

Comparison of Quality of Life and Bone Mass Density among Postmenopausal Women: A Cross-sectional Study

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INTRODUCTION

Menopause is the permanent cessation of menstruation, which is determined 12 months after the last menstrual period. The number of postmenopausal women has been increasing in recent years due to the increase of life expectancy.^[1] During the postmenopausal period, women experience many symptoms including hot flushes, night sweats, sleep and mood disorders, impaired memory, lack of concentration, nervousness, depression, insomnia, bone and joint complaints, and decrease in muscle mass due to fluctuating hormone levels especially linked with depletion of estrogen hormone.^[2] These physiological, emotional, and psychological changes vandalize the health of these vulnerable females in total

and reduce their quality of life (QoL).^[3] Postmenopausal women are also at the highest risk of developing osteoporosis, since their bone mineral density is reduced as a result of a decrease in the estrogen level.^[4]

Varied number of studies of osteoporotic and osteopenic women have been conducted, which has depicted that a poor QoL can be assessed by their functional status,

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ABSTRACT

Background: Postmenopausal women are at highest risk of developing osteoporosis, since their bone mineral density is reduced due to decrease in estrogen level. Various other physiological, emotional, and psychological changes jeopardize the health of these vulnerable females in total and reduce their quality of life (QoL).

Aims and Objectives: To compare the QoL and bone mass density (BMD) among normal BMD, osteopenic, and osteoporotic postmenopausal women.

Setting and Design: A cross-sectional observational study was conducted in the outpatient department of physical medicine and rehabilitation at a tertiary care center of northern India from August 2019 to February 2020. **Materials and Methods:** Baseline sociodemographic characteristics of all postmenopausal women were collected using a quantitative tool. Assessment of QoL was done by pretested and validated QUALEFFO-41 scale. For all the women, a bone mineral densitometry test was performed on the L1–L4 lumbar spine, femoral neck, and forearm by the dual-energy X-ray absorptiometry method. **Statistical Analysis:** One-way ANOVA test was used to compare the mean BMD values across the three groups. Determination of predictive factors for QoL was performed using stepwise logistic regression analysis.

Results: Significant differences were noted for the mean values of the three domains, i.e., pain, physical, and social function ($P < 0.01$). Women with osteoporosis had significantly higher pain scores as compared to others. Among those with osteoporosis, the pain scores have significantly increased gradually as age increases.

Conclusion: Postmenopausal women with osteopenia and osteoporosis have poor QoL as compared to those with normal BMD.

KEYWORDS: Bone mineral density, menopause, osteoporosis, quality of life

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exhibited by a poor state of the osseous system which restricts physical function, deforms body posture, causes immense pain, and also influences the mental state.^[5-7] These papers also indicate that the proportion of patients with osteopenia, osteoporosis, and other bone diseases who assess their QoL as poor is significantly higher than among healthy persons.^[8,9]

While most studies have reported QoL only among osteoporotic women, our study compares the same among postmenopausal women with normal bone mass density (BMD), osteopenia, and osteoporosis, thus giving us a better insight of this health condition. Moreover, there is a paucity of evidence in North Indian setting regarding the status of pain, physical activity restriction, socialization, or mental affliction among postmenopausal women in the three categories of BMD. Hence, the aim of this study was to compare the QoL and BMD among postmenopausal women with normal BMD, osteopenia, and osteoporosis.

MATERIALS AND METHODS

A cross-sectional observational study was conducted in the outpatient department (OPD) of physical medicine and rehabilitation at a tertiary care center of northern India from August 2019 to February 2020. The study participants included postmenopausal women attending the OPD of physical medicine and rehabilitation.

All postmenopausal women aged 50–79 years with no history of menstruation for the last 1 year and not using any hormonal replacement therapy; were free from medical conditions such as diabetes, hypertension, cardiac disease, and thyroid disorder; and consented to participate and cooperate in the study were included.

All subjects with secondary osteoporosis, metabolic bone disease, malignant bone metastasis, hypogonadal states, osteogenesis imperfecta and those treated with glucocorticoids with endocrine, gastrointestinal, rheumatologic and hematologic disorders and diagnosis of osteoarthritis in the patient's history, a current bone fracture and the existence of other diseases or comorbid condition whose presence might influence the QoL were excluded.

Ethical clearance

Ethical clearance was taken from the Institutional Ethical Committee of the tertiary care center with approval number 1747/Ethics/19.

Sample size

The sample size was calculated using finite population correction to the sample size formula, i.e., $n = N \times X / (X + N - 1)$, where $X = Z_{\alpha/2}^2 \times p \times (1 - p) / d^2$, p – estimated sample proportion of postmenopausal women with low BMD (value is 53%),^[10] d – margin of error

for appropriate level of precision (value is 0.07), and N – estimated population size. At 95% confidence interval (CI) and power of 80%, the sample size (n) was 100 patients. Taking 10% nonresponse rate, the minimum sample size was 110 patients and total 113 women were enrolled in the study. However, 2 women were excluded due to history of hormone replacement therapy, so 111 postmenopausal women were analyzed.

Sampling technique

Systematic random sampling was used. Every second postmenopausal woman was enrolled in the study after written consent. If the woman refused to participate in the study, the next second consecutive woman was enrolled.

Data collection

All postmenopausal women attending the OPD for any bone related complaint, who fulfilled the inclusion criteria, were enrolled in the study after written informed consent. A consent form was provided along with the questionnaire and details of the sample population were concealed. In addition, an ID was generated by the digital form, so that participants were not identified by name and hence confidentiality was ensured in data management and analysis. Baseline sociodemographic characteristics were collected using a quantitative tool. Assessment of QoL was done by QUALEFFO-41 scale. This scale is a validated tool, which was designed to evaluate the QoL in five domains, i.e., with respect to pain, physical function, social function, general health perception, and mental function, and is assessed on a scale of 0–100, with 0 indicating the highest QoL and 100 the lowest.^[11] For all the women, a bone mineral densitometry test was performed on the L1–L4 lumbar spine, femoral neck, and forearm by the dual-energy X-ray absorptiometry method using the Lunar DPX-L densitometer.

In line with the BMD definition of the World Health Organization and in accordance with the eligibility criteria, 111 women were enrolled in the study:

1. 51 women in the study group were classified as osteoporotic, with BMD results measured by densitometry and expressed by T-scores ≤ -2.5 standard deviations (SDs)
2. 44 women were osteopenic with T Scores between -1 and -2.5
3. 16 subjects were assessed as normal, with T-scores > -1.0 SD.

Data analysis

The data were analyzed using SPSS version 23.0. Descriptive statistics including mean, SD, and frequencies expressed as percentages were used. One-way ANOVA test was used to compare the mean BMD values across

the three groups. Probability (p) was calculated to test statistical significance at the 5% level of significance. Determination of predictive factors for QoL was performed using stepwise logistic regression analysis. The cutoff for the QUALEFFO-41 scale was set at the median for each area and the overall score. Scores equal to the median, or lower, indicated a high QoL, while scores higher than the median pointed to a low QoL.

RESULTS

Sociodemographic characteristics of study participants

The mean age of the study participants was 62.5 ± 3.4 , 64.2 ± 4 , and 66.2 ± 4.1 years in those with normal BMD, osteopenia, and osteoporosis, respectively. Age of attainment of menopause was lower among the osteoporotic women, i.e., 46.7 ± 2.5 , as compared to other women. The average body mass index (BMI) was 22.9 ± 2.6 , 25.1 ± 3.7 , and 24.7 ± 5.3 kg/m² in the respective groups. Almost more than half of the study participants in the three groups were from rural background with 84.8%, 78.8%, and 69.7% of women

with normal BMD, osteopenia, and osteoporosis, respectively, and had educational status of primary and lower. More than half of the women (54.5%) in the osteoporotic group belonged to lower middle socioeconomic status.

As far as a history of fractures and current smoking is concerned, only 2 women in the osteopenic and 22 in the osteoporotic groups had fractures, while very few women have reported a history of current smoking. 42.1%, 40.0%, and 6.5% of the women with normal BMD, osteopenia, and osteoporosis, respectively, had a history of calcium and vitamin D supplementation. No participants with normal BMD had a history of hormone replacement therapy and bisphosphonates, while only 2 and 28 in the osteoporotic group had a history of hormone replacement therapy and bisphosphonates, respectively [Table 1].

QUALEFFO-41 among the study participants on the basis of bone mass density

When QoL using the QUALEFFO-41 scale was used across the three groups, significant differences were

Table 1: Baseline characteristics of the study participants across the three groups (n=111)

L1-L4 T score	L1-L4 T score	L1-L4 T score	L1-L4 T score
Age (years)	62.5±3.4	64.2±4.8	66.2±4.1
Age at menopause (years)	52.8±2.7	55.3±3.8	46.7±2.5
BMI	22.9±2.6	25.1±3.7	24.7±5.3
Background			
Rural	11 (57.6)	20 (66.7)	40 (65.5)
Urban	8 (42.4)	10 (33.3)	22 (34.5)
Educational status			
Primary and lower	16 (84.8)	23 (78.8)	43 (69.7)
Secondary and higher	3 (15.2)	7 (21.2)	19 (30.3)
Socioeconomic status			
Lower	6 (33.3)	8 (27.3)	13 (21.2)
Lower middle	9 (48.5)	12 (42.4)	33 (54.5)
Middle	4 (18.2)	10 (30.3)	16 (24.3)
History of previous fractures			
Yes	0 (0)	2 (6.7)	22 (35.5)
No	19 (100)	28 (93.3)	40 (64.5)
History of current smoking			
Yes	1 (5.3)	4 (13.3)	2 (3.2)
No	18 (94.7)	26 (86.7)	60 (96.8)
History of Ca and Vitamin D supplementation			
Yes	8 (42.1)	12 (40.0)	4 (6.5)
No	11 (57.9)	18 (60.0)	58 (93.5)
History of bisphosphonates			
Yes	0 (0)	0 (0)	28 (45.2)
No	19 (100)	30 (100)	34 (54.8)
L1-L4 T score	-0.21±0.74	-1.83±0.67	-3.44±0.54
L1-L4 BMD	1.14±0.29	0.88±0.21	0.75±0.07
Femoral neck T score	-0.13±0.62	-1.69±0.41	-3.62±0.32
Femoral neck BMD	0.92±0.08	0.81±0.18	0.62±0.04

*n (%). BMI: Body mass index

noted for the mean values of three domains, i.e., pain, physical function, and social function ($P < 0.01$). Women with osteoporosis had significantly higher pain scores than those with osteopenia and normal BMD. Similar trend was observed for physical and social function scores also, which increased from those with normal BMD and osteopenia to those with osteoporosis indicating poor QoL in the osteoporotic group. There was no significant difference in the mean scores of other domains such as general health perception, mental function, and overall scores [Table 2].

QUALEFFO-41 among the study participants on the basis of bone mass density and age

The following study has also assessed the impact of age on the QUALEFFO-41 scale in the three groups divided on basis of BMD. No significant difference was seen in any of the domains of QUALEFFO-41 scale in women with normal BMD. As far as women with osteopenia were concerned, the mean pain scores were 31.13 ± 3.78 , 36.43 ± 1.98 , and 39.67 ± 2.76 in the age group of 49–60, 60–70, and ≥ 70 years, respectively, and this was statistically significant ($P < 0.01$). Similarly, a significant difference was also noted for physical function domain across the three age groups of the osteopenic group. Among those with osteoporosis, the pain scores have increased gradually as age increases, thereby indicating poor QoL for pain among those with ≥ 70 years, and this was statistically significant. Similar trend was also noted in the osteoporosis group for physical and social function and overall QUALEFFO-41 scale [Table 3].

Factors affecting the various domains of QUALEFFO-41 score among osteopenic and osteoporotic patients

The following table shows the factors associated with QoL for osteoporotic and osteopenic women by logistic regression analysis, using the QUALEFFO-41. Regarding the pain domain, the associated factors were age (odds ratio [OR] = 3.871; 95% CI: 1.056–14.196), age at menopause (OR = 4.381; 95% CI: 1.239–15.490), and history of bisphosphonate supplementation (OR = 3.079; 95% CI: 1.033–9.172). For the physical function domain, the associated factors were BMI (OR = 0.219; 95% CI: 0.69–0.717) and educational status (OR = 5.912; 95% CI: 1.767–19.778). For social function domain, the associated factors were age (OR = 0.096; 95% CI: 0.011–0.857), BMI (OR = 0.056; 95% CI: 0.011–0.296), and background (OR = 0.101; 95% CI: 0.016–0.647). For the general health perception, the associated factors were history of calcium and Vitamin D supplementation (OR = 0.138; 95% CI: 0.028–0.686) and history of bisphosphonate supplementation (OR = 4.562; 95% CI: 1.571–13.247). For the mental function domain, the associated factors were only age at menopause (OR = 0.241, 95% CI: 0.073–0.793) [Table 4].

DISCUSSION

Postmenopausal phase is a very vulnerable and crucial period in a women's life. Women go through various emotional, mental, and physical challenges during this time. This includes fluctuations in periods, hot flushes and/or night sweat, sleeping problems, vaginal dryness,

Table 2: Comparison of QUALEFFO-41 among the three groups on the basis of bone mass density (n=111)

QUALEFFO-41	Normal BMD (T-score > -1.0) (n=19)	Osteopenic (-2.5<T-score ≤ -1.0) (n=30)	Osteoporotic (T-score ≤ -2.5) (n=62)	F	P*
Pain	19.3±3.41	33.8±6.11	48.3±8.11	137.727	0.0001
Physical function	16.0±2.56	21.8±6.76	27.5±4.82	20.992	0.0001
Social function	33.5±4.42	47.6±7.81	49.2±5.73	48.190	0.0001
General health perception	49.0±6.12	50.2±9.92	52.8±6.27	2.496	0.087
Mental function	24.2±6.59	25.7±4.78	26.8±2.46	3.084	0.050
Total QUALEFFO-41 score	28.4±3.72	29.3±2.97	30.1±3.82	1.945	0.148

*One-way ANNOVA

Table 3: Comparison of QUALEFFO-41 among the three groups on the basis of age and bone mass density

Age	QUALEFFO-41, BMD							
	Osteopenic (-2.5<T-score ≤ -1.0) (n=30)				Osteoporotic (T-score ≤ -2.5) (n=62)			
	49-60 (n=16)	60-70 (n=9)	≥70 (n=5)	P*	49-60 (n=15)	60-70 (n=26)	≥70 (n=21)	P*
Pain	31.13±3.78	36.43±1.98	39.67±2.76	0.0001	44.51±3.28	49.32±4.78	53.91±3.71	0.0001
Physical function	19.56±2.96	20.21±4.18	26.12±2.06	0.002	26.13±3.49	29.22±2.56	30.52±2.14	0.0001
Social function	44.12±5.56	45.88±6.78	49.12±5.34	0.267	47.12±2.20	51.45±5.36	52.56±2.23	0.0001
General health perception	55.17±5.98	57.41±7.80	60.77±4.65	0.238	59.12±4.33	60.12±3.13	62.32±8.98	0.469
Mental function	24.76±3.34	25.21±3.66	26.12±3.67	0.748	22.62±1.39	23.76±2.82	23.88±3.03	0.349
Total QUALEFFO-41 score	28.45±2.44	29.45±3.37	30.88±3.12	0.251	29.33±2.49	31.04±2.17	32.66±1.09	0.0001

*One-way ANNOVA. BMD: Bone mass density

Table 4: Factors affecting the various domains of QUALEFFO-41 score among osteopenic and osteoporotic patients (n=92)

QUALEFFO-41 domains	Parameter	OR	P	95% CI	
				Lower	Upper
Pain >41.8	Age	3.871	0.041	1.056	14.196
	Age at menopause	4.381	0.022	1.239	15.490
	History of bisphosphonates intake	3.079	0.043	1.033	9.172
Physical function >23.2	BMI >23	0.219	0.012	0.69	0.717
	Educational status	5.912	0.004	1.767	19.778
Social function >47.8	Age	0.096	0.036	0.011	0.857
	BMI >23	0.056	0.001	0.011	0.296
	Background	0.101	0.015	0.016	0.647
General health perception >50.1	History of calcium and Vitamin D supplementation	0.138	0.015	0.028	0.686
	History of bisphosphonates	4.562	0.005	1.571	13.247
Mental function >25.8	Age at menopause	0.241	0.019	0.073	0.793

BMI: Body mass index, CI: Confidence interval, OR: Odds ratio, BMI: Body mass index

mood swings, trouble in focusing and less hair on the head, more on the face, and experience of age-related decline of physical and mental capacity. These physiological, emotional, and psychological changes jeopardize their health in total and reduce their QoL.^[3]

Numerous scales have been developed for determining the QoL in general among any age group or sample population. Generic tools available for measuring QoL (such as SF-36, WHO-QOL Bref scale) are useful for assessing health in general, but they are not very disease specific.^[12] More recently, some specific instruments were developed to give a more accurate and precise measure of the QoL in osteoporosis patients specifically. One of them was Qualeffo-41 scale, which has been translated and validated in several different languages.^[11] This questionnaire has been found to be repeatable, coherent, and is able to discriminate between patients and controls. Other specific scales have been developed, but not all of them have been validated like QUALEFFO-41.^[13] The QUALEFFO-41 scale is generally used for osteoporotic patients with vertebral fractures. However, in many clinical trials, the scale was also used in patients without vertebral fractures, especially when BMD measurements were made in the lumbar spine. So many studies conducted earlier have demonstrated the use of this scale, not only in patients with vertebral fractures but also in patients with reduced bone mineral density measured at the lumbar spine, with and without vertebral fractures.^[4]

Globally, the natural age at menopause is 45–55 years.^[14] The mean age at menopause was lower among the study participants with osteoporosis and was in agreement with the study by Bączyk *et al.* and Koirala and Manandhar clearly indicating the onset of menopause after 45 years of age.^[4,14] The mean BMI was significantly different in the three groups, and this was consistent with findings of other researchers also.^[4,15] Majority of the study participants in the three groups had educational status of

primary and lower, which clearly indicates their lack of awareness regarding the adverse health outcomes during postmenopausal phase. However, this was contradictory to findings of few researchers who have observed osteoporosis in women with secondary and above education and reported that it was easy to administer the QoL questionnaire to educated females.^[2,4] Almost half of all the study participants in the three groups belonged to lower middle socioeconomic status and this was in parallel with study by Shobeiri *et al.*^[1]

The findings of our study showed that the QoL among osteoporotic and osteopenic women was significantly lower with regard to QUALEFFO-41 domains such as pain, physical function, and social function when compared to the QoL among women with normal BMD. This is in agreement with findings of other researchers also.^[14,15] Osteoporosis is generally considered a silent disease before the occurrence of fractures, but we found that pain was present in majority of the study participants without known fractures and this was adversely affecting their QoL. Chronic pain in osteoporosis is poorly contemplated even in the presence of vertebral fractures, and it is more ignored and underestimated without them.^[16,17] No significant difference was observed in QoL for domains such as general health perception and mental function in our study. In a study by Bianchi *et al.* and Oleksik *et al.*, no significant difference was observed for the mental function domain and this was consistent with our findings also.^[15,18] This is an important fact, as it strongly supports the hypothesis that the physical restraints of the disease and not the mental abnormality causes limitation in physical abilities, and subsequent reduction in social activities and in autonomy, the permanent modification of body image, and the general health perception.^[15]

Our study has also assessed the impact of age on the QoL in study participants with normal BMD, osteopenia,

and osteoporosis. There was no significant change in the mean values of all domains of QUALEFFO-41 scores among various age groups of patients with normal BMD. However, on the other hand, pain and physical function was significantly affected as age progresses in patients with Osteopenia. Similarly, pain, physical and social function, and overall QUALEFFO-41 score significantly differ as age progresses in patients with osteoporosis. The effect of age on the QOL has been assessed by other studies conducted earlier.^[19] These studies have established the appropriateness of age in decreasing QOL in the domains of physical function, which significantly limits physical activity.^[4] The following study has also demonstrated that QoL was significantly poorer among the elderly osteoporotic patients aged ≥ 70 years for the social function domain. In a study by Ma *et al.* among elderly patients with osteoporosis, it was observed that social support and QOL were worse in elderly patients with osteoporosis and this was positively correlated. Patients with osteoporosis also have poorer social support and care, which refers to the help and aid of both spiritual and material needs from family, relatives, friends, colleagues, and other individuals and organizations, as well as the individual's degree of social support utilization.^[20]

The study has also evaluated the various factors affecting QoL among various domains of QUALEFFO-41 scale among patients with osteopenia and osteoporosis. It was observed that BMI was an important determinant of QoL in physical and social function domains of osteopenic and osteoporotic women. This is consistent with findings of Bączyk *et al.*^[4,7,19] Similarly, de Oliveira Ferreira *et al.* found that obese osteoporotic women scored significantly higher (indicating a lower QoL) in the majority of QUALEFFO-41 domains, the trend being most pronounced in relation to both physical and mental functions.^[8] Our study has also demonstrated bisphosphonate supplementation as a factor determining QoL in pain domain of the scale. This is in contrast to study by Bączyk *et al.* where bisphosphonates supplementation was factor associated with QOL in general health perception domain.^[4] It just means that our study says that bisphosphonates is related to QOL in the pain domain among the post menopausal females and Iwamoto *et al* study supports are findings while Sezer *et al* says that there is no relation of osteoporosis treatment with pain domain of QOL.^[21,22] Our study also shows that educational status was associated with physical function domain of QoL, and this was in agreement with study by Karmakar *et*

al.^[23] Other Indian researchers have also demonstrated that physical function was the most affected domain of QoL among osteoporotic postmenopausal women.^[24]

The following study has thoroughly assessed and compared the QoL among postmenopausal females with normal BMD, osteopenia, and osteoporosis as well as has documented the effect of age on the various domains of QOL in the three groups using osteoporosis specific QOL scale. Very few studies have demonstrated similar research in postmenopausal women.

Limitations

The study has got some limitations. First, small sample size restricts the generalizability of its results. Second, the study was cross-sectional in nature and lacked a control group due to which no causal association can be determined between the predictors and outcome. Third, due to financial constraints, no biochemical estimation of Vitamin D and Calcium levels could be done among the study participants.

CONCLUSION

The perception of developing chronic disease always influences the individual in a negative manner due to the risk of losing independence in future endeavors and development of endless pain and physical restrictions, thereby affecting their QoL. The following study has revealed that postmenopausal women with osteopenia and osteoporosis have poor QoL in domains of pain and physical and social function as compared to those with normal BMD, without any effect on their mental state and general health perception.

Recommendations

The study recommends that all postmenopausal women should be thoroughly investigated before disease progression occurs and there can be onset of fractures which will further be debilitating for them and adversely affect their QOL. The information obtained through the use of appropriate questionnaires could be a powerful instrument for the physician or caregiver in the global management of osteoporosis. This will help the patient to develop more efficient strategies for accepting the disease and coping with it with support, love, and care. Moreover, earlier interventions can be given to the women which will retard the disease progression and lead to favorable health outcome.

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Conflicts of interest

There are no conflicts of interest.

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