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# EVALUATION OF SATISFACTION WITH A QUESTIONNAIRE ACCORDING TO FRACTURE LEVEL AND FRACTURE TYPE OF PATIENTS WHO UNDERWENT BALLOON KYPHOPLASTY

Yiğit Kültür[1], Emre Bal[2], Mehmet Nuri Erdem[3], Mehmet Tezer[4]

[1]Taksim Training and Research Hospital, Clinic of Orthopedics and Traumatology, İstanbul, Turkey
[2]Fatih Sultan Mehmet Training and Research Hospital, Clinic of Orthopedics and Traumatology, İstanbul, Turkey
[3]Feyziye Schools Foundation Işık University, Vocational School of Health Services, Department of Operating Room Services, İstanbul, Turkey
[4]Nişantaşı Orthopaedic Center, İstanbul, Turkey

ABSTRACT

**Objective:** The aim of this study is to better understand which type of fracture and localization have more painful or worse outcomes for the kyphoplasty procedure.

**Materials and Methods:** Kyphoplasty cases operated between 2013 and 2018 were included in the study. The patients were contacted through the numbers registered in the hospital system. A questionnaire were asked to the patients. Patients were grouped according to gender, fracture level (T12-L1 and others) and fracture type (Osteoporotic, trauma, malignancy, unknown).

**Results:** Fourty-one patients were included in the study. Three-quarters of the patients were women and average age was 62. Ninety-two percent of the patients stated that the pain of the procedure was tolerable. Seventy percent reported that their pain decreased after the procedure and 75% of the patients stated that they could have this procedure done again. Pain reduction and the desire to have same surgery again were significantly higher in female patients than in the male group ($p<0.05$). In the T12-L1 group and osteoporotic fracture group, the procedure was more easily tolerated, the pain was relieved more and the desire to have the same surgery was higher ($p<0.05$).

**Conclusion:** Kyphoplasty is accepted as an operation that is well tolerated by patients and has good pain relief. Additionally more detailed information was obtained about the patient's complaints after the kyphoplasty procedure, according to the fracture level and type.

**Keywords:** Kyphoplasty, questionnaire, vertebroplasty, vertebra, fracture

## INTRODUCTION

Osteoporosis is a disease of decreased bone density associated with an increased risk of fractures. The most common fractures among osteoporotic fractures are osteoporotic vertebral compression fractures (OVCF). It is also well known that trauma and malignancies can cause compression fractures. The prevalence of OVCF worldwide is between 1.4% and 2.6%[1]. Severe acute or chronic pain may occur after vertebral compression fractures and may affect the quality of life of the person[2]. If more than one segment is affected, short stature and kyphosis can be seen. The goals of OVCF treatment are to reduce the individual's pain, restore vertebral height and angular deformity causing kyphosis. Generally, the approach in the treatment of OVCF is conservative treatments, surgical open procedures and percutaneous minimally invasive procedures. In conservative treatment, after short-term bed rest, the patient is mobilized with an external orthosis; however, the duration of bed rest is prolonged in elderly patients. Pressure ulcers, urinary system infections, vertebral fractures associated with progressive decrease in bone mineral density, malnutrition due to decreased abdominal volume, venous thromboembolism and pulmonary complications can be seen due to the increase in immobilization time. Therefore, surgical or percutaneous minimally invasive treatment procedures should be considered in patient groups suitable for surgery[3,4].

Although it has similar aspects with vertebroplasty, kyphoplasty, which is a very different procedure, was first applied in 1998[5]. Unlike vertebroplasty, cement is injected after the cavity is created with an expandable balloon. High-density cement and trabecular bone around the impacted cavity are thought to prevent cement leakage. While vertebroplasty is mostly applied unipedicularly, kyphoplasty is applied bipedicularly[6].

The aim of this study is to better understand which type of fracture and localization have more painful or worse outcomes for the kyphoplasty procedure.

**Address for Correspondence:** Yiğit Kültür, Taksim Training and Research Hospital, Clinic of Orthopedics and Traumatology, İstanbul, Turkey
**Phone:** +90 538 335 77 06 **E-mail:** yigitkulturr@hotmail.com **Received:** 23.12.2021 **Accepted:** 08.04.2022
**ORCID ID:** orcid.org/0000-0001-8201-6994

## MATERIALS AND METHODS

Kyphoplasty cases operated between 2013 and 2018 were included in the study. Procedures were performed under general anesthesia. Inclusion criteria; age over 50 years old, having a recently vertebra compression fracture, no spinal cord injury or pedicle fracture and pain without radiculopathy. Vertebral compression fracture was detected by X-ray computed tomography magnetic resonance and confirmed by clinical examination. Informed consent was obtained from the patients. Ethics committee approval was obtained from the İstanbul Yeni Yüzyıl University, Science, Social and Non-Interventional Health Sciences Research Ethics Committee (no: 2022/02-811).

Patients who died, patients with spinal canal compression or stenosis greater than 30% of canal diameter, patients with spinal cord injury or cauda equina syndrome and patients with local/systemic infections were excluded from the study.

The patients were contacted through the numbers registered in the hospital system. A 3-question questionnaire was asked to the patients[7]. Patients who did not respond in 3 calls were excluded from the study.

We evaluated our patients in 2 groups as T12/L1 (the most common fracture levels in the spine[8,9] and other levels). We also evaluated according to fracture type (osteoporotic, trauma, malignancy, cause unknown) and gender.

### Statistical Analysis

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) program was used for statistical analysis. While evaluating the study data, chi-square analysis was used to determine the relationship between qualitative data as well as descriptive statistical methods (Mean, Standard Deviation, Median, Frequency, Ratio, Minimum, Maximum). Significance was evaluated at $p<0.01$ and $p<0.05$ levels.

## RESULTS

Fifty-six patients who met the inclusion criteria were identified. Five patients refused to participate in the study. Ten patients could not be reached. Questionnaires were asked to the remaining 41 patients. While 75.6% (n=31) of the participants were female, 24.4% (n=10) were male. The age ranges were 55-76 and the mean age was 62. Type of fracture of the participants were 63.4% (n=26) osteoporotic, 14.6% (n=6) trauma, 9.8% (n=4) malignant and 12.2% (n=5) type of unknown (Table 1). Cement injection into the fracture is a tolerable procedure for 92.7% (n=38) of the participants, while 7.3% (n=3) is not. While the pain disappeared in 70.7% (n=29) of the participants after the injection, 9.8% (n=4) pain did not decreased and slightly decreased 19.5% (n=8). While 75.6% (n=31) of the participants wanted to have the same surgery again, 14.6% (n=6) were not sure and 9.8% (n=4) did not want it (Table 2). Fracture levels are shown in Table 3.

There was no correlation between gender and the tolerability of cement injection into the fracture ($p>0.05$).

A relationship was found between gender and pain relief after injection. The number of female who said yes was higher than that of male. ($p=0.001$; $p<0.01$). The number of female who said somewhat was lower than that of male. ($p=0.001$; $p<0.01$).

A relationship was found between gender and wanting to have the same surgery again. Female patients were more willing to have the same surgery again ($p=0.023$; $p<0.05$). The group that says I'm not sure; Female patients were less than male ($p=0.001$; $p<0.01$) (Table 4).

A statistically significant correlation was found between the fracture level and the tolerability of cement injection into the fracture ($p=0.021$; $p<0.05$). Those who say "yes the procedure is tolerable"; It was found to be high in the T12-L1 group ($p=0.001$; $p<0.01$).

**Table 1.** Demographic data of the study

| | | N | % |
|---|---|---|---|
| **Gender** | **Female** | 31 | 75.6 |
| | **Male** | 10 | 24.4 |
| **Type of Fracture** | **Osteoporotic** | 26 | 63.4 |
| | **Trauma** | 6 | 14.6 |
| | **Malignancy** | 4 | 9.8 |
| | **Unknown** | 5 | 12.2 |
| **Level of Fracture** | **T12-L1** | 29 | 70.7 |
| | **Other levels** | 12 | 29.3 |

**Table 2.** Baloon kyphoplasty questionnaire

| | | N | % |
|---|---|---|---|
| **Is cement injection to the fracture a tolerable process?** | **Yes** | 38 | 92.7 |
| | **No** | 3 | 7.3 |
| **Did your pain ease after injecting cement into your fracture?** | **Yes** | 29 | 70.7 |
| | **No** | 4 | 9.8 |
| | **Somewhat** | 8 | 19.5 |
| **Would you want to be if we offered the same surgery again?** | **Yes** | 31 | 75.6 |
| | **No** | 4 | 9.8 |
| | **I'm not sure** | 6 | 14.6 |

**Table 3.** Fracture levels

| | |
|---|---|
| T8 | 2 |
| T9 | 1 |
| T10 | 2 |
| T11 | 1 |
| T12 | 17 |
| L1 | 12 |
| L2 | 4 |
| L3 | 1 |
| L4 | 1 |

A correlation was found between fracture level and pain relief after injection (p=0.001; p<0.01). Those who say yes; It was found to be high in the T12-L1 group (p=0.001; p<0.01). In patients who say no and somewhat; T12-L1 group was found to be lower than the other levels group (p=0.001; p<0.01).

A relationship was found between the fracture level and the desire to have the same surgery again (p=0.001; p<0.01). The group that said yes; T12-L1 group were higher than the other group (p=0.001; p<0.01). The group that said no and I'm not sure; T12-L1 group were lower than the other (p=0.001; p<0.01) (Table 5).

A correlation was found between the type of fracture and the tolerability of cement injection into the fracture (p=0.003; p<0.01). The group that said "yes the procedure is tolerable"; Osteoporotic group was higher than the malignancy group (p=0.001; p<0.01).

A relationship was found between type of fracture and pain relief after injection (p=0.001; p<0.01). The group that said yes; Osteoporotic group was higher than the trauma and malignancy groups (p=0.001; p<0.01). The group that says somewhat; Osteoporotic group was lower than the trauma and malignancy groups (p=0.001; p<0.01) and trauma group was higher than the groups of unknown (p=0.001; p<0.01). A correlation was found between the type of fracture and the desire to have the same surgery again (p=0.001; p<0.01). The group that said yes; Osteoporotic group was higher than the trauma and malignancy groups (p=0.001; p<0.01). The group that says I'm not sure; The trauma group was found to be higher than the osteoporotic group (p=0.001; p<0.01) (Table 6).

## DISCUSSION

It has been stated in some previous studies that the most common vertebral fractures are in T12 and L1[8-10]. For this reason, we aimed to compare the most common fractures with less frequently seen fractures in order to evaluate the outcomes of kyphoplasty procedure in terms of patient satisfaction. As far as we know, there is no study comparing T12 and L1 with other vertebras. Likewise, we did not find any comparison between

**Table 4.** Relationship between gender and questions

| | | Gender | | p |
|---|---|---|---|---|
| | | Female | Male | |
| **Is cement injection to the fracture a tolerable process?** | **Yes** | 28 (73.7%) | 10 (26.3%) | 0.422 |
| | **No** | 3 (100%) | 0 (0%) | |
| | | Female | Male | |
| **Did your pain ease after injecting cement into your fracture?** | **Yes** | 25a (86.2%) | 4b (13.8%) | **0.001**** |
| | **No** | 4a (100%) | 0a (0%) | |
| | **Somewhat** | 2a (25%) | 6b (75%) | |
| | | Female | Male | |
| **Would you want to be if we offered the same surgery again?** | **Yes** | 25a (80.6%) | 6a (19.4%) | **0.023*** |
| | **No** | 4a (100%) | 0a (0%) | |
| | **I'm not sure** | 2a (33.3%) | 4b (66.7%) | |

Chi-square test, **p<0.01

**Table 5.** Relationship between fracture level and questions

| | | Level of Fracture | | p |
|---|---|---|---|---|
| | | T12-L1 | Other levels | |
| **Is cement injection to the fracture a tolerable process?** | **Yes** | 29a (76.3%) | 9b (23.7%) | **0.021*** |
| | **No** | 0a (0%) | 3b (100%) | |
| | | T12-L1 | Other levels | |
| **Did your pain ease after injecting cement into your fracture?** | **Yes** | 27a (93.1%) | 2b (6.9%) | **0.001**** |
| | **No** | 1a (25%) | 3b (75%) | |
| | **Somewhat** | 1a (12.5%) | 7b (87.5%) | |
| | | T12-L1 | Other levels | |
| **Would you want to be if we offered the same surgery again?** | **Yes** | 28a (90.3%) | 3b (9.7%) | **0.001**** |
| | **No** | 1a (25%) | 3b (75%) | |
| | **I'm not sure** | 0a (0%) | 6b (100%) | |

Chi-square test, **p<0.01

**Table 6.** Relationship between fracture type and questions

| | | Type of fracture | | | | p |
|---|---|---|---|---|---|---|
| | | Osteoporotic | Trauma | Malignancy | Unknown | |
| **Is cement injection to the fracture a tolerable process?** | **Yes** | 26a (68.4%) | 5a, b (13.2%) | 2b (5.3%) | 5a, b (13.2%) | **0.003*** |
| | **No** | 0a (0%) | 1a, b (33.3%) | 2b (66.7%) | 0a, b (0%) | |
| | | Osteoporotic | Trauma | Malignancy | Unknown | |
| **Did your pain ease after injecting cement into your fracture?** | **Yes** | 23a (79.3%) | 1b (3.4%) | 0b (0%) | 5a (17.2%) | **0.001**** |
| | **No** | 2a (50%) | 0a (0%) | 2a (50%) | 0a (0%) | |
| | **Somewhat** | 1a (12.5%) | 5b (62.5%) | 2b, c (25%) | 0a, c (0%) | |
| | | Osteoporotic | Trauma | Malignancy | Unknown | |
| **Would you want to be if we offered the same surgery again?** | **Yes** | 24a (77.4%) | 2b, c (6.5%) | 0c (0%) | 5a, b (16.1%) | **0.001**** |
| | **No** | 2a (50%) | 0a (0%) | 2a (50%) | 0a (0%) | |
| | **I'm not sure** | 0a (0%) | 4b (66.7%) | 2b (33.3%) | 0a, b (0%) | |

Chi-square test, **p<0.01

fracture types (Osteoporotic, trauma, malignancy, unknown) in patients who underwent kyphoplasty.

In the T12-L1 group and osteoporotic fracture group, the procedure was more easily tolerated, the pain was relieved more and the desire to have the same surgery was higher in our study. Some previous studies have compared lumbar and thoracic fractures[11,12]. Better functional scores and less pain were found in thoracic fractures. This was probably because of thoracic fractures are less problematic due to the stability of the rib cage.

Some studies about back pain have found that female consistently report more functional limitations and physical disability and slower recovery from disability than male patients[10,13,14]. Factors contributing to higher reporting of functional disability in osteoporotic vertebra fracture were attributed to the higher incidence of spinal stenosis, degenerative spine diseases, osteoarthritis and chronic joint pain in female[10]. However, since these studies were conducted with patients with low back pain who did not undergo surgery, they do not provide us with data on patients who underwent kyphoplasty. In our study pain reduction and the desire to have same surgery again were significantly higher in female patients than in the male group.

In a multicenter, randomized, double-blind, placebo-controlled study comparing OVCF younger than 6 weeks, it was proven that vertebroplasty has a higher pain relief effect than placebo[15]. Although vertebroplasty is a minimally invasive method, it can cause morbidity and even death in patients due to many complications that may develop during application. Many studies have reported that complications such as radicular pain, paralysis, and cement leaks resulting in death have developed in vertebroplasty surgery[16-18]. Balloon kyphoplasty has been introduced to minimize these disastrous consequences of vertebroplasty. Although the pain relief effect of kyphoplasty and vertebroplasty appeared to be similar, it was observed that kyphoplasty provided better kyphosis angle correction and better restored vertebral height[19]. When patients who underwent kyphoplasty and followed conservatively were compared, it was seen that kyphoplasty was better in improving quality of life, reducing pain, and helping the patient mobilization[20].

In our study, it was determined that the kyphoplasty procedure was successful in relieving the pain of the patients. Most of the participants answered "yes" to the question "Would you accept if we recommend same surgery again?" At the same time, most of the patients stated that the pain felt during the kyphoplasty procedure was tolerable.

### Study Limitations

One of the limitation of our study was that pain assessment was not done with scoring systems such as the visual analog scale or oswestry disability index. Other limitation was that we did not compare the assessment of patient satisfaction with the radiological results. However, the main purpose of this study was to evaluate patient-centered outcome data.

## CONCLUSION

Kyphoplasty is accepted as an operation that is well tolerated by patients and has good pain relief. Additionally more detailed information was obtained about the patient's complaints after the kyphoplasty procedure, according to the fracture level and type of fracture.

### Ethics

**Ethics Committee Approval:** Ethics committee approval was obtained from the İstanbul Yeni Yüzyıl University, Science, Social and Non-Interventional Health Sciences Research Ethics Committee (no: 2022/02-811).

**Informed Consent:** Informed consent was obtained from the patients.

**Peer-review:** Internally and externally peer-reviewed.

**Authorship Contributions**

Surgical and Medical Practices: Y.K., E.B., M.N.E., M.T., Concept: Y.K., E.B., M.N.E., M.T., Design: Y.K., E.B., M.N.E., M.T., Data Collection or Processing: Y.K., E.B., M.N.E., M.T., Analysis or Interpretation: Y.K., E.B., M.N.E., M.T., Literature Search: Y.K., E.B., M.N.E., M.T., Writing: Y.K., E.B., M.N.E., M.T.

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