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Mammotome HH biopsy – the future of minimal invasive breast surgery?

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Summary

Background:

Vacuum-assisted breast biopsy / Mammotome HH ® Breast Biopsy System/ is the milestone in the diagnosis of breast lesions. This system has proven to be as diagnostically reliable as open surgery, but without scarring, deformations and hospitalizations associated with an open procedure. The aim of our study was to assess the role and possibilities of using this biopsy in treatment of benign breast lesions like fibroadenoma.

Material/Methods:

From 2001 to 2004, about 1118 Mammotome biopsies were performed in our Department. Among 445 Mammotome biopsies performed under US control there were 211 cases of fibroadenomas. Follow-up was performed in 156 patients with this result at 6 and 12 months after biopsy. In our study we took into considerations the size, localizations as well as performers.

Results:

In 2002 there were 70.8% patients with total lesion excision, 16.7% with residual lesion and 12.5% women with hematomas or scars. In 2003-2004 there were more women with total lesion excision (84.3%), fewer residual tumors and other lesions.

Conclusions:

In future, Mammotome breast biopsy can replace scalpel, and will become an alternative method to open surgical excision of fibroadenomas. It is important especially in the cases of young women to prevent cosmetic deformations and scars.

Key words:

benign lesions • vacuum-assisted biopsy • Mammotome • excision

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Background

Introduction of mammotome biopsy in 1995 was a milestone in diagnostics of impalpable breast lesions. Combining all the types of biopsy methods used to date, this technique is currently the most modern form of low-invasive diagnostics, allowing to avoid unnecessary surgical procedures.

Special design of the needle, including a „aperture” of different sizes, knife with rotational drive and vacuum assistance facilitates collection of pathologic lesion specimens. The procedure is performed under USG or digital mammography control, which allows to monitor the course of

the procedure continuously. Size of the specimens, possibility of needle rotation in the desired direction, aspiration of blood appearing at the biopsy site, guarantee obtaining representative diagnostic material as a result of the procedure. In comparison with other biopsy types, the technique is characterized by the highest sensitivity and specificity [1–5].

Up to the recent times, mammotome biopsy was applied exclusively for diagnostic purposes. However, attempts to use this technique to remove benign lesions of the breast have been undertaken for many years. In 2006, U.S. Food and Drug Administration and the National Institute of

Health and Clinical Excellence included mammotome biopsy in the group of therapeutic procedures used for resection of benign tumors [6–8].

Aim of the study

In our Laboratory, since the time of introduction of mammotome biopsy, indications for the procedure have included complete resection of fibroadenoma type lesions. The aim of the study was to assess the effectiveness of the method as a therapeutic procedure.

Materials and methods

In 2001–2004, 1118 USG- and MGR-guided mammotome biopsies were performed. Stereotaxic biopsies were performed in 573 patients, USG-guided ones in a total of 445 cases including 211 with histopathologically confirmed fibroadenoma type lesions. Only the patients in whom evident characteristics of fibroadenomas were determined either in USG, or MGR, or both, were qualified for complete resection of the lesions. The group included also some patients with “palpable” lesions who did not want open surgery. The biopsies were performed by two specialists – a surgeon-oncologists and a radiologist. USG-guided procedures were performed using a Kretz apparatus with linear 7.5–10 MHz head and Mammotome HH manufactured by Johnson&Johnson.

After localization of the lesion by USG and inducing local anesthesia with 1 % Xylocaine, the biopsy needle was introduced into the breast through a small cutaneous incision, a few millimeters long, so as to obtain the most convenient position of the aperture, i.e. below the lesion. In case of difficult localizations, parasternal or intercostal, the needle was inserted with lateral approach for safety considerations (risk of disrupting the integrity of the thoracic wall). The needle gauge was determined by the tumor size and equipment availability (8G needle – aperture of 23 mm length, bioplate diameter 3.35 mm, 11G needle – 19.4 mm and 2.16 mm, respectively). After starting the vacuum-assisted drive mechanism the lesion was aspirated into the biopsy chamber and the “sleeve” knife cut a fragment of it. The same suction mechanism propelled the bioplate out of the needle. The biopsies were collected in a fan-like or clock-like pattern. The procedure was repeated until the last lesion fragments visible under USG were removed. Before the completion of the procedure and additional harvesting “round” was performed despite no visible abnormalities, for radicalization of the resection

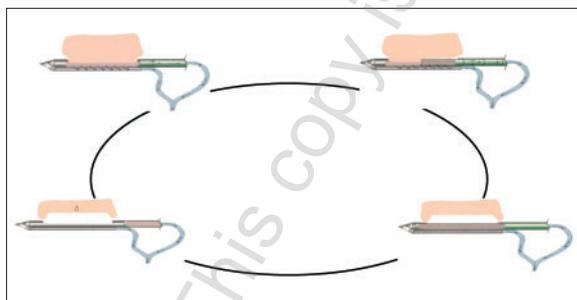


Figure 1. Mammothome excision scheme.

procedure (Figure 1). The tissue material was placed in 10% Formalin solution and sent to the histopathology laboratory. After completion of the procedure and needle withdrawal, the cutaneous incision was covered with sterile dressing and pressure was provided by elastic bandage. The patient returned home after the procedure. The total time was ca. 20 minutes (Figures 2 and 3 a, b).

The post-biopsy follow-up schedule included physical examination one month after the procedure, as well as control USG after 6 and 12 months.

The analyzed group consisted of 155 patients. The remaining 56 were excluded from the study because of a failure to come for follow-up visits or control examinations performed in other diagnostic centers. Control USG was performed by specialists from the Department of Radiology at the Army Hospital. Complications of the procedure included 4 cases of intraoperative profuse bleeding, for which additional pressure dressing was applied and which were treated with anti-hemorrhage drugs and remained for 24 h under observation in the Oncologic Surgery Ward, and one case of uncontrolled skin cut, sutured and dressed in the Laboratory. Hematomas forming at the biopsy site were treated as a normal symptom. No cases of breast deformation were noted.

The mean age of the patients was 42.5 years (range 17–79). The tumor size ranged from 5 to 25 mm (mean 11.8 mm). Seventy two tumors were equal to, or smaller than 1 cm in diameter, and 83 were larger; 121 were located in the external quadrants of the breasts, and 34 in the medial ones. As far as location of the tumors in relation to skin surface and thoracic wall was concerned, 15 lesions were located subcutaneously, 99 at intermediate depth in the breast parenchyma and 41 adjacent to the thoracic wall.

Results

In the group of 72 who underwent mammotomy in 2002, on control USG performed after 6 months, 51 (70.8%) cases



Figure 2. Mammothome needle insertion.



Figure 3 A, B. Biopsy specimens and mammotome result.

of complete lesion removal, 9 (12.5%) hematomas and 12 (16.7%) residual lesions. After one year, USG assessment revealed, respectively 58 (80.6%) tumor-free cases, 5 (6.9%) hematomas and 9 (12.5%) residual tumor fragments. The diversity of results between the two control examinations led to resignation from the USG performed after 6 months in the group of patients treated in 2003–2004 who were followed up according to the following schedule: physical examination one month after the procedure and usg of the breast after 12 months [Tab. 1 i 2].

The analysis was extended to include the factors which could be potential reasons for failure to remove the lesions completely. They included: tumor size, peripheral (para-fascial and subcutaneous) location in the mammary gland, quadrant localization and the person performing the procedure. The assessed parameters demonstrated that the location of the lesion in the breast, both with respect to depth and to the breast quadrant, as well as the operator, have no significant influence of the completeness of the procedure. The only parameter influencing the completeness of resection is the primary tumor size (Tab. 3, 4, 5, 6).

Table 1. Results – 2002 group.

TOTAL	6 MONTHS		12 MONTHS	
	72	72		
HEMATOMA	9	12.5%	5	6.9%
RESIDUAL LESION	12	16.7%	9	12.5%
LESION ABSENT	51	70.8%	58	80.6%

Table 3. Results according to lesion depth.

LOCALIZATION	TOTAL	NO ABNORMALITIES	HEMATOMA	RESIDUAL LESION
SUBCUTANEOUS	15	11 (73.4%)	2 (13.3%)	2 (13.3%)
MEDIAL	99	84 (84.8%)	6 (6.1%)	9 (9.1%)
PARIETAL	41	29 (70.8%)	6 (14.6%)	6 (14.6%)

Discussion

Analysis of the first group of patients of 2002 demonstrated that it seems justifiable to resign from the first USG control after 6 months. The image obtained at that time seems to be dependent on the dimensions of the excised tumor site and possible increased bleeding during and after the procedure. These factors interfere with correct interpretation of the image, which often shows a hypoechogenic area with irregular contour (a developing hematoma), or a mixed echogenicity area where the lesion residues are difficult to detect. After 12 months, the healing processes eliminate to a large extent, or even completely, the hematoma, and in the scar that forms at the resection site it is easier to distinguish the residual lesion. Additionally, for persons with no experience in post-mammotomy image assessment, the view of the site after 6 months may give a false impression of a hyperplastic lesion.

Many physicians performing mammotome biopsies consider the location of the tumor to be an important prognostic factor for complete resection. In very thin patients with dense, compact breast parenchyma, parasternal or

Table 2. Results – 2003-2004 group.

TOTAL	83	
HEMATOMA	5	6%
RESIDUAL LESION	8	9.7%
LESION ABSENT	70	84.3%

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Table 4. Results according to localization quadrants.

QUADRANTS	TOTAL	NO ABNORMALITIES	HEMATOMA	RESIDUAL LESION
LATERAL	121	93 (76.9%)	12 (9.9%)	16 (13.2%)
MEDIAL	34	31 (91.2%)	2 (5.9%)	1 (2.9%)

Table 5. Results according to performing physician.

DOCTOR	TOTAL	NO ABNORMALITIES	HEMATOMA	RESIDUAL LESION
GP	104 (67.1%)	87 (83.7%)	7 (6.7%)	10 (9.6%)
JN	51 (32.9%)	41 (80.4%)	3 (5.9%)	7 (13.7%)

Table 6. Results according to lesion diameter.

LESION SIZE	TOTAL	NO ABNORMALITIES	HEMATOMA	RESIDUAL LESION
≤ 10 mm	72	64 (88.8%)	4 (5.6%)	4 (5.6%)
> 10 mm	83	60 (72.3%)	10 (12%)	13 (15.7%)

intercostal location of the tumor is regarded as difficult because of the risk of disrupting the thoracic wall integrity. The situation is similar in case of subcutaneous lesions. However, the results of the analysis did not demonstrate significant influence of these localizations on the effect of complete resection.

The assessment of the operator concerned the learning curve (more or less experience in the procedure). No significant influence was noted in this case, either. For more detailed analysis, the number of procedures performed by particular physicians according to lesion sizes and locations should be considered.

The results presented above with respect to complete resections fall within the mean rates reported by numerous publications. Nevertheless, reliable comparisons are impossible because of different times of control USG after the procedure. The authors of other publications did not assess any of the failure parameters mentioned in the paper, except for lesion size. However, the percentages of complete resections reported in all papers are, consistently with our results, lower in case of lesions exceeding 1 cm in diameter [9–15].

Conclusions

Treatment of fibroadenoma type lesions with mammotome biopsy is justifiable, because:

- collecting a few specimens from a pathologic change does not solve the problem if it is left in place. Considering the fact that some fibroadenomas tend to grow,

the ultimate effect of treatment is their complete resection, i.e. another invasive procedure,

- the possibility of monitoring the course of mammotome biopsy by means of USG allows to remove the lesions completely and precisely,
- the next surgical procedure may lead to breast deformation and bad cosmetic effect due to the post-operative scar,
- the costs of invasive procedures are limited to one procedure only,
- some patients, despite the diagnosis of a benign lesion, want it to be removed because they are afraid of developing breast cancer,
- excellent cosmetic effect and no breast deformation guarantee complete satisfaction of both the patient and the physician,
- simplicity of the procedure, short duration and possibility to perform it on ambulatory basis allows the patients to return to work and to their private life immediately,
- the use of disposable equipment only guarantees complete safety with respect to HBV, HCV and HIV infections.

All the above conclusions confirm that mammotome biopsy is a safe, esthetic and quick procedure allowing complete resection of benign breast pathologies of fibroadenoma type up to 1 cm in diameter.

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