Osteoporosis: assessing the risk of fragility fracture

NICE guideline

Draft for consultation, February 2012

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

Introduction

Osteoporosis: assessing the risk of fragility fracture

Osteoporosis is a disease characterised by low bone mass and structural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. Osteoporosis leads to nearly 9 million fractures annually worldwide[1], and in the UK, over 300,000 patients present with fragility fractures to hospitals in the UK each year[2].

Fragility fractures are fractures that result from low-level (or 'low energy') trauma[3], that is caused by mechanical forces that would not ordinarily result in fracture. The World Health Organization (WHO) has quantified this as forces equivalent to a fall from a standing height or less. Reduced bone density is a major risk factor for fragility fractures. Other factors that may affect risk of fragility fractures include the use of glucocorticoids, age, sex, previous fractures and family history of osteoporosis. Because of increased bone loss after the menopause in women, and age-related bone loss in both women and men, the prevalence of osteoporosis increases markedly with age, from 2% at 50 years to more than 25% at 80 years[4] in women. As the longevity of the population increases, so will the incidence of osteoporosis and fragility fracture.

Fragility fractures occur most commonly in the spine (vertebrae), hip (proximal femur), and wrist (distal radius). They may also occur in the arm (humerus), pelvis, ribs and other bones. Osteoporotic fragility fractures can cause substantial pain and severe disability, often leading to a reduced quality of life, and hip and vertebral fractures are associated with decreased life expectancy.

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[1] Johnell O and Kanis JA (2006) An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporos Int 17:1726.
[2] British Orthopaedic Association (2007). The care of patients with fragility fracture.
[3] Kanis JA, Oden A, Johnell O, Jonsson B, de Laet C, Dawson A. The burden of osteoporotic fractures: a method for setting intervention thresholds. Osteoporos Int 2001;12:417-27
[4] NICE indicator guidance for QOF – Osteoporosis: secondary prevention of fragility fractures

Hip fracture nearly always requires hospitalisation, is fatal in 20% of cases and permanently disables 50% of those affected; only 30% of patients fully recover[5]. Current projections suggest that, in the UK, hip fracture incidence will rise from the current figure of 70,000 per year to 91,500 in 2015 and 101,000 in 2020[6].

Direct medical costs from fragility fractures to the UK healthcare economy were estimated at £1.8 billion in 2000, with the potential to increase to £2.2 billion by 2025, and with most of these costs relating to hip fracture care[7].

There are a number of therapies and treatments available for the prevention of fragility fractures in people who are thought to be at risk, or to prevent further fractures in those who have already had one or more fragility fractures, however, identifying who will benefit from preventative treatment is difficult. A number of risk assessment tools are available to predict fracture incidence over a period of time, and these may be used to aid decision-making. These tools are limited in that they may not include all risk factors, or may lack detail of some risk factors. Tools validated in other populations may not apply to the UK, and are dependent on the accuracy of the epidemiological data used to derive them. Two tools, FRAX and QFracture, are available for use in the UK. It is not clear which of these tools should be used in different circumstances. This short clinical guideline aims to provide guidance on the selection and use of risk assessment tools in the care of people who may be at risk of fragility fractures in all settings in which NHS care is received.

[5] Sernbo I, Johnell O. Consequences of a hip fracture: a prospective study over 1 year. Osteoporosis International 1993;3:148-53

[6] Department of Health. Hospital Episode Statistics (England) 2006.

[7] Burge RT, Worley D, Johansen A, Bhattacharyya S, Bose U. The cost of osteoporotic fractures in the UK: projections for 2000–2020. Journal of Medical Economics 2001;4:51–52

Patient-centred care

This guideline offers best practice advice on the assessment of fragility fracture risk in adults.

Treatment and care should take into account patients' needs and preferences. People at risk of fragility fracture should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

1 Guidance

The following guidance is based on the best available evidence. The full guideline [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the guidance.

Targeting risk assessment

1.1 Consider assessment of fracture risk in women of 65 years and over and men of 75 years and over.

1.2 Consider assessment of fracture risk in women under 65 years and men under 75 years if they have any of the following risk factors:

- previous fragility fracture
- current use or frequent past use of oral glucocorticoids
- history of falls
- family history of hip fracture
- other secondary causes of osteoporosis[8]
- low body mass index (BMI) (less than 18.5 kg/m^2)
- smoking more than 10 cigarettes per day
- alcohol intake of more than 4 units per day.

1.3 Do not routinely assess fracture risk in people under 50 years unless they have major risk factors (for example, current or regular oral glucocorticoid use, untreated premature menopause or

[8] Secondary causes of osteoporosis include endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; type 1 diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatological (rheumatoid arthritis; other inflammatory arthropathies), haematological (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility.

previous fragility fracture) because they are unlikely to be at high risk.

Methods of risk assessment

1.4 Calculate absolute risk when assessing risk of fracture (for example, the percentage predicted risk of major osteoporotic fracture over 10 years).

1.5 Use either FRAX[9] (without a bone mineral density [BMD] value) or QFracture[10] to calculate 10-year predicted absolute fracture risk when assessing risk of fracture in people of between 40 and 84 years.

1.6 Use clinical judgement when assessing fracture risk in people of 85 years and over, because predicted 10-year fracture risk may underestimate their short-term fracture risk.

1.7 Do not routinely measure BMD to assess fracture risk without prior assessment using FRAX (without a BMD value) or QFracture.

1.8 Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD:

- in people whose fracture risk is in the region of an intervention threshold[11] for a proposed treatment **or**
- before starting treatments that may adversely affect bone density (for example, high-dose glucocorticoids or treatment for breast or prostate cancer).

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[9] FRAX, the WHO fracture risk assessment tool, is available from www.shef.ac.uk/FRAX

[10] QFracture is available from www.qfracture.org

[11] An intervention threshold is the level of risk at which an intervention is recommended. Patients whose risk is in the region from just below to just above the threshold may be reclassified if BMD is added to assessment. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

Following BMD measurement in these situations, recalculate absolute risk using FRAX with the BMD value.

1.9 Measure BMD to assess fracture risk in people under 40 years who have a major risk factor, such as history of multiple fragility fractures, major osteoporotic fracture or high-dose oral glucocorticoid use.

1.10 Consider recalculating fracture risk only:

- after a minimum of 2 years and if the original calculated risk was close to the intervention threshold[12] for a proposed treatment **or**
- when there has been a change in the person's risk factors.

1.11 Take into account that risk assessment tools may underestimate fracture risk in the following situations:

- history of multiple fractures
- previous vertebral fracture(s)
- high alcohol intake
- high-dose oral glucocorticoid therapy
- other secondary causes of osteoporosis[13]
- obesity.

1.12 Take into account that fracture risk may be affected by factors that are not included in FRAX and/or QFracture assessment, for

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[12] An intervention threshold is the level of risk at which an intervention is recommended. It is out of the scope of this guideline to recommend intervention thresholds. Healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds.

[13] Secondary causes of osteoporosis include: endocrine (hypogonadism in either sex including untreated premature menopause and treatment with aromatase inhibitors or androgen deprivation therapy; hyperthyroidism; hyperparathyroidism; hyperprolactinaemia; Cushing's disease; type 1 diabetes), gastrointestinal (coeliac disease; inflammatory bowel disease; chronic liver disease; chronic pancreatitis; other causes of malabsorption), rheumatology (rheumatoid arthritis; other inflammatory arthropathies), haematology (multiple myeloma; haemoglobinopathies; systemic mastocytosis), respiratory (cystic fibrosis; chronic obstructive pulmonary disease), metabolic (homocystinuria), chronic renal disease and immobility.

example frequent falls, living in a residential care home, use of drugs that may impair bone metabolism (such as anti-epileptic drugs) or immobility.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover. The scope of this guideline is available here.. For the final guideline this should read, "The scope of this guideline is available here [hyperlink to be added for final publication] – click on 'How this guidance was produced'."

How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations.

There is more information about how NICE clinical guidelines are developed on the NICE website. A booklet, 'How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS' is available.

3 Implementation

NICE has developed tools to help organisations implement this guidance.

Note: these details will apply when the guideline is published.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and

patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.

4.1 Using GP practice lists to identify people at high risk

What is the clinical and cost effectiveness of using GP practice lists to identify people at high risk of fracture, leading to formal risk assessment and possible treatment?

Why this is important

Fracture risk is currently assessed opportunistically. GP records are now universally computerised and contain information that may be useful in identifying patients at high risk of fracture (for example, age, record of prescriptions, major diagnoses and previous fracture). A study is needed to assess whether people at higher risk can be identified by using risk assessment tools to obtain an estimate of risk based on pre-existing information and inviting people at highest risk for a clinical assessment and risk-factor estimation. This could result in a more effective and efficient use of staff time and health service resources than an opportunistic approach.

4.2 FRAX and QFracture in adults receiving bone protective therapy

What is the utility of FRAX and QFracture in adults receiving bone protective therapy?

Why this is important

Because of concerns about rare but serious side-effects of long-term anti-resorptive therapy, many physicians prescribe these drugs for a finite period of time, usually 3–5 years. Reassessment of fracture risk at the end of this treatment period is important, since some people remain at high risk of fracture and require continued treatment whereas others may benefit from a 'drug holiday' for 1 or more years. Neither FRAX nor QFracture has been tested in treated patients, and it is not known whether the ability of clinical risk factors with or without measurement of BMD to predict fracture risk is similar in untreated and treated patients. There is therefore a need for prospective

studies to investigate the predictive power of these tools to assess fracture risk in patients after a period of bone protective therapy.

4.3 FRAX and QFracture in adults with secondary causes of osteoporosis

What is the utility of FRAX and QFracture in detecting risk of fragility fracture in adults with secondary causes of osteoporosis?

Why this is important

If secondary osteoporosis is entered as a risk factor in FRAX, the algorithm assumes that the effect is mediated solely through effects on BMD. Input of BMD into the questionnaire in such patients will therefore generate the same fracture risk whether or not secondary osteoporosis is entered. However, it is likely that at least some secondary causes of osteoporosis (for example, inflammatory bone disease) affect fracture risk by mechanisms that are partially independent of BMD and fracture risk may therefore be underestimated in such patients. There is therefore a need to investigate the accuracy of FRAX in predicting fracture risk in patients with secondary causes of osteoporosis other than rheumatoid arthritis and to establish whether their effect on fracture risk is mediated solely through effects on BMD.

4.4 BMD with FRAX

What is the added prognostic value of BMD in the assessment of fracture risk with FRAX?

Why this is important

The 10-year fracture risk as estimated by FRAX is calculated using clinical risk factors with or without BMD. The clinical risk factors are routinely available, making calculation of fracture risk possible at the time of consultation. However, refinement of a patient's 10-year fracture risk using BMD requires assessment using DXA scanning equipment.

Currently, there are no definitive studies in primary or secondary care evaluating whether the addition of BMD to FRAX improves the accuracy of the predicted fracture risk. There is a need for studies to examine whether adding

BMD to FRAX results in the correct reclassification of patients from low risk to high risk (and vice-versa). Furthermore, studies are also needed to evaluate the clinical usefulness (net benefit) of adding BMD to FRAX; that is, how many more patients are correctly classified as high risk (true positives) and low risk (true negatives).

4.5 FRAX and QFracture in adults living in long-term care

What is the utility of FRAX and QFracture in detecting risk of fragility fracture in adults living in long-term care?

Why this is important

Care home residents are at high risk of fragility fracture. This is probably related to increased age and frailty with multiple comorbidities, which increase fracture risk. There is also evidence that care home residents have lower BMD, with 70% assessed as having osteoporosis using densitometry criteria alone. However, tools such as FRAX and QFracture, which only estimate fracture risk up to the ninth decade and use 10-year fracture risk, may underestimate short-term risk in care home residents, who have a mean age of approximately 85 years and a life expectancy of less than 5 years.

A study is required to assess whether care home residents should have targeted fracture risk assessment and whether residents at higher risk of fracture can be identified, using FRAX or QFracture. This could result in a more effective and efficient strategy for fracture prevention targeting health service resources on those at the very highest fracture risk.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, 'Osteoporosis: assessing the risk of fragility fracture' contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre, and is available from our website. Note: these details will apply to the published full guideline.

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a NICE pathway. Note: these details will apply when the guideline is published.

5.3 'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available.

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N[XXXX]). Note: these details will apply when the guideline is published.

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information about assessment of fragility fracture.

6 Related NICE guidance

Published

- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance TA161 (2011).
- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. NICE technology appraisal guidance TA160 (2011).
- The management of hip fracture in adults. NICE clinical guideline 124 (2011).
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women. NICE technology appraisal guidance TA204 (2010).
- Falls. NICE clinical guideline 21 (2004).

Under development

NICE is developing the following guidance (details available from the NICE website):

- Patient experience in adult NHS services. NICE clinical guideline. Publication date to be confirmed.

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Clinical Guideline Centre and NICE project team

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