Acta Orthop. Belg., 2012, **78**, 512-518

ORIGINAL STUDY

Complications of vertebroplasty and kyphoplasty in the treatment of vertebral fractures : Results of a questionnaire study

Kourosh ZARGHOONI, Jan SIEWE, Thomas KAULHAUSEN, Rolf SOBOTTKE, Peer EYSEL, Marc RÖLLINGHOFF

From the University of Cologne, Germany

Percutaneous vertebroplasty (VP) and balloon kyphoplasty (BKP) are minimally invasive procedures performed to stabilize vertebral fractures. With continuing expansion in clinical use, a broad spectrum of complications has been reported for both interventions. The goal of the current study was to compare the safety of these procedures using a questionnaire completed by practitioners.

A questionnaire was developed with multiple choice and open questions. General data as well as information regarding complications which occurred during the year 2007 were requested. The incidence and odds ratios (OR) of complications for both procedures were analysed.

One hundred and sixteen questionnaires detailing 3216 VP and 5139 BKP procedures were included for evaluation. The risk of cement extrusion from the vertebra (OR 2.64, $p < 0.01$) and into the spinal canal (OR 4.35, $p < 0.01$) was markedly increased for VP. The odds ratio for neurologic complications (OR 2.56, $p = 0.1$) and secondary fracture (OR = 0.99, $p = 0.96$) did not indicate significant predisposition for either procedure. Secondary fracture occurred in 5% of VP and 5.1% of BKP procedures. Overall, 80% of practitioners subjectively considered BKP the safer procedure.

Overall, BKP appears safer than VP. Symptomatic complications are rare with both procedures. Additional prospective data is necessary to reach more definitive conclusions.

Keywords : complications ; vertebroplasty ; kyphoplasty ; minimally invasive ; percutaneous ; vertebral fractures.

INTRODUCTION

Percutaneous vertebroplasty (VP) and balloon kyphoplasty (BKP) are procedures that treat spinal compression fractures through injection of bone cement, usually polymethylmethacrylate (PMMA), into the fractured vertebral body (*11*). The percutaneous VP technique was developed by Galibert and was attempted clinically for the first time in 1984 on a patient with a cervical haemangioma (*8,9*). Later, indications for vertebroplasty were expanded to include osteoporotic compression and pathologic fractures (*5*). BKP was developed primarily for use in osteoporotic bone and was performed for the first

■ Kourosh Zarghooni, MD, Orthopaedic surgeon.
■ Jan Siewe, MD, Orthopaedic surgeon.
■ Thomas Kaulhausen, MD, Orthopaedic surgeon.
■ Rolf Sobottke, MD, PhD, Orthopaedic surgeon.
■ Peer Eysel, MD, Professor of Orthopaedic surgery.
Department of Orthopaedic and Trauma Surgery, Clinical Trials Centre Cologne, BMBF 01KN1106, University of Cologne, Germany.
■ Marc Röllinghoff, MD, Orthopaedic surgeon.
Department of Orthopaedics and Traumatology, Faculty of Medicine, Martin-Luther-University of Halle-Wittenberg, Halle, Germany.
Correspondence : Dr med. Kourosh Zarghooni, Department of Orthopaedic and Trauma Surgery, University of Cologne, Josef Stelzmannstr. 9, 50924 Cologne, Germany.
E-mail : kourosh.zarghooni@uk-koeln.de

Implementation of this study was supported financially by Kyphon®, now Medtronic®.

time in 1998 by Riley after approval by the U.S. Food and Drug Administration (FDA) (*11*). With this method, controlled inflation of the balloon catheter within the vertebral body compresses cancellous bone, creating a void. This should yield fracture reposition and thus reestablishment of vertebral body height prior to controlled cement application (*3,16*).

Use of both procedures has expanded in recent years, and is now indicated for patients with osteoporotic and traumatic compression fractures, pathologic fractures, and primary benign vertebral body tumours (e.g., haemangiomas) (*2,20,23*). The goal of both interventions is long-term stabilisation of the fractured vertebra, quick pain reduction, and therefore improved patient mobilisation compared to conservative therapy (*7,12*). The theoretic advantage of kyphoplasty versus vertebroplasty is better reduction of segmental kyphosis as well as increased procedure safety (*17*). However, the technical and material complexity required to perform kyphoplasty is considerably higher than that for vertebroplasty. Extrusion of cement from the vertebra is the most frequently encountered problem of both procedures and entails a risk for serious complications (*17,22,24,26*). In addition to cement leakage with or without the presence of neurologic deficits, other complications such as secondary fractures of neighbouring vertebrae, increased pain, lung emboli, neurologic complications, infection, rib fractures, radiculopathy, as well as pelvic and lower extremity venous thromboses have been reported (*10,17,18,19, 23*).

The goal of the current study was to evaluate the incidence of complications occurring as a result of treatment for vertebral fractures with kyphoplasty or vertebroplasty in Germany. By comparing the risks of complications for both augmentation procedures, the relative safety of these interventions can be verified.

MATERIALS AND METHODS

We developed a multiple-choice questionnaire with closed and open questions regarding vertebroplasty and kyphoplasty. Preliminary verification of the questionnaire was carried out by five spine surgeons who perform both VP and BKP. The questionnaire comprised a general section (underlying data) as well as a specialized section with questions regarding VP and BKP. The following parameters were collected : duration of VP/BKP use as well as number of VP and BKP procedures performed overall and in the year 2007. Complications were classified under : secondary fractures, cement leakage (subclassified as without clinical relevance, with emboli, in the spinal canal with and without nerve structure compression), and not otherwise specified (NOS) with write-in space. To minimize the risk of recall bias, only complications occurring in the 2007 calendar year were requested. For subjective estimation by the practitioners, we posed the following question : "In the hands of an experienced practitioner, which procedure has a smaller complication rate ?" (VP/BKP/both equal).

On 4 August 2008, the questionnaires with postage paid return envelopes were sent to all clinics and private practices of physicians performing kyphoplasty in Germany. Questionnaires were only evaluated if they were completed by practitioners reporting use of both VP and BKP and returned prior to 30 November 2008. Data was entered after the questionnaires were made anonymous by two impartial study physicians. After integration of the data by the two physicians, the data bank was adjusted and released for analysis. The data was evaluated descriptively, and statistic significance of the odds ratio (OR) was tested using the Fisher exact test (2-sided) with the statistics program SPSS 16.0 (SPSS Inc. Chicago, USA). The level of significance was set at $p \leq 0.05$.

RESULTS

A total number of 580 questionnaires was sent. From these, 327 questionnaires (56.4%) were completed and returned. Twenty-one questionnaires (3.6%) were undeliverable because of incorrect address. One hundred and fifty-one (46.2%) clinics/practices reported performing both VP and BKP, and 176 (53.8%) BKP only (Table I). For the evaluation of complications, 116 questionnaires (35.5%) were included. Thirty-five clinics/practices (10.7%) were excluded because they reported no vertebroplasties performed during the year 2007. The duration of VP practice averaged 5.0 ± 2.4 years (range ; 1-11) and of BKP 3.7 ± 1.7 years (range ; 1-8) (Table II).

There were 25 practitioners performing VP (21.9%) and 33 performing BKP (28.4%) during

Table I. — Study schedule (VP : Vertebroplasty, BKP : Balloon Kyphoplasty)

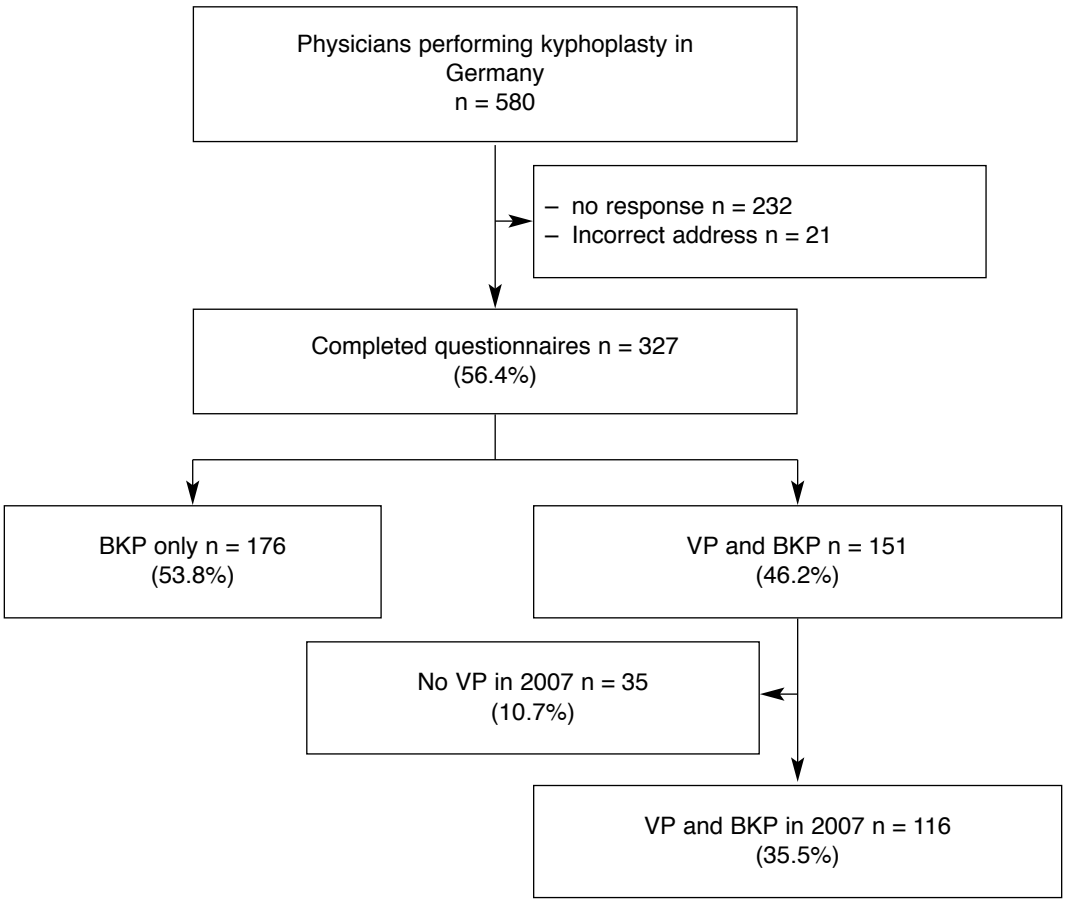

Table II. — Basic characteristics of the study and experience of the surgeons performing Vertebroplasty (VP) and Balloon kyphoplasty (BKP) within the survey

	VP	BKP
Experience (years)	5 (1-11)	3.7 (1-8)
Mean (SD)	27,7 (41.7)	44,3 (44.9)
Range	1-250	3-250
Sum	3216	5139

the observed year of 2007. Complication rates were calculated on the basis of 3216 VP and 5139 BKP procedures (Table III). Overall, the rate of cement leakage after VP was significantly higher than after BKP with rates of 27.2% and 12.4%, respectively (Table III). Clinically relevant cement-associated complications were similarly frequent with 0.6% in BKP and 0.4% in VP. The OR (VP/BKP) for overall cement leakage was 2.64 (95% CI : 2.36-2.96, $p < 0.01$) ; for cement leakage without clinical symptoms, it was 2.26 (95% CI : 2.00-2.56, $p < 0.01$), and for leakage into the spinal canal without neurologic compromise it was 4.35 (95% CI : 3.22-5.87, $p < 0.01$). Calculation of OR for VP versus BKP showed no statistically relevant difference for secondary fractures ($p = 0.96$), cement emboli ($p = 0.67$), or cement extrusion into the spinal canal with neurologic deficits ($p = 0.10$). The OR (VP/BKP) for NOS complications was 0.37 (95% CI : 0.15-0.89, $p = 0.02$). For cement leakage with neurologic symptoms, there was no significant difference between the groups. In the free space beneath

Table III. — Incidence of complications of Vertebroplasty (VP) and Balloon kyphoplasty (BKP) : Absolute numbers and percentage (%). Complications not otherwise specified (NOS) in the questionnaire are listed separately in Table V

	VP	BKP
Adjacent segment fractures	161 (5%)	260 (5.1%)
Cement leakage overall	885 (27.5%)	650 (12.6%)
– without clinical symptoms	704 (21.9%)	566 (11.0%)
– with cement embolism	10 (0.3%)	13 (0.3%)
– into spinal canal without neurology	157 (4.9%)	60 (1.7%)
– into spinal canal, with neurology	8 (0.2%)	5 (0.1%)
Not otherwise specified (NOS)	6 (0.2%)	26 (0.5%)

Table IV. — Comparison of complications of Vertebroplasty (VP) and Ballonkyphoplasty (BKP) : [1]Odds-Ratio (VP/BKP). [2]Confidence intervals, [3]Fisher's Exact-Test

	OR[1]	95% CI[2]	p[3]
Adjacent segment fractures	0.99	[0.81-1.21]	0.96
Cement leakage overall	2.64	[2.36-2.96]	< 0.01
– without clinical symptoms	2.26	[2.00-2.56]	< 0.01
– with cement embolism	1.23	[0.54-2.81]	0.67
– into spinal canal without neurology	4.35	[3.22-5.87]	< 0.01
– into spinal canal, with neurology	2.56	[0.84-7.83]	0.10
Not otherwise specified (NOS)	0.37	[0.15-0.89]	0.02

[1]Odds ratio ; [2]confidence interval, [3]p-value (Fisher's Exact Test).

complications NOS, respondents offered 6 VP and 26 BKP complications, which are listed individually in Table IV. The incidence of complications NOS was 0.2% for VP and 0.5% for BKP, and the OR (VP/BKP) was 0.37 (95% CI : 0.15-0.89, 0 = 0.02). The OR (VP/BKP) for complications NOS and neurologic complications combined was 0.72 (95% CI : 0.38-1.36, p = 0.36), and showed no significant predisposition. From the subjective observations, 80% (n = 93) and 1% (n = 1) of respondents estimated BKP and VP, respectively, to have a lower complication rate. Nineteen percent (n = 22) considered both procedures to be equal regarding complication rates.

DISCUSSION

Using our questionnaire, we were able to evaluate complications reported by 116 physicians performing BKP and VP in Germany. Overall, 3216 VP and 5139 BKP procedures were reportedly performed during the year under observation (2007).

Cement leakage was the most frequent complication after both procedures, with incidences of 27.5% and 12.6% respectively for VP and BKP. With an OR of 2.64 (95% CI : 2.36-2.96, p < 0.01), the risk of cement extrusion from the vertebral body after vertebroplasty was significantly higher. In the literature, the rate of cement leakage is quoted as 3-

Table V. — Complications not otherwise specified (NOS) in the questionnaire

Vertebroplasty (n = 6)	Kyphoplasty (n = 26)
	5× Dura perforation with CS fluid drainage
2× Cement leakage	Collapse of the vertebra
Spondylitis	3× Leaks toward intervertebral disc
1× Collapse of the vertebra	1× Cement leakage
Osteonecrosis of the vertebra	Pneumothorax
	Cement embolism to right atrium
	Pulmonary cement embolism
	Allergy towards Biocement
	Temporary myelopathy
	Retroperitoneal haematoma
	Blood Transfusion
	Wrong segment
	Termination due to X ray

76% after VP and 5-27% after BKP (*1,4,6,7,13,14,17, 25,27,31,32*).

Our study is in line with previous reports that cement extrusion often remains asymptomatic and thus has no consequences for the patient. For this reason, some authors make a distinction between cement leakage with and without complications (*33*). The spectrum of treatments required to treat neurologic complications from cement extrusion into the spinal canal extends from close neurologic observation (*15*) to multiple level decompression procedures, when necessary with removal of the displaced cement (*21,29,30,34*). In our study, cement extrusion into the spinal canal without neurologic deficits was reported with frequencies of 4.9% for VP and 1.7% BKP. The OR (VP/BKP) was 4.35 (95% CI : 3.22-5.87), reflecting a significant difference ($p < 0.01$). Neurologic complications from cement leaking into the spinal canal were reported in 0.2% of cases for VP and 0.1% for BKP, and the OR (VP/BKP) was not significant ($p = 0.1$).

Symptomatic lung embolism from cement extrusion is a rare complication. The severity of clinical symptoms is extremely variable and can reach cardiogenic shock requiring embolectomy (*18,28*). The reported incidence in our study was 0.3% for both procedures. In systematic reviews of vertebroplasty and/or kyphoplasty, the incidence of neurologic complications from cement leakage ranges from 0.4-23% for VP and 0.03-2.9% for BKP (*1,14,17,27, 31,32*).

In a systematic review study, Felder-Puig *et al* could not answer unequivocally whether VP or BKP leads to more secondary fractures or whether one of these procedures is better on this regard (*7*). The rate of new vertebral fractures in the studies reviewed was very inconsistent (0-52%). In our inquiry, the reported incidence of secondary fracture was around 5% for both procedures and the odds ratio showed no significant difference between groups.

Overall, the literature reports a higher incidence of clinically relevant complications with VP than with BKP (*7*). In systematic reviews, this incidence is quoted as 1-15% for VP and 0-3% for BKP (*7*). In our study, the reported incidence of symptomatic complications NOS was 0.7% for VP and 0.9% for BKP : the difference is not significant. Overall, according to current consensus, the risk of secondary fractures is minimal for both procedures and the risk of clinically relevant complications is moderate (*7*).

Subjectively, practitioners perceive that BKP is the safer procedure. One contributing factor to this could be the more frequent occurrence of cement

leakage with VP versus BKP. Statistically, there is no increased OR, i.e., predisposition, for relevant complications with VP.

One limitation of this study is that the participating practitioners performed predominantly BKP. Furthermore, only practitioners performing both procedures were contacted ; thus not all practitioners performing either VP or BKP in Germany were sampled. Because of the selected observation time of one year, it could be that more rare complications are underrepresented. For these reasons, our results allow only limited conclusions regarding the complication rates of both procedures. A prospective documentation and evaluation of the efficiency and safety of vertebroplasty and kyphoplasty in a spine surgery registry could overcome the limitations of the data we have today.

To conclude, eighty percent of questionnaire respondents considered BKP as the safer procedure. Our data identified no statistically relevant differences as indicated by the odds ratio, for symptomatic complications comparing VP and BKP. The incidence of secondary fractures was around 5% for both procedures. In our study, the risk of cement extrusion overall, as well as in the spinal canal without neurologic deficit, was markedly higher in VP compared to BKP. In summary, there was a more favourable risk profile regarding complications after BKP than after BP. Serious, relevant complications are seldom for both procedures. Additional prospective data are necessary to make definitive conclusions regarding complication risks of both procedures.

REFERENCES

1. **Bouza C, Lopez T, Magro A, Navalpotro L, Amate JM.** Efficacy and safety of balloon kyphoplasty in the treatment of vertebral compression fractures : a systematic review. *Eur Spine J* 2006 ; 15 : 1050-1067.
2. **Bouza C, Lopez-Cuadrado T, Cediel P, Saz-Parkinson Z, Amate JM.** Balloon kyphoplasty in malignant spinal fractures : a systematic review and meta-analysis. *BMC Palliat Care* 2009 ; 8 : 12.
3. **Coumans JV, Reinhardt MK, Lieberman IH.** Kyphoplasty for vertebral compression fractures : 1-year clinical outcomes from a prospective study. *J Neurosurg* 2003 ; 99 : 44-50.
4. **De Negri P, Tirri T, Paternoster G, Modano P.** Treatment of painful osteoporotic or traumatic vertebral compression fractures by percutaneous vertebral augmentation procedures : a nonrandomized comparison between vertebroplasty and kyphoplasty. *Clin J Pain* 2007 ; 23 : 425-430.
5. **Deramond H, Depriester C, Galibert P, Le Gars D.** Percutaneous vertebroplasty with polymethylmethacrylate. Technique, indications, and results. *Radiol Clin North Am* 1998 ; 36 : 533-546.
6. **Eck JC, Nachtigall D, Humphreys SC, Hodges SD.** Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures : a meta-analysis of the literature. *Spine J* 2008 ; 8 : 488-497.
7. **Felder-Puig R, Piso B, Guba B, Gartlehner G.** [Kyphoplasty and vertebroplasty for the management of osteoporotic vertebral compression fractures : a systematic review.] (in German). *Orthopade* 2009 ; 38 : 606-615.
8. **Galibert P, Deramond H**. [Percutaneous acrylic vertebroplasty as a treatment of vertebral angioma as well as painful and debilitating diseases.] (in French). *Chirurgie* 1990 ; 116 : 326-335
9. **Galibert P, Deramond H, Rosat P *et al.*** [Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty.] (in French). *Neurochirurgie* 1987 ; 33 : 166-168.
10. **Gangi A, Guth S, Imbert JP *et al.*** Percutaneous vertebroplasty : indications, technique, and results. *Radiographics* 2003 ; 23 : e10.
11. **Garfin SR, Yuan HA, Reiley MA.** New technologies in spine : kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures. *Spine (Phila Pa 1976)* 2001 ; 26 : 1511-1515.
12. **Grohs JG, Krepler P.** [Minimal invasive stabilization of osteoporotic vertebral compression fractures. Methods and preinterventional diagnostics]. (in German). *Radiologe* 2004 ; 44 : 254-259.
13. **Grohs JG, Matzner M, Trieb K *et al.*** Minimal invasive stabilization of osteoporotic vertebral fractures : a prospective nonrandomized comparison of vertebroplasty and balloon kyphoplasty. *J Spinal Disord Tech* 2005 ; 18 : 238-242.
14. **Hadjipavlou AG, Tzermiadianos MN, Katonis PG, Szpalski M.** Percutaneous vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures and osteolytic tumours. *J Bone Joint Surg* 2005 ; 87-B : 1595-1604.
15. **Harrington KD.** Major neurological complications following percutaneous vertebroplasty with polymethylmethacrylate : a case report. *J Bone Joint Surg* 2001 ; 83-A : 1070-1073.
16. **Heini PF, Orler R.** Kyphoplasty for treatment of osteoporotic vertebral fractures. *Eur Spine J* 2004 ; 13 : 184-192.
17. **Hulme PA, Krebs J, Ferguson SJ *et al.*** Vertebroplasty and kyphoplasty : a systematic review of 69 clinical studies. *Spine (Phila Pa 1976)* 2006 ; 31 : 1983-2001.

18. **Jang JS, Lee SH, Jung SK.** Pulmonary embolism of polymethylmethacrylate after percutaneous vertebroplasty : a report of three cases. *Spine* 2002 ; 27 : E416-418.
19. **Jensen ME, Evans AJ, Mathis JM *et al.*** Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures : technical aspects. *Am J Neuroradiol* 1997 ; 18 : 1897-1904.
20. **Karlsson MK, Hasserius R, Gerdhem P, Obrant KJ, Ohlin A.** Vertebroplasty and kyphoplasty : New treatment strategies for fractures in the osteoporotic spine. *Acta Orthop 2005 ;* 76 : 620-627.
21. **Lee BJ, Lee SR, Yoo TY.** Paraplegia as a complication of percutaneous vertebroplasty with polymethylmethacrylate : a case report. *Spine (Phila Pa 1976)* 2002 ; 27 : E419-422.
22. **Lee ST, Chen JF.** Closed reduction vertebroplasty for the treatment of osteoporotic vertebral compression fractures. Technical note. *J Neurosurg* 2004 ; 100 : 392-396.
23. **Meeder PJ, DaFonseca K, Hillmeier J *et al.*** [Kyphoplasty and vertebroplasty in fractures in the elderly : effort and effect.] (in German). *Chirurg* 2003 ; 74 : 994-999.
24. **Moreland DB, Landi MK, Grand W.** Vertebroplasty : techniques to avoid complications. *Spine J* 2001 ; 1 : 66-71.
25. **Pflugmacher R., Kandziora F, Schroder R *et al.*** [Vertebroplasty and kyphoplasty in osteoporotic fractures of vertebral bodies – a prospective 1-year follow-up analysis]. (in German) *Rofo* 2005 ; 177 : 1670-1676.
26. **Phillips FM, Todd Wetzel F, Lieberman I, Campbell-Hupp M.** An in vivo comparison of the potential for extravertebral cement leak after vertebroplasty and kyphoplasty. *Spine* 2002 ; 27 : 2173-2178 ; discussion 2178-2179.
27. **Ploeg WT, Veldhuizen AG, The B, Sietsma MS.** Percutaneous vertebroplasty as a treatment for osteoporotic vertebral compression fractures : a systematic review. *Eur Spine J* 2006 ; 15 : 1749-1758.
28. **Pott, L, Wippermann B, Hussein S *et al.*** [PMMA pulmonary embolism and post interventional associated fractures after percutaneous vertebroplasty.] (in German). *Orthopäde* 2005 ; 34 : 698-702.
29. **Rauschmann MA, von Stechow D, Thomann KD, Scale D.** [Complications of vertebroplasty.] (in German). *Orthopade* 2004 ; 33 : 40-47.
30. **Shapiro S, Abel T, Purvines S.** Surgical removal of epidural and intradural polymethylmethacrylate extravasation complicating percutaneous vertebroplasty for an osteoporotic lumbar compression fracture. Case report. *J Neurosurg* 2003 ; 98 **:** 90-92.
31. **Taylor RS, Fritzell P, Taylor RJ.** Balloon kyphoplasty in the management of vertebral compression fractures : an updated systematic review and meta-analysis. *Eur Spine J* 2007 ; 16 : 1085-1100.
32. **Taylor RS, Taylor RJ, Fritzell P.** Balloon kyphoplasty and vertebroplasty for vertebral compression fractures : a comparative systematic review of efficacy and safety. *Spine* 2006 ; 31 : 2747-2755.
33. **Weill A, Chiras J, Simon JM *et al.*** Spinal metastases : indications for and results of percutaneous injection of acrylic surgical cement. *Radiology* 1996 ; 199 : 241-247.
34. **Wenger M, Markwalder TM.** Surgically controlled, transpedicular methyl methacrylate vertebroplasty with fluoroscopic guidance. *Acta Neurochir (Wien)* 1999 ; 141 : 625-631.