NICE news in the annals

Recent NICE Guidance of interest to surgeons

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Interventional Procedures

Therapeutic endoscopic division of epidural adhesions (February 2010)

In a small proportion of patients, chronic back or leg pain is caused by adhesions around the spinal nerve roots. If conservative treatments such as analgesics, non-steroidal anti-inflammatory drugs and physical therapy fail, surgical procedures (including open or blind adhesiolysis and spinal fusion) may be used.

Endoscopic division of epidural adhesions (or adhesiolysis) is used in patients with symptoms refractory to other treatments, and for whom there is suspicion that the aetiology of their pain relates to adhesions around spinal nerves. It involves inserting an endoscope and catheter into the epidural space under fluoroscopic guidance. Endoscopic instruments are used to divide epidural adhesions around the spinal nerve roots or the spinal cord.

NICE recently reviewed 'special arrangements' guidance published in 2004 which was based on one non-randomised controlled trial, six small case series with a maximum follow-up of 1 year, and three case reports. The updated evidence presented to the Committee included a randomised controlled trial of 85 patients, comparing endoscopic adhesiolysis with endoscopy alone, a non-randomised comparative study of 183 patients and four case series. The maximum follow-up was again 12 months. The RCT reported significantly greater pain relief in the treatment group compared with the control group at 12-month follow-up.

Despite this evidence of some efficacy, the Committee chose not to change its recommendation. Case selection remained somewhat unclear and, in addition, there were some safety concerns, with regard to dural puncture in 3% (4/124) and 2% (1/58) of patients in two case series; subarachnoid puncture and subarachnoid block in 12% (7/60) and 7% (4/60) of patients; and other adverse events including visual disturbance and 'non-persistent' lower limb paraesthesia.

The new guidance states that further research should describe case selection clearly and that outcomes should include pain relief, duration of effectiveness and the requirement for further treatment.

Endoscopic submucosal dissection of lower gastrointestinal lesions (March 2010)

Polyps or tumours which cannot readily be removed endoscopically by simple snaring may be dealt with by endoscopic mucosal resection (EMR) which involves removing the lesion piecemeal with a snare. Endoscopic submucosal dissection (ESD) represents an advance on this method, involving *en bloc* removal of lesions by submucosal dissection with an electrocautery knife, after injecting the submucosa with fluid (such as sodium hyaluronate) to create a dissection plane. The aim is to reduce the risk of recurrence and to allow a more accurate histopathological assessment.

The evidence presented to the Committee was based on approximately 2550 patients from a systematic review of 14 studies, one non-randomised comparative study, seven case series and one case report. The systematic review reported *en bloc* resection rates around 85% and complete cure in about 75% of patients. With regard to safety, perforation rates of 1% (7/468), 3% (14/405) and 6% (12/200) were reported. Most perforations were recognised during the procedure and treated successfully by endoscopic clipping. Bleeding, requiring emergency colonoscopic clipping occurred in 1% (2/200) of lesions in a case series of 186 patients.

The Committee considered that there was insufficient evidence on long-term survival when ESD was used to treat malignant lesions and that there were potentially serious implications with regard to perforation, so guidance recommends 'special arrangements' for governance, consent and for audit/research. Particular recommendations have been made about patient selection and about training for this procedure. Further research is encouraged, which should include clear documentation of the incidence of complications, rates of complete resection and long-term local recurrence and survival.

Cytoreduction surgery followed by hyperthermic intra-operative peritoneal chemotherapy for peritoneal carcinomatosis (February 2010)

Treatment for peritoneal carcinomatosis is normally palliative, including surgery for complications such as intestinal

obstruction and selective use of chemotherapy. The combined treatment of cytoreduction surgery, to remove all macroscopic tumours, and intra-operative intraperitoneal administration of chemotherapy, to distribute the drug uniformly to all surfaces of the abdomen and pelvis, aims to increase survival in selected patients.

NICE recently reviewed 'special arrangements' guidance published in 2004 which was based on one randomised controlled trial (RCT), two non-randomised controlled studies and four case series. The procedure is still undertaken in only two hospitals under arrangements of the National Commissioning Group (formerly the National Specialist Commissioning Advisory Group until 2007).

The updated evidence presented to the Committee included three systematic reviews, one RCT, and six other studies, with a total of 8219 patients and follow-up intervals up to 113 months. The largest systematic review of 4500 patients with peritoneal carcinomatosis of colorectal origin reported an overall median 5-year survival of 19% (16 studies). A systematic review of 2787 patients (peritoneal surface malignancies) reported a mean re-operation rate of 11.2% (range, 0–23%; 17 studies).

Despite evidence of some improvement in survival for selected patients with colorectal metastases, evidence was limited for other types of cancer. Because of this, case selection should be carried out by a multidisciplinary team including oncologists and surgeons with experience in this procedure.

The procedure carries significant safety concerns including risk of postoperative death; reported as 7.4% (4/54) in the cytoreduction and hyperthermic intraperitoneal chemotherapy group of an RCT of 105 patients. The same study also reported a gastrointestinal fistula rate of 14.6% (7/48) in the treated group. A systematic review of 2787 patients ('peritoneal surface malignancies') reported a mean sepsis rate in 3% (range, 0–14%) and mean haematological toxicity rate of 5.6% (range, 0–28%; 18 studies). Other serious adverse events included liver failure and acute renal failure.

The guidance encourages further research in the form of RCTs, with special attention to describing case selection, the types of cancer being treated and the precise chemotherapy regimens. Outcomes should include not only survival but also quality of life.

Surgical correction of hallux valgus using minimal access techniques (February 2010)

Symptomatic hallux valgus requiring surgical intervention is most common in women during middle and later life. Traditionally a variety of open osteotomy techniques utilising one long incision have been used to treat symptomatic hallux valgus. In contrast, minimal access techniques use one or more small incisions close to the hallux metatarsophalangeal joint. Special burs are used to remove the 'bunion' and the metatarsal is then divided. The bone fragments are positioned and stabilised to correct the deformity using plates, screws or wires.

Several different osteotomy techniques were described in the evidence presented to the committee, some of which are no longer in common use in the UK.

The evidence was based on 1044 patients from one non-randomised comparative study and 12 case series. In terms of efficacy, the comparative study of 72 patients evaluated the procedure against a conventional open technique and reported a significant mean decrease in pre-operative mean hallux angle in both groups at mean follow-up of 2.5 years. A case series of 204 patients reported no pain postoperatively in 84% (70/83) patients and high patient satisfaction in 74% (61/83) patients after mean follow-up of 8.3 months.

With regard to safety, a case series of 13 patients reported recurrence of hallux valgus (final angle > 15°) in 39% (5/13) patients and postoperative osteonecrosis in one patient. The authors of this study report that the procedure has been discontinued at their institution. Other adverse events included deep infection, delayed union, stress fracture of the second metatarsal and postoperative hallux varus.

The Committee considered that there was limited and inconsistent evidence on efficacy and the evidence related to a range of different techniques. Safety evidence was considered inadequate, so guidance recommends 'special arrangement' for governance, consent and for audit/research. Further research is encouraged which should evaluate clearly described minimal access procedures using well-defined modern forms of osteotomy. Objective and functional outcome measures should be reported, together with pain relief, patient satisfaction, cosmesis and all adverse events.

Other guidance

Between February 2010 and April 2010, NICE published other guidance (or reviews of existing guidance) of potential interest 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

- Arteriovenous crossing sheathotomy for branch retinal vein occlusion
- Endobronchial ultrasound-guided biopsy for peripheral lung lesions
- Transcatheter endovascular closure of perimembranous ventricular septal defects.

Clinical Guidelines

- Chest pain of recent onset
- Unstable angina and NSTEMI
- Neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings.

The new NICE Evaluation Pathway for medical technologies

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Chair, Medical Technologies Advisory Committee

In his report on the NHS published in 2008, Lord Darzi stated: 'For new clinical technologies, we will simplify the way in which they pass from development into wider use by creating a single evaluation pathway, and will develop ways to benchmark and monitor their successful uptake'. This was the genesis of the new NICE 'Evaluation Pathway' which has started its work in recent months. The concept is to identify promising new devices and diagnostic products which seem to offer advantages to patients or more efficient use of NHS resources; to facilitate any necessary research or information gathering about them; and to encourage their adoption into practice.

Creating a system to achieve this has been highly complex. How should technologies best be identified and selected? What about similar technologies from different manufacturers? Will there be adequate data for evaluation (a traditional problem for devices, in contrast to new drugs)? How can NICE best facilitate research and/or data collection and how should this be funded? How should cost be calculated, especially when new technologies affect the use of other related services? What about 'disinvestment' in current technologies, over which the new ones appear to have advantages?

These issues, and many others, have been debated with a wide range of interested parties throughout recent months. The scheme which has resulted involves notification of technologies by manufacturers via the NICE website. In order to be eligible for entry to the Pathway, technologies need to have received a CE mark (or for this to be imminent) and not to be the subject of other current national evaluation. Although it is anticipated that most technologies will be novel, there will be no bar to ones which have been available for some time but which have not been widely adopted despite good evidence of substantial advantage. The quest is for devices or diagnostics which offer some kind of step change in patient benefit, resource use, or both, whether they are very new or already in patchy use.

Advantages over currently used management will be the key to progress of technologies further through the Pathway. Each will be the subject of a Briefing Document based on information provided in the Notification, with additional data obtained by the NICE team. This will be scrutinised by the Medical Technologies Advisory Committee (MTAC) who will select technologies for further evaluation, based on evidence of plausible advantages. The committee will consider:

1. The extent to which the technology claims measurable benefit to patients over currently available NHS technologies in terms of its impact on quality or quantity of life.
2. The extent to which the technology is likely to reduce use of staff or facilities: for example, facilitating out-patient (instead of in-patient) diagnosis or treatment, or replacing several technologies in current use.
3. The impact of the disease or condition on quality or length of life, and the size of the population of patients who might benefit.
4. For technologies aimed at treatment, the likely degree of improvement in life expectancy, disease severity and quality of life, paying particular attention to conditions that incur social stigma.
5. The potential costs of the technology to the service, including initial acquisition costs, direct revenue costs, and influence of use of the technology on total system costs.
6. Likely contribution of the technology to the sustainability agenda e.g. less energy usage or less waste generation during production or clinical usage.

When MTAC considers that a technology merits adoption for further evaluation in the Pathway, it will decide where to 'route' the technology for that evaluation. For high cost, high impact technologies, the NICE Technology Appraisals Programme is the likely route. If the technology involves a new procedure which has been little used in the UK, then the Interventional Procedures Programme may be appropriate for that procedure. Diagnostics that are likely to provide benefit but at greater cost will typically be routed to the new NICE Diagnostics Programme.

MTAC will also have the option to 'route technologies to itself' – in other words to produce its own guidance about them. This Medical Technologies guidance – a completely new type of guidance from NICE – is likely to be chosen for products which pose no issue of increased net cost (they may well be less costly) and which appear to offer clear advantages over current methods of management. For these technologies, a more detailed assessment will be carried out, in collaboration with the manufacturer. When MTAC has considered this information, it will draft guidance, which will be subject to the usual public consultation

– giving clinicians, manufacturers, patients, commissioners and others the opportunity to comment, so that appropriate changes may be made before the guidance is finalised and published.

MTAC guidance may recommend that NHS organisations consider adopting the technology. Guidance will not be mandatory, but will present the advantages that the technology appears to have for patients, and the costs associated with its use (typically in comparison with the costs of alternative methods in current use). The guidance will, therefore, often suggest sensible disinvestment in currently used technologies when better, new ones are available.

Guidance may recommend specified research which is necessary to provide more data to support the apparent benefits of the technology. This could be particularly helpful for small manufacturers who have produced a promising product but who are inexperienced in evaluation. NICE is engaged in discussions about how such research might best be fostered: creation of research opportunities cannot unreasonably favour one manufacturer over another in terms of the amount of assistance given, nor can research carried out for the benefit of manufacturers be funded from taxpayers' money, so this is a complex area.

In addition, it is likely that some technologies will be

recommended for use conditional upon submission of selected data by clinicians using them, in order to monitor whether they really do achieve specific benefits in practice. The precise mechanism for collecting data needs to be developed but, in concert with specified research, 'use with evidence development' may prove to be a useful aspect of the overall evaluation of new technologies which are recommended as potentially advantageous for NHS use.

Technologies notified by manufacturers to the Evaluation Pathway which are not selected will be returned to them with some comment and explanation about why they were not considered suitable. If MTAC decides that a technology is 'not for progression' this does not mean that NICE is giving it any kind of stamp of disapproval. It simply means that MTAC did not consider that there was sufficient advantage, or that the product was of sufficient importance to the NHS, to justify its further evaluation in the Pathway.

The Evaluation Pathway has an altogether positive mission. It offers the potential to: (i) identify promising new devices and diagnostics; (ii) liaise fruitfully with manufacturers; (iii) improve research and data collection in useful ways; and (iv) speed uptake by the NHS of technologies with real advantages.