

DIAGNOSTIC ACCURACY OF BARIUM SWALLOW STUDY FOR DIFFERENTIATING BENIGN AND MALIGNANT ESOPHAGEAL STRICTURES USING ENDOSCOPY WITH BIOPSY AS GOLD STANDARD

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How to cite this article

Syed H, Khan AN, Umer US, Hasnat M, Khattak S, Naz M, et al. Diagnostic Accuracy of Barium Swallow Study for Differentiating Benign And Malignant Esophageal Strictures Using Endoscopy with Biopsy as Gold Standard. J Gandhara Med Dent Sci. 2026; 13(4): 14-19. <http://doi.org/10.37762/jgm.13-4.862>

Date Submission: 05-02-2026

Date Revised: 05-09-2026

Date Acceptance: 05-09-2026

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ABSTRACT

OBJECTIVES

This study aimed to determine the diagnostic accuracy of barium swallow for differentiating malignant from benign oesophageal strictures using endoscopy with biopsy as the reference standard.

METHODOLOGY

This cross-sectional validation study included 88 consecutively selected adults with dysphagia at Rehman Medical Institute from 1 March 2023 to 1 August 2025. Barium swallow and endoscopic biopsy were performed within two weeks. Malignancy was the positive condition. Diagnostic indices, likelihood ratios, Cohen's kappa and the area under the receiver operating characteristic curve (AUC) were calculated with 95% confidence intervals (CIs).

RESULTS

Biopsy identified 26 malignant and 62 benign strictures. There were eight true positives, 20 false positives, 18 false negatives and 42 true negatives. Sensitivity was 30.8% (95% CI 14.3–51.8), specificity 67.7% (54.7–79.1), positive predictive value 28.6% (13.2–48.7), negative predictive value 70.0% (56.8–81.2) and accuracy 56.8% (45.8–67.3). Positive and negative likelihood ratios were 0.95 (0.48–1.88) and 1.02 (0.75–1.39), respectively. Kappa was -0.015 (-0.222 to 0.193), and binary-score AUC was 0.493 (0.385–0.600). Malignancy remained present in 18/60 benign-appearing examinations (30.0%; 18.8–43.2).

CONCLUSION

Barium classification provided little discrimination and missed most biopsy-confirmed malignancies. A benign-appearing examination should not be used to exclude malignancy or defer indicated endoscopy with biopsy: the small cohort and incomplete masking documentation limit generalisability.

KEYWORDS: Barium Sulfate; Esophageal Stenosis; Esophageal Neoplasms; Deglutition Disorders; Sensitivity and Specificity

INTRODUCTION

Oesophageal strictures cause dysphagia and create a substantial diagnostic and healthcare burden.¹ Initial assessment must distinguish benign narrowing from malignancy rather than demonstrate luminal obstruction. Contemporary European recommendations identify upper gastrointestinal endoscopy as a central investigation for adult oesophageal dysphagia, with additional tests selected according to the structural or functional question.² Barium oesophagography provides information about oesophageal calibre, contour and bolus transit, and has a complementary role in evaluating obstructive symptoms.³ Irregular narrowing and shouldering may suggest malignancy, whereas smooth, gradually tapering narrowing may suggest a benign stricture. Evidence that barium detects a narrowing must nevertheless be distinguished from evidence that it reliably determines the cause of that

narrowing.⁴ Endoscopic biopsy provides tissue for aetiological classification; guidance on oesophageal strictures recommends histological assessment to exclude malignancy.⁵ Dysphagia also warrants endoscopic evaluation rather than reliance on an assumed reflux-related explanation.⁶ The clinically relevant question is whether a benign barium classification lowers cancer probability sufficiently to reassure the clinician. This requires diagnostic-performance and post-test probability estimates with uncertainty, not an association test alone. This study evaluated barium swallow as an adjunct for aetiological classification in symptomatic adults, not as a population screening test or a measure of anatomical imaging utility. Its objective was to determine the diagnostic accuracy of barium swallow for differentiating benign and malignant oesophageal strictures, using endoscopy with biopsy as the reference standard.

METHODOLOGY

This cross-sectional validation study was conducted in the Departments of Radiology and Gastroenterology, Rehman Medical Institute, from 1 March 2023 to 1 August 2025 after obtaining approval from the Institutional Review Board vide ref no: REC-PG-RMI/Ethical Approval/PG-SYNOPSIS/109. Reporting was revised using STARD 2015 and its explanation and elaboration; incompletely documented items are identified in the supplementary reporting map.^{7,8} Consent forms were also obtained from the patients prior to the conduct of the study. Eligibility comprised age ≥ 18 years, either gender, dysphagia, and completion of barium swallow followed by upper gastrointestinal endoscopy with biopsy within two weeks. Recruitment was described as non-probability consecutive sampling. Patients with previous oesophageal surgery, prior treatment for known oesophageal malignancy, or incomplete or poor-quality imaging or histopathology records were excluded. The presenting symptom and participating departments are documented, but the specific clinic, referral register and screening workflow used to identify every potentially eligible patient are not. The analytical cohort comprised 88 participants with both test results. A screening log was unavailable for this analysis, so the number initially assessed, exclusions by reason and timing of exclusions relative to enrolment could not be reconstructed. Completion of both tests is therefore established for the 88 analysed participants, not for every initially eligible patient. Figure 1 distinguishes the known paired-test pathway from unavailable recruitment counts.

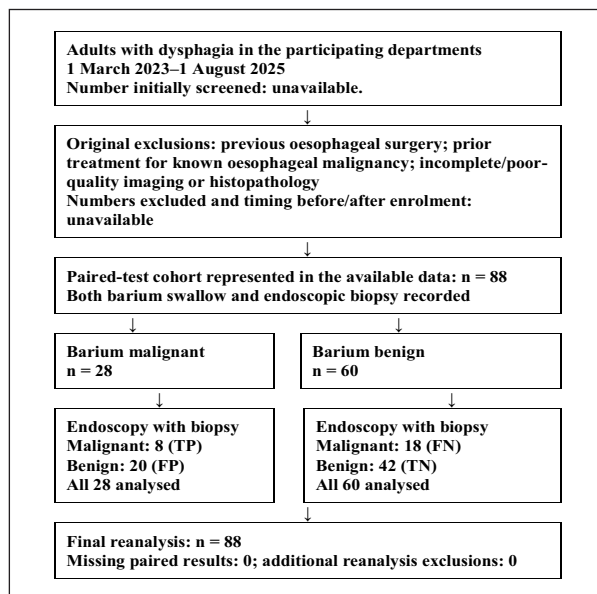


Figure 1: Participant Flow Based on the Available Study Records.

The original account attributed planning to a WHO sample-size calculator and recorded a target of 80 participants plus eight additional participants for incomplete data, giving 88. Assumptions were sensitivity 100%, specificity 94.4%, malignancy prevalence 30%, 95% confidence and 10% absolute precision. The calculator module/output and a verifiable source for the paired performance assumptions were unavailable. These inputs do not reproduce the stated requirements of 80 for sensitivity and 49 for specificity using standard prevalence-adjusted precision formulas.⁹ Sensitivity of 100% gives a degenerate normal-approximation variance, while the specificity calculation gives 29.01, rounded up to 30, rather than 49. Accordingly, 88 is reported as the achieved cohort without claiming that the intended precision was established. The supplementary audit shows the calculations; no replacement post hoc planning assumptions were introduced. Barium swallow examinations were performed under fluoroscopic guidance using the departmental protocol. Stricture location, length and morphology were assessed. The study description specified predefined qualitative criteria: irregular margins, mucosal irregularity, abrupt tapering and shouldering suggested malignancy, whereas smooth, symmetric and gradually tapering narrowing suggested a benign stricture. A formal feature-combination rule, structured reporting template, contrast protocol and equipment details were not available for verification. Analysis used the recorded binary classification without reinterpreting images or changing its threshold. An experienced gastroenterologist performed upper gastrointestinal endoscopy, and multiple biopsies were obtained from the stricture. A consultant pathologist classified specimens as benign or malignant and was blinded to imaging findings. Histopathological malignancy was the positive reference condition because the question concerned tissue-confirmed aetiology rather than appearance alone.⁵ Detailed specimen numbers and processing, histological subtypes, and repeat sampling or follow-up confirmation of initially benign biopsies were unavailable. Radiologist masking to clinical, endoscopic and histopathological information was not documented. Information available to the endoscopist, the number and experience of radiologists, and independent or consensus reading procedures were also unspecified. One final barium classification per patient was retained in the data; this does not establish that only one reader interpreted each examination. Reader-specific and repeat-reading results were unavailable, precluding interobserver and intraobserver reproducibility analyses. The stated interval between examinations was no more than two weeks. Individual test dates and treatment between examinations were not

recorded in the analytical dataset. Test-related adverse-event data were unavailable. The original descriptive and crosstab outputs were generated in IBM SPSS Statistics version 23.0, as identified in the output metadata. Supplementary diagnostic calculations were independently reproduced in Python with SciPy. The SPSS and Excel files were compared row by row. Age was summarised as mean $\pm$ standard deviation and range, and categorical variables as numbers and percentages. There were no missing values in age, gender or either diagnostic classification among the 88 records. No indeterminate category was recorded, and no imputation or reassignment was performed. Malignant barium findings were index-test positive and benign findings negative. The 2×2 table was used to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, false-negative rate and malignancy probability after a benign barium result. Two-sided 95% Clopper-Pearson exact binomial CIs were calculated for proportions.¹⁰ Positive and negative likelihood ratios (LR+ and LR-) and the diagnostic odds ratio (DOR) were reported with log-scale Wald 95% CIs; no zero-cell correction was required.¹¹ Between-test agreement was quantified using unweighted Cohen's kappa, with an asymptotic multinomial-variance 95% CI.¹² This assesses agreement between diagnostic classifications, not reader reproducibility. AUC was calculated from the binary index score (malignant = 1; benign = 0), with ties given half credit and a DeLong nonparametric variance-based 95% CI.¹³ Only one nontrivial ROC operating point was available; binary AUC equalled the average of sensitivity and specificity. No continuous-score ROC curve, threshold optimisation or test-label reorientation was undertaken. The original Pearson chi-square association results were reproduced for the supplementary audit, but not used to judge diagnostic usefulness or agreement. Gender analyses were presented as descriptive diagnostic estimates with exact CIs. Exploratory age analysis used a $<60/\geq 60$ -year division introduced during revision, not a prespecified or validated clinical cut-off. No subgroup hypothesis tests or interaction claims were made. Lesion location, stricture length and histological subtype analyses were not possible because these variables were absent from the patient-level files.

RESULTS

All 88 available records were included. Mean age was 53.74 ± 14.42 years (range 31–79); 55 participants were

male and 33 female (Table I). Histopathology identified malignancy in 26/88 participants (29.5%; 95% CI 20.3–40.2). No additional records were excluded during reanalysis. This complete-case count does not resolve unavailable pre-analysis screening and exclusion totals (Figure 1). The paired classifications yielded eight true positives, 20 false positives, 18 false negatives and 42 true negatives (Table 2). The false-negative rate among biopsy-confirmed malignancies was 69.2% (18/26; 95% CI 48.2–85.7). Among benign barium classifications, 18/60 were malignant on biopsy (30.0%; 95% CI 18.8–43.2). These percentages have different denominators and address different diagnostic questions. Table 3 reports the principal estimates with 95% CIs. Sensitivity was 30.8%, specificity 67.7% and accuracy 56.8%. LR+ was 0.95, LR- 1.02 and DOR 0.93. Observed agreement was 50/88 (56.8%), compared with 57.4% expected agreement from the marginal totals, giving kappa -0.015. Binary-score AUC was 0.493. Exploratory age and gender estimates, subgroup counts and exact CIs appear in Supplementary Tables SI–SII. Gender-specific NPVs were 75.6% in males (34/45; 95% CI 60.5–87.1) and 53.3% in females (8/15; 95% CI 26.6–78.7), with barium-negative participants as the denominator. Subgroup sensitivity estimates were imprecise, particularly with only eight malignancies in participants aged ≥ 60 years. Lesion-specific or histological determinants could not be analysed.

Table 1: Characteristics and Diagnostic Classifications (n = 88)

Characteristic	Value
Age (years), mean $\pm$ SD	53.74 $\pm$ 14.42
Age (years), range	31–79
Gender: male	55 (62.5%)
Gender: female	33 (37.5%)
Barium: malignant	28 (31.8%)
Barium: benign	60 (68.2%)
Biopsy: malignant	26 (29.5%)
Biopsy: benign	62 (70.5%)

Table 2: Transvaginal Ultrasonography and Histopathological Findings (n = 93)

Barium Classification	Biopsy		Total
	Malignant (positive)	Benign (negative)	
Malignant (positive)	8 (TP)	20 (FP)	28
Benign (negative)	18 (FN)	42 (TN)	60
Total	26	62	88

TP: true positive; FP: false positive; FN: false negative; TN: true negative. Malignancy is the positive Condition for both tests.

Table 3: Diagnostic Performance and Between-Test Agreement (n= 88)

Measure	Calculation	Estimate (95%CI)
Sensitivity (%)	8/26	30.8 (14.3–51.8)
Specificity (%)	42/62	67.7 (54.7–79.1)
Positive predictive value (%)	8/28	28.6 (13.2–48.7)
Negative predictive value (%)	42/60	70.0 (56.8–81.2)
Overall accuracy (%)	50/88	56.8 (45.8–67.3)
False-negative rate (%)	18/26	69.2 (48.2–85.7)
Malignancy after benign barium (%)	18/60	30.0 (18.8–43.2)
Positive likelihood ratio	Se / (1 – Sp)	0.95 (0.48–1.88)
Negative likelihood ratio	(1 – Se) / Sp	1.02 (0.75–1.39)
Diagnostic odds ratio	LR+ / LR–	0.93 (0.35–2.51)
Cohen's kappa	Unweighted	–0.015 (–0.222 to 0.193)
Binary-score AUC	(Se + Sp) / 2	0.493 (0.385–0.600)

CI: confidence interval; Se: sensitivity; Sp: specificity; LR+: positive likelihood ratio; LR–: negative likelihood ratio; AUC: area under the receiver operating characteristic curve. Se and Sp are proportions in the ratio/AUC formulas.

CI: exact Clopper–Pearson for proportions; log-scale Wald for ratios; asymptotic multinomial for kappa; DeLong variance-based for AUC. The binary AUC has one nontrivial ROC point and is not a continuous-score threshold analysis.

DISCUSSION

Barium classification did not meaningfully separate malignant from benign strictures in this cohort. The central finding was not the non-significant association test, but failure to identify 18 of 26 biopsy-confirmed malignancies. Sensitivity and accuracy were clinically unsatisfactory for an exclusion strategy; describing specificity alone as -moderate would obscure this limitation. LR+ and LR– were approximately one, while kappa and AUC point estimates were close to values indicating little agreement beyond chance and little discrimination. Their CIs remain important: these data neither establish exact equivalence to chance performance nor exclude all potentially useful performance in other settings. The observed malignancy probability was 29.5% before considering the barium result and 30.0% after a benign classification. NPV of 70.0% should not be interpreted apart from the prevalence or the 18 cancers among 60 benign-appearing examinations. Using such a result to defer indicated biopsy could delay diagnosis, although diagnostic delays, tumour stage and patient outcomes were not measured. The supported implication is to avoid treating benign radiological appearance as

evidence that cancer has been excluded. The contrast with earlier evidence requires attention to design. Gupta et al. classified 100 examinations as benign (75), malignant (11) or equivocal (14); none of the 75 benign classifications had carcinoma on endoscopy, whereas one carcinoma occurred in the equivocal group. Brushings or biopsy were performed in only 57 patients. Their three-category classification and mixed endoscopic/pathological verification differ from the binary classifications and biopsy results available for every analysed participant here.⁴ In a series of 50 confirmed cancers, Levine et al. reported radiographic diagnosis or suspicion of carcinoma in 48 cases (96%). That cancer-enriched sensitivity series is not directly comparable with this mixed stricture cohort.¹⁴ Possible explanations include differences in examination technique, luminal distension, lesion morphology, reader expertise and the threshold for a malignant label. These are hypotheses, not demonstrated explanations: the files lacked the necessary technical and lesion-level information. Qualitative descriptors alone also do not establish application of a reproducible standardised scoring rule. The study cannot determine whether poor performance arose from the imaging method, local implementation, referral spectrum or a combination of factors. Selection and verification require separate consideration. Diagnostic estimates may change with patient spectrum, reference-standard application and readers' access to other test results.^{15,16} Every analysed participant had the same type of reference examination, limiting differential verification within this cohort. Nevertheless, restricting analysis to complete paired investigations without a screening log leaves open whether unverified or technically difficult cases were excluded beforehand. Consecutive sampling does not eliminate this uncertainty or referral-related selection in a single-centre cohort. Pathologist blinding is a strength, but radiologist masking remains unknown rather than demonstrably present or absent. Endoscopic biopsy is an operational reference standard, not infallible adjudication of every stricture. Cao et al. described selected smooth malignant strictures despite negative conventional biopsies, with diagnosis established by ultrasound-guided sampling.¹⁷ Min et al. likewise studied ultrasound-guided sampling in suspicious, often biopsy-negative strictures.¹⁸ These reports do not estimate the false-negative biopsy rate in the present patients, but explain why persistent clinical suspicion cannot automatically be dismissed after a negative mucosal biopsy. Without repeat sampling or follow-up, reference-standard misclassification cannot be excluded; these estimates are relative to recorded biopsy classifications. Current dysphagia guidance

places barium examinations alongside, rather than in place of, endoscopic and other targeted investigations.^{2,3} The results argue against using binary barium classification as a stand-alone malignancy rule-out test in a comparable symptomatic population. They do not negate anatomical or functional benefits that were not measured, and should not be extrapolated to screening populations or centres using different acquisition and interpretation protocols.

LIMITATIONS

The study was small, single-centre and non-probabilistic, with only 26 malignant cases and wide CIs. Screening totals, exclusion timing, data-collection timing relative to testing, radiologist masking and acquisition/reporting details were incompletely documented. Disease stage, benign aetiologies, lesion site and length, histological subtype, individual test intervals, intervening treatment, adverse events and follow-up were unavailable. Interobserver and intraobserver reproducibility could not be assessed; between-test kappa does not replace these analyses. Exploratory subgroups do not establish age or gender differences. These limitations restrict precision, reproducibility and generalisability and prevent attribution of low sensitivity to a specific mechanism.

CONCLUSIONS

In adults with dysphagia and oesophageal strictures, barium swallow showed low sensitivity, poor overall accuracy and likelihood ratios close to one for malignant classification. A benign-appearing examination did not exclude malignancy and should not defer clinically indicated endoscopy with biopsy. These findings require interpretation alongside the sampling, documentation and precision limitations.

CONFLICT OF INTEREST: None

FUNDING SOURCES: None

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The authors accept responsibility for all aspects of the work and will ensure that any concerns regarding the accuracy or integrity of any part are properly investigated and resolved.



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