Excision of breast fibroepithelial lesions: when is it still necessary?—A 10-year review of a regional centre

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Abstract

Purpose Fibroepithelial lesions (FEL) range from benign fibroadenoma (FA) to malignant phyllodes tumor (PT), but can be difficult to diagnose on core needle biopsy (CNB). This study assesses risk factors for phyllodes tumor (PT) and recurrence and whether a policy to excise FELs over 3 cm in size is justified.

Methods Patients having surgery for FELs from 2009 to 2018 were identified. The association of clinical, radiology and pathological features with PT and recurrence were evaluated. Trend analysis was used to assess risk of PT based on imaging size.

Results Of the 616 patients with FELs, 400 were identified as having FA on CNB and 216 were identified as having FEL with a comment of concern for phyllodes tumor (query PT, QPT). PT was identified in 107 cases; 28 had CNB of FA (7.0%), while 79 had QPT (36.6%). Follow-up was available for 86 with a mean of 56 months; six patients had recurrence of PT, all of whom had QPT on CNB. The finding of PT was associated with CNB of QPT, increasing age and size on multivariate logistic regression. All patients diagnosed with PT following CNB of FA had enlarging lesions with a mean size of 38.3 mm.

Conclusions Our data does not support routine excision of FELs based on size alone. All patients with QPT on CNB, regardless of size should consider excision due to high risk of PT and recurrence, and the decision to excise FAs to rule out PT should also consider whether the lesion is enlarging.

Keywords Fibroadenoma · Phyllodes tumor · High-risk breast lesion · Core needle biopsy · Surgical excision

Introduction

Fibroepithelial lesions (FEL) are a heterogeneous group of neoplasms that range from benign fibroadenoma (FA) to malignant phyllodes tumor (PT). While FAs do not require routine excision, and many can be safely managed with observation, PTs require excision due to concerns about the potential for malignant transformation and recurrence. Prior to the use of Core Needle Biopsy (CNB), larger lesions were excised to avoid missing PT, but it is unknown whether this remains necessary.

It can be difficult to distinguish FA from PT on CNB due to overlapping histological features even when multiple stringent histological criteria are applied [1]. In such instances, pathologists may designate the lesion as FEL and then add a comment of concern such as “cannot rule out phyllodes”, however, there is no standardized way of reporting FEL lesions on CNB, and there is variability between centers in how the term FEL is used. When there is histological ambiguity, the World Health Organization recommends favouring a diagnosis of FA over PT in order to avoid overtreatment [2]. However, there is a concern that a PT may be missed, so many patients and surgeons favor excision.

The chance of identifying PT after selective excision of FELs ranges from 18 to 42%, depending on the study [3–7]. Recent studies continue to find significant rates of PT after excision of masses not diagnostic of FA [6, 7]. Although the risk of PT following a CNB of FA is thought to be low,
there is little recent data. There has been a convention in our region to consider excision of all FELs at 3 cm (including FA), however, we have been unable to find literature to support this size threshold. In 2008 the National Comprehensive Cancer Network (NCCN) guidelines recommended excision of FEL (including FA) over 2 cm in size [8] to avoid missing PT, and as of 2020, NCCN recommended excision of FELs over 3 cm [9]. More recently, at our institution, we have not been routinely excising FAs when they reach 3 cm. We have been excising FELs if there is a concern for PT on CNB, and we have individualized decisions for surgery when the CNB showed FA, taking into account size, radiology-pathology concordance, symptoms, enlargement, and patient preference.

The first objective of this study is to assess whether the convention to excise all fibroepithelial lesions 3 cm in size or greater is empirically supported. The second objective is to look for risk factors for upstaging to PT and identify a low-risk group that can be spared surgery.

Methods

This study received ethics approval from the University of British Columbia Research Ethics Board.

Patients having surgical excision of FELs on CNB at Mount Saint Joseph Hospital from 2009 to 2018 were identified from a prospective database and chart review was used to supplement clinical data and obtain follow-up. Patients were included in the study if they had a FEL on CNB and excluded if the CNB was diagnostic of PT or if the CNB also had other pathology concerning for malignancy, such as ductal carcinoma in situ or atypical ductal hyperplasia. Patients having surgery to exclude recurrence of PT or that had only a clinical diagnosis of FEL (no CNB) were excluded. When patients had more than one FEL on CNB at presentation, the most concerning lesion was included: a lesion that had QPT was included and FA lesions excluded, and in cases where the CNB diagnosis was the same, the larger lesion was included. If patients had a second FEL lesion excised during the study period, only the first FEL procedure was included. Demographics, clinical presentation, radiology, pathology, operative details and follow-up/recurrence data were collected.

In our region, patients with breast complaints or abnormal screening mammograms have diagnostic workups, including CNB at 28 diagnostic centers, and are then referred by their primary care physician for surgical management. All patients having CNB at our own institution are seen at our Breast Clinic and referred to the surgeon as appropriate. Surgery and surgical pathology were all performed at our institution. Preoperative review of pathology and radiology at our institution was selective as per our regional process. Original radiology reports were used to determine imaging size and pre-op diagnosis on CNB. The largest reported size from mammography, ultrasound or MRI was used as the imaging size. The type of CNB available at the different diagnostic centers varies, with only five centers having stereotactic core biopsy. The technique, size of CNB needle and number of passes were at the discretion of the radiologist.

CNB results were classified as FA or query phyllodes tumor (QPT). For this study, patients were classified as FA on CNB if the CNB report stated “fibroadenoma” or FEL most consistent with or favored to be FA. CNB reports that did not favor FA were classified as QPT and included results with comments such as “suspicious for PT” and “fibroepithelial lesion, cannot exclude PT, or gave a differential that included PT. PT at excision was classified as benign, borderline, or malignant.

In order to provide context for the management of patients with FA and QPT at our center all patients having CNB at our own institution in 2018 were identified. The proportion and management of patients with FA and QPT were determined.

Chi-squared test was used for categorical variables and Student’s t test for continuous variables. Univariable and multivariable logistic regression analyses were conducted to identify risk factors of upstage to PT. To assess the convention of excising FELs at 3 cm, trend analysis was done for FA and QPT cases at various tumor size thresholds. The negative predictive value (NPV) for upstaged tumors were plotted on a spectrum of imaging size thresholds to identify patients who would be more likely to be upstaged to PT based on size. For this analysis, the NPV of 95% was identified. All statistical analyses were performed using R (ver.3.6.1). P < 0.05 was considered significant for all tests.

Results

During the study period, 616 patients had surgical excision of FELs. All patients were female and had a mean age of 36.8 years. CNB was classified as FA in 400 cases and QPT for 216 cases. Patients with QPT were older and were more likely to have a palpable and larger lesion (Table 1). Diagnostic workups were performed at 28 centers with no statistical difference in diagnostic centers between FA and QPT groups (p = 0.31).

Figure 1 outlines reason for excision and final pathology with 107 cases of PT. No study patients were diagnosed with adenocarcinoma. All patients with a post-operative diagnosis of PT had their CNB performed under ultrasound, and none of the patients having stereotactic CNB were diagnosed with PT at excision. Seventy-nine cases of PT had QPT on CNB, but 28 cases of PT upstaged from
All patients that upstaged to PT with CNB of FA had a reason for excision of enlarging lesion \((p < 0.001)\) with a mean size of 38.3 mm.

Logistic regression (Table 2) found a higher risk of PT to be associated with CNB of QPT, older age, and larger lesion. When looking at risk factors for the FA and QPT subgroups, larger lesions are more likely to have PT at excision, and age is a risk factor in the QPT group (Supplemental Tables). We were unable to include indication for excision in this model for FA, as every finding of PT was associated with excision for an enlarging lesion.

Follow-up information was available for 86/107 patients with PT with a median of 44 months (Fig. 1). Recurrence was found in 6 patients, all of whom had QPT on CNB. For FA patients with imaging sizes of ≥ 30 mm, three had borderline PT, all of which had negative margins, and the rest had benign PT with 6/22 having positive margins. There was no recurrence at a median of 51 months follow-up. For

### Table 1 Patient characteristics stratified by CNB pathology

| Characteristic                              | FA on CNB (400 patients) | QPT on CNB (216 patients) | \(p\) value |
|---------------------------------------------|---------------------------|---------------------------|----------------|
| Palpable                                    | 258 (64.5%)               | 164 (75.9%)               | 0.003*        |
| Family history of breast cancer             | 48 (12.0%)                | 41 (18.1%)                | 0.051         |
| Age at OR: mean ± SD (min–max)              | 35.5 ± 11.3 (14–78) \(n = 398\) | 39.3 ± 11.0 (16–68) \(n = 212\) | <0.001*       |
| Clinical Exam size (mm)**: mean ± SD (min–max) | 30.0 ± 13.4 (10–80) \(n = 258\) | 34.9 ± 25.2 (10–180) \(n = 164\) | 0.023*        |
| Imaging size (mm): Mean ± SD (min–max)      | 25.8 ± 12.6 (4–82) \(n = 358\) | 30.8 ± 22.7 (7–170) \(n = 201\) | 0.004*        |
| Type of biopsy                              |                           |                           |               |
| Ultrasound core biopsy                      | 340 (85.0%)               | 168 (77.8%)               | <0.001*       |
| Stereotactic biopsy                         | 42 (10.5%)                | 46 (21.3%)                |               |
| Fine needle aspirate                        | 18 (4.5%)                 | 2 (0.9%)                  |               |
| Phyllodes found at excision                 |                           |                           | <0.001*       |
| Yes                                         | 28 (7%)                   | 79 (36.6%)                |               |
| No                                          | 372                       | 136                       |               |

\(FA\) fibroadenoma, \(CNB\) core needle biopsy, \(QPT\) query phyllodes tumor on CNB

\(*p < 0.05\)

\(**For those lesions that were palpable\)

### Fig. 1 Breakdown of CNB diagnoses, indication for excision, final pathology and recurrence of PT. \(FEL\) fibroepithelial lesion, \(FA\) fibroadenoma, \(QPT\) query phyllodes tumor, \(PT\) phyllodes tumor

FA. All patients that upstaged to PT with CNB of FA had a reason for excision of enlarging lesion \((p < 0.001)\) with a mean size of 38.3 mm.

Follow-up information was available for 86/107 patients with PT with a median of 44 months (Fig. 1). Recurrence was found in 6 patients, all of whom had QPT on CNB. For FA patients with imaging sizes of ≥ 30 mm, three had borderline PT, all of which had negative margins, and the rest had benign PT with 6/22 having positive margins. There was no recurrence at a median of 51 months follow-up. For
FA patients with imaging sizes of < 30 mm, all had benign PT at excision, and one had positive margins. There was no recurrence at a median of 31 months follow-up.

The cases of PT that had CNB of FA were reviewed. The three cases of borderline PT following CNB of FA were 4, 6, 8 cm in size and had surgery in 2009–2010. The proportion of patients with PT and a CNB diagnosis of FA decreased over the study period (Fig. 2). Two patients had FNA diagnosing FA (2009, 2011) rather than CNB, and three had comments indicating some cellularity (2010 × 2, 2015), although the sign out diagnosis was FA. Most patients had comments in the radiology or clinical reports that the mass had quickly doubled in size, although two patients reported slower enlargement. There were seven cases of PT in patients with lesions less than 30 mm based on recorded imaging size. On reviewing these cases, the physical exam and/or pathology lesion size at excision was 30 mm or larger in all cases except one in which the imaging and excision specimen demonstrated a 29 mm lesion. In most cases, the imaging size was more than six months prior to surgery (median 9 months CNB to surgery), with enlargement on physical exam leading to excision.

To assess the convention of excision FELs at 3 cm, we looked at the chance of finding PT at various sizes (stratified by CNB diagnosis and indication for excision) and performed a trend analysis. Table 3 looks at the risk of finding PT based on CNB diagnosis and last recorded imaging size and stratifies the FA subgroup by whether lesions were enlarging. Fifty-seven (9%) of patients did not have a recorded lesion size on imaging reports and instead had narrative descriptions such as “large mass” or “lobulated mass”, and as noted above, in the FA group imaging and CNB for lesions < 30 mm were often months prior to excision with subsequent enlargement leading to excision.

To further assess the convention of excision at certain sizes and to determine the minimum lesion size required to detect virtually all PT (95%), the NPV of lesion size cut-off as a diagnostic metric to detect PT was plotted as a function of lesion size (Fig. 3). Among all patients with

| Characteristics                  | OR   | 95% CI     | p value |
|----------------------------------|------|------------|---------|
| CNB pathology (QPT vs FA)        | 7.661| 4.826      | 12.478  | <0.001* |
| Age (per year)                   | 1.052| 1.032      | 1.073   | <0.001* |
| Palpable vs image detected       | 2.259| 1.370      | 3.891   | 0.002*  |
| Family history of breast cancer  | 1.639| 0.935      | 2.782   | 0.074   |
| Max imaging size (per mm)        | 1.039| 1.026      | 1.054   | <0.001* |
| Ultrasound size (per mm)         | 1.040| 1.026      | 1.055   | <0.001* |
| Mammography size (per mm)        | 1.024| 1.001      | 1.054   | 0.073   |

FA fibroadenoma, QPT query phyllodes tumor, OR odds ratio, CI confidence interval
*p < 0.05
FA on CNB, lesions smaller than 37 mm had a 95% probability of not being PT. The first tumour size threshold among QPT patients where NPV drops below 95% was at 11 mm, which included the smallest QPT tumour in the study, which was upstaged.

In order to provide context to patients going for surgery all patients having breast CNB in our own radiology department in 2018 were reviewed. Eighty-eight patients had a CNB showing a fibroepithelial lesion. Of the six patients that had QPT on CNB, three went on to excision with one patient having PT followed by recurrence, two opted for observation following multidisciplinary review suggesting low likelihood of PT, and one patient cancelled her appointments. For the 82 patients with FA on CNB, 4 had excision, with one patient with an 11 cm tumor having PT, the other patients had excision for symptoms. One patient with CNB showing FA went on to excision following enlargement of the lesion with final pathology showing FA.

### Discussion

To assess the convention of excision of FELs at 3 cm, we looked at the chance of finding PT at various sizes stratified by the CNB category of QPT and FA. While size is a risk factor for PT, and lesions over 3 cm do have a greater risk of PT than those under 3 cm, the overall results do not support routine excision of all FELs at 3 cm. Our study looks at patients from multiple diagnostic centers demonstrating a high risk of PT (36.6%) in patients with QPT on CNB and a low risk (7%) in patients with FA. However, when the FA lesions are stratified by indication for excision, all PTs were found in patients having excision for enlarging lesions. In recent years, the use of lesion size as a sole discriminatory parameter for FA excision and reliability of the 3 cm threshold has been questioned [1, 3]. There seems to be an emerging consensus that the growth rate of FA may be a more useful criteria for excision [3, ...]
10–15], and our results further support this. To our knowledge, this is the first study looking at the convention of excision based on CNB diagnosis.

The overall upstage to PT in our study is 17.4% which is on the lower end of results in the literature for selective excision of FELs that ranges 18–42% [3–6]. However, when we stratify the findings on CNB, those patients with FA have a risk of 7%, but those with QPT have a risk of 36.6%. Logistic regression demonstrates that QPT is a risk factor for PT, and the size analysis did not find a size at low risk, supporting our current practice of excising all QPT lesions. These findings are consistent with other studies that have found that in contrast to size, the sensitivity and specificity of pathologists’ comment of concern has been reported as 82% and 93%, respectively [6]. Although further sampling such as larger gauge or vacuum-assisted CNB could be considered to try to differentiate PT and FA, we believe that excision is appropriate for QPT lesions regardless of size due to the high chance of finding PT.

Patients with CNB of FA have a lower risk of upstage to PT and with FAs thought to occur in 7–13% [10] of women, defining a low-risk group is an opportunity to spare many women a more invasive surgical procedure. In our patients where the pathologist indicated confidence in the likelihood of FA on CNB, we found PT at excision in 7%. Because we selectively excise FA, this may be an overestimate of the overall rate of detection of PT due to referral and management bias, as non-operatively managed patients would not have been included in our study. Our review of all FELs on CNB at our own hospital indicated, that in 2018, 8% had excision and one patient was diagnosed with PT. Additionally, we found that fewer PTs had a prior CNB diagnosis of FA over time, suggesting a change in categorization by pathologists, perhaps reflecting changes in the NCCN guidelines over the study period. Although different patients and physicians will have a different perspective on whether surgery is warranted for a 7% risk of finding PT at excision, our results suggest that risk for FA patients can be further stratified with PT found in 17% of patients having excision for enlarging lesions and no PT found with other indications for excision; this suggests that rapid enlargement may be a more important consideration than size alone. Other studies have found varying results regarding the significance of size as a criterion for excision; some authors did not find any significant difference in tumor size between groups of FA and PT upon excision [1, 3, 4, 16], while others did find PTs to be larger [13, 17, 18].

Clearly, all FAs grow to a macroscopic size at the time of diagnosis, and it is the unknown relationship of growth to the timing of CNB that poses the management dilemma. According to Foxcroft et al. [13], FAs usually tend to grow to 20–30 mm in size and then stabilize or regress on serial ultrasound examination, and only a small subset of FAs may grow to giant proportions of 60 mm. Most recent studies [13–15, 19] have found an association between rapid growth and PT. We found only one study in which growth rate was not associated with the presence of PT [20]. Dialani et al. [20] report that in their cohort of 378 biopsy-proven FA, the only circumstance where PT was found on excision were in cases where atypia was noted at initial core biopsy. While clinical features such as ulceration, nipple retraction and palpable lymphadenopathy have been reported with PT, they remain extremely uncommon [21]. Our findings further support the importance of enlargement of FA lesions in identifying possible PT.

Similar to other studies, [13–15, 20, 22] none of the growing FAs in our study upstaged to malignant PT. Hence, the main risk in observing a growing FA is missing a benign/borderline PT as malignant PTs usually have concerning features on CNB. When looking at the recurrence of PT following excision and stratifying by preoperative CNB diagnosis, all recurrences were in patients with QPT on CNB. Notably, only one patient with PT in our cohort had a lesion <30 mm at surgery, and we did not see any recurrence of PT in the patients with FA and imaging sizes <30 mm, supporting that it is reasonable to observe enlarging FAs until they reach about 30 mm by any examination method.

While our sample size of enlarging FAs is larger than other studies, we could not calculate the growth rate due to the lack of standardized follow-up, and this is a limitation of the present study. Further study in this area would be beneficial to further refine management algorithms. The other main limitation of this study was the lack of consistent imaging size reporting. Although a central review of pathology or radiology would increase consistency of diagnostic information, we opted to design the study using information that surgeons had at the time of surgical consultation, as it came from multiple diagnostic centers, each having various radiologists and pathologists. We believe this better reflects the heterogeneity of practice, making results more generalizable than a single institution study. The reporting of CNB diagnoses is also not standardized and some of the patients in the QPT group may have been classified as QPT based on a general comment about PT meant to alert the clinician to consider under-sampling. Going forward, if there is such uncertainty, further clarification of the CNB may save some patients excision.

In this study cohort (Fig. 1) and our practices, we see that there are various tumor and patient factors that lead to excision. While this study has looked at size and CNB criteria for considering excision, some patients will have a smaller lesion that is symptomatic or discordance on radiology-pathology correlation, and these results should not preclude excision in these situations. Conversely, our results support offering a follow-up to a patient with a
lesion at 3 cm in a larger breast on screening mammography. Having the risks associated with PT from this study will help us have a more detailed discussion with patients about the surgical and follow-up options for their lesions, and we anticipate that this will allow for more individualized risk assessment and decision making.

In our multi-center cohort of 616 patients with selective excision of FELs, the finding of PT was strongly correlated with CNB concern for PT (QPT) and indication for excision of FA (enlarging lesion), although age and larger size were also risk factors. Our size analysis did not support routine excision of all FELs at 3 cm but does suggest that FAs under 3 cm in size have a low risk of PT, even if enlarging. The September 2021 NCCN guidelines update has removed FELs with a CNB of FA from the indications for routine excision [23]. The guidelines note that a constellation of clinical symptoms should be considered for lesions with a CNB of FA. Our study findings support this change.

Conclusion

Our study found that patients with CNB diagnosis of QPT were at high risk of PT and associated with recurrence, even at small tumor sizes. Comparatively, among patients with CNB of FA, all cases of PTs were among enlarging tumors. These findings underscore the importance of tumor growth rate and pathology of FELs when considering whether excision is required but provide no empirical evidence to support the routine excision of FELs larger than 3 cm.

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Data availability All data generated or analysed during this study are reported in this published article.

Code availability N/A.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This retrospective study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The research ethics board of the University of British Columbia and Providence Health care approved this study.

Consent to participate N/A.

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