MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.7.208.211

OPEN ACCESS

Key Words
Osteoporosis, fracture, zoledronic acid, functional

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Received: 18 April 2024
Accepted: 11 June 2024
Published: 13 June 2024

Citation: S.L. Binesh, Zakir Hussain Mohamed, G. Rohin and M.D. Sheriff, 2024. Functional Outcome and Efficacy of Zoledronic ACID in Patients With Vertebral Osteoporosis: A Prospective Study. Res. J. Med. Sci., 18: 208-211, doi: 10.36478/makrjms.2024.7.208.211

Functional Outcome and Efficacy of Zoledronic Acid in Patients With Vertebral Osteoporosis: A Prospective Study

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Abstract
Osteoporsis is a condition characterized by decreased bone strength and abnormal bone quality predisposing a person to an increased risk of fracture. The most common fractures seen in osteoporotic patients are vertebral compression fractures, followed by hip fractures. Zoledronic acid reduces the rate of bone resorption. This study evaluates the functional effect of zoledronic acid in vertebral osteoporosis. This is a prospective study done at Sree Mookambika Institute of Medical Sciences, Kulasekharam. Patients of both the sexes presenting with low back pain for more than 6 weeks duration were screened, 30 patients were selected for the study. VAS chart and Oswestry Disability Index questionnaire were given. 5 mg zoledronic acid infusion was administered over a minimum duration of 15 min under monitoring and observed for one day for adverse events and allergic reactions. A total of 30 patients were selected for the study. Major age group of patients with low back ache are between the age of 56-60 years. 3s0 patients included in the study who were found to be osteporotic, among them, 20 were females and 10 were male patients. All the patients were followed at 3 months and 6 months At the end of 6 months ODI scores were 31.4. Comparison of T-score of initial visit and after 6 months follow-up after infusion of zoledronic acid showed excellent results. In patients with vertebral Osteoporosis, Zoledronic acid is considered as very effective and preferable bisphosphonates for the treatment and prevention.

INTRODUCTION

Osteoporosis is a condition characterized by decreased bone strength and abnormal bone quality predisposing a person to an increased risk of fracture. It is prevalent among postmenopausal women but also occurs in men and women with underlying conditions or major risk factors associated with bone demineralization[1]. The earliest clinical feature of osteoporosis is usually chronic low back ache which can be associated with a wide spectrum of diseases and is often under diagnosed. Hence, many cases present in the health care system with osteoporotic fractures. The most common fractures seen in osteoporotic patients are vertebral compression fractures, followed by hip fractures. Both anabolic and antiresorptive therapies are available to use separately or one after another and even in combination for osteoporosis. the management of osteoporosis has revolutionized after the discovery of bisphosphonates. Zoledronic acid is an anti-resorptive agent which has a high affinity for mineralized bone. It reduces the rate of bone resorption[2]. This study evaluates the functional effect of zoledronic acid in vertebral osteoporosis.

MATERIALS AND METHODS

This is a prospective study done at Sree Mookambika Institute of Medical Sciences, kulasekharam . Patients of both the sexes presenting with low back pain for more than 6 weeks duration were screened, 30 patients were selected for the study. Patients of either sex aged above 50 years, Patients experiencing back pain which was insidious in onset for more than six weeks of duration and Pain not relieved by NSAIDs, Opiods and Physiotherapy were included in the study. And Patients with primary and/or secondary tumors of the spine and Patients on bisphosphonates therapy were excluded .Patients with traumatic fractures of the spine ,Disc diseases and lysthesis were also excluded.

Screening the patients with detailed history and clinical examination for factors suggestive of osteoporosis. VAS chart and Oswestry Disability Index questionnaire were given and baseline scores were recorded. Radiographs of the Dorsal- lumbar spine/ LS spine(AP and LATERAL view) were taken to assess for osteoporosis. Patients suspected of having osteoporosis were evaluated with a DEXA. All routine blood investigations and ECG was taken to rule out contraindications for infusion. Patients who did not have contraindications were admitted and 5 mg zoledronic acid infusion was administered over a minimum duration of 15 min under monitoring and observed for one day for adverse events and allergic reactions. Calcium 500 mg and vitamin D3 60000 IU supplement were advised for a period of 6 months.

RESULTS AND DISCUSSIONS

A total of 30 patients were selected for the study. Mean age of the study was 59.1 years. Major age group of patients with low back ache are between the age of 56-60 years. 30 patients included in the study who were found to be osteoporotic, among them, 20 were females and 10 were male patients. In our study, 15 patients presented with symptoms for 1-6 months, 10 patients presented with symptoms for 7 months to 1 year and 5 patients presented with symptoms for more than 1 year. The initial mean VAS score was 7.06. All the patients were followed at 3 months and 6 months. At the end of 3 months Mean VAS was 5.2 and at the end of 6 months mean VAS was 4.16. All the patients showed improvement at follow up. The initial mean Oswestry Disability Index score was 40.53. patients were followed at 3 months and 6 months. At the end of 3 months Oswestry scores were 36.36. At the end of 6 months ODI scores were 31.4. Comparison of T-score of initial visit and after 6 months follow-up after infusion of zoledronic acid showed excellent results. Among 30 patients, Only few adverse events have been noticed after the delivery of zoledronic acid infusion in which 4 patients had headache and 3 patients had fever for which NSAIDS was given and managed conservatively.

In our present study female are more prone for osteoporosis which was 20 patients(66%.66) and 10 male patients (33.34%). Mean age of our study was 59.1 years. Major age group of patients with back ache are between the age of 56-60 years. A study done by ramalingaiah[3] among 50 patients in which 30 patients(60%) were females and 20 patients (40%) were males. Mean age was 51.5 years. In our study, 15 patients presented with symptoms for 1-6 months, 10 patients presented with symptoms for 7 months to 1 year and 5 patients presented with symptoms for more than 1 year. A study done by umesh[4] on 70 patients, 27 patients had mean duration of symptoms for more than 3 years, followed which 21 patients had symptoms for 1-2 years. In our study the initial mean VAS score was 7.06. All the patients were followed at 3 months and 6 months. At the end of 3 months Mean VAS was 5.2 and at the end of 6 months mean VAS was 4.16. All the patients showed improvement at follow up. A study done by ramalingaiah[3] which showed initial mean VAS score was 7.46 followed by mean VAS score at 12 weeks and 24 weeks was 6.41 and 4.51. The initial mean Oswestry Disability Index score was 40.53. patients were followed at 3 months and 6 months. At the end of 3 months and 6 months Oswestry scores were 36.36 and 31.4. Study done by ramalingaiah[3] showed initial mean ODI score was 42.28 followed by 12 weeks and 24 weeks mean ODI scores was 41.20 and 36.4.In our study, Among 30 patients, Only few adverse events have been noticed

after the delivery of zoledronic acid infusion in which 4 patients had headache and 3 patients had fever. A study done by umesh[4] showed adverse events like headache in 42 patients, fever in 34 patients and 15 patients had post transfusion palpitation. Cauley[5]. done a study on zoledronic acid for chronic low back pain and stated that treatment with zoledronic acid significantly reduced hospital admission duration and limited activity. Jane A Cauley[6] concluded that in women with postmenopausal osteoporosis, a once-yearly infusion with zoledronic acid over a 3-year period significantly reduced the number of days that patients reported back pain, limited activity. Orwoll[7] in the study comparing IV zoledronate and oral alendronate, compliance with zoledronic acid is significantly better than with alendronate. The study also demonstrates that zoledronate is effective in

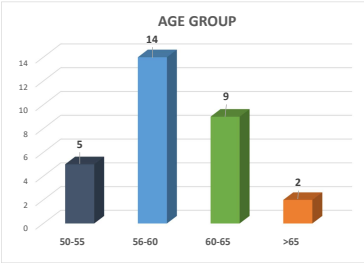

Fig. 1: AGE Group

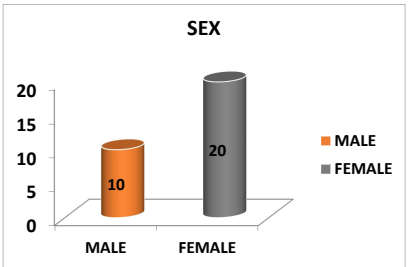

Fig. 2: Sex

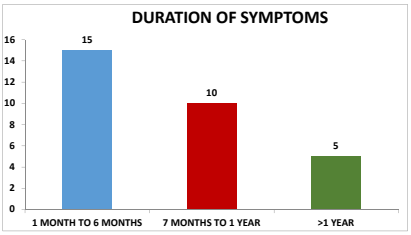

Fig. 3: Duration of symptoms

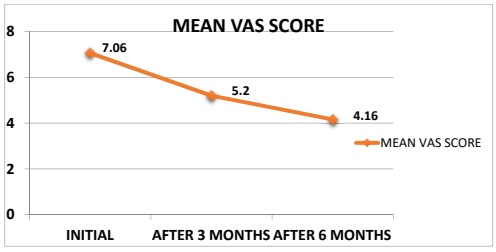

Fig. 4: Mean VAS score

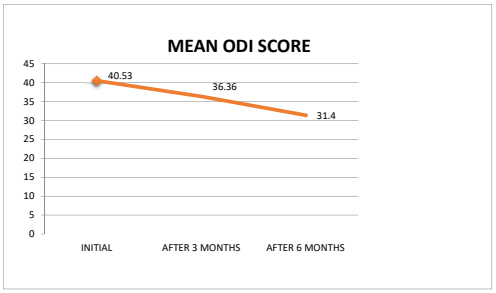

Fig. 5: Mean ODI score

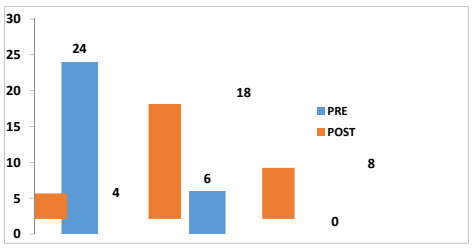

Fig. 6: Comparison of T-score of initial visit and after 6 months follow-up after infusion of zoledronic acid.

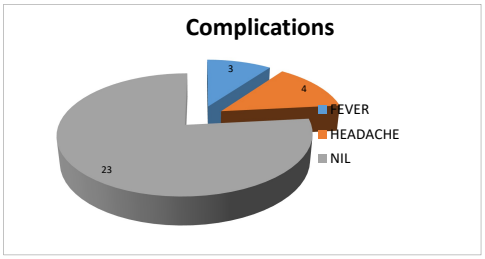

Fig. 7:Complications

treating osteoporosis. A study by Koivisto[8] on the efficacy of zoledronic acid for chronic back pain showed that improvement in the intensity of chronic lower back ache (LBA) was more significant with zoledronic acid.

CONCLUSION

Elderly patients presenting with low back pain without any identifiable causes can be due vertebral osteoporosis. Zoledronic acid is an anti-resorptive drug with potent and better compliance. Zoledronic acid is very effective in controlling low back pain, improving BMD and preventing the occurrence of atraumatic compression fracture. Zoledronic acid infusion over a period of six month duration significantly reduced the chronic low back pain with minimal adverse drug reaction and improves the overall functional outcome. With all the above factors, zoledronic acid can be considered a preferable bisphosphonates for the treatment and prevention of osteoporosis.

Limitations of the Study: No control was done to note their effect. Patients were advised only topical irritants for pain after infusion.

REFERENCES

1. Lambrinoudaki, I., S. Vlachou, F. Galapi, D. Papadimitriou and K. Papadias, 2008. Once-yearly zoledronic acid in the prevention of osteoporotic bone fractures in postmenopausal women. Clin. Interv. Aging, 3: 445-451.
2. Sunyecz, J., 2010. Zoledronic acid infusion for prevention and treatment of osteoporosis. Int. J. Women's Health, 2: 353-360.
3. Ramalingaiah, A. and R. Sridhar, 2016. Study of effect of zoledronic acid in patients with low back pain associated with vertebral osteoporosis. Int. J. Orthop. Traumatol. Surg. Sci., 3: 367-370.
4. Umesh, M., P. Ethiraj, S.M. Nazar, S. Agarawal and A.H. Shanthappa, 2023. Does zoledronic acid provide a good clinical outcome in patients with chronic back pain associated with vertebral osteoporosis?. Cureus, Vol. 15 .10.7759/cureus.33328.
5. Black, D.M., P.D. Delmas, R. Eastell, I.R. Reid and S. Boonen *et al.,* 2007. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. New Engl. J. Med., 356: 1809-1822.
6. Cauley, J.A., D. Black, S. Boonen, S.R. Cummings and P. Mesenbrink *et al.* 2011. Once-yearly zoledronic acid and days of disability, bed rest and back pain: Randomized, controlled horizon pivotal fracture trial. J. Bone Miner. Res., 26: 984-992.
7. Orwoll, E.S., P.D. Miller, J.D. Adachi, J. Brown and R.A. Adler *et al.,* 2010. Efficacy and safety of a once-yearly iv. infusion of zoledronic acid 5 mg versus a once-weekly 70-mg oral alendronate in the treatment of male osteoporosis: A randomized, multi center, double-blind, active-controlled study. J. Bone Mineral Res., 25: 2239-2250.
8. Koivisto, K., E. Kyllönen, M. Haapea, J. Niinimäki and K. Sundqvist *et al.,* 2014. Efficacy of zoledronic acid for chronic low back pain associated with modic changes in magnetic resonance imaging. BMC Musculoskelet. Disord., Vol. 15 .10.1186/1471-2474-15-64.