The evidence base on the orthopaedic NICE report

Since the publication of its first guidelines the National Institute for Clinical Excellence (NICE) has come under a lot of criticism, particularly with respect to its recommendations in medicine (Bratby, 2001). The first appraisal in the field of surgery was on total hip replacement (THR) and was issued in April 2000 (NICE, 2000).

There are a very large number of hip prostheses available, many of which have been subject to incremental design change and evolution over the years. It was therefore decided to produce benchmarks that would not only be applicable to current prostheses but also to those that might be produced in the future. The decision to introduce benchmarks has been widely welcomed in order to reduce the risks of poor quality prostheses being implanted in large numbers before their drawbacks are recognized, e.g. the Capital hip (Massoud et al, 1997).

Concern has been expressed that these recommendations aim mainly to limit prosthesis selection, thereby rationing health care, rather than promoting best practice.

ORTHOPAEDIC LITERATURE

The orthopaedic literature examining THR is vast, but most reports are survival studies. These commonly rely on revision as being the end point as an indicator of failure. This is rather a coarse indicator and, regrettably, many prostheses are loose and symptomatic for many years before being revised. Other patients may die with loose prostheses in situ. Clearly such patients should not be regarded as successes and should not be included in evidence designed to influence the choice of prosthesis used. However, the introduction of 'soft' outcome measures, for example pain, would introduce a further degree of subjectivity to the whole process and may not enhance the actual definition of failure. It is therefore difficult to produce quality evidence-based guidelines or standards from the current literature.

THE NICE REPORT

NICE acknowledged this in their appraisal document and concluded that there was an urgent need for randomized controlled trials including economic evaluation, particularly in the younger patient. However, this does not change the fact that the evidence base for any recommendations was poor.

The following guidance was issued:

- A revision rate of 10% or less at 10 years should be regarded as the current benchmark for the selection of primary THRs
- For those prostheses where available follow up is less than 10 years, a minimum of 3 years revision rate experience is required and performance consistent with the 10-year benchmark (1% revision rate per year)
- Prostheses not meeting the above benchmarks should be the subject of comparative clinical evaluation before being recommended for routine use in the NHS.

NICE found only four randomized controlled trials of 5 years or more duration and only one of these passed the NICE quality assessment (Garellick et al, 1999):

1. Clarity of randomization process
2. Blinding of outcome assessment
3. Clarity of losses to follow up and technique of statistical analysis.

There were no systematic reviews available. It was suggested that these trials demonstrated lower revision rates for cemented *vs* cementless prostheses but there were no long-term data and only one acceptable randomized controlled trial does not make a quality evidence base.

Ten comparative observational studies of 5 years or more are quoted; the assessment of quality was based on:

1. Use of unselected cases
2. Use of case mix adjustments
3. Appropriate statistical analysis.

The ten papers demonstrate mixed compliance with the above standards. However, twelve prostheses had met the selection criteria (three of these were uncemented), and thirteen had not (one of which was uncemented). It is not at all clear on what scientific basis NICE determined the level of their benchmark at 10 years. They follow this statement with a note of caution, explaining that the results of many of these observational studies may not be reliable as they are of variable quality and a number failed to use survivorship methods to analyse the results. If this was the case then these studies did not fulfil the quality inclusion criteria (point 3) and should not have been used to form the basis of the guidelines.

NICE go on to present an economic evaluation of primary THR based on two papers which used modelling methods to assess cost effectiveness. This seems to form the basis for their concluding statement recommending the use of cheaper cemented prostheses, although they clearly accept that these models are based on assumptions and poor quality data.

INTERNATIONAL FINDINGS

There is currently more literature on the long-term viability of cemented prostheses (particularly in the British literature for obvious historical reasons), which in many cases occupy the lower end of the cost range. No mention is made of the increasing body of American and European literature reporting excellent medium-term results from the second generation cementless prostheses. In this respect NICE appears to have been highly selective in its review of the literature and has emphasized the good results for cemented prostheses only. No mention is made, for example, of the

Harris–Galante uncemented cup, which has shown a survivorship rate of 97.7% at 11 years (Böhm and Bösche, 1998) or the JRI Furlong uncemented THR, which has shown a survivorship of 97% at 10 years (McNally et al, 2000).

It is important to appreciate the extraordinarily long lengths of time that are required for hip prostheses to prove themselves. While there is no doubt that prostheses such as the Charnley and Exeter have achieved excellent long-term results, these are designs that originated from the 1960s and have been modified over time. Many of the quoted long-term results rely upon relatively small numbers of surviving patients. The use of large national databases, however, is increasing the accuracy and reliability of these long-term statistics. It is vital that progress in implant design should continue to be made. It should be recognized that there may be many new implant improvements and designs that will prove themselves over the next 10 years. The concept of achievable benchmarks before widespread introduction is useful but these standards should be based on sound evidence and not cost.

NICE has been criticized for its role in health-care rationing and for undermining the concept of evidence-based decision making in medicine (Smith, 2000; Bratby, 2001). Within the field of orthopaedics its guidelines on hip prostheses appear to be out of step with both the world literature and current practice.

Overall it appears that there was inadequate high quality literature with which to establish evidence-based guidelines and the resulting recommendations seem to reflect an attitude where decisions have been made largely on cost. HM

KEY POINTS

- The National Institute for Clinical Excellence performed an appraisal of primary total hip replacement in April 2000.
- The appraisal accepts that there were problems with the quality of the literature, but still included papers that failed the quality assessment.
- The evidence base on which the guidelines are based is weak, but both the selection of the literature and the interpretation appear to be flawed.

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