2—Photographs show vesselplasty procedure using Vessel-X Bone Filling Container System (A-Spine Holding Group Corporation). (Courtesy of A-Spine Holding Group Corporation)
A, Bone access needle is introduced through pedicle, retaining it 2–3 mm anterior to posterior wall of vertebra body.
B, Precision drill is introduced through cannula tube until tip of drill is positioned 2–3 mm posterior to anterior wall of vertebra.
C, Precision drill is removed, and Vessel-X bone filling container (balloon catheter) is inserted into cannula tube.
D, Controlled cement extrusion.
E, Process is repeated through contralateral pedicle.

deliver the high-viscosity cement; and Vessel-X bone filling container. The last item comprised a Vessel-X introducer (with a bone filling container, the PET container) and a pushing rod. The Vessel-X introducer, available in two diameters (20 or 25 mm) depending on vertebral body size, is used for the injection and containment of bone cement within the created void. The pushing rod serves as a fluoroscopic reference of the tip of the vessel and gives stability to the PET container during introduction in the vertebral body; it also avoids the leakage through the cannula and introducer throughout the cement injection.

The bone cement used was Opacity Plus (Teknimed), which is PMMA mixed with barium sulfate to increase its imaging opacity.

The procedures were performed in a consistent manner (Fig. 2). Each patient was placed in the prone position on an angiography table (Allura Xper, Philips Healthcare) for the procedure, which we describe in eight steps.

First, the fractured vertebral body was localized under fluoroscopic control in both the anteroposterior and lateral planes. The pedicle was isolated on the lateral plane for positioning in the craniocaudal plane and anteroposterior oblique plane for a lateral to medial approach.

Second, conscious sedation (IV fentanyl and midazolam) and local anesthetic in the skin over the pedicle (0.25% bupivacaine) were administered to the patient. A small skin incision was made, and the bone access needle (10-gauge needle with an inner stylet) was advanced into the fractured vertebral body creating a path through the pedicle (Fig. 2A). The bone access needle was halted 2–3 mm anterior to the posterior wall of the vertebral body. This transpedicular approach, which was either uni- or bipedicular, was empirically chosen to avoid the risk of leakage outside the vertebral body throughout the needle tract. Although a unipedicular approach does require a more oblique route, it was used because correct expansion of the vertebral body can be achieved with the placement of the needle tip in a middle position. Due to technical characteristics of the equipment used, a left transpedicular approach was selected (Fig. 3).

An alternative approach is the parapedicular route, which is most often used to access the thoracic spine. The parapedicular route involves inserting the needle between the lateral margin of the pedicle and the head of the rib.

Third, the stylet was then removed, leaving the cannula tube in the vertebral body.

Fourth, the precision drill was introduced into the vertebral body through the cannula tube forging a path through the pedicle until the tip of the drill was 2–3 mm posterior to the anterior wall of the vertebra (Fig. 2B).

Fifth, the precision drill was removed.

Sixth, the Vessel-X bone filling container was next inserted into the cannula tube and the introducer sheath was firmly pushed, lodging it 2–3 mm posterior to the anterior wall (Fig. 2C).

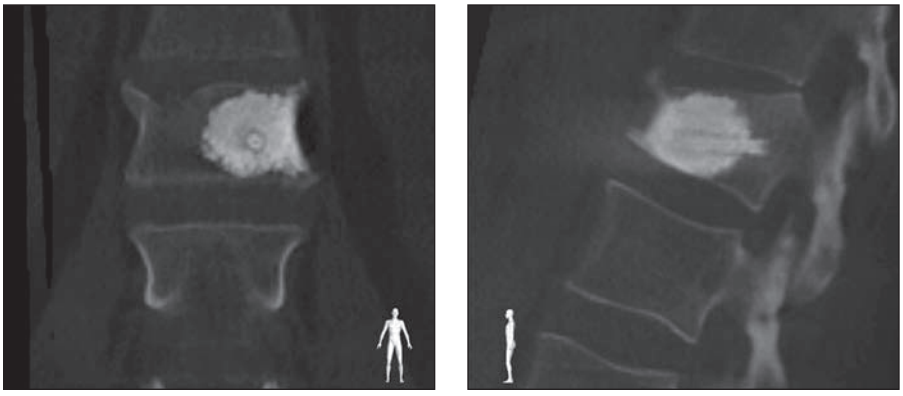
Seventh, the cement delivery system was connected, and the bone cement was progressively filled in (Figs. 2D and 4). Injection of PMMA was performed under fluoroscopic guidance and continued until maximal expansion of the PET vessel (20 or 25 mm) was achieved, no more material could be injected, or extravasation was noted.

Eighth, the Vessel-X introducer and the pushing rod were then removed, followed by the cannula tube. Once these elements had been removed, the posterior opening of the PET container was mostly sealed because of the cement's short solidification time.

At the end of the procedure, IV methylprednisolone (1 mg/kg) was administered empirically to all patients to reduce the local inflammatory response associated with the procedure. After a 24-hour hospital stay, all patients were examined by an interventional radiologist before discharge from the hospital.

Data Collection

Between April 2006 and February 2008, 37 vesselplasty procedures were performed in the 29 patients included in the study. Before the procedure, institutional review board approval and patient informed consent were obtained.



A B

Fig. 3—43-year-old woman with traumatic vertebral compression fracture.
A and **B,** Coronal (**A**) and sagittal (**B**) images obtained after 180° C-arm rotation show vesselplasty being performed transpedicularly with left unilateral approach.

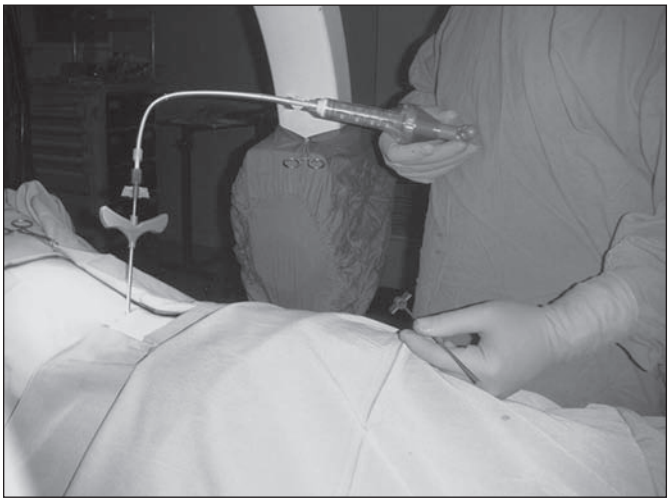


Fig. 4—Photograph shows bone cement being injected into vertebral body of patient with vertebral compression fracture. Precision drill has been removed and is being held in operator's left hand. Cement delivery system is connected to Vessel-X Bone Filler Container (A-Spine Holding Group Corporation).

The clinical characteristics of each patient (age, sex, cause of VCF or VCFs, and level and age of the fracture or fractures) and key technical details of the procedure (transpedicular vs parapedicular approach, unipedicular or bipedicular route) were collected.

Complications of the procedure including pulmonary embolism, spinal or neural compression by cement, infection, bleeding, and rib fractures were collected through patient interviews.

Pain, mobility, and analgesic use scores were obtained during telephone calls and clinic visits; visits were the day of the procedure and 3 months after treatment.

Pain was characterized using a scale, a verbal version of the visual analog scale, from 0 to 10: 0, none; and 10, the worst pain that the patient could consider in his or her life.

Mobility was described using a scale from 0 to 5: 0, full activity; 1, walking with assistance; 2, walking with assistance for only short periods; 3, walking with assistance for activities of daily living; 4, wheelchair-bound; and 5, bedridden.

Analgesic use was characterized on a scale from 0 to 5: 0, none; 1, nonsteroidal antiinflammatory drugs; 2, prescription nonnarcotics; 3, oral narcotic as needed; 4, scheduled oral narcotic; and 5, parenteral narcotics.

Fracture reduction was evaluated according to the change in the vertical height of the treated vertebral body. Digital images obtained by the same diagnostic technique (radiography, fluoroscopic spot, CT, or MRI) before and after the procedure were selected. The radiographs and fluoroscopic images obtained before and after the procedure were used for measurements. Digital calipers were used to measure vertical height (in millimeters) in the anterior, mid, and posterior portions of the vertebral body. Differences within 1 mm were considered unchanged.

Statistical Analysis

Descriptive statistics were calculated for each questionnaire item: scales of pain, mobility, and analgesic use.

Normal distribution of the quantitative data were assessed by the Kolmogorov-Smirnov test. All variables showed a normal distribution.

Differences in the mean levels of pain, mobility, and analgesic use before and after the procedure were compared with a two-tailed paired Student's *t* test. The paired Student's *t* test was also used to evaluate changes in vertebral body height.

Subgroups according to the age and cause of the fracture were analyzed. The one-way analysis of variance test was used to analyze the influence of the age of the fracture in variations in the pain, mobility, and analgesic use scores, expressed as [(final value – initial value) / initial value] and formulated as a percentage. To analyze the influence of the cause of the fracture, two groups were constructed: those with benign (osteoporotic and traumatic) versus malignant (metastatic and myeloma) causes; and the unpaired Student's *t* test was again used.

A p value of < 0.05 was considered significant.

Results

All patients met the established criteria for suitability for vesselplasty. Of the 29 patients enrolled in the study, seven patients had fractures in more than one level, necessitating a total of 37 procedures.

The average age of the patients was 69 ± 12 years (range, 36–85 years); 65.5% (19/29) were women and 34.5% (10/29) were men. The cause of vertebral collapse was osteoporosis in 27 (73%) of the treated vertebrae: It was primary osteoporosis in 20 cases (74%) and secondary to steroid use in seven (26%). Other causes of VCF were high-impact trauma in five VCFs (13.5%), myeloma in three (8%), and metastatic fracture in two (5.4%). The time between the fracture and vesselplasty ranged between 2 and 240 days, with a mean of 75 ± 64 days (Table 1).

The VCFs treated in our study extended from T6 to L5 (Fig. 5). L1 (n = 8), T12 (n = 7), L2 (n = 5), and L3 (n = 5) were the most commonly fractured vertebral levels (67.6%).

Of the 29 patients, 22 (76%) were treated for one vertebral fracture, whereas six (21%) underwent treatment of fractures of two vertebral levels, four (14%) simultaneously at the same session and two (7%) on different days. In the one remaining patient (2.7%), three fractures were treated at the same session. The transpedicular approach was used in 35 (94.6%) of the cases and the parapedicular in two (5.4%). The route was unipedicular in 26 (70%) (left, n = 23; right, n = 3) and bipedicular in 11 (30%).

There was no evidence of clinical complications and only one technical complication

TABLE 1: Clinical Characteristics of the 29 Patients With a Vertebral Compression Fracture or Fractures in the Study Cohort

Characteristic	No. (%)
Age (y) (*n* = 29 patients)	
35–45	2 (6.9)
46–55	3 (10.3)
56–65	2 (6.9)
66–75	12 (41.4)
76–85	10 (34.5)
Sex (*n* = 29 patients)	
Male	10 (34.5)
Female	19 (65.5)
No. of fractures (*n* = 29 patients)	
1	22 (76)
2 or 3	7 (24)
Cause of fracture (*n* = 37 fractures)	
Primary osteoporosis	20 (54.1)
Secondary osteoporosis	7 (18.9)
High-impact trauma	5 (13.5)
Myeloma	3 (8.1)
Metastasis	2 (5.4)
Time from fracture to vesselplasty (*n* = 23 patients)[a]	
Acute (0–15 days)	2 (8.7)
Subacute (16–60 days)	9 (39.1)
Early chronic (61–365 days)	12 (52.2)
Late chronic (> 365 days)	0 (0)

Note—Data are expressed as number of patients with the only exception of cause of fracture which refer to treated vertebrae.
[a]The age of the fracture or fractures was unknown in six patients.

(2.7%), a small intradiskal leakage in a case of vertebral endplate comminuted fracture with marked vertebral height loss, without clinical repercussion.

The pretreatment pain score was 8.72 ± 1.25 (mean ± SD), whereas the posttreatment pain score was 3.38 ± 2.35. These differences are statistically significant ($p < 0.001$). The postprocedure pain score was less than the pretreatment pain score in all patients, with a decrease of 5.3 ± 2.4 points (range, 2–10 points).

The pretreatment mobility score was 2.31 ± 1.94, whereas the posttreatment score was 0.59 ± 1.05 ($p < 0.001$). Ninety-three percent (27/29) of patients had an improved mobility score, with a decrease of 1.7 ± 1.6 points (range, 0–4 points).

The pretreatment analgesic use score was 3.07 ± 1.46; the posttreatment score decreased to 1.86 ± 1.90 ($p < 0.001$). Sixty-two percent (18/29) of patients had an improved analgesic score, with a decrease of 1.2 ± 1.3 points (range, 0–4 points) (Table 2 and Fig. 6).

The benefit of vesselplasty was analyzed according to the age of the fracture (time from fracture to vesselplasty) and the cause of the fracture (benign vs malignant) (Table 3). The differences in the improvement of each of the scales among the fracture age subgroups were not statistically significant ($p > 0.05$). Patients with a malignant cause of VCF (myeloma or metastasis) experienced worse clinical outcome with less improvement in pain score and no improvement in mobility and medication requirement than patients with a benign cause of VCF ($p < 0.05$).

Vertebral body height increased in six of the 37 treated VCFs: Four experienced a minimal height gain (1–3 mm), whereas two increased more than 3 mm. The average increase in the vertebral body was 0.47 mm (range, 0–8 mm). The average pretreatment anterior vertebral body height was 24.2 ± 5.8 mm (mean ± SD) and increased to 24.6 ± 6.0 mm after the procedure ($p = 0.03$). The average central vertebral body height before the procedure was 24.6 ± 5.4 mm and rose to 25.2 ± 5.8 mm after the procedure ($p = 0.042$). The average posterior vertebral body height was 29.0 ± 4.7 mm before the procedure and enlarged to 29.5 ± 4.8 mm after the procedure ($p = 0.044$).

The average increase in the anterior vertebral body height was 0.44 ± 1.2 mm (range, 0–6 mm); in central body height, 0.53 ± 1.5 mm (0–8 mm); and in posterior portion height, 0.44 ± 1.2 mm (0–5 mm). There was no significant difference in the height increase of each portion of the vertebral body.

There was no difference in the percentage height increase between the anterior and central portions of the vertebral body ($p = 0.249$), between the anterior and posterior portions ($p = 0.77$), or the central and posterior sections ($p = 0.5$). The anterior portion increased in six of the 37 treated VCFs, with an increase of 10.74% ± 8.2% (mean ± SD) (range, 6.25–27.27%). The central portion also increased in six of the 37 treated VCFs, with an increase of 12.62% ± 11.7% (6.67–36.36%). The posterior portion increased in five of the 37 treated VCFs, with an increase of 11.54% ± 5.8% (4.17–19.23%) (Fig. 7).

Discussion

VCFs often cause severe, disabling pain and progressive deformity of the spine. Vesselplasty is a new, appealing treatment technique and an alternative to conventional medical treatment. Two other minimally invasive percutaneous approaches have been developed for the management of symptomatic VCFs: classic percutaneous vertebroplasty

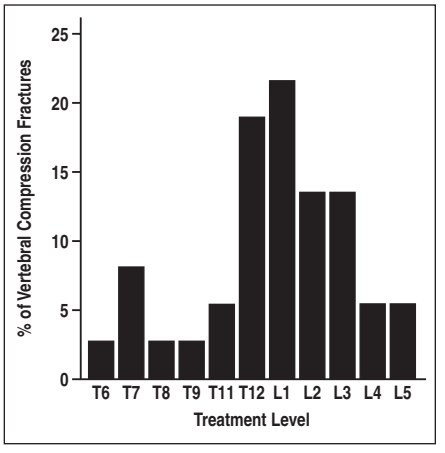


Fig. 5—Bar graph shows distribution of vertebral compression fractures by treatment level.

TABLE 2: Functional Status and Quality of Life Before and After Vesselplasty in 29 Patients With a Vertebral Compression Fracture or Fractures

Functional Status and Quality-of-Life Indicators	No. (%) of Patients (n = 29)	
	Before Vesselplasty	After Vesselplasty
Pain		
None	0 (0)	5 (17.2)
1–2	0 (0)	5 (17.2)
3–4	0 (0)	10 (34.5)
5–6	1 (3.4)	5 (17.2)
7–8	11 (37.9)	4 (13.8)
9–10	17 (58.6)	0 (0)
Mean score ± SD	8.72 ± 1.25	3.38 ± 2.35[a]
Mobility		
Full activity = 0	6 (20.7)	21 (72.4)
Walking with assistance = 1	9 (31.0)	2 (6.9)
Walking with assistance for short periods = 2	0 (0)	3 (10.3)
Walking with assistance for activities of daily living = 3	5 (17.2)	3 (10.3)
Wheelchair = 4	2 (6.9)	0 (0)
Bedridden = 5	7 (24.1)	0 (0)
Mean score ± SD	2.31 ± 1.94	0.59 ± 1.05[a]
Analgesic use		
None = 0	0 (0)	10 (34.5)
Nonsteroidal antiinflammatory drugs = 1	7 (24.1)	6 (20.7)
Prescription nonnarcotics = 2	4 (13.8)	4 (13.8)
Oral narcotic as needed = 3	2 (6.9)	0 (0)
Oral narcotic scheduled = 4	12 (41.4)	5 (17.2)
Parenteral narcotics = 5	4 (13.8)	4 (13.8)
Mean score ± SD	3.07 ± 1.46	1.86 ± 1.90[a]

[a] $p < 0.001$ compared with before vesselplasty.

and balloon kyphoplasty. Our study evaluated the effectiveness of vesselplasty for treating patients with symptomatic VCFs. To our knowledge, this study is the first of its kind about this procedure.

Because primary osteoporosis was the dominant cause of the treated VCFs in our study group, 70% of the patients in our study were older than 65 years and 65.5% were women.

Because of concern about its risk–benefit ratio, vertebroplasty has traditionally been reserved for treatment of patients in whom a course of conservative treatment has failed [23] and is generally performed 6–12 weeks after the onset of pain. This time frame has been used because the natural history of osteoporotic compression fractures has been described to result in spontaneous resolution of pain within 4–6 weeks in a substantial percentage of patients [24, 25].

Recently, clinicians have begun to offer early minimally invasive treatment of VCF. This change in practice is due to greater experience with these procedures, generally positive patient outcomes, and the attempt to avoid the use of potent analgesics and immobilization in elderly patients. Also of note, patients with chronic fractures may develop a chemical dependency, which could explain the continued requirement of medication after the procedure [26].

Acute, subacute, and early chronic fractures were treated in our study. Although we did not find a statistically significant relationship between early treatment and improved patient outcomes as measured by

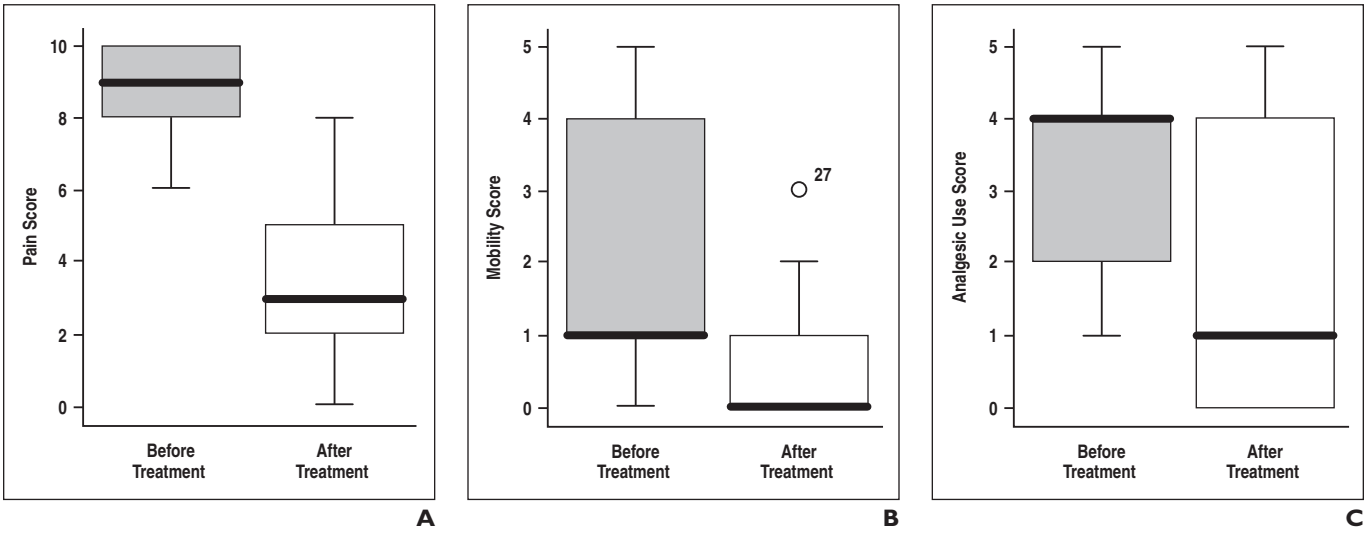


Fig. 6—Treatment outcomes for 29 patients in study cohort.
A–C, Box plots compare pain (**A**), mobility (**B**), and analgesic use (**C**) scores before and after vesselplasty. Whiskers indicate smallest and largest non-outlier observations; thin black lines, lower and upper quartiles; thick black line, median; and circle in **B**, outlier value in patient 27.

TABLE 3: Improvement in Pain, Mobility, and Analgesic Use After Vesselplasty Among Subgroups With a Vertebral Compression Fracture (VCF) or Fractures

Subgroup	No. of Patients	Improvement in Scores[a]		
		Pain	Mobility	Analgesic Use
Time from fracture to vesselplasty[b]				
Acute (0–15 days)	2	87.5 ± 17.6	50 ± 70.7	100
Subacute (16–60 days)	9	56.3 ± 25.6	63 ± 41.7	38.9 ± 41.6
Early chronic (61–365 days)	12	60.6 ± 28.1	65.8 ± 44.8	43.7 ± 42.8
p		0.345	0.901	0.181
Cause of VCF				
Benign[c]	25	65.1 ± 0.2	72.7 ± 0.4	57 ± 0.4
Malignant[d]	4	37.1 ± 0.1	0	0
p		0.044	0.001	0.012

[a]Improvement in the scores is expressed as follows: [(final value – initial value) / initial value] (%). Values are given as mean ± SD.
[b]The age of the fracture or fractures was unknown in six patients.
[c]Osteoporotic and traumatic VCF.
[d]Metastasis and myeloma.

pain relief, mobility, and need for analgesia, the results of our study do reveal greater improvements in pain and analgesic use in patients with acute fractures. These findings support the trend to offer early intervention to these patients.

Our study found that T12, L1, L2, and L3 were the most commonly fractured levels. This observation is consistent with previous epidemiologic studies that have evaluated the incidence and clinical profile of osteoporotic VCFs [25].

In most of the procedures reported in this work, the transpedicular with left unipedicular approach was used. The transpedicular approach is intended to avoid the risk related to leakage of cement along the needle because of the relative safety of positioning the needle within the bone—specifically, in the pedicle—throughout the procedure and during removal. Only for the treatment of one thoracic vertebra was the parapedicular approach used; in fact, even several lower thoracic vertebrae (T11–T12) were treated with the transpedicular approach. In most cases, vertebral bodies were adequately treated with the unipedicular approach without the need for a second needle placement, reducing the total procedure time.

The absence of symptomatic complications in our study population attests to the safety of the vesselplasty procedure. Only one case (1/37, 2.7%) of intradiskal leakage occurred, without clinical repercussion. To our knowledge, this new technique has not been reported in the literature, so there are no studies with which to compare our results. The reported rate of symptomatic complications for vertebroplasty as a treatment of osteoporotic compression fractures is less

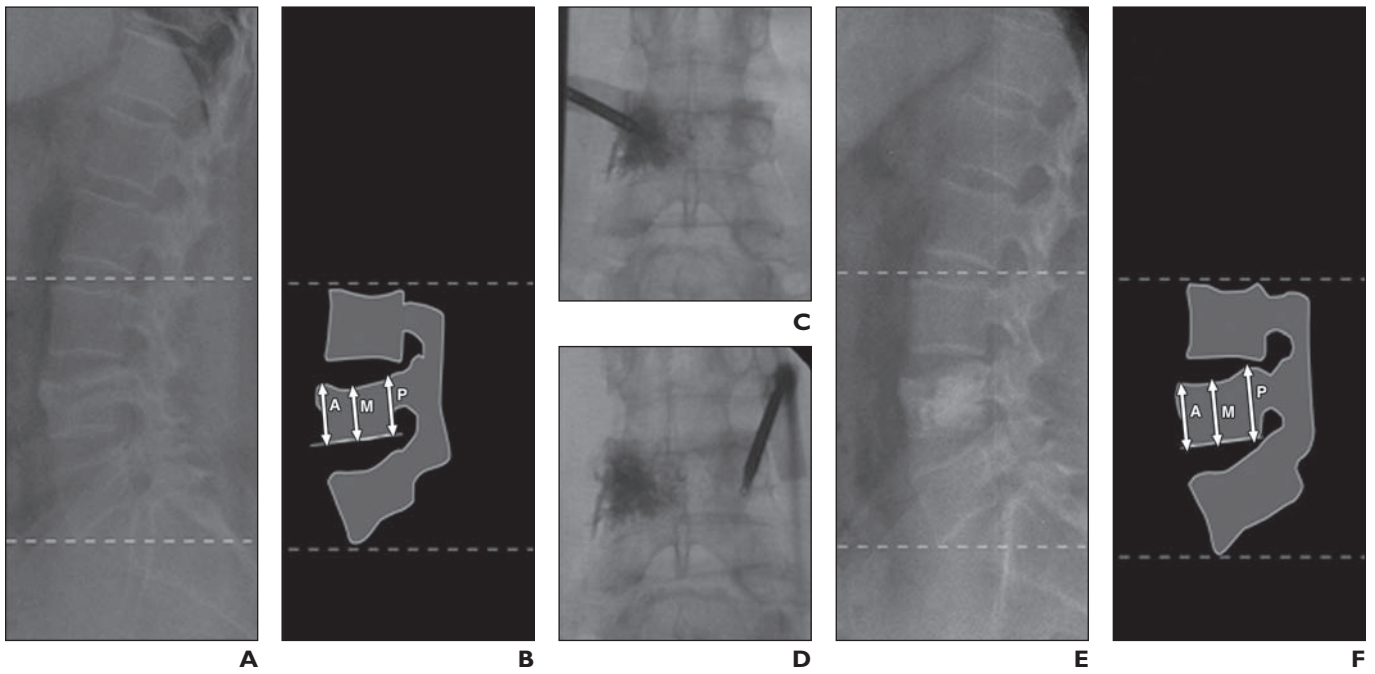


Fig. 7—55-year-old man with corticoid-induced osteoporosis and lower back pain. Vesselplasty with transpedicular and bilateral approach was performed.
A, Lateral radiograph of lumbar spine shows L4 vertebral compression fracture.
B, Schematic drawing of preoperative measurements of anterior (A), medial (M), and posterior (P) vertebral body heights.
C and **D,** Vesselplasty was performed using right transpedicular approach (**C**) and left transpedicular approach (**D**).
E, Lateral radiograph shows final result.
F, Schematic drawing of postoperative measurements of anterior (A), medial (M), and posterior (P) vertebral body heights. Increments of 2 mm in A, 3 mm in M, and 5 mm in P were observed.

than 6% [27, 28], consisting mostly of minor complications such as rib fractures and temporary radicular pain. Major complications such as permanent neurologic injury or serious pulmonary embolism occur in fewer than 1% of cases [28, 29].

Little has been published regarding the complications of kyphoplasty: Majd et al. [30] described 13 complications in 254 (5.1%) procedures. Extravasation of cement outside the vertebral body as a consequence of vertebroplasty or kyphoplasty has, however, received great attention. It is reported in 3–70% of vertebroplasties, but in only 3–27% of patients who underwent vertebroplasty for treatment of osteoporotic VCFs [28]. The incidence of cement extrusion with kyphoplasty is 8.6–33% [28, 31]. The rate of cement extrusion with kyphoplasty has been postulated to have decreased because of the greater viscosity of the cement and the use of a preformed cavity that necessitates a lower-pressure injection [28]. Vesselplasty adds to this advantage by controlling cement extrusion through the utilization of the PET artificial vessel.

Pain, mobility, and analgesic use scores improved significantly after vesselplasty ($p < 0.001$). The pain score improved in all patients, the mobility score in 93%, and the analgesic use score in 62%. A beneficial effect was observed for acute, subacute, and chronic fractures. Patients with malignant (from myeloma or metastatic disease) VCFs experienced less pain relief and worse clinical outcomes, showing no improvement in mobility or medication requirement. Because of the low number of recruited patients in this neoplastic subgroup, the clinical guidelines in cases of malignant VCF need further investigation to clearly show whether vesselplasty has a clinical therapeutic role in the treatment of these patients.

Radiologically, vertebral height restoration was observed in six of the 37 treated vertebrae, remaining unchanged in the others. In the cases in which an increase was achieved, the change was noted throughout the whole vertebral body. Minimal augmentation in height was achieved in our study (mean, 0.47 mm), and height in most of the vertebral bodies remained unchanged. Nevertheless, the clinical significance of increasing vertebral body height is unknown, and pain relief can certainly be achieved with procedures such as vertebroplasty [32] and kyphoplasty [33] in the absence of significant height restoration. McKiernan et al. [34] found no association between pain relief and height restoration. These findings could be extrapolated to vesselplasty.

The main limitations of our study were the low number of patients and the short follow-up period. Therefore, this study is intended to be a preliminary trial of this new technique. Without a comparison group, we are unable to quantify the relative benefit of vesselplasty compared with that which might be expected with medical treatment alone or with vertebroplasty or kyphoplasty. Our study results indicate the need for a prospective, treatment-randomized, controlled study with a larger number of patients and long-term follow-up.

In conclusion, the results of our study prove that vesselplasty offers statistically significant benefits in the improvement of pain, mobility, and analgesic use in patients with symptomatic VCFs. Vesselplasty provides a safe alternative in the treatment of these fractures. This improvement is independent of the age of the fracture. However, patients with malignant (from myeloma or metastatic disease) VCFs had no significant improvement in mobility and analgesic use; they had a decrease in only the pain score. In general, a minimal increase in vertebral body height was obtained in our study, although most cases remained unchanged.

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