



Percutaneous retroperitoneal endoscopic necrosectomy

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG33.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous retroperitoneal endoscopic necrosectomy is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- The procedure should only be carried out by a team experienced in the management of complex pancreatic disease.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Pancreatic necrosis (also called necrotising pancreatitis) is a serious complication of acute pancreatitis that can occur in some patients. It is associated with significant morbidity, requiring prolonged hospitalisation, and high mortality.
- 2.1.2 Traditionally pancreatic necrosis has been treated by open necrosectomy via laparotomy, but image-guided drainage or laparoscopic drainage may also be used.

2.2 Outline of the procedure

- 2.2.1 Percutaneous retroperitoneal endoscopic necrosectomy aims to remove necrotic tissue under direct vision. The procedure is less invasive and may improve prognosis compared with traditional open surgery. Percutaneous drainage may be attempted as part of the management prior to the procedure.
- 2.2.2 With the patient under general anaesthesia, an endoscope (which may be rigid or flexible) is inserted via a posterolateral approach into the retroperitoneal space to visualise the area of necrosis. Dead tissue is removed, for example using suction, lavage or forceps, and debrided where necessary using forceps. Drains may be placed for irrigation in the postoperative period. The procedure may be repeated if required.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- 2.3.1 A randomised controlled trial (RCT) of 88 patients treated by a step-up protocol involving drainage followed-up as required by percutaneous retroperitoneal endoscopic necrosectomy versus primary open necrosectomy, reported mortality rates of 19% (8 out of 43) and 16% (7 out of 45) respectively (p=0.70; patients in this study were followed-up for up to 6 months from hospital discharge). In the group randomised to drainage followed as required by percutaneous retroperitoneal endoscopic necrosectomy 60% (26 out of 43) of patients underwent the procedure, 35% (15 out of 43) of patients required drainage alone and 5% (2 out of 43) of patients with multiple organ failure were too unstable for the procedure and underwent endoscopic transgastric drainage.
- 2.3.2 A non-randomised controlled study of 189 patients treated by the procedure or open pancreatic necrosectomy reported mortality rates of 19% (26 out of 137) and 38% (20 out of 52) respectively (p=0.009; follow-up not stated).
- 2.3.3 A non-randomised controlled study of 30 patients treated by the procedure or

- open necrosectomy reported in-hospital mortality rates of 7% (1 out of 15) and 40% (6 out of 15) respectively (p=0.08).
- 2.3.4 The non-randomised controlled study of 30 patients treated by the procedure or open necrosectomy reported postoperative multiple organ failure in 13% (2 out of 15) and 67% (10 out of 15) of patients respectively (p=0.008).
- 2.3.5 The RCT of 88 patients comparing drainage followed as required by percutaneous retroperitoneal endoscopic necrosectomy with primary open necrosectomy, reported a composite rate of major complication or death in 40% (17 out of 43) and 69% (31 out of 45) of patients in either group respectively (p=0.006; follow-up of up to 3 months from hospital discharge).
- 2.3.6 The Specialist Advisers listed key efficacy outcomes as a reduction in mortality and morbidity, reduction of requirement for postoperative critical care, number of interventions required and length of hospital stay.

2.4 Safety

- 2.4.1 The RCT of 88 patients comparing percutaneous retroperitoneal endoscopic necrosectomy with primary open necrosectomy, reported fistula formation or perforation requiring intervention in 33% (14 out of 43) and 22% (10 out of 45) of patients respectively (p=0.32; patients in this study were followed-up for up to 6 months from hospital discharge).
- 2.4.2 Bowel perforation occurred in 7% (1 out of 15) of patients treated by the procedure and in 13% (2 out of 15) of patients treated by open necrosectomy in the non-randomised controlled trial of 30 patients (p=not significant). In the same study, pancreatic fistula developed in 13% (2 out of 15) of patients and 0% (0 out of 15) of patients respectively (p=not significant; follow-up not stated).
- 2.4.3 The RCT of 88 patients reported that bleeding requiring intervention occurred in 16% (7 out of 43) of patients treated in the percutaneous retroperitoneal endoscopic necrosectomy group and in 22% (10 out of 45) of patients treated by open necrosectomy (p=0.48).

2.4.4 The Specialist Advisers stated that adverse events reported in the literature include incomplete drainage and/or sepsis control, iatrogenic injury to the kidney or spleen, colonic necrosis, pseudocyst formation, venous thrombosis and death.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.