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# Performance and role of the breast lesion excision system (BLES) in small clusters of suspicious microcalcifications

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ABSTRACT

*Purpose:* To assess the diagnostic performance of the BLES as a biopsy tool in patients with ≤1 cm clusters of BIRADS 4 microcalcifications, in order to possibly avoid surgical excision in selected patients.
*Materials:* This is a retrospective study of 105 patients undergone to stereotactic breast biopsy with the BLES. It excises a single specimen containing the whole mammographic target, allowing better histological assessment due to preserved architecture.
*Results:* Our case series consists of 41 carcinomas (39%) and 64 benign lesions (61%). Cancer involved the specimen margins in 20/41 cases (48.8%) or was close to them (≤1 mm) in 14 cases (34.1%); margins were disease-free in only 7 DCIS (17.1%). At subsequent excision of 39/41 malignant cases, underestimation occurred for 5/32 DCIS (15.6%), residual disease was found in 15/39 cancers (38.5%) and no cancer in 19/39 cases (48.7%). For DCIS cases, no residual disease occurred for 66.7% G1–G2 cases and for 35.3% G3 cases ($P = 0.1556$) as well as in 83.3%, 40.0% and 43.8% cases respectively for negative, close and positive BLES margins ($P = 0.2576$).
*Conclusions:* The BLES is a good option for removal of small clusters of breast microcalcifications, giving better histological interpretation, lower underestimation rates and possibly reducing the need of subsequent surgical excision in selected patients.



## 1. Introduction

At present VAB systems under stereotactic guidance are the gold standard for percutaneous biopsy of suspicious breast microcalcifications, [1–5] with reported sensitivity of 98% versus 65–97% of CNB. [4], However their accuracy is hampered by underestimation, that is the finding of more severe disease (upgrade) at surgical excision that may occur after percutaneous diagnoses of atypical hyperplasia or in situ carcinoma; reported rates are 2–40% cases for atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS) [6], 0–38% cases for atypical ductal hyperplasia (ADH), and 4–33% for ductal carcinoma in situ (DCIS) [7]. In the meta-analysis by Yu et al. [4] the underestimation rates were 20.9% for ADH and 11.2% for DCIS. Underestimation for VAB systems seems not substantially affected either by the gauge of the needle [8] or the number of the retrieved specimen [9].

The latest available biopsy tool is the Breast Lesion Excision System (BLES) that by means of a radiofrequency cutting system can excise a single specimen measuring on average 21 ≪ 15 mm containing in most cases the whole mammographic target [10–16]. The removal of an intact lesion with preserved architecture can increase the accuracy of pathologic assessment mainly in the case of pre-neoplastic lesions and low-grade in situ carcinoma. BLES has proved safe, with mostly minor complications [16] and able to decrease the underestimation rates to 9.4% for ADH and 5.2% for DCIS [10]. In prospect, BLES can warrant for complete excision of small benign and selected high-risk lesions instead of surgical excision [12].

The aim of our study was to assess the diagnostic performance of BLES in patients with small clusters of variably suspicious microcalcifications in terms of diagnostic underestimation, as well as

*Abbreviations:* VAB, vacuum-assisted biopsy; CNB, core-needle biopsy; ALH, atypical lobular hyperplasia; LCIS, lobular carcinoma in situ; ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; BLES, breast lesion excision system; BI-RADS, Breast Imaging Reporting And Data System; RF, Radio-Frequency; H–E, Haematossylin–Eosyn; G1,2,3, (Malignancy) Grade 1, 2, 3; HIFU, high-intensity focused ultrasound.

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of margins' status and completeness of the excision, in order to possibly avoid further surgical excision in selected patients.

## 2. Materials

### 2.1. The BLES

THE BLES (Intact Medical Corporation, Natick, MA, USA) is a biopsy tool for percutaneous removal of a single gross breast specimen. The BLES procedure has been described in detail elsewhere [10,11]. Briefly, the handle device is mounted on a bracket of the stereotactic table and its 6 gauge probe is inserted into the breast under local anaesthesia through a small skin incision (6–8 mm) and moved under stereotactic guidance to reach the edge of the target; at the distal end of the probe, a capture snare with metallic struts is then activated that in a few seconds advance within the breast to encompass and resect en-bloc a sample of tissue measuring 15 or 20 mm in the longest axis, with the biopsy target included; the capture snare then retracts the specimen out of the breast through the biopsy channel and the skin incision. The cutting system used in the procedure is supplied by Radio-Frequency (RF) electrosurgical power, and haemostasis and clearing of the biopsy cavity is obtained by vacuum-assisted suction. Following specimen radiography to assess the presence of the target lesion and the completeness of the excision, the sample is placed in formalin and sent to the Pathologic Department. Through the biopsy channel a marker clips is deployed in the cavity, then the incision is dressed with steri-strips and compressive bandage is applied.

The RF cutting system may interfere with cardiac pacemaker or other implantable electronic devices, so these are absolute contraindications for BLES. Moreover, because of the risk of thermal burn and necrosis, lesions too near the skin or the deep fascia as well as those located in the axilla are not suitable. Finally, it is not recommended to perform BLES in pregnant women and in patients with breast implants, and caution has to be given in patients with anticoagulation therapy and clotting disorders, as with other large needle biopsy systems.

Reported complications of BLES include bleeding and haematomas, usually not requiring surgical intervention, and very few cases of wound infection, that resolve with antibiotic therapy. Thermal effects are often found by the pathologist on the surface of the specimen, usually <1 mm in thickness, rarely interfering with the histological assessment: a larger probe can partially obviate this risk by creating a potential separation between the edge of the lesion and the surface artifact [19]. Failure of the procedure is reported in 2.4–4.6% of the cases [11,13] and it occurs because of retrieval of an empty basket or breaking of the metallic struts by RF-induced overheating.

### 2.2. Our study

Our study is a retrospective analysis of 105 patients (mean age of 55 years, range 38–81 years) who between September 2010 and February 2014 underwent stereotactic breast biopsy for single clusters of BI-RADS 4 microcalcifications [17,18] measuring up to 1 cm using the BLES device (Intact Medical Corporation, Natick, MA, USA). No prospective trial comparing VAB and BLES was undertaken; in our experience with VAB devices before BLES was available, we found an underestimation rate for DCIS of 26.5% when biopsying the same type of target: this figure and data from literature were considered for comparison with BLES results.

Stereotactic VAB procedures with the Hologic Multicare Platinum Plus prone stereotactic table have been routinely performed since 2006 by three of the Authors, while BLES procedures were all performed by the same radiologist with 20 years of experience in breast imaging and biopsy. The BLES system was used for the first time in Italy in our department since 2010. The cost of the disposable package for the BLES procedure is approximately 20–30% higher than for the VAB procedure, and both of them are covered by the reimbursement from National Health System (the two procedures have the same code).

In this study were included eligible patients of any age scheduled for stereotactic procedures because of clusters of BI-RADS 4 microcalcifications measuring up to 1 cm at mammography, that may be represented by grouped coarse heterogeneous microcalcifications (less worrisome) or fine pleomorphic elements (more suspicious). [17,18] All the patients provided written informed consent to undergo breast biopsy: the radiologist decided to perform the BLES or a traditional VAB procedure after reviewing the patient and her mammography.

Exclusion criteria were the technical and patient contraindications to BLES reported in the previous section.

Data were recorded about patients' age, mammographic features, histological findings both at BLES and at subsequent excision for malignant and atypically hyperplasic cases. In malignant cases histological report was reviewed for tumor size (both the invasive and the in situ component), histological subtype and grade 1–3 classification. Given the removal of a single gross specimen by BLES, this was histologically assessed for the margins status, in order to establish if they were disease free (*negative*) or the disease was near to (<1 mm) (*close*) or involved one of the margins (*positive*). The specimens were managed in the Pathology Department as follows: any case was fixed in neutral buffered formalin at 10% for at least 12 h and no more than 24 h. The specimen were inked with Indian ink and then bisected along long axis or sliced as "bread-loaf" depending on their size. After routine processing, histological sections were prepared and stained with Haematossylin–Eosyn (H–E).

Most of the patients had subsequent surgical excision at our Institution. Eight patients with DCIS at BLES were treated in other Centers: rough data about surgical follow-up after BLES were collected from 6 patients through phone calls; of the remaining two, one patient had radiotherapy instead of excision and another was lost at follow-up. Overall, histological data are available for 39/41 malignant cases.

Comparing BLES results and final histological findings, *concordance* means that the same BLES pathological diagnosis was confirmed at surgical excision; *upgrade* means that at surgical excision a more severe disease was found as compared with BLES results, that is invasive carcinoma at surgery in case of DCIS or atypical hyperplasia at BLES (and possibly DCIS in case of atypical hyperplasia); *downgrade* means that: (a) in case of invasive cancer at BLES, no invasive foci were found at surgical excision, but only in situ carcinoma or even no residual disease; (b) after a diagnosis of DCIS at BLES, no residual disease was found at surgical excision.

The results obtained by BLES and by subsequent excision were tabulated by means of contingency tables reporting absolute frequencies. Statistical analysis was applied to the subset of DCIS cases at BLES, comparing margins' status and malignancy grade with the outcome at subsequent surgical excision. The significancy level was set at $p < 0.05$.

## 3. Results

The histological assessment on specimens obtained by the 105 BLES procedures showed 41 malignant lesions (39.0%), consisting in 3 invasive carcinomas, 4 DCIS with micro-invasion and 34 pure DCIS, and 64 benign lesions (61,0%) including 7 cases of atypical ductal or columnar cell lesions Table 1.

Table 2 highlights the margin status at BLES and the surgical outcome for the 41 malignant lesions. Among the 3 invasive cases