

Balloon Sacroplasty as a Palliative Pain Treatment in Patients with Metastasis-Induced Bone Destruction and Pathological Fractures

Ballonsakroplastie als palliative Schmerztherapie bei Patienten mit metastasenbedingten ossären Destruktionen und pathologischen Frakturen

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Key words

- balloon sacroplasty
- metastasis-induced bone destruction
- interventional pain therapy
- palliative therapy
- os sacrum

Zusammenfassung



Ziel: Bei einem Metastasenbefall des Os sacrum mit Destruktion und konsekutiver pathologischer Fraktur, stehen stärkste invalidisierende Schmerzen im Vordergrund. Es sollte die Durchführbarkeit, Sicherheit und Schmerzentwicklung einer Zementaugmentation überprüft werden.

Material und Methoden: Bei 10 Patienten mit einer metastasenbedingten ossären Destruktion des Os sacrum wurde eine CT-gesteuerte Ballonsakroplastie durchgeführt. Nach Festlegung der Eingangsebene erfolgte das Vorbringen eines Kirschner-Drahts bis in die zentrale Tumorerläsion über die kurze- oder transiliakale Achse. Über den Draht wurde dann eine Hohlnadel eingebracht. Hierüber wurde ein Ballonkatheter eingeführt und unter CT-Kontrolle mehrmals in- und deflatiert. In den vorgefertigten Hohlraum erfolgte dann die PMMA-Zementapplikation. Den Abschluss der Intervention bildete eine Spiral-CT-Kontrolle in Dünnschichttechnik. Die Schmerzintensität wurde vor der Intervention, am 2. postoperativen Tag und 6 Monate post interventionem mittels visueller Analogskala (VAS) bestimmt. Abschließend wurde die Patientenzufriedenheit erfragt.

Ergebnisse: Bei allen Patienten ließ sich die Ballonsakroplastie technisch gut durchführen. Es zeigte sich im Kontroll-CT eine zentrale Zementverteilung in der Tumorerläsion. Im Durchschnitt wurden pro versorgter Läsion 6 +/- 1,78 (4 - 10) ml PMMA-Zement eingebracht. Bei allen Patienten fand sich eine signifikante ($p < 0,001$) Schmerzreduktion nach VAS von 9,3 +/- 0,67 (8 - 10) präinterventionell auf 2,7 +/- 1,28 (1 - 5) am 2. postoperativen Tag und auf 2,9 +/- 0,81 (2 - 5) 6 Monate post interventionem. Alle Patienten konnten nach der Intervention remobilisiert und den weiter geplanten therapeutischen Maßnahmen zugeführt werden.

Abstract



Purpose: In the case of metastatic involvement of the sacrum with destruction and consecutive pathological fracture, intense disabling pain is one of the defining factors. The feasibility, safety and pain development with cement augmentation were to be investigated.

Materials and Methods: CT-guided balloon sacroplasty was conducted in 10 patients with metastasis-induced bone destruction of the sacrum. After establishment of the entry point, a K-wire was first introduced as far as the central tumor lesion via the short, or transiliac axis. A cannula was then positioned over the wire. Under CT guidance, a balloon catheter was introduced through the cannula and inflated and deflated several times. The PMMA cement was then injected into the preformed cavity. The procedure was completed by a spiral CT control using the thin-slice technique. Pain intensity was determined using a visual analog scale (VAS) before the procedure, on the 2nd postoperative day and 6 months after the intervention. Finally, the patients were asked to state how satisfied they were.

Results: Balloon sacroplasty was technically feasible in all patients. The control CT scan showed central distribution of the cement in the tumor lesion. On average 6 +/- 1.78 (4 - 10) ml of PMMA cement were introduced per treated lesion. A significant ($p < 0.001$) reduction in pain according to the VAS occurred in all patients from 9.3 +/- 0.67 (8 - 10) pre-operatively to 2.7 +/- 1.28 (1 - 5) on the 2nd postoperative day and 2.9 +/- 0.81 (2 - 5) 6 months after the intervention. All of the patients were remobilized after the procedure and underwent the further therapeutic measures as planned.

Conclusion: Balloon sacroplasty is a helpful therapeutic option in the overall palliative treatment of patients with tumor-induced destruction. It is a safe and practicable procedure that markedly reduces disabling pain.

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Bibliography

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Schlussfolgerung: Die Ballonsakroplastie ist zur Behandlung von Patienten mit tumorbedingten Destruktionen eine hilfreiche Therapieoption im palliativen Gesamtkonzept. Sie ist eine sichere und gut durchführbare Prozedur, welche die invalidisierenden Schmerzen deutlich reduziert.

Kernaussagen:

- ▶ Die Ballonsakroplastie ist bei ossären Destruktionen ein sicheres Verfahren zur Zementaugmentation
- ▶ Mit der Ballonsakroplastie lassen sich invalidisierende Kreuzschmerzen signifikant reduzieren
- ▶ Die Ballonsakroplastie ist eine hilfreiche Therapieergänzung im palliativen Gesamtkonzept

Introduction

In the advanced stages of malignant diseases such as breast cancer, prostate cancer, lung cancer, renal cell cancer, thyroid cancer, multiple myeloma and lymphoma, metastases in the axial skeleton are common [1]. Bone metastases are the most common malignant bone disease in adults. They have a negative impact on the quality of life and worsen the patient's prognosis [1]. If the sacrum is affected with destruction and consecutive pathological fracture, the cardinal symptom is disabling pain in the region of the lower lumbar spine and pelvis. As in the case of insufficiency fractures, conservative treatment by means of bed rest and analgesic therapy rarely achieves a satisfactory reduction in pain. Pain-related immobility can lead to the development of decubitus ulcers, venous thrombosis and pulmonary embolism, pneumonia and further deterioration of the musculoskeletal system [2]. The aim of interventional treatment is a rapid reduction in pain, with a resulting increase in mobility and improvement in quality of life [3], so that the further necessary therapeutic measures, such as chemotherapy, hormone and radiotherapy, can then be performed in an overall palliative concept. Additional pharmacotherapy with bisphosphonates is considered to be obligatory. It minimizes the loss of bone mass and delays the development of pathological fractures, reduces metastasis-induced bone pain and possibly increases the apoptosis rate of metastasized tumor cells [1]. Analogous to percutaneous cement augmentation in vertebral body metastases, for which very good pain reduction has been described [4–6], there have been reports of good experience with cement augmentation of the sacrum in osteoporosis-induced insufficiency fractures [2, 3, 7] and good initial results in the case of malignant destruction, whereby sacroplasty analogous to the vertebroplasty technique is mostly applied here [8–17].

Key points:

- ▶ Balloon sacroplasty is a safe method of cement augmentation for osseous destruction
- ▶ With balloon sacroplasty debilitating lower back pain can be significantly reduced
- ▶ Balloon sacroplasty is a helpful supplement in palliative therapy

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We report on our first clinical experience with the application of balloon sacroplasty in patients with metastasis-induced destruction and provide an overview of the relevant literature concerning cement augmentation in the os sacrum.

Under CT guidance, a balloon catheter was introduced through the cannula and inflated and deflated several times, partly over-

Materials and Methods

CT-guided balloon sacroplasty was carried out in 5 female and 5 male patients with metastasis-induced bone destruction of the os sacrum, with an average age of 64.3 +/- 10.06 (49–79) years (▶ **Table 1**). The volume of each lesion was measured on the CT scans. The indication for cement augmentation was established in an interdisciplinary case conference with oncologists/specialists in internal medicine, orthopedic/trauma surgeons, neurosurgeons and interventional radiologists.

The procedure was performed under intubation anesthesia and anesthetic monitoring. Patients were placed in the prone position in the CT scanner. Single-shot antibiotic prophylaxis was routinely given (cefazoline 2 g i. v.). After establishment of the entry point and usual preparation, a Kirschner wire was first introduced as far as the central tumor lesion via the short or transiliac axis (▶ **Fig. 1–3**). A cannula was then positioned over the wire. Under CT guidance, a balloon catheter was introduced through the cannula and inflated and deflated several times, partly over-

	sex/age	primary tumor	location of the lesion in the sacrum/tumor volume	approach [3]
pat. 1	58 yrs./f	multiple myeloma	bilateral: lateral mass right/6.8 ml, lateral mass with involvement of the intermediate zone left/8 ml	short axis bilateral
pat. 2	52 yrs./f	multiple myeloma	lateral mass left/ 6.6 ml	short axis
pat. 3	69 yrs./m	multiple myeloma	lateral mass right/ 7.1 ml	short axis
pat. 4	74 yrs./m	multiple myeloma	bilateral with involvement of the vertebral body zone/right: 8 ml, left 11.7 ml	transiliac bilateral
pat. 5	49 yrs./f	breast carcinoma	lateral mass left/ 7.3 ml	short axis
pat. 6	63 yrs./f	renal cell carcinoma	lateral mass right/ 8.8 ml	short axis
pat. 7	57 yrs./m	urothelial carcinoma	lateral mass right/ 7.1 ml	short axis
pat. 8	69 yrs./m	hepatocellular carcinoma	lateral mass right up to the vertebral body zone/ 11.3 ml	transiliac
pat. 9	79 yrs./f	lung carcinoma	vertebral body zone/ 10.8 ml	transiliac
pat. 10	73 yrs./m	lung carcinoma	lateral mass left with spread up to the sacral vertebral body S 2 / 12.1 ml	transiliac

Table 1 Patient characteristics.

Tab. 1 Charakteristik der Patienten

lapping in a central to peripheral direction. The polymethyl methacrylate (PMMA) cement was then injected into the preformed cavity with low pressure under CT single slice guidance. The procedure was completed by a spiral CT control using the thin-slice technique with coronal and sagittal reformation with a 2-mm slice thickness.

Examples of cement augmentation via the short axis are shown in **Fig. 2a–c** and via the transiliac approach in **Fig. 3a–d**.

Pain intensity was determined using a visual analog scale (VAS) before the procedure, on the 2nd postoperative day and 6 months after intervention. The results were tested for significance by rank variance analysis for several connected samples according

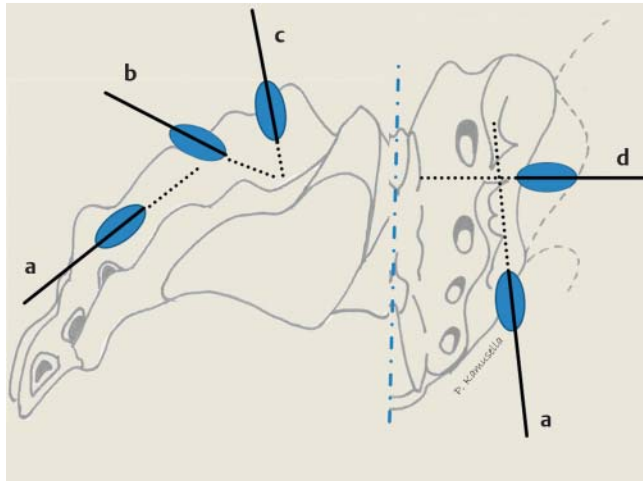


Fig. 1 Illustration of the possible approaches for gaining access to a fracture or bone destruction zone in the sacrum. **a** shows the approach via the long axis, **b** via the angulated short axis, **c** via the short axis and **d** via the transiliac axis. All of the metastasis-induced lesions could be effectively accessed via the short or transiliac axis.

Abb. 1 Illustration der möglichen Zugangswege zur Erreichung einer Fraktur oder ossären Destruktionszone im Os sacrum. Mit **a** ist der Zugang über die lange Achse, mit **b** über die angulierte kurze Achse, mit **c** über die kurze Achse und mit **d** über die transiliakale Achse dargestellt. Alle metastasenbedingten Läsionen ließen sich gut über die kurze oder transiliakale Achse erreichen.

to Friedman. All values are stated as mean \pm standard deviation and in their range.

Finally, the patients were asked to state how satisfied they were after the intervention.

Results

The balloon sacroplasty was performed successfully from a technical point of view in all patients. All of the sacral lesions could be accessed via the short or transiliac axis (**Fig. 1–3**, **Table 1**). The control CT scan showed central distribution of the cement in the tumor lesion. Leakage of the cement in the direction of the neuroforamina, iliosacral joints or visceral surface with sacral plexus could be ruled out. On average 6 ± 1.78 (4–10) ml of PMMA cement were introduced per lesion treated. The volume of the lesions ranged from 6.6–12.1 ml. A significant ($p < 0.001$) reduction in pain was observed in the VAS in all patients on the 2nd postoperative day (**Fig. 4**), whereby the pain was reduced on average from 9.3 ± 0.67 (8–10) pre-operatively to 2.7 ± 1.28 (1–5) score points on the 2nd postoperative day and to 2.9 ± 0.81 (2–5) 6 months postoperatively. All of the patients were remobilized after the procedure and underwent the further therapeutic measures as planned. Two patients (pat. 8 and pat. 9) died 3 and 5 months post-intervention due to their underlying disease.

With regard to the question of patient satisfaction, all of the patients were very satisfied. They all felt that their quality of life had improved and said that they would undergo the intervention again without reservation.

Discussion

The experience gained to date with cement augmentation analogous to the vertebroplasty technique shows good technical feasibility with sufficient safety and convincing post-interventional pain reduction in patients with metastasis-induced bone destruction [10–19]. The mechanism of the pain reduction after cement introduction is not yet sufficiently understood. Stabilization of the destroyed bone by the cement filling appears to be the

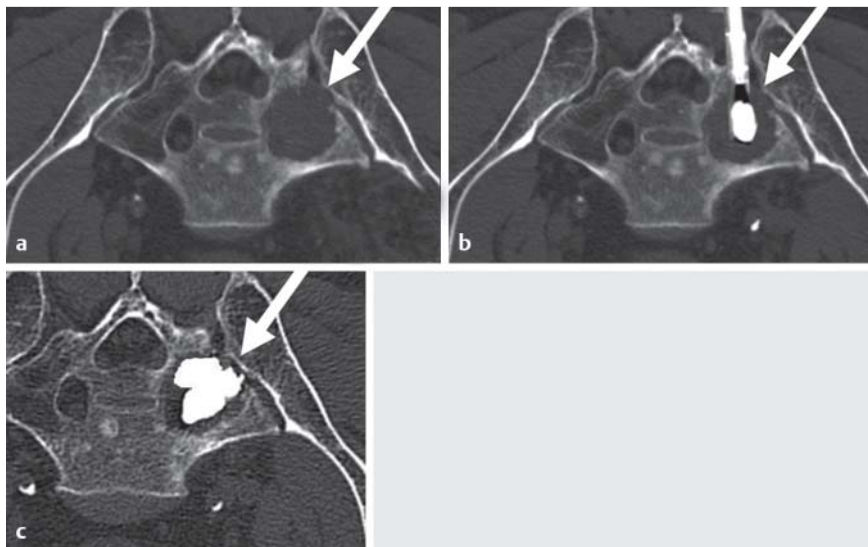


Fig. 2 **a–c** (**Table 1**, Pat. 7) **a** Axial CT slice of the os sacrum: image of an osteolysis in the lateral mass on the right. **b** Inflated balloon centrally in the bone destruction of the right lateral mass. The approach was via the short axis. **c** Centrally positioned cement filling in the metastasis-induced osteolysis. There is no evidence of cement leakage.

Abb. 2 **a–c** (**Tab. 1**, Pat. 7) **a** Axiales CT-Schnittbild des Os sacrum: Darstellung einer Osteolyse in der Massa lateralis rechts. **b** Inflatiertes Ballon zentral in der ossären Destruktion der rechten Massa lateralis. Der Zugang erfolgte über die kurze Achse. **c** Zentral liegende Zementplombe in der metastasenbedingten Osteolyse. Es findet sich kein Anhalt für eine Zementleckage.

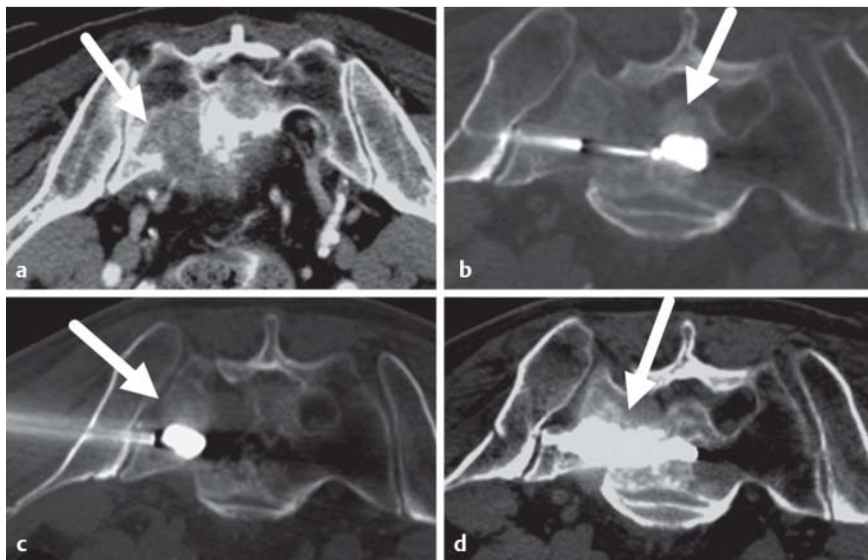


Fig. 3 a–d (Table 1, Pat. 10) **a** Axial CT slice of the os sacrum: tumor infiltration of the sacrum on the left with infiltration of the lateral mass, the transforaminal zone up to the sacral vertebral body. The tumor has destroyed and exceeded the central and dorsal cortical boundary. **b** Inflated balloon in the sacral vertebral body via a transiliac approach from the left. The balloon is inflated and deflated several times, thus shifting it from a central position laterally. **c** Inflated balloon after having been shifted from the central zone into the area of the lateral mass on the left. Roughly the same plane as in Fig. 2a, the cannula inserted via a transiliac approach and the inflated balloon are captured centrally. For a better understanding, Fig. 2a, b have been reflected vertically, the intervention was performed in the prone position. **d** The post-interventional control CT scan shows the cement distribution, whereby the lateral mass, the transforaminal zone and the sacral vertebral body have been augmented. There is no evidence of leakage.

Abb. 3 a–d (Tab. 1, Pat 10) **a** Axiales CT-Schnittbild des Os sacrum: Tumorinfiltration des Os sacrum links mit Infiltration der Massa lateralis, der transforaminalen Zone bis hin zum Sakralwirbelkörper. Der Tumor destruiert und überschreitet die ventrale und dorsale kortikale Begrenzung. **b** Inflatierter Ballon im Sakralwirbelkörper über einen transiliakalen Zugangsweg von links. Der Ballon wird mehrere Male in- und deflatiert und hierbei von zentral nach lateral verlagert. **c** Inflatierter Ballon nach Verlagerung aus der zentralen Zone in den Bereich der Massa lateralis links. Annähernd gleiche Ebene wie in Abb. 2a, die transiliakal eingebrachte Hohlnadel und der inflatierte Ballon sind zentral getroffen. Zum besseren Verständnis wurden die Abb. 2a, b vertikal gespiegelt, die Intervention erfolgte in Bauchlage. **d** Im postinterventionellen Kontroll-CT Darstellung der Zementverteilung, wobei die Massa lateralis, die transforaminale Zone und der Sakralwirbelkörper augmentiert sind. Eine Leckage ist nicht nachweisbar.

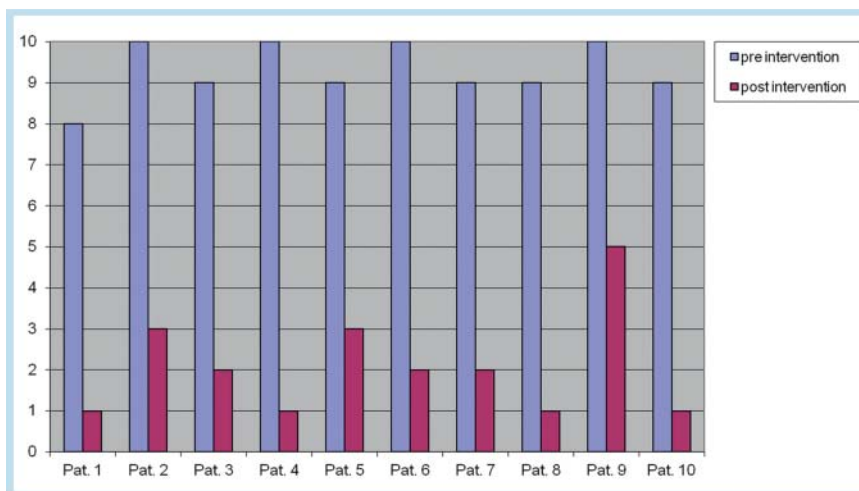


Fig. 4 Illustration of the course of the patients' pain according to the VAS.

Abb. 4 Darstellung des Schmerzverlaufes der Patienten nach VAS.

main reason for the pain reduction experienced immediately after the intervention, while the thermal effect caused by cement hardening also plays a role [11, 20].

Cement augmentation analogous to kyphoplasty is less well known at present, but shows comparably good results with regard to pain reduction [8, 9, 21]. Using a balloon catheter, a central cavity is created in the lesion for the introduction of the cement, whereby a compaction of peripheral tumor tissue and the

adjacent pathological fracture zone closes possible fissures [8], and thus makes it more difficult for cement to leak in the direction of the neuroforamina, iliosacral joints and visceral surface of the sacrum. Reduction of cement leakages represents an advantage of sacro-kyphoplasty [3, 9] over sacro-vertebroplasty [22, 23] in patients with insufficiency fractures as well as in patients with osseous destruction. Leakages can cause severe complications such as radiculopathies with strong pain, which in the

author	number of patients	primary tumor	follow-up/pain reduction
Basile et al. [18]	8	multiple myeloma	3 – 27 months, yes
Butler et al. [7]	1	multiple myeloma	2 weeks, yes
Wee et al. [13]	2	multiple myeloma/ renal cell carcinoma	3 – 6 months, yes
Hierholzer et al. [11]	1	lung carcinoma	2 months, yes
Masala et al. [12]	1	lung carcinoma	4 months, yes
Shah et al. [9]	5	lung carcinoma/ neuroendocrine carcinoma	2 days, yes
Zhang et al. [14]	2	lung carcinoma/ lymphoma	12 – 20 weeks, yes
Toro et al. [31]	1	hepatocellular carcinoma	2 months, yes
Uemura et al. [20]	1	hepatocellular carcinoma	10 days, yes
Georgy et al. [15]	11	breast carcinoma	4 weeks, yes
Valencia-Anguita et al. [19]	1	breast carcinoma	6 months, yes
Lüdtke et al. [8]	1	rectal carcinoma	2 days, yes
Dehdashti et al. [32]	1	not known	2 days, yes
Sun et al. [16]	7	3 lung carcinomas, 2 breast carcinomas, 1 renal cell carcinoma, 1 hepatocellular carcinoma	1 month, yes
Kortman et al. [17]	35	24 metastases from different malignant tumors, 11 multiple myelomas	1 month, yes

Table 2 Literature overview of sacroplasties in patients with malignant tumors.

Tab. 2 Literaturübersicht von Sakroplastien bei Malignompatienten

worst case have to be treated with surgical decompression [23]. In our own patients as well as the sacrokyphoplasty cases published to date, no leakage was seen in the post-operative imaging even though the degree of bone destruction varied considerably [8, 9, 21], which in our view is a great advantage of the balloon technique. Cement augmentation using a vesselplasty balloon can possibly be guided even more accurately in tumor tissue with a pronounced soft tissue component and destruction-related loss of bony landmarks, which can reduce the risk of leakages even further [24]. The complex anatomy of the sacrum must be taken into account when performing sacroplasty [25] and visualization of the bone destruction and fracture analysis by means of CT are absolutely necessary before the intervention. This makes it possible to plan the approach pre-operatively. All lesions can be accessed using an approach via the short, modified angulated short, long, or transiliac axis, and augmented with sufficient cement [3, 8, 9, 26 – 28]. The CT-guided insertion of the needle system and the balloon catheter can be achieved safely with appropriate practice and does not differ from the treatment of insufficiency fractures. The cement application can be guided under simultaneous conventional fluoroscopy using an additional C-arm or CT-fluoroscopy [16, 29, 30], but this does not appear to be absolutely necessary if the approach is taken via the short axis [3, 13, 30, 31] or transiliac axis [3, 8]. The approach via the transiliac axis is easy to guide in the CT gantry as a plane-parallel alignment to the ray path, whereby, depending on the position and extent of the tumor destruction, the lateral, transforaminal and central zone are easy to access in the sacrum (◉ Fig. 3) [8, 16]. In view of the generally widespread structural rarefaction and destruction of bone, which reduce the bone landmarks, we consider an intervention solely under fluoroscopy [9, 14] to be too inaccurate and very risky, as signs of leakage cannot be recognized in good time.

Metastases are the most common malignant lesions in the sacrum [32]. Currently, reports of around 80 patients with metastasis-induced osteolyses who were treated with cement augmentation in the sacrum can be found in the literature from throughout the world. They involved metastases from primary malignant tumors of multiple myeloma [7, 13, 17, 18], lung cancer [9, 11, 12,

14, 16], renal cell cancer [13, 16], hepatocellular cancer [16, 20, 33], breast cancer [15, 16, 19], lymphoma [14], rectal cancer [8], neuroendocrine cancer [9] and a cancer of unknown primary origin or a tumor not stated [17, 34] (◉ Table 2). It must be taken into account that metastases from renal cell cancer and hepatocellular cancer [30] are strongly vascularized and tend to bleed during the intervention.

In addition, the primarily benign lesions that were found included a symptomatic cyst [17], two symptomatic aggressive sacral hemangiomas [17, 20] and two actinically related osteonecroses with consecutive pathological fracture [7, 35].

In our patients and the published cases [7 – 9, 11 – 20, 33 – 36], a significant and sustained reduction in the disabling pain was observed (◉ Fig. 4), whereby no major difference was found compared with the data of patients treated for insufficiency fractures [3, 8, 9, 17]. Long-term follow-up in this kind of treatment is extremely rare. In our patients the pain reduction lasted up to 6 months postoperatively. Basile et al. [18] and Wee et al. [13] show similar results for patients with multiple myeloma.

A further advantage for cancer patients is that the alleviation of the strong pain symptoms makes it much easier to perform other necessary measures such as radiotherapy and chemotherapy.

Conclusion



Cement augmentation is a helpful therapeutic option in the overall palliative concept for patients with tumor-related destruction of the os sacrum. In the form of balloon sacroplasty, it is a safe and practicable procedure that markedly reduces disabling pain and thus increases the patient's quality of life. This markedly improves the feasibility of other necessary therapeutic measures.

Clinical Relevance of the Study

In a comprehensive palliative therapy concept, balloon sacroplasty is an important supplement which significantly reduces the debilitating pain that is associated with metastatic osseous destruction. Cement leakages can be minimized by the use of a balloon catheter.

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