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COST-EFFECTIVENESS AND PHARMACOECONOMIC ANALYSIS OF TWO DIFFERENT COMBINATIONS OF DRUGS USED IN OSTEOPOROSIS PATIENTS IN A TEACHING HOSPITAL

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ABSTRACT: The purpose of the study is to update and review the latest developments related to modelling and economic evaluation of osteoporosis and further to present a reference model for the assessment of the cost of the prevention and treatment of osteoporosis. To find out the most cost-effective drug combination between the two combinations (Alendronate + Vitamin D supplements & Strontium ranelate + Calcium supplements) in osteoporotic & severe osteoporotic patients and health related quality of life of osteoporotic patients. A prospective observational comparative study (Cost-effectiveness Analysis) was carried out in 60 patients in which 30 each in severe and very severe Osteoporotic groups, who are prescribed with any one of the following combinations (Alendronate+Vitamin D supplements and Strontium ranelate+Calcium supplements) were selected. We have used 3 different parameters such as bone mineral density test (initial and final values), health related quality of life and X-Ray. Comparison of costs and effects were done. The mean of the calcium values of group I (Alendronate + Vitamin D supplements) during their initial visit were found to be 2.35 mmol/L and the calcium values are profoundly increased after the final visit to 3.75 mmol/L. This increase highly significant statically at 95% of CI. The mean calcium values for the group II (Strontium ranelate + Calcium supplements) during their initial visit were found to be 2.5 mmol/L and this was also increased up to 3.375 mmol/L which was very low when compared to the increment of group I patients who are prescribed with medication (Alendronate+Vitamin D supplements). The overall cost for group I and group II subjects during the 6 months study period was Rs. 40953/- and 54839/- respectively. Also a questionnaire was taken during initial and final visit to measure the quality of life of Osteoporotic patients. Group I patients was responded more positively than group II patients. The model is flexible and allows for the estimation of the cost-effectiveness over different ranges for a selected number of variables (E.g. Age, fracture risk, cost of intervention), thus suggesting that health care costs would also be affected positively. Results from our study show that Alendronate+Vitamin D supplements and supportive care was effective strategy to treat osteoporosis. The usage of strontium ranelate was also effective but its usage caused many side effects and increase in cost to treat those side effects.

INTRODUCTION: Osteoporosis is a major public threat and a common disease of older adults and is a major public health problem worldwide.¹

As the population ages, the incidence of osteoporosis and resulting osteoporotic fractures is increasing. Although osteoporosis is more common in women than in men, the incidence in men is also increasing.² The disability, mortality and cost of hip and vertebral fractures are substantial in the rapidly growing, aging population so that prevention and treatment of osteoporosis is a major public health concern. This study reviews the impact of osteoporosis and provides an evidence

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based approach towards preventing and treating osteoporosis and its complications.³

The Consensus Development Conference statement in 1993 defined osteoporosis as “a disease characterized by low bone mass and micro architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk”.⁴ In 1994, the World Health Organization (WHO) established bone mineral density (BMD) measurement criteria allowing the diagnosis of osteoporosis before incident fractures.⁵ This practical definition is based on its major risk factor: reduced bone strength or density and includes those individuals who are at a high risk but without fractures.

TABLE 1: DIAGNOSTIC CATEGORIES FOR OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN BASED ON WORLD HEALTH ORGANIZATION

Category	Definition By Bone Density
Normal	A value for BMD that is not more than 1 SD below the young adult mean value.
Ostopenia	A value for BMD that lies between 1 and 2.5 SD below the young adult mean value.
Osteoporosis	A value for BMD that is more than 2.5 SD below the young adult mean value.
Severe Osteoporosis	A value for BMD more than 2.5 SD or below the young adult mean in the presence of one or more fragility fractures.

BMD: Bone mineral density, SD: Standard deviation.

Methodology:

We planned a cost-effectiveness analysis (CEA) on two different drug combinations (Alendronate+Vitamin-D supplements and Strontium ranelate+Calcium supplements). The CEA is the typical economic evaluation that should be performed when comparing 2 or more therapeutic alternatives whose clinical efficacy is not equivalent. In this analysis, both the costs and the health consequences of the alternatives are examined.

The two therapeutic alternatives considered were:

- ✓ Alendronate 5mg+Vitamin-D supplements were given to the patients whose BMD that

is between 2 to 2.5 SD below the young adult mean value and whose calcium values are less than 2.0 millimoles/litre.

- ✓ Strontium ranelate+Calcium supplements were given to patients whose value for BMD more than 2.5 SD or below the young adult mean in the presence of one or more fragility fractures.

The direct comparison between two alternatives is obtained through the Incremental Cost Effectiveness Ratio (ICER). Comparing strategy 1 with strategy 2, the ICER value represents the relative increment of cost at which a relative unitary increment of benefit could be obtained. If we indicate the cost of the two alternatives by C1 and C2 and the benefits (for instance, life years saved, hospitalization avoided by B1 and B2 this gives Eq. (1)

$$ICER=C1-C2/B1-B2 \text{ ----- (1)}$$

Study site:

This study was conducted in the out-patient and inpatient setup of general medicine department of Owaisi Hospital and Research Centre, Hyderabad, Telangana State, India. It is a 1000-bedded teaching Hospital situated in the heart of the city of Hyderabad, providing specialized health care services to all people.

Study design:

A Hospital based Prospective Observational Comparative study was conducted on 60 osteoporotic patients. In this data was collected from both case records and patients.

Study period: 6 months

Sample size:

A total of 60 patients who were taking treatment for osteoporosis are selected according to inclusion and exclusion criteria for the study.

Study criteria:

The following categories of patients were admitted in MICU ward Inpatients and also out patients were enrolled into the study.

Inclusion criteria:

Those patients who are prescribed with any one of the following drug combination:

- ✓ Alendronate+Vitamin D supplements
- ✓ Strontium ranelate+Calcium supplements.
- ✓ Patients who are willing to give their informed consent to participate in the study.
- ✓ Patients in MICU who are diagnosed with osteoporosis.
- ✓ Patients in outpatient department with osteoporosis.

Exclusion criteria:

- ✓ Patients who are not willing to participate in the study.
- ✓ Pregnant woman are excluded.

Source of data:

Patient's data relevant to the study was obtained from the following sources:

- ✓ Patient case record
- ✓ Patient counseling

Expected outcomes:

- ✓ The six months average cost of patients participated in the study.
- ✓ Calcium levels improvement

Costs and cost perspective:

- ✓ Direct costs take into account hospitalizations, medical visits, laboratory investigations, pharmaceutical treatments (different from alendronate or strontium ranelate), oxygen therapy, lung ventilation, travelling cost and rehabilitative therapy.
- ✓ Indirect costs account for lost productivity of the patient and first degree relatives.

- ✓ We have classified both direct and indirect costs in two parts, one caused directly by fracture, pain and one independent of them.
- ✓ The pharmaceutical cost for the active treatment (alendronate or strontium ranelate) should be added to direct exacerbation independent cost.

Statistical Analysis:

Data were analyzed by using Statistical Program for Social Science (SPSS) version: 13.0. For testing significance between groups, student's t-test was used. Descriptive statistics for cost and calcium level are presented as mean and 95% confidence interval (CI).

RESULTS: A total of 60 osteoporotic patients were assessed for Cost-effectiveness of combined Alendronate +Vitamin-D and Strontium ranelate+Calcium supplements with respect to Bone mineral density and Cost (direct, indirect and total cost) during the period of six months. These 60 osteoporotic patients are divided into two groups (Group I, Group II), each group consisting of 30 patients with equal number of severe and very severe osteoporotic patients. Group I subjects are those who are prescribed with medication Alendronate+vitamin-D, group II subjects with medication Strontium ranelate+Calcium supplements. Data was collected at two points one at the initial visit i.e. as soon as the patient diagnose with osteoporosis and was prescribed with any one of the two combinations either Alendronate+Vitamin-D or Strontium ranelate+Calcium supplements and final visit i.e. after using the same medication for 6 months (which was prescribed at the initial visit). The test data obtained is enumerated as follows.

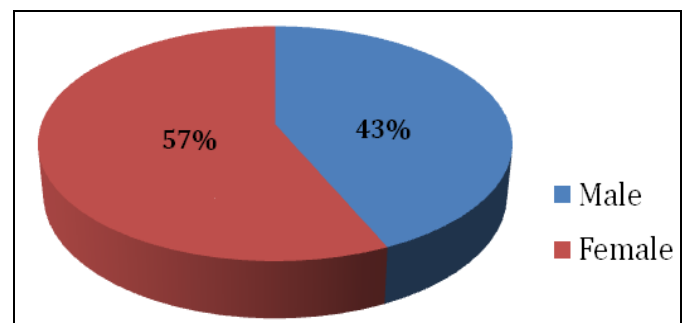


FIG.1: GENDER DISTRIBUTION OF OSTEOPOROSIS PATIENTS

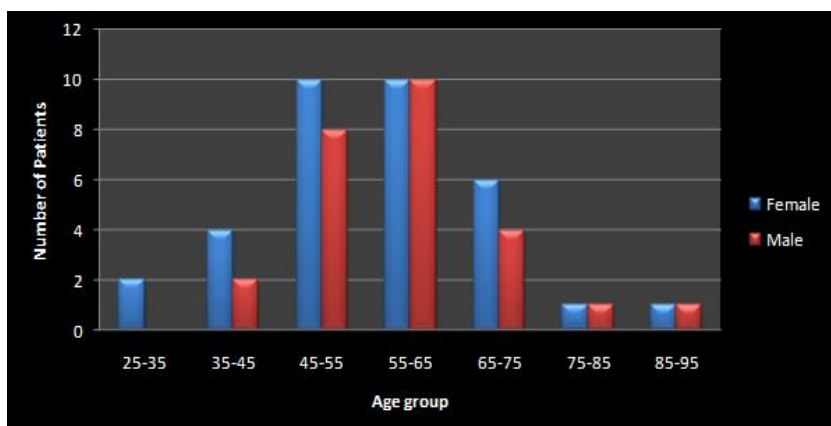


FIG. 2: AGE DISTRIBUTION OF PATIENTS

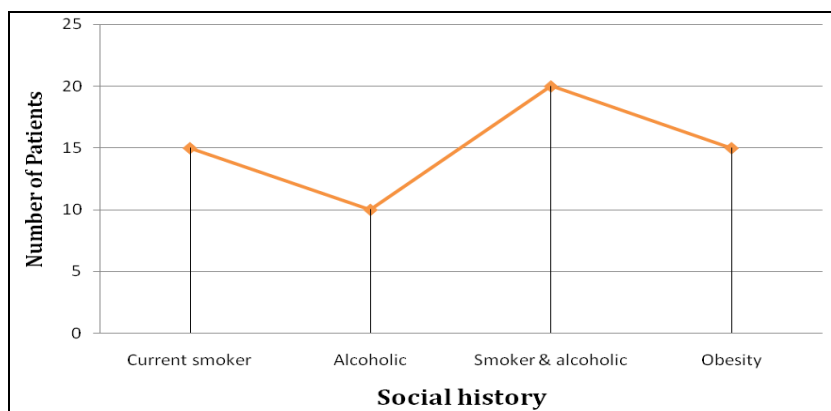


FIG.3: SOCIAL HISTORY OF OSTEOPOROSIS PATIENTS

TABLE 2: MEAN CALCIUM VALUES (INITIAL & FINAL VISIT)

Drug Combination	Initial visit	Final visit
Alendronate +Vitamin D	2.35 mmol/L	3.75 mmol/L
Strontium ranelate+Calcium supplement	2.5 mmol/L	3.375 mmol/L

TABLE 3: COSTS (RUPEES) & OUTCOMES AT THE END OF 6 MONTHS (AVERAGE VALUES PER PATIENT)

Combination used	Type of osteoporosis	Direct cost	Indirect cost	Total cost
Alendronate +Vitamin D	Severe and very severe osteoporosis	25,455	15,498	40,953
Strontium ranelate+Calcium supplements	Severe and very severe osteoporosis	36,885	17,954	54,839

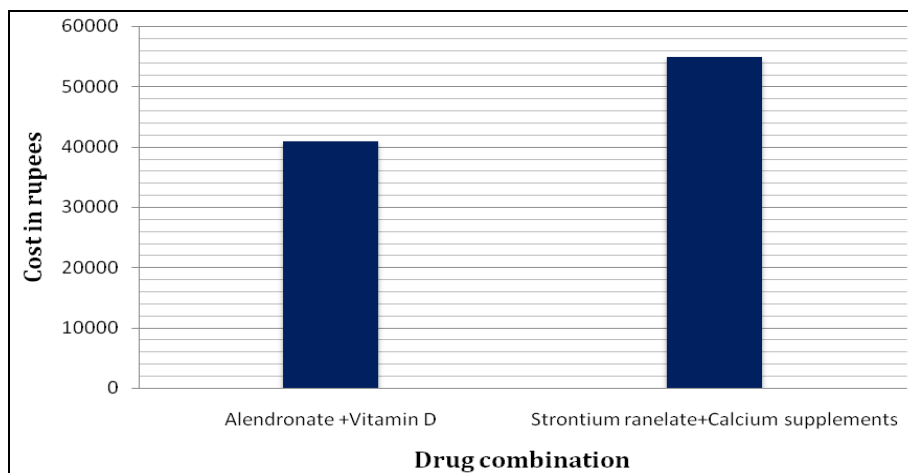


FIG.4: TOTAL COST WITH DIFFERENT TREATMENT GROUPS

DISCUSSION: According to the 2009 WHO Report Healthy Aging, 3% of men and 19% of women aged 50 or older reported having been diagnosed with osteoporosis.⁶ Cost-effectiveness analysis is a method for assessing costs and benefits of alternative ways of allocating resources in order to assist decisions aiming at achieving efficiency. It is important that these decisions are based on reliable and valid assessment of cost effectiveness. New opportunities for the prevention and treatment of osteoporosis will continue to be developed and established methods need to be reassessed in view of new evidence.⁷

Modeling will always play an important role in the assessment of the cost-effectiveness of the prevention and treatment of osteoporosis. A reference model may contribute to increasing the quality and reliability of cost effectiveness analyses of new technologies in the osteoporosis field. It further provides opportunities for validation and discussion of results from other models, which may clarify reasons for discrepancies.^{8,9}

We conclude that the costs of osteoporosis for the public health system are staggering. However, the federal or the provincial governments have not made the disease a high priority.¹⁰ Efforts for the prevention of the disease are urgently needed; some recommendations follow: Physicians should be urged to identify patients at high risk of fragility fractures to promptly confirm the diagnosis of osteoporosis and to start treatment if necessary. Access to reimbursement of bone mineral density scans must be improved for people at high risk of fragility fractures, especially before any fracture event. Media campaigns to increase the awareness of prevention and treatment possibilities towards fighting against osteoporosis. Medical institutions should establish programs to ensure adherence of osteoporotic patients to the indicated treatment plans.

Better nutrition for children, adolescents, pregnant women and the elderly; fortification of food with calcium and Vitamin D. Priority should be given to these measures in geographic areas at high risk of hypovitaminosis D. Encouragement of adequate exercise programs for adults and the elderly. Better practices to produce practical, cost-effective

strategies with measurable targets for reducing osteoporotic fractures must be implemented. Education starting in primary school and sustained in high school and the tertiary level. Improved accessibility to diagnosis and proven therapies alone is not enough. Better education of policy makers, healthcare professionals, and the general public is necessary to reduce the incidence and burden of osteoporotic fractures.^{11,12}

The main scope of this study was to evaluate the clinical and economic consequences of implementation of guidelines given by International Osteoporosis Foundation for severe and very severe osteoporosis patients.

A prospective observational comparative study (pharmacoeconomic analysis) was conducted to assess the cost-effectiveness of combined use of Alendronate and Vitamin D supplements, Strontium ranelate and Calcium supplements. We developed a Cost-Effectiveness Analysis (CEA) on two alternative therapeutic strategies (Alendronate and Vitamin D Supplements; Strontium ranelate and Calcium supplements). During six months study period a total of 60 osteoporosis patients among which 26 males (44%) and 34 females (56%) were assessed for cost-effectiveness of combined use of Alendronate and Vitamin D supplements, Strontium ranelate and Calcium supplements. The highest number of patients were in the age group 65-75 years. Among 60 patients enrolled for the study, 24 (40%) patients are employed, 25 (41%) patients are house wives, 11(19%) are retired patients.

In our study of 60 osteoporosis patients, it was observed that 20 patients work on daily wages, that they stand and work for long hours, 25 patients who work in offices sitting for long hours without any movement and the rest 15 were occasional workers. Among 60 osteoporosis patients 10 patients were co-morbid with diabetes mellitus type 2 and hypertension. In our study no patient was found to be smoker or alcoholic. No family history of osteoporosis to any of the patients who was enrolled in the study.

CONCLUSION: In Conclusion, we can say that combined use of drugs are essential for the

treatment of severe and very severe Osteoporosis. Results from our study showed potential increment in calcium as well as improvement in quality of life without further increasing social cost. Combined use of Alendronate and Vitamin D was found to be more effective compared to Strontium ranelate and Calcium supplements.

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CONFLICT OF INTERESTS: Declared none

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