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Breast Lesion Excision System in the diagnosis and treatment of intraductal papillomas – A feasibility study

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Abstract

Objectives: This study aims to evaluate the feasibility of Breast Lesion Excision System (BLES) in the treatment of intraductal papillomas.
Material and methods: All patients with a needle biopsy –based suspicion of an intraductal papilloma who consequently underwent a BLES procedure at Helsinki University Hospital between 2011 and 2016 were included in this retrospective study. The purpose of the BLES procedure was either to excise the entire lesion or in few cases to achieve better sampling.
Results: In total, 74 patients underwent 80 BLES procedures. Pathological diagnosis after the BLES biopsy confirmed an intraductal papilloma without atypia in 43 lesions, whereas 10 lesions were upgraded to high-risk lesions (HRL) with either atypical ductal hyperplasia or lobular carcinoma in situ. Five cases were upgraded to malignancy, two were invasive ductal carcinomas and three were ductal carcinoma in situ. Additionally, 18 lesions were diagnosed as other benign lesions. Four procedures failed. Complete excision with BLES was achieved in 19 out of 43 intraductal papillomas, 6 out of 10 HRL and two out of five malignant lesions. No major complications occurred. The BLES procedure was adequate in the management of the 71 breast lesions.
Conclusion: The BLES procedure is an acceptable method for the management of small benign and high-risk breast lesions such as intraductal papillomas in selected patients. Thus, a great amount of diagnostic surgical biopsies can be avoided.

Keywords: Intraductal papilloma; Breast Lesion Excision System (BLES); High risk lesion; Surgical excision; Core needle biopsy

Introduction

Clinical, radiological and histological interpretation of papillary lesions of the breast remains challenging due to their wide morphological spectrum. Papillomas may be broadly divided into two groups: peripheral and central. Peripheral papillomas are often multiple and central are solitary. Papillomas may on the basis of the morphology be classified into benign or papillomas associated with atypical ductal hyperplasia (ADH) or papilloma associated with ductal carcinoma in situ (DCIS) or malignant subtype e.g. papillary carcinoma with adjacent invasive carcinoma. Papillomas presenting as papillomatosis confers a higher risk of malignancy [1,2].

It is not possible to exclude atypia nor malignancy by core needle biopsy (CNB) or imaging [2–5]. Thus, the standard of care in the management of papillomas is surgical excision. Intraductal papillomas without atypia could be managed by follow-up and a surgical procedure could be avoided [6]. However, follow-up can be stressful for the

Abbreviations: BLES, Breast Lesion Excision System; HRL, high-risk lesion; ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ; CNB, core needle biopsy; VACNB, vacuum-assisted core needle; FNAC, fine needle aspiration cytology; MDT, multidisciplinary team; LCIS, lobular carcinoma in situ.

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patient and is a notable expenditure too. It has been suggested that a larger biopsy sample might decrease the risk of sampling error [7–9].

The Breast Lesion Excision System (BLES; Intact™; Intact Medical Corporation, Framingham, USA) is a biopsy device, which uses radiofrequency cautery to excise a single spheroid tissue sample without fragmentation thus making the histopathological analysis more accurate than by CNB. In the USA, BLES was approved by the Food and Drug Administration for sampling in 2001 and for complete removal of lesions in 2005. The BLES technique has shown to be a safe and potential alternative to traditional surgical excision for removal of small breast lesions [10–14]. The underestimation rate seems to be lower with the BLES than with vacuum-assisted core needle biopsy (VACNB) [15,16]. Other benefits of the BLES in comparison to VACNB are the possibility to evaluate histological margins and the ability of the BLES wire basket to perform hemostasis. The BLES biopsy can be carried out as an outpatient procedure.

The aim of this study is to evaluate the feasibility of BLES in the treatment of intraductal papillomas in selected patients.

Patients and methods

Patients

All patients with a needle biopsy –based suspicion of an intraductal papilloma who consequently underwent a BLES procedure at the Department of Radiology of Helsinki University Hospital (HUH) between November 2011 and June 2016 were included in this retrospective study. The patients had a prior CNB or a fine needle aspiration cytology (FNAC) sample taken. In one BI-RADS 4 lesion, neither previous CNB nor FNAC was performed, but the lesion was biopsied with the BLES at the same session with another papilloma with a previous CNB. Only four of our patients had had nipple discharge. The purpose of the BLES was either to excise the entire lesion or in few cases to get a greater amount of tissue for better sampling of the lesion.

The patient data were collected into a database at the time of the BLES procedure. The HUH Department of Radiology is the first unit in Finland to use the BLES since 2011. The very first BLES procedures of our institute were also included in this series. At the beginning, four of the patients with a high-risk lesion (HRL) and positive margins in the BLES specimen were referred to surgical excision in order to confirm the diagnosis and a complete removal. The patients have been followed up since the first BLES procedure until June 2016. The procedure data was collected from the prospective database and additional data was gathered from electronic patient records retrospectively. The institutional research permission was granted by HUH Comprehensive Cancer Center.

BLES procedure

The BLES device consists of a biopsy basket, which is mounted into a wand. A wire basket emerges from the tip of the wand cutting and cauterizing the breast tissue with radiofrequency energy enveloping the target lesion. A single intact spherical tissue sample may then be removed. The basket sizes in our unit are 12 mm, 15 mm and 20 mm. The aim was always to use the largest basket when possible (Fig. 1).

Contraindications for the BLES procedure were a cardiac pacemaker, pregnancy and breastfeeding. Anticoagulants such as clopidogrel and warfarin were recommended to be stopped one week prior to the procedure.

The maximum size of the lesions was 10 mm in breast ultrasound in order to achieve a complete excision. The thickness of the breast, i.e. the distance between the pectoralis muscle and the skin should be more than 14 mm so that the wire basket could open safely and successfully. The distance from the lesion to the skin and the pectoralis muscle should be 3 mm and to the nipple 6 mm. Hereby, the most peripheral or most central papillomas are not feasible for the BLES.

The procedure was performed under ultrasound or stereotactical guidance by experienced senior breast radiologists. If residual lesion was seen, the procedure could be repeated. In case of two samples, the nipple's side of the specimen was inked so that the pathologist could better orientate for excision completeness. Clip mark was inserted into the biopsy site. The 1 cm skin incision was closed with strips. Total procedure time was approximately 50 min.

BLES samples optimally fixed in 10% buffered formalin were sliced for processing, sectioning into 3 μm thick sections and staining with hematoxylin and eosin according to approved methods and protocols in pathology laboratory. Samples were examined by pathologists specialized in breast pathology. In case of suspicion of e.g. ADH or malignancy adjunctive immunohistochemical stains were performed. The sections were stained with Ventana Benchmark XT (Roche, Ventana, Tucson, AZ), using biotin-free, three step multimer based detection kit Optiview (760-700, Roche, Ventana, Tucson, AZ). The protocol was based on heat-induced epitope retrieval using standard pretreatment buffer CC1, 64 min. The slides were incubated for 40 min with the primary antibody to CK5/6, ER and SMMHC diluted 1:100. The slides were then dehydrated and mounted for viewing with microscope.

Histological margin status of the BLES sample was recorded and categorized into two groups: complete removal and partial removal (positive margin).

Data analysis

All cases were discussed at a multidisciplinary team (MDT) meeting after final histopathological diagnosis in order to decide upon definitive management: routine

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