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ORIGINAL ARTICLE

Prediction of immediate and long-term benefit after kyphoplasty of painful osteoporotic vertebral fractures by preoperative MRI

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Abstract
Background It is unclear if an MR-detectable bone marrow edema is a prerequisite for pain reduction and morphological correction by kyphoplasty. This comparative trial evaluates clinical and radiomorphological outcomes after kyphoplasty of painful osteoporotic vertebral fractures with and without preoperative MR-detectable bone marrow edema for 1 year of follow-up.
Methods Preoperative MR-images of 45 patients who received kyphoplasty for treatment of painful osteoporotic vertebral fractures were evaluated with regard to presence ($n = 27$) or absence ($n = 18$) of vertebral bone marrow edema. Pain scores (VAS 0-100) and radiomorphological measures (midline vertebral height, kyphosis angle) were analysed at baseline, postoperatively and after 12 months.
Results In the "bone edema" group, pain scores improved from 72.7 to 46.8 (postoperative) and 48.0 (12 months, $P < 0.001$, both). In the group without preoperative bone edema, pain score improved from 70.7 to 60.3 (postoperative, $P = 0.013$) and to 50.1 (12 months, $P = 0.001$). Pain scores of both groups were significantly different directly postoperative ($P = 0.026$), but not after 12 months ($P = 0.714$). Vertebral height restoration was slightly greater in the "bone edema" group (10.2% vs. 7.8%, $P = 0.289$). Correction of the kyphosis angle was greater in the "bone edema" group ($P = 0.014$) compared to the "no bone edema" group ($P = 0.838$).
Conclusion A preoperative MR-detectable vertebral bone marrow edema predicts a better short-term outcome after kyphoplasty, but is not a prerequisite for long-term pain reduction in patients with old, chronically painful osteoporotic vertebral fractures.

Keywords Kyphoplasty · Vertebral fracture · Bone marrow edema · Back pain · MRI

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Introduction

Kyphoplasty is a procedure to treat painfully fractured vertebral bodies [1–7]. Localized back pain is a prerequisite for a successful kyphoplasty in terms of pain reduction at the treated site. In patients with multiple, painful osteoporotic vertebral fractures, it is often difficult to determine which of the deformed vertebrae benefits most from balloon kyphoplasty. Therefore, in addition to a thorough physical examination of the spine to identify the most painful vertebral bodies, MRI is often used to reveal the presence of vertebral bone marrow edema as an indicator for acutely fracturing vertebrae [8]. Bone marrow

edema (BME) is detectable by MRI for a period of at least 3–6 months and disappears after fracture stabilization. MR-detectable BME may be associated with pain in fracturing vertebrae, which is consistent with the observation that vertebroplasty of non-deformed painful osteoporotic vertebrae with BME reduces pain [9]. Therefore, the presence of a BME may be an essential predictor for a successful pain relief and correction of deformity after treatment of painful vertebral fractures by kyphoplasty. As a consequence, several authors included only patients with vertebral BME revealed by MRI in their trials [1, 4, 10–14] and observed pain relief after kyphoplasty. To our knowledge, a comparative evaluation of the short and long-term outcomes of kyphoplasty in painful osteoporotic vertebral fractures with and without MRI edema has not been reported previously. Therefore, the prognostic value of a preoperative bone marrow edema in painful osteoporotic vertebral fractures treated by kyphoplasty is unclear.

Recently, we have shown that patients with chronically painful osteoporotic vertebral fractures older than 12 months also exhibit a clinical benefit from kyphoplasty compared to a conservatively treated control group [6, 7]. Therefore, in this retrospective study we tested whether an MR-detectable BME is a predictor for pain reduction and morphological correction by kyphoplasty of osteoporotic vertebral fractures.

Materials and methods

All patients of this study had localized back pain due to osteoporotic vertebral fractures in spite of conservative treatment. In all patients the painfully fractured vertebral bodies were treated by kyphoplasty; pain levels were assessed preoperatively and on follow-up visits [standardized visual analogue scale (VAS): 100 (=maximum pain) – 0 (=no pain)] [15]. In addition, plain X-rays of the spine in supine position were obtained as a standard procedure pre- and postoperatively and on follow-up visits. Kyphoplasty of fractured vertebral bodies was performed if the fracture location corresponded to the location of the most severe back pain in a clinical examination. Clinical examination included identification of the major pain location by exerting vertical compression onto the spine, by knocking on the spinal processes along the thoracic and lumbar spine and by identification of the major pain location during careful rotation of the spine. Technical feasibility of kyphoplasty in general anaesthesia was evaluated for each patient by an interdisciplinary team of orthopaedic surgeons, radiologists and endocrinologists. Patients received a preoperative MRI of the spine (T1-weighted, T2-weighted and fat-suppressed T2-weighted [turbo inversion recovery magnitude (TIRM), Siemens Avanto, 1.5 tesla]) to identify acutely fracturing vertebral bodies with bone marrow edema (BME) (Fig. 1). In addition, other causes of spinal pain, e.g., vertebral disc damage, spinal stenosis or nerval injury (exclusion criteria) can be detected by MRI in unclear situations. Other exclusion criteria for kyphoplasty were the presence of a vertebra plana, a fractured posterior vertebral wall, severe degenerative changes of the spine and a severely increased cardiopulmonary or hemostatic risk for general anesthesia. Patients with a clear association of the region of the most severe back pain with a fractured vertebral body received kyphoplasty even in the absence of a BME ($n = 45$, Table 1). All patients eligible for kyphoplasty were informed of possible risks of the intervention and gave written informed consent. Kyphoplasty of 1–4 vertebral levels per patient was performed in general anesthesia according to customary standards [1, 2, 6]. All patients received a pharmacological antiosteoporosis treatment consisting of 1,000 mg calcium + 1,000 IE vitamin D and a standard dose of an aminobisphosphonate. Furthermore, physiotherapy was prescribed. The study protocol was approved by the local ethics committee of our institution.

All patients with available preoperative MR-images and 12 month follow-up VAS pain scores were included in the retrospective evaluation of this study. MR-images were evaluated with regard to the presence or absence of a preoperative BME by two independent readers who were blinded to the outcome of the pain questionnaires. The presence of BME was defined as an increased signal intensity on fat-suppressed T2-weighted (TIRM) MR-sequences. Depending on the findings of this evaluation,

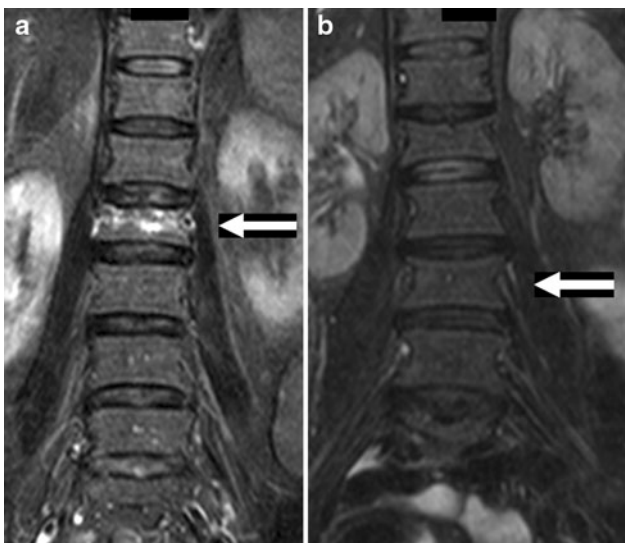

Fig. 1 MR images of painful osteoporotic vertebral fractures with (**a**) and without (**b**) bone marrow edema. The presence of bone marrow edema was defined as an increased signal intensity on fat-suppressed T2-weighted turbo inversion recovery magnitude sequences (*TIRM*) of the vertebral fractures (Siemens Avanto, 1.5 tesla)

Table 1 Baseline characteristics

		Bone marrow edema in MRI		No bone marrow edema in MRI		Total		*P* value bone edema vs. no bone edema
		(*n*)	%	(*n*)	%	(*n*)	%	
n		27	60	18	40	45	100	–
Sex	Male	8	29.6	3	16.7	11	24.4	0.482
	Female	19	70.4	15	83.3	34	75.6	
Age	Mean ± SE	66.5 ± 1.8		63.1 ± 2.5				0.261[+]
Vertebrae	Total	37		38		75		0.970[‡]

Baseline characteristics of treated patients with and without bone marrow edema

* Fisher's exact test

[+] Two-sample *t* test

[‡] Mann–Whitney *U* test

patients with at least one clearly discernable BME in a fractured vertebral body scheduled for kyphoplasty were allocated to the "bone edema" group, patients without BME were allotted to the "no bone edema" group (Fig. 1). In all patients the midline vertebral body height [defined as the percentage of the intact posterior height of the fractured vertebrae or of the closest non-deformed vertebral body (=100%)], the height restoration and the kyphosis angle of the treated vertebral bodies were measured on X-rays preoperatively, postoperatively and after 1 year of follow-up. The percentage of height restoration was calculated as: [(postoperative height − preoperative height) × 100%/height of intact vertebral body]. Radiomorphological measurements were performed by two independent readers who were blinded to the findings of the MR-images and to the pain questionnaires. In addition, the preoperative, postoperative and 1-year follow-up pain (VAS) scores of these patients were analyzed.

Statistical analyses

For the analysis of VAS scores, midline vertebral body height and kyphosis angle, repeated measures ANOVAs were performed in order to compare the response profiles of the two groups. If the overall test was significant, we used paired *t* tests in order to compare two different time points within each group. In addition, we used two sample *t* tests to compare the two groups at different time points. Categorical data and, in particular, improvement rates were compared using Fisher's exact test. To compare the number of treated vertebral fractures between both groups Mann–Whitney *U* test was performed in order to account for a varying amount of fractures in different patients. A statistical result with $P < 0.05$ was considered to be significant. SAS statistical software (release 9.2, SAS Institute Inc., Cary, NC, USA) was used for all calculations.

Results

Pain

In the "bone edema" group the VAS score improved from 72.7 (baseline) to 46.8 postoperatively ($P < 0.001$) and remained significantly improved at 48.0 after 12 months ($P = 0.630$ vs. postoperative, $P < 0.001$ vs. baseline). In the "no bone edema" group the VAS score improved significantly from 70.7 (baseline) to 60.3 (postoperative, $P = 0.013$) and to 50.1 after 12 months ($P = 0.077$ vs. postoperative, $P = 0.001$ vs. baseline). Therefore, the "bone edema" group exhibited a significantly lower pain level immediately after kyphoplasty compared to the "no bone edema" group ($P = 0.026$). After 12 months there was no significant difference between both groups ($P = 0.714$), both groups exhibited similarly improved VAS scores (Fig. 2).

Proportion of patients with improved pain score

Postoperatively, 96% of the patients in the "bone edema" group showed an improvement of pain compared to 72% of patients in the "no bone edema" group ($P = 0.031$, Fisher's exact test). After 12 months, 93% of the patients in the "bone edema" group showed an improvement of pain compared to 83% of patients in the "no bone edema" group ($P = 0.375$, Fisher's exact test).

Radiomorphological changes

At baseline, the mean midline vertebral body height of the fractured vertebrae was lower in the "bone edema" group (52.8%) compared to the "no bone edema" group (61.7%; $P = 0.015$). There was a slightly greater height restoration of the treated vertebral fractures by kyphoplasty in the "bone edema" group compared to the "no

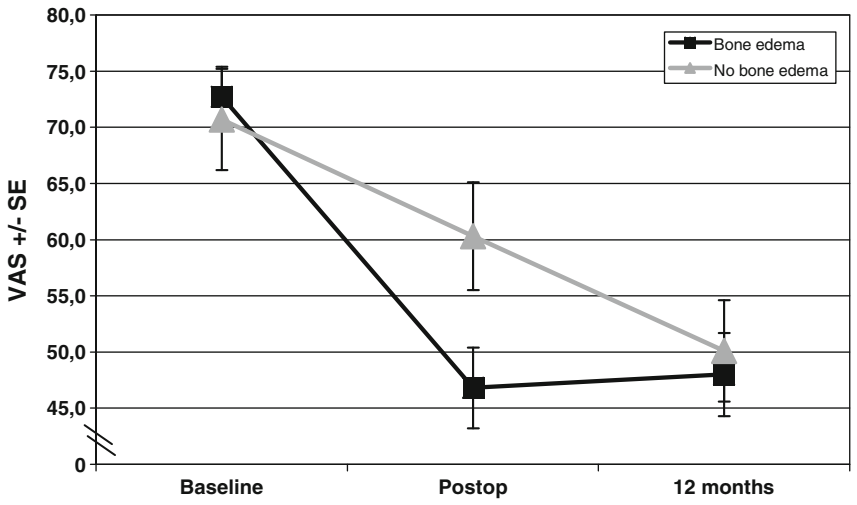

Fig. 2 Pain scores (*VAS*) of both groups at baseline and during follow-up. There was no significant difference in VAS scores between "bone edema" and "no bone edema" group at baseline. The immediate postoperative pain score of the "bone edema" group was significantly more improved compared to the "no bone edema" group, however, no significant difference remained after 12 months. *n*, number of patients; +, paired *t* test; ‡, two-sample *t* test

	Baseline mean ± SE	**Postoperative** mean ± SE	*Postoperative vs. baseline*	**12 months** mean ± SE	*12 months vs. postoperative*	*12 months vs. baseline*
Bone edema in MRI	72.7 ± 2.7 (n=27)	46.8 ± 3.6 (n=27)	*P<0.001* +	48.0 ± 3.7 (n=27)	*P=0.630* +	*P<0.001* +
No bone edema in MRI	70.7 ± 4.5 (n=18)	60.3 ± 4.8 (n=18)	*P=0.013* +	50.1 ± 4.5 (n=18)	*P=0.077* +	*P=0.001* +
Bone edema vs. no bone edema	P=0.678 ‡	P=0.026 ‡	—	P=0.714 ‡	—	—

Pain scores (VAS) of both groups at baseline and during follow-up. There was no significant difference in VAS scores between "Bone edema" and "No bone edema" group at baseline. The immediate postoperative pain score of the "Bone edema" group was significantly more improved compared to the "No bone edema" group, however, there was no significant difference any more after 12 months.

[n number of patients]
+ paired t-test
‡ two-sample *t*-test

bone edema" group (postoperative: 10.2 vs. 8.7%; 12 months: 10.2 vs. 7.8%), however, these differences were not statistically significant [$P = 0.450$ (postoperative), $P = 0.289$ (12 months)] (Fig. 3).

The initial kyphosis angle of the fractured vertebral bodies of the "bone edema" group was higher compared to the "no bone edema" group at baseline, however, this difference was not statistically significant ($P = 0.108$). A higher degree of vertebral deformity with consequent unphysiological loading and a greater mechanical strain within bone tissue may be relevant for detecting a BME by MRI in old osteoporotic vertebral fractures. The kyphosis angle of the treated vertebrae in the "bone edema" group changed from 10.7° (baseline) to 8.3° after kyphoplasty ($P < 0.001$) and to 8.4° after 12 months ($P = 0.060$ vs. postoperative, $P = 0.014$ vs. baseline). In the "no bone edema" group there was no significant change of the kyphosis angle after kyphoplasty or 12 months postoperatively ($P = 0.204$ and $P = 0.838$, respectively) (Fig. 4).

Discussion

This study shows that the presence of a preoperative MRI-detectable bone marrow edema (BME) in painful osteoporotic vertebral fractures is a predictor for a faster response in terms of pain reduction after kyphoplasty compared to fractured vertebrae without edema, although there was a significant pain reduction in both groups. Immediately after kyphoplasty 96% of the patients of the "bone marrow edema" group and only 72% of the patients without BME showed an improved pain score. Consequently, in patients

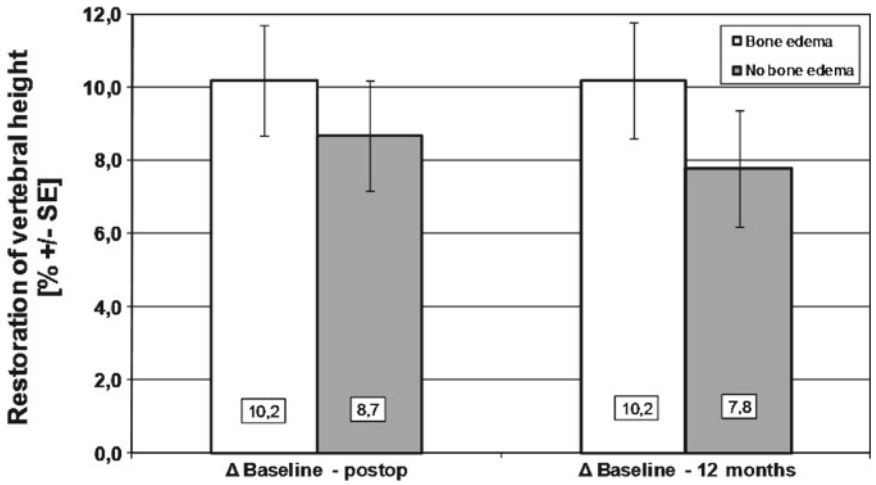

Fig. 3 Height restoration of both groups during follow-up. Midline vertebral body height at baseline was lower in the "bone edema" group compared to the "no bone edema" group. The height restoration in the "bone edema" group was slightly greater compared to the "no bone edema" group during follow-up, however, these differences were not statistically significant. The percentage of height restoration was calculated as: Height restoration = [(postoperative height (%) − preoperative height (%) × 100)/100%]. *n*, number of vertebral bodies; ‡, two-sample *t* test

	Midline vertebral body height **at baseline** [% ± SE]	**Height restoration** [% ± SE]	
		Baseline - postoperative	**Baseline - 12 months**
Bone edema in MRI	52.8 ± 2.9 (n=37)	10.2 ± 1.5 (n=37)	10.2 ± 1.6 (n=29)
No bone edema in MRI	61.7 ± 2.1 (n=38)	8.7 ± 1.5 (n=38)	7.8 ± 1.6 (n=33)
Bone edema vs. no bone edema	P=0.015 ‡	P=0.450 ‡	P=0.289 ‡

Height restoration of both groups during follow-up. Midline vertebral body height at baseline was lower in the „Bone edema" group compared to the „No bone edema" group. The height restoration in the "Bone edema" group was slightly greater compared to the "No bone edema" group during follow-up, however, these differences were not statistically significant. The percentage of height restoration was calculated as:
Height restoration = [(postoperative height [%] – preoperative height [%])*100) / 100 %].

[n = number of vertebral bodies]
‡ two-sample *t*-test

selected for kyphoplasty by a thorough clinical localization of the area of the most severe back pain (and its association to a vertebral fracture on conventional X-rays), the presence of an MRI-detectable BME is a predictor for a more rapid pain improvement after kyphoplasty.

Interestingly, due to a further pain improvement of the group without BME after 1 year, there was no significant difference in mean VAS pain scores and in the proportion of patients with an improved pain score between both groups after 12 months. According to our previous findings, the significant pain improvement in the group without BME may not reflect the natural course of fracture healing associated pain reduction in patients with chronically painful osteoporotic vertebral fractures, since we have demonstrated that kyphoplasty in these patients leads to a significantly greater pain reduction compared to a conservatively treated control group for at least 3 years of follow-up [7, 16]. Considering the results of the present study, kyphoplasty of painful vertebral fractures without BME may have a delayed, but also significant pain reducing effect, which may be due to a destruction of pain fibers located close to sites of multiple microcracks (not causing MRI detectable bone marrow edema). However, our previous study was a non-randomized controlled trial comparing pain reduction after kyphoplasty to a conservatively treated group, whereas the impact of an invasive procedure may play a role in the pain reducing effect of kyphoplasty. A long-term randomized controlled trial comparing the outcome after kyphoplasty with a sham operated group would be required to solve this issue.

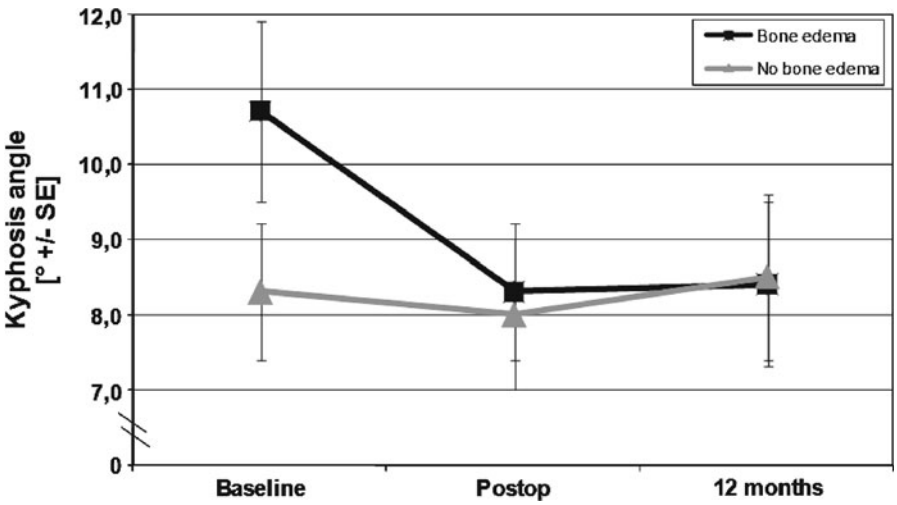

Fig. 4 Kyphosis angle of both groups at baseline and during follow-up. There was a significant correction of the kyphosis angle in the "bone edema" group after kyphoplasty. No significant changes of the kyphosis angle in the "no bone edema" group were observed. *n*, number of treated vertebrae; +, paired *t* test; ‡, two-sample *t* test

	Baseline mean ± SE	**Postoperative** mean ± SE	*Postoperative vs. baseline*	**12 months** mean ± SE	*12 months vs. postoperative*	*12 months vs. baseline*
Bone edema in MRI	10.7° ± 1.2 (n=37)	8.3° ± 0.9 (n=37)	*P<0.001* +	8.4° ± 1.1 (n=29)	*P=0.060* +	*P=0.014* +
No bone edema in MRI	8.3° ± 0.9 (n=38)	8.0° ± 1.0 (n=38)	*P=0.204* +	8.5° ± 1.1 (n=33)	*P=0.470* +	*P=0.838* +
Bone edema vs. no bone edema	P=0.108 ‡	P=0.787 ‡	—	P=0.943 ‡	—	—

Kyphosis angle of both groups at baseline and during follow-up. There was a significant correction of the kyphosis angle in the "Bone edema"-group after kyphoplasty. No significant changes of the kyphosis angle in the "No bone edema"-group were observed.

[n = number of treated vertebrae]
+ paired t-test
‡ two-sample *t*-test

Several reports have studied the implications of the presence of a preoperative vertebral BME on postoperative pain relief after vertebroplasty. In short-term observations, Tanigawa et al. [17] observed greater immediate pain relief (day 1–3) after vertebroplasty of vertebral fractures with a more intense BME, and Voormolen et al. [18] reported significantly better improvement of pain 3 months after vertebroplasty of vertebral fractures with a BME compared to vertebrae without an edema. These findings are supported by the observation of faster pain reduction after vertebroplasty of vertebral fractures with preoperatively increased activity in bone scan imaging [19]. In accordance with our observations, Brown et al. [20] observed that the presence of an MR-detectable BME is not required to accomplish significant pain relief after vertebroplasty of old painful vertebral fractures after a mean follow up period of 13.1 months. Both kyphoplasty and vertebroplasty appear to have a faster effect in terms of pain reduction when treating more acute vertebral fractures exhibiting a BME.

Regarding the morphological correction by kyphoplasty, we observed a tendency to a greater height restoration and correction of the kyphosis angle in vertebral fractures exhibiting a BME compared to vertebral fractures without edema, which may indicate a more mobile state in vertebral fractures with a BME. Our observations are consistent with the findings by Crandall et al. [21], who reported a better morphological correction by kyphoplasty of acute vertebral fractures $\leq$10 weeks old compared to chronic fractures $\geq$4 months old, whereas BME was a prerequisite for kyphoplasty in this trial. Interestingly, the authors observed a similar pain reduction in both groups after two weeks and

a further decrease in pain from the 2-week to the 6-week follow-up in the chronic fracture group, supporting our finding of a beneficial effect on pain reduction after treating old vertebral fractures by kyphoplasty.

This study has several limitations. The two cohorts had small group sizes. Additionally, routine MRI technology was applied which may not exclude the possibility that more advanced MRI technologies, such as contrast medium-enhanced MR-imaging or diffusion-weighted MRI, might also have been able to detect edema in individuals of our no-edema-group. Furthermore, the follow-up period was limited to 1 year, thus it cannot be excluded that both groups will show differences with regard to back pain and occurrence of follow-up fractures in long-term follow-up. Therefore, randomized controlled prospective trials with larger cohorts of patients and a longer duration of follow-up are needed to verify the findings of this study regarding the implications of the presence or absence of a preoperative MR-detectable BME on the long-term outcome after kyphoplasty. However, a thorough clinical identification and localization of the most painful osteoporotic vertebral fractures is a crucial prerequisite for effective pain relief after kyphoplasty.

This study demonstrates that a preoperative MR-detectable bone marrow edema in painful osteoporotic vertebral fractures allows us to predict a more rapid pain resolution response to an internal stabilization by kyphoplasty compared to fractures without MRI edema. A preoperative MRI also provides additional information to discern causes of back pain other than fracture, and may also indicate acutely fracturing vertebrae which are not discernable on X-ray based technology in early stages of the fracture [14]. However, a significant and long-term pain reduction was also observed after kyphoplasty of chronically painful osteoporotic vertebral fractures without MR-detectable BME, a finding which needs to be confirmed by a sham-controlled randomized prospective trial.

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Conflict of interest None.

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