NICE news in the annals

Recent NICE Guidance of interest to surgeons

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Interventional Procedures

Intra-operative red blood cell salvage during radical prostatectomy or radical cystectomy (April 2008)

Blood loss during radical prostatectomy and radical cystectomy may sometimes be substantial and, conventionally, blood is replaced by transfusion of allogeneic, banked blood. This carries a small risk of infection (*e.g.* hepatitis, human immunodeficiency virus, variant Creutzfeldt–Jakob disease), or antibody-mediated transfusion reaction. Intra-operative red blood cell salvage offers an alternative strategy, with particular relevance for patients who object to allogeneic blood transfusion on religious or other grounds. Although this method has been widely used in other areas, such as aortic surgery, there has been uncertainty about its use in operations for malignancy – specifically with regard to the theoretical consequences of infusing malignant cells from the operative field.

Red cell salvage involves aspiration of blood from the operative field using a suction catheter. The blood is filtered to remove debris (usually with a leukocyte depletion filter, to minimise the risk of re-infusion of malignant cells that may be present in the aspirate), and is then washed and spun. The red cells are suspended in saline for transfusion during or after the operation.

The only meaningful efficacy outcome for this procedure is successful replacement of sufficient functioning red blood cells, and the best available surrogate for this is peri-operative survival, although this is, of course, influenced by many other factors. A case series of 49 patients treated with red blood cell salvage during radical cystectomy reported overall and disease-free survival rates of 88% and 80%, respectively, at 24-month follow-up. A non-randomised, controlled study of patients who were treated with radical prostatectomy reported similar rates of biochemical prostate cancer recurrence in 265 patients treated intra-operatively with salvaged red blood cells and 773 patients who did not require re-infusion during their operation.

A non-randomised, controlled study of patients undergoing cystectomy reported no significant difference in the

3-year overall survival rate between a group of 65 patients treated intra-operatively with salvaged re-infused blood and 313 patients who did not receive re-infusion (64% and 66%, respectively).

In summary, there was no evidence from these series to support the concern that red cell salvage increased cancer recurrence rates, and Specialist Advisers also considered re-infusion of cancerous cells leading to distant metastases to be only a theoretical adverse event.

Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus (April 2008)

Type 1 diabetes mellitus is caused by insufficient insulin secretion. This may result in hypoglycaemic episodes, which are usually easily recognised and treated. In some people, hypoglycaemia occurs without warning, with life-threatening consequences. Patients with type 1 diabetes require life-long treatment with exogenous insulin, often involving multiple daily insulin injections, together with dietary management to reduce the risk of hypoglycaemia or hyperglycaemia. In some patients whose blood sugar level is not well controlled by these methods, whole pancreas transplantation may be a surgical option.

An alternative possibility for patients whose diabetes is particularly difficult to control is islet cell transplantation. For this procedure, islet cells are obtained from pancreases of brain-dead donors, and prepared using specialised techniques. Under local anaesthesia and using imaging guidance, a catheter is inserted percutaneously into the patient's portal vein and the islet cells infused into the liver. Multiple infusions may be required. Long-term immunosuppressive therapy is essential following islet cell transplantation.

The published evidence was limited to case series. One series reported no hypoglycaemic episodes, in patients with residual islet cell function among 36 patients followed up for 12 months (however, 28% of patients only had partial islet cell function and still required exogenous insulin). A second case series of 65 patients reported significantly reduced hypoglycaemia unawareness and improved diabetic

control compared with baseline, 4 years after transplantation. For patients who remained insulin-dependent, insulin requirements were reduced. Specialist Advisers stated that complications arising from the procedure may include intraperitoneal bleeding, portal (or branch) vein thrombosis, and gall bladder puncture requiring laparotomy. A single case report described a patient who died of West Nile virus encephalitis – a potential infection in immunosuppressed patients.

The Interventional Procedures Advisory Committee considered that there was evidence of short-term efficacy for allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus, and that important adverse events were largely related to the immunosuppression required. The Committee's guidance supported the use of the procedure in units with established experience in allogeneic pancreatic islet cell transplantation. It was recommended that patient selection should take into account that the procedure is particularly suitable for patients with hypoglycaemia unawareness and/or those already on immunosuppressants following renal transplantation.

NICE is also looking at islet cell transplantation for improved glycaemic control in patients who have had pancreatectomy, and guidance will be published shortly.

Endo-aortic balloon occlusion for cardiac surgery (May 2008)

Application of an external cross-clamp is the usual method of occluding of the aorta during cardiac operations, such as replacement or repair of the mitral or aortic valve, and coronary artery bypass grafting. With increasing interest in minimally invasive techniques, other means of achieving aortic occlusion are being sought, and endo-aortic balloon occlusion is one alternative option. In this procedure, a balloon catheter is inserted, usually via the femoral artery, and manipulated into place. The balloon is filled with saline to occlude the aorta and to prevent back flow into the operative field.

Evaluation of the efficacy of the procedure proved surprisingly difficult, because no outcomes were reported in the literature which related directly to the success of the occlusion of the aorta (they were all concerned with the success of the cardiac intervention being undertaken). For example, the 30-day mortality rate in a case series of 106 patients was reported as 1% and the rate of late deaths (mean follow-up 20 months) 2%.

With regard to safety, a case series of 449 patients reported no significant differences in the incidences of arrhythmias, pulmonary dysfunction, bleeding, renal failure or low cardiac output between those treated with endo-aortic balloon occlusion and those treated with transthoracic clamping. However, the rates of neurological complications (stroke and transient hemiplegia) were higher in patients

who had endo-aortic balloon occlusion. Specialist Advisers reported anecdotal adverse events including aortic dissection, rupture and migration of the balloon, damage to aortic intima, and inability to complete planned surgery because of failure of the balloon to occlude the aorta. Advisors said that monitoring by transoesophageal echocardiography was important for the safety of the technique.

The Committee considered that there was enough implicit evidence that the procedure was efficacious, and that the risk of serious complications was sufficiently low that it could be used with normal arrangements for governance, consent and audit. It was noted that there have been technical modifications to the design of the balloons with the intention of improving their performance, and that newer designs may result in fewer complications.

Based on the published evidence and the specialist advice received, it was recommended that the procedure should only be used by highly experienced teams and with continuous monitoring by transoesophageal echocardiography.

Stent insertion for bleeding oesophageal varices (June 2008)

Bleeding from oesophageal varices, associated with portal hypertension, is a cause of considerable morbidity and significant mortality. The traditional method for emergency control of bleeding, using a Sengstaken tube, is uncomfortable and distressing for patients.

The aim of stent insertion is to apply pressure to the bleeding oesophageal varices by the use of a purpose-made, self-expanding stent device inserted with a special delivery system. The stent is left in position for a number of days, maintaining a patent oesophageal lumen for passage of saliva, other fluids and food. The stent is removed at a second endoscopy, using a foreign body extractor which grasps the proximal loop of the stent triggering a mechanism of automatic elongation (and narrowing) of the stent, to allow withdrawal.

Only one case series of 20 patients was available: this reported successful stent placement in all patients. Among the 19 patients with oesophageal bleeding only (no gastric bleeding), the circulation was stabilised within 2 h of implantation. Small ulcers developed in the oesophageal wall of one patient but no other local complications were reported.

On the basis of this single, small series the evidence on the safety and efficacy of the procedure was inadequate to support its use without special arrangements for clinical governance, consent and audit or research. However, the Committee regarded the concept of the procedure to be promising, and thought that it was likely to be more acceptable to patients than tamponade of bleeding varices using an oesophageal tube. The guidance, therefore, encourages reporting of results in order to provide more information on

the efficacy and safety of this type of stent. NICE will review the procedure when further evidence is available.

Clinical Guidelines

Management of inadvertent peri-operative hypothermia in adults (April 2008)

Inadvertent peri-operative hypothermia is a common, but preventable, complication of surgical procedures, particularly among those who are assessed as having a poor American Society of Anesthesiologists' physical status (ASA grade), and those patients who are at high cardiac risk. Inadvertent peri-operative hypothermia is associated with increased peri-operative blood loss, longer post-anaesthetic recovery, postoperative shivering and discomfort due to coldness, cardiac arrhythmias, altered drug metabolism, increased risk of wound infection, longer hospital stay, and generally reduced levels of patient satisfaction. Inadvertent peri-operative hypothermia is quite different from the deliberate induction of hypothermia for medical reasons, which is not covered by this guideline. The key recommendations are:

- 1. General** – Patients should be informed that staying warm before surgery will lower the risk of postoperative complications and that the hospital environment may be colder than that in their own home. They should bring additional clothing, and they should tell staff if they feel cold at any time during their hospital stay. When using any device to measure patient temperature, adjustments should be made order to obtain an estimate of core temperature from that recorded at the site of measurement
- 2. Before surgery** – Each patient should be assessed for their risk of inadvertent peri-operative hypothermia before transfer to the theatre suite. Patients should be managed as higher risk if any two of the following apply: (i) ASA grade II–V; (ii) pre-operative temperature below 36.0°C; (iii) patients undergoing combined general and regional anaesthesia; or (iv) patients undergoing surgery at risk of cardiovascular complications. If the patient's temperature is below 36.0°C, forced air warming should be started preoperatively and be maintained throughout the operation.
- 3. At the time of operation** – The patient's temperature should be measured and documented before induction of anaesthesia and then every 30 min until the end of surgery. Induction of anaesthesia should not begin unless the patient's temperature is 36.0°C or above (unless there is a need to expedite surgery). Intravenous fluids (500 ml or more) and blood products should be warmed to 37°C using a fluid-warming device before delivery. All patients who are anaesthetised for longer than 30 min should be warmed intra-operatively from induction of anaesthesia using a forced-air warming device.
- 4. Postoperative recovery** – The patient's temperature should be measured and documented on admission to the recovery room and then every 15 min. Transfer to the ward should not be arranged unless the patient's temperature is 36.0°C or above.

Other Guidance

Between April and June 2008, NICE published further 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

- Interstitial photodynamic therapy for malignant parotid tumours
- Canaloplasty for primary open-angle glaucoma
- Suburethral synthetic sling insertion for stress urinary incontinence in men
- Single-incision sub-urethral short tape insertion for stress urinary incontinence in women
- Implantation of multifocal (non-accommodative) intra-ocular lenses during cataract surgery
- Lumbar infusion test for the investigation of normal pressure hydrocephalus
- Surgical repair of vaginal wall prolapse using mesh
- Transcatheter aortic valve implantation for aortic stenosis.

Clinical Guidelines

- Diabetes type 2 (update)
- Prophylaxis against infective endocarditis
- Prostate cancer.

Technology Appraisals

- No Technology Appraisals of direct relevance to surgeons were published by NICE during this period.