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Treatment of Vertebral Fractures by Kyphoplasty

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Purpose. To conduct a retrospective clinical and radiological study of the first few cases operated by kyphoplasty at one center of Madrid.
Materials and methods. Thirty patients were reviewed (43 vertebrae) who were operated between December 2002 and May 2005. The etiological distribution was as follows: 24 patients with an osteoporotic fracture and 6 with osteolytic tumors (lung cancer, 1 case; breast cancer, 2; hypernephroma, 1; and myeloma, 2). Mean follow-up was 13.2 months. Pain reduction was assessed by means of the Visual Analog Scale (VAS), the Karnosfky score and the amount of analgesia used before the procedure and during follow-up. Pre- and postoperative endplate angles were measured to assess the restoration of the sagittal alignment.
Results. A 93.2% of patients improved. Mean VAS increased by 5 points ($p < 0.05$). Karnosfky score went from 70.63 to 90 points ($p < 005$). Patients using major opioids went from 53% befofre surgery to 6.6% postoperatively ($p < 0.05$). 20 cases (46.5%) showed radiological improvement. If we exclude uncorrected vertebrae, the improvement obtained was 21.7% as regards crushing (range: 5-70%) and 13.86° as regards Cobb's angle (range: 3-30°). There were 6 instances of anterolateral cement extravasation, all of them asymptomatic. Two adjoining fractures were detected (both in the first three months post-op), one of them with clinical repercussions. In the group of patients with tumors, final results were comparable to the general series.
Conclusions. Most cases show a significant improvement with no associated complications. Kyphoplasty is a highly effective minimally invasive technique with a low degree of morbidity.

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Tratamiento de las fracturas vertebrales mediante cifoplastia

Objetivo. Análisis retrospectivo clínico y radiológico sobre los primeros casos intervenidos mediante cifoplastia en un centro de la Comunidad de Madrid.
Material y método. Se revisaron 30 pacientes (43 vértebras) intervenidos entre diciembre 2002 y mayo 2005. La distribución etiológica fue: 24 pacientes con fractura osteoporótica y 6 con implantes tumorales líticos (1 caso de cáncer de pulmón, 2 de mama, un hipernefroma y 2 mielomas). El seguimiento medio fue de 13,2 meses. Se valoró la escala analógica visual (EAV), el índice de Karnosfky y la analgesia empleada antes del proceso y tras el seguimiento. También se midió el porcentaje de aplastamiento, el ángulo de Cobb local y la corrección de ambos.
Resultados. El 93,2% de los pacientes mejoraron. La media de la EAV aumentó 5 puntos ($p < 0,05$). El índice de Karnosfky pasó de 70,63 a 90 puntos ($p < 0,05$). El 53% usaba opiáceos mayores antes de la cirugía, pasando el porcentaje después de la cirugía al 6,6% ($p < 0,05$). Veinte casos (46,5%) mejoraron radiológicamente. Excluyendo aquellas vértebras que no se corrigieron, la mejora obtenida fue de 21,7% de aplastamiento (rango 5-70%) y 13,86° de corrección ángulo de Cobb (rango 3-30°) respectivamente. Hubo 6 extravasaciones anterolaterales, todas asintomáticas. Se detectaron 2 fracturas adyacentes (ambas en los tres primeros meses tras la cirugía), una con repercusión clínica. En el subgrupo de pacientes tumorales los resultados finales fueron comparables a la serie general.
Conclusiones. La mayoría de los casos mejoran sustancialmente sin complicaciones asociadas. La cifoplastia es una técnica de baja morbilidad y alta eficacia.

Palabras clave: *cifoplastia, fractura vertebral, osteoporosis, metástasis.*

Osteoporotic vertebral fractures (VF) constitute a significant healthcare problem in the industrialized world[1,2]. Classical treatment, based on rest and lower activity levels, entails acceptance of an often unfavorable clinical and mechanical situation, characterized by an imbalance in the transmission of forces to the vertebral body, a gradual increase in kyphosis, persistent pain and a reduction in quality of life[3].

To address the problem, minimally invasive percutaneous cementing techniques (vertebroplasty and kyphoplasty) have been developed in the last ten years, Kyphoplasty makes it possible to correct and stabilize the vertebral fracture, relieve pain, improve the patient's level of activity and lower the complications rate[4-11].

A similar development has happened in the field of tumoral lesions. This technique provides patients with osteolytic lesions with immediate stabilization and fast mobilization, without interfering with the baseline treatment for their disease (radiation therapy, chemotherapy)[4,12,13].

The purpose of this study is to review the first 30 patients treated by means of kyphoplasty at the Department of Orthopedic and Trauma Surgery of the San Carlos Clinical Hospital in Madrid.

MATERIALS AND METHODS

A retrospective study was drawn up of patients treated with kyphoplasty between December 2002 and May 2005. The series included 23 females and 7 males subjected to surgery (43 vertebrae). In 20 patients a single level was treated, in 7 two levels and in 3 three vertebrae were approached. Lesions were located in the thoracic region in 23 cases and in the lower-back in 20. Mean patient age was 70.9 years (42-84 years) and mean follow-up was 13.2 months (4-32 months). The main etiology was a painful osteoporotic fracture (24 patients), followed by lytic tumoral lesions (6 patients). The neoplasm associated was: lung cancer (1 case), breast cancer (2 cases), hypernephroma (1 case) and myeloma (2 cases). Five patients had died when the study was concluded, all of them with a follow-up longer than 3 months (4-15 months) and for reasons unrelated to the surgery. In three cases, death was the result of a baseline tumoral condition; the other two belonged to the group of osteoporotic fractures. One died of an acute coronary episode 6 months after kyphoplasty and the other of a respiratory infection 12 months after surgery.

Surgical indication in osteoporotic lesions is determined by the clinical-radiological correspondence between the severity of pain and the presence of an osteoporotic fracture with lesional edema on MRi. To establish the indication for tumoral patients, an assessment was made of the extent of the lytic lesion, the risk of collapse or major crushing, pain and the need for a diagnostic biopsy. This technique makes it possible to take a cylindrical sample of the vertebra during the same surgical event. This is particularly important in the case of vertebral lesions about which there is diagnostic doubt since biopsy and kyphoplasty can be performed during the same procedure.

Figure 1. *Osteoporotic L1 vertebral fracture.*

The mean time elapsed between the onset of symptoms and surgery was 3.5 months; 7 patients were operated during the first month and in 8 cases surgery was carried out after the first 6 months since pain persisted after ordinary conservative treatment.

The majority of levels were approached transpedicularly, following the usual technique[6] (Instrumental Kyphon ®), injecting cement (polymethylmetacrylate) in all cases. The technique was performed in the usual orthopedic operating rooms with radioscopic control (figs. 1-4).

Patients were allowed to sit the same day and to walk the following day. They were discharged during the next 24-48 hours (oncologic patients were required to remain hospitalized).

Both clinical and radiological results were studied. In both analyses, we compared patients' pre-op situation with their status at the end of follow-up, which was 13.2 months long on average (range 4-32 months). Clinical evaluation consisted in obtaining pain-related data through the Visual Analog Scale (VAS), the Karnosfky scale and type of analgesia used. Radiological evaluation was made in two ways.

Figure 2. *Surgical field used to perform the kyphoplasty.*

Figure 3. *Radiological postoperative follow-up. A/P view.*

The first consisted in studying the degree of crushing of the injured vertebra in relation with the health upper and lower vertebrae. The second involved a calculation of the local Cobb's angle. The observer was independent and did not carry out any of the procedures.

Statistical analysis of data was made by means of chi square tests, the Wilcoxon W test and correlations for non-parametric quantitative variables.

Figure 4. *Radiological postoperative follow-up. Lateral view.*

RESULTS

All patients but two improved (93.2%). Mean VAS value before surgery was 8.04 (Standard deviation [SD] 2.603; mean 9) points as compared to a final score of 3.81 (SD 2.370; mean 4). This entails a 5-point global improvement of the series' mean score (range 1-10) ($p < 0.05$). The Karnosfky score went from 70.63 (SD 21.758; range 30-100) to 87.33 (DE 14.368; range 60-100) ($p < 0.05$).

Preoperative analgesia consisted, preferably, of narcotic painkillers (53%), followed by lesser opioids (26,7%) and non-steroid antiinflammatory drugs (NSAIDs) (20%). In the final assessment, only five patients (16.7%) required major opioids and 16 patients (53%) ($p < 0.05$) used no analgesia or used it only occasionally (table 1). There were no statistically significant relationships between the variation of the previously mentioned parameters and etiology, the location of the different levels or their amount, the degree of correction achieved or the time of evolution.

Mean vertebral crushing was 42.50% (SD 27,030; mean 45%) with a Cobb's angle of 15.27° (SD 12.097; mean 18.50°). The correction achieved was 12.17% (SD 17.205; range 0-70%) for crushing and 6.93° (SD 8,870; range 0-30°) for the local Cobb's angle. Twenty vertebrae (46.5%) improved radiologically. The improvement obtained in

Table 1. Outcome of use of analgesics before and after surgery

	Previous analgesia	Final analgesia
Major opioids	16	5
Lesser opioids	8	2
NSAIDs	6	7
Occasional	0	3
Without analgesia	0	13

NSAIDs: non-steroid antiinflammatory drugs.

these fractures was 21.7% in terms of correction of crushing (range 5-70%); and 13,86° for correction of Cobb's angle (range 3-30°). No relationship was found between recovery of height or kyphosis correction as a function of crushing, initial deformity, the level of the injury or the time of evolution. In cases where several levels were treated there was generally one more severely involved level, whereas in the others the crushing was slighter.

The subgroup of tumoral patients improved to a lesser extent, with their final varies at very similar levels (initial VAS initial 3.5; final: 4), (initial Karnosfky: score 85; final 90). Of the 6 patients all but one improved. Two of the patients had a slight improvement, since their initial symptoms were scarce as compared with subjects treated for osteoporosis. No statistically significant differences were found between this subgroup and the general series.

Nor any kind of complications were observed as regards the surgical process. The postoperative radiolological studies revealed 6 cases of extravasation in 43 levels approached (13.95%), all of them anterior or anterolateral with no associated symptoms.

Six new fractures were detected; 3 occurred at some distance from the operated vertebra, with no bearing on the technique used, 2 in adjacent vertebrae and one in the same vertebra. Four of these lesions were either asymptomatic or slightly symptomatic, they went unnoticed for the patients and their detection was an incidental finding. Only one patient was able to associate the new injury to trauma (a fortuitous fall). One of the two symptomatic injuries occurred in the adjacent upper vertebra in a patient with an osteoporotic fracture, which obtained a poor final outcome (lower VAS score); the other consisted in the collapse of the operated vertebra in one oncologic patient with a large osteolytic lesion, in which cement prevented complete crushing. This crushing was attributed to a slight reversal of the initial improvement.

DISCUSSION

Osteoporotic VFs are a healthcare problem in industrialized nations. If we use a loss of vertebral height of over 15% as our diagnostic criterion, women older than 50 have a prevalence of 26%[1]. The appearance of an osteoporotic VF is one of the most significant risk factors that lead to further spinal fractures[2]. Classical treatment, based on rest and lower activity levels, leads to an inhibition of bone-forming stimuli with bone loss that may reach 2% a week. This involves accepting an unfavorable mechanical situation with an imbalance in the transmission of forces in the vertebral body and the presence persistent pain in spite of applying a correct treatment. Furthermore, kyphosis resulting from successive osteoporotic VFs causes a reduction in the pulmonary capacity of older patients, a deterioration of their quality of life and an increase in mortality[2,3].

To address this situation, minimally invasive percutaneous cementing techniques (vertebroplasty and kyphoplasty) have been developed in the last 10 years. We opted for kyphoplasty since it makes it possible to reduce and maintain the height of the vertebral body, relieve pain and improve the patients' activity level, as well as diminish the complications rate (extravasations into the medullary canal)[4-11].

A similar trend has occurred in the field of tumoral lesions. Up to 40% of cancer patients have vertebral lytic lesions. Conventional surgical or medical management of these lesions is sometimes ineffective or too invasive for weakened patients. Several studies have pointed out the efficacy of kyphoplasty for treating these lesions, with very low mortality rates[4,12,13].

This series reflects our experience of the use of kyphoplasty in the last 3 years. Since this is a recently introduced technique, our cases come from a variety of sources; the majority of them were referred to us either by other departments or by the emergency services, where patients consulted for persistent pain caused by an initially unnoticed injury. The standard protocol consists in checking the clinical-radiological correspondence between pain and the plain film, in addition to performing a STIR MRi to confirm the correspondence. Tumoral patients were different in that the main reason why they were referred to us was that they had uncontrollable pain, although two patients came to us with large partially unstable lesions that, nonetheless, produced few symptoms. Kyphoplasty was indicated in order to prevent crushing; we also took a biopsy simple since we wanted to confirm the diagnoses made and, in one case, identify the primary tumor.

Globally, mean time to surgery was 3.5 months, which makes it possible to define the treated lesions as subacute. Results have been compared as a function of the patients' time of evolution and no significant differences were found[6,7].

Measurements for height have been made based on plain lateral films performed prior to surgery and at the end of follow up. We decided to calculate the degree of crushing with respect to the uninjured adjacent vertebrae in order to avoid problems related to technique variability. The as-

sessment of the degree of correction achieved based on the amount of initial crushing corrected aims to take account of any kina of recovery, but also proportionally reduces the significance of the results obtained in badly crushed vertebrae like those in our series[14]. The results recorded are similar to those of other published series as regards the number of levels treated that recover their height[4,5,10]. However, height recovery values are lower than those in other series[4,7,8,10,11], even if we exclude cases of no improvement at all (21.4%, range 5-70%). This could be related to the high percentage of patients we operated who were in a subacute phase (some over 8 months into their pre-op). In spite of this, the remaining parameters studied are more in line with the data in the literature. Correction of Cobb's angle is proportionally higher than would be expected considering the improvement in crushing obtained, and is similar to the highest values reported in the literature[5,6,8,14]. This is probably due to the fact that most of the correction occurs in the anterior half of the vertebral body, which affords more in terms of a significant sagittal alignment than as regards height correction.

All patients (both osteoporotic and tumoral) improved, with the exception of two (93.2%). These results are in line with those of other series that report 95% improvement with kyphoplasty. If we compare VAS scores with those of other studies, we shall see that initial data is somewhat higher (less involvement) in the preoperative period and slightly lower in the final results[5,6,15]. In any case, clinical improvement was significant.

The other parameters measured to determine clinical outcome confirm the effectiveness of the technique. The Karnosfky score reflects a very significant change in the patients' quality of life. Before surgery, 70.63% of patients were incapable of normal activity whereas postoperatively 87.33% of patients performed their activities normally, with no functional limitations and only mild symptoms. Likewise, reduction in pain killer intake was remarkable. Up to 53% of patients ceased to require analgesia, or only required occasionally. Only 16% (5 patients) used narcotic analgesics; two of these did not improve and three showed an improvement in their VAS values in spite of all. These results are very similar to other previously reported ones[15].

No complications occurred during the perioperative period. Six cases of extravasation were observed (13.95%), all of them anterior or anterolateral. There were no cement leaks into the canal nor were there any associated symptoms. After having created a cavity in the vertebra, kyphoplasty makes it possible to inject cement at high viscosity, controlling risk and the leakage area. This data is in line with the reports in the literature (about 10%) and, in addition to a low incidence rate, in the majority of cases they have no clinical repercussion[4,5,6,15].

In two cases in our series the amount of VFs adjacent to the level treated is in line with the figures published in the literature[6,8,10,15,16]. Of these cases only one was associated with a poor clinical outcome. This complication would seem to be less of a problem with kyphoplasty than with vertebroplasty, since it corrects kyphosis and pushes back the center of gravity. Other 4 fractures occurred, 3 distant ones and one in the same vertebra in a tumoral patient. This complication marred the previously obtained result, although the VAS score remained below the preoperative value. This patient was one of the first cases we treated and his problems could be attributed to the fact that not enough cement was introduced to stabilize the vertebra; in spite of this, his clinical evolution was satisfactory, even after his refracture, with the cement stopping the fracture to subside fully. All the distant injuries went unnoticed for the patient and were not associated to a poorer clinical outcome. The frequency with which these fractures lead to symptoms has not been defined, nor is the indication for a new kyphoplasty clear in these cases.

Tumoral involvement of the vertebrae is a common occurrence and it is often managed conservatively since surgical options are, on occasion, too aggressive for these patients. Kyphoplasty makes it possible to treat some of these cases with minimum associated comorbidity and good clinical results[12]. After treatment, all patients with a tumoral pathology, of diverse etiologies, achieved good results, except for one. Clinical improvement rates are lower than those for the general series, mainly due to a lower initial clinical involvement. Final results are comparable to those of the series treated for osteoporosis.

To conclude, we can say that kyphoplasty is an effective technique to treat both osteoporotic fractures refractory to medical treatment and for selected tumoral patients. The poor results in our series have been attributed to poor patient selection and the presence of adjacent fractures.

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Conflict of interests

The authors have declared to have no conflict of interests.