

The breast lesion excision system (BLES)

A preliminary experience



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OBJECTIVE: *BLES (Intact Breast lesion Excision System) is a new defined system which can remove the lesion completely. We aimed to evaluate and compare the results of BLES used for breast lesions requiring histological verification with other percutaneous biopsy methods in the literature.*

METHODS: *Patients with breast lesions smaller than 20mm and for whom biopsy was indicated were involved in the study. 18(1 male, 17 female, mean age: 41. 83, age range: 26-72) patients were included the study. BLES is applied with a single insertion. Radiofrequency is used to excise the breast tissue after the insertion. Around the lesion, tissue capture basket is moved back and forth. Once captured, the basket and the probe is removed from the incision area.*

RESULTS: *All of the lesions were excised en-bloc. The only complication occured was subdermal hematoma in one case (5.5%) which resolved spontaneously. Pathological analysis of the specimens revealed 9 fibroadenoma, 3 fibroadenomatosis hyperplasia, 3 complicated and calcified cysts, 1 ductal epithelial hyperplasia, 1 carcinoma in situ with intraductal papillary carcinoma focus and 1 ductal carcinoma in situ with 2 mm invasive carcinoma focus. The last two cases underwent resection and sentinel lymph node procedure.*

CONCLUSION: *BLES is a non-invasive method which has no need for additional initiatives in benign cases, provide sufficient samples for pathological diagnosis and remove the lesion in one piece. BLES method can be applied in selected cases.*

KEY WORDS: Breast Lesion Excision System, Breast, Biopsy, Radiofrequency, Lesion

Introduction

Breast Cancer is second common cancer in all humans, after lung cancer and the most frequent malign tumor in many of developed and developing countries¹.

Hence, masses in breast should be examined very carefully. Beside of the widely use of mammography and ultrasonography in the diagnosis of early breast cancer, the rate of incidentally detected non-palpable breast lesions are increased; interventional methods such as fine-needle and tru-cut needle biopsies, vacuum assisted biopsy devices for closed procedures and excisional biopsy for open procedures are needed for diagnosis and treatment of these lesions⁵⁻⁷. In the diagnosis of some small solid lesions seen in the breast radiological methods and even biopsies accompanied radiology may be insufficient. Excisional biopsy may be preferable to some of the centers in such cases and often the final pathology report comes as benign. Vacuum assisted biopsy method is recently defined radiological excision method for lesions known as benign, such as fibroadenoma⁸. These meth-

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ods has an increasing popularity especially among young women with the advantages to do the procedure with local anesthesia and less scarring compared to excisional biopsy. Fewer complications and indication up to lesions of 30 mm are the other advantages⁹⁻¹¹. The disadvantage of this method is the removal of the lesion in pieces. Therefore the method cannot answer questions such as the status of surgical margins and the possibility to remain pieces of the lesion behind⁷. Breast lesion excision system (BLES) method, applied safely since 2001, is an alternative method to vacuum assisted biopsy of larger biopsies. The most important feature of this method is extraction of the entire lesion as a single piece with clean surgical margins⁷.

The purpose of any biopsy is to detect all characteristics of malign breast lesions and to diagnose benign lesions accurately. Intact Breast Lesion Excision System

(Breast Lesion Excisional System; BLES) is right a method of removing en-block all detected masses in breast. This study is aimed to determine if Intact Breast Lesion Excision System is a favorable alternative to other biopsy methods.

Material and Methods

Three hundred patients who applied to General Surgery Sisli Etfal hospital with mastalgia last year were included in the study. Axilla and breast examinations were done to all patients followed by the ultrasonography. Mammography was also performed on patients over 35 years. 18 patients (1 male, 17 female, mean age: 41.83, age range: 26-72) who accept to join the study having a single lump of 20mm or smaller at Ultrasonography (USG) and/or at mammography were chosen for the study group. The patients having masses larger than 20mm and didn't accept to join the study were excluded. Informed consent forms were obtained from all the patients. The biopsies were performed with breast lesion excision system (Intact Medical Co. MA/USA), under supervision of same radiologists and general surgeons.



Fig. 1: Two cm lesion in the breast, hours level 12.



Fig. 2: The line of BLES is anesthetized with local anesthesia.



Fig. 3: Space between lesion and skin is anesthetized with local anesthesia by USG probe.

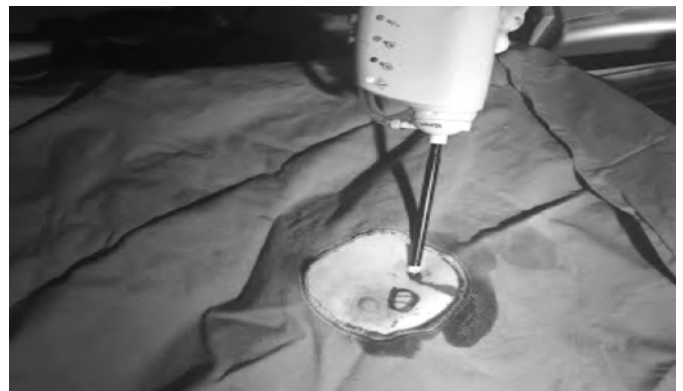


Fig. 4: Mass is excised with the aid of BLES probe.

Infiltration anesthesia (Citanest ®) were administered to all patients of the study group before the operation. Subsequently, according to the size of the mass a 0,5-2 cm incision in the breast skin was performed. Then probe is advanced to the hardness of the mass. Arms coming from the probe tip, the lesion was detached from the surrounding tissues, using a basket catheter which is expanded out from the end of the probe and can sep-

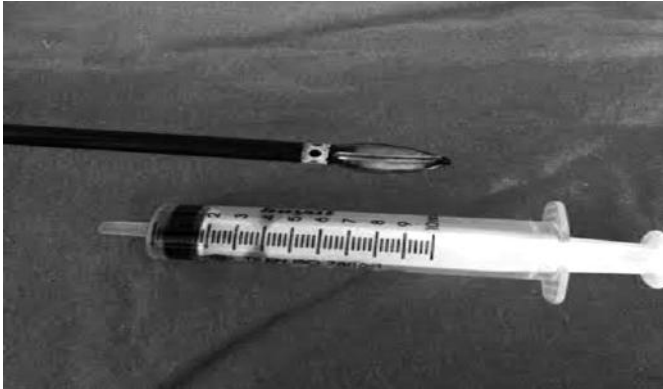


Fig. 5: Mass in the basket of probe.



Fig. 6: The mass removed from the basket.

arate the tissues using radiofrequency (RF). Afterwards, the mass locked in the basket was removed with the probe (Fig. 1-6). The removed masses were sent to histopathological examination. According to the size of tissue defect, incisions were sutured with 5/0 polypropylene or closed with sterile strips, and pressure dressings were applied to avoid hematoma. Patients were given anti-inflammatory tablets after biopsy. Dressings were opened and wounds were checked on the day 1. Complications were recorded. Sutures were removed a week after and control USG was performed. According to pathological results these patients were categorized according to their diagnosis and the maligncases were considered for advanced surgery.

Results

A total of 18 patients's lesions were excised totally. While only one complication of hematoma was detected in one patient (5,5%), it receded by medical treatment. Median follow up was 9 (5-12) months for all patients. Mean size of the lesions were 11,5 mm (5-20mm). Pathological results were presented in Table I.

Pathological assessments has revealed 9 fibroadenomas, 3 fibroadenomatous hyperplasia, 3 complicated cysts and calcification, 1 ductal ephitelial hyperplasia, 1 ductal carcinoma in situ and 1 case of ductal carcinoma in situ containing 2mm of invasive carcinoma. Re-excision and sentinel lymph node procedures were applied to these

TABLE I - The patient characteristics

Order no	Sex	USG findings of lesions	Pathological result
1	F	15x10 mm in size; hypoechoic lesion	Fibroadenomatosis
2	F	7x7 mm in size; hypoechoic lesion	Cyst and calcification
3	M	10x8 mm in size; hypoechoic lesion	Ductus Epithel Hyperplasia
4	F	15x10 mm in size; hypoechoic lesion	Fibroadenomatosis
5	F	15x12 mm in size; hypoechoic lesion	Hyperplasia
6	F	15x12 mm in size; hypoechoic lesion	Fibroadenomatosis
7	F	7x8 mm insize; irregular, hypoechoic lesion with microcalcification	Cyst and calcification
8	F	17x8 mm in size; hypoechoic lesion	Fibroadenomatosis
9	F	6x5 mm in size; hypoechoic lesion	Cyst and calcification
10	F	14x8 mm in size; solid lesion	Fibroadenomatosis
11	F	8x5 mm'ik in size; regularly countured hypoechoic lesion containing microcalcification	Hyperplasia
12	F	14x11mm in size; hypoechoic lesion	Ductal carcinoma in situ
13	F	14x10 mm in size; lobular hypoechoic lesion containing cystic focus	Fibroadenomatosis
14	F	14x15 mm in size; hypoechoic lesion	Ductal carcinoma in situ
15	F	20x15 mm in size; hypoechoic lesion	Fibroadenomatosis
16	F	11x6 mm in size; hypoechoic lesion	Fibroadenomatosis
17	F	12x6 mm in size; hypoechoic lesion	Hyperplasia
18	F	16x7 mm in size; hypoechoic lesion	Fibroadenomatosis
	F	10x7 mm in size; hypoechoic lesion	Fibroadenomatosis

TABLE II - Pathological characteristics

Pathology	Number
Fibroadenomas	9
Fibroadenomatous hyperplasia	3
Complicated cysts and calcification	3
Ductal epithelial hyperplasia	1
Ductal carcinoma in situ	1
Ductal carcinoma in situ containing 2mm of field of invasive carcinoma	1

last two cases. A 30mm ductal carcinoma in situ was detected through the re-excision of the first case. Lobular carcinoma with diameter of 2mm were detected in the re-excision of the invasive focused carcinoma. Sentinel lymph nodes were found negative for both cases.

Discussion

As a method, ultrasound-guided breast biopsy with BLES, is similar to USG biopsies of other organs, and requires experience of USG ¹².

Synchronized ultrasound imaging permits the immediate determination of displacement of the lesion due to the possible compression of the probe and needle, hence it provides the facility ¹³ of adjustment; therefore this character can be evaluated as an advantage to stereotaxic method. (p13) ¹³.

Probability of failure is higher in cases of microcalcifications and during mammography-guided markings. The most significant factor affecting the success in marking is the relationship wire-lesion. Failure can be also originating from surgery itself. The experience of radiologist in marking and communication between the surgeon and radiologist is of importance. Furthermore, the failure rate increases while the excised tissue volume decreases ¹⁴. Breast Lesion Excisional System procedure is the method of interventional diagnosis and treatment for breast lesions that had been in use since 2002 ⁷. Because simpler, comparatively inexpensive, cosmetically acceptable, it has been an alternative method to open surgical biopsy since the beginning of its application. It has to be emphasized that, achievement of cosmetic results while preserving the normal tissue, as well as the way of correct removal of lesion, should be the goal of every biopsy procedure ⁷. Amongst other methods of biopsies, it can ensure the total removal of the lesions up to 20mm, hence it can be considered as an alternative to open and stereotaxic biopsies. The amount of tissue to be removed is related to the size of the basket used.

Maximum benefit is provided through a minimal incision, owing to size of incision is almost the same size of the lesion, therefore, cosmetically good result is obtained, as a solution to one of the concerns of younger population

⁷. Open biopsy methods, especially with deep lesions, require larger incision and larger amount of tissue dissection. Applicability in polyclinic conditions, with local anesthetic, no need of hospitalization, would be the reasons of choice for elderly and for patients with systemic problems; therefore BLES is able to address entire patient population. In our study, although the average diameter of 18 lesions was larger than 11.5 mm, baskets were chosen larger than the lesions. The aim was leaving intact breast tissue around the lesion and therefore provision of negative surgical margin. While there is pain and hemorrhage by VAB (vacuum assisted biopsy) and CNB (cutting needle biopsy) due to repeated intervention into the lesion region, the risk of hemorrhage is expected lower since there is only one intervention required and radiofrequency (RF) is used in BLES procedure.

All needle biopsies can serve only the diagnosis, by breaking off tissue from the lesion and even if the diagnosis is benign, follow-up can be required ¹⁵. Radiological regular follow-ups should be applied with the duration of at least 3 years, with intervals at 6 months first, then at 12 months if any diagnostic biopsies are used ¹⁶. If the size of lesion increases during the period, surgical biopsy becomes necessary ¹⁶. However, since entire lesion can be excised by BLES method, both diagnosis and treatment can be provided in benign cases, hence, the patient can be saved from the trouble of follow-ups of excised lesion. As results of pathological assessments of series of our 18 cases, 9 fibroadenomas, 3 fibroadenomatous hyperplasia, 3 complicated cysts and calcification, 1 ductal epithelial hyperplasia, 1 ductal carcinoma in situ and 1 case of ductal carcinoma in situ containing 2 mm of invasive carcinoma field were detected. Healthy tissue were found at periphery of the lesions in 8 out of 9 fibroadenomas, only one lesion was removed entirely and was adjacent to surgical margin. Following vacuum-assisted biopsies, a lesion, may be lost radiologically however that does not mean that the lesion histologically disappeared. It has been shown, by surgical excision, residual tumor were detected in 73-80% of such cases ¹⁷. In our study, although there is a negative surgical margin, re-excision and sentinel lymph node procedure was applied on our first case with DCIS (Ductal carcinoma in situ), since micro-invasive field is available. Residual ductal carcinoma was not seen in situ lobular focus of carcinoma detected in re-excision. No malignancies were encountered in sentinel lymph node procedure. No micro-invasion were seen in the re-excision of our second case with DCIS, however a DCIS of 30mm was detected. Likewise, no malignancies were seen in sentinel lymph node procedure of latter. Both cases were discharged from hospital without any development of complication.

By definition, histologically incomplete diagnosis means that histological characteristics are not reflected on the result of needle biopsies ¹⁸. Occurrence of such cases can be more frequent especially in biopsies of microcalcifi-

cations. As an example, it is often possible to meet cases in which ADH (atypical ductal hyperplasia) found in biopsy, in surgery were detected as DCIS, or cases in which DCIS found in biopsy were detected as IDC (Invasive ductal cancer) in surgery²⁴. In addition, it is reported that, since incomplete diagnosis is a possibility in some particular histological diagnosis by biopsy, definite diagnosis should be achieved through excisional biopsy¹⁹⁻²¹.

In the study conducted by Killebrew et al with 1600 cases, consisting of two groups, in which VAB and BLES were compared, researchers have defined, the "underestimation rate of the biopsy method" which is the ratio of the number of IDC cases at surgical follow up to the total number of diagnosis of DCIS, after an initial biopsy diagnosis of DCIS (22). According to this definition while 19.4% (7/36) were found by VAB, 3.2% (1/31) were found by BLES. Despite the difference of 6-fold difference between these results, statistical difference was not found ($p=0.06$). In the same study, DCIS were entirely removed in 38.7% (12/31) of cases by BLES, and it is determined that no residual tumor left. This ratio was found 11.1% (4/36) for VAB and significantly lower than BLES ($p<0.01$)²². Underestimation ratio varies between 10% and 50% for ADH, 4% and 28.6 for DCIS in the literature^{22,24,25}.

In a multicentral study with a series of 742 cases conducted by Sie et al, in which 34 ADH, 119 DCIS detected by BLES, open surgery were performed according to biopsy results, and DCIS was detected in 3 cases initially diagnosed ADH, and also, IDC was detected in 6 cases initially diagnosed DCIS. Accordingly, Sie et al found underestimation rates of 9.4% (3/34) for ADH and 5.2% (6/115) for DCIS²⁶.

Despite the lower underestimation rates of BLES than VAB found in both studies, both researchers reported that the use of the BLES would not obviate the need for surgical excision with a primary diagnosis of ADH or DCIS, but it can provide a possible option for percutaneous biopsies^{22,26}.

In conclusion, due to the reasons such as the possibility of removing masses up to 2 cm in one piece with surgical margins, provision of opportunity of both diagnosis and treatment for especially benign lesions, maintenance of the normal tissue in place from where the needle enters into skin and to the lesion area, removal of the mass in breast using radiofrequency waves instead of knives and heated wires, we consider BLES is a minimally invasive and safe method which forms a good alternative to surgery and other biopsy methods, especially for selected cases.

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Riassunto

Il BLES (Intact Breast lesion Excision System) è un nuovo sistema finalizzato alla rimozione completa di una lesione mammaria. Lo scopo del nostro studio è quello di valutare e paragonare i risultati ottenibili con il BLES nei confronti di lesioni mammarie con necessità di esame istologico a confronto con altri metodi di biopsia percutanea della letteratura.

Sono stati utilizzati 18 pazienti con lesioni mammarie di dimensioni inferiori ai 20 mm, per i quali era indicato l'accertamento biotico, di cui un uomo e 17 donne, dell'età media di 41, 83 anni (da 26 a 72). Il BLES è stato inserito solo una volta, e per l'escissione del tessuto mammario è usata la radiofrequenza, ed il cestello di raccolta del tessuto viene mosso avanti e dietro attorno alla lesione. Terminata la raccolta del tessuto il cestello e la sonda vengono rimossi dall'incisione.

In tutti i casi le lesioni sono state escisse in blocco. La sola complicazione rilevata è stato lo sviluppo di un ematoma sottodermico in un solo caso (5,5%) con risoluzione spontanea.

L'esame istopatologico dei campioni di tessuto ha dimostrato 9 fibroadenomi, 3 iperplasie fibroadenomatose, 3 cisti complicate e calcifiche, 1 iperplasia epiteliale duttale, 1 carcinoma in situ con un focus di carcinoma papillare intraduttale e 1 carcinoma duttale in situ con un focus di carcinoma invasivo di 2 mm.

Negli ultimi due casi si è proceduto a resezione chirurgica con procedura del nodulo sentinella.

In conclusione il BLES si è dimostrato un metodo non invasivo che non necessita di ulteriori procedure in caso di benignità, fornisce sufficiente materiale per l'esame istopatologico e rimuove la lesione in blocco, e dunque trova la sua applicazione in casi selezionati.

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