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VACUUM ASSISTED BREAST BIOPSY: EXAMINATION TECHNIQUE AND DIAGNOSTIC ACCURACY OF THE PROCEDURE

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Abstract

Vacuum Assisted Breast Biopsy (VABB) is an increasingly utilized technique for providing an accurate diagnosis of breast carcinoma, especially in cases where mammographic examinations yield indeterminate findings. The objective of this study is to examine the results of the VABB technique and evaluate its diagnostic accuracy. The study involves a retrospective analysis of stereotactic-guided biopsies performed at the Senology Unit of the "San Giovanni di Dio e Ruggi D'Aragona" University Hospital between 2021 and 2023. VABB is a safe and highly accurate procedure that allows for an adequate tissue sample to be obtained with a single needle insertion. In the case of suspicious or neoplastic cell-positive lesions, this procedure helps prevent diagnostic delays by detecting them early and allowing for prompt action. Moreover, in the case of benign lesions, it spares the patient from undergoing further, sometimes invasive, instrumental examinations.

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INTRODUCTION

Breast carcinoma is the most commonly diagnosed neoplasm in Italy, with approximately one malignant tumor in every three cases being breast carcinoma. It is estimated that there were about 55,700 new cancer diagnoses in women in 2022, representing a 0.5% increase compared to 2020 (9). However, despite the rising incidence, there has been a continuous decrease in mortality since the late 1990s, attributed to the wider implementation of screening programs and therapeutic advancements. Early-stage diagnosis allows for more intervention options (2).

Once a suspicious lesion is identified on mammography, further second-level instrumental characterization is performed. Until a few years ago, histological diagnosis was achieved through surgical biopsy, which required patient hospitalization, longer recovery times, higher costs, and left a visible scar on the patient's skin.

Today, the most widely used procedure is vacuum-assisted breast biopsy guided by stereotactic imaging. With the innovation of techniques, tomosynthesis can also be used as a guiding imaging modality, overcoming the limitations of tissue overlap and lesion masking, while reducing examination time and radiation dose (7).

VABB has now become the elective technique for obtaining a histological diagnosis of non-palpable or non-ultrasound-visible breast lesions, such as small opacities, calcifications, and structural distortions, which may indicate the presence of pathology (12).

With a single needle insertion, this technique allows for multiple sampling, necessary for characterizing the suspicious area and subsequently making a differential diagnosis, optimizing the diagnostic and therapeutic management of the patient.

This study is based on a case series of 58 patients who underwent Vacuum Assisted Biopsy at the "San Giovanni di Dio e Ruggi D'Aragona" University Hospital in Salerno.

Based on the clinical and instrumental indications, this study thoroughly analyzes the utilized technique, highlighting its advantages and limitations, with the aim of evaluating the reliability and precision of the method.

VACUUM ASSISTED BREAST BIOPSY UNDER STEREOTACTIC GUIDANCE

Vacuum-assisted biopsy is part of an invasive diagnostic procedure, thus a second-level examination. For this type of procedure, needles with gauges of 8, 9, 10, or 11 are used to retrieve tissue samples necessary for obtaining a histological diagnosis of the suspicious lesion.

This study will focus on vacuum-assisted breast biopsy under stereotactic guidance performed using Mammotome Revolve and ATEC Sapphire devices with ATEC and EVIVA handles on the Ho-

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logic Selenia Dimension mammography system.
The most important instrument for performing the biopsy is the needle, which, after precise targeting, is inserted into the patient's breast at the location of the lesion to be investigated. The biopsy needle has a variable length ranging from 9 to 13 cm and consists of a tip and the so-called "biopsy window." In particular, the needles used by the aforementioned systems are automatic needles with a scalpel tip, eliminating the need to make an incision with a scalpel on the patient's skin before inserting the needle. The access site is directly opened by the biopsy needle.
Other important features concern the opening from which the breast tissue is retrieved: the suction window. Its size can be adjusted according to the clinical case. In the case of superficial lesions, a reduction in size may be necessary to safely perform the procedure. Another feature is the ability to rotate 360 degrees.
The device used for performing stereotactic-guided breast biopsy is the mammography system (11). To enable the mammography system to perform a biopsy, additional components are added to it (Figure 1): a support for the biopsy needle that allows for movement in the x, y, and z planes to target the lesion accurately, a display to visualize the target coordinates, and a specially designed compression plate with an opening that allows access for the needle.
Furthermore, a needle control system is necessary, such as the ATEC Suros Sapphire console (Figure 2) or the Mammotome Revolve (Figure 3), which controls the needle's movements and enables the retrieval of tissue samples through suction.
Vacuum Assisted Biopsy is a procedure that allows for the retrieval of breast tissue samples to be subsequently analyzed for lesion characterization. This technique ensures high diagnostic reliability due to its specificity and high positive predictive value, which reduce inadequate examinations (4).
The execution of this procedure involves several phases, listed below:

Preparation of the room

Before the patient enters the room, it is recommended to perform quality checks, both daily for the mammography machine and specific to the biopsy system's accuracy.

Case evaluation

Based on the patient's previous mammograms, the radiologist and the radiology technician discuss the best approach, including the type of compression to be applied and the access point to optimize the biopsy and ensure patient comfort.
During this phase, a fundamental parameter must be considered: the stroke margin. The stroke margin is the distance between the tip of the needle in the post-fire position and the mammography detector or the skin surface opposite the needle entry point (Figure 4).

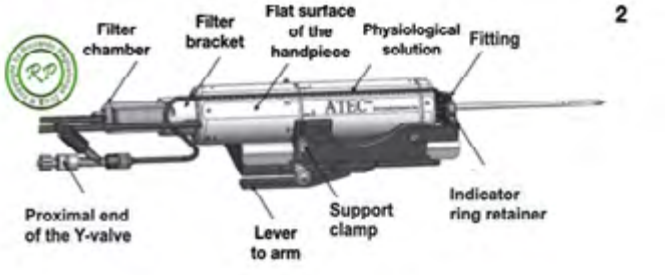

***Figure 1**. Representation of the mammography biopsy system. (Available online at www.3dimensionsmammography.eu)*

***Figure 2**. Representation of the ATEC Sapphire console.*

***Figure 3**. Representation of the Mammotome Revolve. (Available online at www.mammotome.com)*

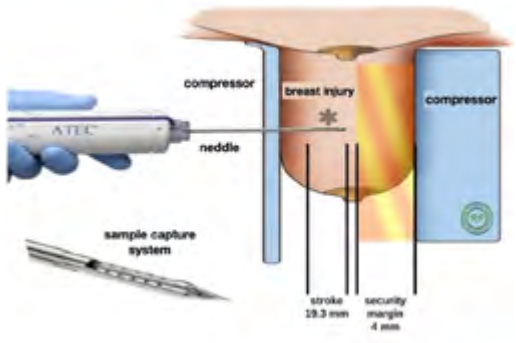

Figure 4. Positive stroke margin.

This parameter must always be ensured to ensure the procedure is performed safely. It should always have a positive value (at least 4 mm) to prevent the needle from surpassing the breast and impacting the sensitive plane (Figure 5).

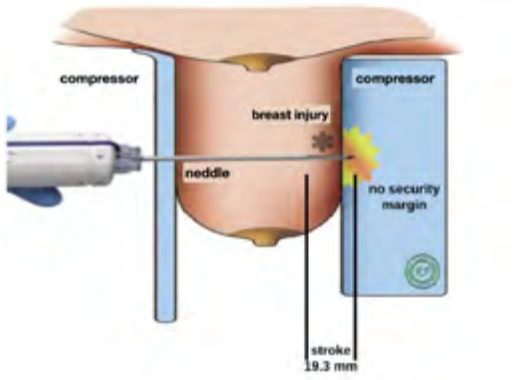

Figure 5. Negative stroke margin.

Patient acceptance and preparation

The patient is greeted by healthcare staff, their identification is verified using their name, surname, and date of birth. They are then asked to take a seat in the room, and the procedure is explained to them. Providing the patient with a detailed description of the procedure, including what will be done and what sensations they may experience, significantly reduces anxiety and concern, contributing to the success of the procedure itself. It is essential to obtain the patient's cooperation, and it is particularly important for them to remain as still as possible to prevent movement of the lesion. After signing the informed consent form, the patient is directed to the changing room where they are provided with a disposable gown with a front opening to wear. At this point, they are ready to enter the procedure room.

Positioning

The patient is seated on a special chair in front of the mammography machine, with the breast under examination placed on the sensitive plane of the equipment. At this point, the chosen compression is applied, aiming to position the lesion as centrally as possible within the dedicated compression opening.

Lesion targeting

The breast under examination is cleansed, and a scout image is acquired to verify the targeting. If the positioning is correct, an image is taken using tomosynthesis to determine the depth of the target. After the software processes the target's position, the three-dimensional coordinates and graphical representation of the breast thickness and lesion depth can be viewed on the monitor to assess the stroke margin. If the stroke margin is ensured, the examination can proceed, and the localization of the lesion is sent to the positioning device, which moves to the desired x and y coordinates. At this point, the anesthetic is injected to provide both surface and deep anesthesia. Another image is then taken to verify that the target, with the anesthetic injection, has not shifted. If any shifting has occurred, the target is repositioned, and the coordinates are sent to the positioning device again.

Biopsy procedure

The needle is inserted into the breast, guided down to the target (reaching a countdown of 0 for the z coordinate). To ensure that the needle tip is positioned at the lesion, two control X-rays are taken at -15° and +15° angles. This is called the pre-fire control (3). If the position is correct, the "fire" or "shot" can be initiated, which involves advancing the cutting needle so that the lesion is centered within the biopsy window (Figure 6). It is crucial at this moment to inform the patient about the loud noise they will hear and encourage them to remain as still as possible without getting scared. Following the needle advancement, a post-fire X-ray control is performed to verify that the biopsy window has reached the target site.

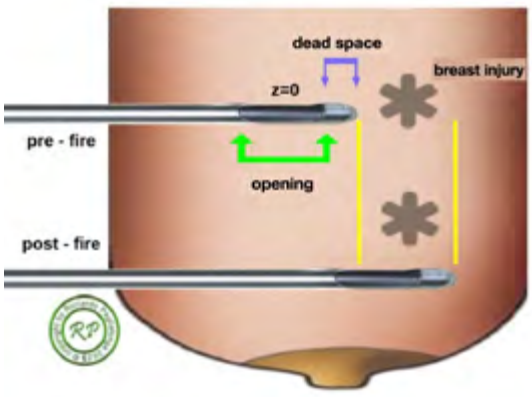

Figure 6. Needle position in "pre-fire" and "post-fire".

After confirming the correct needle position, the retrieval of 12 tissue cores can be performed using the rotational suction technique. As the needle

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gauge increases, the amount of aspirated tissue also increases. The 10-gauge needle samples the even-numbered chambers first, followed by the odd-numbered chambers, while the thicker 8-gauge needle requires alternating sampling in sets of three. Once the tissue samples have been collected, the biopsy cavity is flushed to minimize the risk of hematomas (5).

Placement of the clip

After performing the biopsy, a non-magnetic metal clip is placed at the site of the tissue retrieval. The proper positioning of the clip is verified by acquiring two projections at +15° and -15° angles.

Final dressing

The patient is instructed to lie in a supine position, and a compression with ice is applied to the biopsy site for approximately ten minutes to reduce potential bleeding. Subsequently, the nurse dresses the needle entry site and advises the patient to get dressed. The patient is then discharged, with instructions to rest the arm on the same side as the biopsy and use ice to reduce the risk of hematoma. The patient is reminded of the timeline for histological analysis and the communication process for receiving the report.

Radiographic control of the tissue cores

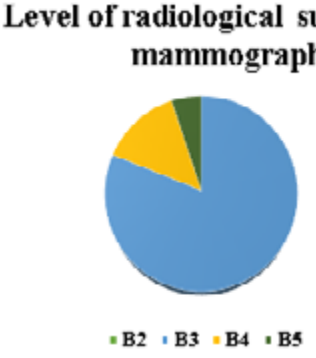
If the biopsy was performed for microcalcifications, the radiologic technologist performs an X-ray of the tissue cores to ensure they contain the calcifications. However, if the procedure was conducted for indications other than microcalcifications, the biopsy specimens are directly placed in formalin for fixation and preservation until they reach the pathology laboratory.

Advantages and disadvantages

Vacuum-assisted biopsy guided by stereotactic imaging offers the advantage of obtaining a significant number of tissue cores through a single needle insertion. The use of forced suction ensures the integrity of the samples and eliminates residual blood. This state-of-the-art system serves as an alternative to surgical biopsies, providing minimally invasive diagnostic results that are comparable in accuracy. The procedure can be performed on an outpatient basis or in a day surgery setting, without the need for an operating room, resulting in significantly lower costs. Furthermore, patients benefit from being able to return home immediately without requiring hospitalization. This is a significant advantage compared to surgical biopsies, which typically involve hospital stays and longer recovery times. Another benefit is related to scarring: surgical biopsies often require sutures, leaving noticeable scars on the patient's skin. In contrast, with vacuum-assisted biopsy, the needle entry site is very small, and the wound can be covered with simple Steri-Strip adhesive strips, resulting in minimal scarring.
The main limitation of this method is the size of the breasts. In cases where small breasts do not provide a 4 mm safety margin after compression, it may not be possible to safely perform the biopsy. Another limitation is the presence of marginal lesions: superficial lesions located too close to the skin or deeply situated lesions near the pectoral muscle.

Materials and Methods

In the study conducted on Vacuum Assisted Breast Biopsy guided by stereotactic imaging, 58 patients were included. These patients were followed at the Senology Unit of the "San Giovanni di Dio e Ruggi D'Aragona" University Hospital between 2021 and 2023. These patients had suspicious or indeterminate lesions identified on mammography, for which further diagnostic investigation such as biopsy was deemed necessary. Radiological suspicion levels were assigned to the lesions based on the BI-RADS classification, ranging from B3 to B5. The patients were classified as follows: B3 in 47 patients, B4 in 8 patients, and B5 in 3 patients.

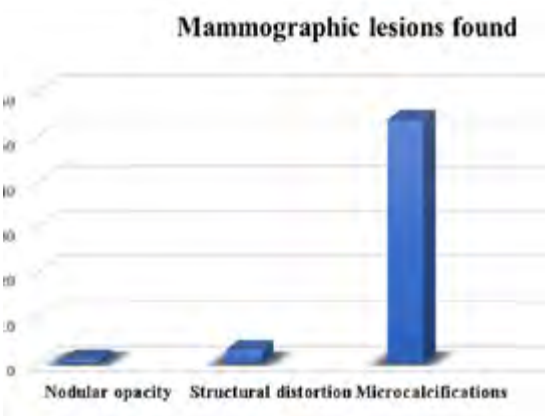


BI-RADS	NUMBER OF PATIENTS	PERCENTAGE
B2	0	0%
B3	47	81%
B4	8	14%
B5	3	5%

The age of the patients was less than 40 years in 2 patients, between 40 and 50 years in 18 patients, between 50 and 60 years in 22 patients, between 60 and 70 years in 13 patients, and over 70 years in 3 patients.

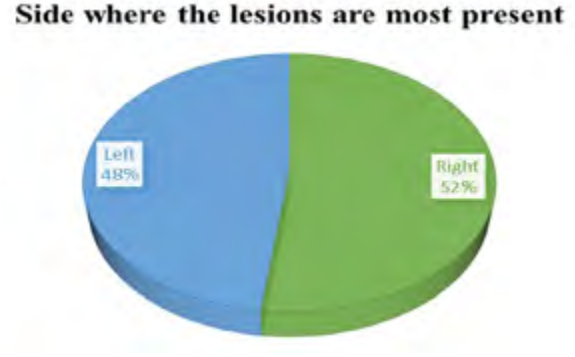
AGE	NUMBER OF PATIENTS	PERCENTAGE
< 40 years	2	4%
Between 40 and 50 years	18	31%
Between 50 and 60 years	22	38%
Between 60 and 70 years	13	22%
>70 years	3	5%

The most commonly observed mammographic lesions were: microcalcifications in 54 patients, structural distortion in 3 patients, and nodular opacity in 1 patient.



LESIONS	NUMBER OF PATIENTS	PERCENTAGE
Microcalcifications	54	93%
Structural distortion	3	5%
Nodular opacity	1	2%

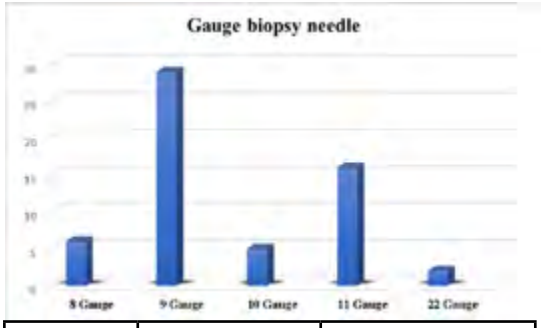
The lesions occurred in the right breast in 52% of cases and in the left breast in the remaining 48% of cases.



SITE	NUMBER OF PATIENTS	PERCENTAGE
Right	30	52%
Left	28	48%

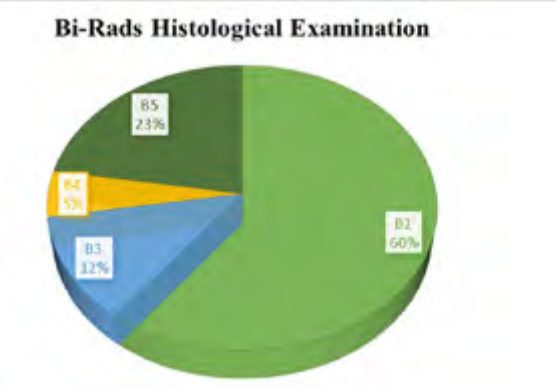
Results and Discussion

Based on the type of mammographic abnormality, lesion location, and patient's body mass index, the size and type of biopsy needle were selected: 8 Gauge in 6 patients, 9 Gauge in 29 patients, 10 Gauge in 5 patients, 11 Gauge in 16 patients, and 22 Gauge in 2 patients. In these two patients, a 22 Gauge needle, which is a cytology needle, was used because the size of their breasts did not allow for safe biopsy sampling. Therefore, it was deemed appropriate to perform a cytology procedure under stereotactic guidance using a small-gauge needle instead of a biopsy.



GAUGE NEEDLE	NUMBER OF PATIENTS	PERCENTAGE
8 Gauge	6	10%
9 Gauge	29	50%
10 Gauge	5	9%
11 Gauge	16	28%
22 Gauge	2	3%

To mark the biopsy site, clips called HydroMARK, MammoSTAR, and Tumark were inserted. After each biopsy performed for calcifications or lesions associated with them, the Radiology Technician conducted a radiograph of the biopsy samples to verify the proper retrieval of tissue and the presence of microcalcifications. The success rate was 100% as calcifications were identified in at least one sample in every control radiograph. The biopsy specimens (at least 12 tissue cores) were placed in formalin and sent to the Pathology Laboratory of "San Giovanni di Dio e Ruggi D'Aragona" Hospital for histological analysis. The pathology report includes an analytical description of the identified lesion and its classification according to BI-RADS guidelines (ranging from B1 for normal tissue to B5 for carcinoma). In our study, out of 58 patients, they were classified as B2 in 35 patients, B3 in 7 patients, B4 in 3 patients, and B5 in 13 patients.



BI-RADS	NUMBER OF PATIENTS	PERCENTAGE
B2	35	60%
B3	7	12%
B4	3	5%
B5	13	23%

Based on the collected data, the diagnostic accuracy of our procedure was estimated by comparing the radiological suspicion level assigned after the suspicious mammogram and the histological diagnosis obtained after the analysis of biopsy samples.
The study revealed the following: in 10 cases, there was concordance between the BI-RADS assigned to the suspicious mammogram and the histological diagnosis result; in 14 cases, the histological examination revealed a carcinoma (BI-RADS 5) that was underestimated on mammography; and in the remaining 34 cases, the patients were downgraded after the histological examination results.
Vacuum Assisted Breast Biopsy (VABB) under stereotactic guidance is a highly reliable technique that provides a diagnosis for breast abnormalities that may indicate pathology. It is an accurate and clinically useful method that supports therapeutic decisions. The use of this technique has significantly reduced the number of surgical biopsies, resulting in lower costs and considerable advantages in terms of patient compliance. It is particularly beneficial for the evaluation and histological characterization of microcalcifications, which are the main indication for the procedure.
Based on the data obtained from our study, it is evident that this examination, performed under stereotactic guidance using Mammotome Revolve and ATEC Suros Sapphire devices on a Hologic Selenia Dimensions mammography system, has a high diagnostic accuracy. The mammographic abnormalities presented by the patients, who subsequently underwent biopsy, were mainly microcalcifications (93%), followed by structural distortion (5%) and nodular opacity (3%). The right breast was the predominant site (52%). Needle gauges used for biopsy included 8 Gauge (10%), 9 Gauge (50%), 10 Gauge (9%), 11 Gauge (28%), and 22 Gauge (3%). The larger gauge needle (8 Gauge) was used when analyzing larger lesions to obtain a sufficient tissue sample. Smaller gauge needles (10-11 Gauge) were used for small, well-defined lesions or in cases with a smaller stroke margin. The 22 Gauge needle, a cytology needle, was used in two cases where a cytology examination under stereotactic guidance was preferred to assess positivity or negativity, rather than a biopsy, due to the small breast size.
The selection of clips was based on their intrinsic characteristics, such as ultrasound visibility, needle gauge, and lesion location. The most commonly used clips were Hydromark, followed by Tumark and Mammostar.
The diagnostic accuracy of this procedure has proven to be high, thanks in part to the excellent work performed by the team in various stages of the procedure. The nursing, medical, and technical staff ensure excellent patient management, precise lesion targeting, and consequently, accurate diagnostic results. The sampling is performed by the radiologist, with lesion targeting performed by the Radiology Technician, in the area where the lesion has been identified.
It can be stated that this procedure essentially has two main purposes: to early identify malignant lesions, preventing any diagnostic delays, and to avoid unnecessary surgical interventions in cases of clearly benign lesions. In our study, by comparing the radiological suspicion level assigned after the initial mammography and the BI-RADS of the histological examination, it emerged that this method is capable of providing an accurate estimation of the malignancy grade of the neoplasm, allowing the identification of lesions that were underestimated in the initial assessment and later revealed to be carcinomas. This was observed in 24% of cases, and thus, thanks to the sensitivity of this method, malignant lesions could be quickly identified, enabling timely intervention with the most suitable surgical procedure and therapy. The most appropriate treatment for malignant neoplasms depends on several parameters, such as macroscopic characteristics and extent of the lesions, tumor type, degree of differentiation, and prognostic factors.
In another 59% of cases, the mammographic examination overestimated the lesions, resulting in a lower BI-RADS on histological examination than initially assigned after mammography. The identified lesions were clearly benign, without the need for any further treatment. The patients were reassured and advised to undergo regular clinical and instrumental follow-ups.
In the remaining 17% of patients, the histological biopsy result confirmed the BI-RADS assigned on mammography. In these cases, a B5 category had already been assigned, and the examination was primarily performed to determine the receptor status and accordingly select the best treatment option.

Conclusions

The purpose of this study was to evaluate the diagnostic accuracy of Vacuum Assisted Breast Biopsy (VABB) and analyze its technique. A total of 58 patients who underwent the aforementioned procedure at the "San Giovanni di Dio e Ruggi D'Arago-

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na" University Hospital were included in the study. The patients were divided based on the indication for the examination, as well as other aspects such as the motivation for the examination, type of needle used, and type of clip used.

From a technical perspective, the use of a state-of-the-art mammography system with tomosynthesis provided numerous advantages for performing the biopsy. The most significant advantage was the precise lesion targeting achieved by the Radiology Technician. This ensured accurate targeting of the lesion in every instance during the procedure. It was possible to confirm this accuracy with specimen radiography in cases of biopsies performed for calcifications or lesions associated with calcifications, where calcifications were present in at least one specimen in 100% of cases. These new technologies also allowed for shorter exposure times and consequently reduced radiation dose, making the procedure faster and more tolerable for the patient. The Radiology Technician plays a crucial role in this procedure as the healthcare professional responsible for lesion targeting and all subsequent checks to verify the correct execution of the procedure, following the physician's instructions. The accuracy of the method was evaluated through a comparative method, where the assigned Breast Imaging-Reporting and Data System (BI-RADS) category after the initial suspicious mammogram was compared with the histological examination result obtained from the biopsy. It was observed that the histological examination enabled the identification of carcinomas (BI-RADS 5) that were underestimated in the initial mammographic assessment, which assigned a lower BI-RADS category, as well as the downgrading of lesions that were initially assigned a higher BI-RADS category compared to the histopathological result.

This study revealed that Vacuum Assisted Breast Biopsy is a technique with high diagnostic reliability, allowing for a differential diagnosis among various breast pathologies. Performing VABB reduces the rates of histological underestimation, as it provides larger samples with a higher retrieval rate. In many cases, complete removal of the lesion is achieved, reducing or eliminating sampling errors, decreasing the likelihood of histological underestimation, and reducing the need for rebiopsy. The experience of the dedicated team and the characteristics of the equipment used have allowed for precise sampling, which reflects on the accuracy of the diagnosis. As the diagnosis supports clinical and therapeutic decisions, it enables optimal determination of the most suitable therapeutic approach for each patient.

In the case of suspicious or neoplastic cell-positive lesions, this procedure helps prevent diagnostic delays by detecting them early and allowing for prompt action. For benign lesions, it spares patients from undergoing further unnecessary instrumental examinations or surgeries. Therefore, it can be concluded that Vacuum Assisted Biopsy performed with precision, speed, and usefulness in defining the diagnostic and therapeutic pathway based on the histological outcome. The high accuracy, low cost, and minimal complications associated with this method make it an excellent alternative to surgical biopsies and an effective way to characterize suspicious areas.

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