REVIEW ARTICLE
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Vacuum-assisted biopsy and excision of breast lesions: review and current indications

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ABSTRACT

Vacuum-assisted biopsy is an advance in breast diagnostics because it is a less invasive and more practical approach than conventional surgery, capable of diagnosing and treating certain lesions. Despite the still limited availability of the method, related to its cost and the number of professionals qualified to perform it, the potential of vacuum-assisted biopsy and excision in the practice of mastologists is unquestionable. The attending physician is expected to understand the methods, as well as the indications pertinent to them. Recognizing the impossibility of exhausting the subject, the objective of this study is to conduct a narrative review, summarizing the indications for vacuum-assisted breast biopsy and excision currently, according to the available scientific evidence.

KEYWORDS: biopsy; large-core needle; image-guided biopsy.

INTRODUCTION

The evolution of breast biopsy techniques began in 1960, with the advent of fine-needle aspiration biopsy (FNA), widely used until the 1990s, enabling cytopathological analysis of the lesion and the possible distinction between malignancy and benignity. Incorporated into the routine diagnosis of breast lesions, together with clinical evaluation and imaging examination, FNAB had a non-diagnosis rate of 40%[1]. Given the diagnostic limitations of the method, a new puncture technology was developed: core needle biopsy, also known as core biopsy. This new technique consists of an automatic device, with a large-caliber needle, capable of biopsying an entire fragment of the lesion and thus providing histological study, providing greater detail on benignity or malignancy, as well as the diagnosis of ***in situ*** or invasive lesions. In the mid-1990s, core biopsy became the standard intervention for diagnosing breast lesions with superiority based on a successful biopsy rate of 99% of cases, compared to 60-75% for FNA[2], and a sensitivity of 80-93%, compared to 65-82% for FNA[3].

Approved by the Food and Drug Administration (FDA) in April 1995, vacuum-assisted biopsy, also known by the abbreviation VAB, has been used in medical practice in Brazil ever since, and has been progressively incorporated into the list of mandatory minimum coverage for health insurance plans in the country by the National Supplementary Health Agency (ANS). With the latest update in February 2021, ANS began granting access to VAB via ultrasound, stereotactics and magnetic resonance imaging in certain clinical contexts[4,5].

VAB is a safe, fast and effective technique for excising breast fragments, whose equipment basically consists of a biopsy needle coupled to a rotational cutter, a suction chamber and a device capable of creating a vacuum. The procedure is performed through a single incision in the skin, with the biopsy needle being inserted only once, since the material collected in each cycle is collected by suction into the reservoir chamber[6]. The effectiveness of VAB is based on its greater technical precision and broader sampling compared to core biopsy, since VAB needles range from 8G to 14G, with the capacity to collect between 40 mg and 300 mg of tissue per fragment, while core biopsy has an average collection of 17 mg of tissue per fragment[7].

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Explored in the context of breast biopsy for years, VAB has become a consolidated and improved technique, which culminated in the idea of also making it an option for therapeutic proposal for some types of breast lesions. With the approval of the FDA in 2002, vacuum-assisted excision, recognized by the abbreviation VAE, proposes the complete excision of breast lesions using needles larger in diameter than those used in VAB, but maintaining its outpatient nature, under local anesthesia to avoid surgical excision, whose complexity and costs are significantly greater[6,7].

METHODS

This study aimed to address the topic of vacuum-assisted biopsy and excision of breast lesions, with an emphasis on current indications for the procedure. The search was conducted in the PubMed, Medline, Embase, and Cochrane databases, using the following search terms: "Biopsy", "Large-Core Needle", and "Image-guided biopsy". Articles published between 2006 and 2023, in English and Portuguese that directly addressed breast biopsy and vacuum-assisted excision of breast lesions were included. The period from 2006 to 2023 was chosen to cover the development and consolidation of the techniques, considering from the approval of vacuum-assisted excision by the Food and Drug Administration (FDA) in 2002 to the most recent studies available. The inclusion criteria considered original articles, reviews, clinical practice guidelines, and relevant studies related to the topic. Duplicate publications, articles that dealt with techniques unrelated to the topic, and those unavailable in full text were excluded. The articles identified in the search were screened in two stages: initially, through the analysis of titles and abstracts; then, by reading them in full to determine if the inclusion criteria were met. After applying the inclusion and exclusion criteria, 20 articles were selected for analysis, considering their relevance and alignment with the objective of this study. In addition to the articles, the normative resolutions of the National Supplementary Health Agency (ANS) were analyzed, especially with regard to the coverage of procedures by supplementary health in Brazil, to complement the analysis on clinical applicability. Because this is a narrative review, the absence of systematic criteria and the subjective choice of articles may limit the reproducibility of the study and introduce biases. However, efforts were made to ensure the inclusion of relevant and updated publications, with the aim of providing a comprehensive and informative view on the topic.

RESULTS AND DISCUSSION

Core needle biopsy vs. vacuum-assisted biopsy

Core needle biopsy is the routine diagnostic method because it provides a quality diagnosis, is easy to perform, is minimally invasive and has a lower cost than surgical excision. In this scenario, both core biopsy and vacuum-assisted aspiration are feasible options, although the clinical decision to choose one or the other is sometimes not simple and carries doubts about the possibility of false negatives and diagnostic underestimation[8,9]. Compared to core biopsy, vacuum-assisted biopsy offers larger samples, lower false negative rates, lower rebiopsy rates and lower diagnostic underestimation[7,10]. In this scenario, the indications for vacuum-assisted aspiration have grown and have been reaffirmed by studies and positive statistical numbers.

Regarding concerns about false-negative results and diagnostic underestimation, the diagnostic upgrade rate is the parameter for comparison between methods. The upgrade rate is defined by the presence of malignancy after surgical excision of the lesion previously biopsied or during its clinical-imaging follow-up[11].

Regarding the use of VAB in the diagnostic investigation of breast lesions with malignant potential, comparative studies show that, in cases of atypical ductal hyperplasia, the diagnostic upgrade rate for ductal carcinoma ***in situ*** was reduced from 50% to 20%; but in cases of ductal carcinoma ***in situ,*** the diagnostic upgrade rate for invasive ductal carcinoma was 30% to 10%, when comparing the results of core biopsy and VAB, respectively[12].

Other studies analyzing the upgrade rate in VAB show variable trends towards malignancy in specimen analysis or in clinical follow-up. A retrospective study showed an upgrade rate of 0.4% and a confidence interval between 0.1% and 2.1% when analyzing lesions of uncertain behavior without atypia, while the upgrade rate for lesions of uncertain behavior with atypia, such as flat epithelial atypia, atypical ductal or lobular hyperplasia, and lobular carcinoma ***in situ***, was 4.7% with a confidence interval between 2.9% and 7.5%. The same study showed that the upgrade rate is significantly increased when two or more lesions coexist in the same biopsied area[11].

VAB has a higher cost per biopsy needle when compared to core biopsy needle; therefore, for lesions in which VAB is not the first method of choice, cost-effectiveness should be taken into consideration and core biopsy should be considered. On the other hand, in lesions for which VAB is used, the higher cost of the needle is outweighed by the benefits of diagnostic accuracy. Grady et al.[13] refers to a study conducted in 2015 reviewing data from the American Society of Breast Surgeons between 2001 and 2014, containing data from 31,451 patients, in which information on biopsy, rebiopsy, instrument used to perform the biopsy and the cost per breast cancer diagnosis in each situation were evaluated, using a linear mathematical model. The study resulted in an average cost per case diagnosed by core biopsy of $4,346 (4,327–4,366) and of $3,742 (3,732–3,752) to $4,779 (4,750–4,809) per VAB, with variation related to the brand of the device used. The study concluded that VAB would be more cost-effective, provided that the best-performing devices were chosen.

Vacuum-assisted biopsy vs. Vacuum-assisted excision

In addition to its investigative role, VAB also has an established therapeutic role. Unlike vacuum biopsy, which has a purely diagnostic purpose and does not require complete removal of the lesion, VAE aims to replace diagnostic surgical biopsy by removing the lesion in its entirety. The VAE technique stipulates that the aspiration be orthogonal, rather than oblique, to the lesion, and it also stipulates complete removal of the lesion and its periphery to ensure greater diagnostic accuracy[14]. To perform VAE, the needles used are larger in size, ranging from 7G to 10G, with the capacity to obtain large and varied amounts of tissue. There is no consensus on the size of the lesion to be approached, and according to Park et al.[15], there is no limit to the size to be excised, which should be guided by the characteristics of the lesion, its location and the patient's particularities. At the end of the procedure, radiological verification showing the absence of the target lesion is mandatory, as well as subsequent assessment of imaging and histopathological compatibility.

Vacuum-assisted excision vs. conventional surgical approach

VAE is a subject of broad debate due to the high variability in the rates of upgrade to malignancy of lesions treated with the technique. The defense of vacuum excision with subsequent clinical follow-up is based on the personalization of treatment and advocates the de-escalation of invasive procedures associated with strategies to not underestimate the patient's subsequent specific risk of developing breast cancer, while opposition to vacuum aspiration points to the lack of standardized protocols and robust evidence as factors that prevent the widespread use of the method[11]. Based on the BI-RADS (Breast Imaging Reporting and Data System) classification system, an upper safety limit can be inferred to be an underestimation rate of up to 2% after vacuum-assisted aspiration procedures, which would be equivalent to a lesion classified as BI-RADS 3, in terms of probability of malignancy. Therefore, breast lesions with upgrade rates ≤2% after the procedure – a group generally composed of lesions without atypia – would be eligible for clinical follow-up in to avoid surgical approaches subsequent to biopsy.

In cases of lesions with atypia, carcinomas *in situ*, invasive carcinomas and lesions with clinical-radiological-histopathological discordance, conventional surgery is mandatory in the therapeutic management, since vacuum aspiration violates the basic principle of oncological surgery, which is the ability to perform a single-block excision of the lesion, in addition to the possibility of evaluating the margins of the specimen, which must be free of neoplasia[8]. However, there are studies aimed at proving the role of excision by vacuum aspiration even in these scenarios.

Valadares et al.[16] published in 2023 a retrospective study evaluating data from 116 patients who underwent vacuum aspiration of BI-RADS 4, BI-RADS 5 breast lesions or lesions with a diagnosis of uncertain malignant potential (B3) in a previous core biopsy, with anatomopathological results of *in situ* or invasive breast carcinoma of the aspirated specimens. These patients subsequently underwent conventional surgery to evaluate the existence of residual disease, and the result of the study was promising, mainly for low or moderate grade pT1a and pT1b tumors, which provides data to support the selection of criteria for future prospective trials on the subject. Regarding data on cost and effectiveness, Whitworth et al.[17] conducted a retrospective cohort study, analyzing the amounts spent on the treatment of benign lesions and high-risk lesions treated by vacuum aspiration compared to similar lesions treated surgically. The study showed that VAE, in both the scenario of benign lesions and in the scenario of high-risk lesions, has a cost approximately 60% lower than the surgical approach, without compromising the quality of treatment.

Indications for vacuum-assisted biopsy

VAB has proven to be an accurate technique for treating suspicious breast calcifications, as shown in Figure 1, significantly reducing the need for rebiopsy (8), since this is a small breast alteration that can be seen primarily only on mammography, making core biopsy even more technically difficult and with less favorable success rates. The same logic applies to tiny, non-palpable lesions and intracystic lesions, for which core biopsy needle shots are less likely to be accurate in relation to the lesion and, therefore, have lower diagnostic sensitivity, making VAB the best option in this scenario[1,5,6]. With advances in imaging in the context of the breast, magnetic resonance imaging has become an important imaging method for detecting lesions suspected of malignancy. With an emphasis on lesions seen only by this method, areas of nodular or non-nodular enhancement, with no corresponding second-look ultrasound directed at such areas, have become lesions with indication for magnetic resonance-guided VAB[18]. Finally, some individual details of the cases make VAB

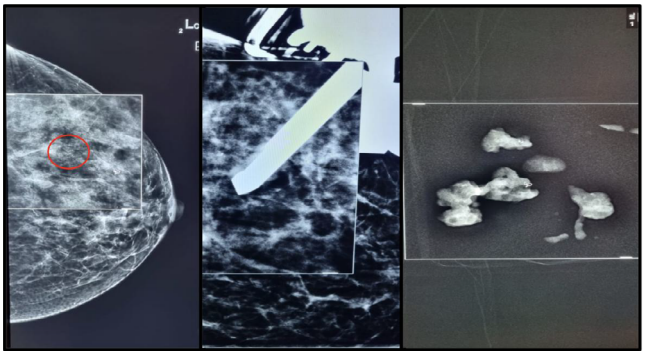

Figure 1. (A) Suspicious calcifications seen on mammography (red rim); (B) Image showing biopsy needle positioned below lesion; (C) Mammography image of biopsied tissue containing calcifications.

the method of choice, since, as it does not require triggering or advancement, it is safer when investigating nodules close to the chest, close to the skin, the nipple or implants[6].

Indications for vacuum-assisted excision

Regarding nodules that show growth, such as phyllodes tumor, studies demonstrate that VAE has a recurrence rate of 5% to 17% when evaluating lesions up to 3.3 cm, with lower recurrence rates in lesions less than 1.5 cm, which makes the procedure an alternative to surgery for benign tumors[19]. The method can be used to treat fibroadenoma, the most common benign breast tumor, with good results[10,12], and is also a potential treatment option for minor gynecomastia, for which there is no need for surgical reduction of the skin or the nipple-areola complex[20]. The indication for excision by vacuum aspiration extends to other breast lesions, such as radial scar and flat epithelial atypia, as long as they do not present atypia[14]. VAE is still the treatment used for intraductal papillary lesions, as show in Figure 2, with studies showing resolution in 97% of cases, in addition to preserving the viability of the function and sensitivity of the nipple-areola complex, which is often compromised after a conventional surgical approach[8]. However, it is important to emphasize that surgery is still the rule in cases of lesions with atypia, carcinomas in situ and lesions with clinical-radiological-histopathological discordance.

Complications

The possible complications of core biopsy and VAB are similar and are represented by hematoma, pain, infection, pneumothorax and skin injury. Hematoma is the main complication after vacuum-assisted aspirations, and small-volume hematomas do not require treatment. Surgery is necessary for hemostasis or debridement if there is suspicion of active bleeding or large-volume hematoma causing severe pain or secondary infection[5,10]. A 2019 retrospective study[21], including 4,776 patients undergoing VAB, identified complication in 6.7% biopsy cases. Of these, 96.2% were mild complications, which included hematoma that did not require treatment, mild pain, nausea, dizziness and itching or skin irritation, while only 3.8% were moderate complications, which included hematoma or bleeding requiring compressive treatment, vasovagal reaction or observation in the emergency room. Finally, in this study, no patient displayed serious complications, which would include post-biopsy infection, hematoma or bleeding requiring surgical treatment and death, arguing in favor of the safety of the method.

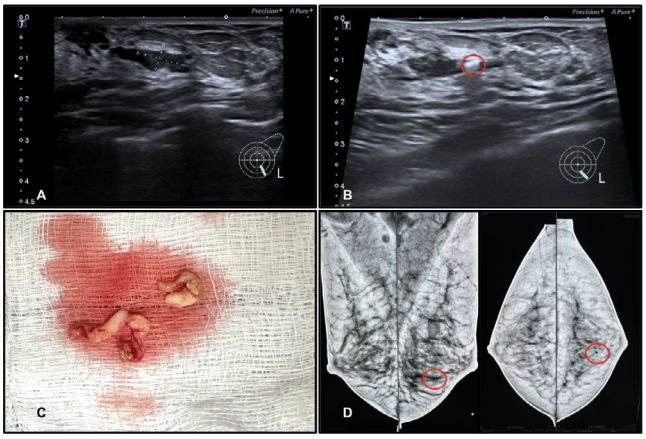

Figure 2. (A) Mixed intraductal lesion on USG; (B) Metal clip inserted after the procedure at the biopsy site (red rim); (C) Macroscopic image of the biopsied tissue; (D) Mammography image after the procedure with confirmation of clip at the biopsy site.

CONCLUSIONS

Vacuum-assisted aspiration has proven to be a highly valuable and potential procedure. Approved by the ANS in 2021, it is mandatory for health insurance plans to provide histopathological studies of non-palpable lesions, breast microcalcifications, intraductal or intracystic lesions suspected of being papillomas, nodular or non-nodular enhancements seen on magnetic resonance imaging, categorized as 4 or 5 in the BI-RADS classification, or in cases of nodules smaller than 2 cm, also categorized as 4 or 5 in the BI-RADS classification, in scenarios where doubts remain after core biopsy[4]. It is a comprehensive diagnostic and therapeutic method that because of its minimally invasive nature and association with high efficacy tends to contribute greatly to mastology[5,10,11]. Future studies will be essential to guide, on the basis of robust evidence, protocols that optimize the application of the technique for each type of breast lesion, ensuring greater precision and clinical benefit.

AUTHORS' CONTRIBUTION

LMACL: Conceptualization, Data curation, Methodology, Project administration, Writing – original draft, Writing – review & editing. GRA: Data curation, Formal Analysis, Supervision, Validation, Writing – review & editing. TPM: Data curation, Formal Analysis, Supervision, Validation, Writing – review & editing. JLCJ: Formal Analysis, Supervision, Validation, Writing – review & editing. EASA: Formal Analysis, Supervision, Validation, Writing – review & editing. RCSF: Formal Analysis, Supervision, Validation, Writing – review & editing. ADS: Formal Analysis, Supervision, Validation, Writing – review & editing. WJAJ: Formal Analysis, Supervision, Validation, Writing – review & editing. FMOC: Formal Analysis, Supervision, Validation, Writing – review & editing. JTCA: Conceptualization, Formal Analysis, Methodology, Project administration, Supervision, Validation, Writing – review & editing.

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