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Mammotome biopsy in the diagnostic management of non-palpable breast pathologies

Biopsja mammotomiczna w diagnostyce niepalpacyjnych zmian patologicznych piersi

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Summary

Background: The aim of the study was to determine the effectiveness of mammotome biopsy (MB) in detecting preclinical breast pathologies.

Material/Methods: The material consisted of 847 women, of whom, based on mammography and ultrasound, 349 patients were referred to have stereotactic mammotome biopsy (SMB) guided by digital mammography and 498 women were subjected to hand-held mammotome biopsy (HHMB) guided by US.

Results: Ultimately, MB was done in 819 women. In all cases where breast carcinoma or atypical ductal hyperplasia (ADH) were detected, the patients were operated on and postoperative histopathology was treated as the reference for post-biopsy histopathology. Patients in whom post-MB histopathology detected benign lesions were subjected to a strict long-term follow-up using imaging studies. Ultimately, thanks to MB, 94 cases of breast cancer (12%) were detected as well as 725 (88%) cases of benign lesions, which corresponds to a sensitivity of 98.9% and 100% specificity.

Conclusions: MB is an alternative to surgical biopsy in differentiating preclinical breast lesions. It is associated with a minimal risk of complications and may be successfully performed in an outpatient setting.

Key words: mammotome biopsy • vacuum assisted core needle biopsy • pre-clinical cancers: non-palpable breast lesions

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Background

The incidence and mortality rates of breast cancer are on the steady and fast increase in Poland. The incidence coefficients increased from 14.6% in 1963 (the standardized incidence per 100,000 inhabitants) to 35.3 % in 1995; in the same period, mortality increased from 9.3 to 16.3%. Concurrently, in 2000, the 5-year relative survival rate for the entire country was below 50%. In countries where effective systems of early breast cancer detection have been introduced, the rates of 5-year survival range from 72.5% to 78.9% (Europe and the US, respectively) [1, 2].

The notion of "early detection" encompasses both the detection of tumors in their earliest stages (preinvasive carcinoma) and as early as possible detection of all malignancies, what is understood as the body of activities aiming at detecting a neoplastic lesion (regardless of its stage) earlier than it would be revealed without such activities. The difficulty lies in pinpointing the presence of tumors when they are in the above-described early stage. It is a difficult task, as they are usually less than 1 cm in size, non-palpable, and may be detected only by diagnostic imaging. On the other hand, establishing the diagnosis of preinvasive carcinoma – *ductal carcinoma in situ* (DCIS) while it is still

a non-palpable lesion, less than 1 cm in size, results in the 100% cure rate [3, 4]. The detection of grade 1 invasive carcinoma (IC) (T1,N0,M0 according to the TNM classification), i.e. a tumor up to 2 cm in size, offers a 90% chance for a complete recovery [5].

The symptoms of preclinical carcinoma that are usually seen in imaging studies include microcalcifications (42%), small nodules (39%) and abnormalities of the mammary gland architecture (19%). Today, in the case of these pathological lesions (i.e. small and non-palpable), there is no sufficiently effective method of biopsy verification available other than surgical intervention [6].

Fine needle aspiration biopsy (FNAB) is characterized by a relatively low sensitivity, even as low as 53% [7]; additionally it does not afford for determining the grade of a tumor. Core needle biopsy (CNB), although its effectiveness is higher when compared to FNAB, yields results that are closely dependent on the volume of collected tissue; during a standard biopsy this necessitates the breast to be punctured several times with a core needle (14-11 Ga) [6]. The sensitivity of CNB, depending on the clinical experience, ranges from 53 to 94% [8].

A method that so far has been yielding the best results, i.e. one that has the sensitivity and specificity that approximate 100%, is open surgical biopsy. In the case of non-palpable lesions, it is performed with a prior insertion of a location needle under ultrasonographic or mammographic guidance. The procedure is performed in the operating room and thus is relatively expensive. In addition it is always associated with breast deformation (a tumorectomy scar), a risk of infection and at least 1–3 days absence from work.

In view of the above considerations, in the last few years the key issue has been the development of a new, relatively non-invasive method allowing for a reliable detection of preclinical breast cancers.

The aim of the present investigations is the assessment of the effectiveness of core needle vacuum-assisted biopsy – Mammotome biopsy (MB), guided either by ultrasonography or digital mammography, in differentiating suspect preclinical breast lesions.

Material and methods

The material consisted of 847 women aged 32–72 years of life (mean age, 56 years) seen at the Regional Center of Early Diagnostic and Therapeutic Management of Breast Diseases, whose were referred to MB. All these patients had been subjected to clinical examinations, comparative mammography and ultrasound. When mammography detected microcalcifications and structural distortions, magnified spot images were additionally obtained.

All the thus revealed lesions were undetectable by physical examination and their size at the longest dimension did not exceed 1 cm.

Depending on the imaging method that allowed for a more precise visualization of the suspect lesion, the patients were divided into two groups:

– Group 1 consisted of 349 females referred to digital mammography-guided MB. Of this number, the procedure was ultimately employed in 323 patients (93%). In 26 cases (7%), the biopsy could not have been accomplished for the following reasons: the location of the lesion was too close to the digital detector, what posed a risk of hitting its surface with the needle (10 patients), the lesions was situated too superficially with respect to the skin surface, what rendered the complete introduction of the biopsy chamber into the breast impossible (14 women), and no consent for MB was given (2 females) (Table 1). In this group, pathological lesions where biopsy was indicated included: suspicious microcalcifications (N = 257; 79%), structural distortions in the form of asymmetric abnormalities of breast architecture (N = 42, 13%) and masses with irregular shapes, not observed in previously performed ultrasonography (N = 24, 8%).

– Group 2 included 498 patients, who were referred to ultrasonography-guided MB. Of this number, biopsies were ultimately performed in 496 women (99.6%). The remaining two females (0.4%) refused their consent (Table 1).

– All the lesions in this group were classified by USG as solid, irregular in shape masses with retrotumoral shadowing.

In Group 1 eight patients (2.5%) (Table 1), repeated MB procedures were performed due to bleeding that rendered continuing the biopsy impossible (5 cases) and not completed biopsy in three patients (follow-up mammography demonstrated that the major part of the lesion was left intact, while histopathology showed the lesion to be non-atypical ductal hyperplasia (NADH)).

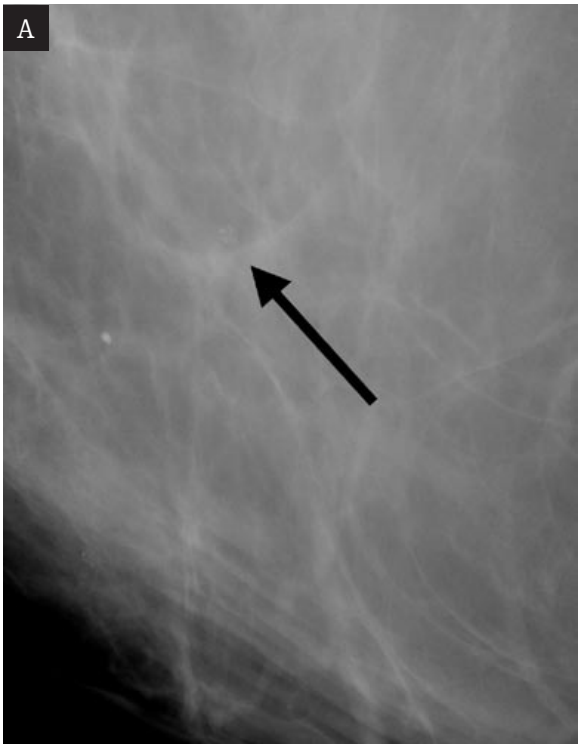
In Group 2, rebiopsies were performed in three patients (0.6%) (Table 1) due to bleeding not allowing for continuing the procedure (N = 2) and not completed biopsy in one female (follow-up ultrasonography demonstrated that a major part of the lesion persisted, while histopathology confirmed the lesion as NADH).

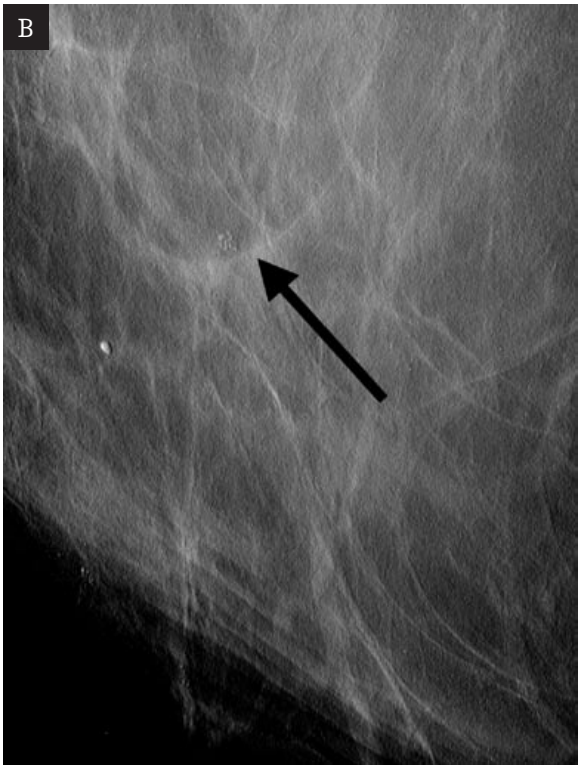
Table 1. Number of patients subjected to mammotome biopsy procedures.
Tabela 1. Liczba pacjentów skierowanych do biopsji mammotomicznej.

	No. of patients referred to MB	No. of finally performed MB	No. of not performed MB	No. of rebiopses
GROUP 1	349 (100%)	323 (93%)	26 (7%)	8 (2.5%)
GROUP 2	498 (100%)	496 (99.6%)	2 (0.4%)	3 (0.6%)
TOTAL	847 (100%)	819 (97%)	28 (3%)	11 (1.3%)

Digital mammography-guided MB was performed using a unit composed of two parts: a stereotactic biopsy table with a CCD camera and a Mammotome biopsy device.

The construction of the table necessitated placing the patient in the prone position, with the biopsied breast protruding below the tabletop through a special opening. Below the tabletop there was a mobile L arm equipped with a CCD camera, digital detector, a compression paddle with a window (5x5 cm in size) corresponding to the examined part of the breast, and a computer-controlled attachment with the holder for mounting a mammotome device with the biopsy needle. The method of stereotaxy is based on determining three coordinates illustrating the location of the lesion (which is positioned centrally in the compression paddle's window) from three exposures – one scout view (Fig. 1), performed along the long axis of the L arm – 0°, and two (the so-called stereo views) taken with the arm with its CCD camera deflected at the same 15° angle, but in two opposite directions (+15° and –15°). Subsequently, the operator used a mobile mark to select the same target point in the two resultant stereotactic views seen on the monitor, as well as the previously programmed needle type. Since both the length of the needle and the length of the path leading to the target constituted parameters that were





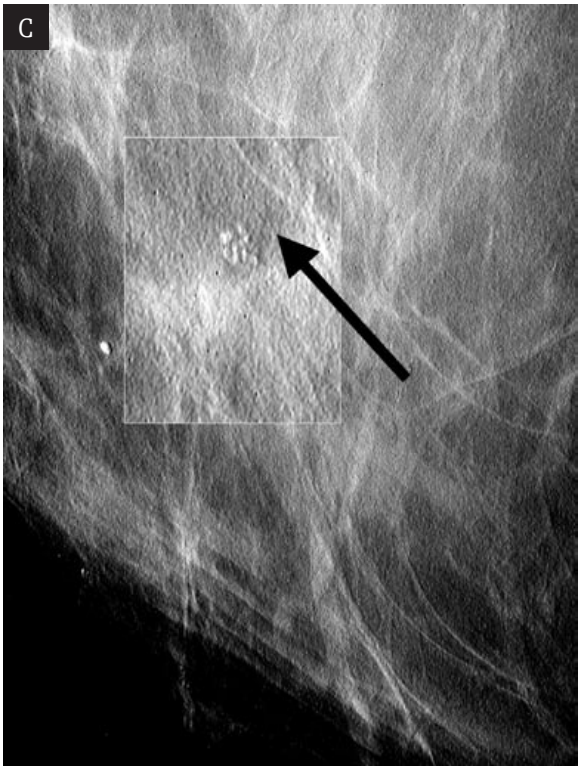


Figure 1 a,b,c. Pleomorphic clustered microcalcification (ductal carcinoma in situ) **a.** scout view **b.** scout view with edge enhancement option **c.** scout view with edge enhancement and zoom options.

Rycina 1 a,b,c. Skupisko pleomorficznych mikrozwapnień (ductal carcinoma in situ) **a.** zdjecie „na wprost" **b.** zdjęcie „na wprost" po zastosowaniu opcji „wzmocnienia krawędzi" **c.** zdjęcie „na wprost" po zastosowaniu opcji „wzmocnienia krawędzi" oraz dodatkowego powiększenia (zoom).

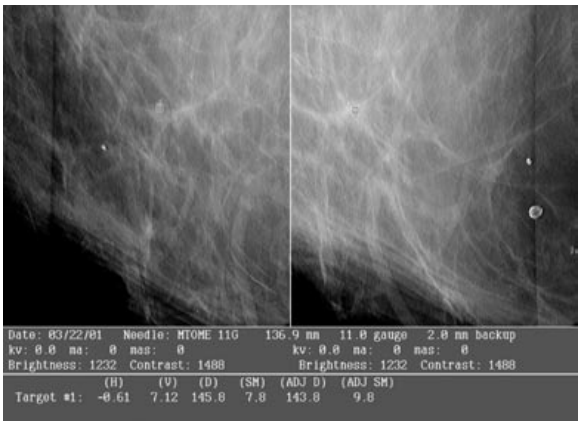


Figure 2. Microcalcification cluster in the two stereotactic views, already marked, with calculation of x, y and z coordinates of the target.

Rycina 2. Dwa zdjęcia stereotaktyczne z zaznaczonym skupiskiem mikrozwapnień z wyliczonymi współrzędnymi celu x, y, z .

encoded by the unit as the safety margin, the computer calculated the values of the x, y and z coordinates and automatically signaled the possible risk of puncturing the breast through and hitting the detector with the needle (Fig. 2). The needle itself was blind-ended and collected tissue specimens through a biopsy window, which was connected with a vacuum suction device. In addition, the needle was equipped with a mobile co-axial core with a cutting section adapted to collecting tissue specimens for histopathology. In our material, one 11 Ga needle served to collect 16–30 cylindrical tissue specimens, what corresponded to collecting the total of 50 to 150 mg of the tissue.

All the computer-determined coordinates were subsequently transmitted to the stereotactic attachment equipped with a biopsy needle and the attachment was automatically set to target site.

During the entire procedure, both before and after introducing the needle into the breast, the position of the cutting section was monitored via serial stereo images (Fig. 3–4).

Following the connection of the vacuum device to the biopsy needle, the needle was introduced manually into the breast, and then a spring pull mechanism were used, reaching the previously determined depth. Immediately prior to introducing the needle into the breast, the area of the skin in front of the needle was sterilized and an approximately 3–4 mm long incision was made. The collected cylindrical specimens were placed in special X-ray-transparent cassettes. Each time prior to withdrawing the mammotome needle from the breast, a titanium marker was introduced into the biopsy site through the biopsy canal to allow for future localization of the site. A single X-ray exposure of the cassettes made it possible to confirm the presence of microcalcifications in the bioptates (Fig. 5–6). Confirmation of sample collection from a lesion that did not contain microcalcifications was obtained by visualizing a density focus at the biopsy site in a follow-up mammographic picture taken immediately upon withdrawing the biopsy needle, which corresponded to local bleeding (Fig. 7). Due to the employed vacuum-assisted device, a single needle insertion allowed

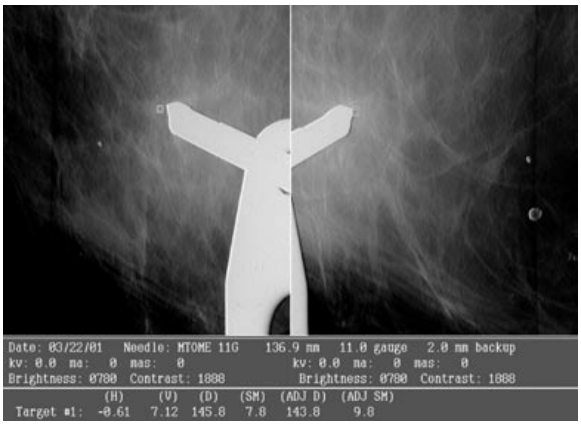


Figure 3. Two control stereotactic views after manually introduced mammotome needle into the breast.

Rycina 3. Dwa kontrolne zdjęcia stereotaktyczne wykonane po „ręcznym" wprowadzeniu w pierś igły mammotomicznej.

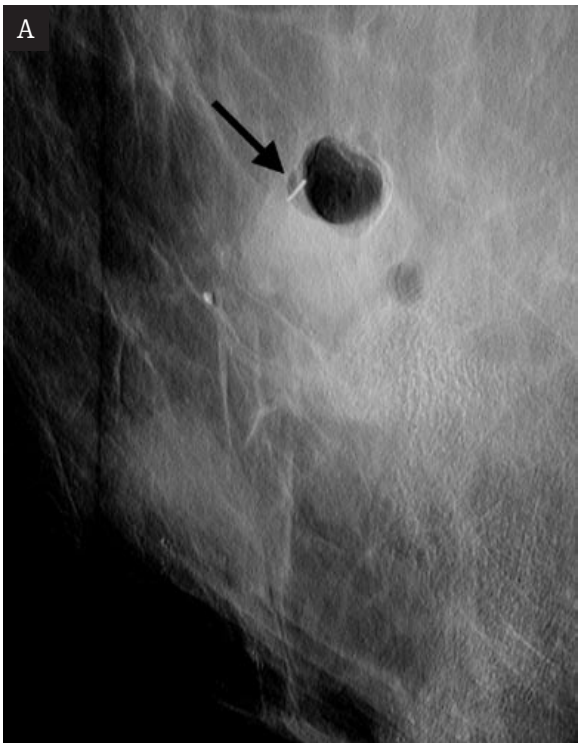
Figure 4. Next two control stereotactic views after using spring pull mechanism. On both views, marks are located within biopsy window (arrows) which means that needle reached previously determined target.

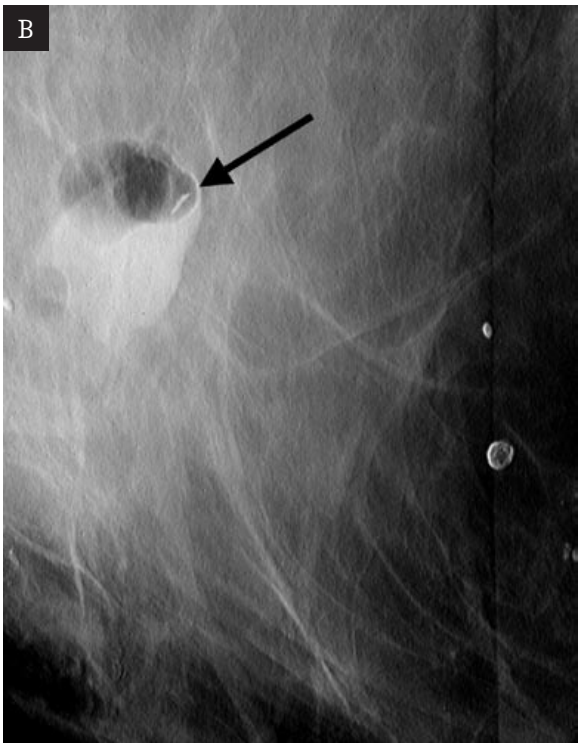
Rycina 4. Kolejne dwa kontrolne zdjęcia stereotaktyczne wykonane po zwolnieniu naciągu sprężynowego. Na obu zdjęciach w rzucie okienek biopsyjnych widoczne markery co oznacza, że igła znajduje się dokładnie w wyliczonej wcześniej lokalizacji.

for collecting samples within the radius of 1.5–2 cm from the puncture axis. After the procedure, the patients were under observation for 3 to 4 hours.

Digital technology allowed for taking advantage of all opportunities offered by computerized image processing (post-processing), such as smooth regulation of contrast, focus and negative-positive opposition, additional edge enhancement, measurement taking, enlarging selected image fragments and finally storing data in the electronic format.

An ultrasound-guided MB unit consisted of the above described biopsy unit connected with a vacuum device. The ultrasonograph was not connected to the unit and constituted a separate entity – in the present investigations it was a Hitachi EUB 450 with a 7.5 MHz linear probe.





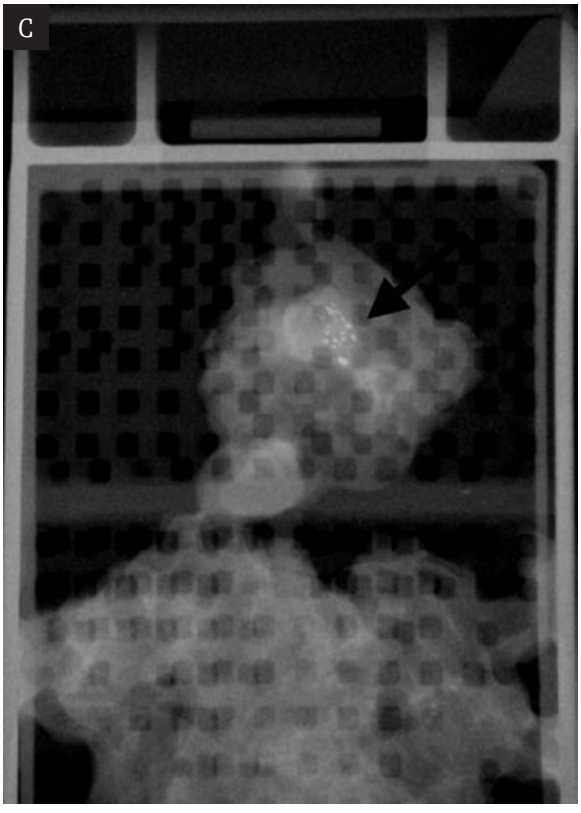


Figure 5 a,b,c. Verification images directly after biopsy procedure. **a, b.** 2 control stereotactic views showing biopsy site with titanium marker (arrows). There is no any more microcalcifications seen **c.** Single x-ray of the cassettes with biopsy speciment confirm presence of microcalcification (arrow).

Rycina 5 a,b,c. Zdjęcia kontrolne zrobione bezpośrednio po biopsji **a, b.** 2 zdjęcia stereotaktyczne loży po zmianie z widocznym znacznikiem tytanowym. Nie uwidacznia się mikrozwapnień (strzałka) **c.** Pojedyncze zdjęcie kasetki zawierającej pobrane próbki, z widocznym usuniętym skupiskiem mikrozwapnień (strzałka).

In addition to examining the biopsy materials in the form of serial, paraffin-embedded sections, they were also analyzed by immunohistochemistry and cytometry to establish a firm diagnosis and – in the case breast cancer was detected – to precisely determine the grade.

In each case of carcinoma detection, the patient was referred to surgery. In benign lesions (diagnosed based on post-MB histopathology), the patients were included in long-term follow-up using imaging studies.

Results

Based on post-MB histopathology results, the following conditions were detected in Group 1: 21 (6.5%) cases of invasive ductal carcinoma (IDC), 28 (8.7%) instances of DCIS and 34 (10.5%) cases of atypical ductal hyperplasia (ADH). The remaining 240 patients (74.3%) had benign lesions (Table 2).

Histopathology performed after MB revealed in Group 2 a total of 42 (8.5%) IDC, 3 (0.6%) cases of DCIS and 5 (1%) cases of ADH. The remaining 446 women (89.9%) were demonstrated to have benign lesions (Table 2).

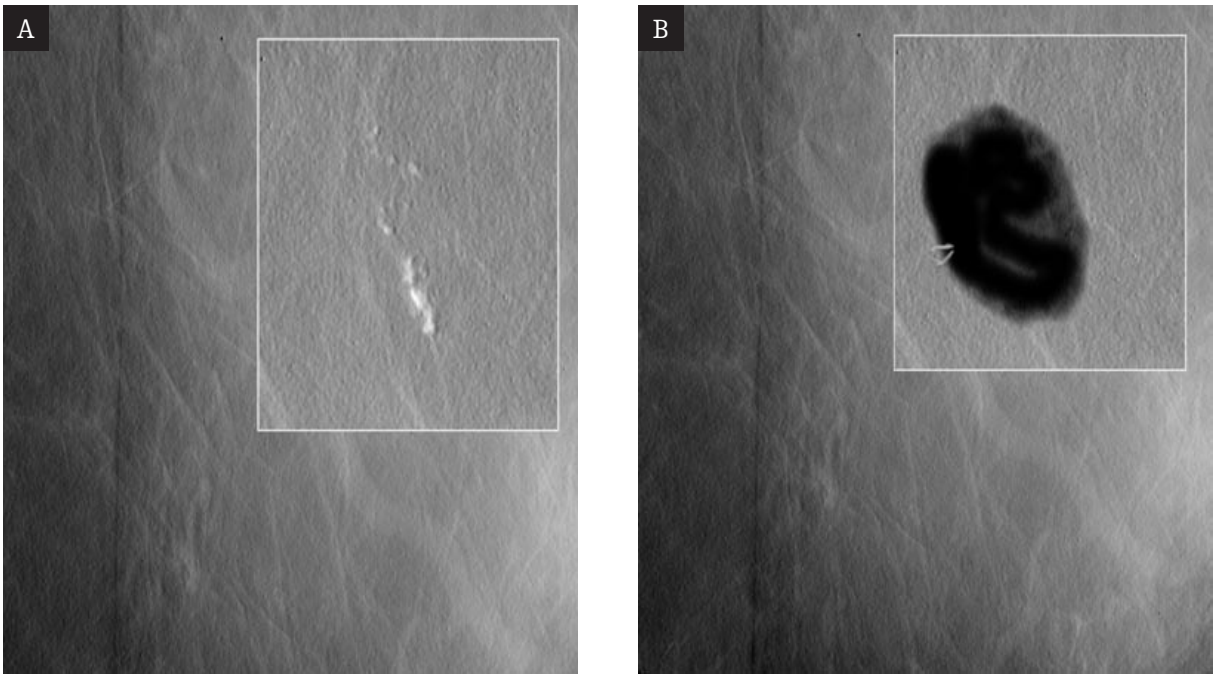


Figure 6 a,b. Linear branching calcifications (invasive ductal carcinoma) **a.** Stereotactic view with the lesion before mammotome biopsy (zoom option) **b.** Control stereotactic view with the biopsy site after procedure (zoom option).

Rycina 6 a,b. Linijne, rozgałęziające się mikrozwapnienia (invasive ductal carcinoma) **a.** Zdjęcia stereotaktyczne zmiany wykonane przed biopsją mammotomiczną (włączona opcja dodatkowego powiększenia) **b.** Kontrolne zdjęcia stereotaktyczne loży wykonane po biopsji mammotomicznej (włączona opcja dodatkowego powiększenia).

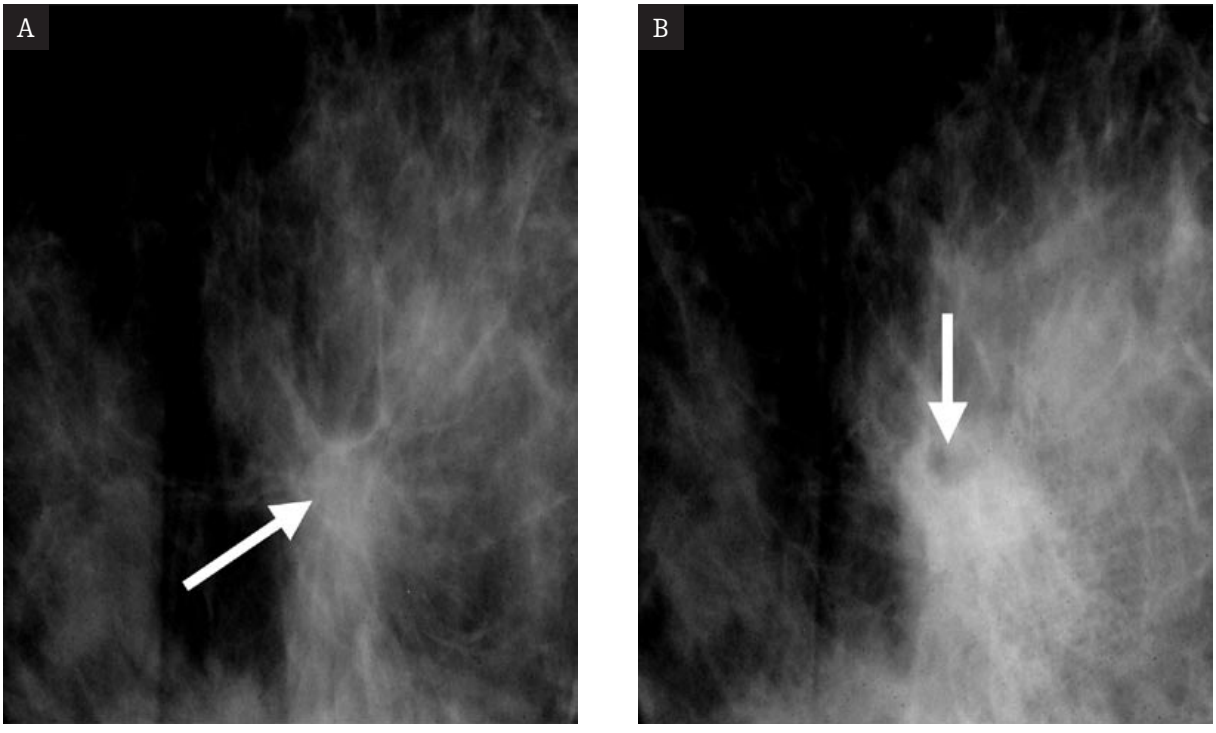


Figure 7 a,b. Non-palpable mass with irregular shape and spiculated margin, 8x7 mm in dimentions, not visible in US (invasive ductal carcinoma) **a.** Scout view with the lesion before mammotome biopsy **b.** Control scout view with the biopsy site after procedure.

Rycina 7 a,b. Niepalpacyjne, spikularnego kształtu zacienienie, o nieregularnym obrysie, o wym. ok. 8x7 mm, niewidzialne w badaniu USG (invasive ductal carcinoma) **a.** „Zdjęcie na wprost" zmiany wykonane przed biopsją mammotomiczną **b.** Kontrolne „zdjęcie na wprost" loży wykonane po biopsji mammotomicznej.

Table 2. Post-mammotome biopsy histopathological findings.
Tabela 2. Wyniki badań histopatologicznych po biopsji mammotomicznej.

	No. of IDC	No. of DCIS	No. of ADH	No. of benign lesions
GROUP 1	21 (6.5%)	28 (8.7%)	34 (10.5%)	240 (74.3%)
GROUP 2	42 (8.5%)	3 (0.6%)	5 (1.0%)	446 (89.9%)
TOTAL	63/819 (7.7%)	31/819 (3.8%)	39/819 (4.8%)	686/819 (83.7%)

Table 3. Postoperative histopathological findings.
Tabela 3. Wyniki badań histopatologicznych po zabiegu operacyjnym.

	No. of IDC	No. of DCIS	No. of ADH
GROUP 1	24 (7.4%)	26 (8.1%)	33 (10.2%)
GROUP 2	43 (8.7%)	2 (0.4%)	5 (1.0%)
TOTAL	67/819 (8.2%)	28/819 (3.4%)	38/819 (4.6%)

Of the total number of 819 females (i.e. 97% of all patients included into the investigation), rebiopsies were performed in 11 (1.3%) women. The criterion for referring patients to a repeated biopsy was the simultaneous occurrence of three phenomena: persistent suspicious character of the detected pathological lesion, NADH detected in histopathology after the first mammotome biopsy, and a large fragment of the lesion left in situ. Of 11 rebiopsies, histopathological qualification was changed in three patients (27%).

In Group 1, a repeated MB led to changing the histopathology result in two cases. In one patient ADH was diagnosed, while another was found to have DCIS.

In Group 2, the rebiopsy changed the histopathology assessment in one patient, who was ultimately diagnosed as ADH.

To control biopsy site bleeding, all the patients were subjected to follow-up ultrasound performed 1 and 7 days after the biopsy. Fifty-eight (7%) women developed hematomas of more than 1 cm in diameter. Of this number, in 54 cases the hematomas did not exceed 2 cm and were absorbed spontaneously; only in four patients (0.5%) was the diameter larger than 2 cm and the hematomas needed to be aspirated.

In eight patients (0.9%), bleeding occurred in the course of MB that prevented the continuation of the procedure. All these patients were rebiopsied.

Fifteen women of Group 1 (1.8%) subjected to digital mammography-guided MB, complained of cervical spine troubles associated with the position they had to assume on the biopsy table.

As the reference study the authors adopted the surgical procedure performed in all the women, in whom MB had detected a cancer or ADH. Patients, in whom post-MB histopathology indicated an unmistakable benign character of the biopsied lesion were closely followed-up using imaging techniques. To-date, none of them has revealed the appearance of new, suspect lesions within the biopsy site.

In Group 1, histopathological examinations of postoperative preparations revealed 24 (7.4%) cases of IDC, 26 (8.1%) DCIS and 33 (10.2%) cases of ADH (Table 3).

Postoperative histopathology showed in Group 2 a total of 43 (8.7%) IDC, 2 (0.4%) cases of DCIS and 5 (1%) cases of ADH (Table 3).

When we compare post-MB histopathological results with reference postoperative histopathology findings, we note that the sensitivity of the method in detecting breast cancer in Group 1 was 98% and the specificity amounted to 100%. In Group 2 both the sensitivity and specificity amounted to 100%. In general, the sensitivity of MB in detecting preclinical breast cancers measuring less than 1 cm was 98.9% and the specificity was 100% (Table 4). The positive result prediction value (PPV) for Group 1 was 100%, while the corresponding value for negative results (NPV) amounted to 99.7%. In Group 2, the same indices were PPV – 100% and NPV - 100%. The combined value of PPV for MB equaled 100%, while NPV was 99.8% (Table 4). The reliability index BM LR+ was 98.9.

Discussion

The methods of percutaneous biopsy employed today in the diagnostic management of preclinical carcinomas, despite their widespread use, are not characterized by high effectiveness.

Table 4. Sensitivity, specificity, and prediction coefficients for mammotome biopsy in detection of preclinical neoplastic lesions.
Tabela 4. Czułość, swoistość oraz wartości predykcji biopsji mammotomicznej w wykrywaniu przedklinicznych zmian nowotworowych piersi.

	SENSITIVITY	SPECIFICITY	PPV	NPV
GROUP 1	98%	100%	100%	99.7%
GROUP 2	100%	100%	100%	100%
TOTAL	98.9%	100%	100%	99.8%

We must agreed that FNAB – in view of the fact that only cellular material is collected – has a low sensitivity, ranging from 54 to 78%, which, nevertheless, increases with the growing size of the biopsied lesion [9]. In addition, what is emphasised by cytologist, FNAB is not a method that would be capable of assessing the grade of invasive carcinoma [10].

The sensitivity of CNB, similarly as in the case of FNAB, increases with the increase of the biopsied lesions. In the case of all non-palpable lesions, two or three punctures are necessary for the sensitivity of CNB to go beyond the threshold value of 90% [11, 12, 13, 14].

The employed today open surgical biopsy requires the lesion to be identified with the help of a localization needle and then the procedure has to be performed in the operating room setting. It is also associated with complications resulting from general anesthesia, inflammatory processes, hematomas and always with breast-deforming scars. One needs also to bear in mind the fact that when a small lesion is operated on, often intraoperative histopathology (in a frozen preparation) is not done because its result is often falsely negative and at the same time the technique rules out any verification of the same preparation using the paraffin method. The latter, if the result is positive, heralds at least two surgical procedures [15].

In our experience, in MB thanks to the use of vacuum and the multidirectional method of biopsy specimen collection, already the first introduction of the mammotome needle to the area where the suspect lesion is situated allows for performing a successful biopsy. As accent by others this not only shortens the duration of the procedure, but is also less painful and stressful for the patient. Additionally, the use of imaging techniques in evaluating the biopsy site both in the course of the procedure and immediately afterwards gives an opportunity – unrivalled by other methods – of visualizing and assessing the effectiveness of the biopsy [13, 14].

The fact that MB visualized almost unchanged contours of the biopsied lesions combined with a low number of tissue samples collected allowed for reaching a decision to rebiopsy the patient. In consequence, in three cases the final diagnosis was changed. Yet we should stress here that the total percentage of rebiopsies required in our material was only 1.7%.

A comparison of histopathological findings obtained after MB and after the surgery showed only relatively slight differences. Of 323 women belonging to Group 1, the diagnosis was changed in three cases (0.9%), while in Group 2 such a change occurred solely in one patient (0.2%). Only the grade of the tumor was underestimated in all these patients. The errors of underdiagnosis following MB did not affect the diagnostic and therapeutic management, since the differences involved solely ADH-type lesions or carcinomas, which anyway required surgical treatment.

The achieved by us 98.9% sensitivity and 100% specificity of MB in detecting preclinical breast cancers is very high and comparable to the results obtained by others in open surgical biopsy, the latter being presently regarded as "the golden standard" [12, 16, 17]. The differences seen in the results obtained in both groups have their origin in the very biopsy technique employed. Ultrasound-guided MB provides an opportunity of correcting the position of the needle during the procedure, while the puncture site remains unchanged, since the biopsy unit is stabilized by the hand of the operator. This allows for a more "elastic" approach to the biopsied lesion without the need of additionally damaging the skin. In digital mammography-guided MB, each correction of the positioning of the needle, which is stabilized by the holding device on the L arm, requires – apart from forward and backward motions – the needle to be withdrawn and another target to be adopted, what in the majority of cases is associated with the computer determining another puncture site. This is why problems associated with unsuccessful biopsing of a lesion were encountered only in Group 1 and originated mainly from our lack of experience and our desire to spare the patient from additional stress associated with another insertion of the biopsy needle.

The high values of the PPV and NPV coefficients in MB indicate that the method allows for a reliable differentiation between malignant and benign lesions.

Similarly as open biopsy, MB allows for obtaining material for histopathology, but the latter is at the same time a procedure of low degree of invasiveness and may be performed under local anesthesia in an outpatient setting.

The risk of complications in mammotomy is low and includes bleeding from the puncture site, subcutaneous hemorrhages and petechiae that are resorbed within one week after the procedure. In our material only four patients developed difficult resorbable hematomas, which required aspiration. They might have been caused by the fact that those patients had failed to discontinue their anticoagulants.

The procedure of MB leaves only a several millimeter-long scar, which disappears after 3–4 months, thus ensuring a very good cosmetic effect.

The present results reliably confirm the very high effectiveness of MB in differentiating preclinical carcinomas that require unequivocal verification. Our ability to perform MB both under the guidance of a mammography or ultrasonography allows for performing the procedure regardless of the character of the lesion and the type of breast structure, what emphasizes the complementary character of both MB types.

Conclusions

1. Mammotome biopsy is an alternative method to open surgical biopsy in differentiating preclinical breast cancers of less than 1cm in size.

2. MB is a method of low invasiveness, well tolerated by the patients and associated with a minimal risk of complications.

3. Depending on the indications, MB may be performed either under ultrasonography or mammography guidance.

4. MB is a procedure performed in an outpatient setting that leaves a minimal scar, which does not deform the breast.

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