NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Subcutaneous automated low-flow pump implantation for refractory ascites caused by cirrhosis

Long-term liver damage (cirrhosis) can cause fluid build-up in the abdomen (ascites). This can lead to poor appetite, fatigue, difficulty in breathing and infection. In this procedure, a battery-powered pump is put under the skin. It is connected to the abdomen and bladder by 2 tubes, and the battery is charged using wireless technology. The aim is to pump excess fluid from the abdomen to the bladder where it is passed in the urine.

The National Institute for Health and Care Excellence (NICE) is looking at subcutaneous pump implantation for refractory ascites caused by cirrhosis. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

Issue date: June 2018

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

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

Closing date for comments: 19 July 2018

Target date for publication of guidance: October 2018

1 Draft recommendations

1.1 Current evidence on the safety of subcutaneous automated low-flow pump implantation for refractory ascites shows there are serious but well-recognised safety concerns, including device failure and acute kidney injury. Evidence on efficacy is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do subcutaneous automated low-flow pump implantation for refractory ascites should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information to support shared decision-making. In addition, the use of NICE's information for the public *[URL to be added at publication]* is recommended.
- Audit and review clinical outcomes of all patients having subcutaneous automated low-flow pump implantation for refractory ascites. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

1.3 All device failures should be reported to the Medicines and Healthcare products Regulatory Agency.

1.4 Patient selection should be done by clinicians experienced in managing acute and chronic liver disease.

1.5 Further research should report details of patient selection, the frequency of pump-related complications, and whether regular albumin infusions are needed.

2 The condition, current treatments and procedure

The condition

2.1 Ascites is a common complication of cirrhosis of the liver. Build-up of fluid causes the abdomen to swell and may lead to discomfort, difficulty breathing, fatigue, nausea and poor appetite.

Current treatments

2.2 Treatment is usually diuretics and advice about dietary sodium restriction. For refractory ascites, treatment options include large-volume paracentesis, albumin infusion and insertion of a transjugular intrahepatic portosystemic shunt. These procedures may be used to support a patient who is waiting for a liver transplant.

The procedure

2.3 Subcutaneous automated low-flow pump implantation for refractory ascites is usually done with the patient under general anaesthesia, typically through 3 small incisions in the abdominal wall. A battery-powered pump with internal pressure sensors is implanted on the right side above the belt line. One catheter connects the pump to the peritoneal cavity, and another connects it to the urinary bladder. The pump and both catheters are secured with sutures to prevent migration. The pump removes fluid from the peritoneal cavity through the first catheter, and puts it into the bladder through the second catheter. The fluid is eliminated through normal micturition. The pump is programmed to remove pre-set daily volumes of fluid, and the pressure sensors prevent it from over-distending the bladder.

2.4 A clinician programs the pump wirelessly using an external hand-held charging device, according to the needs of the patient (based on previous large-volume paracentesis requirements, observed accumulation of ascites and body weight). The hand-held device is also used by the patient to charge the pump wirelessly, by holding it above the pump for about 30 minutes each day. The hand-held

device collects data sent by the pump, which are downloaded to a computer for review by the clinician. Anonymised data are sent to the manufacturer, which sends a report to the clinician with a detailed analysis of the data and any recommendations.

2.5 The aim of the procedure is to avoid the accumulation of fluid, abdominal swelling and accompanying complications.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 7 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (described in 2 publications) and 5 case series, and is presented in table 2 of the interventional procedures overview *[URL to be added at publication]*. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in need for paracentesis, and quality of life (including disease specific outcomes).

3.3 The specialist advisers and the committee considered the key safety outcomes to be: technical failure (including pump durability), infection and acute kidney injury.

3.4 This guidance is a review of NICE's interventional procedures guidance on subcutaneous implantation of a battery-powered

catheter drainage system for managing refractory and recurrent ascites.

Committee comments

3.5 The committee noted the published evidence showed a relatively high incidence of device failure.

3.6 The committee noted that the procedure is associated with an increased incidence of acute kidney injury.

3.7 The committee was informed that after the procedure patients need regular monitoring, and they may need infusions of albumin.

3.8 The committee noted that most of the published evidence on the procedure only included patients for whom a transjugular intrahepatic portosystemic shunt is unsuitable.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
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