

## Evaluation of prescription pattern and quality of life in postmenopausal osteoporosis: a cross sectional study

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### ABSTRACT

**Background:** Osteoporosis (OP) is a silently progressing metabolic bone disease that results in loss of mineralized bone and subsequent fractures with minor trauma. Fracture related pain and physical inability to perform activities of daily living can lead to psychological consequences that impair Quality of Life (QoL). However, much less is known about Indian scenario. Hence, our study becomes imperative. Aim of this study to the drug utilization pattern and to analyze Quality of life of postmenopausal women suffering from osteoporosis.

**Methods:** An analytical cross-sectional study was done on 91 post-menopausal osteoporotic women. Drug utilization pattern was evaluated. Pre-validated QUALEFFO-31 questionnaire was administered to each patient to record patient's perceived QoL. Scores were calculated according to the algorithm. Higher scores indicated poor QoL. The collected data was analyzed with SPSS software (version 23) and p value  $\leq 0.05$  was considered as statistically significant.

**Results:** The mean age group of presenting patients was  $56.2 \pm 6.6$  years. All the patients received Calcium and vitamin D supplements and non-steroidal anti-inflammatory drugs for pain relief. But only 33% of the patients received any one of the bisphosphonates (BP). For analysis, patients were grouped into Group-1 (n=60) who did not and Group-2 (n=31) who did receive a BP. QoL analysis showed that pain domain was affected the most. Also, patients in Group 2 reported worse score in all the domains in comparison to Group 1 ( $P < 0.05$ ). It is likely that BP might need more time to show considerable effect or because it was added only to those patients who already had more complaints and could afford the high cost.

**Conclusion:** BP in spite of being the drug of choice for OP is used less commonly in India. OP causes pain and physical debilitation with detrimental effect on mental health. Longer duration prospective studies are needed to study the association of QoL and use of BP in OP patients.

**Keywords:** Drug utilization study, Epidemiology, Osteoporosis

### INTRODUCTION

The word Osteoporosis (OP) literally translates as "porous bones" and is the most common bone disease found in humans. It is a silently progressing metabolic bone disease causing considerable cause of morbidity and mortality.<sup>1-3</sup> An Indian study estimated the prevalence of osteoporosis as 24.6% in men and 42.5% in women above 50 years of age.<sup>4</sup>

As age advances, there is continuous loss of trabeculae in bone, leading to imbalance between bone breakdown and build up. And in postmenopausal females, the deficiency of hormone estrogen causes exaggerated loss in bone mass, which in turn causes fractures after minor trauma, especially of spinal vertebrae, the bones of the forearm and hip. Frequent fractures after minor trauma, chronic back pain, loss of height, increased kyphosis, immobility, distorted body image, inability to perform activities of

daily living thus resulting in depression are common presenting features.<sup>1</sup>

Measures most commonly applied for OP management are regular weight bearing exercises, oral calcium and Vitamin D supplementation and drugs which either decrease bone resorption or stimulates new bone formation. Drugs that decrease osteoclastic bone resorption are bisphosphonates (risedronate, alendronate, etc), Estrogen replacement therapy, Selective Estrogen Receptor Modulators (eg Raloxifene), Calcitonin, Strontium ranelate and Denosumab.<sup>5</sup> Teriperatide, a congener of parathyroid hormone has been recently introduced as pulse therapy for OP and it has been shown to increase new bone formation.<sup>6</sup> Despite of these modalities, OP has a profound negative impact on the Quality of Life (QoL) as pointed out by numerous studies.<sup>7</sup> Therefore, it is necessary to evaluate physical functioning and psychosocial suffering of the patient along with the disease itself. Measurement of QoL not only helps in predicting clinical evolution of the disease, but also improves our understanding that can lead to developing better treatment plans. Furthermore, there is a paucity of Indian studies in this field.<sup>3,4</sup> Hence the QoL evaluation of post-menopausal patients suffering from OP becomes imperative. To measure quality of life is to assess subjective feelings objectively and can be best accomplished by use of standardized questionnaires.<sup>8</sup> The Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) is the OP specific questionnaire most commonly used in the literature and focuses on patients with vertebral deformities. The 31-item QUALEFFO was developed as a shortened version of the QUALEFFO-41 and consists of three domains (pain, physical function, and mental state).<sup>7</sup> This questionnaire has proven to be reproducible, practical, effective and globally validated and most extensively tested, therefore, we decided to use this questionnaire.<sup>8</sup> Authors aimed to study the drug utilization pattern and to analyze Quality of life of postmenopausal women suffering from osteoporosis.

## METHODS

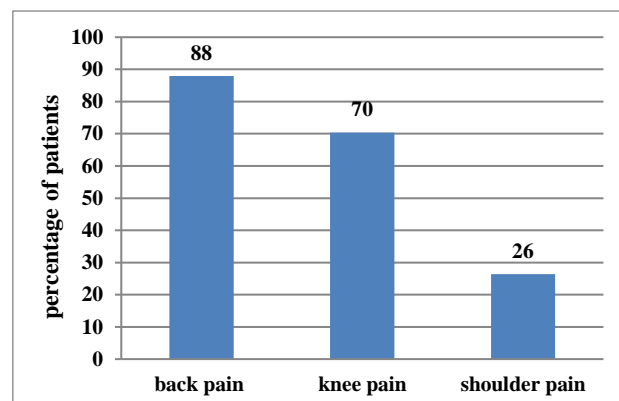
The study was started after obtaining permission from the Indian Council of Medical Research and the Institutional Ethics Committee. This analytical cross-sectional study of 8 weeks duration was carried out in the Out-patient unit of Orthopedics department at a tertiary care teaching hospital in India. All the women who presented between May and June 2018 with clinical features of OP and diagnosed with OP (with or without fractures) were included into the study after obtaining their written informed consent in the vernacular language. Women who suffered from any co-morbid conditions known to affect QoL (E.g.- chronic depression, rheumatoid arthritis, etc.) were excluded from the study. Patients who were unable to understand questions of the questionnaire or who suffered from secondary osteoporosis were also excluded.

Pre-validated QUALEFFO-31 QoL questionnaire (in vernacular language) was administered to each patient

enrolled into the study. There are 3 domains viz-pain, physical function and mental function. Responses of each of the 31 questions were analyzed. The scores were calculated according to published scoring algorithm of QUALEFFO-31.<sup>9</sup> Each question in the questionnaire has 4 or 5 options with scores ranging from 1-5. All the answers are standardized so that 1 represents the best and 5 (or 4) represents the worst quality of life (reverse scores on questions 25, 26, 27, 28 and 30). Hence, higher score represents worse the QoL. Domain scores were calculated by averaging the answers of one domain and transforming the scores to a 100 point score. The total score was calculated by summing all answers of questions 1-31 and then transformed to scores from 0 to 100. Total Qualeffo score=(Actual score - lowest possible score/ range) x 100. The domain score as well as total Qualeffo score was then compared between patients who were on different treatment plans. The collected data was analyzed using SPSS software version 23 and windows excel 2013. P value  $\leq 0.05$  was considered as statistically significant.

## RESULTS

A total of 91 post-menopausal osteoporotic patients were enrolled in our study. The mean age of participants was  $56.2 \pm 6.6$  years. The average duration since menopause was  $8.2 \pm 5.1$  years. Back pain followed by knee and shoulder pain was the most common presenting complaint (Figure-1). Out of 91 patients, 19 patients gave a history of one fracture, while 5 patients had developed 2 fractures in the past.



**Figure 1: Clinical presentation with chief complaints.**

All the patients received daily calcium (500 mg) and vitamin D3 (250 I.U.) supplementation. All the patients additionally received any one of the analgesic preparation (paracetamol with tramadol or aceclofenac or ibuprofen or diclofenac) for pain relief. Group 1 consisted of sixty patients out of 91, who did not receive any specific drug for OP. The reasons for not availing OP specific treatment cited were patient preference, not affordable, clinical discretion of the treating clinician.

But, nearly one-third (n=31) of the patients received one of the bisphosphonates for OP and these patients comprised of group 2. Risedronate (35 mg oral once a week) was most

prescribed bisphosphonate (21%), followed by alendronate (70 mg once a week oral) (5.4%), ibandronate (4.3%) (150mg once a month oral) and zoledronate (5 mg intravenous drip once a year) (2.1%). (Figure-2) Out of 91 patients, 42 (46%) patients had started drug treatment within a month. Mean±SD for duration of treatment was 2.75±3.3.

QUALEFFO-31 measures 3 domains: PAIN (4 items; Questions 1 to 4), PHYSICAL FUNCTION (17 items; Questions 5 to 23) and MENTAL FUNCTION (9 items; Questions 24 to 31). Score of each question, domain wise score and grand score was calculated as presented. These scores were then compared between group 1 and group 2 (Figure 3). All the patients experienced included in the study experienced some degree of pain. The overall mean score of pain domain was 62.84±16.28. Patients in group - 1 had significantly lower pain score (58.5±13.5) as compared to group 2 (71.1±18), p value 0.0003. Overall physical function domain score was 52.69±9.22.

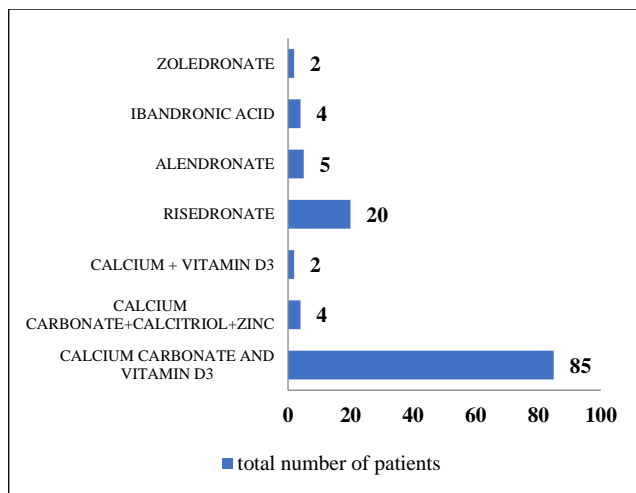
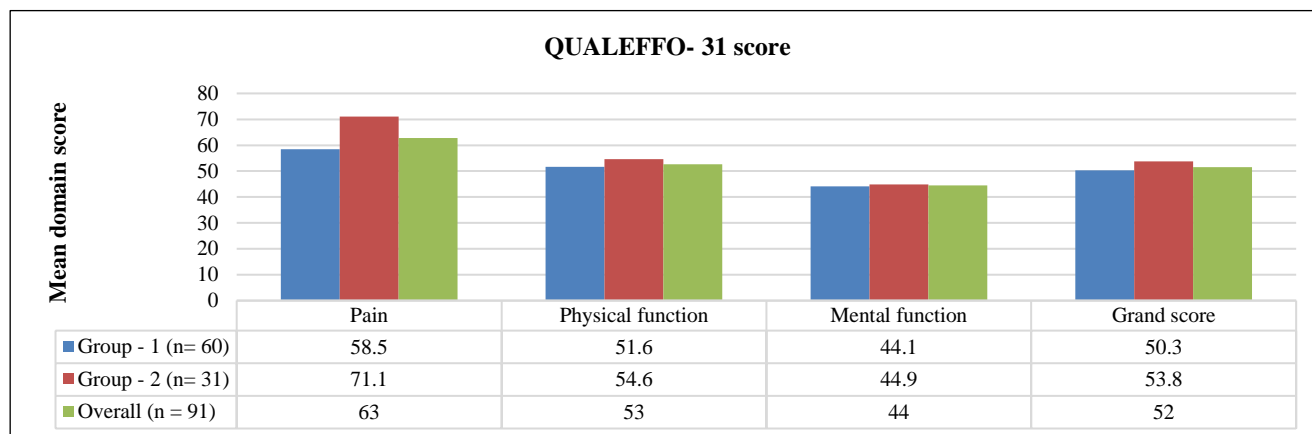


Figure 2: Most frequently prescribed drugs for Osteoporosis.



\*\* p value is <0.05 i.e. significant

Figure 3: QUALEFFO-31 score.

Patients in group 1 had score of 51.66±7.58 and that of group- 2 was 54.68±11.67, the difference being not significant (p value=0.13). Overall mental domain function score was 44.4±9.9. Patients in group-1 had score of 44.17±8.54 and that of group- 2 was 44.98±12.47, the difference being not significant (p value=0.71). Mean ±SD of grand score was 51.54±8.2. The score of group-1 was 50.33±6.8 and that of group-2 was 53.89±10.2. The difference between the groups was statistically significant (p value=0.05).

**DISCUSSION**

Osteoporosis is a metabolic bone disease that can result in impairment of physical, emotional, and social spheres of a patient’s life, thus affecting patient’s perceived quality of life. In the present study, a total of 91 postmenopausal females diagnosed with OP were enrolled. All the patients received

calcium and vitamin D supplementation and one of the non-steroidal anti-inflammatory drugs as analgesic. Sixty of them formed group 1. The remaining 31 patients, who additionally received any one of the bisphosphonate, were considered as group 2. In our study, Risedronate (88.2%) was most commonly prescribed bisphosphonate, followed by alendronate (5.4%), ibandronate (4.3%) and zoledronate (2.1%). This is unlike the study done in Kasturba Medical College, Manipal University which reported that alendronate was most commonly prescribed in India.<sup>8</sup> None of the patients in our study were prescribed other modalities of treatment like SERM, calcitonin, strontium renolate, denosumab or teriperatide. This is strikingly in contrast to the western scenario, where majority of the patients diagnosed with OP receives specific anti-osteoporotic treatments like bisphosphonate or SERM.<sup>9</sup> The possible explanation could be that in India specific anti-osteoporotic treatment is reserved for those who have severe clinical presentation and /or who

can afford the high cost therapies. Another important factor is the risk of atypical fractures and delayed healing due to long term use of bisphosphonates as reported by many foreign studies. An Indian study on adherence to anti OP treatment suggested that even after starting the treatment, many patients stopped the treatment due to its high cost. This could have impacted physician's prescribing pattern.<sup>10,11</sup>

In our study, the mean age group of presenting patients was 56.2±6.6 years. The mean duration since menopause among these patients was 8.2±5.1 years. This is in parallel to a study conducted in Postgraduate Institute of Medical Education and Research at Chandigarh which stated that the mean age group presenting with OP was found to be 52.50±5.94 years and the average period since menopause was 5.06±3.8 years.<sup>12</sup> However, western studies found that the peak of incidence of OP was in the age group of 70-80years, which suggests that the onset of disease in India is earlier.<sup>13</sup>

Pain was the most common presenting feature in our study. We found that almost all the patients (88%) in our study had some degree of back pain. Chronic back pain could be the result of underlying undiagnosed vertebral fracture. Other studies have also reported that vertebral fractures are most common presenting feature of OP.<sup>14</sup> In our study we observed that the pain domain was affected the most which is like a study done in Poland.<sup>15</sup> The mean score of pain domain (n=91) was 62.84±16.28. Patients in group-1 had significantly lower pain score (58.5±13.5) as compared to group 2 (71.1±18), p value=0.0003. Higher pain domain score in group 2 as compared to group 1 could be attributed to the fact that most of the patients in group 2 (23 out of 31) had started treatment with bisphosphonates within one month of administration of QoL. It is likely that as the severity of complaints of pain increased, they were given the bisphosphonates in addition to calcium supplementation despite the economic burden.

An elevated mean physical domain function score (52.69±9.22) could be related with pain and deformity secondary to fractures. Similar studies commented that the functional impairment resulting from vertebral fractures was substantial and reduced the ability to perform both daily household and self-care activities.<sup>15,16</sup> Patients in group -1 (score of 51.66±7.58) and group- 2 (54.68±11.67) had similar scores (p value=0.13) and faced similar severity of problems in their day-to-day lives like dressing, bathing and cleaning, using washroom, cooking, cleaning dishes, etc.

Mean mental domain function score was 44.4±9.9. This was in accordance to a QoL study done in San Paolo Hospital in Italy which concluded that patients with osteoporosis, even in the absence of fractures, had a more depressed mood and a lower quality of life than that of the control group.<sup>17</sup> Patients in group-1 had score of 44.17±8.54 and that of group-2 was 44.98±12.47, the difference being not significant (p value=0.71). Patients in both groups felt tired, downhearted, lonely, less energetic, upset over little things, faced difficulty in communicating with people and felt low spirited. 13.3% patients in grp-1 and 51.6% patients in grp-2 reported their

quality of life as below satisfactory (p<0.05). 61.3% patients in group-2 were more hopeful for a better future while only 33% in group-1 felt the same (p<0.05). As the patients receiving bisphosphonates are spending more on treatment than the group receiving only calcium they may feel that they are getting better treatment and hence are more hopeful about their future.

The Mean±SD of Grand qualeffo score was 51.54±8.2 suggesting decline in QoL in all the aspects. The score of group 1 was 50.33±6.8 and that of group-2 was 53.89±10.2. The difference between the groups was statistically significant (p value=0.05).

Thus, OP leads to severe discomfort and/or disability and disturbs personal life owing to chronic pain, reduced physical and social activity and affective symptoms like low mood and anxiety.

Limitations of the study authors understand that our study is of short duration and with limited number of patients.

## CONCLUSION

The results of our study stated that even though Bisphosphonates are first choice of drugs for OP, they are less routinely used in our setup. Patients who were recently started on bisphosphonates reported worse score in all the domains in comparison to patients who received only calcium and vitamin supplementation. It is likely that bisphosphonates might need more time to show considerable effect or because it was added only to those patients who already had more complaints and could afford the high cost. OP among postmenopausal women causes pain and physical debilitation that compromises their ability to carry out day to day tasks at a normal efficiency and in turn has detrimental effect on mental health as evident on patient's perceived QoL score.

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