

Evaluation of a portable device for vacuum-assisted biopsy of breast microcalcifications*

Avaliação de um dispositivo portátil para biópsia vácuo-assistida de microcalcificações mamárias

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Abstract **OBJECTIVE:** Vacuum-assisted biopsy is the percutaneous technique of breast biopsy with the lowest underestimation rate. However, the cost of such procedure is high and currently there is a considerable interest in developing less expensive techniques. The present study was aimed at testing a less expensive device for vacuum-assisted biopsy of breast microcalcifications. **MATERIALS AND METHODS:** Thirty-five patients with clustered microcalcifications classified as BI-RADS[®] 4 or 5 were submitted to biopsy. Collected specimen appropriateness, difficulties in the reinsertion of the cannula and number of biopsy passes were evaluated. **RESULTS:** Successful specimens collection was achieved in all of the patients. Histo-radiological disagreement, difficulties in the cannula reinsertion or severe complications were not observed. **CONCLUSION:** The authors conclude that the method is effective in terms of specimens appropriateness and cost-benefit ratio as compared with of biopsy techniques for breast microcalcifications. Such findings are compatible with data reported in the literature.

Keywords: Breast biopsy; Vacuum-assisted biopsy; Mamotomy; Mammography; Microcalcifications; Vacora.

Resumo **OBJETIVO:** A biópsia vácuo-assistida é a forma percutânea de biópsia de microcalcificações que obtém a menor taxa de subestimação, porém, seu custo é alto, havendo interesse em se conseguir formas mais baratas de biópsia vácuo-assistida. O objetivo deste trabalho foi testar um dispositivo portátil de biópsia vácuo-assistida que apresenta custo menor. **MATERIAIS E MÉTODOS:** Foram biopsiadas 35 pacientes que apresentavam agrupamentos de microcalcificações BI-RADS[®] 4 ou 5. Foram testados a representatividade dos fragmentos colhidos, as dificuldades na reintrodução da cânula e o número de ciclos de colheita. **RESULTADOS:** Houve obtenção de calcificações representativas em todas as pacientes. Não houve discordância anatomoradiológica, dificuldade na reintrodução da cânula ou complicações graves. **CONCLUSÃO:** Os dados permitem concluir que o sistema apresenta boa eficácia na obtenção das amostras e com relação de custo-benefício favorável em relação a outros sistemas para a biópsia de microcalcificações, achados em concordância com outras publicações da literatura.

Unitermos: Biópsia mamária; Biópsia vácuo-assistida; Mamotomia; Mamografia; Microcalcificações; Vacora.

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INTRODUCTION

Vacuum-assisted biopsy is a percutaneous (non-surgical) way to obtain breast tissue for histological analysis, thus being considered as a minimally invasive procedure.

It can be performed under mammographic guidance (in this case requiring the use of stereotactic resources), sonographic guidance or magnetic resonance imaging guidance. It is the type of percutaneous biopsy that obtains the largest sampling of tissue⁽¹⁾, and studies have demonstrated that the adoption of such technique results in a lower underestimation rate in the diagnosis of breast microcalcifications as compared with simple stereotactic core biopsy (that is, non-vacuum-assisted biopsy), decreasing the need for surgical biopsies^(2,3). The disadvantage of the vacuum-assisted biopsy is related to cost, which is considerably higher than that of simple core biopsy.

Initially, there was a single sales representative of vacuum-assisted biopsy devices in Brazil, and the most common name attributed to the procedure in Portuguese, *mamotomia*, is actually a reference to the trademark of such device. Currently, other vacuum-assisted biopsy devices are available in Brazil. One of them is a handheld device (Figure 1) that does not require cables or a separate vacuum generating unit. This system has a considerably lower cost (approximately 75% lower), and for this reason it may be an advantageous alternative when the economic reality of our country is considered. The potential disadvantage of the method lies in the need of repeated probe insertions at each sample

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Figure 1. Portable vacuum-assisted biopsy device.

collection, which may increase the time required for the procedure and affect the method accuracy. Additionally, one might question whether the vacuum produced by such portable system has enough pressure to produce samples with diagnostic quality.

The present study was designed to test the performance of such equipment in microcalcifications biopsy concerning the appropriateness of tissue samples for histopathological analysis, and the possible inconveniences caused by the need of repeated probe insertions.

MATERIALS AND METHODS

Vacuum assisted biopsies were performed with a Vacora[®] device (Bard Biopsy Systems; Temple, AZ, USA) in 35 consecutive patients presenting with BI-RADS[®] 4 or 5 microcalcifications between January and October 2008. Mean patients' age was 54 years. The exclusion criteria would be patients with allergy to anesthetics or those unable to remain still during the time required for the procedure, but no patient of the sample was excluded.

All the procedures were performed by one of two practitioners, both of them with more than seven-year experience in breast radiology.

Stereotactic guidance was utilized in all cases with a dedicated Giotto system (IMF; Bologne, Italy), with the patient positioned in ventral decubitus, the breast being approached through an aperture on the examination table (Figure 2). Local anesthesia (lidocaine), without vasoconstrictor on the skin, and with vasoconstrictor in the deep planes, was utilized. On average, 12 fragments were obtained in each collection cycle.

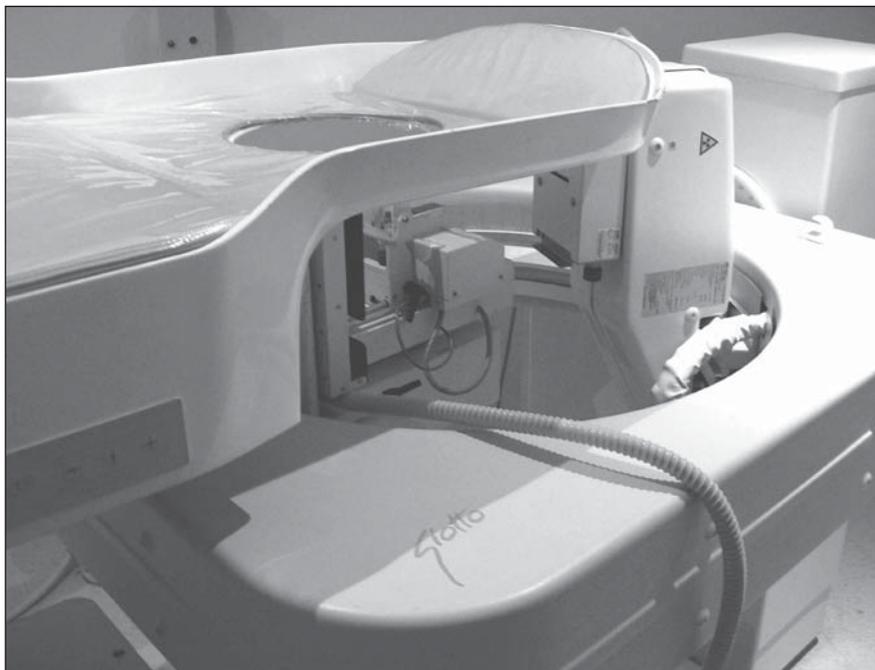


Figure 2. Dedicated examination table for stereotactic biopsy with the patient in ventral decubitus.

The device's conventional technique was utilized. The cannula is always positioned on the lesion central point, as determined by stereotaxy. Successive collections are then performed, in radial orientation at 30° steps, until a complete circumference is completed around the cannula. The device is removed for tissue sample retrieval after each collection, and is then reinserted in the same position. The change in orientation of the collection window of the cannula is selected on the device itself (Figure 3). The presently tested system is not equipped with a post-collection hematoma aspiration device.

The following parameters were tested: sample appropriateness, number of collection cycles and technical difficulty in the repeated cannula insertion.

The retrieved fragments (Figure 4) were radiographed (Figure 5). In the presence of representative calcifications, a metal clip was placed, marking the biopsy site (Figure 6), except in cases of very evident residual lesions that could be utilized as a biological marker in the case of re-intervention. In the absence of representative calcifications, the procedure was repeated until they were obtained.

Representative calcifications were so considered when at least five clustered calcifications were obtained, and such calcifications included some of the most suspicious for malignancy.

After the procedure was completed, two mammographic views were performed to confirm the calcifications extraction and the clips positioning.

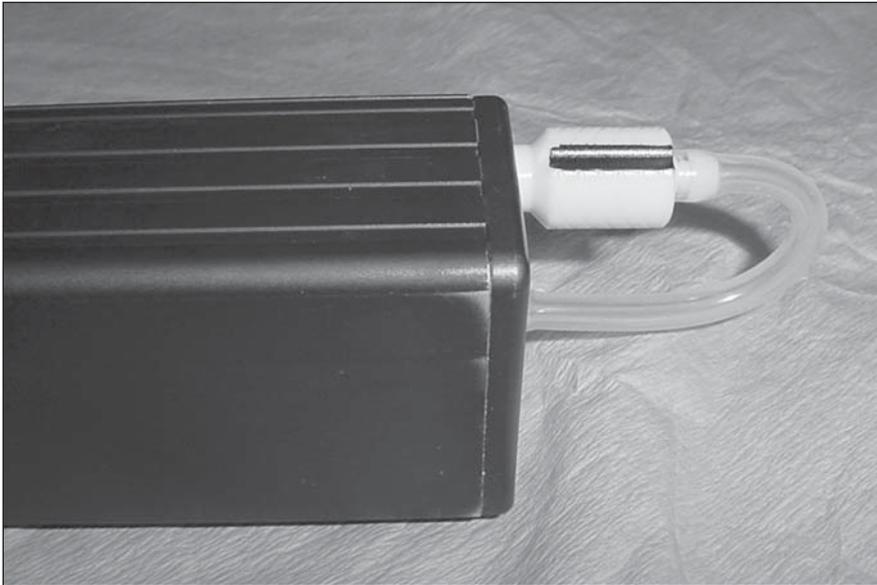


Figure 3. Button for cannula radial orientation selection.



Figure 4. Fragment retrieved with the device being studied compared with fragment retrieved by means of simple core biopsy.

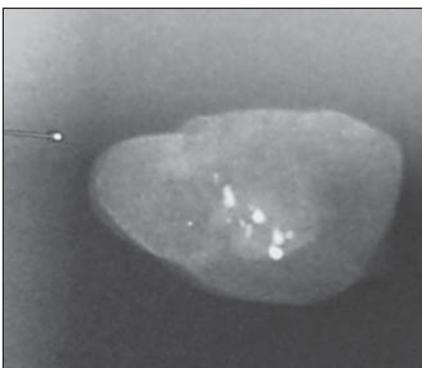


Figure 5. Radiographic image of one fragment retrieved with the device in study containing representative calcifications of the lesion.

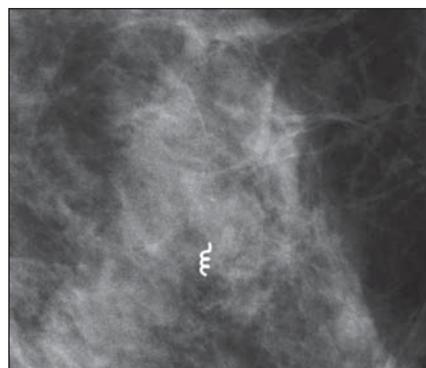


Figure 6. Metal clip marking the biopsy site.

In the cases diagnosed as benign, a six-month radiological follow-up was recommended.

RESULTS

All the biopsies obtained calcifications representative of the radiological lesions. Anatomopathological studies revealed benign findings in 23 cases (typical hyperplasia in 5, psammomatous calcifications in 6, simple adenosis in 1, dystrophic calcifications in 2 and benign calcifications not specified in the anatomopathological reports in 3), ductal carcinoma *in situ* in 8 cases, 4 of them high-grade, invasive ductal carcinoma in 2 cases, both of them high-grade, and high risk lesion (atypical ductal hyperplasia) in 2 cases. Among the 8 cases of ductal carcinoma *in situ*, definitive surgery revealed invasive ductal carcinoma in 1 case. In the 2 cases of high-risk lesions, the patient was submitted to surgical biopsy, and the diagnosis was confirmed as benign. In 6 cases two collection cycles were required, and in the remaining 29 cases a single collection cycle was performed. Technical difficulties were not observed with the repeated probe insertions, as it was demonstrated that the stereotactic guides directed the probe exactly to the skin nick previously made, since the patient's breast remains fixed during the whole procedure.

Lesions were completely removed in 8 cases and partial sampling occurred in 27 cases. Metal clips were utilized in 31 cases. No error was observed in the marker clips placement.

Severe complications were not observed. Hematomas occurred in 15 cases (43%), 3 of them being large (9%). There was no need to drain such hematomas.

On average, each collection cycle took eight minutes to be completed.

With respect to pain, the procedure was well tolerated by all the patients. Occasionally, additional local anesthetic administration was required because of pain complaint during the procedure. The tested device does not allow the application of anesthetics directly through the biopsy cannula. Therefore, whenever necessary, the additional anesthetic application was performed by means of a needle inserted be-

side the probe, or by removing the cannula and inserting the needle in the same biopsy pathway.

DISCUSSION

This study was aimed at testing the performance of a hand-held vacuum assisted device and has found results similar to those achieved with non portable equipment.

The paradigm to be taken into consideration in the selection of a method for a given breast lesion biopsy should be the utilization of a less invasive and less expensive method capable of supplying sufficient material for analysis⁽⁴⁾. In the case of microcalcifications, vacuum-assisted biopsy is less invasive than surgery and presents a lower smaller underestimation rate than simple core biopsy^(1,5-7).

A problem related to vacuum-assisted biopsy is its cost, not only in set-up and device acquisition but also the disposable consumables utilized the process. The cost of biopsies of lesions detected at screening programs may represent up to one-third of the program costs⁽⁸⁾. The rational utilization of resources may produce savings and allow the application of such resources in other health-related activities, for example, extend the access to screening programs to more women⁽⁹⁾. The tested system presents a considerably lower set-up cost, although the cost of disposable consumables is similar to that of other systems⁽¹⁰⁾.

No difficulty was observed with the cannula reinsertion for additional collections.

Among the different vacuum-assisted devices currently available, some of them operate with a single cannula insertion, and others that operate with multiple insertions. In the first ones, there is a sampling chamber coupled to the cannula into where the collected fragment is moved, allowing its retrieval without removing the probe from the patients breast. In the presently tested device, the probe must be removed from the patient's breast for the retrieval of the collected sample, and then be reinserted for collection of a new fragment. This caused some preoccupation that the system might cause additional trauma for the breast because of the repeated probe insertions, and that the collection accuracy might be af-

ected as a result of the target lesion displacement caused by the probe movements, but such complications were not observed.

On average, each collection cycle took eight minutes to be completed, longer than the time spent with single cannula insertion systems. Part of this time was spent with the repeated probe insertions. This longer collection time may potentially limit the method accuracy due to patients' movements. The biopsy samples appropriateness suggests that accuracy was not compromised. It is important to remind that all biopsies performed in the present study were carried out on a dedicated examination table, on which the patient's immobilization tends to be more efficient. Hypothetically, when such procedure is performed with the patient on a sitting position, the probability of undesired movements is higher as the patient's torso retraction is not as well prevented by gravity force as it is with the dedicated prone examination table. In fact, the authors have observed that, during stereotactic biopsies with the patient on a sitting position (not included in this study), movements are not rare (which is easily noticed when the skin nick loses its alignment with the direction of the biopsy guide). The remaining question is whether, in the case of biopsies performed with the patient on a sitting position, the longer time required by the collection cycle with the portable device object of the present study, might interfere with the sampling accuracy.

One limitation of the present study is that the low number of cases does not allow comparisons of rates of complications (among which the main one is the development of hematoma) with other vacuum-assisted biopsy methods. As the tested device is not equipped with resources for post-collection wash out and hematomas aspiration, hypothetically its use might result in a higher number of hematomas. A previous study has evaluated this matter and found that, with the handheld device, there was higher incidence of pain and lower incidence of early and late hematomas as compared with non-portable vacuum-assisted biopsy devices⁽¹¹⁾.

Another limitation of the present study that is also related to the low number of

cases is the fact that it did not compare the biopsies underestimation rate with that of non-portable devices.

Finally, the tested portable vacuum-assisted biopsy device obtained appropriate samples in all cases, and is a lower-cost alternative for the performance of such biopsies. This was the first test of the device in our country, and the results are compatible with other studies in the literature that likewise have demonstrated its good performance^(12,13).

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