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Original Article

Internal Medicine Section

Hypovitaminosis D and Other Risk Factors of Femoral Neck Fracture in South Indian Postmenopausal Women: A Pilot Study

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ABSTRACT

Background: Non-communicable diseases like hip fractures are a significant problem in a developing country like India. The risk factors for hip fractures vary according to local practices and the availability of preventive health care delivery systems. There is paucity of data on risk factors for hip fracture in the south Indian population.

Aim: This study was undertaken to assess risk factors associated with femoral neck (FN) fracture in South Indian postmenopausal women along with subsequent one year mortality.

Materials and Methods: One hundred four postmenopausal women with FN fracture and 104 age and BMI matched controls were included. Sedative use, visual impairment and other relevant risk factors were assessed. Bone biochemistry and Bone Mineral Density (BMD) were evaluated. A telephonic interview was done at the end of one year to ascertain the well-being.

Results: Sedative use, visual impairment, low FN BMD and vitamin-D deficiency (<20 ng/ml) were seen more in fracture subjects compared to controls ($p \leq 0.05$). At the end of one year, 20% of the fracture subjects and 5% of the controls had died ($p=0.001$).

Conclusion: Risk factors identified in our study are potentially correctable, and needs special attention in an Indian context to prevent hip fractures.

Keywords: Sedative use, Vitamin-D deficiency, Visual impairment

INTRODUCTION

Non-communicable diseases like hip fractures are a major health problem in a developing country like India [1]. There is at least a two-fold increased risk of mortality within one year in patients who sustain hip fracture [2]. A recent Indian study showed a crude incidence of hip fracture to be 129 per 100000 in people above 50 y of age [3]. Considering the population of about 100 million post menopausal women in India [4], osteoporosis and hip fracture will have a significant impact on morbidity and mortality. This underscores the need for assessment of risk factors and intervention for prevention of fractures.

Osteoporosis at the femoral neck is an important risk factor for femoral neck fracture. In a community based study of south Indian post menopausal women, prevalence of osteoporosis at the femoral neck was found to be 26% [5]. The onset of menopause triggers a rapid phase of bone loss in women due to reduced ovarian function. Advancing age and low BMI are other known risk factors for osteoporosis [5]. In addition, calcium absorption is reduced in postmenopausal women, and a large proportion of these women take inadequate amounts of calcium in their diet [5,6]. Calcium supplementation has been indisputably shown to reduce age related bone loss and decrease the risk of hip fractures [7,8]. The other risk factors for osteoporosis and subsequent fracture include premature menopause, glucocorticoid use or abuse in the past, untreated hyperthyroidism, rheumatoid arthritis, parental hip fracture, smoking and alcohol consumption [9].

Vitamin-D deficiency is a significant problem in Indian postmenopausal women due to the traditional clothing pattern and these women most often remain indoors [4,10]. Vitamin-D deficiency predisposes to fall because of decreased muscle strength, and to fracture due to impaired skeletal mineralization [10,11]. The other potential risk factors for fall also include visual impairment and sedative use [12,13]. The degree of impact of the above mentioned risk factors on hip fracture has not been adequately studied in the south Indian population.

Aim of the Study

To assess the various potential risk factors including sedative use, visual impairment, vitamin-D deficiency, low femoral neck BMD and dietary calcium intake for fracture of the femoral neck in previously ambulatory south Indian post-menopausal women and the subsequent mortality at the end of one year.

MATERIALS AND METHODS

Patient Population

We selected consecutive previously ambulatory postmenopausal women aged above 60 y (n=104) with recent (< 1 wk old) femoral neck fracture following a trivial fall (defined as a fall from the standing height which may have otherwise would not resulted in a fracture) from the local community who were hospitalised in the orthopaedic ward in our institution. The patients with past history of prolonged immobilisation were excluded. The patients who were on bone active medications before sustaining fracture were also excluded.

Age and BMI matched ambulatory women (n=104) from the community health database attached to our institution were recruited as controls. These subjects were from the local area who received the primary and secondary health care services for diseases like diabetes mellitus and hypertension from our Community Health Department (CHAD).They were group matched for cases. They did not have illnesses which could limit their mobility (e.g.: deforming arthritis).Thus controls were ambulatory and were able to carry out daily activities without any aid. All subjects included in the study provided informed consent. This study was approved by the institutional review board.

Study Period

1st January 2011 – 1st November 2013.

Assessment

History and Clinical Assessment

The patients were interviewed in the hospital during their admission. All the controls were assessed in the hospital. All the patients were

questioned about the place (inside or outside their residence) and mode of fall. History of glucocorticoid use for more than three months at a dose of prednisolone of 5 mg daily or more (or equivalent doses of other glucocorticoids), untreated hyperthyroidism, premature menopause, sedative use, history of rheumatoid arthritis, previous fractures following trivial trauma, parental hip fracture, history of smoking and alcohol consumption and details about any other chronic illness like diabetes, hypertension and coronary artery disease were assessed. The duration of exposure to sunlight (number of hours per day) and the usual type of clothing worn at that time were noted [4]. The current medication lists of all the subjects were reviewed and any sedative use was recorded. Dietary calcium intake was assessed by an experienced dietician. Qualitative and quantitative aspects of food intake were assessed using an oral freely usable semi-quantitative food frequency questionnaire [14]. The height, weight, BMI and blood pressure were measured. Vision was assessed by a Snellen's chart. Visual impairment was defined as binocular best corrected visual acuity of less than 6/18 [15].

Biochemistry

Fasting blood samples were collected to measure serum albumin, serum calcium (8.3-10.4mg/dl), phosphate (2.5-4.6mg/dl), alkaline phosphatase (40-125u/L), albumin (3.5-5g/dl), creatinine (0.5-1.4mg/dl) and 25-hydroxy Vitamin-D (25-OHD) and intact PTH (Parathyroid Hormone, 8.0-50pg/ml). All biochemical variables except vitamin-D and PTH were measured in a fully automated and computerised micro analyser (Hitachi model 911; Boehringer Mannheim, Mannheim, Germany). The intra-assay and inter-assay coefficients of variation for these analyses were 1% to 5%. A radioimmunoassay (DiaSorin, Stillwater, Minnesota) was used for determination of 25-OHD. The analytical sensitivity of this assay, when defined as the lowest quantity differentiated from zero standard (N = 20), has been shown to be 1.5ng/mL. Vitamin-D deficiency was defined by 25-hydroxyvitamin-D level of less than 20ng/ml (50n.mol/liter) [16]. Intact PTH was measured by chemiluminescence method using Immulite analyser 2000.

Bone Mineral Density (BMD)

Bone mineral density of all the subjects was assessed by Dual-Energy X-Ray Absorptiometry (DXA) technique using the Hologic machine (QDR 4500; Discovery A Hologic, Inc., Waltham, Massachusetts) at the lumbar spine (L1 to L4) and the femoral neck. In patients with fractures, femoral neck BMD was assessed on the contralateral side. The reference population consisted of normal Caucasian subjects (manufacturer's database). The precision was 2% at both measured sites (spine and neck of femur). The World Health Organization criteria for osteoporosis were used [17].

Follow up

Subjects with a femoral neck fracture and controls were followed up through phone-based interviews with either a family member of the patient or with the patient herself at the end of one year following recruitment. They were enquired with regards to their health status. Among subjects who were reported to be dead, the time, place and cause of death were recorded. In subjects who were alive, the overall well being of the patients was recorded, in addition to their ambulatory status.

STATISTICAL ANALYSIS

We collected the demographic, clinical, BMD and biochemical data of the all the subjects at our institution. Data was recorded as mean ± SD or frequency of categorical variables. An independent t-test was used to compare the means of 2 groups if they were normally distributed, and nonparametric tests were used if their distribution was not normal. The correlation between two continuous variables was assessed with use of the Pearson correlation when they were normally distributed. This was used to look at the correlation between BMI and BMD as well other factors affecting BMD. Univariate regression analysis was carried out to assess the effect of individual risk factors on femoral neck fracture. The factors which emerged as significant (p-value ≤ 0.10) in univariate analysis were further analysed by multiple logistic regression analysis and variables were considered to be significant when p-value was ≤ 0.05 and Odds Ratio was calculated. The Chi-square test was used to compare the presence of various risk factors and the mortality between cases and controls. Statistical analysis was done using the SPSS 17 software package.

RESULTS

The study included 104 postmenopausal women who sustained FN fracture and 104 age and BMI matched control subjects. Of the FN fracture subjects, 96 sustained fracture following a fall inside their homes, while 8 suffered a fall outside their residence.

The demography, BMD and biochemical profile of both groups are shown in [Table/Fig-1].

Parameter	Cases (n=104) Mean±(SD)	Controls (n=104) Mean±(SD)	p-value
Age (years)	71.8 ±4.2)	69.7 ±(4.6)	0.223
Dietary calcium intake (mg/day)	443.4 ±(200)	350.3± (122)	0.069
Sunlight exposure (minutes/day)	40± (23)	32 ±(23)	0.263
BMI (kg/m^2)	22.3± (4.8)	23.4 ±(5.6)	0.171
Lumbar spine - BMD (g/cm^2)	0.688± (0.127)	0.735 ±(0.130)	0.160
Femoral neck - BMD (g/cm^2)	0.525± (0.080)	0.647 ±(0.140)	0.001
Corrected Calcium (mg/dl)	8.9± (0.4)	8.7 ±(0.5)	0.127
Serum Phosphorus (mg/dl)	3.4± (0.9)	3.8 ±(0.6)	0.069
Alkaline Phosphatase (U/L)	80 ±(29.2)	84.4± (33.9)	0.637
Serum Creatinine (mg/dl)	0.8± (0.18)	0.8 ± (0.13)	0.125
Vitamin-D (ng/ml)	14.3± (7.8)	20.8± (9.8)	0.007
Serum PTH (pg/ml)	61.8± (41)	47.5 ±(18)	0.094

[Table/Fig-1]: Demography, BMD & Biochemistry (Independent T-test)

The prevalence of various risk factors for fall, associated systemic diseases, vitamin-D status, secondary hyperparathyroidism and osteoporosis in the two groups are compared in [Table/Fig-2].

Sedative use and visual impairment were noted in significantly larger proportion of subjects with FN fracture when compared to controls ($p < 0.05$). The mean BMD (SD) at the femoral neck was significantly lower in the fracture group with a greater proportion of them had osteoporosis in comparison to controls (p=0.005).

The mean serum 25-hydroxy vitamin-D was significantly lower in subjects who had sustained a femoral neck fracture when compared to controls (14.3 (7.8) vs 20.8 (9.8) p=0.007) with a greater proportion of patients in this group had vitamin-D deficiency (74% versus 45%, p=0.02) and secondary hyperparathyroidism (61% vs. 35%, p=0.039).

Advancing age had a significant negative correlation with femoral neck BMD (r=0.368; p ≤ 0.05). BMI had a significant positive correlation with femoral neck BMD (r=0.436; p=0.001). There was no correlation between 25 hydroxy vitamin-D levels and BMD at the femoral neck (r=0.08; p=0.541). There was a positive correlation between the duration of sunlight exposure and vitamin-D among cases (r=0.26; p=0.05) and controls (r=0.36; p=0.044). An inverse correlation was noted between serum PTH and 25 (OH) vitamin-D in the fracture group (r=-0.332; p=0.01).

On multivariate analysis, only sedative use, visual impairment, low femoral neck BMD and low 25(OH) vitamin-D levels were significantly associated with fracture at the femoral neck [Table/Fig-3].

Parameter	Cases (n=104) n (%)	Controls (n=104) n (%)	p-value
Sedative use	22(22)	3(3)	0.023
Hypertension	47(45)	30(29)	0.118
Diabetes Mellitus	33(32)	26(25)	0.277
Coronary Artery Disease	12	9	0.119
Past history of any fractures	4	3	0.1
Parental hip fracture	2	3	0.1
Visual impairment	80(77)	52(50)	0.006
Steroid use	3	4	0.1
Rheumatoid arthritis Untreated hyperthyroidism Premature Menopause Smoking Alcohol consumption	Nil	Nil	-
Vitamin-D Deficiency (< 20 ng/ml)	77(74)	47(45)	0.02
PTH (> 50 pg/ml)	63(61)	36(35)	0.039
Osteoporosis (T-score minus ≤ 2.5) LumbarSpine Femoral Neck	 84(81) 73(71)	 76(74) 33(32)	 0.364 0.005

[Table/Fig-2]: Prevalence of risk factors, systemic diseases, vitamin-D status and secondary hyperparathyroidism in two groups (Chi-square test)

Risk factors	Univariate			Multivariate		
	ODDS Ratio	C.I	P	ODDS Ratio	C.I	P
Sedative use	8.7	1.06-7.6	0.04	105	3.9-282	0.005
Visual impairment	5.4	1.5-19.7	0.009	11	1.46-84	0.02
Low BMI (<18.5 kg/m^2)	1.0	0.8-5.4	1.0	1.4	0.2-12	0.742
Femoral Neck osteoporosis (T<-2.5)	5.5	1.8-16.7	0.003	10.1	1.8-56	0.008
Low Vitamin-D (<20 ng/ml)	3.7	1.2-11.3	0.019	9.7	1.8-52	0.008

[Table/Fig-3]: Logistic Regression (Multivariate) – Various factors contributing to fracture at neck of femur

At the end of one year, family members of 92 subjects in the fracture treated group and 98 subjects in the control group could be contacted by telephone. Eighteen of 92(20%) fracture treated patients compared to 5 of 98 (5%) control subjects had died (p=0.001). Rest of the fracture subjects (n=74) were ambulant and mostly confined indoors. The mortality in fourteen of fracture subjects and 4 controls that died in the first year was due to an acute coronary event. In remaining subjects (4 in the fracture group and 1 in control group), cause of death could not be ascertained as they died at their residence.

DISCUSSION

In the present study, we found that sedative use and visual impairment were significantly associated with fracture neck of femur. The study also demonstrated a high prevalence of vitamin-D deficiency and osteoporosis at the femoral neck in postmenopausal women with recent femoral neck fracture.

Risk factors for hip fracture [18-23] [Table/Fig-4] and prevalence of hypovitaminosis D [24-28] [Table/Fig-5] has been described in different population based hip fracture studies previously.

S.No.	Authors	Year	Number	Prevalence (%)	Population
1.	Moniz C et al., [24]	2005	103	81.6%	United Kingdom
2.	Sakuma M et al., [25]	2006	50	62%	Japan
3.	Dhanwal DK et al., [11]	2013	90	77%	North India
4.	Johnson AL et al., [26]	2013	448	65.8%	USA
5.	Ramason R et al., [27]	2014	412	57%	Singapore
6.	Current study	2015	104	74 %	South India

[Table/Fig-5]: Prevalence of hypovitaminosis D in hip fracture subjects from different countries [24-28]

Sedative Use

Sedative use was a significant factor associated with femoral neck fracture in our study, as also demonstrated in other studies. Nurmi-Luthje studied 223 patients with acute hip fracture and found that 50 per cent of them were on benzodiazepines [28]. However, no other study has looked at this factor in an Indian context.

Visual Impairment

Squirrell et al., studied a cohort of 89 elderly patients with hip fractures and found significant visual impairment in 58% [29]. Since, visual impairment has emerged as an important factor contributing to the fracture; it underscores the need for appropriate visual assessment in this age group and early correction of visual defects [12].

Vitamin-D Deficiency

Low 25 (OH) vitamin-D levels have been documented in various studies on hip fracture [2,11,24-27]. A high prevalence of vitamin-D deficiency and secondary hyperparathyroidism noted in our patients with recent hip fracture implies that these subjects were vitamin-D deficient even before the occurrence of fracture. Vitamin-D deficiency is probably due to the traditional clothing pattern, greater degree of skin pigmentation, and inadequate dietary intake of vitamin-D [4]. The positive correlation noted between the duration of sunlight exposure and 25 hydroxy vitamin-D levels, and inverse correlation between vitamin-D and PTH have been described in previous studies [30].

BMD and Other Risk Factors

Our study showed that a significantly higher proportion of patients with hip fracture had low BMD and osteoporosis at femoral neck, consistent with previously published observations [32]. The BMD measurement at the femoral neck with DXA is a strong predictor of hip fractures in men and women with a similar predictive ability [31,32].

S.No.	Authors	Study	Year	Risk factors	Population
1,	Haentjens P et al., [18]	Case-control study	2002	Residence not equipped enough to perform daily activity, previous fractures and falls, chronic use of psychotropic drugs	Belgium
2.	Grisso JA et al., [19]	Case-control study	2006	Lower limb dysfunction, visual impairment, previous stroke, Parkinson's disease, long acting barbiturates	USA
3.	Hreybe H et al.,[20]	Case-control study	2009	Previous fractures, systemic illness, sedative use	Lebanon
4.	Jha RM et al., [21]	Case-control study	2010	Visual impairment, decreased agility, long-term medications, chronic illnesses, caffeine intake	North India
5.	Bawab W et al., [22]	Case-control study	2014	Chronic disease, anti-hypertensive drug intake, previous fracture, family history of fracture, smoking	Lebanon
6.	Thorell K et al., [23]	Case-control study	2014	Advancing age, multiple comorbid illnesses usage of drugs like - opioids, dopamine agonist, anxiolytics, antidepressants and hypnotics	Sweden
7.	Current study	Case-control study	2015	Visual impairment, sedative use, low femoral neck BMD	South India

[Table/Fig-4]: Studies showing risk factors for hip fracture among various population [18-23]

Age had a significant negative correlation and higher BMI had a positive correlation with femoral neck BMD in our study, similar to the findings of earlier studies [33,34]. Low body mass index (BMI) and low dietary calcium intake are also a well-documented risk factors for osteoporotic fracture [18], but were not significant in our study probably due to the small sample size.

Femoral Neck Fracture & Mortality

The increased mortality associated with hip fracture emphasizes the need to undertake measures for fracture prevention. In a recent meta-analysis by Haentjens et al., hip fracture patients were found to have a 5-8 fold increased hazard for all-cause mortality during the first 3 months after the fracture [35].

Need for Intervention

In a pilot study by Jha et al., dietary calcium intake, dietary vitamin-D intake, increased BMI and a higher physical activity levels had a protective effect on hip fracture in urban North Indian population [21]. Multi–factorial risk assessment and interventional programmes have been shown to be beneficial in reducing the risk of fall and fractures [32]. Similar interventions need to be studied in the Indian setting at the community level to assess their impact on reduction of hip fracture.

LIMITATIONS

This is the first study in south Indian women to look at the multiple risk factors associated with fall and hip fracture, and subsequent mortality. These risk factors can be addressed easily in the Indian context in order to reduce morbidity, mortality and the economic burden associated with hip fractures. The risk factors like proximal muscle weakness, physical activity levels and peripheral neuropathy which could have contributed to fall and fracture were not assessed. Another limitation was the small sample size.

CONCLUSION

Visual impairment, sedative use, vitamin-D deficiency and osteoporosis are significant risk factors for femoral neck fracture in postmenopausal women from South India. These are potentially correctable, and need special attention in this high risk group.

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