NICE news in the annals

Recent NICE Guidance of interest to surgeons

Sally Gallagher and Bruce Campbell

Interventional Procedures

Ultrasound-guided catheterisation of the epidural space (January 2008)

Ultrasound can be used in two ways to assist catheterisation of the epidural space. The first is prepuncture ultrasound, in which an ultrasound scan of the lumbar spine is used to mark anatomical points on the skin which then guide the conventional epidural technique. The second method is to use real-time ultrasound imaging to guide the needle into the epidural space.

The small amount of published literature available (one randomised controlled trial [RCT] and a number of case series) has described the use of this procedure in pregnant women, children and neonates, and patients with scoliosis. The reports were a mixture of studies using prepuncture and real-time ultrasound. The evidence indicated that the use of ultrasound was safe and that it may be helpful in achieving correct needle placement. For example, in the RCT of 300 pregnant women, the mean number of puncture attempts needed to achieve correct placement using a prepuncture ultrasound was 1.3 compared with 2.2 using no ultrasound guidance ($P < 0.015$). NICE recommended that normal arrangements for clinical governance, consent and audit should be in place when using this procedure.

Intra-operative nerve monitoring during thyroid surgery (March 2008)

Damage to a recurrent laryngeal nerve during thyroid surgery causes hoarseness, and bilateral damage may result in respiratory difficulties. It is normal practice to identify the recurrent laryngeal nerves visually during the operation, but sometimes this may be difficult and use of a hand-held nerve stimulator is advocated by some surgeons. This is used to produce contraction of the vocal cord muscles.

The technique involves placement of monitoring electrodes near the vocal cords using an endotracheal tube. The electrodes are connected to a monitor which alerts

the surgeon by sound and graphics displayed on a screen if a surgical instrument comes close to the nerve.

The evidence on this procedure included case series of large numbers of patients (approximately 18,800 patients). Despite all these data, there was no compelling evidence that intra-operative nerve monitoring significantly reduced nerve damage during surgery. Some Specialist Advisers were concerned that undue reliance on the monitoring system might be a disadvantage, by distracting from efforts to visualise the nerves and perhaps by giving inexperienced surgeons an inappropriate feeling of confidence. However, there was no evidence to support any safety concerns, and other Specialist Advisers stated that nerve monitoring might be helpful in performing more complex operations, and in teaching thyroidectomy. NICE guidance, therefore, advised that intra-operative nerve monitoring could be used with normal governance, consent and audit arrangements.

Laparoscopic mobilisation of the greater omentum for breast reconstruction (February 2008)

Breast reconstruction is usually carried out using a prosthetic implant or autologous tissue from the back or abdomen, mobilised by conventional open surgery. An alternative is to use laparoscopically harvested omentum – either in the form of a free flap or a pedicled flap. When a free flap is used, the greater omentum is removed through a small incision in the abdominal wall and inserted through the mastectomy wound. Its blood supply is re-established using microsurgical anastomosis of the gastro-epiploic artery to the internal mammary artery. When a pedicled flap is used, the greater omentum remains attached to the gastro-epiploic artery. After creating a subcutaneous tunnel from the inframammary skin fold, forceps are inserted into the abdomen through an incision in the linea alba and used to draw the greater omentum through the tunnel.

There was a limited amount of evidence on this procedure – five case series with approximately 58 patients in total. However, in the light of the fact that the safety and efficacy of the open technique is considered to be well

known. NICE guidance recommends that the laparoscopic procedure may be carried out with normal arrangements for consent, audit and clinical governance.

Liposuction for chronic lymphoedema (February 2008)

Treatments available to patients with chronic lymphoedema are generally rather unsatisfactory. Conservative methods include massage, to manually assist lymph drainage, and compression with bandaging or hosiery to limit swelling and discomfort. Surgical debulking procedures are sometimes used when lymphoedema is gross, with the aim of reducing the size of the limb.

Liposuction has been attempted in this patient group but there is little available evidence to date: most relates to chronic lymphoedema of the arm. The procedure needs to be followed by application of well-fitted compression garments and it is important that patients understand this will be a long-term requirement.

The case series on liposuction for lymphoedema reported few complications but there was insufficient evidence of efficacy, particularly in the long-term (with follow-up to 12 months only). This led NICE to recommend that clinicians wishing to use this procedure should do so only with special arrangements for clinical governance, consent and for audit or research.

Laser-assisted cerebral vascular anastomosis without temporary arterial occlusion (February 2008)

In certain patients who undergo surgery for intracerebral vascular disease (including cerebral aneurysms), arterial bypass may be necessary to maintain the blood supply to vital areas of the brain. Conventionally, this requires temporary arterial occlusion while anastomoses are performed; however, in some circumstances, even this duration of interrupted arterial flow may pose a significant risk of ischaemic damage. Laser-assisted cerebral vascular anastomosis aims to achieve high-flow bypass without the need for temporary occlusion of the blood supply.

After stitching a platinum ring to the wall of the recipient vessel at the anastomosis site, the bypass graft is sutured to the vessel outside the ring. A combined laser-vacuum suction catheter is introduced through the graft into the ring: laser pulses combined with vacuum suction are used to resect and remove a disc-shaped area in the vessel wall. This disc is withdrawn while still attached to the vacuum catheter, completing the anastomosis without interrupting cerebral blood flow. The graft is then temporarily clipped to prevent backflow while the arterial wall is closed.

Only five relevant studies were identified – three case series and two case reports with a total of 128 patients. None were comparative studies of ischaemic complications compared with conventional surgery. Based on the lack of sufficient evidence, NICE recommends that this procedure should be used only with special arrangements for clinical governance, consent, and audit or research.

Comment on the selection of procedures for NICE guidance

In the context of the procedures described above, a reminder is perhaps worthwhile about the selection of procedures for production of NICE Interventional Procedures guidance. Procedures are taken on because they have been notified to NICE by any interested party. The underlying reasons for notifying them are diverse, for example: (i) clinicians may wish to start doing procedures which are novel; (ii) others may be unsure about procedures which have been used infrequently over many years and which have uncertain safety and efficacy; (iii) manufacturers may wish to have a device-dependent procedure scrutinised; or (iv) a procedure may be notified because concern has arisen about its safety. Once a procedure has been notified, NICE assesses whether it falls within the remit of the Interventional Procedures programme with advice taken from Specialist Advisers and the Committee. For more information about the Interventional Procedures programme please refer to the NICE website (<www.nice.org.uk/IPprocessmanual>).

Other guidance

Between January and March 2008, 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

Arteriovenous extracorporeal membrane carbon dioxide removal.

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) for mediastinal masses.

Suburethral synthetic sling insertion for stress urinary incontinence in men.

Clinical guidelines

Surgical management of OME.

Prophylaxis against infective endocarditis.

Prostate cancer.

No technology appraisals of direct relevance to surgeons were published by NICE during this period.