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BREAST

Role of one-pass breast lesion excision system in complete excision of high-risk breast lesions with atypia expressed as clusters of microcalcifications

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Abstract

Purpose To assess the role of the breast lesion excision system (BLES) in complete removal of clusters of microcalcifications found on mammogram proved histologically to be high-risk lesions with cell atypia.

Methods and materials Three hundred ninety-four consecutive women (mean age 58.5 years, range 39–78 years) with 400 clusters of suspicious microcalcifications underwent stereotactic biopsy using the intact BLES device between January 2014 and January 2016. All cases proved histologically to be high-risk lesions were subsequently assessed for complete removal. The underestimation rate was also assessed.

Results Thirty-eight out of 400 (9.5%) lesions were high-risk lesions with atypia with mean size 7.63 mm (st. dev. = 4.03 mm) which was within the size that the BLES needle can excise (20 mm). Four (10.5%) papillomas with atypia, 14 (36.8%) cases with flat epithelial atypia (FEA), 10 (26.3%) cases with lobular intraepithelial neoplasia (LIN-LIN 1, LIN 2), 8 (21.2%) with atypical ductal hyperplasia (ADH) and 2 (5.3%) cases with mucocele-like lesions (MLL) with atypia were found. Twenty-nine out of 38 lesions had subsequent surgery. Complete excision was achieved in 23/29 lesions (79.3%). No underestimation was found. Two-year mammographic stability was found in all lesions. Non-parametric statistical analysis showed no other significant predictive factor for complete excision apart from the distance of the lesions from the specimen margins ($p = 0.031$ Mann-Whitney test).

Conclusion One-pass BLES intact biopsy technique is a safe method of complete removal of high-risk atypical lesions with high accuracy rates for certain histologies and could be potentially used as an alternative excision method to diagnostic surgery in selected cases.

Key Points

- *Breast lesion excision system (BLES) is an image-guided biopsy technique that uses radiofrequency to remove an intact piece of tissue including the target breast neoplasm.*
- *Breast lesion excision system (BLES) under stereotactic guidance is able to accurately biopsy high-risk breast lesions expressed mammographically as clusters of suspicious microcalcifications.*
- *BLES under stereotactic guidance is an accurate technique for en bloc excision of selected cases of small clusters of suspicious microcalcifications proved to be high-risk lesions with histopathologically disease-free margins of excision.*

Keywords Breast neoplasms · Image-guided biopsy · Margins of excision

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Abbreviations

ADH	Atypical ductal hyperplasia
AUC	Area under the curve
BI-RADS	Breast Imaging Reporting and Data System
BLES	Breast lesion excision system
CB	Core biopsy
CC	Craniocaudal
DCIS	Ductal carcinoma in situ
FEA	Flat epithelial atypia
F-up	Follow-up
LIN	Lobular intraepithelial neoplasia
LIN 1	Lobular intraepithelial neoplasia type 1
LIN 2	Lobular intraepithelial neoplasia type 2
MLL	Mucocele-like lesion
MLO	Mediolateral
mm	Millimetres
MRI	Magnetic resonance imaging
RF	Radiofrequency
ROC	Receiver operating characteristic
st. dev.	Standard deviation
VAB	Vacuum-assisted biopsy

Introduction

The diagnosis and treatment of high-risk breast lesions have been greatly improved in the past few decades. Earlier diagnosis has been achieved with systematic mammographic screening, and minimally invasive diagnostic procedures, such as image-guided core biopsy (CB) and vacuum-assisted biopsy (VAB), have become part of the initial diagnostic approach of many breast abnormalities; moreover, in some cases, VAB can be the only treatment instead of surgical biopsy or excision.

High-risk breast lesions may appear as clusters of microcalcifications within the breast, and this might be the only imaging finding, such as in cases of flat epithelial atypia (FEA) or as clusters of microcalcifications with or without associated mass, such as papillary lesions and mucocele-like lesions (MLLs), or may be associated with incidental findings, such as in cases of lobular carcinoma in situ (LN 2) [1–4].

At present, VAB under stereotactic guidance is the gold standard method for percutaneous biopsy of suspicious clusters of microcalcifications found on mammogram [5–9]. The literature reported underestimation rate for lobular intraepithelial neoplasia (LIN) is 2–40% of the cases, for atypical ductal hyperplasia (ADH) 0–38%, for FEA 0–42%, for atypical papillomas 1.6–31% and for atypical MLL 0–43% [10–15]. The management of high-risk lesions with cell atypia is still under investigation and requires radiological and pathological concordance as well as clinical correlation. Due to their different potentiality of malignant upgrade and due to their increased risk of future cancer developing after VAB or surgical excision, close follow-up is mostly recommended in these cases [16].

The intact breast lesion excision system (BLES) is an automated vacuum-assisted single-pass biopsy device that uses radiofrequency (RF) under stereotactic guidance, allowing monobloc excision of breast lesions. Several reports suggest that intact-specimen breast biopsy devices provide a feasible alternative to VAB. According to this biopsy technique, one intact spheroid specimen, rather than a set of smaller cylindrical cores of breast tissue, is removed which provides a sufficient tissue sample for pathology diagnosis and also the possibility of tissue margin evaluation [17–19].

In more recent studies, the value of BLES for complete excision of suspicious breast lesions has been tested with controversial results [20–22].

In our study, we evaluate the stereotactic one-pass BLES intact biopsy technique in complete removal of high-risk breast lesions with cell atypia presenting mammographically as suspicious clusters of microcalcifications.

Methods and materials

This is a single-centre retrospective study conducted in our department. Between January 2014 and January 2016, 400 biopsies of suspicious microcalcifications were performed in our department using the intact BLES device under stereotactic guidance. The biopsy equipment is consistent with the Fischer digital stereotactic device (Mammotest, Fischer Imaging) and the BLES device (Breast Lesion Excision System®, B.L.E.S., Intact Medical). In all cases, the main indication was suspicious microcalcifications found on mammogram from external referral.

From the total of 400 biopsies, 38 cases found to be high-risk lesions with cell atypia which were collected for the purposes of the study. From the 38 cases, 29 had a subsequent surgery due to their result. The remaining 9 cases did not have a surgical treatment but instead were followed up for 2 years and were excluded from the statistical analysis. All high-risk cases, regardless having been treated surgically or not, were followed up with annual mammogram for 2 years.

Only the first BLES biopsies were included in this study. Exclusion criteria were: presence of cardiac pacemaker or other implantable electronic devices as the BLES radiofrequency (RF) cutting system may interfere with these devices; pregnancy due to the radiation risk; breast implants due to increased risk of implant rupture and breast thickness less than 30 mm on compression and/or target lesion distance less than 6 mm from the skin or the deep fascia due to the increased risk of thermal burn and necrosis with the RF cutting system. Precaution was taken regarding patients with anticoagulation therapy and clotting disorders who—according to our protocol—had to stop the therapy for 48 hours before the procedure.

Informed consent for the percutaneous biopsy was obtained from all patients, and ethical approval for the conduction of the study was also obtained.

The age, the BI-RADS classification and the side of the biopsy were recorded. The mammographic size, the histology size, the shortest distance (in mm) of the lesion from the BLES specimen margins, the residual post-BLES mammographic disease, the surgical result and the 2-year follow-up mammographic results were also recorded for the purposes of this study.

BLES procedure

All BLES biopsies were performed with a 20-mm probe. The probe was mounted into a handle that contains a motor and a drive mechanism activating the mechanics of the capture basket. Because the device employs an RF tissue cutting mechanism, a patient return electrode was applied to the upper back on the contralateral side of the breast to be biopsied.

The BLES probe used in this study employs an RF capture snare to harvest the biopsy specimen. The snare is mounted on the distal end of a basket that expands to the maximum diameter (20 mm) and then contracts to isolate the specimen tissue from the rest of the breast. The probe uses an RF cutting mechanism to navigate through the breast tissue and to harvest the specimen.

Initial stereotactic localisation of the targeted area was performed by the radiographer under the supervision of a radiologist. The biopsy procedures were performed by one of two experienced radiologists (DK, AC).

The patient was placed in a prone position and cutaneous breast local anaesthesia was performed. According to our guidelines, we applied the local anaesthetic around the lesion in 12, 3, 6 and 9 o'clock positions. The amount of the local anaesthetic (lidocaine 2%) used was 20 ml and a delay of at least 5 min between anaesthesia, and the beginning of the biopsy procedure was required for acceptable local anaesthesia.

During this period, a control mammographic view of the location of the target was performed because of frequent shifts of the target (1–10 mm) due to the amount of anaesthetic solution injected. An 8-gauge probe was used for the stereotactic biopsies. After the biopsy completion, a clip marker was positioned in the cavity through the biopsy channel. Radiographic image of the removed specimen was performed to assess the presence of the target lesion. The specimen was then placed in formalin and sent to the pathology department for histopathology testing.

After the completion of the procedure, external compression on the incisional site was applied for at least 5 min for haemostasis. The incision site was then dressed with steristrips and compressive bandage was applied.

A post-procedure two-view mammogram was also performed to show the post-biopsy cavity and the achievement of complete removal of the target lesion, the correct placement of the clip marker and any immediate complications such as haematoma.

All patients had a control post procedure clinical follow-up 48 h after the biopsy to assess the healing of the incision and check for any complications, such as haematoma or infection.

Histopathology analysis

Measurement of the size of the BLES biopsy specimen and inking of the margins of the specimen were performed. The presence and the type of cell atypia, the size of the high-risk lesion and the distance from the margins (in mm) were mentioned in all pathology reports. Thermal artefacts when present and significant for the pathology diagnosis were also noted in the final report. The final surgical excision report mentioned in all cases the cavity from the BLES biopsy and, if present, the type of cell atypia.

Statistical analysis

The mean values and the respective standard deviations were used to describe scale measurements such as the mammographic size and the margins (in mm), while frequencies and percentages were used for categorical variables such as the surgical results and the lesion type.

The Mann-Whitney test was used to assess differences between complete removal and not in the initial mammographic size of the lesion and in the distance of the lesion from the margins. The correlations between sizes measured were assessed with the Spearman's Rho statistic. Specifically, the statistic was used to assess the correlations between:

- The mammographic size of the lesion and the lesion size found on the BLES specimen
- The size of the lesion measured on the BLES specimen and the residual lesion
- The distance (in mm) of the lesion from the specimen margins and the achievement of complete removal, based on surgical results
- The post-BLES mammographic residual microcalcifications and the achievement of complete removal, based on surgical results
- ROC analysis was used to determine effective cutoffs and the sensitivity of the technique to excise high-risk breast lesions.

All analyses were carried out with the use of the SPSS v22.0 Software (IBM Corp). Statistical significance was set at 0.05 in all cases.

Results

From the total of 400 BLES biopsies performed for suspicious microcalcifications, 38 (9.5%) were found to be high-risk lesions with cell atypia. The radiological characterisation of the

Table 1 Incidence of high-risk lesion types (ADH, LIN 1/LIN 2, FEA, MLL plus atypia, papilloma plus atypia) in our sample

Lesion type	Frequency	Percentage
ADH	8	21.1
LIN 1/LIN 2	10	26.3
FEA	14	36.8
MLL plus atypia	2	5.3
Papilloma plus atypia	4	10.5
Total	38	100.0

Total number of cases, 38. The frequency and the corresponding percentages are presented

groups of microcalcifications was mainly fine amorphous in 21/38 cases (55.2%), coarse heterogeneous in 10/38 cases (31.2%) and fine pleiomorphic in 7/38 cases (18.4%), and their classification was BI-RADS 4.

In the total of 38 high-risk lesions with atypia, 4 cases of papillomas with atypia (10.5%), 14 cases of FEA (36.8%), 10 cases of LIN (LIN 1/LIN 2) (26.3%), 8 cases of ADH (21.2%) and 2 cases of MLLs with atypia (5.3%) were found (Table 1). The mean size of the lesions was 7.63 mm (st. dev. = 4.03 mm).

From the 4 papillomas with atypia, ADH was found in all cases and FEA was also found in two cases. With regard to the MMLs with atypia, in one case, ADH was found and in the second case, FEA was found in the histology result. With regard to lobular neoplasia in 8 out of 10 cases, pure LIN 1 was found; in one case, a combination of LIN 1 and FEA was found, and in one case, LIN 1 and LIN 2 were found.

From the 38 high-risk lesions with cell atypia, 29 had subsequent surgery (76.3%): 3 out of 4 papillomas (75%), 1 mucocele-like lesion (50%), 4 out of 8 cases of ADH (50%), 11 out of 13 cases of FEA (84.6%) and 8 out of 10 cases of LIN (80%). The remaining 9 cases had a 2-year follow-up to monitor for stability (Table 2).

In the cases with supplementary surgery, complete removal was achieved in 23 out of 29 lesions (79.3%): in all 3 papillomas with atypia and in 1 MLL with atypia (100%), in 3 out of 4 ADH cases (75%), in 5 out of 8 LIN cases (62.5%) and in 11/13 FEA cases (84.6%) (Figs. 1 and 2). No cancer upgrade was found in the cases that had undergone subsequent surgery (accuracy 100%) (Table 2).

From the 29 lesions that had subsequent surgery, 6 showed residual disease (20.6%). Among these, in only one case, the surgical result was different from the BLES result and showed a different type of atypia; one case of FEA showed no FEA but LIN 2 in the subsequent surgery (Table 3).

A 2-year mammographic follow-up of all the cases with subsequent surgery showed no recurrence and no interval change.

Nine of 38 cases (23.6%) did not have a supplementary surgery. A 2-year mammographic follow-up confirmed stability in all nine cases.

Non-parametric statistical analysis showed no statistically significant correlation between the initial mammographic size of the lesions and the lesion size found on the BLES specimen ($p = 0.657$, Spearman's Rho). The mean mammographic size of the area of the calcifications was 7.63 mm (st. dev. = 4.03 mm, range from 3 to 18 mm) and the mean size of the lesions found on BLES was 2.20 mm (st. dev. = 1.68 mm, range from 0.5 to 8 mm).

No statistically significant correlation was found between the size of the lesion measured on the BLES specimen and the residual lesion (microcalcifications) seen on the post-BLES control mammogram ($p = 0.808$, Spearman's Rho).

No statistically significant correlation was found between the presence of microcalcifications on post-BLES control mammogram and the achievement of complete removal. Residual calcifications were found only in three cases ($p = 0.515$, Fischer's extract test).

No statistically significant difference was found in the initial mammographic size of the lesion and the achievement or not of complete excision of the lesion ($p = 0{,}813$ Mann-Whitney test).

A statistically significant difference was found between the distance of the lesion from the margins and the complete

Table 2 Incidence of surgery, follow-up and complete removal of each type of the high-risk lesions of our sample

		Surgery		Total (%)	Complete removal after surgery (%)
		Yes (%)	No (%)		
Lesion	ADH	4 (50)	4 (50)	8	3 (75)
	LIN 1/LIN 2	8 (80)	2 (20)	10	5 (62.5)
	FEA	13 (92.8)	1 (7.2)	14	11 (84.6)
	MLL plus atypia	1 (50)	1(50)	2	1 (100)
	Papilloma plus atypia	3 (75)	1 (25)	4	3 (100)
Total		29 (76.3) (F-up = 2 years)	9 (23.7) (F-up = 2 years)	38	23 (79.3)

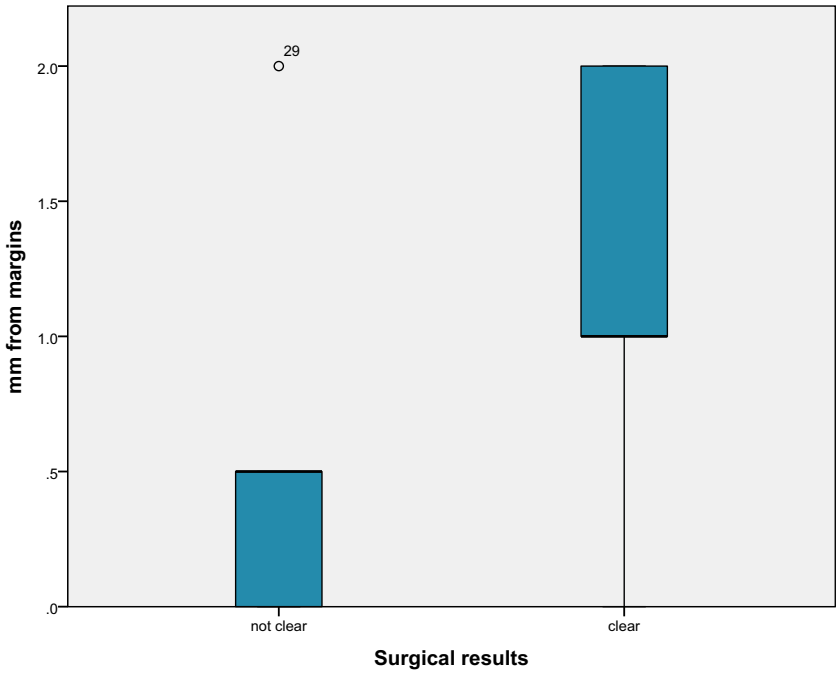

Fig. 1 Box plots of BLES cases of complete removal or not according to surgical results (clear/not clear) and the distance of the lesion from the margins on BLES histopathology specimens. The upper and lower lines of the box plots show the longest and shortest distance of the lesion from the margins. The total number of the cases is 29

removal or not of the lesion. Complete removal was mostly achieved when the distance was more than 1 mm compared to cases where the distance was 0.5 mm or smaller ($p = 0.031$, Mann-Whitney test). Specifically, 18/19 lesions (94.7%) were removed when the distance was over 1 mm (3/4 cases of ADH, 5/10 cases of LIN, 8/13 cases of FEA, 1/3 cases of papilloma and 1/1 case of MLL), whereas 5/10 lesions (50%) were removed when the distance was 0.5 mm or 0 mm from the ink. ROC analysis showed area under the curve (AUC) 0.79. At a 0.25-mm cutoff of disease-free distance of the lesion from the specimen margins, the sensitivity of complete removal was 95.7% (Figs. 1 and 2).

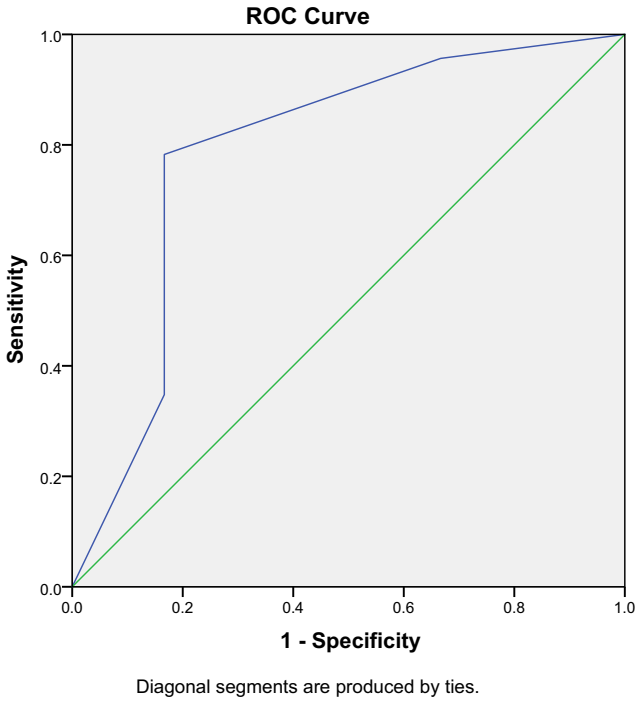

Fig. 2 ROC analysis of the distance (in mm) from the specimen margins and the BLES achievement of complete removal based on the final surgical results

Examples of complete removal are illustrated in Figs. 3, 4, 5, and 6.

In the 9 cases that did not have a complementary surgery, no residual microcalcifications were seen on the post-BLES mammograms. The mean size of the lesions measured in the initial mammogram was 6.67 mm (st. dev. = 3.24 mm). The mean BLES specimen size of the lesions was 2.55 mm (st. dev. = 2.24 mm). The distance of the lesion from the BLES

Table 3 BLES results—surgical results cross tabulation

BLES results	Surgical results					Total
	ADH	LN1	No disease	FEA	LN2	
ADH	1	0	3	0	0	4
MLL plus ADH	0	0	1	0	0	1
LIN 1	0	2	5	0	0	7
LIN 1 plus LIN 2	0	0	0	0	1	1
Papilloma plus atypia	0	0	3	0	0	3
FEA	0	0	11	1	1	13
Total	1	2	23	1	2	29

BLES histopathology results and the associated surgical histopathology results of the 29 cases that had subsequent surgery. In 23/29 cases, no residual disease was seen in the surgical specimen. The remaining six cases showed residual disease in surgical specimens, and in one case (FEA on BLES specimen), the result was different (LIN 2 on surgical specimen). No cancer upgrade was found

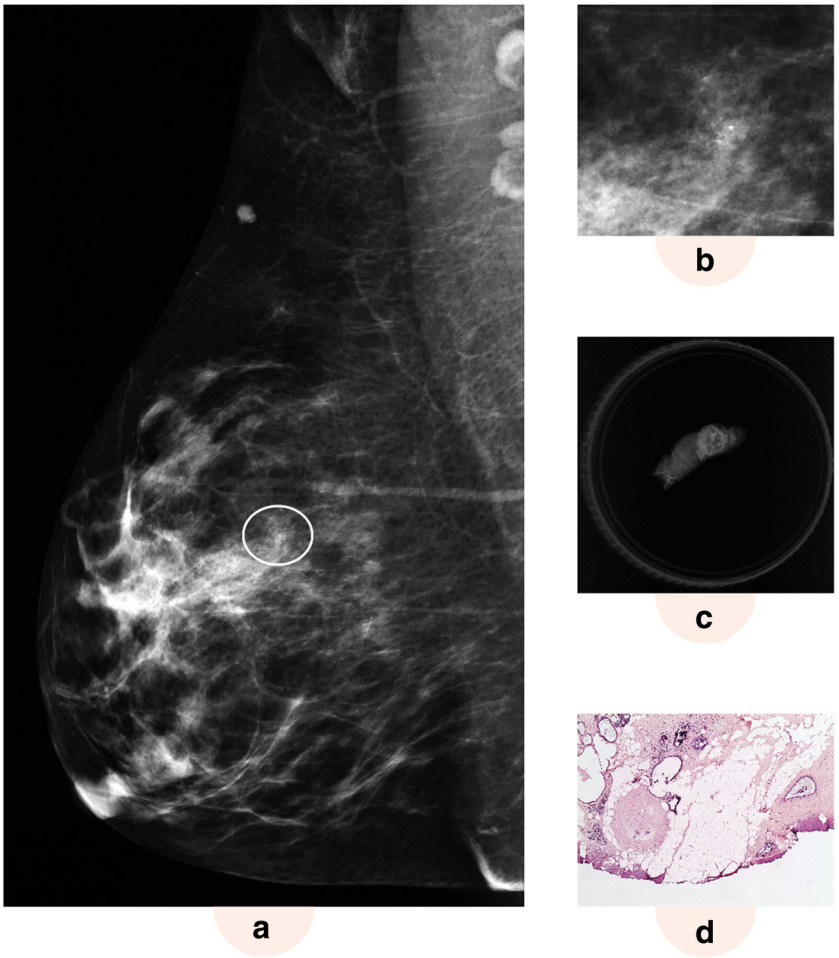

Fig. 3 Mediolateral (MLO) view of the right breast (**a**) and magnification view (**b**) shows a cluster of suspicious microcalcifications at the upper part of the breast (circle). **c** BLES specimen x-ray shows the cluster of microcalcifications included in the specimen and the margins seem to be clear. **d** Histopathology image from the BLES specimen shows ADH with disease-free margins. The final surgical result confirmed complete excision in this case

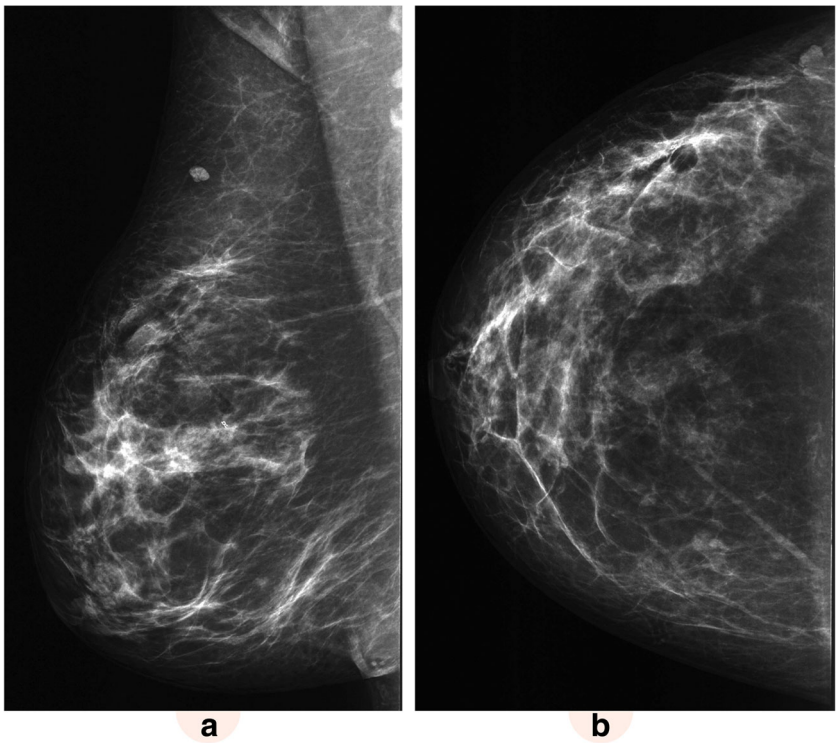

Fig. 4 Post-BLES mediolateral (MLO) view (**a**) and craniocaudal view (**b**) of the right breast of the same case show the biopsy cavity with the clip marker in place and no residual volume of calcifications

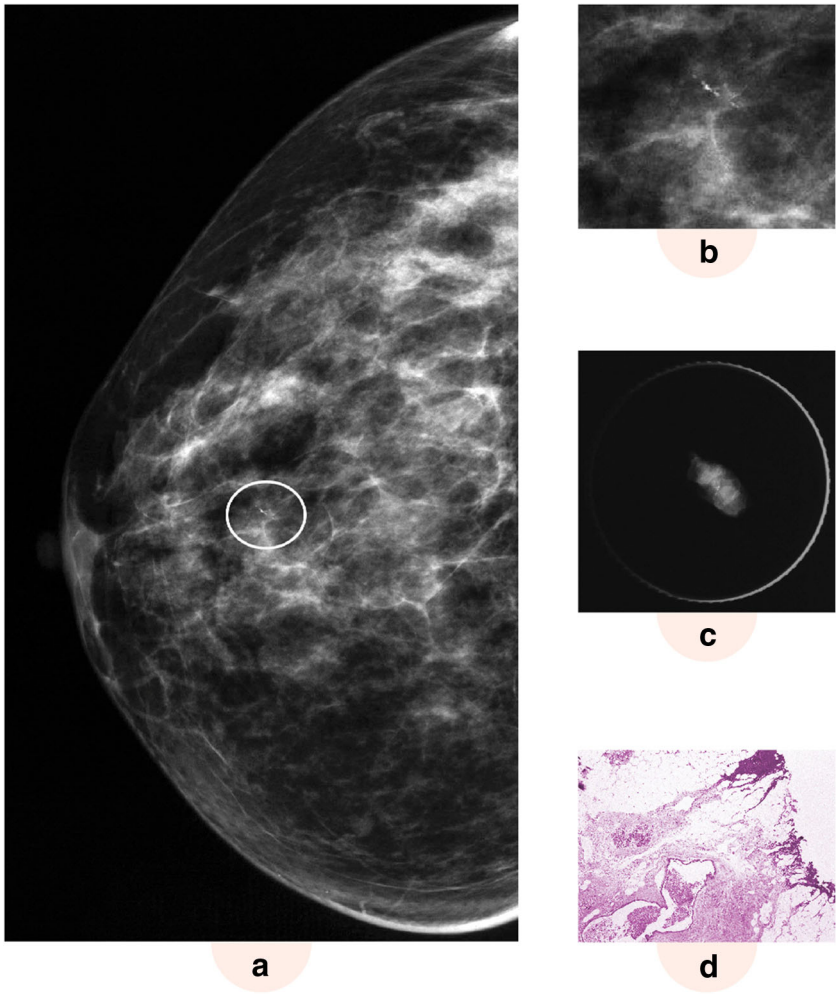

Fig. 5 Craniocaudal view (CC) of the right breast (**a**) and magnification view (**b**) shows a cluster of suspicious microcalcifications at the outer part of the breast (circle). **c** BLES specimen x-ray shows the cluster of microcalcifications included in the specimen and the margins seem to be clear. **d** Histopathology image from the BLES specimen shows ALH with disease-free margins. The final surgical result confirmed complete excision in this case

specimen margins was ranging between 0.1 and 2 mm. Follow-up of these cases for 2 years showed no change in the mammographic appearances.

No major complications occurred as a result of the BLES procedures. Thermal artefacts were mentioned in the histological report in only one case, and there was no change of the result or upgrading in the subsequent surgery. There were only two cases with haematoma which did not require any drainage.

Discussion

According to our results, BLES is a good alternative option for percutaneous stereotactic biopsy of suspicious microcalcifications found to be high-risk lesions with cell atypia and could potentially be used as a therapeutic tool in selected cases.

In several previous reports, the underestimation rate of biopsied high-risk lesions with BLES is low ranging from 0 to 9.2% with very high accuracy [21, 23–26]. This could be explained by the larger tissue sample achieved by the BLES probe compared to CB or VAB. In fact, several studies suggest that the increased size of a biopsy specimen improves the accuracy of histopathologic assessment, and this is particularly consistent in the reliable differentiation between ADH and ductal carcinoma in situ (DCIS) [27, 28]. In our study, we used a 20-mm probe which enables excision of a spheroid specimen with around 20-mm length and 10-mm thickness. Our results show excellent accuracy with no underestimation rate in our target population supporting the fact that adequate tissue sampling can be achieved with BLES and thus subsequent surgical sampling can be avoided.

The main practical advantage of this technique is that apart from the larger sample, an intact tissue specimen is excised for histological interpretation with no fragmentation. This allows better histological evaluation of the breast tissue regarding the size and the margins of the lesion as well as the lesion's architectural and cytological diagnostic criteria [17, 29]. In our study, we achieved complete excision of the high-risk lesions with atypical cells in 79.3% of the cases; thus, in 79.3% of our cases, the subsequent excisional surgery could have been avoided.

High-risk breast lesions with cell atypia are a heterogeneous group of breast abnormalities, consisting of low but also different potentiality of malignancy [30]. The management and treatment of these lesions are still challenging and under investigation for consensus. The more recent recommendations suggest that apart from ADH and papillomas imaged guided excision with VAB of the remaining high-risk lesions (LIN 1, LIN 2, FEA) is feasible and acceptable if the lesions are small and completely removed on post excision imaging control [31]. Also, annual mammogram is recommended to follow up high-risk patients. Our series includes 38 cases of atypical high-risk breast lesions from different subgroups expressed mammographically as clusters of microcalcifications (ADH, LIN, FEA, MLL and papilloma with atypia) with relatively small size (mean size 7.63 mm). Regarding the post-BLES mammographic control, only in three cases, a residual volume of calcifications was detected and in all 3 cases, the high-risk lesion was completely removed supporting the fact that benign calcifications can coexist. Also, the 2-year follow-up mammogram showed no interval mammographic change.

The literature reported results regarding VAB excision conducted by the International Breast Ultrasound School and the Swiss Minimally Invasive Breast Biopsy Group in a large population of 3344 participants showed that the upgrade results after VAB were 5% for ADH, 18% for LIN, 9% for FEA and 2.6% for papillomas [31]. This shows that the evaluation of the lesion margins is essential; high-risk lesions often show significant upgrade rates to malignancy after VAB as there is always a possibility of having not detected the malignant tissue component at the edge of the lesion and thus, traditionally, surgical excision or biopsy is recommended. Margins are considered adequate if a 1-mm free margin around the lesion is obtained.

In our series, the lesion margins were evaluated and the disease-free distance (in mm) from the specimen-inked margins was mentioned in all pathology reports; either complete excision, lesion at ink or 0.1−2-mm distance from margins was mentioned according to the shortest distance of the edge of the lesion to the ink. We achieved over 1-mm disease-free margins in 19/29 cases (65.5%), and the success rate of complete removal in these cases was 94.7%. At a cutoff of 0.25-mm disease-free margins, the sensitivity was 95.7%.

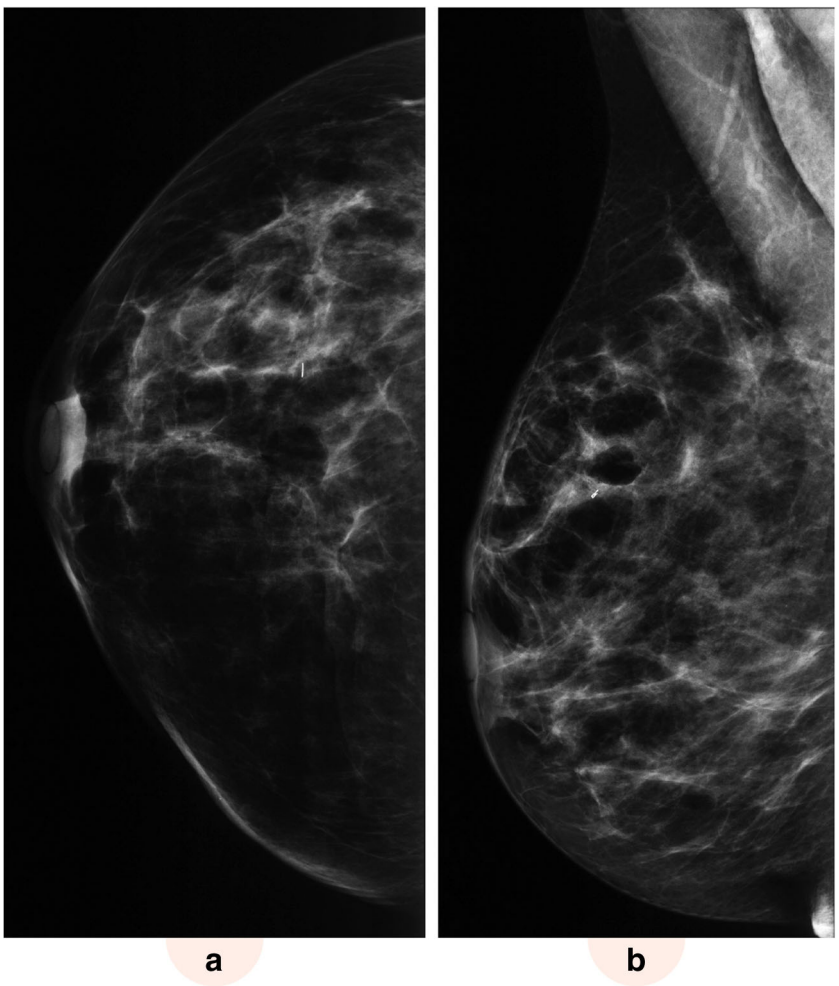

Fig. 6 Post-BLES craniocaudal view (**a**) and mediolateral (MLO) view (**b**) of the right breast of the same case show the clip marker in place and no residual volume of calcifications

It must be noted that the subgroup size samples were small for acceptable statistical analysis of BLES efficacy in complete excision for each subgroup and thus this was not performed. However, according to our results, BLES performance in complete excision of high-risk lesions was mostly achieved in cases of FEA (84.6%). Our results are in agreement with current recommendations that suggest that if small areas of FEA are completely excised with VAB and radiological-pathological concordance is achieved, no further surgery is required [16, 31]. In only one case of FEA which was completely removed with BLES, the surgical result showed a different atypia (LN2) in the surrounding tissue. However, in this case, although the initially diagnosed atypia was removed, BLES specimen failed to diagnose the surrounding LN2.

Regarding ADH, we achieved complete removal in 75% of pure ADH and in 100% of PL and MLL cases which showed ADH as the main atypia. However, our PL and MLL target group is small. Since ADH cases show a relatively high risk of DCIS upgrade and potential risk to develop DCIS if not completely removed, the complete excision of ADH is essential. In our series, half of our ADH population did not have a subsequent surgical excision; in all of our cases, disease-free margins of 0.5−1.5 mm were achieved, apart from one case in which disease was found at the ink of the tissue specimen, and residual disease was eventually found in the subsequent surgery. However, based on the small sample size, the incomplete excision rate of 25% and the relevant risk of DCIS upgrade, the management of ADH by BLES remains questionable. A large-sample multicentre study with long-term follow-up is probably needed to better define the role of BLES in the management of ADH lesions.

Regarding LIN cases and especially LIN 2, the risk of malignancy is increased for both breasts. Current recommendations suggest to surgically biopsy extensive LIN 2 to exclude the invasive potential, and an annual mammogram is recommended for follow-up as the potentiality of malignancy is not always directly related to the area of LIN 2 [31, 32]. Also, additional imaging with breast MRI has been currently suggested to investigate the extent of disease and also the presence of malignancy as it has been shown that absence of enhancement can exclude the presence of invasion [33]. Thus, the sufficient sampling to exclude local invasion and also annual follow-up to monitor stability are of high importance. In our series, we included 10 cases of localised LIN with no underestimation indicating that the sampling was sufficient, and a 2-year mammogram follow-up showed no interval changes. However, no additional imaging with MRI was performed in our target population.

The limitations of this study are several. The most important limitations are the small sample size of the different histologic types and the relatively short follow-up of 2 years. High-risk breast lesions with atypia are rare cases, and this is a single-centre study, so further multicentre studies with a longer follow-up should be performed to support our results. Moreover, not all cases underwent surgical removal, so a percentage of 23.6% of our cases was excluded from the statistical analysis. Additionally, we did not have a control group using VAB excision to compare our results and show the performance of BLES. However, upgrade results mentioned in the literature for VAB show that BLES, possibly due to the larger tissue sample and the evaluation of the margins, could potentially be a more adequate technique. Finally, we assessed only the cases of microcalcifications having been biopsied with the BLES device under stereotactic guidance. We did not include cases found and biopsied on ultrasound.

In conclusion, our results support the view that BLES is an accurate, minimally invasive technique to biopsy high-risk breast lesions with cell atypia expressed as small clusters of microcalcifications, with the potential to decrease unnecessary surgical excisions in selected cases and especially in cases where 1-mm disease-free tissue margins are achieved.

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Compliance with ethical standards

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Conflict of interest The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article.

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Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

Methodology
- retrospective
- diagnostic or prognostic study
- performed at one institution

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