

**CLINICAL OBSERVATION OF VERTEBROPLASTY AND
KYPHOPLASTY IN THE TREATMENT OF PATIENTS
WITH VERTEBRAL COMPRESSION FRACTURES
IN DUC GIANG HOSPITAL FROM 2015 TO 2018**

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Summary

Objectives: To investigate the clinical efficacy of cement augmentation procedures on patients diagnosed with vertebral compression fracture. **Subjects and methods:** A serial cross-sectional study on 66 patients (76 compressed vertebrae) who underwent vertebroplasty or kyphoplasty at Duc Giang Hospital from 2015 to 2018. The data on vertebral height and kyphosis angle was collected from patient records using a data collection checklist. We used the Oswestry Disability Index (ODI) for functional disability and the Visual Analog Scale (VAS) for pain severity. ODI and VAS were collected using face-to-face patient interviews. All data was recorded pre-operative, at the time of discharge from the hospital, one-month follow-up, three-month follow-up, six-month follow-up, 12-month follow-up, 18-month follow-up, and 24-month follow-up. **Results and conclusion:** The mean age of patients was 68.9 ± 10.3 (50 to 95 years old), and 14 (21.2%) were male. The most commonly affected vertebrae were L1 and T12. Thirty-one vertebrae (40.8%) were treated by kyphoplasty and 45 vertebrae (59.2%) were treated by vertebroplasty. The average vertebral height and Cobb angle had significant recovery ($p < 0.001$). Following cement augmentation procedures, VAS and ODI values decreased significantly in the 12-month follow-up compared to pre-operative levels ($p < 0.001$).

* *Keywords: Vertebral compression fracture; Vertebroplasty; Kyphoplasty; Clinical efficacy.*

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Date received: 15/6/2022

Date accepted: 28/6/2022

<http://doi.org/10.56535/jmpm.E20220527>

INTRODUCTION

The increase in the number of osteoporosis, trauma, and tumour cases, and the ageing population, has increased the incidence of vertebral compression fractures (VCFs). VCFs are considered the most common single osteoporotic fracture worldwide; they occur in 30 - 50% of people over 50[1]. Vertebroplasty involves the injection of cement into the vertebral body using a large-bore needle under fluoroscopic guidance via a transpedicular approach. Kyphoplasty is a modified vertebroplasty technique that allows the restoration of vertebral body height through an expandable balloon, and has rapidly gained popularity in the treatment of osteoporotic vertebral fractures. Several studies have confirmed the effectiveness of vertebroplasty and kyphoplasty in the treatment of VCFs [2, 3].

In Vietnam, during the last two decades, some publications reported the application of cement augmentation of the vertebral body [4, 5]. However, they generally focused on the osteoporosis-related VCF. Thus, this paper aims: *To investigate the clinical efficacy of cement augmentation procedures, including vertebroplasty and kyphoplasty, on patients diagnosed with vertebral compression fracture at Duc Giang Hospital from 2015 to 2018.*

SUBJECTS AND METHODS

1. Subjects

All patients were admitted to Duc Giang Hospital from 2015 to 2018 and underwent cement augmentation procedures (i.e., vertebroplasty, kyphoplasty).

* *Inclusion criteria:* Patients were more than 18 years old at the time of the study, had back pain corresponding to the compressed site, little or no response to treatment (at least for one month); and were diagnosed with vertebral body compression fracture (with or without a history of trauma); Pre-operative MRI showed the corresponding edema; the spinal cord was not compressed; patients consented to participate in the study.

Sampling method: All patients satisfied the inclusion criteria in the study.

2. Methods

* *Study design:* Serial cross-sectional study.

* *The procedure:*

These procedures were performed in the operating room under general anaesthesia. All patients were placed in the prone position, and a C-Arm scopy (X-ray) was positioned appropriately. A fractured vertebra was identified in both anteroposterior and lateral view

images. C- Arm was positioned for an anteroposterior view to visualize the pedicles of the affected vertebra. The procedures of vertebroplasty and balloon kyphoplasty have been well described previously. We adopted a bilateral approach for all patients in this study. Injected cement volume was recorded. After the procedure, all patients remained supine in bed for 24 hours.

** Key variables:*

We recorded the following key variables: The socio-demography characteristic of patients; pre-operative features of compressed vertebrae (e.g., location, anterior vertebral body height, posterior vertebral body height, middle vertebral body height, Cobb-angle), characteristics of the procedure (e.g., the volume of cement injection, size of needles, size of balloon in kyphoplasty), functional disability measured by the Oswestry Disability Index (ODI) and pain severity measured by the Visual Analog Scale (VAS).

** Data collection tools and methods:*

We developed a data collection checklist to collect data from patient records using. We used the Oswestry Disability Index (ODI) for functional disability and the Visual Analog Scale (VAS) for pain severity. The ODI and

VAS were collected using face-to-face patient interviews.

** Data analysis:*

SPSS 18.0 was used for the statistical analysis of the data. The paired t-test statistical test compares changes in treatment results over time for time-dependent variables such as before treatment - immediately after treatment, before treatment - 3 months after treatment, before treatment - 6 months after treatment, and before treatment - 12 months after treatment. The mean difference between the two quantitative independent variables was compared using an independent T-test. The Chi-square test was performed to compare the differences between categorical variables. The difference was statistically significant at 0.05 and 0.001).

RESULTS

Table 1 summarizes the general characteristics of included patients. The mean age of patients was 68.9 ± 10.3 (50 to 95 years old), and 14 (21.2%) were male. Almost all patients had one fractured vertebra being treated. 95.5% of patients completed the 3-month follow-up interview, and only 18.2% of patients completed the 24-month follow-up interview.

Table 1: Baseline characteristics of 76 patients who underwent cement augmentation procedures.

Characteristics of patients		Both		Male		Female	
		n	%	n	%	n	%
Age group	≤ 59	25	14.5	6	15.8	19	14.1
	60 - 69	62	35.8	13	34.2	49	36.3
	70 - 79	48	27.7	10	26.3	38	28.1
	≥ 80	38	22.2	9	23.7	29	21.5
Marriage status	Have a spouse	59	89.4	13	92.9	46	88.5
	Widowed/divorced	7	10.6	1	7.1	6	11.5
Follow-up time	Pre-operative	66	100.0	14	100.0	52	100.0
	1-month follow up	63	95.5	13	92.9	50	96.2
	3-month follow up	63	95.5	14	100.0	49	94.2
	6-month follow up	58	87.9	13	92.9	45	86.5
	12-month follow-up	57	86.4	13	92.9	44	84.6
	18-month follow up	13	19.7	6	42.9	7	13.5
	24-month follow up	12	18.2	4	28.5	8	15.4
Height (in meter)	mean (SD)	1.55 ± 0.06		1.64 ± 0.04		1.53 ± 0.05	
	Min; Max	1.40; 1.70		1.55; 1.70		1,4; 1,70	
Weight (in kilogram)	mean (SD)	53.4 ± 8.3		59.9 ± 6.8		51.7 ± 7.8	
	Min; Max	35; 72		49; 70		35; 72	
Hospitalization day	Mean (SD)	10.1 ± 4.2		10.7 ± 4.9		10.0 ± 4.1	
	Min; Max	4.0; 28.0		4.0; 25.0		4.0; 28.0	
Number of treated vertebrae	1	57	86.4	13	92.9	44	84.6
	2	8	12.1	1	7.1	7	13.5
	3	1	1.5	0	0.0	1	1.9

Table 2 details the characteristic of compressed vertebrae treated by the cement augmentation procedure. 76 vertebrae were treated. The most common fractured vertebrae were T12 and L1. The most common fracture type was wedge fracture (72.4%). According to Genant classification of severity, 47.4% of vertebrae were

diagnosed as mild vertebral fractures, 38.2% of vertebrae were diagnosed as moderate fractures, and the rest of 18.4% of vertebrae were severe vertebral fractures. More vertebrae were treated with the vertebroplasty procedure (59.2%) than with kyphoplasty (40.8%). None of the common complications (i.e. cement leakage, subsequently fractured vertebrae, and other complications) was observed. The average cement volume injected was 3.02 ± 0.80 mL. The average cement penetration rate reached 80%, with 48.1% (± 12.7).

Table 2: Characteristics of compressed vertebrae and treatment procedure (n = 76 vertebrae).

Evaluation criteria		Both		Male		Female	
		n	%	n	%	n	%
Location of treated vertebrae	Thoracic (T8-T12)	33	43.4	4	5.3	29	38.2
	Lumbar (L1-L5)	43	56.6	11	14.5	32	42.1
Genant Classification	Mild (20 - 25%)	36	47.4	6	7.9	30	39.5
	Moderate (25 - 40%)	29	38.2	4	5.3	25	32.9
	Severe (> 40%)	11	14.5	5	6.6	6	7.9
Kannis Classification	Wedge fracture	55	72.4	13	17.1	42	55.3
	Biconcave fracture	14	18.4	1	1.3	13	17.1
	Crush fracture	7	9.2	1	1.3	6	7.9
Technique	Kyphoplasty	31	40.8	3	20.0	28	34.4
	Vertebroplasty	45	59.2	12	80.0	33	65.6
Syringe size	11 G	65	85.6	13	86.6	42	85.2
	13 G	11	14.4	2	13.4	9	14.8
Balloon size	15 mm	1	3.1	0	0.0	1	3.4
	20 mm	31	96.9	3	100.0	28	96.6
Intravertebral Pressure (mmHg)	Mean (SD)	15.4 ± 2.0		15.5 ± 0.6		15.4 ± 2.1	
	Min; Max	10.0; 20.0		15.0; 16.0		10.0; 20.0	
Cement volume (mL)	Mean (SD)	3.02 ± 0.80		3.12 ± 0.82		2.99 ± 0.79	
	Min; Max	2.0; 5.0		2.0; 4.5		1.5; 5.0	
Cement penetration rate	Mean (SD)	$48,1 \pm 12,7$		$50,8 \pm 10,2$		$47,3 \pm 13,2$	
	Min-max	20,0; 80,0		30,0; 65,0		20,0; 80,0	

All vertebrae experienced vertebral height restoration and kyphosis correction before being discharged compared to pre-operative (Table 3). Indeed, anterior vertebral body height significantly increased from 19.75 ± 3.29 mm pre-operative to 23.61 ± 2.03 mm before being discharged and remained at 23.09 ± 1.99 mm 12-month follow-up ($p < 0.001$). Middle and posterior vertebral body height had more modest changes than the anterior wall. Cobb angle was also significantly improved after the cement augmentation procedure ($p < 0.001$).

Table 3: Vertebral height restoration and kyphosis angle correction after vertebroplasty and kyphoplasty.

Vertebral compress	Pre-operative (1)	Before discharged (2)	12-month follow-up (3)	p
Vertebral height restoration				
Anterior vertebral body height	19.75 ± 3.29	23.61 ± 2.03	23.09 ± 1.99	$p_{1,2} < 0.001$ $p_{1,3} < 0.001$
Middle vertebral body Height	22.68 ± 3.53	23.87 ± 2.21	23.90 ± 2.02	$p_{1,2} < 0.001$ $p_{1,3} < 0.001$
Posterior vertebral body height	27.0 ± 3.00	27.86 ± 1.86	27.70 ± 1.90	$p_{1,2} < 0.05$ $p_{1,3} < 0.05$
Kyphosis correction				
Cobb angle	15.43 ± 1.99	$7,99 \pm 2.08$	8.11 ± 2.02	$p_{1,2} < 0.001$ $p_{1,3} < 0.001$

Figure 1 shows the proportion of vertebral height improvement. Indeed, in the kyphoplasty group, there were more vertebrae gained a significant improvement in height restoration (51.6%) than that of the vertebroplasty group ($p < 0.001$).

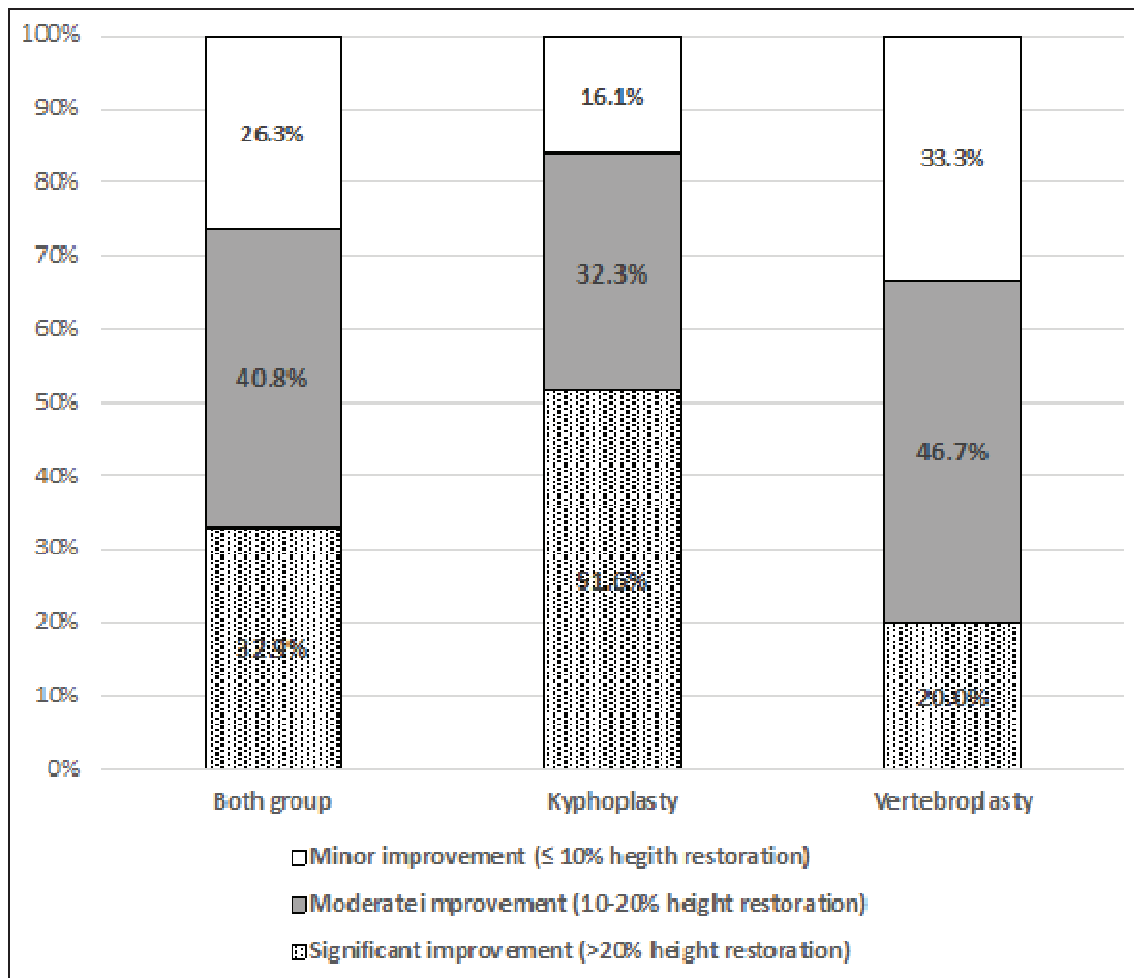


Figure 1: Observation of clinical efficacy of kyphoplasty and vertebroplasty in restoring vertebral height (pre-operative and before discharged from the hospital).

Table 4 showed the significant improvement in VAS and ODI scores after cement augmentation in all patients ($p < 0.001$). The mean VAS score pre-operatively of 8.41 was reduced to 2.9 before being discharged and gradually decreased after treatment (Figure 2). ODI scores also declined from 81.8 pre-operatively to 20.4 at 12-month follow-up.

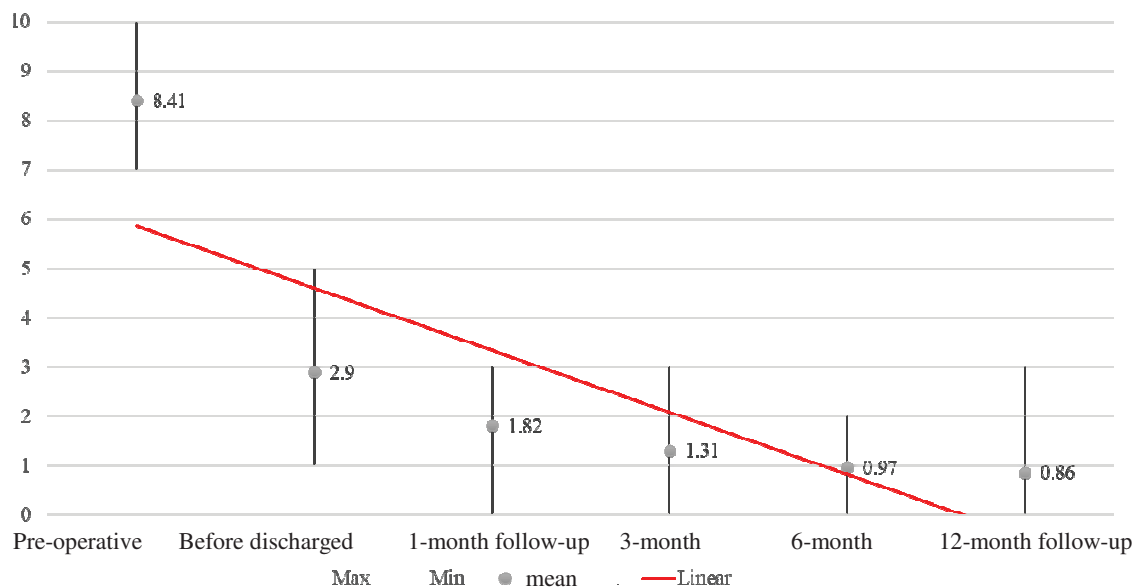


Figure 2: VAS scores pre-operative and follow-up.

Table 4: Improvement in VAS and ODI scores after cement augmentation procedure.

Score	Pre-operative (1)	Before discharged(2)	3-month follow-up(3)	12-month follow-up(4)	p
VAS	8.41	2.9	1.31	0.86	p1,2; p1,3; p1,4 < 0.001
ODI	81.8	46.3	22.3	20.4	p1,2; p1,3; p1,4 < 0.001

* Paired T-test.

DISCUSSION

In our study, almost patients were treated with one fractured vertebra (57 patients, accounting for 86.4% of the total patient). Only eight patients (12.1%) and one case were treated for 2 and 3 vertebrae. In other countries, the trend of simultaneous treatment of

three vertebrae in the same patients is not rare. For example, Meirhaeghe et al. (2013) reported that 10.1% of the patients were treated for three vertebrae at the same time [6]. In Vietnam, the cost of treatment might be the main barrier for the patients and the doctors to treat more than two vertebrae simultaneously.

The volume of cement injected in our study was 3.0 mL. This volume was lower than the previous study by Do Manh Hung (2018), with a cement volume of 6.1 mL. It was similar to other research by Bozkurt (2014), with the cement volume of 2.9 mL among the vertebroplasty group and 3.0 mL among the kyphoplasty group [7]. Several authors concluded that the volume of cement injected is not significantly associated with the clinical outcome of vertebroplasty and kyphoplasty in treating VCFs [8].

Vertebroplasty and kyphoplasty are accepted treatment modalities for osteoporotic, malignant, and traumatic spinal fractures. Good clinical outcomes have been previously reported for vertebroplasty and kyphoplasty in treating painful VCFs. As in other studies, both vertebroplasty and kyphoplasty achieved satisfactory clinical outcomes, providing pain relief and improvement in the quality of life after surgery. There was no apparent difference between the two procedures observed in our study. In our research, 31 fractured vertebrae were treated with kyphoplasty (40.8%), and 45 fractured vertebrae were treated with vertebroplasty (59.2%). In our study,

we did not observe any case of cement leakage after the surgery in both groups. There was also no other complication and subsequent fractures. Several authors still reported that kyphoplasty might have advantages in minimizing cement leakage and stabilising the vertebrae shape over a longer period. However, kyphoplasty might be more invasive, have more extensive anaesthesia, and induce higher costs. As mentioned above, the higher cost of treatment may limit the patients' choice of vertebroplasty. Thus, all the above information should be well provided for patients to support them in making a treatment decision, taking all possible advantages and disadvantages of the two techniques into account.

Our study showed that the height of the fractured vertebrae had a significant improvement before being discharged from the hospital and after a 12-month follow-up. The difference in the height of the anterior, medial, and posterior walls of the collapsed vertebra was statistically significant before and after surgery. There is a wide variant of the average height of the fractured vertebrae's anterior, middle and posterior walls among studies. For example,

Do Manh Hung (2008) reported a lower anterior wall (14.3 mm compared to 19.75 mm in our study), middle wall (13.3 mm compared to 22.68 in our study) and posterior wall (21mm compared to 27.00 mm in our study). Wang (2021) reported a higher level of the anterior wall (20,95 mm compared to 19,75 mm in our study). These differences are understandable because of the different distribution of vertebrae, differences in severity, types of fractures, other racial characteristics, and time of the study (that affect the nature height of vertebrae).

Despite all of the differences, the level of vertebral height restoration in our study is similar to other studies. Indeed, the degree of restoration of anterior wall height in our study and that of author Do Manh Hung before and after the surgery was 3.86 mm, and 4.1 mm, respectively. However, some studies show a more modest vertebral height. For example, the restoration of the middle wall of the collapsed vertebra in Noriega's study (2019) is 1.14 mm after six months and 1.31 mm after 12 months.

Our study also showed that the average recovery rate of collapsed vertebrae height was $16.63 \pm 9.24\%$.

Vertebrae in the kyphoplasty group had an average height recovery rate of $19.98 \pm 9.83\%$, higher than that of the vertebroplasty group ($14.32 \pm 8.14\%$) (statistically significant). This partly shows the advantage of kyphoplasty (bilateral approach) in restoring collapsed vertebral height.

In our study, the Cobb angle significantly decreased from 15.43 ± 1.99 degrees to 7.91 ± 2.28 degrees, 7.99 ± 2.08 degrees. This improvement was maintained even up to 12 months post-operation. These results are pretty similar to other studies in Vietnam [5] and other countries. For example, Bai M (2017) reported the change of Cobb angle from 19.7 degrees before surgery to 3.6 degrees right after surgery and 4.2 degrees after three months [9].

In our study, we found a statistically significant difference ($p < 0.001$) between the mean VAS scores of the patients at the time of follow-up. Before surgery, the average VAS score was 8.41 ± 0.68 . Right before discharge, the VAS score dropped to only 2.90 ± 0.88 . After one month, three months, 6 months and 12 months of follow-up, the VAS score was only 1.82 ± 0.90 ; 1.31 ± 0.95 ; 0.97 ± 0.82 and 0.86 ± 0.85 , respectively. Similarly,

the rate of spinal function loss measured by the ODI scale pre-operatively was 81.8%, reduced to only 46.3% right after, 22.3% after three months, and 20.4% after 12 months of surgery ($p < 0.001$). A downward trend in VAS and ODI scores was also observed in other studies [6, 10]. However, we did not find a statistically significant difference in pain relief and physical function between vertebroplasty and kyphoplasty. Factors related to pain reduction for patients need to be studied more carefully in the future in order to identify the predictors that could help health care providers in better pain control for the patient.

CONCLUSION

This study confirmed the clinical efficacy of vertebroplasty and kyphoplasty in vertebral height restoration and kyphosis correction, providing pain relief and improved quality of life after surgery. Although there was no apparent difference between the two techniques, kyphoplasty was related to more cases with significant improvement in vertebral height (i.e., vertebral height restoration was more than 20%), but also associated with higher cost. Evidence from this study

could support doctors and patients in making treatment decisions, taking all possible advantages and disadvantages of the two techniques into account.

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