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Study of effect of zoledronic acid on back pain in patients with osteoporosis

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ABSTRACT

Background: The objective of the study was to assess functional result in back pain treated with a Zoledronic acid.
Methods: A prospective observational study was conducted over period of 18 months. SMIMER-Surat Municipal Institute of Medical Education and Research, Surat, Gujarat, India. Thirty-eight patients with various stages of back pain treated with zoledronic acid fulfilling selection criteria admitted in department of orthopaedics in tertiary health care hospital in Surat. Follow up was done after 2nd and 6th month and recording of pain relief in term of VAS and MODQ score.
Results: We expected that Patients after receiving Zoledronic acid shows an appreciable and statistically significant improvement in back pain & related complains as well as improvement in monthly follow-up period compared to previous status based on VAS score & MODQ.
Conclusions: Our findings have shown that there is a statistically significant improvement in complain of back pain over period of 6 months as compared to previous status of patient.

Keywords: Back pain, Osteoporosis, Zoledronic acid

INTRODUCTION

Osteoporosis is known as a chronic disorder of progressive type systemic and skeletal disease characterized by decreased bone mass and micro-architectural reduction of bone tissue with consequent fragile bones which can lead to increased risk of osteoporotic or fragility fractures.[1,2] It often remains asymptomatic as well as undiagnosed until it presents with fractures involving the spine, hip, pelvis, and wrist resulting from small trauma which leads to multiple times hospitalization. Sometimes it also presents with loss of height and severe backache.[3] According to World Health Organization's data, In India, one third of total women and one of every eight men the over age of 50 are osteoporotic. It is calculated in different studies that around 6.1 crore Indians are osteoporotic, out of whom 80 percentage are females.[5,6] Chronic back ache is generally the first clinical symptom of osteoporosis which can be related with a wide range of diseases and is many times less diagnosed. Verbal compression fractures are one of the commonest fractures seen in osteoporotic patients followed by hip fractures.[4,5] Osteoporotic fractures have a number of important consequences, including back pain, disability, and death.[8] People with prevalent vertebral fractures complain of back pain and limitations in physical function.[5] Incident vertebral fractures, even if not clinically recognized, also result in an increase in back-related disability and bed-rest days.[6] Women who experience a hip fracture are 50% less likely to walk independently or achieve their pre fracture ability to carry out their activities of daily living. Following a hip fracture, the functional decline estimated specifically due to hip fractures was 24% during the first year.[6] The reduction in quality of life was found for all domains like symptoms,

physical functioning, and activities of daily living. Alendronate has been proved to decrease the number of bed-rest days and limited-activity days relative to placebo in women with prevalent vertebral fractures.[7] Hormone therapy has reduced clinical fractures, including hip fractures, but with no effect on life quality based on MODQ or visual analog scale (VAS) scoring. Both antiresorptive and anabolic treatments are available to use individually or in combination and even one after another for osteoporosis.[8] Zoledronic acid which is generally given once in a year dose with intravenous infusions a 5 mg dose over 15 minutes, is a potent bisphosphonate which is used presently in many cases for treatment. Present study was done on the patients who received zoledronate as treatment to see effect of treatment.

To evaluate outcomes of treatment of backpain with zoledronic acid injection, thirty-eight patients aged between 41-80 years with chronic backpain were selected for the study among them 10 were males and 28 were females.

METHODS

Study place

The place of study was at SMIMER-Surat Municipal Institute of Medical Education and Research, Surat, Gujarat, India.

Study design

This was prospective observational study over 18 months from August 2022 to January 2024 conducted at department of orthopaedics at tertiary care hospital, Surat**.** All patients between 41 to 80 years age seeking treatment for chronic back pain and fulfilling selection criteria were recruited for the study.

Sample size was 38.

Calculation of no of cases (Sampling size)- P= 0.033

Q= (1-0.033)

Zα½= Standard normal value at 95% level is 1.96

L= allowable error = 5%

N= Z2α½PQ/L2

N=38

Ethical approval

This research work was unanimously approved by the Institutional ethical committee meeting held at SMIMER hospital on 11th July 2024. This was certified through order SMIMER/IEC/OUT/NO.92 ref no 148.

Informed written consent was taken from the participants after explaining the possible benefits as well as implications of the study.

Inclusion criteria

Back pain symptoms for at least 3 months. Male and female both patients included in the study. Back pain interfering daily activities were included.

Exclusion criteria

Renal impairment, known hypersensitivity to zoledronic acid, patient with neurological involvement, pre-menopausal women with willingness of child bearing, non-osteoporotic causes of backpain**,** pregnant women, breast feeding mother.

Figure 1: X-ray of osteoporotic vertebra AP and lateral view.

Zoledronate is available as an intravenous injection. It was administrated in concentration of 5mg in 100 ml solution slowly once a year.

In follow up patient was examined in detail at 2 months and 6 months in terms of VAS Score and MODQ Score.

Scoring system

VAS score

VAS are psychometric measuring tools designed to demonstrate disease-related symptoms severity in individual patients.[6] It can be used to obtain a quick

classification of the severity of symptoms and the controlling of the disease. VAS can also be beneficial in day-to-day history taking and to monetarize the course of the chronic disease. Patients were classified to be having no, mild, moderate and worst (severe) pain if the VAS scores were 0, 1-3, 4-6, and 7-10 respectively.

Figure 2: A picture of patient receiving intravenous zoledronic acid.

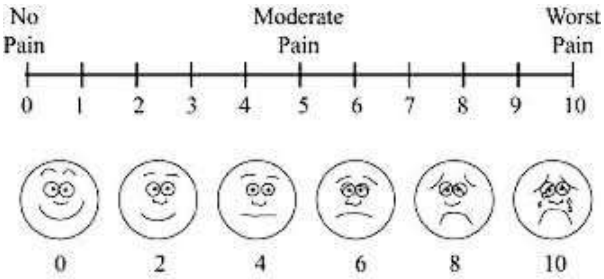

Figure 3: VAS score.

Grading of MODQ

0%-20% - minimal disability, 21%-40% - moderate disability, 41%-60% - severe disability, 61%-80% - crippled, 81%-100% - either bed bound or exaggerating their symptoms.

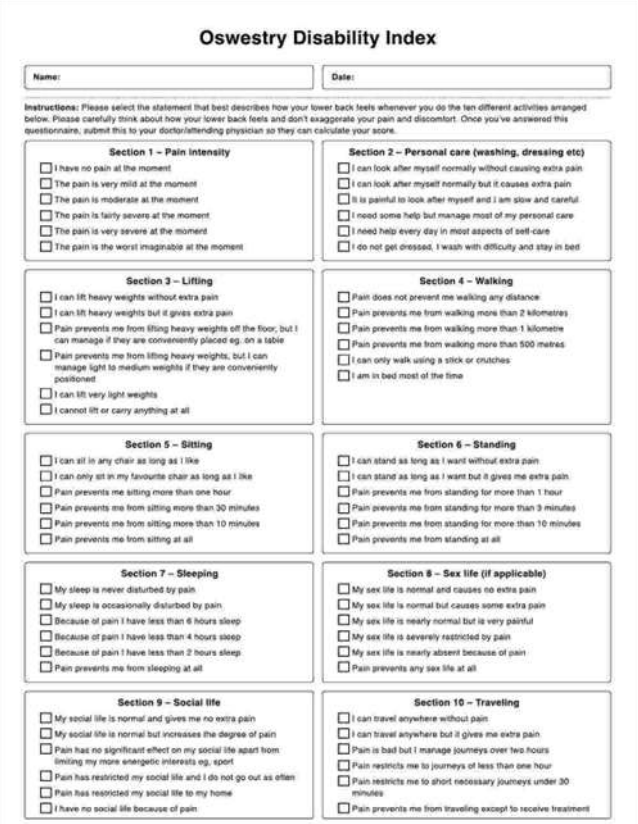

Figure 4: Modified Oswestry disability questionnaire (MODQ)[17]

Statistical analysis

Data entry was done in Microsoft Excel. Chi square test was applied to see the significance and statistically significant difference was found between pre and post treatment interval patients. ($p<0.05$). Statistically significant pain reduction and improvement in quality of life was observed in terms of VAS Score, MODQ Score & MODQ grade. Chi square test was applied to see the significance and statistically significant difference was found between pre and post treatment interval patients. ($p<0.05$)

RESULTS

This prospective observational study was performed on 38 patients admitted in department of general orthopedics at tertiary care hospital who were having back pain and osteoporosis. Aim of the present study is to evaluate effect of zoledronic acid on parameters of pain improvement and MODQ score.

Table 1: Sex wise distribution of study patients.

Gender	Number	Percentage
Male	10	26.3
Female	28	73.7

Table 2: Age group wise distribution of study patients.

Age (in years)	Male N (%)	Female N (%)	Total N (%)
41-50	00 (0.0)	10 (35.7)	10 (26.3)
51-60	06 (60.0)	10 (35.7)	16 (42.1)
61-70	04 (40.0)	04 (14.3)	08 (21.1)
71-80	00 (0.0)	04 (14.3)	04 (10.5)
Total	10 (100)	28 (100.0)	38 (100.0)

Most of the patients reported significant pain reduction and improvement in quality of life.

As shown in Table 1 out of total 38 study patients total no. of male were 10 (26.3%) and total no. of female were 28 (76.7%). This table clearly suggests female proportion is very high in comparison of males.

Table 3: VAS score comparison among study patients.

	Mean	SD	F value	P value
Pre zoledronic acid treatment VAS Score	6.9	1.0	44.35	<0.05
Post zoledronic acid treatment VAS Score at 2 months	5.6	1.0		
Post zoledronic acid treatment VAS Score at 6 months	4.7	1.0		

Table 2 shows age group wise distribution of study patients. Out of total 38 patients highest were of age group 51-60 (16, 42.1%) followed by 10 (26.3%) patients were from 41-50 years age group. Eight (21.1%) patients were from 61-70 years age group and 04 (10.5%) patients were from 71-80 years age group. Minimum age of patient was 44 year and maximum age of patient was 79 years. Mean age of patients was 57.41 years. In male out of 10 patients, 6 were from 51-60 years age group and 4 were from 61-70 years age group. In Female out of 28 patients 10 patients each were from 41-50- and 51-60-years age group and 4 patients each were from 61-70- and 71-80-years age group.

Comparison for mean VAS score was done in Table 3 before treatment of zoledronic acid and after treatment of zoledronic acid at 2 and 6 months. Mean VAS score was 6.9 before treatment and it was 5.6 after treatment at 2 months and 4.7 at 6 months.

On applying paired ANOVA test between pre and post treatment groups, statistically significant difference was found between them ($p<0.05$).

Table 4: MODQ score comparison.

	Mean	SD	F value	P value
Pre zoledronic acid treatment MODQ Score	40.3	9.7	72.04	<0.05
Post zoledronic acid treatment MODQ Score at 2 months	25.4	8.4		
Post zoledronic acid treatment MODQ Score at 6 months	17.3	7.1		

As described in Table 4, comparison for MODQ score was done between before treatment of zoledronic acid and after treatment of zoledronic acid at 2nd and 6th month groups. Mean MODQ score was 40.3 before treatment and it was 25.4 after treatment at 2 months and 17.3 at 6 months.

Table 5: MODQ grade comparison.

	Pre-treatment N (%)	Post treatment at 2 months N (%)	Post treatment at 6 months N (%)	P value
Minimal	1 (2.6)	15 (39.5)	26 (68.5)	<0.05
Moderate	23 (60.5)	21 (55.3)	11 (28.9)	
Severe	12 (31.6)	02 (5.2)	01 (2.6)	
Crippled	02 (5.3)	00 (0.0)	00 (0.0)	
Total	38	38	38	

On applying paired ANOVA test between pre and post treatment groups, statistically significant difference was found between them ($p<0.05$)

Table 5 shows MODQ grade comparison between Pre zoledronate treatment and post zoledronic acid treatment at 2 and 6 months. In pre zoledronate treatment patient, more than half (23, 60.5 %) patients were having moderate grade of MODQ while 12 (31.6 %) patients had severe MODQ grade only 1 (2.6 %) patient was having mild MODQ grade and 2 patients were having crippled MODQ grade. Post treatment with zoledronate at 2 months no patient was having crippled MODQ grade while 15 (39.5 %) patients were having only minimal MODQ grade. Post treatment with zoledronic acid at 6 months only 1 patient was having severe MODQ grade while more than two third (68.5 %) people were having minimal MODQ grade.

DISCUSSION

Present prospective observational study was done on 38 patients who were having back pain symptoms for at least 3 months and pain was interfering with daily activities and in whom zoledronate was given as treatment VAS Score and MODQ score were studied as an outcome parameter.

Zoledronic acid is an approved drug for use in Osteoporosis. It is generally given IV as a once-a-year dose concentrations of 4 mg/5 ml and 5 mg/100 ml and has excellent compliance compared to other oral bisphosphonates due to their GI irritability and daily dose/ once a month regimen.

As per findings of all studies in different geographical settings it was observed that female patient reported with back ache and osteoporosis were more in proportion as compared to male.

In study done by Ramalingaiah et al mean age of patients was 51.5 years which in present study was 57.4 years.[9] According to study done by Nayak et al around equal distribution was observed of patients in age group of 50-60, 60-70 and 70-80 years with mean age was 67.3 years.[11] In another study done by Umesh et al 65-70 and 70-75 years age groups were commonest affected age groups in study.[10] From all of these findings it is concluded that majority of patients suffering from chronic back pain were predominantly of above 55 years of age.

In present study mean duration of symptoms was 9 months and more than half of patients were having pain from 6-12 months. In study done by Umesh et al.[10] 22 out of 70 patients were suffering from back pain since more than 3 years followed by 21 patients were suffering from back pain from 1 to 2 years.

In present study VAS Score and MODQ score was measured to see the effect of zoledronate on pain. Observations were gathered at pretreatment stage and after treatment at 2 and 6 months. Regarding VAS Score at pretreatment stage mean score was 6.9 which improved 2 months after treatment and reduced to 5.9 and after 6 months of treatment it was 4.7. In study done by Umesh M et al observations were conducted at pretreatment stage, 12 weeks after treatment, 24 weeks after treatment and after 1 year of treatment.in pre-treatment stage mean VAS score was 5.95 which reduced to 4.16 at 12 weeks and after one year it was reduced to 2.54. in another study done by Ramalingaiah et al patients follow up were done on week 12 and 24.[9,10] During initial presentation mean VAS score was 7.4 which improved after treatment. At 12 weeks VAS score was 6.41 and it improved further at 24 weeks. Nayak et al study showed similar findings in which mean VAS score at patient presentation was 6.16.[11] After 12 weeks after treatment, it was 4.11 and after 1 year it was 2.46 which is in similar line with all of the previous study findings. All of these findings including present study shows statistically significant difference among them which shows zoledronate shows significant improvement in VAS score after administration.

Regarding MODQ score in present study pretreatment MODQ score was 40.3. after 2 months after treatment MODQ score 25. 4 and after 6 month it was 17.3. In study done by Umesh et al mean MODQ Index score 47.55 which improved at 12 weeks which was 31.84 after 24 weeks it was 31.84 and after 1 year it was 18.98.[10] In another study done by Nayak et al mean MODQ Index score at the presentation was 46.98.[11] 12 weeks after treatment it was 30.22 and after 24 weeks it was 31.1, after 1 year mean MODQ Index score was 18.21 which shows gradual improvement over time. In another study done by Ramalingaiah et al similar line of findings was observed in which at pretreatment stage mean Oswestry score was 42.48 and after treatment at 12-week mean Oswestry score was 41.20.[9] All of these study findings show improvement after treatment of zoledronate which was highly statistically significant.

A study by Koivisto et al on the effect of zoledronate for back pain of long duration stated that compared to placebo, improvement in the intensity of chronic backpain was more significant with zoledronate.[12] They have also said that it is useful treatment option for backpain with osteoporosis, which is difficult to treat with a conservative approach.

Orwoll et al in the study comparing oral alendronate and IV zoledronate, compliance with zoledronic acid is far on better side than with alendronate.[13] The study also shows that zoledronate is effective in management of osteoporosis in males.

Cauley et al in their study on zoledronate, said that treatment with zoledronate significantly decreased hospital admission time and limitation in activity.[15] More over to that, the study concluded that a 3-year treatment with zoledronic acid in women with osteoporosis significantly decreased disability and fracture compared with a placebo.

Taking into consideration of all of these findings, the patients' early follow-ups revealed very good clinical improvement as a result of zoledronic acid infusion. In addition to its analgesic effects, zoledronic acid infusion-induced pain reduction may also be due to the strengthening of the spine's trabeculae and the prevention of future compression fractures. Thus, zoledronate is very helpful in all osteoporosis related back pain problems.

CONCLUSION

Back pain in aged patients of longer duration without identifiable causes is usually due to osteoporosis of vertebra. Zoledronic acid with its potent action and with good patient adherence, is very effective in control of back pain, improvement of bone marrow density and in prevention of the occurrence of traumatic injuries. It has

better patient compliance due to once-a-year dosing. Considering all these points, zoledronic acid can be selected as a first-choice bisphosphonate for the prevention as well as treatment of osteoporosis, with no history of anaphylaxis or heart and kidney impairment.

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Ethical approval: The study was approved by the Institutional Ethics Committee (SMIMER/IEC/OUT/ NO.92 ref no 148)

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