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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Analysis of risk factors for cement leakage in percutaneous kyphoplasty – does sedoanalgesia increase the risk?

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SUMMARY
Introduction/Objective Several studies have evaluated anesthesia type as a possible risk factor for cement leakage in percutaneous vertebral augmentation procedures. This study has the largest series in the literature revealing data on the incidence of cement leakage in percutaneous kyphoplasty under sedoanalgesia. The aim of the study was evaluating the possible association between sedoanalgesia and cement leakage in percutaneous kyphoplasty procedures.
Methods In this study, 195 vertebral compression fractures treated with percutaneous kyphoplasty under sedoanalgesia in 165 patients were retrospectively reviewed. The association between sedoanalgesia and cement leakage in percutaneous kyphoplasty procedures was evaluated.
Results The mean age (years) of study population was 64.37 years (range 24–108 years), and the male–female ratio was 71/94. No significant difference in the proportion of males (n = 71, 43.03%) and females (n = 94, 56.96%) was observed between groups. Among the 195 fractured segments, most frequent fractures were observed at the T12 (n = 41, 21.02%) and L1 (n = 65, 33.33%) levels.
Conclusion Sedoanalgesia is not a risk factor for cement leakage in percutaneous kyphoplasty and offers a safe anesthesia option to avoid possible complications.
Keywords: vertebral compression fracture; percutaneous kyphoplasty; cement leakage; sedoanalgesia

INTRODUCTION

Spinal fractures secondary to trauma, osteoporosis and osteolytic metastasis are a common cause of severe pain, neurological deficit, morbidity, and profoundly impaired quality of life [1].

Proponents of surgery believe that decompression, fracture reduction and instrumentation are essential for stabilising the spine and reducing pain [2].

Surgical management of thoracolumbar fractures is preferred for patients with progressive neurological loss, unstable fractures or polytrauma, who require fixation for earlier and easier rehabilitation.

For neurologically intact patients, surgical management of thoracolumbar fractures remains controversial. Several authors have reported good clinical results after nonoperative management without fracture reduction and using conservative treatments, including analgesics, bed rest, spinal (thoracolumbosacral or lumbosacral) orthoses and calcium, magnesium, and vitamin D supplements [3].

For those who are intolerant to the side effects of conservative approaches or those who have failed to achieve pain control, percutaneous cement augmentation procedures represent a minimally invasive adjunct [4]. Percutaneous vertebroplasty (PV) and percutaneous kyphoplasty (PK) have gained widespread recognition as successful techniques for reducing pain and improving functional measures and quality of life [4]. The indications for PV and PK include painful osteoporotic vertebral fractures, vertebral fractures caused by neoplasms and various types of traumatic fractures, such as vertebral compression fractures in the absence of neurological symptoms. These minimally invasive techniques reduce blood loss and avoid damage to the paraspinal muscles [5].

Cement leakage is a serious complication of PV and PK, which may cause severe chemical or thermal injury to neurovascular structures and pulmonary embolism [6]. Cement may leak into the spinal canal or epidural, paravertebral, and intradiscal spaces. Although rare, venous leakage can occur mostly in neoplastic or osteoporotic fractures [7].

Various factors can influence the incidence of cement leakage, such as cement viscosity, injected cement volume and intravertebral clefts [8]. Leakage during PK occurs in 25% of cases, which is significantly lower than the rate in PV (70%) [9]. The differences in leakage rates between PK and PV were attributed to the cavity-creation approach by balloon filling in PK, which helps contain the cement within the vertebral body [1]. The height of the fractured vertebral body is reconstructed by balloon filling during PK. This procedure may also affect the shape and size of an intervertebral cleft, which has been proven to be a risk factor for cement leakage in PK in previous studies [10].

Several studies have evaluated anaesthesia type as a possible risk factor for cement leakage

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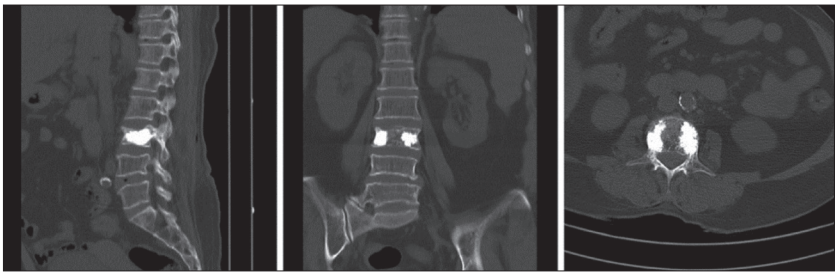

Figure 1. Computed tomography images presenting the ideal cement distribution to fractured vertebral body after bipedicular approach; a – sagittal; b – coronal; c – axial

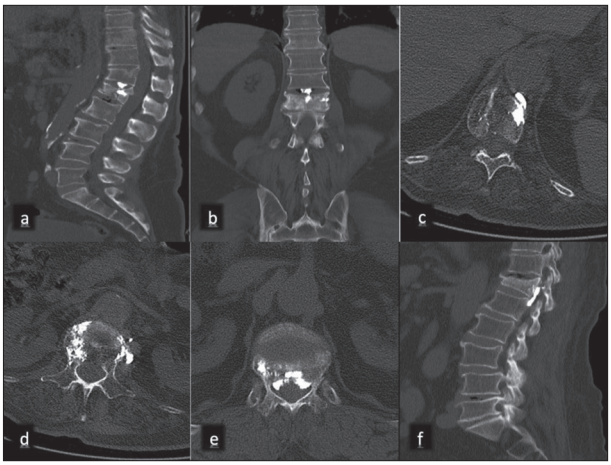

Figure 2. Cement leakage types, computed tomography images; a – intradiscal (sagittal); b – mixed – intradiscal and left paravertebral (coronal); c – paravertebral – anterior (axial); d – paravertebral – left (axial); e – epidural (axial); f – epidural (sagittal)

in PV and/or PK procedures; however, most studies have involved a small sample size or they did not interpret the data independently for each procedure type [3, 9, 11, 12]. Therefore, a procedure-specific incidence rate of cement leakage in large series could not be revealed in recent studies. To recent knowledge, this study has the largest series in the literature revealing data on the incidence of cement leakage in PK under sedoanalgesia. This study was conducted to evaluate the association between sedoanalgesia and cement leakage in PK procedures.

METHODS

Study design

This study was approved by the Ethical Committee of our institution, and written informed consent was obtained from all patients. In this study, 195 vertebral compression fractures treated with PK under sedoanalgesia at our hospital in 165 patients from January 2015 to January 2018 were retrospectively reviewed.

The inclusion criteria were as follows: 1) severe back pain; 2) failure of conservative treatment; 3) more than 50% loss of vertebral body height presented on sagittal X-ray film and/or computed tomography (CT), and 4) high signal intensity on short tau inversion recovery (fat-suppressed) sequence on magnetic resonance imaging (MRI) confirming recent vertebral body fractures of the thoracolumbar region (Figure 1). The exclusion criteria were as follows: 1) fracture accompanied by neurological deficit; 2) radicular pain; 3) intolerance to bone cement material, and 4) contraindication to MRI.

Data regarding age, sex, number of treated vertebrae, location, fracture morphology, surgical approach, duration of surgery, amount of injected cement, and the presence and distribution of cement leakage were collected. Cement leakage was assessed on postoperative axial, coronal, and sagittal CT scans of the spine and classified into four locations, as defined by previous studies: epidural, intradiscal, paravertebral, and mixed [3, 13, 14].

In the literature provided by Scopus and PubMed databases for the last 10 years, medical documents published in English on cement leakage in PK under any type of anesthesia were reviewed (keywords: 'cement leakage,' 'kyphoplasty,' 'general anesthesia,' 'local anesthesia,' and 'sedoanalgesia'). The results of this study were compared with the literature data.

Patient characteristics

In this study, 165 patients with 195 fractured segments of T5–L4 were enrolled. Among the patients enrolled in this study, 94 were women (56.9%) and 71 were men (43.1%), and their age ranged 24–108 years, with a mean of 64.3 ± 10.1 years.

Surgical procedure

All PK procedures were performed with the patients under sedoanalgesia in a prone position by the same right-handed, senior surgeon.

For conscious sedoanalgesia, 1-μg/kg intravenous fentanyl, 20-μg/kg intravenous midazolam, and 25-mg intravenous ketamine were administered. If needed, 20-μg/kg additional doses of intravenous midazolam were repeated during the procedure. For local anesthesia, 5-mL 1% lidocaine was injected intradermally. A guidewire was inserted after the appropriate entry point was identified under fluoroscopy. As soon as the fractured vertebra was confirmed, a working tunnel was inserted into the vertebral body until it passed the pedicle border. The core drill and balloon were inserted through the working tunnel to the anterior two-thirds of the vertebral body. The balloon was expanded with a contrast agent under fluoroscopy until a satisfactory restoration of vertebral body height was achieved. Following the withdrawal of the contrast agent and balloon, in this order, preprepared bone cement at a semisolid state was injected into the cavity created in the vertebral body. At that stage of the procedure, multiple fluoroscopic images were obtained at both axial and coronal planes, and the patients were instructed to move their lower extremities to confirm that the neurovascular structures were not injured. Lastly, the working tunnel

Figure 3. High signal intensity on short tau inversion recovery (fat-suppressed) sequence on sagittal magnetic resonance imaging confirming recent L1 vertebral compression fractures

was removed, and the entry point was closed with a single simple suture (Figure 2).

Assessment indices

Postoperative CT images were obtained to assess the presence of cement leakage and leakage sides. Cement leakages were grouped into the four following sides on axial, coronal and sagittal CT scans (Figure 3): epidural, paravertebral, intradiscal, and mixed. All radiographic evaluations were independently performed in a double-blinded fashion by the same radiologist. All the patients were grouped according to the surgical approach (bipedicular or unipedicular), fracture pathology, fractured segments, number of treated segments, and injected cement volume per segment. The incidence rate of cement leakage and leakage locations were evaluated and compared with the data from similar studies in the literature.

Statistical analysis

Statistical analyses were conducted using SPSS, version 18.0 (SPSS Inc., Chicago, IL, USA). Quantitative data were presented as means and standard deviation. The χ^2 test was performed to determine significant associations between demographic characteristics, fracture pathologies, cement volumes, surgical approaches, fractured segments, and cement leakages. A logistic regression model was used to examine the association between the type of fracture pathology and cement leakage occurrence. P-values of less than 0.05 were used to denote statistical significance.

RESULTS

Bone cement distribution and leakage rate

The mean age (years) of the study population was 64.37 years (range, 24–108 years), and the male–female ratio was 71/94. No significant difference in the proportion of males (n = 71, 43.03%) and females (n = 94, 56.96%) was observed between the groups. Among the 195 fractured segments, most frequent fractures were observed at the T12 (n = 41, 21.02%) and L1 (n = 65, 33.33%) levels.

Among the 195 fracture segments, 168 (86.15%) were treated using the bipedicular approach, and among the 165 patients, 79 (47.87%) had traumatic fractures. The mean volume of injected cement per segment was 3.8 ± 0.7 mL. The number of patients treated for two consequent segments, three consequent segments and two or more non-consequent segments was 17 (10.3%), 1 (0.6%), and 10 (6.06%), respectively. The mean duration of surgery was 39.86 ± 5.6 minutes (range 25–70 minutes). Data obtained from the assessment of cement leakage locations revealed that the intradiscal space was the most common (12.3% of 51) leakage site. Table 1 presents the patients' demographic characteristics, characteristics of fractured segments, and surgical features.

Table 1. Characteristics of the patients

Characteristic	Value
Sex	71 males / 94 females (total 165 patients)
Mean age (range) (years)	64.37 (24–108)
Surgical approach (195 segments)	
Unipedicular	27 (12 right /15 left)
Bipedicular	168
Fractured segments (195 segments)	
T5	1
T6	2
T7	2
T8	6
T9	4
T10	5
T11	7
T12	39
L1	63
L2	28
L3	23
L4	15
Duration of surgery (165 patients)	
Range (minutes)	25–70
Mean (minutes)	39.86
Multiple segments	28 of 165 patients
Two consequent segments	17
Three consequent segments	1
Two or more non-consequent segments	10
Leakage locations	51 of 195 segments
Epidural	6 (3.07%)
Foraminal	4 (2.05%)
Mixed	4 (2.05%)
Paravertebral	13 (6.66%)
Intradiscal	24 (12.3%)
Pathology of fracture (165 patients)	
Osteoporosis	63
Trauma	79
Neoplasm	23

Cement leakage risk factor analysis

According to the postoperative CT scans, cement leakage was detected in 37 of the 165 patients (22.42%) and in 51 of the 195 segments (26.15%). No patients with cement leakage revealed neurological deficits or any other clinical symptoms.

A statistically significant relationship was observed between cement leakage and fracture pathology ($\chi^2 = 12.673$; $p = 0.002$).

The bipedicular approach group yielded a higher cement leakage rate than the unilateral approach group (94.11%, 5.88%, respectively; $p = 0.055$) but no statistical significance was revealed. Table 2 presents the risk factor analysis of cement leakage.

Table 2. Cement leakage (risk factor analysis)

Characteristic	Leakage (n/%)	No leakage (n/%)	χ^2	p
Sex			1.347	0.246
Male	19	52		
Female	18	76		
Pathology of fracture			12.673	0.002
Osteoporosis	6	57		
Trauma	21	58		
Neoplasm	10	13		
Surgical approach			3.672	0.055
Unipedicular	3	24		
Bipedicular	48	120		
Fractured segments			2.496	0.287
Thoracic	10	17		
Thoracolumbar (T12–L1)	27	75		
Lumbar	14	52		
Cement volume			0.023	0.88
≤ 3.8 mL	24	66		
> 3.8 mL	27	78		

DISCUSSION

In a developing society, osteoporotic vertebral compression fractures are frequently observed with the prolongation of life span. Apart from osteoporotic compression fractures, traumatic and neoplasm-related vertebral fractures are frequently encountered in our daily practice. Bed rest and orthosis are typical conventional treatments for vertebral compression fractures, as most are stable fractures without neurological deficits. As an alternative treatment option for vertebral compression fractures without any neurological deficits, percutaneous vertebral augmentation procedures provide many advantages, including early pain relief, shorter hospital stay, and early mobilization that can reduce thromboembolic complications, especially in elderly patients [15]. Since these minimally invasive treatments provide an early return to work, they are the preferred treatment methods for vertebral compression fractures in young adults [16].

Despite being minimally invasive, the complications of PV and PK are not rare; however, in most cases, they have no clinical significance. Persistence of pain, cement leakage, paralysis, allergic reaction to bone cement, pulmonary embolism and bleeding (epidural hemorrhage) are potential complications of these minimally invasive procedures [17]. Among these complications, cement leakage is the most common, which can occur in the epidural, paravertebral or intradiscal spaces [14]. Several studies have focused on the incidence of and risk factors for cement leakage in PK and PV under general anesthesia [18–21].

Lee et al. [6] revealed that the incidence rate of cement leakage per number of treated patients was significantly higher in the PV group than that in the PK group under local anesthesia. The most prominent advantage of PK over PV is the balloon that reduces the cement perfusion pressure during the procedure [3].

The type of anesthesia, amount and viscosity of the bone cement injected, fracture characteristics (type, severity, pathology, segment, etc.), approach (bilateral or unilateral), sex, age, and surgery duration have been assessed as risk factors for cement leakage so far [17, 20].

Especially, elderly patients present with a higher an aesthetic risk because of comorbidities, including cardiopulmonary diseases, that make surgeries in the prone position under general anesthesia significantly more difficult. All PK procedures included in the study were applied under sedoanalgesia, which provides the advantage of perioperative neurological examination and prevention of general anesthesia complications. Lavelle et al. [16] preferred general anesthesia in their 94 cases of kyphoplasty and revealed that elderly patients could not tolerate the procedures in the prone position unless performed under general anesthesia. Cagli et al. [11] have reported four cases of cement leakage (three for PV and one for PK) in their series of 91 PV and PKP cases operated on under local anesthesia. However, both in the study by Cagli et al. [11] and in this study, none of the operations was terminated because of intolerance to the type of anesthesia.

In the literature, this study has the largest sample size to retrospectively investigate the incidence rate of cement leakage specifically in PK procedures under sedoanalgesia.

The pooled studies have shown that the incidences of cement leakage for PV and PK were 59.7% and 18.4%, respectively [17]. In this study, the overall incidence rate of bone cement leakage was consistent with previous reports (51 of 195 segments, 26.15%) (Table 3) [6, 22–25].

Table 3. Recent studies presenting cement leakage rates in percutaneous kyphoplasty procedures

Author	Vertebral segments	Cement leakage	Incidence
Chen et al. [22]	44	34	77.27%
Rebolledo et al. [23]	56	9	16.07%
Vogl et al. [24]	65	42	64.61%
Lee et al. [6]	59	29	49.2%
Mishra et al. [25]	61	9	14.75%

Fracture pathology and severity and cement volume were significant predictors of cement leakage according to previous studies [17, 20, 26]. In addition, this study revealed that only fracture pathology was a statistically

Table 4. Logistic regression analysis among fracture pathology subgroups in patients with cement leakage

Subgroups	Coefficient B	Standard error	Z	p	OR	95% CI
Osteoporosis	-1.99	0.599	3.322	0.001	0.137	0.042–0.442
Trauma	-0.748	0.491	1.524	0.128	0.473	0.181–1.239
Constant	-0.249	0.42	0.593	0.553	0.78	

significant risk factor for cement leakage (Table 4). The incidence of cement leakage in the osteoporosis group was higher than the rest (Figure 4). This finding might be due to the weakness of the cortical bone structure in osteoporotic vertebrae. Although no evident intervertebral cleft was observed in preoperative radiological images, cement leakage may have occurred due to the weak structure of the cortical walls in osteoporotic vertebral bodies that cannot resist the cement perfusion pressure.

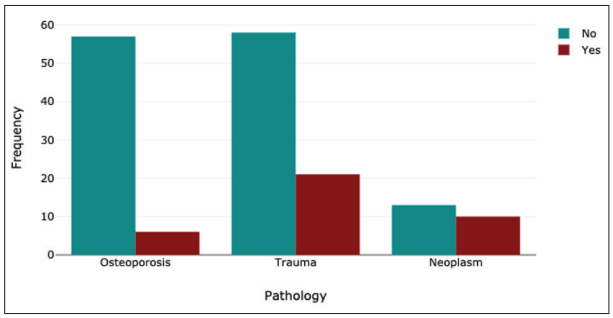

Figure 4. Cement leakage – fracture pathology relationship

The incidence and extent of bone cement leakage invading the spinal canal in the thoracic group were significantly higher than those in the lumbar group (10.1% *vs.* 3.7% and 22.5% *vs.* 11.4, respectively). This finding suggests that the morphological features of the posterior wall of the middle and lower thoracic vertebrae are a risk factor for cement leakage into the spinal canal during PK [13].

Analysis of the leakage locations showed that the intradiscal space was the most prominent side for cement leakage in this case series. Nieuwenhuijse. et al. [26] have reported similar results and attributed this finding to the frequent connection of intravertebral clefts with the intervertebral disc space. The presence of an intravertebral cleft was assumed to be a significant predisposing factor for cement leakage in PV and PK [18].

Some studies have reported that the bilateral percutaneous augmentation approach is more effective for pain relief with the advantage of symmetrical bone cement distribution in the vertebral body [27, 28]. Alternatively, the unilateral approach has significant benefits, including less operation duration and X-ray exposure. Most recent studies have revealed that the amount of bone cement introduced was significantly less in the unilateral approach [8, 12]. However, no definite conclusion has been made regarding whether cement volume is a risk factor for cement leakage. Chen et al. [22] have found that the unilateral approach decreases the incidence of cement leakage according to the meta-analysis of randomized controlled trials involving unilateral and bilateral percutaneous vertebral augmentation for osteoporotic compression fractures. Five of six trials in that meta-analysis included PK procedures, and the following factors were compared between the groups: operative method, surgical approach (unilateral/bilateral), sex, age, number of treated vertebrae, and cement volume. In that study, the type of anesthesia was not examined as a risk factor for cement leakage. This study identified that cement volume and surgical approach were not risk factors for cement leakage in PK under sedoanalgesia ($p = 0.88$ and $p = 0.055$, respectively). Meanwhile, the bipedicular approach group had a higher incidence rate of cement leakage than the unipedicular approach group. This could be attributed to the wider distribution of bone cement via the bipedicular approach that resulted in more cement leakage. Although this finding is consistent with the results of the study by Chen et al. [22], it did not reveal a statistical significance ($p = 0.055$).

The mean operation duration was 39.86 minutes, and 20 of the 165 patients underwent surgery for multiple-segment fractures. Nevertheless, the mean operation duration in this study was consistent with those in previous studies [3, 8].

Due to the retrospective nature of this study, operation comparison is not suitable for the random, control, and blind methods. Despite this limitation, we believe that the number of patient cases available is adequate to accept the results as meaningful.

CONCLUSION

Sedoanalgesia is not a risk factor for cement leakage in PK. However, sedoanalgesia offers a safe anesthesia option to avoid possible complications. Only fracture pathology was shown to be a potential risk factor for cement leakage in PK.

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Conflict of interest: None declared.

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Анализа фактора ризика од цурења цемента у перкутаној кифопластици – да ли седоаналгезија повећава ризик?

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САЖЕТАК

Увод/Циљ Неколико студија је оценило врсту анестезије као могући фактор ризика за цурење цемента у поступцима перкутане аугментације кичме. Ова студија има највећу серију у литератури која открива податке о учесталости цурења цемента у перкутаној кифопластици под седоаналгезијом.

Циљ студије био је процена могуће повезаности између седоаналгезије и цурења цемента у кожним процедурама кифопластике.

Методе У овој студији ретроспективно је прегледано 195 прелома вертебралне компресије лечених перкутаном кифопластиком под седоаналгезијом код 165 пацијената. Процењена је повезаност између седоаналгезије и цурења цемента у перкутаним поступцима кифопластике.

Резултати Просечна старост истраживане популације била је 64,37 година (распон 24–108 година), а однос мушкараца и жена био је 71/94. Није уочена значајна разлика у уделу мушкараца (n = 71, 43,03%) и жена (n = 94, 56,96%) међу групама. Међу 195 преломљених сегмената, најчешћи преломи су примећени на нивоима Т12 (n = 41, 21,02%) и Л1 (n = 65, 33,33%).

Закључак Седоаналгезија није фактор ризика за цурење цемента у перкутаној кифопластици и нуди сигурну могућност анестезије како би се избегле могуће компликације.

Кључне речи: фрактура компресије кичме; перкутана кифопластика; цурење цемента; седоаналгезија