

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis

Long-term liver scarring (cirrhosis) can cause fluid to build up (ascites) in the abdomen, causing difficulty in breathing, nausea, bloating, acid reflux, abdominal pain, poor appetite and infection. The fluid can be drained in hospital (peritoneal drainage) with a temporary drainage tube (catheter) to help relieve the symptoms but the fluid recurs (refractory). So drainage needs to be repeated every 1 to 2 weeks. This may cause pain and infection.

In this procedure, with a local anaesthetic (or occasionally under sedation or a general anaesthetic) a catheter is inserted (tunnelled) under the skin into the abdomen. Excess fluid can then be drained when needed, at home or in community care into a bottle or a bag. In between times, the catheter is capped and covered with a clean dressing. The aim is to reduce the need for hospital admissions and improve quality of life.

NICE is looking at long-term tunnelled peritoneal drainage catheter insertion for refractory ascites in cirrhosis.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

NICE interventional procedures consultation document, March 2022

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 25 April 2022

Target date for publication of guidance: September 2022

# 1 Draft 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 safety concerns. 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 5 cm 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 randomised controlled trials (1 of which 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.

#### Committee comments

- 3.4 The primary intention of the procedure is to improve health-related quality of life and reduce the number of hospital visits.
- 3.5 This guidance does not cover the use of this procedure for malignant ascites. [NICE has guidance on PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites](#).
- 3.6 The committee was informed that:

- the procedure may increase the 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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Chair, interventional procedures advisory committee

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