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Research Article

Evaluation of Prescribing Pattern in Postmenopausal Osteoporotic Women with Different Complications at Gynaecology Hospital

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Abstract

The global burden of osteoporosis includes considerable numbers of fractures, morbidity, mortality and expenses, due mainly to vertebral, hip and forearm fractures. Under diagnosis and under treatment are common. Several studies have shown decreased health-related quality of life (HRQOL) after osteoporotic fracture, but there is a lack of data from long-term follow-up studies, particularly regarding vertebral fractures, which are often overlooked despite patients reporting symptoms.

Objective:

- To study the different clinical complications associated with osteoporosis.
- To study and assess the therapeutic regimen of postmenopausal osteoporosis.

Methodology: The prospective study was conducted over a period of six months in the Department of Gynecology. A total of 80 postmenopausal patients who fulfilled the inclusions criteria were recruited in the study. The data was analyzed by significant statistically analysis that is SPSS ver. 21.

Conclusions: Through the existing prescribing patterns, attempts can be made to improve the quality and efficiency of drug therapy. Hence in future, improving the patient knowledge regarding the drug therapy, dose and frequency will perhaps improves the quality of life in postmenopausal osteoporotic patients.

Keywords: *Osteoporotic; patients; postmenopausal*

Introduction

Osteoporosis is a common and serious public health problem. Diagnosis and osteoporosis-specific treatment have not been available for more than 20 and 15 years, respectively. Much about osteoporosis, its etiology and its consequences, remains to be explored. Osteoporosis is a silent disease until it results in fractures after minimal trauma or spontaneously. Worldwide, by the year 2000 there were an estimated nine million new osteoporotic fractures annually, of which 1.7 million were in the forearm, 1.6 million were in the hip, and 1.4 million were clinical vertebral fractures [1]. In Sweden, more than approximately 70,000 clinical osteoporotic fractures occur annually. More than every second Swedish woman suffers at least one osteoporotic fracture during her lifetime [2]. Osteoporosis occurs in a wide range of severity, from mild cases with no fracture or only a single forearm fracture during a lifetime to severe disease with accumulating Sequelae.

Today, there are effective diagnostic and treatment methods, but still the majority of individuals with osteoporosis and osteoporotic fractures are left without examination and treatment due to lack of knowledge and financial incitement. There is growing evidence that pharmacological treatment prevents new fractures, but much less is known about its potential to improve or maintain health-related quality of life (HRQOL) after osteoporotic fracture. It is noteworthy that only a few clinical trials have shown treatment benefits regarding

HRQOL. The goal of osteoporosis care must be to prevent new fractures and to improve HRQOL in individuals with an osteoporotic fracture. The ultimate goal of preventing and treating disease is for each individual to achieve optimal health and well-being according to the WHO definition [3].

The overall aim of this thesis was to evaluate the usefulness of a recent low energy fracture as index event in a case-finding strategy for osteoporosis and to describe and analyses long-term health-related.

Need for the study

Menopause is a part of every woman's life. It is the stage when the menstrual period permanently stops. This stage usually occurs between the age of 40 and 60 associated with hormonal, physical and psychological changes. These changes can occur gradually or abruptly. It can start as early as the age of 30 and last until as late as the age of 60. It can also occur when the ovaries are removed or stopped functioning. Symptoms include irregular menstruation, changes in sexual desire, hot flashes, vaginal dryness and urinary problems, changes in appearance, mood changes, sleep disturbances, palpitation and backache. When the body produces less estrogen and progesterone, the parts of the body that depends on estrogen to keep them healthy will react and this often causes the discomfort in women .The duration, severity, and impact of menopausal symptoms vary from person to person, and population to population. Some women have severe symptoms that profoundly affect their personal and social functioning and quality of life.

Background of study

The World Health Organization (WHO) defines osteoporosis as a "systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture".

Osteoporosis has been operationally defined on the basis of bone mineral density (BMD) assessment. The WHO has proposed diagnostic thresholds based on both low BMD and fracture anamnesis and has defined the following criteria based on the BMD, for diagnosing and assessing osteoporosis:

- Normal: A BMD not more than 1 standard deviation (SD) below the young adult normal mean (T-score >-1).
- Osteopenia (or low bone mass): A BMD between 1 and 2.5 SD below the young adult normal mean (T-score <-1 and >-2.5).
- Osteoporosis: A BMD 2.5 or more SD below young adult normal mean (T-score <-2.5).

Objectives of study

- To study the different clinical complications associated with osteoporosis.
- To study and assess the therapeutic regimen of postmenopausal osteoporosis.

Novelty of project proposal

The present study will help to find out current prescribing pattern of postmenopausal medications with different comorbidities.

It also highlights the need for comprehensive management of postmenopausal osteoporotic females, including life-style changes, dietary control, treatment of complications and co-morbidity.

Therefore, through the existing prescribing patterns, attempts can be made to improve the quality and efficiency of drug therapy.

In future, improving the patient knowledge regarding the drug therapy, dose and frequency will perhaps improves the quality of life in postmenopausal osteoporotic female.

Methodology

Sources of data: Patient case sheet and medications chart and laboratory tests reports, data will collect in Data collection form.

Methods of collection of data

1. Study site: Study will be conducted, at GYNAECOLOGY OPD patient
2. Study design: Prospective Observational study after getting approval from Institutional Ethical Committee (Annexure III).

Study criteria

Postmenopausal Osteoporotic Women (above 40 years) patients will be enrolled into the study by considering following criteria.

Inclusion criteria

Females diagnosed by the clinician to have Postmenopausal Osteoporosis.

Exclusion criteria

Method and collection of data: Based on the inclusion and exclusion criteria the patient's after signing the Informed consent form will be collected from the patient case file, case reports, and laboratory reports. A Data collection form will be used for data collection.

Patient information regarding demographics, socioeconomic, lifestyle (smoking, alcohol consumption) and medication will be collected from patient's case file and through patient interview.

Analysis of data

The patients recruited for the study will be grouped based on the class of drugs used for the treatment.

Results

Prescribing pattern in postmenopausal osteoporosis:

Age group wise distribution

Out of 80 postmenopausal osteoporotic women admitted, majority of them falling under age group between 51-60 years that is 33 (41.25%) patients and 10 (12.5%) patients were above 80 years. Mean (μ) and Standard Deviation (S.D) were found to be 64.275 and 12.65 respectively. Detailed representation is shown in Table 1.

Age group in Years	No. of patient (n =80)	Percent (%)
41-50	6	5
51- 60	31	41.25
61- 70	18	25
71-80	15	16.25
>80	10	12.5
Total	**80**	**100**

Table 1: *Age group wise distribution of postmenopausal osteoporotic women.*

Weight wise distribution

Out of 80 postmenopausal osteoporotic females admitted, majority of them falling underweight group between 71-75 kg that is 23 (28.75%) patients and 8 (10%) patients were above 81 kg. Mean (μ) and Standard Deviation (S.D) were found to be 69.125 and 9.44 respectively. Detailed representation is shown in Table 2.

Weight Distribution (Kg)	No. of patients (n=80)	Percent
50- 55	07	8.75
56-60	10	12.5
61-65	12	15
66-70	11	13.75
71-75	23	28.75
76-80	09	11.25
>81	08	10
Total	**80**	**100**

Table 2: *Weight wise distribution of postmenopausal osteoporotic females.*

Duration of postmenopausal osteoporosis

On evaluation of history of postmenopausal osteoporosis, among 80 patients 33 (41.25%) were between >5 years, 26 (32.5%) patients were between 5-10 years and 21 (26.25%) had more than 10 years of postmenopausal Osteoporosis. Data were represented in the Table 3.

Duration of postmenopausal osteoporosis (yrs)	No. of patients (n=80)	Percent
>05	33	41.25
05-10	26	32.5
>10	21	26.25
Total	80	100

Table 3: *Status of postmenopausal osteoporosis.*

Different manifestation of osteoporosis

Out of 80 postmenopausal osteoporosis female patients admitted 9 (11.25%) had only postmenopausal osteoporosis and rest having various other complications as shown in Table 4.

Diagnosis	No. of patients (n=80)	Percent
Postmenopausal osteoporosis with diabetes	07	8.75
Postmenopausal osteoporosis with HTN	05	6.25
Postmenopausal osteoporosis with fractures	13	16.25
Postmenopausal osteoporosis with leg pain	10	12.5
Postmenopausal osteoporosis with restlessness	14	17.5
Postmenopausal osteoporosis with back pain	22	27.5
Postmenopausal osteoporosis	09	11.25
Total	**80**	**100**

Table 4: *Different manifestation of osteoporosis.*

Status of lab investigations of postmenopausal osteoporosis.

Out of 80 female patients admitted, 15 (31.25%) had normal calcium level and 25 (81.25%) had normal vitamin D level and remaining 65 (68.75) and 55 (18.75) had abnormal calcium and vitamin D level respectively. Shown in Table 5.

Calcium	Frequency	Percent
8.5-10.2 (mg/dl)	15	18.75
<8.5 (mg/dl)	65	81.25
Total	**80**	**100**
Vitamin D	**Frequency**	**Percent**
20-50 (mg/dl)	25	31.25
<20 (mg/dl)	55	68.75
Total	**80**	**100**

Table 5

Hemoglobin level

On evaluation of 80 patient admitted, 55(68.75%) had abnormal level of hemoglobin and 25 (31.25%) had normal level. Mean and standard deviation were found to be Data was shown in Table 6.

Hemoglobin	Frequency	Percent
12.1-15.1 (g/dL)	25	31.25
>12.1 (g/dL)	55	68.75
Total	**80**	**100**

Table 6

Choice of postmenopausal osteoporotic drugs

Out of 80 patients half of the patients 40 (50%) were on monotherapy of which bisphosphonate was given to maximum number of patients in monotherapy. In combination therapy of parathyroid hormone with bisphosphonate was given to maximum patient 10 (12.5%). Show table 7 and figure 1.

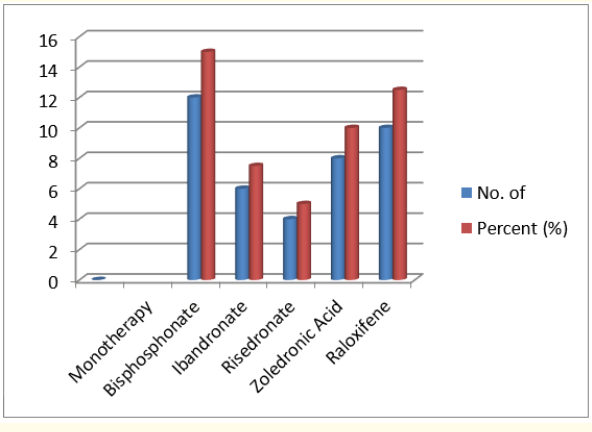

Figure 1

Regimens	No. of patients	Percent (%)
Monotherapy		
Bisphosphonate	12	15
Ibandronate	06	7.5
Risedronate	04	5
Zoledronic Acid	08	10
Raloxifene	10	12.5

Table 7: *Choice of postmenopausal osteoporotic drugs.*

Combination Therapy		
Parathyroid hormone + bisphosphonate	10	12.5
Raloxifene + bisphosphonate	05	6.25
Alendronate + raloxifene	15	18.75
Raloxifene + PTH	05	6.25
Calcium + vitamin D	05	6.25

Table 8: *Choice of postmenopausal osteoporotic drugs.*

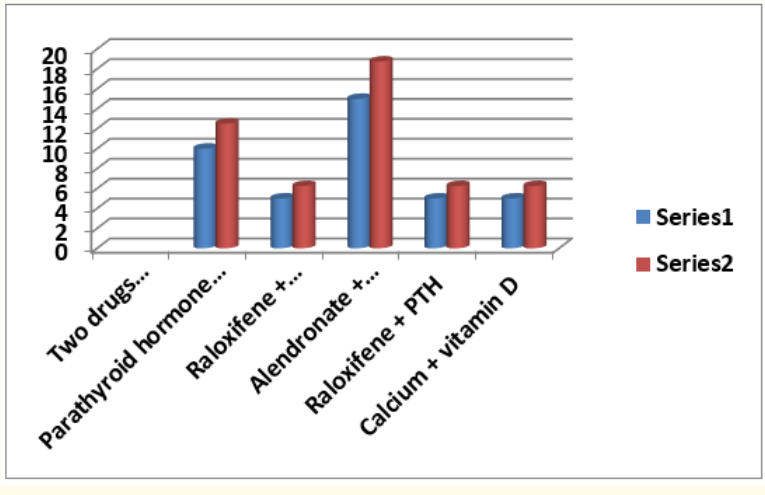

Figure 1

Discussion

In today's sceanerio women suffering from post-menopausal osteoporosis, majority are falling under age group between 51-60 years that is 33 (41.25%) as observed in our study which is contrasting to the study done in past decades where most the women fall under the age of 41-50 [4] which may be due to the environmental and genetic factors causing hormonal changes.

On evaluation of social status from present study majority of osteoporotic, majority of them 25 (31.25%) were smoker. Maximum addicted drug abuse 20 (25%) and least to not addicted 2 (2.5%) which is totally contradicted to the past years where there were least women addicted to such substances [5].

Out of 80 female patients admitted 9 (11.25%) had only postmenopausal osteoporosis and rest having various other complications.

One of the most important decisions to make regarding the treatment of osteoporosis is whether or not to initiate treatment. To withhold treatment will allow the age related decline in BMD to continue and may leave the women at a high risk of fracture. However, initiating treatment too freely may result in many women who do not have a high fracture risk being treated. This would expose many women to the potential side effects of bisphosphonate therapy for little gain and would have important cost implications for a health system with finite resources. The key to determining the initial treatment decision is to estimate each individual woman's fracture risk and only treating those women with a fracture risk, which is deemed to be high. Since then data from the large multicenter Eurofors study has been published which also demonstrates a large increase in BMD at both spine (7.8%) and hip (1.6%) in response to 18 months teriparatide despite prior anti resorptive therapy [6].Prior didronel users, 8% of my study population, achieved a better BMD response to teriparatide in the Eurofors study which may explain the slightly better BMD response in prior bisphosphonate users reported in this thesis. Bisphosphonates are currently regarded as first line therapy although women may subsequently switch to other classes of therapy due to side effects or a poor clinical response. Bisphosphonates have a profound effect on bone turnover, which persists after discontinuation. When therapy is switched, the persistent action of bisphosphonates may interfere with the subsequent response to a different class of treatment. However this area of management is poorly studied. To my knowledge there are no such studies with fracture as the primary endpoint as such a study would require thousands of women and would be very expensive. Fracture prevention studies are usually funded by pharmaceutical companies who have little to gain, and perhaps a lot to lose, by investigating whether their already licensed therapy interacts negatively with other osteoporosis therapies. In current study also out of 80 patients half of the patients 40 (50%) were on monotherapy of which bisphosphonate is given to more number of patients in mono therapy and in two drug therapy combination of parathyroid hormone with bisphosphonate was given to maximum patient 10 (12.5%).

Conclusions

The present study help to find out current prescribing pattern of postmenopausal osteoporosis with different co-morbidities with respect to diagnosis and it also highlight the need for comprehensive management of postmenopausal osteoporotic females, treatment of complications and co-morbidity. Therefore, through the existing prescribing patterns, attempts can be made to improve the quality and efficiency of drug therapy. Hence in future, improving the patient knowledge regarding the drug therapy, dose and frequency will perhaps improves the quality of life in postmenopausal osteoporotic females.

In the present study majority of them falling under age group between 51-60 years that is 33 (41.25%) patients and majority of them were weighing between 71-75 kg. Among them 55 (68.75%) had abnormal level of hemoglobin and 25 (31.25%) had normal level.

Out of 80 patients half of the patients 40 (50%) were on monotherapy of which bisphosphonate is given to more number of patients in monotherapy. In two drug therapy combination of parathyroid hormone with bisphosphonate was given to maximum patient 10 (12.5%).

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