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Diagnostic accuracy of gastrointestinal filling contrast-enhanced ultrasonography for differentiating benign from malignant gastric ulcerative lesions: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - This study received no specific funding.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 October 2026 and was last updated on 22 October 2026.

INTRODUCTION

Review question / Objective What is the diagnostic accuracy (pooled sensitivity, specificity, positive and negative likelihood ratios, diagnostic odds ratio, and summary ROC AUC) of gastrointestinal filling contrast-enhanced ultrasonography - oral contrast-enhanced ultrasonography (OCUS) and double contrast-enhanced ultrasonography (DCEUS) - in differentiating benign from malignant gastric ulcerative lesions, using pathological diagnosis as the reference standard?

Rationale Gastroscopy with biopsy is the reference standard but is invasive and poorly tolerated by some patients. Oral contrast-enhanced ultrasonography is non-invasive, repeatable and widely used in Asia, yet previous syntheses have focused on tumour staging rather than the specific question of benign versus malignant gastric ulcer differentiation. A quantitative synthesis of the available English-language accuracy data is therefore needed.

Condition being studied Benign versus malignant gastric ulcerative lesions (benign gastric ulcer versus ulcerative gastric cancer or gastric lymphoma) in patients in whom gastric wall lesions had been detected or suspected at gastroscopy.

METHODS

Search strategy PubMed/MEDLINE and Europe PMC were searched from database inception to 16 October 2026, restricted to English-language publications. Index-test terms (oral contrast-enhanced ultrasound/ultrasonography, double contrast-enhanced ultrasound, gastrointestinal filling contrast-enhanced ultrasound, gastric filling ultrasound, gastric distention, hydrosonography, CEUS) were combined with condition terms (gastric ulcer, peptic ulcer, gastric lesions, gastric wall, gastric tumour) and accuracy terms (benign,

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malignant, differential diagnosis, sensitivity, specificity, ROC) using Boolean operators. Reference lists of included studies and relevant reviews were hand-searched.

Participant or population Symptomatic patients and screening cohorts in whom gastric wall lesions (including ulcerative lesions) were detected or suspected at gastroscopy; no restriction on age or sex.

Intervention Transabdominal gastrointestinal filling contrast-enhanced ultrasonography: OCUS with an orally administered acoustic agent to distend the gastric lumen; DCEUS with additional intravenous microbubble contrast; qualitative five-layer wall assessment, ulcer-crater morphology or quantitative perfusion parameters.

Comparator Benign gastric lesions (benign ulcers, gastritis, inflammatory masses, polyps) within the same cohorts, finally classified by the reference standard.

Study designs to be included Prospective or retrospective diagnostic accuracy cohort/cross-sectional studies reporting sensitivity and specificity or derivable 2 x 2 data.

Eligibility criteria Inclusion: (1) patients with gastric wall lesions including ulcerative lesions detected at gastroscopy; (2) transabdominal OCUS or DCEUS as index test; (3) benign gastric lesions as comparators; (4) reference standard of surgical pathology, gastroscopic biopsy or gastroscopy; (5) accuracy reported or 2 x 2 data derivable; (6) English-language publication. Exclusion: case reports, reviews, conference abstracts, animal studies; studies limited to T/N staging, Borrmann classification or treatment response without a benign comparator; cohorts without a benign comparator; studies without extractable accuracy data; duplicate publications of the same cohort.

Information sources PubMed/MEDLINE and Europe PMC, from database inception to 16 October 2026; hand-searching of reference lists.

Main outcome(s) Pooled sensitivity and specificity with 95% confidence intervals (bivariate random-effects model); positive and negative likelihood ratios; diagnostic odds ratio; SROC area under the curve and Q* index.

Additional outcome(s) Between-study heterogeneity (Cochran Q, I-squared); threshold effect (Spearman correlation between logit sensitivity and logit [1 - specificity]); post-test probabilities at selected pre-test probabilities (Fagan nomogram); subgroup and leave-one-out sensitivity analyses.

Data management First author, year, country, design, setting, reference standard, contrast protocol, numbers of malignant and benign lesions, and sensitivity/specificity were extracted. Where only Se/Sp were reported, the 2 x 2 table was back-calculated and rounded to integers; a 0.5 continuity correction was applied when specificity equalled 100%.

Quality assessment / Risk of bias analysis QUADAS-2 across four domains: patient selection, index test, reference standard, flow and timing.

Strategy of data synthesis Bivariate random-effects model (Reitsma et al.); SROC derived from bivariate (HSROC-equivalent) parameters; AUC 95% CI by non-parametric study-level bootstrap (500 replicates with refitting); DerSimonian-Laird univariate pooling of logit-transformed Se, Sp and log DOR as sensitivity analysis. Computations performed in R (version 4.6.1) using the packages metafor (bivariate random-effects model and SROC), meta (DerSimonian-Laird univariate pooling) and mada.

Subgroup analysis Studies whose benign comparators explicitly included benign gastric ulcers versus those using gastritis/polyp comparators; symptomatic versus screening settings.

Sensitivity analysis Leave-one-out exclusion of each study; additional scenario including a 14,963-participant rural screening cohort; univariate DerSimonian-Laird pooling as an alternative model.

Language restriction English-language publications only.

Country(ies) involved China.

Other relevant information Strictly framed benign-versus-malignant gastric-ulcer accuracy studies are sparse; the most directly relevant study (Yu et al., 47 patients with 22 benign and 25 malignant ulcers) reported perfusion parameters without accuracy measures and was synthesised narratively rather than pooled.

Keywords gastric ulcer; contrast-enhanced ultrasonography; oral contrast agent; double contrast-enhanced ultrasonography; diagnostic accuracy; meta-analysis.

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Dissemination plans Submission of the full report to a peer-reviewed journal; results to be shared with the participating departments and presented at academic conferences.

Contributions of each author

Author 1 - HongMei Wang - WHM screened the literature, verified the extracted data, and critically revised the manuscript.
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Author 2 - WeiJie Shi - WJS conceived the study, performed the literature search, extracted and analysed the data, and drafted the manuscript.
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