NICE guidance

Laparoscopic insertion of peritoneal dialysis catheter

Interventional procedures guidance
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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 Guidance

1.1 Current evidence on the safety and efficacy of laparoscopic insertion of peritoneal dialysis catheter appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Clinicians should ensure that patients understand the potential risks and benefits of the procedure, and the alternatives, and should provide patients with clear written information. In addition, use of NICE's information for the public is recommended.

1.3 The evidence on the selection of patients for this technique of peritoneal dialysis catheter insertion is unclear. Publication of further relevant evidence will be useful in guiding clinical practice.

2 The procedure

2.1 Indications

2.1.1 Peritoneal dialysis is an alternative to haemodialysis and is used to treat patients with end-stage renal disease. It involves infusing fluid into the peritoneal cavity via a catheter and leaving it there for sufficient time to allow metabolic waste products to diffuse through the peritoneal membrane into the dialysis fluid, which is then drained away.

2.1.2 A peritoneal dialysis catheter is conventionally inserted through a small incision in

the abdomen, under local or general anaesthesia. The catheter is directed towards the pelvis, which is the best place for the tip to lie. The catheter can also be placed using a percutaneous technique.

2.2 Outline of the procedure

2.2.1 Laparoscopic insertion of a peritoneal dialysis catheter is usually performed under general anaesthesia. The abdomen is insufflated and several small incisions are made. The tip of the catheter is advanced into the pelvis, and may be sutured in place. The proximal end of the catheter is then tunnelled subcutaneously to an exit-site incision in the abdomen. Use of the laparoscope allows visualisation of the catheter's location during the procedure, ensuring that it lies in the pelvis. Concomitant procedures can be performed during laparoscopy.

2.3 Efficacy

2.3.1 A randomised controlled trial reported that 57% (12 out of 21) of catheters inserted laparoscopically and 54% (13 out of 24) of those inserted via an open incision were still in use after a median follow-up of 18.5 months (p value not stated).

2.3.2 A non-randomised controlled trial of 42 patients reported catheter survival at 12 months to be 91% in the laparoscopic group and 71% in the open-insertion group (p=0.019). A second non-randomised controlled trial reported revision-free catheter survival probabilities at 1, 2 and 3 years to be significantly higher after laparoscopic insertion than after open insertion: 87%, 81% and 76%, respectively, after laparoscopic insertion (n=150) compared with 74%, 57% and 39%, respectively, after open insertion (n=63) (p<0.001). A third non-randomised controlled trial of 102 patients reported catheter survival at 1, 2 and 3 years to be 79%, 53% and 37%, respectively, in the laparoscopic group, compared with 65%, 43% and 29%, respectively, in the open-insertion group (differences were not statistically significant). Another non-randomised controlled trial reported that 70% (16 out of 23) of catheters inserted laparoscopically were still functioning at

the end of the study (follow-up period not stated), compared with 40% (8 out of 20) of catheters inserted using a single trocar peritoneoscopic technique (p value not stated). For more details, see the overview.

2.3.3 The Specialist Advisers did not note any concerns about the efficacy of the procedure.

2.4 Safety

2.4.1 The randomised controlled trial reported that 29% (6 out of 21) of patients in the laparoscopic-insertion group had peritonitis more than 6 weeks after catheter insertion, compared with 46% (11 out of 24) of patients in the open-insertion group (p value not stated). One non-randomised controlled trial reported similar rates of peritonitis after laparoscopic and open insertion (32% [16 out of 50] versus 25% [13 out of 52] after mean follow-up of 26 and 19 months, respectively). Another non-randomised controlled trial reported a significantly lower rate of peritonitis after laparoscopic insertion than after open insertion more than 4 weeks after the procedure (5% [1 out of 21] versus 14% [3 out of 21], $p<0.05$).

2.4.2 In the randomised controlled trial, exit-site infections more than 6 weeks after catheter insertion were reported in 29% (6 out of 21) of patients in the laparoscopic-insertion group, compared with 17% (4 out of 24) of patients in the open-insertion group (p value not stated). Two non-randomised controlled trials reported exit-site infections more than 4 weeks after the procedure in 5% (1 out of 21) and 6% (3 out of 50) of laparoscopic procedures, compared with 10% (2 out of 21) and 10% (5 out of 52) of open procedures (difference not significant). One large case series reported recurrent peritonitis or exit-site infection after 18% (26 out of 148) of laparoscopic procedures.

2.4.3 Two non-randomised controlled trials reported that 14% (3 out of 21) and 12% (3 out of 25) of patients in the laparoscopic groups needed surgical revision, compared with 38% (8 out of 21) and 17% (4 out of 23) of patients, respectively, in the open-surgery groups (p values not stated). Two case series of laparoscopic insertion reported surgical revision rates of 20% (25 out of 123) and 24% (8 out of 34).

2.4.4 Eight studies reported catheter leakage rates ranging from 0% (0 out of 25) to 10% (2 out of 21) of laparoscopic procedures. Five studies reported catheter blockage rates ranging from 0.5% (1 out of 200) to 29% (10 out of 34) of laparoscopic procedures.

2.4.5 Two non-randomised controlled trials and one case series reported peri- or postoperative haemorrhage in 0% (0 out of 200), 2% (1 out of 50) and 5% (7 out of 148) of laparoscopic procedures. Another case series of 34 patients reported that one patient died of haemorrhage 6 days after surgery, having resumed oral anticoagulation treatment immediately after the procedure. For more details, see the overview.

2.4.6 The Specialist Advisers listed potential adverse events as bowel perforation, catheter leakage, infection, catheter migration or blockage, and bleeding. Two advisers noted that potential adverse events were mainly those associated with laparoscopic surgery per se. Other adverse events may occur with laparoscopic or open procedures for catheter insertion.

2.5 Other comments

2.5.1 The Committee noted that no evidence on the use of a peritoneoscope for this procedure was considered.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.