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# Tomosynthesis-Guided Vacuum-Assisted Excision of B3 Breast Lesions: Reducing Overtreatment Without Compromising Safety

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## ABSTRACT

**Objective:** Breast lesions of uncertain malignant potential (B3) pose a diagnostic and management challenge. Surgical excision (SE) has traditionally been the standard for definitive diagnosis, but it may represent overtreatment. Percutaneous vacuum-assisted excision (VAE) offers a minimally invasive alternative. This study aimed to evaluate the safety and efficacy of VAE compared with SE for the management of B3 breast lesions, with the aim of reducing overtreatment.

**Materials and Methods:** This retrospective single-center study included 64 patients with histologically confirmed B3 lesions diagnosed by tomosynthesis-guided vacuum-assisted breast biopsy between January 2018 and January 2024. Patients were managed by SE, VAE, or imaging follow-up, based on multidisciplinary team recommendations. Imaging characteristics, histopathology, upgrade rates, and follow-up outcomes were analyzed.

**Results:** Most lesions presented as microcalcifications (92%). The most common histological subtypes were atypical intraductal epithelial proliferation (37.5%) and lobular neoplasia (25%). SE was performed in 26 patients (40%), VAE in 22 (34%), and 16 (25%) underwent follow-up. Malignant upgrades occurred in 8 of 26 SE-treated lesions (30.8%), predominantly atypical intraductal epithelial proliferation, while no upgrades were observed in the VAE group ($p = 0.007$). Mean follow-up was longer for SE (42 months) than VAE (21 months, $p = 0.036$). One SE patient developed invasive carcinoma at 48 months; no malignant progression occurred after VAE.

**Conclusion:** VAE is a safe, minimally invasive and effective alternative to SE for carefully selected B3 lesions, particularly those without atypia and with imaging-pathology concordance, potentially reducing overtreatment. Multidisciplinary evaluation remains essential.

**Keywords:** Lesions of uncertain malignant potential; second-line breast biopsy; surgery; vacuum-assisted biopsy; vacuum-assisted excision

## KEY POINTS

- B3 breast lesions represent a heterogeneous group with variable malignant potential and remain a management challenge.
- Vacuum-assisted excision (VAE) demonstrated safety and efficacy in carefully selected B3 breast lesions, avoiding surgical excision (SE) in more than one-third of patients in this single-centre series.

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- All malignant upgrades (30.8%) occurred in the SE group, while no malignant upgrades were observed after VAE, though follow-up duration was shorter compared to SE (21 vs. 42 months).
- Findings support VAE as a safe, effective and minimally invasive alternative to SE in selected B3 lesions, but larger prospective studies with longer follow-up are required.

## Introduction

B3 lesions, which account for 3-21% of all breast lesions, represent a heterogeneous group with a low but significant risk of malignancy, ranging from 21% to 35% (1). The increasing use of mammography screening has contributed to these lesions being detected more frequently, especially in asymptomatic patients. Breast biopsies are usually performed to assess these suspicious lesions, which can be further classified according to the presence or absence of atypia. Some authors suggest a histological subdivision into B3a (without atypia) and B3b (with atypia) to achieve better risk stratification (2, 3).

The treatment of B3 breast lesions continues to be the subject of considerable debate, as reflected in various guidelines, including those of the American Society of Breast Surgeons (4), the UK National Health Service (NHS) (5) and the 2016 (6) and 2018 (7) international consensus conferences with a European focus. Possible management options for B3 lesions include surgical biopsy, percutaneous vacuum-assisted excision (VAE), and imaging surveillance (8, 9).

Traditionally, surgical excision (SE) has been considered the standard of care for many B3 lesions in order to exclude associated malignancy. Nevertheless, accumulating evidence suggests that routine SE may constitute overtreatment in a substantial proportion of patients, given the relatively low upgrade rates for selected lesions and the morbidity, cost, and psychological burden associated with surgery. Consequently, minimally invasive alternatives have gained increasing attention (5, 10-12).

Vacuum-assisted breast biopsy (VABB) and VAE are percutaneous techniques performed under imaging guidance, most commonly stereotactic or ultrasound guidance, using large-core needles (typically 7- or 8-gauge). While VABB is primarily a diagnostic procedure aimed at obtaining larger and more representative tissue samples compared with core needle biopsy (CNB), VAE is designed to achieve complete or near-complete removal of the targeted lesion through a single percutaneous approach. The technical principle involves continuous tissue aspiration and cutting, allowing sequential sampling or excision without repeated needle insertions (5, 10).

Initially introduced for the management of benign breast lesions, such as fibroadenomas up to 2 cm, VAE has progressively been adopted for the treatment of selected B3 lesions. Several consensus statements and national guidelines now support VAE as a safe and effective alternative to SE for a substantial proportion of B3 lesions, particularly those without atypia and with imaging-pathology concordance. This approach offers the advantages of reduced invasiveness, shorter recovery time, improved cosmetic outcomes, and lower healthcare costs, while maintaining diagnostic accuracy (4-12). In this setting, diagnostic VAE is used as a replacement for surgical diagnostic biopsy.

Beyond its established role in benign and high-risk lesions, VAE has also been explored as a therapeutic tool in carefully selected malignant breast lesions. In particular, small, low-grade ductal carcinoma *in situ* (DCIS) and selected invasive carcinomas diagnosed on VABB have been evaluated in feasibility studies and observational series (13-16). These studies suggest that, in carefully selected cases, VAE may achieve complete lesion removal and provide valuable pathological information regarding tumor extent, margins, and biological characteristics. Although VAE is not intended to replace surgery in malignant disease, its role as a therapeutic or staging tool in specific clinical scenarios is increasingly recognized and contributes to the evolving spectrum of minimally invasive breast interventions.

Thus, VAE represents a pivotal technique at the intersection of diagnosis and treatment, challenging the traditional dichotomy between biopsy and surgery. Even in cases where malignancy is subsequently identified, VAE may reduce the extent of surgical intervention by obviating diagnostic surgery and streamlining definitive treatment planning.

This retrospective, single-center study evaluated the safety and efficacy of VAE, compared with SE in the management of B3 breast lesions, with the objective of reducing overtreatment.

## Materials and Methods

This retrospective, single-centre study was approved by the Ethical Committee of Clinical Hospital Centre Rijeka, Croatia (date: 24 June 2020; approval number: 003-05/20-1/92), which waived the requirement for individual informed consent.

### Study Population

At the Clinical Hospital Centre Rijeka, all B3 lesions were routinely managed with SE until 2018. However, the final pathological results frequently revealed benign outcomes, which raised concerns about overtreatment. Since 2018, all B3 lesions diagnosed at the institution have been reviewed

by a multidisciplinary team (MDT). In the absence of national guidelines in Croatia, management decisions have been guided by the UK NHS recommendations for lesions of uncertain malignant potential (5). Within this framework, the present study was designed to evaluate the safety and efficacy of VAE as a complementary procedure to SE.

The study cohort was identified from the institutional database and consisted of consecutive patients with histologically proven B3 lesions diagnosed between January 2018 and January 2024. All lesions were confirmed histologically using tomosynthesis-guided VABB.

Before undergoing biopsy, all patients were informed about both VABB and VAE procedures and provided written informed consent.

The inclusion criteria were: female patients with complete clinical data; mammographically detected lesions not visible on ultrasound; referral for VABB after mammography or digital breast tomosynthesis; histopathological confirmation of a B3 lesion and subtype after VABB; referral for either VAE or SE after VABB; and availability of follow-up data at the Clinical Hospital Centre Rijeka.

The exclusion criteria were: technically inadequate VABB or VAE procedures; lesions that were unsuitable for VAE due to their location in the breast (for example, too close to the skin or nipple-areolar complex); patients with biopsy-proven cancer elsewhere in the breast; and lesions classified as malignant on histopathology after VABB.

Clinical and demographic characteristics, including age, prior breast surgery or biopsy, date and type of procedure, histopathological findings, and follow-up data, were obtained from institutional records. For patients in the VAE group, mammograms were re-evaluated to measure lesion size at three time points, before VABB, after VAE, and during follow-up imaging, in order to assess for residual disease. The follow-up period was defined as the interval between the initial VABB and the final imaging assessment.

### Interventional Procedures and Data Collection

Tomosynthesis-guided vacuum-assisted biopsies were performed using 10-gauge needles ("Mammotome Revolve", Devicor Medical Products, Cincinnati, OH, USA), while 8-gauge needles were used for tomosynthesis-guided VAE on a Selenia Dimensions mammography unit (Hologic, Bedford, MA, USA), with patients lying in the prone position. According to the needle specifications, 12 core samples per lesion and 4 g of tissue were collected. A marking clip ("Mammotome HydroMARK 8G", Devicor Medical Products, Cincinnati, OH, USA) was placed at the end of each procedure for both VABB and VAE, to mark the site of biopsy and subsequent excision. After the procedure, a mammogram was performed to determine whether the lesion and/or a previously placed marking clip had been removed and whether the clip placed after the VAE was in a satisfactory position. Radiological data, including morphology, distribution and extent of calcifications, and presence or absence of microcalcifications after VABB on mammography were analysed. Radiological suspicion was assessed according to the American College of Radiology Breast Imaging Reporting and Data System (ACR BI-RADS) (17).

In the absence of national guidelines, institutional management recommendations were developed through a structured multidisciplinary approach and were aligned with the International Consensus Guidelines for B3 lesions and the UK NHS recommendations. All B3 lesions were systematically reviewed in MDT meetings, attended by a breast radiologist, histopathologist, cytologist, oncologist, and surgeon, with explicit assessment of radiologic-pathologic concordance. MDT allocation was guided by predefined, objective criteria, including lesion type, imaging characteristics, adequacy of sampling, presence or absence of atypia, and the degree of concordance between imaging findings and histopathological results (Table 1). Lesions demonstrating adequate sampling and radiological-pathological concordance without high-risk features were preferentially managed with VAE, whereas discordant findings or features suggestive of potential underestimation prompted SE. Specifically, lesions such as radial scars, as well as lesions with complete radiological-pathological concordance were considered suitable for VAE, with additional factors including lesion size, patient age, and presence of residual calcifications taken into account. In contrast, lesions with atypical ductal hyperplasia, lobular neoplasia (LN), papillary lesions with atypia, particularly when imaging findings suggested possible underestimation or sampling was deemed insufficient, were preferentially referred for SE. For epithelial proliferative lesions MDT decisions incorporated lesion extent, residual imaging abnormalities following biopsy, patient-specific risk factors, and published upgrade rates. Although no single variable independently predicted MDT allocation, management decisions reflected an integrated evaluation of radiological and pathological factors, rather than subjective judgment. The primary aim of this structured, guideline-based MDT process was to reduce unnecessary surgery while maintaining diagnostic accuracy.

### Surgical Excision

SE was performed using wire guidance following mammographic localization. The tip of the guidewire was placed within the residual lesion, or, in cases of complete removal of the target lesion during VABB, within the post-biopsy hematoma; in other cases, it was positioned adjacent to the non-migrated marking

**Table 1. The relationship between radiological and pathological morphological characteristics of the lesions and MDT recommendations**

| | Lesions with or without atypia | | | MDT recommendation | | | |
|---|---|---|---|---|---|---|---|
| | Lesions without atypia | Lesions with atypia | p-value | Monitoring | SE | VAE | p-value |
| Age | | | | | | | |
| ≤60 | 9 | 34 | 0.282 | 6 | 16 | 21 | 0.158 |
| >60 | 7 | 14 | | 4 | 12 | 5 | |
| **Initial mammography BI-RADS** | | | | | | | |
| 0 | 8 | 28 | 0.300 | 8 | 15 | 13 | 0.507 |
| 2 | 1 | 0 | | 0 | 0 | 1 | |
| 3 | 1 | 1 | | 0 | 0 | 2 | |
| 4 | 6 | 16 | | 2 | 11 | 9 | |
| 5 | 0 | 3 | | 0 | 2 | 1 | |
| **Magnification BI-RADS** | | | | | | | |
| 0 | 0 | 1 | 0.566 | 0 | 1 | 0 | 0.468 |
| 3 | 1 | 1 | | 0 | 0 | 2 | |
| 4 | 12 | 38 | | 10 | 22 | 18 | |
| 5 | 0 | 3 | | 0 | 2 | 1 | |
| **ACR** | | | | | | | |
| A | 3 | 0 | 0.012 | 1 | 1 | 1 | 0.949 |
| B | 4 | 22 | | 4 | 11 | 8 | |
| C | 8 | 20 | | 3 | 11 | 12 | |
| D | 1 | 6 | | 1 | 3 | 2 | |
| **MDT recommendation** | | | | | | | |
| Monitoring | 4 | 6 | 0.365 | | | | |
| SE | 5 | 23 | | | | | |
| VAE | 7 | 19 | | | | | |

SE: Surgical excision; VAE: Vacuum assisted excision; BI-RADS: Breast imaging reporting and data system; MDT: Multidisciplinary team; ACR: American College of Radiology

clip. Intraoperative mammographic imaging of the excised specimen was carried out to confirm complete inclusion of the target lesion. If incomplete resection was identified, immediate re-excision was undertaken.

In the management of borderline and benign breast lesions, surgical margins are generally not of clinical significance. The primary objective in these cases is complete excision of the lesion to enable accurate histopathological assessment, rather than achieving tumor-free margins, given the minimal risk of recurrence or progression. Emphasis on surgical margins may result in overtreatment and the unnecessary removal of healthy breast tissue.

Final histopathological assessment of specimens obtained via SE or VAE served as the gold standard. An upgrade was defined as the histological detection of DCIS or invasive carcinoma within the excised specimen. The upgrade risk was subsequently assessed for each subset of B3 lesions.

### Statistical Analysis

Statistical analyses were performed with MedCalc for Windows, version 23.0.2 (MedCalc Software, Ostend, Belgium) and the program Statistica Software Package for Windows 10, 14 (StatSoft, Inc., Tulsa, OK, USA). Descriptive statistics were used to characterize the study population. Upgrade rates from B3 lesions to higher pathological categories were compared between patients who underwent vacuum-assisted needle excision VAE and those who were treated with SE. Differences in categorical variables were analysed using the pearson chi-square test.

Duration of follow-up was compared for patients who underwent VAE, surgical biopsy or surveillance using Student's t-test for independent variables. Duration of follow-up was assessed

for both the VAE and SE groups and was calculated in months from the time of diagnosis of the B3 lesion to the diagnosis of breast cancer or the last recorded follow-up. The occurrence of breast cancer during follow-up and its association with clinical and pathological parameters were evaluated using descriptive statistics.

All statistical values were considered significant if the *p*-value (*p*) was <0.05.

## Results

Between January 2018 and January 2024, 64 B3 lesions were diagnosed at the Clinical Hospital Centre Rijeka using tomosynthesis-guided VABB. The final study group consisted of these 64 patients with a mean age of 56.7±9.2 years (range 41–80 years). Of the 64 patients enrolled in the study, i.e. those who underwent VABB, SE was recommended for 28 patients and VAE for 26 patients. Ultimately, 26 (40.6%) patients opted for SE, while 22 (34.4%) patients chose VAE. Follow-up after VABB was recommended for 16 patients (25%) (Figure 1).

On mammography, the majority of lesions were identified as clusters of microcalcifications (59 cases, 92%). A smaller number presented as architectural distortions (4 cases, 6%), while only one lesion (2%) appeared as a mass.

The initial BI-RADS assessments included 36 lesions (56.2%) classified as BI-RADS 0, 22 lesions (34.4%) classified as BI-RADS 4, three lesions (4.7%) classified as BI-RADS 5, two lesions (3.1%) classified as BI-RADS 3, and one lesion (1.6%) classified as BI-RADS 2. Magnification views were obtained in 56 patients (87.5%). In this subgroup, the most common BI-RADS category was BI-RADS 4 (89.2%), followed by BI-RADS 5 (5.4%), BI-RADS 3 (3.6%), and BI-RADS 0 (1.8%).

Breast density was assessed according to the ACR classification. Twenty-eight patients (43.7%) had heterogeneously dense breasts (ACR C), 26 patients (40.6%) had scattered density (ACR B), seven patients (10.9%) had extremely dense breasts (ACR D), and three patients (4.7%) had entirely fatty breasts (ACR A).

Histopathological analysis revealed that the most common diagnosis was atypical intraductal epithelial proliferation (AIDEP) in 24 cases (37.5%). This was followed by LN in 16 cases (25%), papillary lesions without atypia in 12 cases (18.8%), flat epithelial atypia in eight cases (12.5%), radial scars in three cases (4.7%), and epithelial proliferation without atypia in one case (1.6%). A representative VABB sample demonstrating AIDEP and LN2 is shown in Figure 2.

No significant correlation was observed between BI-RADS classification on mammography and histological subtype ($p$ = 0.300) or between BI-RADS classification on magnification views and histological subtype ($p$ = 0.566). However, a statistically significant association was found between dense breast tissue (ACR categories C and D) and the presence of atypia ($p$ = 0.012).

The majority of B3 lesions managed with VAE appeared as clusters of calcifications on mammography (94%), with only one lesion presenting as parenchymal distortion. Lesion size ranged from 3 mm to 21 mm, with a mean size of 6.7±5.4 mm.

SE was recommended in 28 cases. Ultimately, 26 patients (40%) underwent SE. VAE was recommended in 26 cases, and 22 patients (34%) underwent the procedure, while three converted to SE and 1 declined further intervention. Follow-up without further intervention after VABB was recommended in 16 patients (25%).

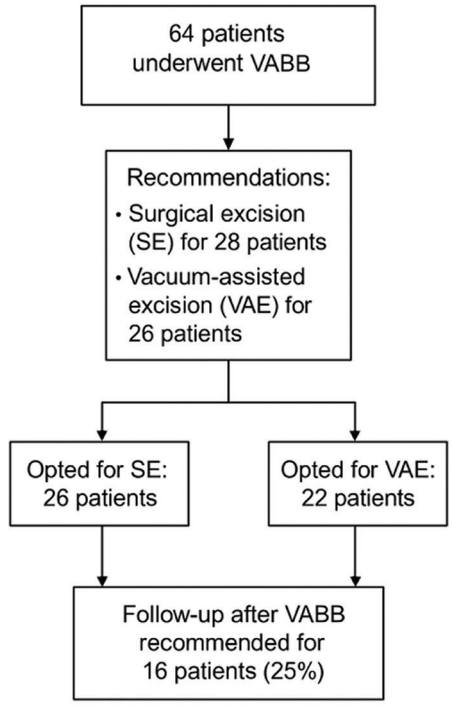


**Figure 1.** Patient management algorithm following VABB in our study

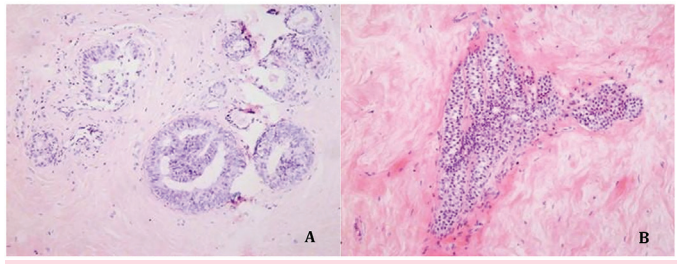


**Figure 2.** A) Atypical intraductal epithelial proliferation in the vacuum-assisted breast biopsy (VABB) sample. B) Lobular neoplasia 2 in VABB sample. Magnification 100x. Clinical Department of Pathology and Cytology, Clinical Hospital Centre Rijeka

The decision to recommend SE versus VAE was not significantly influenced by patient age ($p = 0.158$), breast density ($p = 0.949$), or the presence of atypia ($p = 0.365$) (Table 1). Similarly, the histological subtype diagnosed by VABB did not significantly predict MDT recommendations ($p = 0.223$). Among patients with AIDEP, however, SE was more frequently recommended (14 cases), compared with VAE (9 cases) or follow-up alone (1 case).

All malignant upgrades occurred in the SE group. Specifically, 8 of 26 SE-treated lesions (30.8%) were upgraded to DCIS or invasive carcinoma. In contrast, no malignant upgrades were identified in the VAE group (0%), representing a statistically significant difference ($p = 0.007$). Although upgraded lesions were more frequently classified as BI-RADS 4 on mammography, this association did not reach statistical significance ($p = 0.149$). When histological subtypes were analyzed, AIDEP accounted for the majority of upgrades (6 of 8 cases), followed by papillary lesions and flat epithelial atypia, although this association was not significant ($p = 0.201$). However, this finding was statistically significant when AIDEP was analyzed separately ($p = 0.040$).

Follow-up duration differed between groups, with a longer mean follow-up in the SE group compared with the VAE group (42 *vs.* 21 months, $p = 0.036$). During follow-up, invasive carcinoma was identified in one patient in the SE group, occurring 48 months after the initial biopsy. This patient had an initial diagnosis of LN grade 2, and the subsequent lesion was classified as classic invasive lobular carcinoma. No carcinomas were detected within the first 36 months of follow-up in either group.

## Discussion and Conclusion

VAE is increasingly recommended for the treatment of B3 breast lesions without atypia, according to the third consensus of the European Society of Breast Imaging (18). However, SE is still favored in the current literature, despite concerns about potential overtreatment due to the low overall risk of malignant progression (5, 11, 12).

The aim of this study was to evaluate the safety and efficacy of diagnostic VAE in the removal of breast lesions of uncertain malignant potential, focusing on lesions identified by VABB and occult on ultrasound. To our knowledge, this is the first longitudinal study directly comparing VAE and SE in B3 lesions initially sampled by VABB.

The distribution of B3 lesions in our study was influenced by the inclusion criteria, which were limited to mammographically detected lesions, most of which appeared as calcifications (Figure 3). Other studies generally included all B3 lesions, some even B2 lesions (10, 12, 19, 20).

In our cohort, the most common lesion types were AIDEP (37.5%) and LN (25%), with 75% of all lesions categorized as high-risk

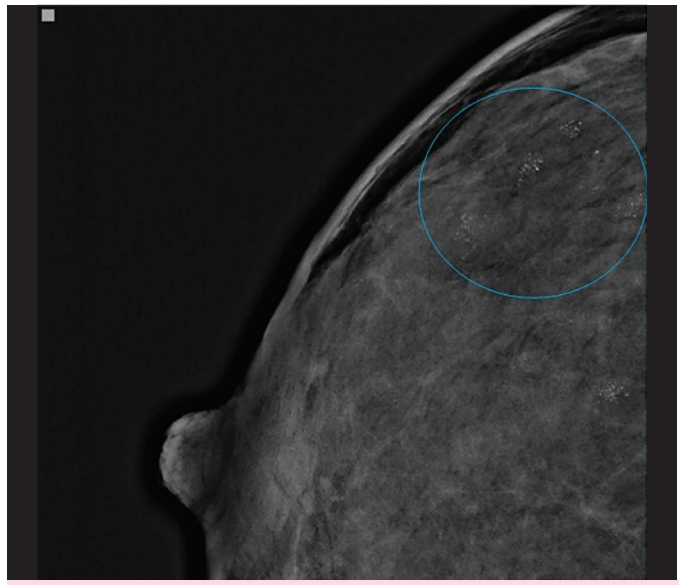

**Figure 3.** The mammographic view of the lateral part of the right breast shows a small cluster (blue circle) of calcifications in a 63-year-old female participant. A vacuum-assisted biopsy was performed, which revealed a flat epithelial atypia in the form of a cluster of microcalcifications. Department of Diagnostic and Interventional Radiology, Clinical Hospital Centre Rijeka

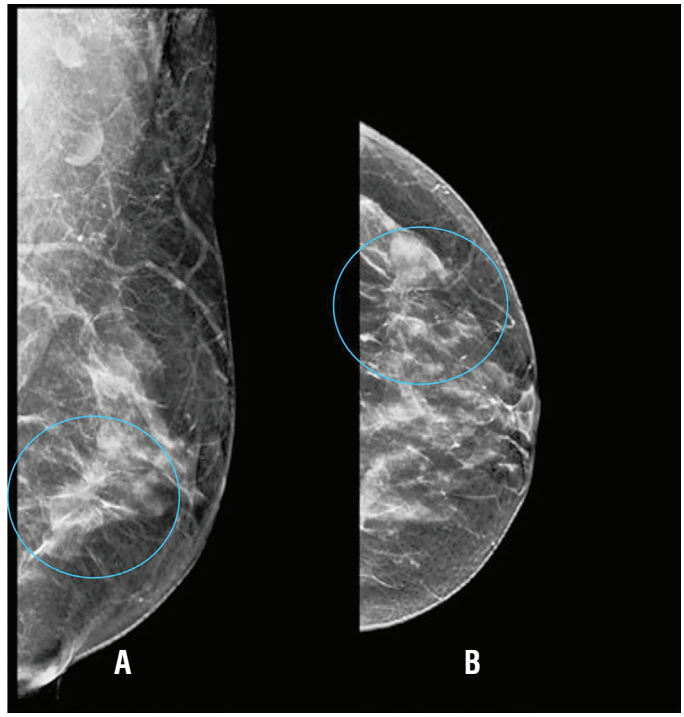


**Figure 4.** Mediolateral oblique (A) and craniocaudal (B) standard projections of the left breast of a 59-year-old female participant. The radial scar appears on mammography as an architectural distortion (blue circle). Department of Diagnostic and Interventional Radiology, Clinical Hospital Centre Rijeka

lesions. We observed no phyllodes tumors (PT) and only a few radial scars (Figure 4). The distribution of AIDEP was consistent with other studies (20–39%), while LN was slightly more common (10-21%) and other types of lesions were underrepresented (21-24).

Our results showed that no immediate upgrade to DCIS or invasive carcinoma occurred after VAE, while 30.8% of lesions treated with SE underwent an upgrade. Upgrade rates reported in the literature range from 3.6% to 21.5% overall (20-22, 24-28) and from 2.5% to 8.6% for VAE alone (29, 30). For B3 lesions with atypia after VAE, one study reported an upgrade rate of 20% (20).

The absence of upgrades in our VAE group may be explained by several factors. The exclusive use of tomosynthesis-guided VABB as the initial biopsy technique likely played a role, as it permits the retrieval of larger tissue volumes compared with CNB. Other published series that reported upgrades after VAE often used CNB or a combination of CNB and VABB for initial diagnosis, resulting in smaller tissue samples and a potentially higher risk of underestimation. However, the use of VABB alone does not fully account for the absence of upgrades in our VAE cohort, as lesions that were ultimately upgraded following SE had also been initially sampled with VABB. Importantly, baseline lesion characteristics differed between treatment groups. A higher proportion of atypical lesions was present in the SE group compared with the VAE group, reflecting differences in pre-procedural risk profiles. Therefore, the difference in upgrade rates cannot be attributed solely to the biopsy technique. Rather, it is more plausibly explained by the MDT-driven selection process: lesions referred for VAE generally demonstrated imaging-pathology concordance, limited extent of calcifications, and lower radiologic suspicion, whereas lesions triaged to SE more often exhibited features raising concern for potential underestimation despite adequate VABB sampling. Consequently, the absence of upgrades in the VAE group likely reflects careful MDT risk stratification and patient selection rather than differences in diagnostic sampling alone.

Our results support the view that VAE can safely replace SE in a subset of B3 lesions. In our study, VAE avoided open surgery in 34.4% of patients. Although this rate is lower than the 62% reported by Strachan et al. (30), with no adverse outcomes over a three-year follow-up, both studies support the role of VAE as a safe alternative to SE in appropriately selected cases.

The findings of our study should also be interpreted in the context of evidence indicating that follow-up after VABB may be sufficient for selected B3 lesions. In the study by Strachan et al. (30), VABB was performed after core biopsy in cases with B3 lesions, providing larger tissue samples, and no upgrades were observed during follow-up. Their results therefore support the safety of follow-up after VABB rather than indicating a specific need for VAE. In our cohort, no malignant upgrades occurred in patients for whom the MDT did not recommend SE, suggesting that these cases might also have been safely monitored without proceeding to VAE. Consequently, our data indicate that in carefully selected patients, particularly those for whom MDT consensus does not favor SE, follow-up based on high-quality VABB results may represent an appropriate and safe management strategy. In such scenarios, VAE may not be essential, and its use should be considered on an individualized basis rather than routinely applied. This interpretation reinforces the importance of MDT-guided stratification and supports a tailored approach to the management of B3 lesions. As the rate of malignant enhancement after VAE was low in our series, the majority of women can be diagnosed as benign without the need for further treatment.

Furthermore, B3 lesions are traditionally treated by SE, which is likely overtreatment given the low rate of malignant upgrades also demonstrated in this study. Importantly, even when VAE fails to completely resolve a lesion or when malignancy is subsequently identified, it offers the advantage of consolidating diagnosis and therapy into a single surgical procedure. This contrasts with the traditional two-step pathway of diagnostic excision followed by therapeutic surgery.

Of note, almost all upgrades were AIDEP lesions (6/8), which is consistent with recommendations in the literature that these lesions should be surgically removed. Our overall upgrade rate for AIDEP was 26.5%, and this rate includes all AIDEP lesions, regardless of whether they were managed with SE or VAE. As all upgrades occurred in the SE group, calculating the upgrade rate only within SE-treated AIDEP lesions yields a higher, selective upgrade rate of 40%, which is consistent with previously reported rates of 20.6 to 41% (21, 24, 28-32).

During follow-up, we observed progression of malignancy in one lesion treated with SE (6%), but no progression in B3 lesions treated with VAE. In previous studies, no progression of malignancy was observed in VAE-treated lesions during follow-up (29-31), with the exception of one group that reported a progression rate of 9.2% (16). In SE-treated lesions, progression rates range from 0% to 9.2% (20, 24, 32). The patient in our cohort developed breast cancer in the ipsilateral breast after four years of follow-up.

In the earlier years of our research, SE was predominantly recommended for almost all B3 lesions. In the last two years, VAE has become the preferred treatment (62%), with fewer cases treated with SE (28%) or retreatment (10%). This shift explains the shorter follow-up time for lesions treated with VAE, which may have influenced our results. However, the median follow-up time of 21 months is still remarkable.

Bianchi et al. (22) similarly analyzed B3 lesions detected by VABB that presented as calcifications directly removed by SE to

determine whether VABB alone was sufficient. Our study builds on this by including VAE as a second line for larger excisions, comparing it with SE, and including follow-up data. Bellini et al. (20) retrospectively compared SE and VAE, but included both mammographic and ultrasonographic lesions and had an unequal distribution of treatment modalities, with nearly 90% of patients undergoing SE. Furthermore, the immediate upgrade rates between VAE and SE were not compared. Strachan et al. (30) demonstrated that VAE safely prevented SE in 62% of cases, with no adverse events reported during a median follow-up of three years.

The main limitations of our study include the small overall sample size of only 64 patients, which limits the generalizability of the results, as well as the relatively small number of patients treated with VAE, which restricts the statistical power to detect rare adverse outcomes and precludes definitive conclusions regarding long-term safety and upgrade risk. In addition, the single-center design may introduce bias and limit the transferability of the results to other institutions with different resources or expertise. Finally, the shorter follow-up duration for patients treated with VAE, with a median follow-up of only 21 months, may lead to an underestimation of late complication or long-term outcomes.

In addition, some concerns about the generalizability of our results may paradoxically be due to the greater experience of the dedicated radiologists and pathologists at our institution, where all cases were collected. In other words, the specific subspecialities of the surgeons involved in this study may limit the generalizability of these results to centers with similar characteristics and likely explain the lower upgrade rates in our series compared to those reported in more recent summaries of the available literature.

Future larger prospective studies with a longer and consistent follow-up period are needed to more accurately assess the risk of malignant progression in B3 lesions treated with VAE. In addition, performing detailed analyses of different B3 subtypes would help to refine treatment strategies for specific lesion types. Nonetheless, current evidence favors a broader application of VAE to reduce the incidence of SE, which is associated with higher complication rates, scarring, and a greater economic burden.

In conclusion, VAE represents a minimally invasive procedure that can be safely performed in the outpatient setting under local anesthesia. Compared with SE, VAE is associated with smaller incisions, minimal scarring, and faster recovery. It provides sufficient tissue for accurate histopathological analysis and, in selected cases, enables complete removal of small benign and borderline breast lesions.

Based on our findings, VAE appears to be a safe and effective alternative to open surgery for carefully selected B3 lesions, particularly those without atypia and with imaging–pathology concordance, potentially reducing overtreatment. Nevertheless, appropriate patient selection remains crucial, and management decisions should be made within a multidisciplinary framework, taking into account lesion characteristics, patient factors, and institutional expertise.

**Ethics**

**Ethics Committee Approval:** This retrospective, single-centre study was approved by the Ethical Committee of Clinical Hospital Centre Rijeka, Croatia (date: 24 June 2020; approval number: 003-05/20-1/92).

**Informed Consent:** Retrospective study.

**Footnotes**

**Authorship Contributions**

Surgical and Medical Practices: P.V.Z., A.C.P.; Concept: P.V.Z., N.B., A.C.P.; Design: P.V.Z., N.B.; Data Collection or Processing: J.R., L.V., M.M., M.A., A.C.P.; Analysis or Interpretation: J.R., L.V., M.M., M.A., A.C.P.; Literature Search: N.B., M.M.; Writing: P.V.Z., N.B., A.C.P.

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