Original Article

Comparison of Trabecular Bone Score-Adjusted FRAX™ and FRAX™-Bone Mineral Density in Postmenopausal Women with Clinical Vertebral Fractures: A Cross-Sectional, Analytic Study

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Background: Ethnicity differentially modulate fracture risk prediction using FRAX™-bone mineral density (BMD).

Objective: To compare FRAX™-BMD and trabecular bone score (TBS)-adjusted FRAX™ in the 10-year probability of fracture among Thai postmenopausal woman (PMW) with vertebral fracture (VF).

Materials and Methods: The present study was a cross-sectional study conducted by retrospective review of medical records of PMW with VF older than 45 years undergoing lumbar and hip DXA scan. The authors excluded the PMW having been treated with metal implant at the spine, 3 or more lumbar VF, or cancer spreading to vertebral spine. The authors assessed the difference in means of normally distributed data by dependent sample t-test, the correlation between TBS and LS BMD by Pearson correlation, and the difference in proportions of PMW who met intervention threshold (IT) before and after TBS-adjusted FRAX™ by McNemar's test. A $p<0.05$ was considered statistically significant.

Results: Of the 119 patients, the mean age was 70.8±8.1 years. The mean 10-year probability of a hip fracture by TBS-adjusted FRAX™ was significantly higher than that by FRAX™-BMD with the mean difference of 0.44% (95% CI 0.13 to 0.76). The higher difference in means, using TBS-adjusted FRAX™, was even significantly greater in the 10-year probability of major osteoporotic fractures. For either the IT of major osteoporotic fracture or hip fracture, TBS-adjusted FRAX™ resulted in four added PMWs who needed treatment, but without statistical significance.

Conclusion: TBS-adjusted FRAX™ had a higher 10-year probability of fracture than FRAX™-BMD.

Keywords: Trabecular bone score; FRAX™; Bone mineral density; Postmenopausal women; Osteoporosis

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Fractures attributable to osteoporosis have been increasingly common in women after age 55 years. This condition leads to significant morbidities, and increased mortality and health-care costs[1]. The decrease in estrogen in the postmenopausal women (PMW), resulting in faster bone resorption than the premenopausal women is recognized as a main cause of osteoporosis. The Fracture Risk Assessment Tool (FRAX™) is a worldwide risk assessment tool to identify those at high risk for osteoporotic fractures by calculating the 10-year probability of a hip fracture (HF) and the 10-year probability of major osteoporotic fracture (MOF) based on clinical and personal characteristics as well as bone mineral density (BMD) at the femoral neck[2]. In the last decade, several studies have found that FRAX™ underestimates risk of osteoporotic fractures. Bone strength depends not only on BMD, but also on factors other than BMD, so-called bone quality[3]. Therefore, to improve prediction of the 10-year probability of a HF and the 10-year probability of MOF, additional bone quality-related markers are needed to be incorporated with FRAX™. Trabecular bone score (TBS), a marker of bone quality, is a gray-level textural index of bone microarchitecture derived from lumbar spine dual-energy X-ray absorptiometry (DXA) images[4-7]. Several case-control and cross-sectional studies have shown that TBS is associated with osteoporotic fractures independently of lumbar

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spine BMD measurements in PMW[8-13]. Prospective studies have also shown that TBS predicts fracture in PMW[14-17]. According to the 2019 International Society for Clinical Densitometry (ISCD) Official Positions, TBS can be used in association with FRAX™ and BMD to adjust FRAX™-probability of fracture in PMW[18]. In Asia, many studies have been conducted with regard to the value of TBS for calculating the 10-year probability of HF or MOF in various conditions[16,19-21]; however, there was no such study being conducted in Thailand. As differing in ethnicity differentially modulates fracture risk prediction by using TBS[22], it is thus important to examine if TBS-adjusted FRAX™ would provide advantage in fracture risk prediction in Thai PMW.

The aim of the present study was to compare the 10-year probability of MOF between the use of FRAX™-BMD and TBS-adjusted FRAX™ among PMW who had vertebral fractures and to evaluate the association between lumbar spine BMD and TBS.

Materials and Methods

Study participants and design

The present study was a cross-sectional study conducted at Srinagarind Hospital, a tertiary care, university hospital, in Khon Kaen, Thailand between November 2019 and February 2020. The authors retrospectively reviewed medical records of PMW who met the following criteria 1) age 45 years old or more, 2) clinical and radiographic evidence of vertebral fracture from low-energy trauma history, and 3) undergoing lumbar and hip DXA. The authors excluded any PMW who had one of these conditions 1) treatment with a metal implant at the vertebral area, 2) cancer spreading to the vertebral spine, or 3) three or more lumbar spine fractures. One hundred nineteen PMW with clinical spine fracture were included. The sample size calculation was based on the equation to test the difference in mean of the 10-year probability of MOF between the use of TBS-adjusted FRAX™ and the use of FRAX™-BMD of at least 2.33[20] with alpha error of 0.05 and beta error of 0.2. The study protocol was approved by the Institutional Review Board of the Khon Kaen University Ethics Committee in Human Research (HE621454).

Bone mineral density

BMDs at the lumbar spine, femoral neck, and the total hip areas were measured by DXA by certified radiological technologists using any of the two DXA scanners, GE Healthcare Lunar Prodigy or Discovery A, Hologic, and following the manufacturer's protocol. The entire lumbar spine was scanned in the posteroanterior projection, and BMD at the lumbar spine was calculated for the first to fourth vertebrae using densitometric software (version 14.1, Lunar Prodigy, Inc., or software version 3.3.0.1, Hologic, Inc.). In accordance with the ISCD rules for excluding individual vertebrae, neither were vertebrae with fractures nor degenerative changes causing BMD more than one standard deviation (SD) greater or lower compared with the immediately adjacent vertebrae included for lumbar spine BMD calculation. Least significant change of lumbar spine BMD was 0.034 g/cm².

TBS calculations

Lumbar spine TBS was calculated at the same regions of interest used for BMD measurements using TBS iNsight software (version 2.2.0.1, Med-Imaps, Bordeaux, France). Lumbar spine TBS was calculated as the mean value of the individual measurements for vertebrae L1-L4 vertebrae. The authors also performed analyses after excluding the TBS values for the corresponding vertebrae excluded in the BMD analyses. Least significant change of L-spine BMD was 0.055.

Operational definitions

The authors classified PMW with clinical vertebral fracture to be normal, osteopenia, or osteoporosis according to BMD measurement at the lumbar spine.

Osteoporosis: Osteoporosis was defined as a BMD that lies 2.5 SDs or more below the average value for young healthy women or a T-score of less than –2.5 SD, using the Thai nationwide reference database. The corresponding absolute values were 0.569 g/cm² or less and 0.682 g/cm² or less for the femoral neck and lumbar spine (L1-L4), respectively[23].

Osteopenia: Osteopenia was defined as a BMD lies between –1 to –2.5 SDs of average value for young healthy women or a T score –1 to –2.5 SD. The corresponding absolute values were 0.570 to 0.715 g/cm² and 0.683 to 0.846 g/cm² for femoral neck and lumbar spines (L1-L4), respectively[23].

Trabecular bone score: The included PMW would be categorized into three groups according to their TBS values, which are degraded at less than 1.230, partially degraded between 1.230 and 1.310, and normal at greater than 1.310[24].

Intervention threshold: Intervention threshold (IT) was defined as the fracture probability, determined by FRAX™-BMD either with or without taking TBS into

account, at which to recommend treatment. In this research, a MOF probability of greater than or equal to 20% and a HF probability of greater than or equal to 3% were set as IT.

Statistical analysis

Statistical analysis was performed using Stata, version 10.1 (StataCorp LP, College Station, TX, USA). The data were presented as mean ± SD, or as percentages. The normality of the distribution was tested using the Shapiro-Wilk normality test. For comparing normal distribution data of the 10-year probability of MOF and the 10 year-probability of HF between the use of various FRAX™, the dependent sample t-test was used. The authors assessed the association between TBS and lumbar spine by BMD were investigated by Pearson correlation. A comparison of the proportion of patients needing therapeutic intervention before and after TBS adjustment of FRAX™ was performed using McNemar's test. Multivariate linear regression analysis was performed to explore associated variables for TBS. The potential variables included in the present study model were age, year since menopause, height, weight, body mass index (BMI), BMD and other clinical risk factors in FRAX™. A value of p-value less than 0.05 was set as a significance criterion.

Results

One hundred nineteen PMW with clinical vertebral fractures were included. The baseline demographic and densitometric characteristics are shown in Table 1.

The mean age (±SD) of the included PMW was 70.8±0.9 years. The means (±SDs) of TBS, lumbar spine BMD, and femoral neck BMD were 1.23±0.11, 0.83±0.18, and 0.67±0.12, respectively. Table 2 shows the distribution of TBS status and BMD of the included PMW. Of note, among 47 PMW with normal BMD, the degraded, partially degraded, and normal TBS were identified in 19 (40.4%), 14 (29.8%), and 14 (29.8%) women, respectively. In the osteopenic group, the proportion of TBS status was comparable to that in the normal BMD group. On the other hand, normal TBS scores were less observed in the osteoporotic group compared to the osteopenic and the normal BMD group (Table 2).

Table 3 shows the means of hip FRAX™-BMD with or without taking TBS into account were higher than 3% 10-year probability of a HF, which is the IT; while all means of MOF FRAX™ were below 20% 10-year probability of MOF, which is the IT. The mean 10-year probability of a HF by using TBS-adjusted FRAX™ was significantly higher than that by FRAX™-BMD with the mean difference of 0.44% (95% CI 0.13 to 0.76). The higher mean differences were even greater in the 10-year probability of MOF. For the IT of HF and MOF, using TBS-adjusted FRAX™ resulted in a non-significant increase in PMW who met IT, compared to FRAX™-BMD. It is of interest that the number of PMW who had a 10-year probability of MOF of more than 20% was the highest by using FRAX™, with statistical significance. The result for 10-year probability of HF of more than 3% was also similar but without statistical significance.

The associations between lumbar spine BMD and TBS values are shown in Figure 1. Pearson correlation coefficient showed a significantly strong positive association between lumbar spine BMD and TBS only in the osteoporosis BMD group (r=0.590,

Table 1. Baseline demographic and densitometric characteristics of participants

Variable	n=119; mean±SD
Age (years)	70.8±8.1
Menopausal age (years)	49.6±4.1
BMI (kg/m^2)	23.8±3.8
Smoker; n (%)	1 (0.8)
Glucocorticoid use; n (%)	3 (2.5)
Rheumatoid arthritis; n (%)	2 (1.7)
Secondary osteoporosis; n (%)	9 (7.6)
High alcohol intake; n (%)	1 (0.8)
Parental hip fracture; n (%)	2 (1.7)
Previous fracture; n (%)	119 (100)
L-spine BMD (g/cm^2)	0.83±0.18
Femoral neck BMD (g/cm^2)	0.67±0.12
TBS	1.23±0.11

BMI=body mass index; TBS=trabecular bone score; BMD=bone mineral density; SD=standard deviation

Table 2. Distribution of TBS status according to BMD status of the PMW

BMD status	TBS status; n (%)			Total; n (%)
	Degraded	Partially degraded	Normal	
Normal	19 (40.4)	14 (29.8)	14 (29.8)	47 (39.5)
Osteopenia	21 (44.7)	15 (31.9)	11 (23.4)	47 (39.5)
Osteoporosis	14 (56.0)	9 (36.0)	2 (8.0)	25 (21.0)
Total	54 (45.3)	38 (32.0)	27 (22.7)	119 (100)

TBS=trabecular bone score; BMD=bone mineral density

Table 3. The 10-year probability of MOF, the 10-year probability of hip fracture, the number of PMW with 10-year probability of greater than or equal to IT by FRAX-BMD™ and TBS-adjusted FRAX™

	Mean±SD or MD (95% CI)	Number of PMW with FRAX™ ≥IT (%) or case difference/100 PMW (95% CI)
10-year probability of MOF		
FRAX™-BMD	14.07±6.07	19 (15.9)
TBS-adjusted FRAX™	15.01±6.44	23 (19.3)
TBS-adjusted FRAX™ vs. FRAX™-BMD	0.94 (0.56 to 1.31)	3.36 (–2.10 to 8.82)
10-year probability of hip fracture		
FRAX™-BMD	5.83±4.90	84 (62.2)
TBS-adjusted FRAX™	6.27±5.75	88 (73.9)
TBS-adjusted FRAX™ vs. FRAX™-BMD	0.44 (0.13 to 0.76)	3.36 (–2.10 to 8.82)

BMD=bone mineral density; MD=mean difference; MOF=major osteoporotic fracture; PMW=postmenopausal women; TBS=trabecular bone score; CI=confidence interval

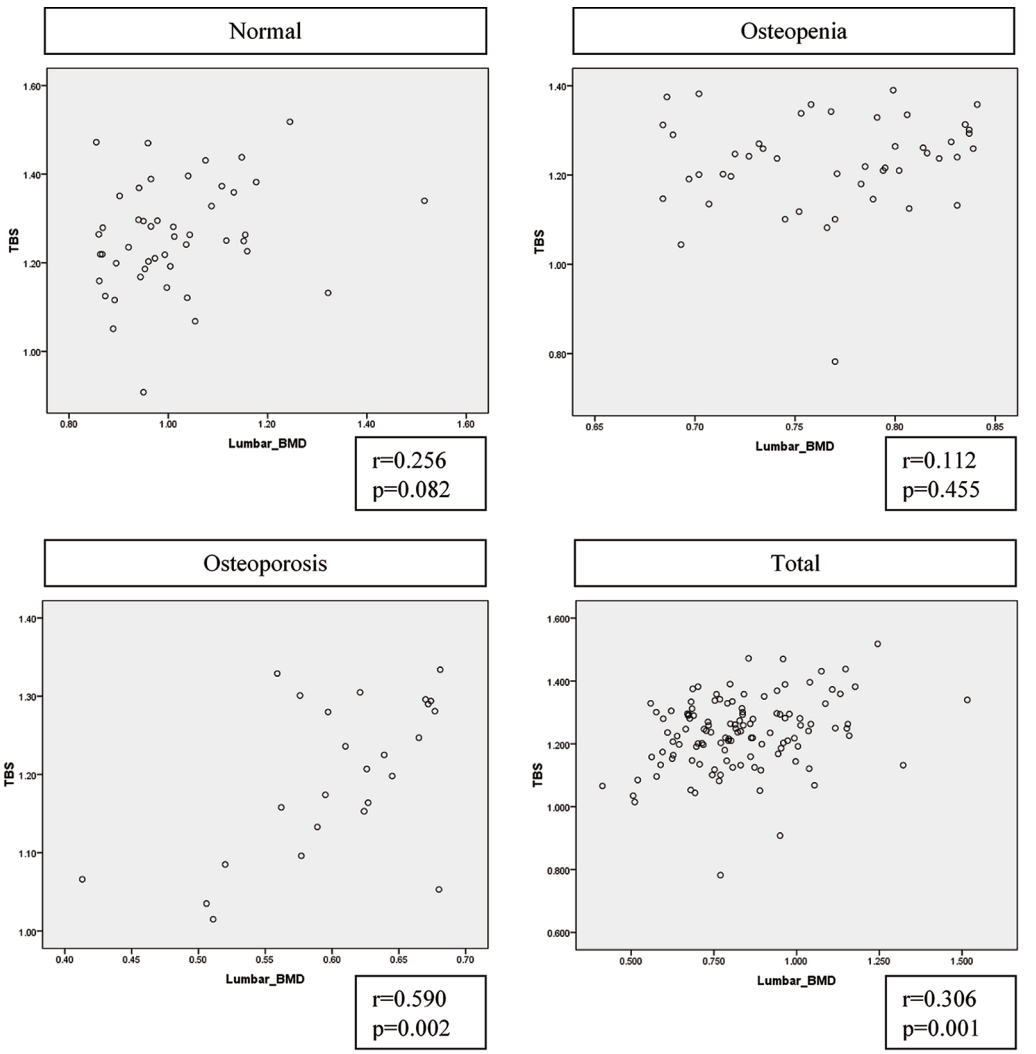

Figure 1. Scatter plots of correlation between TBS and LS BMD according to WHO classification.

TBS=trabecular bone score; BMD=bone mineral density.

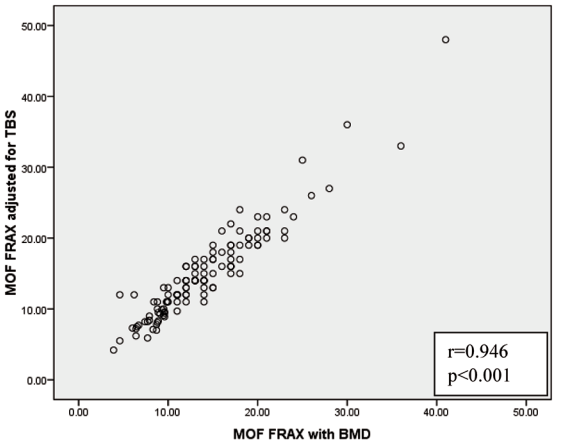

Figure 2. Scatter plots of correlation between MOF FRAX™ with BMD and MOF FRAX™ adjusted for TBS.

TBS=trabecular bone score; BMD=bone mineral density; MOF=major osteoporotic fracture

p-value=0.002), but neither normal BMD group nor osteopenia BMD group.

A significantly robust association between FRAX™-BMD and TBS-adjusted FRAX™ for prediction of MOF (r=0.95, p=0.000) is shown in Figure 2. By multiple linear regression, no potential variables, including age, year since menopause, height, weight, BMI, BMD, and other clinical risk factors in FRAX™, was associated with TBS.

Discussion

The main results of the present study showed that by using TBS-adjusted FRAX™, the means of 10-year probability of a HF and the 10-year probability of any MOF were significantly higher than those derived by FRAX™-BMD. When comparing to FRAX™-BMD, four additional PMW would have a 10-year probability of MOF and HF of higher than IT by using TBS-adjusted FRAX™. However, the extra four PMW did not achieve statistically significant difference. A cross-sectional study in 358 postmenopausal Iranian women showed a trend for better fracture prediction by using TBS-adjusted FRAX™ but the difference was not significant (p=0.19)[25]. In line with the present study result, the proportion of patients who needed therapeutic intervention did not significantly change after FRAX™ adjustment on TBS[25]. In Asia, results from the Japanese Population-Based Osteoporosis (JPOS) Cohort study also suggests that TBS improved the predictive ability of both areal BMD (aBMD) alone and that for aBMD and other clinical risk factors combined[16]. Results from several reports, including a systematic review[24], were in line with the present study. In 2016, a meta-analysis that utilized individual-level data from 17,809 participants in 14 prospective population-based cohorts, found that the adjustment of FRAX™ probability on TBS resulted in a small increase in the gradient of risk (GR) with 1.76 (95% CI 1.65 to 1.87) versus 1.70 (95% CI 1.60 to 1.81)(24). A smaller change in GR for HF was also observed (FRAX™ HF probability GR 2.25 versus 2.22)[24]. A narrative review of several trials also confirmed this[26]. Taken together, the use of TBS-adjusted FRAX™ can change management in a modest number of patients, particularly in those close to an IT.

BMD is a major index in assessing bone strength and predicting the risks of HF or MOF[27,28]. The present study findings addressed the insufficient predictive value of lumbar spine BMD, given that only 21.0% PMW with clinical spine fracture had osteoporosis. Of note, almost half of PMW with clinical spine fracture in the present study had a degraded TBS despite normal BMD. These are not surprising as cumulative evidence has consistently indicated a low sensitivity of BMD when used alone as a screening test for a high-risk case of fragility fracture[27,29-31]. Results from several cross-sectional studies have consistently supported that the discriminating value of TBS is likely to be as good as, or better than, that of BMD[13,32,33]. A prospective study in 929 women aged 50 years or older with an incidence vertebral fractures of 9.9% also found that TBS value lower by one SD was significantly associated with vertebral fracture risk but only in the osteopenia or normal BMD group[34]. The present study demonstrated a significantly strong positive association between lumbar spine BMD and TBS only in the osteoporosis BMD group. Rajaei et al conducted a cross-sectional study in Iran and reported a strong correlation between TBS and lumbar spine BMD (r=0.5, p<0.001)[35]. In the normal or the osteopenia BMD group, modest association between lumbar spine BMD and TBS was found in other studies[26,36,37]. As a result, this evidence should emphasize to clinicians that, although the patients had normal BMD, spinal fractures could occur if degraded TBS was present. A robust positive correlation between FRAX™-BMD and TBS-adjusted FRAX™ in predicting osteoporotic fracture risks found in the present study is also in agreement with the result in a previous study among PMW[25].

As a rather point of interest in the field of FRAX™, in the present study, around 70% of vertebral fractured PMW had FRAX™-BMD and TBS-adjusted FRAX™ for 10-year probability of HF of

more than 3%, which is generally considered as a cut-off point for pharmacological prevention of fragility fracture. Therefore, this underlines the importance of prevalent vertebral fracture as an indication for pharmaceutical intervention regardless of whether the 10-year probability of osteoporotic fracture retrieving from FRAX™, otherwise around 30% of PMW would not receive pharmaceutical intervention. The most recent prospective study has confirmed the predictive value of prevalent vertebral fracture on the risk of subsequent osteoporotic fracture[38]. Compared to no prevalent vertebral fracture, those with definite prevalent vertebral fracture had higher hazard ratios for incident hip (HR 1.95, 95% CI 1.45 to 2.62), non-vertebral (HR 1.99, 95% CI 1.68 to 2.35), and clinical vertebral fracture (HR 2.68, 95% CI 1.69 to 4.23) adjusted for age, BMD, BMI, prior fracture, parental HF, glucocorticoid use, alcohol use, smoking, and rheumatoid arthritis[38]. These associations did not vary by FRAX™ fracture risk estimates or BMD category[38].

The authors could not identify factors associated with TBS. It is likely to be from a limited number of the included PMW. This limitation might also explain the non-significant difference in the number of PMW with 10-year probability of greater than or equal to IT between the use of FRAX™-BMD compared to the use of TBS-adjusted FRAX™ In a review, the authors found variations in TBS due to gender and ethnicity, but much less than for lumbar spine BMD[26]. BMI and body composition also influence TBS; however, the updated version of the TBS algorithm (since v 2.1) lessen the effects of these variables[26].

The mean difference of the 10-year probability of MOF obtaining in the present study was less than the value used for sample size calculation might be explained by the differing in ethnicity. Although accurate predictions cannot be guaranteed by cross-sectional study, the similar results of the present study with others suggest the importance of taking TBS into consideration alongside not only FRAX™-BMD but also the World Health Organization (WHO) BMD classification for preventive management of fragility fracture. According to the Thai clinical practice guideline as spinal fracture is an indication for pharmaceutical therapy, all the included PMW should receive pharmaceutical treatment[39]. If clinical fracture is not an indication for treatment, TBS-adjusted FRAX™ would still enhance the chance for PMW to get treatment. The authors selected to include PMW with clinical spinal fracture for study because they had a very high risk of subsequent fracture. However, it is likely to be a limitation on generalizability of the present study due to the inclusion of PMW with vertebral fracture. A prospective study conducting in non-vertebral fracture Thai PMW or Asian PMW with adequate follow-up duration is valuable for assessment of various tools, FRAX™, FRAX™-BMD, TBS-adjusted FRAX™, for fracture prediction. Moreover, a well-designed cohort study to find out the appropriate approach of IT for Thai PMW, whether it should be fixed, age-dependent or hybrid, would convey a great advantage in preventive management of fragility fracture.

In conclusion, TBS-adjusted FRAX™ had a higher 10-year probability of fracture than FRAX™-BMD in Thai PMW with clinical spine fracture. However, the increased number of PMW who met IT was not statistically significant. From a clinical perspective, the greatest utility of TBS-adjusted FRAX™ is for those individuals who lie close to IT.

What is already known on this topic?

According to the 2019 ISCD Official Positions, TBS can be used in association with FRAX™ and BMD to adjust FRAX™-probability of fracture in PMW. However, the value of TBS for calculating the 10-year probability of HF or MOF was not evaluated in Thai PMW.

What this study adds?

In Thai PMW, TBS-adjusted FRAX™ had a higher 10-year probability of fracture than FRAX™-BMD. From a clinical perspective, the greatest utility of TBS-adjusted FRAX™ might be for those individuals who lie close to IT.

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Conflicts of interest

The authors declare no conflict of interest.

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