NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of image-guided vacuum assisted excision biopsy of benign breast lesions

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 February 2005.

Procedure name

- Ultrasound guided vacuum assisted excision biopsy
- Percutaneous mammotomy.

Specialty societies

- Royal College of Radiologists (Breast Group).
- British Association of Surgical Oncologists.
- British Association of Endocrine Surgeons.

Description

Indications

Vacuum-assisted core biopsy guided by ultrasonography, magnetic resonance imaging, or X-Ray stereotactic localisation has been regularly used for gathering samples of tissue in women with breast lesions suspicious of breast cancer, or when histological proof of a benign lesion is required. This process can also be used to remove completely benign breast lesions for example fibroadenomas. This could reduce the need for open surgical biopsy or excision

Current treatment and alternatives

Diagnosis of benign breast disease is usually done by clinical examination, imaging, and fine needle biopsy; known as the triple test. Women who have negative results in all three tests may have benign lumps removed. Open surgical biopsy is the gold standard for diagnosis, although image guided vacuum assisted biopsy offers reduced recovery time and a more acceptable aesthetic result.

What the procedure involves

The procedure uses a needle probe device with vacuum suction to remove breast tissue under imaging guidance (commonly ultrasound). The aim of the procedure is to continue using the biopsy device until the lesion visible on imaging is removed. The procedure is performed under local anaesthesia. An incision a few millimetres long is made in the breast and an 8- or 11-gauge probe is inserted through the lesion. Small amounts of tissue are aspirated and the probe is withdrawn further into the lesion and the process repeated. When the device is removed the site of incision is compressed for a short time. This can be preformed as an outpatient procedure.

Efficacy

In the studies looked at, the main efficacy outcome of the procedure, complete lesion excision, was achieved in between 22% (21/95)[1] to 98% (121/124)[2] of lesions biopsied. The success rate may depend on the gauge of the probe used and the size of the lesion to be removed (these are often dependant variables). The accuracy of this outcome assessment may depend on the quality of the imaging technique used. In only one case series was there a follow-up time of 2 years. Shorter follow-up assessment than this may miss recurrence of lesions.

In one case series, 23% (3/13) of cases with incompletely excised lesions with vacuum assisted biopsy had subsequent open surgery biopsy[3].

The procedure duration ranged from 13[2] to 60[3] minutes, depending on the size of lesion being removed; however, there were no data available to assess a possible operator learning curve.

Safety

Few data are available on the operative safety of this procedure, or about postprocedural events.

The most frequent complication of this procedure is development of a haematoma. This complication was recorded in 13% (24/186) [2] cases in one case series, but none of these were classified as serious. In another study, no clinically problematic haematomas were reported in 20 cases that were followed up for 4 months[4].

The methods used to assess pain differed widely between studies; in one large case series 39% (78/186) complained of mild postoperative pain, and 4% (8/186) of moderate pain, no patients reported severe pain[2].

The adverse event that was most often reported on in the studies is bleeding during the procedure, this occurred in 4% (2/56)[3] of patients in one case series, and 2% (3/186) [2] in a larger case series, however all three cases resolved with little or no intervention.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to ultrasound-guided minimally invasive breast surgery Searches were conducted via the following databases, covering the period from their commencement to June 2004, MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these 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 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, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Women with benign breast mass/fibroadenomas.
Intervention/test	Image-guided vacuum assisted excision biopsy of benign breast lesions.
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.

The search located many studies regarding the use of the vacuum assisted excision device for diagnostic purposes rather than with the intent for full excision, these were excluded from the overview

List of studies included in the overview

This overview is based on four case series, one of which is an ongoing multicentre study.

Existing reviews on this procedure

No systematic reviews or evidence based guidelines on ultrasound-guided minimally invasive breast surgery were identified during the literature search.

Table 1 Summary of key efficacy and safety findings on image-guided vacuum assisted excision biopsy of benign breast lesions

Abbreviations used: Ultrasound – US,			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Sperber F (2003)[3] Case series Israel n = 52 (56 lesions) palpable mass = 22 inconclusive needle biopsy = 14 inconclusive imaging = 8 new mass = 3 unwillingness to undergo open biopsy = 9 Age = 19 to 68 lesion diameter mean 1.03 cm (range 0.3 to 2.8 cm) Single skilled radiologist 11-guage mammotome vacuum biopsy system with variable 7.5-10 MHz transducer ultrasound guidance. Attempt was made to continue until no remaining sonographic evidence of lesion Ambulatory setting with local anaesthesia 2-year follow-up	**Biopsy confirmation of benign nature** In all cases tissue was confirmed as being fibroadenoma; in one case it was fibroadenoma with multiple foci of lobular carcinoma in situ **Excision success** Complete excision was possible in 77% (43/56) of lesions All lesions > 2 cm were incompletely excised For all incompletely excised lesions the volume reduction achieved ranged from 55 to 80% **Long term follow up** Patients were followed up for 2 years and no recurrence was noted. Of the cases with incompletely excised lesions 23% (3/13) underwent open excision **Operative time** The procedure time was 40 minutes (mean) and ranged from 20 to 60 minutes	**Adverse events** Most patients were compliant and only minimal pain was reported 4% (2/56) of patients had excessive bleeding, which was controlled by local ice compression and pressure.	Not stated how patients were selected. No details of loss to follow-up, if any. Removing the whole lesion, avoids missing malignancies. Further studies comparing this procedure with standard surgical excision should be done.

Abbreviations used: Ultrasound – US,

Study details	Key efficacy findings	Key safety findings	Comments
Jackman R J (1998)[1] Case series (consecutive) USA n = 594 (667 lesions) Age = 52 years mean lesion length = 12mm 14-gauge large core biopsy = 422 14-gauge vacuum assisted biopsy = 95 11-gauge vacuum assisted biopsy = 150 No lesion or patient variables were used to determine the biopsy technique used Median follow-up to repeat mammography = 7 months	**Excision success** Changes in lesion size were classified by a 5-point mammography score with a score of 1 indicating an increased size, 3 the lesion was stable, and 5 that the lesion was no longer evident Device / Score 1 / Score 3 / Score 5 14-G large core / 2.4% (10/422) / 40% (167/422) / 9% (40/422) 14-G vacuum assisted / 0% / 17% (16/95) / 22% (21/95) 11-G vacuum assisted / 0% / 9% (13/150) / 64% (96/150) p < 0.0001 All ten lesions that were found to increase size on repeat mammography following large core biopsy had a repeat biopsy and three of these were found to be malignant (ie false negative on first biopsy) The 14-G large core biopsy technique, the 14-G vacuum assisted biopsy, and the 11-G vacuum assisted biopsy method removed a mean 17, 37, and 95 mg specimen respectively	No safety data reported	Patients underwent biopsy using the three techniques in consecutive case series, with the 11-gauge vacuum-assisted technique the most recent tried. There were significantly more patients with lesions classified as calcifications than masses in the 11-gauge vacuum-assisted biopsy group than the other two. The authors postulate that if the lesion is completely removed, incomplete or inaccurate histological assessment should be diminished or eliminated.

Abbreviations used: Ultrasound – US,			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Baez E (2003) [4] Case series Germany n = 20 (20 lesions) Patients who were referred for surgical removal of a clinically benign breast tumour causing irritation or showing growth, who opted for mammotome biopsy over open biopsy. 11-guage mammotome vacuum biopsy system Age = 39 years mean lesion length = 14 mm mean lesion volume = 0.85 ml Ultrasound assessment and guidance using 3D imaging Follow-up 4 months	**Operative characteristics** The duration of the procedure was between 20 to 45 minutes **Excision success** Complete excision was possible in 80% (16/20) of lesions All lesions > 1.5 cm were incompletely excised For all incompletely excised lesions the volume of the lesion was reduced, with no irritation and no further intervention was performed **Biopsy confirmation of benign nature** In 50% (10/20) cases excised tissue was confirmed as being fibroadenomas, in 30% (6/20) the assessment was sclerosing adenomatosis, and in 20% (4/20) it was sclerosing mastopathy	**Adverse events** No patients complained of side effects of pain during the procedure of the following day. No patient developed a clinically problematic haematoma	Small sample size. Not controlled study. Self-selected patient cohort, with single lesions only. Short follow-up may not capture regrowing lesions in those not fully excised. Authors note that improved non-invasive diagnosis and counselling should reduce the number of biopsies for benign lesions.

Abbreviations used: Ultrasound – US,

Study details	Key efficacy findings	Key safety findings	Comments
Fine R E (2002) [2] Case series (15 sites) USA n = 124 Women with low-risk palpable mass Exclusion criteria included bleeding disorders, nursing or pregnant women, or a condition that would impair healing Age = 35 years mean lesion length 18 mm 11-gauge mammotome for lesions < 15 mm, 8-gauage mammotome for lesions 15-30 mm Follow-up 6 months	**Biopsy confirmation of benign nature** In 70% (87/124) cases tissue was confirmed as being fibroadenoma, in 18% (22/124) cases fibrocyctic changes, and in 2% (3/124) biopsied lesions were malignant or suspected malignancy **Excision success** Complete excision was possible in 98% (121/124) of lesions. With no differences found in completeness of tissue removal between the two probe size groups (evaluation made immediately after procedure) **Operative characteristics** The mean duration of the procedure was 16 minutes, 18 minutes for the 8G probe and 13 minutes for the 11G probe respectively **Patient assessment of procedure** 97% of patients were satisfied with the cosmetic appearance of the incision	**Procedural complications** Mild / Moderate Bleeding 1% (1/186) / 1% (2/186) Post-op pain 39% (73/186) / 4% (8/186) haematoma 10% (19/186) / 3% (5/186) One patient discontinued the study because of serious postoperative bleeding	All investigators were given standard 1-day training session in the procedure. 6% (7/124) patients required additional surgery and were removed from the study. Completeness of lesion removal not yet confirmed at 6-month follow-up.

Abbreviations used: Ultrasound – US,

Study details	Key efficacy findings	Key safety findings	Comments
Johnson A T (2002)[5] Case series USA n=81 (101 lesions) Complete percutaneous removal of small benign lesions under ultrasound guidance. 8 or 11 gauge multi directional vacuum assisted needle. Excision area viewd in the transverse plane to document complete removal Age = 47 years, mean lesion size = 1.15 cm Follow up = 286 days	**Operative success** The operation was aborted in 1% (1/81) of cases owing to inability to pass the 11 gauge needle through dense male breast tissue **Biopsy confirmation of benign nature** In 93% of cases tissue was confirmed as being benign (absolute figures not presented)	**Complications** Post procedural pain in 1% (1/81) lesions requiring narcotics. <5% cases required the use of an harmonic scalpel for bleeding after 15 minutes of pressure. Post operative wound infection occurred in 25 (2/81) of cases, and was treated by oral antibiotics and drainage.	One patient refused surgery Not all patients followed up for 6 months outcome assessment and no US assessment of lesion removal All patients who had a premalignant or malignant lesion excised were recommended for re-excision.

Abbreviations used: Ultrasound – US,

Study details	Key efficacy findings	Key safety findings	Comments
Huber S (2003)[6] Case series Austria n=105 (108 lesions) Directional vacuum assisted 11 gauge mammotome. Age = 26 to 72 years.	**Operative characteristics** The mean duration of the procedure was 26 minutes (± 7.9 minutes) with ultrasound guidance, and 24 minutes (± 7.9 minutes) with stereotactic guidance **Excision success** At 6 months follow up there was an area of increased focal density on mammography in 1% (1/74) of cases, however in terms of US morphological features no abnormalities were found. **Biopsy confirmation of benign nature** In 84% of lesions, tissue was confirmed as being benign. Subsequent analysis is limited to these 91 cases. **Patient satisfaction** A subjective multistage scoring questionnaire was completed by 84 patients classifying their acceptance of the procedure and detailing specific complaints In the first days after biopsy an excellent score was recorded by 94% (72/77) of patients undergoing stereotactic biopsy, and 82% (9/11) of those in whom the procedure was US guided.	**Clinical findings** At one week follow up Superficial haematoma 79% (72/91) Pain 1% (1/91) Fever 1% (1/91) Inflammatory reaction 1% (1/91) Scar formation 1% (1/91) **Complications** Severe bleeding occurred in 2% (2/80) patients undergoing stereotectic biopsy, and a vaso-vagal reaction occurred in 2% (2/80) of cases Additional local anaesthetic was required in 40% (32/80) of stereotactic procedures and 36% (4/11) of US procedures	Treatment using stereotactic or ultrasound guidance. Two assessors evaluated mammographic and US images. Cases for treatment with US guidance were selected on the basis that the lesion was better visualised or could only be visualised with that medium rather than stereotactic observation. Patients in whom the biopsy result was positive were excluded from the satisfaction analysis and their results could be expected to be lower.

Validity and generalisability of the studies

No issues to note.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Dr Chris Flowers, Mr Roger Watkins, Prof. Steve Heys, Dr Glenda Kaplan, Mr Mark Lansdown

- Advisors saw this procedure as being a variation on the established use of this technique for biopsy purposes.
- The procedure is likely to produce less scarring making it more acceptable to patients, it can be undertaken without general anaesthetic, and may be quicker to complete than alternatives.
- Observed complications include haemorrhage, haematoma formation, vasovagal response, and failure to excise the correct area. In addition, theoretical events may include incomplete excision, wound infection, and excision of skin if undertaken too shallowly.
- Useful audit criteria would include operative time, freedom from recurrence, late discomfort, the rate of subsequent open surgery, and complication rates.
- There is need for training in the use of the mammotome device, and especially ultrasound guidance techniques if not performed by a radiologist..
- The procedure is undertaken by breast surgeons and radiologists.

Issues for consideration by IPAC

- This overview does not look at comparative accuracy compared with other diagnostic techniques for suspected malignancy, but at the safety and efficacy of removal of presumed benign lesions.
- Many image-guidance systems are used with this technique, including stereotactic and MR imaging, however ultrasound guidance is most commonly reported. 3D ultrasound imaging may have added advantages over 2D systems in terms of assessment of lesion dimension and identification of completed excision.
- This technique has also been used in men with gynaecomastia.

References

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(3) Sperber F, Blank A, Metser U, Flusser G, Klausner JM, Lev-Chelouche D. Diagnosis and treatment of breast fibroadenomas by ultrasound-guided vacuum-assisted biopsy. Archives of Surgery 2003; 138(7):796-800.

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(5) Johnson AT, Henry-Tillman RS, Smith LF, Harshfield D, Korourian S, Brown H et al. Percutaneous excisional breast biopsy. American Journal of Surgery 2002; 184(6):550-554.

(6) Huber S, Wagner M, Medl M, Czembirek H. Benign breast lesions: minimally invasive vacuum-assisted biopsy with 11-gauge needles patient acceptance and effect on follow-up imaging findings. Radiology 2003; 226(3):783-790.

Appendix A: Literature search for image-guided vacuum assisted excision biopsy of benign breast lesions

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

#	Search History	Results	Display
1	mammotome.mp.	52	Display
2	VACB.tw.	11	Display
3	(vacuum adj4 biopsy).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]	160	Display
4	(vacuum adj2 assisted).mp. [mp=title, abstract, cas registry/ec number word, mesh subject heading]	318	Display
5	3 or 4	372	Display
6	breast.tw.	128795	Display
7	fibroadenoma.tw.	1039	Display
8	mammary.tw.	35955	Display
9	or/6-8	156967	Display
10	9 and 5	152	Display
11	10 or 1 or 2	183	