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Resotration of Bone Mineral Density in Postmenopausal Indian Women with Weekly Alendronate Therapy and Preferred Screening Age for Osteoporosis in Indian Women: Brief Report from Editor

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Abstract

Total 74 postmenopausal osteopenic women confirmed by DEXA with T score <-1.5 were recruited. Group 1 (n=37), received 70 mg oral alendronate and calcium 500mg and VitD 200 IU, Group 2 (n=37) received calcium and VitD in same doses. Therapy was given for 6 months and followup DEXA was done at 6 months. Out of 102 postmenopausal cases 74 were found eligible (71% showing low T score, 30% had osteoporosis and 41% had osteopenia). They presented at median 7 years after menopuase at mean age of 46.7 years. In lumber spine, T score, Z score and BMD (gm/cm^2) improved from -2.4±1.4, -1,8 0.9, 0.751 to -2.2± 1.1, -1.4± 0.9, 0.815 (p=0.001); at hip joint 1.5±0.89, 0.8±1.5, 0.734 to -1.3±1.0, -0.9±0.8, 0.762 (p=0.01) respectively in group 1 wheras in group 2, in lumbar spine, -2.2± 0.85, -1.3± 0.72, 0.808 to-2.1± 0.89, -1.3±1.40, .818, (p>0.05) at hip joint -1.5±0.74, 0.8±0.71, .767 to -1.4±0.67, -1.1±1.50,.764 (p=0.07). There was improvement in BMD by 8.5% in spine and 3.8%in hip in group 1 and 1.2% in spine and no effect in hip in group 2. Hence weekly alendronate is effective and safe. Screening by DEXA in postmenopausal women should be started at 55 years of age in Indian senario.

Keywords:

INTRODUCTION

Reduction in bone mineral density and poor bone health is a foremost health problem after menopause. Hot flushes which can create a menopausal storm, are harmless for long term woman's health whereas osteoporosis may be a silent killer. Osteoporosis is called silent disease because first visible clinical sign of osteoporosis may be fracture of spine or hip.[1] Osteporosis is highly prevalent in India.[2] Risk of postmenopausal hormone replacement therapy long term use for prevention of osteoporosis is a matter of concern now. There is no proper program or recommendation for prevention of osteoporosis[3] Bisphosphonate for treatment of osteoporosis is first line therapy for postmenopausal women now.

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But its daily oral intake at empty stomach is a major cause of poor compliance. Weekly administration of Alendronate can overcome this and is a better option for these patients. Efficacy of weekly alendronate therapy in postmenopausal osteopenic Indian women has not been assessed.

METHODS

Prospective clinical trial was conducted after ethical clearance. Postmenopauasal women who were showing osteopenia or osteoporosis were included in study. Dual energy X-ray absorptionometry (DEXA) was measured. T score of ≤-1.5 in lumbar spine was considered for inclusion. T score ≤-1.5 to ≥2.5 was taken as osteopenia and T score ≤ -2.5 as osteoporosis as recommended criteria. Cases with history of peptic ulcer, traumatic bone fracture and inability to sit up for >30 minutes were not included for therapy. Cases were randomized in two groups. Symptoms were noted down if any. Group 1 received 70 mg oral alendronate (Bifosa – Troikka pharmaceuticals)+ calcium 500mg and Vit.D 200IU Group 2 only calcium and Vit.D. Therapy was started on a fixed day of week with empty stomach in morning, kept upright for 30 minutes and refrain from eating. Treatment continued for 6 months. Side effects were assessed at 1, 3 and 6 months, symptoms relief at 3 and 6 months. Bone mineral Density (BMD) was again measured by DEXA at 6 months and T and Z score at lumber spine and hip joint were computed in both the groups. Long term followup was done at 5-10 years in cases available for follow up.

RESULTS

Out of 102 postmenopausal cases 74 were found eligible (72% showing low T score). They presented at median 7 (range 1-25) years after attaining menopause, with mean age of women being 47.6±3.7 years. Out of 74, 27 cases had T score<2.5 Thus nearly 31 (29.8%) osteoporosis and 43 (41.3%) osteopenic. Out of 74 cases recruited, 37 were randomized to group 1 and 37 to group 2. Total 43 had spontaneous menopause, group 1 - 21(48%) and group 2 -22 (52%) and 31 surgical menopause, group 1 -16(48.8%), group 2 15 (51.2%). Symptoms noted were backache in 29(78.3%) and 27(72.9%) and leg cramps in 20(54.1%), 22(59.4%) in group 1 and group 2 respectively. Side effects noted Gastric ulcer in 5(15%), diarrhoea 1(3%), tremors in 1(3%) in group 1 and gastritis in 2(6%) cases in group 2. Three cases, all in group 1, stopped the therapy. Two patients in group 1 and 5 in group 2 were lost to follow-up, hence 32 cases could be followed in each gp. Overall tolerance to alendronate in 32 women in group 1 was excellent in 6 (18.8%), good in 20(62.5%), average in 5 (15.6%) and poor in 1 (3.1%) cases.

T and Z score and BMD values initially and after 6 months in spine and hip joint in both groups are shown in table 1. Percetage of rise is depicted in table 2.

Long term follow could be done in 9/32 (28.1%) of group 1. Six cases requested for repeated therapies and took 2-3 years medication every 5-7 years and no fractures occurred and tolerated the therapy well. In 4 cases no osteoporosis found which were osteopenic before.

Table 1: DEXA scan initial and after therapy

Site	Group 1	Group 1	Group 2	Group 2
	Pre-therapy	Post-therapy	Pre-therapy	Post-therapy
Lumber Spine			-	
T score	-2.4±1.4	-2.2± 1.1	-2.2± 0.85	-2.1± 0.89
Z score	-1.8±0.9	-1.4± 0.9	-1.3± 0.72	-1.3±1.4
BMD (g/cm^2)	0.751	0.815	0.808	0.818
Hip Joint				
T score	-1.5±0.89	-1.3±1.0	-1.5±0.74	-1.4±0.67
Z score	-0.8±1.5	-0.9±0.8	-0.8±0.71	-1.1±1.5
BMD (g/cm^2)	0.734	0.762	0.767	0.764

Table 2: Rise in BMD after 6 months therapy

BMD site	Rise in BMD group 1	Rise in BMD group 2
Spine	8.5%	1.2%
Hip joint	3.8%	No effect

DISCUSSION

Studies have shown rise in range of 2-15% depending on type of alendronate route and dose. Alendronate 10mg per day for 10 years resulted in 13.7% rise in lumber spine and 5.4% rise in the femour neck,[4] On prolonged used there is concern

of brittle bones. Two years use of risendronate showed 3% overall rise in BMD.[5] Ibandronate monthly use has shown rise of 5% in spine.[6]

The rise of 8.5% in spine T score with weekly alendronate was found comparable to other dosages used in other studies.[6-8] Risk of gastric ulcer and side effects much less. Efficacy on improving hip joint T score was lesser than the spine as only 3.8% rise was observed in our study. Nearly 5% rise in BMD is observed in spine in 1 year.[7] Less rise has been observed even with daily dosages and long term use.[4] Recently Alendronate with metformin is being studied in diabetic mice to improve glucose metabolism and bone health,[9] studies can be conducted in human also.

As far as screening for osteoporosis is concerned, it is recommended at 65 years in normal postmenopausal women in most places[10], including United States also.[11] These guideline are drawn on basis of age of development of osteoporosis in western countries although, they have reported nearly 20% osteoporosis at 50 years. Author observed that in Indian women at mean 7 year postmenopause, 30% developed BMD in osteoporosis range and another 40% were having osteopenia hence screening probably should be started early in our Indian post-menopausal women. Average age of menopause is also early in our Indian women. Hence screening should be started at 55 years of age, so that preventive measures can be taken in time. It will prevent not just fracture but osteoporosis also in women with osteopenia who are already at high risk for development of osteoporosis. It can be applied to other part of world also and screening by DEXA, at least at lumbar spine, and hip joint can be initiated early at 55 years. The age of 65 years late for preventive purpose.

CONCLUSION

Alendronate oral weekly therapy can be instituted safely for postmenopausal women with osteopenia and osteoporosis. This will prevent fracture risk and improve BMD T score in women with osteoporosis also. Long term intermittent therapy can be given with regular followups and supervision. Age for screening by DEXA in postmenopausal women should be decreased to 55 years in India to preserve good bone health and for adequate prevention of osteoporosis and fractures.

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