The Added Value of Trabecular Bone Score in Fracture Risk Assessment of Kidney Transplant Recipients

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Introduction. Trabecular Bone Score (TBS) is an index of bone microarchitecture independent of Bone Mineral Density (BMD). Recently, TBS data has been used to optimize the predictive value of the Fracture Risk Assessment Tool (FRAX). The aim of this study was to evaluate the clinical value of FRAX adjustment with TBS in kidney transplant recipients.
Methods. Seventy post-transplant Iranian kidney recipients were included in this study. After the evaluation of BMD and TBS, the risk of major osteoporotic fracture (MOF) and hip fracture (HF) was assessed once with and once without TBS adjustment. The proportion of patients who needed a therapeutic intervention was compared before and after TBS adjustment. The association between TBS and BMD data was also evaluated.
Results. The mean age of the patients was 54 ± 8.8 years (range: 40 to 77). The mean TBS of the patients was 1.30 ± 0.12. In multivariate analysis, the TBS was significantly associated with the age ($P < .05$) and dialysis period ($P < .05$). A strong correlation was found between the spine BMD and TBS data ($r = 0.612$, $P < .001$). A significant correlation was found between the MOF and HF of the patients before and after adjustment for TBS. The proportion of patients needed a therapeutic intervention significantly increased from 17.1% to 25.7% after TBS adjustment of FRAX.
Conclusion. Adjustment of FRAX with TBS will reclassify the treatment decision in a considerable number of kidney transplant recipients. This clinical value warrants the adjustment of FRAX data with TBS in future workouts.

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INTRODUCTION

Osteoporosis is a major public health problem and a leading cause of fragility fracture.[1] Kidney transplant recipients are at increased risk of osteoporosis as well as fragility fracture.[2] It has been revealed that bone mineral density (BMD) declines by 4% to 10% in the first six months after transplantation by several mechanisms such as immunosuppression, alterations in the parathyroid hormone, changes in mineral metabolism, and glucocorticoid administration post-transplant.[3] This bone loss contributes to an increased risk of fragility fractures so that nearly 22.5% of kidney transplant recipients experience a fracture in the first five years after transplantation, an incidence that is four times greater than in the general population.[4] Considering the severe mortality and morbidity of fragility fracture and its remarkable

health and economic impact, the development of new diagnostic techniques for the prevention of osteoporotic fragility fractures is of significant importance.[5]

In the general population, low BMD strongly reflects the presence of osteoporosis and the risk of fragility fracture. However, conflicting results are reported in the kidney transplant recipients as BMD may be falsely elevated in these patients due to aortic calcification, particularly in long-term dialysis patients.[6-8] Accordingly, the bone quality may also be adversely affected besides bone density, and if not considered, the fracture risk of kidney transplant recipients might be underestimated.[9]

Although bone biopsy provides adequate information about bone quality, it is an invasive test and not suitable for routine workouts.[10] Thus, more practical approaches are needed for the evaluation of bone quality in kidney transplant recipients.

Trabecular bone score (TBS) is a novel, noninvasive measure of bone quality derived from lumbar spine dual-energy X-ray absorptiometry (DXA) images. It is a texture measurement that quantifies local variations in gray level distribution from the DXA image and is significantly correlated with 3-dimensional parameters of bone microarchitecture, independently of BMD. In this regard, a higher TBS value is indicative of better bone structure, vice versa.[11-5] Hence, attempts are being made to include TBS data in the fracture risk assessment.

Fracture risk assessment tool (FRAX) is a supportive software in osteoporosis management that provides a 10-year percentage of the risk of hip fracture (HF) and major osteoporotic fracture (MOF). Before the introduction of TBS, the FRAX assessment was based on the BMD information. Recently, FRAX data are adjustable with TBS information, providing a fracture risk assessment based on a combination of TBS and BMD.

The main goal of this study was to assess the association between BMD and TBS data in Iranian kidney transplant population as well as to evaluate the added value of TBS-adjusted FRAX in the reclassification of treatment threshold in these patients.

MATERIALS AND METHODS

This study was approved by the review board of our institute under the code of 9511402001, and written informed consent was obtained from the patients before their participation in the research. In a cross-sectional study, Iranian kidney transplant recipients were recruited from the nephrology clinic of Shahid Hashemi Nejad nephrology Hospital, Tehran, Iran. The patients were referred to the densitometry department for BMD and TBS examination providing that they were identified as eligible for the study. Inclusion criteria were the age of more than 40 years, at least six months past the date of transplantation, and a glomerular filtration rate (GFR) of more than 30 mL/min. Exclusion criteria included the patients undergoing osteoporosis treatment within the past two years, a history of Cushing's syndrome, malabsorption syndrome, liver failure, or any chronic disorders affecting the mineral metabolism. Since TBS can solely be computed for patients with a Body Mass Index (BMI) ranging from 15 to 37 kg/m^2, patients with a BMI of less than 15 or higher than 37 were also excluded.

BMD of the spine (L1 to L4) and femoral neck were assessed by a DXA machine (Hologic Horizon WI). The region with the lowest T-score was used for the evaluation of osteoporosis. According, the patients were categorized into osteoporotic (T-score < -2.5), osteopenic (-1 < T-score < -2.5), and normal (T-score > -1).

TBS measurement was performed at the same time with BMD evaluation using TBS software version 3.0.2.0, which determines the variogram of the trabecular bone projected image concerning the sum of the squared gray level differences between pixels at a specific distance and angle.[16] TBS results were considered degraded if < 1.2, partially degraded if 1.2 to 1.35, and normal if > 1.35.

MOF and HF risks were calculated using the FRAX calculator defined for the Iranian population. According to the guideline of the National Osteoporosis Foundation, cutoff values of 20% and 3% were considered as high absolute ten years risk of fracture for MOF and HF risk, respectively.[17] The FRAX calculation was done once without TBS adjustment and once with TBS adjustment (TBS-adjusted FRAX).

Statistical Analysis

SPSS version 16 was used for the statistical analysis of the data. Paired data were compared

using a paired t-test or its nonparametric counterpart (Kruskal-Wallis Test). A comparison of the mean value of two independent groups was made using an independent t-test or its nonparametric equivalent (Mann–Whitney U test). A multiple linear regression analysis was used to evaluate the association of TBS value with independent variables. A chi-square test was used for the evaluation of the difference between categorical variables. Pearson's correlation coefficient test was used for the evaluation of potential correlations. The proportion of patients needing a therapeutic intervention before and after TBS adjustment was compared using a McNemar's test. A *P* value of fewer than .05 was considered as statistically significant.

RESULTS

A total of 70 kidney transplant recipients were identified as eligible for the study. The patient's population included 30 (42.9%) females and 40 (57.1%) males with the mean age of 54 ± 8.8 years (range: 40 to 77 years). The mean glomerular filtration rate (GFR) of the patients was 66.3 ± 21.7 mL/min (range: 30 to 112.1 mL/min). The mean dialysis period before transplantation was 26.9 ± 31.2 months (range: 0 to 204 months). The mean time passed the transplantation date was 5.1 ± 5.7 years (range: 0.5 to 31 years). The mean parathyroid hormone (PTH) of the patients was 75.8 ± 63.2 pg/mL (range: 13.5 to 356 pg/mL). The mean serum vitamin D level was 20.1 ± 13.1 ng/mL (range: 3 to 75 ng/mL). In 44 (62.8%) patients, the kidney was transplanted from a living donor, while in 26 (37.2%) cases; it was transplanted from a deceased donor. Based on the routine protocol of our center, all the patients were under prednisolone, mycophenolate mofetil, and CN inhibitor medications. Eleven (15.7%) patients also were receiving mTOR inhibitors. None of the patients were receiving osteoporosis treatment. The clinical and demographic characteristics of the patients are demonstrated in more detail in Table 1.

The mean femoral neck and spine T-score of the patients were -1.49 ± 1.09 and -1.56 ± 1.3, respectively. According to the results of BMD evaluation, 19 (27.1%) patients were identified as osteoporotic, 36 (51.4%) patients were characterized as osteopenic, and 15 (21.4%) patients were normal. The mean TBS of the patients was 1.296 ± 0.123 (range: 0.93 to 1.56). Based on the TBS results, degraded, partially degraded, and normal bone quality was identified in 15 (21.4%), 24 (34.3%), and 31 (44.3%) patients, respectively. The densitometric data of the patients are demonstrated in Table 2.

In bivariate analysis, the mean TBS was significantly different in two dialysis groups (≤ 12 months and > 12 months dialysis; $P < .05$).

Table 1. The Demographic, Clinical, and Laboratory Data of Kidney Transplant Patients

Variables	Mean ± SD Number (%)
Age, year	54 ± 8.8
Gender	
Male	40 (57.1)
Female	30 (42.9)
Body Mass Index, k/m^2	25.7 ± 3
Etiology of ESKD	
Unknown	25 (35.7)
Glomerulonephritis	14 (20)
Type 2 Diabetes	13 (18.5)
ADPKD	9 (12.8)
Infection	3 (4.2)
Hypertension	2 (2.8)
Reflux Nephropathy	1 (1.4)
Urate Nephropathy	1 (1.4)
mTOR Inhibitors Medication	
Yes	11 (15.7)
No	59 (84.3)
Glomerular Filtration Rate, mL/min	66.3 ± 21.7
Pre-transplant Dialysis Period, mo	26.9 ± 31.2
Time Past the Transplant, year	5.1 ± 5.7
Time Past the Transplant	
≤ 5	49 (70)
> 5	21 (30)
Donor	
Living	44 (62.8%)
Deceased	26 (37.2%)
Parathyroid Hormone, pg/mL	75.8 ± 63.2
Serum Vitamin D, ng/mL	20.1 ± 13.1

ESKD, end-stage kidney disease; ADPKD, autosomal dominant polycystic kidney disease.

Table 2. The Densitometric Characteristics of the Kidney Transplant Patients

Variables	Mean ± SD
Femoral Neck BMD, g/cm^2	0.71 ± 0.14
Femoral Neck T-score	-1.49 ± 1.09
L1-L4 Spinal BMD, g/cm^2)	0.90 ± 0.15
L1-L4 Spinal T-score	-1.56 ± 1.3
TBS	1.30 ± 0.12
BMD-based MOF	6.03 ± 4.06
BMD-based HF	2.05 ± 2.89
TBS-adjusted MOF	6.98 ± 7.73
TBS-adjusted HF	2.53 ± 4.32

MOF, major osteoporotic fracture; HF, Hip fracture.

Besides, the mean TBS was significantly lower in diabetic patients compared with non-diabetic patients ($P < .05$). However, the mean TBS was not significantly different in two GFR groups (30 to 60 mL/min and > 60 mL/min, $P > .05$). In addition, the mean TBS was not significantly different between patients who had been transplanted for more than five years and those who had been transplanted for less than five years ($P > .05$). Also, the mean TBS was not significantly different in patients who received mTOR inhibitors and those who did not ($P > .05$). A significant negative correlation was also found between the age and TBS of the patients (r = -0.381, $P < .05$).

In multivariate analysis, TBS was still significantly associated with the age ($P < .05$, 95% CI: -0.008 to -0.001) and dialysis period ($P < .05$, 95% CI: -114 to -0.005) but not with the GFR ($P > .05$) and diabetic status ($P > .05$).

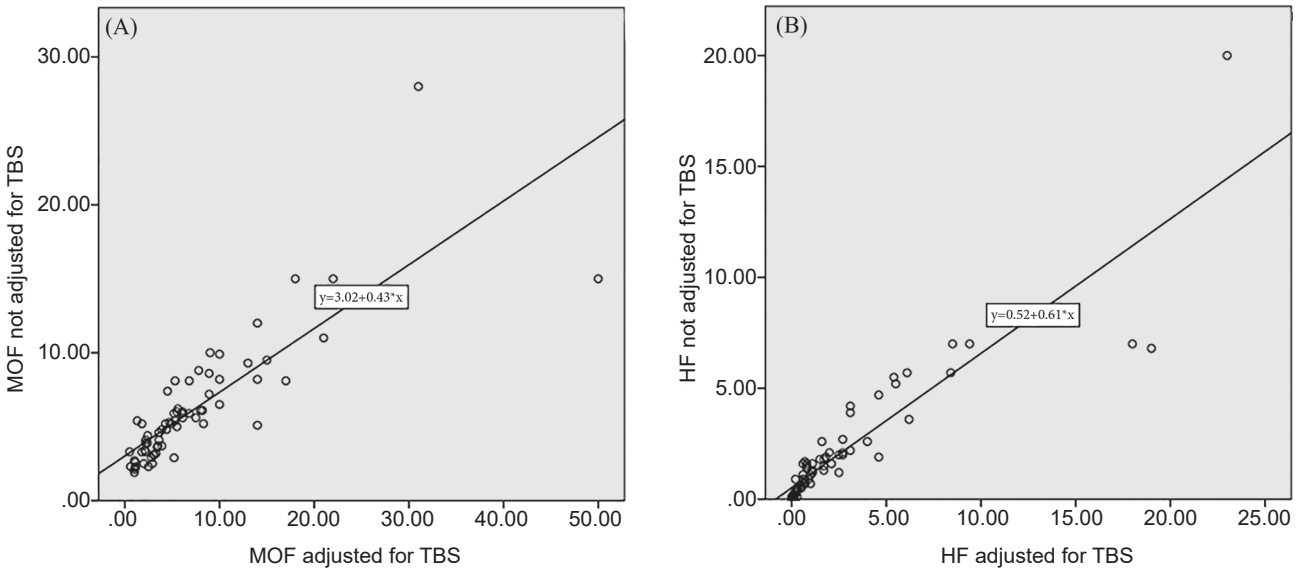
A significant correlation was found between the femoral neck BMD and TBS (r = 0.38, $P < .05$) as well as spine BMD and TBS (r = 0.61, $P < .001$). Moreover, a significant association was found between the BMD status (osteoporotic, osteopenic, and normal) and TBS status (degraded, partially degraded, and normal) of the patients ($P < .001$). In this respect, almost half of patients with an osteoporotic BMD had a degraded TBS, while the majority of patients with a normal BMD also had a normal TBS (Table 3).

The mean MOF of the patients was 6.03 ± 4.06 before the adjustment with TBS and 6.98 ± 7.73 after the adjustment with TBS. This difference was not statistically significant ($P > .05$). A significant positive correlation was found between the MOF of the patients before and after adjustment with TBS (r = 0.82, $P < .001$; Figure A).

The mean HF of the patients was 2.05 ± 2.89 before the adjustment with TBS and 2.53 ± 4.32 after the adjustment with TBS. This difference was not statistically significant, as well ($P > .05$). A significant positive correlation was also found between the HF of the patients before and after adjustment with TBS (r = 0.90, $P < .001$, Figure B).

Table 3. The Association Between BMD and TBS Status of the Kidney Transplant Patients

BMD Status	TBS Status			Total	*P*
	Degraded	Partially Degraded	Normal		
Osteoporosis	9 (47.4)	9 (47.4)	1 (5.3)	19 (27.1)	< .001
Osteopenia	5 (13.9)	14 (38.9)	17 (47.2)	36 (51.4)	
Normal	1 (6.7)	1 (6.7)	13 (86.7)	15 (21.4)	
Total	15 (21.4)	24 (34.3)	31 (44.3)	70 (100)	



It shows scatter plots showing the strong correlation of major osteoporotic fracture (A) and hip fracture risk (B) of the kidney transplant patients before and after adjustment with TBS.

Before TBS adjustment, MOF risk of only one patient passed the treatment threshold (> 20%). After TBS adjustment, the MOF of three other patients passed the treatment threshold. Before the TBS adjustment, HF of 11 patients was above the treatment threshold (> 3%). After TBS adjustment, The HF of three additional patients passed the treatment threshold. These patients were not the same patients who their MOF was reclassified after TBS adjustment. Overall, before the TBS adjustment, 12 (17.1%) patients needed a therapeutic intervention, while after TBS adjustment, 18 (25.7%) patients were required therapeutic intervention. This difference was statistically significant ($P < .05$). TBS adjustment did not result in the reduction of fracture risk below the treatment threshold in any patient.

DISCUSSION

In this study, we evaluated the BMD and TBS in a series of Iranian kidney transplant recipients.

The effect of TBS adjustment of FRAX on the MOF and HF of the patients and the treatment strategy was evaluated as well. Based on the result of multivariate analysis, TBS was significantly lower in patients with dialysis history of ≥ 12 months. Besides, TBS was negatively correlated with the age of patients. However, TBS was not associated with the GFR and diabetic status of the patients. A significant positive correlation was also found between the TBS and femoral neck/spine BMD of the patients. The FRAX score of the patients revealed a significantly strong correlation before and after adjustment with TBS as well. Despite this correlation, the treatment decision was reclassified in six patients after TBS adjustment (three patients based on MOF and three patients based on HF). In other words, the FRAX score of these six patients crossed the treatment threshold after TBS adjustment, indicating a pharmacologic osteoporosis treatment.

Naylor *et al.* compared the TBS in the kidney transplant population with the age and sex-matched general population from Manitoba, Canada. Based on their results, TBS was significantly lower in kidney transplant recipients when compared with the general population (1.37 vs. 1.41). Moreover, TBS was associated with a fracture rate independent of BMD.[9] Lower mean TBS was also noticed in kidney transplant recipients of the study of Pasquali *et al.* when compared with age-matched normal control Italian population (1.32 vs. 1.40).[18] Similarly, Bonani *et al.* observed a lower mean TBS in kidney transplant recipients (1.31) in comparison with the published reference value in a normal control Italian population (range: 1.36 to 1.47).[19] We did not find any previous study evaluating the TBS value in either Iranian kidney transplant recipient or the general population. The mean TBS of the patients in the current series was 1.30 that was considerably lower than the TBS of the general population in the study of Naylor *et al.*, as expected. The mean TBS of the present series was also remarkably lower than the TBS of kidney transplant recipients in the earlier investigations.[9,18-9] This difference could be attributed to the different characteristics of patients. According to the results of the present study, factors such as age and dialysis period might affect the TBS of the patients. The negative correlation between age and TBS has been reported in earlier studies.[20,21] Lower TBS level in diabetic patients has been reported in other investigations.[22-3] In the present study, the diabetic status of the patients was significantly associated with TBS in the bivariate analysis but not in multivariate analysis, suggesting that this association could be confounded by other variables. The present study revealed a significant negative association between the dialysis period and TBS in both bivariate and multivariate analyses. By contrast to the present study, the study of Shevroja *et al.* revealed no effect of the pre-transplant dialysis period on post-transplant TBS.[24] Naylor *et al.* evaluated the association between TBS and incident fractures in adults with reduced kidney function. Based on their results, mean TBS was significantly lower in adults with reduced kidney function compared with those with normal kidney function (n: 1.28 vs. 1.30).[24] The TBS was not significantly associated with GFR of the patients in the current series, either in bivariate or in univariate analysis. However, it should be noted that the patients' number was markedly higher in the study of Naylor *et al.*

The value of TBS in the kidney transplant population has been acknowledged in other investigations as well.[25-7] As a new field of interest in osteoporosis, the number of studies on the potential optimizing effect of TBS on the predictive value of FRAX for fracture (MOF and HF) is increasing.

Couraud *et al.* compared the proportion of patients at high fracture risk before and after adjustment with TBS in 413 patients hospitalized for a non-vertebral fracture. Based on their results, the proportion of patients with a risk of MOF ≥ 20% before the fracture was similar before and after TBS adjustment (24.7% vs. 25.4%). The proportion of patients with a risk of MOF above the threshold of the therapeutic intervention was significantly higher after TBS adjustment for the age categories of 60-70years (38.3% vs. 30.9%) and 70 to 80 years (31.2% vs. 26.6%).[28]

Mirzaei *et al.* evaluated the effect of TBS adjustment on the FRAX algorithm in 358 postmenopausal Iranian women. Based on their results, the proportion of the women requiring a therapeutic intervention remained unchanged after FRAX adjustment with TBS. They reported no clinical benefit for FRAX-adjustment with TBS in postmenopausal women.[14]

Tamaki *et al.* aimed to find if TBS improves the predictive ability of FRAX for MOF in the Japanese population-based osteoporosis cohort study. They compared the predictive ability of the FRAX model before and after combination with TBS in 1541 women aged ≥ 40 at baseline. They identified 67 events of MOF in their cohort during a 10-year follow-up period. Based on their results, the model incorporating FRAX with TBS demonstrated a better fit compared to a model consisting of FRAX alone.[29]

To the best of our knowledge, no study has been performed to evaluate the effect of TBS adjustment on the MOF and HF risk of the kidney transplant population. Based on the results of the current study, the proportion of patients needing a therapeutic intervention significantly increased from 17.1% to 25.7% after TBS adjustment of FRAX. These findings reveal that TBS adjustment of FRAX contains valuable clinical utility in kidney transplant recipients.

One patient of the current series had normal BMD despite fully degraded TBS (Table 3). In reviewing her documents, we noticed aortic calcification along L1 to L4 lumbar vertebra, which could be responsible for misleading normal BMD. Aortic calcification in renal transplant patients is considered an important predisposing factor for falsely elevated bone density in the lumbar spine, and adding TBS to the bone evaluation partly resolves this problem. This point is highlighted in the study of Aleksova *et al.*, which aimed to evaluate the association of the TBS with abdominal aortic calcification in patients with chronic kidney disorders receiving dialysis. They evaluated 146 patients, of whom 49% had prevalent calcification and found an inverse association between TBS to vascular calcification.[30]

The value of TBS in fracture risk assessment has also been reported in other diseases such as Ankylosing Spondylitis, in which BMD results could be falsely elevated by the presence of typical syndesmophytes.[13]

Although mTOR inhibitors have revealed on the bone quality,[31] no significant association was found between the mTOR inhibitors medication and TBS of the patients in the present study. However, this results could have been adversely affected by the small number of patients who were taking mTOR inhibitors in the current series. Therefore, further studies are required to evaluate the effect of mTOR inhibitors on TBS.

The present study was not without weakness. The main weakness of this study was the small number of patients that could have affected the power of statistical analysis. Therefore, future investigations with a larger sample size will provide valuable complementary information regarding the value of TBS in kidney transplant recipients.

CONCLUSION

TBS was impaired in Iranian kidney transplant recipients. Factors such as age and duration of dialysis are associated with TBS. Despite a significant correlation between MOF and HF risk before and after adjustment with TBS, the proportion of patients who needed a therapeutic intervention significantly increased after FRAX adjustment with TBS. These findings highlight the complementary role of TBS in kidney transplant recipients and suggest TBS adjustment of FRAX in future workouts evaluating the bone quality of patients after kidney transplant. Moreover, the evaluation of TBS beside BMD provides awareness regarding the misleading BMD results caused by aortic calcification in the kidney transplant recipient.

CONFLICT OF INTEREST

The authors of this article declare no conflict of interest to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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