



Questionnaire Study in Post Menopausal Women on Bisphosphonates for Osteoporosis

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Abstract:

Background: *Osteoporosis is a highly prevalent condition. Bone fractures, especially of the hip and vertebrae, are the most burdensome complications of osteoporosis. Numerous drugs are currently available to treat osteoporosis such as bisphosphonates.*

Materials And Methods: *A structured validated questionnaire containing questions was circulated amongst post menopausal women and orthopedic Surgeons. In this Questionnaire study we have tried to estimate the preference of drugs, which Bisphosphonates, the Patient compliance, by post-menopausal women and the orthopedic surgeons views on bisphosphonates from their experience while prescribing them to post menopausal women.*

Results: *The questionnaire was filled by 50 post menopausal women during a period of 8 months. 90% of the women were on oral Risedronate 70 mg once monthly and 10% women were on oral Alendronate 5 mg once daily. None of the women experienced a single fracture since menopause. 5(10%) women had Hypertension and remaining 90% had no other comorbid conditions. 40 (80%) women were on treatment for osteoporosis since 3 months while 10(20%) were on treatment for 6 months. 5(10%) women were bothered by GI side effects for atleast 3 days on taking medication while 45(90%) on once monthly dose were bothered by side effects for 1 day. On the satisfaction response scale, 30 (85.2%) women were very satisfied in Risedronate and 5(33.3%) in the alendronate group. 5(14.3%) in Risedronate and 10(66.6%) in the Alendronate group were somewhat dissatisfied about the frequency of medication.*

Orthopedic surgeons commonly prescribed Risedronate. The medication was affordable to all the patients. The adherence of patients was 40(80%) women most of the times. The most common side effects were nausea and vomiting seen in 45(90%) patients.

Conclusion: *Amongst the Bisphosphonates once monthly Risedronate was the most commonly prescribed drug. The patient adherence and compliance was also better for once monthly dose of Risedronate. The Orthopaedic Surgeons got better compliance with once monthly Risedronate.*

Background

Osteoporosis is a highly prevalent condition characterized by decreases in bone mass and

microarchitectural alterations. According to the World Health Organization (WHO), osteoporosis is defined as a bone mineral density (BMD) at the

hip and/or the spine at least 2.5 standard deviations below the mean peak bone mass of young healthy adults as determined by dual-energy X-ray absorptiometry (DXA).¹ Mortality associated with osteoporotic fractures ranges from 15 to 30%, a rate similar to breast cancer and stroke.²

Secondary osteoporosis may be the consequence of endocrine and metabolism disorders or certain drugs (e.g., corticosteroids, selective serotonin reuptake inhibitors, anticoagulants and antidiabetic medications)². Regardless of the etiology, in all cases of osteoporosis an imbalance exists between bone resorption and formation: the rate of bone formation is often normal, whereas resorption by osteoclasts is increased.³ Postmenopausal osteoporosis is characterized by accelerated loss of bone mass and deterioration of bone architecture, leading to increased fracture risk¹. The population of India is expected to increase to 1,367 million by 2020 and 1,613 million by 2050; of which 9.8% (134 million) and 19.6% (315 million), respectively, will be adults over 60 years⁴. These staggering numbers give some idea of the population at risk for osteoporosis in India in the years to come.

Osteoporosis is becoming a serious problem for the public economy and health, because of the increase in elderly population in the near future. Conservative estimates in a study suggest that 20% of women and about 10-15% of men are osteoporotic in India⁵. From longtime osteoporosis therapeutics have been dominated by anti-resorptive agents like bisphosphonates. According to the evidences available it is found that they can reduce fracture risk by only 50%⁶. The antifracture efficacy and relative safety of the aminobisphosphonates have been well established in clinical trials. There have been concerns that prolonged use of these drugs may cause rare but serious adverse events such as Osteonecrosis of the jaw and Nephrotoxicity.

Aims

- To find out Bisphosphonate's preferred for treatment of Osteoporosis.
- To detect various adverse effects seen with Bisphosphonates.

Materials And Methods

A structured, validated questionnaire containing questions related to Bisphosphonates therapy was formed. This questionnaire was circulated amongst 50 post menopausal women on Bisphosphonates. In this questionnaire study we have tried to find out Patient compliance and preference to Bisphosphonates. Another Questionnaire was formed for 50 Orthopaedic Surgeons to know their views on Bisphosphonates therapy. Based on their experience while prescribing Bisphosphonates, information was collected through the Questionnaire.

Results

The Questionnaire was given to 50 postmenopausal women on Bisphosphonates for Osteoporosis. And another questionnaire was given to Orthopedic doctors.

Demographic findings are as follows in table no 1

Table no 1: Demographic findings:

ITEM	RISEDRONATE	ALENDRONATE
Mean age (years)	63	64
Living situation		
Living alone	0(0%)	0(0%)
Living with family	35(100%)	15(100%)
Work status		
Working		
Retired	35 (100%)	15(100%)
Education		
Secondary school	Nil	2(66.7%)
University	35(100%)	1(33.3%)
Mean BMI	29.6	30.5

35(70%) women had Hypertension, 10(20%) women had Diabetes Mellitus and 5(10%) had no other co- morbid conditions.

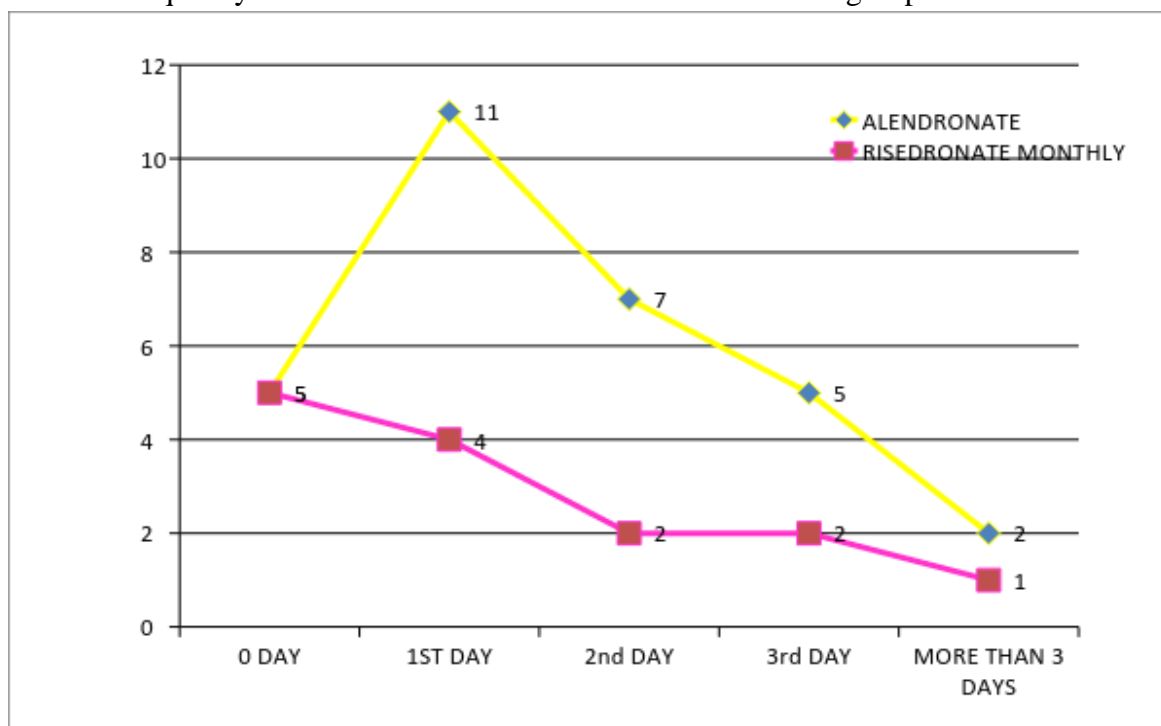
Currently 35 (70%) were taking tab Risedronate once monthly and 15(30%) were taking tab Alendronate once daily.20(40%) women were on bisphosphonates since 6 months,10(20%) since 1 year,10(20%) since 9 months, 5(10%) since 4 months and 5(10%) since 8 months respectively.

Adverse effects:

The common adverse effects experienced were as follows:

10(20%) women had acid reflux on day 0,30(60%) had Acid reflux on day 1,10(20%) had Acid reflux on day 2 of taking the medication.30(60%) women had diarrhoea on day 0,15(30%) had diarrhoea on day 1. 5(10%) women had stomach pain on day 0, 15(30%) had stomach pain on day 1,20(40%) had on day 2 and5(10%) had on day 3 respectively.

The figure no 1: Frequency of Gastro intestinal adverse effects in the two groups:



Patient satisfaction measures:

On the satisfaction response scale, 30 (85.2%) women were very satisfied in Risedronate and 5(33.3%) in the alendronate group. 5(14.3%) in Risedronate and 10(66.6%) in the Alendronate group were somewhat dissatisfied about the frequency of medication.

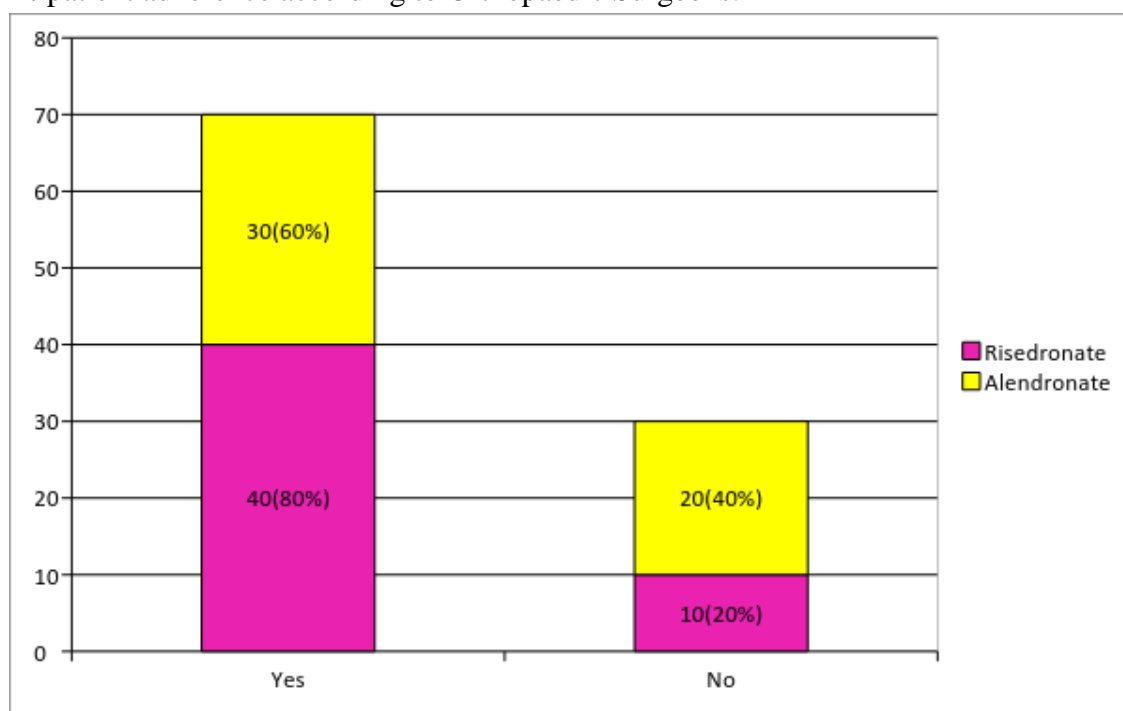
30 (85.0%) women were very satisfied in Risedronate group and 6(40%) in the Alendronate group. 5(14.3%) in Risedronate and 9(60.%) in the Alendronate group were somewhat dissatisfied to continue their respective medications.

About the ease of taking the medication 5(14.4%) women, in the Risedronate group 12(80%) in

alendronate were somewhat dissatisfied. 3(20%) in alendronate group, 30(85.7%) in the Risedronate group were very satisfied about the daily medication schedule.

28 (80%) women were very satisfied in Risedronate and 10(66.7%) in the Alendronate group respectively. 7(20%) in Risedronate and 5(33.3%) in the Alendronate group were somewhat dissatisfied about the cost of medication.

According to Orthopaedic surgeons patients compliance was better with Risedronate than alendronate.

Figure no 2: patient adherence according to Orthopaedic Surgeons:

Discussion

Osteoporosis is characterized by decrease in bone mass and microarchitectural alterations. WHO defines Osteoporosis as a Bone Mineral Density at the hip and/or the spine at least 2.5 standard deviations below the mean peak bone mass of young healthy adults as determined by dual-energy X-ray absorptiometry (DXA). There is imbalance between bone resorption and bone formation. Postmenopausal osteoporosis is characterized by accelerated loss of bone mass and deterioration of bone architecture, leading to increased fracture risk. Bisphosphonates (Alendronate, Risedronate, Zoledronate) are First Line Therapies for prevention of Fractures.

This study tried to evaluate the commonly used Bisphosphonate and patient compliance and incidence of adverse effects. Post menopausal women with Osteoporosis showed better compliance with Risedronate as compared to Alendronate. The GI side effects were more with Alendronate than Risedronate. The Orthopaedic surgeons concluded that post menopausal women taking Risedronate monthly preferred it over Alendronate daily. The factors contributing to this preference were GI adverse effects which were

more in those taking Alendronate daily. Also, the cost of Risedronate and Alendronate were related to patient satisfaction with Risedronate being preferred over Alendronate. On the satisfaction response scale women taking Risedronate were more confident about being active and were very satisfied with it.

These findings in contrast to a study conducted by Emuella M et al 2006. In this study the findings were that weekly Alendronate was preferred by 61(59%) of post menopausal women. The most common regimen was weekly alendronate (59%), followed by weekly Risedronate (20%), daily alendronate (13%), and daily Risedronate (6%).

Limitation: One limitation of the study is that the focus groups comprised a sample of volunteers, which is not representative of all women with osteoporosis taking bisphosphonates.

Conclusion

Bisphosphonates are most commonly prescribed drugs for osteoporosis in post menopausal women with Osteoporosis. Risedronate monthly is more preferred to Alendronate daily both by post menopausal women and Orthopaedic surgeons.

References

1. Genant HK, Cooper C, Poor G, et al. Interim report and recommendations of the World health organization task force for osteoporosis. *Osteoporos Int.* 1999;10:259-264.
2. Società Italiana dell'Osteoporosi, del Metabolismo minerale e delle Malattie dello Scheletro (SIOMMMS). Linee guida per la diagnosi, prevenzionee terapia osteoporosi. 2012. Available at http://www.siomms.it/downup/LINEE_GUIDA_DIAGNOSI_PREVENZIONE_TERAPIA_OSTEOPOROSI_2012.pdf. Accessed January 9, 2014
3. Akesson K. New approaches to pharmacological treatment of osteoporosis. *Bull World Health Organ.* 2003;81:657-664.
4. World Population Prospects: The 2008 Revision Population Database. United Nations Population Division. <http://esa.un.org/unpp>, 2010.
5. Malhotra N, Mithal A. Osteoporosis in Indians. *Indian J Med Res.*2008; 127:263-8.
6. Cranney A, Guyatt G, Griffith L, Wells G, Tugwell P, Rosen C *et al.* Meta-analyses of therapies for postmenopausal osteoporosis.IX: Summary of meta-analyses of therapies for postmenopausal osteoporosis. *Endocr Rev* 2002; 23:570-8.