NICE guidance

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

Interventional procedures guidance
Published: 14 November 2018
nice.org.uk/guidance/ipg631

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. However, 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.

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.

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 IPG479.

1 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 procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support shared decision-making. In addition, the use of NICE's information for the public 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 has developed an audit tool (which is for use at local discretion).

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

1.4 Patient selection should be done in specialist centres, by clinicians experienced in managing liver disease and in the various options available for managing ascites.

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

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 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 8 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (described in 2 publications) and 6 case series, and is presented in table 2 of the interventional procedures overview. 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 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted the published evidence shows 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.

3.9 The committee was informed that the procedure has the potential to improve

quality of life for patients with refractory ascites, and also that of their families or carers.

3.10 The committee was informed that the technology for this procedure is evolving.

ISBN: 978-1-4731-3118-7

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation