

DIAGNOSTIC ACCURACY OF ULTRASOUND BI-RADS CATEGORIES 4 AND 5 FOR BREAST CANCER DETECTION

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Abstract

Background: Breast cancer is the most frequently diagnosed malignancy and a leading cause of cancer-related mortality among women worldwide, with a disproportionately heavy burden in Pakistan. Ultrasound BI-RADS categories 4 and 5 are the thresholds at which tissue biopsy is recommended, yet local data describing the diagnostic performance of these categories against histopathology remain scarce.

Methods: This cross-sectional diagnostic accuracy study was conducted in the Departments of Radiology at Nishtar Medical University and Bakhtawar Amin Medical and Dental College, Multan, over four months from May 2026 to Sep 2026. 105 women aged 14–80 years with clinically suspected breast lesions were enrolled by purposive sampling. All underwent high-resolution ultrasound (5–10 MHz linear probe), BI-RADS categorisation, and subsequent core-needle or excisional biopsy. Histopathology served as the reference standard. Diagnostic accuracy indices were derived from a 2×2 contingency table in which BI-RADS 4/5 was taken as test-positive and BI-RADS 2/3 as test-negative.

Results: Among 105 women (mean age 34.17 ± 11.34 years), histopathology confirmed malignancy in 52 (49.5%) and benign disease in 53 (50.5%). BI-RADS 4/5 was assigned to 56 women (53.3%) and BI-RADS 2/3 to 49 (46.7%); malignancy rates were 0% in BI-RADS 2, 12.5% in 3, 53.8% in 4A and 100% in 4B, 4C and 5. Ultrasound BI-RADS 4/5 achieved a sensitivity of 96.15% (95% CI 87.02–98.94), specificity of 88.68% (95% CI 77.42–94.71), positive predictive value of 89.29% (95% CI 78.53–95.00), negative predictive value of 95.92% (95% CI 86.29–98.87), and overall diagnostic accuracy of 92.38% (95% CI 85.68–96.09).

Conclusion: Ultrasound BI-RADS categories 4 and 5 show excellent diagnostic accuracy for discriminating benign from malignant breast lesions

and can dependably guide biopsy decisions, although histopathology remains the definitive diagnostic standard.

INTRODUCTION

Breast cancer remains the most common malignancy diagnosed in women and a leading cause of cancer-related mortality worldwide. According to the most recent Global Cancer Observatory (GLOBOCAN) 2024 estimates released by the International Agency for Research on Cancer, approximately 2.4 million new cases of female breast cancer and nearly 694 000 deaths occurred globally in 2024.¹ Breast cancer now accounts for roughly one in four cancer diagnoses among women and continues to rise in many low- and middle-income countries. Pakistan bears a particularly heavy burden: breast cancer is the most frequent malignancy among Pakistani women, representing 44.0% of all female cancers, with an estimated 43 721 new cases and 20 039 deaths in 2024.² This elevated incidence, combined with persistently high mortality, reflects both genuine epidemiological trends and longstanding gaps in organised early-detection and referral pathways.

Early and accurate characterisation of breast lesions is essential for timely management and improved survival. Mammography remains the primary population-based screening tool in high-resource settings and has contributed substantially to mortality reduction where organised programmes exist. However, its sensitivity declines markedly in dense breast tissue—a feature common among younger, predominantly pre-menopausal women who constitute a large proportion of patients presenting in South Asian populations.^{4, 5} Studies from Pakistan and neighbouring countries have documented that more than half of women undergoing mammography have heterogeneously or extremely dense parenchyma, substantially increasing the likelihood of missed lesions and false-negative examinations.^{5, 6} Consequently, reliance on mammography alone is often inadequate for the demographic profile

encountered in routine clinical practice across much of Pakistan.

Ultrasound offers several practical advantages in this demographic. It is non-ionising, widely available even in secondary and many primary-care facilities, relatively inexpensive, and particularly well suited to the evaluation of dense breasts and palpable lesions in younger women. In addition, ultrasound permits real-time image guidance for percutaneous core-needle biopsy, thereby integrating diagnosis and tissue sampling in a single visit.^{7, 8} Meta-analyses and regional studies have shown that ultrasound can achieve sensitivity comparable or superior to mammography for solid masses, especially in women under 40 years and those with dense parenchyma.^{8, 9} Magnetic resonance imaging (MRI) provides even higher sensitivity but remains far less accessible and substantially more costly in resource-constrained environments such as Pakistan, limiting its role to selected high-risk or problem-solving cases.

The American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) supplies a standardised lexicon and risk-stratification framework for ultrasound interpretation. Category 4 lesions (suspicious; subdivided into 4A, 4B and 4C) carry an estimated probability of malignancy ranging from approximately 2% to 95%, while category 5 lesions (highly suggestive of malignancy) carry a probability of $\geq 95\%$; both categories therefore warrant tissue diagnosis.^{10, 11} Although ultrasound BI-RADS is used routinely, many published studies evaluate it only in combination with mammography or MRI, thereby obscuring the standalone performance of ultrasound, particularly for the higher-risk categories 4 and 5. Locally generated Pakistani data that isolate this standalone performance remain limited, despite ultrasound frequently being the only imaging modality available in many public-sector hospitals and primary healthcare units.¹² The present study

was therefore designed to evaluate the diagnostic accuracy expressed as sensitivity, specificity, positive and negative predictive values, likelihood ratios and overall accuracy of ultrasound BI-RADS categories 4 and 5 against histopathology as the reference standard, in women presenting with clinically suspicious breast lesions at tertiary-care centres in Multan, Pakistan. The study also examined the graded relationship between ordinal BI-RADS categories and the probability of malignancy and summarised overall discriminatory performance by receiver-operating-characteristic (ROC) analysis.

Methods

Study Design and Setting

This was a cross-sectional diagnostic accuracy study conducted in the Departments of Radiology at Nishtar Medical University and Bakhtawar Amin Medical and Dental College, Multan, Pakistan from May 2026 to Sep 2026. The study protocol was reviewed and approved by the Institutional Review Board of Times University, Multan. Reporting followed the STARD 2015.

Study Period and Participants

Recruitment took place over a continuous four-month period. Women aged 14 to 80 years who

presented with clinically suspected breast lesions were considered for enrolment. All participants underwent both ultrasound BI-RADS categorisation and histopathological examination. Sampling was purposive. Women with a known bleeding diathesis and those with a previously histopathologically confirmed diagnosis of breast carcinoma were excluded.

Sample Size

The required sample size was calculated using Daniel's formula for diagnostic accuracy studies, assuming an expected overall accuracy of 92.63% (derived from a prior regional study),⁹ a 95% confidence level and a 5% margin of error. This yielded a minimum requirement of 105 participants.

Ultrasound Technique and BI-RADS Categorisation

All participants underwent bilateral breast ultrasound performed with a high-resolution linear-array transducer operating at 5–10 MHz. Each lesion was systematically assessed for size, shape, margins, echo pattern, posterior acoustic features, internal calcification and anatomical quadrant according to the BI-RADS ultrasound lexicon. Categories were assigned by experienced consultant radiologists as follows:

Table 1. Operational definitions of ultrasound BI-RADS categories used in the present study

BI-RADS Category	Probability of Malignancy	Test Classification in This Study
2 (Benign)	Essentially 0%	Test-negative
3 (Probably benign)	≤2%	Test-negative
4A (Low suspicion)	>2% to ≤10%	Test-positive
4B (Moderate suspicion)	>10% to ≤50%	Test-positive
4C (High suspicion)	>50% to <95%	Test-positive

5 (Highly suggestive)	≥95%	Test-positive
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For the primary diagnostic-accuracy analysis, categories 4A, 4B, 4C and 5 were combined as test-positive, while categories 2 and 3 were combined as test-negative.

Biopsy and Histopathology

Ultrasound-guided core-needle biopsy or excisional biopsy was performed under aseptic conditions for every enrolled participant. Specimens were examined by histopathologists and classified as benign or malignant. Histopathology constituted the reference standard. A positive reference-standard result was defined as any histopathological diagnosis of invasive carcinoma or ductal carcinoma in situ; all other diagnoses were classified as benign.

Data Collection and Variables

Demographic variables (age, marital status, parity and menopausal status) and clinical findings (skin changes, nipple changes, axillary adenopathy and family history of breast cancer) were recorded on a structured proforma for every participant. Ultrasound morphological descriptors and the final BI-RADS category were documented at the time of examination. Radiologists assigning BI-RADS categories were blinded to the histopathological results, and histopathologists were blinded to the ultrasound BI-RADS category.

Statistical Analysis

Data were analysed using R version 4.6.0 with RStudio (2026.05.0+218 “Golden Wattle”) as the interface. Continuous variables are presented as mean ± standard deviation (or median where appropriate); categorical variables are summarised as frequencies and percentages. From the 2×2 contingency table, sensitivity, specificity, positive predictive value (PPV), negative predictive value

(NPV), overall diagnostic accuracy, positive and negative likelihood ratios, and Youden’s index were calculated, each with 95% confidence intervals. A receiver-operating-characteristic (ROC) curve was constructed across the ordinal BI-RADS categories (treating the six categories as an ordered scale), and the area under the curve (AUC) was computed as a summary measure of discriminatory performance. The pre-specified clinical threshold (BI-RADS ≥4 versus ≤3) defined test positivity for the primary analysis.

Ethical Considerations

Written informed consent was obtained from every participant (or from a legal guardian in the case of minors) prior to enrolment. Confidentiality was maintained through the use of coded participant identifiers. The study was conducted in accordance with the Declaration of Helsinki (2024 revision).

Results

Sociodemographic and Clinical Characteristics

A total of 105 women were enrolled (mean age 34.17 ± 11.34 years; range 14–80 years). The largest age group was 25–44 years (70 women, 66.7%), confirming a predominantly young to middle-aged cohort. Women with malignant lesions were on average older (36.54 ± 12.86 years; median 35) than those with benign lesions (31.85 ± 9.16 years; median 30). Most women were married (81, 77.1%), parous (79, 75.2%) and premenopausal (96, 91.4%). Axillary adenopathy was the most frequent clinical finding (64, 61.0%), followed by skin changes (34, 32.4%) and nipple changes (33, 31.4%); a family history of breast cancer was reported by 13 women (12.4%) (Table 2).

Table 2. Baseline demographic, reproductive and clinical characteristics (N = 105)

Characteristic	n (%) or mean $\pm$ SD
Age, years (mean $\pm$ SD)	34.17 $\pm$ 11.34
15–24 years	19 (18.1)
25–44 years	70 (66.7)
45–59 years	9 (8.6)
≥ 60 years	6 (5.7)
Married	81 (77.1)
Parous	79 (75.2)
Pre-menopausal	96 (91.4)
Skin changes present	34 (32.4)
Nipple changes present	33 (31.4)
Axillary adenopathy present	64 (61.0)
Family history of breast cancer	13 (12.4)
Histopathology – Malignant	52 (49.5)
Histopathology – Benign	53 (50.5)

Ultrasound Morphological Features and BI-RADS Distribution

On ultrasound morphological assessment, most lesions had an irregular shape (55, 52.4%), followed by oval lesions (48, 45.7%); round lesions were uncommon (2, 1.9%). Margins were irregular in 51 lesions (48.6%), regular in 50 (47.6%) and circumscribed in only 4 (3.8%). Calcification was identified within 48 lesions (45.7%). The upper-outer quadrant was the most frequent anatomical location (24, 22.9%), followed by the lower-outer quadrant (18, 17.1%). Representative ultrasound images are shown in Figure 1.

Distribution across ultrasound BI-RADS categories was as follows: category 2 in 33 women (31.4%), category 3 in 16 (15.2%), category 4A in 13 (12.4%), category 4B in 10 (9.5%), category 4C in 14 (13.3%) and category 5 in 19 (18.1%). Overall, 56 lesions (53.3%) fell into the combined BI-RADS 4/5 group, while the remaining 49 lesions (46.7%) fell into the probably-benign BI-RADS 2/3 group (Table 3).

Table 3. Ultrasound BI-RADS category distribution and corresponding histopathological outcomes

BI-RADS Category	n (%)	Malignant	Benign	Malignancy rate
2	33 (31.4)	0	33	0%
3	16 (15.2)	2	14	12.5%
4A	13 (12.4)	7	6	53.8%

4B	10 (9.5)	10	0	100%
4C	14 (13.3)	14	0	100%
5	19 (18.1)	19	0	100%
Combined 2/3 (test-negative)	49 (46.7)	2	47	4.1%
Combined 4/5 (test-positive)	56 (53.3)	50	6	89.3%

Histopathological Outcomes

On histopathological examination, 52 lesions (49.5%) were malignant and 53 (50.5%) were benign. A clear graded relationship was observed between rising BI-RADS category and the probability of malignancy: none of the 33 BI-RADS 2 lesions were malignant, 2 of 16 BI-RADS 3 lesions were malignant (12.5%), 7 of 13 BI-RADS 4A lesions were malignant (53.8%), and all lesions classified as BI-RADS 4B (10/10), 4C (14/14) and 5 (19/19) proved malignant, with no false-positive results in these three highest categories (Table 3).

Diagnostic Accuracy of BI-RADS 4/5 versus Histopathology

When BI-RADS 4/5 was treated as test-positive and BI-RADS 2/3 as test-negative, the 2×2 contingency table yielded 50 true positives, 6 false positives, 47 true negatives and 2 false negatives (Figure 2). From this table, ultrasound BI-RADS 4/5 demonstrated a sensitivity of 96.15% (95% CI 87.02–98.94), specificity of 88.68% (95% CI 77.42–94.71), PPV of 89.29% (95% CI 78.53–95.00), NPV of 95.92% (95% CI 86.29–98.87), and overall diagnostic accuracy of 92.38% (95% CI 85.68–96.09) (Table 4). The positive likelihood ratio was 8.49, the negative likelihood ratio 0.043, and Youden's index 0.848.

Table 4. Diagnostic accuracy of ultrasound BI-RADS 4/5 versus histopathology (N = 105)

Measure	Estimate (95% CI)
Sensitivity	96.15% (87.02–98.94)
Specificity	88.68% (77.42–94.71)
Positive predictive value	89.29% (78.53–95.00)
Negative predictive value	95.92% (86.29–98.87)
Overall diagnostic accuracy	92.38% (85.68–96.09)
Positive likelihood ratio	8.49
Negative likelihood ratio	0.043
Youden's index	0.848
AUC (ordinal BI-RADS scale)	0.983 (0.967–0.999)

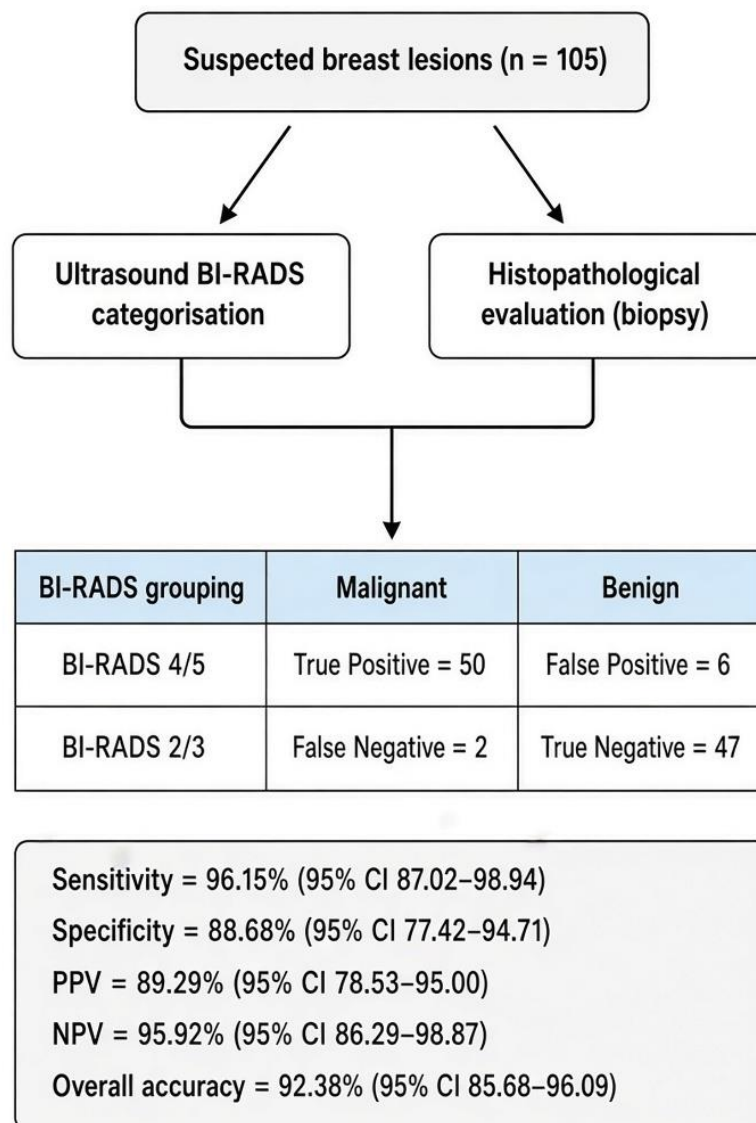


Figure 1. 2×2 contingency table for ultrasound BI-RADS 4/5 versus histopathology (N = 105)

TP = true positive; FP = false positive; FN = false negative; TN = true negative.

Receiver-Operating-Characteristic Analysis

The ROC curve constructed across the six ordinal BI-RADS categories yielded an area under the curve of 0.983 (95% CI 0.967–0.999), indicating outstanding overall discriminatory ability (Figure 3). This AUC reflects performance across the entire ordered scale rather than solely at the binary

4/5-versus-2/3 threshold used for the primary contingency-table analysis. The steep rise of the curve toward the upper-left corner is consistent with the observation that malignancy rates increased sharply once the BI-RADS category reached 4B and higher.

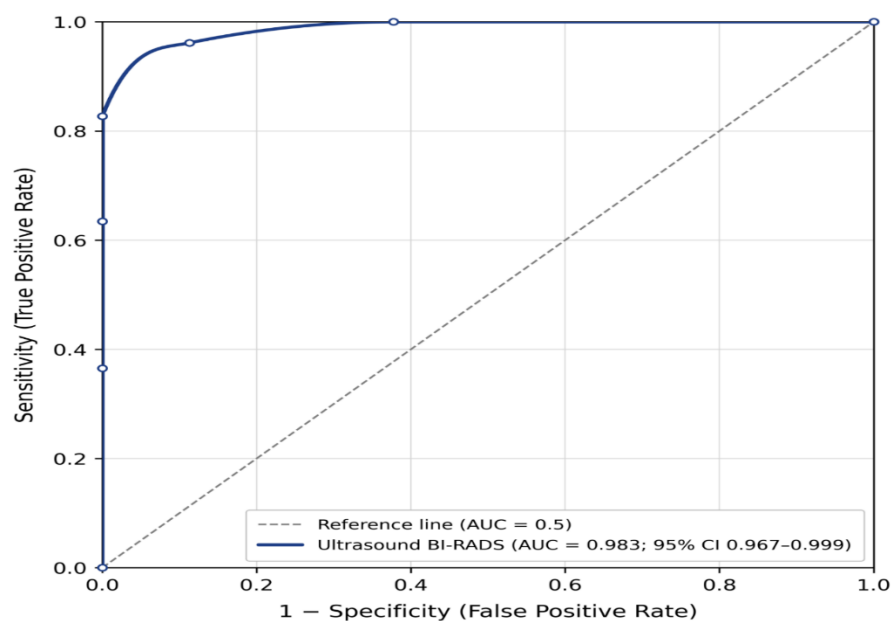


Figure 2. Receiver-operating-characteristic (ROC) curve for ordinal ultrasound BI-RADS categories against histopathology



Figure 3. Ultrasonographic Images of the Left Breast and Axillary Lymph Nodes

Discussion

In this cross-sectional study of 105 women with clinically suspected breast lesions,

ultrasound BI-RADS categories 4 and 5, taken as test-positive, had a sensitivity of 96.15%, a specificity of 88.68% and an

overall accuracy of 92.38% against histopathology. The area under the ROC curve across the ordinal BI-RADS scale was 0.983. These findings support the use of ultrasound BI-RADS as a triage tool for biopsy decisions where ultrasound is the main imaging modality available. The accuracy observed here is comparable with, and in some respects higher than, that reported in recent regional studies. A study of 240 women with dense breasts in Islamabad reported an ultrasound sensitivity of 85.3%, a specificity of 88.4% and an AUC of 0.89,¹⁴ and a prospective study of 160 women with BI-RADS 3–5 lesions in Baghdad reported an AUC of 0.85.¹¹ Differences in case mix, disease spectrum and reader experience probably contribute to these differences. The proportion of malignant lesions in our sample (49.5%) was also higher than in the Islamabad study (28.3%), which would raise predictive values in a referral-based cohort such as ours. Malignancy rates increased stepwise from 0% in BI-RADS 2 and 12.5% in BI-RADS 3 to 53.8% in 4A and 100% in 4B, 4C and 5, which reflects the probability-based design of the lexicon. Several observed rates, however, were above the benchmark ranges of BI-RADS: category 3 ($\leq 2\%$), 4A ($>2\%$ to $\leq 10\%$) and 4B ($>10\%$ to $\leq 50\%$). A prospective multicentre study from China also found rates outside the expected range for one subcategory (4B: 61.4%), while 4A (7.4%) and 4C (93.0%) were within range.¹³ The departures in our series were larger and affect three categories. Each subcategory contained only 10 to 16 lesions, so these estimates are imprecise, and the sample consisted of women already suspected of having breast disease. Subcategory-specific conclusions should therefore not be drawn from these data. The negative predictive value (95.92%) and negative likelihood ratio (0.043) indicate a low probability of

malignancy after a negative ultrasound result. Two of the 16 BI-RADS 3 lesions (12.5%) were malignant, however, so a BI-RADS 3 assignment in this setting should not be taken to exclude cancer, and tissue sampling or short-interval follow-up should be considered, particularly when clinical findings are discordant. The positive predictive value of 89.29% and positive likelihood ratio of 8.49 support tissue diagnosis for every category 4 or 5 lesion. All six false-positive results were in category 4A. Adjunct assessment of vascularity and elasticity, and quantitative ultrasound parameters, have been proposed to improve discrimination in this group.^{13, 16, 17} The cohort was young (mean age 34.17 years) and mostly pre-menopausal (91.4%), and women with malignant lesions were older than those with benign lesions (36.54 versus 31.85 years). Ultrasound is well suited to this population because the sensitivity of mammography falls with increasing breast density. In symptomatic women, mammographic sensitivity was 63.5% in heterogeneously dense and 16.3% in extremely dense breasts, compared with 86.5% and 72.1% for ultrasound.¹⁵ In a Pakistani cohort, ultrasound sensitivity remained 84.4% to 86.1% across dense breast categories, while mammographic sensitivity fell to 43.8% in extremely dense breasts.¹⁴ Irregular shape, non-circumscribed margins and calcification, the descriptors on which BI-RADS category assignment depends, were common in this series. Category 5 assessments are intended for lesions with a probability of malignancy of at least 95%, and a large outcomes analysis found that this is achievable in practice when several suspicious descriptors are present together.¹² This supports systematic descriptor-based assessment as the basis of

BI-RADS category assignment on ultrasound.

Limitations

This study has several limitations. The study was conducted at two centres within a single city and recruited over a relatively short four-month window; larger multicentre studies with longer accrual would strengthen generalisability. Direct head-to-head comparison with mammography or MRI was not performed, so the incremental value of ultrasound relative to these modalities could not be quantified. Benign lesions were not subjected to long-term imaging follow-up, leaving open the theoretical possibility of later malignant transformation, although the short-term histopathological reference standard remains robust for the primary accuracy estimates. Finally, purposive sampling of women suspected of having breast cancer may have enriched the prevalence of malignancy relative to an unselected screening population; the reported predictive values should therefore be interpreted in the context of a symptomatic, referral-based cohort.

Conclusion

Ultrasound BI-RADS categories 4 and 5 provide high sensitivity, specificity and overall diagnostic accuracy for the detection of breast cancer when histopathology is used as the reference standard. Incorporation of standardised BI-RADS ultrasound assessment into routine clinical pathways can facilitate timely and appropriate biopsy referral although BI-RADS 3 lesions in this series carried a 12.5% malignancy rate, so deferring biopsy in lower-risk categories should be approached cautiously. Histopathology remains indispensable as the definitive diagnostic standard. Multicentre studies with larger samples, longer follow-up of benign lesions, and direct multimodality comparison are recommended to further validate and extend these findings.

Declarations

Conflict of Interest: None declared.

Funding Source: None.

Ethics Approval: Institutional Review Board, Times University, Multan.

STARD Adherence: The study was reported in accordance with the STARD 2015 guidelines; the completed checklist, mapping each item to its location in the manuscript, is provided as Supplementary File S1.

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