North of Tyne Osteoporosis Treatment Guidelines

Fragility Fracture

No Fragility Fracture

Postmenopausal ♀ ≥75 yrs

Postmenopausal ♀ ≤ 75 yrs
OR ♂ ≥50 yrs

Postmenopausal ♀ OR ♂ ≥ 50 yrs
with ≥ 1 Clinical Risk Factor (CRF)*

Osteoporosis Treatment

Falls Assessment/ Rx
Lifestyle Advice
Ca and Vit D supplements
Alendronate

if intolerant
consider **Risedronate** (or other formulary bisphosphonate)
OR
if intolerant/ bisphosphonate contraindication
Strontium ranelate

calculate FRAX®
fracture probability
www.shef.ac.uk/FRAX

Medium

High

DEXA & recalculate FRAX®

Low

Reassure
Lifestyle advice

Basic Inv
FBC, CRP
U/E's, LFT's, gGT
Ca^{2+} and Phosphate
TFT's

Exclude Secondary Causes
especially if fragility fractures or Z score < -1.5

Investigations to consider if Secondary Cause Suspected
TTG-(marked unexplained osteoporosis and/ or suspicion of Coeliac disease)
Testosterone (9 am), SHBG, FSH/LH (men)
PSA (male vertebral or path. fractures)
Serum Vit D and PTH (see Vit D guidelines)
Serum/urine electrophoresis- if Vertebral fracture

Refer for the management of
- painful, acute vertebral fractures and multiple vertebral fractures.
- patients unable to take, tolerate or failing to respond to oral treatment.
- osteoporosis with complex medical problems.
- fragility fractures due to other bone disease.

Lifestyle Advice
- Adequate nutrition especially with calcium and vitamin D
- Regular weight bearing exercise
- Avoidance of tobacco use and alcohol

***Clinical Risk Factors for FRAX®**
BMI<19, smoker, alcohol≧3u day, previous fragility fracture, parental fractured hip, steroids>3 months, rheumatoid arthritis, secondary osteoporosis (see below).
Secondary causes of osteoporosis include:
- Untreated hypogonadism, Premature Menopause<45, Prolonged immobility, Organ transplantation, Type I diabetes, Hyperthyroidism, Chronic malnutrition, Malabsorption, Chronic liver disease, Chronic Obstructive Pulmonary Disease

Review need for continuing treatment and FRAX risk on a 5 Yearly Basis exp 7-2013

North of Tyne Osteoporosis Treatment Guidelines

Rationale

In October 2008 NICE produced TA160 and TA161 for the primary and secondary prevention of osteoporotic fractures. This guidance is restricted to postmenopausal women with osteoporosis as defined by a bone mineral density T-score of ≤-2.5, and does not include men with osteoporosis or individuals treated with glucocorticoids. Several recently approved interventions, including ibandronate and zoledronate, are also not included in the guidance. As yet NICE has not produced a clinical guideline nor is one imminent. The National Osteoporosis Guideline (NOG) was launched in October 2008 to address these deficits. It is endorsed by many scientific and professional organisations including the National Osteoporosis Society and the Royal College of Physicians.

Areas of agreement between NICE and NOG include recommendations to treat elderly postmenopausal women with a fragility fracture and the use of generic alendronate as a first line option. There is also agreement that bone mineral density measurements may be useful in reaching treatment decisions in younger postmenopausal women with a fragility fracture. However, whereas NICE requires a T-score ≤-2.5 in most women for either primary or secondary prevention, NOG recognises the added contribution of independent clinical risk factors to fracture prediction and recommends the use of the WHO-supported fracture risk algorithm FRAX®. In addition, NICE guidance for second line options demands different combinations of bone density and risk factors for different treatments; not only is this complex to operate in a primary care setting, it also raises difficult ethical issues, since some patients who meet the criteria for alendronate treatment ,but are unable to take it, cannot have an alternative therapy until there is evidence of further disease progression. In contrast, NOG adopts a more pragmatic approach and does not require different criteria for second-line treatments in those who are unable to tolerate alendronate.

In order to provide comprehensive and practical guidance for the management of osteoporosis in clinical practice, the following guideline suggests a combination of NICE and NOG that retains the main principles of NICE guidance but incorporates the greater workability and ethical acceptability of NOG in its approach to second line treatments. It also incorperates NOG guidance for men with osteoporosis, individuals treated with glucocorticoids, and the use of more recently approved interventions.

Pharmacological intervention

Generic alendronate is the first line option for the majority of patients. In those in whom it is contraindicated or associated with side-effects, particularly upper gastrointestinal symptoms, other bisphosphonates or strontium ranelate are possible options.

Secondary care may use raloxifene, or intravenous zoledronic acid, the later is indicated for patients with intestinal malabsorption and those who are unable to tolerate oral therapy. In selected cases it may also be used to ensure compliance with treatment. Teriparatide (PTH1-34) is a parathyroid hormone peptide which may also be used.

Alendronate is contraindicated in the presence of abnormalities of the oesophagus that delay emptying, inability to stand or sit upright for at least 30 minutes and hypocalcaemia. It should be used with caution in patients with other upper gastrointestinal disorders and is not recommended in patients with renal impairment (eGFR<35 ml/min). Side-effects include upper gastrointestinal symptoms, bowel disturbance, headaches and musculoskeletal pain.
It should be taken after an overnight fast and 30 minutes before the first food or drink (other than water) of the day or any other oral medicinal products or supplementation (including calcium). Tablets should be swallowed whole with a glass of plain water (≥ 200 ml) while the patient is sitting or standing in an upright position. Patients should not lie down for 30 minutes after taking the tablet. **The dose is 70 mg once weekly**.

Risedronate is contraindicated in the presence of hypocalcaemia, pregnancy and lactation, and severe renal impairment (creatinine clearance <30ml.min). It should be used with caution in patients with upper gastrointestinal disease. Side-effects include upper gastrointestinal symptoms, bowel disturbance, headache and musculoskeletal pain. It should be taken after an overnight fast and 30 minutes before the first food or drink (other than water) of the day or any other oral medicinal products or supplementation (including calcium). Tablets should be swallowed whole with a glass of plain water (≥ 120 ml) while the patient is sitting or standing in an upright position. Patients should not lie down for 30 minutes hour after taking the tablet. **The dose is 35 mg once weekly**.

Strontium ranelate should be used with caution in patients with severe renal impairment (creatinine clearance < 30 ml/min) and in patients with risk factors for venous thromboembolism. Side-effects include diarrhoea, headache, nausea and dermatitis. A small increase in the risk of venous thromboembolism was seen in the Phase III trials and, very rarely, hypersensitivity reactions may occur. Strontium ranelate should be taken between meals and at least 2 hours after the last meal. It is usually taken at bedtime. **The dose is 2g daily**.

Calcium and vitamin D supplements should be co-prescribed with these treatments unless there is evidence of an adequate dietary calcium intake. Calcium and vitamin D supplements should be routinely prescribed for frail elderly individuals who are housebound or in nursing homes .**The doses used should be 1-1.2g/day of calcium and 800-1000 IU/day of colecalciferol.**

Adherence with bone protection treatments
A number of studies have show adherence with bone protection treatments to be low, with a recent systematic review showing persistence with treatment being as low as 17% in some patients. There is evidence to suggest that a low adherence is associated with smaller changes in bone mass density and increased fracture risk. From this research, the key factors that affect adherence to treatment are adverse events, lack of understanding of the condition/ disease being treated, lack of information about the treatment (including potential side effects) and lack of follow up. The North of Tyne Osteoporosis Guideline Group suggests the following measures to help improve adherence with treatment:

- Ensure patients understand what is being treated (fracture risk/ osteoporosis)
- Give patient detailed information about the treatment (how it works, why they have to take it long term and potential side effects)
- Follow up the patient – a telephone follow up 3-6 months after starting treatment to ensure that they are experiencing no problems
- Encourage patients to contact practice if they have any side effects/ problems

Abbreviations

FRAX® is a WHO supported fracture risk algorithm and can be accessed on www.shef.ac.uk/FRAX

DEXA dual energy X-ray absorptiometry measurement of bone mineral density.

References

http://www.shef.ac.uk/NOGG/NOGG_Pocket_Guide_for_Healthcare_Professionals.pdf

http://www.nice.org.uk/nicemedia/pdf/TA160quickrefguide.pdf

Department of Health Commissioning Toolkit for Falls and Fractures-http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_103146

NHS North of Tyne

Clinical Guidelines

Guideline Number: NoT 11

North of Tyne Osteoporosis Treatment Guidelines

Ratified by:	NHS North of Tyne Commissioning Integrated Governance Committee
Date ratified:	September 09
Date issued:	September 09
Review date:	September 2013
Organisations signed up to this guideline:	NHS North of Tyne (on behalf of the PCT's), Northumbria and Newcastle Foundation Trusts
Name of originator/author:	Guidelines produced by consensus of the guidelines group- chair was Dr Alistair Blair
Target audience:	All clinicians in the Newcastle, North Tyneside and Northumberland areas
Consultation Process:	Guideline group was multidisciplinary from all representative organisations