



EFFECT OF BISPHOSPHONATES ON FRACTURE HEALING AMONG THE ELDERLY PEOPLE WITH INTERTROCHANTERIC FRACTURE

Orthopedics

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ABSTRACT

Background: Hip fractures in the elderly are commonly associated with osteoporosis, and the surgical outcome is therefore influenced by its concurrent management. Understanding the role of the osteoporosis drug and its healing mechanism with the fracture is crucial for managing the fracture and osteoporosis properly. The purpose of our study is to determine whether bisphosphonate administration in stable intertrochanteric (IT) fractures helps in early fracture healing. **Aim:** The aim of the study is to assess the effect of bisphosphonates on intertrochanteric fracture among elderly people aged >50 years in preoperatively confirmed osteoporotic patients. **Methodology:** This is a non-randomized study done in the Department of Orthopaedics at Assam Medical College, Dibrugarh for a period of 1 year, from May 2021 to April 2022. The total sample size attained was 50, consisting of 25 patients in each group. Demographic details like age, sex, mean bone mineral density of hip and spine, and mean body mass index were obtained. The collected data was entered into MS Excel and statistics were done with SPSS 16. **Results:** Among the study participants, the majority were female: 15(60%) in the bisphosphonate group and 19(76%) in the control group; the rest were males. The mean age of the study participants was 56 ± 2.1 years. In both groups, fixation of the fracture was done by intramedullary nailing. The mean time difference in fracture healing between the two groups was not found to be significant. **Conclusion:** The mean healing time for the fracture healing was not found to be statistically significant when compared with the placebo group.

KEYWORDS

Bisphosphonates, Placebo, Healing, Fracture.

INTRODUCTION:

Femoral intertrochanteric fractures account for approximately half of the hip fractures in elderly patients. Because they are frequently associated with osteoporosis, they are often associated with notable morbidity and mortality (1). The co-existence of medical comorbidities, particularly osteoporosis, in a sizable proportion makes controlling these fractures the most difficult element. The estimated proportion of osteoporosis among the men is 20% and that of women is 50% (2). Osteoporosis is a silent disease that is diagnosed only at the time when a person presents with a fragile fracture(3)(4). This skeletal disease is defined by low bone mass and bone tissue microarchitecture deterioration, which increases both susceptibility and fragility to fractures(5). Thus, it is important for an orthopaedicians to initiate the screening for osteoporosis and treatment of the elderly person presenting with fractures.

To manage the fracture and the osteoporosis correctly, it is essential to understand the role of drugs and its healing mechanism in the fracture. These drugs generally act by counteracting bone resorption and promoting the formation of bone. Bisphosphonates decrease bone loss and improve bone strength by inhibiting osteoclast-mediated bone resorption. (6)(7)(8) However, osteoclasts play a critical role in the remodelling procedure required to convert the callus into the lamellar bone. As a result, usage of Bisphosphonates for fracture healing for the patients with osteoporosis still remains controversial. Thus, the main aim of our study is to find the effect of bisphosphonates on fracture healing in the intertrochanteric fracture among patients aged above 50 years.

METHODOLOGY:

A non-randomised control trial was conducted in the Department of Orthopaedics, Assam Medical College & Hospital, Dibrugarh for a period of one year from May 2021 to April 2022 in 50 patients Intertrochanteric fracture patients preoperatively confirmed as having osteoporosis by BMD and T score <-2.5 and not taken bisphosphonate prior to the fracture for past 2 years were included in the study.

Patients with chronic renal failure, Mental illness, Diseases affecting bone metabolism like Diabetes, Thyroid disorders, Rheumatoid arthritis, adrenal and renal insufficiency, Open fractures, unstable

fractures and Polytrauma patients were excluded from the study. After obtaining informed written consent, all the study subjects were evaluated by a thorough clinical history, physical examination, and appropriate investigations. Demographic information such as the patient's age, gender, fracture details, body mass index, and bone mineral density were collected.

The study participants were divided into two groups conveniently. One group of study participants starts receiving bisphosphonates within 2 days of the postoperative period, and the other group starts receiving placebo.

For the bisphosphonate group, an i.v. bisphosphonate (zoledronic acid) 5 mg per 100 ml infusion was given once in the postoperative period. The patients were routinely followed at 2 weeks, 6 weeks, 10 weeks, 16 weeks, and 6 months after surgery.

Statistical analysis:

After collecting the data, it was entered into MS Excel Windows 10. Statistical analysis was done in SPSS 23. Continuous data were expressed in terms of Mean $\pm$ Standard deviation and categorical variables were expressed in terms of numbers (percentages). P value of <0.05 is considered as significant.

RESULTS:

Table 1: Baseline characteristics of the two groups

Characteristics	Bisphosphonates group	Placebo group	P Value
Mean age	58.16 ± 4.32	58 ± 4.21	0.89
Sex			0.23
Male	10(40)	6(24)	
Female	15(60)	19(76)	
Mean body mass index (Kg/m ²)	26.12 ± 2.84	26.04 ± 2.89	0.92
Mean Bone Mineral density			<0.853
Hip	$3.04 \pm .28$	$3.36 \pm .20$	
Spine	$3.96 \pm .38$	$3.59 \pm .34$	

Type of Implant			0.24
Short Proximal femoral nail	14	18	
Proximal femoral antirotation nail	11	7	

Among our study participants, the mean age of Bisphosphonate group is 58.16 ± 4.32 years and that of the placebo group is 58 ± 4.21 years. Among the Bisphosphonate group (15) 60% and in the Placebo group 19 (76%) were females, followed by males. Thus female preponderance is observed in our study. For all the cases, intramedullary nailing was used in both groups. In Short proximal femoral nail (BP group -14 and Placebo group is 18) followed by proximal femoral antirotation nail (BP group - 11 and Placebo group is 7). The mean body mass index was found to be similar in both groups ranging from 26 to 30. The age, sex, mean body mass index, and mean bone mineral density were not found to be statistically significant.

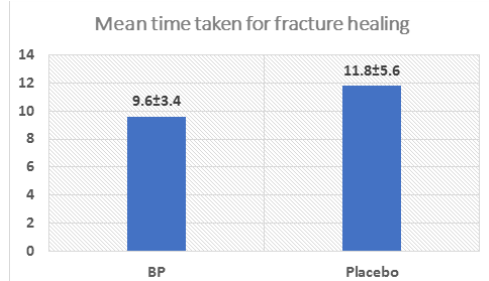


Figure 1: Mean time for fracture healing among both the groups

P Value 0.099

The mean time taken for fracture healing among the bisphosphonates group was less compared to the placebo group. But the difference is found to be not statistically significant.

DISCUSSION:

The dynamic process of fracture healing depends on bone formation and resorption. Bisphosphonates are widely used for Osteoporosis and metabolic bone diseases.

In older, osteoporotic people, hip fractures are significant causes of morbidity (9,10). It has been amply proven that BP plays a positive impact in lowering the risk of osteoporotic hip fractures(11).The treating surgeon must take into account the effects of Bisphosphonate in situations including changes in bone mineral density (BMD), fracture healing, and patient mortality. However, the research literature is still debatable in this regard.

The mean age of our study participants was found to be 58 ± 2.1 years. Female preponderance was noted, which is similar to Kim et al. study(12).The most common type of fracture is a stable fracture, and the most common implant used in our study was intramedullary nailing in both the groups .A similar result was also observed in the study conducted by Kim. In our study, we found a relatively lesser time of healing in the bisphosphonate group compared to the placebo group, but the difference was not found to be statistically significant.

The mortality due to hip fracture and its secondary fracture risk has been found to be reduced following bisphosphonate therapy among the elderly people. The optimal timing for the administration of the bisphosphonates remains unclear. In the study done by Odvina et al. (13), the results showed that study participants on long-term alendronate use had significant delayed healing of fracture.

The study done by Rozenenthal et al. (14)among the 43 patients with radial fracture compared with their 153 controls stated that the time taken for union was more in the BP group (55 days) compared to the control group (49 days). Health Outcomes and Reduced Incidence with Zoledronic Acid Once yearly (HORIZON) recurrent fracture trial was done by Eriksen et al. (15) to find whether early infusion time relates to the healing of fractures.

The results finally stated that administering zoledronic acid postoperatively increases the bone mineral density of the hip and reduces the fractures of the hip & vertebrae subsequently. Dirschl et al. (16) discovered that the loss of bone mass density of the femoral neck was five times greater than in the general population.

Kim et al.(12),Gong et al.(17) and Seo et al.(18) in their randomised

control trial stated that there is no difference found to be associated with the radiographic union between the treatment started in the early weeks or later.

Limitations:

The small sample size is one of the major limitations, which is not enough to assess the outcome of fracture healing. The patients taking bisphosphonates prior to surgery were excluded, so our results cannot be generalised. This study was a single-center study, so the implant suggestion is based on the availability and choice of surgeon. The follow-up period is very short, so we cannot find the complications as well as the long-term effects of the early initiation of the Bisphosphonates treatment.

CONCLUSION:

Thus, in our study, it is found that whether bisphosphonates are given in the early postoperative period, i.e., in the immediate post-op period or not given to the postoperative patient, there is no statistically significant difference noted in the radiological time taken for healing the fracture. The clinical data is also found to be insignificant for the early administration of bisphosphonates.

Recommendations:

Long term follow up studies have to be done to elicit the long term effect of bisphosphonates and to find the complications. Given the poor awareness and financial constraints, osteoporosis management often gets neglected in developing nations. Multi-centred studies have to be done to find the effectiveness of different types of bisphosphonates. None of the authors received funding for this study and there is no conflict of interest.

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