

Differing perceptions of intervention thresholds for fracture risk: a survey of patients and doctors

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Abstract

Summary This survey suggests that patients are prepared to accept higher absolute fracture risk than doctors, before considering pharmacological therapy to be justified. Patients require that drug treatments confer substantial fracture risk reductions in order to consider long-term therapy.

Introduction Absolute fracture risk estimates are now incorporated into osteoporosis treatment guidelines. At present, little is known about how patients regard fracture risk and its management. We set out to describe and compare the views of patients and doctors on the level of fracture risk at which drug treatment is justified.

Methods A cross-sectional survey was conducted on 114 patients referred for bone density measurement and 161 doctors whose practice includes management of osteoporosis. Participants were asked about fracture risk thresholds for pharmacological intervention.

Results The absolute risk of both major osteoporotic fracture and hip fracture at which drug treatment was considered by patients to be justifiable was higher than that reported by doctors [major osteoporotic fracture, median (interquartile range): patients, 50% (25 to 60); doctors, 10% (10 to 20); $P<0.0001$; hip fracture: patients, 50% (25 to 60); doctors, 10% (5 to 20); $P<0.0001$]. Patients required that a drug provide a median 50% reduction in relative risk of fracture in order to consider taking long-term therapy,

irrespective of the treatment mode or dosing schedule. Among doctors, there was an inverse relationship between the number of osteoporosis consultations conducted each month and threshold of risk for recommending drug treatment ($r=-0.22$ and $r=-0.29$ for major osteoporotic fracture and hip fracture, respectively, $P<0.01$ for both). **Conclusions** Patients are prepared to accept higher absolute fracture risk than doctors, before considering pharmacological therapy to be justified. Patients require that drug treatments confer substantial fracture risk reductions in order to consider long-term therapy.

Keywords Doctors · Fracture · Medications · Patients · Risk

Introduction

Osteoporosis is a common disorder: approximately 50% of women and 20% of men over the age of 50 will suffer a fracture during their lifetime [1]. Fragility fractures are associated with very substantial health care costs, considerable morbidity, and increased mortality [1]. Currently, strategies for reducing fracture risk are centred on pharmaceutical interventions in people estimated to be at high fracture risk [2], using algorithms which integrate clinical risk factors and bone mineral density (BMD) measurements [3, 4]. Absolute fracture risk estimates have been incorporated into treatment guidelines developed by influential scientific and advocacy organisations [5–7].

Treatment guidelines advise practitioners about levels of fracture risk at which intervention should be considered. However, a decision to intervene involves two parties, the practitioner and the patient, who must reach agreement in order that treatment is successfully undertaken. Discordance between the views of the patient and the physician on

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the necessity of intervention may adversely affect adherence to, and persistence with, treatment [8]. Several effective medications are available to reduce fracture risk [2], but rates of initiation of therapy are low [9], medium-term persistence with treatment is low [10], and low perceived need for treatment predicts non-persistence [11].

At present, little is known about the views of patients on fracture risk and its management. In the current work, we surveyed views on fracture risk and its management in patients referred for measurement of BMD and physicians involved in management of skeletal health. We specifically aimed to compare the views of patients and doctors on the severity of osteoporosis and the levels of fracture risk justifying pharmaceutical intervention, and to investigate the effects of dosing regimens and mode of administration of currently available therapies on the degree of fracture risk reduction required by patients to consider taking the medication.

Methods

Participants

Adult (>18 years) patients referred for BMD measurement to a public hospital bone densitometry service were eligible to participate unless they were unable to speak English or cognitively impaired. Invitations to participate were mailed with the appointment for BMD measurement to 247 consecutive patients over a 3-month period. At the time of BMD measurement, consenting participants completed a written questionnaire and a structured interview with a research staff member (FD). All patients gave written, informed consent.

Survey information and documents were mailed to 786 general practitioners and 70 specialists in the greater Auckland area. All general practitioners and all specialists practising in disciplines likely to involve management of skeletal health (endocrinology, rheumatology, geriatrics) in the region were invited to take part. The study was approved by the Northern X regional ethics committee.

Questionnaires

Patients and doctors were asked to rate the severity of osteoporosis in comparison with that of other common disorders [12]. A score of 1 was ascribed if the disease was considered more severe and -1 if the disease was considered less severe, than osteoporosis.

Patients and doctors were asked what level of 10-year risk of breaking a bone in the spine, leg, arm, shoulder, pelvis (major osteoporotic fracture), or specifically of breaking a hip, on a scale from 0% no chance to 100% definitely will have a fracture, they would regard as high enough to consider taking or prescribing a preventative medicine.

Patients were asked what reduction in fracture risk they would require, from 0% no reduction to 100% completely prevent, in order to accept lifelong treatment with a daily tablet (modelling use of calcium supplements), a weekly tablet (oral bisphosphonates), a yearly infusion (zoledronate), a daily subcutaneous injection for 2 years followed by either a weekly tablet or a yearly infusion (teriparatide followed by a bisphosphonate), or a 6-monthly subcutaneous injection (denosumab). Patients were asked to estimate, on a scale from 0% no chance to 100% will definitely have a fracture, their personal 10-year risk of major osteoporotic fracture or specifically of hip fracture.

Patients already receiving treatment for osteoporosis were asked whether their doctor had discussed fracture risk with them before recommending treatment. Doctors were asked about their use of strategies for discussing management of fracture risk with patients, specifically absolute risk reduction, relative risk reduction, and number needed to treat.

Fracture risk estimation

Information on clinical risk factors for fracture was gathered from a questionnaire completed as part of clinical care. These data were integrated with the BMD result to estimate each participant's 10-year absolute risk of major osteoporotic fracture and hip fracture using the FRAX (New Zealand version) risk algorithm [13].

Statistics

With 161 responding doctors from a sample of 856, the accuracy of response is $\pm 6.9\%$; with 114 patients agreeing to participate from a sample of 247, the accuracy of response is $\pm 6.7\%$. The achieved sample size allows differences between doctors and patients of at least 7% to be detected with 80% power at the 5% significance level (PASS 2002, NCSS and PASS Number Cruncher Statistical Systems, Kaysville, Utah, www.NCSS.COM), assuming non-normal distribution of data.

Non-normal data were compared between doctors and patients using the Mann–Whitney test. Correlations between variables were assessed using Spearman's rank correlation coefficient. Logistic regression was used to model the effects of age, gender, prevalent fracture, and prevalent osteoporosis therapy on patients' threshold of fracture risk justifying treatment. The Kruskal–Wallis test was used to compare the reduction in relative risk of fracture required by patients to justify intervention with currently available treatment regimens. A significant main effect was further examined using the Mann–Whitney test with the critical value of P corrected using the Bonferroni method to preserve an overall 5% significance level. All tests were two tailed. SAS (v9.2) and Prism (www.graphpad.com v5.2) were used for the analyses.

Results

Participants

One hundred twenty-one patients (49% of those invited) agreed to participate, of whom two were excluded because of language incompatibility. Five patients did not complete the interview. Clinical and demographic characteristics of the patients are shown in Table 1. Eighty-seven percent of the cohort were female and 83% older than 60. Almost half of the participants were taking a medication for skeletal health, of whom 24 (21% of the cohort) were taking only calcium and/or vitamin D, and 31 (27%) were taking an anti-resorptive agent, either a bisphosphonate or oestrogen.

Of the 161 doctors (19% of those invited) who completed the questionnaire, 1 did not indicate the nature of their practice. Among those who did, 136 (88%) were general practitioners (Table 2). The median (interquartile range) number of patients advised each month on skeletal health was 8 (3–15). One hundred and fifteen doctors

Table 1 Patient characteristics

Characteristic	
Age (years)	
18–59	31 (27)
60–79	66 (58)
≥80	17 (15)
Gender (M/F)	99/15
Neck of femur BMD (T-score)	-1.6±1.0
Current osteoporosis therapy	
Ca and/or vitamin D only	24 (21)
Anti-resorptive therapy	31 (27)
Body mass index (kg/m ²)	
<19	9 (8)
19–25	47 (41)
25–30	35 (31)
>30	23 (20)
Prevalent fragility fracture ^a	32 (28)
Current glucocorticoid use ^b	13 (11)
Current smoker	8 (7)
Alcohol intake >3 drinks/day	5 (4)
Falls in the past year ^c	
0	77 (69)
1	22 (20)
≥2	13 (11)

Data are n (%), n, or mean ± SD

^a Defined as low-trauma fracture during adulthood, excluding those of the hands, feet, face, skull, or ribs

^b ≥5 mg/day prednisone or equivalent

^c Percentage adjusted for non-respondents (n=2)

Table 2 Doctor characteristics

Characteristic	
Type of practice ^a	
Specialist	24 (15)
General practice	136 (84)
Consultations about skeletal health (n/month) ^b	
<10	81 (50)
10–20	39 (24)
≥20	36 (22)
Not specified	5 (3)
Attended an educational meeting in past 2 years	115 (71)

Data are n (%)

^a One doctor did not specify type of practice

^b Includes reporting bone density scans

(71%) had attended an educational meeting involving bone health within the previous 2 years.

Perceptions of disease severity

Patients and doctors ranked osteoporosis in the same position among the list of other common diseases (Fig. 1).

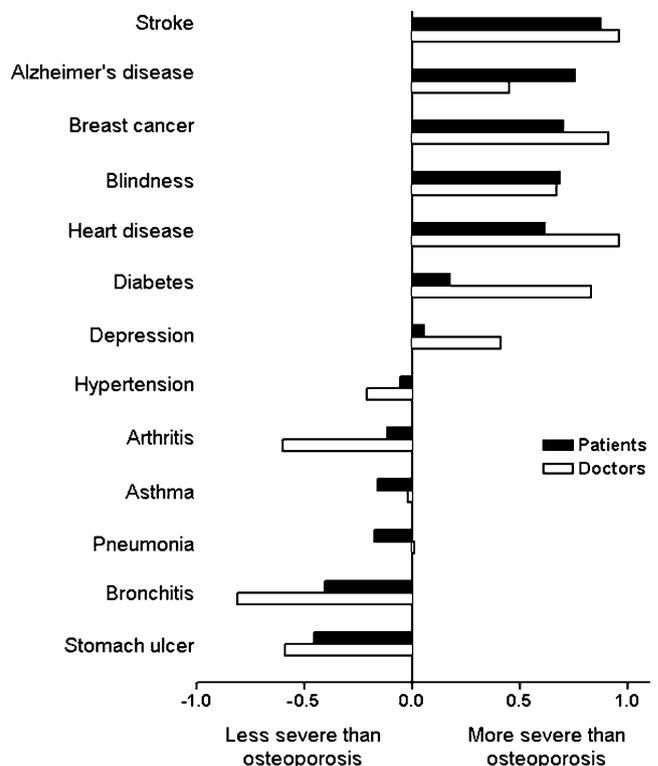


Fig. 1 Ratings of severity of osteoporosis by patients (solid bars) and doctors (open bars). Data are mean values. Mean values >0 signify that participants considered the indicated disease to be more severe than osteoporosis; those <0 signify that participants considered the disease to be less severe than osteoporosis

Patients' estimates of their 10-year risk of both major osteoporotic fracture and hip fracture exceeded those predicted by the risk calculator [median (interquartile range) major osteoporotic fracture: patients' estimate, 50% (30–65); FRAX calculator, 6% (4–11); hip fracture: patients' estimate, 50% (25–70); FRAX calculator, 2% (1–4); $P < 0.0001$ for each fracture type].

Thresholds of risk justifying pharmacological treatment

The level of risk identified by patients as justifying pharmacological intervention was higher than that identified by doctors for both major osteoporotic fracture [median (interquartile range) patients, 50% (25–60); doctors, 10% (10–20); $P < 0.0001$] and hip fracture [patients, 50% (25–60); doctors, 10% (5–20); $P < 0.0001$] (Fig. 2). There was no evidence that age, gender, history of fracture, or current osteoporosis treatment influenced the patients' threshold for considering therapy justified (all $P > 0.15$).

Among doctors, there was evidence that the greater the number of consultations conducted per month for advice on skeletal health, the lower the threshold at which intervention was recommended ($r = -0.22$ and $r = -0.29$ for major osteoporotic fracture and hip fracture, respectively, $P < 0.01$ for both). Intervention thresholds for major osteoporotic fracture were similar between specialists and general practitioners [specialists, 10% (10–15); general practitioners, 10% (10–20); $P = 0.29$], but lower for hip fracture among specialists [specialists, 5% (3.5–10); general practitioners, 10% (5–20); $P = 0.003$].

Perceptions of efficacy of treatments

The reduction in fracture risk required by patients in order to accept long-term treatment with each of the currently available therapies is shown in Fig. 3. The median required fracture risk reduction was at least 50% for each dosing

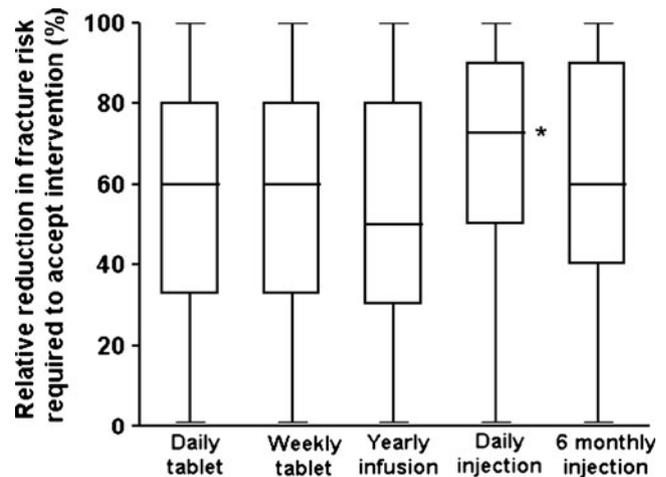


Fig. 3 Relative risk reductions required by patients to justify pharmacological intervention, according to dosing schedule. Values are median and range, and the *box* indicates the interquartile range. * $P < 0.05$ vs each of the other treatments

regimen. A greater fracture risk reduction was required for acceptance of daily subcutaneous injection for 2 years, followed by treatment with a weekly tablet or a yearly infusion, than for any other regimen. More patients ($n = 38$) indicated that they would not consider the daily subcutaneous injection treatment irrespective of efficacy than did so for any of the other regimens ($4 \leq n \leq 8$).

Eighty-three percent of patients indicated that they would find a discussion with their doctor about the amount of benefit likely to be obtained from a treatment helpful in guiding their decision as to whether to take it. Among the 55 patients already taking treatment for osteoporosis, only 58% could recall their doctor discussing fracture risk before initiating therapy. Among the doctors, 106 (66%) reported using either absolute risk reduction or number needed to treat when discussing treatment with a patient.

Discussion

The findings of this study suggest that, although patients and doctors have similar views on the importance of osteoporosis, they have disparate views on the threshold of fracture risk that justifies pharmacological intervention. Patients accept considerably higher fracture risk than doctors before considering drug treatment to be justified. Patients regard a 50% reduction in relative risk of fracture as necessary to justify long-term drug therapy, a level of efficacy that is not dependent upon the dosing regimen of the proposed intervention. This suggests that patients regard treatment efficacy as being more important in deciding whether to take a medication than the convenience of its administration. Only one half of patients taking treatment for osteoporosis recalled receiving advice about fracture

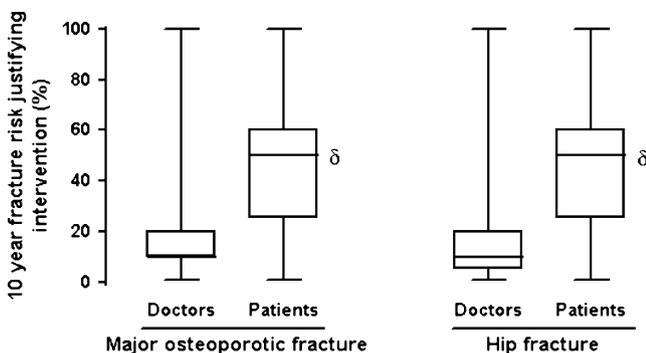


Fig. 2 Levels of absolute fracture risk at which patients and doctors considered pharmacological intervention to be justified. Values are median and range, and the *box* indicates the interquartile range. $\delta P < 0.0001$ vs doctors

risk before commencing therapy. Among doctors, fracture risk thresholds for intervention were lowest in those who advised patients on skeletal health most frequently.

Little is currently known about patients' and doctors' views on intervention thresholds for fracture risk. Studies similar to ours in other areas of medicine are uncommon. Our finding that patients are prepared to tolerate higher risks of a morbid event than doctors before considering drug therapy is consistent with evidence from cardiovascular medicine that members of the public chose lower values than doctors of number needed to treat with anti-hypertensive drugs to prevent a fatal event [14]. A typical patient in our study required a 50% absolute fracture risk and 50% relative risk reduction (giving an absolute risk reduction of 25%) before considering long-term drug therapy. This finding is similar to that in patients with prevalent ischemic heart disease, who regarded a 20% reduction of absolute risk as being the minimum benefit required to take a preventive therapy [15]. In the management of hypertension, specialist doctors chose higher numbers needed to treat than general practitioners [14], consistent with our finding that intervention thresholds were lowest among doctors participating most frequently in clinical interactions for skeletal health advice.

Our results may have relevance to clinical practice. A prominent current guideline for treatment to prevent fractures, based on cost-effectiveness analyses, recommends pharmacologic intervention at thresholds of 10-year risk of 20% for major osteoporotic fracture or 3% for hip fracture [5]; applying these cut points, 125 (77%) of doctors in our study would recommend treatment, but only 24 (21%) of our patient cohort would consider treatment justified. A second guideline recommends treatment for patients whose estimated risk exceeds that of a person the same age who has already had an osteoporotic fracture [7]. Applying this guideline produces intervention thresholds that vary by age, but favours treatment of younger people at low–moderate risk (10–20% over 10 years) [16]. These guidelines, which are produced by authoritative national bodies and are likely to influence physician behaviour, promote pharmacological intervention for patients who are at sufficiently low fracture risk that the likelihood they will benefit from the treatment is low [17, 18]. In addition, the cost-effectiveness analyses that underpin some of the treatment recommendations may be unduly optimistic in assessing the value of pharmacological intervention [18].

Current treatment recommendations also do not address the role that patients' views play in determining treatment decisions and outcomes. Patients who are recommended therapy but do not believe they need it are less likely to begin, and persist with, drug treatment [8, 11]. It is possible that the disparity we found between the intervention thresholds of doctors and patients contributes to the low

levels of treatment uptake and persistence commonly reported in management of skeletal health [12, 19].

Our study has some limitations. Participation rates for both patients and doctors were below 50%. Sampling of patients was limited to those who had been referred for investigation of skeletal health, so the results might not apply generally. Doctors who participated might have been those with particular interest or expertise in skeletal health, so their views might not be representative of physicians generally. We asked patients to consider their willingness to take a treatment indefinitely, when use of some therapies (specifically, bisphosphonates) might involve drug “holidays”. We did not ask patients to consider drug side effects in their consideration of intervention thresholds.

Shared decision-making, in the form of careful discussion between doctor and patient about the risk of fracture and the benefits likely to accrue from drug therapy [20], and acceptance by doctors that individual patients may not consider intervention worthwhile at levels of risk recommended by practitioners or guidelines may help to mitigate low levels of treatment persistence. Future research might prospectively explore the relationships between patients' perceptions of intervention thresholds and persistence with medication.

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Conflicts of interest None.

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