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Original Article

CLINICAL OUTCOME OF CALCIUM, VITAMIN D3 AND PHYSIOTHERAPY IN OSTEOPOROTIC POPULATION IN THE NILGIRIS DISTRICT

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ABSTRACT

Objective: Osteoporosis and associated fractures are an important cause of mortality and morbidity. The aim of the study is to evaluate the effects of different treatment modalities calcium, calcium+VitD3 and calcium+physiotherapy and finds their effects on the quality of life in osteoporotic patients using International Osteoporosis Foundation Qualeffo-41Questionnaire and calculates the prevalence in the study sites.

Methods: An open, randomized study comparing the effect of three treatment modalities was carried out in 100 patients (expecting 20%drop out) for six months between September 2013 and March 2014.

Results: On the evaluation of 82 patients for 6 mo it showed that prevalence of osteoporosis is 4.82% in Nilgiris district, TamilNadu. Among the different domains of QUALEFFO-41questionnaire of osteoporotic international foundation (IOF), patients treated with calcium were effective in improving leisure, social activity (at P<0.01). Calcium &physiotherapy was found to be effective in improving mobility and pain (at P<0.0001). But Calcium & Vitamin D3 group proved to be effective in improving Physical function like activities of daily living (at P<0.001).

Conclusion: Osteoporotic population taking calcium along with physiotherapy showed an improvement in the total quality of life.

Keywords: Osteoporosis, QOL, Calcium, Vitamin D3, Physiotherapy, Nilgiris, QUALEFFO-41questionnaire

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INTRODUCTION

Osteoporosis is a disease in which bones become fragile and weak; leading to an increased risk of fractures. Osteoporosis has no signs or symptoms until a fracture occurs this is why it is s called a 'silent disease' [1]. It occurs in approximately, one-fourth of all elderly persons and most commonly in women between 50 and 70 y old. Epidemiologic data revealed that its prevalence increases with age, and it is particularly common in postmenopausal women. With increasing longevity of the Indian population, it is now being realized that, as in the West, osteoporotic fractures are a major cause of morbidity and mortality in the elderly in our nation [2]. As it is not a benign disease it has an impact on mortality, quality of life, the burden on the family, costs to the health care system and it will cause repeated fracture in people thus this condition worsen the life of the world population. Thus, it is important that treatment goals should not be directed towards improving physiological end point but also patient's physical and mental health (i.e. Quality of life with the overall goal of reducing the debilitating impact of osteoporosis on patient's lives)[3]. Generic health-related quality of life instrument used in osteoporosis is International Osteoporosis Foundation Qualeffo-41Quality of Life Questionnaire. The study is focused on finding the prevalence and the effect of three different treatment lines, (calcium, calcium+vitamin D3 & calcium+ physiotherapy) on total quality of life in osteoporotic population of Nilgiris district using Qualeffo-41 Questionnaire [4].

MATERIALS AND METHODS

The study started with the preparation of the study protocol by a systematic literature survey, a protocol was prepared and was approved by the intuitional review board JSSCP/DPP/ IRB/018/ 2013-14 of J. S. S College of Pharmacy, Udhagamandalam, Tamil Nadu, India. The study sites were identified as Government Headquarters Hospital, Ooty and the private orthopedics clinics in Ooty. The data collection form was prepared to collect the necessary data from the patients. IOF QUALLEFFO-41 questionnaire was used to assess the quality of life of patients enrolled in the study. The validation of the Qualeffo-41 Questionnaire for internal consistency was done using SPSS v17, the values of Cronbach's alpha is 0.78 considered that the questionnaire has internal consistency. The patients informed consent form and the data collection form was prepared in both English and Tamil. The study design was an open label, pilot, randomized study, which was scheduled for a period of 6months with a total sample size of 100 patients (expecting 20% drop out). The study accepts no healthy volunteers within the age groups of 18 to 80 y and both the genders. The inclusion criteria included patients with age 18 and above, both smokers and nonsmokers, both alcoholics and non-alcoholics and subjects with exercising and non-exercising habits, the exclusion criteria included pregnancy and lactating women, patients with psychiatric issues, patients on antiepileptics, Patients with $HIV^{+VE,}$ Thyroid patients, Patients with Rheumatoid Arthritis, Patients with Chronic Kidney Disease (CKD), Patients with Congestive cardiac failure (CCF). The source of data included Patient interview, Medical records and Laboratory data. Patient satisfying inclusion criteria after giving informed consent were enrolled for the study and the purpose of the study was explained in detail to the patient before enrollment. Initially, the demographic of the patient like gender, age, marital status, education, occupation, food habits, social habits, educational status, exercise, lab parameters, BMI and presence of other specific health problems, family history, past medication and medical history and current treatment were collected. Then the patients were allocated into groups according to the therapy:

- Group-I: Patients with Calcium (500 mg) dose as prescribed by the physician.
- Group II: Patients with Calcium (500 mg)+Physiotherapy as prescribed and advised by physician
- Group III: Patients with Calcium+Vitamin D3 (Ultra-D3 25µg) dose as prescribed by a physician.

After an explanation of the International Osteoporosis Foundation, Qualeffo-41 Questionnaire was administered to the patients and the answers were recorded. The first recording is considered as a baseline (V0) and the follow-up was done at mid visit i.e., V3 and at last visit i.e., V6. Each follow-up was done at 30 d intervals between each visit. The blood samples were collected from the patient at

baseline (V0), mid visit (V3) and end of the study (V6) for analysis serum calcium. The patients were provided with leaflet both in English and Tamil for better understanding of the disease. The counseling was provided to the patients during all their follow up visits (V0 to V6). The obtain data was entered to Microsoft Excel sheet, mean and standard deviation were calculated. The obtained values of standard deviation and mean were incorporated into statistical software 'Instat version 3.00' and the significance was calculated by student t-test and one way ANOVA. A P value less than 0.05 were considered as significant (P<0.05).

Parameters and follow up visits

Parameter	V_0	V_1	V_2	V_3	V_4	V_5	V_6
Body weight (Kg)	√			√			√
Height (cm)	√			√			√
BMI	√			√			√
ALP#							
CBC#							
SERUM CALCIUM LEVELS	√			√			√
LFT#							
Counseling	√	√	√	√	√	√	√

Represents tests done before the subject enrollment

RESULTS

Table 1 shows that 80.48% of the sample was female. About half of the samples were aged above 60 (53.65%). In relation to their habit, 87.80% were nonsmokers; about54.87% has no exercise habit. In the context of their dietary habit, about three-quarters of the population enrolled in the study was non-vegetarian 76.82%. Regarding their educational status, 68.29% was literate, and majorities were married 93.30 %.

Regarding the effect of calcium alone in osteoporotic patients on various domains like pain, activities of daily living, jobs around the house, mobility, leisure, social activities, general health perception and mental function are represented in table 2. From this study, a slight improvement in physical function (leisure, social activities) was observed in this treatment group (P<0.01). No significance change was found in other domains like pain, physical function (activities of daily living, mobility, general health perception, mental function and jobs around the house) in Qualeffo-41Questionnnarie of international osteoporosis foundation.

As regards calcium+physiotherapy, the result indicates that a significant change on different domains in osteoporosis patients with Qualeffo-41Questionarrie was tabulated in table 3. There was a significant decrease in the mean pain score after three months and six months of therapy (P<0.001) when compared with the basal score. A similar effect was also observed in physical function (mobility7.53±7.24 and 9.92±2.57) at mid and final visits respectively. Similarly, a significant improvement in physical function (jobs around the house and leisure, social activities) were found. A slight improvement in physical function (activities of daily living) after 3 mo of therapy was observed. In mental function, calcium+physiotherapy showed a decrease in the mental function when compared to the baseline and the end of the therapy.

Table 4 shows about the effect of calcium+vitamin D3 on various domains in International Osteoporosis Foundation Qualeffo-41Questionarrie. A significant change was observed in domains like activities of daily living, (17.03±12.67 at P<0.001) and jobs around the house (23.4±13.35at P<0.01), when compared between baseline (v0) and six months of treatment (v6), were as leisure, social activities, mental function, mobility, pain and general health perception showed no significant change in this treatment modality.

Concerning total quality of life, table 5 indicates that among three different treatment modalities like Calcium, Calcium+physiotherapy and calcium+vitamin D3, patient who were on treatment with calcium+ physiotherapy (P<0.0001) were showing a significant improvement in total quality of life when compared with other treatment group, like calcium(P<0.7484) and calcium+vitamin D3(P<0.3588).

Considering the average serum calcium levels of the population enrolled in each treatment group like calcium alone at the baseline visit (v0) and at end visit (v6) were 7.5 mg/dL and 8.96 mg/dL respectively. For calcium+vitamin D3 group showed v0 of 7.3 mg/dL and v6 of 9.02 mg/dL. Whereas for calcium+physiotherapy group showed the value of 7.56 mg/dL and 8.81 mg/dL respectively. An averaged BMI of the study population was found to be 22.3.

Table 1: Characteristics of osteoporotic patients

Patients (N=82)	N (%)
Gender	
Male	16(19.51)
Female	66(80.48)
Age	
18-40	2(2.43)
41-50	18(21.95)
51-60	18(21.95)
Above 60	44(53.65)
Education	
Illiterate	26(31.70)
Literate	56(68.29)
Smoking	
Yes	10(12.19)
No	72(87.80)
Marital status	
Married	77(93.30)
Unmarried	5(6.09)
Food habits	
Vegetarian	19(23.17)
Non Vegetarian	63(76.82)
Exercise	
Yes	37(45.12)
No	45(54.87)

Table 2: Effect of calcium on quality of life in osteoporotic patients

Domain	V0mean±SD (N=28)	V3mean±SD (N=25)	V6mean±SD (N=25)
Pain	17.58±8.41	17.59±8.30	15.76±7.50
Activities of daily living	21.43±11.77	22.51±11.21	22.27±9.81
Jobs around the house	15.62±8.62	16.72±6.70	15.68±6.15
Mobility	11.62±7.15	9.13±3.53	9.68±3.39
Leisure, social activities	10.65±5.4	6.62±5.24##	6.89±5.88@
General health Perception	14.48±17.88	13.96±14.42	16.10±13.58
Mental Function	14.41±7.56	13.79±7.91	12.89±7.37

Data expressed in mean±SD, ##: P<0.001 compared V0 and V3, @: compared V0 & V6.

Table 3: Effect of calcium and physiotherapy on quality of life in osteoporotic patients

Domain	V0 mean±SD (N=25)	V3 mean±SD (N=25)	V6 mean±SD (N=25)
Pain	30±20.59	7.30±7.10###	12.30±7.10@@@
Activities of daily living	15.38±23.53	3.07±3.96#	6.76±2.94
Jobs around the house	13.07±13.93	3.84±6.67##	4.61±2.41@@
Mobility	18.92±7.98	7.53±7.24###	9.92±2.57@@@
Leisure, social activities	14.88±5.40##	20.88±9.05	18.07±12.18
General health Perception	16.53±20.33	18.46±14.88	29.16±4.25@@
Mental Function	13.84±5.89	4.56±4.56###	16.76±5.33

Data expressed in mean±SD, #: P<0.01, ##: P<0.001, ###P<0.0001 compared V0 &V3, @@: P<0.001, @@@: P<0.0001 compared V0 and V6.

Table 4: Effect of calcium and vitamin D3 on quality of life in osteoporotic patients

Domain	V0 mean±SD(N=29)	V3 mean±SD(N=29)	V6 mean±SD(N=29)
Pain	24.66±22.77	22.96±16.73	22.63±16.58
Activities of daily living	26.4±11.09	24.66±13.13	17.03±12.67@@
Jobs around the house	30.66±11.72	24.0±14.87	23.4±13.35@
Mobility	23.4±9.34	22.23±7.95	20.5±8.02
Leisure, social activities	18.2±9.45	19.06±8.63	18.0±6.34
General health Perception	27.3±19.82	24.8±20.96	23.43±21.19
Mental Function	18.53±10.07	16.5±9.22	16.56±7.49

Data expressed in mean±SD, @: P<0.01, @@: P<0.001compared V0 & V6.

Table 5: Total quality of life (TQOL)

Visits	V0	V3	V6	P-value
QOL in calcium alone	54.10±6.97	55.41±5.76	55.23±7.99	P<0.7484
QOL in calcium and physiotherapy	47.34±5.76	35.96±6.02	26.34±5.52	P<0.0001**
QOL in calcium and vitamin D3	51.86±7.99	51.83±7.45	49.4±6.91	P<0.3588

Data expressed in mean±SD** P<0.0001

DISCUSSION

Osteoporosis is an important health-related problem that reduces the quality of life. In our present study 82 osteoporotic patients were enrolled according to our inclusion and exclusion criteria. They were categorized according to socio-demographic, lifestyle, food habits and medical variables.

Out of the total population of 7, 35,394 in the Nilgiris district, approximately about 49,384 were found to be elderly, among the total elderly population a ratio of 1: 20 were found to be osteoporotic. This is because of various reasons such as high altitudes, less exposure to sunlight and poor socio-economic status.

Of the total study population, 80.48% were females. They constituted two third of the study population. Females have shown more prevalence than males because of the hormonal changes in post menopause cause decrease in bone mineral density due to estrogen deficiency which leads to excessive bone resorption than bone formation [5].

The elderly may have the lower total quality of life for two reasons: either because they really do have a less varied life, because its seems possible that elderly people are engaging in less outside activities and, therefore, have less varied life. There was a substantial difference in activity level as a function of age. Our findings suggest that Quality of life judgment is based not only on the activities restricted but also on emotional reactions to any restriction [6].

The number of literates in the study counts over illiterates. Three-fourth of the study patients were non–smokers 72(87.80%). A meta-analysis of studies looking at the effect of smoking found that BMD in smokers was 2% lower with each increasing decade after the menopause than in non-smokers, with a 6% difference at 80 y. Men who smoke show a greater bone loss at the trochanter. Female smokers have been shown to be at greater risk of hip fracture than nonsmokers, with the risk increasing in line with cigarette consumption.

The level of risk declines on giving up smoking, but is not significantly reduced until 10 y after cessation. Smokers should be considered at greater risk of osteoporosis than non-smokers, and advised to stop, for this and other reasons. All the smokers 10(12.19%) in our study were counseled to quit the smoking.

In our study population, 54.87% were non-exercising, and the remaining 45.12% were exercising. However, a study of an

Australian population has shown that individuals with a sedentary adolescent lifestyle should be considered at higher risk of osteoporosis and thus the patients who were not exercising are counseled to do exercise to avoid worsening of the condition.

Non-vegetarians 63(76.82%) were more in our study population than the vegetarian 16(19.51%). Bone mass and quality is mainly determined genetically, many other factors, including lifestyle and nutrition, also have an impact on bone health. It has been suggested that dietary protein intake may be a risk factor for osteoporosis, and high-protein diets are associated with increased bone loss.

In our study, a patient treated with calcium has improved domains like leisure, social activity; a slight improvement was noticed in pain and mobility. A study by Ronald Hamdy et. al., showed that Calcium supplements appear to be effective in reducing bone loss in women late post menopause (>5 y post menopause), particularly in those with low habitual Calcium intake (<400 mg/d). In women early post menopause (<5 y post menopause) who are not vitamin D deficient, Calcium supplementation has little effect on bone mineral density [7].

The effect of calcium & physiotherapy showed improvement in specific domains like pain and mobility, it may be due to strengthening of the muscles and reducing the spasm around the joints, thereby relieves the pain and improves the mobility or by enhancing the bone mineralization which can modify involutional bone loss in women after menopause and thereby strengthening the bones and decrease the pain and improve the mobility [8]. While the other domains like jobs around the house, mental function, and general health perception showed slight improvement.

Calcium and vitamin D3 showed significance improvement on activities of daily living and jobs around the house by decreasing the fall and preventing fractures which is similar to the earlier findings by Susan [9].

Among the three different modalities, calcium and physiotherapy proved to have a significant improvement in the total quality of life than calcium and its combination therapy with vitamin D3, which is similar to the earlier study done by Guido Schröder *et al.,* (2012) [10].

CONCLUSION

The prevalence of osteoporosis in the Nilgiris district was found to be 4.82%.

Among the different domains of QUALEFFO-41questionnaire of osteoporotic international foundation (IOF), patients treated with calcium were effective in improving leisure, social activity.

Calcium & physiotherapy was effective in improving mobility and pain.

Calcium & Vitamin D3 group was effective in improving Physical function (activities of daily living).

From this study, it can be concluded that calcium & physiotherapy may be helpful to improve the total quality of life in osteoporotic patients.

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CONFLICT OF INTERESTS

The author(s) declare that they have no competing interests

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