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CT-guided percutaneous vertebroplasty in the therapy of vertebral compression fractures

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Abstract The purpose of this study was to determine the efficacy and safety of CT-guided percutaneous vertebroplasty in the treatment of vertebral compression fractures. The primary objectives were pain reduction and bone-cement leakage during a long-term follow-up in patients with osteoporotic vertebral compression fractures. CT-guided percutaneous vertebroplasty was carried out in 61 patients (mean age 71.4 years; range 42–83; female ratio: 73.8%) with vertebral compression fractures. Treatment was carried out on an outpatient basis. Pain, bone-cement leakage and complications were monitored and recorded. The mean follow-up time was 19.8 months (range 3–52). Paired comparison procedures were used for the analysis of the results, which showed that all patients had a significant reduction of pain. The mean visual-analogue scale (VAS) before treatment was 8.8 points (range 6.5–9.8 points). The mean VAS score after treatment was significantly reduced to 2.6 points (range 1.5–4.1 points; $p<0.01$). No clinical or neurological complications were documented. Minor and asymptomatic bone-cement leakage was observed in 54% of the cases. Percutaneous vertebroplasty is an efficient and safe interventional procedure which rapidly improves the mobility and quality of life of patients with vertebral compression fractures. CT-guidance is a reasonable upgrade in the treatment procedure which reduces the amount of bone-cement leakage.

Keywords Vertebroplasty · Spine · Osteoporosis · Percutaneous vertebroplasty · Bone cement

Introduction

Percutaneous vertebroplasty is used in the therapy of vertebral compression fractures to augment and immobilize the vertebral body and therefore to relieve pain and restore mobility and quality of life. It was developed by Galibert and Deramond in 1987 and describes the injection of bone cement (polymethylmethacrylate) into a collapsed vertebral body [1]. Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures. The consequences of this chronic disease and public health threat will increase rapidly in the next decades [2]. The spine is the most frequently affected localization for osteoporosis-induced fractures [3, 4]. Today, in the USA, 10 million individuals already have osteoporosis and 34 million more have low bone mass, which puts them at an increased risk of getting this disease. Osteoporosis is responsible for more than 1.5 million fractures annually, including approximately 700,000 vertebral fractures. The consequences of these fractures include pain, collapse of the vertebral body and loss of the physiological posture. Concomitant complications are various and comprise orthopaedic, pulmonary, cardiovascular and neurological diseases; while the socio-economic consequences include high national direct expenditures for osteoporosis and related fractures Morbidity, the increased mortality-rate and loss in quality of life together with high national direct expenditures, are critical arguments for prevention and therapy of osteoporosis. The objective of this study is to assess the efficacy, safety and risks of percutaneous vertebroplasty in conjunction with polymethylmethacrylate in the treatment of painful vertebral fractures guided by combined computed-tomography and conventional fluoroscopy.

Materials and methods

Patients

Sixty-one patients with osteoporotic vertebral compression fractures were treated on an outpatient basis under local anesthesia. The primary indication for therapy was pain and the need for improvement in the quality of life as well as imminent fracture or instability of the bone. Before therapy, all patients underwent clinical and laboratory examinations. After therapy, all patients were observed for at least 6 h on our ward. Another radiological examination was carried out the day after the intervention. All patients were contacted 1 week and 6 months after interventional therapy in order to assess the outcome and possible complications. Follow-up was done via imaging and/or contacting the patients by phone.

Assessment of pain

Pain was assessed and documented using the visual analogue scale (VAS) [6]. VAS is an easy-to-administer score. Patients were given a special scale calibrated between 0 (no pain) and 10 (maximum and worst pain).

Pretreatment examination

All patients underwent physical examination before entering treatment. A complete blood count and coagulation laboratory was obtained from each patient at least 24 h before treatment. Pretreatment radiographics containing CT-scans, MRI and X-ray were evaluated. Due to the ongoing increasing number of treated patients (Fig. 5), quality improvement guidelines were set up to ensure high standards. Tables 1, 2 and 3 show indications and contraindications for vertebroplasty as set up by the American Society of Interventional Radiology and the German Society of Radiology [7, 8] (see Tables 1, 2 and 3).

Table 1 Indications for percutaneous vertebroplasty [6, 7]

Indications
1. Painful primary and secondary osteoporotic vertebral compression fracture
2. Painful vertebrae with extensive osteolysis or invasion secondary to benign or malign tumor
3. Painful vertebral fracture associated with osteonecrosis (Kummell Disease)
4. Adjuvant pre-, peri- or intraoperative percutaneous stabilization-vertebroplasty before a spinal decompressive produre

Table 2 Absolute Contraindications for percutaneous vertebroplasty [6, 7]

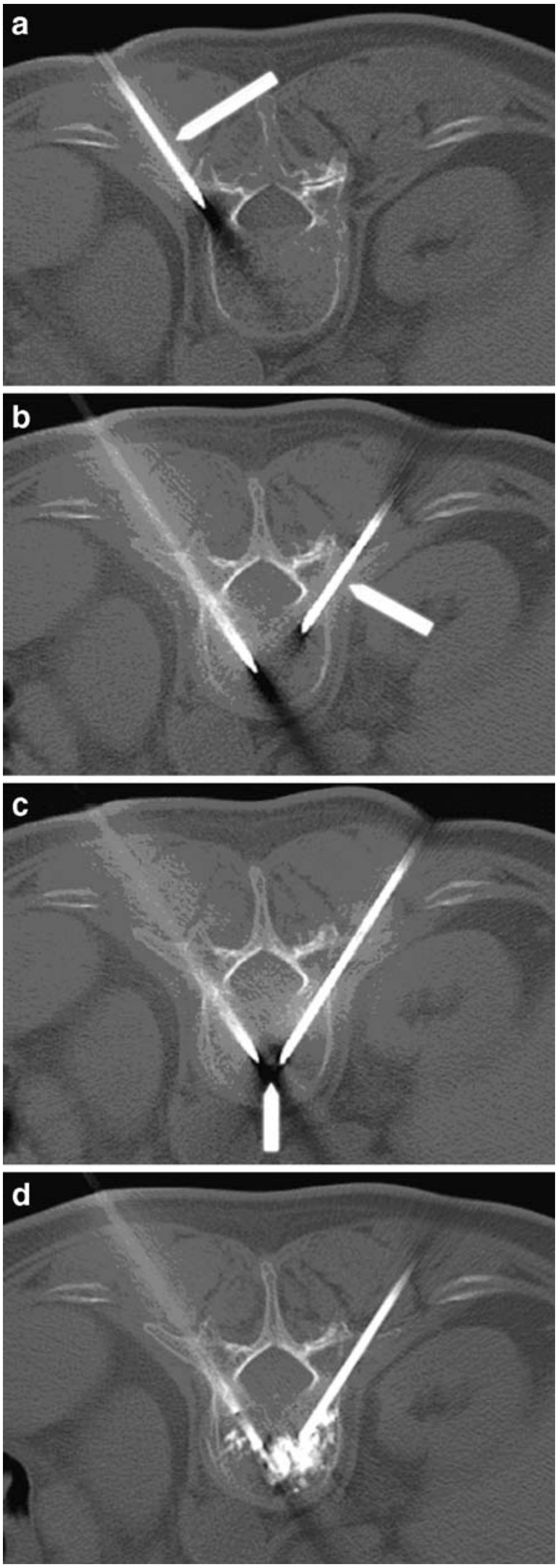
Absolute Contraindications
1. Asymptomatic vertebral body compression fractures
2. Patient improving on medical therapy
3. Prophylaxis in osteoporotic patients
4. Ongoing local or systematic infection
5. Retropulsed bone fragment resulting in myelopathy
6. Spinal canal compromise secondary to tumor resulting in myelopathy
7. Uncorrectable coagulopathy
8. Allergy to bone cement or opacification agent

CT-guided percutaneous vertebroplasty

All procedures were performed in a strictly sterile manner in the CT room. All patients were treated under local anesthesia using Mepivacain (0,5% Scandicain, Astra Zeneca, Wedel, Germany). Intravenous analgetic and sedation therapy consisted of Piritramid (Dipidolor, Janssen–Cilag, Neuss, Germany) and Midazolam (Versed; Roche Pharma, Manati, Puerto Rico), which allow for conscious sedation. With the patients in a prone position, the affected vertebral body was identified via computed tomography (Siemens Volume Zoom, Erlangen, Germany) and fluoroscopy (Siemens Siremobil, Erlangen, Germany). The area to be treated was prepared in a strictly sterile manner and a local anaesthesia was used. Under CT-guidance and after a

Table 3 Relative Contraindications for percutaneous vertebroplasty [6, 7]

Relative contraindications
1. Radiculopathy in excess of vertebral pain, caused by a compressive syndrome unrelated to vertebral collapse. Occasionally preoperative percutaneous vertebroplasty can be preformed before a spinal decompressive procedure
2. Asymptomatic retropulsion of a fracture fragment causing significant spinal canal compromise.
3. Asymptomatic tumor extension into the epidural space
4. Therapy of more than 3 vertebrae in one session
5. Osteoplastic metastases



◀ **Fig. 1** **a** Axial CT-scan is showing the transpedicular approach to the vertebral body (L1) using a vertebroplasty needle (arrow) **b** Axial CT-scan is showing the bipedicular approach to the vertebral body (L1) using a second vertebroplasty needle (arrow) **c** Axial CT-scan is showing the bipedicular approach to the vertebral body (L1). Note the arrow pointing to the central positioning of both needles in the anterior half of the vertebral body **d** Axial CT-scan is showing the filling of the vertebral body (L1) with bone cement. No bone cement leakage is detected

small skin incision, a vertebroplasty cannula (11 g, Somatex Apart Standard, Somatex Medical Technologies, Teltow, Germany) was used to gain access to the affected vertebral body. A transpedicular access was used and the tip of the trocar was placed in the anterior half of the vertebral body. The positioning of the instruments was controlled precisely by computed tomography and fluoroscopy (Figs. 1 and 2). Five-ml Luer-lok syringes and an application system (CIS, Somatex GmbH, Teltow, Germany) were utilized for the application of the bone cement

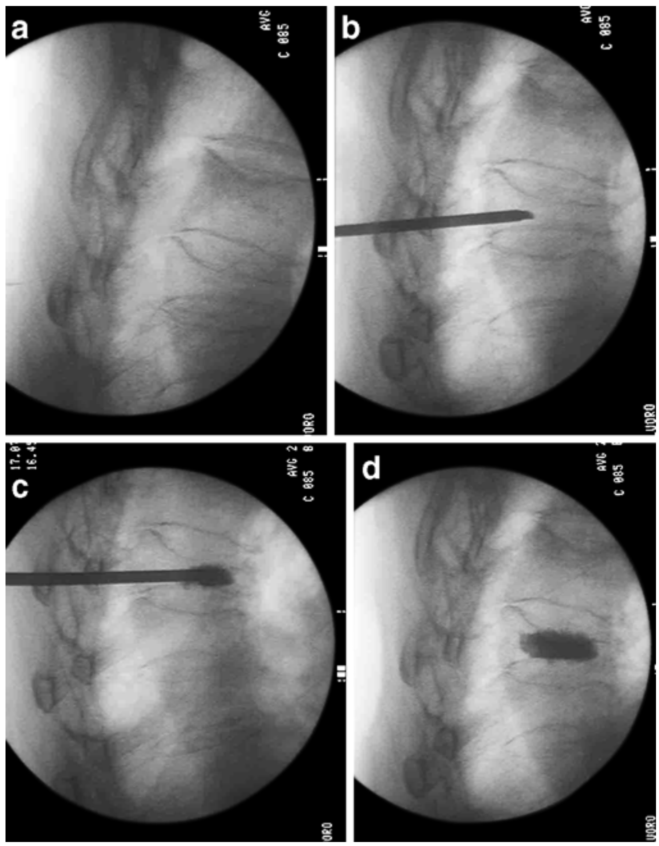


Fig. 2 **a** Localization of an osteoporotic fracture under fluoroscopic control (lateral view). Note the vertebral collapse **b** Transpedicular positioning of an 11-gauge needle into the vertebral body under fluoroscopic control (lateral view) **c** Injection of bone cement under fluoroscopic control (lateral view) **d** Control radiograph shows satisfactory filling of the vertebral body

(Vertebroplastic, Somatex GmbH, Teltow, Germany). During injection of the cement, continuous observation by fluoroscopy and CT was carried out to prevent excessive bone-cement leakage. Although bone cements achieve approximately 90% of their ultimate strength within 1 h of injection [9], hospitalization of the patients on the day of intervention (for at least 6 h) was preferred. Postprocedural CT was performed to confirm the lack of soft tissue swelling and haematoma. All patients were discharged after clinical and functional examination.

Data analysis

The study design, which was approved by the institutional review board, is retrospective using retrospective data evaluation. Mean values were calculated and the *t*-test paired comparison procedures were used (paired *t*-test) for analysis of the primary and secondary endpoints. Primary end points corresponded to the reduction of the worst and average amounts of pain (VAS, score 0–10). A p value of $p \leq 0.05$ was considered to be statistically significant.

Results

Epidemiology

Sixty-one patients with osteoporotic vertebral compression fractures due to low-velocity trauma were treated via CT-guided vertebroplasty. The mean duration of the symptoms was 19 days (range 1 day–8 weeks). The mean age was 71.4 years (range 42–83). The female ratio was 73.8% (45 female and 16 male patients). The average follow-up time was 19.8 months (range 3–52; Table 4).

CT-guided vertebroplasty

The average number of treated vertebrae per patient was 1.6. In the majority of the patients, only one vertebra was treated (77%). In 13.1% of the patients, two vertebrae were treated in one session, while in 8.2%, three to four vertebrae were treated. In only one case (1.6%) five vertebrae were augmented by percutaneous vertebroplasty (see Fig. 3). The mean volume of injected bone cement was 5.1 ml (range 2.1–8.1).

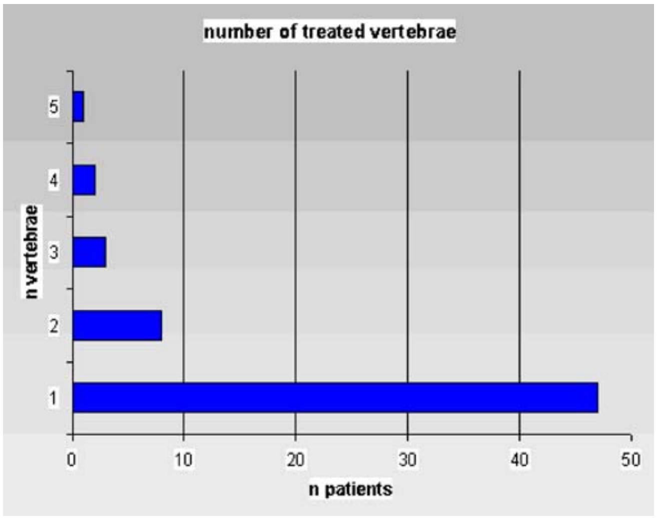


Fig. 3 Number of the treated vertebrae ranged from 1 to 5 per session

The mean visual-analogue scale (VAS) before treatment was 8.8 points (range 6.5–9.8) points; Table 5). The mean VAS score after treatment was significantly reduced to 2.6 points (range 1.5–4.1 points; Table 5; $p<0.01$). The mean actual VAS (3–52 months after therapy) was 4.1 points (range 2.4–6.2 points; Table 5; $p<0.01$). All patients had a mean reduction of pain of 53.4% with a decrease of pain of at least 3.5 points and a maximum decrease of 8.3 points.

Complications were documented and divided into symptomatic and asymptomatic complications as well as into serious and nonserious complications. No symptomatic or serious complications were documented. Minor bone-cement leakage was documented in 54%. The localization of the leakage was divided into intradiscal, epidural, postero-lateral and paravertebral (see Fig. 4). In our study, bone-cement leakage most often occurred paravertebrally (28 cases), while posterior-lateral leakage occurred in only 6 cases (see Fig. 4). In the majority of the cases, only minor cement leakage has been found.

Table 4 Demographic overview

No. of patients	61
Female	45
Male	16
Female-ratio	71.4%
Med. age (years)	71.4
Age min.–max.	42–83
Mean follow-up (months)	19.8

Table 5 Pain documentation using the Visual-Analogue-Scale (VAS). VAS is divided into VAS pre (before treatment) and VAS post (after treatment). VAS actual describes pain documentation during the actual follow-up

Mean Vas pre	Mean Vas post	Mean Vas 4 w	Mean Vas 3 m	Mean Vas actual
8.8	2.6	2.4	2.3	4.1

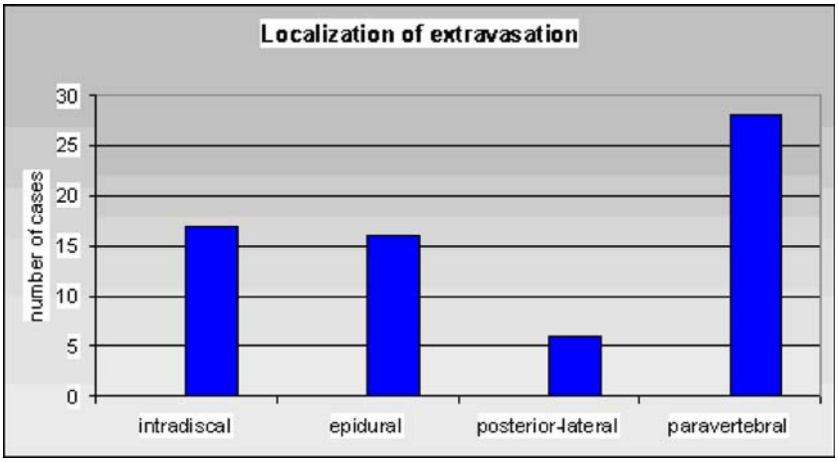


Fig. 4 Localization of the extravasation during percutaneous vertebroplasty. More than one localization per patient is possible

Discussion

Percutaneous vertebroplasty is used in the therapy of vertebral compression fractures to augment and immobilize the vertebral body and to, therefore, relieve pain and restore mobility and the quality of life of the patients. Percutaneous vertebroplasty was developed by Galibert and Deramond in 1987 and describes the injection of bone cement (polymethylmethacrylate) into a collapsed vertebral body [1]. Since then, and especially in the last 4 years, percutaneous vertebroplasty has become a potential therapy option for a rapidly increasing number of treated patients (see Fig. 5).

In our series, CT-guidance in combination with fluoroscopy was used for percutaneous vertebroplasty. This combination technique was first described by Gangi et al. in a series of 10 patients [10]. CT-scans in combination with fluoroscopy during vertebroplasty provide excellent imaging and the possibility of exact positioning of the vertebroplasty needle. They provide an optimal filling of the vertebral body due to the possibility of detailed localization of the injected bone cement. Potential bone-cement leakages can be detected before using fluoroscopy, especially cement leakage into smaller veins. Comparing our rate of cement leakages (54%) to the rates found in the literature (8–87.5%; [11–18]), there seems to be no significant reduction of bone-cement leakages using CT-guidance. But it has to be pointed out, that the amount of cement leakage seems to be less due to the earlier and exact detection of bone-cement leakage using axial CT-scans.

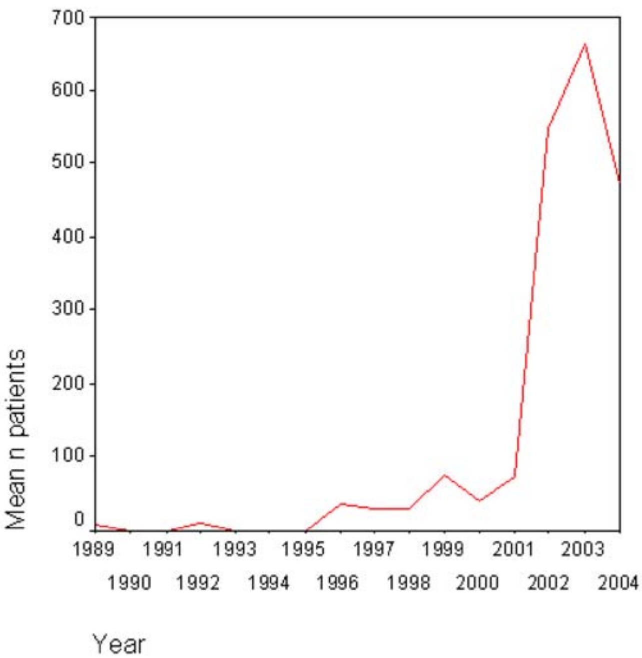


Fig. 5 Number of treated patients per year found in literature between 1989 and 2004 [7, 9, 11–16, 19–29]

Vertebral compression fractures are determined by the destruction of the vertebral body's architecture. This, in turn, is mainly caused by osteoporosis. Consequences arising out of this chronic disease are not only the high rates of morbidity and mortality especially of the elder generation. Due to the epidemiological shift to an increasingly number of elderly people, at least 30% is expected to include men and women over 65 years of age, while 5–10% of the total population is expected to include men and women over 80 years of age [2]. The socio-economic consequences correspond to high national direct expenditures (hospitals and nursing homes) for osteoporosis and related fractures.

The consequences of vertebral body fractures are pain and reduced mobility. In the literature, a significant reduction of pain after percutaneous vertebroplasty is reported in nearly all studies [7, 9, 11–16, 18–29]. Our series confirms this reduction of pain. The analgesic effect can be explained by the immobilization of the vertebral-body fracture and the heat effects on nerve-endings [11, 12, 15]. Changes in bone matrix structural factors lead to microdamage of the bone and therefore especially to fractured trabeculae [30]. It might therefore be, that microfractures already generate pain and that bone-cement leads to a stabilization and immobilization of the vertebral body with a subsequent reduction of pain [30]. Osteoporosis and the osteoporotic vertebral body fracture do not only affect one part of the vertebral body, but also the complete vertebral body. It is therefore important to stabilize the whole vertebral body. Otherwise, there might be an increased risk of additional instabilization of the noncemented part of the vertebral body with concomitant danger of adjacent vertebral fractures. We therefore prefer the bipedicular bone-cement filling of the vertebral body.

Polymerization heat is another important factor in the reduction of pain. Our own in vitro measurements of temperature in bone after injection of bone cement over a period of 30 min showed maximum temperatures of 105°C inside the bone. It seems to be that pain-sensitive nerve endings are damaged by the extensive impact of heat and therefore local pain is also reduced. Long-term effects of bone cement, and especially the potential risk of new fractures of adjacent vertebrae due to the immobilized vertebral segments, have to be analyzed in prospective randomized trials. Retrospective findings are promising and do not show any major negative effects [17, 21, 25, 27].

Complications in percutaneous vertebroplasty can be divided into technical complications and bone-cement-induced complications. Technical complications are rare and have been reported in the literature in less than 1% of the treated patients [7, 9, 11–16, 19–29]. The bone-cement leakage rate in our series was 54% and is not significantly higher then the data found in the literature (range 8–87.5%; [7, 9, 11–16, 19–29]). However, the majority of the extravasations were asymptomatic. No symptomatic or serious complications were documented in our series. The average volume of injected bone cement was 5.3 ml (min. of 2.1 ml; max. 8.1 ml) and was comparable to the volume used in other series [7, 9, 11–16, 18–29]. Hodler et al. divided extravasation into two grades [24]. Grade 1 leakage describes a minor extravasation with a bone-cement collection less than the longest diameter of the closest pedicle. Grade 2 leakage describes moderate extravasation with a bone-cement collection greater than the longest diameter of the closest pedicle but less than the nearest normal vertebral body [24]. In our series, most of the extravasations were grade 1 leakages (73.8%). As described in other series before, in nearly all cases there is minor leakage when the maximum of injectable bone cement is reached [11–13, 31, 32].

Conclusion

CT-guided vertebroplasty in combination with fluoroscopy provides excellent imaging and the possibility of exact positioning of the vertebroplasty needle. Potential bone cement leakages can be detected earlier than when using fluoroscopy alone. The amount of leakage is reduced and an optimal filling of the vertebral body is reached. CT-guidance during percutaneous vertebroplasty results in an interventional procedure that is safer and more efficient.

References

1. Galibert P, Deramond H, Rosat P, Le Gars D (1987) Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. Neurochirurgie 33:166–168
2. European Prospective Osteoporosis Study (EPOS) (2002) J Bone Miner Res 17:716–724
3. Melton LJ, Kan S, Frye MA, Wahner HW, Riggs BL (1989) Epidemiology of vertebral fractures in women. Am J Epidemiol 129:1000–1011
4. Kanis JA, Pitt F (1992) Epidemiology of osteoporosis. Bone 13(Suppl. 1): 7–15
5. Osteoporosis, N.I.o.H., Epidemiology of Osteoporosis (2003)
6. Deschamps M, Band P, Coldman AJ (1988) Assessment of adult cancer pain: shortcomings of current methods. Pain 32(2):133–139
7. Helmberger T, Bohndorf K, Hierholzer J, Vorwerk D (2003) Leitlinien der Deutschen Röntgengesellschaft zur Vertebroplastie. Radiologe 43:703–708
8. McGraw JK, Cardella J, Barr JD, Mathis JM, Sacks D (2003) Society of Interventional Radiology Quality Improvement Guidelines for Percutaneous Vertebroplasty. J Vasc Interv Radiol 14:827–831
9. Gangi A, Kastler BA, Dietemann JL (2001) Percutaneous Vertebroplasty: a developing standard of care for vertebral compression fractures. AJNR 22:373–381
10. Gangi A, Kastler BA, Dietemann JL (1994) Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. AJNR 15:83–86
11. Heini PF Walchli B, Berlemann U (2000) Percutaneous transpedicular vertebroplasty with PMMA. Eur Spine J 9:445–450
12. Heini PF, Orler R (2004) Vertebroplastik bei hochgradiger Osteoporose. Orthopäde 33:22–29
13. Legroux-Gerot I, Lormeau C, Boutry N, Cortet B (2004) Long-term follow-up of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. Clin Rheumatol 23:310–317
14. Winking M, Stahl JP, Ortel M, Schnettler R, Böker DK (2003) Polymethylmethacrylat-Vertebroplastie. Dtsch Med Wochenschr 128:2525–2530
15. Winking M Stahl JP, Ortel M, Schnettler R, Böker DK (2004) Treatment of pain from osteoporotic vertebral collapse by percutaneous PMMA vertebroplasty. Acta Neurochir 146:469–476
16. Martin JP, Wetzel SG, Seium Y, Dietrich PY, Ruefenacht DA (2003) Percutaneous vertebroplasty in metastatic disease: transpedicular access and treatment of lysed pedicles-initial experience. Radiology 229:593–597
17. Evans AJ, Jensen ME, Kip KE, Dunnagan SA (2003) Vertebral compression fractures: pain reduction and improvement in functional mobility after percutaneous vertebroplasty. Radiology 226:366–372

18. Kobayashi K, Shimoyama K, Nakamura K, Murata K (2005) Percutaneous vertebroplasty immediately relieves pain of osteoporotic vertebral compression fractures. Eur Radiol 15 (2):360–367
19. Martin JB, Jean B, Sugiu D, Piotin K, Murphy B, Rüfenacht DA (1999) Vertebroplasty: clinical experience and follow-up results. Bone 25(2):11S–15S
20. Alvarez L, Perez-Higueras A, Quinones D, Calvo E, Rossi RE (2003) Vertebroplasty in the treatment of vertebral tumors: postprocedural outcome and quality of life. Eur Spine J 12:356–360
21. Perez-Higueras A, Alvarez L, Rossi RE, Quinones D, Al-Assir I (2002) Percutaneous vertebroplasty: long-term clinical and. Neurorad 44:950–954
22. McGraw JK, Lippert JA, Minkus KD, Rami PM, Davis TM (2002) Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. J Vasc Interv Radiol 13:883–886
23. Gaughen JR, Jensen ME, Schweickert PA, Kaufmann TJ, Kallmes DF (2001) Relevance of antecedent venography in percutaneous vertebroplasty for the treatment of osteoporotic compression fractures. AJNR 23:594–600
24. Hodler J, Peck D, Gilula LA (2003) Midterm outcome after vertebroplasty: predicitve value of technical and patient-related factors. Radiology 227:662–668
25. Peh WCG, Gilula LA, Peck DD (2002) Percutaneous vertebroplasty for severe osteoporotic vertebral compression fractures. Radiology 223:121–126
26. Kaufmann TJ, Jensen ME, Schweickert PA, Marx FW, Kallmes DF (2001) Age of fracture and clinical outcome of percutaneous vertebroplasty. AJNR 22:1860–1863
27. Grados F, Depriester C, Cayrolle G, Hardy N, Deramond H (2000) Long-term observation of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. Rheumatol 39:1410–1414
28. Cyteval C, Sarrabere MP, Roux JO, Thomas E, Taourel P (1999) Acute osteoporotic vertebral collapse. AJR 173:1685–1690
29. Cortet B, Cotten A, Voutry N, Flipo RM, Delcambre B (1999) Percutaneous vertebroplasty in the treatment of osteoporotic vertebral compression fractures. J Rheumatol 26:2222
30. Aaron J (2003) Bone turnover and microdamage. Adv Osteopor Fract Manag 2(4):102–110
31. Laredo JD, Hamze B (2004) Complications of percutaneous vertebroplasty and their prevention. Skelet Radiol 33 (9):493–505
32. Jensen ME, Evans A, Mathis JM, Kallmes DF (1997) Percutaneous PMMA vertebroplasty in the treatment of osteoporotic vertebral compression fractures. AJNR 18:1897–1904