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CLINICAL ARTICLE

Cement leakage as a possible complication of balloon kyphoplasty—is there a difference between osteoporotic compression fractures (AO type A1) and incomplete burst fractures (AO type A3.1)?

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Abstract
Background Besides the treatment of osteoporotic vertebral compression fractures of AO type A1, balloon kyphoplasty (BKP) is seen as a therapeutic option even in the treatment of incomplete osteoporotic burst fractures (AO type A3.1). However, due to involvement of the posterior vertebral body wall, the risk of cement leakages is considered to be higher. This study focuses on the frequency and pattern of cement leakages in AO type A3.1 fractures compared with osteoporotic compression fractures (AO type A1).
Patients and methods Retrospective cohort analysis was done of all patients (n=138) treated by BKP for osteoporotic vertebral fractures (n=173) between January 2007 and December 2010 in our department. Cement extravasations into three pre-defined anatomical compartments were evaluated on postoperative CT scans of the augmented vertebral bodies, with even minor cement detections beyond the vertebral body's wall being strictly inidicated as leakages. The frequency of cement leakages in relation to the fracture type was statistically analyzed using Pearson's chi-square test. Clinical and radiological follow-up was done 6 weeks, 3 and 6 months postoperatively.
Results The overall cement leakage rate of BKP in 173 treated osteoporotic vertebral fractures was 30.6%. Cement extravasations were detected in 20.3% of A1.1, 30.5% of A1.2, 37.8% of A1.3, and 39.0% of A3.1 fractures, respectively. There was no statistically significant difference in the leakage rate between A3.1 and all A1 fractures (28.0%; $p > 0.05$), but between A3.1 and A1.1 fractures ($p < 0.05$). Intraspinal cement extravasations, being the most dangerous, were seen in 25.5% of all leakages (n=53), whereas in relation to the total number of treated fracture types, there were only 5.1% intraspinal leakages in A1.1, 5.6% in A1.2, 10.9% in A1.3, and 9.8% in A3.1 fractures. Two of 13 patients with intraspinal leakages and 1 patient with a paraaortal anterolateral cement extravasation needed surgical revisions. Two pulmonary PMMA cement embolisms were detected, but without any clinical consequences. None of the patients with cement leakages during BKP suffered from new neurological deficits.
Conclusions Cement leakages remain a problem in BKP. Although there was no significant difference between AO type A3.1 and all A1 fractures, subgroup analysis revealed a statistically significant higher risk of cement extrusions in A3.1 compared to A1.1 fractures. None of the affected patients showed new neurological deficits due to cement extravasations. Still, balloon kyphoplasty can be considered a safe procedure, even in the treatment of painful osteoporotic vertebral fractures of AO type A3.1.

Keywords Osteoporosis · Vertebral fractures · Ballon kyphoplasty · AO type A3.1 · Cement leakage

Introduction

During the last years balloon kyphoplasty (BKP) has become an overall accepted option in the treatment of painful

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and disabling osteoporotic vertebral compression fractures [1, 4]. Its positive effect concerning pain reduction and increase of mobility in affected patients is well documented [20, 27]. Therefore, BKP has become one of the most frequently performed minimally invasive spinal surgical procedures. Besides metastatic vertebral fractures, incomplete burst fractures of the vertebrae (AO type A3.1) have evolved as new therapeutic targets [3, 5, 7, 13]. However, despite the quite simple operative technique, the treating physician has to be aware of possible complications such as symptomatic cement leakages with subsequent neurological deterioration. Especially in incomplete burst fractures with an involvement of the vertebra's posterior wall, the frequency of cement leakages is thought to be higher [13]. Hence, AO type A3.1 fractures were considered a relative contraindication for BKP, but until now there have only been a few reports dealing with this problem explicitly [12, 19, 27].

The purpose of this study was to evaluate cement leakages as one of the major complications of BKP, focusing on the frequency and pattern of cement extravasations in relation to the vertebral fracture type according to the AO classification [17].

Patients and methods

Due to the improved restoration of vertebral body height and spinal alignment compared to vertebroplasty [8, 14, 23, 28], since 2007 we have solely applied BKP in the treatment of stable osteoporotic and metastatic fractures of the vertebrae. All patients treated are consecutively documented in a standardized database.

For this study the data of all 138 patients undergoing BKP for osteoporotic vertebral fractures (n=173) between January 2007 and December 2010 were retrospectively evaluated. The fracture types were classified according to the AO classification. The demographic data of the patients and classification of vertebral fracture types are shown in Table 1. Forty-one of all 173 osteoporotic vertebral fractures treated by BKP showed an involvement of the vertebra's posterior wall and were classified as incomplete burst fractures (AO type A3.1).

Preoperative diagnostics comprised spinal X-ray and computertomographic (CT) examination of the fractured vertebral bodies in all patients. An additional spinal magnetic resonance imaging (MRI) was done in 133 of the 138 patients. Five patients could not receive MRI diagnostics because of ferromagnetic implants. Osteoporosis was confirmed by preoperative osteodensitometry in all patients.

The operative procedure was done according to the manufacturer's recommendations under general anesthesia in prone position. After transpedicular insertion of the balloons under biplanar fluoroscopic visualization, the polymethylmethacrylate (PMMA) bone cement was inserted bipedicularly with a high, "chewing gum"-like viscosity in the anterior two-thirds of the vertebral body (median cement volume: 4.9 ml, mean: 6.1 ml, range: 2.8–8.3 ml per vertebra).

All kyphoplasty procedures were controlled again 1 day postoperatively with spinal X-ray and CT scans of the augmented vertebral bodies. Whenever intraoperative fluoroscopy gave a hint of an intraspinal or massive paravertebral PMMA-cement extrusion, an immediate postoperative CT scan was performed. In cases of suspected pulmonary embolisms, chest X-ray and contrast-enhanced spiral CT were added. During evaluation of the postoperative spinal CT scans, even minor cement extrusions beyond the vertebral body wall were strictly indicated as positive cement leakages.

Three different anatomic compartments were defined to classify the site of possible cement leakages: (1) through the anterolateral wall of the vertebral body (= anterolateral), (2) into the intervertebral disc space (= intradiscal), and (3) into the spinal canal (= intraspinal). Furthermore, distant cement detections like pulmonary embolisms were detected. For

Table 1 The patient demographic data and distribution of type A vertebral fractures according to the AO classification. In AO type A2, A3.2, and A3.3 fractures there were no indications for kyphoplasty. Total number of cement extrusions and percentage of leakages in relation to the number of fractured vertebral bodies

Patients	138		
Ratio male:female	48:90		
Mean age	Male: 70.1 years (range: 49–86 years)		
	Female: 77.8 years (range: 47–89 years)		
A Compression injury			
		Fracture	Leakage
A1 Impaction fracture	A1.1 Endplate impaction	n=59	n=12/20.3%
	A1.2 Wedge impaction	n=36	n=11/30.5%
	A1.3 Vertebral body collapse	n=37	n=14/37.8%
A1 Total		n=132	n=37/28.0%
A3 Burst fracture	A3.1 Incomplete burst fracture	n=41	n=16/39.0%
Total		173	n=53/30.6%

statistical analysis we used Pearson's chi-square test to determine the frequency of cement extrusions in relation to the AO fracture type. The level of significance was defined at $p \leq 0.05$.

Follow-up was done for the medium-term evaluation according to our outpatient protocol with physical and radiological examinations 6 weeks, 3 and 6 months after the procedure. Additionally, the amount of pain medication pre- and postoperatively was recorded. Furthermore, the mean pain level according to the visual analog scale (VAS) was assessed in all patients at the different follow-up presentations.

Results

One hundred thirty-eight (90 females, 48 males) patients with stable osteoporotic vertebral fractures were treated with BKP. The average age was 77.8 (range: 47–89) years in female and 70.1 (range: 49–86) years in male patients. The fractures were caused in 79 patients by minor accidents, like falls from low height. Five patients had suffered from ladder falls and 18 from traffic accidents. Thirty-six patients did not remember any relevant trauma or accident.

One hundred seventy-three vertebrae were augmented by BKP. The majority of fractures treated were located at the thoraco-lumbar junction, with L1 beeing the most frequently affected vertebra (n=48, 27.7%) (Fig. 1a, Table 2). According to the AO classification, there were 59 A1.1, 36 A1.2, and 37 A1.3 fractures. Split fractures (A2) were not treated with kyphoplasty. Furthermore, 41 A3.1 injuries were augmented (Fig. 1b, Table 1). One hundred ten patients were treated at one vertebral level, 24 for two level fractures, and 4 at three levels in one combined or two single procedures, respectively. Twelve patients received a second kyphoplasty for a newly occurring vertebral body fracture within the follow-up period.

Cement leakages

The overall cement leakage rate of BKP in 173 treated osteoporotic vertebral AO type A1 and A3.1 fractures was 30.6%. Cement extravasations were detected in 20.3% of A1.1, 30.5% of A1.2, 37.8% of A1.3, and 39.0% of A3.1 fractures, respectively (Fig. 1b, Table 1). Group comparison of all 37 cement leakages in 132 vertebrae treated for osteoporotic A1 fracture (28.0%) with 16 leakages in 41 augmented A3.1 fractures (39.0%) showed no statistically significant

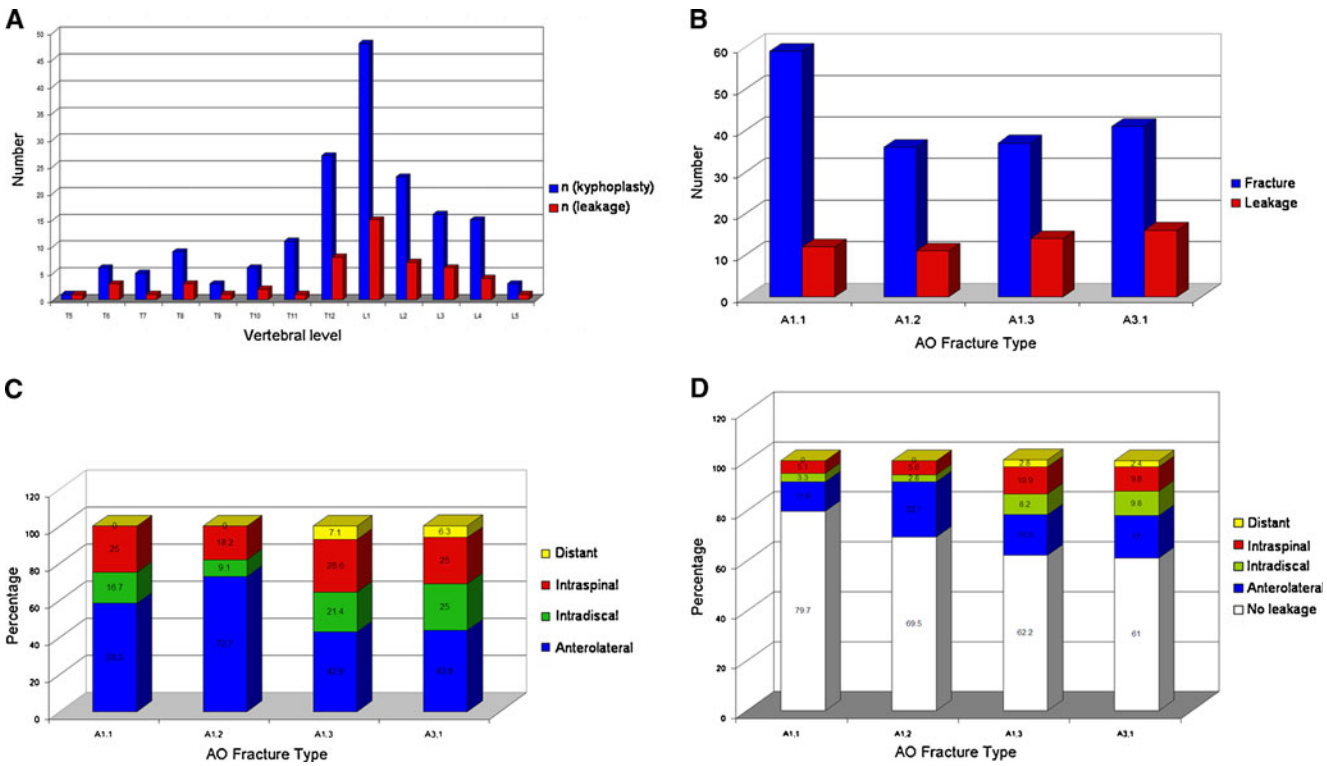

Fig. 1 (a) Distribution of fractured vertebral levels that were treated by balloon kyphoplasty and corresponding cases of cement leakages. (b) Total number of cement extrusions compared to the distribution of fractured vertebral bodies according to the AO classification. (c) Percentaged distribution of all cement leakages in relation to the vertebra's AO fracture type. (d) Fracture type-specific percentaged distribution of the cement leakages in relation to all treated vertebrae

Table 2 Number of fractured vertebral levels that were augmented by balloon kyphoplasty and corresponding number of cement leakages, respectively

Vertebral body	n (kyphoplasty)	n (leakage)
T5	1	1
T6	6	3
T7	5	1
T8	9	3
T9	3	1
T10	6	2
T11	11	1
T12	27	8
L1	48	15
L2	23	7
L3	16	6
L4	15	4
L5	3	1
Total	173	53

difference (p=0.244). However, subgroup analysis revealed a significantly higher rate of cement extrusions during BKP of A3.1 fractures in contrast to A1.1 fractures (p=0.046).

The major part of the cement extrusions occurred at the anterior and lateral vertebral body (52.8%), followed by intraspinal (24.5%), which is known to be the clinically most important site of an unwanted cement accumulation, and intradiscal (18.9%) PMMA leakages. In only two cases (3.8% of all cement extravasations) could pulmonary embolisms be detected. Analysis of the fracture type-specific site of cement extravasations revealed that 58.3% of the 12 leakages in A1.1 fractures were seen into the anterolateral, 16.7% intradiscal, and 25.0% intraspinal compartments. Of the 11 cement leakages in A1.2 fractures, 72.7% were into the anterolateral, 9.1% the intradiscal, and 18.2% the intraspinal compartments. In A1.3 fractures 42.9% of all 14 leakages were anterolateral, 21.4% intradiscal, and 28.6% intraspinal, compared to 43.8% anterolateral, 25.0% intradiscal, and 25.0% intraspinal cement extrusions in all 16 leakages in A3.1 fractures. There were no significant differences between the site of cement extrusion and the corresponding AO fracture type (Fig. 1c, Table 3). However, looking at the total number of treated fractures, we saw only 11.9% anterolateral, 3.3% intradiscal, and 5.1% intraspinal cement leakages in all A1.1 fractures, compared to 22.1% anterolateral, 2.8% intradiscal, and 5.6% intraspinal cement leakages in all A1.2 fractures; 16.3% anterolateral, 8.2% intradiscal, and 10.9% intraspinal cement leakages in all A1.3 fractures; and 17.0% anterolateral, 9.8% intradiscal, and 9.8% intraspinal cement leakages in all A1.3 fractures, respectively (Fig. 1d, Table 3). In 11 procedures the extrusions affected two of these compartments at once, and during one intervention we had cement leakage into all three compartments, respectively (Fig. 2).

The number of fractured vertebral levels that were treated by balloon kyphoplasty and corresponding cases of cement leakages are listed in Table 1 (Fig. 1a). Table 2 lists the distribution of type A vertebral fractures according to the AO classification, the total number of cement extrusions, and percentage of leakages compared to the number of fractured vertebral bodies (Fig. 1b). The localization, number, and percentage of cement leakages in relation to the AO fracture type is seen in Table 3 (Fig. 1c-d).

Clinical results

None of the patients with cement leakages, especially intraspinal ones, suffered from procedure-related new neurological deficits. Still, 2 of the 13 patients with intraspinal cement leakage needed surgical revision with cement removal because of spinal occlusion of about 30%. In another patient with an osteoporotic incomplete burst fracture of L1 (AO type A3.1), a ventral paraaortal cement leakage resulted in an acute aortic wall affection, which made removal of this PMMA-cement block, performed by the vascular surgeons via a median laparatomy, necessary (Fig. 3a-d). In two further cases, we radiologically documented a pulmonary embolism in a patient with an A1.3 injury of L1 (Fig. 3e-h) and another patient with an A3.1 fracture of T12, respectively. Fortunately both leakages caused no clinical consequences.

Table 3 Localization, number, and percentage of the cement extravasations in relation to the AO fracture type (row) and site of leakage (column), respectively (multiple localizations possible). Percentages are stated in relation to the total number of leakages, whereas in the last column the number and percentage of no leakages refer to the AO fracture type

AO fracture type	Anterolateral	Intradiscal	Intraspinal	Distant	Total	No leakage
A1.1	n=7	n=2	n=3	n=0	n=12 (20.3%)	n=47 (79.7%)
A1.2	n=8	n=1	n=2	n=0	n=11 (30.5%)	n=25 (69.5%)
A1.3	n=6	n=3	n=4	n=1	n=14 (37.8%)	n=23 (62.2%)
A3.1	n=7	n=4	n=4	n=1	n=16 (39.0%)	n=25 (61.0%)
Total	n=28 (52.8%)	n=10 (18.9%)	n=13 (24.5%)	n=2 (3.8%)	n=53	n=120 (69.4%)

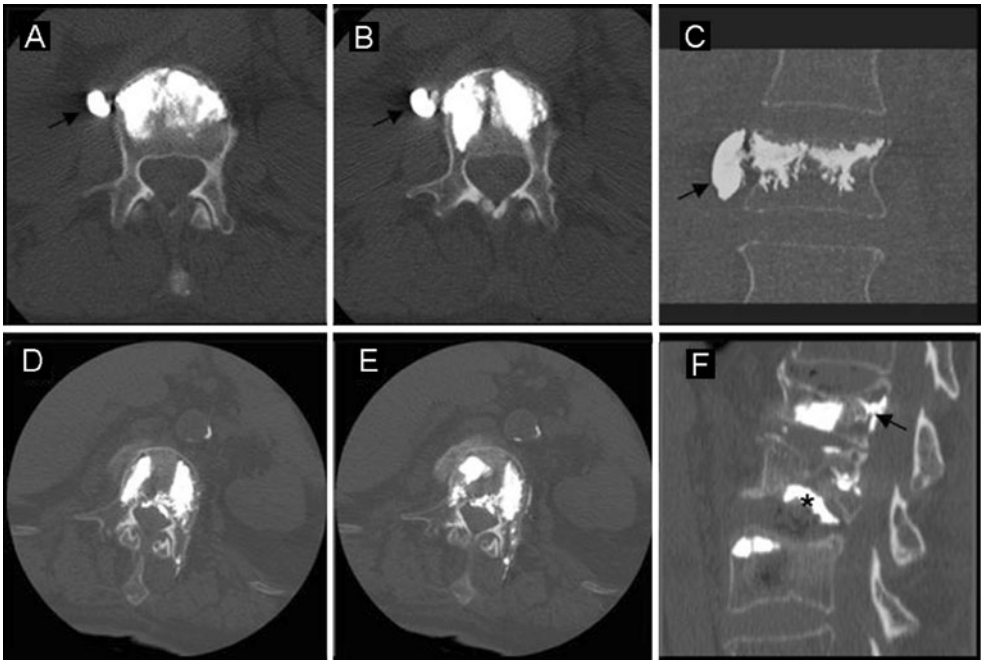

Fig. 2 (a-c) Periprocedural PMMA-cement extrusion into the lateral paravertebral space during kyphoplasty of an A1.1 L1 fracture, without any revision necessary. (d, e) Axial and sagittal (f) CT scans of combined three-level kyphoplasty of L1, L2, and L3 due to spontaneous osteoporotic fractures with intraspinal (arrow) and intradiscal (asterisk) cement leakages

Compared with the preoperative mean pain level on the visual analog scale (VAS) of 7.8±1.8, there was a clear improvement of the VAS (2.9±1.6) 6 weeks postoperatively described by 76.8% of the patients. Among the patients, 71 did not use analgesics, and 29 only needed occasional pain medication for back pain. After the 3-month follow-up, 78.3% of the 100 patients described a further pain reduction (VAS 2.1±1.2). There were no significant differences in the level of pain reduction between the 3- and 6-month follow-ups (VAS 1.9±1.4).

Discussion

Objective and study limitations

To our knowledge, this is one of the first systematic study investigating a possible impact of the AO fracture type classification on the incidence of a periprocedural bone cement extravasation during balloon kyphoplasty. Despite an overall acceptance [10, 25]—even for safety aspects—of this technique, severe complications caused by cement

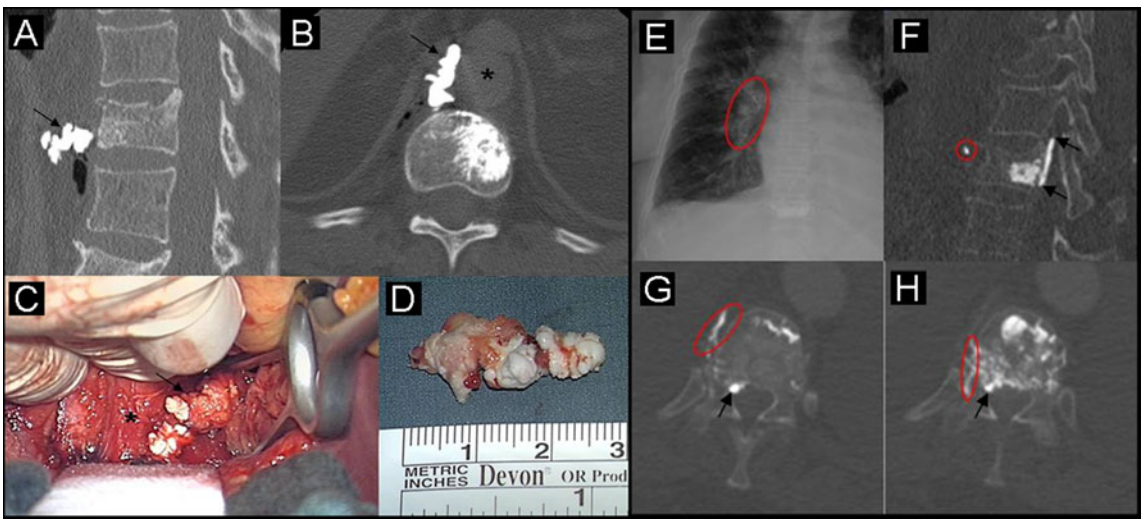

Fig. 3 Postoperative sagittal (a) and axial (b) CT scans demonstrating a ventral paraaortal PMMA-cement block extrusion (black arrow) after BKP of osteoporotic L1 fracture that led to a chronic aortic wall (black asterisk) affection. (c) Intraoperative view during surgical revision for removing the cement block. (d) Complete removal of the whole 28-mm PMMA block. (e) Postoperative chest X-ray documenting pulmonary embolisms (red circle) after kyphoplasty of a L1 fracture. (f) Sagittal and (g, h) axial CT scans showed the far lateral cement extrusions into the paravertebral veins and a further intraspinal leakage (black arrows) without any relevant compression of the terminal cone

leakages are still possible [23]. This has to be considered, especially when thinking of new therapeutic targets for balloon kyphoplasty, such as A.3 fractures [13, 22]. The intention of this study was not to confirm the well-known positive short- and long-term results concerning pain and mobility, which were recently verified in a randomized controlled trial [27], but to focus on a possible severe complication of this well-established and widely used method. For this reason, the study had to be designed in a retrospective manner. Due to our standardized database and a very rigid and clear institutional protocol, concerning the inpatient management as well as outpatient follow-up, with routine physical and radiological examinations, a very exact evaluation could be achieved.

Complications and clinical results

In our patient group with A1 and A3.1 fractures we had an overall cement leakage rate of 30.6% documented by immediate or postoperative CT scans, representing the most frequent adverse event. In the literature, cement extrusions after BKP are described with an overall incidence between 7% and 49% [6, 15, 18, 26, 27], depending on the definition and the radiological technique. Compared with vertebroplasty, adverse events are still rare in balloon kyphoplasty [6, 15, 20], and in the vast majority they cause no clinical consequences. However, neurological injuries and pulmonary embolism due to an intraoperative cement extravasation have already been reported to be adverse events of this technique. Whereas neurological injuries were only described in a few case reports, the incidence of pulmonary embolisms is estimated between 5% and 23%, especially during kyphoplasty [12]. In our series we observed only two cases (3.8%) of radiologically documented pulmonary embolisms, fortunately without any clinical evidence. In 24.5% of the cases intraspinal cement extravasations were documented, and in one patient a ventral cement leakage led to affection of the lumbal aorta. Due to an increased risk of damage of the aortic wall, this extruded cement block had to be removed. Two patients had to be reoperated because of an intraspinal cement accumulation that occupied more than one third of the spinal canal in this segment. None of these patients suffered from a new persistent neurological deficit.

Reasons for cement leakages, despite an incorrect application, have not been adequately investigated yet. The amount of applied PMMA cement, the consistency of the cement, different kinds of fracture entities (e.g., osteoporotic vs. non-osteoporotic), and the different fracture types (e.g., AO type A1 vs. A3.1) are discussed as possible reasons for cement extrusions [12, 15]. Especially the risk of leakage into the spinal canal is considered to be higher when the posterior vertebral wall is affected by the fracture, as is the case in A3.1 fractures. The rate of cement leakages in burst fractures (AO type A3) is specified between 23% and 47% [9, 13], a number that only partly correlates with our data. Looking only at augmented A3.1 fractures, we observed a rate of intraspinal cement leakages of 9.8%. However, even in A1 injuries intraspinal cement extrusions could be detected in 6.8% of all leakages. Possible reasons could be undetected defects of the posterior wall or cement extrusions through the pedicle's base during the procedure [16]. After reevaluation of the computer tomgraphic data we could assume this mechanism in at least seven of the patients treated for an A1 fracture.

Although there was no significant difference between the overall rate of cement extrusions comparing AO type A1 and A3.1 fractures, we could demonstrate a fracture subtype-dependent significantly higher rate of PMMA extrusions in AO type A3.1 compared to AO type A1.1 fractures.

A greater volume of applied cement is thought to be associated with more caudal vertebral levels, different surgeons, and a larger fractured vertebral body volume. In the vertebroplasty study by Jin, the highest intravertebral cement volume was even 6.7±2.1 ml [11]. Otherwise, there are a few but contradictory reports dealing with the question of cement leakages occurring in vertebroplasty when the injected cement volume increases [21, 24]. In kyphoplasty the amount of applied cement can be even higher because of the intravertebral cavity created during balloon inflation and height restoration. Against this background the median volume of applied cement in this study of 4.9 ml (mean: 6.1 ml) seems not to account for the higher incidence of paravertebral leakages.

The results concerning pain reduction confirm the overall accepted short- and mid-term success rates, with 76.8% of the patients reporting a significant decrease in the mean pain level at the 6-week follow-up and 78.3 % at the 3-month mid-term follow-up [23]. Nevertheless, the positive effect of BKP in respect to pain reduction and restoration of vertebral height [2] should still be a decisive argument for this procedure in patients with stable osteoporotic vertebral fractures. Nevertheless, cement leakages as possible and serious complications have to be taken into account when surgery is scheduled.

Conclusions

This is one of the first systematic studies elucidating the rate of cement leakages during balloon kyphoplasty in osteoporotic compressions fractures (AO type A1) compared to incomplete burst fractures (AO type A3.1). There was no statistically significant difference in the cement leakage rate between all AO type A1 and the treated A3.1 fractures in this large series of 173 augmented vertebrae. However, there is still a clear

trend toward a higher risk of adverse events and intraspinal cement extravasations in AO type A3.1 fractures with partial inclusion of the posterior wall of the vertebral body. Furthermore, fracture type-specific subgroup analysis revealed a statistically significant higher rate of cement extrusions in A3.1 fractures compared to A1.1 fractures. Besides these results, the positive clinical effects regarding mid-term pain reduction of balloon kyphoplasty could be underlined, bearing in mind that complications are still possible.

Conflicts of interest None

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