



International Journal of Pharmaceutical and Phytopharmacological Research (eIJPPR) [Impact Factor – 0.7826]

Journal Homepage: www.eijppr.com

Research Article

Comparative Assessment of Oral Estrogen and Calcium Supplement Therapy in Osteoporosis Management

Amin Prakruti Mukund*, Pachpute Dipali Subhash, Amin Pragati Mukund, Rakibe Vaishali Dnyaneshwar, Baisane Vrushali Vasantao

Department of Pharmaceutics, M.G.V's Samajshri Prashantdada Hiray College of Pharmacy, Pune University, Malegaon Camp, Malegaon Dist. Nasik, India

Article info

Article History:

Received 1 September 2013

Accepted 23 October 2013

Keywords:

Osteoporosis, Calcium, Vitamin D, Estrogen therapy

Abstract

Osteoporosis is a global public health problem currently affecting more than 200 million peoples worldwide. Eighty percent of people who suffer osteoporosis are women. Primary objective of our study was to carry out the comparative assessment of Estrogen and calcium supplement therapy in osteoporosis management and to assess the views of physician towards these both therapies. Secondary objectives are to determine the fastest moving brands and mostly preferred therapy for osteoporosis and prevention of this disease to the maintenance of health and quality of life. Coming to the drug therapy, about 40.5% physician reveals that Bisphosphonate therapy is used to treat osteoporosis and about 31% physician preferred calcium supplement and 20.5% physician used Estrogen replacement therapy for management of osteoporosis. 7% physicians suggest calcitonine for osteoporosis management. Chemists survey shows that the fastest moving brand of calcium are Shelcal tablet (calcium and vitamin D) and Ostocalcium tablet. In case of estrogen, Premarin tablet is the fastest moving brand. Calcium reach diet, exercise and exposure to the sun light are supportive measures for osteoporosis management.

1. INTRODUCTION

Osteoporosis is a widespread metabolic bone disease characterized by low bone mass with micro architectural deterioration of bone tissue leading to enhance bone fragility thus increasing to susceptibility to fracture. Its prevalent among postmenopausal women is more but also occurs in men and women with underlying conditions or major risk factors associated with bone demineralization. Its chief clinical manifestations are vertebral and hip fractures, although fractures can occur at any skeletal site. 80%, 75%, 70% and 58% of forearm, humerus, hip and spine fractures, respectively, occur in women. Overall, 61% of osteoporotic fractures occur in women, with a female-to-male ratio of 1:6¹. Osteoporosis is a global public health problem currently affecting more than 200 million people worldwide. As the worldwide population ages, the prevalence of osteoporosis is increasing. About 70% people of India suffering from osteoporosis. In India the number of osteoporosis patients is approximately 26 million (2003 figures) with the numbers projected to increase to 36 million by 2013. It is because of increase in life expectancy (1947- 37 yrs to 2006, 67yrs) and populations. Another reason is that the peak incidence of osteoporosis in India is 50-60 years, as compared to 70-80 years in the West. The acute and long-term medical care expenses associated with these fractures cost across the world an estimated \$17 billion in 2009. The cumulative cost over the next two decades is estimated to be \$474 billion. In addition to a financial burden, osteoporosis-related fractures bring a burden of pain and disability, resulting in lost work time or inability to perform daily living activities¹.

1.1 Incidence and Prevalence of Osteoporosis in India

- 1 out of 8 males and 1 out of 3 females in India suffers from osteoporosis, making India one of the largest affected countries in the world².
- Expert groups peg the number of osteoporosis patients at approximately 26 million (2003 figures) with the numbers projected to increase to 36 million by 2013³. Two points worth noting about osteoporosis in India - the high incidence among men and the lower age of peak incidence compared to Western countries.
- The incidence of hip fracture is 1 woman to 1 man in India⁴.
- In most Western countries, while the peak incidence of osteoporosis occurs at about 70-80 years of age, in India it may afflict those 10-20 years younger i.e. at age 50-60⁴.

1.2 Risk Factors

Human beings of all races and ethnicity are prone to osteoporosis and fracture. It has been shown that blacks have greater and Asians have lower bone mass than whites. Several risk factors contribute to low bone mass. These include non-modifiable factors like female sex, old age, small thin built, Caucasian/Asians and family history of fractures. Ethnic differences in bone mineral density (BMD) are strongly influenced by body weight. Important modifiable risk factors include calcium and vitamin D deficiency, sedentary life style, smoking, excessive alcohol and caffeine intake. A case control interview based study on postmenopausal women showed history of fracture in relatives, weight <60 kg, height <155 cm as significant risk factors for osteoporosis and regular consumption of milk, almonds, fruits as protective factors. Medical conditions like hypogonadism, thyrotoxicosis, Cushing syndrome, anorexia nervosa, malabsorption syndromes, chronic liver and renal disease, drugs like glucocorticoids and anticonvulsants, and chronic inflammatory conditions like rheumatoid arthritis may lead to secondary osteoporosis⁵⁻⁶.

*Corresponding Author

Amin Prakruti Mukund

Mahatma Gandhi Vidyamandir's Samajshri

Prashantdada Hiray College of Pharmacy,

Loknete Vyankatrao Hiray Marg, Malegaon Camp,

Malegaon-423105, India

E-mail : prakrutiamin@gmail.com

Mobile No.: +91-9890085132

Table 1: Risk factors for Osteoporosis

Risk factors for Osteoporosis	
Non Modifiable	Modifiable
Personal History of fracture As an adult Female sex Advanced age Caucasian race Dementia	Current cigarette smoking Low body weight(<50 kg) Estrogen deficiency Low calcium intake Alcoholism Recurrent falls Inadequate physical inactivity Poor health

Until recently, osteoporosis was an under-recognized disease and considered to be an inevitable consequence of ageing. Perceptions have changed since epidemiological studies have highlighted the high burden of the disease and its costs to society and health care agencies, as well as the adverse effects on millions of patients worldwide.

1.2 Management

There is a range of drug treatment available for postmenopausal osteoporosis. Different studies have consistently shown that, depending on the drug and the patient population, treatment reduces the risk of vertebral fracture by between 30-70%, non-vertebral fractures by between 15-20%, and hip fractures up to 40%. Treatment of established osteoporosis is cost-effective irrespective of age and therapies with proven rapid efficacy may offer important value to healthcare payers, providers and patients. The two FDA approved indications for osteoporosis medication - prevention and treatment - were created. The 'prevention' of osteoporosis indication applies the drugs that demonstrate maintenances of BMD above the osteoporosis threshold. The 'treatment' indication however is based on a drug ability to demonstrate fracture risk reduction. There is pharmacological and non-pharmacological intervention for the management of osteoporosis. Non pharmacological intervention includes universal public health measures such as calcium supplements along with vitamin D and exercise are recommended in all patients regardless of BMD, as they are efficacious, safe and cost effective. Non-pharmacological interventions alone are not always sufficient to prevent osteoporosis -related fractures and drug therapy is often necessary. The choice of pharmacotherapy depends on many individual patient specific characteristics and preferences. The education of women about the risk factors and strategies for prevention, screening and treatment of osteoporosis by health care providers can help in the prevention of osteoporosis.⁷ In general, pharmacological agents either decrease bone resorption to produce secondary gains in bone mass or are anabolic and produce direct increases in bone mass. Ideally, such drugs also should increase bone strength and bone quality. As the turnover of bone is slow, the time between starting treatment and assessing its effect on bone mass or fracture takes several years. Because this makes it difficult to show the effect of treatments on the dichotomous and uncommon key outcome of fracture, the continuous variable bone mass is often used as a surrogate measure. An increasing number of randomized controlled trials of several anti-osteoporotic drugs have fracture as an endpoint, however, and show reductions in the incidence of fractures within 1-3 years. In addition to estrogen, drugs with specific anti-resorptive actions are available for the treatment of osteoporosis, including bisphosphonates, calcitonin, and selective estrogen receptor modulators. Furthermore, calcium and vitamin D act on bone by decreasing resorption, while calcium also is regarded as an essential building block for bone.⁸

2. OBJECTIVES

The study aims to evaluate following:

2.1 Primary objectives

- To carry out the comparative assessment of oral Estrogen and calcium therapy in osteoporosis management.
- To assess the views of physician toward these both therapies

2.2 Secondary Objectives

- To determine the fastest moving brand in both therapies.

- View of physician towards prevention of this disease and to maintenances of health and quality of life.

3. METHODOLOGY

A. Primary Source: Primary data was obtained by administering questionnaires to Physician and Chemist.

B. Secondary Source: The related information was obtained from journals, Pharmaceutical magazines, Internet and other sources.

C. Methods of Data Collection:

- Preliminary communication with Physician, and Chemist.
- Preparation of sets of questionnaire to evaluate perception of the selected target group and administering questionnaire.

D. Sampling Procedure: Simple convenient sampling.

E. Sample Size: Total of 50 comprising, orthopedics -10 gynecologists -10, General physician -5 and Chemists- 25

F. Survey Area: Malegaon, (District- Nashik).

4. RESULTS AND DISCUSSION

Although various pharmacological and non pharmacological therapies are available for the treatment of osteoporosis. Drug therapy is considered as major component of patient care in health care setting. The present study focus on estrogen and calcium supplement therapy in osteoporosis.

4.1 Age Group and Common Cause of Osteoporosis

The study result shows that, the patient from the age group 50 years suffers from osteoporosis. The most common cause of osteoporosis is Vitamin D deficiency, followed by estrogen deficiency in the women (After post menopause). Prolonged use of medicines for the chronic disease is also responsible for disease condition as its leads to impaired liver function. Other causative factors are aging, physical inactivity, lifestyle related factors (such as smoking and alcohol). Distribution of various risk factors of osteoporosis is shown in fig.1.

Vitamin deficiency induced osteoporosis is very common.

Most of the physician reviewed that low vitamin-D level (low calcium intake) seems to be a major contribution factor in poor bone health in India. Followed by poor sunlight exposure and lack of exercise and vitamin-D deficient diet are some obvious causes.

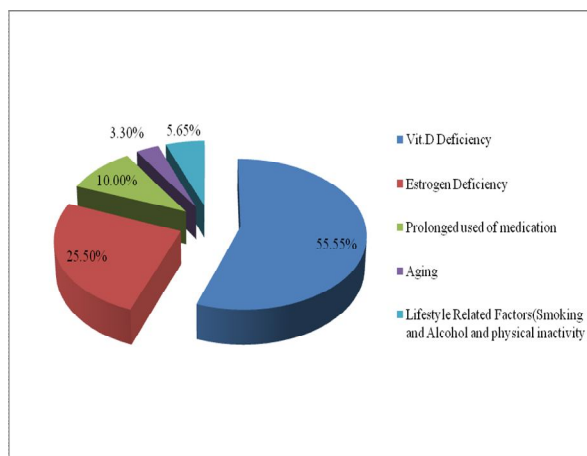


Figure 1: Distribution of various risk factors of osteoporosis

4.2 Comparison of Therapies for Osteoporosis.

Basically treatment for the patient with osteoporosis frequently involves management of fractures and associated pain. The present study focus on preferences on pharmacological and non pharmacological treatment. Most of the physician aimed towards non pharmacological measures includes calcium rich diet, Calcium supplement with Vitamin D₃ and exercise regardless of their BMD as they are safe, cost effective and efficacious. Most of the physician opined that it is depends on patient condition, individual value, risk

of fracture and cost. Bisphosphonates is the drugs of choice in usual to moderate cases. Gynecologist suggests that women near to postmenopausal go for Estrogen or Hormone therapy. As ET maintained BMD in their senior age. ET or HT shows that there is decrease in the risk of vertebral, hip and other types of fractures. Various dosage form for estrogen therapy are available - oral, transversal, ET implants and intrauterine impregnated devices and creams shows positive effect on bones.

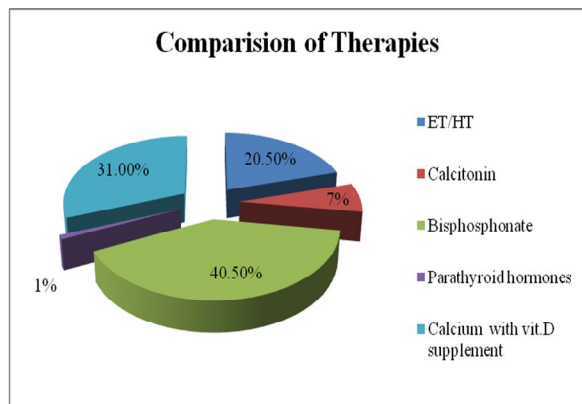


Figure 2: Comparison of therapies

Chemists survey shows that the fastest moving brand of calcium are Shelcal tablet (calcium and vitamin D) and Ostocalcium tablet. According to 50% chemists, shelcal tablet is economically preferred brand of calcium. In case of estrogen, Premarin tablet is the fastest moving brand.

5. CONCLUSION

Primary data was obtained from market research. Secondary data was obtained from pharmaceutical magazines, journals and Internet. The method of data collection was preliminary communication with chemists and doctors to get consent to participate in the survey. The sampling technique adopted was convenience sampling. The data obtained was tabulated and compared. The study shows that 90% of the physician opined that, the patient from the age group above 50 years suffers from osteoporosis. While coming to the drug therapy, about 40.5% physician reveals that Bisphosphonate therapy is used to treat osteoporosis and about 31% physician preferred calcium supplement and 20.5% physician used Estrogen replacement therapy for management of osteoporosis. 7% physicians suggest

calcitonine for osteoporosis management. Chemists survey shows that the fastest moving brand of calcium are Shelcal tablet (calcium and vitamin D) and Ostocalcium tablet. According to 50% chemists, shelcal tablet is economically preferred brand of calcium. In case of estrogen, Premarin tablet is the fastest moving brand. Calcium reach diet, exercise and exposure to the Sun light are supportive measures for osteoporosis management. Most of the physician opines that to minimize future predicted costs, morbidity, and mortality from increasing numbers of osteoporosis fractures in our rapidly aging population, should become a national public health priority. It appears that overall Indians have poor bone health and now osteoporosis is becoming common in India. High prevalence of vitamin D deficiency in India contributor to low bone mass. It is observed that women's from low income group, who consumes diet with inadequate calcium, proteins and micronutrients, are suffer from osteoporosis. Various guidelines are prepared and published for the management of osteoporosis. All these guidelines due importance to nutrients, balance diet with average calcium intake of 750 mg per day in women and 1000 mg per day in men. As a public health measure, it is important to encourage the children to take calcium rich food and regular exercise along with adequate exposure to sunlight. These three elements such as calcium intake, vitamin D synthesis and exercise are crucial elements for the management of osteoporosis. There is thus an urgent need for greater public awareness in this regards.

REFERENCES

1. "State by State Prevalence Report" by National Osteoporosis Foundation, "1996 and 2015 <http://www.outlookindia.com> 2004.
2. "Action Plan Osteoporosis consensus statement of an expert group" Osteoporosis Society of India (2003).
3. Damodaran P, Subramaniam R, Omar SZ, Nadkarni P, Paramsothy M., "Profile of a menopause clinic in an urban population in Malaysia" *Singapore Med J.* 2000; 41(9): 431-435,
4. Malhotra N., Mithal A. "Osteoporosis in Indians" *Indian J Med Res.* 2008; 127: 263-268.
5. Harrison T. R. ,Kasper D. I., Hauser, S. L, et al Harrison's Principles of Internal Medicines, 16th edition, McGraw-Hill Medical Publishing Division, New Delhi,2005,2269-2270.
6. Dipiro J.T., Talbert R. L., et al Pharmacotherapy A Pathophysiologic Approach, 6th edition, McGraw-Hill Medical Publishing Division, New Delhi, 2005,1652-1660.
7. Kristina Å., "New approaches to pharmacological treatment of osteoporosis" *Bulletin of the World Health Organization* 2003, 81 (9): 658.