Position statement on the use of quantitative ultrasound in the management of osteoporosis

National Osteoporosis Society

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Foreword by the Chief Medical Officer

I welcome the NOS' 'Code of Practice for a quantitative ultrasound service'. The Code of Practice lays out clear minimum standards for a service in the NHS or private sector. When quantitative ultrasound (QUS) services follow this code of conduct QUS can be a useful tool in identifying those at risk of osteoporosis among women going through or after the menopause. Osteoporosis is a serious and painful condition and QUS services have an important role to play, but only if targeted appropriately.

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The use of quantitative ultrasound in the management of osteoporosis

The following statement has been prepared to outline the current policy of the National Osteoporosis Society (NOS) on the clinical application of quantitative ultrasound (QUS), a portable and quick method of bone mass assessment. It is particularly pertinent to health care commissioners who may be considering the merits of purchasing this technology for use in either primary or secondary care.

This position statement applies to QUS of the heel using both wet and gel (dry) systems as well as QUS of the finger and is based only on full-length research papers published in peer-reviewed journals as of September 2001. It will be reviewed on a bi-annual basis, or as required in the light of new research findings, especially relating to multi-site QUS devices.

This statement was prepared by Professor DM Reid and Dr A Stewart for the NOS Bone Densitometry Forum Committee. The statement is endorsed by the NOS Council of Management and Scientific Advisory Group.

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Key recommendations

1 As quantitative ultrasound (QUS) does not measure bone mineral content or density directly, it cannot be used to diagnose osteoporosis as currently defined by bone mineral content (BMC) or bone mineral density (BMD) assessment.

2 Low QUS is an independent risk factor for future osteoporotic fracture in post-menopausal women.

3 Low QUS parameters are stronger predictors of low bone mass than clinical risk factors; individuals found to have low QUS parameters (as defined by machine-specific normative data) may *either*

- be referred for confirmation of the **diagnosis** by axial (preferably hip) BMD measurement *or*
- be advised to receive preventative therapy if other strong clinical risk factors are present.

4 In most cases QUS measurements cannot be used to monitor bone loss or assess response to therapy in an individual patient.

5 At present the use of QUS for assessment of bone mass in children, pre-menopausal women and men for clinical care purposes is not recommended.

6 Trained staff must operate all QUS devices and they should be able to demonstrate precision of measurement within the manufacturer's specification. An experienced physician with specific knowledge of osteoporosis and its management must interpret results.

Background

Quantitative ultrasound (QUS) measurement of the calcaneus (heel)[1] has been available since 1984. This new health technology has attracted considerable scientific and clinical interest as a potential tool in the management of osteoporosis. As a new technique, which is non-invasive, involves no radiation, and can be provided by easily portable and relatively inexpensive machines, it has the potential for considerable benefits to patients and doctors in the assessment of osteoporosis[2].

Axial dual energy x-ray absorptiometry (DXA) is the current preferred method for identifying individuals at risk of osteoporosis and monitoring response to treatment[3]. While diagnosis of osteoporosis can theoretically be undertaken with any method of BMD assessment (including forearm and heel BMD as assessed by DXA), because of regional variations in BMD and the lack of a uniform normative range, the International Osteoporosis Foundation (IOF) have recently advised that hip BMD be used as the primary diagnostic method[4].

Axial DXA however, is not readily portable, and is relatively expensive unless used efficiently. Hence, there is now potential for the widespread clinical application of QUS in the community, as suggested below, but further research is required before its use as a single measurement technique used as part of a comprehensive osteoporosis service can be recommended.

Marketed QUS devices rely either on the transmission of ultrasound through accessible limb bones, specifically the heel or phalanges, or the reflectance of the ultrasound waves from the bone surface. Parameters assessed by transmission QUS, which uses either gel or water as a coupling agent, include broad-band ultrasound attenuation (BUA), speed of sound (SOS) and the combined indices quantitative ultrasound index (QUI) and "stiffness". Reflectance QUS reports simply on SOS.

A recommended Code of Practice for a QUS service for osteoporotic fracture risk assessment is provided as an appendix.

Can QUS be used to diagnose osteoporosis?

The diagnosis of osteoporosis in women currently relies on the finding of BMC or BMD more than 2.5 standard deviations below the young normal mean[5] (T-score < -2.5). While all assessed QUS indices correlate *in vivo* with site-specific and distant-site BMD measurements, the correlation co-efficients are insufficiently strong to imply that the measurement is assessing only bone mineral content or density.

Studies show that QUS correlates relatively poorly *in vivo* with axial bone densitometry by DXA[6], although site-specific correlations are better[7] and, *in vitro*, calcaneal BUA is highly correlated with bone mineral content[8]. Further it is clear that while QUS parameters are related to BMC or BMD they also reflect other structural[9] or mechanical bone properties[10] including stiffness[11] and elasticity[12], all of which contribute to bone strength[13]. Recent work *in vitro* does demonstrate weak, density independent, relationships between QUS and trabecular architecture although the cause of all the acoustic variation remains obscure[14].

As the World Health Organisation (WHO) has defined osteoporosis in terms of BMC or BMD in women[5], a diagnosis of the condition can only be based on technology which assesses these parameters alone although this does not imply that the other bone properties assessed by QUS are of no value – the reverse is likely to be the case.

Do QUS parameters predict future fracture?

Recent data from prospective cohort trials demonstrate the potential value of QUS technology and point the way in which the devices could be rationally used in the community. The EPIDOS study, a large prospective trial of the risk of hip and other fractures in France demonstrated that the two measured parameters, i.e. broadband ultrasound attenuation (BUA) and speed of sound (SOS), can both predict hip fracture risk in elderly women (75 +) as well as, and in part independent of, DXA[15]. In addition similar prospective data from the *Study of Osteoporotic Fractures* have demonstrated that BUA is a significant predictive factor for hip fractures[16]. Both of these studies used water-based QUS systems assessing the *os calcis.* However, in a more recent study[17] using a dry/gel system assessing the *os calcis*, low BUA/SOS were also demonstrated to be highly predictive of hip fractures in elderly women and men but also showed potential in predicting any fracture. Similar predictive effects have been demonstrated with the dry finger system[18].

These studies have been carried out in the elderly but recently QUS has been demonstrated to show predictive value for any fracture in women in their peri-menopausal years[19] and of Colles' fracture in women in their early post-menopausal years[20].

The power of QUS to discriminate prevalent or predict incident osteoporotic fractures other than those of the hip or wrist remains in doubt with studies involving patients with, or at risk of, vertebral fractures giving conflicting data when compared with DXA[21-28]. Site-specific bone density measurement remains the current best predictor of vertebral[3] and probably other fractures.

QUS parameters therefore predict wrist and hip fractures in post-menopausal women with similar effectiveness to axial DXA. However, due to the relatively poor correlation between bone mass measurement techniques, labelling a woman at risk with one technique will not necessarily imply that the woman will be predicted to be at risk with any other technology.

Can QUS be used to target women for axial BMD assessment?

Recent studies demonstrate how QUS could be used in the community. Langton et al[29] demonstrated that QUS parameters are much better predictors of women with low bone mass than summated clinical risk factors in a random population of women, while Stewart et al[30] showed similar results in a mixed age-range population of post-menopausal considered by the GP/consultant to be at risk of osteoporosis and who had been referred for assessment. Benitez et al[31] also examined a post-menopausal group of women and compared a risk factor score and QUS measured by phalangeal ultrasound (adSOS) and found similar results. Langton and colleagues have recently confirmed these finding in a further peri-menopausal population[32].

It is likely therefore that QUS parameters will have a better sensitivity and specificity for low BMD measurements than clinical risk factors, such as early menopause, pre-existing fragility fractures, family history of osteoporosis, long-term treatment with oral corticosteroids etc. In other words, post-menopausal women could be selected more effectively for assessment of axial BMD based on QUS measurements rather than clinical risk factors. However there are as yet no data to suggest the cost-effectiveness of such an approach when used to screen an unselected population of women compared with a risk factor selected population. Population screening using this method can therefore not be recommended at present.

Can QUS be used to target therapy in the absence of a confirmatory DXA assessment?

Targeting of fracture prevention treatment in the UK is currently advised in those women who are diagnosed as having osteoporosis based on assessment of axial BMD[33-34]. However, the universal WHO cut-off for diagnosis[5] (a T-score <-2.5) does not apply equally to all technologies[35] and has been shown to be inappropriate with some[36-38] QUS devices and derived parameters, although the derived T-scores do match fairly effectively T-scores based on appendicular BMD[37]. Appropriate axial BMD T-score cut-offs for intervention cannot therefore be directly translated into identical intervention cut-offs for QUS parameters. Furthermore, no universal cut-off for QUS parameters can be produced at present as there are no universally accepted reference phantoms allowing cross-calibration and standardisation between different manufacturers' devices. The lack of agreement between apparently identical QUS parameters assessed in the same population using different manufacturers' devices[39] (r values between 0.4 and 0.8) makes it unlikely that cross-calibration equations can be derived in the short-term and hence there is no immediate possibility of producing a standardised normal range such as has been produced for hip BMD as assessed by DXA[40]. Arbitrary cut-offs for diagnosis as used by some manufacturers, in addition to be scientifically incorrect, may lead to some patients being falsely reassured or alarmed.

Some practitioners may decide to use QUS as an indicator of risk, for example scoring individuals as high, medium or low risk based on fracture algorithms with treatment decisions being based on QUS parameters and the presence of strong clinical risk factors. Recently this approach has been partially endorsed by the Scientific Advisory Group of the International Osteoporosis Foundation[4]. If practitioners do use QUS in this way, they must realise that a subsequent BMD measurement may not show high risk subjects to have osteoporosis and that some antiresorptive therapies may only have clinical anti-fracture efficacy in women with low BMD, as has recently been demonstrated with alendronate[41].

Can QUS parameters be used clinically to monitor rates of bone loss or response to antiresorptive osteoporosis therapy?

Currently the precision of ultrasound[5,38,42], combined with the low rate of change of bone mass at peripheral sites, suggests that it is impossible to assess increases in bone mass in an individual patient over a short period of time (up to two years) with therapies such as hormone replacement therapy (HRT)[43], calcitonin[44] or bisphosphonates, although it is clear that QUS parameters do demonstrate response to therapy in groups of women in some clinical trials[43-45]. However, the mean changes after 2-4 years do not exceed the least significant change detectable, which is represented by a figure 2.8x the precision error[46]. On the other hand, if extensive bone loss occurs such as after prolonged bed rest, it may be measurable in individual subjects[47].

The potential use of QUS as a tool for assessing response to therapy therefore will be highly dependent on the precision of the method in the population in whom treatment is being offered. The smaller the precision error and the larger the expected change in bone mass, the greater will be the monitoring potential for the equipment. While for some QUS devices, precision may be equally as good in subjects with low bone mass when compared to younger subjects with normal bone mass[38], for most QUS devices, the combination of limited precision and the slow rate of change of bone mass at appendicular sites, means that use of QUS to monitor rates of bone loss or bone gain with treatment cannot be recommended at present.

QUS measurements suffer from some technical problems, which do not appear to be replicated with other bone mass measurement technologies. For example dry systems in particular may give falsely low readings in patients with peripheral oedema[48] and this will adversely affect precision for follow-up measurements as well as producing falsely high fracture prediction algorithm. A further problem is temperature dependency, which may be partly mediated by the ambient temperature of the room[49] but is also dependent on heel temperature[50]. Care must be exercised therefore in using the technology in environments with variable temperature and repeated measurements should be undertaken at the same ambient temperature to minimise precision errors. Use of devices with a water-bath heated to a uniform temperature may reduce the significance of this problem[49].

Can QUS be used for clinical purposes in males, young pre-menopausal women and children?

Although there are now some data showing the predictive capacity of QUS parameters for fracture in men[16], more data are required before QUS can be recommended as a universal bone mass measurement technique for both sexes and at all ages.

Summary

In summary, based on current published peer-reviewed data QUS and its assessed parameters, BUA, SOS or derived indices, can be used in the following situations:

- for assessing the risk of osteoporotic fractures in the community in post-menopausal women,
- as an improved method of targeting women for axial BMD measurement to diagnose osteoporosis,
- with care, to target antiresorptive treatments when low QUS measurements are present in addition to major clinical risk factors.

QUS measurements must be made by appropriately trained personnel and the results require interpretation by an experienced physician with specific knowledge of osteoporosis and its management.

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Appendix

National Osteoporosis Society (NOS) Code of Practice for the use of quantitative ultrasound (QUS) in the management of osteoporosis

This recommended Code of Practice was produced by the NOS Bone Densitometry Forum Committee in December 2001.

Referral

1. QUS scans should be requested by the general practice team.
2. Referral should follow the recognised guidelines issued by the Royal College of Physicians, although these were intended originally for referral to DXA.

Organisation

3. Clinical responsibility for the service should rest only with a registered medical doctor, experienced in bone mass measurement.
4. Operators should preferably be qualified health care professionals (such as a nurse, radiographer or clinical technologist) and should be registered with a professional body.
5. Operators must have received clinical training in osteoporosis, the basic principles of QUS and its use for fracture risk assessment, in addition to a detailed knowledge of their specific QUS equipment.
6. A QUS service should not be linked to the sale of dietary supplements or other products.

Procedure

7. All measurements should be carried out according to manufacturer's standard operating procedures and should aim to minimise variability in heel and ambient room temperature.
8. Equipment must be subject to a regular service (at least once a year) and a quality assurance assessment (at least once a week) using manufacturer or appropriate specific phantoms (i.e. a device used to ensure the machine gives consistent results).

Interpretation of results

9. It must be made clear to the patient that QUS results cannot be used to diagnose osteoporosis but can be used as an independent risk factor for future osteoporotic fracture in peri-menopausal and post-menopausal women (i.e. women going through or after the menopause). The use of QUS for the assessment of bone mass in children, pre-menopausal women and men is not recommended.
10. The results of QUS should only be interpreted by an experienced medical doctor with specific knowledge of osteoporosis and its management. A health care professional, with training and expertise in the clinical use of QUS, may assist the patient's understanding of osteoporosis and provide information on lifestyle and therapeutic options as appropriate.
11. The woman's referring doctor should be provided with written results of their QUS scan. Women with abnormal results should be advised to discuss the results further with their GP/referring doctor.
12. Prescription of therapeutic intervention should only be provided by a registered medical doctor, who must take other relevant risk factors for osteoporotic fracture into account.

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