What impact have NICE guidelines had on the trends of hip arthroplasty since their publication?

THE RESULTS FROM THE TRENT REGIONAL ARTHROPLASTY STUDY BETWEEN 1990 AND 2005

V. I. Roberts,
C. N. Esler,
W. M. Harper
From the Trent and Wales Arthroplasty Audit Group, Leicester, England

The National Institute for Clinical Excellence (NICE) published the guidelines on the selection of prostheses for primary hip replacement in 2000. They supported the use of cemented hip prostheses to the exclusion of uncemented and hybrid implants. The information from the Trent (and Wales) Regional Arthroplasty Study has been examined to identify retrospectively the types of hip prostheses used between 1990 and 2005, and to assess the impact that the guidelines have had on orthopaedic practice.

The results show that the publication of the NICE guidelines has had little impact on clinical practice, with the use of uncemented prostheses increasing from 6.7% (137) in 2001 to 19.2% (632) in 2005. The use of hybrid prostheses has more than doubled from 8.8% (181) to 22% (722) of all hips implanted in the same period. The recommendations made by NICE are not being followed, which calls into question their value.

The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom was originally set up in 1999 as the National Institute for Clinical Excellence, and is responsible for providing national guidelines on the promotion of good health and the prevention and treatment of ill health. Once NICE publishes clinical guidelines, health professionals are expected to take them into account when deciding on the treatment to give patients and commissioners are expected to give them regard when negotiating contracts.

In April 2000, NICE published the Technology Appraisal Guidance (TAG) No. 2 - "Guidance on the selection of prostheses for Primary Total Hip Replacements" which has remained unaltered following review in 2003. Like most NICE guidelines, TAG No. 2 contains several related sections, including guidance, evidence and implementation. The section on guidance recommends the use of a prosthesis which meets the standard as set by the ten-year ‘benchmark’ with a revision rate of 10% or less at ten years. However, the institute also recommends the use of prostheses with a minimum of a three-year revision rate if their performance is consistent with the ten-year benchmark.

Also in its guidance (Section 1.5), NICE recommends the use of cemented prostheses as a result of there being “currently more evidence of the long-term viability of cemented prostheses, than there is for uncemented or hybrid prostheses.” The recommendation to use cemented prostheses to the exclusion of uncemented and hybrid implants was strengthened by the evidence in TAG No. 2, in which NICE states that there was “no cost effective data, based on revision rate of ten years or more follow-up, to support the use of generally more costly uncemented and hybrid hip prostheses.” It also advised that there was “no reliable evidence to support the proposition that the potential case of revision of a hip prosthesis would outweigh its poorer revision rate.” In other words the use of an uncemented prosthesis would not be advantageous in a younger patient who may need a revision when that particular prosthesis has a higher rate of failure and revision. Instead NICE supported the use of cemented prostheses.

As more than five years have passed since the publication of these guidelines, we decided to review the effect it has had, and the extent to which the guidelines have influenced clinical practice and contracting.

Patients and Methods
The Trent Regional Arthroplasty Study is based at Glenfield General Hospital NHS Trust, Leicester. Since the beginning of 1990, and with the agreement of all consultant orthopaedic surgeons in the region, all primary total hip and knee replacements (THR, TKR) performed throughout the Trent region were
recorded prospectively. In 1990, the region had a population of 3.9 million (1991 census), served by 24 hospitals. In 2005, the population had risen to 4.0 million (2001 census), served by 21 hospitals.

The register consists of two standardised questionnaires, and requires patient consent. The first questionnaire is completed by each surgeon at the time of the operation and it records demographic, medical and operative details for each patient and implant. This information is validated by a peripatetic clerk and entered onto a database. The second form is a one year post-operative, self-administered, validated questionnaire which is sent to all patients to assess their level of satisfaction. The register has details of 42,403 primary hip replacements and resurfacings performed to date.

Results

In 1990, 2,285 people (1,400 female, 885 male) had a primary hip replacement entered in the registry, but the number had increased to 3,058, with a further 238 patients undergoing hip resurfacing (i.e., 3,296), in the year 2005. The rise in the number of operations registered is multifactorial. It reflects the inclusion of more surgeons in the Arthroplasty Audit Group, the increase in population in the region, and the increasing acceptance and expectation of joint replacement surgery.

Although the numbers of patients have increased over the 15 years, the percentage in each age group has remained unchanged. There has been a relative increase in the elderly population, but without any reciprocal rise in the proportion of patients aged 75 or over who received a joint replacement. In 1990, 28.9% (660) of patients were aged 75 or over. In 2005 this percentage was 28.1% (925). The ratio of females to males remains constant at approximately 3:2.

In 2000, when the NICE published guidelines supporting the use of uncemented prostheses, there was a marginal increase in the proportion of uncemented hips implanted in the Trent and Wales regions (Fig. 1). However, within a year of the publication of the NICE guidelines, the use of uncemented prostheses has increased overall. The proportion of uncemented hip replacements had increased dramatically. The year before the publication of the NICE guidelines they accounted for 6.7% (137) of prostheses used but in 2005 accounted for 19.2% (632).

Before the publication of the NICE guidelines there was an increasing trend to use hybrid prostheses typically with an uncemented acetabular component and a cemented stem, with their popularity steadily increasing since the early 1990s (Fig. 2). In the two years after NICE published its guidance, there was a reduction in this trend. However, since then, there has been a continued rise in the use of hybrid hips. In 2004, the proportion of THRs that were hybrid peaked at 25.9% (907).

As expected, these increases in both hybrid and uncemented prostheses over the past five years have led to a reciprocal decline in the use of fully cemented prostheses (Fig. 3).

One potential explanation for this increase in the use of hybrid and uncemented prostheses is a younger population requiring THRs. However, the proportion of patients, aged less than 55 years, who have had a THR has remained similar over the past 15 years. In 1990, this age group constituted 11.8% (269) of all the patients receiving hip replacements, and in 2005 it constituted 12.6% (416).

Figure 4 highlights the distribution of prosthesis type in each age group and compares the results of 1999 with those of 2005. It is evident from the figure that uncemented and hybrid prostheses are now more favoured in patients under the age of 60 years than they were 15 years ago.

In 2002, the NHS Purchasing and Supply Agency set up the Orthopaedic Data Evaluation Panel (ODEP),2 to independently evaluate the effectiveness of prostheses. In March 2004, ODEP3 published the first list of all products...
that comply with the ten-year benchmark set by NICE. This has since been revised to include prostheses that attain any of the NICE benchmarks. In 2001, 42 different acetabular components were used, but in 2005, this number had increased to 44. In 2001, ten acetabular components were responsible for 80% (2012) of the acetabular implants used. At that time, only three of these ten would have attained the minimum NICE guideline of at least three years revision rate experience, on target with the ten-year benchmark. In 2005, the same ten acetabular components constituted 79% (2409) of the market use. However, eight of these ten have now attained this minimum NICE guideline (Fig. 5). In 2001, a total of 36 different stems were used, but in 2005, this number had again increased to 44. In 2001, eight stems were responsible for 76% (1912) of all femoral components used, and in that year, five of these eight would have attained the minimum NICE guideline of three years revision rate experience. In 2005, the same eight femoral stems were responsible for 79% (2604) of market use and seven of these eight have now passed the minimum NICE benchmark (Fig. 6).

Discussion

The National Institute for Health and Clinical Excellence publishes guidelines on the management of many diseases and causes of ill health, which affect policy decisions on purchasing and provision. These guidelines are prepared after evaluation of published evidence and research and are issued to influence doctors in their management of patients. The initial NICE document on primary THR advocated the use of cemented hip prostheses to the exclusion of hybrid and uncemented implants. However, since their publication, the proportion of both uncemented and hybrid prostheses has increased in our region, from 6.7% (137 prostheses) in 1999 to 19.2% (632 prostheses) in 2005, and from 8.8% (181) to 22% (722) respectively. The year before the NICE guidelines were published, cemented prostheses accounted for 84.5% (1735) of all prostheses used in THRs and, five years after their publication, this had fallen to 58.8% (1937).

Other studies that have audited the implementation of various NICE guidelines in clinical practice have found similar results. Price-Forbes et al felt that their results may be explained by clinicians needing to make an individual decision for each case rather than prescribe arbitrarily according to NICE guidelines. Arasaradnam et al stated that clinicians might not be adhering to NICE guidelines purposely because they disagreed with certain aspects of the recommendations.

It is not certain why these guidelines have not been followed but the method of fixation for THRs has always been a controversial topic. There is now an increasing number of long-term studies which support the use of uncemented and hybrid hip replacements. These reports were not all published when the NICE guidelines were being prepared. The emerging literature, which is frequently presented at scientific meetings before full publication, may influence the selection of prostheses by the surgeon. This may explain why almost 10% of patients over the age of 70 received uncemented prostheses.

Another possible reason for not following the guidelines is that the selection of a prosthesis may be undertaken by the patient, or be operation-dependent. Hip resurfacings are becoming more popular in patients under the age of 60, and in 2005 accounted for 7.2% of all hip replacements. The majority of these are hybrid prostheses, with an uncemented acetabular component and a cemented femoral component by design. Surgeons may also believe that the patient who is
likely to outlive their prosthesis may be best served by an implant which they feel will maintain bone stock.

The NICE guidelines also recommended selecting a prosthesis that attained the ten-year benchmark of a revision rate of 10% or less at ten years, or that had a minimum of three years revision rate experience and was on target to reach this benchmark. Since the publication of the guidelines, the number of prostheses used which have attained these standards has increased.

The introduction of ‘Payment by Results’ by the Department of Health, where every operation has a set non-negotiable fee, may have an impact on the future choice of prosthesis used in THR. Financial constraints faced by each trust may force increased use of cemented devices at a time when increasing evidence is emerging for the long-term effectiveness of uncemented implants.

The authors would like to acknowledge the surgeons of the Trent (and Wales) Regional arthoplasty study for their ongoing help and support.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References