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ORIGINAL ARTICLE

The care gap in diagnosis and treatment of women with a fragility fracture

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Abstract
Summary In women aged 50 years or more who experienced a fracture, 81% suffered a fragility fracture. Six to eight months after fragility fracture, 79% had either not been investigated for osteoporosis or prescribed anti-fracture therapy. Despite fragility fractures being common in this population osteoporosis is under-diagnosed and under-treated.

Introduction The objective of this study was to evaluate the diagnostic and treatment rates for osteoporosis six months following fragility fracture.
Methods This prospective cohort study was set in the general community from the Province of Quebec, Canada. Women at least 50 years of age who suffered a fracture were recruited during their initial visit to the hospital and had their fracture type classified as either fragility or traumatic. Six-to-eight months after fragility fracture, women were again contacted to evaluate the diagnostic and treatment rates of osteoporosis.
Results Of the 2,075 women recruited over a 25 month period 1688 (81%) sustained a fragility fracture and 387 (19%) sustained a traumatic fracture. Nine hundred and three participants with a fragility fracture were again contacted six-to-eight months after fracture. For the 739 women not on treatment on the recruitment day, only 15.4% initiated pharmacological therapy in the six-to-eight-month period following fracture and 79.0% had either not been investigated for osteoporosis or prescribed anti-fracture treatment.
Conclusions The proportion of fragility fractures to total fractures is higher than previously reported. Despite the availability of diagnostic modalities, effective treatments, and adequate health care assessments, there is a substantial care gap in the management of osteoporosis.

Keywords Care gap · Diagnosis · Fragility fracture · Osteoporosis · Treatment

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Introduction

A personal history of fragility fracture is one of the most robust and easily-identifiable predictors of future fragility

fracture. With the risk of future fracture being increased 1.5 to 9.5 fold following a fragility fracture [1, 2], clinicians should undertake a thorough clinical investigation to identify the cause of weakened bones, educate the patient to recognize the consequences of bone fragility and fracture, and offer appropriate anti-fracture interventions. It has been previously shown that 20–25% of women who suffer fragility fractures are subsequently investigated for osteoporosis and less than half of those receive proven anti-fracture treatment [3]. Thus, a substantial care gap exists in both diagnosis and treatment of these most at-risk, and easily-identifiable, individuals.

The objectives of this paper are to report the proportion of fragility to all clinically-identifiable fractures and to determine the diagnostic and treatment care gaps six-to-eight months following a fragility fracture in women from the Province of Quebec, Canada.

Materials and methods

Recognizing Osteoporosis and its Consequences in Quebec (ROCQ) is a patient health-management programme and a prospective cohort study. The ROCQ programme enrols women 50 years old and over who have recently suffered a fracture and determines the subsequent diagnostic and treatment rates for osteoporosis in those who experienced a fragility fracture. Following this, the women with a fragility fracture are randomized into one of two specific educational interventions, designed to improve osteoporosis management, or into a control group (results of this segment of the study reported in subsequent papers).

Setting and participants

The protocol was submitted to 24 community and university hospitals in three socio-demographic regions in the Province of Quebec, Canada. The ethics committees of 18 hospitals, representing 70% of the orthopaedic practice for the three regions, accepted to participate in the ROCQ programme. This population represented approximately half of all postmenopausal women residing in Quebec. Consecutive women presenting to hospitals or to rehabilitation centres with a fragility or a traumatic fracture were potentially eligible. Inclusion criteria were as follows: aged 50 years or over, not residing in a long-term care hospital before fracture, able to understand programme information and consent form, and able to answer questionnaires via phone interviews. Fragility fracture was defined as a fracture that occurs spontaneously or following a minor trauma, such as a fall from standing height or a height less than a meter, a fall from sitting or a fall from laying down from less than a meter high, a fall after having missed one to three steps, after a movement outside of the typical plane of motion, or coughing [4–9].

Participants with a fracture of one of the following sites were ineligible: cervical spine, skull or face, hand or finger, toe, metatarsus, or patella. These fracture sites were not considered osteoporotic, because they are not associated with low bone mineral density (BMD) and their frequency does not increase with age [8].

Patients were excluded from the programme if their fracture was deemed pathologic, defined as occurring at the site of an underlying metabolic bone disease, such as Paget's disease of bone, a brown tumor associated with hyperparathyroidism, multiple myeloma, osteopetrosis, renal osteodystrophy, osteomalacia, osteogenesis imperfecta, or an osteolytic lesion related to a benign tumor or primary/metastatic neoplasia. Women participating in a clinical trial requiring them to take an osteoporosis medication were also excluded.

Study design

Phase 1

Women were initially approached either by ROCQ personnel or a member of the hospital staff in outpatient or cast clinics, or during their stay in either the orthopaedic unit or in a rehabilitation centre up to 16 weeks following their respective fracture date. Potential participants were invited to sign an authorization form allowing ROCQ personnel to later contact them by phone. Each woman received two copies of the consent form.

Within one week after receiving the authorization form, responding patients were contacted by phone by a trained interviewer. A predetermined phone script was read in order to standardize the method of recruitment. During this call no reference was made to the link between fragility fracture and osteoporosis. However, the link between a fracture and the risk of sustaining a subsequent fracture was revealed. During the phone contact, inclusion and exclusion criteria were reviewed and information pertaining to the programme was provided. Those agreeing to participate were asked to sign, date, and return one copy of the consent and to retain one copy for their records. Women who provided consent agreed to be contacted again by the ROCQ personnel by phone six-to eight months following the fracture date to complete a questionnaire.

All women, whether they accepted or refused to enter the programme, were asked to complete either an entry questionnaire or a refusal questionnaire that collected information regarding the anatomic site, cause and circumstances of their fracture. These questionnaires, which were adapted with permission from the Canadian Multicentre Osteoporosis Study fracture questionnaire [10], helped determine whether their fracture was a fragility or traumatic

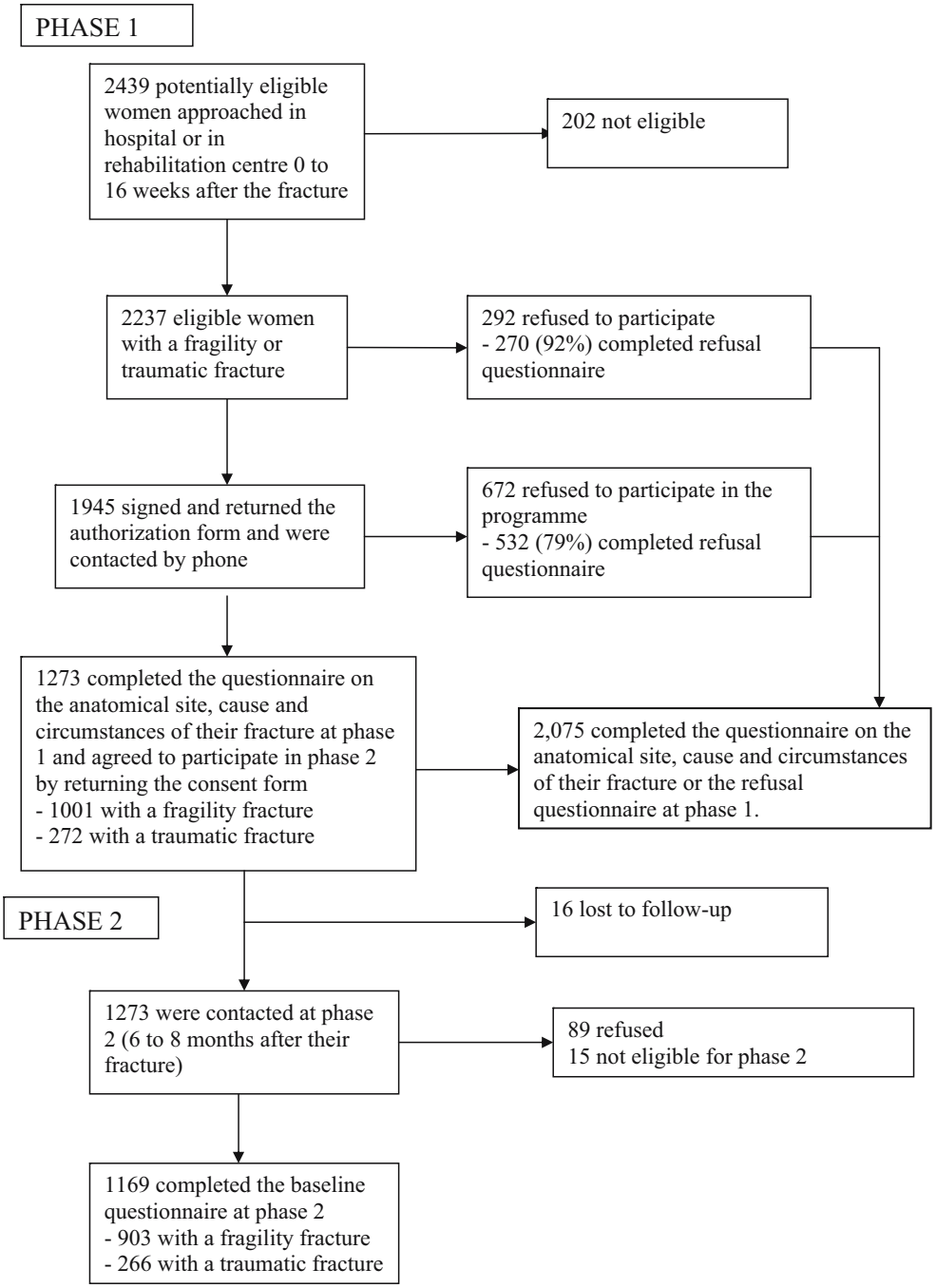

Fig. 1 Patient flow through the study

fracture. If doubt existed as to the fracture type, the fracture was categorized by an osteoporosis-specialist committee within the ROCQ programme.

Phase 2

Six to eight months after the fracture, all consenting participants were re-contacted by phone for the phase 2 baseline questionnaire which was completed with a 45 to 60-minute phone interview using a predetermined phone script. At this point, participants were informed about the relationship between their fracture and osteoporosis. For participants with a fragility fracture, the questionnaire reviewed personal and clinical characteristics, current and past anti-fracture medication use, investigations for osteoporosis, any co-morbidities, risk factors for fracture, and health care resources utilization. The interviewer and the investigator had no access to the BMD test results, if applicable. However, participants who had a BMD test were asked if their bone density was “high or normal”, “low without osteoporosis (osteopenia)”, or “low or osteoporotic”. This questionnaire contained questions that

established the baseline level of care provided by the health care system. Therefore, the "baseline care gap" in diagnosis and treatment was measured by evaluating the current diagnostic and treatment rates for osteoporosis and then comparing it to the optimal situation. Women who refused to participate in phase 2 were invited to answer a short refusal questionnaire in order to evaluate possible selection bias. Participants with a traumatic fracture had a similar but shorter questionnaire. The characteristics of this group at phase 2 will not be presented in this paper.

Outcomes and measurements

The primary outcomes were 1) the relative proportion of fragility and traumatic fractures in women aged 50 years or over at phase 1, 2) the proportion of women with fragility fracture who received a diagnosis between phases 1 and 2, and 3) the proportion of women with fragility fracture who received a treatment, between phases 1 and 2. The primary end-points were evaluated by using the questionnaires administered in phases 1 and 2. For the primary outcome of osteoporosis diagnosis, a woman was considered "diagnosed" if one or more of the following occurred: 1) received a central DXA BMD test between phases 1 and 2 with a diagnosis of osteoporosis 2) informed by a physician that she suffers from osteoporosis; and/or 3) initiated a pharmacological therapy. For the primary outcome of osteoporosis treatment, if a woman initiated a bisphosphonate, raloxifene, nasal calcitonin or teriparatide, she was considered "treated."

Statistical analysis

From the database, standard descriptive statistics (proportions, mean, SD, median and quartiles) were performed to characterize the study population. The relative proportions of fragility and traumatic fracture and the proportions of women having received a diagnosis and/or a treatment for osteoporosis were obtained by performing contingency tables. For the comparison of proportions a Chi-squared test was used and for the comparison of means a t-test was used. All statistics were performed using SAS software version 9.1 (SAS, Cary, NC, USA).

Results

Recruitment started in September 2003 and all centres were recruiting by November 2004. After 25 months of recruitment, 2,439 women were approached and 2,237 were eligible to participate in the programme. Figure 1 displays patient flow through the study. The participation rate at Phase 1 was significantly ($p<0.05$) lower among older women (70+ years old) as compared to younger women (50–69.99 years of age). The mean (SD) age of the refusal group was 70.2 (11.2) years compared with 63.2 (9.0) years of those who agreed to participate ($p<0.001$). The proportion of fragility fractures was significantly higher in the group of women who refused to participate in phase 2 of the programme (85.7% vs.78.0%; $p<0.001$). The distribution of fracture sites was similar between groups, except for the proportion of hip/femur fracture, which was higher in the refusal group (12% vs.5%; $p<0.001$).

Phase 1 - proportion of fragility vs. traumatic fractures

The proportion of fragility and traumatic fractures was determined with data from the 2,075 women (mean age: 65.8 SD:10.4 years) who completed the questionnaire on the anatomic site, cause and circumstances of their fracture or the refusal questionnaire at the first contact in the hospital or during the phone interview at phase 1. Of these women, 1,688 sustained a fragility fracture (81%) and 387 (19%) experienced a traumatic fracture. The proportion of fragility fractures was higher than expected in all age groups and increased significantly with age ($p<0.001$; Fig. 2). Between the ages of 50 to 59 years old, 75.7% of the women approached to participate in the programme suffered of a fragility fracture. This proportion increased to 91.8% in the group over the age of 80.

The most common fracture sites were of the wrist/forearm, ankle, humerus, and tibia/fibula (Table 1). The distribution of fracture sites was similar for both fragility and traumatic fracture groups. For each fracture site, the proportion of fragility fractures varied from 70% to 90%. The proportion of fragility fractures was the highest for those women who sustained a fracture of the hip or femur.

A total of 167 women with hip/femur fracture were approached to participate in the programme and 66 (40%) signed the consent form to participate in phases 1 and 2. These women were difficult to recruit because they were on average older, had more comorbid conditions, and were

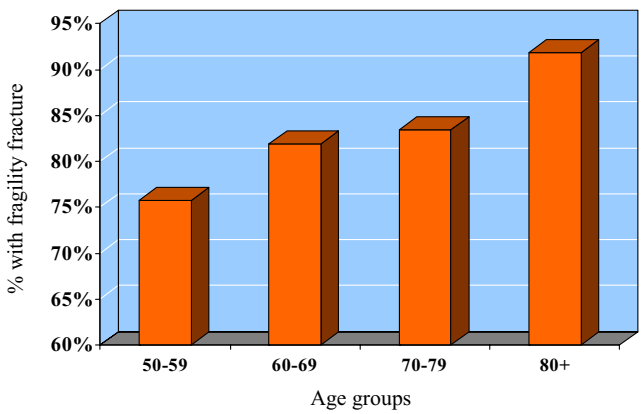

Fig. 2 Proportion of fragility fracture by age group

Table 1 Fracture distribution profile for all women approached to participate in the ROCQ programme

Site of fracture		Fragility fracture		Traumatic fracture	
	% of all fractures	% by site[a]	Proportion (%)[b]	% by site[a]	Proportion (%)[b]
Wrist/forearm	43.2	44.0	82.0	39.9	18.0
Ankle	16.6	17.3	84.0	13.5	16.0
Humerus	12.6	12.1	77.2	14.7	22.8
Tibia/fibula	7.8	6.9	71.3	11.4	28.7
Hip/femur	7.6	8.5	89.2	4.2	10.8
Other	12.2	11.3	74.1	16.3	25.9

[a] For fragility and traumatic fractures, distribution by site
[b] For each site, proportion of fragility vs.traumatic fracture

often confused due to analgesic medications. Lastly, very few women with vertebral fractures were recruited in the study (0.5% of all fractures observed).

Phase 2 - the care gap

Of the 1,273 participants who accepted to participate in phases 1 and 2 of the programme, 1,001 (79%) experienced a fragility fracture as determined at phase 1. Of the women with a fragility fracture who were contacted again for phase 2 (mean time of 7.5 months±1.2), 903 (90%) accepted to complete the questionnaire 6 to 8 months after their index fracture (mean age: 63.5 SD: 9.2 years). The baseline characteristics of this group are presented in Table 2. Ninety-four percent of the participants had a regular medical clinic or physician to attend to their health care. During the 6 to 8 months following their fracture, 14.2% of the participants with a fragility fracture consulted a physician, other than an orthopaedic surgeon, regarding their fracture and 66.0% for unrelated health problems. Overall, 71.1% consulted a physician after the fracture event and had the chance to be informed of the relation between their fracture and osteoporosis.

Of the 903 women with a fragility fracture, 31.8% had at least one other fracture after the age of 40 years and before the index fracture for this investigation. Twenty-four percent of the participants had been informed by a physician of having osteoporosis before the current fracture. More than half (52%) of the women had their BMD assessed by dual-energy x-ray absorptiometry before the programme. Of these 470 who had a BMD measurement, 43% were told that they had a diagnosis of osteopenia or osteoporosis based on the BMD results.

One hundred and sixty four women (18.2%) were already on treatment for osteoporosis at the time of their fracture at phase 1 and 7.0% had previously received a treatment for osteoporosis but had stopped before the index fracture (Table 2). Of those with no treatment at phase 1 (739 participants), 15.4% initiated a pharmacological therapy in the 6 to 8-month period following their fracture. At phase 2, 21.0% of participants either received a diagnosis of osteoporosis or were on treatment (Table 3). Only 10% were informed that the cause of their fracture was bone fragility or osteoporosis.

Twenty-eight percent (207 participants) of the women not treated at phase 1 had a BMD measurement between phases 1 and 2. Table 4 shows the influence of the BMD test and the result the test had on treatment. Generally, women were more likely to start treatment if they had a

Table 2 Baseline characteristics of women with a fragility fracture who completed the phase 2 questionnaire six to eight months after the fracture event (n=903)

Baseline characteristic	%
≥65 years	39.3
Education level	
Elementary/secondary	56.1
College/university	43.9
Employment status	
Employed	35.9
Retired	42.4
Other	21.7
Living alone	37.2
Smoker	15.2
Currently taking calcium supplements	62.5
Currently taking vitamin D supplements	58.2
Fracture >40 years	31.8
Family history of osteoporosis	44.4
Participants with a regular medical clinic of physician	93.8
Consulted a physician other than orthopaedic surgeon between phases 1 and 2	
For all participants	71.1
For participants not treated at phase 1 (n=739)	70.0
Informed of having osteoporosis before the current fracture	24.0
Treatment for osteoporosis before the current fracture	
Received a diagnosis, never treated	7.0
Treatment stopped before the current fracture	7.0
On treatment for osteoporosis when started ROCQ	18.2
BMD measurement before the current fracture	52.0
BMD measurement between phases 1 and 2	26.1

Table 3 Diagnostic and treatment rates of osteoporosis between phases 1 and 2 for those women not treated at Phase 1

N=739	%
No diagnosis or treatment between phases 1 and 2	79.0
Diagnosis only	5.5
Received a treatment but discontinued before phase 2	2.2
Prescribed, but have not started the treatment	1.2
Treated at phase 2	12.0

BMD measurement and if that test resulted in a diagnosis of osteopenia or osteoporosis. Women aged 65 years and older were more likely to start a medication for osteoporosis compared to the younger group (22.4% vs.11.6%). Other factors such as marital status and living alone, education level, employment status, history of fracture after age of 40 years and family history of osteoporosis were not associated with initiation of osteoporosis treatment.

Discussion

In this investigation, the proportion of fragility fractures to all clinically-apparent fractures was approximately four out of five women over 50 years of age who sought medical attention. Few studies have reported the proportion of fragility and traumatic fractures in the general population. Iskrant et al. [11] prospectively reported the incidence of fragility fracture in 2100 Michigan women aged 45 and older. Of the 325 women who sustained a fracture over a 3-year period, 70% were diagnosed as osteoporotic. However, the diagnosis of osteoporosis was based on bone density assessed by a lateral x-ray of the thoraco-lumbar spine and the circumstances surrounding the fracture were not recorded. More recently, Sanders et al. [12] estimated that the proportion of fragility fractures in women aged 35 years and older to be 77% based on criteria similar to those used in this investigation.

It is assumed that bone fragility does not contribute to fractures associated with high trauma. However, trauma is difficult to define given that the forces applied to a bone cannot be accurately deduced from a description of the event. Although 81% of the fractures were considered fragile in the ROCQ programme, it is also likely that a proportion of the traumatic fractures were experienced by women with bones that would be considered fragile in atraumatic circumstances. This was suggested by Sanders et al. [12] in a study in which the authors compared the BMD of women who sustained fractures in either low or high trauma events with the BMD of a random sample of women from the same population. They showed that the BMD Z-scores were reduced similarly in both the low and high trauma groups. Those who sustained a fracture, irrespective of the classification of trauma, were approximately three times more likely to have osteoporosis compared to women in the same population without a fracture. Karlsson et al. [13] also reported that people with a previous traumatic tibial or ankle fracture had a higher risk of sustaining a future fragility fracture compared with people who did not have a previous fracture.

Table 4 Influence of the BMD test and BMD result between phases 1 and 2 on the care gap for the women not treated at phase 1 (n=739)

	% Starting treatment between phases 1 and 2
No BMD test (N=532)	10.5
BMD test between phases 1 and 2 (N=207)	28.0
Result of the BMD test	
Don't know (N=65)	16.9
Normal (N=67)	9.0
Low or osteopenia (N=34)	29.4
Very low or osteoporosis (N=41)	75.6

The occurrence of a prior fragility fracture is easily identifiable and should result in diagnostic tests and effective treatment, if required. This investigation found that a low number of women were properly diagnosed with osteoporosis and a lower proportion was provided anti-fracture therapy. Several therapeutic options available for the treatment of osteoporosis have demonstrated rapid anti-fracture efficacy within the first year of therapy [14–17], some within the first six months [16, 18]. Therefore, it is possible that if many of these women had received timely diagnoses and treatment, they may have benefited from their therapies already at the 6–8 month follow-up period. More than half of the women at baseline were taking calcium (62%) and vitamin D (58%), which can be considered a form of active anti-fracture therapy. According to Osteoporosis Canada's evidenced-based guidelines for the treatment and prevention of osteoporosis [19] adequate calcium and vitamin D are important adjuncts to therapies with proven anti-fracture efficacy, but are not enough alone to prevent fractures in those with osteoporosis. The superiority of calcium and vitamin D combined with a proven anti-fracture therapy compared to calcium and vitamin D alone can be easily supported by comparing the treatment (active therapy + calcium and vitamin D) and "active placebo" (calcium + vitamin D) arms from many of the large RCTs dealing with anti-fracture therapies [14, 20, 21].

In Quebec, there is universal healthcare and coverage for anti-fracture therapy; therefore, there is both access to medical treatment and funds available to offset therapy cost. Despite this, very few women were properly diagnosed and fewer received treatment for their disease. Furthermore, access to care was not a problem since 71% of these women consulted a physician, other than an orthopaedic

surgeon, within six months following their fracture. However, the reason for medical consultation was not recorded. Compared to other health problems, physicians may give a low priority to osteoporosis and fracture prevention.

The results of this investigation demonstrate that physicians based their decision to treat on the BMD results and not on the clinical event (fragility fracture) despite evidence clearly showing that the very occurrence of a fragility fracture represents a greater risk of future fragility fracture than a low BMD measurement. It is critical to recognize that low BMD is only a surrogate marker of osteoporosis, and that the clinically significant event resulting from the disease is fragility fracture.

There are a few limitations to this study. The distribution of women was skewed with an over-representation of younger women and an under-representation of older women. This trend was due to the significant number of refusals in those who suffered a fragility fracture and were above 70 years of age (>40%). The recruitment strategy used in this protocol didn't capture vertebral fractures as patients with vertebral fracture are generally not seen in cast or outpatient clinics during their follow-up. Approximately two-thirds of vertebral fractures go unnoticed [22]. In this investigation, vertebral fractures accounted for a small proportion (0.5%) of all fractures, whereas data from CaMos would suggest that at least a quarter of individuals over 50 years of age have a vertebral fracture [23].

In summary, 81% of eligible women approached to participate in the ROCQ programme were deemed to have suffered a fragility fracture. Therefore, a large proportion of women over the age of 50 who suffer a fracture could be diagnosed as osteoporotic or as having suboptimal bone strength and would likely benefit from anti-fracture therapies. Approximately three out of every four women who suffered a fragility fracture did not receive a diagnosis or treatment for osteoporosis 6–8 months following their fragility fracture. These findings underscore the high prevalence of fragility fractures and the lack of diagnosis and treatment of osteoporosis in the Province of Quebec in women over the age of 50 years. Strategies to increase diagnosis and osteoporosis treatment to close the care gap are needed.

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