International Journal of Research in Orthopaedics
Santosha. Int J Res Orthop. 2017 Jul;3(4):805-808
http://www.ijoro.org

Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20172877

A comparative evaluation of intanasal salmon calcitonin and intravenous zolondrinic acid in the treatment of postmenopausal osteoporosis

Santosha*

Department of Orthopaedics, Shimoga Institute of Medical Sciences, Shimoga, Karnataka, India

Received: 27 February 2017
Revised: 13 June 2017
Accepted: 13 June 2017

***Correspondence:**
Dr. Santosha,
E-mail: santosh2ortho@gmail.com

ABSTRACT

Background: Osteoporosis is a progressive disorder of the bones which is characterized by reduction in bone mass and increased risk of fractures. Various drugs are available for the treatment of osteoporosis and prevention of osteoporotic fractures. Zolindronic acid and salmon calcitonin are the first line of therapy among these. The aim of the study was to compare the effectiveness intanasal salmon calcitonin and intravenous zolondrinic acid the treatment of postmenopausal osteoporosis
Methods: The study was conducted in the Department of Orthopaedics at a tertiary care centre from January 2015 to Jan 2017. One group received treatment with intravenous zolindronic acid 5mg administered as a single dose. Other group received a salmon calcitonin which was administered intranasally 100IU/day. Results were compared.
Results: Total 80 patients were included in the study. Forty patients were allotted to each group. Mean T score of BMD of the patients in the salmon calcitonin group before the start of study was -3.38 and mean T score of the patients in the zolindronic acid group was -3.4. Which improved to -1.9 and -1.49 for the calcitonin group and zolindronic acid treated group respectively.
Conclusions: Once yearly intravenous zolindronic acid is superior to intranasal salmon calcitonin in the treatment of post-menopausal osteoporosis.

Keywords: Osteoporosis, Bone mineral density, Osteopenia, Zolindronic acid, Salmon calcitonin, Postmenopausal

INTRODUCTION

Osteoporosis is a progressive disorder of the bones which is characterized by reduction in bone mass and increased risk of fractures. Until it is complicated by fractures, which can occur after trivial trauma, the condition remains asymptomatic. These fractures represent up to 80% of all fractures in menopausal women over 50 years of age.[1] Osteoporosis results in a huge medical burden on elderly individuals and results in a major economic toll on the healthcare system.[2] A literature review focusing on prevalence in various countries showed point estimates for femoral osteoporosis ranging from 7.9% to 16% in women 50 years or older.[3] The disease is characterized by low bone mineral density (BMD) and degeneration of the bone micro architecture, which increase the bone brittleness and fracture risk. The disease is identified clinically by the occurrence of non-traumatic fractures, especially in the lumbar spine (vertebral fractures) and forearm, and by the occurrence of femoral fractures after fall from height. The greatest loss of bone mass occurs in women during perimenopause and is associated with estrogen insufficiency, a condition of menopause.[4]

Diagnosis of osteoporosis uses data on below-normal BMD for young adults (T score). According to these criteria, bone densitometry with T score ≤-2.5, associated with fragility fractures, indicates established osteoporosis; T score ≤-2.5 alone, osteoporosis; T score from -1 to -2.5, osteopenia; and T score <-1, normal fractures due to osteoporosis can be prevented after early diagnosis.[4] Further, even after the first fracture has occurred, risk of further fractures can be decreased by appropriate treatment.[5] Various drugs are available for the treatment of osteoporosis and prevention of osteoporotic fractures. Hormone replacement therapy may inhibit bone loss; however, long-term use of hormone treatment may cause venous thrombo-embolism, coronary heart disease and stroke.[6-8]

Oral bisphosphonates, first-line therapy for most patients with osteoporosis, are associated with suboptimal adherence to therapy due to factors that include a complex dosing regimen and gastrointestinal intolerance in some patients. Intravenous bisphosphonates address these limitations through infrequent injectable dosing that assures 100% bioavailability. Intravenous zoledronic acid is the newest bisphosphonate to be approved for the treatment of osteoporosis.[9]

Salmon calcitonin is another drug (sCT) is a classic anti-osteoporosis drug, and is an active peptide, comprised of 32 amino acids with a molecular weight of 3,500 Da.[12] Experimental administration of sCT in rats increases cancellous (spongy) bone volume and trabecular number and may reduce the number of osteoclasts.[10,11] In our study we are comparing the effectiveness of intanasal salmon calcitonin and intravenous zolondrinic acid the treatment of postmenopausal osteoporosis

Aim

To compare the effectiveness intanasal salmon calcitonin and intravenous zolondrinic acid the treatment of postmenopausal osteoporosis

METHODS

The study was conducted in the Department of Orthopaedics at Shimoga Institute of Medical Sciences, Shimoga, Karnataka from January 2015 to Jan 2017 after taking clearance from the Ethical Committee. All the patients postmenopausal age group presenting in orthopaedic outpatient department and emergency, having various complaints with underlying osteoporosis(BMD documented osteoporosis -T-score ≤-2.5 at femoral neck or at anterior-posterior [AP] spine), after obtaining written informed consent, were included in the study. Patients were completely evaluated by all routine blood tests and X-rays to rule out secondary causes of osteoporosis. Patients with non-osteoporotic pathological fractures, patients with head injury, creatinine clearance <35 ml/min, patients already using bisphosphonates or salmon calcitonin for the treatment of osteoporosis or with chronic use of glucocorticoids, and patients with conditions associated with low bone density (e.g., diabetes mellitus, rheumatoid arthritis, cystic fibrosis, Parkinson's disease, etc.) were excluded from the study.

Patients are randomly allotted into either of the groups and started on treatment. One group received treatment with intravenous zolindronic acid 5 mg administered as a single dose. Other group received a salmon calcitonin which was administered intranasally 100 IU/day. Both groups received equal amount of supplemental calcium and calcitriol combination. Patients were reviewed at 6, 9 and 12 months. Bone Mineral Density (BMD) was done by duel energy x-ray absorptiometry (DEXA) at 6 months and 1 year. Statistical analysis is done by using data based programme, descriptive statistics such as mean, proportion, percentage is used. The result of the study is interpreted using SPSS software 2012 version.

RESULTS

Total 80 patients were included in the study. Forty patients were allotted to each group. Mean age of the patients in the Salmon calcitonin group was 65 years and mean age of the patients in the zolindronic acid group was 71 years. All the patients were available for the follow up till the end of the study. Mean T score of BMD of the patients in the salmon calcitonin group before the start of study was -3.38(ranged from -3.01 to -3.72) and mean T score of the patients in the zolindronic acid group was -3.4(ranged from -3.72 to -3.11). P value for both groups was 0.32, which was not significant. So both groups were comparable. Mean T score of BMD after 6 months of therapy in the salmon calcitonin group was -2.67(Ranged from -2.15 to -3) and for the zolindronic acid group -2.47(ranged from -2 to -3.12). P value was 0.00 which was significant rejecting the null hypothesis. After 1 year of therapy, the patients in the calcitonin treatment group had mean T score of -1.90 and those who are treated with Zolindronic acid had mean T score of -1.49. P value was 0.01 which was significant again. Degree of freedom was 78 for all the tests (Table 1). Three (7%) patients treated with intransal calcitonin had nasal irritation and rhinitis. Flu like symptoms were noted in one patient (2.5%) and myalgia in 2 patients treated with intravenous zolindronic acid.

Table 1: Age demography.

Age in years	Number of patients	%
Less than 60	15	18.75
60 to 75	43	53.75
More than 75	22	27.5
Total	80	100

Table 2: Results compared.

	At the beginning of treatment T score (Mean)	At 6 month of follow up T score (Mean)	1 year of follow up T score (Mean)
Salmon calcitonin group	-3.3861	-2.6793	-1.9007
Zolindronic acid group	-3.4029	-2.4726	-1.4992
P value	0.742	0.0009	0.0104

DISCUSSION

Women in the post-menopausal age group are susceptible for the osteoporotic fractures due to deficiency of estrogen. Due to estrogen deficiency there will be an imbalance between the amount of bone formation by osteoblasts and the amount of bone resorption by osteoclasts, resulting in the decrease in bone mineral density. Being the global problem various treatment options are available for the treatment of osteoporosis and for restoration of BMD. Hormone replacements are used very cautiously now days due to the risks and side effects assosciated with the use of these drugs. Bisphophonates and Salmon Calcitonin are used as first line drugs now days in the treatment and prevention of osteoporosis.

In our study mean age group was 69 years. Javeri et al in their study on osteoporosis mean age group was 51 to 60 years.[12] In our study both the drugs have significantly increased the Bone mass which was evident on improvement of T score at 6 months and 1 years of BMD check-up. But the amount of improvement which was achieved by single intravenous dose of Zolindronic acid 5 mg is significantly higher than whatever the improvement achieved with the 100 IU of intranasal salmon calcitonin.

Salmon calcitonin has improved the mean T score of lumbar spine by 1.48 over one year. Patients also reported some analgesic affect compared to the patients who are treated by Zolindronic acid. Regnister JY et al who conducted study on 79 women who had been menopausal for less than 36 months intranasal salmon calcitonin 50 IU/day for 5 days per week reported an increase in BMD by 1.38.[13] This was comparable with our study. Intravenous Zolindronic acid has improved the mean T score of lumbar spine by 1.91 over one year. This was comparable to study conducted on 152 patients treated by Zolindronic acid by Recker et al.[14]

Limitation of our study was small number of the patients and study duration was short.

CONCLUSION

From our study it can be concluded that once yearly intravenous zolindronic acid is superior to intranasal Salmon Calcitonin in the treatment of post menopausal osteoporosis. Ease of administration, definite increase in the mean T score which was more than salmon calcitonin and lesser side effects favours zolindronic acid over the intranasal salmon calcitonin.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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Cite this article as: Santosha. A comparative evaluation of intanasal salmon calcitonin and intravenous zolondrinic acid in the treatment of postmenopausal osteoporosis. Int J Res Orthop 2017;3:805-8.