NICE news in the annals

Recent NICE Guidance of interest to surgeons

STEVEN BARNES and BRUCE CAMPBELL

Interventional Procedures

Shoulder resurfacing arthroplasty (July 2010)

Shoulder resurfacing surgery is being used increasingly as an alternative to total shoulder arthroplasty. Insertion of the humeral head stem component of a total arthroplasty has a risk of fracturing the humerus and resurfacing avoids this. Degenerative arthritis is the usual indication and this can result from a range of conditions, most commonly osteoarthritis, rheumatoid arthritis or avascular necrosis. Conservative treatment with analgesics and non-steroidal anti-inflammatory drugs, and corticosteroid injections often provide adequate relief but, when symptoms persist, an arthroplasty may be required.

The aim of shoulder resurfacing arthroplasty is to replace only the damaged joint surfaces (not necessarily the whole humeral head) with minimal bone resection. Using a deltopectoral or anterosuperior approach, the deltoid muscle is split exposing the humeral head which is reamed if necessary to restore its shape. A hole is drilled and an articular prosthesis covering the whole or part of the humeral head is fitted using a small anchoring peg, often with morcellated bone or bone cement. As with conventional shoulder arthroplasty, the procedure may be a hemi-arthroplasty where only the humeral component of the joint is replaced, or may involve resurfacing/replacement of the glenoid when necessary.

Considering the numbers of shoulder resurfacing arthroplasties which are being done, the published evidence base was rather sparse, with just two comparative studies against another surgical intervention (total shoulder arthroplasty, or fusion). These, and four case series reported improvements in range-of-motion and shoulder function scores. Specialist Advisors stated that no particular complications were likely over or above those that would be expected using a traditional stemmed prosthesis. On the basis of all this, NICE guidance recommends normal arrangements for use of this procedure in clinical practice.

Phototherapeutic laser keratectomy for corneal surface irregularities (September 2010)

This procedure uses a similar technique to that regularly used on the high street for laser correction of refractive

errors, but in this context it is used to improve the shape of the surface of the cornea to encourage development of healthy corneal epithelium. Local anaesthetic eyedrops are applied and the corneal epithelium is mechanically removed. A laser is used to ablate thin layers of corneal tissue sequentially. Postoperative management consists of an eye pad or bandage contact lens until epithelialisation, topical antibiotics and non-steroidal anti-inflammatory drugs for a few weeks, and sedatives. The indications for this procedure include a range of pathologies that result in symptomatic corneal surface irregularities, such as band keratopathy, corneal scarring (resulting from trauma or previous corneal surgery), nodular degeneration, and epithelial basement membrane dystrophy. Common symptoms include pain, foreign body sensations, and hypersensitivity to light. In addition to relieving these symptoms, successful surgery may also provide benefits in terms of visual acuity if corneal clarity is improved by the removal of the irregular surface and a healthy epithelium is achieved.

Data on 661 patients were available including a case series of 216 patients in whom 103 eyes with recurrent erosion were followed up for a minimum 12 months following the procedure. Further recurrent erosion occurred in only 9% (9/103) of eyes. Specialist Advisers nominated by the Royal College of Ophthalmologists and the College of Optometrists reported that, despite theoretical complications such as corneal ectasia, scarring, and induction of astigmatism/refractive error, the procedure provides an effective alternative treatment to more invasive interventions such as lamellar keratoplasty. The Interventional Procedures Advisory Committee concluded that the safety and efficacy of this procedure is adequate to support its use with 'normal arrangements', but stipulated that patient selection and treatment should be carried out only by ophthalmologists who specialise in corneal surgery.

Percutaneous intradiscal laser ablation in the lumbar spine (September 2010)

This is the third intradiscal ablation procedure for symptomatic herniation of lumbar intravertebral discs that the NICE Interventional Procedures Programme has been

asked to consider. The procedure (also commonly referred to in the literature as percutaneous laser disc decompression) is undertaken under fluoroscopic guidance: a spinal needle is inserted through the annulus fibrosus into the nucleus pulposus, and an optical fibre is introduced. Laser energy is used to vaporise part of the nucleus pulposus, to reduce compression of adjacent nerves. The alternative options for treating patients with nerve compression causing weakness or persistent symptoms from lumbar disc herniation include microdiscectomy, and percutaneous disc decompression.

The largest study published compared 1000 patients who were treated either with percutaneous intradiscal laser ablation (500) or microdiscectomy (500). At 2-year follow-up, an excellent or good clinical outcome was reported in 84% (419/500) and 86% (428/500) patients, respectively. Neurological symptoms improved in both groups, and the rate of re-intervention for re-herniation or persistent pain was 3% (16/500) in the laser ablation group and 7% (35/500) in the microdiscectomy group. One Specialist Adviser commented that the procedure is thought to be particularly valuable for patients with early disc degeneration and those with leaking discs.

Guidance for this procedure recommends normal arrangements for clinical governance, consent and audit. Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression.

Clinical Guidelines

Barrett's oesophagus – ablative therapy (August 2010)

Barrett's oesophagus resulting from chronic gastro-oesophageal reflux disease can become dysplastic and may result in oesophageal cancer. Oesophagectomy is the standard treatment for high-grade dysplastic Barrett's oesophagus or intramucosal cancer, but it is associated with significant morbidity and mortality. A new clinical guideline has been published which makes recommendations on alternative treatments – endoscopic mucosal resection, ablative therapies (argon plasma coagulation, laser ablation, multipolar electrocoagulation, radiofrequency ablation and photodynamic therapy), and combinations of these.

The guideline is based on a systematic review of the relevant published clinical studies, and on an economic model of treatment options. The recommendations include:

1. Before considering endoscopic therapy as an alternative to surgery, a confirmed diagnosis of high-grade dysplasia or intramucosal cancer in Barrett's oesophagus should

be agreed by a designated specialist multidisciplinary team for oesophagogastric cancer.

2. All treatments for high-grade dysplasia and intramucosal cancer in Barrett's oesophagus should be performed by specialist oesophagogastric cancer teams with the experience and facilities to deliver the treatments recommended in the guideline.
3. Consider using endoscopic mucosal resection alone to treat localised lesions.
4. Use circumferential endoscopic mucosal resection with care because of the high incidence of stricture formation.
5. If using endoscopic mucosal resection, consider following this with an additional ablative therapy (radiofrequency ablation, argon plasma coagulation or photodynamic therapy) to remove residual flat dysplasia completely, taking into consideration the side-effect profiles.
6. Consider using radiofrequency ablation alone or photodynamic therapy alone for flat high-grade dysplasia, taking into account the evidence of their long-term efficacy, cost and complication rates.
7. Do not use argon plasma coagulation, laser ablation or multipolar electrocoagulation alone, or in combination with each other, except as part of a clinical trial.

Other Guidance

Between July and September 2010, NICE published further guidance (or reviews of existing guidance) of relevance to surgeons (listed below) which could not be summarised here. Please refer to the NICE website (<www.nice.org.uk>) for details.

Interventional Procedures Guidance

- Endoscopic submucosal dissection of oesophageal dysplasia and neoplasia
- Laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer
- Percutaneous mitral valve annuloplasty

Clinical Guidelines

- Metastatic malignant disease of unknown primary origin.

Requests by NICE for advice from specialists

BRUCE CAMPBELL

Chair, Interventional Procedures Advisory Committee

A fundamental principle of all NICE guidance is that it is based on the best available evidence. Whatever the amount and quality of published evidence (which is often limited), there is always a need for contributions from ‘stakeholders’ of all kinds, including patients, carers and industry, to complement the evidence in the literature. Clinical specialists are particularly important and NICE relies heavily on them for their knowledge and advice.

All NICE’s advisory committees and guideline development groups have a range of specialists on them – all appointed after advertisement. They appraise the evidence and reach consensus with other members about what NICE guidance should recommend. They depend, in turn, on the contributions of many other specialists relevant to each specific topic. These specialists are generally identified and ratified by their specialist organisations: the aim is to get advice from people who are recognised by their peers as respected opinions for each topic. This means that specialist organisations may receive a variety of requests from NICE relating to advice for its different guidance programmes. This article aims to describe very briefly these different programmes and what they ask of their advisers. Note that they use different terms (italicised in the text) to refer to the specialists who help them, for a variety of considered reasons.

NICE’s Technology Appraisals Programme

This produces guidance on the clinical and cost effectiveness of licensed medications and other technologies. While pharmaceuticals tend to dominate its agenda, surgical interventions have included laparoscopic procedures, endovascular stent grafts for aneurysms and hip surgery. All requests for advice from clinical specialists are directed through professional organisations. Written commentary and advice on the ‘scope’ for each topic is prepared by specialists whom they choose and returned to NICE in an anonymous format. Next, nominated specialists attend a ‘scoping workshop’ in which the interventions and indications that NICE will aim to evaluate are properly specified. Months later, once all of the available evidence has been assembled, *Clinical Experts* nominated by their organisations come to the Appraisals Committee meeting. They are asked to provide brief written submissions in advance and then attend to answer detailed questions from the committee (Patient Experts attend in just the same manner).

The Interventional Procedures (IP) Programme

This publishes guidance on the safety and efficacy of procedures (including open, percutaneous and endoscopic procedures and those involving radiation such as X-rays or laser). The published evidence is often limited, so specialist advice is of great value. Following discussions with specialist societies and Royal Colleges, *Specialist Advisers* are normally requested via those organisations for each procedure. Each Specialist Adviser is asked to complete a proforma of questions about the procedure. Occasionally, NICE may need to contact Specialist Advisers to ask about specific aspects of the procedure (this may happen on an informal basis in other programmes, too). When there is no relevant specialist on the Advisory Committee, then NICE calls on one Specialist Adviser to join the committee meeting by telephone to offer comments and to answer any questions. Despite the best intentions of one and all, getting specialist advice remains the rate-limiting step for the IP programme.

The Evaluation Pathway Programme for Medical Technologies

This is one of NICE’s newest work programmes. It aims to identify devices and diagnostics which offer advantages to patients and/or to the health service and to route them for evaluation to the most appropriate NICE programme for production of guidance, with the goal of encouraging their adoption into the NHS. Guidance may also recommend research into promising new technologies. All this is driven by the Medical Technologies Advisory Committee (MTAC), which depends on *Expert Advisers* for their help – both via a questionnaire (several Advisers for each technology) and by joining the committee meeting by telephone (usually one Adviser for each technology). Some Expert Advisers for technologies may not be medical specialists, but from other disciplines within the NHS. Published evidence on new devices and diagnostics may be as sparse as for interventional procedures; and so the contributions of Expert Advisers are crucial.

The Diagnostics Assessment Programme

This started its work this year. As with the Technology Appraisals Programme, specialists nominated by their professional organisations attend scoping meetings.

Thereafter, it has decided on a model for getting specialist advice which is a hybrid between other standing committees and guideline development groups – advertising for *Specialist Committee Members* who join the committee for the meetings relating each specific technology (usually about six specialist members for two meetings).

NICE Clinical Guidelines on the management of particular conditions or symptoms are produced by specifically appointed groups, made up of specialists, lay members and others appointed by advertisement. In some cases, guideline groups may request advice from other specialists about specific matters. Similar principles apply to the groups devising *NICE Quality Standards*.

For all the NICE programmes, advisers are automatically notified about the start of public consultation on draft guidance, so that they have a good opportunity to study it and to send any comments for consideration by the committee.

Specialist advice can be hugely influential, particularly when specialists offer thoughtful insights about the use, context and place of interventions, and reasoned comments about matters such as patient preferences, training, effects on related services, or other issues which may not be dealt with in the published literature. If there is ever doubt about the kinds of advisers who are needed, or about what is required in terms of specialist advice, each of the programme teams will always be pleased to discuss these matters. With the pressure of time that often exists, prompt advice (or even a prompt refusal) is of great value, and the analysts and others at NICE welcome close engagement with the specialists who are helping them.

NICE depends on the goodwill of specialists for their time and effort in giving advice. Thanks to all of you who have contributed in the past – and a message of gratitude in advance to those who I hope will help in the future.