NICE National Institute for Health and Care Excellence

NICE guideline

Osteoporosis: assessing the risk of fragility fracture

Clinical guideline
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www.nice.org.uk/guidance/cg146

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guideline is the basis of QS149.

Overview

This guideline covers assessing the risk of fragility fracture in people aged 18 and over with osteoporosis. It aims to provide guidance on the selection and use of risk assessment tools in the care of adults at risk of fragility fractures in all NHS settings.

Who is it for?

- Healthcare professionals
- Adults with osteoporosis and their families and carers

Introduction

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 (Johnell and Kanis, 2006), and over 300,000 patients present with fragility fractures to hospitals in the UK each year (British Geriatrics Society good practice guide on the care of patients with fragility fracture).

Fragility fractures are fractures that result from mechanical forces that would not ordinarily result in fracture, known as low-level (or 'low-energy') trauma (Kanis et al. 2001). 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 fracture. Other factors that may affect the risk of fragility fracture include the use of oral or systemic 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 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 fractures are defined as fractures associated with low bone mineral density (BMD) and include clinical spine, forearm, hip and shoulder fractures. 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. 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 (Sernbo and Johnell, 1993). Projections suggest that, in the UK, hip fracture incidence will rise from 70,000 per year in 2006, to 91,500 in 2015 and 101,000 in 2020 (Department of Health and Social Care Hospital episode statistics 2006).

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 (Burge et al. 2008).

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 1 or more fragility fractures. However, identifying who will benefit from preventative treatment is imprecise. 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 details of some risk factors. Tools are dependent on the accuracy of the epidemiological data used to derive them and tools validated in other populations may not apply to the UK. Two tools, Fracture Risk Assessment tool (FRAX) and QFracture, are available for use in the UK. It is not clear whether these tools are equally accurate and whether choice of tool should depend on 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.

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

Targeting risk assessment

1.1 Consider assessment of fracture risk:

- in all women aged 65 years and over and all men aged 75 years and over
- in women aged under 65 years and men aged under 75 years in the presence of risk factors, for example:
  - previous fragility fracture
  - current use or frequent recent use of oral or systemic glucocorticoids
  - history of falls
  - family history of hip fracture
  - other causes of secondary osteoporosis
  - low body mass index (BMI; less than 18.5 kg/m^2)
  - smoking

- alcohol intake of more than 14 units per week for men and women.

  Causes of secondary 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; 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 (due for example to neurological injury or disease).

1.2 Do not routinely assess fracture risk in people aged under 50 years unless they have major risk factors (for example, current or frequent recent use of oral or systemic glucocorticoids, untreated premature menopause or previous fragility fracture), because they are unlikely to be at high risk.

Methods of risk assessment

1.3 Estimate absolute risk when assessing risk of fracture (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage).

1.4 Use either FRAX (without a bone mineral density [BMD] value if a dual-energy X-ray absorptiometry [DXA] scan has not previously been undertaken) or QFracture, within their allowed age ranges, to estimate 10-year predicted absolute fracture risk when assessing risk of fracture. Above the upper age limits defined by the tools, consider people to be at high risk.

FRAX can be used for people aged between 40 and 90 years, either with or without BMD values, as specified. QFracture can be used for people aged between 30 and 84 years. BMD values cannot be incorporated into the risk algorithm.

1.5 Interpret the estimated absolute risk of fracture in people aged over 80 years with caution, because predicted 10-year fracture risk may underestimate their short-term fracture risk.

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

1.7 Following risk assessment with FRAX (without a BMD value) or QFracture, consider measuring BMD with DXA in people whose fracture risk is in the region of an intervention threshold for a proposed treatment, and recalculate absolute risk using FRAX with the BMD value.

An intervention threshold is the level of risk at which an intervention is recommended. People 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.

1.8 Consider measuring BMD with DXA before starting treatments that may have a rapid adverse effect on bone density (for example, sex hormone deprivation for treatment for breast or prostate cancer).

1.9 Measure BMD to assess fracture risk in people aged under 40 years who have a major risk factor, such as history of multiple fragility fracture, major osteoporotic fracture, or current or recent use of high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer).

1.10 Consider recalculating fracture risk in the future:

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

  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.

1.11 Take into account that risk assessment tools may underestimate fracture risk in certain circumstances, for example, if a person:

- has a history of multiple fractures
- has had previous vertebral fracture(s)
- has a high alcohol intake
- is taking high-dose oral or high-dose systemic glucocorticoids (more than 7.5 mg prednisolone or equivalent per day for 3 months or longer)
- has other causes of secondary osteoporosis.

  Causes of secondary 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; 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 (due for example to neurological injury or disease).

1.12 Take into account that fracture risk can be affected by factors that may not be included in the risk tool, for example, living in a care home or taking drugs that may impair bone metabolism (such as anti-convulsants, selective serotonin reuptake inhibitors, thiazolidinediones, proton pump inhibitors and anti-retroviral drugs).

Recommendations for research

The guideline development group has made the following recommendations for research.

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.

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 to 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 examined in patients who had treatment, and it is not known whether

the ability of clinical risk factors with or without measurement of bone mineral density (BMD) to predict fracture risk is similar in patients who had or did not have treatment. 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.

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 causes of secondary osteoporosis (for example, inflammatory bowel 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 causes of secondary osteoporosis other than rheumatoid arthritis and to establish whether their effect on fracture risk is mediated solely through effects on BMD.

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 dual-energy X-ray absorptiometry (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).

5 FRAX and QFracture in adults living in residential care

What is the utility of FRAX and QFracture in detecting risk of fragility fracture in adults living in residential 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 9th 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.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic page on musculoskeletal conditions.

For full details of the evidence and the guideline committee's discussions, see the full guideline. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

Update information

February 2017: This guideline was updated to correct reference to the World Health Organization (WHO) in relation to the FRAX tool.

Minor changes since publication

August 2019: We updated the weekly alcohol intake for men in recommendation 1.1 in line with the UK chief medical officers' low risk drinking guidelines.

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Accreditation