

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon catheter insertion for Bartholin's cyst or abscess

The Bartholin's glands are at the entrance of the vagina. A cyst or abscess can occur in the Bartholin's duct (which drains the glands) if it becomes blocked or infected. The usual treatment of cysts is either 'incision and drainage' or 'marsupialisation', which involves cutting into the cyst and placing stitches to make a permanent opening so that the gland can drain freely. Insertion of a balloon catheter is a non-surgical alternative to incision and drainage or marsupialisation.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in April 2009.

Procedure name

- Balloon catheter insertion for Bartholin's cyst or abscess

Specialty societies

- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists.

Description

Indications and current treatment

Bartholin's glands are located bilaterally at the base of the labia minora near the opening of the vagina. They secrete a lubricant when a woman is sexually aroused, which drains through ducts that empty into the vestibule. They are only palpable if infected or diseased. A cyst may form in the duct if it becomes obstructed and secretions are retained in the duct. The cyst may become infected and develop into an abscess. An abscess may also develop from infections of the gland or of the genitourinary system (such as gonorrhoea or chlamydia).

Bartholin's cysts or abscesses typically present as painful swelling around one or both glands. Symptoms include local tenderness and pain, fever, and dyspareunia.

Diagnosis is usually made by physical examination. A biopsy may be taken (particularly in women over 40 years with Bartholin's gland cysts or abscesses because they are thought to be at an increased risk of adenocarcinoma of the Bartholin's gland). Swabs may also be taken to test for sexually transmitted diseases (STDs).

Treatment depends on the size of the cyst or abscess, the severity of symptoms and microbiological examination findings. Conservative management of symptomatic cysts/abscesses includes warm baths or compress and analgesics to alleviate symptoms. If there is an infection, antibiotics are sometimes used. Problematic cysts or abscesses are often marsupialised surgically; this is a procedure performed under local anaesthesia or pudendal nerve block that involves draining the cyst and inverting its wall with absorbable sutures to create a tract that will re-epithelialise. The cyst can also be incised and drained, treated by carbon dioxide laser vaporisation, or silver nitrate can be inserted into the cyst/abscess cavity. Asymptomatic cysts are not usually treated, but are usually excised in women over 40 to rule out cancer.

What the procedure involves

The aim of the balloon catheter insertion is to create an epithelialised fistula or sinus tract to allow drainage during a simple outpatient procedure. The catheter has a stem (3 cm long) and an inflatable balloon tip to hold saline, which allows the catheter to remain in the cyst or abscess cavity. The underlying principle is that a foreign body prevents wound closure, resulting in an epithelialised fistula.

With the patient usually under local anaesthesia (though general anaesthesia may also be used or required), a stab incision approximately 3–4 mm long is made into the abscess or cyst on the mucosal surface of the labia minora, adjacent but external to the hymenal ring. A tissue specimen and/or swab may

be taken to test for cancer and/or STDs. The abscess or cyst is drained manually.

The catheter is inserted deep into the abscess or cyst cavity and the balloon is inflated with approximately 2–4 ml of saline. The incision should be large enough to allow drainage, but small enough to enable retention of the inflated balloon catheter. If pain persists after the balloon is inflated, it is partially deflated, leaving enough fluid to keep the catheter in place. A suture may be used to close the incision and hold the catheter in place. The free end of the catheter is tucked into the vagina and stays in place for up to 4 weeks to allow epithelialisation of the tract.

Oral antibiotics may be given postoperatively, and specific treatment is given if an STD is detected. Patients are instructed to have two to three warm baths each day, to provide comfort and promote healing, and sometimes are instructed to avoid intercourse, tampon insertion or douching to avoid catheter expulsion or infection.

After epithelialisation is judged to have occurred, the catheter is deflated and removed.

List of studies included in the overview

This overview is based on 149 patients from three case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Efficacy

A prospective case series of 35 women with Bartholin's abscess treated with the balloon catheter reported operative success (defined as short-term abscess resolution with no need for marsupialisation and no recurrence) in 97% (34/35) of women. There was insertion failure in one woman (not otherwise described), however, the patient's abscess did not form again so further treatment was not needed¹.

Of the 34 catheters inserted, 7 fell out: 3 after 24 hours, 3 after 1 week and another after 11 days. However, despite the catheter falling out, six of the seven women were reported as having successful operations. One woman had subsequent marsupialisation. Epithelialisation was judged to have occurred in the remaining 27 women 4 weeks after treatment.

In the same study, there was no recurrence in any of the women treated at 6-month follow-up (confirmed by follow-up telephone call).

In the same study, few women reported lifestyle restrictions while the catheter was in place. They reported feeling comfortable riding bicycles, running and

rowing at the gym, but two reported continual worry that the catheter would fall out. Though they were told sexual intercourse was possible, most women were too afraid to have it. Three patients had intercourse within the two weeks with the catheter in place and reported no pain.

The study reported that 89% (24/27) of women who retained the catheter for 4 weeks would recommend the procedure to a friend.

A case series of 46 women with Bartholin's cyst or abscess treated with balloon catheter reported recurrence in 17.4% (8/46) of patients requiring another procedure at a mean follow-up of 9 months (range from 5 to 42 months). The procedure was performed again on all of these patients².

A case series of 68 women with Bartholin's cyst or abscess treated with the balloon catheter reported two recurrences in simple cyst (without infection) 6 months and 5 years after the procedure. In the first, it was thought that the catheter was removed prematurely. The other occurred 5 years after the procedure; it is uncertain why it recurred. Both patients were treated again and were asymptomatic at the time of writing the report (it was not stated how long it was from occurrence to the writing of the report)³.

The same study did not report how many catheters had fallen out, but did describe a patient whose catheter was reinserted by anchoring the catheter with a cotton suture and suturing the stem of the catheter to the cutaneous surface of the labium. The ends of the suture were passed through a rubber tube and then tied to prevent skin necrosis. Epithelialisation was judged to have been complete after 3 weeks.

Safety

The case series of 35 women reported that 5 women complained of mild discomfort on sitting at 1-week follow-up (2–3 on a pain scale of 10). One woman reported moderate discomfort (pain score 5 out of 10) and a continuous sensation of labial swelling which subsided when 2 ml of fluid was removed from the balloon (time of pain not stated)¹.

The case series of 68 women reported a necrotic abscess in one patient caused by erosion of the balloon into the cutaneous surface of the labium, which was caused by improper insertion of the catheter (time of occurrence not stated)³.

The same case series reported that a patient was admitted to hospital for 9 days because the catheter had been inserted between the vestibular mucosa and the cyst wall. A year after the operation, the cyst remained.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to balloon catheter insertion for Bartholin's cyst or abscess. Searches were conducted of the following databases, covering the period from their commencement to 7 April and updated to 1 September 2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with abscess or cyst in their Bartholin's gland.
Intervention/test	Balloon catheter insertion.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Table 2 Summary of key efficacy and safety findings on balloon catheter insertion for Bartholin's cyst or abscess

Abbreviations used: none			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Haider (2007)¹</p> <p>Prospective case series</p> <p>Country: UK</p> <p>Study period: December 2004 to December 2005</p> <p>Study population: women presenting at the Acute Gynaecology unit at St George's Hospital with Bartholin's abscess (confirmed with observation and palpation) who chose this procedure over marsupialisation</p> <p>n = 35</p> <p>Mean age: 29.7 years (range: 16 to 51)</p> <p>Exclusion criteria: none</p> <p>Technique: administration of local anaesthetic (5 ml of 2% lignocaine), insertion of a balloon (Word) catheter using approximately 5 ml of water by one doctor; postoperative care included use of a sanitary towel to absorb discharge; the women were told that the catheter did not require lifestyle restrictions; follow-up appointment at 1 and 4 weeks and at catheter removal (telephone follow-up at 6 months); removal after four weeks if epithelialisation occurred.</p> <p>Follow-up: 6 months</p> <p>Conflict of interest: catheters were supplied by Teleflex Medical; no other conflicts stated.</p>	<p>Operative success</p> <p>97% (34/35) had operative success (defined as short-term abscess resolution with no need for marsupialisation and no recurrence).</p> <p>34 were inserted and there was one insertion failure, however, this patient had no abscess reforming and no further treatment was needed. Of 34 catheters inserted, 7 fell out (3 after 24 hours, 3 after one week and another after 11 days). Despite the catheter falling out, 6 of the 7 had operative success (one subsequently underwent marsupialisation).</p> <p>Recurrence rates</p> <p>There was no recurrence in any of the women treated with the catheter at 6-month follow-up (on telephone call).</p> <p>Patient reported outcomes</p> <p>Few lifestyle restrictions were reported by women. They reported feeling comfortable riding bicycles, running and rowing at the gym, but two reported continual worry that the catheter would fall out.</p> <p>While informed that intercourse was possible, most were too afraid to have it. 3 had intercourse within 2 weeks and reported no pain.</p> <p>89% (24/27) of women who retained the catheter for four weeks said they would recommend the procedure to a friend.</p> <p>Other</p> <p>Epithelialisation was judged to have occurred in all 27 women in whom the treatment was successful at 4 weeks.</p>	<p>Adverse events</p> <p>All women were asked to fill in a daily questionnaire reporting discomfort (on a increasing scale of 1 to 10) and discharge.</p> <p>Five women complained of mild discomfort on sitting at 1-week follow-up (2–3 out of 10 pain score).</p> <p>One woman reported moderate discomfort (pain score 5 of 10) and a continuous sensation of labial swelling. This was relieved upon releasing 2 ml of fluid.</p> <p>Another woman reported initial difficulty inserting tampons</p>	<p>This was described as a preliminary study.</p> <p>A total of 58 women with Bartholin's abscesses presented at the hospital. After counselling, 35 chose a Word catheter and 23 chose marsupialisation.</p> <p>Data on recurrence after marsupialisation was collected retrospectively – 14 of the 35 women were available for follow-up by telephone 6 months after surgery; none had recurrences.</p>

Abbreviations used: none			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Yavetz (1987)²</p> <p>Case series</p> <p>Country: Israel</p> <p>Study period: 1972–1985</p> <p>Study population: women with Bartholin's abscess or cyst</p> <p>n = 46</p> <p>Age: not stated</p> <p>Inclusion criteria: not stated</p> <p>Technique: insertion of a balloon (Word) catheter using approximately 2–3 ml sterile indigo tindisulfonate sodium solution (under local or general anaesthesia), 2 silk sutures ligated the balloon's track; postoperatively the patients were instructed to avoid intercourse; the catheter was removed after 6 weeks.</p> <p>Mean follow-up: 46 months (range: 6–140)</p> <p>Conflict of interest: not stated</p>	<p>Recurrence rates</p> <p>17.4% (8) of patients were readmitted because of recurrence at a mean follow-up of 9 months (range from 5 to 42 months). The procedure was performed again on all of these patients.</p> <p>In the discussion section, the authors state that the catheter was expelled spontaneously in 4 patients early in the series before the removal date.</p> <p>Success was defined if there was a patent duct and orifice at 3-month follow-up and the duct had resumed its normal functioning.</p>	<p>No data on safety were reported.</p>	<p>This study is of all patients presenting with Bartholin's abscess or cyst treated with this procedure. There were an additional 3 patients who presented; however, they were treated by extirpation of the gland (it was not stated why).</p>

Abbreviations used: none			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Word (1968)³</p> <p>Case series</p> <p>Country: USA</p> <p>Study period: not stated (from 1947)</p> <p>Study population: women with Bartholin's cyst or abscess (3 pregnant women with a cyst were treated) n = 68 (72 lesions: 40 cysts, 32 abscesses)</p> <p>Age: not stated</p> <p>Inclusion criteria: not stated</p> <p>Technique: insertion of a balloon (Word) catheter using 2–4 ml water without any form of anaesthesia; catheter removed after 6 weeks</p> <p>Follow-up: not stated</p> <p>Conflict of interest: not stated (however, the author was the developer of the catheter)</p>	<p>Recurrence rates</p> <p>There were two recurrences of cysts (both were simple and not infected) 6 months and 5 years after the procedure. In the first, it was thought that the catheter was removed prematurely. The other occurred 5 years after the procedure; it is uncertain why it recurred. Both were treated again with the catheter and were asymptomatic at the time of writing the report (how long from occurrence to the writing of the report was not stated).</p> <p>Other</p> <p>While most catheters were removed at 6 weeks, one woman did not return until 14 weeks after the catheter was inserted to have it removed.</p> <p>It was not stated how many catheters fell out. However, the author described one patient whose catheter had fallen out. The cavity had shrunk, so the stem was anchored with a cotton suture and a suture was placed in the stem of the catheter to the cutaneous surface of the labium. The ends of the suture were passed through a rubber tube and then tied to prevent skin necrosis. Epithelialisation was complete after 3 weeks.</p>	<p>Adverse events</p> <p>One patient had a necrotic abscess because the inflated balloon eroded the labium on the cutaneous surface (it was not stated when this developed). This opening closed when the catheter was removed. This was stated to be because of the way the catheter was inserted.</p> <p>One patient 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.</p>	<p>This is the designer of the catheter.</p> <p>This is mostly a description of the context of the catheter and the description of the use of the catheter.</p> <p>There was no measurement of functional, patient-reported outcomes.</p>

Validity and generalisability of the studies

- The timing of appearance of the three publications is very spread out: one occurred in the 60s, another in the 80s and one in 2007.
- The first report was by the developer of the procedure.
- There are no controlled studies of this procedure.
- Bartholin's cysts and abscess tend to recur, even with conventional management. The actual efficacy of the procedure in terms of recurrence is therefore difficult to judge from available evidence.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Tom Bourne, Dr J Pundir (Royal College of Obstetricians and Gynecologists).

- Both Specialist Advisers considered this procedure to be established and no longer new.
- It is commonly used in the United States where it is more likely to be considered established practice. It was not used much in the UK until recently and, therefore, may not be considered established for routine use. There is little published research on its use.
- The Advisers noted that standard practice would be marsupialisation of the abscess under general anesthetic.
- The Advisers highlighted the limited research on this procedure, particularly the lack of a randomised controlled trial. One highlighted the impossibility of blinding patients to their intervention group as the comparator involves the use of a general anaesthetic, whereas this procedure can be done under local anaesthetic.
- This is a minor outpatient surgical procedure under local anaesthetic so it can be carried out in a standard treatment room; minimal training is required but it should involve observation.

- The Adviser highlighted that the advantages of the procedure are reduced time off work compared with marsupialisation (which often requires general anaesthetic), successful resolution and an improved pain score.

Efficacy

- The Advisers considered that the key efficacy outcome to be healing in the short term and absence of abscess recurrence 6 months after the procedure.

Safety

- The Advisers considered theoretical events to include widespread infection, abscess recurrence, bleeding, pain from having the catheter in situ, scarring, expulsion of the bulb of the catheter and dyspareunia.
- Anecdotal events include pain if the catheter is overfilled but this can be relieved by slightly deflating it.

Patient Commentators' opinions

Unfortunately the NICE's Patient and Public Involvement Programme PPIP were unable to obtain patient commentary for this procedure.

Issues for consideration by IPAC

- Please see comments in 'validity and generalisability of the studies' section.

References

1. Haider Z, Condous G, Kirk E, et al. (2007) The simple outpatient management of Bartholin's abscess using the Word catheter: a preliminary study. *Australian & New Zealand Journal of Obstetrics & Gynaecology* 47: 137–40
2. Yavetz H, Lessing JB, Jaffa AJ, et al. (1987) Fistulization: an effective treatment for Bartholin's abscesses and cysts. *Acta Obstetrica et Gynecologica Scandinavica* 66: 63–4
3. Word B. (1968) Office treatment of cyst and abscess of Bartholin's gland duct. *Southern Medical Journal* 61: 514–8

Appendix A: Additional papers on balloon catheter insertion for Bartholin's cyst or abscess

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Patil S, Sultan AH, and Thakar R. (2007) Bartholin's cysts and abscesses. Journal of Obstetrics and Gynaecology 27: 241–245.	Systematic review All published studies included are already presented to the Committee.	Same as stated in this overview.	No new data.

Appendix B: Related NICE guidance for balloon catheter insertion for Bartholin's cyst or abscess

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for balloon catheter insertion for Bartholin's cyst or abscess

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	01/09/09	Issue 3, 2009
Database of Abstracts of Reviews of Effects – DARE (CRD website)	01/09/09	N/A
HTA database (CRD website)	01/09/09	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	01/09/09	Issue 3, 2009
MEDLINE (Ovid)	01/09/09	1950 to August Week 3 2009
MEDLINE In-Process (Ovid)	01/09/09	August 31, 2009
EMBASE (Ovid)	01/09/09	1980 to 2009 Week 35
CINAHL (NLH Search 2.0)	01/09/09	1981 to present
BLIC (Dialog DataStar)	01/09/09	1995 to date

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

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1 Catheterization/
2 Catheters, Indwelling/
3 ((Balloon* or Word* or Indwell*) adj3 Cathet*).tw.
4 Rusch.tw.
5 Teleflex.tw.
6 or/1-5
7 Bartholin's Glands/
8 (Bartholin* or Vestibular*).tw.
9 or/7-8
10 Cysts/
11 Abscess/
12 (Cyst* or Abscess* or Gland*).tw.
13 or/10-12
14 9 and 13
15 Vulvar Diseases/
16 (Vulvar* adj3 Diseas*).tw.
17 or/14-16
18 6 and 17
19 Animals/ not Humans/
20 18 not 19

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