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Efficacy of single dose of zoledronic acid in treating post-menopausal osteoporosis

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Abstract

- The purpose of this study is to analyse the effect of single dose of zoledronic acid in treating post-menopausal osteoporosis

Aim of the study

- To show the significance increase in bmd with zoledronic acid infusion in single dose.

Materials

- Study design - prospective study.
- Study population - patients attending opd in department of orthopaedics with osteoporosis evaluated by bone mineral density (bmd) scan in govt. kilpaukmedical college hospital.
- Duration of study – 1 year
- After patients were screened with peripheral BMD densitometry patient were selected then they were subjected to do bmd dxa scan to confirm osteoporosis.
- Those who were in osteoporotic group were included in our study.

Method

- After patient is evaluated, they were instructed to drink 500ml-1000ml of water for hydration.
- Then single dose of Zoledronic acid in 100 ml of Normal saline was infused intravenously over 15 mins.
- Patient were observed for two hours then were discharged with prophylactic Paracetamol tablets.

Keywords: Osteoporosis, post-menopausal, zoledronic acid

Introduction

- Bisphosphonates, the most commonly used treatment for established osteoporosis, inhibit osteoclast-mediated bone resorption.
- A single infusion of intravenous zoledronic acid has been reported to decrease bone turnover and improve bone density for atleast 12 months after infusion.
- In our study, single infusions of zoledronic acid (5 mg) were evaluated to determine the increase of BMD.
- Adherence to a regimen of oral bisphosphonates is challenging because the drug must be taken with a full glass of water when the patient is fasting, and the patient must remain upright for at least 30 minutes after taking the medication to avoid gastritis.
- As reported with other bisphosphonates when administered intravenously, mild-to-moderate post-dose symptoms occurred.
- These symptoms typically resolved within 2 days.
- Treatment with antipyretic analgesics (e.g., acetaminophen) appeared to mitigate these symptoms.

Follow up

- All patients were checked after one week for any adverse renal effects with Renal function test.
- Then they were checked with BMD after 1 year.

Scoring system**Table 1:** WHO score

Individual	T Score
Normal	-1 or below
Osteopenia	-1 to -2.5
Osteoporosis	-2.5 OR above

Inclusion criteria

- Post-menopausal female with bone mineral density T score of -2.5 or less
- Age 45-60 years
- No Co- morbid conditions.

Exclusion criteria

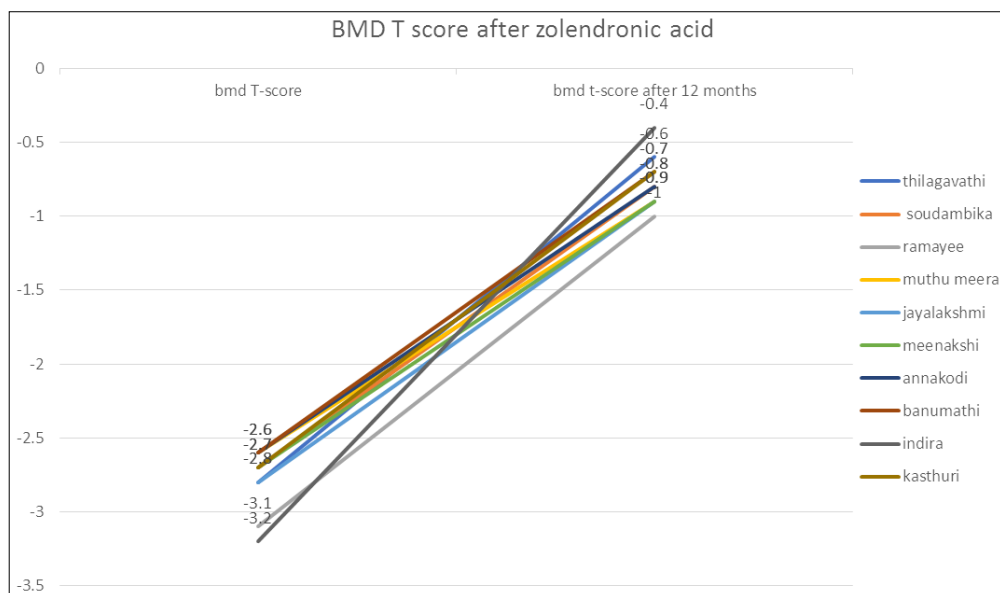
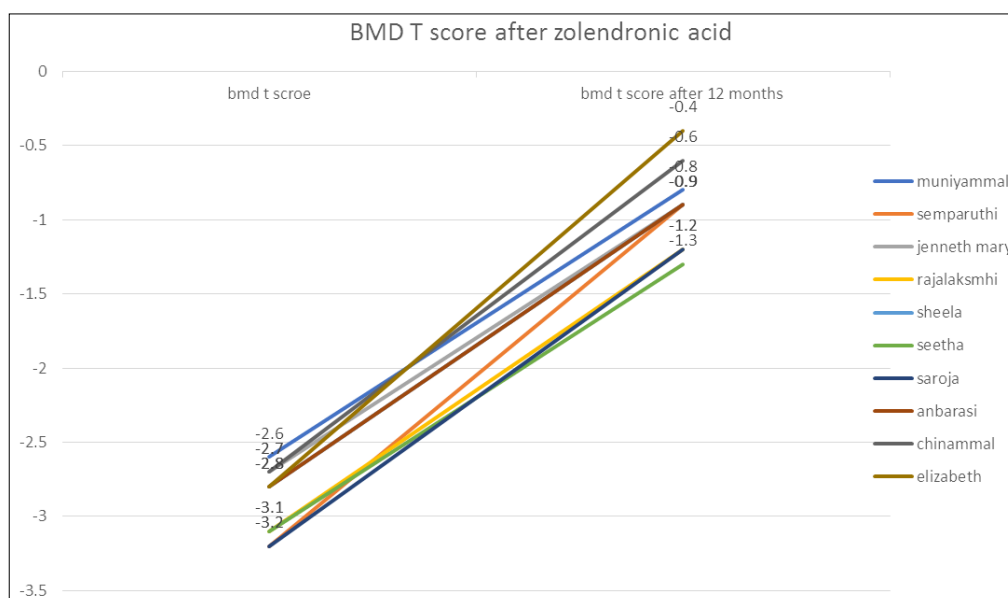
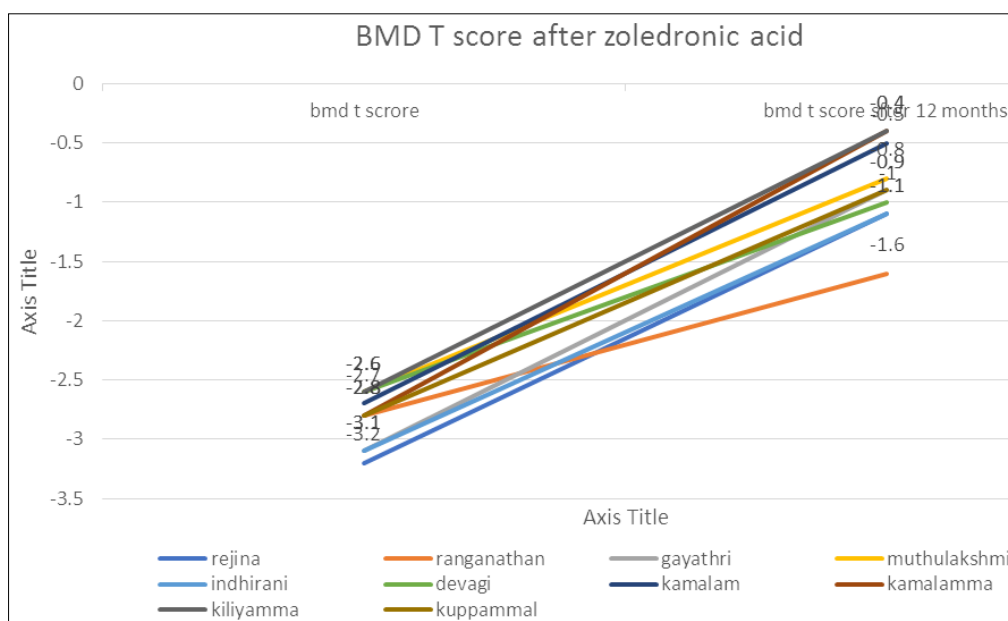
- Age <45 & >60 years
- Co Morbid conditions like Systemic Hypertension, type 2 Diabetes Mellitus, Coronary Artery Disease

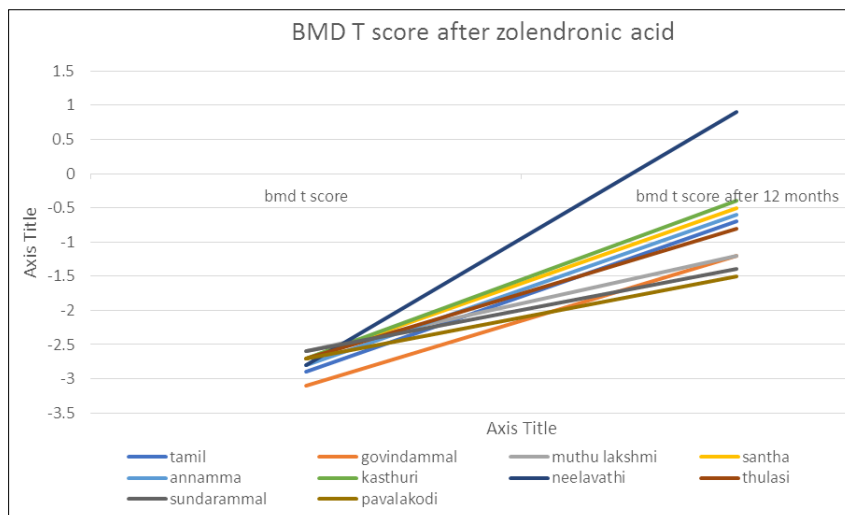
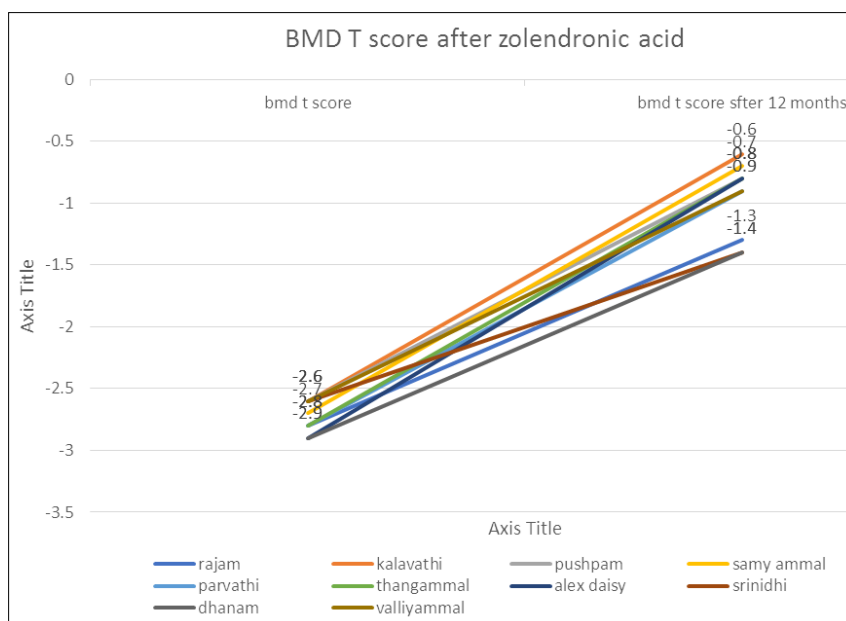
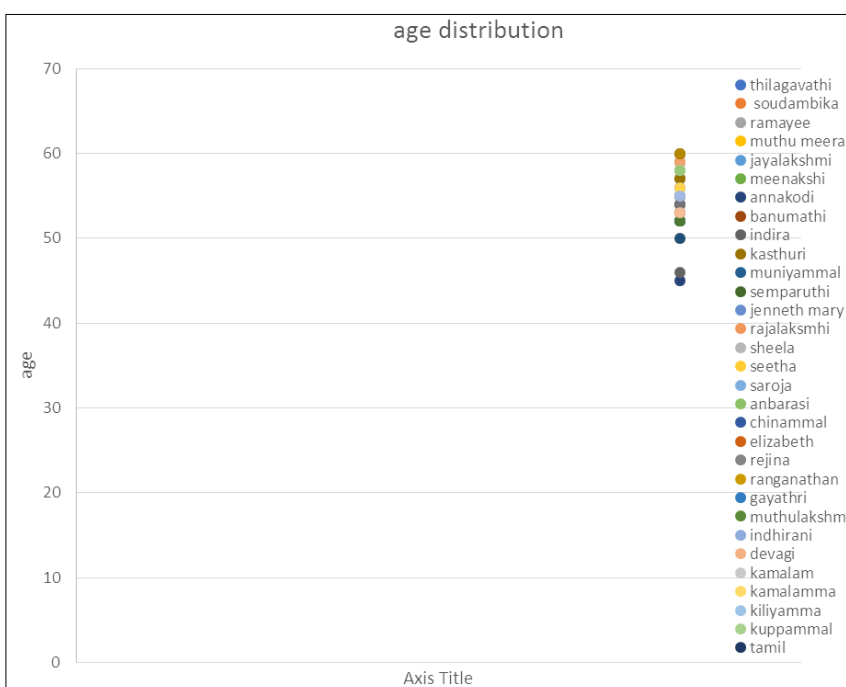
Patient evaluation

- Renal function test
- Blood pressure
- Random blood sugar
- Bone mineral density

Table 2: Master chart table

S. No	Age	Sex	IP. No	Date of Admission	BMD T-score on day of admission	Date of Zoledronic infusion	Bmd t-score after 12 months of infusion
1.	59	female	32764	02-05-2018	-2.8	02-05-2018	-0.6
2.	59	female	36752	01-05-2018	-2.7	01-05-2018	-0.8
3.	60	female	37721	04-05-2018	-3.1	04-05-2018	-1
4.	58	female	37383	06-05-2018	-2.6	06-05-2018	-0.9
5.	60	female	37562	06-05-2018	-2.8	06-05-2018	-0.9
6.	58	female	39268	15-05-2018	-2.7	15-05-2018	-0.9
7.	45	female	39722	18-05-2018	-2.6	18-05-2018	-0.8
8.	57	female	40449	22-05-2018	-2.6	22-05-2018	-0.7
9.	46	female	42160	02-06-2018	-3.2	02-06-2018	-0.4
10.	57	female	43029	06-06-2018	-2.7	06-06-2018	-0.7
11.	56	female	42749	02-06-2018	-2.6	02-06-2018	-0.8
12.	60	female	43578	09-06-2018	-3.2	09-06-2018	-0.9
13.	60	female	46728	13-06-2018	-2.7	13-06-2018	-0.9
14.	59	female	15288	10-01-2018	-3.1	10-01-2018	-1.2
15.	53	female	2946	21-01-2018	-2.8	21-01-2018	-0.9
16.	50	female	3535	25-01-2018	-3.1	25-01-2018	-1.3
17.	52	female	4743	02-02-2018	-3.2	02-02-2018	-1.2
18.	59	female	5284	06-02-2018	-2.8	06-02-2018	-0.9
19.	55	female	7208	18-02-2018	-2.7	18-02-2018	-0.6
20.	54	female	8012	23-02-2018	-2.8	23-02-2018	-0.4
21.	55	female	8586	27-02-2018	-3.2	27-02-2018	-1.1
22.	52	female	9282	03-03-2018	-2.8	03-03-2018	-1.6
23.	52	female	9259	06-03-2018	-3.1	06-03-2018	-0.9
24.	55	female	10314	09-03-2018	-2.6	09-03-2018	-0.8
25.	56	female	10430	11-03-2018	-3.1	11-03-2018	-1.1
26.	55	female	10804	13-03-2018	-2.6	13-03-2018	-1
27.	53	female	10888	13-03-2018	-2.7	13-03-2018	-0.5
28.	60	female	11540	18-03-2018	-2.8	18-03-2018	-0.4
29.	55	female	12282	23-03-2018	-2.6	23-03-2018	-0.4
30.	52	female	12827	27-03-2018	-2.8	27-03-2018	-0.9
31.	54	female	13583	01-04-2018	-2.9	01-04-2018	-0.7
32.	53	female	13603	01-04-2018	-3.1	01-04-2018	-1.2
33.	55	female	14027	03-04-2018	-2.6	03-04-2018	-1.2
34.	55	female	14846	09-04-2018	-2.7	09-04-2018	-0.5
35.	50	female	645	05-01-2018	-2.8	05-01-2018	-0.6
36.	52	female	1062	07-01-2018	-2.7	07-01-2018	-0.4
37.	55	female	1063	07-01-2018	-2.8	07-01-2018	0.9
38.	59	female	2037	14-01-2018	-2.7	14-01-2018	-0.8
39.	58	female	2581	19-01-2018	-2.6	19-01-2018	-1.4
40.	56	female	2912	21-01-2018	-2.7	21-01-2018	-1.5
41.	60	female	3476	25-01-2018	-2.8	25-01-2018	-1.3
42.	58	female	4019	29-01-2019	-2.6	29-01-2019	-0.6
43.	52	female	4636	01-02-2018	-2.6	01-02-2018	-0.8
44.	60	female	4715	01-02-2018	-2.7	01-02-2018	-0.7
45.	54	female	6174	12-02-2018	-2.8	12-02-2018	-0.9
46.	60	female	6609	14-02-2018	-2.8	14-02-2018	-0.8
47.	52	female	6628	14-02-2018	-2.9	14-02-2018	-0.8
48.	52	female	7235	18-02-2018	-2.6	18-02-2018	-1.4
49.	55	female	7380	19-02-2018	-2.9	19-02-2018	-1.4
50.	53	female	8952	01-03-2018	-2.6	01-03-2018	-0.9

**Fig 1: BMD T score after zolendronic acid****Fig 2: BMD T score after zolendronic acid****Fig 3: BMD T score after zolendronic acid**

**Fig 4: BMD T score after zolendronic acid****Fig 5: BMD T score after zolendronic acid****Fig 6: Age distribution**

Results

- Out of 60 patients 50 patients in our study showed increase in BMD after single dose of Zoledronic acid infusion.
- 10 patients were lost follow up.
- 50 patients showed a significant increase in BMD

Adverse effects

The common adverse effects seen are

- Influenza like illness
- Pyrexia
- Myalgia
- Dehydration
- Transient increase in renal parameters
- Gastrointestinal symptoms like- nausea, dyspepsia, abdominal pain

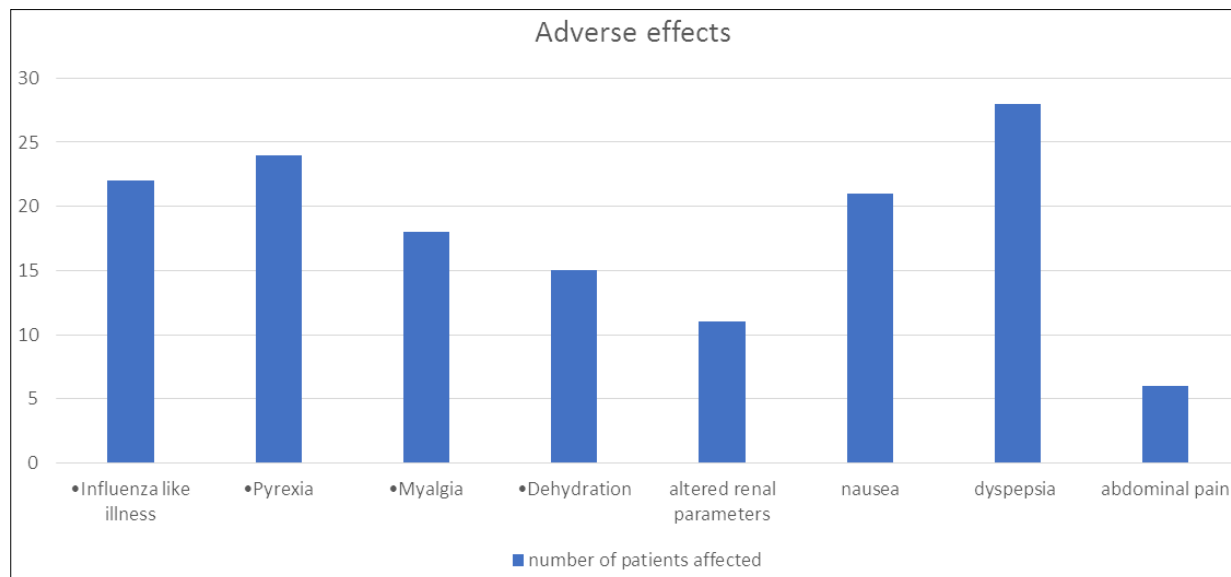


Fig 7: Adverse Effects

- Patients with influenza, myalgia, pyrexia are treated with paracetamol
- Patients presented with dehydration and altered renal parameters are treated with iv fluids
- Patients with gastrointestinal symptoms are treated with proton pump inhibitors and antiemetics
- All off the patients are found symptom free after respective treatments
- Two of patients presented with dehydration and pyrexia, both of them treated with respective treatments and kept under observation for 2 days and became symptom free then both of the patients discharged

Conclusion

- A single dose infusion of zoledronic acid was associated with a significant and sustained increase in bone mineral density. And with the supplement of oral daily elemental calcium and vitamin D3, a better balance ability was obtained after treatment course.
- In addition, the treatment had a favourable safety profile and was generally well tolerated.
- Given the relatively poor adherence to oral bisphosphonate therapy in clinical practice, an annual infusion of zoledronic acid may provide a promising approach in treating osteoporosis and reducing the risk of osteoporotic fracture during the follow up period of 1 year.

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