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Research papers

The breast lesion excision system (BLES) under stereotactic guidance cannot be used as a therapeutic tool in the excision of small areas of microcalcifications in the breast

Ruxandra-Iulia Milos[a], Maria Bernathova[a], Pascal A. Baltzer[a], Katja Pinker-Domenig[a], Panagiotis Kapetas[a], Margaretha Rudas[b], Thomas H. Helbich[a,*]

[a] Department of Biomedical Imaging and Image-guided Therapy, Medical University of Vienna, Austria
[b] Department of Clinical Pathology, Medical University of Vienna, Austria

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ABSTRACT

Objective: The breast lesion excision system (BLES) is a new, automatic percutaneous breast biopsy device that excises single large specimens using radiofrequency cutting. The aim of this study was to determine whether BLES, under stereotactic guidance, can be used as a therapeutic tool in the assessment of small areas of microcalcifications in the breast by providing samples with clear margins.

Material and methods: In this retrospective study, 149 patients with suspicious (BIRADS 4 or 5) small areas of microcalcifications underwent stereotactic-guided BLES. Of these, 34 patients (22.8%) with microcalcifications that had a diameter smaller than the basket size (≤15 mm) underwent both BLES and subsequent surgery. Histopathology findings from BLES and subsequent surgery were compared. Identical, underestimation and total excision findings were assessed.

Results: BLES revealed fourteen (41.1%) high-risk lesions, ten (29.4%) ductal carcinomas in situ, and ten (29.4%) invasive cancers. Identical results between BLES and surgery were seen in 17/34 (50%) lesions. Surgery confirmed total excision of BLES in 15/34 (44.1%) lesions. Underestimation was seen in 2/34 (5.8%) lesions.

Conclusion: BLES allows accurate diagnosis of small areas of microcalcifications, with few underestimates. BLES is a diagnostic, but cannot be considered to be a therapeutic tool in the case of suspicious microcalcifications because total excision was seen in only 44.1% of these lesions. Studies are needed to address the therapeutic benefit of this procedure in solid lesions.

1. Introduction

The breast lesion excision system (BLES) represents an innovative advance in breast biopsy technology and an alternative to image-guided core needle biopsy (CNB) and vacuum-assisted breast biopsy (VABB) [1–3]. Using radiofrequency (RF) cutting, this system can remove a larger intact tissue specimen in a biopsy basket, with preserved histological architecture. The system can be used percutaneously with either stereotactic or ultrasound guidance [4]. It was shown to be a safe biopsy method with low complication rates and most of the complications were minor [5]. However, the use of RF limits its use for patients with an implanted electronic device, for lesions situated close to the skin or chest wall, and for lesions in small breasts [6].

Reports suggest that BLES is a useful diagnostic tool with increased accuracy and an underestimation rate comparable to those previously reported for VABB in the histopathological assessment of high-risk lesions [7,8], and for ductal carcinoma in situ (DCIS) [1,8]. It has been shown that BLES could enable the complete removal of small target lesions considered to be indeterminate or suspicious [3,8–11]. These reports, which suggested that BLES can be used in some cases as a therapeutic tool, inspired us to perform the following study. The purpose was to determine the value of BLES under stereotactic guidance as a therapeutic tool by providing samples with clear margins to manage small areas of suspicious microcalcifications (BIRADS 4 or 5) that are smaller than the size of the biopsy basket.

Abbreviations: ADH, atypical ductal hyperplasia; BLES, breast lesion excision system; CNB, core needle biopsy; DCIS, ductal carcinoma in situ; IDC, invasive ductal carcinoma; LCIS, lobular carcinoma in situ; RF, radiofrequency; US, ultrasound; VABB, vacuum-assisted breast biopsy; Ø, diameter; μCa, microcalcifications

* Corresponding author at: Department of Biomedical Imaging and Image-guided Therapy, Head: Division of Molecular and Gender Imaging, Medical University Vienna – General Hospital Vienna, Waehringer Guertel 18-20, Floor 7F, 1090 Vienna, Austria.
E-mail address: thomas.helbich@meduniwien.ac.at (T.H. Helbich).

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2. Material and methods

2.1. Study design

This retrospective single-center study was approved by the local institutional review board, and all study participants provided written informed consent prior to biopsy. We collected data from the institutional database for all consecutive patients who underwent BLES (Intact Medical, Framingham, USA) procedures at our institution from October 2011 until February 2015 (n = 149) due to suspicious (BIRADS 4 or 5) lesions. We included only patients with (a) stereotactic guided BLES biopsies for (b) single areas of microcalcifications in which (c) a safe margin of at least 5 mm between the size of the tissue basket and the lesion size could be provided (i.e., for the largest basket size available with 20 mm diameter, only lesions smaller than 15 mm diameter were included) and in which (d) a final diagnosis had been established by open surgery. Patients were excluded if (a) no surgery was performed (due to benign lesions at BLES; high-risk lesions with only follow-up as patients refused to undergo surgery; suspicious lesions that were lost to follow-up), (b) biopsy was performed using sonography, (c) lesions were larger than 15 mm diameter, or multifocal lesions or mass lesions and (d) the probe showed extensive thermal damage that impeded the diagnosis of the lesion.

Based on these criteria, 34 women (median age 55; range, 31–75) were included in our study population (Fig. 1).

2.2. BLES technique

All patients underwent stereotactic guided BLES, which was performed as previously described [1,2,4,9]. Briefly, BLES consists of a biopsy basket which is available in four sizes between 10 and 20 mm diameter (i.e.,10, 12, 15, and 20 mm). This basket is positioned under imaging guidance (ultrasound or, as in our study, X-ray stereotaxis) through a small skin incision and advanced to the anaesthetized target area. Upon activation, five metallic prongs with their tips connected by a cutting RF wire expand and then ensnare the target lesion [4,9]. The RF waves excise the tissue and allow hemostasis [9]. The single, large sample with preserved histological architecture [2] is then withdrawn through the same tract. The use of RF waves is associated with a risk of thermal burns and skin necrosis. As recommended by the manufacturer, BLES was not performed in lesions situated close to the skin or chest wall (less than 6 mm between target lesion and skin or muscle) and in small breasts (breast thickness under compression less than 30 mm) [3].

Patients were placed in the prone position on a dedicated biopsy table (Mammotest; Fischer Imaging, Denver, CO, USA). The patient's breast was positioned between the detection and compression plates, with the lesion in the window of the compression plate. Scout and targeting stereotactic images were obtained. The area of microcalcifications served as target. Local anesthesia was performed by injecting 25 ml lidocaine hydrochloride (Xylanest 2%,Gebro Pharma GmbH, AT), subsequently a skin incision of 1 cm was performed. The probe was advanced to the lesion and the target tissue was captured. The probe was then withdrawn. Standardized specimen radiographs were obtained to document the retrieval of microcalcifications [12]. All probes were positive for microcalifications, thus confirming the correct targeting of the lesion. In all cases, a localizing clip (BiomarC 1 × 5 mm, Carbon Medical Technologies, MI, USA) was placed at the biopsy site [13]. Subsequent mammography in the craniocaudal and mediolateral views were performed to assure clip position. No clips dislocations (more than 10–15 mm from the biopsy site) were noted. This mammogram was also used to analyze residual calcifications, which has been performed by the attending radiologist.

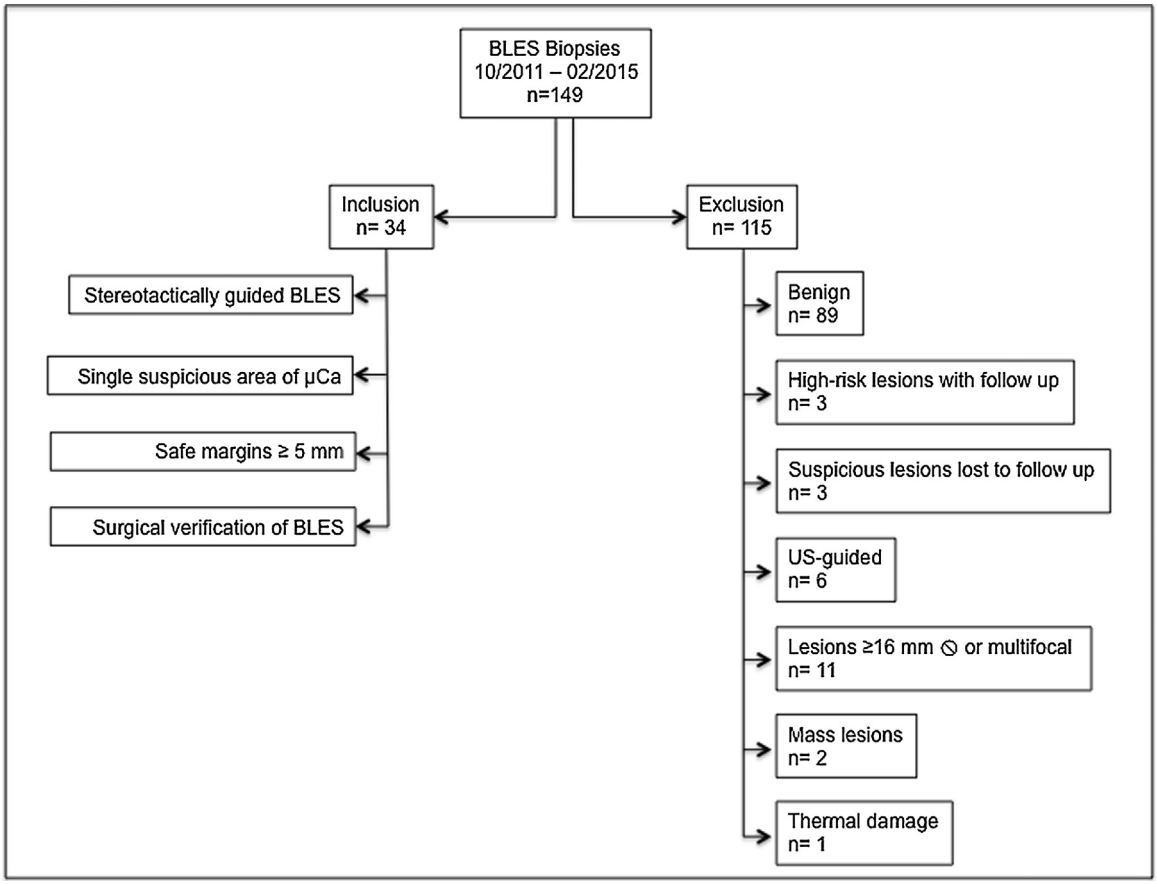

Fig. 1. Study design flowchart.