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Research Article

The Influence of Pharmacological Osteoporosis Treatment on Refractures Following a Kyphoplasty

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Abstract

The aim of this study was to examine the relationship between pharmacological osteoporosis treatments on the refracture rate in patients who have had a thoracic or lumbar level Kyphoplasty. A Kyphoplasty is a non-invasive vertebral augmentation surgery used to treat compression fractures. A single center observational cohort study with 192 patients who had Kyphoplasty from 2015 until 2019 was conducted. The cohort was divided into two main groups with a 1:1 ratio. A Chi Square Independence Test, a 2 tailed 2 sample difference of proportions Z-test, and a confidence interval were used to analyze the data. The Chi Square Independence Test suggested a strong dependent relationship between pharmacological osteoporosis treatment and the refracture rate following kyphoplasty and determined significance in data. In addition, by taking pharmacological treatment, the patient has 13.54 percentage points to reduce the refracture rate to 0 compared to when patients were not taking medication. This study gave physicians a treatment method to reduce the chance of patients having recurrent fractures due to a Kyphoplasty. Thus leading to far less future kyphoplasty procedures.

Keywords: Bone transport; Chronic osteomyelitis; External fixator; Femoral defect

Introduction

In the United States, 1.5 million fractures due to osteoporosis occur every year and 50% of those are vertebral fractures [1]. Osteoporosis is a chronic disease that causes reduction in bone density and bone mass. A Dual Energy X-ray Absorption (DEXA) scan or Bone Mineral Density (BMD) scan are used to measure the progression of osteoporosis [1]. Compression fractures are considered osteoporotic fractures [2]. Most patients are automatically diagnosed with osteoporosis after they have compression fracture due to compression fracture being osteoporotic in nature. A kyphoplasty is a minimally invasive vertebral augmentation surgery that is used to treat compression fractures, with other treatment methods for compression fractures include bracing, pharmacological treatment, and physical therapy [2]. A Kyphoplasty allows for restoration of height and stability to the affected vertebrae which results in back pain relief and correction of poor posture in patients who have a compression fracture [3].

The main post-operative complication that occurs due to a Kyphoplasty is refracturing at adjacent levels to the initial procedure [3,4]. Refracturing in this study is defined as having at least one future osteoporotic compression fracture which requires an additional kyphoplasty.

Currently, the understood mechanisms that cause the recurring fractures are due to the cement that is inserted into the specific vertebrae causing increased stiffness which can lead to increased levels of strain and stress on the adjacent levels or the cement leaking from the vertebrae [2,3]. According to Fribourg et al., there is a 3 to 29% chance of recurring fractures after the initial Kyphoplasty procedure [5]. Other studies have found similar results for fractures rates. Eck et al. found a 14.1% refracture rate [6]. Levy et al. found refractures rates at 18.1% in a surgical-only treatment group and at 32.5% in a medical plus surgical treatment group [7].

The lack of preventive medicine in regards to the refracturing is one of the main reasons for why patients are having multiple Kyphoplasty procedures. The focus on creating a preventive treatment plan post initial Kyphoplasty is needed in order to reduce refracture rates. According to the National Osteoporosis Foundation, only 9% of female patients received a BMD test within 6 months of having an osteoportic fracture [8]. This means that patients are not getting tested for osteoporosis after having an osteoportic fracture.

Several studies are focusing on improving technical aspects

of the Kyphoplasty in order to decrease the refracture rate. According to a study by Iida et al., overcorrection during the Kyphoplasty procedure can cause adjacent fracturing to occur [2]. Surgeons tend to overcorrect the amount of cement or they make technical changes due to the severity of the compression fracture [2]. As a result, these overcorrections could lead to increased refracturing, thus leading to the necessity of further Kyphoplasty procedures [2].

Our single center observational cohort study focuses on examining the relationship between pharmacological osteoporosis treatment and the refracture rate in patients who have had a Kyphoplasty. We wanted to determine whether pharmacological osteoporosis treatment could impact the refracture rate in patients. We hypothesize that pharmacological osteoporosis treatment would reduce the refracture rate of patients after their initial Kyphoplasty procedure.

This would give physicians and patients a simple preventive treatment method to reduce recurrent fractures and the need for further Kyphoplasty procedures. In addition, this study can provide further insight as to why there is a recurrence in fractures.

Methods

A single center observational cohort study with 192 patients who had kyphoplasty from 2015 until 2019 was conducted. Patient information was collected through the electronic medical records software at the center. All patients who had at least one kyphoplasty from the center were included in the study with the exception of patients who were affected by bone metastasis and multiple myeloma. Patients whose compression fractures were successfully treated with bracing and nonoperative treatment methods were exempt from the study. Patients who were exempt from this study were not included in the 192 patient sample sizes. Demographic's did not play a role in determining patient group placement. Refracture rate was determined by the number of total fractures post the initial Kyphoplasty procedure.

The cohort was divided into two groups with a 1:1 ratio. The two groups were labeled Group I (pharmacological osteoporosis treatment) and Group II (no pharmacological osteoporosis treatment). Patients were placed in Group I based on their chart stating that they were prescribed osteoporosis medication. The classification of medication did not impact their placement. Patients in both Groups I and II were broken down into 2 further subgroups based on the number of refractures. Patients that had at least 1 subsequent fracture following the initial kyphoplasty procedure were labeled as "Post Kyphoplasty Refracture" (PKR), whereas those that didn't have a fracture subsequent to the initial kyphoplasty were categorized as "No Post Kyphoplasty Refracture" (NPKR). Patients who self-reported the intent to start osteoporosis treatment with their Primary Care Provider (PCP) and were placed in Group I based on the assumption that they were an Intended to Treat Group (ITT). Figure 1 depicts a flow chart of how patients were separated into their groups. A Chi Square Independence Test was done to determine the relationship between pharmacological treatment and refracture rate and to determine significance of data.

Figure 1: The flowchart showed the breakdown of the number of patients in each group and subgroup. Group I was the pharmacological treatment group. Group II was the no pharmacological treatment group. The PKR group (grey) was the post kyphoplasty refracture group and NPKR (red) was the no post kyphoplasty refracture group. The ITT group (orange) was an intended to treat group. Patients were placed in Group I or II based on their chart stating that they were prescribed pharmacological osteoporosis treatment. Patients were placed in the PKR group if they had at least one Kyphoplasty procedure after the initial. Patients were placed in NPKR if they didn't have any additional Kyphoplasty procedure after the initial one. Patients were placed in the ITT group based on their chart stating they would start pharmacological osteoporosis treatment with their Primary Care Provider.

Results

The sample size of the study was 192 patients (121 females and 71 males). The average age of the patient was 77 years. There was a significant reduction in the refracture rate between Group I and Group II (96/192, 96/192). Group I PKR showed a 20.8% refracture rate (20/96) versus a 34.4% refracture rate in Group II PKR (33/96). In Group I NPKR, 58% (44/76) of patients claimed to start pharmacological osteoporosis treatment with their PCP. These patients were part of the ITT population. In Group I, the ITT group (44/76) were the only patients who were lost to follow up. No patients in Group II were lost to follow up.

Figure 2 shows how taking pharmacological treatment allowed for a higher probability of not having a refracture. A Chi Square Independence Test was used to analyze the data. There was a reduction in the refracture rate (x^2=4.4045, p=0.036). The Chi Square Independence Test suggested a significant and strong dependent relationship pharmacological osteoporosis treatment and the refracture rate following kyphoplasty.

A 2 tailed 2 sample difference of proportions Z-test was done (p=0.036). The estimated proportion of Group I NPKR patients was 13.54 percentage points greater than Group II NPKR. With 95% confidence the proportion of patients who were in Group I NPKR is by at least 1.04 percentage points and at most 26.04 percentage points greater

than Group II NPKR. Since 0 is not in this interval, we conclude that the proportion from Group I is greater than Group II. The standard error was 0.0638 and the confidence interval at 95% was +/- 12.5 percentage points.

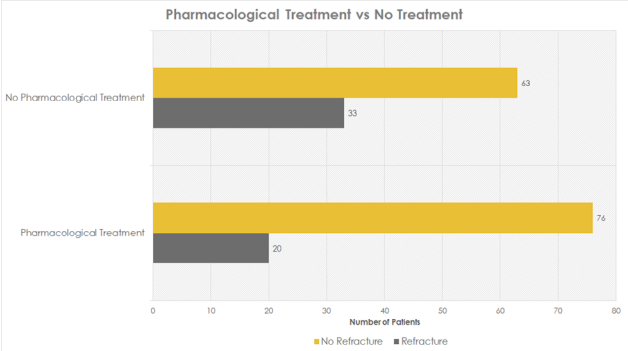

Figure 2: The red group is the refracture (PKR) group and the orange group is the no refracture (NPKR) group. The y-axis signified the number of patients in each group and the x-axis displayed the breakdown of the total number patients in each group. The graph showed that patients receiving pharmacological treatment had the greatest reduction in refractures. Group II NPKR and PKR differences were much smaller compared to Group I's.

Discussion

Currently, there are multiple understandings as to why the refracturing occurs due to a Kyphoplasty. One study indicates that the over correction by surgeons can cause this refracturing [2]. Other studies suggest that the stress and strain caused by the cement is impacting adjacent vertebrae thus leading to recurrent fracturing [3,4,5]. Instead of focusing on how to technically change the Kyphoplasty to reduce the number of refractures, our study suggests prescribing pharmacological osteoporosis treatment as a method to handle the main complication that comes with having a Kyphoplasty, naming refracture.

Our study suggested that there was a reduction in refractures following a Kyphoplasty in patients who had pharmacological osteoporosis treatment. Therefore, the results of our study determined a rejection of the null hypothesis. The Chi Square Independence Test suggested that there was a strong dependent relationship between pharmacological osteoporosis treatment and the refracture rate following a Kyphoplasty. This is clinically significant because it allows physicians to treat the recurrent fracture complication pharmacology rather than changing technical aspects of the procedure. In the past, changing technical aspects of the Kyphoplasty has resulted in an increase of refractures [2]. One study by Kao et al., focused on comparing whether taking oral or injected pharmacological osteoporosis treatment would reduce the refracture rate more [9]. They found that patients who were taking pharmacological treatment and who had a Vertebroplasty or Kyphoplasty resulted in less overall number of procedures [9]. However, the focus of their study was on which type of pharmacological osteoporosis treatment was more effective at reducing the number of overall procedures. Our study's support each other in that taking pharmacological treatment will reduce the number of refractures by demonstrating a reduction in the number of overall procedures [9].

The limitations of this study include the ITT group being lost to follow up, the lack of non Kyphoplasty treatment options being tracked, and that all patients analyzed in this study were from one center. A multicenter study could more accurately demonstrate how the patients placed in the ITT group truly affected the study.

Post-procedural treatment should include immediate action involving a DEXA scan to determine bone mineral density as well as pharmacological osteoporosis medication in order to reduce the chance of recurrent fractures due to the Kyphoplasty. Our study's results suggest that by starting pharmacological osteoporosis treatment after the initial Kyphoplasty, patients will be less likely to require additional Kyphoplasty procedures, thus saving the patient time, suffering, and money. The average admission cost of a Kyphoplasty is $ 18,000 with an average readmission rate due to recurrent fracturing at 14.5% [10]. If a patient has to have multiple Kyphoplasties due to refracturing or other reasons then their total medical costs would substantially increase. Our data suggests that by taking pharmacological treatment, the patient has 13.54 percentage points to reduce the refracture rate to 0 compared to when patients were not taking medication. This could result in reduction in medical expenditures. Further analysis and study of the potential cost saving by reduction in procedures needs to be done.

Conclusion

Our future studies will entail comparing the different classes of osteoporosis medications and seeing which type of pharmacological treatment works best at reducing the refracture rate. At this moment, there are a limited number of studies that compare pharmacological treatment to the refracture rate due to a Kyphoplasty. Other future studies should focus on increasing sample size and follow a similar procedure to our study in order to validate statistical significance. In summary, the data from this study can be used by physicians to create better preventive postoperative treatment plans and validates a physician's decision to order a DEXA scan and initiate osteoporosis therapy as early as possible.

Acknowledgement

There are no acknowledgements at this time.

Conflict of Interest

The authors declare that there are no conflicts of interest.

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