Prospective evaluation of fracture risk in osteoporotic patients after low cement volume vertebroplasty

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Résumé
Suivi prospectif du risque fracturaire après vertébroplastie utilisant un faible volume de ciment chez des patients ostéoporotiques

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Objectif. Comparer, de façon prospective, la survenue de nouvelles fractures (dépistées par IRM) dans les trois mois suivant la première fracture dans une population traitée par vertébroplastie avec de très faible volume de ciment et dans une population traitée de façon conventionnelle.

Matiériel et méthode. Sur les 49 patients hospitalisés pour fracture vertébrale d’origine ostéoporotique, 22 ont bénéficié d’une vertébroplastie sous TDM avec injection de 1 à 3 cc de polyméthylméthacrylate et 27 ont suivi un traitement médical classique. Tous les patients ont été évalués par IRM lombaire à l’inclusion et 3 mois après pour juger de l’éventuelle survenue de nouvelle fracture.

Résultat. Parmi les patients ayant bénéficié d’une cimentoplastie 12 présentent de nouvelles fractures (54 %) contre 10 dans le groupe témoin (37 %) sans que la différence soit significative (p = 0,049). Dans le premier groupe, les vertèbres fracturées étaient adjacentes à la vertèbre cimentée dans 77 % des cas avec une différence significative (p = 0,009) par rapport au groupe témoin, dans lequel les vertèbres adjacentes n’étaient touchées que dans 15 % des cas. Pendant les 3 mois de suivi, 3 patients dont 2 cimentés ont nécessité une nouvelle hospitalisation pour lombalgia auqé seconde à une nouvelle fracture.

Conclusion. La faible quantité de ciment injecté n’empêche pas l’apparition de nouvelle fracture adjacente à la vertèbre traitée mais limite la fuite de ciment extra-vertébrale.


Abstract

Purpose. To prospectively compare the incidence of new fractures (as demonstrated on MR) within the first 3 months after an initial fracture in a population treated with low cement volume vertebroplasty and a population treated conservatively.

Materials and methods. From 49 patients admitted for osteoporotic vertebral compression fracture, 22 underwent CT guided vertebroplasty with injection of 1-3 ml of PMMA, and 27 were treated conservatively. All patients underwent MR at presentation and at 3 months to detect new compression fractures.

Results. Twelve patients (54%) treated with vertebroplasty showed new fractures at 3 months compared to 10 (37%) in the control group. This was not statistically different (p=0.049). In the vertebroplasty group, the new fractures involved vertebra adjacent to the treated vertebra in 77% of cases (p=0.009) compared to only 15% in the control group. During the 3-month period, 3 patients, including 2 treated with vertebroplasty, required hospital admission due to fracture related acute lumbar back pain.

Conclusion. The small amount of injected cement does not prevent fractures of adjacent vertebrae but does reduce the extravasation of PMMA in adjacent tissues.


Nearly 440,000 vertebral fractures are diagnosed each year in the European Union, with 10% requiring hospital admission. Formerly, these were treated conservatively with a combination of bed rest and pain medication followed by rehabilitation. Treatment of these fractures using vertebroplasty was first introduced in 1987 (1). Several studies have since documented the efficacy of vertebroplasty with symptomatic improvement or relief within 48 hours after the procedure, allowing early mobilization of these elderly patients, and reducing the risks of complications related to prolonged bed rest (2-5). Complications from vertebroplasty are rare, especially for osteoporotic vertebral compression fractures (0.5% to 2%) (6). However, studies have reported the occurrence of fractures involving vertebrae adjacent to the cemented vertebra (7, 8). This may reflect the natural history of the disease since the presence of vertebral compression fractures is an independent risk factor for future compression fractures (9), but fractures of vertebrae adjacent to a treated vertebra may also be caused by the increased stiffness of the cemented vertebra. It has been shown that the outcome following vertebroplasty was not related to the degree of vertebral filling (10). In our institution, we have elected to perform low cement volume vertebroplasty (1 to 3 ml) hence reducing the risk of peri-vertebral cement extravasation. Biomechanical studies have shown that 14% filling was sufficient to restore vertebral stiffness whereas 30% filling increased vertebral stiffness by 50% (11). To our knowledge, no clinical study has evaluated
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The effect of cement volume on the risk of fracture of adjacent vertebrae following vertebroplasty.

The purpose of this prospective study was to compare the occurrence of vertebral fractures (as demonstrated on MR) at three months in a patient population treated with low cement volume vertebroplasty and a patient population treated conservatively.

Population

Forty-nine patients admitted in the Montpellier university hospital for acute mechanical lumbar back pain secondary to spontaneous vertebral compression fracture with pain > 35 on a visual analog scale (VAS) were prospectively included. The T score of patients was < –2.5. The patients were known to have osteoporosis, treated for a mean time of 11 years (range: 25 years to current year at the time of presentation).

The osteoporotic nature and acuteness of the fractures were confirmed on MR. MR was used as the gold standard examination (day 0).

Demographic data from our patient population are summarized in table I. A single patient underwent 4 level vertebroplasty and 7 patients underwent 2 level vertebroplasty in a single setting.

Method

The procedures were performed under CT-guidance with conscious sedation. A single transpedicular approach was used and a low cement (PMMA + barium sulfate) volume was injected (1-3 ml) per vertebra (fig. 1).

Follow-up MR was performed at 3 months using similar acquisition parameters and pulse sequences (contiguous 4 mm thick sagittal T1W and TIRM) to look for interval fractures.

The following findings were analyzed on each MR examination: vertebral body height from T7 to L5, and height loss relative to adjacent vertebrae, using a 4 point semi-quantitative scale as proposed by Genand (Stage 1: 0-25% height loss; stage 2: 25-50% height loss; stage 3: 50-75% height loss; stage 4: 75-100% height loss), presence of vertebral marrow signal abnormality. The recent nature of a vertebral compression fracture was confirmed by the presence of low T1W and high TIRM signal intensity, consistent with edema, within the vertebral body. The chronic nature of a compression fracture was confirmed when the compressed vertebral body was hyperintense relative to disk and isointense relative to other vertebrae on T1W images and hypointense on the inversion recovery sequence. An interval compression fracture (new compression fracture on follow-up MR) was defined by the presence of morphological alteration of the vertebral body with progression of height loss between initial and follow-up MR examinations.

Different characteristics at the time of initial presentation were correlated with the development of interval fractures: age, T score, VAS, fracture location, number of chronic or recent fractures. Also, hospital admissions for acute low back pain of study patients during the 3-month interval were recorded.

Table I

<table>
<thead>
<tr>
<th>Patient demographics.</th>
<th>Control 27 patients</th>
<th>Vertebroplasty 22 patients 32 fractures</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>78,7</td>
<td>77,5</td>
<td>NS</td>
</tr>
<tr>
<td>Females / Males</td>
<td>17 / 10</td>
<td>15 / 7</td>
<td>NS</td>
</tr>
<tr>
<td>Recent/Chronic</td>
<td>46 / 51</td>
<td>46 / 43</td>
<td>NS</td>
</tr>
<tr>
<td>Fracture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T score</td>
<td>3,4</td>
<td>3,7</td>
<td>NS</td>
</tr>
<tr>
<td>VAS day 0</td>
<td>5,9</td>
<td>6,3</td>
<td>NS</td>
</tr>
<tr>
<td>Total number of fractures at day 0</td>
<td>3,615</td>
<td>4,045</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic fractures at day 0</td>
<td>1,889</td>
<td>1,955</td>
<td>NS</td>
</tr>
<tr>
<td>Recent fractures at day 0</td>
<td>1,704</td>
<td>2,091</td>
<td>NS</td>
</tr>
</tbody>
</table>

Fig. 1: CT showing needle placement in the vertebral body and diffusion of the cement during vertebroplasty.

Statistical analysis

An overall description of the sample was performed by listing the frequency of different categories for each qualitative variable. The distribution of quantitative variables was non-Gaussian; these variables were described using mean values with maximum and minimum values.

Both groups were compared for age, sex, total number of compression fractures at presentation (day 0), and the total number of chronic and recent fractures at day 0 using the Student t-test and Chi-square test. The number of interval compression fractures significantly different from 0 was verified with the Wilcoxon matched pairs test.

The correlation between initial and interval fractures was evaluated using the non-parametric Spearman test.
Both groups were compared for: (a) total number of interval fractures, (b) number of interval fracture of vertebrae adjacent to the treated vertebra at the time of initial admission.
Comparison of the number of interval fractures was performed with the Chi-square test or the Fisher’s exact test if validity criteria were not verified.

Results
Both groups were considered statistically comparable. At 1 week, the VAS was 82% for the treated group compared to 34% for the control group. At 3 months, low back pain was at a mean of 3.3 on VAS for the treated group compared to 3.9 for the control group.
In treated patients, 12 (54%) presented new compression fractures compared to 10 (37%) in control patients. The difference was not statistically significant (p=0.049) (fig. 2). In the treated group, interval fractures involved vertebrae adjacent to a cemented vertebra in 77% of cases whereas 15% of interval fractures in the control group involved a vertebra adjacent to the one fractured at initial presentation (p=0.009) (fig. 3).

About one third of patients had less than 2 compression fractures at initial presentation (9 control and 7 treated patients). Of these, 2 control patients (22%) and 3 treated patients (43%) presented with interval fractures compared to 38% and 60% respectively for the remaining 2/3 of patients with more than 2 compression fractures at initial presentation.

During the 3-month follow-up period, 4 treated patients (18%) and 3 control patients (11%) consulted for recurrent acute lumbar pain secondary to a new compression fracture. Three patients required hospital admission. Of these, 2 were treated patients who had resumed normal activities and fractured a vertebra at 1 month and 2.5 months respectively. The third patient was from the control group and experienced a new fracture immediately upon resuming activities after a 15-day period of bed rest.

Discussion
Osteoporosis is the most important risk factor for new vertebral fracture (12-14). In our study, patients from both groups experienced interval fractures, consistent with the natural history of the disease and its impact on the spine. All of our patients showed significant loss of bone mineral density with T score < -2.5, explaining the high rate of interval fractures in both groups. In addition, the criteria correlating most with the occurrence of new fractures is the number of fractures (recent or chronic) already present at the time of presentation. This is consistent with results from Lindsay et al (12) who reported the risk of new vertebral fracture in osteoporotic patients in the year following a fracture as a function of the number of fractures at presentation (5% with no fracture and 24% with 2 or more fractures). The authors explained this evolution as the result of spinal deformity with secondary kyphosis that occurs following compression fractures resulting in an alteration of mechanical forces on the spine; the redistribution of forces occurs mainly at the adjacent vertebral levels (12, 14). The cement does not a priori cause vertebral body consolidation (7). These mechanical constraints will lead to additional compression fractures.

Several studies have described the increased risk of new compression fracture following vertebroplasty (7, 8, 15). While this was the case in our study, the difference was not statistically significant, presumably due to our small patient sample. There are multiple causes for subsequent fracture following vertebroplasty. This may in part be explained by the level of patient activity. Patients with symptomatic compression fractures treated conservatively typically have reduced activities due to pain, which may act to prevent additional fractures. On the other hand, patients undergoing vertebroplasty with symptomatic relief usually have higher levels of activity, which may predispose to new fractures. Future studies comparing level of activity and development of new fractures would certainly be of value.

In vitro studies have also shown that osteoporotic vertebral bodies treated with vertebroplasty were stiffer and more resistant than non-treated osteoporotic vertebrae (15). Dean et al (16) have shown in vivo a reduction in compliance of vertebral bodies following vertebroplasty during flexion and extension as well as lateral bending movements. Based on these results, while vertebroplasty consolidates...
and strengthens treated vertebral bodies resulting in increased resistance, it also increases stiffness, which modifies the distribution of forces applied on vertebrae. It increases mechanical constraints and the risk of compression fracture (7, 8). Our results show that there is a significant increase (p=0.009) in the number of subsequent compression fractures at levels immediately adjacent to a cemented vertebra in the treated group. These results are consistent with and not superior to results from prior reports: Voorhmolen et al (5) reported a 50% rate of new fractures in 66 patients, with 50% involving vertebrae adjacent to a cemented vertebra; Uppin et al (8) reported a 67% rate of adjacent fractures; Grados et al (7) reported a 1.44 relative risk of fracture for vertebrae adjacent to a fractured but non-cemented vertebra compared to 2.27 for vertebrae adjacent to a fractured cemented vertebra. The lower cement volume used in our patient population does not seem to reduce the risk of subsequent fracture. Specifically, it does not appear to have a favorable impact on reducing the risk of subsequent fracture of vertebrae adjacent to a cemented vertebra. The percentage of filling seems to have little impact on the biomechanical characteristics of the treated vertebra. This is consistent with the report from the in vivo study by Molloy et al (17) describing that strength and stiffness were weakly correlated with the percentage fill volume of cement injected during vertebroplasty. However, injection of a small amount of cement reduces the risk of perivertebral extravasation. Komemushi et al (18) have reported that extravasation of cement into the intervertebral disk was associated with an increased risk of subsequent fracture. Injection of a small amount of cement would reduce this risk and intradiskal extravasation of cement occurred in only 2 of our patients with subsequent fracture of the adjacent vertebra in one case.

In our study, 3 patients required subsequent admission due to recurrent acute lumbar back pain, without significant difference between both groups. It would then seem that vertebroplasty, even if it increases the risk of subsequent vertebral compression fracture, does not significantly alter the clinical follow-up of these elderly patients. Additional evaluation of a larger patient population with longer term follow-up should help establish if vertebroplasty has a negative effect on the long term clinical outcome.

References


Fig. 3: Sagittal T1W MR images at the time of admission (a) and at 3 months following vertebroplasty (b) showing a new fracture of the subjacent vertebra. Note the presence of intradiskal cement at the superior disk, possibly the cause of minor retropulsion of the posterior T12 vertebral margin.

Conclusion

Results from this study seem to indicate that the risk of fracture of vertebrae adjacent to a cemented vertebra is increased, even following low volume cement injection. However, this therapeutic option should not be dismissed because subsequent fractures are not necessarily symptomatic. The purpose of the procedure is thus achieved since patients experience symptomatic relief allowing prompt return to normal activities without increasing the risk of major mid term complications from prolonged bed rest, and even repeat hospital admission.


