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Advances in Fracture Risk Assessment among Patients with Type 2 Diabetes Mellitus

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Abstract

Type 2 diabetes mellitus (T2DM) and osteoporosis are both common age-related metabolic diseases, and their coexistence significantly increases the fracture risk of patients. Patients with T2DM often present with normal or even increased bone mineral density, yet exhibit a higher incidence of fractures, making it difficult to accurately reflect their true bone fragility by relying solely on bone mineral density assessment. Currently available clinical assessment methods include bone mineral density measurement, Fracture-risk assessment tool (FRAX), Trabecular Bone Score, Vertebral fracture assessment (VFA), Quantitative CT, Bone Turnover Markers, and Quantitative ultrasound, but each method has varying degrees of risk underestimation or applicability limitations in the T2DM population; Although FRAX integrates multiple clinical risk factors, it does not include diabetes as an independent risk factor. Although it can be improved through correction with various parameters, there is currently no unified standard. In recent years, artificial intelligence and radiomics technology have opened new avenues for predicting T2DM fracture risk, giving rise to several machine learning models and nomogram models. However, due to limited sample sizes, insufficient external validation, and a focus mainly on overall fracture risk such as hip fractures, simple clinical prediction models targeting vertebral fractures remain scarce. This article reviews the assessment methods and research progress on fracture risk in patients with T2DM, points out the shortcomings of existing prediction models, and provides ideas for developing a new, simple, and clinically applicable T2DM vertebral fracture risk prediction model.

Keywords

Type 2 Diabetes Mellitus, Osteoporotic Fracture, Vertebral Fracture, Risk Assessment, Prediction Model

1. Introduction

With population aging and changes in lifestyle, diabetes and osteoporosis have become two major chronic metabolic diseases among the middle-aged and elderly population. The International Diabetes Federation (IDF) 2021 report indicates that there are approximately 537 million people aged 20 - 79 with diabetes worldwide, which is expected to reach 783 million by 2045, predominantly Type 2 Diabetes Mellitus (T2DM) [1]. The prevalence of diabetes increases with age, with T2DM being predominant among the elderly population; the prevalence of osteoporosis also increases significantly with age, and is higher in women than in men [2] [3]. The high degree of overlap between T2DM and osteoporosis makes fracture a health threat that cannot be ignored in these patients.

Studies have shown that the risk of hip, upper arm, and ankle fractures in T2DM patients is significantly higher than in non-diabetic individuals, with the risk of fracture at any site increasing by approximately 20% [4] [5]. Especially for vertebral fractures, the risk of vertebral fracture is significantly elevated in T2DM patients, and this is not only related to changes in the bone itself but is often closely associated with falls, frailty, or cardiovascular conditions [6]. After fracture, patients' disability rate and mortality rate increase, and quality of life decreases.

However, fracture-risk assessment in T2DM patients has always faced particular difficulties. Studies have pointed out that the bone mineral density of T2DM patients is generally 5% - 10% higher than that of healthy people, yet the fracture probability is greater, a phenomenon known as the "diabetic bone paradox" [7]. Bone mineral density measurement cannot well distinguish the actual fracture risk of such patients, indicating that changes in bone strength are not solely determined by bone mass. Epidemiological investigations show that the fracture risk of T2DM patients during the low bone mass stage is higher than during the osteoporosis stage, and there is currently no consensus on this [8]. Therefore, how to accurately and conveniently identify individuals at high risk of fracture among T2DM patients has become a clinical challenge faced jointly by endocrinology and orthopedics. This article reviews the current major methods for fracture-risk assessment in T2DM patients, FRAX adjustment strategies, and research progress on artificial intelligence prediction models, and on this basis points out the shortcomings of existing prediction models, aiming to provide a reference for developing a new, simple, and clinically applicable T2DM vertebral fracture risk prediction model.

2. Mechanisms of Increased Fracture Risk in T2DM Patients

Understanding the pathophysiological basis of T2DM-related bone fragility is a prerequisite for rationally selecting assessment tools. The increased fracture risk in T2DM patients is not caused solely by reduced bone mass, but is the result of the combined effects of impaired bone quality and increased fall risk. At the skeletal level itself, T2DM patients are mostly in a state of low bone turnover, with

relatively suppressed osteoblast activity and an imbalance in the coupling between bone formation and bone resorption, leading to degradation of bone microarchitecture and reduced trabecular connectivity. Under hyperglycemia, Advanced Glycation End Products (AGEs) accumulate in bone tissue and abnormally cross-link with collagen, leading to reduced bone toughness and increased brittleness; at the same time, enhanced oxidative stress, impaired Insulin-like Growth Factor-1 (IGF-1) signaling, and elevated sclerostin expression all contribute to weakening bone strength [9]. These changes occurring at the level of bone material and microstructure are precisely what conventional bone mineral density measurements cannot capture. At the level of fall risk, T2DM patients often have hypoglycemia, increased nocturia, orthostatic hypotension, decreased vision, reduced balance and reaction ability, and sequelae of stroke; these factors significantly increase the risk of falls, thereby indirectly raising the incidence of fractures [10]. In addition, the incidence of sarcopenia is significantly increased in patients with T2DM, and sarcopenia has been proven to be closely related to falls and fractures; cognitive decline, vitamin D deficiency, and the effects of some hypoglycemic drugs on bone metabolism have also jointly increased fracture risk [11]. It is precisely the superposition of the above intraosseous and extraosseous factors that determines that relying solely on bone mineral density cannot adequately perform fracture-risk assessment in patients with T2DM.

3. Traditional Fracture-Risk Assessment Methods and Their Limitations

3.1. Bone Mineral Density Measurement

Dual-Energy X-Ray Absorptiometry (DXA) bone mineral density is the gold standard for the diagnosis of osteoporosis. It should be pointed out that the diagnostic threshold for osteoporosis and fracture-risk assessment represent two different concepts: according to WHO criteria, the diagnostic cutoff of T-score ≤ −2.5 applies only to postmenopausal women and men over 50 years of age, with measurement sites at the lumbar spine (L1 - L4), femoral neck, or total hip; osteoporosis can be diagnosed if any one site reaches this cutoff [12]; Fracture-risk assessment, on this basis, requires estimating the absolute fracture probability by combining clinical risk factors such as age and prior fracture history, and the two should not be conflated. Therefore, even when T2DM patients' T-scores do not reach the diagnostic threshold, their fracture risk may still be significantly elevated, and relying solely on diagnostic criteria is insufficient to assess fracture risk. For every 1 standard deviation decrease in bone mineral density, fracture risk increases by approximately 1.4 - 2.6 times [13]. However, bone mineral density can only reflect approximately 70% of bone strength, and T2DM patients' bone mineral density is usually normal or even elevated, so using DXA to assess their fracture risk has notable limitations. Under the same femoral neck bone mineral density T-score, the fracture risk of T2DM patients is significantly higher than that of non-diabetic patients, with their fracture risk being 30% - 50% higher than that of

the non-diabetic population; conversely, under the same hip fracture risk, the femoral neck bone mineral density T-score of T2DM patients is about 0.5 standard deviations higher than that of non-diabetic patients [14].

3.2. Osteoporosis Self-Assessment Tool for Asians

The Osteoporosis Self-Assessment Tool for Asians (OSTA), proposed by Koh *et al.* is calculated as $\text{OSTA} = (\text{Weight} - \text{Age}) \times 0.2$, and is used to quickly assess the risk of osteoporosis in postmenopausal women. An index ≥ −1 indicates low risk, −1 to −4 indicates medium risk, and ≤−4 indicates high risk. This tool is simple and easy to use, but it includes too few indicators and has low specificity. T2DM patients often have higher body weight than the normal population, so OSTA may underestimate their fracture risk. It also lacks validation in large male samples and does not include T2DM-specific risk factors such as falls, making it suitable only as a preliminary screening tool for the general population and difficult to promote for use in T2DM patients.

3.3. Quantitative CT

Quantitative computed tomography (QCT) can measure volumetric bone mineral density (vBMD) based on conventional CT scan data, with bone loss first appearing in trabecular bone. By measuring trabecular bone, QCT can more quickly reflect changes in bone mineral content and bone microarchitecture, making it more sensitive than DXA for diagnosing osteoporosis. Studies show that bone quality parameters such as volumetric bone mineral density (vBMD) in T2DM patients are closely related to fracture risk, and can serve as an important supplement to DXA results [15]. CT-based finite element analysis can assess vertebral bone strength and predict vertebral fracture risk, and has potential value in vertebral fracture-risk assessment in the T2DM population [16]. The implementation pathways of QCT need to be distinguished: one is opportunistic analysis, which retrospectively extracts volumetric bone mineral density from routine CT scan data that patients have already completed for other clinical reasons, without adding any additional radiation or cost, making it a feasible screening approach closer to clinical practice; The second is the dedicated QCT examination, which requires placing a quantitative phantom during scanning and following a standardized protocol to complete; its radiation dose is higher than DXA, and the availability of equipment and software is also limited, so it is not recommended as a simple screening method.

3.4. Trabecular Bone Score

Trabecular Bone Score (TBS) is an indicator that summarizes the microstructural state of trabecular bone based on the grayscale texture observed on lumbar spine DXA, without directly measuring bone mineral density, and has indicative significance for bone quality; clinically, it is usually considered that TBS ≥ 1.350 indicates normal microstructure, 1.200 - 1.350 indicates partial degradation, and

≤1.200 indicates significant degradation; It should be noted that this cutoff value originates from a consensus reference range established using postmenopausal women as the reference population, and thus has only rough reference significance. Studies have shown that TBS is lower in T2DM patients than in non-diabetic individuals, and TBS has stronger explanatory power for vertebral fracture than bone mineral density, making it a useful supplement to bone mineral density analysis [17] [18]. However, the calculation of TBS is based on DXA images, which are prone to distortion due to noise or soft tissue thickening, and is also related to the type of equipment used; the BMI adjustment method has not been fully standardized, and there is currently no unified normal/abnormal threshold validated across devices and populations (especially for men, premenopausal women, and T2DM patients), nor is there reference data available for men or premenopausal women, so the indicated differences also cannot fully explain the cause of fracture risk in T2DM patients.

3.5. Bone Turnover Markers

Bone Turnover Markers (BTM) indirectly reflect bone metabolism status by detecting the concentration of substances related to bone formation and bone resorption in body fluids. Serum Procollagen I N-terminal Propeptide (P1NP) and serum Beta-CrossLaps (β-CTX) are commonly used as recommended reference markers. Bone Turnover Markers are mainly used to differentiate primary from secondary osteoporosis and monitor the efficacy of anti-osteoporosis treatment, reflecting changes in efficacy earlier than bone mineral density. However, bone turnover markers are influenced by factors such as age, sex, race, menstrual cycle, exercise, and diet, and not all fracture patients show elevated markers; moreover, there is a lack of clear fracture-prediction threshold values, so they are not recommended for the diagnosis of osteoporosis, and are even less suitable for use alone in fracture-risk assessment for patients with T2DM.

3.6. Quantitative Ultrasound

Quantitative ultrasound (QUS) uses the speed of sound and broadband ultrasound attenuation in bone tissue to reflect bone quality and bone strength, and has the advantages of no radiation, no trauma, portability, and simple operation, making it suitable for primary screening of osteoporosis at the grassroots level. However, the detection sites are mostly limited to peripheral bones such as the calcaneus and radius, and cannot assess key sites such as the spine and hip; the technical details and standards vary greatly among devices of different brands, resulting in poor reproducibility; The diagnostic threshold has yet to be unified, so it can only be used as a screening tool rather than for definitive diagnosis.

3.7. Vertebral Fracture Assessment

Vertebral fracture is one of the most common types of fragility fracture in T2DM patients, and most vertebral fractures have no obvious acute symptoms, making

them easily missed by routine inquiry and bone mineral density measurement alone. Therefore, imaging evaluation of vertebral morphology has irreplaceable value. DXA-based Vertebral Fracture Assessment (VFA) acquires lateral thoracolumbar spine images concurrently with routine bone mineral density examination and uses the Genant semiquantitative grading method to interpret the morphology of T4 - L4 vertebrae; patients do not need separate positioning or appointments, the radiation dose is far lower than that of conventional thoracolumbar spine X-ray imaging, and bone mineral density measurement and vertebral fracture screening can be completed simultaneously in a single examination; The International Society for Clinical Densitometry (ISCD) has issued a dedicated position statement on the assessment standards and follow-up review of VFA [19]. Standard lateral thoracolumbar spine X-ray imaging remains the classic method for vertebral fracture assessment, with image spatial resolution higher than VFA, suitable for confirming and grading suspicious vertebral deformities detected by VFA. In the T2DM population, a study by Lin *et al.* [20] on 285 postmenopausal women with T2DM showed that the prevalence of vertebral fractures detected via lateral lumbar spine imaging reached 11.2%, and the AUC of TBS for discriminating vertebral fractures was 0.775, suggesting that such fractures are not uncommon in this population, yet are often overlooked due to insidious symptoms. VFA and standard spinal imaging can directly detect vertebral fractures that have already occurred, providing definitive evidence for initiating anti-osteoporosis treatment, and are key tools for achieving the goal of early identification of vertebral fractures in T2DM patients. Its limitation is that image quality can affect visualization of the mid-thoracic vertebrae (e.g., T7 - T9), and agreement in identifying mild (grade 1) fractures is relatively low.

4. Application of FRAX in Fracture-Risk Assessment for T2DM and Correction Strategies

4.1. Overview of FRAX and Its Limitations

FRAX was launched by WHO in 2008. Based on age, sex, weight, fracture history, parental hip fracture history, smoking, glucocorticoid use, Rheumatoid Arthritis, Secondary Osteoporosis, excessive alcohol consumption, and Femoral neck bone mineral density, it calculates an individual's 10-year probability of hip and major osteoporotic fracture. It has been calibrated in more than 60 countries and is freely available online, making it the most widely used fracture-risk assessment tool in clinical practice [21]. However, FRAX does not incorporate diabetes or its duration and severity, generally underestimating fracture risk in T2DM patients. Even when FRAX probabilities are the same, the actual fracture risk in T2DM patients remains significantly higher than in the non-diabetic population. Although population studies in some regions show that FRAX has certain predictive value for T2DM and can serve as an initial screening tool, its applicability varies greatly across different regions and ethnicities, and its specific predictive efficacy for particular sites such as vertebral fracture remains unclear.

4.2. Four Main Correction Strategies

Regarding the issue of underestimation with FRAX, there are currently four types of international correction approaches: 1) TBS correction: incorporating TBS as part of the FRAX calculation. A study of adults aged 50 - 90 with diabetes in Taiwan region showed that FRAX corrected by TBS could identify more female patients meeting the intervention criteria for severe osteoporotic fracture than classic FRAX [22]. However, the conclusions of various studies are not entirely consistent. A Korean community cohort study has pointed out that TBS correction does not necessarily outperform FRAX alone, and TBS is a variable limited by age, sex, and intervention thresholds, with insufficient clinical evidence [23]. 2) Lower the bone mineral density T-score by 0.5 standard deviations: based on the fact that T2DM patients have a bone mineral density T-score at the hip approximately 0.5 standard deviations higher than non-diabetic individuals, the T-score is lowered before being entered into FRAX to correct for underestimation. The Manitoba study confirmed that this method has a clear predictive advantage, but its applicability may mainly be for older age, low body weight, poor bone mineral density, or those with prior fractures; data for the Chinese population are still lacking [24]. 3) Add 10 years to age: shift the age of T2DM patients up by 10 years to match their fracture risk. This adjustment is somewhat helpful for those with a disease duration greater than 10 years, but although an increase in age helps identify fractures, it may also increase the chance of death, and the two are difficult to separate; the statistical significance of the data obtained is limited, and its practical value is restricted. 4) Replacing Rheumatoid Arthritis (RA) with T2DM: given that RA and T2DM carry roughly equivalent weight in their impact on fracture risk in FRAX, T2DM is substituted for RA in FRAX calculation. A study of 1047 Chinese T2DM patients suggested that the FRAX involving RA correction has a sensitivity of 0.4761 and a specificity of 0.9642 for hip fracture intervention, with males and individuals with higher BMI or femoral neck bone mineral density benefiting more; it is recommended to use a 10-year hip fracture risk ≥ 3% as the intervention threshold [25]; In a cross-sectional study by Monteiro *et al.* [26] involving 100 adult T2DM patients (mean age 68.4 years), the Portuguese version of FRAX with integrated T2DM variables (FRAX-Port®) was directly applied for assessment, and the results showed a median major osteoporotic fracture probability of 6.8% and hip fracture probability of 2.4%, with 41% of patients reaching the high fracture risk level, 45% having indications for anti-osteoporosis treatment, while only 6% actually received treatment; Although this study did not perform substitution correction for FRAX input variables, it confirmed the operability and identification value of localized FRAX in the T2DM population, indirectly suggesting that correction strategies such as RA substitution still need to be compared head-to-head with such tools. Overall, TBS has not yet been widely implemented in China, and age adjustment and T-score downward correction also lack support from local population data; substituting RA is currently a more feasible correction approach. This method does not rely on additional testing and is easy to imple-

ment in outpatient settings, but its effectiveness still needs to be confirmed by large-sample prospective studies.

5. Novel Imaging Techniques and Artificial Intelligence Prediction Models

In addition to DXA and TBS, other imaging techniques such as high-resolution peripheral quantitative computed tomography (HR-pQCT), hip structural analysis, FEA, and radiofrequency ultrasound multispectrometry can also be used for fracture-risk assessment in patients with T2DM. HR-pQCT is a non-invasive three-dimensional imaging technology that can measure volumetric bone mineral density and bone microarchitecture at the distal radius and tibia, and combines micro-finite element analysis to calculate bone strength indicators. Bone Microarchitecture is a predictor of fracture risk independent of Bone mineral density and FRAX, but this equipment is costly, requires professional operation, and data from first-generation and next-generation devices lack comparability, so it is currently mainly used for scientific research rather than routine clinical practice. HSA evaluates cortical bone stability based on DXA images, and its parameters are not affected by anti-osteoporosis treatment, but it can only be used for the hip; QCT-based FEA can predict hip and vertebral fracture risk in postmenopausal women and elderly men, but it cannot yet be used for osteoporosis diagnosis, and confirmatory studies remain scarce. By analyzing raw ultrasound images of the lumbar spine and femoral neck, REMS provides bone mineral density values equivalent to DXA and can assess bone strength; a 5-year follow-up study involving over 1500 women aged 30 - 90 showed high correlation and similar predictive ability with DXA, but the results are influenced by operator factors [27].

In recent years, machine learning and radiomics have opened new avenues for fracture prediction, Chu *et al*. [28] used clinical data from 775 hospitalized patients with diabetes. With diabetes-related fractures as the outcome, they compared seven machine learning algorithms: logistic regression, support vector machine, random forest, decision tree, gradient boosting decision tree, extreme gradient boosting (XGBoost), and probabilistic classification vector machine (PCVM). After feature selection, they identified 17 key predictors. The PCVM model was the best at discrimination, with an F1 score of 0.97. In a study by Kong *et al*. [29] they developed a CatBoost machine learning model to predict fragility fractures and studied 2227 participants (1257 women) from the Korean Ansan-Ansung community cohort who had baseline bone mineral density and TBS measurements. During a mean follow-up of 7.5 years, 537 participants (25.6%) had a fragility fracture. The model had an AUC of 0.688, significantly better than traditional FRAX (0.663).

For vertebral fracture, Li *et al*. [30] collected 128 vertebrae from 57 patients (64 occult vertebral fractures and 64 control vertebrae), and divided the training set and validation set at a ratio of 8:2 to construct a CT radiomics model. Among these, the logistic regression model based on sagittal features achieved an AUC of

0.882 in the validation set, with accuracy, sensitivity, and specificity all at 0.846. Wei *et al.* [31] included 1486 T2DM patients over 50 years old without baseline vertebral fracture for longitudinal follow-up. During the follow-up period, 135 new-onset vertebral fractures occurred. The combined model of CT radiomics and bone CT attenuation value achieved an AUC of 0.795 - 0.842 for predicting vertebral fracture risk at 2 to 4 years, and calibration and decision curve analyses showed good calibration and clinical net benefit.

In terms of nomograms and clinical prediction models, Liu *et al.* [32] developed a nomogram for osteoporotic fracture risk based on single-center retrospective data from 868 T2DM patients, dividing the training and validation sets at a ratio of 8:2, with an AUC of 0.831 and a Hosmer-Lemeshow test P = 0.406 indicating good calibration; Tan *et al.* [33] developed an osteoporosis risk prediction model based on 21,070 elderly hospitalized T2DM patients from 6 tertiary hospitals in southwestern China, with AUCs of 0.713, 0.716, and 0.694 for the training set, internal validation set, and external validation set, respectively, and the calibration curve was plotted using 1000 bootstrap resamplings, yielding satisfactory calibration results. These models are intuitive and easy to use, but most are still based on single-center, retrospective designs. Sample sizes and validation strategies vary widely. Some studies did not report calibration, and outcome measures are inconsistent (fracture vs. osteoporosis). So far, no widely accepted standardized model has emerged.

6. Limitations of Existing Assessment Tools and Challenges Faced

Current tools for fracture-risk assessment in T2DM patients each have their own shortcomings. First, bone mineral density and the DXA system systematically underestimate fracture risk in T2DM; normal or elevated bone mineral density masks damage to bone material and microstructure, and vertebral fractures are often asymptomatic and easily missed. Second, FRAX does not include key variables such as diabetes, its duration, and glycemic control, making it difficult to fundamentally correct the underestimation of risk; The four correction methods each have limitations: TBS correction is constrained by image quality and sex, age correction lacks statistical significance, T-score downward adjustment lacks local data, and although RA substitution is relatively feasible, it has not been validated on a large scale; there is still no unified standard or intervention threshold. Third, advanced technologies and equipment such as QCT, HR-pQCT, and FEA are expensive, require specialized operation, and some involve relatively high radiation, making them difficult to popularize in primary hospitals and among the large T2DM population. Fourth, existing machine learning and nomogram models are mostly limited to single-center small samples and lack external validation, mostly focusing on overall or hip fracture risk, while simple prediction models specifically targeting T2DM vertebral fracture are very scarce. Particularly notable is that vertebral fracture-risk assessment has long been overlooked: vertebral fracture is

the most common and prognostically significant fracture type in T2DM patients, showing a stronger correlation with bone microarchitecture degradation than with bone mineral density, yet existing tools lack a dedicated and simple assessment method specifically for vertebral fractures.

7. Summary and Outlook

The assessment of fracture risk in T2DM patients is currently transitioning from "bone mineral density alone" to "multidimensional bone quality plus comprehensive risk factors". DXA bone mineral density remains an important basic indicator, and FRAX is currently the most clinically accessible risk assessment tool, but its problem of underestimation in the T2DM population urgently needs to be addressed; Bone quality assessment methods such as TBS and QCT, as well as FRAX improvement strategies such as RA correction, provide useful supplementation, while artificial intelligence and radiomics represent the direction of future development. However, there remain clear gaps in existing assessment systems: on the one hand, there is currently no fully validated prediction model that is convenient for clinical use and specifically targets T2DM vertebral fracture; on the other hand, various tools each have their shortcomings, either systematically underestimating risk, or relying on expensive equipment, or lacking local and external validation, or being applicable only to overall fractures rather than vertebral fractures. Therefore, among the large T2DM population, the clinical need for early identification of patients at high risk of vertebral fracture remains far from met, and developing a new, simple, and clinically applicable T2DM vertebral fracture Fracture Risk Prediction Model is of urgent practical significance.

Author Contributions

Concept and design: Bo Zhou, Xiuling Shen.

Acquisition, analysis, or interpretation of data: Xiuling Shen, Bo Zhou.

Drafting of the manuscript: Xiuling Shen.

Critical revision of the manuscript for important intellectual content: All authors.

Supervision: Bo Zhou.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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