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Original Article

INTRODUCTION OF STEREOTACTIC VACUUM-ASSISTED BREAST BIOPSY IN BULGARIA

Ivelina Y. Petrova-Burdzheva,
Martin P. Karamanliev,
Daniela P. Simova¹,
Dobromir D. Dimitrov

*Department of Surgical Oncology,
 Medical University - Pleven, Bulgaria
¹Third Clinic of Anesthesiology, Dr.
 Georgi Stranski University Hospital,
 Pleven, Bulgaria*

Summary

Breast cancer is the most common cancer in women worldwide. The gold standard for biopsy is core needle biopsy. However, in certain cases, core needle biopsy cannot be applied, and the method of choice is vacuum-assisted biopsy. It is a minimally traumatic and precise method for diagnosing microcalcifications and small breast lesions. We aimed to present the initial experience with stereotactic vacuum-assisted biopsy in breast diseases at the Department of Surgical Oncology. We show indications and contraindications for this kind of biopsy and present our initial experience. From February 2020 to December 2022, 29 stereotactic vacuum-assisted biopsies were performed. Benign histology was found in 9 cases, malignant – in 15, and 5 cases were precancerous. Therefore, being an innovative, minimally invasive, and highly accurate method for diagnosing breast lesions with a good cosmetic effect, it allows early diagnosis of breast cancer, and, last but not least, the procedure can be curative for benign lesions.

Keywords: stereotactic vacuum-assisted breast biopsy, microcalcifications, breast cancer

Introduction

The Global Cancer Observatory (GLOBOCAN) 2020 database establishes breast cancer as the most common malignant neoplasm and the most common cause of death in women worldwide. There are 2.3 million new cases and nearly 700 000 deaths worldwide, estimated for 2020. The latest cases in Bulgaria for 2018 were 4016 and the deaths – 1387 [1, 2].

Early diagnosis is associated with a better prognosis. Therefore, modern efforts aim to prevent, diagnose, and treat the disease at an early stage before its clinical manifestation. Diagnosing and treatment follow national and global algorithms based on a multidisciplinary

Corresponding Author:

Ivelina Yurieva Petrova-Burdzheva
e-mail: ivelina_jurieva@abv.bg

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approach [3-5]. Mammography is the primary radiological method for breast cancer diagnostics [2]. New technologies - 3D and contrast-enhanced mammography provide even better and more precise visualisation. Echomammography and magnetic resonance imaging play a key role in diagnosing mammary gland malignant neoplasms [2]. After an imaging test, the result is evaluated according to the BI-RADS system, and subsequent procedures could be carried out to clarify the finding [2]. Lesions scored as BI-RADS 4 or 5 are recommended for biopsy and histological verification. The gold standard for breast cancer diagnostics is core needle biopsy, which can be performed under manual or imaging guidance [2-5, 12]. However, sometimes core needle biopsy cannot be applied, as in cases of non-palpable or too small palpable lesions or clustered microcalcifications [6-8, 11, 12]. Vacuum-assisted biopsy - a cutting-edge, minimally traumatic, and precise method for diagnostics of suspected malignant lesions could be the method of choice. Also, it is applicable in precancerous and benign breast conditions [6-8]. In 1995, Mark Retchard (medical engineer) and Fred Burbank (radiologist) developed the vacuum-assisted biopsy technique, and shortly afterwards, it was introduced in practice [6].

Our study aims to present the initial experience with stereotactic vacuum-assisted biopsy in mammary gland diseases at the Department of Surgical Oncology at Dr. Georgi Stranski University Hospital.

Materials and Methods

From February 2020 to December 2022, in the Department of Surgical Oncology, 29 stereotactic vacuum-assisted biopsies were performed in collaboration with X-ray technicians. The patients in the study were selected according to the criteria presented in Table 1.

Indicated for stereotactic vacuum-assisted biopsy are patients with BI-RADS 4 mammography description with microcalcifications, non-palpable or very small palpable lesions (<5 mm); atypical or unclear histology by the core needle biopsy; BI-RADS 3 description from the mammography; hard-to-reach lesions - near the papilla, chest wall or axilla; atypical or borderline lesions (precancerous), papillomas, atypical ductal hyperplasia, and mucinous lesions [7, 8]. Contraindications for stereotactic vacuum-assisted biopsy are lesions not seen on mammography), anticoagulant/antiplatelet therapy, abnormal coagulation, previous excision, and inability to position the breast on the device [10]. The risk of bleeding and postoperative hematoma is higher in anticoagulant or antiplatelet therapy patients. Anticoagulant/antiplatelet therapy should be discontinued to perform biopsy. Contraindicated are also women who could not assist in carrying out the procedure (uneducated, mentally ill, etc.). In these patients, general anesthesia and wire-guided breast excision are recommended. A special device (Brevera Biopsy Sistem) adapted to the mammograph (Siemens – Mammomat Inspiration) is needed from a technical point of view (Figure 1).

After calibrating the device, the breast is positioned on the mammograph. The system software allows for a precise biopsy needle direction in three dimensions due to the two images (+ 30 and – 30 degrees of the breast) taken before needle positioning. After an accurate position selection on the software, the stereotactic device localizes the needle position and the tip of the needle just as selected on the software. A local anesthetic is applied. Next comes the skin incision - about 2-3 mm, and the procedure itself. An aspiration biopsy is performed using a 9G factory-made needle and an aperture of 12 or 20 mm (Figure 2).

Table 1. Indications and contraindications for stereotactic vacuum-assisted biopsy

Indications	Contraindications
grouped microcalcifications – BI-RADS 4	lesions non-visible at mammography
non-palpable, X-ray positive lesions – BI-RADS 4,5	inability to position the breast to perform the biopsy
atypical/unclear histology from core needle biopsy	anticoagulants/antiplatelets intake
hard-to-reach lesions	abnormal coagulation
atypical/borderline lesions	non-cooperative patients for conducting the biopsy
lesions described as BI-RADS 3	



Figure 1. Mammograph and stereotactic vacuum-assisted biopsy equipment

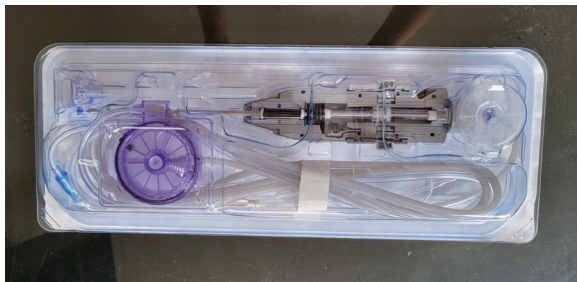


Figure 2. Biopsy needle for stereotactic vacuum-assisted biopsy

The tissue cylinders are aspirated, and each one is visualized radiologically at the time of the procedure by an X-ray device inside the Brevera biopsy system (Figure 3).

This allows for early confirmation if the desired area is taken for examination. The patient is under local anesthesia during the whole process. The procedure finishes with lavage and sterile dressing. The biopsy taken is sent for histological verification (Figure 4).

Following the guidelines, all the patients we investigated signed informed consent and underwent mammographic examination. All had positive X-ray findings. A stereotactic vacuum-assisted biopsy was taken and sent for histology.



Figure 3. Tissue cylinders: material for histology

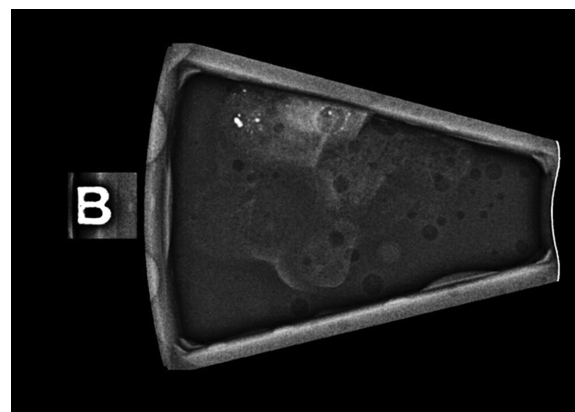


Figure 4. Tissue cylinders: X-ray image

The study was approved by the Ethics Committee of Scientific Research of Medical University – Pleven (Approval Code: 610-CENID/21.01.2020) and was conducted in accordance with the Declaration of Helsinki.

Results

The average age of the patients included in the study was 56.1 ± 5.5 years. Three of them had BI-RADS 3 findings from mammography, 24 - BI-RADS 4 findings (22 microcalcifications, 2 non-palpable lesions), and 2 had BI-RADS 2 findings (Figure 5). The average procedure time

Distribution of patients according to mammographic findings

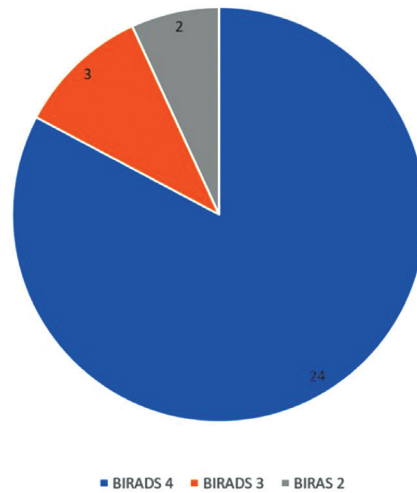


Figure 5. Distribution of patients according to mammographic findings

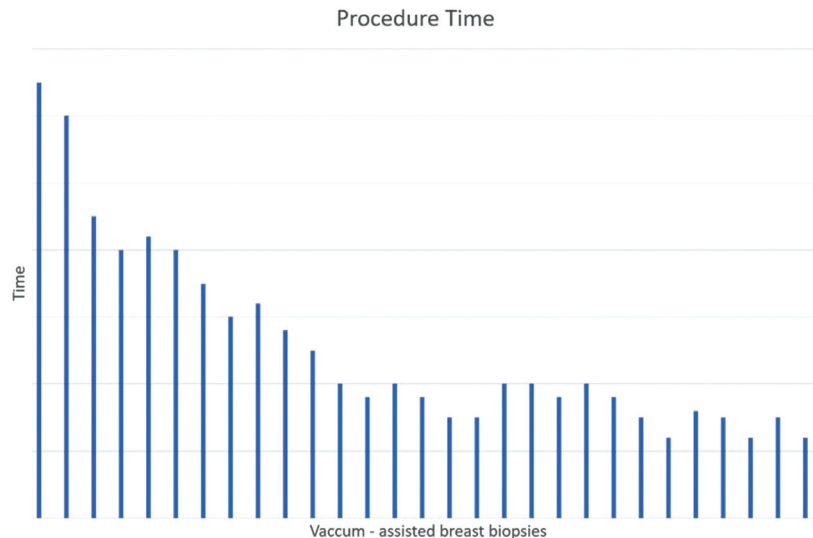


Figure 6. Procedure time

of the entire intervention was 25.2 ± 4.2 minutes (Figure 6). Throughout the learning curve, it decreased significantly. The last biopsies took 12-15 minutes. The time to calibrate the device, the actual biopsy taking time, and the time after the actual biopsy was performed were studied. A 9G biopsy needle with a 12 mm aperture was used in 8 of the biopsies. A 9G biopsy needle with a 20 mm aperture was used in 21 of the biopsies.

Repositioning was done on one patient, and the standard biopsy was then conducted. In 9 of the biopsies, the histology was benign, 15 of the histologies were malignant, and 5 were precancerous. The procedure was curative

for one of the patients with benign histology (fibroadenoma); the entire lesion was removed. In this case, there were clinical, mammographic, and ultrasound data for fibroadenoma. The whole lesion was removed during the vacuum-assisted biopsy, and the control mammography during the procedure confirmed this. Follow-up examinations once again confirmed the removal of the entire lesion. Fourteen of the patients with breast cancer were in the first stage, one – in the second stage. All cases were presented at a board meeting, and decisions were made for further treatment. The patient in the second stage was referred for neoadjuvant chemotherapy, and the others were offered surgical treatment. Thirteen

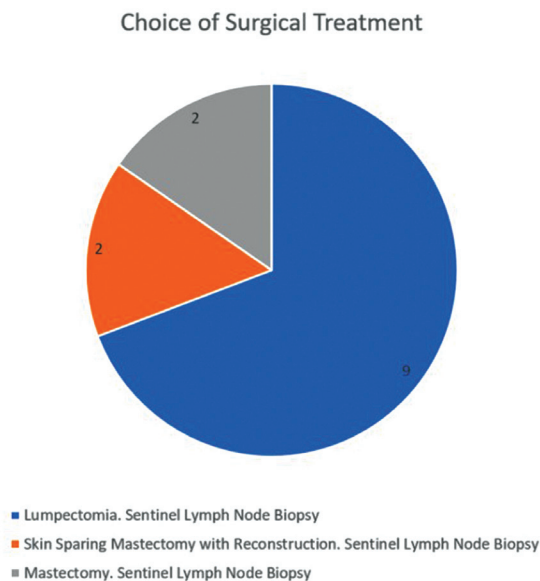


Figure 7. Choice of surgical treatment

women chose surgical treatment by our team, and one chose another. The surgical intervention was selected according to contemporary standards and with patient participation (Figure 7).

Currently, there is no data on relapse or persistence in the follow-up patients. The women with precancerous lesions and benign lesions underwent follow-up examinations.

Complications reported in the literature are not frequent [11]. They are associated with pain during or after the procedure, bleeding, hematoma, and infection [6-8, 10]. They are comparable to the complications of core needle biopsy. One of the patients in our trial had a post-procedure hematoma (Clavien Dindo grade I).

Discussion

Vacuum-assisted biopsy is a relatively new method with a significant role in diagnosing and treating mammary gland lesions. A vacuum-assisted biopsy can be performed under ultrasound, mammography, or MRI control [7, 8, 13]. Numerous studies have classified it as

a reliable, minimally invasive, and effective method [6-8]. A vacuum-assisted breast biopsy is included in national and world standards to diagnose and treat precancerous, benign, and malignant lesions [3-5]. Its main application is related to the histological verification of non-palpable lesions and microcalcifications, for which it has become the gold standard for diagnosis and the treatment of benign formations in the mammary glands [7-9]. The main application is related to the histological verification of non-palpable lesions and microcalcifications suspicious for malignancy and the treatment of benign formations in the mammary glands. The conventional method for diagnosing small, non-palpable lesions or microcalcifications is by marking them with a wire, followed by surgical excision guided by the wire under imaging control of the excised material to objectify whether we have accurately removed the target area. Vacuum-assisted biopsy has undebatable advantages over wire-guided excision biopsy (Table 2).

A conventional excision biopsy is usually

Table 2. Advantages of stereotactic vacuum-assisted biopsy over wire-guided excision biopsy

Characteristics	Vacuum-assisted breast biopsy	Wire-guided excision biopsy
Type of anesthesia	Local	General
Skin incision	2-3mm	3-4cm
Cosmetic effect	Perfect	Unsatisfactory
Time	Over 30 min	Under 30 min

performed under general anesthesia, while a vacuum-assisted biopsy is performed under local anesthesia, which is more sparing to the patient. In the case of excisional biopsy, the surgical intervention takes longer because, during the surgical stage, we wait to take an x-ray of the sample, while in the case of stereotactic vacuum-assisted biopsy, the x-ray image goes synchronously with the biopsy. The removed breast parenchyma in vacuum-assisted biopsy is much smaller and associated with less postoperative pain with better cosmetic effects. Because of the facts mentioned above, a vacuum-assisted biopsy is undoubtedly both tissue-sparing and adequate; therefore, it is the method of choice in these cases. Apart from diagnostic purposes, a vacuum-assisted biopsy can also be a curative procedure, providing a significant advantage for women with benign lesions [8, 14-16]. The entire lesion is aspirated in such cases. The definite clinical and imaging data for a benign formation (most often fibroadenoma) gives the patients a choice between stereotactic vacuum-assisted biopsy and surgical intervention. In terms of time, the procedure is a fast method. However, going through the learning curve is necessary to achieve the best possible results, as was the case with our team.

Conclusion

Performed by an experienced team, stereotactic vacuum-assisted biopsy has undeniable advantages for patients. Being an innovative, minimally invasive, and highly accurate method for diagnostics of breast lesions with a good cosmetic effect, it allows early diagnosis of breast cancer, and, last but not least, the procedure can be curative for benign lesions.

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