

Research Article

A Prospective Comparison Study of Early Complications of a Few-Level *versus* Multi-Level Vertebroplasty and Kyphoplasty

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Abstract

Purpose and Introduction: Vertebroplasty and Kyphoplasty are commonly used to treat vertebral body destruction to decrease pain and restore vertebral height. These procedures have complications that related to cement leakage or emboli which almost asymptomatic. The aim of this prospective study is trying to answer the question, Do multi-level vertebroplasty complications differ from that of a few-level.

Methods: Seventy six patients were treated at our hospital for pathological fractures with kyphoplasty or vertebroplasty. According to the number of operated vertebrae we divided them into 2 groups: group I (36 patients with 40 procedures) included 1 or 2 vertebrae and group II (40 patients with 355 procedures) included >3 vertebrae. We study the complications of each group in a comparison way.

Results: Eleven patients (30.55%) of group I with 11 vertebrae (26.4%) developed complications, which most of them (10 of 11) were cement leakage around the vertebral body. Twelve patients (30%) with 21 (5.95%) vertebrae of group II developed complications and most of them (10 patients) were intra vascular and around the vertebral body. *P*-value was <0.0001. All cases were asymptomatic except one of each group with intra spinal cement leakage and paraparesis. One patient of group I developed aspiration pneumonia and death. One case developed bilateral pneumothorax and one case of cardiac cement embolus whom were successfully treated of group II.

Conclusion: A few-level *versus* multi-level vertebroplasty and kyphoplasty has the same number of patients, who developed complications with less percentage of complicated vertebrae in multi-level group.

Keywords: Complications; A few-level *versus* multi-level; Vertebroplasty; Kyphoplasty; Cement leakage

Introduction

Vertebroplasty were first used to treat haemangioma and then widely used to treat vertebral fractures associated with osteoporosis or malignancy [1,2]. Complications of Vertebroplasty and Kyphoplasty are early due to cement leakage around the vertebral body, through vascular embolization or bleeding and late due to infection and fracture of the adjacent vertebra [3,4]. The most majority of these complications are asymptomatic and insignificant [1-5].

Many previous studies mentioned leakage of the cement inside the soft tissue anterior and lateral to the body is asymptomatic, while posterior or posterolateral (intraspinous or intra-foraminal) is probably symptomatic. Some papers mentioned some case reports about rare complications: intradural, cardiac, pulmonary embolus, cerebral arterial embolus and refracture of the same vertebra [3-10].

Nizar A. Al-Nakshabandi classified complications into three groups: mild includes paraspinal cement leakage, transient hypotension and pain, moderate includes epidural cement leakage and infection and severe includes cardiac, pulmonary and cerebral

emboli [3]. Avoidance of complications was discussed in many studies which include patient selection, cement selection and insertion of working cannula in its appropriate position [5].

This is a prospective study to compare complications of multilevel (>3 vertebrae) *versus* single or double levels (<2 vertebrae) of kyphoplasty and vertebroplasty treated at our institute.

Methods

We treated 76 patients; age range was between 19 and 86 (mean=57.3+SD=15.2) years and male: female was 39:37, with Vertebroplasty and Kyphoplasty for different causes of vertebral body destruction (Malignancy, osteoporosis or haemangioma) during the last 2 years. We divided them according the number of vertebrae into 2 groups:

Group I: (A few-level) included 36 patients with range of age was 19 and 74 (mean=58.36) years and male: female ratio was 19:17, who underwent 1 or 2 levels (total levels=40) of vertebroplasty and kyphoplasty.

Table 1: Shows indicated diseases for kypho or vertebroplasty and number of patients: P (Patient), L (Level), (K (Kyphoplasty) and V (Vertebroplasty).

Indication Group	Osteoporosis	Haemangioma	Multiple Myeloma	Lymphoma	Metastasis	Total
Group I	24 P {25 L =K(25)+V(0)}	3 P {4L=K(1)+V(3)}	1 P {1 L =K(1)+V(0)}	6 P {8 L =K(2)+V(6)}	2 P {2L = K(2)+V(0)}	36 P {40 L =K(31)+V(9)}
Group II	13 P {69 L =K(23)+V(46)}	3 P {11 L = K(0)+V(11)}	15 P {210 L =K(17)+V(193)}	6 P {51 L =K(6)+(45)}	3 P {14 L = K(0)+(14)}	40 P {353 L =K(46)+(309)}

Table 2: Shows numbers of complications of each group, time, location, treatable or not, symptomatic or asymptomatic, life threatening or not and P-value of each group and P-value of two compared groups. Anterior Cement Leak (ACL), Intra Discal Cement Leak (IDCL), Intra Spinal Cement Leak (ISCL), Lateral Cement Leak (LCL), Intravascular Cement Leakage (IVCL), Intra Cardiac Cement Embolism (ICCL), Aspiration Pneumonia (AP) and Bilateral Pneumothorax (BP).

Groups	Time of complications		Treatable		Life threatening		Location		Symptomatic		2-Tailed P-value	Levene's P-value
	Intra- operative	Post-Operative	Yes	No	Yes	No	Local	General	Yes	No		
Group I	10 cases: ACL=3 LCL=4 IDCL=1 IVL=1 ISCLwith Paraparesis=1	1 Aspiration Pneumonia	0	10	1 AP	10	8	2: (1 AP & 1 IVCL)	2=ISCL with Paraparesis=1 + 1 Aspiration Pneumonia	9	0.012	< 0.001
Group II	12 cases: IVCL=6 ISCL=2(1 with paraparesis) ACL=2 BP= 1 ICCL=1	0	2= ICCL=1 BP=1	10	2: ICCL & BP	10	10	ICCL=1 BP=1	3=ICCL ISCL+Paraparesis +1 BP	9	0.007	

Group II: (Multi-level) included 40 patients with range of age was 26 and 86 (56.75) years and male: female ratio was 20:20, who underwent >3 levels (total=353 ranged between 3 and 16 vertebrae per case) of vertebroplasty and kyphoplasty.

All patients were evaluated pre and post-operatively by a team of physicians clinically, radiologically and laboratory. All patients were operated by a single surgeon using transpedicular axis for vertebrae D10 and below and extra pedicular axis above D10. Patients with osteoporosis, hemangioma, lymphoma, multiple myeloma or metastasis were included in this study (Table 1). Vertebroplasty was used for diseased non-fractured vertebrae, while balloon-kyphoplasty was used for diseased vertebrae with compression fractures.

Patients with platyspondyly (severely crushed vertebra) or spinal canal encroachment by tumor mass were excluded. As most complications were seen during and early post-operative, we concentrated on the three days Peri-operatively. Consent form was signed by patients and Institutional Review Board (IRB) approval was obtained.

We classified complications into intra-operative or post-operative (within 48 hours), local or general, symptomatic or asymptomatic, and treatable or non-treatable. Most of complications were related to bone cement leak around the vertebral body or emboli inside blood. Less complications were general surgical complications; *i.e.* pneumothorax (unilateral or bilateral), pulmonary embolism (blood clot), bleeding or wound infection.

Statistically, we used SPSS version 20 to evaluate the results. Levene's test for equality of variances to evaluate segments results gives means values, standard deviation and P-value. T-test for equality means to evaluate number of patients with complication; 2-tailed significance.

Results

Group I included 36 patients with 40 vertebrae (average+SD=1.11+0.319). Thirty patients (83.33%) (31 vertebrae (77%)) underwent kyphoplasty and 6 patients (16.67%) (9 vertebrae (22.5%)) underwent vertebroplasty. Eleven patients (30.55%) with 11 vertebrae (26.4%) had complications and 2-tailed P-value=0.012. Ten of complications were intra-operative due to bone cement leak and one was 4 days post-operative due to aspiration pneumonia.

Anterior cement leak was seen in 3 patients (osteoporotic fractures) and lateral leak in 4 patients (2 osteoporosis+1 multiple myeloma+1 non-Hodgkin's lymphoma), which were considered open spaces (Figure 1). Intra-discal leak was seen in 1 patient (osteoporosis), intraspinal with paraparesis (type C according to ASIA classification) in 1 (osteoporosis) and small intravascular in 1 (osteoporosis), which were considered closed space. All of intra-operative complications were asymptomatic except the intraspinal cement leak was associated with paraparesis.

Aspiration pneumonia was life threatening complication, which ended with death, while the rest were not life threatening. All of the complications were untreatable or treatment were not needed (Table 2).

Group II included 40 patients with 355 vertebrae (average+SD=8.875+5.3). Four patients (10%) {15 vertebrae (4.22%)} underwent kyphoplasty and 24 patients (60%) {241 vertebrae (67.89%)} underwent vertebroplasty. Twelve patients (30%) {99 vertebrae (27.89%)} underwent both kyphoplasty and vertebroplasty {kyphoplasty=31 (8.73% of total vertebrae)} and vertebroplasty = 68 (19.16% of total vertebrae)}.

Twelve patients (30%) with 21 vertebrae (5.95%) developed complications, 2-tailed P-value=0.007. All complications were intra-



Figure 1: Lateral leakage of cement during kyphoplasty.



Figure 2: Intravascular leakage of cement during multi-level vertebroplasty.



Figure 3: Intraspinal leakage of cement.

Discussion

This is a prospective comparative study of complications of a few-level *versus* multi-level vertebroplasty and kyphoplasty procedures done at our institute during the period between December, 2014 and 2016. Most majority of previous studies mentioned complications of a few-level vertebroplasty and kyphoplasty patients, of whom most of them were asymptomatic [1-5]. We couldn't find any study at the literature discussing complications of multi-level vertebroplasty or kyphoplasty.

A Chotivichit, *et al.* found 88 (27%) complications of 325 vertebroplasty and kyphoplasty, which were done for 236 patients with 26 (8%) were symptomatic. Leakage of cement was found in 70 of 325 procedures (21.5%); intra-discal in 30 (42.8%), paravertebral in 22 (31.4%), intraspinal in 14 (28.6) and intravenous in 4 (5.7%) [2]. KaanYaltiric, *et al.* reported 7 complications of cement leak out of 175 segments of vertebroplasty and kyphoplasty (100 patients); 6 were intra-discal and asymptomatic and one intraspinal, which was symptomatic and needed surgery [12].

Cement leakage was found in 3 asymptomatic cases out of 14 cases of multi-level vertebroplasty and kyphoplasty used for multiple myeloma patients [11]. Ru XL, *et al.* reported 27 complications (15.1%) of 175 cases related to bone cement leakage and other complications in 15 cases as intraspinal hematoma, infection or fall in blood pressure [13]. Yohan Robinson, *et al.* treated 102 patients (135 segments) for osteoporotic fractures with kyphoplasty and found 7 asymptomatic cement leakage, one spondylitis and 11 adjacent fractures [14]. Most of complications except cement leakage are less common and most of them are case-reports or case-series [3-10].

Our results of group I was comparable with previous studies; 11

operative; included 10 bone cement leak, one Intracardiac cement embolus and bilateral pneumothorax in A chronic Obstructive Pulmonary Disease patient. Intravascular leak was seen in 6 patients (15 vertebrae) treated with Vertebroplasty (Figure 2). Intraspinal leak were seen in 2 patients (3 vertebrae) with paraparesis (type B according to ASIA classification) in one patient and anterior leak in 2 patients (3 vertebrae of kyphoplasty) (Figure 3). All cases of cement-leakage were asymptomatic except the intra-cardiac big embolus and right pulmonary artery embolus, which was associated cardiac perforation, pericardial tamponade and shock (Table 2).

All patients with asymptomatic cement-leakage didn't need treatment. The Intracardiac and right pulmonary artery emboli threatened the life and was treated with open heart and pulmonary vascular surgery. The complication of bilateral pneumothorax threatened the patient's life and was treated by bilateral chest for 4 days and discharged home at the 5th day.

Levene's test *P*-value <0.001. Mortality rate was same in 2 groups.

patients (30.55%) with 11 segments (26.4%) developed complications. The majority (25%) were due to cement leakage around the vertebral body one complication, (1.5%) was aspiration pneumonia that ended with death. Most of cement leakage didn't need treatment except intraspinal leakage, which underwent laminectomy and decompression as mentioned in previous studies.

In group II we found complications in 12 (30%) with 21 segments (5.95%) out of 40 patients with 355 segments. Most of complications were due to cement leakage; 6 patients with 15 segments (4.23%) were intravascular and 2 patients with 3 segments (0.85%) were intraspinal. None of previous studies discussed complications of multi-level vertebroplasty and kyphoplasty.

Both groups had nearly the same number and percentage of patients, who developed complications. The number of complicated segments of group I was 11 of 40, while that of group II was 21 of 355, Levene's test p -value was <0.001 . We believe the cause of cement leakage around the vertebral body was higher in group I was due to body cortical defect. In group II, vertebroplasty procedures were used more than kyphoplasty, in which vertebral cortices were mostly intact; intravascular leakage of cement was the majority of complications.

We found at our institute; to do multi-level vertebroplasty and kyphoplasty for a patient with multi-level pathology (osteoporosis, multiple myeloma, hemangioma, etc.) at the same time doesn't increase the risk of complications. The limitations of this study are the low number of patients, vertebroplasty were used more than kyphoplasty in multi-level group and we focused on early complications. Further studies are needed to clear this observation more.

Conclusion

Vertebroplasty and kyphoplasty (bone cement augmentation) are widely used to treat different pathologies of the vertebral body. Leakages of cement around the vertebral body and inside the vessels are the most common complications. General complications and cement remote emboli are rare. This comparison study of complications of a few-level *versus* multi-level vertebroplasty and kyphoplasty showed same number of patients of both groups and less percentage of levels in multi-level group, who developed complications.

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