NICE news in the annals

Recent NICE Guidance of interest to surgeons

STEVEN BARNES and BRUCE CAMPBELL

Interventional Procedures

Percutaneous laser revascularisation for refractory angina pectoris (May 2009)

Treatment of angina pectoris depends on its severity and on angiography findings, and may include anti-anginal medication, percutaneous coronary angioplasty/stenting or coronary artery bypass surgery. Percutaneous laser revascularisation is intended for patients in whom open surgery would be contraindicated, but NICE has advised against its use.

Percutaneous laser revascularisation is performed under local anaesthesia by a transfemoral approach. Ischaemic areas of the myocardium are selected for treatment using echocardiography or a myocardial perfusion scan and coronary angiography. A Holmium:YAG laser coupled to an optical fibre and a lens system is introduced via a catheter and used to drill 9–12 parallel channels in the myocardium at least 1 cm apart. The objective of these channels is to carry blood from the ventricular cavity into the myocardium and, therefore, into the coronary circulation, thus relieving myocardial ischaemia and the symptoms of angina. However, the evidence presented below throws doubt on any effect of the procedure in improving myocardial perfusion.

Two RCTs (439 patients) showed no significant differences in the proportions of patients whose Canadian Cardiac Society Angina score improved by two or more classes at 6-month follow-up. In terms of safety, the pooled myocardial infarction rate from six RCTs including almost 1000 patients was higher in patients undergoing percutaneous laser revascularisation (7%) than in control groups (4%) receiving medical management, sacral nerve stimulation or sham therapy.

Given this evidence, the Advisory Committee concluded that percutaneous laser revascularisation for refractory angina pectoris showed no efficacy and that the procedure may pose unacceptable safety risks. Their decision was that this procedure should not be used. This is one of the very few interventional procedures for which a 'do not use' recommendation has been made by NICE.

NICE is also developing a clinical guideline on the management of stable angina. See www.nice.org.uk.

Tenotomy of horizontal eye muscles for nystagmus (May 2009)

Nystagmus usually involves involuntary oscillatory movement of the eyes from side to side, but sometimes up and down, or in a circular motion. It may be present at birth, caused by defects of the eye or the visual pathway to the brain, and can occur in a wide range of childhood eye disorders: it is often found in children with multiple disabilities. Nystagmus can also occur as a result of stroke, multiple sclerosis or head injury.

There is no curative treatment for nystagmus. Spectacles or contact lenses may improve visual acuity but they do not correct the nystagmus.

Tenotomy has been used for nystagmus in the form of detaching the two horizontal rectus muscles of each eye from the sclera. The muscles are then re-attached at their original location. This procedure is similar to that used to treat strabismus (squint). It aims to reduce the frequency and amplitude of nystagmus and to improve visual acuity, but the exact mechanism by which detaching and then re-attaching the muscles might improve nystagmus is unknown.

Published evidence on this procedure is very limited. A case series of 10 adults reported that nine had increased eXpanded Nystagmus Acuity Function (NAFX) scores at 1 year (an objective measure used to predict visual acuity on the basis of the patient's ability to fix an image on the fovea, the most visually precise part of the retina). Another case series of five patients reported that all had improved time-to-target acquisition (focusing time) measured by infrared reflection or high-speed digital video, 1 year after the procedure.

No complications were described in the literature but the opinions of Specialist Advisers were that adverse events might include damage to the retina or perforation of the globe, infection and misalignment of muscles, diplopia, and induced strabismus.

On the basis of such limited evidence, it was recommended that tenotomy of the horizontal eye muscles should be used only with special arrangements for clinical governance (*i.e.* 'tell your hospital'). Consent should include discussion

with the patient of the uncertainties about the results of the procedure. Patient selection and follow-up should take place in specialist units with experience in the management of ocular motility disorders.

Sinus tarsi implant insertion for mobile flatfoot (July 2009)

This is a controversial procedure for a complex condition. In people with mobile flatfoot, the foot arch is effaced only on weight bearing. Manipulation or standing on tiptoe can restore its normal shape. Many children have flatfoot during growth without any disability or long-term disadvantage, as the condition resolves. However, in a few individuals, it is permanent as a result of neuromuscular disorders, skeletal dysplasias or ligamentous laxity. Mobile flatfoot is also common in adults and may be associated with tibial tendon insufficiency.

Although usually asymptomatic, particularly in children, some people with flatfoot may have foot pain. This is normally managed with orthotics and physiotherapy. In a few cases, corticosteroid injections (in adults), or surgical correction of the tendons and bones is required.

Sinus tarsi implant insertion (also known as subtalar arthroereisis) can be performed with either general or local anaesthesia. Exact technique varies but most commonly the sinus tarsi is exposed through a lateral incision. Trial implants may be used with simulated weight bearing in order to direct appropriate placement and degree of correction, and then a definitive implant of the correct size is inserted. Adjunctive bone or soft tissue procedures may be carried out at the same operation. Postoperatively, compression dressings or a plaster cast are usually applied and, thereafter, the use of modified footwear and/or orthotics is common. The implant may ultimately need to be removed, particularly in children.

The available evidence lacked any controlled data and patient numbers were very small: in addition specialist advice was cautious. Based on this, NICE guidance emphasises that the procedure is likely to be appropriate for very few children with flatfoot. It recommends that surgeons should tell patients about the uncertainty in relation to symptom relief, quality of life, and long-term outcomes; and that there may be a need for adjunctive or subsequent procedures.

Placement of pectus bar for pectus excavatum (also known as MIRPE or the Nuss procedure) (Aug 2009)

This was a review of guidance published in 2003 and it provides an example of using a specially designed register to increase the available evidence. The submission of data by surgeons to this register has been an important contribution to our knowledge about the procedure. The accompanying article describes the need for registers of this kind to support NICE in reviewing its guidance.

Pectus excavatum is the most common congenital deformity of the sternum and anterior chest wall. The cosmetic disfigurement of pectus excavatum may occasionally be accompanied by impaired cardiac or respiratory function.

Surgical correction is most often done for cosmetic reasons, commonly in mid-to-late childhood. The traditional procedure is by open repair involving resection of abnormal costal cartilages, transverse osteotomy and internal fixation of the sternum (Ravitch procedure). By contrast, placement of pectus bar is performed through small incisions on either side of the chest, usually under visualisation by thoracoscopy. A curved steel bar is inserted behind the ribs and sternum with its concavity facing anteriorly. The bar is then rotated through 180° using a 'flipper' device, pushing the sternum forward and so correcting the deformity. A variety of fixation techniques can be used to keep the bar in place, including lateral stabilisers attached to the bar and ribs using wires and/or sutures. In some patients, the bar is removed once the correction has stabilised.

NICE considered data from a UK register to which submission had been recommended in the original guidance of 2003. Data had been submitted on 260 patients. Cosmetic appearance scores (on a scale from 1 [dislike] to 10 [perfect]) improved from 3.1 points at baseline to 8.4 points postoperatively (mean follow-up 369 days). In other available data, a case series of 947 patients reported that, of 521 patients who had the bar removed, 83% had an 'excellent' cosmetic result, 12% had a 'good' result, 2% had a 'fair' result and 2% had recurrence of pectus excavatum (follow-up 1–15 years).

Complications reported in the published literature included intra-operative liver or cardiac perforation (resulting in one death), and pneumonia and pericarditis. In three case series, pneumothorax occurred in 7% (24/322), 3% (5/172) and 9% (15/167) of patients. Data from the UK registry indicated a pneumothorax rate of 2% (6/260). The register showed incidences of complications which were similar to those in the published literature, and no important complications which were not described in the literature.

Based on this evidence, NICE guidance now recommends that placement of pectus bar for pectus excavatum may be done with 'normal arrangements' in clinical practice – but only by surgeons with cardiac and thoracic training and experience, who are capable of managing the rare cardiac or liver injuries which can occur. The procedure should be done only in hospitals where there are facilities for managing these complications.

Clinical Guidelines

Low back pain. Early management of persistent non-specific low back pain (May 2009)

Low back is very common so the ways in which it is managed have significant implications for the NHS and for the

economy in general, because of the amount of time off work which it can cause. This guideline covers the early management of persistent or recurrent low back pain which has been troublesome for more than 6 weeks, but for no longer than 12 months. It does not address the management of severe disabling low back pain that has lasted over 12 months.

In relation to surgical treatments, the guidelines recommend:

1. Consider referral for an opinion on spinal fusion for people who have completed an optimal package of care, including a combined physical and psychological treatment programme and still have severe non-specific low back pain for which they would consider surgery.
2. Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion.
3. Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient.
4. Do not refer people for any of the following procedures: intradiscal electrothermal therapy (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), or radiofrequency facet joint denervation.

Recommendations relating to non-surgical treatments included:

1. Consider offering a structured exercise programme tailored to the person:
 - This should comprise up to a maximum of eight sessions over a period of up to 12 weeks.
 - Offer a group supervised exercise programme, in a group of up to 10 people.
 - A one-to-one supervised exercise programme may be offered if a group programme is not suitable for a particular person.
2. Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks.
3. Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks.

4. Do not offer injections of therapeutic substances into the back for specific low back pain.

Other Guidance

Between May 2009 and September 2009, 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.

Interventional Procedures guidance

- Percutaneous endoscopic laser lumbar discectomy
- Transmyocardial laser revascularisation for refractory angina pectoris
- Corneal endothelial transplantation
- Percutaneous endoscopic laser cervical discectomy
- Image-guided radiofrequency excision biopsy of breast lesions
- Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure due to neurological disease
- Prosthetic intervertebral disc replacement in the lumbar spine
- Extracorporeal shockwave therapy for refractory Achilles tendinopathy
- Extracorporeal shockwave therapy for refractory plantar fasciitis
- Extracorporeal shockwave therapy for refractory tennis elbow
- Percutaneous mitral valve leaflet repair for mitral regurgitation
- Ultrasound-guided foam sclerotherapy for varicose veins
- Extracorporeal albumin dialysis for acute liver failure
- Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants
- Individually magnetic resonance imaging-designed unicompartamental interpositional implant insertion for osteoarthritis of the knee

Clinical Guidelines

The management of type 2 diabetes

Data collection for new procedures and devices

BRUCE CAMPBELL

Chairman NICE Interventional Procedures Advisory Committee and Medical Technologies Advisory Committee

The amount of published evidence about new procedures is often poor in quantity, in quality or both. Even when procedures start to enter practice with a better than average evidence base, there may still be uncertainties about important aspects of their safety or efficacy in the longer term. This lack of data applies also to new medical technologies (devices and diagnostics) largely because they are not subject to the same kind of rigorous regulatory demands for testing in research as pharmaceutical products (for licensing, devices simply need a CE mark to reach the market). NICE has been pursuing the goal of good observational data collection for interventional procedures for some time: in addition, its new Evaluation Pathway for medical technologies will be recommending observational data collection for some new devices.¹⁻⁵

Around the world, people interested in health technology assessment have been debating schemes to address the evaluation of new surgical and other interventional procedures. An international group which met in Oxford during 2007–2009 has recently published a suggested model – the IDEAL recommendations – describing how important data could be acquired during the sequential stages of: Idea, Development, Exploration, Assessment and Long-term study.⁴

The concept of observational data collection on procedures or technologies is by no means new. All surgeons are likely to have contributed to professional or commercial registers for particular procedures or devices and there are now established national registers in many specialties which gather varying amounts of information, for a variety of purposes (<www.hqip.org.uk>). There are, however, significant obstacles to setting up new registers. Lack of dedicated funding for their creation and supervision is a fundamental issue. Research funders have held them in low regard as scientific tools, because they have often not been planned with clear aims and because data submission has been poor. Poor data submission results from inadequate support for data input at local level, and reluctance by some clinicians to submit their data. Registers have been regarded as a low priority by commissioners and hospitals because they fail to see obvious short-term gain. In addition, issues relating to informed consent, anonymisation of data, and data protection all contribute to the complexity of setting up new registers.

Improving the usefulness and reputation of registers as tools to generate new evidence, improve clinical practice and provide quality assurance requires them to be well planned, well supported and well analysed – with explicit aims and a pre-determined conclusion. Being very clear about the aim(s) of any register is fundamental to good planning: the dataset should include only items which are of real relevance and interest. Good support includes both support at the ‘the centre’ to maintain the register and to provide advice as required; and also good support at local level, giving clinicians the assistance they need to collate and input data (either by staff whose job it is to do so, or by recognising the personal time needed to submit data as part of the time dedicated to each procedure). I use the phrase ‘good support’ also to cover the vital point that all clinicians doing the procedure should ‘support’ any register: collection of data on all patients treated is very important for its credibility and usefulness. The data need to be analysed in a thorough and timely manner, and presented and disseminated in a way which best capitalises on their original purpose. There should be clear plans about the length of time for which data collection is needed, and about what will happen to the register and to the data after that time. It may be that data collection would continue in the longer term for just a few selected items (for example serious, but uncommon, adverse events or the durability of novel prostheses).

The words used to describe this kind of data collection can be confusing and there is no universal acceptance about which is best. Registers or databases are the terms most often used (registries is semantically incorrect) but within the research community (not least funders of research) these words may have the negative connotations described above. A ‘register’ which is well planned and which fulfils the criteria set out in the preceding paragraph is really prospective cohort study. I am using ‘registers’ in this article, but with the qualification that any register should fulfil the standards described above. Another relevant phrase is ‘use with evidence development’ which describes an understanding that a procedure will be performed only in the context of collecting more data about it on each occasion when it is used (either by data collection or in other research).

From the perspective of NICE, recommending submission of data to registers is aimed at obtaining more evidence in order to inform the production of guidance about a procedure or device in due course. For interventional procedures that means largely data about their ‘real world’ safety and/or efficacy, but information about other aspects of the introduction of novel devices into clinical practice may be useful (*e.g.* whether they really do reduce the need for additional interventions or other resources).

Some national registers are now well established (for example, the Central Cardiac Audit Database at <www.ccad.org.uk> and the National Joint Registry at <www.njrcentre.org.uk>) and NICE Interventional Procedures guidance has recommended submission of data to these. However, experience has shown that even these big, national registers may not always produce the outcomes of interest on safety and efficacy; and they do need to be specially adapted for each new procedure. Professional societies (for example, the British Association of Urological Surgeons at <www.baus.org.uk>) run databases which have the potential to be most useful sources of data, but they too need to be honed to collect the relevant data on novel procedures. Registers run by manufacturers may also have a part to play, but only if they are subject to external (professional) scrutiny and supervision so that there is confidence that all relevant data are made available. Historically, NHS systems have been unequal to the task of collecting the kinds of outcome data which are required. A particular problem for novel procedures is that specific codes are often not available at an early stage. Increasing liaison between the NICE Interventional Procedures Programme and the NHS Centre for Coding and Classification is addressing this issue.

One solution for the many procedures or devices which cannot readily be accommodated in the major national audit databases is a (small) central unit which would set up and supervise well planned registers, with small relevant, datasets, which can be cross-linked to other datasets like HES (routinely collected Hospital Episodes Statistics). This is an aim for which NICE has been negotiating for some time, to fulfil the need for more data when the available evidence is inadequate. Datasets for these procedure/device specific registers would be aimed strictly at obtaining the

‘missing’ evidence required for a well-informed judgement that a procedure or device is efficacious and safe. Getting data on all patients would require buy-in from clinicians and their specialist organisations (who would be fundamental in designing each dataset). Ideally, NHS tariff would include an allowance for time and other costs involved in data submission: it would be an expectation that the specified procedures would only be done if data were submitted. The issue of patient consent would need to be simplified as far as possible: it would arguably be in the public interest that patients should only receive the procedure if they consent to their anonymised data being submitted. A system like this ought to be possible within the clinical governance structures of the NHS, but negotiations to achieve it have been protracted, and the eventual goal is still elusive.

The many agendas and requests for data which assail clinicians are daunting – notably, at present, the prospect of needing data for revalidation. However, if specialists want to see new procedures and devices being adopted and paid for, then gathering information about them will become essential. Comprehensive collation of data from the UK could produce substantial and timely additions to the international evidence base on new procedures and devices, enabling their introduction into clinical practice (or their abandonment) with much greater confidence than in the past. I would encourage colleagues to embrace the opportunity to contribute to data collection on new procedures, capitalising on the facilities and support which should accompany these initiatives.

References

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