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ORIGINAL ARTICLE **CME**

Analysis of Discordant Histologically Benign Breast Lesions and Predictive Factors Associated with True Discordance on Imaging

FFY Wan, KM Chu, TWY Chin, L Xu, WL Wong, JLF Chiu

Department of Radiology and Imaging, Queen Elizabeth Hospital, Hong Kong SAR, China

ABSTRACT

Introduction: *Discordant benign breast lesions are suspicious for malignancy on imaging but show benign histology on initial biopsy. These lesions require further histological workup. This study sought to determine the frequency of discordant benign lesions and the rate of true discordance among them, and to identify predictive factors associated with true discordance.*

Methods: *Clinical, radiological, and pathological data on all discordant benign breast lesions biopsied between 2012 and 2021 were retrieved from the departmental database of a Hong Kong hospital. Rate of discordant benign lesions, true and false discordance rates, and proportion of high-risk and benign lesions among false discordance were calculated. If the discordant benign lesion was found to be malignant in repeat percutaneous biopsy or excisional biopsy, it was true discordance. If a lesion's benignity was confirmed with excisional biopsy, it was false discordance. Univariate analysis was performed followed by multivariable logistic regression analysis to identify independent predictors associated with true discordance.*

Results: *A total of 3080 breast biopsies were performed during the study period, of which 64 lesions (2.1%) were discordant benign lesions. Among 55 lesions with available additional workup results, 17 lesions (30.9%) were true discordant and 38 (69.1%) were false discordant. Nine (23.7%) of the false discordant lesions were high-risk lesions on final pathology. Older age (p = 0.019), presence of symptoms (p = 0.046), BI-RADS category 5 (p = 0.028), presence of microcalcifications with suspicious morphology (p = 0.047), and presence of architectural distortion (p = 0.04) were identified as independent predictors of true discordance.*

Conclusion: *The high true discordance rate confirmed the importance of further histological workup in discordant benign breast lesions.*

Key Words: *Biopsy; Breast; Histology; Neoplasms*

Correspondence: *Dr FFY Wan, Department of Radiology and Imaging, Queen Elizabeth Hospital, Hong Kong SAR, China*
Email: wfy471@ha.org.hk

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中文摘要

不一致組織學良性乳房病變及與影像學真正不一致相關的預測因子分析

尹芳盈、朱嘉敏、錢永恩、徐璐、黃慧琳、趙朗峰

引言：不一致良性乳房病變在影像學上疑似惡性腫瘤，但在初次活檢時顯示良性組織學，這些病變需要進一步組織學檢查。本研究旨在確定不一致良性病變的發病率以及它們真正不一致的比率，並確定與真正不一致相關的預測因子。

方法：我們從香港一家醫院的部門資料庫中檢索於2012至2021年間活檢的所有不一致良性乳房病變的臨床、放射學和病理數據，並計算不一致良性病變率、真假不一致率及假性不一致中的高風險病例和良性病變比例。如果重複經皮活檢或切除活檢發現不一致的良性病變為惡性，則為真正不一致；如果切除活檢證實病變為良性，則屬假性不一致。本研究先進行單變量分析，然後進行多變量邏輯迴歸分析，以確定與真正不一致相關的獨立預測因子。

結果：研究期間共進行了3080例乳房活檢，其中64例（2.1%）病灶為不一致良性乳房病變。在55例有額外檢查結果的病灶中，17例（30.9%）為真正不一致，38例（69.1%）為假性不一致。9例（23.7%）假性不一致病變在最終病理學上屬高風險病變。年齡較大（p = 0.019）、存在症狀（p = 0.046）、BI-RADS（乳房影像報告和數據系統）類別5（p = 0.028）、存在形態可疑的微鈣化（p = 0.047）以及存在結構扭曲（p = 0.04）為真正不一致的獨立預測因子。

結論：真正不一致比率高證實了對不一致良性乳房病變進行進一步組織學檢查的重要性。

INTRODUCTION

Image-guided core needle biopsy is the current standard for initial workup and diagnosis of most BI-RADS (Breast Imaging Reporting and Data System) category 4 and 5 breast lesions detected on mammography. With technological advancements in both imaging techniques and core biopsy devices, the false-negative rates of image-guided core needle biopsy have been reported to be down to 2.5%,[1] with most cases identified because of radiological-pathological discordance. Such discordance happens when the pathology results do not match the imaging features, indicating that the lesion may not have been sampled adequately and creating the need for further histological workup.

Discordant benign lesions are lesions radiologically suspicious for malignancy (BI-RADS category 4 or 5) with a histological result that does not account for the radiological suspicion.[2] Up to 64% of discordant benign lesions from image-guided core needle biopsy turned out to be malignant in subsequent excisional biopsy.[3] If there is any concern regarding a discordant benign breast lesion, further investigation by repeating image-guided core needle biopsy or performing excisional biopsy is then be considered. If a true discordant benign lesion is recognised promptly, a missed malignancy can be identified, thus avoiding delay in diagnosis and treatment.

This retrospective analysis aimed to determine the frequency of discordant benign lesions and the proportion of true discordance among them. Potential predictive factors associated with true discordance were identified to assist radiologists in better evaluating for discordance.

METHODS

Data Collection

All cases with discordant benign breast lesions from 2012 to 2021 were retrieved from the departmental database of Department of Radiology and Imaging of Queen Elizabeth Hospital, Hong Kong. Data including patients' clinical details, radiological features, pathological findings, and imaging methods for biopsy guidance were described.

Discordant benign lesions were defined as lesions showing radiological findings suspicious for malignancy with no evidence of malignancy on initial pathological examination. In our institution, excisional biopsy was

the standard of care for patients with discordant benign pathological findings after two image-guided core needle biopsies. If a lesion was found to be malignant with repeat percutaneous biopsy or excisional biopsy, it was considered to represent true discordance. If a lesion's benignity was confirmed with final excisional biopsy, it was considered to represent false discordance (or concordance). The rates of discordant benign lesions, true discordance (Figure 1), and false discordance (Figure 2) were calculated.

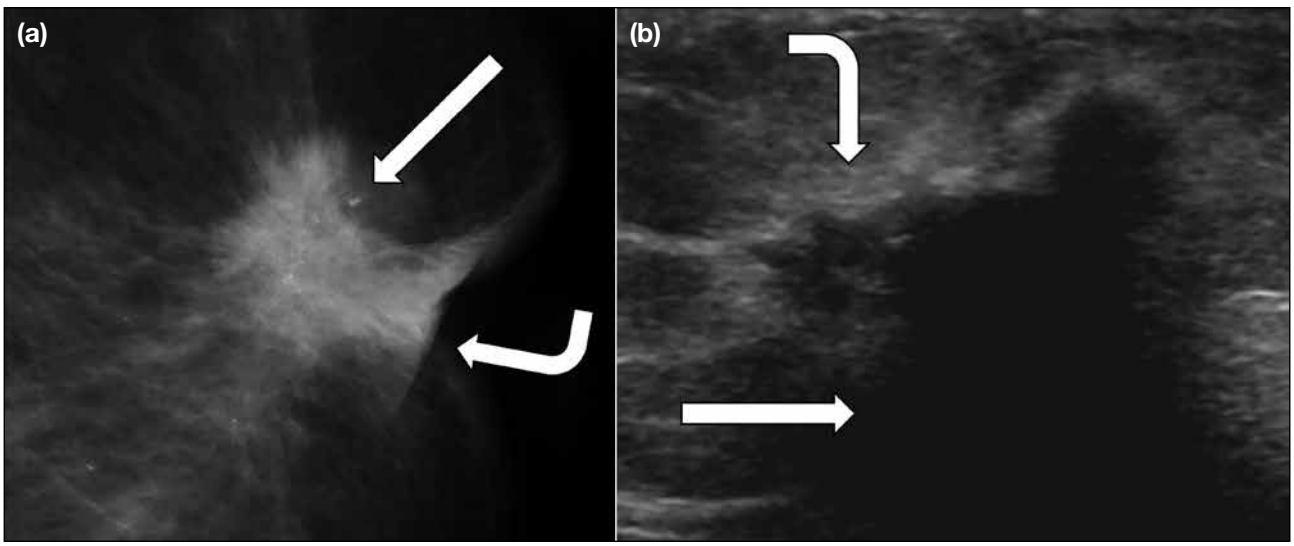

Figure 1. True discordance. An irregular high-density mass showing spiculated margins was noted to have fine pleomorphic calcifications (straight arrow) and architectural distortion in magnified craniocaudal view on mammogram (a). Associated skin and nipple retraction (curved arrow) was noted. Ultrasound of the mass (b) also showed suspicious features, including irregular shape, spiculated margin, significant posterior shadowing (straight arrow), and echogenic halo (curved arrow). The lesion was classified as Breast Imaging Reporting and Data System category 5 lesion. Ultrasound-guided biopsy of the mass was performed and the initial pathological diagnosis of fibrofatty tissue was considered discordant with the imaging findings. On repeat ultrasound-guided biopsy, the diagnosis of invasive ductal carcinoma was made.

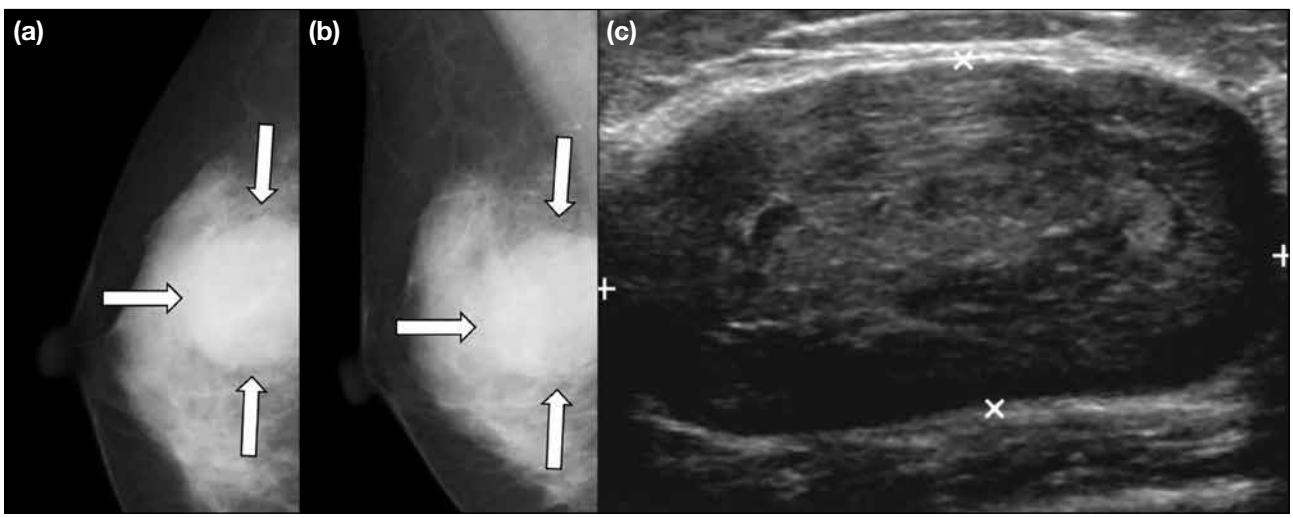

Figure 2. False discordance (concordance). (a) Craniocaudal view and (b) mediolateral oblique view of a large isodense mass with partially obscured margins (outlined by the arrows) was seen at the 9 o'clock position of the right breast on mammogram. No suspicious microcalcifications or architectural distortion was noted. Corresponding ultrasound of the mass (c) showing an oval circumscribed parallel hypoechoic mass with no definite posterior features. Ultrasound-guided biopsy was performed and the initial diagnosis of epidermal cyst was considered discordant, mainly due to the large lesion size. The same pathological diagnosis was noted on repeat ultrasound-guided biopsy. The patient subsequently underwent surgical excision of the breast mass and the final histological diagnosis was confirmed to be an epidermal cyst.

Patients' clinical details including age, presence of signs and symptoms (e.g., palpable breast mass or pathological nipple discharge), synchronous breast malignancy, past medical history or family history of breast cancer, and history of previous ipsilateral breast procedure were collected. Radiological features including lesion size (measured on ultrasound except for lesions only visualised on mammogram), BI-RADS category, presence of suspicious microcalcifications or architectural distortion on mammogram, presence of other radiologically suspicious lesions in the ipsilateral or contralateral breast, and presence of axillary lymphadenopathy on ultrasound or mammogram were reviewed. The imaging method for biopsy guidance was also noted, and all the above features were evaluated for their potential association with true or false discordance.

Diagnostic Imaging Workup

All patients had had mammography and ultrasound of both breasts performed as the initial diagnostic workup, with interpretation and reporting performed by breast radiologists (years of experience: mean, 8.3 years; median, 7; range, 1-30). Assessment for any suspicious radiological features was made in accordance with the American College of Radiology BI-RADS Atlas.[4] The major findings to be evaluated included mass, microcalcifications, architectural distortion, and axillary lymphadenopathy. Suspicious features of masses include irregular shape, non-parallel orientation, non-circumscribed margins, and posterior shadowing on ultrasound. Morphology was useful in predicting the likelihood of malignancy for microcalcifications and other suspicious calcification morphologies including amorphous, coarse heterogeneous, fine pleomorphic, fine linear, and fine linear-branching microcalcifications. Linear or segmental distribution of the microcalcifications also elevated the suspicion for malignancy since they suggest deposits within the ductal system. Examples of other associated suspicious features were duct changes and skin changes. Suspicious lymph nodes usually displayed cortical thickening and hilar compression or displacement. The BI-RADS category indicates the likelihood of malignancy and guides the next step of management. Any lesions of BI-RADS category 4 or 5 require tissue diagnosis. BI-RADS category 4 lesions present with imaging findings that do not possess the classic appearance of malignancy but are sufficiently suspicious to indicate biopsy. BI-RADS category 5 lesions carry a very high probability of malignancy for which any non-malignant biopsy results are automatically considered discordant, leading to repeat percutaneous biopsy or excisional biopsy. Any radiologic-pathologic discordances were established in multidisciplinary meetings.

Biopsy Technique

The choice of imaging modality for biopsy guidance was based on factors including lesion visibility, operator's and patient's preference, and availability of equipment. All sonographic-guided biopsies were performed with an automated biopsy gun (Bard; Magnum, Covington [GA], US) and a 14-gauge core needle with a 22-mm throw. A minimum of three core samples were obtained. All stereotactic-guided biopsies were performed with a directional vacuum-assisted device (Eviva Breast Biopsy System; Hologic, Marlborough [MA], US) and a 9-gauge core needle, and approximately 12 tissue samples were acquired. Biopsies were performed by breast radiologists. If microcalcifications or architectural distortion were deemed to be well-visualised and targeted on ultrasound, sonographic guidance was considered for biopsy. After biopsy of calcifications, specimen radiographs were acquired to verify sampling of the target calcifications. A marker clip was placed at the biopsy site, and its location on post-biopsy mammographic images was confirmed. Correlation with initial diagnostic imaging was performed to confirm biopsy of the targeted lesion.

Statistical Analysis

The distribution of the numerical variables was first assessed for normality by using the Shapiro–Wilk test. If the data are not normally distributed, they are expressed as medians with interquartile ranges and analysed using Mann-Whitney *U* test.

Categorical variables were reported as counts and proportions. If there were <20% of cells with an expected frequency of <5 in a contingency table, the analysis of differences in characteristics between groups was performed using the Chi squared test. If there were ≥20% of cells with an expected frequency of ≤5 in a contingency table, the analysis between groups was assessed using Fisher's exact test for a 2 × 2 contingency table and Fisher-Freeman-Halton exact test for a contingency table larger than 2 × 2.

The variables with $p < 0.1$ in the univariate analysis were included in the multivariable logistic regression analysis to assess their abilities as independent predictors. The variables with $p < 0.05$ were considered statistically significant.

Statistical analyses were performed using SPSS (Windows version 28.0; IBM Corp, Armonk [NY], US).

RESULTS

A total of 3080 breast biopsies were performed from 2012 to 2021, of which 64 lesions (2.1%) were discordant benign lesions. Among the 55 lesions with available additional workup results, 17 lesions (30.9%) were true discordant and 38 (69.1%) were false discordant (concordant). Overall, there were 14 lesions (25.5%) graded BI-RADS category 5, 13 lesions (23.6%) graded BI-RADS category 4C, and 28 lesions (50.9%) graded BI-RADS category 4B. There were no BI-RADS category 4A lesions. Repeat biopsy of the lesions was performed under either sonographic (n = 50, 90.9%) or stereotactic guidance (n = 5, 9.1%).

In univariate analysis, older age (p = 0.002), larger lesion size (p < 0.001), presence of symptoms (p = 0.076), BI-RADS category 5 (p < 0.001), presence of microcalcifications with suspicious morphology (p = 0.062), and presence of architectural distortion (p = 0.091) were predictors of true discordance. Synchronous breast malignancy (p = 0.149), past medical history (p = 1) or family history of breast cancer (p = 1), history of previous ipsilateral breast procedure (p = 0.309), presence of other radiologically suspicious lesions in the ipsilateral or contralateral breast (p = 0.36), presence of axillary lymphadenopathy (p = 0.435), and imaging guidance methods (p = 0.31) were non-significant variables (Tables 1 and 2).

In multivariable logistic regression analysis, older age (p = 0.019), presence of symptoms (p = 0.046), BI-RADS category 5 (p = 0.028), presence of microcalcifications with suspicious morphology (p = 0.047), and presence of architectural distortion (p = 0.04) were independent predictors of true discordance, while lesion size (p = 0.196) failed to remain a statistically significant independent predictor (Tables 1 and 2).

Table 1. Association of patient demographics with true and false discordance.*

	Total (n = 55)	True discordance (n = 17)	False discordance (n = 38)	p Value from univariate analysis	p Value from multivariable analysis
Age, y	59 (49-65)	63 (59.5-72)	54.5 (42.3-62.5)	0.002	0.019
Presence of symptoms	31 (56.4%)	13 (76.5%)	18 (47.4%)	0.076	0.046
Synchronous breast malignancy	10 (18.2%)	5 (29.4%)	5 (13.2%)	0.149	
Past medical history of breast cancer	12 (21.8%)	4 (23.5%)	8 (21.1%)	1	
Family history of breast cancer	3 (5.5%)	1 (5.9%)	2 (5.3%)	1	
History of previous ipsilateral breast procedure	5 (9.1%)	0	5 (13.2%)	0.309	

* Data are shown as No. (%) or median (interquartile range).

Table 2. Association of radiological features with true and false discordance.*

	Total (n = 55)	True discordance (n = 17)	False discordance (n = 38)	p Value from univariate analysis	p Value from multivariable analysis
Lesion size, cm	1.6 (0.9-2.6)	2.6 (1.7-5.4)	1.15 (0.78-1.93)	< 0.001	0.196
BI-RADS category				< 0.001	0.028
4	41 (74.5%)	7 (41.2%)	34 (89.5%)		
5	14 (25.5%)	10 (58.8%)	4 (10.5%)		
Presence of microcalcifications with suspicious morphology	16 (29.1%)	8 (47.1%)	8 (21.1%)	0.062	0.047
Presence of architectural distortion	8 (14.5%)	5 (29.4%)	3 (7.9%)	0.091	0.04
Presence of other radiologically suspicious lesions in the ipsilateral or contralateral breast	19 (34.5%)	4 (23.5%)	15 (39.5%)	0.36	
Presence of axillary lymphadenopathy	9 (16.4%)	4 (23.5%)	5 (13.2%)	0.435	
Imaging method for biopsy guidance				0.31	
Ultrasound-guided	50 (90.9%)	17 (100%)	33 (86.8%)		
Stereotactic-guided	5 (9.1%)	0	5 (13.2%)		

Abbreviation: BI-RADS = Breast Imaging Reporting and Data System.
* Data are shown as No. (%) or median (interquartile range).

A total of 9 out of 38 (23.7%) false discordant lesions were high-risk on final pathology. The high-risk lesions included atypical ductal hyperplasia as the commonest pathology, followed by intraductal papilloma and lobular carcinoma in situ. The common final pathologies in concordant cases were sclerosing adenosis, fat necrosis, and fibroadenoma (Table 3).

DISCUSSION

The reported percentages of imaging-pathology discordant lesions among biopsied breast lesions ranged from 2.2% to 5.8%.[5-7] The prevalence of discordant benign breast lesions in our institution was relatively low (2.1%). This might be explained by our quality control methods. During ultrasound-guided biopsy, satisfactory needle position was confirmed by obtaining post-fire images in orthogonal planes. For breast lesions with suspicious microcalcifications, specimen radiographs were performed to confirm the presence of target microcalcifications. Moreover, adequate sampling was achieved by obtaining at least three cores with minimal fragmentations.

In our institution, excisional biopsy is the standard of care for patients with discordant benign pathological findings after two image-guided core needle biopsies. Recently, vacuum-assisted breast biopsy has emerged as a potentially less invasive alternative to excisional biopsy for discordant benign lesions, with an upgrade rate ranging from 4.6% to 22.7%.[8] Because of the high sensitivity of contrast-enhanced magnetic resonance imaging (MRI) for detection of breast malignancies, it has been suggested to be of value in patients with discordant benign breast lesions to avoid further excisional biopsy. In a recent retrospective analysis, incorporating MRI into the algorithm for management of discordant benign breast lesions was shown to obviate the need for excisional biopsy in nearly 70% of patients with BI-RADS category 4 findings (excluding clusters of microcalcifications which are suspicious of underlying ductal carcinoma in situ).[9] A previous study also supported the use of MRI in determining the need for biopsy of BI-RADS category 4 lesions.[10] MRI is a potential tool for further workup of discordant benign breast lesions in the BI-RADS 4 category, especially in patients reluctant to undergo invasive excisional biopsy. However, using the criterion of non-enhancement to justify non-surgical management warrants further studies with larger populations since false-negative results could still occur with MRI.[10] Of note, the use of MRI in this setting has not been studied for BI-RADS category 5 lesions, likely due to the assumption that BI-RADS 5 category from mammography and ultrasound studies is unlikely to be overridden by the absence of suspicious malignant findings on MRI. Surgical resection still remains the gold standard for management of discordant benign lesions of BI-RADS category 5.

Table 3. Final pathologies of false discordant lesions (n = 38).

High-risk lesions	Total No.	Benign lesions	Total No.
Atypical ductal hyperplasia	3	Sclerosing adenosis	5
Intraductal papilloma	2	Fat necrosis	5
Lobular carcinoma in situ	2	Fibroadenoma	4
Atypical lobular hyperplasia	1	Fibrocystic change	3
Complex sclerosing lesion	1	Usual ductal hyperplasia	3
		Benign breast tissue	2
		Lymphocytic mastopathy	2
		Stromal fibrosis	2
		Granulomatous mastitis	1
		Granulation tissue	1
		Epidermal cyst	1

To our knowledge, this is the first study to evaluate for the potential predictive factors associated with true discordance. Although determining radiological-pathological concordance is crucial, no standard or guideline is currently available to assist in decision making. For this reason, evaluating for concordance still remains a subjective decision which could certainly vary among radiologists. Identification of predictors for true discordance may therefore be useful in decision making, especially in equivocal cases.

From our study, older age was a significant predictor of true discordance. The incidence of breast cancer is strongly related to older age, with the highest incidence rates in older women. For example, in Hong Kong from 2000 to 2020, more than half of the new cases of invasive breast cancers were in people aged ≥55 years.[11] The increase in incidence with age largely reflects cell DNA damage accumulating over time, which can be related to biological processes or exposure to risk factors. Hence, it is worth considering the age of the patient when assessing concordance of breast lesions. On the contrary, personal history and family history of breast cancers were not significant predictors for true discordance in this study. However, a definite conclusion could not be arrived at due to the small number of patients having a personal or family history of breast cancer in this study.

Imaging findings in patients with postprocedural

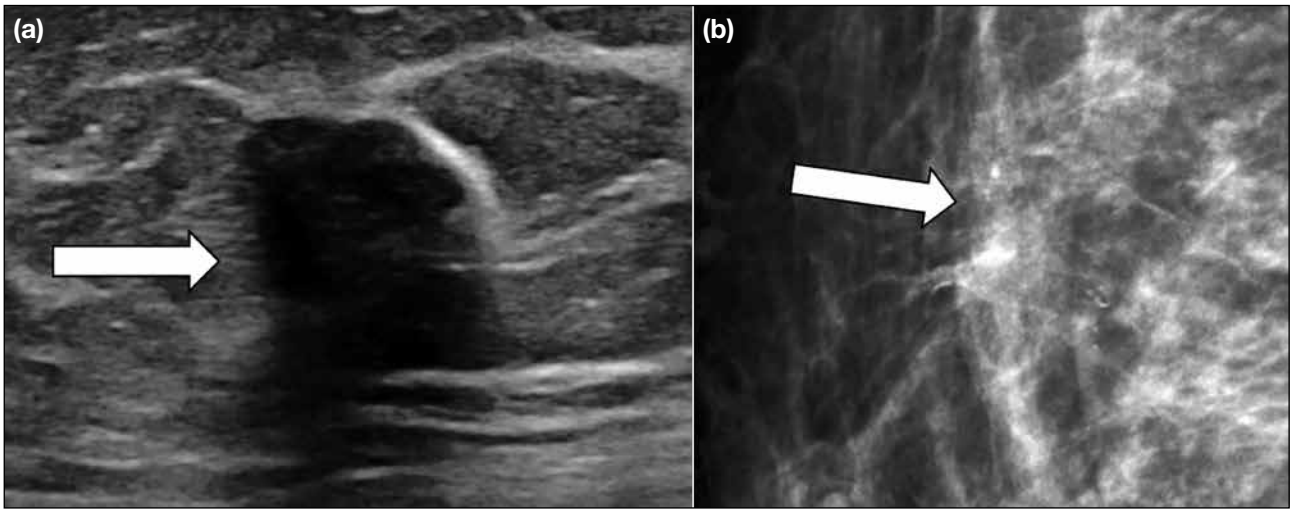

Figure 3. Examples of false discordance with final pathological diagnosis of fat necrosis. (a) A hypoechoic mass with significant posterior shadowing (arrow) on ultrasound was confirmed histologically to be fat necrosis. (b) Amorphous microcalcification (arrow) in magnified mediolateral oblique view on mammogram was considered suspicious and pathological workup also confirmed it to be fat necrosis.

changes may pose challenges in imaging interpretation and assessment of concordance, especially in view of the differential diagnosis of recurrent lesions.[1] Five discordant benign breast lesions in our study had a history of previous ipsilateral breast intervention. Subsequent histological workup confirmed all to be non-malignant with four of them being fat necrosis. Fat necrosis is an inflammatory condition commonly seen after breast surgery, radiation, infection or trauma. It is known to be a mimicker of malignancy both clinically and radiologically. Knowledge about the spectrum of suspicious radiological features of fat necrosis (Figure 3) as well as careful review of the biopsy technique and confirmation of biopsy adequacy are useful in the assessment for concordance in these patients.

BI-RADS is the internationally accepted standard for reporting breast imaging and BI-RADS category 5 lesions are highly suggestive of malignancy. With >95% probability of malignancy, BI-RADS category 5 was proven in our study to be a reliable factor in identifying true discordance. This also showed that our radiologists can successfully stratify lesions using BI-RADS risk assessment categories. In addition, microcalcifications of suspicious morphology and architectural distortion (Figure 4) are suspicious imaging findings included in the BI-RADS lexicon. Among the discordant benign breast lesions in this analysis, the presence of either finding was shown to be associated with a statistically significant higher malignancy rate.

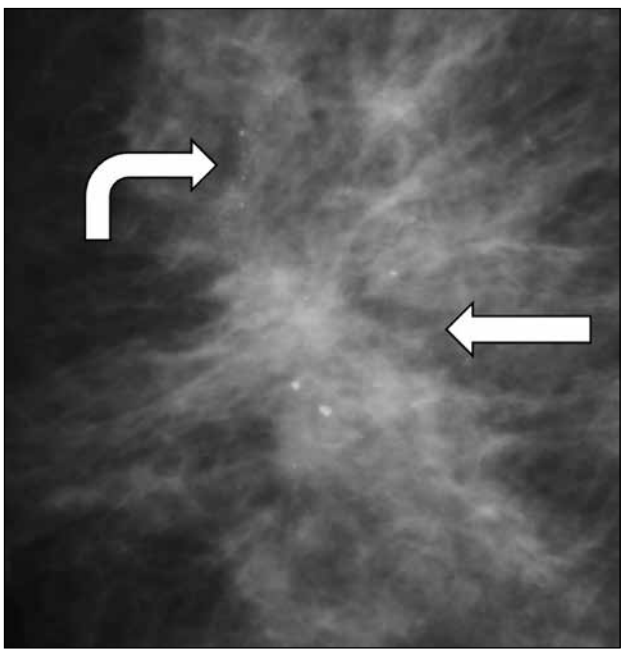

Figure 4. Fine pleomorphic microcalcifications (curved arrow) and architectural distortion (straight arrow) were seen with no definite associated mass in magnified mediolateral view on mammogram. Initial pathological diagnosis of atypical ductal hyperplasia was considered discordant with radiological findings. Repeat image-guided biopsy showed ductal carcinoma in situ, which was confirmed on subsequent surgical resection.

Lesion size was not a criterion for determination of the BI-RADS category and was confirmed in this study to be a non-significant predictor of true discordance. Although

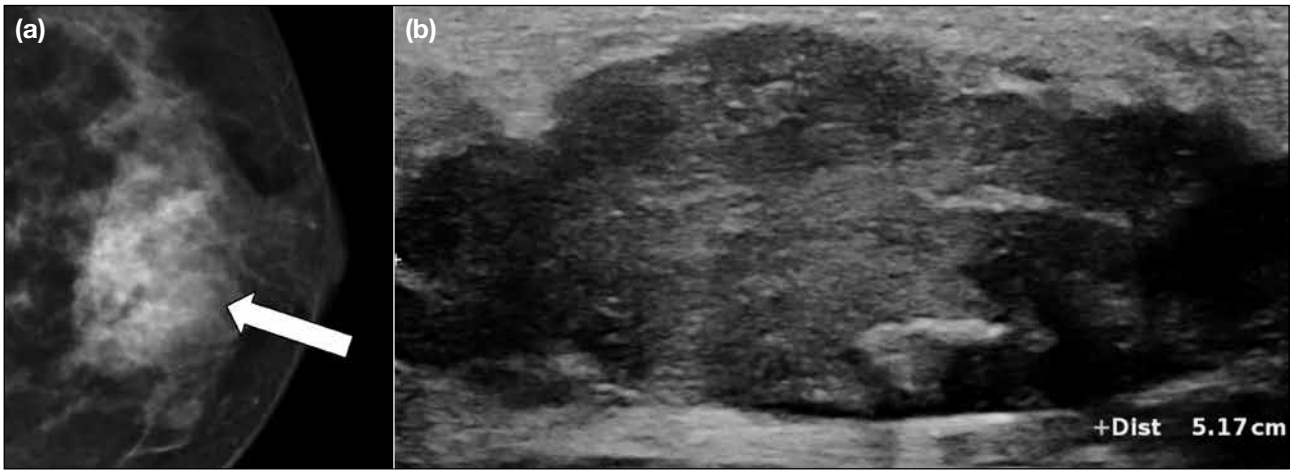

Figure 5. A large (>5 cm) oval high-density mass with partially obscured margins (arrow) was seen in craniocaudal projection on mammogram (a). No suspicious microcalcifications or architectural distortion were noted. Corresponding ultrasound of the mass (b) showing an oval circumscribed parallel hypoechoic mass with no definite posterior features. The pathological diagnosis of granulomatous mastitis was made on both initial and repeat ultrasound-guided biopsy. The result was considered discordant in view of the large lesion size. The patient underwent surgical excision of the mass and the final diagnosis was confirmed to be granulomatous mastitis. This was considered false discordance.

large breast masses (>5 cm) are understandably worrying for both patients and doctors, not all of them are malignant. Some benign breast lesions can present as large breast masses (Figure 5). According to the study by Sickles,[12] no statistically significant difference in the likelihood of cancer was found in relation to lesion size in non-palpable breast masses.

The imaging method for biopsy guidance was not found to be a significant factor in predicting true discordance. In our department, ultrasound-guided core needle biopsies were often performed with 14-gauge biopsy needles, while stereotactic-guided biopsies were usually done with 9-gauge vacuum-assisted biopsy devices. Since the size of the biopsy needles used between these two methods was also different, this acted as a potential confounder limiting proper comparison. However, it was worth noting that all five discordant benign lesions biopsied with stereotactic-guided vacuum-assisted biopsy were false discordant. This observation could possibly be explained by the higher biopsy adequacy obtained using a larger-bore biopsy needle with a vacuum-assisted device.

Among the false discordant lesions in our study, nearly one-fourth were high-risk lesions. This category refers to non-malignant lesions with increased lifetime risk of developing breast cancer, including atypical ductal hyperplasia, lobular neoplasia, papillary lesion, and radial scar.[13] Controversy exists regarding the appropriate management of these lesions, which is primarily related to the need for subsequent surgical excision. These patients should be managed by a multidisciplinary team with personalised management recommendations based on clinical, imaging, and pathological correlations.[14] For example, a pathological diagnosis of atypical ductal hyperplasia in a small lesion that was nearly entirely removed by vacuum-assisted biopsy may not require subsequent surgical resection.[15] On the other hand, if the same pathological diagnosis of atypical ductal hyperplasia was obtained with imaging showing extensive suspicious findings, there was a high possibility of co-existing higher-grade lesions and further surgical excision would be justified. Therefore, a single-standard approach does not exist for high-risk breast lesions and individualised management should be offered.

Limitations

Our study was limited by its small sample size and retrospective approach. The strength of association between the independent predictors and true discordance (i.e., odds ratio) therefore cannot be reliably assessed and reported.

CONCLUSION

The high true discordance rate of this study emphasised the importance of careful radiological-pathological correlation. Radiologists performing breast biopsy

should be aware of the possibility of false-negative diagnoses and be familiar with how to determine radiological-pathological concordance as well as the appropriate subsequent management. Future studies with larger populations are necessary to develop a predictive model for true discordance.

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