



Balloon catheter insertion for Bartholin's cyst or abscess

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of balloon catheter insertion for Bartholin's cyst or abscess is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Bartholin's glands are located at the vaginal entrance. During sexual arousal, they secrete a lubricant which enters the vagina through a small duct from each gland. A cyst may form if the duct becomes obstructed, and if the cyst becomes infected then an abscess develops.
- 2.1.2 Conservative management of symptomatic cysts or abscesses may include warm baths, compresses, analgesics, and antibiotics when appropriate. Persistent and symptomatic cysts or abscesses are often treated surgically, by incision and drainage, or by marsupialisation (where the cyst is opened, and the skin edges are stitched to allow continual free drainage of the fluid from the cyst cavity).

2.2 Outline of the procedure

2.2.1 The aim of the procedure is to establish drainage of the abscess or cyst by creating a fistula or sinus track that will remain open in the long term. The

underlying principle is that a foreign body reaction (to the balloon and catheter) induces formation of an epithelialised fistula.

- 2.2.2 With the patient under local or general anaesthesia, an incision is made into the abscess or cyst on the mucosal surface of the labia minora. A tissue specimen (biopsy) and/or swab may be taken to test for neoplasia and/or infection (including sexually transmitted diseases). The abscess or cyst is drained.
- 2.2.3 A specially designed balloon catheter is inserted into the abscess or cyst cavity through the incision, and the balloon is inflated with saline to secure it in place. If pain persists after the balloon is inflated, it is partially deflated, leaving enough fluid to keep the catheter in position. A suture may be used to partially close the incision and hold the catheter in place. The catheter stays in, usually for up to 4 weeks, to allow epithelialisation of the tract, after which it is deflated and removed.
- 2.2.4 A period of a few weeks may be required for epithelialisation.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- A prospective case series of 35 women with Bartholin's abscess treated by balloon catheter insertion reported operative success (defined as short-term abscess resolution with no need for marsupialisation and no recurrence) in 97% (34 out of 35) of women. The study reported that 89% (24 out of 27) of women who retained the catheter for 4 weeks would recommend the procedure.
- In the case series of 35 women, catheters were successfully inserted in 34. Of these, 7 fell out: 3 after 24 hours, 3 after 1 week and 1 after 11 days. Despite their catheters falling out, 6 of the 7 women were reported as having successful outcomes. One woman had subsequent marsupialisation. Epithelialisation was judged to have occurred in the remaining 27 women 4 weeks after treatment.

- A case series of 46 women with Bartholin's cyst or abscess treated by balloon catheter reported recurrence in 17% (8 out of 46) of women, and the procedure was repeated in all patients (the paper did not state whether these repeat procedures were successful or not). Another case series (68 women with Bartholin's cyst or abscess) reported 2 cyst recurrences (without infection) 6 months and 5 years after the procedure. For the first recurrence, it was thought that the catheter was removed prematurely.
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as healing in the short term and absence of abscess recurrence 6 months after the procedure.

2.4 Safety

- 2.4.1 The case series of 68 women reported necrotic abscess development in 1 woman because the inflated balloon eroded the cutaneous surface of the labium (time of occurrence not stated). This was considered to have been caused by improper insertion of the catheter. The same case series reported that another woman was admitted to hospital for 9 days because the catheter had been inserted between the vestibular mucosa and the cyst wall. The cyst remained 1 year after the operation.
- The case series of 35 women reported that 5 women complained of mild discomfort (scoring 2 to 3 on a pain scale from 0 [no pain] to 10 [severe pain]) on sitting at 1-week follow-up. One woman reported moderate discomfort (scoring 5 on the same scale) and a continuous sensation of labial swelling, which subsided when 2 ml of fluid was removed from the balloon (time of occurrence not stated).
- 2.4.3 The Specialist Advisers listed an anecdotal adverse event as pain if the catheter is overfilled, which could be relieved by slightly deflating it. They considered theoretical adverse events to include infection, abscess recurrence, bleeding, pain from having the catheter in situ, scarring, expulsion of the bulb of the catheter and dyspareunia.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.