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ORIGINAL ARTICLE

Management and Prognosis of Breast Intraductal Papilloma Diagnosed by Core Needle Biopsy: Comparing Vacuum-assisted Excision, Surgical Excision, and Surveillance

HL Chan[1], KH Wong[1], KF Tam[1], HHL Chau[2]

[1]Department of Radiology, North District Hospital, Hong Kong SAR, China
[2]Department of Imaging and Interventional Radiology, Prince of Wales Hospital, Hong Kong SAR, China

ABSTRACT

Introduction: *Intraductal papilloma (IDP) is a common breast lesion that is often excised, but the treatment of choice for IDP without atypia diagnosed on core needle biopsy (CNB) remains controversial due to its low risk of malignancy. Besides surgery, vacuum-assisted excision (VAE) has emerged as a less invasive alternative. This study aimed to compare the management and prognosis of IDP without atypia diagnosed by CNB across surgical excision, VAE and surveillance, and to identify risk factors predicting papilloma malignant transformation.*

Methods: *This single-centre retrospective review included 107 consecutive samples diagnosed with IDP without atypia with ultrasound-guided CNB from 2016 to 2020. The patients underwent surgical excision, ultrasound-guided VAE or surveillance. The malignant transformation and recurrence rates were evaluated, and potential risk factors for malignant transformation were analysed.*

Results: *The overall malignant transformation rate was 3.7%. The malignant transformation rates were 10.3% in the surgical excision group and 2.1% in the VAE group. No IDP recurrence was identified in either group. For the group that underwent surveillance, none of the lesions showed significant size increase during follow-up. Lesions ≤1 cm and nonpalpable lesions showed low malignant transformation rates of 1.3% and 1.2%, respectively. Risk factors for malignant transformation included larger size ($p = 0.002$), palpability ($p = 0.016$), multiple lesions ($p = 0.045$), and a positive family history of breast cancer ($p = 0.035$).*

Conclusion: *Imaging surveillance may be an alternative management option for IDP in low-risk groups given its low malignant transformation rate. VAE is a safe and effective choice. Surgery may be considered for larger sized lesions with risk factors.*

Key Words: *Biopsy, large-core needle; Papilloma, intraductal; Radiology information systems*

Correspondence: *Dr HL Chan, Department of Radiology, North District Hospital, Hong Kong SAR, China*
Email: hollischanrad@gmail.com

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中文摘要

芯針活檢診斷乳腺導管內乳頭狀瘤的治療和預後：比較真空輔助切除、手術切除和非外科監測

陳凱玲、黃健開、譚國輝、周海倫

引言：導管內乳頭狀瘤是一種常見的乳腺病變，通常外科切除，但由於其惡性風險較低，對於經芯針活檢診斷無異型增生導管內乳頭狀瘤的治療選擇仍存在爭議。除了手術之外，真空輔助切除成為創傷較小的替代方案。本研究旨在比較芯針活檢診斷的無異型增生導管內乳頭狀瘤的手術切除、真空輔助切除和非外科監測的治療和預後，並找出預測乳頭狀瘤惡變的風險因素。

方法：本單中心回顧性研究納入了2016至2020年間經超音波引導下的芯針活檢診斷為無異型增生導管內乳頭狀瘤的107例連續樣本。患者接受了手術切除、超音波引導下的真空輔助切除或非外科監測。我們評估了惡變和復發率，並分析了惡變的潛在風險因素。

結果：整體惡變率為3.7%。手術切除組的惡變率為10.3%，而真空輔助切除組的惡變率為2.1%。兩組均未發現導管內乳頭狀瘤復發。接受非外科監測組在隨訪期間沒有病變顯示出明顯大小增加。≤1 cm 的病灶和不可觸及病灶的惡變率低，分別為1.3%和1.2%。惡變的風險因素包括體積較大（p = 0.002）、可觸及（p = 0.016）、多發性病灶（p = 0.045）和乳癌陽性家族史（p = 0.035）。

結論：鑑於影像監測的惡變率低，因此它可以是治療低風險群導管內乳頭狀瘤的替代方案。真空輔助切除是安全有效的選擇。具有惡變風險因素的較大病變可以考慮外科手術。

INTRODUCTION

Intraductal papillomas (IDPs) of the breast are common benign lesions that arise from the epithelium lining the lactiferous ducts. They can be found incidentally during mammography, ultrasonography (US), or magnetic resonance imaging, or present with symptoms such as nipple discharge, palpable masses, or asymptomatic. IDPs can be classified as solitary or multiple, and with or without atypia. IDPs without atypia are benign lesions with a low risk of developing into breast cancer.[1-3] However, IDPs with atypia have a higher risk of malignant transformation. Consensus exists regarding the need for surgical excision of IDP with atypia diagnosed on core needle biopsy (CNB), owing to a pooled malignant transformation rate of up to 36.9%.[4] However, despite numerous published studies, the management of IDP without atypia diagnosed by CNB is still a matter of debate.[5] Surgical excision has been the standard approach for many years, with the goal of establishing a definitive diagnosis, excluding coexisting malignancy, and preventing progression to cancer. It is the most commonly used management strategy, but it has some drawbacks, such as the need for general anaesthesia, potential complications, and possible deformity. In recent years, vacuum-assisted excision (VAE) has emerged as an alternative to surgical excision, as it is less invasive, more convenient, and associated with lower morbidity.[6] Follow-up breast imaging has also been proposed as an alternative to excisional management in selected patients, with the advantage of avoiding the risks and complications associated with surgery.[7]

Studies have reported the malignant transformation rate and the recurrence rate after surgical excision or VAE of IDP without atypia.[1,7] However, there is still no consensus on the best management strategy for this lesion, and some studies have suggested that follow-up breast imaging may be a safe and effective management strategy in selected patients.[3,4,7] The aim of this study was to estimate the feasibility of VAE or surveillance for the management of IDP without atypia compared to surgical excision, with regard to malignant transformation rate and the recurrence rate. The potential risk factors for malignant transformation were also analysed.

METHODS

We conducted a retrospective analysis of 173 consecutive biopsy specimens of IDP without atypia obtained with CNB under US guidance at our centre between 1 January 2016 and 31 December 2020. We excluded patients with

ipsilateral breast cancer who underwent total mastectomy and patients lost to follow-up. For multiple IDPs diagnosed on CNB in the same patient, only the largest IDP was included in the study and the rest were excluded.

The management strategy for each patient was determined in multidisciplinary team meetings with breast radiologists, breast surgeons, and pathologists. The management options included surgical excision, VAE, and surveillance by follow-up breast US. During the multidisciplinary meetings, pathologists meticulously reviewed the tissue slices for any atypical features and the adequacy of core samples for diagnostic confidence. Radiologists analysed the ultrasound images to establish concordance between radiological and pathological findings, making sure no possible malignancy was present. Additionally, the feasibility of surgery or VAE was assessed based on factors such as lesion size, location (peripheral or central) and depth from the skin. Multidisciplinary team members also identified potential risk factors associated with malignant transformation, including patient demographics, family history of breast cancer, larger lesion size, and related symptoms. Most importantly, patients' willingness to proceed to lesion removal or preference of imaging surveillance was addressed. Ultimately, the decision to pursue imaging surveillance, surgery or VAE was guided by a multidisciplinary evaluation of risks and benefits, and most importantly respecting the patient's wishes.

For patients in the surgical excision group, the surgical excision was performed by the surgical team, and the information was extracted from the surgical record. For patients in the imaging surveillance group, the size and location of each lesion were recorded at the time of initial diagnosis and latest follow-up.

For patients in the VAE group, the procedure was performed by radiologists in our department. The technique of US-guided VAE is illustrated in Figures 1 to 3. The targeted lesion, which was previously proven IDP without atypia on CNB, would first be identified on preliminary US. Infusion to the skin with 1 to 5 mL of 2% lignocaine and the perilesional region with 5 to 10 mL 1:200000 adrenaline was used as local anaesthesia. The probe was introduced through a small skin incision and the IDP was positioned within the margins of the closed sampling aperture (Figure 2) and satisfactory positioning was confirmed on imaging in a plane perpendicular to the first image (Figure 3). In our institute, we used a 10-gauge EnCor Enspire Breast Biopsy System needle (SenoRx, Aliso Viejo [CA], United States). Samples were taken with adjustment (rotation and repositioning) of the needle, if necessary, until the papilloma was indiscernible on US.

Patients' demographics and clinical data, radiological data, histopathological diagnosis, malignant

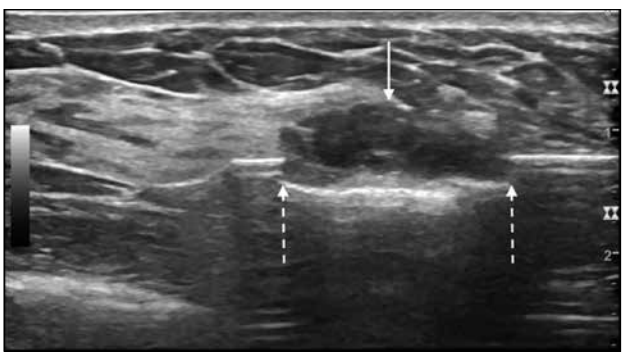

Figure 2. A 10-gauge breast biopsy system needle was positioned beneath the papilloma (arrow), with its closed sampling aperture (dashed arrows) enclosing the papilloma's margins.

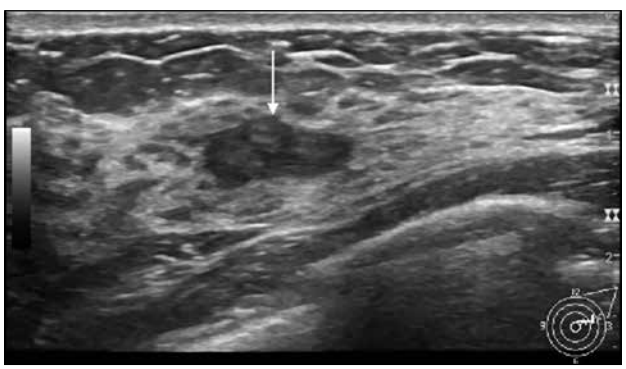

Figure 1. The targeted papilloma was identified on ultrasonography as a hypoechoic solid lesion (arrow) in the 2 o'clock position of the left breast in a 40-year-old female patient.

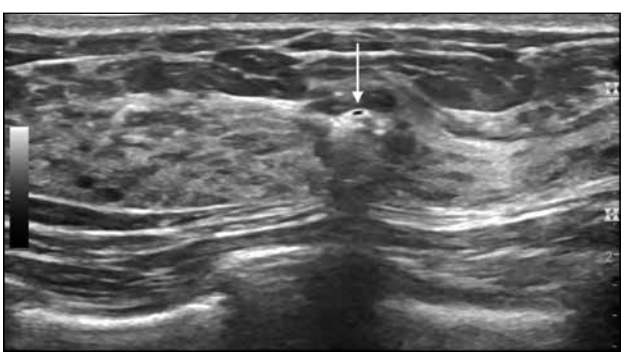

Figure 3. Perpendicular transverse ultrasonography shows the biopsy needle (arrow) within the targeted lesion, indicating satisfactory positioning.

Table 1. Demographics and malignant transformation rate of patients in each management group.*

	Total (n = 107)	Surgical excision group (n = 28)	Vacuum-assisted excision group (n = 48)	Follow-up US group (n = 31)
Malignant transformation	4 (3.7%)	3 (10.7%)	1 (2.1%)	0
Age, y	52.6 ± 11.0	50.4 ± 10.1	51.2 ± 10.0	56.8 ± 12.6
Follow-up time, mo	32.7 ± 19.1	29.1 ± 17.0	36.8 ± 20.5	29.7 ± 18.1
Size of IDP, cm	1.0 ± 0.7	1.6 ± 1.0	0.8 ± 0.3	0.8 ± 0.5
Distance of IDP from nipple, cm	1.7 ± 1.4	1.4 ± 1.4	1.7 ± 1.3	1.7 ± 1.6
Menopausal	50 (46.7%)	15 (53.6%)	16 (33.3%)	19 (61.3%)
History of breast cancer	17 (15.9%)	2 (7.1%)	7 (14.6%)	8 (25.8%)
Family history of breast cancer	15 (14.0%)	4 (14.3%)	6 (12.5%)	5 (16.1%)
Multiple IDPs	14 (13.1%)	1 (3.6%)	9 (18.8%)	4 (12.9%)
Presenting symptoms				
Asymptomatic	44 (41.1%)	7 (25.0%)	21 (43.8%)	16 (51.6%)
Palpable lump	26 (24.3%)	9 (32.1%)	12 (25.0%)	5 (16.1%)
Non-bloody discharge	27 (25.2%)	7 (25.0%)	14 (29.2%)	6 (19.4%)
Bloody discharge	10 (9.3%)	5 (17.9%)	1 (2.1%)	4 (12.9%)

Abbreviations: IDP = intraductal papilloma; US = ultrasonography.
* Data are shown as No. (%) or mean ± standard deviation.

transformation rates, and recurrence rates were recorded (Table 1). These data were extracted from the electronic health record and the radiology information system.

On ultrasound, IDPs typically present as solid or complex cystic and solid masses. It is also possible to identify the lesion within a dilated duct in some cases, as demonstrated in Figure 1. The size of the IDP was measured as the longest dimension on ultrasound, and the location of the lesion was measured as the distance from the nipple (in cm). The malignant transformation rate was defined as the percentage of patients who were diagnosed with malignancy on surgical excision or VAE after the initial diagnosis of IDP without atypia. The recurrence rate was defined as the percentage of patients who were found to have evidence of recurrence (i.e., the rate of returning to previous histological grade) of the lesion on follow-up imaging after surgical excision or VAE. A patient was considered to have multiple IDPs if there was a previous history of IDP, or if multiple biopsies had been performed at different sites within 60 days diagnosing IDPs.

A previous personal history of breast cancer included a history of invasive disease or ductal carcinoma in situ. The follow-up period was defined as the time from the initial diagnosis to the last imaging study.

Statistical Analyses

Statistical analyses were performed using commercial software SPSS (Windows version 26.0; IBM Corp, Armonk [NY], United States). Categorical variables were expressed as frequencies and percentages, and continuous variables were expressed as means ± standard deviations (SDs). The Pearson Chi squared test or Fisher's exact test was used to compare the categorical variables, and the independent *t* test or Mann-Whitney *U* test was used to compare the continuous variables between groups. A p value of < 0.05 was considered significant.

RESULTS

The 173 consecutive samples with pathological diagnosis of IDP without atypia in 2016 to 2020 were reviewed. After excluding lesions except the largest one in one patient with multiple IDPs (n = 40), patients with ipsilateral breast cancer with total mastectomy (n = 3) and patients who were lost to follow-up (n = 23), we included 107 patients for subsequent analysis (Figure 4).

Malignant Transformation Rate

The demographics and malignant transformation rates of the patients are shown in Table 1. The mean age of the study population was 52.6 years (SD = 11.0, range = 29-75) and the mean follow-up time was 32.7 months (SD = 19.1, range = 3-77). All patients were female.

Of the 107 patients in the study, four (3.7%) were diagnosed with malignancy after excision, for a malignant transformation rate in the surgical excision group of 10.7% and 2.1% in the VAE group. There was no recurrence identified in either group. For the group

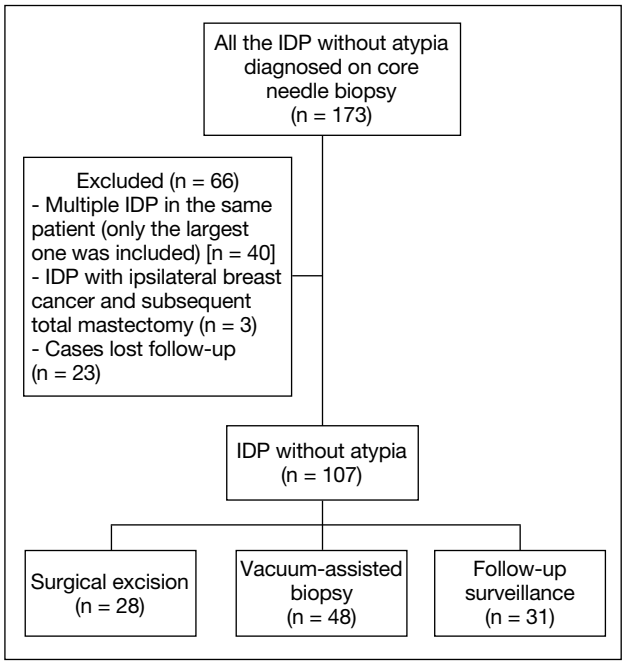

Figure 4. Inclusion and exclusion criteria, with subsequent management of intraductal papilloma without atypia on core needle biopsy.
Abbreviation: IDP = intraductal papilloma.

that underwent follow-up breast imaging, none of the lesions showed increase in size during a mean follow-up of 29.7 months (SD = 18.1, range = 5-63).

The mean size of the lesions in the surgical excision group was larger (1.6 cm) compared to the VAE group (0.8 cm) and the breast imaging follow-up group (0.8 cm). The distance of the lesion from the nipple was similar in all three groups (1.4 cm in the surgical excision group, 1.7 cm in the VAE group, and 1.7 cm in the breast imaging follow-up group) [Table 1].

The clinical and lesion characteristics were analysed to explore the potential association with histopathological malignant transformation. The results of the marginal analysis revealed that family history of breast cancer ($p = 0.035$), presenting symptom of palpable mass ($p = 0.016$), multiple IDPs ($p = 0.045$), and lesion size ($p = 0.002$) were significantly associated with malignant transformation (Tables 2 and 3). Lesions ≤1 cm and nonpalpable lesions showed low upgrade rates (i.e., malignant transformation rates) of 1.33% and 1.23%, respectively (Table 4). Although the presenting symptom of bloody nipple discharge was more frequent in the malignant transformation group, it did not reach statistical significance (Table 2). Similarly, lesions that were located farther from the nipple were also found to be more frequent in the malignant transformation group, but this did not reach statistical significance either ($p = 0.400$). There were no significant differences in patients' age ($p = 0.055$), menopausal status ($p = 0.352$), or personal history of breast cancer ($p = 0.376$) among the malignant transformation group versus the non-malignant transformation group (Table 2).

Of the four cases that underwent malignant transformation, one was invasive ductal carcinoma and the remaining three were ductal carcinoma in situ. Table 5 summarises the clinical and radiological details of these cases.

Safety and Efficacy of Vacuum-assisted Excision

During each VAE procedure, the lesion was removed with real-time US guidance until it became completely undetectable on US. The number of cores taken depended on the size of the lesion and the position of the VAE needle. The number of cores collected had a mean of 8.43 per procedure (SD = 2.35).

Common complications of VAE include haematomas, pain, and ecchymosis.[8] These are usually self-limiting and do not require further medical attention and management.[9] Any that may have developed after the patient has left our department were not documented in the radiological procedure report.

The procedure duration of VAE was documented based on the time log on US capture images which indicated the amount of time the radiologist spent for the procedure, from the first captured US image to the final image. The mean procedure time was 18 minutes (SD = 6.44). Note that the documented procedure time did not include post-procedure wound care, wound dressing, or manual compression (routine postprocedural manual compression of 10 minutes to ensure haemostasis).

DISCUSSION

Breast IDP without atypia can be difficult to diagnose accurately; it is impossible to predict its malignant transformation potential using radiological imaging alone.[1,10,11] CNB is often used to obtain the diagnosis, but there is controversy whether surgical excision is necessary. In our study, we found that the malignant transformation rate was 3.7% in the total study population, consistent with published literature malignancy ranges from 0 to 29%.[1-3,12-17]

Table 2. Clinical characteristics of patients with and without malignant transformation of intraductal papillomas (n = 107).*

	Malignant transformation (n = 4)	No malignant transformation (n = 103)	p Value
Age, y	42.3 ± 3.6	53.0 ± 11.0	0.055
Menopausal			
Yes	0	50 (48.5%)	0.352
No	4 (100%)	53 (51.5%)	
Personal history of breast cancer			
Yes	0	17 (16.5%)	0.376
No	4 (100%)	86 (83.5%)	
Family history of breast cancer			
Yes	2 (50%)	13 (12.6%)	0.035
No	2 (50%)	90 (87.4%)	
Multiple IDPs			
Yes	2 (50%)	14 (13.6%)	0.045
No	2 (50%)	89 (86.4%)	
Symptoms			
No	0	44 (42.7%)	0.14
Yes			
Palpable mass	3 (75%)	23 (22.3%)	0.016
Non-bloody nipple discharge	0	27 (26.2%)	N/A
Bloody nipple discharge	1 (25%)	9 (8.7%)	0.27

Abbreviations: IDP = intraductal papilloma; N/A = not available.
* Data are shown as No. (%) or mean ± standard deviation, unless otherwise specified.

Table 3. Lesion characteristics of papilloma with and without malignant transformation (n = 107).*

	Total (n = 107)	Malignant transformation (n = 4)	No malignant transformation (n = 103)	p Value
Size of lesion, cm	1.0 ± 0.7	2.05 ± 1.39	0.97 ± 0.64	0.002
Distance of lesion from nipple, cm	1.7 ± 1.4	2.25 ± 0.96	1.63 ± 1.45	0.400

* Data are shown as mean ± standard deviation.

Table 4. Subgroup analysis of malignant transformation rates.

	Malignant transformation	No malignant transformation	% of upgrade	p Value
Lesion size ≤1 cm	1	74	1.33%	0.045
Nonpalpable lesion	1	80	1.23%	0.016

Surgical excision has traditionally been the standard management strategy for breast IDP,[18,19] but VAE has gained popularity in recent years due to its minimally invasive nature.[6] In our study, we found that there was no recurrence of papillomas in patients undergoing VAE with a mean follow-up period of 36.8 months (SD = 20.5) and those undergoing surgical excision with a mean follow-up period of 29.1 months (SD = 17.0) [Table 1], suggesting that both strategies are effective in preventing recurrence.

VAE is a more minimally invasive approach compared with surgical excision. It has a shorter procedure time, requiring only local anaesthesia, and results in minimal scarring and a lower possibility of breast deformity. Complication rates are very low and are self-limited.[20] Therefore, VAE is particularly suitable for low-risk lesions and patients with cosmesis concern.

However, there are several drawbacks of VAE. First, VAE removes the lesion in a 'piecemeal' fashion, which precludes pathologists from assessing the margins of the excision.[21] Also, the completeness of excision relies on the sonographic appearance of the lesion. IDP can grow into small branches of the ducts. There is difficulty in differentiating adherent debris from IDP, especially in peripheral ducts.[10,22] Therefore, there is a potential increased risk of residual lesional tissue.[23] Lastly, there is a size limit for VAE, as larger sized lesions are more technically difficult to excise, with a high risk of

Table 5. Details of the malignant transformation cases.

Case no.	Age, y	Meno-pausal	History of breast cancer	Family history of breast cancer	Known multiple IDPs	Presenting symptom	Location*	Manage-ment	Lesion size (in maximal dimen-sion), cm	Distance from nipple, cm	Follow-up duration, mo	Malignant pathology	Final management
1	43	No	No	Yes	Yes	Palpable lump	Left breast 4H	Surgery	2.1	2	34	DCIS	Mastectomy
2	40	No	No	Yes	No	Bloody discharge	Left breast 4H	Surgery	4	3	32	IDC	WLE
3	47	No	No	No	No	Palpable lump	Right breast 8H	Surgery	1	1	20	DCIS	Mastectomy
4	39	No	No	No	Yes	Non-bloody nipple discharge	Left breast 4/5H	VAE	1.1	3	22	DCIS	Mastectomy

Abbreviations: DCIS = ductal carcinoma in situ; IDC = Invasive ductal carcinoma; IDP = intraductal papilloma; VAE = vacuum-assisted excision; WLE = wide local excision.
* Using the clock-face method, e.g., 4H refers to the 4'o clock position in the respective breast.

haemorrhage and incomplete excision. Surgical excision is preferred for lesions >2.5 cm.[24]

Our study also found that breast imaging follow-up alone may be a reasonable management strategy for selected patients with IDP without atypia. Breast IDPs without atypia had a low malignant transformation rate of 3.7% in our study. However, the overall malignant transformation rate in our study remained higher than the 2% threshold in category 3 of the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS).[25] This may make radiologists reluctant to assign IDPs without atypia for follow-up surveillance only. Nonetheless, for IDPs of sizes ≤1 cm and nonpalpable lesions, the percentage of upgrade to malignancy were 1.3% and 1.2% respectively, justified to be classified as BI-RADS category 3 lesions. Additionally, in our study, none of the patients in the surveillance group experienced a significant increase in lesion size or malignant transformation during a mean follow-up of 29.7 months. This is also consistent with reported literature.[26,27] Therefore, we propose that lesions with lower risk (≤1 cm or nonpalpable) and/or without any risk factors (i.e., positive family history of breast cancer and/or multiple IDPs) are justified to undergo follow-up imaging surveillance in accord with BI-RADS.

Research has been carried out to identify the possible risk factors for malignant transformation. In our study, we identified several associated factors in line with previous studies, including lesion size,[26-29] palpability,[26,30] multiplicity,[28] and a family history of breast cancer.[28] Previous studies have suggested that older age correlates with higher potential for malignant transformation.[14,31,32] However, in our study, we could not demonstrate such correlation.

Limitations

Our study has several limitations. First, it was a retrospective study conducted at a single institution, which may limit the generalisability of our findings. Second, as a retrospective study, the assignment of patients to each management group was based on multiple factors rather than randomisation, which resulted in selection bias and therefore may be the reason for the different malignant transformation rates in the three groups. Third, the sample size was relatively small, which limits the statistical power of our study. Meanwhile, the types of core biopsy needle and the number of passes were not documented, which may have affected the diagnostic accuracy of CNB. Also, the follow-up period was relatively short, and longer follow-up may be necessary to fully evaluate the efficacy of each treatment approach. Lastly, as a retrospective study, there was no established protocol specified for IDP imaging follow-up. The follow-up radiological examination appointment was assigned as per clinical request. This would be a very important topic for future study.

CONCLUSION

Our study confirmed low malignant transformation and recurrence rates of IDP without atypia. Follow-up imaging surveillance for low-risk lesions may be a

promising alternative management. We also suggest the feasibility of using VAE instead of surgical excision when clinically indicated, as a less invasive yet safe and effective method of choice. Patients who undergo follow-up with breast imaging should be closely monitored for changes in the lesion size and should be advised to undergo biopsy or excision if there is any suspicion of malignancy. Surgery may be considered for larger or palpable lesions, as well as for patients with multiple IDPs or a positive family history of breast cancer, due to their association with an increased risk of malignant transformation. Further studies with larger sample sizes and longer follow-up periods are needed to validate our findings.

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