

# PERCUTANEOUS VERTEBROPLASTY

## A comparison between the procedure using the traditional and the new side-opening cannula for osteoporotic vertebral fracture

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**Abstract** – A total of 47 percutaneous vertebroplasties (PVs) were performed for osteoporotic vertebral fractures in 31 patients, 25 PVs were performed using the frontal-opening cannula (FOC) and 22 using the new side-opening cannula (SOC), randomly distributed. The incidence of cement extrusion was 27% with the SOC, and 68% with the FOC, all asymptomatic ( $p < 0.01$ ). The pain control was similar for both groups, with good improvement of pain in most of the patients, and there were no clinical relevant complications. The cement leakage can be significantly reduced with this new SOC, which allows for a better cement injection toward the center of the vertebral body, increasing the safety of the procedure, with no increase in cost.

KEY WORDS: percutaneous vertebroplasty, osteoporotic vertebral fractures, cannula.

### Vertebroplastia percutânea: uma comparação entre o procedimento usando a cânula tradicional e a nova cânula de orifício lateral para fratura vertebral osteoporótica

**Resumo** – Um total de 47 vertebroplastias percutâneas (VP) foram realizadas para fraturas vertebrais osteoporóticas em 31 pacientes, 25 VP foram realizadas usando-se a cânula de orifício frontal (COF) e 22 com a nova cânula de orifício lateral (COL), distribuídos randomicamente. A incidência de extrusão de cimento ortopédico ocorreu em 27% com a COL, e 68% com a COF, todas assintomáticas ( $p < 0,01$ ). O controle da dor foi similar em ambos os grupos, com boa melhora da dor na maioria dos pacientes, sem complicações clínicas relevantes. A extrusão do cimento pode ser significativamente reduzida com esta nova COL, que permite uma melhor injeção do cimento para o centro do corpo vertebral, aumentando a segurança do procedimento, sem aumento no seu custo.

PALAVRAS-CHAVE: vertebroplastia percutânea, fratura vertebral osteoporótica, cânula.

Percutaneous vertebroplasty (PV) is a minimally invasive technique that helps to stabilize an osteoporotic fractured vertebra, which afflicts millions of people worldwide<sup>1-7</sup>. The PV decreases the pain and improves activities of the patients, and has proved to be a very effective treatment for osteoporotic vertebral fracture (OVF), and early clinical improvement has been demonstrated with this procedure in 80 to 90% of cases<sup>8-11</sup>. Percutaneous vertebroplasty was developed in 1984 and first described by Deramond et al.<sup>12</sup> in 1987. PV entails injection of polymethyl methacrylate (PMMA) cement into the collapsed vertebra, reinforcing and stabilizing the fracture which seems to alleviate pain<sup>8-10</sup>.

As with any other invasive procedure, PV can cause

complications. These complications include those related to needle insertion and those associated to cement leakage, either locally or distally. The cement may leak laterally to the soft tissues in the lateral aspect of the vertebra, into the adjacent disc space, and posteriorly, where it may involve the exiting nerve root or the spinal canal, that may lead to neurologic complications needing urgent surgical intervention<sup>13-15</sup>. Cement leakage during vertebroplasty is a common occurrence, at frequencies of 11–73% for OVF, the majority of which is asymptomatic. The risk of cement leakage is a major concern with the use of percutaneous vertebroplasty. Its occurrence is affected by the viscosity of the cement, the anatomic peculiarities at the injection site, and the cannula placement<sup>16-18</sup>.

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With the traditional front-opening cannula (FOC) the cement flow is directed anteriorly, toward the periphery of the vertebral body, increasing the risk of cement leakage into adjacent veins and subsequent embolization. Directing the cement flow medially with the use of a new side-opening cannula (SOC), as described by Heini and Allred in 2002,<sup>19</sup> may reduce the likelihood of this problem and contribute to the safety of the technique.

The senior author initiated vertebroplasty in 2001, and published his initial series in 2003<sup>11</sup>. The technique was very efficient, with 90.9% of great improvement of pain, with no clinical complications. The main objective of this prospective study was to compare the risk of cement extravasation with PV for OVF, using the FOC and the new SOC.

**METHOD**

**Patients**

Between March 2001 and February 2008, 68 PVs were studied in 43 patients with OVFs. A total of 47 PVs in 31 patients were

included, between 2003 and 2008, following the specific protocol for this study. Twenty eight of the patients were female and 3 were male, with ages varying from 48 to 91 years.

A prospective, controlled and randomized study was performed comparing the PVs, being randomly distributed 22 PVs to the experimental group, using the SOC, and 25 PVs to the control group, using the FOC (Table).

Informed consent was obtained from all patients before they participated in the study, and they were distributed in randomized manner. Institutional and National review board approval was also previously obtained. All selected patients had painful OVF from T4 to L5, who did not responded to the clinical therapy for at least one month, and had the proper radiologic assessment, including magnetic resonance imaging (MRI). The experimental device is not approved in the United States.

The authors obtained and analyzed sociodemographic, radiologic, procedural, and clinical data on all patients. The clinical result of the procedure was measured using the visual analog scale (VAS) for pain<sup>20</sup> (Fig 1).

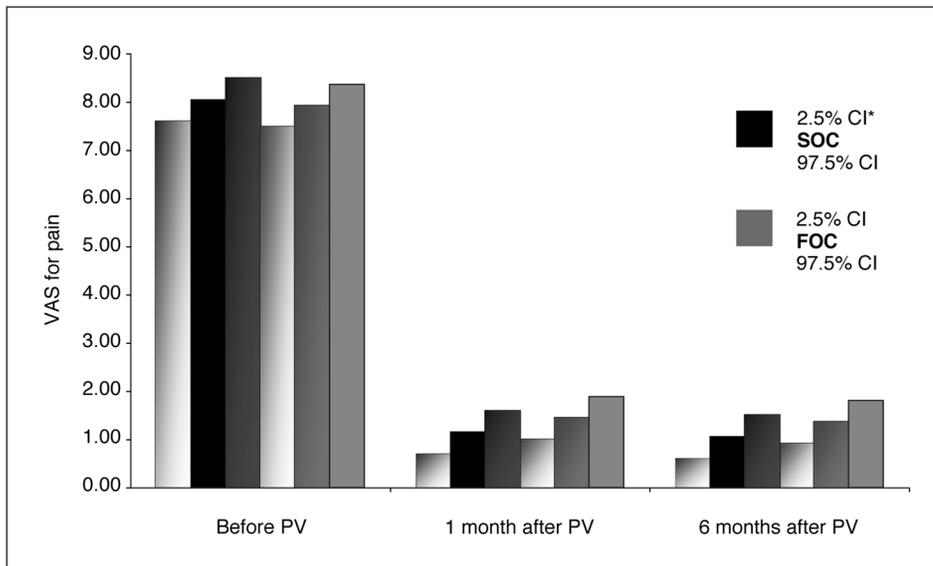


Fig 1. Graph comparing the visual analog scale (VAS) for pain before and after 1 month and 6 months post percutaneous vertebroplasty (PV) using the side and the front-opening cannula. SOC=side-opening cannula; FOC=front-opening cannula;  $p>0.05$  before and at 1 month post PV;  $p<0.05$  at 6 months post PV; \*Confidence interval.

Table. Cement leakage with side and front-opening cannula for percutaneous vertebroplasty (PV).

Cannula for PV	Cement leaks		Total
	Yes (N=23)	No (N=25)	
Side-opening cannula (SOC)	27% (6)*	73% (16)	100% (22)
Front-opening cannula (FOC)	68% (17)*	32% (8)	100% (25)
Relative risk (RR)	2,27*		
	CI=1.27 to 4.04 <sup>†</sup>		

\* $p<0.01$ ; \*\*The RR of cement extrusion is 2.27 lower with the SOC compared to the FOC; <sup>†</sup>Confidence Interval (CI)=1.27 to 4.04.

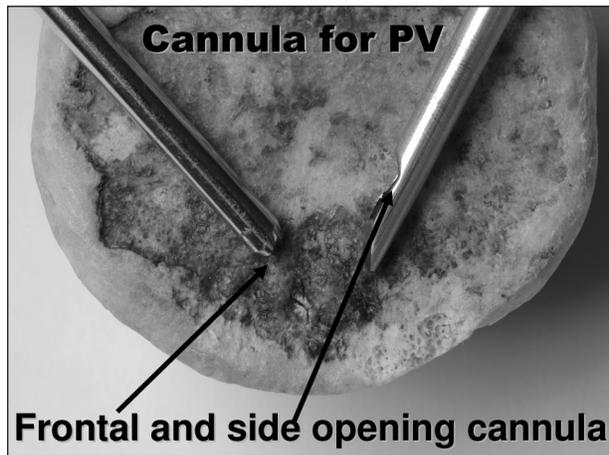


Fig 2. Lumbar vertebrae of cadaver showing the standard frontal (left) and the new side-opening (right) cannulas for percutaneous vertebroplasty.

#### Operative procedure

They were submitted to the PV by the same team, at the Hemodynamic Unit of the senior author's institution, under local anesthesia and conscious sedation. The patients were in prone position, in slight hyperextension with pillows inserted under the chest and pelvis to achieve some fracture reduction, using the standard transpedicular technique, as reported previously<sup>71</sup>, guided by fluoroscopy, uni or bipedicularly, according to the distribution of cement. A postprocedural radiography (including chest and spine X-ray), and computed tomography (CT) of the PV level was performed in all cases to scan for the presence or not of cement leaks.

#### Cannulas and bone cement

Two kinds of disposable 11 or 13-gauge, 10 or 15 cm long bone marrow needles were used randomly for the PV, the FOC and the SOC (Fig 2). Standard cannulas were manually modified to create the side-opening, by sealing the front-opening in the distal end<sup>19</sup>. The authors routinely used the larger cannulas for lumbar and thoracolumbar PVs, and the smaller ones for thoracic PV. Both kinds of cannulas, SOC and FOC, were appropriately kept inside sterile, hard closed boxes with the identification only of the cannula's size, and mixed previously. At the time of the procedure, the box for the proper size was opened, to achieve the desired randomization, and only the surgical team was aware of the kind of cannula that was going to be utilized.

A radiopaque, high viscosity, polymethyl methacrylate bone cement (CMM<sup>®</sup>, São Paulo, Brazil) containing powdered polymer and liquid monomer was used. The mixture was left to harden at room temperature until the desired consistency was reached, and manual injections with 1 ml syringes were performed.

#### Radiographic evaluation

An independent radiologist from the hospital performed evaluation of the postoperative films. Based on postoperative

X-ray and CT scan, they could decide whether or not the patient had cement leakage, and they could also locate it.

#### Statistical analysis

The incidence of cement leakage and the clinical outcome of each group was recorded and analyzed using the appropriate tests. A difference of  $p < 0.05$  was considered to be statistically significant, using statistical tests and  $\chi^2$  (PHStat<sup>®</sup>, R<sup>®</sup> and S-Plus<sup>®</sup>).

## RESULTS

#### Cement leakage and operative procedure

The FOC was used in 25 PVs, resulting in cement leaks in 68 % (17) of the procedures. The SOC was used in 22 PVs, resulting in 27% (6) of cement extrusion (Table). The difference between both groups was statistically significant ( $p < 0.01$ ).

Among the 23 cases of cement leakage, there were some procedures in which there were more than one leakage, distributed as follows: four cases into the disk with the SOC and six with the FOC; three with the SOC and ten with the FOC to the para-vertebral space; two cases of epidural cement extrusion with the FOC and none with the SOC; one case of lung cement embolism with the FOC and none with the SOC.

The average number of injections was higher in the control group (1.75) in comparison with the experimental group (1.53), but with no statistical significant difference ( $p > 0.05$ ). The volume of injected cement was also reduced from 6.3 ml to 5.5 ml ( $p > 0.05$ ) using the FOC and SOC, respectively. There was a proportional reduction of cost with materials during the procedure with the FOC, compared to the new SOC, because of the reduced number of bilateral injections with the experimental cannula, without a significant difference ( $p > 0.05$ ).

#### VAS score

The VAS score was similar in both groups before the PV, 8.04 (ranging from 7.59 to 8.49) with the SOC and 7.92 (7.47 to 8.37) with the FOC. At 1 month follow-up, the mean pain score were also similar, 1.14 (0.69 to 1.59) with the SOC and 1.44 (0.99 to 1.89) with the FOC, without significant differences ( $p > 0.05$ ). There were a slightly better pain improvement for the SOC group at 6 months follow-up, 1.05 (0.60 to 1.50) for the SOC, and 1.36 (0.91 to 1.81) for the FOC ( $p < 0.05$ ).

#### Complications

There were no clinical relevant complications, but there were two cases of bending at the tip of the SOC during the procedure, one of those broke and the tip was left inside the vertebral body with the bone cement, with no detrimental consequences. After that, the modified cannula was improved by making it sharper.

## DISCUSSION

Osteoporotic vertebral fracture is a very common disease in women older than 60 years, and may result in debilitating pain and spinal deformity. Although many patients respond to conservative treatment with medications, injections, bracing, physical therapy and bed rest, some do not. However, prolonged bed rest can result in a vicious cycle of increased bone loss caused by inactivity and correspondingly, increased vertebral fracture risk. Thus, interest has been fostered in percutaneous cement injection methods for fracture stabilization that can reduce severe pain, allowing a return to normal activity in a short period of time, either using vertebroplasty or kyphoplasty (KP)<sup>2,4,5,21,22</sup>.

Hulme et al.<sup>23</sup> published a systematic review of 69 clinical studies about vertebroplasty and kyphoplasty, to evaluate the safety and efficacy of both techniques. They noticed that a large proportion of patients had some pain relief, including 87% with PV and 92% with KP. Leakage rates were higher for PV (41%) than KP (9%). The meta-analysis of Eck et al.<sup>24</sup> also showed reduced risk of cement leakage with KP in comparison with PV, but PV group had a significantly greater improvement of pain scores.

Leakage of bone cement is one of the main potential complications following percutaneous cement injection, especially vertebroplasty<sup>13-15,17,18</sup>. Polymethyl methacrylate may exit the vertebral body through deficiencies, fractures in the vertebral cortex, or by injection of cement into the vertebral venous system<sup>25</sup>.

Heini et al. developed this new cannula for cement injection which allows the flow of cement to be redirected. They compared both cannulas in cadavers and also used it in 9 PVs of 7 patients, but they did not make a clinical comparison with the traditional cannula<sup>19</sup>.

Considering the mean VAS score, the clinical result was considered good to excellent with both cannulas, and the VAS score was slightly better at 6 months follow-up using the SOC ( $p < 0.05$ ). The occluded tip of the SOC has to be sharp to avoid bending, breakage and some potential complications.

The main goal of this study was to verify the efficiency and safety of this new side-opening cannula for PV, comparing it to the traditional front-opening cannula. The most notable finding, however, was the significant reduction of cement extrusion (27%) with the new SOC, compared to the traditional FOC (68%), all asymptomatic. The authors noted that this new cannula improved the injection of the cement medially, toward the center of the body, reducing significantly the extravasation of cement.

Further studies with a higher number of cases should be performed, helping to encourage the routine replacement of the traditional front-opening cannula for PV by this side-opening cannula. The results of this study

showed the efficacy and reduced chance of cement extravasation using this new side-opening cannula, with no increase in cost.

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