ORIGINAL ARTICLE

Percutaneous Vertebroplasty in Vertebral Compression Fractures of Benign or Malignant Origin

A Prospective Study of 1188 Patients With Follow-up of 12 Months

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SUMMARY

Background: Vertebral body fractures are a source of high costs for the health care system and will continue to be one as the population ages. Cost-effective treatment is thus all the more important. In this study, we evaluated patients' quality of life during the first 12 months after they had undergone percutaneous vertebroplasty for vertebral body fractures which were refractory to conservative treatment. Our analysis took the causes of the fractures into account.

Methods: Pain, mobility, and need for analgesics were assessed prospectively on verbal rating scales one day before and one day after vertebroplasty, as well as over a follow-up period of up to 12 months. The same examiner interviewed each patient at all time points to obtain this information.

Results: 1188 patients underwent vertebroplasty for 1980 vertebral body fractures; the most common etiology was osteoporosis (75%). There was statistically relevant improvement in all three of the variables studied from the day before the procedure to the last follow-up, regardless of the cause of fracture ($p < 0.01$). Most of the clinical benefit was already evident on the day after the procedure. Patients with fractures due to osteoporosis experienced further statistically relevant improvement by 6 months after treatment.

Conclusion: Percutaneous vertebroplasty immediately relieves the pain of vertebral body fractures, improves patients' mobility, and lowers their consumption of analgesics. There can be further clinical improvement up to 6 months after the procedure, particularly in patients with fractures due to osteoporosis. As osteoporosis is the most common cause of vertebral body fractures, this patient group is important not just clinically, but economically as well.

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Vertebroplasty involves the percutaneous injection of viscous bone cement, usually polymethyl methacrylate (PMMA), into a fractured vertebral body. Its purpose is to relieve fracture-related pain and to restore mobility. It was first used by Galibert and Deramond (1) in France in 1984 to treat cervical hemangiomas. It was developed as a standard treatment for osteoporotic vertebral body fractures in the 1990s, particularly by Jensen et al. (2), and its indications were then extended to include vertebral body fractures of metastatic and traumatic origin (3–5). Guidelines on vertebroplasty were published in 2003 by the German Radiological Society (*Deutsche Röntgengesellschaft*), and an interdisciplinary consensus paper on vertebroplasty and ky-phoplasty followed in 2005 (6, 7).

Vertebral body fractures

Epidemiology

More than 400 000 vertebral body fractures are newly diagnosed in Europe each year (8), and this number will probably double by 2050 as a result of demographic changes (9). Osteoporosis is the main cause of vertebral body fractures (in more than 80% of cases), followed by vertebral body metastases and trauma; an increasing percentage of cases are due to more than one of these causes (10). Osteoporosis is more common in women than in men, and women are thus more likely to sustain a vertebral body fracture. The prevalence of osteoporotic fractures rises with age, from 5% to 20% among 50-year-olds to more than 50% among persons over age 80 (11, 12).

Clinical manifestations and complications

The main manifestation of a vertebral body fracture is back pain, with resulting functional limitation of mobility. The loss of height of the fractured vertebral body leads to a kyphotic deformity of the spine, and thereby to further potential complications including restrictive pulmonary dysfunction, pulmonary embolism, and compression of the abdominal viscera

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TABLE 1

Pre-interventional status of all patients (scores)

		Osteoporosis	Tumor	Trauma	Overall
Number of patients		896	192	100	1188
Men / Women		284 / 612	96 / 96	36 / 64	416 / 772
Age (years) (mean ± SD)		73 ± 9	66 ± 9	70 ± 9	71 ± 9
Age range (years)		33–91	40–82	45–85	33–91
Pain	0	4	24	0	28
	1	4	8	0	12
	2	4	8	0	12
	3	84	40	8	132
	4	236	24	32	292
	5	332	44	32	408
	6	232	44	28	304
Mobility	0	4	28	0	32
	1	300	56	24	380
	2	492	96	68	656
	3	100	12	8	120
Analgesic requirement	0	80	36	12	128
	1	72	28	4	104
	2	328	64	28	420
	3	340	64	52	456
	4	76	0	4	80

Pain: 0 = no pain, 1 = almost no pain, 2 = mild pain, 3 = moderate pain, 4 = severe pain, 5 = very severe pain, 6 = extreme pain

Mobility: 0 = no limitation, 1 = limitation without the need for orthopedic aids, 2 = limitation necessitating orthopedic aids, 3 = bedridden

Analgesic requirement: 0 = no analgesics required, 1 = occasional need for analgesics, 2 = regular consumption of non-steroidal anti-inflammatory drugs (NSAID) with sustained effect, 3 = regular consumption of NSAID with variable effect, 4 = additional consumption of opioid derivatives

(13). Limitation of mobility by pain increases the risk of pneumonia, deep venous thrombosis of the lower limbs, pulmonary embolism, and decubitus ulcers (14). A vertebral body fracture elevates the probability of another fracture elsewhere to four to five times higher than normal; 25% of the affected patients have a second vertebral body fracture within one year (15).

Socioeconomic consequences

Vertebral body fractures and their medical consequences incur high costs for the health care system because they necessitate hospitalization, rehabilitative measures, medications, interventional treatments, and orthopedic aids. The hospital costs alone amount to about 4000 euros per vertebral body fracture and per patient (an average figure for Europe). The overall costs across Europe come to some 400 million euros per year, not including costs after discharge from the hospital, such as for ambulatory

treatment. These costs are also becoming higher over time (16). Thus, any treatment that might lower the relative risk of a second fracture within one year and improve these patients' quality of life would presumably not just lessen morbidity, but reduce health-care expenditures as well (9).

Treatment by vertebroplasty

The treatment of a vertebral body fracture by vertebroplasty begins with a single shot of antibiotic for anti-infective prophylaxis. Next, the patient is positioned prone, the affected segment is localized fluoroscopically with a biplanar C-arm, and the skin and periosteum are locally anesthetized under sterile conditions. The vital signs are continuously monitored. Small stab incisions are made, through which 11- or 13-gauge hollow needles are then inserted and driven into the pedicles on both sides with gentle hammer blows under fluoroscopic guidance. The aim is to position the needle tips at the junction of the middle and anterior thirds of the vertebral body. Once this has been accomplished, and once the cement has become sufficiently viscous, 1.5 to 2 mL of PMAA is injected through each of the two hollow needles into the vertebral body, under continuous observation by biplanar fluoroscopy. If any cement leakage is seen the injection is stopped at once. The final result is documented with images in two planes.

Goals of the study

The purpose of this study was to assess patients' quality of life in terms of pain, mobility, and need for analgesic medications for up to twelve months after vertebroplasty for vertebral body fracture.

Materials and methods

From 2002 to 2008, we documented the course of all patients who underwent vertebroplasty for acute and subacute (≤ 3 months) vertebral body fractures of osteoporotic, traumatic, or neoplastic origin. We obtained verbal rating-scale data on pain, mobility, and the need for analgesic medications by interviewing each patient one day before the procedure and one day, one week, and 3, 6, and 12 months afterward.

Statistical methods

The temporal development of these variables within the time frame of this exploratory study was calculated with established non-parametric statistical methods, both synchronously among all patient groups and separately for each group (for an extensive discussion of the statistical methods used, see the *eBox*). First, a comparison across all groups regarding pre-interventional pain, mobility, and analgesic requirement was performed with a global Kruskal-Wallis test. This test revealed statistically significant differences ($p < 0.001$). We therefore went on to analyze differences in pre-interventional status between groups in pairwise comparisons, using the Mann-Whitney U test.

The patients' course over the duration of post-interventional follow-up was first assessed with the Friedman test to determine whether any differences with respect to pain, mobility, or analgesic requirement could be found, either in the overall patient group or in the three subgroups defined by the condition underlying the vertebral body fracture; the asymptotic significance was $p < 0.001$ in all cases. Next, a Wilcoxon test for paired samples was performed to compare pain, mobility, and analgesic requirements after the procedure with the same variables before the procedure, in each of the three patient groups. For the 180 patients in whom a cement dislocation into the paravertebral venous plexus was found, results over the entire follow-up period were compared by a Mann-Whitney U test with the results of the remaining 1008 patients who did not have this complication.

The statistical analysis was performed with the aid of the PASW Statistics Version 17 program (SPSS Inc., Chicago, IL, USA).

Results

We treated a total of 1085 patients (91%) from 2002 to 2008 in one of the two study centers, and 103 patients (9%) from 2007 to 2008 in the other.

Pre-interventional status of the patient group

We will now consider the frequencies of the various conditions underlying the fractures, as well as the pattern of distribution of the fractures and the inter-group differences in pre-interventional status.

Frequency of underlying conditions and pattern of distribution of fractures – Among the 1188 patients whom we consecutively followed, osteoporosis (75%) was the most common cause of vertebral body fracture, followed by metastatic tumors (16%) and trauma (9%).

More than one vertebral body was affected in 532 patients. A total of 324 vertebral bodies were treated in this group. Only one vertebral body was affected in 656 patients. Thus, a total of 1980 vertebral bodies were treated in 1188 patients. More than two-thirds (68.9%) of the solitary fractures were in the region T12 to L4, most commonly in the L1 vertebral body (21.3%). The commonest site of vertebral body fracture in the thoracic spine (9.8%) was at the apex of the thoracic kyphosis (T8).

Differences in pre-interventional status – Table 1 contains an overview of the patients' pre-interventional baseline data and of the scores that they reported in further interviews. These data are shown for each of the three patient groups as well as for the overall group.

With respect to the underlying conditions, pairwise group comparisons of ordinal data with the Mann-Whitney U test revealed that patients with osteoporotic fractures were significantly less mobile than tumor patients before the intervention ($p < 0.001$), and that they also had more pain and needed more

TABLE 2

Median values for pre-interventional status (scores)

	Osteoporosis	Tumor	Trauma	Overall
Pain	5	4	5	5
Mobility	2	2	2	2
Analgesic req.	2	2	3	2

Overview of median scores for pain, mobility, and analgesic requirement one day before the intervention, for each of the three patient groups (osteoporosis, tumor, trauma) and for the overall patient collective

analgesic medications ($p < 0.001$ for both of these findings as well). The same was found in a comparison of trauma patients with tumor patients (here, too, $p < 0.001$ for all three findings). On the other hand, no significant differences were found in a comparison of the osteoporotic patients with the trauma patients. The median pre-interventional pain score was 5 in the osteoporotic patients and trauma patients, and 4 in the tumor patients. The median scores of all three variables examined, listed for each of the three patient groups and for the overall patient collective, are shown in Table 2.

Post-interventional status

We were able to follow up 964 patients (81%) for the entire intended 12-month period of post-interventional observation. The post-interventional status was assessed one day after the procedure in all patients, one week after the procedure in 1128 patients, and 3 and 6 months afterward in 980 patients.

As early as the first day after the procedure, the overall patient collective experienced a statistically significant ($p < 0.001$) improvement in pain, mobility, and analgesic requirement scores compared to their pre-interventional status, regardless of the condition underlying the vertebral body fracture. A further significant improvement in the pain and analgesic requirement scores was found between the first day after the procedure and one week afterward. At times later than one week after the procedure, further statistically significant improvement was found with respect to mobility in the osteoporosis and trauma groups. The tumor patients had no further statistically significant improvement at times later than one week after the procedure.

The osteoporotic patients had significantly less pain and needed significantly less analgesic medication 6 months after the procedure than 3 months after it ($p < 0.01$ and $p < 0.001$, respectively). Furthermore, with respect to mobility, this patient group experienced statistically significant improvement from 6 months after the procedure to the end of follow-up ($p < 0.05$).

None of the variables examined ever worsened to a statistically significant extent in any patient group

TABLE 3

Statistical significance of relative pain reduction compared to the immediately preceding time point over the course of post-interventional follow-up (Wilcoxon test for paired samples)

	1 day before vs. after intervention	7 days vs. 1 day after intervention	3 mo vs. 7 days after intervention	6 mo vs. 3 mo after intervention	12 mo vs. 6 mo after intervention
Osteoporotic patients	p<0.001	p<0.001	p<0.001	p=0.005	p=1
Tumor patients	p<0.001	p<0.001	p=0.52	p=0.25	p=0.005
Trauma patients	p<0.001	p<0.001	p=0.38	p<0.001	p=0.046
Overall	p<0.001	p<0.001	p<0.001	p<0.001	p=0.42

TABLE 4

Statistical significance of relative improvements in mobility compared to the immediately preceding time point over the course of post-interventional follow-up (Wilcoxon test for paired samples)

	1 day before vs. after intervention	7 days vs. 1 day after intervention	3 mo vs. 7 days after intervention	6 mo vs. 3 mo after intervention	12 mo vs. 6 mo after intervention
Osteoporotic patients	p<0.001	p<0.001	p<0.001	p<0.001	p=0.015
Tumor patients	p<0.001	p=0.051	p=0.011	p=0.087	p=0.371
Trauma patients	p<0.001	p<0.001	p=0.046	p=1	p=1
Overall	p<0.001	p<0.001	p<0.001	p=0.005	p=0.01

during the time period of the study. All of the statistically significant improvements that were observed in any of the three variables examined from any time point to the next time point, in the three patient subgroups separately and in the overall patient collective, are shown in *Tables 3-5*.

In summary, regardless of the underlying cause of the vertebral body fracture, statistically significant improvements ($p < 0.01$) were seen in all three of the variables examined—pain, mobility, and analgesic requirement—when the patients' status before the procedure was compared with their status at the end of the follow-up period twelve months later. The positive effect on each of these three variables reached a maximum for the overall patient collective six months after vertebroplasty. The distribution of individual pain scores before the intervention and at the end of the study are presented in the *Figure*.

Complications

Dislocation of cement into the paravertebral venous plexus was seen in 180 patients (15%). None of these patients went on to sustain any symptomatic complication, either during or after the procedure; in particular, no patient had cement embolization to an internal organ, and none developed a focal neurological deficit. Statistical analysis showed that these patients' post-interventional course did not differ

significantly in terms of pain, analgesic requirement, and mobility from that of patients in whom no cement dislocation was seen (statistical power >99%).

Discussion

The purpose of this study was to assess the efficacy of vertebroplasty in the treatment of vertebral body fractures due to osteoporosis, trauma, and tumors, in terms of potential improvements in three variables: pain, mobility, and analgesic requirement. Clear improvement was found in all three variables over the short and intermediate term after the procedure.

The low complication rate is noteworthy, particularly so because all of the complications that did occur were of types that are rated as clinically insignificant by the criteria of the Society of the Interventional Radiology (SIR complication category A). No patient had a cement leak extending beyond the paravertebral venous plexus. The results in patients with cement dislocation (15% of the overall group) did not differ in respect to any of the variables examined from the results in patients without any cement dislocation. Nor did we find any significant differences in complication rates among the three patient groups (osteoporosis, trauma, and tumor patients). Similar findings have been reported in other studies (17–19).

The low rate of cement dislocation and the lack of clinically significant complications in this series can

TABLE 5

Statistical significance of relative reduction of analgesic requirement compared to the immediately preceding time point over the course of post-interventional follow-up (Wilcoxon test for paired samples)

	1 day before vs. after intervention	7 days vs. 1 day after intervention	3 mo vs. 7 days after intervention	6 mo vs. 3 mo after intervention	12 mo vs. 6 mo after intervention
Osteoporotic patients	p<0.001	p<0.001	p<0.001	p<0.001	p=0.083
Tumor patients	p<0.001	p<0.001	p=0.45	p=0.59	p<0.001
Trauma patients	p<0.001	p<0.001	p=1	p=0.01	p=1
Overall	p<0.001	p<0.001	p<0.001	p=0.015	p<0.001

be attributed to its organizational and technical features. Suitable patients for the study were selected according to strict criteria, and vertebroplasty was performed in the two study centers by experienced interventionalists adhering to a standardized technique. Two important technical aspects were that, from the beginning of the study onward, careful attention was paid to the injection of cement in a highly viscous, paste-like state (the “hanging drop” method), as well as to the injection of no more than a small amount of cement.

Although highly viscous cement has the disadvantage of requiring a higher injection pressure than less viscous cement does to overcome the resistance of the injecting canula, biomechanical studies have shown that highly viscous cement is more homogeneously distributed within the vertebral body after injection and is less likely to leak outside it (20–25). The literature contains conflicting information on the influence of the amount of cement injected on the clinical outcome. Most studies have failed to reveal any correlation between the amount of cement injected and the benefit of the procedure with respect to pain, though there is clearly a positive correlation between the amount injected and the rate of cement leakage (e1, e2). In a recent study, Nieuwenhuijse et al. found that cement viscosity has no effect on clinical outcomes, yet low viscosity is an independent predictive factor for cement leakage (e3).

Restoring the original height of the vertebral body seems not to improve the clinical manifestations to any significant extent (e4). In the present study, no more than 4 mL of PMMA was injected into any vertebral body. In view of the results of other studies mentioned above and the very good clinical results in the present study (no symptomatic complications whatsoever in 1188 patients, in whom 1 980 vertebral bodies were treated), the authors think that a low cement volume of no more than 4 mL of PMMA per vertebral body is both safe and effective. We recommend injecting cement under high-resolution fluoroscopic guidance in two planes; experience

suggests that this enables the interventionist to detect cement leaks more easily, and perhaps more rapidly as well.

Only a few published studies have included an assessment of all three variables that were examined here (pain, analgesic requirement, and mobility) before vertebroplasty as well as during a long follow-up period after it. In this study, we found that statistically significant relief of pain generally occurs immediately after the procedure, and that further improvement can be expected for up to six months afterward. The same holds for the improvement in mobility, which may potentially lead not just to a better quality of life for the patient, but also to a lower rate of the complications that can result from immobilization, including deep venous thrombosis. Rousing et al. showed that vertebroplasty shortens patients’ stay in the hospital (e5).

A further noteworthy finding of this study was the rapid decline of the analgesic requirement among the patients treated. Vertebroplasty may thus have the further benefit of lessening the occurrence of analgesic-induced side effects in the old and often polymorbid patients who commonly undergo this procedure. Moreover, this study showed that the significant reduction in the need for analgesic medication compared to the patients’ pre-interventional state was still evident 12 months after the procedure. In another study, Wang et al. showed that patients who underwent vertebroplasty for the treatment of osteoporotic vertebral body fractures needed significantly less analgesic medication 12 months later than did a conservatively treated control group (e6). Looking back on the results of the present study, the authors think that proper patient selection is an important determinant of the quality of the long-term outcome. Specifically, we recommend treating only fractures that are no more than three months old, and that all other potential causes of the pain that these patients complain of should be meticulously excluded by means of a thorough physical examination, including a neurological examination, as well as by imaging studies as needed.

Overview of pain scores before the procedure and on final follow-up (all 1188 patients)

FIGURE

Limitations

The information that the present study can provide is limited by its lack of a control group, as well as by its design as an exploratory study employing the rating scales that were chosen at the outset for the three variables that we examined (pain, mobility, and analgesic requirement). Among these three scales, only the verbal rating scale for pain, whose structure corresponded to the well-studied scale of the SF 36, has been validated. The scales that we used for mobility and analgesic requirement were constructed on the basis of our clinical experience and the constraints of the telephone interview setting, and were not validated. No multivariate analysis was performed. On the other hand, the major positive aspects of this study included the large number of cases, the strict inclusion criteria, the large percentage of patients followed up for the entire intended duration (one year), and the fact that all patient interviews were conducted by the same person.

Critical assessment in the light of recent literature

The results presented here need to be considered in the critical light of two randomized, controlled, and blinded clinical trials published in 2009, in which the results of vertebroplasty were compared to those of a sham procedure (e7, e8) and no benefit of vertebroplasty was found. These findings have had a strong negative influence on the frequency with which vertebroplasty is performed, reversing the upward trend of the years just before their publication, and have given rise to potential misunderstandings and worries among referring and treating physicians. In the meantime, many authors have subjected these two trials to critical analysis (e9–e11). The trial by Buchbinder et

al. (e7) has been criticized both for its unsuitable methods and for the small number of cases in relation to the four-year duration of the study. Some of the participating centers treated only very few patients (2 to 13 patients in total). Moreover, in the Kallmes trial (e8), 27 patients crossed over from the placebo arm to the treatment arm of the study at three months.

Patients were not asked in either trial about the type and amount of analgesic medication that they consumed after the procedure. It also seems highly inappropriate to use vertebroplasty for fractures that are up to one year old, as was done in both trials: relevant publications and the known pathophysiology of vertebral body fractures clearly imply that fractures are likely to be fully healed after such a long interval.

It is particularly noteworthy that the Kallmes trial was on the verge of showing a statistically significant benefit for vertebroplasty ($p = 0.06$), yet its authors chose not to discuss the implications of this important result. Statistical “significance” and “insignificance” always depend on the more or less arbitrary threshold level for significance that is selected before the data are in and cannot, therefore, be thought of as an entirely objective matter.

The recently published Vertos II study is a non-blinded, prospective, randomized, multicenter trial involving 202 patients who were followed up for 12 months (e12). Among patients with osteoporotic vertebral body fractures, pain was found to be reduced to a greater extent in the vertebroplasty group than in the control group (conservative treatment) at every observational time point of the study ($p < 0.001$). The fractures that were treated were no more than six weeks old, and bone-marrow edema on MRI was an inclusion criterion as well. No clinically relevant

complications of vertebroplasty occurred. The Vertos II study thus resembled the present study in that it involved similarly strict inclusion criteria and did not result in any clinically apparent complications.

Overview

Vertebroplasty is an important component of the multidisciplinary treatment of vertebral body fractures. All of the outcome variables examined in the present study improved to a statistically significant extent in comparison to their pre-procedural baseline values, not just in the intermediate term, but actually within 24 hours of the performance of the procedure. Thus, vertebroplasty offers patients a realistic chance of nearly immediate relief from their most pressing symptoms. Moreover, further improvement can occur for up to six months after the procedure, particularly in the socioeconomically most important group of patients with vertebral body fractures, namely, those whose fractures are due to osteoporosis.

Before this study was carried out, it was approved by the institutional ethics committees. It was performed in accordance with the ethical standards of the Declaration of Helsinki (1964). All patients gave their informed consent to participation in the study.

Conflict of interest statement

The authors declare that no conflict of interest exists.

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KEY MESSAGES

- Suitable patients for vertebroplasty should be selected according to strict criteria in an interdisciplinary consensus. It is recommended that vertebroplasty should be performed with standardized technique by experienced interventionists in high-volume centers.
- The findings of this study suggest that the use of high-viscosity cement (the “hanging-drop” method), combined with the injection of only a small amount of cement, helps keep the rate of cement leakage to a minimum.
- The symptoms of vertebral body fractures usually improve immediately after vertebroplasty, and further improvement can be expected for up to six months after the procedure.
- Pain reduction, a reduced need for analgesic medications, and improved mobility were observed as sustained benefits of vertebroplasty in all three patient groups in this study over the entire duration of post-procedural follow-up.

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Percutaneous Vertebroplasty in Vertebral Compression Fractures of Benign or Malignant Origin

A Prospective Study of 1188 Patients With Follow-up of 12 Months

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Further Information on Materials and Methods

From 2002 to 2008, 1 188 patients who underwent vertebroplasty for the treatment of acute and subacute vertebral body fractures of osteoporotic, traumatic, or neoplastic origin were followed prospectively in two treatment centers in Germany, the Knappschaftskrankenhaus Bottrop (Center 1) and the Klinikum Vest (Center 2, a treatment center of the Knappschaftskrankenhaus Recklinghausen). The initially recorded data for each patient included sex, age, and the number, site(s), and cause of vertebral body fracture(s).

Vertebroplasty was considered only for patients who had had their symptoms for no longer than three months. All patients underwent a symptom-oriented physical examination as well as documentation of the affected vertebral body (or bodies) with conventional radiography in 2 planes. If the fracture was due to an acute event, computerized tomography was performed to visualize the fracture, the posterior surface of the vertebral body, and the spinal canal. Non-acute fractures were studied either with magnetic resonance imaging for the detection of bone-marrow edema or with bone scintigraphy for the detection of nuclide accumulation in the affected vertebral body.

The inclusion criteria were defined as follows, with different criteria depending on the underlying cause of the fracture:

- Osteoporosis: Painful fracture with loss of height of the vertebral body, without any precipitating trauma, and with persistent symptoms despite conservative treatment in conformity with the relevant guidelines
- Trauma: Painful, stable fracture with persistent symptoms despite conservative treatment, in the absence of an indication for standard surgical treatment
- Tumor: Painful osteolytic lesion or fracture associated with a malignant tumor; vertebroplasty performed as a palliative adjunct to the overall oncological treatment plan

The exclusion criteria included florid infection, coagulopathy, vertebral body instability, focal neurological deficits, and allergy to the material used for vertebroplasty.

The conceptual background and methods of this study are in conformity with the guidelines of the German Radiological Society, which were published one year after the initiation of the study, as well as with the interdisciplinary consensus paper on vertebroplasty and kyphoplasty that was published in 2005 (6, 7). Accordingly, there was no need to make any further changes in study design once the study was in progress.

Vertebroplasty was performed in Center 1 by two experienced interventional radiologists and in Center 2 by one experienced interventional radiologist. The needle system of the Stryker company (USA) was used: 11-gauge hollow needles for lumbar vertebroplasty, and 13-gauge hollow needles for thoracic vertebroplasty. The cement used was Mendec Spine, obtained from Tecres S.P.A. (Italy).

After cement injection, the result (including any potential cement dislocation) and the quantity of cement injected were documented in all patients with x-ray imaging in two planes.

Data on pain, mobility, and analgesic requirement were obtained by patient interviews on the day before the procedure as well as one day, one week, and 3, 6, and 12 months afterward.

Patients rated their pain themselves at one of seven possible levels: 0 = no pain, 1 = almost no pain, 2 = mild pain, 3 = moderate pain, 4 = severe pain, 5 = very severe pain, 6 = extreme pain.

The analgesic requirement and the patients' mobility were rated at each time point by a single interviewer (there was only one interviewer for all of the patients) who asked the patients for the relevant information. The scale for analgesic requirement was as follows: 0 = no analgesics required, 1 = occasional need for analgesics, 2 = regular consumption of non-steroidal anti-inflammatory drugs (NSAID) with sustained effect, 3 = regular consumption of NSAID with variable effect, 4 = additional consumption of opioid derivatives. The scale for mobility was as follows: 0 = no limitation, 1 = limitation without the need for orthopedic aids, 2 = limitation necessitating orthopedic aids, 3 = bedridden.

The pain scale corresponded to the established scale of the SF 36, with the addition of a seventh level (extreme pain) to avoid a potential ceiling effect.