Recent NICE guidance of interest to surgeons

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Interventional procedures

Single incision laparoscopic cholecystectomy (IPG508)

This is an update of previous guidance published in May 2010 that gave a 'special arrangements' recommendation, based on limited evidence at that time. The new guidance specifies 'normal arrangements' (for clinical governance, consent and audit) in the light of a greatly increased and favourable evidence base. Alongside this is a clear recommendation that single incision laparoscopic cholecystectomy should only be performed by experienced laparoscopic surgeons who have had specific training in the procedure. The Interventional Procedures Advisory Committee noted recent developments in instruments used.

By any standards, there was a large amount of evidence, in particular two systematic reviews: one of 25 randomised controlled trials (RCTs) including 1,841 patients and another of 40 RCTs including 3,711 patients. All the studies used conventional multiport laparoscopic cholecystectomy as the comparator. Meta-analyses showed no differences in the proportions of patients who required conversion to open surgery or in blood loss. 'Additional surgical instruments' needed to be used more frequently during single incision procedures. Pain was less at 3–4 and 2–8 hours after single incision surgery, and cosmesis scores were better, which is a fundamental aim of those who promote this procedure.

No significant differences were reported for any type of adverse event. In particular, the frequency of bile duct injury was the same for single incision and multiport surgery.

This is a good example of a procedure (with an initially inadequate evidence base that has expanded rapidly) for which a change of recommendation has been allowed. It is frustrating that so many other procedures do not follow the same course.

Insertion of a collagen plug to close an abdominal wall enterocutaneous fistula (IPG507)

This procedure can be done in a variety of ways, usually under sedation. The fistula track is visualised by fluoroscopy. It may need to be dilated to accommodate the plug and it is debrided to encourage incorporation of the plug. A guidewire and then a delivery sheath are passed down the track into the bowel. The plug is placed in the fistula track under fluoroscopic guidance and secured in place with absorbable sutures or a Molnar disc, which lies on the skin at the external opening of the fistula. A radio-opaque

footplate on the internal end of the plug aids visualisation during insertion and thereafter obstructs the entry of intestinal fluid into the track.

Strict bed rest is usually advised for a few days to minimise the risk of plug displacement. The plug is designed to act as a scaffold for tissue growth, becoming incorporated into the surrounding tissue and causing the fistula to close.

There were just 3 published case series, including only 11 patients. In one, all six patients' fistulas had closed at two weeks; two recurred but one healed after a repeat procedure. In a case series of five patients, four were healed after insertion of either one plug (2 patients) or a second plug (2 patients). Another case series of five patients reported healing in four at a follow-up duration of 30–120 days. Two patients suffered complications caused by migration of the footplate of the plug: one had a pelvic abscess and the other a presacral fluid collection.

Despite so little evidence, a recommendation of 'only in research' was not considered appropriate. The Interventional Procedures Advisory Committee was mindful of the serious impact that enterocutaneous fistulas can have on patients and that treatment options may be very limited, especially when conservative management has failed and/or if surgery poses a high risk for them. The recommendation was for the use of this procedure only in the context of special arrangements for governance, consent and audit or research. Explicit encouragement was given for prospective studies.

Medical technologies

As a reminder, medical technologies guidance is about single technologies (devices and diagnostics) notified to NICE by manufacturers. It is based on whether a case can be made for advantages to patients at the same or lesser cost than current management. It is not intended to prevent the use of similar products with equally good evidence.

It has the potential to steer practice in new directions, which will benefit patients and the National Health Service, based on the attributes of new technologies. In a sense, it is trying to pre-empt futures instances of 'Why didn't we start using that earlier?'.

A major challenge is the paucity of good evidence for many technologies. The recent examples below are both technologies with clear promise but currently without sufficient evidence to recommend widespread adoption.

The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury (MTG21)

This is an interesting and promising technology with potential to improve healing in acute burns, especially for patients with burns that need skin grafting. It comprises a rapid autologous cell harvesting, processing and delivery system, which requires a piece of skin only 2cm x 2cm from a donor site close to the burn.

The donor skin is processed in an enzyme solution and then scraped with a scalpel to remove a plume of cells. These are placed in a buffer solution and processed further to produce a suspension, which is either sprayed or dripped on to the debrided burn. The cells are claimed to proliferate rapidly and migrate over the wound, leading to growth of healthy skin and rapid healing.

The available evidence suggested that ReCell® (Avita, Royston, UK) may be an effective alternative to skin grafting for mid-dermal to deep partial-thickness burns but the Medical Technologies Advisory Committee was advised that this application was not likely to be adopted by surgeons in the UK. Instead, experts informed the Medical Technologies Advisory Committee that the ReCell® system has most clinical potential in patients with large full-thickness or deep partial-thickness burns that need meshed skin grafting. They advised that the system could also be used on donor sites to reduce healing time and therefore potentially to allow further grafts to be taken sooner from the same site. However, the evidence to support this use of the system was inconclusive. Both evidence and expert consensus were also inconclusive regarding the claim that use of ReCell® could reduce the occurrence of hypopigmentation in healed burns.

Overall, the evidence was judged insufficient to support the use of ReCell® in clinical practice at the present time but research was recommended to investigate its potential (that might include good data collection). NICE will update this guidance if and when substantive new evidence becomes available.

Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers (MTG20)

Prevention of pressure damage is an important and topical subject. Considerable progress has been made in recent times to educate everyone dealing with patients and introduce

measures to reduce the risk but any new technology that advances this cause would be welcome.

Parafricta® fabric (APA Parafricta, London, UK) has a friction coefficient that is substantially lower than that of most fabrics. It has no stiction, which is the additional force needed to overcome skin sticking to a surface before sliding. The lower the friction and stiction, the less likely it is that shear forces will develop and cause skin damage.

Parafricta® bootees and undergarments can be attached to the patient with hook and loop fastenings, and are designed to be used in the areas most at risk. Based on limited evidence and the advice of experts, the Medical Technologies Advisory Committee saw great potential for the use of Parafricta® garments, both in hospital and in the community. However, the published studies were simply not enough to support a recommendation for routine adoption and the recommendation was therefore for research.

This is a technology for which NICE will explore the development of appropriate further evidence, in collaboration with the manufacturer as well as clinical and academic partners. The guidance will be updated when more evidence is available.

Clinical guidelines

The diagnosis and management of colorectal cancer (CG131)

This will already be well known to all those in the field. It sets out practice guidelines covering the whole spectrum of the management of colorectal cancer.

Technology appraisals

Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism (TA327)

This recommends dabigatran as an option for treating and preventing recurrent deep vein thrombosis and pulmonary embolism. There is likely to be an increasing move away from warfarin to the newer oral anticoagulants and surgeons will need to become familiar with their use.