KLİNİK ARAŞTIRMA

Non-Balloon Kyphoplasty with High Viscosity Cement: Short-Term Clinical Outcomes

Yüksek Viskoziteli Çimentoyla Balon Kullanılmadan Yapılan Kifoplasti: Kısa Dönem Klinik Sonuçları

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SUMMARY

Aim: Vertebral compression fractures (VCF) can lead to severe acute and chronic pain, impaired mobility, reduced quality of life, and an increased risk of mortality due to limited mobility. Percutaneous vertebroplasty (VP) and kyphoplasty (KP) are two vertebral augmentation procedures (VAPs) which are minimally invasive surgical options in the treatment of painful VCFs. Vertebral fractures may result in acute pain around the fracture site, loss of vertebral height due to vertebral collapse, spinal instability, and kyphotic deformity. The main goal of the VP and KP procedures is to provide immediate pain relief for patients and restore the vertebral height lost due to the fracture. This study aims to evaluate KP in terms of pain, disability, and quality of life. Cost-effective radiological variables (i.e., vertebral height restoration) and KP for cement extravasation and complications profile were analyzed. Unipedicular or bipedicular approaches were compared.

Methods: Following an injury, the patients had conservative treatment of VCFs including bed-rest bracing and analgesics for four weeks. In 55 patients, a total of 83 vertebral fractures were present. The main causes were falling from a height, traffic accident, and malignancies. We used spinal anesthesia for all patients. Vertebral augmentation was done under fluoroscopy.

Results: The mean age was 59.18 years (SD16.13). The rate of female population (56.4%) and osteoporotic patients (54.5%) was higher. Thoracolumbar junction (T10-L2) fractures were the most common fractures of spinal column. L1 was the most often affected vertebra (24.09%). After VAP, pain scores of the patients statistically significantly decreased. Unipedicular or bipedicular approaches provided the same pain reduction. The pain scores of osteoporotic patients and preoperative and postoperative pain scores were higher than non-osteoporotic groups. Preoperative and postoperative pain scores of the female patients were higher than male patients. Seven patients (12.7%) had cement leakages.

Conclusion: Our study result suggest that the use of the optimal material to provide the optimal result for patient is at the discretion of the surgeon. Clinicians can take the advantage of increased working time. Creating cavity by using drill and curve curette or a balloon and high-viscosity cement under low pressure can minimize leakage complications.

Keywords: Kyphoplasty, Cement, Spinal trauma, Visual Analogue Scale, Oswestry Disability Index.

ÖZET

Amaç: Vertebra sıkışma kırıkları (VSK); şiddetli akut ağrı, kronik ağrı, hareketliliği kısıtlama, hayat kalitesini azaltma ve hareket kısıtlanmasından ötürü mortalite riskini artırmaya öncülük edebilir. Perkütan Vertebroplasti (VP) ve Kifoplasti (KP), ağrılı VSK'da minimal girişimsel cerrahi seçenekleri olan iki vertebra yükseltme yöntemidir. Vertebra kırıkları; kırık etrafında akut ağrı, vertebra çökmesine bağlı yükseklik kaybı, omurga instabilitesi ve kifotik deformiteye sebep olabilir. VP ve KP işlemlerinin hedefi hızlıca hastaların ağrıdan kurtulması ve kırık nedeniyle oluşan yükseklik kaybını onarılmasıdır. Bu çalışma kifoplastinin; ağrı, hayat kalitesi ve yetersizlik gibi faktörler üzerine olan etkilerini değerlendirmek amacındadır. KP ve radyolojik değişkenler (vertebra yükseklik onarımı, vb), çimento kaçakları ve komplikasyon profilleri ile analiz edildi. Tek veya iki taraflı pediküler yaklaşımlar karşılaştırıldı. Materyel ve Metod: Yaralanma sonrası VSK hastaları; 4 haftalık yatak istirahati, korse ve analjezik tedavi gibi konservatif tedaviler aldılar. 55 hastada toplam 83 vertebra kırığı mevcuttu. Yüksekten düşme, trafik kazası ve malignensiler ana nedenleriydi.

Tüm hastalar için spinal anestezi uyguladı. Vertebra yükseltme işlemleri floroskopi altında yapıldı. Bulgular: Ortalama yaş 59.18 (±16.13) idi. Kadın hasta populasyonu (% 56.4) ve osteoporotik hasta populasyonu (% 54.5) yüksekti. Omurga sütununun kırıklarının en sık olduğu yer torakolomber kesişim noktasıydı. Lomber birinci vertebra en çok etkilenen vertebraydı (%24.9). Vertebra yükseltme işlemi sonrası hastaların ağrı skorları istatiksel olarak belirgin azaldı. Tek veya iki taraflı pediküler yaklaşımlar, aynı ağrı skoru düzelmesi sağladı. Osteoporotik hastaların operasyon öncesi ve sonrası ağrı skorları osteoporotik olmayan hasta grubundan daha yüksekti. Bayan hastaların operasyon öncesi ve sonrası ağrı skorları erkek hastalardan daha yüksekti. Yedi hastada çimento kaçağı oluştu. Sonuç: Çalışmamızın sonucu; hasta için en uygun sonuçları sağlamak için en uygun material ve yöntemin kullanılmasının cerrahın tercihinde olmasını önermektedir. Klinisyen, çalışma zamanını azaltmanın avantajlarını alabilir. Vertebrada balonla, dril ve küret yardımıyla kavite oluşturmak ve yüksek viskositeli çimentoyu düşük basınçla vermek, çimento kaçağı komplikasyonlarını minimuma indirebilir.

INTRODUCTION

Vertebral compression fractures (VCF) can lead to severe acute and chronic pain, impaired mobility, reduced quality of life, and an increased risk of mortality due to limited mobility(3).The application of these procedures has recently expanded to include the treatment of traumatic, osteoporotic, and metastatic compression fractures(3). Vertebral fractures are the most common complications of osteoporosis, which are associated with increased morbidity and mortality rates, and, in a minority of patients, considerable pain (1). VFs 3% are pathological, 14% are trauma-related, and 83% are osteoporotic (1, 38). Women aged at 50 years and older are particularly vulnerable due to postmenopausal osteoporosis, of which about 25% suffer from compression fractures (1, 3). This number dramatically increases to 40% at 80 years old (1, 2).

In addition to pain, compression fractures also lead to additional morbidities including an increased risk of an additional VCF, height loss, kyphosis, loss of mobility depression, and pulmonary dysfunction, even. The treatment of VCFs in the elderly focuses on pain control, prevention of progression and deformity, and treatment of the underlying osteoporosis. The main goal in this vulnerable patient population is to maintain their independence and functional status, while avoiding prolonged hospitalizations and bed rest. Several treatment options are available to achieve these goals, varying from conservative treatment including pain management to invasive interventions (4, 5). The main indications for VP are intractable intense pain due to the fracture of osteoporotic fractures, as confirmed by X-ray, computed tomography (CT), and magnetic resonance imaging (MRI) and refractory to conservative management for at least three to four weeks (6,7).

In addition, aggressive treatment has a particular importance. Traditional surgeries such as laminectomy and internal fixation bring large traumas, cause more blood loss, and have a high failure rate. However, conservative treatment can not reduce pain symptoms early and improve function. In recent years, surgical VAPs have been gaining a high degree of importance and have become the standard of care to manage pain and disability (8). The symptomatic pain relief of these procedures has been described in clinical trials (9). The patient can soon return to activity. Early effective rehabilitation is also important. Despite the high rate success of augmentation, procedures may carry complications involving cement leakage, ranging from asymptomatic damage to systemic complications (8, 9, 10).

Although VAPs are usually safe, they may result in rare serious complications such as temporary increase in pain after the procedure, transient arterial hypotension, cement leakage into the intervertebral disc space, of little or no clinical consequence, or into the paravertebral soft tissues, and an increased risk for new fractures, infection, cement leak into the epidural/foraminal space, spinal stenosis, cord or nerve root compression and misplaced needle in the tract, cement leakage into the paravertebral veins leading to pulmonary embolism, cardiac perforation, cerebral embolism, and even death (8, 9, 15, 17, 28, 29, 30, 31).

A higher risk of cement leakage has been noted in vertebroplasty (30 to 75%), compared to kyphoplasty (8 to 33%) (32). The rate of pulmonary embolism ranges from 3.5 to 23% in the literature (32). Less than 1% of patients have clinical symptoms (32, 33). The rates of neurological complications with VP and KP were 0.6% and 0.03%, respectively (4, 5, 6), and fatal conditions such as pulmonary embolism occur in 0.6% (VP) to 0.01% (KP) (6, 15, 40). The rate of extravasation may also significantly vary between operators due to different techniques used (CT versus X-ray) fracture level, cement volume, and viscosity (34).

Mechanism of pain relief

There are three points to consider: chemotoxicity of polymethylacrylate (PMMA), thermal necrosis during polymerization, and mechanical stability (6, 11, 12). The first was known for its toxicity on cells and, thus, a

chemical effect was postulated for pain relief. However, without any toxic monomer, calcium phosphate bone cements were used in a control clinical study and similar pain relief was observed (6, 12). None of the bone cements maintained the temperature at 45°C for more than 30 min necessary for thermal necrosis of sensory nerve. In animal studies, it has been shown that thermal necrosis of bone tissues occurs, when the temperature exceeds 50°C for over 1 min (6, 13, 22). However, all these studies ruled out chemical effect and the thermal necrosis of sensory nerves as the cause of pain relief in VP.

Bone cement restoration of mechanical stability can be regarded as the most probable mechanism for pain relief. The pain is mainly related to the motion of end plate and the micro-motion of trabecular fractures (6, 14).

In addition, PMMA is more elastic than human bone and can cause osteopenia. It takes about 20 min to set and achieve 90% strength within 24 hours. The patient is expected to feel pain relief within four to 24 hours. The entire process is guided with real-time fluoroscopy (15, 16).

The PMMA injection consistency is a critical factor associated with the risk of leakage when using a toothpaste-like liquid with low viscosity and high pressure. If applied while injecting, it may result in cement extravasation. Increased temperature during cement injection may also result in rapid polymerization, causing damage and lack of bioactivity. However, high volumes of cement injection may be associated with leakage (17, 20, 21, 22).

Bone cement has two phases: solid and liquid phases. The ideal material for filler use during KP should have a shorter liquid phase working and longer partially doughy phase working time. The viscosity is the most important handling property for a surgeon which determines the working properties of the cement. Timing for the injection of the cement is also critical for the success of surgery. To reduce the possibility of thermal injury and cement leakage, new bone cements with properties of lower temperature, longer handling time, higher viscosity have been developed. Alternative materials include calcium phosphate, and calcium sulfate cements. These are non-toxic, bioabsorbable, osteoconductive, and euthermic with less stiff than PMMA (15, 17, 18, 19).

Biomechanical studies have demonstrated that small cement volumes (14% or 3 to 5 cc in L1) may be adequate to restore stiffness of fractured vertebrae body levels. According to some
reports, higher volumes (16 to 30%) are needed (15, 17, 23, 24, 25, 26, 27).

MATERIAL AND METHODS

Patient Selection

In this short-term, prospective study, a total of 83 vertebral fractures of 55 patients were evaluated. The main causes were falling from a height, traffic accident, and malignancies. Following injury, the patients received conservative treatment of VCFs including bed-rest bracing and analgesics for four weeks. We evaluated KP in terms of pain, disability, and quality of life. Cost-effective radiological variables (i.e., vertebral height restoration) and KP for cement extravasation and complications profile were analyzed. Unipedicular or bipedicular approaches were compared. The severity of pain was assessed using the Visual Analogue Scale (VAS). The Oswestry Disability Index (ODI) was used to assess the functional status. The study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by Local Medical Ethical Committee. An informed consent form was obtained from each participant (Acceptance Nr: 25.12.2015-55727).

Surgical Technique

All patients underwent spinal anesthesia. Imaging plays an important role in the process of vertebral augmentation, particularly fluoroscopy. Bipolar or C-arm fluoroscopy is often used to maximize safety. A small incision is made to insert the 11-inch cannulated trocar and biopsy needle. The unipedicular approach involves the insertion between the middle and anterior thirds of the vertebral body. After removal of the wire pin and insertion of drill, curve curette, and cavity formation, cement injection is initiated. The cessation stopped, when leakage was seen (3, 6, 14, 35).

Statistical Analysis

Statistical analysis was performed using SPSS v20.0 (SPSS Inc., Chicago, IL, USA). Descriptive data were expressed in frequency, rate, arithmetic mean, and standard deviation. Data were analyzed using the Student's t-test. A p value of <0.05 was considered statistically significant. We performed multiple logistic regression analysis for independent predictors.

RESULTS

The mean age was 59.18 years (SD16.13) with a range of 20 to 87 years. A slight majority of the patients were over 60 years (52.7%) with female predominance (56.4%). Due to elderly female population, the rate of osteoporotic patients was higher (T-score<-2.5). The number of farmers particularly while picking fruit from tree falls, and constructer workers who fell from a height was higher (Table 1).

Table 1- Demographic characteristic and injury types

	N(number)	%(Percentage)
Male	24	43.6
Female	31	56.4
Diabetes mellitus	5	9.09
Hypertension	23	41.8
Osteoporosis	30	54.5
Age lower than 40	8	14.5
Age between 40 and 60	18	32.7
Age older than 60	29	52.7
Falling from height	35	63.6
Traffic accident	12	21.8
Others(malignancy/hemangioma)	8	14.5

Thoracolumbar junction (T10-L2) fractures were the most common fractures of spinal column: thoracic (T) 12 (14.45%), lumbar (L) 1 (24.09%), L2 (22.89%), L3 (15.66%)). L1 was the most often affected vertebra. We made a total of 83 VAPs in 55 patients. This procedure can be made unilaterally or bilaterally. The rates of unilateral and bilateral VAPs were 63.85%and 36.15%, respectively (Table 2).

Table 2- Approaches unilateral or bilateral used and the level of approaches.

Level and fractured number (n)	Unilateral approach	Bilateral approach
T8 (n=2)	2	-
T11 (n=5)	3	2
T12 (n=12)	8	4
L1 (n=20)	10	10
L2 (n=19)	10	9
L3 (n=13)	10	3
L4 (n=8)	6	2
L5 (n=4)	4	-
Total(n=83)	53	30

However, we analyzed non-parametric variables of 55 patients including age, sex, osteoporosis, number of fractured vertebrae, vertebral height loss, preoperative and postoperative VAS scores, and cement leakage. There was a statistically significant correlation between the age and sex (p =0.00), osteoporosis (p =0.00), and preoperative and postoperative VAS scores (p =0.036), (p =0.016). There was a correlation between sex and osteoporosis (p =0.00) and between sex and postoperative VAS scores (p =0.023). However,

there was no correlation between sex and number of fractured vertebrae, height loss, preoperative VAS scores, or cement leakage. The mean age was high (59.18 SD16.13) with female predominance; therefore, the VAS scores were higher in osteoporotic patients. Furthermore, there was a statistically significant correlation between osteoporosis and vertebral height loss (p = 0.044), preoperative VAS scores (p =0.046), and postoperative VAS scores (p = 0.014). We also found a correlation between the number of fractured vertebrae and height loss (p = 0.024); however, there was no correlation with age, sex, osteoporosis, and cement leakage. In addition, there was a statistically significant correlation between preoperative VAS scores and cement leakage (p = 0.009), while no correlation between preoperative VAS scores and sex, number of fractured vertebrae, height loss, and postoperative VAS scores was observed. Also, there was a statistically significant correlation between postoperative VAS scores and osteoporosis, while there was no correlation between postoperative VAS and number of fractured vertebra, vertebra height loss, preoperative VAS scores, and cement leakage. I n addition, there was a statistically significant correlation between cement leakage and preoperative VAS scores (p =0.009), although there was no correlation between cement leakage and age, sex, osteoporosis, number of fractured vertebrae, height loss, and postoperative VAS. We also analyzed non-parametric variables of osteoporosis, number of fractured vertebrae, height loss, preoperative-postoperative VAS scores, cement leakage, and unilateral or bilateral VAPs. Among them, we only found a correlation between postoperative VAS scores and osteoporosis (p =0.014). Independent sample t-test revealed no statistically significant correlation between cement leakage with osteoporosis, number of fractured vertebrae, height loss, and unilateral or bilateral VAP (p >0.05). We performed multiple logistic regression analysis for independent predictors for cement leakage and postoperative VAS scores. We used the following variables: age, sex, osteoporosis, pre- and postoperative VAS scores, and unilateral or bilateral VAP. However, we only found a correlation between preoperative VAS scores and cement leakage (p=0.029), (B) 20.96, (95%CI). The Student's t-test was used for the correlation analysis of pain score lower than 3 and more with osteoporosis, number of fractured vertebrae, height loss, unilateral or bilateral VAP, and cement leakage. There was only a correlation between the pain scores and osteoporosis (p =0.002). Following VAP procedures, pain scores statistically significantly decreased (p <0.05) (Table 3).

Table 3-Descriptive statistics and preoperative and postoperative VAS scores

VAS	N	Minimum	Maximum	Mean	Std. Deviation
Preop-VAS	55	7,00	10,00	8,7818	1,03084
Postop-VAS	55	2,00	4,00	2,6000	,89443
VAS: Visual analog score					

Both pre and postoperative pain scores of female patients were higher than male scores. Postoperative pain scores were statistically higher in females and correlated with female sex (p =0.023). In the present study, osteoporotic female patients were predominant (Table 4).

Table 4- T-test between sex and preoperative (preop) and postoperative (postop) pain scores.

VAS and Sex	N	Mean	Std. Deviation	Std. Error Mean
Preop-VAS male	24	8,5833	1,05981	,21633
Preop-VAS female	31	8,9355	,99785	,17922
Postop-VAS male	24	2,2917	,69025	,14090
Postop-VAS female	31	2,8387	,96943	,17411

The rate of falling from a height was high in both groups. Being a constructer worker or farmer (falling down from fruit trees and falling down from horses) were the risk factors. The other group included metastasis, malignancy, and hemangiomas of spinal vertebra (Table 5).

Table 5- Causes of vertebral fractures and female or male group cross tabulation (Traffic accident (TA), falling from height (FFH), Others (malignancy, hemangioma).

Causes	Female(n)	Male(n)	Total(n)
Others	2	6	8
TA	6	6	12
FFH	23	12	35
Total(n)	31	24	55

We had a small non-traumatic vertebral fracture group, spinal malignancy, hemangioma group with eight cases and two leakages in this group. Of all, seven patients (12.7%) had cement leakage. There were three cement leakages in the spinal canal, six in the paravertebral area, and two in the disc space (Table 6), (Figure-1).

Table 6- Causes of vertebral fractures and cement leakage cross tabulation (Traffic accident (TA), falling from height (FFH), Others (malignancy, hemangioma).

Cause	Leakage(+)	Leakage(-)	Total
Others	2	6	8
TA	4	8	12
FFH	1	34	35
Total	7	48	55

Figure 1. Samples of cement leakage.
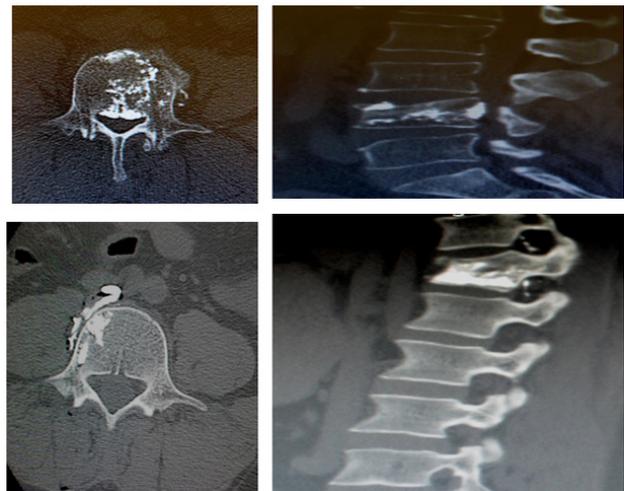
Both high-impact energy spinal trauma and spinal malignancies may cause multiple-level vertebral fractures (Table 7).

Table 7- Causes and number of vertebral fracture cross tabulation (Traffic accident (TA), falling from height (FFH), Others (malignancy, hemangioma).

Cause	Number Of Fractured vertebra(n)				Total
	1,0	2,0	3,0	4,0	
Others	4	2	2	0	8
TA	10	0	2	0	12
FFH	18	14	2	1	35
Total(n)	32	16	6	1	55

All pain scores decreased after VAPs. The pre- and postoperative pain scores of osteoporotic patients were higher than non-osteoporotic patients (p =0.046, p =0.014) (Table 8).

Table 8- T-test results of preoperative and postoperative VAS scores and osteoporosis

VAS	Osteoporosis	N	Mean	Std. Deviation	Std. Error Mean
preop	(+)	30	9,0333	,99943	,18247
preop	(-)	25	8,4800	1,00499	,20100
postop	(+)	30	2,8667	,97320	,17768
postop	(-)	25	2,2800	,67823	,13565

The correlation between unilateral and bilateral approaches and postoperative pain was analyzed using the Student's t-test. Following these procedures, although pain scores decreased, there was no statistically significant correlation between them (Table 9).

Table 9- T-test between unilateral and bilateral approaches and postoperative pain scores.

Approach type	Postop-VAS	N	Mean	Std. Deviation	Std. Error Mean
Unilateral	VAS≤3	40	,8250	,78078	,12345
Unilateral	VAS>4	15	1,3333	,97590	,25198
Bilateral	VAS≤3	40	,6500	,76962	,12169
Bilateral	VAS>4	15	,2667	,45774	,11819

DISCUSSION

Vertebral fractures constitute major health care problem, not only due to their high incidence, but also both direct and indirect consequences on health-related quality and health care expenditures (8). Conservative treatment of VCFs includes bed-rest bracing and analgesics. Inactivity and immobility have their own morbidities such as increased rates of pneumonia, decubitus ulcers, venous thromboembolism, and even death (8). Unfortunately, non-surgical management commonly results in slow resolution of pain or no relief. Several studies have shown that VAPs are superior to non-surgical management, offering immediate pain relief and improved physical functioning (8, 10). Most authorities advocate a two- to six-week trial of conservative treatment before VAP (4, 5, 6, 8, 35). Consistent with the literature data, we waited four weeks for VAP after injury.

Our study population consisted of a mixture of young, middle-aged, and elderly patients. They were more often employed in physical, labor-intensive occupations such as farming. Females were predominant (56.4%) and a high number of patients (54.5%) were osteoporotic. As elderly women mostly worked at farms, particularly were picking fruit from trees and riding horses, they were was at a higher risk of falling from a height than other injuries. Younger men were often working in construction. Following VAP, pain reduction was good and all the patients were able to ambulate without using an orthosis and discharged on the day of the procedure (1). As the same results were in our study population.

In addition, disruptions of thoracolumbar spine are often a result of high-energy injuries. Traumatic fractures of thoracolumbar spine, particularly the thoracolumbar junction (T10-L2), are the most common fractures of spinal column. The transition from the less mobile thoracic spine with its associated ribs and sternum to more dynamic lumbar spine makes this an area of high biomechanical stress (46). In the present study, the VF levels and rates were similar to the literature data (L1 (24.09%), L3 (15.66%), L2 (22.89%), T12 (14.45%).

In 55 patients, a total of 83 vertebral fractures were present. The rate of additional fractures (n=28; 50.9%) was higher than the previously reported findings due to the presence of osteoporosis and high-impact energy injuries (24).

Furthermore, PMMA has some merits including bio-inertness, ease of handling, good biomechanical strength, and cost effectiveness (6). All these make it an ideal choice for the bone cement. However, the major disadvantages of PMMA are the toxicity of residual monomer MMA and heat generated during exothermic polymerization (6, 11, 17, 36). The mean polymerization time is around two to five minutes, and the operator has a limited time to deliver the bone cement through the spinal cannula into the body. The short handling time leads to an increased probability that a surgeon may miss the crucial time. Once polymerization ends, the temperature decreases and the cement becomes solid (17, 20).

To reduce the possibility of thermal injury and cement leakage, new bone cements with properties of lower temperature, longer handling time, higher viscosity have been developed. Future perspective on cement properties enables the operator to do the procedure more rapidly and safely. In recent years, unipedicular approach has been gaining popularity, if applicable, particularly with the use of curved curettes, ultra-viscous cement, with specialized delivery equipment allow for uniform, controlled, low pressure cement filling (17,1 8, 19, 37, 30). In our study, we also used high-viscosity cement.

The unipedicular approach includes less operative time, less exposure to radiation, and less cost than suboptimal kyphotic reduction (15). However, both biomechanical data and clinical series have shown that unipedicular procedure is safe and effective. Chung and et al. reported pain reduction in their study with superior kyphosis restoration using the bipedicular approach (48). Only difference may be the smaller cement amount filling in unilateral operations (15, 43, 44, 45, 48). Comparative clinical studies using unipedicular or bipedicular approaches have demonstrated no difference in clinical or radiological variables with same pain reduction rates. Similarly, we observed no statistically significant difference between them in our study.

Cavity creation in KP, either balloon or curettes, allows for low-pressure controlled cement filling. Cement viscosity plays a key role. It has been suggested that this difference reflects the creation of cavity and the use of more viscous cement in balloon KP. Disruption of the endplates and anterior or posterior wall fractures may increase the risk of cement leaks. Although many leakages are asymptomatic, incidental findings, they may lead to complications (7, 15, 38, 39, 40, 41).

Cement leakage was seen less in high-viscosity cement group, and postoperative CT revealed cement leakage in five of 17(29.4%) vertebrae in the high-viscosity group. Fifteen of 22 (68.2%) vertebrae were in the low-viscosity group. In the VAP using high-viscosity, bone cement can provide the same outcome with fewer complications through VAP using low-viscosity bone cements (37). In all, seven patients (12.7%) had leakage in our study. According to the high-viscosity cement used literature cement leakage rate's, our group's percentage was lower (literature 29.4%) and 5 leakages occurred in the traumatic group (5/47 ,10.6%) (Figure-1).

Furthermore, cement leakage can occur at any kind of vertebra fracture. In particular, middle column fractures and high-volume cement injections can cause leakages. According to the literature data, spinal malignancy is a cause of leakage in 10% of cases (47). We had a small non-traumatic vertebral fracture group and spinal malignancy, and hemangiomas. Therefore, the rate of leakage was higher than the literature findings (2/8; 25%), as we used a drill and curette in vertebra corpus to create a cavity and used high-viscosity cement under low pressure (47). There were also three cement leakages in the spinal canal, six in the paravertebral area, and two in the disc space (Figures-1).

Rapid pain relief, improved body functioning, vertebral height gain, and improved spinal alignment are the main advantages of VAPs (6). Pain relief was observed in both groups (VP 87%, KP 92%) (6).In most studies, the follow-up was short; however, pain relief was persistent (6,42). When comparing VP with KP, it seems that both procedures offer a 4 to 5 point mean reduction from baseline (in a 10-point scale) and significant improvement in the VAS and the ODI (15,32). In our study, the mean preoperative pain score was 8.78(SD 1.03), while the mean postoperative pain score was 2.808(SD 0.89). According to ODI scores, 1.8% of patients had severe disability, whereas the rest (98.2%) had minimal disability.

Physical function and disability scores improved in both procedures. For working status, 30/55 (54.55%) returned to their previous level of employment,

20/55(36.36%) were working full-time but a lighter job, and 5/55 (9.09%) were working only part-time. Physical function was normal in 30/55 (54.5%), limited in 20/55 (36.36%), and severely limited in 5/55 (9.09 %).

At the final follow-up, 45 of 55 (81.81%) patients were pain-free with no back pain, nine patients (16.36%) reported only mild back pain. One patient had also mid-upper back pain due to spinal liposarcoma metastasis.

Some surgeons suggest that postural reduction is the most critical factor determining kyphotic post-procedural correction. Extensive literature with balloon KP have claimed that balloon inflation also plays a role (6). Another important issue is whether this degree of kyphotic reduction correlates with clinical improvement. Theoretically, an improvement in spinal alignment and biomechanical behavior of spine should reduce the flexion moments, relax the paraspinal muscles and lead to more upright posture, reduced pain and fewer subsequent fractures (6, 42). Improved vertebral height restoration with KP is also controversial, as the initial height gain is higher in KP; however, this effect is lost subsequently during balloon deflation and repetitive loading (8-10).

Reduction of kyphosis with KP varies from 3.7° to 8° (mean: 4.8°). Using VP, it ranges from 0.5° to 3° (mean: 1.7°)(15) with a mean kyphotic restoration angle of 6.6°. However, there was no vertebral height gain or correction in kyphotic deformity in 39% of VP and 34% KP cases. Restoration of the vertebral height depends on the age of the fracture, as suggested by several authors (6, 49, 50). KP is superior to VP about the restoration of vertebral height (6). The mean height gain was 2°, while 35% of the patients did not gain height restoration in our study.

On the other hand, are VAPs cost-effective?. In the present study, Both KP and VP patients had the short hospital stay but KP causes higher hospital charges than VP (8,6). Therefore, improving quality of life and physical activity, and decreasing the pain with minimal complication should not be measured by money costs alone.

Vertebral augmentation can be completed under sedation, general anesthesia, local or spinal anesthesia. Of these, general anesthesia has several pre- and postoperative complications. Injection of local anesthesia into the periosteum is particularly tricky, as some patients feel discomfort during the advancement of the trocar through the posterior cortical margin with balloon inflation and with injection of bone cement.

Spinal anesthesia is commonly used in spinal operations, rather than general anesthesia, as it reduces morbidity in high-risk patients and inhibits stress after surgery. The main advantages include short preparation time, fast-acting and multiple level treatment, reduced need for painkiller after operation, and an analgesic effect lasting about 4 to 6 hours. In the present study, we used spinal anesthesia for all our patients (6, 3). In general, patients are permitted to resume normal daily activities immediately after a vertebral augmentation without the need for any braces or bed rest, as in our patients.

Patients refusal to surgical or conservative managements were the most common reason for our surgery decision. Several studies with positive results are more likely to be reported and published, while side effects and adverse events are more likely to be underreported; however, most of the cement leakage associated with VP was asymptomatic (6). Nonetheless, further studies are required which concentrate on the development of new materials and alternative techniques with long-term efficacy and improved safety.

On the other hand, this study has limitations such as small sample size and short follow-up period. In addition, none of the patients were able to be randomized to treatment and there were no control subjects.

CONCLUSION

In conclusion, VAP is safe and effective with several advantages of reduced pain, better cosmesis, lower perioperative morbidity, and earlier return to activity. Duration of analgesic use can be also reduced. Direct medical costs and indirect costs in the lost productivity should be also considered. Using high-viscosity cement can minimize exothermic cement, toxic side effects, and hardening time problems. Creating a cavity by a balloon, drill or curve curette and using high-viscosity cement under low pressure are useful methods. On the other hand, the use of the optimal material to provide the optimal result for patient is at the discretion of the surgeon. Clinicians can take the advantage of increased working time and improved injectability without costs by cooling the cement. High-viscosity cement and KP is expensive than VP; however, it has lesser complications and improves quality of life, increases physical activity, and reduces pain. Therefore, such benefits should not be measured by money cost alone. We believe that further studies may be helpful to reach a consensus on the optimal treatment strategies for VCF, minimizing the cost and improving the quality of life.

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