

FRACTURE RISK ESTIMATION IN ALBERTA

BONE MINERAL DENSITY REPORTS AND CLINICAL ASSESSMENTS DO NOT AGREE

A VISUAL RESEARCH ABSTRACT

STUDY POPULATION

190 postmenopausal women who had a recent bone mineral density (BMD) scan and attended a consultation at an osteoporosis specialty clinic.

OBJECTIVE

To determine how frequently the fracture risk estimates on BMD reports (using CAROC) agree with risk estimates generated in a clinical encounter (using FRAX®).

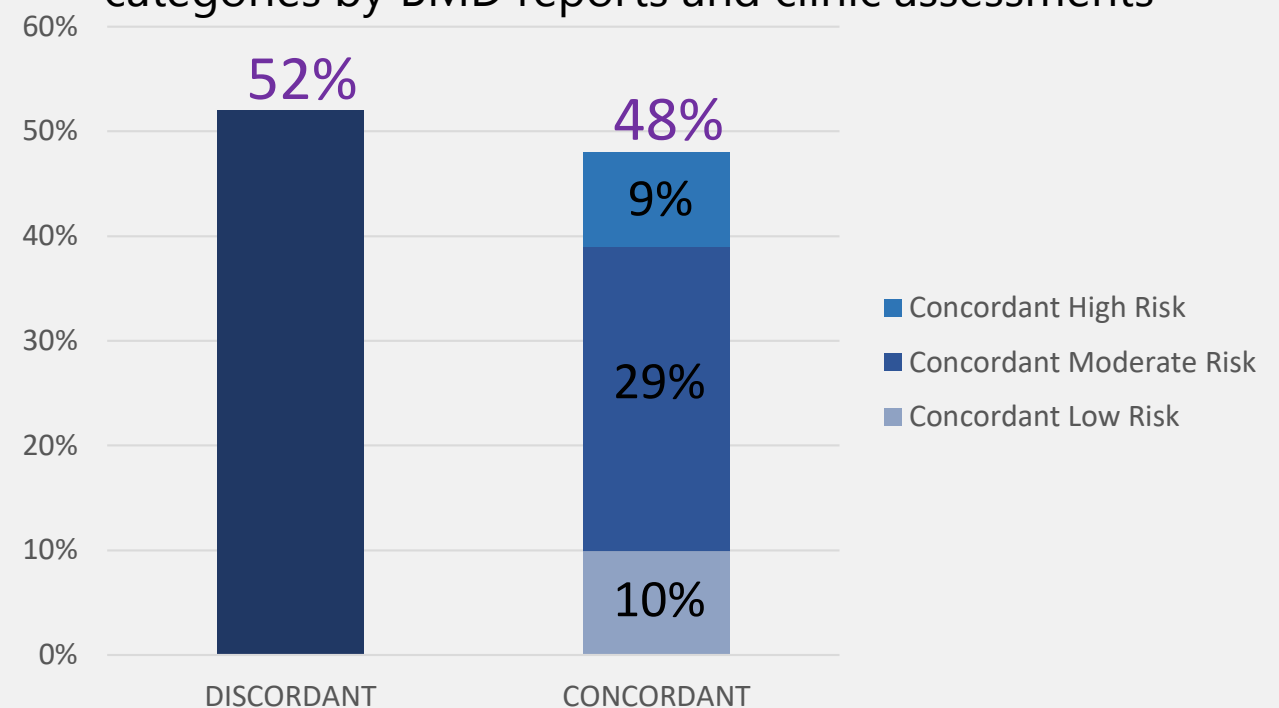
10Y FRACTURE RISK ESTIMATES

	BMD Reports	Clinic Assessments
Low Risk (<10%)	14%	43%
Moderate Risk (10-20%)	68%	38%
High Risk (≥20%)	18%	19%

DOCUMENTED FRACTURE HISTORY

	BMD Reports	Clinic Assessments
Prior fracture documented	21%	31%

Percentage of patients placed in the same (concordant) or different (discordant) fracture risk categories by BMD reports and clinic assessments



Risk estimates and fracture histories provided on bone mineral density reports frequently disagree with clinical assessments.
A consistent and accurate fracture risk assessment process is required.

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Fracture risk estimation in Alberta: Bone mineral density reports and clinical assessments do not agree

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Abstract

Background: Osteoporosis guidelines recommend pharmacotherapy for individuals with ten-year osteoporotic fracture risk $\geq 20\%$, with consideration of pharmacotherapy if risk $\geq 10\%$. Risk can be estimated using either the CAROC or FRAX[®] tools. Risk estimates are routinely provided on bone mineral density (BMD) reports and can also be calculated in the clinical setting. We aimed to determine whether these approaches produce different estimates.

Methods: We reviewed BMD reports and clinic charts of women who attended an osteoporosis clinic. Ten-year osteoporotic fracture risk estimates provided on BMD reports (with CAROC), and generated through osteoporosis clinic consultation (with FRAX[®]), were categorized as low ($<10.0\%$), moderate ($10.0\text{--}19.9\%$), or high ($\geq 20.0\%$). Estimates were considered discordant when they placed the patient in different risk categories.

Results: Of 190 patients evaluated, 99 (52.0%) had discordant risk estimates. Although a similar proportion were considered high-risk by BMD reports (17.9%) and clinic charts (19.5%), these risk estimation methods did not identify the same patients as being high-risk. Around the crucial high-risk treatment threshold, discordance was present in 37 of 71 patients classified as high-risk by either method (19.5% of all patients); discordance around the moderate-risk threshold was present in 32.6% of patients. BMD estimates placed 38.9% of the cohort in a higher risk category than clinic estimates. Disagreement regarding fracture history between BMD reports and clinic charts was observed in 19.8% of patients.

Conclusion: Fracture risk estimates on BMD reports frequently disagreed with estimates calculated at an osteoporosis clinic, highlighting the need for a consistent and accurate fracture risk assessment process.

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Introduction

Up to 50% of women and 20% of men will sustain an osteoporosis-related fragility fracture after age 50.¹ Available treatments can reduce the risk of fracture, but identification of individuals who are at the highest risk of sustaining a fracture and therefore most likely to benefit from therapy has proved challenging.^{2,3}

The Osteoporosis Canada guidelines recommend fracture risk assessment for men and women aged 65 or older, as well as younger individuals with established risk factors. These guidelines recognize a ten-year osteoporotic fracture risk of less than 10% as ‘low risk’, 10-20% as ‘moderate risk’ and 20% or more as ‘high risk’, with pharmacologic therapy to be recommended for individuals in the high risk category and considered for those at moderate risk.⁴ In Canada, either the FRAX^{®5} or the Canadian Association of Radiologists and Osteoporosis Canada (CAROC)⁶ tools can be used to estimate fracture risk. Both of these tools (compared in Table 1) are validated in Canadian populations, incorporate clinical risk factors, and provide a ten-year estimate of osteoporotic fracture risk.⁵⁻⁸ However, FRAX[®] and CAROC have several differences. While both CAROC and FRAX[®] account for patient age, history of fragility fracture, and glucocorticoid use, FRAX[®] alone incorporates several additional key clinical risk factors.

In accordance with current guidelines,⁴ most Canadian BMD reports provide a ten-year fracture risk estimate in addition to the bone density result. Risk estimates can also be calculated in the clinic setting, where they provide an entry point into a shared decision-making process regarding initiation of pharmacologic therapy. However, the current process of generating and

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3 presenting fracture risk estimates on BMD reports frequently differs from the process used in a
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5 clinical osteoporosis assessment. For example, many radiologists prefer to use the CAROC tool
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7 to generate fracture risk estimates for BMD reports,⁹ while the FRAX[®] tool is favoured in clinical
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9 encounters.^{9,10} Additionally, ascertainment of fracture risk factors often varies between the
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11 radiology office, where this information may require collection via patient survey,⁹ and primary
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13 care or osteoporosis clinics, where patients are interviewed directly and medical records
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15 reviewed. These differences in the process of fracture risk assessment may introduce variations
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17 to risk group classification between BMD reports and clinic assessments, and such variation
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19 could have a major impact upon the treatment decision-making process.
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28 The frequency and extent to which risk estimates provided on BMD reports differ from
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30 estimates generated in the clinic setting has not been evaluated in 'real world' practice. We
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32 sought to determine how frequently the risk estimates provided on BMD reports (calculated
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34 using CAROC) place patients in a different fracture risk category than estimates calculated in an
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36 osteoporosis clinic (using FRAX[®]), and to seek possible explanations for these differences.
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Methods

We reviewed the charts of women referred to our multidisciplinary osteoporosis centre for postmenopausal osteoporosis who attended an initial consultation between January 2016 and June 2019. This study was approved by the local Conjoint Health Research Ethics Board.

The Dr. David Hanley Osteoporosis Centre (DHOC) is a multidisciplinary clinic in Calgary, Alberta, serving a catchment area of more than 2 million people. At our centre, bone health consultations involve adjudication of fracture risk factors by an osteoporosis specialist and fracture risk estimation using FRAX®.

Included patients were postmenopausal women age ≥45 years who had a community-based BMD measurement within the 24 months prior to consultation where the report included femoral neck T-score and a fracture risk statement. To qualify for inclusion, patients also had a FRAX®-generated fracture risk estimate documented in their osteoporosis clinic chart, derived at the time of in-person consultation. Patients with complex metabolic bone disease, treatment failure/adverse events, questions about stopping therapy and/or ‘drug holidays’ and those without BMD reports or fracture risk estimates were excluded.

The following information was extracted from each patient’s osteoporosis clinic consultation note: fracture risk factors relevant to FRAX® and ten-year fracture risk estimates (calculated using FRAX® Canada with BMD). In addition to the chart review, each patient’s most recent BMD report was reviewed for the following reported data: BMD T-scores (lumbar spine,

femoral neck, total hip), fracture risk factors relevant to CAROC (prior fracture or glucocorticoid use), and ten-year fracture risk estimate (calculated using CAROC).

Each patient was classified as being 'low risk' (<10.0%), 'moderate risk' 10.0-19.9%) or 'high risk' ($\geq 20\%$) based on the risk estimate provided on their BMD report and the estimate from their osteoporosis clinic consultation. Risk classifications were considered concordant when both estimates placed the patient in the same risk category and discordant when estimates placed the patient in different risk categories.

Clinical risk factors recorded on BMD reports were compared to the risk factors listed in clinic consultation letters. For fracture risk factors that are common to both CAROC and FRAX[®] (i.e. prior fracture and glucocorticoid use), the proportion of patients with discrepancies between recorded risk factor status in BMD reports and clinic charts was calculated. The proportion of patients with FRAX[®]-specific risk factors (Table 1) listed in clinic charts was also determined.

The pre-specified primary outcome was the proportion of patients with discordant risk classifications. Secondary outcomes were: 1) proportion with discordant risk classifications around the high risk treatment threshold, 2) proportion with discordant risk classifications around the moderate-risk threshold, 3) proportion placed in a low risk category by one estimate and high risk category by the other estimate (i.e. severe discordance), and 4) likelihood of having a discordant estimate if there was a discrepancy in risk factor adjudication

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between the BMD report and osteoporosis clinic chart for clinical risk factors common to both CAROC and FRAX[®], or if a FRAX[®]-specific clinical risk factor was present.

Proportions of patients with discordant fracture risk estimates were estimated using the Wilson calculation to determine 95% confidence intervals (CIs).¹⁵ The proportion of patients with FRAX[®]-specific risk factors and the proportion with discrepancies in adjudication of common CAROC and FRAX[®] risk factors (prior fracture and glucocorticoid use) between BMD reports and clinic charts was determined. A two-tailed Chi-square test was used to assess comparisons. Quantitative analyses were done with SAS version 9.4 (SAS Institute, Cary, NC, USA).

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Results

Demographic characteristics and fracture risk factors for all 190 patients are displayed in Table 2. A total of 99 (52.1%, 95% CI: 45.0-59.1%) had discordant risk group classifications, as shown in Table 3. BMD risk estimates placed 74 (38.9%) patients in a higher risk category than osteoporosis clinic estimates, while clinic estimates placed 25 (13.2%) patients in a higher risk category than BMD reports. Importantly, although a similar overall percentage of the study cohort were classified as high risk by clinic estimates (19.5%) and BMD estimates (17.9%), these high-risk patients were not the same individuals in each of the two risk estimation methods. That is, 37 patients (19.5%, 95% CI: 14.5-25.7) had discordance around the clinically relevant high risk (20%) threshold (Table 3). A total of 81 (42.6%) patients were classified as being low risk by osteoporosis clinic estimates, compared to 26 (13.7%) with BMD estimates. In total, discordance around the low-to-moderate (10%) risk threshold was observed for 62 (32.6%) of patients. That is, use of a 10% risk threshold would qualify 164 (86.3%) patients for treatment consideration based on BMD estimates compared to 109 (57.4%) patients based on osteoporosis clinic estimates ($p < 0.0001$ for difference). There were 7 (3.7%, 95% CI: 1.8-7.4) patients with markedly discordant risk classifications (i.e. low risk by one estimate and high risk by the other).

Glucocorticoid use was reported by three (1.6%) of 185 patients for whom data were available, discrepancies between the BMD report and osteoporosis clinic chart were present in two. A

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history of fragility fracture was reported by 67 (35.8%) of 187 patients for whom data were available. As shown in Table 4, discrepancies between the BMD report and the osteoporosis clinic chart were present in 37 (55.2%) of these patients. Patients with discrepancies in fracture history between BMD reports and clinic charts were no more likely to have discordant risk estimates than patients whose fracture history was consistent between the two sources (54.1% vs 52.0%, $p=0.97$). Of the 37 patients with inconsistencies in fracture history between BMD reports and clinic charts, 28 had a history of fracture reported in their clinic chart but not their BMD report. We considered how the inclusion of these fractures in the CAROC-generated risk estimate provided on the BMD report would affect risk category discordance for each of these patients. For 13 of 28 (46.4%), inclusion of the fracture would result in a change from concordant to discordant, while for 12 (42.9%), inclusion of the fracture would result in a change from discordant to concordant. For the remaining three patients, including the fracture in the CAROC-generated risk estimate would not affect the agreement in risk categorization.

The proportion of patients with clinical risk factors that are included in FRAX[®] but not CAROC (i.e. parental hip fracture, smoking, rheumatoid arthritis, alcohol use) are shown in Table 2. In total, 45 individuals had FRAX[®]-specific risk factors, and these patients were no more likely to have discordant risk classifications than those without FRAX[®]-specific risk factors (42.2% vs 55.2%, $p=0.13$) suggesting that discordance in risk classification was not explained by FRAX[®]-specific risk factors.

Discussion

We observed that more than half of women evaluated at an osteoporosis clinic were placed in different fracture risk categories by their BMD reports and their clinic risk assessments.

Discordance around the crucial high risk (20%) treatment threshold was present in a fifth of patients, and discordance around the moderate risk (10%) threshold was present in a third.

BMD reports tended to produce higher risk estimates than clinic assessments. That is, patients were 1.5 times as likely to be classified as moderate or high risk on BMD reports than clinic charts, and 3 times as likely to be classified as low risk in clinic charts than BMD reports. Furthermore, BMD reports and clinic assessments provided differing interpretations of fracture history in a fifth of patients. Despite providing higher risk estimates in general, BMD reports did not account for almost half of the fragility fractures identified at the time of clinic assessment.

Our results corroborate prior literature showing that FRAX[®] and CAROC frequently produce different risk estimates for the same patient, even when fracture risk factors are ascertained and adjudicated in the same manner for both tools. In a prospective evaluation of more than 34,000 individuals from the Manitoba bone densitometry registry, when FRAX[®] and CAROC estimates were generated by a radiologist and then compared with one another, risk category discordance was present in 15%, rising to 31% when considering individuals with prior fracture or glucocorticoid use.¹⁰ In 135 patients from Ontario presenting with a fragility fracture, clinical risk factors were obtained from survey data and risk estimates were calculated with both CAROC and FRAX[®]. Risk category discordance was present in 33%.¹¹ Similarly, in 60 patients

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who presented with a wrist fracture and had fracture risk estimated using both CAROC and FRAX[®], discordance in risk classification was observed in more than 30%.¹²

The novel design of the present study allowed us to not only compare differences between the CAROC and FRAX[®] tools, as has been done previously,¹⁰⁻¹² but also permitted assessment of differences in the risk estimation results according to the process of clinical risk factor ascertainment between BMD assessment and personal osteoporosis clinic evaluation. We hypothesized that discrepancies in ascertainment of risk factors common to both CAROC and FRAX[®] (i.e. fracture history and glucocorticoid use) may explain some of the risk category discordance observed between BMD reports and osteoporosis clinic estimates. While glucocorticoid use was infrequent in our cohort and resulted in only two cases of discrepancy, almost one in five patients had a different fracture status listed on their BMD report than in their clinic chart. Importantly, BMD reports did not identify nearly half of fragility fractures that were documented in clinic charts. When considering the entire study cohort, these isolated discrepancies in fracture history did not change the proportions of women stratified into discordant risk categories. However, for the vast majority of individual patients who had a history of fracture documented in their osteoporosis clinic chart but not their BMD report, the inclusion of a prior fracture in the BMD (CAROC) risk estimation algorithm would result in changes in risk categorization agreement (i.e. from concordant to discordant or vice versa). Therefore, discrepancies in fracture history between BMD reports and clinic assessments are clinically relevant to individual patients and may influence treatment recommendations. Specifically, many osteoporosis guidelines recommend pharmacologic therapy for individuals

with a prior hip or vertebral fracture,^{4,13} or a recent (i.e. within the past year) fragility fracture,¹⁴ regardless of whether ten-year estimated fracture risk exceeds 20%, underscoring the importance of accurate ascertainment of fracture status to clinical decision-making.

Our findings are directly relevant to clinical care. For patients who receive conflicting information regarding fracture risk from BMD reports and clinical health care providers, this can be a cause of confusion and may impair effective shared decision-making. For patients who are provided solely with the fracture risk estimate reported on their BMD, reliance on this estimate may result in a greater proportion of individuals being recommended for pharmacology treatment, but may fail to identify many patients with a history of fragility fracture who would benefit from therapy. This study highlights a need to develop a consistent and accurate process for fracture risk assessment, which in turn raises the question of what the optimal process would entail. Evidence from other cohorts demonstrates that patients' accounts of fracture history are not always accurate, disagreeing with adjudicated data in up to 30% of cases.¹⁵⁻¹⁷ However, interactive interview and review of medical records takes time and may be considered impractical in the radiology setting.⁹ With respect to risk calculators, FRAX[®] considers more clinical risk factors than CAROC and has been shown to be more discriminative for predicting fracture risk in the Canadian population.¹⁰ Additionally, BMD reports containing FRAX[®]-generated estimates are preferred by primary care providers.¹² Taken together, these data suggest that the method of risk estimation utilized in osteoporosis clinics may have the advantage of improving accuracy and primary provider satisfaction compared with standard practice for BMD reporting, while the current BMD reporting process has the benefit of being

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efficient and practical.⁹ Collaborative discussion between radiologists, primary care physicians, and patients will therefore be required in order to reach a consensus on a process for BMD reporting and fracture risk assessment that is practical without compromising accuracy.

Although other groups have previously compared fracture risk estimates using FRAX[®] and CAROC,¹⁰⁻¹² to our knowledge, this is the first study to compare risk estimates provided on BMD reports with estimates calculated during a clinical office visit. Our results account for differences in both the fracture risk estimation tools and methods for assessment of clinical risk factors utilized by radiology and osteoporosis clinics. However, some limitations should be considered. Our inclusion criteria were limited to postmenopausal women with straightforward osteoporosis, and it is therefore unknown as to whether risk discordance may be the same or greater with more complex clinical cases. Our sample size was smaller than prior population-based registries, but our patient-level data review strengthens the validity of the individual risk profile characterizations. While this study compares risk estimates generated using FRAX[®] and CAROC, it was not intended nor powered to evaluate the discriminative accuracy of either tool. Finally, practices for BMD reporting may vary across the country, so our findings may not be applicable in all centres.

Conclusions

In postmenopausal women, fracture risk estimates provided on BMD reports using CAROC are discordant with estimates generated at clinical assessments in more than half of cases. BMD-generated risk estimates may both promote the treatment of individuals who would be

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3 deemed low risk in a clinic assessment and the under-treatment of some individuals who have
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5 previously experienced a fragility fracture. Osteoporosis treatment paradigms rely upon
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7 accurate detection of patients at high risk of fracture, and a consistent process for generation
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9 and reporting of fracture risk estimates is required. Our data support the need for a
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11 collaborative discussion between radiology and treating clinicians about the BMD reporting and
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13 fracture risk estimation process.
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Tables

Table 1. Features of FRAX® and CAROC fracture risk calculators

	FRAX®	CAROC
Clinical Risk Factors	Age (40-90) Sex Weight Height Previous Fracture in Adulthood Parent Fractured Hip Current Smoking Glucocorticoid use ^a Rheumatoid Arthritis Secondary osteoporosis Consumes ≥ 3 units alcohol/day	Age (>50) Sex Fractures since age 40 Glucocorticoid use ^b
Bone mineral density	Femoral neck BMD optional	Femoral neck BMD required ^c
Other Considerations	Incorporates competing risk of mortality Different algorithms can be utilized for different ethnicities and countries Involves interactions between variables	No competing risk of mortality No different algorithms for different ethnicities No interactions between individual variables
Type of Fractures Predicted	Hip fracture within 10y Major osteoporotic fracture within 10y	Osteoporotic fracture within 10y

^aCAROC: History of Glucocorticoid Use for 3 months or more in the past 1 year at 7.5 mg Prednisone equivalent

^bFRAX®: Exposed to oral glucocorticoids for more than 3 months at a dose of Prednisolone of 5mg daily or more or current use

^cIf fracture risk is low or undefined based on femoral neck BMD, and T-score is ≤ -2.5 at either lumbar spine or total hip, fracture risk is increased to moderate

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Table 2. Baseline characteristics of study patients

Characteristic	Mean (SD) / n (%)
Age (years)	63.2 (6.4)
Female sex, n (%)	190 (100%)
Height (cm)	161.7 (6.3)
Weight (kg)	63.6 (10.6)
Body Mass Index (kg/m ²)	24.3 (3.9)
Lumbar spine T-score	-2.34 (0.91)
Femoral Neck T-score	-2.12 (0.75)
Total Hip T-score	-1.78 (0.76)
CAROC Risk Factors, ^a n (%)	
Previous fracture	39 (20.9%)
Glucocorticoid use	1 (0.5%)
FRAX [®] Risk Factors, ^a n (%)	
Previous fracture	59 (31.0%)
Glucocorticoid use	3 (1.6%)
Parental hip fracture ^b	38 (20.0%)
Current smoker ^b	7 (3.7%)
Rheumatoid arthritis ^b	6 (3.2%)
Consumes ≥3 units alcohol/day ^b	3 (1.6%)
Ten-year FRAX [®] MOF risk (%)	13.6 (7.7)
Ten-year FRAX [®] hip fracture risk (%)	3.2 (3.6)
Fracture risk on BMD report, n (%)	
High (≥20.0%)	34 (17.9%)
Moderate (10.0-19.9%)	130 (68.4%)
Low (<10.0%)	26 (13.7%)
Fracture risk on clinic chart, n (%)	
High (≥20.0%)	37 (19.5%)
Moderate (10.0-19.9%)	72 (37.9%)
Low (<10.0%)	81 (42.6%)

Continuous variables are reported as mean (SD) and categorical variables as n (%)
CAROC = Canadian Association of Radiologists and Osteoporosis Canada, FRAX[®] = Fracture Risk Assessment Tool
^aCAROC risk factors were obtained from bone mineral density reports, FRAX[®] risk factors were obtained from osteoporosis clinic charts
^bFRAX[®]-specific risk factors (incorporated by FRAX[®] algorithm but not CAROC)

Table 3. Comparison of ten-year fracture risk estimates reported in osteoporosis clinic charts (calculated using FRAX®) and estimates presented on BMD reports (calculated using CAROC) for 190 postmenopausal women

		BMD Report			Total Discordant
		Low Risk (n=26)	Moderate Risk (n=130)	High Risk (n=34)	
Osteoporosis Clinic Chart	Low Risk (n=81)	19 (10.0%)	57 (30.0%)	5 (2.6%)	62 (32.6%)
	Moderate Risk (n=72)	5 (2.6%)	55 (28.9%)	12 (6.3%)	17 (8.9%)
	High Risk (n=37)	2 (1.1%)	18 (9.5%)	17 (8.9%)	20 (10.5%)
Total Discordant		7 (3.7%)	75 (39.4%)	17 (8.9%)	99 (52.1%)

Data presented are n (%), where percentages represent the proportion of the total cohort (n=190)

Low risk = ten-year osteoporotic fracture risk <10.0%, Moderate risk = 10.0-19.9%, High risk = ≥20.0%

Shaded cells represent patients whose BMD reports and osteoporosis clinic assessments provided discordant fracture risk classifications (i.e. the two estimates placed the patient in different risk categories)

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Table 4. Comparison of prior fragility fractures identified on BMD reports and in clinic charts among postmenopausal women who attended a clinical assessment at an osteoporosis clinic

		BMD Report	
		Fracture reported	No fracture reported
Osteoporosis Clinic Chart	Fracture reported	30 (16%)	28 (15.0%)
	No fracture reported	9 (4.8%)	120 (64.2%)

Data were available for 187 patients
BMD = bone mineral density
Shaded cells represent patients whose BMD reports and osteoporosis clinic charts provided disagreeing interpretations of fracture history

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