Percutaneous vertebroplasty for the treatment of osteoporotic vertebral compression fractures

EVALUATION AFTER 36 MONTHS

In a prospective study between August 2002 and August 2005, we studied the quantitative clinical and radiological outcome 36 months after percutaneous vertebroplasty for intractable type-II osteoporotic vertebral compression fractures which had been unresponsive to conservative treatment for at least eight weeks. We also examined the quality of life (QoL). The clinical follow-up involved the use of a pain intensity numerical rating scale (PI-NRS, 0 to 10), the Short-Form 36 (SF-36) QoL questionnaire and an anamnestic questionnaire before and at seven days (PI-NRS only), and one, three, 12 and 36 months post-operatively.

A total of 30 consecutive patients received percutaneous vertebroplasty for 62 vertebral compression fractures with a mean time between fracture and treatment of 7.7 months (2.2 to 39). An immediate, significant and lasting reduction in the average and worst back pain was found, represented by a decrease of 3.1 and 2.7 points after seven days and 3.1 and 2.8 points after 36 months, respectively (p < 0.00). Comparison of the pre- and post-vertebroplasty scores on the various SF-36 domains showed an ultimate significant increase in six of eight domains and both summary scores. Asymptomatic leakage of cement was found in 47 of 58 (81%) of treated vertebrae. Two minor complications occurred, an asymptomatic pulmonary cement embolism and a cement spur along the needle track.

Percutaneous vertebroplasty in the treatment of chronic vertebral compression fractures results in an immediate, significant and lasting reduction in back pain, and overall improvement in physical and mental health.
recruited at Leiden University Medical Centre. Four men and 26 women with a mean age of 70.7 years (41.5 to 90.6) had a total of 139 pre-existing vertebral compression fractures, with a mean of 4.6 per patient (1 to 13). Of these 139 fractures, 62 were painful and showed bone-marrow oedema on MRI. They were treated by percutaneous vertebroplasty over 32 sessions. Approximately 50% of the procedures were in the thoracolumbar region (Fig. 1).

The inclusion criteria were an osteoporotic vertebral compression fracture including that with a severe compression deformity,14 local mid-line back pain refractory to conservative treatment for at least six weeks, back pain related to the site of the fracture on MRI, the presence of bone-marrow oedema in the collapsed vertebral body on MRI T2-weighted short tau inversion recovery (STIR) sequences, age over 40 years and written informed consent.

Exclusion criteria were vertebral compression fractures due to causes other than osteoporosis, compression of the spinal cord or stenosis of the vertebral canal by > 30% of the local diameter, neurological deficits, an uncorrectable bleeding disorder, infection of the vertebral column, inability to lie prone for two hours, an American Society of Anesthesiologists score ≥ 415 and inability to complete a questionnaire.

When a patient presented with pain after conservative treatment for six weeks, the complete clinical procedure was carried out in two weeks. This protocol ensured that patients were not treated by percutaneous vertebroplasty within eight weeks after the onset after the fracture.

The mean length of follow-up was for 29.2 months (1 to 48). The 36-month follow-up was completed by 80% of the patients. Four died from causes unrelated to the treatment, two were unable to complete the follow-up because of severe cognitive problems, and one was unwilling to participate further. One patient had a history of leukaemia and three had metastasised carcinoma. However, all biopsies during the vertebroplasty confirmed osteoporosis and showed no signs of malignancy.

The mean age of the fracture as established by the time between the onset of new back pain related to a radiologically confirmed fracture and the time of vertebroplasty was 7.7 months (2.2 to 3.9).

Pre-operative anteroposterior and lateral radiographs and MR scans including fat-suppression sequences of the total spine were taken. Single-level percutaneous vertebroplasty was performed in ten patients (33.3%), two levels in 13 (43.4%), three levels in three (10.0%), four levels in three (10%) and five levels (in two sessions) in one patient (3.3%). The approach was unipedicular in 32 vertebral bodies (52%) and bipedicular in 30 (48%).

Percutaneous vertebroplasty was performed using a biplane angiography unit, under sedation and with the patient prone. A 10G vertebroplasty needle (Optimed GmbH, Ehingen, Germany) was advanced into the pedicle and through the posterior wall of the vertebral body using a small mallet. A bone biopsy was taken through the percutaneous vertebroplasty needle using a 13G Cook bone biopsy needle (Cook Medical, Limerick, Ireland) and, after progression into the anteromedial third of the vertebral body, low-viscosity PMMA bone cement (Osteopal-V; Heraeus Medical GmbH, Hanau, Germany) was injected using an Optimed Cemento gun (OptiMed Medizinische Instrumente GmbH, Ettlingen, Germany). If distribution of the cement in the vertebral body was unsatisfactory, a second needle was inserted through the contralateral pedicle, followed by injection of cement.

Fig. 1
Diagram showing the distribution of treated vertebra. The most commonly treated was Th12, followed by the first three lumbar levels.
The aim of the procedure was to symmetrically fill the central and anterior parts of the vertebral body. An immediate post-operative CT scan was taken to reconfirm the correct positioning of the cement and to detect any leakage.

For each patient, the pre- and post-operative clinical characteristics were obtained, including the SF-36 health survey, a 0 to 10 Pain Intensity Numerical Rating Scale (PI-NRS)\textsuperscript{16} for average and worst back pain and a 0 to 10 Satisfaction Numerical Rating Scale (S-NRS).\textsuperscript{17,18} Health state...
scores, thereby indicating a significant overall increase in the quality of life. During the first month after percutaneous vertebroplasty, significant improvement was seen only in the domains of physical function (p = 0.003), bodily pain (p < 0.001) and in the physical component score (p < 0.001) (Fig. 3).

The health state utility, using SF-6D, showed a statistically significant increase from 0.50 pre-operatively to 0.59 (p = 0.03), 0.58 (p = 0.021) and 0.59 (p = 0.032) at three, 12 and 36 months, respectively (paired sample t-test).

The vertebroplasty questionnaire showed significant improvement (McNemar’s test) in the activities of daily life after percutaneous vertebroplasty and the back-pain-related limitation in activities of daily life also decreased significantly (Wilcoxon signed ranks test). Moreover, the intensity, frequency and duration of back pain decreased significantly after vertebroplasty. In those who did not experience complete relief this decrease was also significant, except at the long-term follow-up for the duration of episodes of back pain.

In performing specified movements, only difficulty standing from a chair had immediate and durable significant improvement (Wilcoxon signal ranks test). However, the joy of life improved three months after percutaneous vertebroplasty.

The mean injected volume of cement per vertebral body was 5.3 ml (0.6 to 11.7). The immediate post-operative CT scans were examined for extra-vertebral leakage of cement. Of 58 treated vertebrae examined 67 sites of leakage were found in 47 vertebrae (81.0%).

Minor complications occurred in two patients. In one, leakage of cement during treatment of a thoracic vertebral body caused an asymptomatic cement embolism in the pulmonary vasculature, detected on the post-operative CT scan. In the other, a spur of cement was present which followed the track of the needle from the pedicle to the subcortaneous tissues. This was removed immediately, resulting in a post-operative haematoma and low pain which resolved within two days.

Discussion

The benefits of percutaneous vertebroplasty depend on the selection of the patient, surgical skill, complication rates and procedural characteristics such as the viscosity of the cement, the filling volume and distribution. Hitherto, there have been no definite criteria for the selection of patients for percutaneous vertebroplasty. It is known that 80% of all symptomatic osteoporotic vertebral compression fractures are acute (type I) and heal naturally within four to eight weeks, whereas the remaining 20% are chronic (type II) and heal spontaneously after 45 to 60 weeks. Since the introduction of percutaneous vertebroplasty, both types have been treated by this technique.

Treatment of acute vertebral compression fracture results in an immediate and significant decrease in pain in most cases. This is the only true benefit compared with
conservative management and may be one of the key factors in the success of percutaneous vertebroplasty. However, because this technique is not without risk, the decision as to whether to undertake it before eight weeks from the onset of symptoms should be made according to careful risk-benefit analysis and the experience of the surgeon.

Our mean decreases in the average and worst back pain are in accordance with figures reported in meta-analyses, and from several other prospective studies investigating the effect of percutaneous vertebroplasty on patients with type-II osteoporosis.

Although the severity of pain is generally used as the primary outcome measure, the change in quality of life reflects the overall effect of treatment. Despite the successful use of the SF-36 in evaluation of the quality of life in patients with osteoporotic vertebral compression fractures, back pain, and spinal surgery, there are only three prospective studies specifically examining the effect of percutaneous vertebroplasty on the quality of life using the SF-36 and these are characterised by poor response rates, limited follow-up (≤ 12 months) and the use of different types of bone cement. To our knowledge, our study is the first analysis of prospectively collected data on the quality of life three years after percutaneous vertebroplasty with one type of cement and with a response rate of 80%.

A comparison of the pre- and post-vertebroplasty scores in the various SF-36 domains has shown a significant and clinically relevant increase in six of eight domains and both summary scores, thereby indicating a significant overall increase in the quality of life. Pre-operative SF-36 scores were substantially lower than for gender-corrected scores of the average Dutch population of 65 to 74 years and above, and comparable with those in patients with osteoporotic vertebral compression fractures who are suitable for vertebral augmentation.

During the first month after operation significant improvement was seen only in the domains of physical function, which is known to have the highest correlation with physical ability, and bodily pain, reflecting the results of the numerical pain score. The role physical and role emotional domains showed an obvious, albeit non-significant decrease in the first month, probably due to general post-treatment role-inhibiting behaviour. There was a significant improvement in six of eight SF-36 domains at follow-up at three and 36 months in our series. This contrasts with the study of Do et al., in which a significant improvement in seven of eight domains had already occurred during the first month after percutaneous vertebroplasty. The general health domain perceptions showed no improvement throughout the follow-up period, which is in accordance with other similar studies.

Our role emotional domain results agree with others and show no long-term significant improvement. The physical component score showed an immediate, significant and lasting increase, whereas the mental component score had a gradual, but eventually significant increase after more than 12 months (Fig. 3). The only two studies which have reported SF-36 summary scores showed a significant increase in both summary scores as early as one month after percutaneous vertebroplasty. The delayed response in improvement in scores may be because our study included only patients with type-II osteoporotic vertebral compression fractures, whereas other studies enrolled patients with acute and possibly type-I osteoporotic vertebral compression fractures. Because of the longer period patients had more severe pain and disability and therefore recovery might have been prolonged. However, despite working against the natural decrease in quality of life with ageing, the amount of improvement was comparable.

Health state utility, using the SF-6D, showed a statistically significant increase from 0.50 pre-operatively to 0.59 at three and 36 months after percutaneous vertebroplasty, indicating a post-operative health state which was 18% higher.

The vertebralplasty questionnaire used in our study has not yet been formally validated, but resembles the questionnaire of Evans, Kip and Boutin. When our prospective study began, neither their questionnaire nor any other validated vertebroplasty specific questionnaire was available. The back-pain-related limitation in activities of daily life also decreased significantly after percutaneous vertebroplasty. Moreover, the intensity, frequency and duration of back pain decreased significantly. These outcomes are in line with those of the SF-36 and indicate that the improvement in the SF-36 scores is due to a decrease in the problems which are prevalent in patients with an osteoporotic vertebral compression fracture.

The rate of asymptomatic leakage of cement was comparable with that of other studies, as was our minor complication rate (6.7%).

The limitations of our study were the small sample size, the lack of specific recording of the use of analgesics during follow-up and the absence of a control group. Another limitation was that the SF-36 is a generic health-related instrument which might be influenced by ageing and co-morbidity.

We have shown an immediate, significant and lasting improvement in pain and overall physical and mental health after percutaneous vertebroplasty. However, the decision as to whether to perform percutaneous vertebroplasty should be made carefully and according to risks and potential benefits for each patient.

Supplementary material

Tables showing the PI-NRS and SF-36 scores and outcome relating to activities of daily life, back pain, specific activities and miscellaneous characteristics are available with the electronic version of this article on our website at www.bjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.
References


