

# Experience of a single center with 472 vertebral augmentation surgery in 356 patients

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## Abstract

**Aim:** The objective of this study is to evaluate the clinical series of patients who underwent vertebral augmentation surgery in Neurosurgery department of Baskent University.

**Materials and Methods:** The medical data stored in electronic and print files were retrospectively analyzed and patients operated in recent past were called for evaluation of outcome.

**Results:** One clinical; pain relief and two radiologic, kyphotic angle and vertebral compression, criteria were used to evaluate the final outcome. The statistical analysis revealed that in all three parameters there was significantly important improvement in postoperative values. Procedure related complications were minor. No permanent neurologic deficit or mortality was seen.

**Conclusion:** Both vertebral augmentation techniques are simple, effective and safe procedures provided that surgical indications are correct and surgical technique is properly carried out.

**Keywords:** Surgical technique; vertebral augmentation; vertebral compression

## INTRODUCTION

Osteoporosis is the breakdown of the equilibrium between osteogenesis and osteoclastic activity and is the major cause of vertebral fractures especially in elderly women. The traditional treatment of vertebral fracture is bed rest, medication and bracelet. The introduction of the surgical technique which simply requires percutaneous injection of bone cement into the vertebral body has offered a new option for the treatment of vertebral fractures. The main advantages of vertebral augmentation (VA) are early mobilization, rapid relief of pain and restoration of vertebral height whenever possible.

The first vertebroplasty was performed by two French surgeons, Dr. Deramont and Galibert, in 1984 for an aggressive cervical hemangioma. The publication describing the technique came in 1987.(1) The modified form of vertebroplasty known as kyphoplasty was first performed by Dr. Mark Railey in California, USA in 1998. The same year FDA approved the technique of kyphoplasty. The first vertebroplasty in North America was performed in Virginia University, USA in 1993.

## MATERIALS and METHODS

For this study, a retrospective analysis was performed on the files and films of the patients with vertebral fractures

who were operated at Baskent University Department of Neurosurgery Ankara Hospital, after obtaining the ethics committee approval dated 10/06/2016 and numbered KA 16-217. The series includes 356 patients and 472 vertebra operated upon during the time frame of July 2002- November 2016. The pain of the patients will be evaluated with the visual analog scale (VAS). Parameters such as age, gender, duration of pain, number and levels of fractured vertebrae, kyphosis angle are recorded for examination, and the amount of cement used during the procedure, vertebral height ratios, whether there is any leakage of cement out of the vertebra, and complications that develop in the preoperative or postoperative period will be considered.

Statistical Package for Social Sciences (SPSS) v17.0 (SPSS for Windows version 17.0, Chicago, IL, USA - September 2012 license number: 1093910, Baskent University) was used for statistical evaluation. The compliance of continuous numerical variables to normal distribution was evaluated with the "Kolmogorov-Smirnov normality test". Since numerical variables do not show normal distribution, minimum and maximum values are given with median as descriptive statistics, and numbers and percentages are presented for categorical variables. Whether there is a difference between the Kyphotic Angle, Vertebral Compression Degree and VAS measurements

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taken from the patients before and after the treatment was tested with the "Wilcoxon test" since the parametric test prerequisites were not met. For all tests, Type I error probability was determined as  $\alpha = 0.05$

## RESULTS

The series includes 356 patients and 472 vertebra operated. There were 230 females (64.60 %) and 125 (35.39 %) males. The age range was 18-94 years with an average of 67.6 years. Kyphoplasty was performed in 244 (68.53 %) cases while vertebroplasty was performed in 112 (31.46 %) patients. The type of anesthesia was general in 141 (39.60 %) patients and sedoanalgesia in 215 (60.39 %) patients. The segmental distribution of the operated vertebrae included 301 lumbar (63.77 %), 164 (34.74 %) thoracic, 6 (1.27 %) sacral and 1 cervical vertebrae. A detailed distribution of operated segments is summarized on Table 1.

**Table 1. Segmental distribution of vertebra treated by VA**

T 4: 1	L 1: 105
T 6: 4	L 2: 79
T 7: 13	L 3: 53
T 8: 12	L 4: 45
T 9: 8	L 5: 19
T10: 14	
T11: 34	Cervical: 1
T12: 78	Sacral: 6

An average of 6 cc. cement was injected to each vertebra. No mortality was seen. One elderly male patient had a heart attack in the OR before anesthesia was induced and did not respond to resuscitation. General evaluation of the procedures and outcome results are given on Table 2.

**Table 2. Clinical and radiologic evaluation of the outcome of VA operations**

	Cement Volume	Preop. Kyphotic Angle	Postop. Kyphotic Angle	Preop. Vertebral Compression	Postop. Vertebral Compression	Preop. Vas	Postop. Vas
Median	6.00	14.00	7.5	28.55	15.50	100.00	10.00
Minimum	1.50	1.00	2.0	12.70	5.50	80.00	0.00
Maximum	36.00	48	28.50	54.50	34.40	100.00	20.00

Repeat augmentation surgeries were performed in either the same, adjacent or remote vertebra in 26 (7.30 %) cases. Cement leakage was detected in 15 cases (4.21 %) patients. Only in one patient, cement leakage caused complication. Cement leakage was observed in the intervertebral space in this 74 year old female patient. She had no complaints and was discharged in good neurologic state. She developed signs and symptoms of right L4-5 disc herniation in two weeks. A right L4-5 discectomy was performed and discectomy material contained cement particles. In other patients with cement leakage no problem was faced.

## DISCUSSION

Osteoporosis is the major cause of vertebral fractures especially in the thoracolumbar segments. Trauma, various infectious processes and oncologic diseases are other pathologies that may eventually cause vertebral fractures.

Vertebral fractures of the thoracolumbar region cause chronic back pain, limitation of physical activity and sleep disorders. Multiple fractures are naturally more serious and may lead to kyphosis, pulmonary function disorders and decreased appetite.

The relative risk of dying following a spine fracture was almost 9-fold as reported by Cauley et al.(2) A study in the medicare population included 858,978 vertebral compression fractures.

Kyphoplasty was performed in 119,253 patients while in 63,693 patients vertebroplasty was performed. At up to 4 years follow-up, patients in the operated cohort had a higher adjusted survival rate of 60.8 % compared to 50.0 % for patients in the nonoperated cohort and were 37 % less likely to die.(3)

The VA operations were started in Neurosurgery department of Başkent University in July of 2002. The preoperative diagnosis was made with MRI and particularly with STIR (Short tau inverse recovery) sections. Even if x-ray or CT had been performed elsewhere, MRI was asked for. Bony edema on STIR sections was an important finding for surgical decision. The preoperative general health status of the patients was evaluated by anesthesiology department and 94 % of the patients were evaluated as ASA II or higher. There was a wide spectrum of comorbidities.

Sedoanalgesia was preferred for elderly individuals with serious comorbidities to avoid the risks of general anesthesia. General anesthesia was used for relatively younger patients and for patients with anticipated poor cooperation in sedoanalgesia.

The degree of vertebral compression and time elapsed after trauma were the main factors taken into consideration for determining the type of VA. If the vertebral compression was more than 30% then kyphoplasty was preferred, otherwise vertebroplasty was performed. If the fracture was older than 3 months, vertebroplasty was the choice

since vertebral compression would not benefit from kyphoplasty after that time.

The postoperative routine included x-ray, mobilization and inquiry about pain relief. Nearly all patients were discharged on first postoperative day.

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The indications for VA procedures are indicated in osteoporotic vertebral fractures, traumatic fractures, hemangiomas, osteolytic metastasis and multiple myeloma (4-6).

The contraindications are burst fractures, fractures compressing the spinal cord, posterior cortex fractures, pars/pedicle fractures, vertebra plana, nonvisualization of the pedicles, infection in the target vertebra, radiculopathy, coagulopathy and osteoblastic tumors.(7)

Initially T4 vertebra was defined as the upper limit for VA procedures. In time both the segmental and etiologic restrictions were reduced. Experiences about VA operations performed in cervical segments are reported in the literature. A meta-analysis included six articles of fourth level in which 135 vertebrae were operated in 120 cases. Pain relief rate was 89 % while complication rate was 4%.(8) Sacral procedures are relatively rare and sacroplasty was initially performed for metastatic sacral lesions and afterwards for osteoporotic fractures.(9, 10)

Hentsechel et al. (11) have reported their experience of VA operations in a group of patients with contraindicated pathologies. The authors have divided patients into two groups; first group was operated for indicated pathologies while the second group of patients had contraindicated pathologies. The first group consisted 36 patients, 114 surgical levels and 11 % complication rate. The second group included 17 patients, 18 surgical levels and 39 % complication rate.

Complications may be studied in five subgroups; hematoma formation, infection, cements leakage, postoperative new vertebral fractures and neurologic complications. In the presence of infection in the vertebral body or in close anatomical vicinity VP should be avoided. Postoperative infection is seen more frequently in individuals with comorbidities suppressing the immune system.(12-14)

Zou et al. (15) have reported development of tuberculosis following PV in two patients.

The most frequent and serious complications are related to cement leakage. Leakage of the cement laterally and

anteriorly is mainly a radiologic finding and does not cause any clinical symptoms.

Leakage to intervertebral disc space, to foramina and very rarely to subdural space(16) may be problematic. On the other hand Cotten et al. (17) claim that in most patients, intradiscal leaks of cement have no clinical importance.

Leakage to epidural veins and entering to systemic circulation results in serious complications.

Kim and associates (18) prospectively analyzed the incidence, characteristics and risk factors of pulmonary cement embolism following vertebroplasty. They found 23% of cement embolism developing in the distal to third-order pulmonary arteries and that was related to leakage into the inferior vena cava. Postoperative chest x-ray and thorax CT has been recommended for all patients who have undergone VA procedure (19-21)

Audet et al. (22) have reported a case in whom leaked cement has reached the heart and the cement was removed by open heart surgery. The authors have made a literature survey and have found 15 similar cases. (23, 24) In all but one of the patients cement was removed by open heart surgery while in one patient the cement was extracted via catheterization. Retrieval of cement embolus from inferior vena cava has also been reported.(25)

The cement leakage rate in kyphoplasty is generally reported low compared to vertebroplasty. This is associated with the technique of kyphoplasty. Prevention or minimizing cement leakage depends upon preoperative high quality imaging at every step of the surgical procedure particularly during cement injection. Postoperative radiologic control either by x-ray or with CT serves to detect any leakage and take appropriate action in cases of cement presence in important anatomic compartments.

Hoppe et al. (26) have shown that vertebral body lavage before cement injection reduces cement leakage and produces a better filling pattern.

Cement volume and cement viscosity are accepted as important factors associated with cement leakage. Low viscosity increases the risk of cement leakage. The ideal viscosity is described as "tooth-paste". High viscosity presents hardship in introducing the material into the vertebral body. The cement volume should be enough to relieve pain but surplus volumes of cement increase the risk of extraosseous cement leakage.

Hierholzer et al. (27) evaluated the incidence of new developing vertebral fractures in patients treated by percutaneous vertebroplasty. The series included 316 patients and 486 treated vertebra. Fifty-two (16.4 %) patients were retreated. The number of secondary fractured vertebra was 69 (14.19 %). This incidence of secondary vertebra fracture rate was below the level expected from previous epidemiologic studies. A meta-analysis by Han et al. (28) included 2551 individuals. Of these 1631 underwent vertebroplasty and the remaining 920 individuals composed the control group.

The authors found similar incidence of fractures in surgically and conservatively treated groups and concluded that vertebroplasty does not contribute to increased risk of subsequent vertebral fracture.

Trouillier et al. Proposed that the fractures of the adjacent vertebra are caused by the difference in stiffness between the cement augmented vertebral body and the adjacent vertebra. The authors also pointed out that such fractures are frequently encountered at thoracolumbar junction.(29)

Risk factors associated with adjacent and remote level vertebral compression after kyphoplasty was studied by Faloon et al. (30) Univariate analysis identified age, diabetes mellitus, smoking, nonsteroid anti-inflammatory drug usage and female gender as risk factors for future vertebral fracture. When adjusted for multivariate analysis, no individual factor demonstrated increased risk factor for subsequent fracture.

Li et al. have claimed that the distance between polymethylmethacrylate and endplate is an important factor of recompression of cemented vertebra after kyphoplasty. (31)

Benefit of prophylactic vertebroplasty of the adjacent vertebrae in single segment osteoporotic vertebral body fractures treated with kyphoplasty was investigated, the results showed no decrease in the rate of adjacent fracture. (32)

Pitton et al. have reviewed cement leakage and other complications in 500 procedures. (33) The procedure related morbidity was 2.8%. CT-based cement leak rate was 55.4%, most frequently into intervertebral disc space (25.2%). Adjacent and distant level secondary fracture rate was 17.1 %. The authors concluded that the number of cement leakages alone is not directly associated with clinical complications.

Hulme et al. have analyzed the complication rates in 4456 vertebroplasty and in 1624 kyphoplasty cases. The complication rate was 2% in osteoporotic fractures and 10% in malignant processes. Neurologic complications were observed in 0.6 % of vertebroplasty and in 0.03% of kyphoplasty patients. Pulmonary embolism was detected in 0.03% of vertebroplasty and in 0.01% of kyphoplasty patients.

Several surgical techniques have been developed to increase the efficacy and to reduce the complication rate of VA.

Percutaneous mesh container-plasty involves formation of a cavity in the fractured vertebral body by using a bone expansion brace to cut the bone tissues. The bone expansion is then withdrawn, mesh container is inserted into the cavity and cement is injected into the mesh container. (34)

Anselmetti et al. (35) have reported their experience in vertebral augmentation of painful osteolytic vertebral wall involvement treated by a novel coil shaped polyetheretherketone (PEEK-OPTIMA) implant designed

to internally contain and minimize the risk of cement leakage. The group included 40 patients suffering from a painful spine malignancy with vertebral wall involvement not responding to conventional therapies and with no surgical indication. The authors found the system potentially beneficial for the above described group of patients.

Vesselplasty was developed to decrease the rate of cement leakage where the inflatable ballonn is left in the veretbral body and filled with cement.(36)

Flors et al. (37) have reporetd their results with vesselplasty in 37 procedures performed in 29 patients and they concluded that vesselplasty statistically has offered positive results as far as improvement of pain and the need for analgesia is concerned. In the literature, spinal subarachnoid and subdural hematoma has also been reported as a rare complication of vertebral augmentation. (38)

Open vertebroplasty has been combined to open decompressive procedures in patients with stenotic spinal canal (6,39) and open vertebroplasty has also been performed with instrumentation (40).

## CONCLUSION

Our experience during the past 14 years with VA technique has revealed that these procedures are effective, highly safe and easy to perform. The complications are minor and negligible under the circumstances of correct patient selection and proper surgical technique combined to high quality peroperative and postoperative radiologic examinations.

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