Wireless capsule endoscopy

This is a novel way of investigating obscure gastrointestinal bleeding recurring after a negative initial endoscopy. It is used when bleeding from the small intestine is suspected, caused by vascular lesions, tumours or Crohn’s disease. It has also been used in the diagnosis of coeliac disease. Several methods exist for the evaluation of the small intestine, including push enteroscopy, intra-operative endoscopy, and small bowel follow through; however, these methods may fail to provide a diagnosis. Wireless capsule endoscopy involves the patient swallowing a small capsule containing a camera, a light source and a wireless circuit for the acquisition and transmission of signals. Evidence from a health technology assessment found that the technique detected a bleeding source in 31–76% of patients with obscure gastrointestinal bleeding. Case series have shown that wireless capsule endoscopy can identify small bowel lesions suggestive of Crohn’s disease in 43–71% of patients with normal findings on conventional tests. The NICE Interventional Procedures Committee concluded that this procedure was safe and diagnostic yield sufficient to recommend its use with normal arrangements for consent and audit. However, clinicians should consider alternative diagnostic measures prior to wireless capsule endoscopy in patients with Crohn’s disease in whom strictures are suspected because of the danger of obstruction to progress of the capsule, occasionally requiring laparotomy.

Radiofrequency ablation for colorectal metastases in the liver

Radiofrequency ablation (RFA) is a thermo-ablative technique which produces tumour destruction by heating cancer cells to temperatures exceeding 60°C. It has been used for treatment of hepatocellular carcinoma and also for treatment of hepatic metastases (commonly from colorectal carcinoma). Surgical resection is the standard treatment for patients with localised colorectal liver metastases, but many patients are unsuitable for surgery because of the extent of their metastatic disease. Studies showed that, following RFA, local recurrence ranged from 4% at a median 15 months’ follow-up to 55% at 18 months’ follow-up: results may depend on the method of access used for RFA. It was noted that RFA is less effective for metastatic disease than for primary liver tumours. There were no randomised comparisons of RFA and surgery. Complication rates were low and included bile duct stricture, bowel perforation, wound infection, peritoneal seeding and postoperative bleeding. Specialist Advisors suggested that most tumours require more than one procedure to achieve complete ablation. As there was no evidence for increased survival with this procedure, it is recommended that this procedure is not undertaken without special attention to for patient consent; and that thorough audit is undertaken, to provide better survival data.

Prosthetic intervertebral disc replacement

Artificial intervertebral discs have been developed as an alternative to spinal fusion for patients with refractory back problems and a number of different types are now commercially available. The design of most prosthetic discs is similar, with two metallic endplates separated by a more pliable inner core designed to simulate the biomechanical properties of the nucleus pulposus. The proposed advantages of prosthetic disc replacement compared to discectomy and spinal fusion include maintenance of range of motion, delay in degenerative changes at adjacent levels, and avoidance of pseudoarthrosis and bone graft donor site complications. Prosthetic intervertebral discs may be used in treatment of herniated lumbar intervertebral disc, degenerative lumbar disc disease, post-laminectomy syndrome, or patients with low back pain refractory to conservative treatment. Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement was considered adequate to support the use of this procedure with normal arrangements for governance and consent. However, there is little evidence on outcomes beyond 2–3 years: patients should be told this and reporting of long-term outcomes will help to guide future use of this technology.

Sacral nerve stimulation for faecal incontinence

Initially a treatment for urinary incontinence, sacral nerve stimulation (SNS) is currently used to treat faecal incontinence due to functional (rather than structural) deficits of the anal sphincter. The procedure is performed...
in two stages: (i) peripheral nerve evaluation; and (ii) chronic therapeutic stimulation by a permanent electrode and lead sutured to the sacral periosteum, and a neurostimulator implanted under the skin of the hypogastrium. NICE commissioned a systematic review of the available evidence which included 226 patients from case series. The evidence suggested that SNS is a safe way of treating faecal incontinence. A few patients experienced complications such as implant infection, electrode dislodgement and pain at the implant site. In terms of efficacy, SNS showed good results in patients with faecal incontinence due to functional deficits, although longer-term follow-up is still needed. Clinical benefit may be lost when the stimulator is switched off. Patients’ perceived quality of life was shown to improve as a result of SNS. NICE recommended that SNS should only be used in specialist units by clinicians with a special interest in faecal incontinence.

Crafting interventional procedures guidance

All our guidance is constructed in a standard format. Section 1 sets out the main recommendations and each part must be directive, i.e. it must recommend how clinicians should act. Even if the evidence is limited and poor, it is not sufficient for the Committee simply to state this or to make observations: they must produce directive statements. These are usually based on the premise that the evidence is ‘adequate’; or that it is inadequate, limited or uncertain, prompting recommendation of special arrangements for governance, consent, and audit (or research).

As the programme has developed, we have become increasingly inclined to separate statements about safety and about efficacy. We now try to be explicit about particular aspects of efficacy: for example, in recent recommendations on procedures for prostate cancer, evidence on efficacy was based on PSA levels and biopsy findings, but not on quality of life or survival. The latter would have been desirable but their absence was not considered a good enough reason to demand special arrangements for clinical governance or audit. The guidance makes this clear, recommending that patients should be fully informed about these uncertainties and suggesting the advantage of more data on these outcomes from future trials.

Section 1 of the guidance also includes any other recommendations which the Committee considers relevant – about training, submission of data to registries, or research. It is always the aim that these should be as explicit as possible, specifying which registry or what research outcomes might be particularly helpful. Ideally, any reference to training is accompanied by reference to specific training standards but this is not always possible (specialist organisations are asked if they are able to produce standards or a statement on training, but they are not always able to do so).

One particularly contentious area is that of recommending the circumstances in which a procedure should be carried out – by specifying particular specialists, with particular facilities, or in particular types of teams. This can be very difficult, because it may be clear that a procedure is highly specialist, but it may be done by completely different types of specialist in different places. This is one part of guidance in which skilful wordcraft is vital. This craft is never intended to create weasel words but rather to convey the intended sense of recommendations as clearly as possible and to avoid needless quibbles and criticisms. A recent example was the complaint about guidance on a paediatric cardiac procedure, which had recommended: ‘endovascular atrial septostomy should be undertaken in specialist paediatric cardiology units’. A consultant responded to NICE about two of the words (in bold for the purpose of this example) because his team travelled to other hospitals to perform the procedure. Accepting that this was safe and reasonable practice, the wording was changed to: ‘endovascular atrial septostomy should be undertaken by specialist paediatric cardiology teams’.

The example in the preceding paragraph highlights the importance attached to the words used in our guidance. The choice between ‘must’ and ‘should’ is another example which can tax NICE advisory committees and inflame some clinicians. We need to be as clear and pedantic as possible, but for their part clinicians need to remember that our recommendations are simply guidance and if they are practising responsibly this can very reasonably be sanctioned locally. A previous article has highlighted the debate about the words ‘uncertain’ and ‘inadequate’ when used to describe evidence. They are intended to convey scientific uncertainty but have been used by some healthcare funders and by the press to imply that a procedure is unsafe or that it should not be funded. Finding words which are immune from this kind of misinterpretation is tricky.

The second section of the guidance is about the procedure – its indications and a simple description of what it involves. Relevant alternative treatments may be listed. As described in a previous article all of this is, by design, kept as brief and simple as possible. It is not proper for our guidance to specify indications in the absence of adequate evidence nor can comparisons be made with alternative treatments unless good controlled trials exist (which they seldom do). Advisedly, we often state that indications ‘include’ yet clinicians still write to complain that certain uncommon or controversial indications have been ‘missed out’.

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The ‘Efficacy’ section aims to summarise the results of the best and/or biggest reports found in the literature search. More details can always be found in the overview of the procedure on the NICE website. It is often surprising how limited and inconsistent the data on efficacy are and important limitations may be pointed out (for example no long-term data). If data exist comparing the procedure with a relevant alternative then these may be presented, but frequently the information about established procedures (which the new procedure might replace) are scant or presented in a way which makes direct comparison difficult.

The section on ‘Safety’ lists reported complications. Poor reporting of safety data is common; that is why description of the frequency of adverse events is often based on surprisingly small numbers. When huge case series do exist, their completeness of follow-up is often obscure and suspect. Large numbers of patients are needed to assess the incidence of uncommon complications.

In the sections on both efficacy and on safety, the comments of the Specialist Advisors may be briefly presented. The intention is to divine specialist views from within the UK of how efficacious the procedure is perceived to be and (importantly) to flag up complications which specialists foresee, but which may not have been reported in the literature. This has led to criticism by exponents of new procedures – especially when Advisors have listed serious theoretical complications that they have not seen in practice. How much to include in the guidance of the Specialist Advisors’ comments remains an issue in general, we are publishing rather less, but continue to heed and value their opinions and comments during Committee deliberations. From the beginning of 2005, the identities of Specialist Advisors for each procedure will be in the public domain (previously they were confidential).

In the final section of the guidance (numbered 2.5), the Committee has the opportunity to include comments, cautions, observations or brief explanations which have influenced their discussions. They may be relevant to read in conjunction with Section 1 of the guidance because they may include limitations or qualifying statements about the evidence which did not quite merit inclusion in that section. They may help to explain the conclusions the Committee reached.

We take trouble writing the guidance on interventional procedures, while aiming to keep it as brief as possible. It really is important to read the words carefully: the recommendation ‘Clinicians should...inform clinical governance leads...be sure patients are fully informed...audit and review their results’ does not either say or mean that ‘NICE is stopping clinicians doing this procedure’ (quote from consultant) or ‘NICE says procedure is unsafe...bans procedure in the NHS’ (in the press). Interpretation and implementation of our guidance remains a difficult and contentious issue and will be addressed in the next article of this series.

ONLINE-ONLY CASE REPORTS - new addition
doi 10.1308/147870805X28091

Since the January issue the following case report has been published on our website:
1 SJD Brecker, K Mandal, T Harrison, G Griffin, A Varghese, DJ Pennell, J Lester, M Jahangiri. Hydatid disease of the heart. Ann R Coll Surg Engl 2005 doi 10.1308/147870805X28064

You can access the case reports by using your College-issued Athens username and password to enter the members’ area of the College website (<www.rcseng.ac.uk/members/publications/index_html>) and following the link to the Annals. At the top of the table of contents there is ‘supplementary data’ button which, when clicked, will take you to the list of case reports that have already been released online.

Alternatively, if you type the following URL into the address bar of your web browser <http://dx.doi.org/> and then enter the DOI in the dialogue box presented on this web page, you will be taken directly to the abstract of the article.