

Tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg746

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.

1 Recommendations

- 1.1 Evidence on the safety of long-term tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis is limited but shows well-recognised complications. Evidence on the efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do long-term tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Give people (and their families and carers as appropriate) clear information to support shared decision making, including NICE's information for the public.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection, continued community care support and follow up should be done by a multidisciplinary team experienced in managing the condition. The team should include a hepatologist, a specialist community nurse and specialist level palliative care.
- 1.5 NICE encourages further research into long-term tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis.

2 The condition, current treatments and procedure

The condition

- 2.1 Refractory ascites is a common complication of cirrhosis of the liver. Build-up of fluid causes difficulty in breathing, fatigue, nausea, poor appetite, acid reflux, abdominal pain and infection. Mortality at 2 years in people with refractory ascites is 50% or more, and 5-year survival is normally less than 20%.

Current treatments

- 2.2 Treatment options for symptomatic relief include dietary sodium and fluid restriction, diuretics, large-volume paracentesis (a temporary drain inserted into the abdomen to drain the ascitic fluid) with albumin infusion, or insertion of a transjugular intrahepatic portosystemic stent shunt (TIPSS). If the cause of liver failure and ascites cannot be treated or treatment fails, liver transplantation may be used in some people. If TIPSS or liver transplantation is not suitable, long-term ascitic drainage peritoneal catheters are a palliative treatment option.

The procedure

- 2.3 The procedure is usually done as a day case with local anaesthesia, with or without sedation. Ultrasound, fluoroscopy or both are used to guide catheter insertion and placement. A guidewire introducer needle is inserted percutaneously into the peritoneal cavity and ascitic fluid is aspirated. A guidewire is then inserted through the introducer and into the peritoneal cavity. A fenestrated drainage catheter is tunnelled subcutaneously from a second incision away from the guidewire insertion site. It is then inserted over the guidewire into the peritoneal cavity using a dilator and peel-away sheath. A polystyrene cuff on the catheter is positioned inside the subcutaneous tunnel. The dilator and guidewire are removed and the catheter insertion site and exit sites are sutured. Antibiotics may be offered during and after the procedure.
- 2.4 A lockable drainage line is connected to a valve at the outer end of the catheter to allow the ascitic fluid to be drained into a vacuum bottle or a drainage bag. Before hospital discharge, the ascites is normally drained to dryness and albumin replacement is given. After this procedure, ascites drainage is done in the community or at home without giving replacement albumin. This is typically supervised by district nurses.
- 2.5 People can drain small amounts of ascitic fluid repeatedly from their peritoneal cavity into vacuum bottles. The volume of fluid drained and how often it is done can be adjusted according to their needs.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 small randomised controlled trials (1 of which was a feasibility randomised controlled trial that was described in 2 reports), 1 case report and 1 conference abstract. It is presented in the [summary of key](#)

[evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in health-related quality of life, and reductions in hospital visits, pain and symptoms relating to intra-abdominal pressure.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: peritonitis, catheter insertion site infection, and fluid and electrolyte imbalances.
- 3.4 Patient commentary was sought but none was received. However, a submission from a patient organisation was discussed by the committee.

Committee comments

- 3.5 The primary intention of the procedure is to improve health-related quality of life and reduce the number of hospital visits.
- 3.6 This guidance does not cover the use of this procedure for malignant ascites, see [NICE's medical technologies guidance on PeritX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites](#).
- 3.7 The committee was informed that:
- the procedure has the potential to increase the pre-existing risk of bacterial peritonitis in people with refractory ascites in cirrhosis
 - a National Institute for Health Research health technology assessment (a randomised controlled trial, the REDUCe 2 study) has been funded.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

