Royal Osteoporosis Society

Better bone health for everybody

Clinical case studies- romosozumab

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National Osteoporosis Guideline Group • UK

Clinical case studies- romosozumab

These case studies form part of a Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal.

They characterise the patients who should be prioritised for treatment with romosozumab and are intended to support clinicians to understand the patients who would be eligible and benefit most from romosozumab as a first or second line treatment of severe osteoporosis.

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Case 1- Anne, age 65

- **Presentation and initial assessment**
- Anne attends A&E after developing a sudden onset of severe pain between her shoulders and around her chest when she was hanging out her washing
- On examination, she is tender to percussion over the mid-thoracic spine and X-rays show a severe wedge fracture at T8
- She is prescribed analgesics and referred urgently to the Fracture Liaison Service (FLS)

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Case 1- Anne, age 65

FLS assessment 1

- Anne reports a wrist fracture aged 60 in a fall on the ice but has not previously been investigated or treated for osteoporosis. She recalls that her mother was disabled by severe back pain in her later years and became very stooped
- She is very slim (BMI 19.5), smokes 15 cigarettes daily and did not take HRT after her menopause at the age of 44. She has no other risk factors for fracture

Case 1- Anne, age 65

FLS assessment 2

- FRAX shows 10 year probabilities of 20% for major osteoporotic fracture (MOF) and 8.6% for hip fracture. Probabilities increase slightly to 21% and 9.2% respectively on inclusion of her DXA scan results (LS T-score -3.5, FN T-score -2.7)
- If these FRAX probabilities are adjusted to take account of the recency of fracture, 10-year probabilities increase to 39% for MOF and 16% for hip
- Laboratory tests do not identify any additional underlying causes for her osteoporosis

Case 1- Anne, age 65

Discussion about management

- Anne is advised that her recent vertebral fracture and BMD results indicate a very high risk of further vertebral fracture – which will have been underestimated by FRAX as this does not take account of the spine BMD
- She is keen to consider any treatment that could prevent her "ending up like her Mum" but is initially cautious about the possibility of cardiovascular events with romosozumab because her father died after a heart attack when he was 75
    - Calculation of her cardiovascular risk using Qrisk (1) indicates a 10 year risk heart attack/stroke of 12.8% compared to a risk of 7.8% in a healthy woman matched for age and ethnicity
    - If she were to stop smoking, QRisk suggests her risk would reduce to 8.7%
    - Anne would like to stop, but has been unsuccessful with previous attempts

Case 1- Anne, age 65

Management plan agreed following discussion:

- Romosozumab for 12 months with a plan to transition to annual IV zoledronate on completion
- Calcium and vitamin D supplementation
- Referral to smoking cessation clinic
- Appointment arranged with physiotherapist for pain management and advice on rehabilitation and safe exercise

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Case 2- Geeta, age 69

- **Presentation and initial assessment 1/2**
- Geeta visits her GP asking for painkillers after slipping in the garden and fracturing her humerus during a visit to her daughter
- Her GP sees in her records that she had been prescribed alendronate 5 years ago after a wrist fracture but did not ask for further prescriptions
- Geeta remembers that the tablets had caused terrible heartburn which went away when she stopped them. She wasn’t aware there were any other treatment options so didn’t want to bother her GP by going back

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Case 2- Geeta, age 69

Presentation and initial assessment 2/2

- FRAX assessment, taking into account her fracture history and the fact her father fractured his hip, confirms that treatment is indicated
- Geeta and her GP agree she should avoid further oral treatment. She is happy to accept her GP's offer of referral to the osteoporosis clinic at the hospital to discuss an injectable treatment

Case 2- Geeta, age 69

Osteoporosis clinic evaluation

- Clinical assessment doesn’t reveal any additional risk factors for osteoporosis apart from low dietary calcium intake but bone densitometry shows very low BMD with T-scores of -3.5 at the spine and -3.4 at the hip
- Laboratory tests show vitamin D insufficiency but that she is normocalcaemic with no secondary hyperparathyroidism. There are no other abnormal findings

Case 2- Geeta, age 69

Osteoporosis clinic evaluation and management plan discussion

- Geeta is very worried by her BMD results, especially on hearing that FRAX assessment suggests a 47% 10-year risk of MOF and 23% risk of hip fracture
    - Her consultant explains that Geeta will need to take calcium and vitamin D supplements and that there is a range of injectable treatment options which can all substantially reduce her risk of fracture
    - She also explains that there is evidence suggesting that the treatments that build bone are more effective when they are used as the first treatment
    - After discussion about the risks and benefits of each treatment as they apply to her, including QRisk assessment of her cardiovascular risk, Geeta and her consultant agree she will have initial treatment with romosozumab which will be followed by either zoledronate or denosumab.

Case 3- Maria, age 74

- **Presentation and initial assessment**
- Maria calls 999 after missing the last step coming downstairs, falling awkwardly and being unable to get up
  - X-rays in A&E confirm fractures of her wrist and pelvis (bilateral pubic rami)
  - She has surgical fixation of her wrist but is unable to mobilise and is admitted for pain management and FLS assessment

Case 3- Maria, age 74

FLS assessment 1/3

- Maria does not report any broken bones in the past. She developed rheumatoid arthritis 10 years ago which is well controlled on biologic treatment
    - Her rheumatologist assessed her osteoporosis risk with FRAX and DXA a few years age and she was told she had "osteopenia" and advised to take vitamin D but that she did not need any other treatment
    - The planned follow-up assessment 5 years later was cancelled because of COVID-19 and had not been rearranged

Case 3- Maria, age 74

FLS assessment 2/3

- DXA now shows osteoporosis: FN T-score -2.9 and FRAX indicates 10-year probabilities of 34% for MOF and 13% for hip
    - Spine BMD could not be assessed reliably because of appearances suggesting degenerative change
    - VFA scans suggest three vertebral fractures at the thoraco-lumbar junction

Case 3- Maria, age 74

FLS assessment 3/3

- Vertebral fractures (T10, 11 and 12) and degenerative change are confirmed on spine radiographs but there is no previous imaging to help identify the timing of the fractures
    - Maria has longstanding back pain and remembers this increased about 3-4 years ago after she was knocked over by a dog in the park. The severe pain took several weeks to improve but she thought it was part of her arthritis and didn't report it at her next appointment as it had improved by that time
- Laboratory tests show she is calcium and vitamin D replete on her supplements. No other abnormalities are identified

Case 3- Maria, age 74

Management discussion

- Maria is advised that the presence of vertebral fractures indicates that her risk of further fracture is higher than suggested by her FRAX score
- Her risk of vertebral fracture justifies first-line treatment with anabolic treatment and although the vertebral fractures probably occurred a few years ago, the recent MOF makes her eligible for romosozumab treatment
- Because of her rheumatoid arthritis, Maria's 10-year cardiovascular risk at 22% is higher than the age-matched risk of 16%. After discussion about the potential benefits and risks of both romosozumab and teriparatide, she decides that daily teriparatide injections would be difficult, and although her cardiovascular risk is higher over a 10-year period, she has never had a heart attack or stroke, and on balance she would rather have romosozumab for one-year followed directly by antiresorptive treatment.

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Resources

- 1) QRISK®3 freely available online https://qrisk.org/three/
- NOGG/ROS consensus on ROS web:nogg-ros-romosozumab-statement-may-2022.pdf (windows.net)
- NOGG website:National Osteoporosis Guidelines Group UK (nogg.org.uk)
- NOGG resource centre: https://www.nogg.org.uk/resource-centre
- NICE TA791:Overview | Romosozumab for treating severe osteoporosis | Guidance | NICE

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