



Combined Vertebral Fracture Assessment and FRAX Tool Thailand With or Without Bone Mineral Density for Diagnosis of Osteoporosis in Elderly

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Purpose: To evaluate the reliability of using vertebral fracture assessment by radiography (VFA) in combination with FRAX tool Thailand to diagnose osteoporosis in elderly patients, without the need for bone mineral density (BMD) measurement.

Methods: All elderly individuals who fulfill the criteria for osteoporosis assessment according to the 2021 CPG for osteoporosis care by the Thailand osteoporosis foundation were assessed BMD, VFA, and FRAX tool Thailand with and without BMD. Fracture risk was first evaluated using only FRAX without BMD and the presence of asymptomatic vertebral fractures (AVF). The second assessment used FRAX with BMD, the results of BMD measurements, and the presence of AVF. The results of these two assessments were compared to evaluate the reliability of the osteoporotic diagnosis.

Results: The prevalence of osteoporosis in the study was found to be 67% (95% CI: 60%–72.9%). The test exhibited high sensitivity (90.6%, 95% CI: 84.5%–94.9%) and specificity (92.9%, 95% CI: 84.1%–97.6%), indicating its strong ability to accurately identify both individuals with and without osteoporosis. The Receiver Operating Characteristic (ROC) area of 0.918 (95% CI: 0.879–0.956). For subgroup analysis, in males (n=44), the test demonstrated excellent performance with a sensitivity of 95.2%, specificity of 100%, and a sensitivity of 89.8% and specificity of 89.4% in females (n=165). In the age-based subgroup analysis, the results in those aged >80 years (n=35) had highest sensitivity at 96.8% but lower specificity at 75.0%. For participants aged 70-80 years (n=84), sensitivity was 94.7%, and specificity was 88.9%. The youngest group, aged <70 years (n=90), had the lowest sensitivity of 82.4% but a high specificity of 97.4%. The ROC area ranged from 0.85 in those >80 years, 0.89 in those <70 years, and 0.91 in the aged 70-80 years group.

Conclusions: The combined use of VFA and FRAX without BMD offers a simple, highly effective method for diagnosing osteoporosis in elderly patients, especially in all men and women aged 70-80 years at minimal cost.

Keywords: osteoporosis diagnosis, vertebral fracture assessment, FRAX, Bone mineral density

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Osteoporosis is a skeletal disorder characterized by diminished bone strength, resulting in an increased susceptibility to fractures⁽¹⁾. According to definition by the National Institutes of Health (NIH), bone strength is determined by two principal factors: bone mineral density (BMD) and bone quality⁽²⁾. The World Health Organization (WHO) further defines osteoporosis as a systemic skeletal condition marked by reduced bone mass and micro-architectural deterioration of bone tissue, which contributes to bone fragility and an elevated risk of fractures⁽³⁾.

Osteoporosis is a growing public health concern globally, including in Thailand, where it notably increases the risk of fragility fractures. A national health survey of the elderly population in Thailand found that osteoporosis is among the most prevalent health problems. This condition is becoming increasingly common due to the aging population, with the prevalence of osteoporosis being approximately 23% in women and 12% in men worldwide⁽⁴⁾. Furthermore, osteoporotic fractures, especially those involving the hip, are strongly associated with increased mortality. A study conducted in Chiang Mai between 1987 and 1988 demonstrated that 2.1% of patients died during hospitalization following a hip fracture. Long-term follow-up over a 5-year period revealed an overall mortality rate of 29%⁽⁵⁾.

The main aim of diagnosing and treating osteoporosis is prevention of osteoporotic fractures. Low bone mineral density (BMD) is one of the most predictive factors for osteoporotic fracture^(6,7). The presence of a vertebral fracture is also a strong predictor of new fractures, and this risk is independent of BMD. Therefore, even with only modestly decreased or even normal BMD vertebral fractures can be present. When both of these risk factors, low BMD and prevalent of vertebral fracture are present, the risk of a new fracture may be increased by a factor of 25⁽⁸⁾. The gold standard evaluation of fracture risk is based on the results of BMD test and there are many study suggested using vertebral fracture assessment and FRAX to improved osteoporosis diagnosis⁽⁹⁻¹¹⁾. Following risk stratification, treatment is then guided by the severity of fracture risk.

In clinical practice, diagnosing osteoporosis by BMD testing is challenging, especially for elderly patients who may have difficulty traveling to other medical centers where the necessary diagnostic equipment is available. Moreover, the cost of BMD testing is often prohibitive, and in some cases, patients are unable to access reimbursement for these tests, resulting in a significant number of individuals not receiving proper diagnosis or treatment.

The purpose of this study is to evaluate the reliability of using vertebral fracture assessment by radiography (VFA) in combination with FRAX Thailand to diagnose osteoporosis in elderly patients, without the need for bone mineral density (BMD). By this alternative diagnostic criteria, there could be significantly increase the rate of diagnosis and ensure that more patients receive appropriate management, particularly in community hospitals that lack the resources for BMD testing.

METHODS

The study population consisted of all elderly individuals who fulfill the criteria for osteoporosis assessment according to the 2021 clinical practice guidelines for osteoporosis care by the Thailand osteoporosis foundation⁽¹²⁾ which are 1) Women aged 65 years and older and men aged 70 years and older. 2) Women who experienced menopause before age 45, including those who have had both ovaries removed (bilateral oophorectomy). 3) Women with persistent low estrogen levels for more than 1 year prior to menopause. 4) Postmenopausal women younger than 65 years or men younger than 70 years with at least one of the following risk factors. (Currently using glucocorticoid medication at an equivalent dose of prednisolone 5 mg/day or higher for more than 3 months, Their parents had a hip fracture from a minor accident (low-impact trauma), A body mass index (BMI) of less than 20 kg/m², A height reduction of 4 cm or more compared to the patient's highest recorded height, or a reduction of 2 cm or more from two separate height measurements, Women receiving aromatase inhibitor therapy or men undergoing androgen deprivation therapy,

Radiographic evidence showing osteopenia or vertebral deformity due to vertebral fractures, A history of fragility fractures)

Exclusion Criteria are Elderly individuals who are unable to do bone mineral density testing at either hip or have a history of hip fracture from low-energy trauma (fragility fracture), and who are unable to provide the necessary information for the FRAX Thailand assessment

The study was approved by the Provincial Public Health Office of Sakaeo ethics review board and was considered to be evaluation of modern patient care.

BMD Measurement

BMD was measured by using dual-energy X-ray absorptiometry (DXA) over the lumbar spine and proximal femur. The results were expressed as T-scores⁽¹³⁾. The reference standard of a T-score is the peak bone density, as reached in men or women age 30 years. The T-score is then defined as the number of standard deviations from this value. According to the commonly used World Health Organization definition, "osteoporosis" is defined as a T-score lower than -2.5; "osteopenia" as a T-score between -2.5 and -1.0; and when the T-score is greater than -1.0, the BMD is "normal."

Vertebral Fracture Assessment

Vertebral fracture was assessed by radiograph of thoracolumbar spine in the lateral position. The range of vertebral visualization is from the level of T4 through L4^(14,15). The radiographic images were sent to the radiologist for evaluation of vertebral collapse according to the Genant's classification⁽¹⁶⁾. In this classification, a relative height reduction between 20%-25% was designated a "mild" fracture, 25%-40% was a "moderate" fracture, and >40% was a "severe" fracture. (Figure 1)

Patient was interviewed by orthopedic surgeon to collect various data for the assessment of FRAX Thailand^(17,18), which includes personal information such as age, gender, weight, height, and specific clinical factors. The collected data of each patient was entered into the FRAX Thailand tool twice, once with BMD inserted and once

without BMD. 10-year risk of hip fracture of 3% was determined as high risk group.

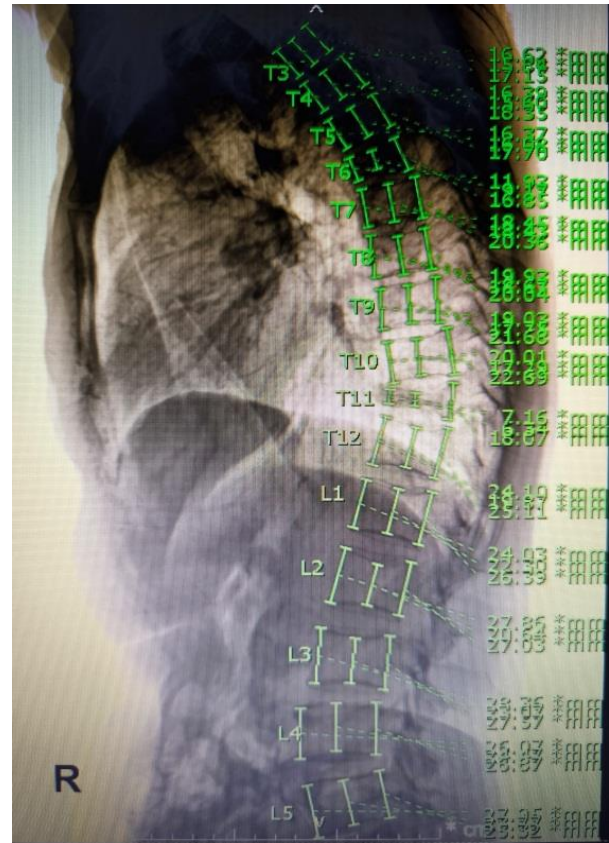


Fig. 1 Vertebral fracture was assessed by radiograph of thoracolumbar spine in the lateral position FRAX.

Interpretation

Fracture risk assessment was performed by two orthopedic surgeons to ensure accuracy of the diagnosis according to the guidelines of the Osteoporosis Foundation of Thailand (2021) which are 1) History of vertebral compression fractures or hip fractures due to osteoporosis, 2) T-score ≤ -2.5 , 3) 10-year risk of hip fracture, assessed by the FRAX tool for Thailand, is $\geq 3\%$, and 4) T-score between -1.0 and -2.5, combined with a history of fragility fractures at sites other than the spine or hip, such as fractures at the proximal humerus, pelvis, or forearm.

First assessment use only FRAX without BMD and the presence of asymptomatic vertebral fractures (AVF), and second assessment use FRAX

with BMD, the results of BMD measurements, and the presence of asymptomatic vertebral fractures. The results of these two assessments were compared to evaluate the reliability in osteoporotic diagnosis. A contingency table was used to calculate the following diagnostic performance metrics including sensitivity, specificity, positive predictive value, negative predictive value, and accuracy.

RESULTS

Patients

This study focuses on elderly individuals who fulfill the criteria for osteoporosis assessment created by Osteoporosis Foundation of Thailand. Most women aged 65 years and men aged 70 years and over were enrolled from out-patient department of Aranyaprathet Hospital in July 2022-December 2023. Of 235 patients, 26 patients were excluded due to previous history of hip fracture from low-energy trauma.

A total of 209 participants were included in the study. The mean age of participants was 71.48 years. The majority of participants were female (78.95%), with a mean Body Mass Index (BMI) of 24.85 ± 4.84 kg/m². Fracture history was reported in 18.18% of the participants, with vertebral compression fractures (VCF) accounting for 35%, distal radius fractures 24%, proximal humerus fractures and distal femoral fractures each 13%, and other fractures 15%. Bone mineral density (BMD) measurements were obtained from several sites. The mean BMD at the neck of the femur was -1.68 g/cm², at the total hip was -1.44 g/cm², and at the L1-L4 vertebral level was -2.21 g/cm². Asymptomatic vertebral fracture was found in 49% of patients.

In terms of specific clinical factors, 14.83% of participants had a previous fragility fracture. 2.87% had a parent with a history of fractured hip. 1.91% were current smokers. 2.39% were using glucocorticoids at the time of the study. 1.43% had a diagnosis of rheumatoid arthritis. 3.34% had secondary osteoporosis. 1.43% reported consuming ≥ 3 alcohol units/day. More patient data are presented in Table 1.

Risk assessments using the FRAX without BMD indicated a mean fracture risk of $3.75 \pm 2.79\%$,

while including BMD in the FRAX calculation led to a mean risk of $2.71 \pm 3.04\%$. When categorized according to risk levels, 37.32% of participants were classified as having low to moderate risk of fracture without BMD data, while 62.68% were classified as high to very high risk. When BMD was included in the FRAX calculation, the proportion of participants in low to moderate risk category decreased to 33.49%, while those in the high to very high risk group increased to 66.15%

Table 1 Baseline Characteristics, Bone mineral density (BMD), Vertebral fracture (VF), Fracture risk assessment tool (FRAX), Risk of fracture.

Variable	Overall (n=209)
Age (years), mean \pm SD	71.48 \pm 6.80
Sex (Female, %)	165 (78.95)
BMI (kg/m ²), mean \pm SD	24.85 \pm 4.84
Fracture history (%)	38 (18.18)
BMD neck (g/cm ²), mean \pm SD	-1.68 \pm 1.00
BMD total hip (g/cm ²), mean \pm SD	-1.44 \pm 0.97
BMD L1-L4 (g/cm ²), mean \pm SD	-2.21 \pm 1.36
Asymptomatic VF, N (%)	103 (49.28)
Previous fragility fracture, N (%)	31 (14.83)
Parent fractured hip, N (%)	6 (2.87)
Current smokers, N (%)	4 (1.91)
Current glucocorticoid use, N (%)	5 (2.39)
Rheumatoid arthritis, N (%)	3 (1.43)
Secondary osteoporosis, N (%)	7 (3.34)
Alcohol ≥ 3 units/day, N (%)	3 (1.43)
FRAX w/o BMD (%), mean \pm SD	3.75 \pm 2.79
FRAX with BMD (%), mean \pm SD	2.71 \pm 3.04
Risk without BMD (%)	
Low - moderate	78 (37.32)
High - very high	131 (62.68)
Risk with BMD (%)	
Low - moderate	70 (33.49)
High - very high	139 (66.15)

Diagnostic Performance

The diagnostic performance of the screening test, combining VFA and FRAX without BMD was evaluated in comparison to VFA, BMD and FRAX with BMD which served as the gold standard

for osteoporosis diagnosis. The prevalence of osteoporosis in the study cohort was found to be 67% (95% CI: 60%–72.9%). The test exhibited high sensitivity (90.6%, 95% CI: 84.5%–94.9%) and specificity (92.9%, 95% CI: 84.1%–97.6%), indicating its strong ability to accurately identify both individuals with and without osteoporosis. The Receiver Operating Characteristic (ROC) area of 0.918 (95% CI: 0.879–0.956) further support the excellent discriminatory power of the test in distinguishing between those with and without the condition.

In terms of predictive accuracy, the positive predictive value (PPV) was 96.2% (95% CI: 91.3%–98.7%), meaning a positive result had a very high likelihood of indicating osteoporosis, while the negative predictive value (NPV) was 83.3% (95% CI: 73.2%–90.8%), suggesting a moderately high ability to rule out the condition. Collectively, these

results highlight the robust diagnostic capabilities of the combined VFA and FRAX test without BMD, demonstrating it as an effective and reliable tool for osteoporosis screening in clinical settings. As shown in Table 2 and Figure 2.

Table 2 Diagnostic Performance of VFA and FRAX (Without BMD) Compared to VFA, BMD, and FRAX (With BMD) as the Gold Standard.

Metric	Value	95%CI
Prevalence	67%	60% - 72.9%
Sensitivity	90.6%	84.5% - 94.9%
Specificity	92.9%	84.1% - 97.6%
ROC area	0.918	0.879 - 0.956
PPV	96.2%	91.3% - 98.7%
NPV	83.3%	73.2% - 90.8%

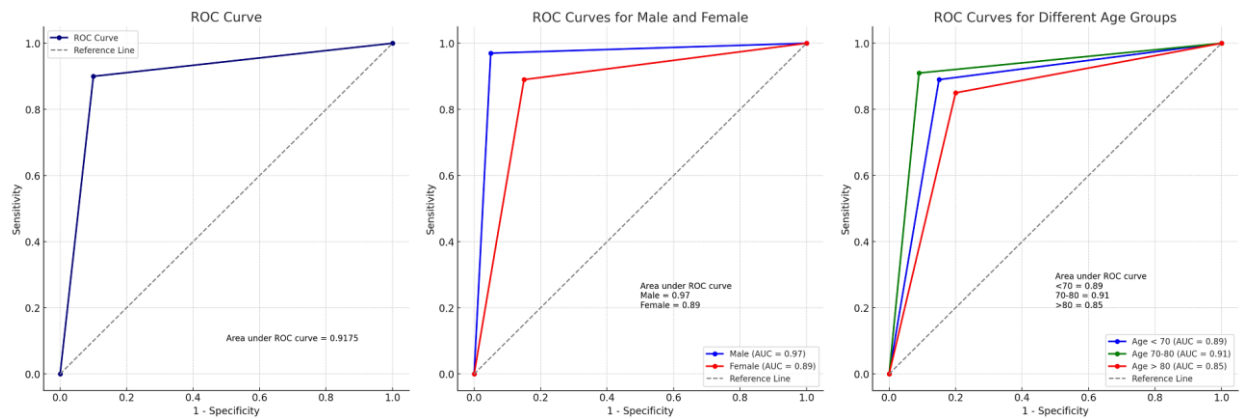


Fig. 2 Receiver Operating Characteristic (ROC) curves for Diagnostic performance, sex subgroups, and age subgroups.

Subgroup Analysis

In a subgroup analysis by sex, the diagnostic performance of the combined VFA and FRAX without BMD revealed notable differences between males and females. In males (n=44), the test demonstrated excellent performance with a sensitivity of 95.2%, specificity of 100%, and a positive predictive value (PPV) of 100%, highlighting its high accuracy in identifying osteoporosis. In contrast, females (n=165) exhibited

a sensitivity of 89.8% and specificity of 89.4%, both slightly lower than in males. The PPV for females was 95.5%, and the NPV was 77.8%, indicating a slightly lower ability to rule out the condition compared to males. The ROC area for males was 0.97, indicating excellent discriminatory ability, while for females it was 0.89.

In the age-based subgroup analysis, the results in those aged >80 years (n=35), had the highest sensitivity at 96.8% but lower specificity at

75.0%. The PPV was 96.8%, and the NPV was 75%. For participants aged 70-80 years (n=84), sensitivity was 94.7%, and specificity was 88.9%, with a PPV of 94.7% and an NPV of 88.9%. The youngest group, aged <70 years (n=90), had the lowest sensitivity (82.4%) but a high specificity of 97.4% and a PPV of 97.7%. The ROC area ranged from 0.85 in those >80 years to 0.91 in the overall group, suggesting strong performance across all age groups, with slightly reduced specificity in older adults. (Figure 2)

DISCUSSION

The aim of this study was to evaluate the reliability of using Vertebral Fracture Assessment (VFA) in combination with FRAX without BMD to diagnose osteoporosis in elderly patients, without the need for bone mineral density (BMD). The results show that the prevalence of osteoporosis in the study population is quite high (67%) compared to a recently published study in Thailand, which reported a prevalence of 30% among elderly individuals over 60 years of age, diagnosed based solely on BMD measurements⁽¹⁹⁾. This suggests that osteoporosis is common in the elderly population and reinforces the need for effective and user friendly diagnostic tools. A sensitivity of 90.6% and a specificity of 92.9% are excellent, indicating that the combined use of VFA and FRAX without BMD is very effective at detecting patients who have osteoporosis and also good at ruling out individuals who do not have the disease. ROC Area of 0.918 (95% CI: 0.879 - 0.956) indicates excellent discrimination between those with and without osteoporosis. The high ROC area supports the validity of the VFA and FRAX without BMD combination as a reliable tool for osteoporosis diagnosis in elderly patients.

All patients were assessed for vertebral compression fractures using lateral thoracolumbar radiographs. If a patient had a compression fracture at only one level, they were diagnosed with osteoporosis. Many studies have now demonstrated good agreement between densitometry and radiography in vertebral fracture assessment, with very good sensitivities and specificities when using radiographs as the gold standard, especially for moderate and severe fractures⁽²⁰⁾. This served as the

first part of screening for osteoporosis without the need for BMD testing. In this study, asymptomatic vertebral compression fracture was found in 49% of patients, similar to a study in postmenopausal Chinese women, which reported the prevalence of vertebral fractures ranged from 13.4% in those aged 50 to 59 years to 58.1% in those aged 80 years or older⁽²¹⁾.

When using the FRAX assessment, in the FRAX without BMD group, the mean score was 3.75 ± 2.79 , compared to 2.71 ± 3.04 in the group with BMD. The FRAX score without BMD was higher than the FRAX score with BMD. Since a FRAX score of ≥ 3 is used to predict the 10-year risk of hip fracture and serves as a criterion for diagnosing osteoporosis, the combination of these factors improves the reliability and accuracy of the diagnosis. Gadam and colleagues compared FRAX calculations with and without BMD to predict the 10-year risk of fracture. Their study found that 84% of patients had an identical fracture risk prediction whether or not BMD was included⁽²²⁾. In a more recent study in 2872 postmenopausal Thai women, using the receiver operating characteristic (ROC) curve to determine the optimal intervention threshold of the Thai-specific FRAX model, the optimal FRAX thresholds for hip fracture with and without BMD were 4% and 4.9% respectively⁽²³⁾. The thresholds for FRAX with and without BMD are still controversial.

In the gold standard for osteoporosis diagnosis, the use of bone mineral density (BMD) in combination with Vertebral Fracture Assessment (VFA) and FRAX with BMD increases the likelihood of accurate diagnosis⁽²⁴⁾. According to established diagnostic criteria, osteoporosis can also be diagnosed based on a BMD T-score of ≤ -2.5 , or a T-score of ≤ -1.0 in the presence of a non-vertebral fragility fracture, such as fracture of proximal humerus, pelvis, or forearm. Our results demonstrate that a higher proportion of individuals were classified as high to very high risk in the group assessed with BMD (66.15%) compared to those assessed without BMD (62.68%). These findings suggest that the inclusion of BMD in the risk assessment slightly increases the proportion of patients classified as high risk for osteoporosis.

However, the use of VFA and FRAX without BMD remains a valuable screening tool, particularly in settings where BMD testing is unavailable or impractical.

The results of the subgroup analysis by sex and age range reveal significant insights into the diagnostic performance of the screening tool across different groups. In terms of sex, males demonstrated slightly better performance, with higher sensitivity, specificity, PPV, and ROC values. Males had an outstanding ROC area of 0.97, suggesting near-perfect diagnostic ability compared to females which had an ROC area of 0.89, although both sexes showed high diagnostic accuracy. Regarding age, the tool's sensitivity increased with age, and specificity decreased with age reflecting its effectiveness in detecting osteoporosis but with higher likelihood of false positives in older individuals. ROC values were highest in the 70-80 age groups (0.91) with the overall ROC was 0.91. This suggests that the test performs best in the 70-80 age groups with a slightly reduced diagnostic performance in the younger and older individuals.

The hypothesized are individuals aged less than 70 years had lower prevalence of asymptomatic vertebral fractures results in a reduced sensitivity of the screening tool, as the absence of fractures diminishes the tool's ability to identify osteoporosis as reported by Zeynep that postmenopausal women in the 50-87 age range, the ratio of vertebral fractures was 21.4% and 46.3% for women over 75 years of age⁽²⁵⁾. Conversely, in individuals aged over 80 years, the increased prevalence of low BMD associated with age-related bone loss leads to a higher rate of osteoporosis diagnoses based on BMD alone. A study of BMD in 2,702 Chinese females aged 5 to 96 years showed that the prevalence of osteoporosis at least one site in these women $23.9 \pm 13.3\%$ in those aged 50-59, $56.3 \pm 20.3\%$ in those aged 60-69, $71.8 \pm 16.7\%$ in those aged 70-79, and $83.2 \pm 12.1\%$ in those aged over 80 years⁽²⁶⁾. This, in turn, results in a reduction in the specificity of the test in this age group, as more individuals are classified as positive for osteoporosis. In contrast, the age group between 70-80 years exhibited the most balanced diagnostic

performance, with optimal sensitivity and specificity.

The cost-effectiveness of combining VFA and FRAX without BMD can be evaluated by considering several factors. This diagnostic approach has a high yield with minimal patient burden, as it can be performed in any hospital in Thailand equipped with plain radiographs and an orthopedic specialist, requiring only a few additional minutes for patient interviews and data entry. The cost is approximately less than 500 baht. The diagnosis of osteoporosis often leads to treatment for many patients who otherwise would not have received it. Several studies have shown that early treatment reduces future fracture risk and hospitalizations⁽²⁷⁻²⁹⁾. One report specifically highlights the cost-effectiveness of VFA in postmenopausal women with osteopenia⁽³⁰⁾. While formal evidence is still limited, the balance between low costs and significant clinical benefits suggests that this diagnostic strategy is likely cost-effective. Thus, using VFA in combination with FRAX without BMD offers a valuable and potentially cost-effective method for osteoporosis diagnosis.

A limitation of the current study is that the sample was not fully representative of the general population. The sample size may also have been insufficient for robust subgroup analyses, particularly in certain age groups, which could potentially lead to misinterpretations of the data. However, the study does reflect the population typically encountered in routine clinical practice, without any selective bias, and provides valuable insights into the management of osteoporosis in this context.

CONCLUSIONS

The combined use of Vertebral fracture assessment and FRAX without BMD offers a simple, highly effective method for diagnosing osteoporosis in elderly patients, especially in all men and women aged 70-80 years at minimal cost. Given its ease of implementation and low resource requirements, we suggest that this approach could serve as a valuable screening tool, particularly in settings where BMD testing is unavailable or impractical.

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