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Ultrasound-Guided, Vacuum-Assisted, Mammotomebreast Biopsy: an Accurate Technique in the Diagnosis Ofearly Breast Lesion

KEYWORDS: Breast lesion, Core needle biopsy, Fine-needle aspiration cytology (FNAC), Mammography, Mammotome vacuum biopsy, Ultrasound-guidance.

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ABSTRACT ***Background:*** *The aim of this study was to evaluate the diagnostic accuracy, feasibility and safety of mammotome vacuum biopsy under ultrasound-guidance for histological diagnosis of early breast lesions.*

Methods: Patient with early breast lesions diagnosed by physical examination, mammography and/or sonography underwent mammotome vacuum biopsy under ultrasound- guidance for histological evaluation. The patient with histological diagnosis of malignancy underwent definitive surgery; those with diagnosis of atypical hyperplasia underwent surgical biopsy. Histological findings of mammotome sampling were compared with the results of surgical biopsy and definitive surgery. The patient with benign lesions underwent a 6-month follow-up.

Results: *The biopsy protocol was completed in all cases. Out of 60 cases, the 21(35%) cases diagnosed as invasive carcinoma and 9 (15%) cases were in situ carcinoma. In 9 cases of in situ carcinoma the 2 cases were found as invasive carcinoma after definitive surgery. In remaining cases the 22(36.7%) lesions were found as benign and 8(13.3%) cases were atypical hyperplasia.*

The subsequent surgical biopsy of 8 atypical cases, the 2 cases were found as in situ carcinoma.

Thereforein our study the diagnostic accuracy of mammotome vacuum biopsy under ultrasound-guidance was 96.7% and specificity was 100%. The overall failure rate of mammotome biopsy was 6.7% (4/60), this likely to be due to an error in the positioning of the needle. The 40% (n=24) patients described postprocedural pain and 18.4% (n=11) patients were found procedural bleeding; all incidents were mild in severity.

Conclusion: *We concluded that histological sampling of early breast lesions by ultrasound-guided mammotome biopsy is very effective and minimally invasive procedure with less complication as well as patient's tolerance and perceptions of the procedure were favorable.*

INTRODUCTION:

Intensified breast cancer screening programs and increasing use of mammography along with ultrasonography has led to the detection of a large number of palpable and impalpable breast lesions, that require further workup to distinguish benign and malignant condion.[1]

The combination of clinical breast examination and imaging technique such as ultrasonography and mammography are assuming an important complementary role for the early detection of breast cancer that require adequate tissue sample for histopathological evaluation.[2]

The traditional open surgical biopsy of all image detected suspicious or indeterminate lesions are done under anesthesia by a trained surgeon. However, this technique would lead to physical and mental stress for the patient, moreover postoperative scarring may lead to impaired diagnostic assessment of future imaging such as mammograms.[3]

Therefore alternative to surgical biopsy for the histopathologic assessment of early breast lesion, the method employs fine needle aspiration cytology (FNAC) and core needle biopsy either stereotactic radiological technique or ultrasonography-guidance. The ultrasound-guided fine needle aspiration cytology is easier, faster and cheaper as well as because it enables multidirectional sampling, it is usually preferred to the stereotactic radiological approach.[4]

The diagnostic accuracy of fine needle aspiration cytology (FNAC) is closely related to correct sampling technique, the careful preparation of tissue sample, and interpretation by a cytopathologist. Furthermore the cases showing atypia for which the pathologist require larger tissue sample for better evaluation of histological typing the role of FNAC was limited.[5]

The limitations of FNAC such as small volume of tissue (or cells only) is achieved for histological evaluation of palpable and impalpable breast lesions does not enable the pathologist to distinguish between in situ carcinoma and invasive carcinoma, therefore definitive diagnosis of some lesion can be difficult to make on the basis of FNAC, has led to increasing use of core needle biopsy.[6]

Core needle biopsy provides a definitive diagnosis in almost all palpable lesions and 80-90% of impalpable lesions. The sensitivity and specificity of these techniques depends on several parameters, including the quality of the pathological specimen and the biopsy technique used. However, conventional core needle biopsy can underestimate some pathology, if small indeterminate lesions or microcalcifications had been biopsied. Moreover core needle biopsy is associated with an increased risk of complications, including hematoma, hemorrhage and needle tract implantation of tumor cells. These are more likely to occur if a large number of biopsies are performed.[7]

Therefore vacuum-assisted mammotome biopsy was developed and used with mammographic or ultrasound-guidance. When compared the results of the mammotome vacuum-assisted breast biopsy with core needle biopsy for

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suspicious lesions of mammograms and/or ultrasonography, the mammotome technique was found to be the most efficient method of biopsy.[8]

Published data of previous studies also confirm the value of mammography and ultrasonography for the diagnosis of breast carcinoma in the preclinical phase and the efficacy of ultrasound-guided mammotome biopsy sampling to confirm the histological diagnosis in non-palpable breast lesions.[9]

There is sufficient evidence to support the effectiveness of the mammotome device using as a diagnostic as well as therapeutic tool for breast abnormalities with low complications rates as well as high patient's satisfaction rates. These abnormalities can range from various benign lesions to malignancies of the breast. [10, 11]

The mammotome breast biopsy system is a minimally invasive, image guided procedure (stereotactic or ultrasound) that helps physicians to locate breast abnormalities and obtain tissue sample for diagnosis, moreover ultrasound-guided mammotome procedure provides real-time images of the breast interior so that the physician can continuously visualize the progress of the procedure.[12]

The aim of the present study was to evaluate the efficacy and feasibility of ultrasound -guided mammotome vacuum biopsy for the diagnosis of early breast lesions.

Data was compiled in MS excel and checked for its completeness, correctness and then it was analyzed**.**

METHODS:

The present study was conducted on patients reporting to Department of Radiotherapy, Pt J.N.M. Medical College and Dr. B.R.A.M. Hospital Raipur (C.G.). From 17 May 2009 to 30 June 2010, 60 patients were evaluated in this study belonged to the age ranging from 30 to 67 years with the median age of 45year. From which 60% (n=36) patients were premenopausal and 40% (n=24) patients were postmenopausal. A woman was considered to be postmenopausal if she had spontaneous cessation of menses for more than one year.

The patients with small palpable (<3cm) or non-palpable breast lesions those were suspicious for malignancy or indeterminate at mammography and/or ultrasonography requiring histological examination, were included in the study. Patients have any cytological or histological diagnosis and patients with history of bleeding disorders are excluded in this study. The study was approved by the institutional ethical committee and all patients gave informed written consent at the time of enrolment.

Mammotome vacuum biopsy system developed specifically for breast biopsies. The system consists of a reusable, non-sterile driver and disposable sterile probe. The mammotome has rotating cutter that excises the tissue and vacuum system draws tissue into a sampling chamber and a second vacuum system transport tissue back through the probe. The probe can be rotated 360°, allowing for multidirectional tissue sampling.

Following local anaesthesia with 10 ml of lidocain, with a 26 gauge needle, a 3-5 mm skin incision was performed and then the mammotome needle was inserted under ultrasound- guidance in order to allow it to be positioned in or near the lesion, after that histological sampling was achieved with the mammotome device using 11-gauge needle. At the end of procedure the incision was compressed and covered with small plaster. All image detected lesions removed by mammotome was sent for histopathologic evaluation.

The patients with histological diagnosis of malignancy by mammotome sampling underwent definitive surgery and the histological diagnosis of mammotome biopsy was compared to the results of definitive surgery.

Those in whom the histological diagnosis did not demonstrate malignancy but who had a histological diagnosis of atypical hyperplasia underwent surgical biopsy to confirm the diagnosis. The remaining patients in which histological diagnosis were negative for malignancy underwent a 6-month follow-up. After 6-month the patients were re-examine with mammography and/or ultrasonography.

Data was compiled in MS excel and checked for its completeness, correctness and then it was analyzed**.**

RESULTS:

After clinical examination of breast we found that the 60% (n=36) patients had palpable breast lesions and 40% (n=24) patients had non-palpable breast lesions. In 90% (n=54) subjects, the breast lesions were visualized both at mammography and ultrasonography whereas in 10% (n=8) subjects visualization was only by ultrasonography. In 90% (n=54) subjects by mammography the lesions were identified as a mass with or without calcification. The average lesion diameter was 10 mm (9-28 mm).

At ultrasonography the lesions consisted of solid nodules with ill-defined margins in 75% (n=45) patients and clearly defined margins in 16.7% (n=10) patients; in the remaining 8.3% (n=5) patients we observed areas with intense hyperechogenicity which corresponded to clusters of microcalcifications at mammography. The average size of the visible lesions was 9 mm (8-25 mm). The ultrasonography and mammographic findings were reviewed by the experienced radiologists.

Table-1 shows the details of the results of ultrasound-guided mammotome biopsy sampling, surgical biopsy and definitive surgery. Histological sampling performed by the mammotome device confirmed the malignancy in 50% (n=30) patients. Out of 30, 18 cases had infiltrating duct carcinomas (IDC_s), 1 case had infiltrating lobular carcinoma (ILC), 2 cases had medullary carcinoma (MC), 7 cases had ductal carcinoma in situ (DCIS), and 2 cases had lobular carcinoma in situ (LCIS). After definitive surgery of all patients having infiltrating carcinomas by the mammotome device confirmed the results same.

On the other hand, among 9 cases of in situ carcinoma diagnosed by mammotome biopsy, surgery confirmed 7 cases, while one case of infiltrating duct carcinoma (IDC), and one case of infiltrating lobular carcinoma (ILC) were found in remaining 2 cases.

The 13.3% (n=8) cases in whom the histological diagnosis of mammotome biopsy indicative of atypia, we found 6 cases of atypical ductal hyperplasia (ADH), and 2 cases of atypical lobular hyperplasia (ALH). After surgical biopsy of all cases of atypical hyperplasia, 1 case was found ductal carcinoma in situ (DCIS) and 1 case was found lobular carcinoma in situ (LCIS) that was further confirmed by definitive surgery.

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Other histological diagnosis of mammotome biopsy such as fibrocystic changes (FC_s) and fibroadenomas (FIB_s) were found in 20% (n=12) cases and 16.7% (n=10) cases respectively, therefore these patients are advised for follow-up at 6 months. Mammography and/or ultrasonography after 6-month follow-up in all patients with benign lesions showed unchanged or reduced findings in comparison to the preliminary examination.

TABLE-1 Result of mammotome sampling, surgical biopsy and definitive surgery.

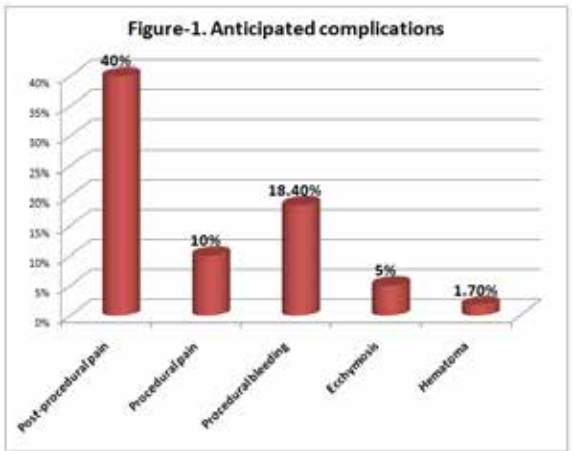
Mammotome vacuum biopsy (n=60)	Surgical biopsy (n=8)	Definitive surgery (n=33)
Malignancy: indicative of definitive surgery (n=30)		
IDC = 18	NP	IDC = 18
ILC = 1	NP	ILC = 1
MC = 2	NP	MC = 2
DCIS = 7	NP	DCIS = 6 + IDC=1
LCIS = 2	NP	LCIS = 1 + ILC= 1
Atypia: indicative of surgical biopsy (n=8)		
ADH = 6	Negative = 5, DCIS = 1	DCIS = 1
ALH = 2	Negative = 1, LCIS = 1	LCIS = 1
Benign: follow-up 6 month (n=22)		
FC = 12	NP	NP
FIB = 10	NP	NP

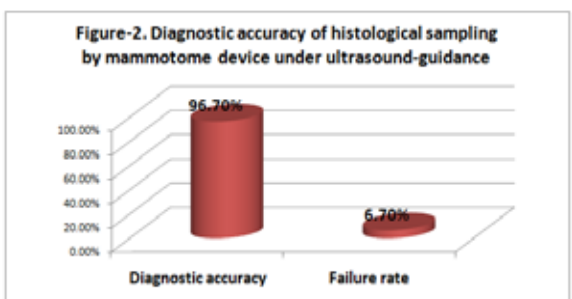
* (IDC=infiltrating duct carcinoma), (MC=medullary carcinoma), (ILC=infiltrating lobular carcinoma), (DCIS=ductal carcinoma in situ), (LCIS=lobular carcinoma in situ), (ADH=atypical ductal hyperplasia), (ALH=atypical lobular hyperplasia), (FC=fibrocystic change), (FIB=fibroadenomas), (NP=not performed).

Details of the most frequently reported complications during and after the procedure are shown in **Table-2 & Figure-1**. Postprocedural pain was the most frequently reported adverse events 40% (n=24), but all incidents were mild in nature except one (moderate in severity). Procedural pain was reported by 10% (n=6) subjects, all incidents were graded mild except two (moderate in severity). Procedural bleeding was found in 18.4% (n=11) of cases, of which 8 cases were found mild and 3 cases were moderate in severity, all resolved with little or no intervention. Ecchymosis and hematoma was reported in 5% (n=3) cases and 1.7% (n=1) case respectively. No complications were found by local anaesthesia.

TABLE-2 Details of procedural complication

Anticipated complications	Severity			Total (n=60)
	Mild	Moderate	Severe	
Post-procedural pain	23	1	0	24(40%)
Procedural pain	4	2	0	6(10%)
Procedural bleeding	8	3	0	11(18.4%)
Ecchymosis	3	0	0	3(5%)
Hematoma	1	0	0	1(1.7%)





In current study we found that the diagnostic accuracy of histological sampling by mammotome device under ultrasound-guidance was 96.7%. **[58/60 x 100]** Failure rate of the test was 6.7%. **[4/60 x 100] [Figure-2]**

DISCUSSION:

In our study, data confirm the increasing role of mammography in conjunction with ultrasonography for the diagnosis of the early breast lesion in the preclinical phase and accuracy of tissue sampling by mammotome under ultrasound guidance for the diagnosis of early breast lesion.

Histological sampling may be performed with percutaneous core needle biopsy, or as in our study, by ultrasound guidance vacuum mammotome device with 11 gauge needle and by open surgical biopsy. Results from published data showed that, when performed vacuum assisted mammotome biopsy under strict standard is a very reliable, accurate and highly effective for the diagnosis, as well as for the therapeutic management of early breast lesions, with minimal negative effects.[13, 14]

Our results show that 35% (n=21) patients who had diagnosed of invasive carcinomas with ultrasound- guided mammotome biopsy, were then confirmed by the definitive surgery, whereas the 15% (n=9) patients with in situ carcinoma with mammotome biopsy, the one patient had diagnosed as infiltrating duct carcinoma (IDC) and one patient had lobular carcinoma (ILC) by definitive surgery.

On the other hand, in 15% (n=9) patients the mammotome biopsy described as atypical hyperplasia, further surgical biopsy identified malignancy in 2 patients. This discordance may be due to an error in the positioning of the needle during procedure. Therefore, overall mammotome biopsy recorded 2 (3.3%) false-negative cases in 60 patients and overall failure rate of 6.7% (one IDC, one ILC, one DCIS, and one LCIS).

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Amongst others, studies have compared of mammotome biopsy versus true-cut method with reference to the diagnosis of atypical lesions (ADH, ALH and in situ carcinomas); the mammotome biopsy under ultrasound-guided was highly effective with the ability to continuously and thourghly biopsied with single insertion.[15, 16]

Commonly reported complications with the use of mammotome device are mild pain, bleeding, often with resulting hematoma, vasovagal attack, syncope, and infection at probe insertion site, and are marginal compared to surgical biopsy.[17, 18]

In our study frequently reported complications are Postprocedural pain, procedural pain, bleeding and hematoma; almost all incidents were mild in nature, except two cases of procedural moderate pain and 3 cases of procedural moderate bleeding.

When compared open surgical biopsy to ultrasound-guidance mammotome biopsy offers numerous advantages: it is a minimally invasive, patient's tolerance and perceptions of the procedure were favorable, minimal side effects, and less expensive than open surgical biopsy performed under general anaesthesia.[19]

Although we recognize that our study is limited by the small number of patients, our intention was to report our early experience with the ultrasound-guided mammotome biopsy of early breast lesions.

Due to our promising initial results we would like to encourage more screening programs in conjunction with the mammography and ultrasonography, followed by mammotome breast biopsy of suspicious lesions. The outcome would be a reduction in the number of open surgical biopsy for benign lesions and a reduction in patient's anxiety and postoperative morbidity, including scarring.

However, breast ultrasound and mammotome biopsy under ultrasound-guidance require considerable expertise. If a histological sampling is indicated of early breast lesions, the benefits of an ultrasound-guided biopsy versus primary surgical removal of the whole lesion should be discussed.

CONCLUSION:

In conclusion, the immediate procedural results from this study demonstrate that histological diagnosis of early breast lesions by mammotome biopsy under ultrasound-guidance is a very reliable and minimally invasive technique with fewer complications as well as patient's tolerance and perceptions of the procedure were favorable. Although our study limited by small number of patients the promising data continue to support the use of the mammotome device under ultrasound-guidance as an alternative approach to the gold standard of open surgical biopsy for patients with early breast lesions. Last but not least, if mammotome biopsy sampling is suggestive of severe atypia, or when the histological sampling assessed as benign, does not correspond to the mammographic and/or ultrasonographic findings, then surgical biopsy is performed for definitive diagnosis.

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