APRIL 2006

Technology Review

MAMMOTOME™ BREAST BIOPSY SYSTEM

HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH

Author
Dr Ainul Nadziha Mohd Hanafiah
Assistant Director
Health Technology Assessment Unit
Medical Development Division
Ministry of Health Malaysia

Reviewed by
Datin Dr Rugayah Bakri
Head
Health Technology Assessment Unit
Medical Development Division
Ministry of Health Malaysia

CONTENT

MAMMOTOME^{TM} Breast Biopsy System

INTRODUCTION

The increasing use of mammography has led to the detection of a large number of lesions that require further histopathologic work-up. However, surgical biopsy of all image-detected suspicious or indeterminate lesions would lead to biopsy of a very high number of eventually benign lesions, associated with physical and psychic stress for the patient, operative and perioperative risks, and, last but not least, high costs. Furthermore, postoperative scarring, particularly scarring after multiple surgeries or complications, may lead to impaired diagnostic assessment of future mammograms. Therefore minimally invasive methods are increasingly recommended for the work-up of image-detected indeterminate lesions. In case of a benign result, the number of unavoidable surgical diagnostic biopsies can be reduced. In case of malignancy, availability of the preoperative histopathologic diagnosis allows to optimize treatment planning. With conventional core needle biopsy or fine needle biopsy a relatively small volume of tissue (or cells only) is obtained and occasional misses may be difficult to exclude, particularly if small indeterminate lesions or microcalcifications had been biopsied. (Rotter et al., 2003, *Level 8*)

The combination of a clinical breast examination, imaging and percutaneous tissue study is referred to as the 'triple assessment approach' and it provides a 95% accurate differentiation between benign and a malignant lesion. Once a diagnosis has been established, the patient is usually offered either surgical removal or conservative management in the form of close follow-up. In the case of fibroadenoma of the breast, a very common problem, especially in young women, fine-needle aspiration, combined with clinical diagnosis of fibroadenoma, can improve the sensitivity and specificity of the diagnosis to 86% and 76% respectively (Sperber et al., 2003, *Level 8*)

OBJECTIVE

To determine the safety, effectiveness, and subsequently cost-effectiveness of the use of Mammotome, a vacuum-assisted breast biopsy device.

METHODOLOGY

Electronic databases like Pubmed, Ovid, Cochrane DSR, Journal @ Ovid full text via OVID, the ACP Journal Club, DARE, CINAHL, were searched. The following keywords were used either singly or in combinations: *Mammotome, ultrasound-guided breast biopsy, vacuum-assisted breast biopsy, breast biopsy, effectiveness, safety, cost-effectiveness, risk, harm.*

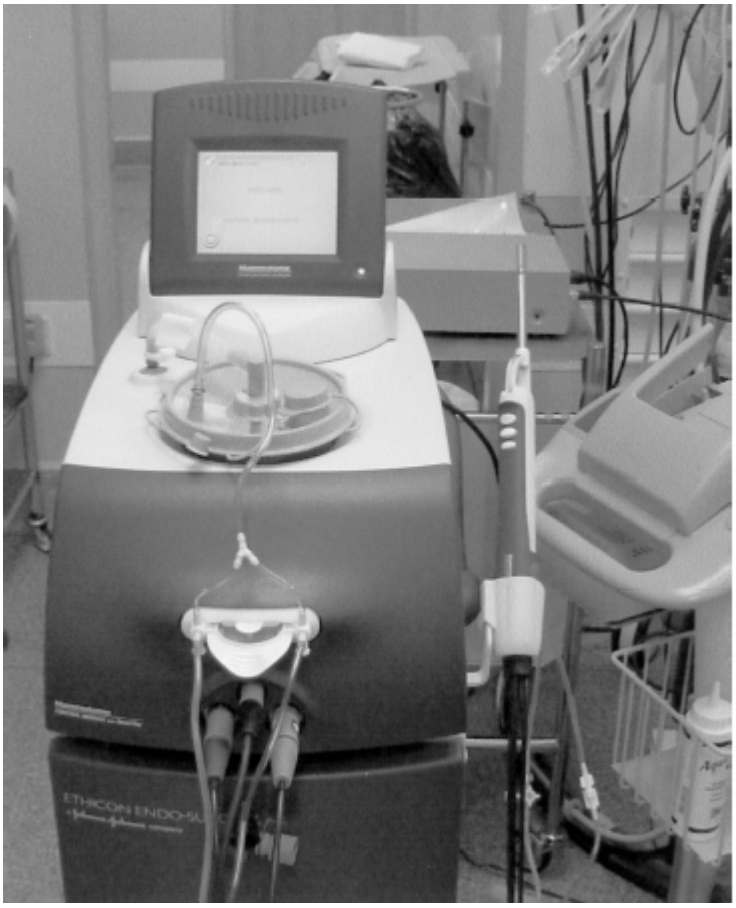
In addition, cross-reference searching was carried out from reference lists and bibliographies of the full text articles retrieved.

From the studies and articles reviewed, none were randomised controlled trials. They consisted of case series, retrospective reviews and technology assessments. Not all were available in full text articles. The results of the studies are not directly similar due to the different designs. 'Effectiveness' was measured differently – successful sampling,

diagnostic accuracy, surgical procedure/s spared and re-biopsy rates; confirmation of diagnoses was not measured in the same way across all studies; type of lesions biopsied differs between studies; and the length of follow up differed.

TECHNICAL FEATURES

Stereotactic vacuum breast biopsy unit (Fisher table, Mammotome ST). (Diebold et al., 2005)



Mammotome equipment, including the screen, probe, and vacuum-suction device. (Iwuagwu et al., 2004)

Mammotome biopsy is a percutaneous large core biopsy needle developed specifically for breast biopsies. The system consists of a disposable sterile probe and a reusable, non-sterile driver. A piercing tip is mounted at the distal end of the probe to penetrate breast tissue. The sterile probe contains a tissue sampling chamber with a vacuum line at its bottom, giving the probe an oval configuration. The chamber is located just below the tip and opens along one side of the probe shaft. The mammotome uses a vacuum system that draws tissue into a sampling chamber, a rotating cutter that excises the tissue, and a second vacuum system that transports tissue back through the probe without the need to withdraw it each time. The aperture can be rotated 360°, allowing for multidirectional tissue sampling. After rotation of the probe, the process is repeated until samples are harvested in all directions around the needle tip. A given lesion can be cored more rapidly and completely because the device remains in the breast at the location of the lesion while the tissue is harvested. Therefore, mammotome biopsy allows for a single needle insertion yielding large tissue cores without fragmentation. The procedure can be done under ultrasound guidance, where tissue acquisition can be monitored by ultrasound, as well as stereotactic guidance (Hung et al., 2001; Joshi et al., 2001; Boehm et al., 2001).

RESULTS AND DISCUSSION

It is in fact not easy to compare one study with the other as there are always differences in indications for biopsy, technique of biopsy and recording of the results obtained (Greenberg et al., 2003, *Level 8*).

EFFECTIVENESS

When performed with strict standards, vacuum-assisted mammotome biopsy is a very reliable, accurate and safe technique for obtaining histologic diagnosis in most patients who have screening-detected lesions. It is found to be effective in tissue sampling, diagnostic accuracy and sparing surgical procedures, especially when 11-gauge needles are used. Open diagnostic biopsy can be effectively avoided by vacuum-assisted breast biopsy in a very high percentage of benign cases (CHERE, 2003, *Level 1*; Rotter et al., 2003, *Level 8*; Wetter & Otto, 2001, *Level 8*).

Results from studies show that Mammotome biopsy is highly effective for the diagnosis, as well as for therapeutic management, of non-palpable breast lesions, with minimal negative effects. (Constantini et al., 2005, *Level 8;* Johnson et al., 2002, *Level 8*). In other studies it was found that the 11-gauge vacuum-assisted mammotome provided excellent accuracy for diagnosing mammographic abnormalities (CHERE, 2003, *Level 1*; Klem et al., 1999, *Level 8*).

Two multicentre, non-randomised studies found the Mammotome system to be a feasible and safe method of percutaneous removal of palpable benign breast masses, yielding high patient satisfaction (Fine et al., 2002, *Level 8*; Fine et al., 2003, *Level 8*). The results at 6 months after biopsy demonstrated no need for additional procedures. The data support the use of Mammotome device as an alternative approach to the gold standard of open surgical excision (Fine et al., 2003, *Level 8*).

As a result of a study by Parker et al. (2001, *Level 8*), it was concluded that the handheld Mammotome eliminates the shortcomings of the automated core-needle biopsy device.

It reduces the possibility of false-negatives and underestimation of disease. In the study, the mammotome biopsy of masses 1.5 cm in size or smaller resulted in no remaining imaging evidence of the lesion almost 90% of the time. The Mammotome eliminates the need for multiple insertions as it uses a vacuum to pull the tissue into the probe and to extract the tissue from the breast without removing the probe. It also reduces the likelihood of epithelial displacement. Consequently, the handheld Mammotome is now used for all sonographically guided biopsies of breast masses smaller than 1.5 cm and it was their recommendation that others consider it for such use.

The ultrasound-guided percutaneous vacuum-assisted core biopsy has been evaluated in clinical trials as a therapeutic tool, with an expanding role in the surgical treatment for excision of benign breast lesions; studies have reported high levels of success with this device (Kepple et al., 2004, *Level 9*). It allows complete excision of benign breast lesions less than 1.5 ml in volume. This can be done safely, with optimal compliance, under local anaesthesia. The ultrasound provides the benefit of better preoperative demonstration of lesions' margins – better assessment of volumetry, better intraoperative needle location and perioperative identification of residual tumour tissue (Baez et al., 2003, *Level 8*). Improvement in technology may further extend its therapeutic role to the excision of small malignant lesions. However, the perceived benefits of minimal invasive breast surgery need to be validated in randomised controlled studies (Iwuagwu & Drew, 2004, *Level 9*).

In a small study on the use of ultrasound-guided mammotome biopsy for the treatment of single duct nipple discharge, 19 of 20 (95%) patients were free of symptoms. One (5%) had recurrence of symptom; surgical excision demonstrated a benign papilloma. It was concluded that ultrasound-guided mammotome biopsy for single duct nipple discharge is an accurate diagnostic and treatment method in the management of single duct discharge. This procedure can be carried out under local anaesthesia by a trained surgeon in clinic (Govindarajulu et al., 2005, *Level 8*).

In a similar study, Dennis et al. (2000, *Level 8*) evaluated the image-guided vacuum-assisted mammotome biopsy as a means of achieving an acceptable diagnosis and removing symptoms of nipple discharge. They concluded that now with the recent advent of sonographically guided vacuum-assisted mammotomy, both diagnosis and treatment of benign papillomas may be combined into one procedure. As a result, irritating nipple discharge can be successfully treated percutaneously in most patients. In their small series, the rate of successful treatment of nipple discharge was at least that of surgical excision.

In a small case series, women with lactational breast abscesses were subjected to drainage with the Mammotome, guided by ultrasound, under local anaesthesia. Although 2 of the 5 women needed repeat evacuation of abscess a week after the procedure, at the end all women had resolution of abscess and continued breastfeeding (Varey et al., 2005, *Level 8*)

Conventionally, the management of breast fibroadenomas involved the use of after fine-needle aspiration and core-needle biopsy. A third approach to the management of breast fibroadenoma was evaluated. In their findings, Sperber et al., (2003, *Level 8*) concluded that lesions less than 1.5 cm at the longest diameter can be excised completely using the 11-gauge mammotome needle. Lesions up to 2 cm can also be completely removed, provided the lesion volume is less than 0.9ml. When most or all of a lesion is removed,

missing malignancies is almost certainly avoided. The benefits of the vacuum-assisted Mammotome method are that it needs only a single insertion without retargeting.

On another aspect of breast abnormalities, namely gynaecomastia, current treatment includes surgical reduction of the hypertrophied breast disc and may involve open surgery, liposuction alone, or a combination of the 2 techniques. The traditional open technique, however, can leave a scaphoid defect in the soft tissue of the chest wall. The Mammotome technique was found to be suitable for therapeutic breast surgery, with a potential improvement in patient cosmesis and a reduction in morbidity. There is no need to withdraw the biopsy probe when taking contiguous cores of a lesion. It was also found to be safe, with high patient satisfaction rates (Iwuagwu et al., 2004, *Level 8*)

With reference to the diagnosis of atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS), amongst others, studies have shown similar findings in the effectiveness of using the Mammotome device. A retrospective study conducted by Joshi et al. (2001, *Level 8*) measuring the accuracy in diagnosing ADH and biopsy of microcalcifications by the mammotome device was compared to that of the tru-cut method. With a single insertion a lesion is continuously and exhaustively biopsied in a time-effective way, leading to a more accurate preoperative diagnosis of ADH, DCIS and invasive carcinoma. The mammotome device replaced the tru-cut device as of March 1996 at their institution because of its ease of use and efficiency of operation, and because of the larger sample size obtainable with no increased risk to the patient. Hoorntje et al. (2003, *Level 1*) reported that the vacuum-assisted biopsy can reduce high-risk and DCIS underestimate rates. However, due to incomplete follow-up, it is unknown if it also has the same beneficial effect on miss-rates of cancer. Evidence obtained by the Medicare Services Advisory Committee (1999, *Level 1*) concluded that the directional, vacuum-assisted breast biopsy is able to obtain larger numbers of specimens at each biopsy and has a higher success rate for removal of microcalcifications. It also has a higher sensitivity rate in detecting DCIS and ADH. In another study, Grady et al. (2005, *Level 8*) found that the ultrasound-guided, vacuum-assisted biopsy is not technically challenging for surgeons to perform, unlike the fine-needle aspiration. Low rates of underestimation indicate that percutaneous ultrasound-guided excision is more accurate and can spare those with ADH open surgical procedure. Ultrasound-guided, vacuum-assisted biopsy is fast adopted due to its advantages over open surgical biopsy, i.e. reduced cost and increased patient demand.

Data confirm the value of the Mammotome device in diagnosing inflammatory breast carcinoma compared with fine-needle aspiration (FNA). It can serve as an alternative to surgical biopsy. (Meloni et al., 1999, *Level 8*). Data also confirm the value of sonography-guided mammotome biopsy for the diagnosis of breast carcinoma in the preclinical phase and the efficacy of ultrasound sampling to confirm the diagnosis in impalpable breast lesions (Meloni et al., 2001, *Level 8*).

Narreddy et al. (2005, *Level 8*) evaluated the accuracy of subareolar mammotome biopsy in preoperative accuracy of preoperative subareolar mammotome biopsy in subcutaneous mastectomy with or without nipple preservation. The Mammotome biopsy results had 100% concordance with the frozen section and final histology. Preoperative subareolar mammotome biopsy is, therefore, thought to be precise in assessing the accuracy of involvement of nipple-areolar complex. It is found to have a high reliability in trained hands and is a better alternative to intraoperative frozen section.

Ohsumi S et al. (2001, *Level 8*) experienced little difficulty when using the combination of Mammotome and an upright-type stereotactic mammography unit, which yielded a very high success rate. Similarly, in a study using the prone-type stereotactic vacuum-assisted breast biopsy system, Matsuzaki et al. (2005, *Level 8*) concluded that Mammotome biopsy is a safe and useful modality for the histological diagnosis of non-palpable microcalcifications.

Velanovich et al. (1999, *Level 8*) compared the results of the Mammotome breast biopsy with core-needle biopsy, advanced breast biopsy instrument (ABBI) and wire-localised biopsy for suspicious mammograms. The Mammotome breast biopsy with core-needle biopsy was found to have high sensitivities and specificities but 20-25% of patients would require an open biopsy due to uncertain diagnosis, unlike in the case of ABBI method. Just based on the abstract, the results were in favour of the ABBI. However, the systematic review by the Centre for Health Economics Research and Evaluation, CHERE (2003, *Level 1*), highlighted that not all women would meet the strict criteria identified by the authors for use of ABBI (breast thickness of more than 30mm when compressed, lesion ≤ 1cm in diameter, lesion must be ≥ 1cm from the chest wall or skin). Only the core-needle biopsy was directly comparable to the Mammotome breast biopsy, and with this done, the Mammotome technique was found to be the most efficient method of biopsy. Hung et al. (2001, *Level 8*), on the contrary, concluded that the fine-needle aspiration (FNA) is the method of choice for sonographically-detected lesions. The Mammotome biopsy is said to be reserved for those lesions which diagnoses are uncertain after FNA. If uncertainty still exists even after Mammotome biopsy, then surgical biopsy is performed.

From the study conducted by CHERE (2003, *Level 1*), comparing vacuum-assisted biopsy with core-needle biopsy, there was no actual difference in the effectiveness of the two techniques.

Reasons for errors in directional, vacuum-assisted breast biopsy, as listed by CHERE (2003, *Level 1*) in its report include:
1. miscalculation of lesion depth
2. deviation of needle within dense tissue
3. patient movement
4. high elasticity of certain tissue which is pushed forward rather than pierced by the needle
5. acquisition of non-representative tissue due to contiguous growth of certain malignancies (sampling error).

SAFETY

The directional vacuum-assisted breast biopsy has been found to be safe, with low minor complication rates and absence of major complications (Medicare Services Advisory Committee, 1999, *Level 1*).

Commonly reported complications with the use of the Mammotome device are mild discomfort or pain, bleeding, often with resulting haematoma, bloody nipple discharge (when mammotome used for treatment of nipple discharge), vasovagal attack, syncope, transient light-headedness and infection at probe insertion site, requiring antibiotics (Govindarajulu et al., 2005, *Level 8*; Alberta Heritage Foundation for Medical Research, 2005, *Level 1*; Rotter et al., 2003, *Level 8*; Ohsumi et al., 2001, *Level 8*; Radiology Info,

2005, *Level 9*; Sperber et al., 2003, *Level 8*; Constantini et al., 2005, *Level 8*; Wetter & Otto, 2001, *Level 8*; Parker et al., 2001, *Level 8*; Dennis et al., 2000, *Level 8*). Other rarer complications which have been reported include pneumothorax, hyperventilation syndrome and skin aspiration (Hahn et al., 2000, *Level 8*; Ohsumi et al., 2001, *Level 8*; Radiology Info, 2005, *Level 9*). These cases of complications tend to be self-limited.

Hung et al., (2001, *Level 8*) reported a rather low mean pain score, i.e. 2, (range 1-5, 5 representing severe pain) during the Mammotome procedure, and no major complications such as wound infection or significant haematoma requiring surgical evacuation.

Greenberg et al. (2003, *Level 8*) reported 2 serious complications in their series. The first was profuse arterial bleeding from the biopsy site requiring surgical suture, followed by surgical evacuation of the haematoma. Factors contributing to this profuse bleeding could be that the patient had 18 cores taken from the same site, and that the arterial bleeder was deep to the puncture site and remote from any bony prominence, making it difficult to compress. The second complication was skin necrosis around the puncture site. This could have been due to the presence of adrenaline in the local anaesthetic administered to the skin or due to the patient's diabetic arteriopathy. There were also cases of minor infections at the puncture site.

Wahner-Roedler et al. (2005, *Level 9*) described a case report on a 43-year old woman who underwent stereotactic biopsy using the 11-gauge vacuum-assisted breast biopsy device (Mammotome). A marker clip was positioned to mark biopsy site after samples of breast tissue were obtained. A follow-up mammogram was done 6 months later during which metallic particles (metal shavings) were discovered embedded within the breast parenchyma (seen as multiple densities perceived as calcifications). This demonstrates malfunction of the device and points out that metal shavings introduced into patients' breast tissue during biopsy may simulate microcalcifications.

Risk factors for complications highlighted by Hahn et al., (2000, *Level 8*) are small breast size, lesions close to the skin or thoracic wall and axillary or retroareolar lesions.
Another report highlighted relative contraindication of the vacuum-assisted device in certain groups of patients – patients unable to lie prone for long (arthritis in neck, back, shoulders or those with severe obstructive lung disease); patients unable to stay immobile (neuromuscular disorders); patients with history of bleeding disorders or on anticoagulants or aspirin (delay biopsy until coagulopathy is corrected) (Alberta Heritage Foundation for Medical Research, 2005, *Level 1*).

The Centre for Health Economics Research and Evaluation, CHERE, (2003, *Level 1*) concluded that the directional, vacuum-assisted breast biopsy done in prone position has its advantages over upright position - less incidence of vasovagal attack, less likelihood of patient movement during procedure, shorter examination time.

Overall, the Mammotome is found to be feasible, safe, with a reduction in morbidity, as well as high patient satisfaction rates. Its complication rates are low and it can serve as an alternative approach to the gold standard of open surgical excision in diagnostic as well as therapeutic purposes (Fine et al., 2002, *Level 8*; Fine et al., 2003, *Level 8*; Iwuagwu et al., 2004, *Level 8*).

COST-EFFECTIVENESS

No evidence is found on the cost-effectiveness of the Mammotome device per se. Varey et al. (2005) found that the cost of treating lactational breast abscess was cheaper when using the Mammotome, compared with the conventional incision and drainage. Vacuum-assisted core biopsy is done at a lower cost with lower resultant morbidity to the patient compared with traditional surgical excisional biopsy. (Wetter & Otto, 2001, *Level 8*). The ultrasound-guided, vacuum-assisted biopsy is fast adopted due to its advantages over open surgical biopsy: reduced cost and increased patient demand (Grady et al., 2005, *Level 8*).

Govindarajulu et al. (2005, *Level 8*) found that this procedure can be carried out under local anaesthesia by a trained surgeon in clinic and this is thought to be cost-effective and simple with a high patient satisfaction. It is also found to be as effective as open surgical biopsy in obtaining tissue samples for histopathologic analysis in the diagnosis of breast cancer. When compared to open surgical biopsy, image-guided, vacuum-assisted breast biopsy can reduce the overall cost of breast diagnosis (Alberta Heritage Foundation for Medical Research. 2005, *Level 1*).

The Medicare Services Advisory Committee (MSAC) (1999, *Level 1*) reported that although no analysis was done on the cost-effectiveness of directional, vacuum-assisted breast biopsy, it was known that the disposables used for vacuum-assisted biopsy are more costly than those used for core biopsy. It costs AUS$15,000 for the Mammotome control module, AUS$250-300 per lesion for disposables (depending on needle gauge) and AUS$100 for Mikromark clip for identifying lesion site, compared to AUS$58 for disposables used during core biopsy. When used with the guidance of ultrasound, the Mammotome breast biopsy also requires an articulated ultrasound arm which costs AUS$10,000. For open biopsy, on the other hand, on top of the AUS$407 for disposables, other costs involved are those associated with operating theatre (general anaesthesia, surgeon) and incidentals for open biopsy.

Similarly, although not comparing cost-effectiveness, Hung et al. (2001, *Level 8*) reported that the automated core (trucut) biopsy device is less expensive than vacuum-assisted mammotome. The mammotome device costs approximately HK$200 000 (AU$50 000) and the disposable mammotome needle is 10 times more expensive than the trucut needle (HK$2500/AU$600 per needle).

CONCLUSIONS

There is sufficient evidence to support the effectiveness of the Mammotome device in its use as a diagnostic as well as a therapeutic tool for breast abnormalities. These abnormalities can range from benign lesions, such as fibroadenomas, nipple discharge, abscesses, gynaecomastia, to malignancies of the breast.
There is sufficient evidence that the Mammotome device is safe, with low complication rates, a reduction in morbidity, as well as high patient satisfaction rates.
There is no retrievable evidence on economic evaluation of the Mammotome. However, the cost of the Mammotome is found to be more expensive than core biopsy.

REFERENCES

1. Adrales G, Turk P, Wallace T, et al. Is surgical excision necessary for atypical ductal hyperplasia of the breast diagnosed by Mammotome? *Am J Surg*. 2000 Oct;180(4):313-5.
2. Alberta Heritage Foundation for Medical Research. Image-guided vacuum-assisted breast biopsy for suspicious, non-palpable breast lesions. *TechNote 50*. 2005 August.
3. Baez E, Huber A, Vetter M, Hackeloer BJ. Minimal invasive complete excision of benign breast tumors using a three-dimensional ultrasound-guided mammotome vacuum device. *Ultrasound Obstet Gynecol*. 2003 March; 21(3):267-72.
4. Boehm T, Malich A, Goldberg N et al. Vacuum-assisted resection of malignant tumors with and without subsequent radiofrequency ablation: feasibility of complete tumor treatment tested in an animal model. *J Vasc Interv Radiol*. 2001; 12:1086-93.
5. Centre for Health Economics Research and Evaluation, University of Technology Sydney. Evaluation of Directional Vacuum-Assisted Breast Biopsy: Report for The National Breast Cancer Centre. 2003 November. Project report 21.
6. Constantini R, Sardellone A, Marino C, et al. Vacuum-assisted core biopsy (Mammotome) for the diagnosis of non-palpable breast lesions: four-year experience in the Italian center. *Tumori*. 2005 Jul-Aug;91(4):351-4.
7. Dennis MA, Parker S, Kaske TI, et al. Incidental treatment of nipple discharge caused by benign intraductal papilloma through diagnostic Mammotome biopsy. *AJR Am J Roentgeno*l. 2000 May;174(5):1263-8.
8. Diebold T, Hahn T, Solbach C, et al. Evaluation of the stereotactic 8G vacuum-assisted breast biopsy in the histologic evaluation of suspicious mammography findings (BI-RADS IV). *Invest Radiol*. 2005;40: 465-471.
9. Fine RE, Whitworth PW, Kim JA, et al. Low-risk palpable breast masses removed using a vacuum-assisted hand-held device. *Am J Surg*. 2003 Oct;186(4):362-7.
10. Fine RE, Boyd BA, Whitworth PW, et al. Percutaneous removal of benign breast masses using vacuum-assisted hand-held device with ultrasound guidance. *Am J Surg*. 2002 Oct;184(4):332-6.
11. Grady I, Gorsuch H, Wilburn-Bailey S. Ultrasound-guided, vacuum-assisted, percutaneous excision of breast lesions: an accurate technique in the diagnosis of atypical ductal hyperplasia. *J Am Coll Surg*. 2005 July;201(1):14-17.
12. Greenberg D, Johnston J, Hart R, Weston M, Benson-Cooper D. Stereotactic breast biopsy: an audit of 18 months at BreastScreen Auckland. *Aust Radiol*. 2003;47:261-7.
13. Govindarajulu S, Narreddy SR, Shere MH, et al. Ultrasound-guided mammotome biopsy by the surgeon as a treatment for single duct nipple discharge. *Br J Surg*. 2005 April; 92(1):16.
14. Hahn M, Scheler P, Pollow B, et al. An evaluation of complications of stereotactic vacuum biopsy with the Mammotome of the breast. *Breast Cancer Res Treat*. 2000 Nov;64(1):57.
15. Hoorntje LE, Peeters PH, Mali WP, Borel Rinkes IH. Vacuum-assisted breast biopsy: a critical review. *Eur J Cancer*. 2003 Aug; 30(12):1676-83.
16. Hung WK, Lam HS, Lau Y, et al. Diagnostic accuracy of vacuum-assisted biopsy device for image-detected breast lesions. *ANZ J Surg*. 2001;71:457-60.
17. Iwuagwu OC, Calvey TA, Ilsley D, Drew PJ. Ultrasound guided minimally invasive breast surgery (UMIBS): a superior technique for gynecomastia. *Ann Plast Surg*. 2004 Feb; 52(2):131-33.

18. Iwuagwu O, Drew P. Vacuum-assisted biopsy device – diagnostic and therapeutic applications in breast surgery. *Breast*. 2004 Dec;13(6):483-7.
19. Johnson AT, Henry-Tillman RS, Smith LF et al. Percutaneous excisional breast biopsy. *Am J Surg*. 2002 Dec;184(6):550-4; discussion 554.
20. Joshi M, Duva-Frissora A, Padmanabhan R, et al. Atypical Ductal Hyperplasia in Stereotactic Breast Biopsies: Enhanced Accuracy of Diagnosis with the Mammotome. *Breast J*. 2001 July/August; 7(4):207-13.
21. Kepple J, Van Zee KJ, Dowlatshahi K, et al. Minimally invasive breast surgery. *J Am Coll Surg*. 2004 Dec;199(6):961-975.
22. Matsuzaki S, Shiba E, Kobayashi Y, et al. [Stereotactic vacuum-assisted breast biopsy (Mammotome biopsy) for non-palpable microcalcification on mammography]. *Nippon Igaku Hoshasen Gakkai Zasshi*. 2005 Jan;65(1):16-22.
23. Medicare Services Advisory Committee (MSAC). Directional, vacuum-assisted breast biopsy. MSAC Final assessment report. MSAC application 1015. 1999 October.
24. Meloni GB, Dessole S, Becchere MP, et al. Ultrasound-guided mammotome vacuum biopsy for the diagnosis of impalpable breast lesions. *Ultrasound Obstet Gynecol*. 2001 Nov;18(5):520-24.
25. Meloni GB, Dessole S, Becchere MP, et al. Effectiveness of “core biopsy” by the mammotome device for diagnosis of inflammatory carcinoma. *Clin Exp Obstet Gynecol*. 1999:26(3-4):181-2.
26. Narreddy SR, Govindarajulu S, Shere MH, et al. Accuracy of subareolar mammotome biopsy in preoperative accuracy of preoperative subareolar mammotome biopsy in subcutaneous mastectomy with or without nipple preservation. *Br J Surg*. 2005 April; 92(1):30.
27. Ohsumi S, Takashima S, Aogi K et al. Breast biopsy for mammographically detected non-palpable lesion using a vacuum-assisted biopsy device (Mammotome) and an upright-type stereotactic mammography unit. *Jpn J Clin Oncol*. 2001; 31(11):527-31.
28. Parker SH, Klaus AJ, McWey PJ, et al. Sonographically guided directional vacuum-assisted breast biopsy using a handheld device. *AJR Am J Roentgenol*. 2001 Aug;177(2):405-8.
29. Rotter K, Haentschel G, Koethe D, et al. Evaluation of mammographic and clinical follow-up after 755 stereotactic vacuum-assisted breast biopsies. *Am J Surg*. 2003;186:134-142.
30. Sperber F, Blank A, Metser U, et al. Diagnosis and treatment of breast fibroadenomas by ultrasound-guided vacuum-assisted biopsy. *Arch Surg*. 2003 July; 138:796-300.
31. Varey AHR, Shere MH, Cawthorn SJ. Treatment of loculated lactational breast abscess with a vacuum biopsy system. *Br J Surg*. 2005;92:1225-6
32. Velanovich V, Lewis FR Jr, Nathanson SD, et al. Comparison of mammographically guided breast biopsy techniques. *Ann Surg*. 1999 May;229(5):625-30.
33. Wahner-Roedler DL, Whaley DH, Brandt KR, Reynolds C. Vacuum-assisted breast biopsy (Mammotome) malfunction simulating microcalcifications. *The Breast J*. 2005; 11(6):474-5.
34. Wetter D, Otto R. [Vacuum needle biopsy of the breast with digital stereotaxic control—initial experiences with the Mammotome in Baden]. *Schweiz Rundsch Med Prax*. 2001 Sep 13;90(37):1582-6.