NICE news in the annals

UK AUDIT OF ALL PATIENTS MANAGED BY LAPAROSTOMY (OPEN ABDOMEN)

Investigating a possible association between the use of negative pressure wound therapy and intestinal fistulae (Interventional Procedures guidance December 2009)

A UK-wide audit is now in progress on all patients who are managed by leaving their abdomen open (laparostomy). This has been developed as a result of a notification to the NICE Interventional Procedures Programme from a specialist unit concerned about patients referred with intestinal fistulae following negative pressure wound therapy (NPWT – also known as VAC therapy). They investigated a series of over 20 tertiary referrals with fistulae and found that NPWT seemed to be the one consistent factor.

NPWT has become popular for the management of the open abdomen, but there is limited published evidence on its safety and efficacy for that indication. In particular, there is a lack of evidence comparing outcomes between patients managed with an open abdomen with NPWT or alternative temporary closure techniques. The recent report of a possible causative link has led to NICE recommending that data on all patients should be audited. It is possible that development of fistulae might be associated only with certain types of NPWT, with variation in technique or simply reflect an underlying predisposition to fistula because of underlying pathology: the audit will address these possibilities.

NICE guidance (NPWT for the open abdomen IPG322) recommends use of a specially prepared 'audit tool' designed to obtain information about all patients with an open abdomen, including those treated by NPWT and by other means: this denominator is important to interpret any data about the incidence of fistulae. The audit tool has been developed in collaboration with specialist societies and their Specialist Advisers. It is available at <www.nice.org.uk/IPG322>.

The audit will run from 1 January 2010 to 30 June 2011. It has the support of the Chief Medical Officers of England and Wales, the Medical Director of the NHS for England, and Presidents of Royal Colleges and relevant specialist societies. Medical directors and tissue viability nurses of all hospital trusts have been requested to identify a lead person for this audit.

If you treat any patient by laparostomy between now and 30 June 2011, please collect data as specified in the audit tool and submit these data to <<https://viis.abdn.ac.uk/HSRU/OpenAbdomen>>. If you have any queries relating to the data collection portal, please email Gladys Mcpherson at the Health Services Research of the University of Aberdeen (g.mcpherson@abdn.ac.uk). Good support of this audit will both advance knowledge of management of the open abdomen and reflect well on the UK surgical and critical care community in the UK.

Recent NICE Guidance of interest to surgeons

Heather Stegenga, Hannah Patrick and Bruce Campbell

Interventional Procedures

Radiofrequency ablation for the treatment of colorectal liver metastases (December 2009)

Liver metastases from colorectal cancer can sometimes be treated by surgical resection (depending on the number, location and size of metastases) but more often metastatic disease is too extensive. Alternative treatments include chemotherapy, radiotherapy, thermal ablation, chemo-embolisation, and selective internal radiation therapy.

Radiofrequency (RF) ablation can be used as primary treatment if the patient is unfit for surgery but also may be used as an adjunct to hepatic resection for small-volume disease. It may be done percutaneously or intra-operatively. It involves the insertion of needle electrodes into the metastases with imaging guidance, followed by delivery of a high-frequency alternating current which causes local coagulative necrosis and thermal destruction of tissue. A number of different types of RF electrodes are available.

This is a review of guidance published in 2004 which was based on a systematic review, one non-randomised controlled trial and two case series with an average follow-up of 1 year and a maximum of 3 years. The original guidance recommended that the procedure only be used with 'special arrangements' for consent and for audit or research. The guidance highlighted the lack of sufficient long-term evidence also recommended that further research include survival as an outcome measure.

There are several problems in appraising the literature for all treatments aimed at ablating liver metastases. Treatment may be carried out with varying intentions: (i) the aim may be palliation only; (ii) it may be as an adjunct to surgery (usually reducing tumour bulk prior to resection); or (iii) it may occasionally be used with curative intent. Judging the 'success' of the treatment depends on the aim: this may be unclear or variable in the literature. Concomitant treatments are commonly reported and differ between studies. In addition, some reports mix different primary tumour types, which further confounds interpretation of the results.

The new literature presented to the Committee consisted of the same systematic review as presented previously, two additional non-randomised controlled trials, three case series and two case reports with follow-up ranging from 17 months to 5 years. Patient selection was largely on the basis that they were not suitable for surgery alone. A non-randomised controlled trial of 418 patients unsuitable for surgery alone reported overall survival rates of 73%, 65% and 58% at 3, 4, and 5 years, respectively, in patients treated with RF ablation and surgery (this was significantly higher than those treated by RF ablation alone). A case series of 243 patients with unresectable metastases reported survival rates of 20% and 18% at 3- and 5-year follow-up.

With respect to safety, complication rates in three case series in the systematic review were between 0–33% (these included bowel perforation, peritoneal seeding, bile duct stricture, wound infection and postoperative bleeding). A case series of 309 patients reported a 1% incidence of haemorrhage requiring transfusion and visceral thermal injury.

The Committee considered the new evidence sufficient to support the use of this procedure with normal arrangements, but stipulated that patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.

NICE has published Interventional Procedures guidance on a number of other treatments for liver metastases. For more information see <www.nice.org.uk>.

Laparoscopic augmentation cystoplasty (including clam cystoplasty) (also known as ileocystoplasty, sigmoideocystoplasty, enterocystoplasty or bladder augmentation) (December 2009)

Treatments for overactive, neurogenic or anatomically/structurally contracted bladder include bladder training, anticholinergic drugs, intravesical botulinum toxin injec-

tions, intermittent self-catheterisation (ISC) or sacral neuromodulation. Patients who do not respond to these treatments may be offered augmentation cystoplasty which aims to increase bladder size, reducing urgency, urge incontinence, and the frequency of voiding: this has traditionally been done by an open operation.

Laparoscopic augmentation cystoplasty is intended to have the usual advantages of laparoscopic over open surgery, including quicker recovery, less blood loss, less pain, shorter hospital stay, and a smaller scar. It is performed under general anaesthesia through four or five laparoscopic ports. The bladder is first incised and then an isolated piece of the bowel (usually the ileum) is sutured to this opening to increase bladder size. Patients must empty the bladder at least every 4 h (passing urine spontaneously or with ISC) to prevent bladder rupture. They may also require ISC and bladder washouts in the longer term to reduce the risk of infection or stones.

The evidence on this procedure was primarily from small case series. A case series of 17 patients reported a significant improvement in bladder control on the Bladder Control Scale at 17-month follow-up. Case series of 23 and six patients reported significant increases in mean postoperative bladder volume compared with the pre-operative volume, from 11 ml to 778 ml at 12-month follow-up ($P < 0.01$) and 48 ml to 260 ml at 13–16-month follow-up, respectively (significance not reported).

With respect to safety, the case series of 23 patients reported multiple bladder stones in one patient and spontaneous rupture of the pouch which was successfully repaired 15 months after augmentation in another (this patient did not undertake ISC as recommended).

Despite the limited quantity and quality of the literature, but in the absence of any major safety concerns, the Committee recommended the procedure should be used with 'normal arrangements'. However, this was in the context of explicit recommendations that patient selection should be carried out by a multidisciplinary team with special expertise in managing urinary incontinence, and that the procedure should be done only by surgeons with experience in complex laparoscopic reconstructive surgery.

In order to monitor safety outcomes in the long-term, the guidance recommended that clinicians submit data on all patients to the database run by British Association of Urological Surgeons.

Percutaneous intradiscal electrothermal therapy for low back pain (November 2009)

The aim of this procedure is to relieve pain in patients with low back pain, caused by disc degeneration, which has been unresponsive to other modes of treatment, such as analgesics, non-steroidal anti-inflammatory drugs and physical therapy. Patients who have not responded to these treat-

ments or who have neurological complications may be considered for surgical interventions such as discectomy, fusion or disc replacement.

Percutaneous intradiscal electrothermal therapy involves heating the affected discs to alter their structure and to destroy nerve fibres transmitting pain. The procedure is usually done under local anaesthetic and light sedation, with fluoroscopic control. Discography helps to identify the affected disc – pain is induced by injection of contrast. An introducer needle is inserted to the target disc and a catheter or electrode is passed through the needle into the disc and heated to 90°C for 15 min.

NICE had previously published guidance on percutaneous intradiscal electrothermal therapy in August 2004, based on one randomised controlled trial, one non-randomised controlled trial and five case series studies with a length of follow-up ranging from 6–24 months. The Committee found the original evidence insufficient so recommended that the procedure should only be used with ‘special arrangements’, and recommended that further research should include the collection of longer-term data.

The new review of the updated literature presented to the Committee showed substantially more data but inconsistent findings. For example, a meta-analysis of 17 studies showed that a pooled mean pain score (on a 10-point visual analogue scale improved by 2.9 points over a follow-up of 6–54 months; however, a non-randomised controlled trial of 109 patients showed that pain relief was significantly greater in patients treated with pain-relieving disc injection than those treated with electrothermal therapy.

In terms of safety, there was one case report of osteonecrosis on magnetic resonance imaging at 3-month follow-up; a remnant lesion was apparent at 12-month follow-up. Another case report described the need to remove a broken catheter tip from the disc space 3 months after the procedure, with some residual lower limb paraesthesia. Transient radiculopathy was reported in 11% of patients among 38 in a randomised controlled trial.

Based on the inconsistent results, the Committee chose not to change its main recommendation and gave more specific

requirements for future research including clear description of how patients were selected, the use of validated measures of long-term pain relief and quality of life, the measurement of long-term safety outcomes, and investigation of whether the procedure reduces the need for major surgery.

Other Guidance

Between November 2009 and January 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.

Clinical Guidelines

- Prevention of venothromboembolism

Interventional Procedures guidance

- Bronchoscopic lung volume reduction with airway valves for advanced emphysema
- Photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus
- Balloon catheter insertion for Bartholin’s cyst or abscess
- Electrocautery cutting balloon treatment for pelvi-ureteric junction obstruction
- Endopyelotomy for pelviureteric junction obstruction
- Negative pressure wound therapy for the open abdomen
- Suction diathermy adenoidectomy
- Total prosthetic replacement of the temporomandibular joint
- Vagus nerve stimulation for treatment-resistant depression.