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Vacuum Assisted Biopsy in Diagnosing and Treatment of Ultrasound-Detected Benign Breast Lesion: Single Center Experience in Taiwan

Cheng-Che Wu[1], Chin-Ju Ko[1], Chung-Liang Li[1], Ming-Feng Hou[1], Ou-Yang Fu[1*]

[1] Department of Breast Surgery, Kaohsiung Medical University Chung-Ho Memorial Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan

Email Address

wuchengche.kmu@gmail.com (Cheng-Che Wu), chinju1060090@gmail.com (Chin-Ju Ko), starsand9101056@gmail.com (Chung-Liang Li), mifeho@kmu.edu.tw (Ming-Feng Hou), kmufrank@gmail.com (Ou-Yang Fu)
*Correspondence: kmufrank@gmail.com

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Abstract:

Benign breast tumor is generally known as non-cancerous breast tumor, and mostly managed with conservative approaches. While the negative psychological issues still relatively high occurrence in patients diagnosed with benign tumors. The Encor® biopsy system, a real-time ultrasound-guided minimal invasive breast biopsy system, was suggested as a minimal invasive technique for benign breast tumors treatment. This study was aimed to determine the treatment efficacy and feasibility of ultrasound-guided encor breast biopsy for palpable benign breast lesion. This retrospective study included a total of 548 palpable breast lesion patients with the Institutional Review Board (IRB) approval. A total of 567 encor breast biopsy procedures were performed at the Department of Breast Surgery, Kaohsiung Medical University Hospital (Kaohsiung, Taiwan) between 2011 and 2015. The histological findings for biopsied specimens were mostly benign (514/567, 90.65%). The high-risk papilloma lesion was reported in 6.00% (34/567) cases. A total of 3.45% (19/567) cases were detected as malignant including ductal carcinoma in situ and invasive ductal carcinoma malignant lesions. We found twenty-five (25/548, 4.56%) patients had received second encor breast biopsy within 3 years, and three (3/25, 12.00%) of them had received third encor breast biopsy within 1 year after secondary encor biopsy. This study is the first time to report the usage of ultrasound-guided encor biopsy experience for benign breast tumors in Taiwan population. The study results revealed this minimally invasive treatment technique was safe and feasible for benign breast tumors diagnosing and treatment.

Keywords:

Benign Breast Tumor, Breast Cancer, Ultrasound-Guided Breast Biopsy, Vacuum-Assisted Breast Biopsy

1. Introduction

Benign breast tumor is generally harmless and known as non-cancerous breast tumor. Transformation from non-cancerous breast tumor to cancer is rare and mostly managed with conservative approaches [1,2]. Fibroadenoma, fibrocystic change including fibrosis and cysts were introduced as the main type of benign breast tumors. Up to 25% of fibroadenoma is introduced with multiple tumors characteristics; and 5 - 10% is characterized by rapid growth to giant size (larger than 5cm and more than 500 grams) [2]. Although most benign breast tumors are asymptomatic, painless and well circumscribed, the benign breast disease still a risk factor to elevate risk of breast cancer, especially in long term follow-up [3,4].

Even the benign breast tumor are introduced as nonfatal disease, the psychological issues including high level anxiety and depressive symptoms still relatively high occurrence in patients with who diagnosed with benign tumors [5]. Traditionally, the suspicious breast lesion generally includes fine needle or core needle biopsy to obtain specimen for further detailed histologic diagnosis. And the wide excisions or open biopsy were conducted to eliminate the breast lesion which required either monitored or general anesthesia. However, the surgery scar formation, permanent breast deformity and risk of complications might lead to overtreatment issues [2]. In addition, the distress emotional was considered associated with the typical breast biopsy [6]. Thus, there is a demand for a less invasive technique to solve these issues.

The Encor® biopsy system (EnCor® Breast Biopsy System, BARD, USA), a real-time ultrasound-guided minimal invasive breast biopsy system, has been suggested as a new strategy for benign breast tumors. The encor biopsy could performed with local anesthesia and available to operate in open patient department (OPD). This minimal invasive technique has equivalent diagnostic accuracy with typical biopsy [7]. The feasibility and safety of encor biopsy have been introduced by previous researches [8,9,10]. Simultaneously, the benefits of encor biopsy can include lower clinical resources, fewer operation time, less complication and recovery time [11]. Recently, ultrasound-guided encor breast biopsy has also been recommends early breast cancer management, and appears to be a valuable technique in these cases [12,13,14]. However, the long term therapeutic effect remains unknown and need further demonstration.

This study was aimed to determine the treatment efficacy and feasibility of ultrasound-guided encor breast biopsy for palpable benign breast lesion. In this study, we present the technique of ultrasound-guided encor breast biopsy, the indications for surgery and the preliminary outcomes on our preliminary experience performing 567 ultrasound-guided encor breast biopsy procedures for the management of benign breast tumor.

2. Materials and Methods

2.1. Patients Selection

This was a retrospective study utilizing the ultrasound-guided encor breast biopsy record of palpable breast lesion patients with the Institutional Review Board (IRB) approval (KMUHIRB-E(II)-20170150). A total of 548 female patients treated with encor breast biopsy at the Department of Breast Surgery, Kaohsiung Medical University Hospital (Kaohsiung, Taiwan) between 2011 and 2015. All patients had previously undergone a breast mammography and a breast ultrasound examination.

Patients with the Breast Imaging Reporting and Data System (BI-RADS) category between 1 and 3 in mammography and/or ultrasound examination were eligible to receive ultrasound-guided encor breast biopsy. Since the ultrasound-guided encor breast biopsy was not covered by National Health Insurance (NHI) in Taiwan, the affordable for the cost of this biopsy method was taking into consideration. A preoperative biopsy (core needle or fine needle biopsy) was not performed prior to the ultrasound-guided encor breast biopsy in newly diagnosed breast benign tumor lesion. Informed consent was obtained from all patients before receive ultrasound-guided encor breast biopsy. The patients who unable to provide inform consent, allergic to the anesthetic drug, existed with skin inflammation or infection wound on breast were excluded from ultrasound-guided encor breast biopsy.

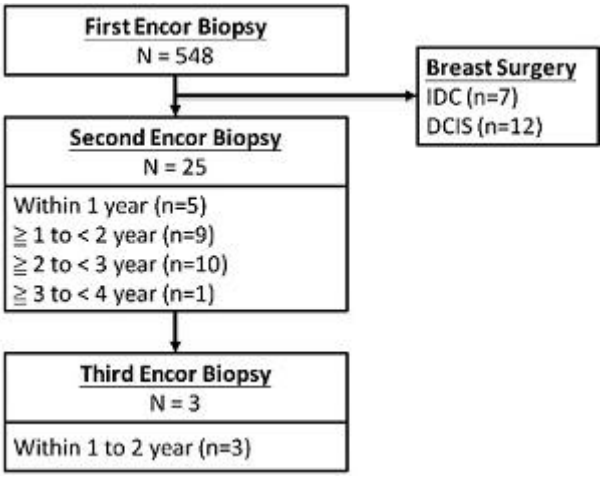

Figure 1. *The follow-up encor biopsy management for all patients. DCIS represents ductal carcinoma in situ. IDC represents invasive ductal carcinoma.*

2.2. Encor Breast Biopsy Procedure

All patients were examined the blood parameter examinations before treatment. The ultrasound-guided encor breast biopsy procedures were performed by three experienced physicians and one ultrasound radiologists. We used 8-gauge encor biopsy system, and a ultrasound system for real-time ultrasound surveillance within the biopsy procedure. A local anesthetic (1% lidocaine) or general anesthesia (if patient requested or physicians recommended for specific situations) followed by sterilized was applied to the target area before biopsy. Skin excision within a range of 3-5 mm was made on the labeled target area to allow the insertion of the 7-gauge probe under the real-time ultrasound surveillance. To ensure the complete excision of the target lesion, the probe was scanned longitudinally and transversely or rotated at a guidance angle, until the hypoechoic lesion on the intraoperative ultrasound no longer be detected. A postoperative ultrasound evaluation was performed to avoid the remaining lesion. Direct compression (approximately 5-10 minutes) and elastic bandage was applied immediately for hemostasis after biopsy. Patients were recommended to take 6 hour bed rest and avoid intense action during wound healing period. Generally, patients were able to return to daily life within 12 to 24 hours. Each resected tissue specimen was preserved and examined by the pathologist. The patients with malignancy histological diagnosis including ductal carcinoma in situ or ductal carcinoma were arranged for further typical breast cancer treatment procedure. Follow-up ultrasound examination was arranged 3-month after encor biopsy, and then every 3- or 6-month for recurrence surveilance.

2.3. Statistical Analysis

The measurements analyzed included the histopathological diagnosis breast lesion and times of received ultrasound-guided encor breast biopsy. All e of statistical analyses were performed using Stata (StataCorp. 2009. Stata 11 Base Reference Manual. College Station, TX: Stata Press).

3. Results and Discussion

A total of 567 encor breast biopsies were performed in 548 patients with averaged age of 50 (ranged between 20 - 75). Table 1 summarized the histopathological diagnosis results of all biopsies. Most of the results were benign (514/567, 90.65%), reported with 60.49% fibroadenoma, 38.45% fibrocystic lesion, 1.94 abscess, 3.88% phyllode , 5.29% adenosis and 6.53% others benign lesion. The high-risk papilloma lesion was reported in 6.00% (34/567) cases. A total of 3.45% (19/567) cases were detected among the biopsies specimen, including 2.12% (12/567) ductal carcinoma in situ and 1.23% (7/567) invasive ductal carcinoma malignant lesions.

Table 1. *Histopathological characteristics of all biopsied tissue specimen in 548 patients. (n = 567).*

	n	%
Total encor breast biopsy procedures	567	
Low-risk lesion		
Fibroadenoma	343	60.49%
Fibrocystic lesion	218	38.45%
Abscess	11	1.94%
Phyllode	22	3.88%
Adenosis	30	5.29%
Others benign	37	6.53%
High-risk lesion		
Papilloma	34	6.00%
Malignant		
Ductal carcinoma in situ (DCIS)	12	2.12%
Invasive ductal carcinoma (IDC)	7	1.23%

Figure 2 showed multiple biopsied benign tumor tissue specimens removed by encor breast biopsy. The size of removal suspicious benign tumor tissue specimen by encor breast biopsy generally retained in small size, which enabled less invasion and excessive removal of normal breast tissue.

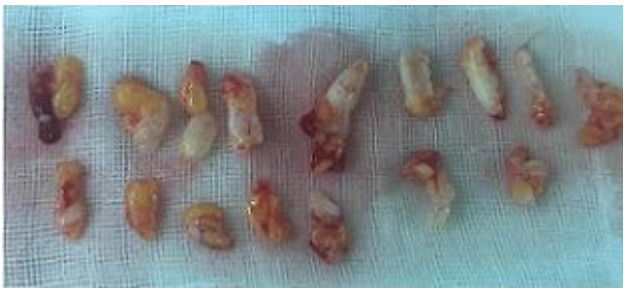

Figure 2. *The biopsied benign tumor tissue specimens removed by encor breast biopsy.*

Within the 567 procedures, we found twenty-five (25/548, 4.56%) patients had received second encor breast biopsy within 3 years, and three (3/25, 12.00%) of them had received third encor breast biopsy within 1 year after secondary encor biopsy. The recurrence status of each encor biopsy findings in 25 recurrence patients were summarized in Table 2. The results showed 16% (4/25) recurrence patients had multiple lesions in initial, and 2 of the 4 patients still obtained multiple benign lesions in the final treatment. Total 32% (8/25) recurrence patients were diagnosed as multiple benign lesions in their recurrent treatment.

Table 2. The follow-up encor biopsy status in recurrent patients. (n = 25).

Patient	Encor biopsy Treatments (times)	Follow-up biopsy status	Multiple lesion at initial treatment	Multiple lesion at final treatment
P01	3	Right breast ipsilateral and local recurrence	No	No
P02	3	Right breast local recurrence	No	No
P03	3	Contra recurrence and local recurrence	No	No
P04	2	Left breast local recurrence	No	Yes
P05	2	Left breast local recurrence	No	No
P06	2	Bilateral breast local recurrence	No	Yes
P07	2	Right breast local recurrence	No	No
P08	2	Right breast local recurrence	No	No
P09	2	Contra breast recurrence	No	No
P10	2	Right breast local recurrence	Yes	Yes
P11	2	Contra breast recurrence	No	No
P12	2	Right breast local recurrence	No	No
P13	2	Right breast local recurrence	No	No
P14	2	Left breast local recurrence	Yes	No
P15	2	Left breast local recurrence	No	No
P16	2	Right breast local recurrence	No	No
P17	2	Contra breast recurrence and Ipsilateral recurrence	No	Yes
P18	2	Bilateral breast local recurrence	No	Yes
P19	2	Bilateral breast local recurrence	No	Yes
P20	2	Contra breast recurrence	Yes	No
P21	2	Left breast ipsilateral recurrence	No	No
P22	2	Right breast ipsilateral recurrence	No	No
P23	2	Bilateral breast local recurrence	No	Yes
P24	2	Left breast ipsilateral recurrence	Yes	Yes
P25	2	Left breast ipsilateral recurrence	No	No

This single-center study demonstrates that ultrasound-guided encor breast biopsy is a painless, favorable cosmetic outcome and safe method with fewer complications for benign breast tumors. The low degree of pain experience and high satisfaction of patients has been reported by previous studies [15,16,17]. According to our clinical records, all of the 25 recurrence patients have been received twice even three times

encor biopsy for benign tumor treatment. Although no comprehensive satisfaction surveyed results, the repeat selection using encor biopsy have been partially demonstrate the high satisfaction among benign tumor patients.

Despite our pathological diagnosis reported 6% of high-risk papilloma lesion and approximately 4% ductal carcinoma cases, fibroadenoma and fribrocystic change still the major type of the benign tumors which accounted for over 90% cases. Excisions of a benign breast tumor may be needed if in large size leading to breast distortion, elder patients, or patients' anxiety. Since the National Health Insurance (NHI) in Taiwan offered the open excision payment only for breast benign tumor cases, typical excision with overnight admission and general anesthesia still remains the main clinical approach for most of the benign tumors. Although encor biopsy could treated the benign breast disease with minimally invasive and less side effects, the promotion of this treatment among patients still need further efforts.

Although the single institution data collection might partly avoid the selection and information bias, while the retrospective nature has limited the comprehensive data collection and covariate analysis for the study outcome. Therefore, the lack of covariate analysis and follow-up information restricted the generalizability of our study results.

4. Conclusions

This study is the first time to report the usage of ultrasound-guided encor biopsy experience for benign breast tumors in Taiwan population. The study result revealed this minimally invasive treatment technique was safe and feasible for benign breast tumors diagnosing and treatment.

Conflicts of Interest

The authors declares that there is no conflict of interest regarding the publication of this article.

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