Correlation of Fall Risk, Fracture Risk and Function in Middle-Aged and Elderly Population of Gujarat, India

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ABSTRACT

Purpose: The purpose of the study was to find out the correlation of fall risk, fracture risk and functional level using Berg Balance scale (BBS), Fracture risk assessment tool (FRAX) and lower extremity functional scale (LEFS) respectively in middle aged and elderly population of Gujarat, India. It was hypothesized that there would be a negative correlation of FRAX with BBS and LEFS and a positive correlation between BBS and LEFS.

Methods: It was an observational study including five hundred participants both men and women, with age group of 40-80 years, selected from the local community of Gujarat from March-December, 2017. The 10-year probability of risk of Major osteoporotic fracture (MOF) and Hip fracture (HF) was calculated by FRAX and the balance and lower limb functional status were assessed by BBS and LEFS respectively. The correlation between the variables was analyzed by the Spearman’s Rho correlation.

Results: The correlation between the variables was found significant at 0.01 level (2-Tailed) There was a strong negative correlation of FRAX HF with BBS(r=−0.61) and FRAX MOF with BBS(r=−0.63), moderate negative correlation of FRAX HF with LEFS (r=−0.58), strong negative correlation of FRAX MOF with LEFS(r=−0.60) and Strong positive correlation between BBS and LEFS (r=0.69).

Conclusion: The study showed a significant moderate to strong correlation of fall risk, fracture risk and function in middle aged and elderly population of Gujarat. The lower balance and functional scores were related to increased risk of falls and probability of fractures and there was a strong positive relationship between balance and the functional status.

Keywords: Correlation, Fracture risk assessment tool (FRAX), Berg Balance scale(BBS), Lower extremity functional scale(LEFS), Balance, Gujarat

INTRODUCTION

Population ageing is a global phenomenon. Per the 2011 population census, there was nearly 104 million elderly in India; 53 million females and 51 million males with the proportion of the elderly population increase in age overtime. [¹] With a large number of the elderly in the population, the country of India will need more and more health and medical services, facilities and resources to predict, prevent and treat age-related conditions. Unlike developed countries, India does not have well-structured health services for the elderly.

Osteoporosis is a worldwide silent disease affecting everyone and the incidence of osteoporotic fractures vary among different populations, greatest in whites and Asians and least popular in blacks. [²] The Indian population would also behave in a similar manner. The onset of osteoporosis is asymptomatic and it is stereotypically recognized after an older person falls and
Osteoporosis is commonly diagnosed using bone mineral density (BMD)-dual energy x-ray absorptiometry (DXA) scans and treated by medication, although many fragility fractures occur in people with a milder form of the disease, known as osteopenia. Osteoporosis-related fractures are common among postmenopausal women and the elderly population. Fragility fractures like vertebral, hip, forearm and others are becoming a significant public health problem. With the increasing life span of the population, this problem is going to reach epidemic proportions, unless patients who are at increased risk for falls and fractures are identified and treated. [3] Although diagnostic tools and clinical data supporting the importance of preventing and treating osteoporosis are available, many patients remain undiagnosed and untreated. [4]

Falls are one of the most common geriatric problems affecting the independence of the elderly population. Middle age is an ideal time in adults for identifying high-risk individuals and applying fracture prevention measures, as fragility fractures are still not as common in this population. [5] Preventive health strategies to minimize the risk associated with osteoporosis and osteopenia may permit the healthy and independent aging to prolong the effect of this silent disease. [6] According to WHO Global Report on ‘Falls Prevention in Older Age’, (2007) worldwide, the number of people over 60 years old is increasing and fall prevention is a challenge to this segment of the population. Falls prevention is one of the issues that have not been given enough attention in a developing country like India where population ageing is occurring rapidly. [7] Most falls are caused by the interaction of multiple risk factors. More risk factors lead to greater chances of falling. Healthcare professionals can lower a person’s risk by identifying and minimizing an individual’s risk factors. Age-related physiological and psychological changes gradually affect the balance, range of motion and speed of movement. As a direct result of balance impairments, the elderly may be unstable on their feet; therefore the possibility of fall increases dramatically. When bones are weak, a simple fall could result in a fracture. Subsequently, since a fall is the most common cause of a fracture, identifying the population most at risk and providing appropriate management for fall-related risk factors, both falls and fractures could be prevented.

Osteoporosis-related studies have shown the direct association between muscle weakness, poor balance and falls. [8] Balance assessments can aid clinicians to identify balance impairment which is one of the key risk factors for falls among the elderly. The Berg Balance Scale (BBS) is a well-established reliable clinical tool used to test for static and dynamic balance, as well as fall risk. [9] A previous systematic review and meta-analysis identified a correlation between measures of balance and lower-extremity muscle strength in healthy individuals across all age groups. [10] Lower limb muscle weakness is one of the identifiable risk factors associated with falls. [11] Lower extremity functional status can be assessed by the lower extremity functional scale (LEFS). [12]

Bone density is an important but not the only determinant of fracture risk. [13] It provides a relative risk assessment rather than absolute risk assessment for predicting fracture risk. Adding clinical risk factors that are able to predict fracture independent of BMD may improve the ability to predict fracture risk. The WHO Fracture risk assessment tool (FRAX) is a diagnostic tool developed and validated to evaluate the 10-year probability of bone fracture risk. [14] FRAX is based on the clinical risk factors and it provides a 10-year probability of major osteoporotic fracture (MOF) (spine, forearm, hip, or shoulder) and hip fracture (HF), with or without BMD. The models used to develop the FRAX diagnostic tool were derived from studying patient populations across the globe to facilitate treatment for
people at high absolute risk of fracture and re-assurance of those at low risk. The benefit of using the FRAX tool is its use of Body Mass Index (BMI) as a simple screening test to predict the fracture probability, thus avoiding unnecessary and costly clinical investigations. Studies have proved that the use of FRAX is high in North America and Europe, intermediate in Latin America and the Middle East and very low in Africa and much of South East Asia including India. [15]

The FRAX underestimates fracture risk in the presence of established fall risk because it does not include falls history. [16] Studying the relationship between Lower extremity functional scale (LEFS) and clinical balance measures like the Berg balance scale (BBS) may assist prediction screening protocols that identify those at highest risk for injury like fracture. Thus, coalescing FRAX data with fall risk measures like BBS and functional measures like LEFS may provide the strong validation required to identify at-risk people susceptible to falls and fractures.

The purpose of the study was to find out the correlation of fall risk, fracture risk and functional level using BBS, FRAX and LEFS respectively in the middle-aged and elderly population of Gujarat, India. It was hypothesized that there would be a negative correlation of FRAX (HF and MOF) with BBS and LEFS and there would be a positive correlation between BBS and LEFS. To the best of our knowledge, this is the first study in Gujarat, India, utilizing FRAX for the assessment of fracture risk and also, the correlation of fall risk, fracture risk and function in the Indian population, which has not been studied extensively until now. Knowledge of the relationship of these outcome measures would help physical therapist and other clinicians to develop strategies to predict and prevent falls and fractures.

METHODOLOGY

An observational analytical study was conducted from March-December; 2017. Ethics committee approval was obtained for the same. The minimum sample size required was 385 for a precision of 5%, 95% Confidence Interval (CI) and power of 80%, With sample size formula

\[ n_0 = \frac{Z^2 p (1-p)}{e^2} \]

where e = 0.05, is the desired level of precision, p = 0.5 is the estimated proportion of population, Z = 1.96 at 95% CI. So for this study, total five hundred participants were selected using convenience sampling method. Participants were educated about the study and written informed consent was obtained from all individual participants included in the study. Elderly and middle-aged men & women were selected in the age group of 40-80 years old, from various local communities in Gujarat, India. The participants already diagnosed with osteoporosis and on anti-osteoporotic medication were excluded from the study. Also participants with any acute injury, illness, surgery, fracture, inability to stand, neurological or cognitive impairment were excluded.

First, the demographic assessment form of each participant was completed. The height (in centimeters) and weight (in kilograms) of each participant was recorded using standardized weighing machine and height caliper respectively. Then the FRAX questionnaire was introduced to each participant and the answers were obtained in the form of “YES” or “NO” for all the clinical risk factors included in the FRAX. 10-year Probability of risk of fracture was calculated from age, BMI calculated from height and weight, previous fracture, parental history of hip fracture, current tobacco smoking, ever long-term use of oral glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and daily alcohol consumption of 3 or more units. The FRAX was calculated without BMD by the web based country specific licensed FRAX-India individual entry version 4.0. The outcome of FRAX calculation was BMI and the 10-year probability of risk of fracture for MOF and HF.

Balance assessment was done by Berg Balance Scale (BBS). [17] BBS consists of 14 common functional activities that are...
scored from 0 to 4, where 0 indicates an inability to perform the task and 4 indicates the task was performed correctly and independently. BBS evaluates balance with a variety of functional activities such as sitting unsupported, standing to sitting transfer and vice versa, turning, transfer, standing with closed eyes, stepping, tandem stance, single leg stance and forward reach. The lowest response category for each item was recorded and scored. The total score of the scale is 56. Higher scores indicate better balance and lower risk of fall. It takes about 15 to 20 minutes to complete this test.

The BBS test was followed by an assessment of lower extremity function by lower extremity functional scale (LEFS). This scale consists of 20 questions, which were answered with the difficulty level of the participant to perform that particular activity. The scale consists of activities with increasing physical demands. The activities included were mainly using the lower limb such as activities of daily living, recreational activities, sitting, standing, walking, turning, running, hopping, turning in bed etc. The LEFS is a five-point scale, ranging from 0-4 where zero indicates inability to do that activity or extremely difficult activity and four indicates no difficulty completing the task. The participants were asked whether they were having any difficulty at all with the activities listed in the scale and the answers were scored. The total score of LEFS is 80 and it takes about 10 min to complete. Translation and cross-cultural adaptation of Gujarati version of LEFS was done for this study and it was validated. [18]

Statistical analyses were carried out using the Statistical Package for Social Sciences (SPSS) version 20. Normality of variables was assessed using Shapiro-Wilk’s test. The data distribution was found to be non-normal so the research hypothesis was analyzed by the non-parametric Spearman’s Rho correlation coefficient. The strength of correlation was interpreted by the r value as 0.00-0.19: very weak, 0.20-0.39: weak, 0.40-0.59: moderate, 0.60-0.79: strong, 0.80-1.0: very strong. Level of significance was kept at 5%.

**RESULTS**

Total 500 participants including 284 females and 216 males with an average age of 56.3±9.7 years (range 40 to 80 years) were included in the study. The details of descriptive data are shown in Table 1. The correlation between the variables was found to be significant at 5% level of significance (2-Tailed) There was a strong negative correlation of FRAX HF with BBS(r = -.61, p < .01) and FRAX MOF with BBS(r = -.63, p < .01). Also there was a moderate negative correlation of FRAX HF with LEFS (r = -.58, p < .01) and a strong negative correlation of FRAX MOF with LEFS(r = -.60, p < .01). Moreover, there was a strong positive correlation between BBS and LEFS (r = .69, p < .01). In addition, there was a very strong positive correlation between FRAX HF and FRAX MOF (r = .92, p < .01). The correlation between variables by scatter plots is shown in figures 1-6. The correlation of FRAX HF with BBS, FRAX HF with LEFS, FRAX MOF with BBS, FRAX MOF with LEFS, BBS with LEFS and FRAX HF with FRAX MOF is shown in figures 1, 2,3,4,5 and 6 respectively.

**Table 1: Descriptive statistics of all participants’ characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Age (yr)</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>BMI (kg/m²)</th>
<th>FRAX HF%</th>
<th>FRAX MOF%</th>
<th>BBS Score</th>
<th>LEFS Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>56.3</td>
<td>162.0</td>
<td>67.3</td>
<td>25.6</td>
<td>1.6</td>
<td>4.8</td>
<td>51.1</td>
<td>61.5</td>
</tr>
<tr>
<td>95% Confidence Interval for Mean</td>
<td>Lower Bound</td>
<td>55.5</td>
<td>161.4</td>
<td>66.3</td>
<td>25.3</td>
<td>1.4</td>
<td>4.3</td>
<td>50.6</td>
</tr>
<tr>
<td></td>
<td>Upper Bound</td>
<td>57.2</td>
<td>162.7</td>
<td>68.3</td>
<td>25.0</td>
<td>1.8</td>
<td>5.2</td>
<td>51.7</td>
</tr>
<tr>
<td>Median</td>
<td>55</td>
<td>162</td>
<td>67</td>
<td>25.3</td>
<td>0.6</td>
<td>2.9</td>
<td>54</td>
<td>63</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>9.7</td>
<td>7.7</td>
<td>11.1</td>
<td>4.0</td>
<td>2.6</td>
<td>4.9</td>
<td>6.1</td>
<td>11.5</td>
</tr>
<tr>
<td>Interquartile Range</td>
<td>14</td>
<td>8</td>
<td>15</td>
<td>5.7</td>
<td>1.5</td>
<td>4.7</td>
<td>8</td>
<td>15</td>
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</table>
The purpose of this study was to determine if there was a correlation of fall risk, fracture risk and function in population of Gujarat, India. The correlation findings...
between the variables using the Spearman's correlation coefficient reject the null hypothesis. This study indicated significant correlation of FRAX with balance and functional measures. There was a strong negative correlation of FRAX (HF and MOF) with the balance score leading to the conclusion that participants with less balance had more risk of fall and fracture. Moreover, the LEFS score had moderate to strong negative correlation with both the FRAX values indicating that lesser the lower limb functional score, higher the risk of fracture. There was a strong positive correlation between the probability of risk of hip fracture and major osteoporotic fracture. Also there was a strong positive relationship between falls risk and lower limb functionality which means more the balance, more functional the individual would be and vice-versa. Hence, the participant with the lowest balance score had the lowest functional score with the highest probability of risk of fracture Hip and MOF, as per the analysis. These findings suggest that combining the balance and functional measures along with FRAX increase the chance of identifying people at risk of fall and related fractures.

In this study there was a significant positive relationship between falls risk and lower limb functionality. Lord et al. and Tinetti et al. stated that functional mobility and balance deficits are common in fallers. Neuls PD et al. explained the usefulness of the Berg Balance Scale to predict falls in the elderly. Also they recommended that clinicians should use the BBS in conjunction with other measures to quantify the chances of falls in older adults. Smee DJ et al. have shown a strong relationship between falls risk and physical functionality in their study. They have also explained how aging and risk of falls are associated with a number of physical impairment factors, such as reduced balance and muscle weakness. In a previous study, the positive relationship was found between balance and performance in activities of daily living among elderly people. With aging, individuals develop progressively poor strength and balance with age-related decrease in physical functionality contributing to fall risk and fracture risk. In this study, high to moderate scores were observed for the LEFS in the majority of the population, although they did decrease with age. Individuals with any lower limb problems had less LEFS score.

There was a significant negative correlation between values of FRAX (HF and MOF) with balance score. Greenspan S et al., suggested in their study that functional impairment in mobility is an important and independent risk factor for fall and related hip fracture. An earlier study concluded that FRAX (HF and MOF) scores with and without BMD were associated with falls in men and women aged 40 and over. M. Runge et al., in their study concluded that considering the interrelationships between muscles, falls and bones, the traditional bone-oriented approach on osteoporosis-related fractures should be supplemented by fall risk assessment, fall management and treatment of muscle function. They specified that the strong correlation between falls and fractures requires the inclusion of a fall risk assessment and a fall prevention program in the management of osteoporosis in contrast to the traditional approach that mainly concentrated on bone strength alone.

Najafi D. et al., showed the association between clinical balance measures and FRAX and explained the use of combining the clinical balance measures and FRAX for the identification of individuals with high risk of falls and thereby fractures which helps healthcare providers in optimizing treatment and prevention of fall-related fractures. Perry SA and Downey PA emphasized the use of FRAX, as a new and simple tool to reinforce a holistic approach to fracture risk. They suggested that combining FRAX data with fall risk measures assists with screening, reimbursement, and intervention plans for adults who are referred for physical therapy.
The results of this study have potential clinical relevance. The physical therapist can use BBS and LEFS to obtain vital information about balance and lower limb functional ability respectively and if the score is less in these scales, the therapist can use the FRAX to estimate the 10-year probability of risk of fracture (HF and MOF) among middle and elderly aged population. The deficit in balance and functional score and the higher values in FRAX may help the therapist in identifying the population at risk of falls and fractures which plays a very important role while prescribing the exercise protocol. Also, the correlation suggests that recovery in balance would also improve the functional status and minimize the risk of fall-related fracture, which is a potential goal for rehabilitation interventions especially in post-menopausal women and in the elderly population. Studies to recognize the effect of balance training and strengthening exercises in older people can be carried out.

The large sample size, with no missing data is one of the strong points of this study. The bone mineral density was not added for the calculation of FRAX; However studies have shown that the clinical FRAX score alone can accurately predict the risk of osteoporotic fracture.\(^{[29]}\)

In addition, though there are multiple risk factors associated with falls, in this study the correlation between fall risk and fracture risk was done considering only the balance and functional status of the participants. Moreover, though this correlation study showed the mere relationship between variables, the cause and effect relationship is yet to be documented.

In conclusion, this study showed a significant moderate to strong correlation of fall risk, fracture risk and function in the middle-aged and elderly population of Gujarat. The lower balance and functional scores were related to increased risk of falls and the probability of fractures and there was a strong positive relationship between balance and the functional status. Hence, the use of balance and functional scores, along with the probability of fracture risk, can improve the identification of individuals with risk of falls and fractures which would assist physical therapist and other healthcare professional to set the goals of rehabilitation and to design early and specific intervention program for the prevention of falls and fractures.

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