

Endoscopic transluminal pancreatic necrosectomy

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg567

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 [Yellow Card Scheme](#).

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG411.

1 Recommendations

- 1.1 Current evidence on the safety of endoscopic transluminal pancreatic necrosectomy shows that there are serious but well-recognised complications. Evidence on efficacy is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection should be done by a multidisciplinary team experienced in the management of the condition.
- 1.3 Endoscopic transluminal pancreatic necrosectomy should only be done in a specialist centre by a team experienced in the management of complex pancreatic disease.

2 Indications and current treatments

- 2.1 Pancreatic necrosis (also called necrotising pancreatitis) is a serious complication of pancreatitis that can occur in some patients. It can occur with or without the formation of pseudocysts and is associated with significant morbidity and high mortality, particularly if it becomes infected. Patients usually need a long stay in hospital with treatment in intensive care.
- 2.2 Current treatment options for pancreatic necrosis include conventional open or

laparoscopic necrosectomy.

3 The procedure

- 3.1 Endoscopic transluminal pancreatic necrosectomy is done with the patient under sedation or general anaesthesia, using upper gastrointestinal endoscopy and endosonographic or fluoroscopic guidance or both. The stomach is distended with carbon dioxide. The area where the necrotic tissue has collected is usually identified as a bulge in the stomach wall. An opening is made in the posterior wall of the stomach. The opening is dilated with a balloon over a guide wire to allow the endoscope to pass through into the area of necrotic tissue. Any fluid that has collected is drained. Necrotic tissue is removed through the endoscope using suction, forceps and irrigation. One or more self-expanding stents or irrigation catheters may be left in place in the stomach wall to help further drainage from the retroperitoneal space into the stomach. Repeated sessions may be needed over many days until the cavity is clean and lined with granulation tissue. The procedure aims to avoid the need for open or laparoscopic necrosectomy and its associated morbidity.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a systematic review of 938 patients, the mean clinical success rate of endoscopic necrosectomy was 89% (range 50 to 100%). In a non-randomised comparative study (included in the systematic review), 24 patients were treated by endoscopic necrosectomy or a step-up approach (percutaneous catheter drainage with possible surgery). Clinical resolution (defined as resolution of primary symptoms and no abdominal pain, nausea, vomiting, fever, leucocytosis or sepsis) was reported in 92% (11/12) of patients after endoscopic necrosectomy and 25% (3/12) of patients after percutaneous catheter drainage in the step-up approach group ($p=0.0028$).

- 4.2 In a systematic review of 455 patients, 16% (73/455) of patients needed additional interventions after endoscopic necrosectomy (18 percutaneous, 46 surgical, 7 percutaneous and surgical, 2 other). In a case series of 81 patients (included in the systematic review of 938 patients), small collections of necrotic tissue and fluid that caused symptoms recurred in 4% (3/72) of patients. These patients needed additional endoscopic treatment, which resulted in complete resolution. In a case series of 57 patients (included in the systematic review of 938 patients), 5% (3/57) of patients had a recurrent cavity after 2 to 8 months; they were successfully treated by endoscopic or percutaneous drainage.
- 4.3 In a randomised controlled trial of 20 patients treated by endoscopic or surgical necrosectomy (included in the systematic reviews), hospital stays after randomisation were 45 and 36 days respectively ($p=0.91$). In a non-randomised comparative study of 32 patients treated by endoscopic or surgical necrosectomy (included in the systematic review of 938 patients), median length of hospital stay was 32 and 74 days respectively ($p=0.006$).
- 4.4 The specialist advisers listed the key efficacy outcomes as resolution of the necrotic cavity, reduced length of stay in a high dependency or intensive care unit, and quality of life.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Overall mortality after endoscopic necrosectomy was reported as 5% (range 0 to 25% per study) in a systematic review of 938 patients. Death was reported in 10% (1/10) of patients treated by endoscopic necrosectomy and 40% (4/10) of patients treated by surgical necrosectomy ($p=0.30$) in a randomised controlled trial of 20 patients (included in the systematic review). The death rate was 0% (0/11) in patients treated by endoscopic necrosectomy compared with 14% (3/21) in patients treated by surgical necrosectomy ($p=0.53$) in a non-randomised comparative study of 32 patients (included in the systematic review). In-hospital mortality was 0% (0/12) for patients treated by endoscopic necrosectomy

- compared with 8% (1/12) for patients treated by a step-up approach in a non-randomised comparative study of 24 patients (included in the systematic review).
- 5.2 Fatal gas embolism after endoscopic transgastric necrosectomy with carbon dioxide insufflation was described in a case report. Air embolism was reported in less than 1% (4/938) of patients in the systematic review of 938 patients.
- 5.3 Bleeding was reported in 11% (103/938) of patients in the systematic review of 938 patients. Bleeding was reported in 8% (1/12) of patients treated by endoscopic necrosectomy and 50% (6/12) of patients treated by surgical necrosectomy in the non-randomised comparative study of 24 patients (included in the systematic review).
- 5.4 Pancreatic fistula was reported in 5% (9/187) of patients in a systematic review of 455 patients. It was also reported in 10% (1/10) of patients treated by endoscopic necrosectomy and 70% (7/10) of patients treated by surgical necrosectomy ($p=0.02$) in the randomised controlled trial of 20 patients (included in the systematic review). Pancreatic fistula was reported in 0% (0/11) in patients treated by endoscopic necrosectomy compared with 38% (8/21) of patients treated by surgical necrosectomy ($p=0.03$) in a non-randomised comparative study of 32 patients.
- 5.5 Spontaneous perforation of a hollow organ (apart from the stomach or duodenum because of the intervention) was reported in 4% (9/249) of patients in the systematic review of 455 patients. Bowel perforation was reported in 1 patient treated by endoscopic necrosectomy in the non-randomised comparative study of 32 patients. Perforation was reported in 5% (3/57) of patients in the case series of 57 patients.
- 5.6 New-onset organ failure was reported in 18% (2/11) of patients treated by endoscopic necrosectomy and 17% (5/21) of patients treated by surgical necrosectomy ($p=0.99$) in the non-randomised comparative study of 32 patients.
- 5.7 Stent complication (not further described) was reported in 9% (2/11) of patients treated by endoscopic necrosectomy in the non-randomised comparative study of 32 patients.

- 5.8 Pneumoperitoneum, without the need for intervention or treated by needle aspiration, was reported in 5% (4/81) of patients in the case series of 81 patients.
- 5.9 New-onset diabetes (assessed 6 months after hospital discharge) was reported in 22% (2/9) of patients treated by endoscopic necrosectomy and 50% (3/6) of patients treated by surgical necrosectomy ($p=0.33$) in the randomised controlled trial of 20 patients.
- 5.10 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: slipping of irrigation tube, stent migration, prolonged hospital stay, and sedation-related adverse reactions. They considered that the following were theoretical adverse events: splenic vein thrombosis with portal hypertension and oesophageal varices, introduction or exacerbation of infection, and fluid overload.

6 Committee comments

- 6.1 The committee noted that necrotising pancreatitis is a severe condition, which has a poor prognosis if untreated.
- 6.2 The committee noted that patients may need the procedure repeating many times and that the procedure does not preclude the subsequent use of other treatments for this condition.
- 6.3 The committee noted the difficulty in doing randomised controlled trials for this procedure.
- 6.4 The committee noted that the techniques used in endoscopic transluminal pancreatic necrosectomy are evolving, including the use of stents, and the use of carbon dioxide instead of air for insufflation.

7 Further information

NICE has produced information on this procedure for patients and carers ([information for the public](#)). 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 [Healthcare Improvement Scotland](#).