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ORIGINAL ARTICLE

Ultrasound-guided Percutaneous Radiofrequency-assisted Breast Excision to Remove En-bloc Specimens: Five Years' Experience

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ABSTRACT

Objectives: *To describe our initial 5-year experience in using the radiofrequency-assisted excision technology in a regional hospital, with an emphasis on the efficacy, techniques, and safety of the procedure.*

Methods: *Clinical records and operative data of all patients who underwent ultrasound-guided radiofrequency-assisted excision of breast lesions between September 2008 and May 2013 in Kwong Wah Hospital, Hong Kong, were retrospectively reviewed.*

Results: *A total of 48 consecutive patients and 50 lesions with a mean diameter of 9.2 mm were included. Of the 50 lesions, 27 (54%) were graded Breast Imaging–Reporting and Data System (BI-RADS) 3, 21 (42%) BI-RADS 4, and 2 (4%) BI-RADS 5. The mean operating duration was 6.3 minutes. Final pathology showed 1 ductal carcinoma in-situ, 20 fibroadenomata, 11 fibrocystic changes, 9 papillomata, and 11 miscellaneous benign entities. Complete removal with histological clear margins was achieved in 82% of the lesions. No histological underestimation or recurrence was found on subsequent open surgery or follow-up. The procedure was well-tolerated, with a mean pain score of 1.35 out of 5. One patient (2%) experienced a complication of haematoma formation requiring surgical treatment.*

Conclusion: *Ultrasound-guided percutaneous radiofrequency-assisted breast excision is a robust diagnostic tool and therapeutic procedure that allows safe, quick, and efficacious en-bloc lesion removal with clear margins. This minimally invasive office procedure is a promising alternative to conventional open excision of benign breast lesions.*

Key Words: *Biopsy; Breast neoplasms; Electrosurgery; Mastectomy, segmental*

中文摘要

超聲引導下經皮射頻輔助乳房切除術行整體標本切除：五年經驗分享

鄭文輝、呂振英、劉仲恒、方俊仁、陳可恩、英偉亮、陳志梅

目的：描述在一所分區醫院中使用射頻輔助切除術的五年初步經驗，集中討論其療效、技術和程序的安全性。

方法：回顧分析在2008年9月至2013年5月期間在香港廣華醫院內接受超聲引導下射頻輔助乳腺腫瘤切除術的病人的臨床紀錄和手術資料。

結果：連續48名患者（50例病變）被納入研究範圍，腫瘤的平均直徑為9.2 mm。50例中，屬於

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BI-RADS（乳房影像－報告與資料系統）三級的有27例（54%），BI-RADS四級的有21例（42%），BI-RADS五級的有2例（4%）。平均手術時間為6.3分鐘。最終的病理學結果發現有導管原位癌（1例）、乳腺纖維腺瘤（20例）、纖維囊性變（11例）、乳頭狀瘤（9例）和其他良性腫瘤（11例）。徹底切除且組織學上邊緣清晰的病變達82%。其後的外科開放手術或隨訪並無發現組織學的低估或復發。這種技術的病人耐受性良好，平均疼痛分數為1.35（最高分為5分）。一名患者（2%）併發血腫，需進行手術治療。

結論：超聲引導下經皮射頻輔助乳房切除術是一種穩健的診斷工具和治療程序，能安全、快速、有效地將腫瘤整塊切除而切緣清晰。這種微創技術可以作為乳腺良性病變傳統開放式切除術的一個替代方法。

INTRODUCTION

Percutaneous radiofrequency (RF)–assisted breast excision is a novel technology for excision biopsy of breast lesions. Using RF cutting, en-bloc removal of specimens can be achieved which allows complete lesion excision and margin assessment. A high diagnostic accuracy has been reported with the procedure.

We describe our initial 5-year experience with the RF excision technology in a regional hospital in Hong Kong, with an emphasis on the efficacy, technique, and safety of the procedure.

METHODS

Study Design

This was a single-centre, retrospective study. All patients who were referred for ultrasound-guided RF excision of breast lesions from September 2008 to May 2013 were included. The clinical records and operative data were retrieved. Patient demographics, previous clinical, imaging and pathological findings, technical details of the excision procedures, and subsequent outcomes on follow-up were reviewed and analysed.

Study Population

A total of 48 consecutive patients were referred for ultrasound-guided RF excision of breast lesions and were included in the study. Patient selection was jointly decided during a multidisciplinary meeting consisting of breast surgeons, nurse specialists, and breast radiologists. Patients with sonographic breast abnormalities who were clinically indicated for surgical excisional biopsy were considered for RF excision, with intent to remove the lesions completely. Common indications include radiological-pathological discordance, cytological atypia, and high-risk or heterogeneous pathologies on fine-needle aspiration or core-needle biopsy. Exclusion criteria included contraindications to the procedure including breast thickness of <25 mm, and presence of implantable electronic devices such as cardiac pacemakers. Known malignant lesions were excluded since this technique is not marketed or approved by the US Food and Drug Administration for removal of malignant lesions.

Procedure and Techniques

Indications, risks, and potential complications of the procedure were explained to the patients. Written informed consent was obtained.

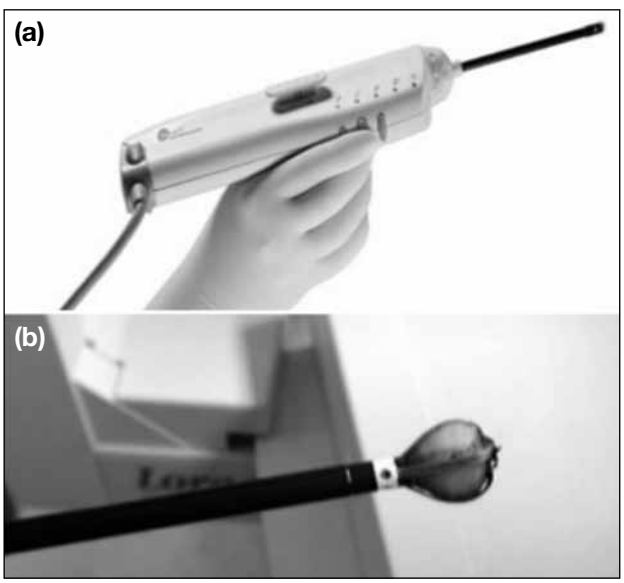

Figure 1. The Intact Breast Lesion Excision System (Intact Medical, Natick [MA], USA). (a) Before basket deployment, and (b) close-up, after basket deployment. The shaft of the radiofrequency wand measures 6.6 mm in diameter and 11.4 cm in length. Various capture basket sizes are available, ranging from 10 mm to 20 mm in diameter when opened.

The RF excisions were performed using the Intact Breast Lesion Excision System (Intact Medical, Natick [MA], USA). All procedures were performed under ultrasound guidance with the patients supine on an examination couch. A pre-procedural ultrasound was performed to identify and document the lesion to be excised; the path and approach to the excision was planned accordingly. After sterilisation of the skin, local anaesthesia was applied to the skin, along the excision tract and around the lesion, using 1:1 dilution of 2% xylocaine with 1:200,000 adrenaline. A small skin incision of 10 mm was made. The biopsy wand was inserted under ultrasound guidance, and advanced towards the lesion with the aid of RF cutting. When the tip of the wand was placed at the periphery of the lesion, the RF-enabled excision basket was deployed and the lesion was ensnared en bloc using RF cutting. The specimen was retrieved by removal of the wand. Vacuum was applied to remove gases and liquids collected at the tip of the wand during the procedure (Figures 1 and 2). Post-procedure ultrasound was performed to document complete lesion removal. Haemostasis was achieved with manual compression and pressure dressing. Various basket sizes were available from 10 mm to 20 mm in diameter, depending on the size of the sample to be captured.

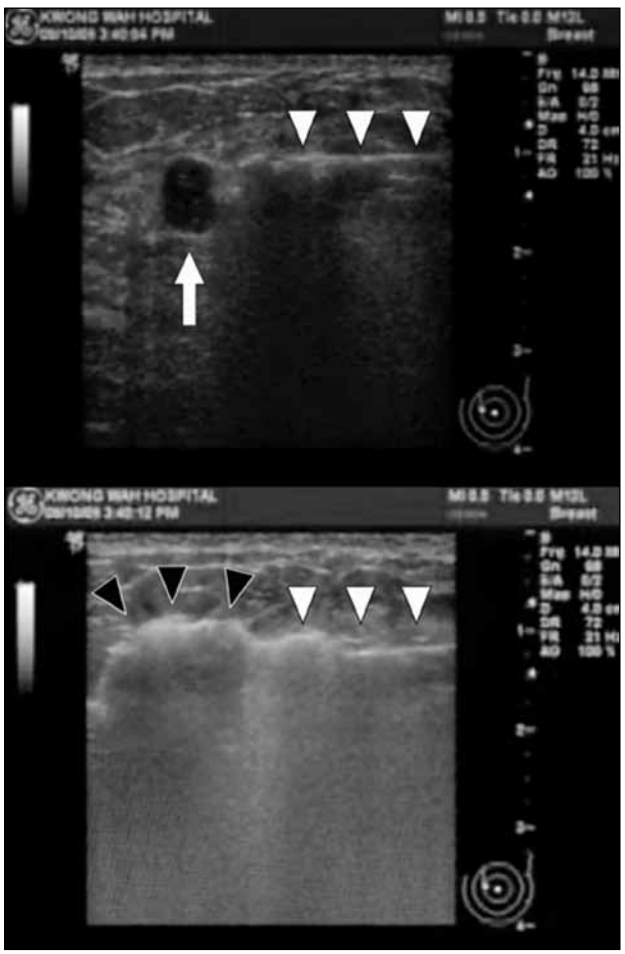

Figure 2. Ultrasound images showing the hypoechoic lesion (arrow) being targeted (top) and after basket deployment (bottom), and the shaft of radiofrequency wand (white arrowheads) and the capture basket after deployment, capturing and obscuring the hypoechoic lesion (black arrowheads).

RESULTS

Demographics and Lesion Characteristics

A total of 48 patients and 50 breast lesions (there were two target lesions in two patients) were included in the study. All patients were females, with a mean (± standard deviation) age of 52 ± 9 (range, 35-73 years). All lesions presented as sonographic masses. Details are summarised in Table 1.

The lesion sizes ranged from 3 mm to 17 mm in diameter, with a mean of 9.20 mm ± 3.55 mm. The distances from the skin and the chest wall ranged from 4 mm to 12 mm and 1 mm to 15 mm, respectively, with mean distances of 7.45 ± 2.31 mm and 6.68 ± 3.27 mm, respectively (Table 2).

Table 1. Characteristics of patients and lesions (n = 50).

Characteristic	No. (%) of lesions*
Mean (range) age (years)	52 (35-73)
Basket diameter size (mm)	
15	2 (4)
20	48 (96)
Indication for excision	
Radiological-pathological discordance	24 (48)
Cytological atypia	15 (30)
Papillary lesion	7 (14)
Complex cystic lesion	4 (8)
BI-RADS category	
Category 1 (Negative)	0
Category 2 (Benign)	0
Category 3 (Probably benign)	27 (54)
Category 4 (Suspicious)	21 (42)
Category 5 (Highly suggestive of malignancy)	2 (4)
Category 6 (Known biopsy-proven malignancy)	0
Previous cytological / histological grading†	
1 (Inadequate or normal breast tissue)	4 (8)
2 (Benign)	17 (34)
3 (Atypia or benign but of uncertain malignant potential)	22 (44)
4 (Suspicious of malignancy)	1 (2)
5 (Malignant)	0
No previous cytology or histology	6 (12)

Abbreviation: BI-RADS=Breast Imaging–Reporting and Data System.
* Except otherwise stated.
† In cases of cytological-histological discordance, the higher grade is taken.

Table 2. Characteristics of the biopsied lesions.

Characteristic	Mean (mm)	Median (mm)	Standard deviation (mm)	95% Confidence interval
Maximal diameter	9.20	8	3.55	8.19-10.21
Lesion length	8.90	8	3.43	7.93-9.87
Lesion height	6.12	6	1.85	5.59-6.65
Distance from skin	7.45	6.5	2.31	6.75-8.16
Distance from chest wall	6.68	6	3.27	5.69-7.68

Table 3. Pathological findings of radiofrequency excision procedures.

Pathology of biopsy specimens	No. (%) of lesions	Follow-up	
		Follow-up clinically / radiologically	Surgical excision
Ductal carcinoma in-situ	1 (2)	0	1
Fibroadenoma	20 (40)	20	0
Fibrocystic changes	11 (22)	11	0
Intraductal papilloma	9 (18)	9	0
Miscellaneous benign entities	11 (22)*	11	0
Total	52	51	1

* Include apocrine cyst (n = 1), benign cyst (n = 1), benign epithelia hyperplasia (n = 1), duct ectasia (n = 1), fat (n = 1), haematoma (n = 1), pseudoangiomatous stromal hyperplasia (n = 1), tubular adenoma (n = 1), and no malignancy (n = 3).

Efficacy

Pathology Results of Biopsy

There was one case of ductal carcinoma in-situ (DCIS) that was subsequently treated with wide excision and radiotherapy, which revealed additional foci of DCIS that were occult on imaging. The other 49 cases showed benign pathologies, namely, fibroadenoma (n = 20), fibrocystic changes (n = 11), intraductal papilloma (n = 9), and other benign entitles (Table 3). There was one case with co-existing fibroadenoma and fibrocystic changes, and one case with co-existing intraductal papilloma and fibrocystic changes. These cases were followed clinically and radiologically.

Rate of Complete Lesion Removal

In the 50 lesions excised, 48 lesions (96%; 95% confidence interval [CI], 85.5-99.7%) showed no residual sonographic abnormality on the immediate post-excision ultrasound (i.e. sonographic complete removal); of these 48 lesions, 41 (82%; 95% CI, 69.0-90.5%) were confirmed to have clear margins on pathological examination (i.e. pathologic complete removal). None of these 41 patients (82%; 95% CI, 69.0-90.5%) showed signs of residual disease upon clinical and radiological follow-up. There was incomplete removal of lesions in nine cases (Figure 3). Of note, all these nine cases occurred during the initial 2 months of the study period, suggesting that the rate of complete lesion removal can be significantly reduced with experience and improved techniques.

Operating Duration

The duration of the procedures ranged from 1 minute to 30 minutes, with a median duration of 5 minutes and a mean duration of 6.26 minutes (95% CI, 4.73-7.79). The start time was defined as the time of injection of local anaesthetics, and the end-point as the time of lesion retrieval by removal of the wand from the patient. We adopted this definition since this was more consistent and reproducible for a given lesion and breast characteristics, and thus, more indicative of the technical aspects of the procedures.

Follow-up Outcomes

Of the 48 patients, 46 (96%) were followed up clinically and radiologically with ultrasound; one (2%) patient

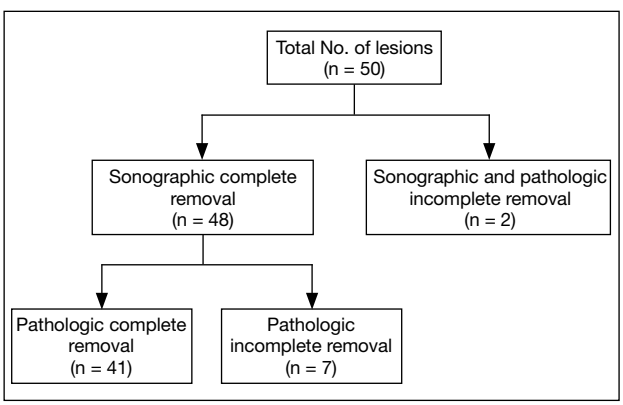

Figure 3. Lesions that were completely and incompletely removed.

was followed up clinically and one (2%) patient was lost to follow-up. The patient with DCIS (2%) was treated with wide surgical excision and radiotherapy, which revealed additional foci of DCIS that were occult on imaging. This patient remained disease-free on follow-up. In the two (4%) patients who were noted to have incomplete lesion removal on post-procedure ultrasound, residual lesions measuring 8 mm and 6 mm in diameter were noted on follow-up ultrasound, with no further invasive procedures performed in view of the benign pathology (fibrocystic changes in both cases). The remaining 44 (92%) patients showed no signs of residual disease during the follow-up period.

Safety

The mean volume of local anaesthetics injected was 13.4 ml (95% CI, 12.42-14.30). The procedure was well-tolerated, with a mean pain score of 1.35 (1 = no pain, 5 = very painful; 95% CI, 1.11-1.57).

Post-procedure haematoma formation requiring hospitalisation and surgical suturing occurred in one (2%) patient. Four other patients (8%) had mild self-limiting haematomas and were treated conservatively. No other adverse events were encountered.

DISCUSSION

Percutaneous Breast Biopsy Techniques

Traditionally, the gold standard for breast biopsy procedures is an open surgical biopsy. This has largely been replaced by various percutaneous needle biopsy techniques owing to their increasing diagnostic accuracy, lower costs, and lower associated morbidities. The chief objectives of a percutaneous breast biopsy are to avoid unnecessary surgery in benign processes, and provide accurate and detailed information on high-risk and malignant lesions to facilitate treatment planning.[1]

Widely used since the 1980s, fine-needle aspiration provides samples for cytology. However, it is limited by high rate of insufficient samples (up to 35%), providing only cytological information, inability to distinguish between invasive and non-invasive diseases, and unreliable measurement of hormone receptor status.[2-4] Gaining increasing favour since the 1990s, spring-loaded core needle biopsy provides histological material for cellular and architectural assessment. However, it has limitations including significant histological underestimation rates (21%-29%), risk of inaccurate tissue sampling, need for multiple needle insertions for retrieving multiple tissue cores, and decreased specimen quality with increasing number of cores; these shortcomings are particularly pronounced in heterogeneous lesions such as papillary tumours, possible phyllodes tumours, and radial scars.[5-11] Vacuum-assisted biopsy (VAB) was subsequently developed, and has the advantage of sampling larger volumes of tissue with multiple specimens in a single pass, allowing less sampling error, more accurate diagnosis, reduced re-biopsy rate, and lower histological underestimation rates (11%-21%) compared with spring-loaded core needle biopsy.[6,7,12-14] VAB can also be used as an alternative to surgical excision of benign lesions.[14,15]

Percutaneous RF breast excision is a novel technology for excision biopsy of breast lesions that can be performed under ultrasound or stereotactic guidance. Using RF energy instead of mechanical cutting, it allows the radiologist to accurately target and remove the target lesion as an en-bloc specimen in a single pass, which allows margin assessment and has been reported to demonstrate a very high diagnostic accuracy and low histological underestimation rate of 3.6% to 9.4%.[16,17] The results of our study suggest that RF excision is a robust diagnostic tool and a promising therapeutic procedure.

Techniques and Challenging Situations

In our experience, a successful RF breast excision, apart from expertise of the operator, depends on careful case selection and pre-procedure planning. General technical considerations include lesion size and location, distance from chest wall and skin, and breast thickness. Various basket sizes (10 mm, 12 mm, 15 mm, 20 mm) are available to choose from, depending on the lesion size, compression characteristics of the breast, and location of the lesion.

In general, a breast thickness of 25 mm and a safety margin of 6 mm around the biopsy basket are recommended to minimise the risk of chest wall and skin burning. Therefore, thin breasts and lesions that are in close proximity to the chest wall and the skin pose a technical challenge for RF excision.

For lesions with a borderline safety margin from the chest wall, copious amounts of local anaesthetic can be injected underneath the lesion in order to further elevate it from the chest wall to reduce the risk of burning the chest wall. It should be injected just prior to wand insertion to decrease the effect of absorption. In

addition, slightly off-centre targeting can be employed to further minimise the risk of chest wall burning (Figure 4).

Similarly, for lesions with borderline safety margin from the skin, copious amounts of local anaesthetic can be injected between the lesion and the skin just prior to wand insertion to avoid skin burning (Figure 5).

Comparison of Vacuum-assisted Biopsy and Radiofrequency-assisted Excision Biopsy

VAB has been the method of choice as an alternative to the more invasive open surgical biopsy for obtaining histological diagnosis in breast lesions. There is growing evidence that RF excision can be a robust diagnostic alternative, particularly in certain patient groups, which is discussed in the following sections.

Quality of Specimens

In VAB, multiple cylindrical tissue cores are obtained by means of vacuum assistance and mechanical cutting. Lomoschitz et al[18] and Pandelidis et al[19] reported that more than 10 to 12 core specimens are required to reduce the atypical ductal hyperplasia (ADH) underestimation rates. In RF excision biopsy, one single en-bloc specimen containing the target lesion is retrieved with RF assistance, which can be likened to that obtained in a surgical excision. Compared with the non-intact specimens with VAB, this enables margin evaluation, thus, allowing determination of the completeness of the excision. The preserved architecture also facilitates easier interpretation on histopathology examination, avoiding the crushing and fragmentation artefacts seen in fragmented tissue cores.[20] A review of the current literature, however, shows that no studies have been made to compare the accuracy between fragmented cores and en-bloc specimens. Further studies are warranted to establish any possible improvements in diagnosis.

On the other hand, in RF excision, a rim of RF-associated thermal damage may be seen at the perimeter of the specimens. However, a case series of 273 RF breast excision procedures demonstrated a low incidence of RF-associated thermal artefacts (5.1%), with no significant effect on the outcomes of histopathological assessment.[21]

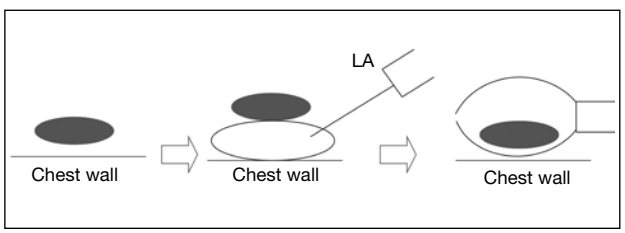

Figure 4. Technique for removing lesions (grey oval) located close to the chest wall.
Abbreviation: LA = local anaesthetic.

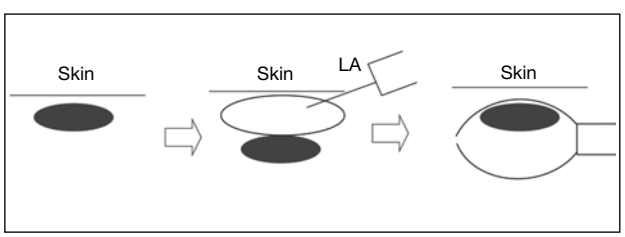

Figure 5. Technique for removing lesions (grey oval) located close to the skin.
Abbreviation: LA = local anaesthetic.

Quantity of Specimens

It is generally preferred to sample a larger volume of tissue sample because this is associated with higher diagnostic confidence and accuracy, and a lower histological underestimation rate.[19] This is particularly useful in lesions that are small or difficult to sample, such as small masses, microcalcifications and distortions, which may be missed by other biopsy techniques.

A typical VAB procedure removes 6 to 12 cylindrical tissue cores, creating a cavity of approximately 7 to 9 mm in diameter and 19 mm in length, with some variation depending on the device model and size. Each tissue core weighs approximately 0.037 g, 0.094 g and 0.133 g with 14-gauge, 11-gauge and 9-gauge core biopsy devices, respectively.[22,23] In a RF excision procedure, a roughly spherical or ovoid specimen is obtained, measuring approximately 10 to 20 mm in diameter and 18 to 25 mm in length, depending on the basket size. The samples weigh approximately 0.8 g, 1.1 g, 2.1 g and 3.0 g with 10 mm, 12 mm, 15 mm and 20 mm baskets, respectively.

The volume of a specimen obtained with a 10-mm RF basket is approximately equivalent to 7 cores of 11-gauge VAB. Similarly, a 20-mm RF basket would yield a volume equivalent to 30 or 23 cores obtained with 11-gauge or 9-gauge devices.

Due to the ovoid shape of RF excision specimens, a larger target lesion volume is obtained for the same

sample volume compared with the cylindrical cores of VAB. When given the same target lesion size, a RF excision would remove less normal breast tissue because of a higher target lesion-to-adjacent breast tissue ratio, compared with VAB (Figure 6).

While it is generally believed that a larger volume of target tissue sampled may lead to fewer targeting and sampling errors, lower histological underestimation rate and higher diagnostic accuracy, further randomised control studies are required to establish these improvements and the effect on patient management and outcomes.

Diagnostic Accuracy and Histological Underestimation Rates

Underestimation rates of ADH and DCIS have been used as benchmarks for the diagnostic accuracy of percutaneous breast biopsy procedures, using open surgical excision as the reference standard.[18,24-26] Certain pathological conditions, including ADH and DCIS, pose a diagnostic challenge with percutaneous biopsy techniques due to the heterogeneity of the pathology, and a large volume, if not a complete excision, of the lesion is often required to avoid histological 'upgrades' or 'underestimates' upon surgical excision.

VAB has been reported to have underestimation rates ranging from 10% to 50% for ADH and 4% to 28.7% for DCIS, depending on the device sizes and study designs.[18,19,24,25,27-46]

In a multicentre trial with 153 patients published by Sie et al,[17] underestimation rates of ADH and DCIS with RF excision were reported to be 9.4% and 5.2%, respectively. In two other studies published by Killebrew and Oneson[45] and Seror et al,[47] the reported underestimation rates ranged from 0% to 20% and 3.2% to 11.1% for ADH and DCIS, respectively. The above data are summarised in Table 4.[17-19,24,25,27-47]

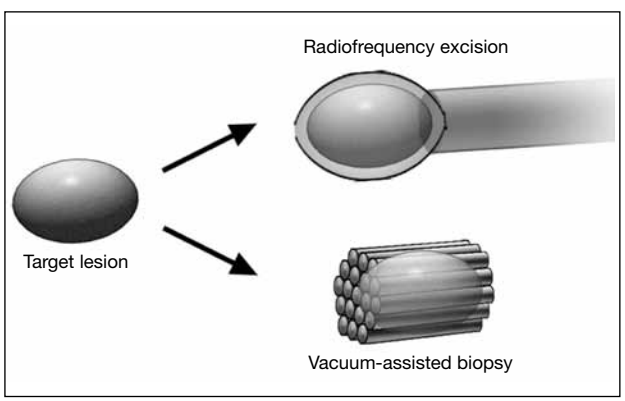

Figure 6. Schematic diagram illustrating the target lesion and adjacent normal breast tissue volumes obtained with radiofrequency excision and vacuum-assisted biopsy.

The current published data on RF excision show that it can achieve a comparable, and possibly lower, histological underestimation rate than with VAB, suggesting that RF excision is a robust alternative to VAB for obtaining an accurate tissue diagnosis. It is postulated that this may be the result of reduction in sampling error and interpretation error due to larger and intact specimens obtained with RF excision. Further and larger studies are warranted to confirm the reduction in histological underestimation, and ultimately, improved patient outcomes.

In our current study, there is one case of DCIS with RF excision biopsy, which did not show histological underestimation upon subsequent surgical excision. The smaller number of malignant lesions in our study could be related to the different inclusion criteria regarding clinical referring indications, as well as the modality of imaging guidance, as DCIS is more commonly associated with microcalcifications that would be biopsied with stereotactic guidance, instead of sonographic masses.

Efficacy in Benign Breast Lesion Excision

Recently, minimally invasive techniques such as VAB devices have been increasingly used for removal of benign breast lesions in place of the conventional open surgical excision. However, it is more challenging to achieve complete lesion removal using multiple small tissue cores as compared with a single en-bloc excision in open or RF excision. The piecemeal nature of the specimens also limits margin evaluation and makes determination of completeness of excision difficult. Fine et al[48] showed a residual lesion rate of 27% after vacuum-assisted biopsy / excision at 6-month sonographic follow-up. In comparison, in the current study, a residual lesion rate of 18% on both pathology result and follow-up is demonstrated with RF excision. A complete lesion excision with clear margins, while not mandatory for benign lesions, is desirable because, apart from removing a symptomatic or radiological abnormality, it can provide the clinician and patient with a higher level of confidence on the benign nature of the lesion, and eliminate the decision dilemma on follow-up.

Table 4. Histological underestimation rates of atypical ductal hyperplasia and ductal carcinoma in-stiu.[17-19,24,25,27-47]

Year	Author(s)	Device	Underestimation rate	
			ADH	DCIS
1998	Liberman et al[37]	11-gauge VAB	1/10 (10%)	1/21 (5%)
1999	Meyer et al[39]	11-gauge VAB	1/9 (11%)	1/28 (4%)
1999	Meyer et al[39]	14-gauge VAB	9/24 (38%)	NR (19%)
2000	Adrales et al[27]	11-gauge VAB	9/62 (15%)	NR
2000	Burak et al[30]	11-gauge VAB	6/46 (13%)	10/89 (11%)
2000	Darling et al[32]	11-gauge VAB	16/86 (19%)	18/175 (10%)
2000	Darling et al[32]	14-gauge VAB	11/28 (39%)	8/47 (17%)
2000	Liberman and Sama[36]	11-gauge VAB	4/17 (24%)	4/14 (29%)
2000	Philpotts et al[42]	11-gauge VAB	6/26 (23%)	9/49 (18%)
2001	Berg et al[29]	11- or 14-gauge VAB	2/16 (13%)	3/16 (19%)
2001	Cangierella et al[31]	11-gauge VAB	2/8 (25%)	1/12 (8%)
2001	Jackman et al[25]	11- or 14-gauge VAB	13/74 (18%)	107/953 (11%)
2002	Jackman et al[24]	11-gauge VAB	22/104 (21%)	NR
2002	Liberman et al[35]	11-gauge VAB	11/48 (23%)	16/119 (13%)
2002	Pfarl et al[41]	11-gauge VAB	6/17 (35%)	11/91 (12%)
2003	Pandelidis et al[19]	11-gauge VAB	5/37 (14%)	12/91 (13%)
2003	Winchester el al[44]	11-gauge VAB	11/65 (17%)	NR
2004	Lomoschitz et al[18]	11-gauge VAB	2/4 (50%)	2/12 (17%)
2005	Grady et al[34]	8- or 11-gauge VAB	6/47 (13%)	NR
2006	Bedei et al[28]	11-gauge VAB	2/17 (12%)	NR
2006	Killebrew and Oneson[45]	11-gauge VAB	5/16 (31%)	7/36 (19%)
2007	Sohn et al[43]	11-gauge VAB	14/78 (18%)	NR
2007	Lourenco et al[38]	11-gauge VAB	13/46 (28%)	35/122 (29%)
2007	Lourenco et al[38]	9-gauge VAB	8/27 (30%)	10/44 (23%)
2008	Eby et al[33]	9- or 11-gauge VAB	26/123 (21%)	NR
2010	Penco et al[40]	11-gauge VAB	13/45 (29%)	NR
2011	Villa et al[46]	11-gauge VAB	8/67 (12%)	NR
2006	Killebrew and Oneson[45]	RF	3/15 (20%)	1/31 (3%)
2006	Sie et al[17]	10-mm or 15-mm RF	3/34 (9%)	6/119 (5%)
2012	Seror et al[47]	10-20–mm RF	0/4 (0%)	3/27 (11%)

Abbreviations: ADH = atypical ductal hyperplasia; DCIS = ductal carcinoma in-situ; NR = not reported; RF = radiofrequency; VAB = vacuum-assisted biopsy.

Technical Aspects of the Procedures

It has been reported in the literature that dense breast tissue may hinder the advancement of a handheld breast biopsy device.[49] In VAB, this depends on the sharpness of the cutting blade, which varies with different devices. In RF excision, the cutting tip of the wand is advanced using RF energy instead of mechanical cutting. This is of particular advantage in dense breast tissues. Duchesne et al[50] reported a statistically significant improvement in the ease of penetration when a RF introducer was used compared with conventional mechanical cutting, particularly in patients with dense breast tissues, without significant increase in procedural time or patient discomfort.

In RF excision, the sample is acquired with a single capture, whereas in VAB, multiple tissue cores are obtained consecutively. There are a few implications of this difference in techniques between the two procedures. Firstly, a single capture could mean shorter procedure duration compared with multiple core acquisition. Szynglarewicz et al[51] reported a mean duration of 12.3 minutes when performing ultrasound-guided VAB. In the current study, the mean procedure duration was 6.26 minutes, which is considerably faster than the reported duration for VAB. On the other hand, VAB may be more convenient in cases with multiple neighbouring lesions as it is capable of sampling and removing multiple lesions using one needle probe. In contrast, in RF excision, separate wands are usually required to remove multiple lesions.

VAB, which is a directional device, is less sensitive to targeting error because minor inaccuracies in targeting can be corrected by rotation of the sampling aperture.[14] In contrast, RF excision requires pinpoint accuracy, particularly because once the excision basket has been deployed, no further adjustments can be made to the

acquisition. This is reflected in our data by significant improvement in the complete removal rate after the initial learning curve.

Another difference between the two techniques is that the currently available RF excision system is compatible with ultrasound and stereotactic guidance, while VAB devices are generally compatible with ultrasound, and stereotactic and magnetic resonance imaging guidance.

RF excision is not suitable for patients fitted with a pacemaker or other RF devices, as the RF waves could potentially interfere with or damage these devices. It is also not recommended for pregnant patients. Lesions that are close to the skin or chest wall are not suitable for RF excision due to reasons described above. Otherwise, RF excision can be considered comparable in invasiveness with VAB; therefore, similar caution should be exercised in patients on anti-coagulation or with bleeding diathesis.[14]

Overall, both VAB and RF excision have been shown to have very high diagnostic accuracy and safety, and are complementary in various radiological situations. The choice largely depends on patient and lesion characteristics, as well as local expertise.

Comparison of Open Surgical Excision and Radiofrequency-assisted Excision Biopsy

Open surgical excision has been the gold standard in breast biopsy procedures. Not only does it provide a confident and accurate histological diagnosis, it also serves as a therapeutic procedure that removes a radiological and, possibly, symptomatic abnormality, which is reassuring both for the patients as well as the clinicians. Each year, it is estimated that over 1.9 million women will undergo breast biopsies in the USA, yielding approximately 1.2 million benign results.[52] Despite the 'benign' biopsy results, many women will eventually opt for the excision of such lesions so as to remove the palpable or symptomatic abnormalities, to avoid the need for frequent follow-up visits, and to eliminate the anxiety of harbouring a possible malignancy. Traditionally, open surgical excision is the mainstay of treatment in these cases. The advent of RF excision offers a promising alternative to conventional surgical excision of benign breast lesions, providing a minimally invasive yet efficacious option to patients and clinicians.

Efficacy in Benign Breast Lesion Excision

Our results have demonstrated a high rate of complete lesion removal (82%), comparable with the published data of 93% in a case series of 100 patients and 106 lesions.[53] Notably, all the nine cases of incomplete lesion removal occurred early during the initial 2 months of the study period. With increased experience in techniques and case selection, no incomplete removal was encountered subsequently.

Procedure Duration

In our study, the duration of RF excision ranged from 1 minute to 30 minutes, with a median and mean duration of 5 minutes and 6.26 minutes, respectively. This is considerably shorter than that of an open surgical excision, which is reported to range from 40 to 45 minutes.[54]

Safety and Complications

Open surgical excision is generally believed to be more invasive with a larger skin incision, higher degree of parenchymal trauma, and a higher risk of complications than with image-guided excision procedures.

In our series, we found that RF excision is associated with a 2% rate of haematoma formation requiring surgical treatment. In a systematic review by Bruening et al,[55] the rate of haematoma formation requiring treatment in open surgical excisions was found to be 2% to 10%.[56] This is higher than in our series. Paterson et al[57] reported a haematoma rate of 39.5% in 162 patients who underwent open surgical excisions, which is also higher than that in our series.

In addition, due to the higher degree of parenchymal manipulation and normal tissue removal in open surgical excision, there is often a greater degree of deformity and scarring, which is of particular concern since the majority of patients undergoing benign breast lesion excision are young and otherwise healthy women. Chun and Velanovich[58] compared the cosmetic outcomes and patient satisfaction 2 years after percutaneous biopsy / excision procedures and open surgical excision, and found that open excision was associated with a higher degree of undesirable cosmetic outcomes and lower patient satisfaction. While this study used vacuum-assisted techniques, it is likely the results would apply to RF excision. In addition to lower complication rates and better cosmesis, our data also demonstrate good patient tolerance, with a generally low pain level (1.35 out of 5).

Overall, the data from our study and the current

literature suggest that image-guided RF excision is a promising, minimally invasive alternative to open surgical excision in benign breast lesions, providing high diagnostic and therapeutic efficacy, with a short procedure time, low complication rate, and good cosmesis.

CONCLUSION

Ultrasound-guided percutaneous RF breast excision is a robust diagnostic tool and therapeutic procedure that demonstrates excellent diagnostic accuracy comparable with that of VAB, a high rate of complete lesion removal with the potential for margin assessment, and is generally quick with minimal complications, provided there is sufficient training and careful case selection. This minimally invasive office procedure is also a promising alternative to conventional open surgical excision in benign breast lesions.

DECLARATION

No conflicts of interest were declared by authors.

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