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BRIEF REPORT

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Value of combined use of fine-needle aspiration and core needle biopsy in palpable breast tumors performed by pathologist: Institut Curie experience

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Abstract

The aim of this study was to determine the accuracy of fine-needle aspiration (FNA) and core needle biopsy (CNB) for palpable breast tumors (PBTs). FNA and CNB of 492 PBTs from 477 patients were analyzed. Tumors were malignant in 473 cases and benign in 19 cases. There was a strong correlation ($P > .05$) between FNA and CNB in terms of malignancy. Among 473 malignant tumors, FNA had better accuracy and less unsatisfactory results (95.6%; 2.7%) than CNB (94.9%; 4.9%). Among 19 benign tumors, CNB was accurate in 100% compared to 94.7% using FNA. There were only two (0.4%) cases where result was unsatisfactory by both FNA and CNB. NPV was 56.3% for FNA, 43.2% for CNB, and 95.0% for FNA and CNB combined. Sensitivity was 97.0% for FNA, 94.7% for CNB, and 99.8% for FNA and CNB combined. PPV and specificity was 100% for FNA and CNB both separately and combined. Combined use of FNA with CNB is an optimal diagnostic method for PBTs. In our opinion, this should be recommended as standard for diagnosis of PBTs.

KEYWORDS

breast carcinoma, core needle biopsy, fine-needle aspiration, palpable tumors

1 | INTRODUCTION

Fine-needle aspiration (FNA) is one of the techniques for accurate and rapid characterization of palpable breast tumors (PBTs).[1] In recent years, FNA has been replaced by core needle biopsy (CNB), which allows a specific diagnosis and evaluation of prognostic factors.[2,3]

More recently, many centers opted for exclusive use of CNB as a pretherapeutic diagnostic method regardless of the number of potential false-negative diagnoses or technical complexity.

Although the performance of FNA and CNB for diagnosis of PBTs is well-characterized, there is a limited number of studies[1,4-6] that have compared performance of FNA and CNB combined, that have been sampled in the same tumors during the same procedure.

The aim of this study was to evaluate the performance of FNA and CNB both separately and combined, in a series of PBTs diagnosed in the same institution.

2 | MATERIALS AND METHODS

Approval for this study by a local ethics committee was not necessary because it is a retrospective and archival data-based series.

Five hundred and four consecutive FNA samples and corresponding CNB from palpable breast tumors were selected from archival files in our Institute. None of the patient had history of previous breast cancer. Cases from 2009 to 2011 were selected to obtain a minimum 8 years follow-up.

Eleven malignant cases were excluded due to lack of clinical follow-up. One case was excluded due to metastasis from lymphoma not primarily manifested in the breast. Eight cases of benign tumors without surgical removal were not excluded but were followed-up clinically (no clinical or radiological evidence of evolution). Consequently, 492 tumors (473 malignant and 19 benign) from 477 patients (15 bifocal or bilateral tumors) remained for further analyses.

All patients were female with median age of 57 years (range: 14-96 years).

Clinical tumor size was recorded in 474 tumors (469 malignant and 5 benign). Largest diameter ranged from 7 to approximately 200 mm (mean 43, median 35). Small tumors were defined as 7-20 mm (n = 119), medium as >20 ≤ 50 mm (n = 245) and large as >50 mm (n = 110) according to the WHO TNM classification.[7]

Among total 473 malignant tumors, 209 (44.2%) tumors were treated by surgical excision, 209 (44.2%) by neoadjuvant chemotherapy, 52 (11%) cases by radiotherapy/hormone therapy/chemotherapy not followed by surgery. Three tumors (0.6%) were treated with palliative treatment. Among the group of 209 cases treated with neoadjuvant chemotherapy with surgical tumor bed removal, 50 surgical excisions showed usual present benign changes encountered in complete response like granulomas, fibrosis, or fat necrosis, and 159 showed residual carcinoma (invasive or in situ carcinoma). Receiving any treatment was assumed as confirmation of a malignant tumor as treatment decision was made on the background of positive triple diagnostic.

Among 19 benign tumors in the CNB group, 11 (58%) cases were treated with surgical excision (four fibroadenomas, four fibrous involutions, two adenoses, and one papilloma). Eight (42%) cases were not surgically excised but were clinically followed-up (adenoses in five cases, fat necrosis in two cases, and fibroadenoma in one case).

All FNA and CNB procedures were performed during the same clinical procedure under palpation by a pathologist (J.K.). FNA diagnoses were performed immediately after clinical consultation in the same day (2-3 hours) without knowledge of histological diagnosis, whereas CNB diagnoses were always performed the next day after technical procedures (24 hours) with knowledge of cytological diagnosis. The diagnosis on among FNA, CNB, and surgical excision were determined by one pathologist from the Institut Curie (J.K.), but difficult cases were discussed at joint consensus meetings. Cases were not reassessed for this study.

FNA specimens were obtained by using a 23-gauge needle without aspiration inserted into target tumor and moved back and forth inside target in various directions. Cellular material was smeared on 2 to 3 slides, air-dried and stained according to MGG and Papanicolaou methods.

FNA diagnoses were classified into four categories: unsatisfactory, benign, suspicious, and malignant. Smears containing acellular or hemorrhagic material not permitting to accurate tumor assessment were classified as unsatisfactory. Benign diagnosis was made when clusters of benign cells were present and the smears showed bare bipolar nuclei, connective tissue fragments, cystic component, or apocrine cells. Suspicious diagnoses were made when isolated or clustered epithelial cells showed cyto-nuclear atypia and when few/technically poorly preserved atypical/most probably malignant cells or admixed population of malignant and benign cells were present. Finally, diagnosis of malignancy was made when the smears showed malignant cells. This categorization is used instead of the five recommended categories (C1-C5) in the routine practice at the Institut Curie, because in our opinion, it gives clearer indications to clinicians about further follow up.

CNB was performed after local anesthesia using Lidocaine 1% with a 14-gauge needle automatic BARD pistol with a sample length of 22 mm. Two to three shots were made in each case. The tissue specimens were fixed and stained according to hematoxylin-eosin-safran method. Additional material was frozen and stored for future investigations.

CNB diagnoses were also classified into the same four categories: unsatisfactory, benign, suspicious, and malignant. The assessment of predictive markers was done on material from CNB only.

Surgically excised malignant tumors without neoadjuvant treatment (n = 209) were classified into five categories: five cases in situ carcinomas, 147 invasive ductal carcinomas not otherwise specified (IDC-NOS), 32 invasive lobular carcinomas, and 25 different types of malignancies (15 invasive tumors with two or more components, five papillary carcinomas, one apocrine carcinoma, one micropapillary carcinoma, one metaplastic carcinoma, and two sarcomas) according to WHO classification from 2012.[7]

True negative (TN) cases were defined as PBTs with benign FNA/CNB and a definitive diagnosis of benignity. True positive (TP) cases were defined as PBTs with suspicious or malignant FNA/CNB and a definitive diagnosis of malignancy as they both lead to same clinical management. False-negative (FN) cases included PBTs with unsatisfactory or benign FNA/CNB and a definitive diagnosis of malignancy, since unsatisfactory biopsies do not give any diagnostic information. False-positive (FP) cases included PBTs with malignant FNA/CNB and a definitive diagnosis of benignity. Sensitivity (=TP/TP + FN), specificity (=TN/TN + FP), positive predictive value (PPV = TP/TP + FP), and negative predictive value (NPV = TN/TN + FN) were calculated for the FNA and CNB group separately and for the FNA and CNB combined. McNemar's chi-square test was used to calculate correlation between the two tests.

3 | RESULTS

There were 473 (96%) malignant and 19 (4%) benign tumors having as a gold standard surgical excision, neoadjuvant treatment, and/or clinical follow-up.

Table 1 shows the comparison of FNA and CNB in our study. In all 492 tumors, FNA resulted in diagnosis of malignancy in 452 (91.9%) cases, suspicious in 7 (1.4%) cases, benign in 20 (4.1%) cases, and unsatisfactory in 13 (2.6%) cases. CNB resulted in diagnosis of malignancy in 449 (91.3%) cases, benign in 19 (4.0%) cases, and unsatisfactory in 14 (3.0%) cases. There was a strong correlation between FNA and CNB results in terms of malignancy (chi-square $P > .05$).

Figure 1 illustrates a case diagnosed cytologically as carcinoma and confirmed as carcinoma on surgical specimen, whereas CNB was negative (adenosis).

Table 2 shows accuracy of diagnosis by FNA and CNB. Among 473 malignant tumors, FNA was accurate in 452 (95.6%), suspicious in 7 (1.5%), false-negative in 1 (0.2%), and unsatisfactory in 13 (2.7%)

TABLE 1 Comparison between FNA and CNB, surgical excision or neoadjuvant treatment and/or clinical follow-up being a gold standard in all 492 cases[a]

	M CNB	S CNB	B CNB	NS CNB	Total
M FNA	433 (88%)	0 (0%)	0 (0%)	19 (3.9%)	452 (91.9%)
S FNA	5 (1%)	0 (0%)	0 (0%)	2 (0.4%)	7 (1.4%)
B FNA	1 (0.2%)	0 (0%)	19 (3.9%)	0 (0%)	20 (4.1%)
NS FNA	10 (2%)	0 (0%)	1 (0.2%)	2 (0.4%)	13 (2.6%)
Total	449 (91.3%)	0 (0%)	20 (4.1%)	23 (4.7%)	492 (100%)

[a]For analysis purposes, suspicious diagnoses were recorded as malignant and unsatisfactory samples were excluded.

Abbreviations: B, benign; CNB, core needle biopsy; FNA, fine-needle aspiration; M, malignant; NS, not significant; S, suspicious.

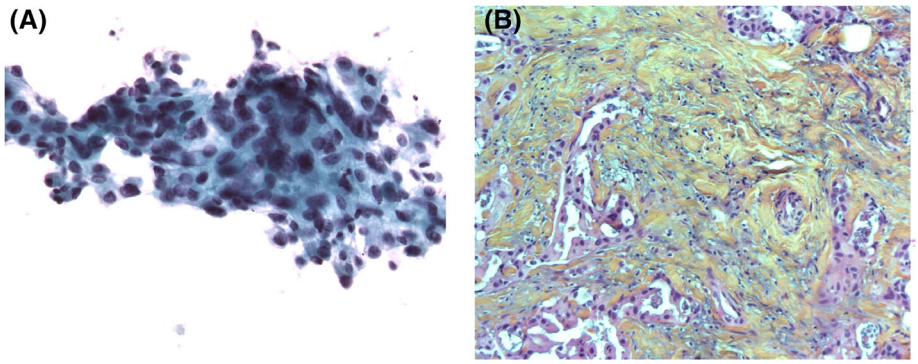

FIGURE 1 Palpable breast carcinoma with malignant FNA and corresponding negative CNB. A, Smear composed of malignant clustered cells. Papanicolaou. B, Apocrine carcinoma confirmed on surgical specimen, Hematoxylin-Eosin-Safran (HES). Corresponding CNB showed adenosis. CNB, core needle biopsy; FNA, fine-needle aspiration

TABLE 2 FNA and CNB accuracy in correlation with final diagnosis including surgical excision or neoadjuvant treatment and/or clinical follow-up being a gold standard in all 492 cases

	Diagnosis	Finally Malignant (n = 473)	Finally Benign (n = 19)
FNA	Malignant	452 (95.6%)	0 (0%)
	Suspicious	7 (1.5%)	0 (0%)
	Benign	1 (0.2%)	18 (94.7%)
	Unsatisfactory	13 (2.7%)	1 (5.3%)
CNB	Malignant	448 (94.7%)	0 (0%)
	Suspicious	0 (0%)	0 (0%)
	Benign	2 (0.4%)	19 (100%)
	Unsatisfactory	23 (4.9%)	0 (0%)

Abbreviations: CNB, core needle biopsy; FNA; fine-needle aspiration.

cases. Among 19 benign tumors, FNA was accurate in 18 (94.7%) cases and one (5.3%) case was unsatisfactory. Among 473 malignant tumors, CNB was accurate in 448 (94.7%), false-negative in 2 cases (0.4%), and unsatisfactory in 23 (4.9%) cases. Interestingly, there were only two (0.4%) cases that were unsatisfactory by FNA and CNB combined, one IDC-NOS and one lobular carcinoma). One case was misdiagnosed by both FNA and CNB as benign. This lesion was 18 mm large and the final diagnosis on surgical excision was IDC-NOS grade I. Among 19 benign tumors, CNB was accurate in all 19 (100%) cases.

No cases were false-positive, yielding positive predictive value (PPV) at 100% for FNA and CNB separately, and 100% for FNA and CNB combined. The negative predictive value (NPV) was 56.3% for FNA, 43.2% for CNB, and 95.0% for FNA and CNB combined. Sensitivity was 97.0% for FNA, 94.7% for CNB, and 99.8% for FNA and CNB combined. Specificity was 100% for FNA, CNB, and for FNA and CNB combined.

Table 3 shows accuracy of diagnosis by FNA and CNB within each tumor histological type. Among 147 invasive IDC-NOS carcinomas, FNA was accurate in 138 (93.9%) cases, suspicious in 3 (2%), false-negative in 1 (0.7%), and unsatisfactory in 5 (3.4%) cases. Among 32 invasive lobular carcinomas, FNA was accurate in 25 (78.1%) cases, suspicious in 3 (9.4%), and unsatisfactory in 4 (12.5%) cases. Among 25 remaining invasive malignancies, FNA was accurate in 23 (92%) cases and unsatisfactory in 2 (8%) cases.

Among the IDC-NOS cases, CNB was accurate in 133 (90.5%) cases, false-negative in 2 (1.2%), and unsatisfactory in 12 (8.2%) cases. Among 32 invasive lobular carcinomas, CNB was accurate in 30 (93.85%) cases and unsatisfactory in 2 (6.25%) cases. Among 25 remaining invasive malignancies, CNB was accurate in 23 (92%) cases and unsatisfactory in 2 (8%) cases.

In the group of IDC-NOS, sensitivity was 95.9% for FNA, 90.5% for CNB, and 98.6% for FNA and CNB combined.

In the group of lobular invasive carcinoma, sensitivity was 80.0% for FNA, 93.8% for CNB, and was 96.9% for FNA and CNB combined.

In the group of remaining invasive malignancies, sensitivity was 92% for FNA, 92% for CNB, and was 100% for FNA and CNB combined.

Table 4 shows accuracy in diagnosis by FNA and CNB for each clinical tumor size (n = 474). Sensitivity by FNA for all sizes was 97.4%, sensitivity by CNB was 94.6%, and sensitivity by FNA and CNB combined was 99.3%. Specificity as well as PPV was 100% for

		IDC-NOS (n = 147)	Lobular (n = 32)	Other (n = 25)
FNA	Malignant	138 (93.9%)	25 (78.1%)	23 (92%)
	Suspicious	3 (2%)	3 (9.4%)	0 (0%)
	Benign	1 (0.7%)	0 (0%)	0 (0%)
	Unsatisfactory	5 (3.4%)	4 (12.5%)	2 (8%)
CNB	Malignant	133 (90.5%)	30 (93.85%)	23 (92%)
	Suspicious	0 (0%)	0 (0%)	0 (0%)
	Benign	2 (1.2%)	0 (0%)	0 (0%)
	Unsatisfactory	12 (8.2%)	2 (6.25%)	2 (8%)

TABLE 3 FNA and CNB accuracy in correlation with histological type in 204 infiltrative carcinomas treated by primary surgery

Abbreviations: CNB, core needle biopsy; FNA, fine-needle aspiration; IDC-NOS, ductal infiltrative.

TABLE 4 FNA and/or CNB accuracy in 474 tumors with known clinical size, unsatisfactory samples are excluded

	Sensitivity			Specificity			PPV			NPV		
Clinical size	FNA	CNB	FNA + CNB	FNA	CNB	FNA + CNB	FNA	CNB	FNA + CNB	FNA	CNB	FNA + CNB
Small (n = 119)	99.1	99.0	99.1	100	100	100	100	100	100	88.9	88.9	88.9
Medium (n = 245)	100	99.6	100	100	100	100	100	100	100	100	83.3	100
Large (n = 110)	100	100	100	100	100	100	100	100	100	100	100	100
Total (n = 474)	99.8	99.5	99.8	100	100	100	100	100	100	92.9	87.5	93.3

Abbreviations: CNB, core needle biopsy; FNA, fine-needle aspiration; NPV, negative predictive value; PPV, positive predictive value.

both FNA, CNB and FNA and CNB combined. NPV was 52.0% for FNA, 35.9% for CNB, and 82.4% for FNA and CNB combined. Two out of 119 small tumors (1.7%) were unsatisfactory by FNA and seven (5.9%) cases were unsatisfactory by CNB. These were nonoverlapping cases, yielding no unsatisfactory cases by FNA and CNB combined. Nine out of 245 medium size tumors (3.7%) were unsatisfactory cases by FNA, and 15 (6.1%) by CNB. Two cases (0.8%) were unsatisfactory by FNA and CNB combined.

One out of 110 large tumors (0.9%) was unsatisfactory by FNA and one (0.9%) by CNB. No cases were unsatisfactory by FNA and CNB combined.

4 | DISCUSSION

Our study demonstrated that both palpation-guided FNA and palpation-guided CNB are highly accurate diagnostic techniques for PBTs. The sensitivity was 97% and 95% for FNA and CNB respectively, and the specificity was 100% by both techniques. These results are in the upper boundaries of published ranges in the literature for palpable breast lesions as well as ultrasound-guided lesions (Table 5). The strengths of our study are that we included both benign and malignant lesions, we included lesions not just surgically removed but also those with clinical follow-up/other treatment and the most important that both FNA and CNB were performed on the same lesion at the same time by one pathologist. This allows for comparison of FNA and CNB. This was done just by some studies where some of them are listed in Table 5.[4,5,8-15]

A false-negative diagnosis may delay the treatment of cancer while false-positive results can cause overtreatment. Using FNA, the false-negative diagnostic rate was 2.8% and using CNB was 4.9%. Interestingly, when both techniques were used in combination, only three cases (0.6%) were not diagnosed. Two of the cases (0.4%) were unsatisfactory (one IDC-NOS and one lobular carcinoma) and one case was misdiagnosed by both FNA and CNB as benign. This lesion, on a surgical specimen, was 18 mm IDC-NOS grade I. In our material, we did not have any false-positive FNA or CNB diagnoses (malignant diagnoses in FNA/CNB and benign SE).

Both FNA and CNB have their benefits and limitations. FNA is a minimally invasive technique with unknown contraindications,[16] it is better tolerated by patients, fast to obtain and the evaluation can be done onsite. It is a low-cost method and with saving some material for cell block, then it can even be used for the receptor status as well as proliferation activity evaluations.[17-20] FNA also samples better different parts of the tumor as the needle passes many times in different directions through the tumor. There are some known pitfalls of the FNA samples regarding distinctions between in situ tumors, noncancerous tumors as atypical ductal hyperplasia, atypical lobular hyperplasia, and invasive cancer where CNB performs better. As CNB is a tissue fragment from one specific place in the tumor it might give false-negative results as well as underestimate the prognostic and predictive information.[21,22] Although increasing passages through the tumor and obtaining more biopsies can increase the accuracy[23-25] as well as increasing the needles diameter.[26] It also takes time from the biopsy is performed until the report is done as it needs fixation and processing which leads to increased cost. It also may lead to more complications.

The diagnostic accuracy of FNA and CNB in different tumor types has been investigated in some studies.[6,27-29] It has been shown that

TABLE 5 Selected literature data concerning palpable and nonpalpable breast lesions

	Author	FNA No. of lesions	Sensitivity	Specificity	PPV	NPV	CNB No. of lesions	Sensitivity	Specificity	PPV	NPV	FNA + CNB No. of lesions	Sensitivity	Specificity	PPV	NPV
Palpation-guided lesions	Nemer[4]	152	83.3	100	100	55.3	152	75.4	100	100	45.6					
	Kurita et al[5]	182	93				56	86				43	72			
	Ballo et al[8]	124	97.5	100			124	90	100			124				
	Westenend et al[14]	286	92	82	100		286	88	90	99						
	Clarke et al[13]	52	60				52	96								
	Our study	492	97	100	100	56.3	492	94.7	100	100	43.2	492	99.8	100	100	95.0
US-guided	Farras et al[1]	2601	92.6	96.8	94.8	95.4										
	Kuo et al[9]	2053	95	86	86.12	73.7	2053	98	99	98.09	63.39	2053			96.09	82.64
	Brancato[10]	1950	93.8	96.4			1283	97.4	88.3			231	97	98.7		
	Hatada et al[11]	172	86.9	78.6	98.6	88.7	82	86.2	95.8	100	76.7	82	100	100	100	100
	Ibrahim et al[12]	298	34.5	47.6	58.7		298	87.7	99.4	98.5						
	Almeida Barra[15]	264	85.6	66.7	100	75.7	264	88.3	95.2	100	74.1	264	95	97.6	100	85.4

Abbreviations: CNB, core needle biopsy; FNA, fine-needle aspiration; NPV, negative predictive value; PPV, positive predictive value; US, ultrasound.

FNA has low success in obtaining a diagnosis of malignancy for invasive lobular carcinoma and that FNA performed worse than CNB. As shown in Table 3 our results suggest the same, that FNA gives more unsatisfactory results than CNB in the diagnosis of invasive lobular carcinoma. For the IDC-NOS, it is the opposite and there is no difference in unsatisfactory rate for other diagnoses. Moreover, we have used 4-tier instead of the actually proposed 5-tier reporting classification, omitting the C3-category following original Zajdela's recommendations,[30] which were elaborated in our Institut.

Some studies are postulating that tumors larger than 4 cm have a higher false-negative rate by FNA due to hemorrhage, necrosis, and cystic degeneration,[4,30,31] but we could not find this connection as showed in Table 4. In our study, there were less unsatisfactory results in the group of large tumors than in the group of small and medium sized. We also found out that FNA performed better than CNB in small tumors with unsatisfactory rate 1.7% and 5.9%, respectively. We showed that there are no substantial differences in the performance for FNA and CNB when analyzed for particular tumor size. Best performance was achieved by combining both tests and was best for large tumors. The one false-negative case by both FNA and CNB was in the group of small tumor size. The only problem was low NPV values for each size. This might be due to small proportion of benign lesions and high proportion of unsatisfactory diagnosis. When FNA combined with CNB the NPV rate gets higher (71-100%), which minimize the under-treatment. High NPV together with high PPV (100%) for the combination of FNA and CNB is a reliable method for guiding clinical management.

Our study has some limitations, mainly represented by the small number of benign lesions as Institut Curie is an oncology hospital where some of the admitted patients are already selected by doctors in primary care or private hospitals in Paris.

For many years, there has been a general trend to replace FNA with CNB when diagnosing breast lesions both palpation- and ultrasound-guided. There was generally accepted view that FNA have high number of unsatisfactory results[10,11] and that diagnosis of breast lesions is easier on tissue samples than cells. Our results show that FNA performs better than CNB in PBTs giving less unsatisfactory results for malignant lesions as shown in Table 1. Most studies have shown similar data to ours as shown in Table 5. When compared to ultrasound-guided FNA/CNB (US-FNA/CNB), there are more important differences in the data with opposite results showing that US-CNB performs better than US-FNA. Some authors conclude that the accuracy of FNA depends on the skills of the pathologist as well as biopsy taker. In our opinion, both methods (FNA and CNB) depend on the qualities of the sample, sampler, and the number of biopsies. It can be assumed that large volume activity and learning through experience can lead to better results as seen in materials done previously at our Institut on palpable or nonpalpable breast lesions.[1,32,33] FNA and CNB are two techniques which should not be considered as two separate diagnostic methods but rather as two complementary methods.[11,34] It is proven[4,9-12] also by our results that combination of these two methods gives optimal results in diagnostics of both PBTs as well as ultrasound guided in both unifocal and multifocal tumors. FNA allows rapid onsite evaluation, which is

cost-effective, and patients with benign lesions can get immediate reassurance, while patients with malignant lesions may be referred directly to the surgeon and be planed for surgery without any delay. CNB helps to distinguish between in situ and invasive carcinoma[35] as well with assessment of predictive markers which are needed for the therapy decision. It was also demonstrated that FNA coupled with rapid onsite evaluation, cell-block studies, and CNB increases significantly the accuracy of preoperative diagnosis. Moreover, immunocytochemistry, immunohistochemistry on cell blocks, and other ancillary studies gave confidence to the clinicians to decide the best treatment strategies.[36,37]

To increase the diagnostic precision even more the multidisciplinary approach with triple test should be use to investigate all breast tumors. This test combines FNA/CNB, radiological imaging, and clinical examination and to some extent overcomes the limitations of each individual method.[16] Cases with discordance among these three modalities should be discussed at multidisciplinary meetings.

CONFLICT OF INTEREST

No conflict of interest.

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