STUDY DESIGN/SETTING: Retrospective cohort.
PATIENT SAMPLE: Patients with a diagnosis of osteoporosis and vertebral compression fracture followed for a minimum of two years with complete clinical and radiographic data. Patients with a diagnosis of metastasis, infection or myeloma and vertebral compression fracture were excluded.
OUTCOME MEASURES: Multivariate logistic regression analysis was performed to analyze comorbidities between two patients' cohorts with emphasis on differences in operative versus non-operative treatment.
METHODS: This is a retrospective cohort comparison of 288 consecutive patients treated for pathologic vertebral compression fractures secondary to osteoporosis with either conservative measures or balloon kyphoplasty with PMMA cement augmentation. Multivariable analysis of patient comorbidities was performed to assess the risks associated with subsequent adjacent and remote compression fracture at a minimum of 2 years of follow up.
RESULTS: Two hundred and eight-eight patients (average age, 78.3 years, 68 males and 220 females) had 438 compression fractures. One hundred and twenty-one patients were treated with non-operative management and 167 underwent balloon kyphoplasty with PMMA cement augmentation. Rate of secondary fracture was 47.1% (57/121) in the non-operative group and 33.5% (56/167) in the operative group. There were no differences found between groups with respect to frequency of individual co-morbidities. Non-operative treatment was identified as a statistically significant independent risk facture for subsequent compression fracture (OR=2.28). Monovariable analysis identified age, diabetes mellitus (OR=2.26), smoking (OR=4.07) and NSAID's (OR=3.22) as risk factors for subsequent compression fracture. Single & double variable log-linear analysis also identified increased age in men and male smokers as an increased risk factor for subsequent fracture.
CONCLUSIONS: Patients diagnosed with vertebral compression fractures secondary to osteoporosis suffer from multiple medical comorbidities. No particular comorbidity was identified as solely attributable for increased risk of subsequent remote or adjacent compression fractures. Patients in this series treated with non-operative conservative management had a 2.28 times greater risk for a subsequent vertebral compression fracture than patients treated with balloon kyphoplasty and polymethylmethacrylate augmentation.
FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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66. Kyphoplasty Versus Percutaneous Vertebroplasty Using the Traditional and the New Side-Opening Cannula for Osteoporotic Vertebral Fracture

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BACKGROUND CONTEXT: Percutaneous vertebral augmentation procedures, also called percutaneous osteoplasties (PO), can include percutaneous vertebroplasty (PV) and baloon kyphoplasty (KP). Both are minimally invasive techniques that involve injection of polymethyl methacrylate (PMMA) cement under radiologic control, helping to stabilize a malignant involvement of the spinal column, hemangioma and mainly osteoporotic fractured vertebrae, which afflicts millions of people worldwideCement leakage during vertebroplasty is a common occurrence, and occurs with a frequency of 11–73% for OVF, being the majority 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. 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, and confirmed by the author's publication in 2009, this new cannula may reduce the likelihood of this problem and contribute to the safety of the technique. Baloon kyphoplasty(KP), involves inflation of a ballon within the collapsed body of a vertebra, before stabilization with PMMA. The risk of cement extravasation seems to be reduced due to injection of high-viscosity cement into a previously formed cavity. Both PV and KP provide pain relieve and can reinforce the structure of a vertebral body.
PURPOSE: The aim of this article was to study the results of two different types of percutaneous vertebroplasty and kyphoplasty to osteoporotic vertebral fractures, focusing at the risk of cement extrusion.
STUDY DESIGN/SETTING: It was prospectively analyzed a series of PVs (percutaneous vertebroplasty) from January 2003 to February 2008, and a consecutive series KPs (kyphoplasties) from March 2008 to November 2010, performed for patients with painful osteoporotic vertebral fractures (OVFs). PVs were performed using the frontal-opening cannula (FOC) and using the new side-opening cannula (SOC), randomly distributed in the PV group.
PATIENT SAMPLE: 68 PVs were studied in 43 patients with OVFs. A total of 47 PVs in 30 patients were included, between 2003 and 2008, following the specific protocol for this study. Twenty eight of the patients were female and 3 were males, with ages varying from 48 to 91 years (median age was 77 years). A prospective, controlled and randomizedstudy was performed comparing the PVs, beeing randomly distributed 22 PVs to the experimental group, using the SOC, and 25 PVs to the control group, using the FOC (Table 1). 41 KPs performed in 24 patients with OVFs were studied prospectively, and the results were compared with the PV group. Fifteen of the patients were female and eight were males, with ages varying from 16 to 87 years. 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 for PV is not approved in the United States.
OUTCOME MEASURES: The authors obtained and analized 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. Independent radiologist from the radiologic unit 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. The authors also reviewed the films searching to any cement extrusion. The incidence of cement leakage and the clinical outcome of each group was recorded and analyzed using the appropriate tests. A difference of $p<.05$ was considered to be statistically significant, using statistical tests and $\chi 2$ (PHStat®, R® and S-Plus®).
METHODS: They were submitted to the PV and KP by the same team, at the Hemodinamic Unit (LACIC – Jardim Cuiaba Hospital, Cuiabá, MT, Brazil), 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 redution, using the standard transpedicular technique, as reported previously, guided by fluoroscopy, uni or bipedicularlly, according to the distribution of cement for PV and bipedicularlly for KP. A postprocedural radiography (including chest and spine X-ray), and computed tomography (CT) of the treated level was performed in all cases to scan for the presence or not of cement leaks. 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. Standard cannulas were manually modified to create the side-opening, by sealing the front-opening in the distal end. The authors routinely used the larger cannulas for lumbar and thoracolumbar PVs, and the smaller ones for thoracic PV. The size of the ballons for KP used were number 10/3, 15/3 or 20/3, according to the vertebrae level and size.
RESULTS: 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 27.3%

(6) of cement extrusion (Table 1). The difference between both groups was statistically significant (p<.01). Among the 23 cases of cement leakage with PV, 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. Among the 6 cases of cement leakage with KV: four cases occurred into the para-vertebral space; one to the disk and one to the epidural space. The average number of injections for PV was higher in the control group (1.75) in comparison with the experimental group (1.53), but with no statistical significant difference (p>.05). The patients submitted to KP received bilateral injections of bone cement. The volume of injected cement for PV was reduced from 6.3 ml to 5.5 ml (p>.05) using the FOC and SOC, respectively. The average volume of cement for KP was 2.87 ml. 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>.05). The cost of KP was significantly superior to PV because the material used was much more expensive (p<.05). The VAS score was analised for all the patients submitted to the osteoplasties until January 2010, to be able to compare the initial and 6 months VAS score. The VAS was similar in all the three groups before the OP, 8.04 (ranging from 7.59 to 8.49) with the SOC, 7.92 (7.47 to 8.37) with the FOC and 7.67 (0.73 to 8.27) with KP. At 1 month follow-up, the mean pain score were also similar, 1.14 (0.69 to 1.59) with the SOC, 1.44 (0.99 to 1.89) with the FOC and 2.33 (1.69 to 2.98) with KP, without significant differences (p>.05). There were a similar pain improvement for all the three groups, for the SOC group, 1.05 (0.60 to 1.50) for the SOC, 1.36 (0.91 to 1.81) for the FOC (p<.05) and 1.11 (0.52 to 1.70) with KP. There were no clinical relevant complications neither in PV nor KP group, but there were two cases of bending at the tip of the SOC during PV, 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.

CONCLUSIONS: The pain control was similar for all groups (p>.05), with good improvement of pain in most of the patients, and there were no clinical relevant complications. The cement leakage was significantly reduced with the KP (14.6%) and the SOC (27,3%) for PV, in comparison with the FOC (68,0%). The cement extrusion was lower with KP (p<.05), comparing with SOC, increasing the safety of the procedure using both the KP and this new SOC.

FDA DEVICE/DRUG STATUS: Vertebroplasty cannula: Approved for this indication; Kyphoplasty kit: Approved for this indication.

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67. Comparison of Unipedicular and Bipedicular Balloon Kyphoplasty for Treatment of Vertebral Compression Fractures: A Prospective Randomized Study

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BACKGROUND CONTEXT: Balloon kyphoplasty for the treatment of patients with vertebral compression fractures (VCFs) has been shown to be successful in providing acute pain relief, enabling improved function, and restoring of vertebral body height. However, limited prospective data exists in the investigation of unipedicular (UP) balloon kyphoplasty as a sufficient alternative to bipedicular (BP) balloon kyphoplasty. In this prospective trial we compare the clinical and radiographic outcomes of UP and BP balloon kyphoplasty.

PURPOSE: To compare the clinical and radiographic outcomes of UP and BP kyphoplasty for the treatment of osteoporotic VCFs.

STUDY DESIGN/SETTING: This is a prospective, randomized study comparing UP and BP kyphoplasty for the treatment of painful osteoporotic VCFs. A total of 45 patients were enrolled in this study at our institution between July 2006 and December 2008. The institutional review board approved this study and informed consent was obtained. This study was performed independently of industrial support and oversight.

PATIENT SAMPLE: Elderly patients 50 years of age and older with painful osteoporotic VCFs.

OUTCOME MEASURES: Clinical improvement using Oswestry Disability Index (ODI), Visual Analog Scale (VAS), Roland Morris Disability Questionnaire (RDQ), and Short-Form 36 (SF-36) questionnaires including both Mental (MCS) and Physical (PCS) component subscores of SF-36. Vertebral height and Cobb (kyphotic) angle were measured from postoperative radiographs.

METHODS: Study participants were randomized preoperatively to either receive a UP (20 patients, 25 VCFs) or BP (20 patients, 27 VCFs) kyphoplasty, via the use of sealed envelopes. Patients were blinded to assigned treatment groups. To evaluate pain and functional outcomes, patients completed the ODI, VAS, RDQ, and SF-36 questionnaires before surgery, and at 3 months and 12 months after surgery. Preoperative and postoperative thoracolumbar radiographs were used to calculate the percent changes in vertebral body heights and differences in Cobb (kyphotic) angle. Total operative time and incidence of cement leakage were recorded for each treatment group. An independent researcher, not the surgeon of the procedures, performed the data analysis of the clinical and radiographic outcomes.

RESULTS: There were no group differences in age, sex, American Society of Anesthesiologists (ASA) score, or fracture location. Both UP and BP kyphoplasty showed significant within-group improvements in all measured clinical scores from preoperative to 12 months postoperatively; except MCS did not improve in either the UP or BP kyphoplasty group. There were no between-group differences in all clinical outcome measures at any time-point (preoperative, 3 months, or 12 months). Radiographic data were available for 13 patients (17 VCFs) in the UP group and 18 patients (23 VCFs) in the BP group. Anterior height restoration was 13±13 percent in the UP group, and 12±13 percent in the BP group (p=.7). Middle height restoration was 14±10 percent in the UP group, and 14±12 percent in the BP group (p=.9). Posterior height restoration was 1±5 percent in the UP, and 5±10 percent in the BP group (p=.1). Cobb angle reduction was similar between UP (1.9±2.7 degrees) and BP (5.5±7.1 degrees) groups (p=.2). Operative time was longer in the BP group (71±20 minutes) than the UP group (47±7 minutes) (p<.001). Incidence of cement leakage was not significantly different between UP and BP groups (p=.3).

CONCLUSIONS: In summary, this study indicates that UP kyphoplasty yields similar clinical and radiographic outcomes compared to the BP kyphoplasty procedure, while reducing the overall duration of the operation. Therefore, we encourage the use of a UP approach as the preferred surgical technique for treatment of VCFs.

FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

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68. Balloon Kyphoplasty Improves Quality of Life, Bodily Pain and Vertebral Body Height among Cancer Patients with Vertebral Compression Fractures Compared to Nonsurgical Management: Results from a Multicenter, Randomized Trial

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BACKGROUND CONTEXT: Vertebral compression fractures (VCF) are a common source of morbidity among cancer patients.