consider whether coronary revascularisation is appropriate, and that this should take into account co-morbidity. Patients with left ventricular systolic dysfunction should be considered for an implantable cardioverter defibrillator (in accordance with 'Implantable cardioverter defibrillators for arrhythmias', NICE technology appraisal guidance 95).

Technology Appraisals

Cardiac resynchronisation therapy for the treatment of heart failure (May 2007)

The guidance provides criteria to help in selecting which patients with heart failure are suitable for cardiac resynchronisation therapy (CRT) with a pacing device, and those who might benefit from a dual-function defibrillator-pacemaker device. The guidance has some overlap with last year's guidance on 'Implantable cardioverter defibrillators for arrhythmias' (NICE technology appraisal guidance 95). The new guidance requires an increase in the number of staff trained in CRT, and the number of centres undertaking these procedures, so the target date for full implementation has been set at November 2008.

Other Guidance

Between April and June 2007, NICE published further guidance of relevance to surgery (listed below) which could

not be summarised here. Please refer to the NICE website (<www.nice.org.uk>) for details.

Interventional Procedures guidance

- Tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium
- Therapeutic sialendoscopy
- Microwave ablation for the treatment of metastases in the liver
- Closure of anorectal fistula using a suturable bioprosthetic plug
- Endoscopic augmentation of the lower oesophageal sphincter using hydrogel implants for the treatment of gastro-oesophageal reflux disease
- Therapeutic percutaneous image-guided aspiration of spinal cord cysts

Clinical Guidelines

- Faecal incontinence: the management of faecal incontinence in adults (please see the article below for more information).

Technology Appraisal guidance

- Carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma

NICE clinical guideline on managing faecal incontinence: evidence of the effectiveness and cost-effectiveness of surgical interventions

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on behalf of the Guideline Development Group

This article outlines the recommendations for surgical options and the underlying clinical and cost-effective evidence base for the recently published NICE clinical guideline on the management of faecal incontinence in adults (<www.nice.org.uk/CG49>).

Faecal incontinence affects over half a million adults in the UK and often has a very profound impact on patients' lives. Despite this, faecal incontinence has been a neglected health-care problem, in the UK and around the world. This, and a paucity of high quality evidence for most assessment and treatment methods, including surgical interventions, has made the task of producing a guideline on the management of faecal incontinence in adults particularly challenging. Consequently, some of the recommendations in the guideline concerning costly, unproven surgical interventions, at least in the absence of very specific indications, may seem conservative. This reflects the reality that, although more sophisticated second treatments

are available, referral for these is not common. Therefore, the guideline developers wished to avoid potentially harmful interventions, pending the availability of better research.

Evidence

For patients with faecal incontinence refractory to medical treatment, surgery may be an option. As surgical intervention is invasive and carries the risk of complications, it was important to assess the likely balance of harms and benefits for patients, considering the efficacy of surgery, incidence of adverse events and whether results of the operation are sustained over time. As with all NICE guidance, it was also important to consider whether the cost of the interventions was justified by the magnitude of benefits for patients – otherwise there would be a danger of diverting scarce surgical resources from alternative uses,

where they would do more good. The deliberations of the Guideline Development Group were thus informed by reviews of both clinical and cost-effectiveness evidence.

Clinical evidence – randomised controlled trials

A randomised cross-over study reported results for 28 patients implanted with a sacral nerve stimulator that had a phase with the stimulator switched 'on' or 'off' and then a second phase with the opposite setting. The patients were selected on the basis that they had reacted positively to an initial trial phase. The study¹ found that the frequency of faecal incontinence episodes was halved. It is suspected that the beneficial effect may be underestimated as it seems patients continue to benefit after the stimulation has ceased. However, another seven patients had dropped out (either before or during the cross-over periods) due to device-related complications.

Another study² randomised 14 adults with severe faecal incontinence to artificial anal sphincter surgery or supportive care. Postoperative continence scores were significantly improved in the surgical group compared to the supportive group, but there were three peri-operative complications reported in the surgical group.

Clinical evidence – observational studies

Given the lack of randomised evidence, observational evidence was systematically retrieved and evaluated. One cohort study³ of 88 patients found that continence scores were significantly improved with dynamic graciloplasty compared to no surgery. However, there were substantial numbers of patients with evacuation difficulties/pain, infection or circulatory problems in the surgical group.

Surgical case series with at least 12-month follow-up were retrieved (range, 12 months to 10 years). Evidence of effectiveness and complications were extracted. Data were retrieved for the following: external sphincter repair (29 studies, 1379 patients), sacral nerve stimulation (7 studies, 188 patients), stimulated graciloplasty (9 studies, 559 patients), artificial anal sphincter (14 studies, 370 patients).

All surgery types had important complications and the effectiveness of the surgery declined over time. The complications were most serious and most frequent for the graciloplasty and artificial anal sphincter.

Cost-effectiveness evidence

A single cost-effectiveness analysis was found that evaluated faecal incontinence surgery from an NHS perspective.³ It compared stimulated graciloplasty with stoma formation and conservative management based on the cohort study mentioned earlier. Using costs from a number of NHS hospitals, it was found that stimulated graciloplasty was cost-saving compared with stoma formation but cost-increasing compared with conservative management. Compared with

conservative management, it was estimated that stimulated graciloplasty would cost £29,000 per quality-adjusted life-year (QALY) gained. This places it on the outer margin of what is usually considered cost-effective for the NHS.

A Swiss study compared the 5-year costs of different types of surgery.⁴ The procedures were ranked as follows: conservative management (lowest cost), external sphincter repair, sacral nerve stimulation, stimulated graciloplasty, stoma formation (highest cost). However, the study did not evaluate cost-effectiveness.

We cautiously conclude that SNS is cost-effective after unsuccessful conservative management on the basis of the case series evidence (above). We already noted that graciloplasty is borderline cost-effective. The case-series evidence shows that SNS has a similar improvement rate and has fewer complications compared with graciloplasty. Furthermore, SNS is associated with a shorter length of stay and lower costs. Therefore, it would seem plausible that SNS is at least as cost-effective as graciloplasty, assuming that the longer term effectiveness, currently unknown, is similar to graciloplasty. By the same logic, it was concluded that external sphincter surgery is cost-effective in those patients for whom it is relevant.

Recommendations for surgical practice

On the basis of the evidence, the Guideline Development Group (GDG) cautiously made a number of recommendations (see Box). They emphasised the need to conduct surgery in specialist centres and the importance of keeping patients fully informed about the relatively poor long-term outcomes and the risk of complications. Given the risk of complications, surgery was recommended only for those patients who have quality of life-limiting disease after exploring all other interventions. The procedures with the highest complication rates were given a lower priority.

Recommendations for further research

The GDG called for long-term follow up of patients to assess: (i) the prognostic value of certain physiological/structural abnormalities in defining surgical outcome; and (ii) the long-term outcome of different surgical procedures. They advised that this research question would be best answered by a multicentre study based on a network of NHS secondary care sites.

Discussion

The lack of high-quality, randomised trial evidence has made the development of evidence-based, cost-effective guidance particularly challenging. However, we believe that the Guideline Development Group has produced a rational, coherent guideline. They achieved this by a thorough evaluation of the effectiveness and adverse event evidence

Box RECOMMENDATIONS FOR SURGICAL PRACTICE**Patient selection**

Patients should be offered faecal incontinence surgery only if they continue to have quality of life-limiting faecal incontinence after having received all of the following:

- thorough baseline assessment
- treatment for specific causes (rectal prolapse, diarrhoea or faecal loading, etc.)
- initial conservative management (diet modification, loperamide, toilet access, etc.)
- specialised conservative management (e.g. exercises, biofeedback, enema, etc.).

Pre-surgical investigations

A combination of anorectal physiology tests and endo-anal ultrasonography will best assist selection of patients for surgery.

Specific types of surgery

People with a full-length external anal sphincter defect that is 90° or greater (with or without an associated internal anal sphincter defect) should be considered for sphincter repair.

A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate.

People with faecal incontinence should be offered permanent sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation.

If a trial of sacral nerve stimulation is unsuccessful, an individual can be considered for stimulated graciloplasty or an artificial anal sphincter. However, if an artificial anal sphincter is to be used, special arrangements should be followed.

A stoma should be considered for people with faecal incontinence that severely restricts life-style only once all appropriate non-surgical and surgical options, including those at specialist centres, have been considered.

Good practice

A specialist surgeon should discuss the potential benefits and limitations/complications of surgical and non-surgical options, particularly long term expectations of effectiveness.

People with internal sphincter defects, pudendal nerve neuropathy, multiple defects, external sphincter atrophy, loose stools or irritable bowel syndrome should be informed that these factors are likely to decrease the effectiveness of anal sphincter repair.

People who have an implanted sacral nerve stimulation device, stimulated graciloplasty or an artificial anal sphincter should be offered training and ongoing support at a specialist centre. These people should be monitored, have regular reviews and be given a point of contact.

(including surgical case series) and by following the principle of providing the simplest, safest treatments first.

The dearth of clinical evidence was unsurprisingly accompanied by a lack of economic evaluation. We have shown that, where you have one good quality economic evaluation, it is

sometimes possible to make broader statements about cost-effectiveness without the need for detailed modelling. However, having some data on effects, complications and costs is essential.

The guideline's general approach was to offer (relatively costly) surgery only after patients have tried both initial and

specialised conservative interventions and still have severe faecal incontinence. Intuitively, it seems plausible that this approach would be cost-effective. Yet this is only true if the specialised conservative management is clinically effective, which remains unclear. If it were found that specialised conservative feedback has little effect on faecal incontinence, then most people will end up being referred to surgery eventually anyway and it would, therefore, be more cost-effective to refer patients for surgery immediately after initial conservative management. This is an area requiring further research.

Evaluating cost-effectiveness requires information about health gain. In the case of faecal incontinence this essentially means measuring changes in health-related quality of life. This is an area that is generally fraught with difficulties – in the case of incontinence, even more so. It is important that health status is elicited from the patients themselves – the guideline's evaluation of case series data showed that cure rates based on patient reports tended to be substantially lower than cure rates reported by clinicians. The impairment of quality of life associated with faecal incontinence has a number of features: (i) functionality – some people with the condition avoid leaving their homes; (ii) discomfort/soreness; and (iii) social stigma. Stigma in particular may not always be captured by generic quality of life instruments. For this reason, in this guideline NICE's upper threshold of £30,000 per QALY gained was employed.⁵

This guideline has illustrated another concern of economists – finding the right comparator. When evaluating the cost-effectiveness of a new type of surgery, it is tempting to compare it to stoma formation and care. However, stoma is not necessarily the most appropriate comparator. Long-term stoma care did not undergo formal cost-effectiveness

analysis at its inception, and may not be cost-effective compared with the best types of conservative management. Hence the cost-effectiveness of a specific type of surgery should be conducted in comparison with conservative management as well as with alternative types of surgery.

NICE's guideline development group has worked hard to produce evidence-based, cost-effective guidance for managing faecal incontinence. We hope that, when the guideline is updated in a few years time, there has been a growth in high-quality clinical trial evidence for surgical and other specialised faecal incontinence interventions. Therefore, we urge research funders to pay more attention to this important, but neglected, area.

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