

Who benefits more in osteoporotic fractures: Pedicle screw instrumentation or kyphoplasty for American Society of Anesthesiologists II/III patients?

ABSTRACT

Purpose: Osteoporotic fractures with posterior wall injury are commonly treated with a pedicle screw instrumentation (PSI) or a balloon kyphoplasty (BKP). A predictor for complications for these patients is the American Society of Anesthesiologists (ASA) class. Clinical results in ASA II/III patients who underwent BKP and PSI due to OF were evaluated to find the optimal treatment regimen.

Materials and Methods: In a retrospective study design, ASA Class II and III patients with OF type OF 2 and OF 3 according to the German Society of Orthopedics and Trauma Surgery classification who underwent surgery between 2011 and 2016 were enrolled. Perioperative data such as time of surgery, cement leakage, adjacent level fractures, screw loosening, wound infections, and segmental kyphosis correction were measured and a statistical analysis was conducted.

Results: Ninety-nine patients met the inclusion criteria, 17 were classified as ASA II and 82 patients were classified as ASA III. Twenty-eight individuals were treated by PSI, whereas 71 underwent BKP. Not only a longer average operation (120 min) and hospital stay (21 days) were documented in the PSI group but also a better kyphosis correction (7.5°). In comparison, the BKP group required an average operation time of 35.5 min with a mean kyphosis correction of 2.1°. A statistical analysis revealed the surgical procedure and not the ASA class to be a relevant factor for complication and revision surgery.

Conclusions: BKP is a safe and effective therapy including also fractures with posterior wall defects while PSI showed advantages in restoring the sagittal realignment but higher complication and revision risk.

Keywords: American Society of Anesthesiologists classification, complications, kyphoplasty, osteoporotic fractures, osteoporotic fractures 2, osteoporotic fractures 3, pedicle screws

INTRODUCTION

Osteoporotic vertebral fractures are a common cause of back pain in the elderly population. Primarily nonoperative and surgical procedures can be applied to the symptomatic patient. To establish guidelines for further treatment, different classification systems were presented aiming for recommendation of operative or nonoperative treatments.^[1-3]


If surgery is indicated, vertebroplasty, kyphoplasty, or a pedicle screw instrumentation (PSI) is typical procedures which are routinely performed in osteoporotic fractures (OFs).

However, there is no clear recommendation which distinct type of operating is indicated when the posterior wall of the spinal column is affected.

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Many authors describe adjacent level fractures, postoperative infections, screw loosening, or implant failure as typical complications of PSI. Other found cement leakage or adjacent level fractures as common complications of balloon kyphoplasty (BKP).^[4,5]

The Working Group on OFs of the German Society of Orthopedics and Trauma Surgery (DGOU) presented a classification system in 2013^[6] [Table 1]. In addition, a score was published which gives recommendations for or against surgical therapy.

However, especially, the treatment of OF 2 and OF 3 fractures with a damage of the posterior wall is often discussed controversial.^[7]

Some authors favor PSI, whereas others recommend kyphoplasty.

Up-to-date, there is no data in the literature comparing different treatment procedures of these types of fractures with regard to the general health status affected of the patients.

Here, the ASA classification system is a widely used and well-accepted scheme in medicine classifying the physical health status and condition of patients preoperatively [Table 2].

The aim of our study is to compare the clinical and radiological findings of patients with an OF 2 or OF 3 according to the DGOU classification treated by BKP or a PSI. In addition, a possible correlation of the general state of health and the clinical results was investigated.

MATERIALS AND METHODS

Ninety-nine patients were enrolled in this study with previous surgery between 2011 and 2016. Inclusion criteria were a thoracic or lumbar osteoporotic vertebral body fracture with a mild or severe destruction of the posterior wall but without any neurological deficits. Preoperative diagnostics included an X-ray of the lumbar or thoracic spine in two planes (anterior-posterior and lateral view) and a magnetic resonance imaging (MRI) or computed tomography (CT) scan for fracture classification and preoperative planning. Only type OF 2 or OF 3 fractures were considered in accordance with the DGOU classification system. Moreover, only patients with ASA class II or III were included in the study.

Exclusion criteria were a relevant trauma, which caused the vertebral fracture and no signs for osteoporosis in X-ray, CT, or MRI scans. Furthermore, fractures of the type OF 1, OF 4, and OF 5 as well as patients with ASA IV and V were not

Table 1: Osteoporotic fracture classification according to the German Society of Orthopedic and Trauma surgery

OF classification	
OF 0:	No deformity, fracture <i>in situ</i> , edema in MRI STIR sequence
OF 1:	Fracture with one endplate
OF 2:	Fracture of one endplate with minor involvement of the posterior wall (<1/5)
OF 3:	Fracture of one endplate with pronounced involvement of the posterior wall (>1/5)
OF 4:	Fracture of both endplates
OF 5:	Injuries with distraction or rotation
OF:	Osteoporotic fracture

MRI - Magnetic resonance imaging; STIR - Short TI inversion recovery;
OF - Osteoporotic fracture

Table 2: American Society of Anesthesiologists classification

ASA class	Definition
I	A normally healthy patient
II	A patient with mild systemic disease
III	A patient with systemic disease which is not incapacitating
IV	A patient with an incapacitating systemic disease that is constant threat to life
V	A moribund patient who is not expected to survive for 24 h with or without operation

ASA - American Society of Anesthesiologists

enrolled. The study design was retrospective.

Two cohorts of patients were evaluated: one was treated by a BKP and the other was treated with PSI in a percutaneous or an open technique (PSI).

Patient's age at the time of surgery and sex was documented. Furthermore, the pre- and postoperative kyphosis angle of the fractured vertebra was measured and the segmental correction was calculated radiologically. The applied bone cement volume in the kyphoplasty group was recorded as well as operation time and duration of hospital stay (in-patient) for both groups were documented. Peri- and postoperative complications such as cement leakage, soft-tissue damage or infections, revision surgery, frequency of adjacent fractures, and implant failure (e.g., screw loosening) were evaluated.

Statistical analysis

To identify potential risk factors for intra- and postoperative complications, an analysis of variance (ANOVA) was used. Here, the different surgical procedures, the ASA, and OF classification were considered. In addition, independent samples *t*-tests were performed to show potential differences in kyphosis correction, length of hospital stay, and operation time between the two groups. The level of significance was set to $P = 0.05$ and highly significance was set to $P < 0.001$. All statistical analyses were conducted using SPSS version 23.0 (IBM, Inc., New York, USA).

RESULTS

There were 81 females and 18 males with an average age of 77.1 years (standard deviation [SD] 9.9). The average age in the BKP group was 76.4 (SD 10.7), and in the PSI group, it was 78.9 (SD 7.3) years. Twenty-seven of the probands had a OF 2 fracture, whereas 72 were classified as OF 3 type. About 28.3% of the patients were treated by a posterior PSI and 71.7% by a BKP. The average follow-up was 24.8 months (SD 16.2). Nearly 82.8% were classified as ASA III patients and 15.2% were assigned to ASA II.

The most vertebral fractures were located in the thoracolumbar junction [Figure 1].

In the BKP group, 4.1 ml (SD 0.5) bone cement was injected into the vertebra on average. Bone cement leakage was observed in 13 of 81 cases of BKP group. There was no leakage in the spinal canal and no need for a specific treatment during follow-up. In addition, there were no major complications in the BKP group except one adjacent-level fracture which required treatment by a second BKP.

In contrast, more complications were observed in the PSI group: there was adjacent level fracture in four cases, wound healing problems in four cases, and screw loosening in eight individuals [Figure 2]. The overall revision rate was 17.9% in the PSI group. The operation time was 35 min (SD 11.9) in the BKP group and 120 min (SD 44.3) in the PSI group. We found a statistical difference between the operation time in BKP and PSI ($P < 0.01$).

Different results were found in the degree of kyphosis correction. In the PSI group, a correction of 7.5° (SD 3.9) was measured, whereas the correction in the BKP group was 2.1° (SD - 2.5) on average [Figure 3]. This was statistically significant with $P < 0.05$.

Patients being treated with a BKP could be discharged faster with an average time of 4.7 days (SD - 3.4) as in-patients, whereas probands which were operated with pedicle screws required a hospital stay of 21 days (SD - 17.6). A *t*-tests analysis showed a statistical relevance with $P < 0.05$ for this parameter too.

In addition, ANOVA was carried out to show possible differences in the groups regarding the individual surgical complications and the ASA classification.

The results showed a highly significant difference in the complication rate between the BKP and PSI group with better



Figure 1: Fracture type OF 3 at level L1 with an osteoporotic fracture osteoporotic fractures 3 at level L1. One the left side, the preoperative sagittal magnetic resonance imaging (short TI inversion recovery sequence) showed a fracture associated bone marrow edema. The X-rays of the lumbar spine in two planes document the postoperative results after balloon kyphoplasty

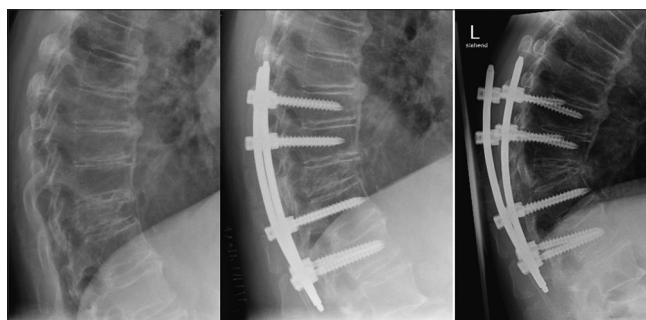


Figure 2: Osteoporotic fractures two fractures of TH 8 which was treated with a percutaneous stabilization from TH 6 to TH 10. The right X-ray shows screw loosening 8-week postoperative



Figure 3: Preoperative computed tomography and postoperative X-rays of an 89-year-old female with a L1 osteoporotic fractures three fracture who was percutaneous stabilized by pedicle screw instrumentation from TH 12 to L2

results and fewer complications in the BKP group. Figure 4 summarizes the results of the two groups regarding kyphosis correction, hospitalization and operative time.

There was no influence of the ASA class and the type of fracture (OF 2 and OF 3) regarding surgical complications ($P = 0.9$) [Table 3].

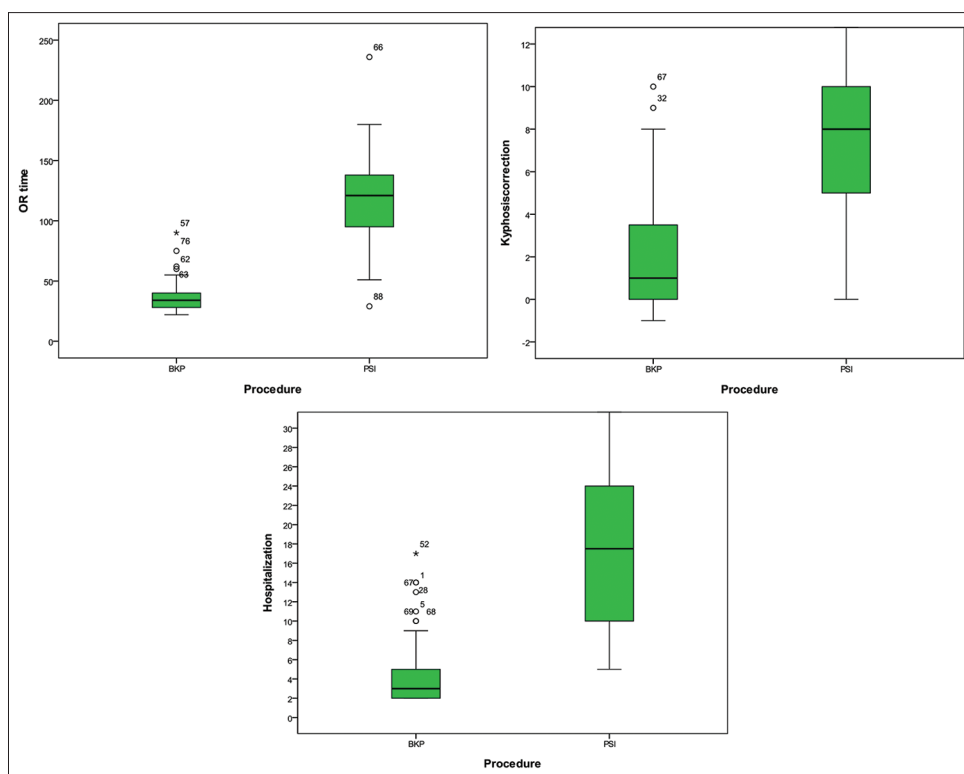


Figure 4: Kyphosis correction in degree, hospitalization in days, and OR time in minutes of the balloon kyphoplasty and pedicle screw instrumentation group

Table 3: The distribution of the cohort to different American Society of Anesthesiologists and osteoporotic fracture types

ASA class	II	III
99 (100%)	15 (15.2%)	84 (82.8%)
OF	II	III
99 (100%)	27 (27.2%)	72 (71.3%)

Most included patients were ASA III and OF 3 individuals. ASA - American Society of Anesthesiologists; OF - Osteoporotic fracture

DISCUSSION

The choice of the correct surgical procedure for the treatment of osteoporotic vertebral fracture appears to be more difficult due to the high comorbidity in elderly patients and associated perioperative complications. First, the indication for surgical therapy compared to nonsurgical therapy must be weighed carefully. Here, different scoring systems and guidelines might lower the risk for failed therapy. One of these is the scoring system of the Spine Section of the DGOU (“OF classification”), which was used in this work.^[6] When the posterior wall is damaged, some authors favor a BKP^[8] and some a PSI.^[9]

A systematic review of the topic by Papanastassiou *et al.* shows a superiority of BKP compared to vertebroplasty and nonsurgical management in osteoporotic compression fractures. In particular, a higher number of subsequent fractures in the group of conservatively treated patients and a higher kyphosis reduction when comparing kyphoplasty and

vertebroplasty (4.8° vs. 1.7°) were noticeable.^[10] The number of adjacent-level fractures averaged 11.7% in the BKP group and 11.5% in the vertebroplasty group. In our data, adjacent level fractures were found in one case of the BKP group compared to four cases of the PSI group corresponding to 14.3%. Another factor that is important for the low rate of adjacent level fractures in BKP is the low amount of applied bone cement. On average, 4.1 ml were filled into the fractured vertebral body in our BKP group. Luo *et al.* demonstrated in a bone model that 3.5 mL of poly(methyl methacrylate) largely restored normal stress distribution to fractured and adjacent vertebral bodies.^[11] In our data, cement extravasation was detectable in the BKP group in 13 cases (18.3%). In the review article released by Papanastassiou, the rate was comparably high with 18.1%.^[10] Another study analyzed the clinical results while using cement-augmented screws in osteoporotic vertebral bodies. There were more than 1000-instrumented vertebral bodies included, and an extravasation rate of 62.3% was found which caused radicular symptoms in 0.6% only. All other cases were asymptomatic. Moreover, in the cited study, 4.1% infections occurred and 17.9% of the probands showed complications such as adjacent level fractures.^[12] As described before, the rate of surgical complications is comparable but higher than our results in the PSI group (14.3%).

We found no leakage of cement into the spinal canal and no indication for an operative revision based on any other

complication in the BKP the BKP group. However, the most likely factor on leakage, cement viscosity,^[10] has not been assessed in the cited study and in our own data.

In our study, the average kyphosis correction for BKP was 2.1%. The low potential to restore the vertebra high and correct kyphosis was confirmed by Papanastassiou *et al.* with 4.9%.^[10]

He *et al.* published a prospective randomized trial and compared internal fixation combined with percutaneous kyphoplasty against percutaneous kyphoplasty only in elderly patients.

In this study, 43 patients with age over 65 were enrolled. There was a higher kyphosis reduction in the first group. It is not surprising that the operation time was much shorter in the group of a kyphoplasty (33.4 min) versus 99.5 min in the combined pedicle screw/kyphoplasty group, but there was no statistical significance.^[9] Our data showed comparable results of OR time in the groups.

Martín-Fernández *et al.* looked at the potential risk of using cement-augmented screws and found a high rate of cement leakage without clinical symptoms.^[13] However, it is obvious that a poor bone quality leads to a very high rate of revision surgery when pedicle screws are used and it does not matter if they are cement augmented or not. We found similar results in our data with a revision rate of 17.9% in PSI group due to wound infection or screw loosening.

However, how are the clinical results of BKP when the posterior wall of the vertebra is damaged such as in type OF 2 and 3 fractures? Abdelgawaad *et al.* showed satisfactory results even when the posterior wall is damaged.^[8] This is different from other investigators. Walter *et al.* described an overall cement leakage of 30.6% and Krüger *et al.* described BKP as a safe procedure in geriatric patients with only partial inclusion of the posterior wall like OF 2.^[14,15] Intradural and epidural cement leakages were only found in a few case reports.^[16-18]

Despite the fact that the chosen surgical procedure is at risk to high complication rates, the influence of the general state of health of the patients is an important factor. Somani *et al.* analyzed more than 5800 patients undergoing adult spinal deformity surgery and concluded that ASA class is a significant risk factor for postoperative mortality and morbidity.^[19] Pateder *et al.* saw an influence of the ASA classification and short-time mortality in adult spine surgery.^[20] Tang *et al.* identified the ASA classification as an independent risk factor for major complications.^[21] Schwab *et al.* conducted

a multicenter, retrospective study and found no differences between the cohorts with complications and without complications.^[22] Other authors did not include ASA class in their complication analysis.^[23,24]

We found no statistically significant influence of ASA class and complication rate in our groups. However, PSI group showed much higher rates for implant-associated complication such as screw loosening and adjacent level fractures. However, we included only patients ASA II and ASA III as a relevant difference to previous published studies and their results. On the other hand, other authors did not analyze the influence of different surgical techniques and procedures on the rate of complication in adult deformity surgery.

In our opinion, it is important to understand that creating the sagittal realignment, a kyphosis reduction and restoring of vertebral height can be done better by PSI although there lies a higher risk of complications and revision surgery in this technique. BKP is a safer procedure with less opportunities for vertebral deformity correction. Therefore, it is necessary to define the aim of surgery before performing.

CONCLUSIONS

BKP is a safe and effective therapy in the surgical treatment of osteoporotic type OF 2 and 3 fractures. In our hands, the risk for cement leakage is limited and there is no contraindication due to posterior wall defects. However, frequently radiographic control is required during cement application to minimize the complication risk. Moreover, there is no effect of ASA class to the complication rates of the PSI and BKP group. Higher complication rates were found in the PSI group. By and large, the aim of surgery (pain reduction only versus pain improvement and alignment restoration) should influence indication for or against one procedure.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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