Article published online: 2024-12-31

Original Article

Vacuum-Assisted Excision of B3 Lesions: A District General Hospital Experience

Anu Sandhya[1] Qurat Ul Ain Tahir[2] Keerthanaa Veerapatheran[3]

[1] Breast Surgery Department, Canada Avenue Surrey and Sussex National Health Service Healthcare Redhill, London, United Kingdom
[2] Dow University of Health Sciences, Pakistan
[3] Surrey and Sussex NHS Healthcare Redhill, London, United Kingdom

Address for correspondence Anu Sandhya, FRCS, FCPS, MBBS, Breast Surgery Department, Canada Avenue Surrey and Sussex National Health Service Healthcare Redhill RH1, 5RH, London, United Kingdom (e-mail: anu.sandhya@NHS.net).

Indian J Radiol Imaging

Abstract

Objective The objective of this study was to evaluate the efficacy of utilizing vacuum-assisted excision (VAE) for the management of B3 lesions and to determine the rate of malignant upgrades.

Materials and Methods This observational study was conducted at Surrey and Sussex NHS Healthcare Redhill. All patients with B3 histology on core biopsy from October 2019 to October 2022 were included in the study. The upgrades in both the B3 group with atypia and the B3 group without atypia were examined in terms of ductal carcinoma in situ (DCIS), invasive status, and grade. The data obtained were analyzed using the SPSS version 21.

Results About 65% of the participants in the present study have B3 lesions in their left breast and 43% of the participants have lesions located in the upper inner area of the breast. The majority of the participants in the study had B3 lesions without atypia (75%). In 70 participants, VAE was performed. Out of 70 participants, only 15 had lesion upgrade after VAE (21.4%). Post-VAE follow-up planning was discussed in multidisciplinary team as per the National Health Service breast screening guidelines.

Conclusion The utilization of VAE is a viable alternative strategy for the treatment of B3 lesions, resulting in a decrease in the necessity for invasive surgical interventions. This observational study shows the efficacy of a less invasive procedure in replacement of a surgical procedure producing optimal long-term benefit and less side effects.

Keywords
- B3 lesion
- breast surgery
- breast surgery
- malignancy
- malignancy
- surgical excision
- VAE

Introduction

Breast cancer is the most commonly diagnosed malignancy in women, with a rising incidence trend. Despite a minor decrease in fatality rates, it remains the primary cause of death among women attributed to oncologic pathology.[1] In recent years, advancements in diagnostic technology and the implementation of screening campaigns have successfully facilitated the early detection of breast cancers in numerous cases. The combination of novel surgical procedures and targeted biological treatments has resulted in a notable improvement in disease-free survival and overall survival rates.[2] There is a substantial body of research that supports the significant influence of lifestyle and environmental factors, including cigarette smoking, physical activity, late pregnancy, and food, on the primary prevention of breast

DOI https://doi.org/10.1055/s-0044-1801267.
ISSN 0971-3026.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

cancer.[3] Nevertheless, it should be noted that primary prevention strategies may not be able to modify all characteristics associated with the development of breast cancer. Nonmodifiable risk factors encompass several characteristics that cannot be altered or influenced by individuals. These factors include age, sex, genetic mutations, breast tissue density, hormone-related factors, a previous history of breast cancer, and noncancerous breast disorders such as breast lesions with unknown malignant potential (B3).[4]

B3 refers to a collection of benign breast lesions that exhibit varying levels of risk of developing breast cancer either concurrently or in the future.[5] B3 lesions encompass several pathological entities, such as flat epithelial atypia, atypical ductal hyperplasia, classic-type lobular carcinoma in situ, atypical lobular hyperplasia, papillary lesions, radial scars (RSs), benign phyllodes tumors, and other unclassified or not otherwise described B3 lesions. The B3 category, however, represents a relatively small proportion of all core biopsies, ranging between 5 and 10%.[6] Management of these lesions has been controversial and challenging for the multidisciplinary team. The risk of malignancy associated with these varies between 9.9 and 35.1% following open excision, with notable variations based on the specific histological subtype.[7]

Currently, there is ongoing debate surrounding the management of B3 lesions due to the high rates of underestimation associated with percutaneous core needle biopsy (CNB) in this category.[8] Therefore, it is crucial to identify clinical, imaging, and histologic characteristics that can aid in excluding malignancy and determining appropriate treatment for patients. Historically, B3 lesions have been managed with diagnostic surgical open excision due to the potential for progression to malignant lesions. Nevertheless, due to the fact that a significant number of these lesions were ultimately determined to be benign based on histological analysis, there has been a shift toward adopting more conservative strategies such as vacuum-assisted excision (VAE) and/or regular monitoring as suggested alternatives.[9] The research endeavors have primarily concentrated on identifying the predictive factors associated with synchronous malignant lesions in the cases diagnosed with B3. It is worth noting that only one study has been conducted thus far to assess the long-term follow-up risk associated with these characteristics.[10] At present, there exists a lack of consensus and established criteria among breast societies regarding the therapy and subsequent monitoring of women who have undergone surgical or percutaneous excision of B3 lesions.

The objective of VAE is to do representative sampling and extract approximately 4 g of tissue, which is equivalent to a diagnostic surgical biopsy. In the event that a B3 lesion undergoes a transformation into malignancy subsequent to a VAE procedure, it becomes necessary to pursue therapeutic surgery. When a VAE procedure results in a benign diagnosis, it is recommended to undergo annual mammographic surveillance for a period of 5 years for lesions that are associated with epithelial atypia. However, no additional surveillance is required for lesions that do not exhibit atypia. This is in accordance with the National Health Service (NHS) Breast Screening Programme, United Kingdom, 2016 on management of B3 lesions[11] (►**Fig. 1**).

In such cases, routine mammographic screening is advised, following the standard screening interval of 3 years.[12]

The objective of this study was to evaluate the efficacy of utilizing VAE for the management of B3 lesions, as well as to determine the rate of malignant upgrades.

Materials and Methods

This observational study was conducted at Surrey and Sussex NHS Trust Redhill from October 2019 to October 2022. Through nonprobability consecutive sampling, 75 women between the ages of 25 and 85 years who were diagnosed with B3 lesion after initial breast screening were included in the present study. Women with concurrent in situ breast or invasive breast cancer were excluded from the present study. The female participants who obtained a B3 result were divided into two groups: those who exhibited atypia and those who did not exhibit atypia. Subsequently, the groups were further categorized into two subgroups: women who met the criteria for VAE and those who met the criteria for surgery. According to the guidelines, women who have had a B3 histology indicating the presence of spindle cell lesions, papilloma with atypia, or fibroepithelial lesions are deemed suitable candidates for surgery instead of VAE. All lesions classified as B3 were diagnosed and their subsequent care was documented. The upgrades in both the B3 group with atypia and the B3 group without atypia were examined in terms of ductal carcinoma in situ (DCIS), invasive status, and grade. The data obtained were analyzed using the SPSS version 21. Continuous variables were presented as mean ± standard deviation (SD), while categorical data were represented as frequency and percentages. Student's *t*-test was employed to assess the disparity in upgrading rates across the study groups. A p-value ≤ 0.05 was considered statistically significant.

Results

►**Table 1** presents the clinical and demographic parameters of the recruited participants. The mean ± SD of the participants' ages in the present study was 52.17 ± 10.3 years. The majority of the participants (65%) in the study had a family history of breast cancer. About 65% of the participants in the present study had B3 lesions in their left breast and 43% of the participants had lesions located in the upper inner area of the breast. The majority of the participants in the study had B3 lesions without atypia (75%). VAE was performed in 70 participants, with 31 participants discharged and 22 remained under surveillance. This was in accordance with NHS Breast screening guidance (►**Fig. 1**). Two patients had continued treatment post-VAE for contralateral cancer. Out of 70 participants, only 15 had lesions upgrade after VAE (21.4%). Fourteen lesions were upgraded to DCIS and microinvasive cancer was seen in only 1 patient. ►**Table 2** presents the clinical and demographic parameters of the study participants without atypia ($n = 56$) and with atypia ($n = 19$) B3

Clinical guidance for breast cancer screening assessment

Guidance on the management of B3 lesions

Lesion diagnosed on 14g or vacuum-assisted biopsy (VAB)	Risk of upgrade	Recommended investigation	Suggested approach for follow-up if no malignancy on VAE – awaiting further evidence review
Atypical intraductal epithelial proliferation (AIDEP)	18-87% with 14g; pooled value 21% after VAB	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores). If larger area of microcalcification, consider sampling more than one area. Consider histological diagnosis in light of all biopsies.	Surveillance Mammography. [The optimal frequency and length of surveillance mammography for these lesions is unclear and awaits further guidance. At present many units are undertaking annual mammography for 5 years.]
Classical (not pleomorphic) lobular neoplasia	Pooled value 27%	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores), even if lesion thought to be co-incidental.	
Flat epithelial atypia	13-21% (in pure form); may co-exist with AIDEP +/- LN and risk then higher	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores). If larger area of microcalcification consider sampling more than one area.	
Radial scar with epithelial atypia	36%	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).	
Papillary lesion with epithelial atypia	36%	Surgical diagnostic excision (because of need to microscopically measure the atypical area for diagnosis)	
Mucocoele-like lesion with epithelial atypia	21%	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).	
Radial scar or papillary lesion without epithelial atypia	<10%	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).	Return to NHSBSP. These lesions are not known to be associated with long-term risk of development of carcinoma.
Cellular fibroepithelial lesion	37% (range 16-76%) phyllodes tumours, but rarely (<2%) malignant	Surgical excision	
Mucocoele-like lesion without epithelial atypia	<5%	Excise/sample thoroughly with VAE, in general equivalent to approx. 4g (12 x 7g cores).	
Miscellaneous others such as some spindled cell lesions, microglandular adenosis, adeno-myoepithelioma	Depends on lesion	Diagnostic surgical excision	

Fig. 1 NHS screening guidance for B3 lesions.

breast lesions. Upgrade to DCIS was higher in the group with atypia (37%). Only one patient had an upgrade to micro-invasive cancer, which was also in the group with atypia.

Discussion

The use of VAE has been recently implemented as a viable alternative to diagnostic surgical excision for specific B3 lesions. The findings of our study indicate that the process known as VAE is both safe and successful. Specifically, we saw that 93% of women diagnosed with a B3 lesion were able to avoid receiving an open surgical biopsy by opting for VAE instead. In our study, the incidence of malignant upgrades following VAE was found to be notably low, specifically at 21%. This outcome indicates that a significant majority of women were able to obtain a benign diagnosis without the need for any additional treatment. Historically, the management of B3 lesions has involved surgical excision.[9] However, it is becoming recognized that this approach may result in overtreatment, as the rates of malignant upgrading are found to be low, as evidenced by the findings of this study. Despite the potential negative consequence of VAE, it has the advantage of facilitating conclusive patient management by a single therapeutic surgical intervention, as opposed to the conventional approach of two separate surgical procedures: one for diagnosis and another for therapy. The underestimation of malignancy in excised B3 lesions has been shown to range from around 10 to 35% according to multiple studies.[6,13–15] There exist empirical data indicating a decline in the proportion with time.[16] For instance, Rakha et al observed a decrease in the positive predictive value of a B3 diagnosis from 25 to 10%.[15] The observed upgrade rate of 21% in this particular series undergoing VAE falls within the lower range as stated in existing literature. There are several possible explanations for the observed decline in cases. One contributing factor could be the enhanced accuracy of mammographic techniques and ultrasound resolution, leading to an increased detection of RSs. Additionally, the growing utilization of vacuum-assisted biopsy may have had a role in this drop.[15] In the present study, the progression to malignancy was found to have an association with

Table 1 Clinical and demographic parameters of the recruited participants

Parameters	Mean/frequency ($n = 75$)
Age (y)	52.17 ± 10.3
Hormone replacement therapy (HRT)	12 (16%)
Family history	49 (65%)
Breast side	
Left	46 (61%)
Right	28(37%)
Size of lesion	14.8 ± 11.57 (3–34 mm)
Breast area	
Central	9 (12%)
Lower inner	11 (15%)
Lower outer	10 (13%)
Inner	2 (2%)
Upper outer	32 (43%)
upper inner	10 (13%)
Type of B3 lesion	
Without atypia	56 (75%)
Atypia	19 (25%)
VAE performed	70 (93%)
VAE results	
Surveillance	22 (31%)
With surgical plan for contralateral cancer	2 (2.8%)
Discharge	31 (44%)
WG diagnostic excision	14 (20%)
Mastectomy	1 (1.4%)
Upgrade	15 (21%)
DCIS	14 (93%)
Microinvasive	1 (7%)

Abbreviations: DCIS, ductal carcinoma in situ; VAE, vacuum-assisted excision; WG, wire guided.

the presence of atypia on the original biopsy, with a rate of 37% (7 out of 19 cases), in contrast to a complete absence of progression if atypia was not detected in the prior biopsy (8 out of 56 cases). The correlation between B3 lesions exhibiting atypia and the heightened likelihood of a malignant outcome is widely acknowledged in the academic literature. The historical data from 1999 to 2006 revealed a notable disparity in the rate of upgrades for B3 lesions, with and without atypia, amounting to 36 and 7%, respectively.[17] In a recent study conducted by Mayer et al, it was shown that there was an overall upgrade rate of 10%. Furthermore, the incidence of malignancy was much lower in lesions without atypia, measuring at 4.8%, compared with lesions with atypia, which had a rate of 24%.[18] The significant disparity in upgrade rates has resulted in implementing a requirement that the presence or absence of epithelial atypia must be explicitly indicated for all B3 lesions.[19] The advantages of VAE include the avoidance of hazards commonly associated with cost-effectiveness, general anesthesia, high levels of patient satisfaction, and favorable cosmetic outcomes.[20,21] In the case of minor B3 lesions, the objective was to eliminate the anomaly with the use of VAE. If a lesion is localized and has a size of less than 15 mm, there is a high probability that it can be completely removed with diagnostic excision of VAE. However, it should be noted that this may not accurately represent the number of pathological alterations.[22] In the cases in which the lesions exceeded a size of 15 mm, complete sampling was not consistently achievable. However, the primary objective remained getting a sample of the abnormality that was adequate enough to rule out any associated cancer. In our analysis, it is reassuring to note that there was no observed correlation between the size of the lesion and the likelihood of it progressing to malignancy. This could be due to a smaller sample size. It is worth mentioning, however, that earlier studies have shown such a link.[8] It is not anticipated that open diagnostic surgical methods would completely eliminate big lesions. In instances of this nature, a surgical specimen with an approximate weight of 4 g is deemed suitable for diagnostic purposes. The VAE has the objective of achieving a similar outcome.[5]

The follow-up plan is based on the guidance provided by the NHS Breast Screening Programme, 2016,[11] where the indication for 5 yearly surveillance mammogram is mainly based on the presence of atypia. However, in our study, 32% of patients without atypia were followed up with a mammogram due to low- to moderate-risk family history.

Conclusion

In summary, based on the available literature, it is generally recommended to conduct additional sampling to rule out any potential malignancy when a B3 lesion is found. The conventional method of utilizing an open diagnostic surgical excision is often considered excessive treatment by a significant number of women. The utilization of VAE presents a secure and efficient approach for the treatment of B3 lesions, resulting in a decrease in the frequency of invasive surgical interventions. This study provides evidence supporting the effectiveness of this method, as the incidence of malignant transformations following a VAE is found to be minimal, especially for B3 lesions lacking epithelial atypia.

Authors' Contributions

A.S. was responsible for conceptualization, data curation, formal analysis, methodology, supervision, writing the original draft, and review and editing of the manuscript. Q.A.T. was responsible for formal analysis and writing the original draft. K.V. was responsible for data curation and methodology.

Table 2 Comparison of clinical and demographic parameters of the participants in study groups

Parameters	Atypia ($n = 19$)	Without atypia ($n = 56$)	*p*-value
Age	52.11 ± 9.9	52.6 ± 10.6	0.391
Hormone replacement therapy (HRT)	2 (11%)	10 (18%)	1.000
Family history	9 (11%)	40 (71%)	0.495
Breast side			
Left	12 (63%)	34 (61%)	0.749
Right	7 (37%)	19 (34%)	
Size of lesion	17.875 ± 12.04 mm	14.6 ± 11.4 mm	0.194
Breast area			
Central	2 (11%)	7 (13%)	
Lower inner	5 (26%)	6 (9%)	
Lower outer	1 (5%)	9 (16%)	
Inner	0 (0%)	2 (3%)	
Upper outer	10 (53%)	22 (39%)	
Upper inner	1 (5%)	9 (16%)	
VAE performed	16 (84%)	54 (96%)	0.083
VAE results			
Surveillance	4 (21%)	18 (32%)	
With surgical plan for contralateral cancer	2 (9%)	0 (0%)	
Discharge	2 (11%)	29 (51%)	
WG diagnostic	10 (53%)	6 (9%)	
Mastectomy	1 (5%)	0 (0%)	
Up gradation	7 (37%)	8 (14.2%)	0.96
DCIS	7 (37%)	7 (13%)	0.96
Invasive	1 (5%)	0 (0%)	0.331

Abbreviations: DCIS, ductal carcinoma in situ; VAE, vacuum-assisted excision.

Ethical Approval
Ethical approval was not required for this study as anonymous and retrospective data were used.

Funding
None.

Conflict of Interest
None declared.

References
1 Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2023. CA Cancer J Clin 2023;73(01):17–48
2 Sankatsing VDV, van Ravesteyn NT, Heijnsdijk EAM, de Koning HJ. Authors' reply to: "Questionable method for estimating the influence of mammography screening on breast cancer mortality in the Netherlands". Int J Cancer 2017;141(08):1709–1710
3 Poorolajal J, Heidarimoghis F, Karami M, et al. Factors for the primary prevention of breast cancer: a meta-analysis of prospective cohort studies. J Res Health Sci 2021;21(03):e00520
4 Łukasiewicz S, Czeczelewski M, Forma A, Baj J, Sitarz R, Stanisławek A. Breast cancer—epidemiology, risk factors, classification, prognostic markers, and current treatment strategies: an updated review. Cancers (Basel) 2021;13(17):4287
5 Pinder SE, Shaaban A, Deb R, et al. NHS Breast Screening multidisciplinary working group guidelines for the diagnosis and management of breast lesions of uncertain malignant potential on core biopsy (B3 lesions). Clin Radiol 2018;73(08):682–692
6 Bianchi S, Caini S, Renne G, et al; VANCB Study Group. Positive predictive value for malignancy on surgical excision of breast lesions of uncertain malignant potential (B3) diagnosed by stereotactic vacuum-assisted needle core biopsy (VANCB): a large multi-institutional study in Italy. Breast 2011;20(03):264–270
7 Rageth CJ, O'Flynn EAM, Pinker K, et al. Second International Consensus Conference on lesions of uncertain malignant potential in the breast (B3 lesions). Breast Cancer Res Treat 2019;174(02):279–296
8 Houssami N, Ciatto S, Ellis I, Ambrogetti D. Underestimation of malignancy of breast core-needle biopsy: concepts and precise overall and category-specific estimates. Cancer 2007;109(03):487–495
9 Giannotti E, James JJ, Chen Y, et al. Effectiveness of percutaneous vacuum-assisted excision (VAE) of breast lesions of uncertain malignant potential (B3 lesions) as an alternative to open surgical biopsy. Eur Radiol 2021;31(12):9540–9547
10 Hennessy G, Boland MR, Bambrick M, et al. Value of long-term follow-up in surgically excised lesions of uncertain malignant

potential in the breast: is 5 years necessary? Clin Breast Cancer 2022;22(07):699–704
11 GOV.IN. Clinical guidance for breast cancer screening assessment. Accessed December 5, 2024 at: publishing.service.gov.uk
12 Giannotti E, James JJ, Chen Y, et al. Correction to: Effectiveness of percutaneous vacuum-assisted excision (VAE) of breast lesions of uncertain malignant potential (B3 lesions) as an alternative to open surgical biopsy. Eur Radiol 2022;32(01):742–742
13 Strachan C, Horgan K, Millican-Slater RA, Shaaban AM, Sharma N. Outcome of a new patient pathway for managing B3 breast lesions by vacuum-assisted biopsy: time to change current UK practice? J Clin Pathol 2016;69(03):248–254
14 Abdulcadir D, Nori J, Meattini I, et al. Phyllodes tumours of the breast diagnosed as B3 category on image-guided 14-gauge core biopsy: analysis of 51 cases from a single institution and review of the literature. Eur J Surg Oncol 2014;40(07):859–864
15 Rakha EA, Ho BC, Naik V, et al. Outcome of breast lesions diagnosed as lesion of uncertain malignant potential (B3) or suspicious of malignancy (B4) on needle core biopsy, including detailed review of epithelial atypia. Histopathology 2011;58(04):626–632
16 El-Sayed ME, Rakha EA, Reed J, Lee AH, Evans AJ, Ellis IO. Audit of performance of needle core biopsy diagnoses of screen detected breast lesions. Eur J Cancer 2008;44(17):2580–2586
17 Rakha EA, Lee AH, Jenkins JA, Murphy AE, Hamilton LJ, Ellis IO. Characterization and outcome of breast needle core biopsy diagnoses of lesions of uncertain malignant potential (B3) in abnormalities detected by mammographic screening. Int J Cancer 2011;129(06):1417–1424
18 Mayer S, Kayser G, Rücker G, et al. Absence of epithelial atypia in B3-lesions of the breast is associated with decreased risk for malignancy. Breast 2017;31:144–149
19 Forrai G, Kovács E, Ambrózay É, et al. Use of diagnostic imaging modalities in modern screening, diagnostics and management of breast tumours 1st central-eastern European professional consensus statement on breast cancer. Pathol Oncol Res 2022; 28:1610382
20 Mathew J, Crawford DJ, Lwin M, Barwick C, Gash A. Ultrasound-guided, vacuum-assisted excision in the diagnosis and treatment of clinically benign breast lesions. Ann R Coll Surg Engl 2007;89 (05):494–496
21 Alonso-Bartolomé P, Vega-Bolívar A, Torres-Tabanera M, et al. Sonographically guided 11-G directional vacuum-assisted breast biopsy as an alternative to surgical excision: utility and cost study in probably benign lesions. Acta Radiol 2004;45(04):390–396
22 Sharma N, Wilkinson LS, Pinder SE. The B3 conundrum-the radiologists' perspective. Br J Radiol 2017;90(1071):20160595

