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Endoscopic ultrasound-guided antegrade treatment versus balloon enteroscopy endoscopic retrograde cholangiopancreatography for choledocholithiasis in patients with Roux-en-Y gastric bypass: a systematic review and meta-analysis

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Abstract

Background The safety and technical success of endoscopic ultrasound-guided antegrade treatment (EUS-AG) compared to balloon enteroscopy-assisted endoscopic cholangiopancreatography (BE-ERCP) for choledocholithiasis in Roux-en-Y gastrectomy has not been well documented. We performed a systematic review and meta-analysis to assess the safety and efficacy of the 2 procedures.

Methods A systematic search of multiple databases was undertaken through January 25, 2024, to identify relevant studies comparing the 2 procedures. Standard meta-analysis methods were employed using a random-effects model. For each outcome, risk-ratio (RR), 95% confidence interval (CI), and P-values were generated. P<0.05 was considered significant. Heterogeneity was assessed using the I^2 statistic.

Results Three studies with 795 patients (95 in the EUS-AG group and 700 in the BE-ERCP group) were included. The technical success rate was similar between EUS-AG and BE-ERCP (RR 1.08, 95%CI 0.84-1.38; P=0.57; I^2=56%). The overall rate of adverse effects was higher in the BE-ERCP group than in the EUS-AG group (RR 1.95, 95%CI 1.21-3.15; P=0.006; I^2=0%). Rates of clinical success, pancreatitis, perforation, and bile peritonitis were similar between the 2 procedure techniques.

Conclusions Our analysis showed no distinct advantage in using one technique over the other for patients with Roux-en-Y anatomy in achieving technical and clinical success. However, the incidence of adverse effects was greater in the BE-ERCP group than in the EUS-AG group.

Keywords Roux-en-Y gastric bypass, endoscopic ultrasound, balloon enteroscopy

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Conflict of Interest: None

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has evolved greatly over recent years, from a diagnostic and therapeutic procedure for hepatobiliary diseases such as choledocholithiasis to management of pancreatic duct stones, benign and malignant structures, and bile and pancreatic leaks [1]. Although considered safe, ERCP poses a significant risk of post-ERCP pancreatitis (PEP) which occurs in 3-15% of ERCP cases, increasing up to 25% in high-risk cases, even in experienced hands [2]. Additional complications and difficulties can arise in patients with surgically altered anatomy depending on the postoperative anatomy. Some of

the difficulties include traversing the anastomosis to reach the pancreaticobiliary tract and cannulation of the papilla [3].

Patients with Roux-en-Y gastric bypass (RYGB) require an alternative approach to ERCP, as traditional ERCP endoscopes are not long enough to reach the papilla in these patients [4]. Different approaches for ERCP can be employed in patients with Roux-en-Y anatomy, including laparoscopic-assisted ERCP (LA-ERCP), endoscopic ultrasound (EUS)-directed transgastric ERCP (EDGE), balloon enteroscopy-assisted ERCP (BE-ERCP), and EUS-guided antegrade (EUS-AG) treatment for biliary disease [5]. BE-ERCP is performed using a single or double balloon enteroscope transorally, through the Roux limb and the jejunostomy up to the pancreaticobiliary limb to identify the papilla [6]. EUS-AG treatment involves left intrahepatic bile duct puncture under EUS guidance, guidewire advancement into the bile duct, guidewire manipulation through the papilla or the anastomosis, tract dilation, and then performing EUS-guided transhepatic AG stone removal and/or AG balloon dilation for anastomotic strictures [7].

Studies have reported similar technical success rates and adverse effects when EDGE is compared to LA-ERCP for RYGB [8].

Recent studies have evaluated the efficacy and safety of EUS-AG vs. BE-ERCP in treating biliary diseases in patients with RYGB. Given the limited sample sizes in individual studies, we conducted a systematic review and meta-analysis of the existing literature to provide a conclusive assessment of this topic.

Materials and methods

This study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and no language restriction was applied [9].

Search strategy

A detailed and comprehensive search of the following databases was conducted from inception through January 25, 2024: MEDLINE (PubMed, National Center for Biotechnology Information), Embase(Embase.com, Elsevier), Web of Science Core Collection, Korean Journal Index, and SciELO Citation Index (Web of Science Platform, Clarivate), Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley), and Global Index Medicus (World Health Organization). An additional manual hand search was also performed. The keywords and subject terms for the concepts of "Roux-en-Y gastric bypass", "balloon enteroscopy", "endoscopic retrograde cholangiopancreatography", "endoscopic ultrasonography" and "interventional ultrasonography" were developed for Embase and translated to the vocabulary of other databases.

The search strategy was created by an experienced librarian (WL-S) and reviewed by another investigator (AI). The detailed search strategy for Embase is provided in Supplementary Table 1. All results were exported to EndNote 20 citation management software (Clarivate, Philadelphia, Penn., USA) and duplicates were removed by successive iterations of EndNote's duplicate detection algorithms and manual inspection. Screening of the articles was performed by 2 independent reviewers (AI and ZA) and any discrepancy was resolved through mutual discussion. Bibliographies of the articles included were also checked to see if any additional articles fulfilled our study criteria.

Inclusion and exclusion criteria

We included studies based on the following criteria: 1) randomized controlled trials (RCTs), prospective or retrospective cohort studies, and cross-sectional studies comparing EUS-AG and BE-ERCP directly; and 2) studies that documented outcomes relevant to our research and included all studies with comparative arms. We excluded case reports, review articles and conference abstracts.

Data collection and outcomes

Two independent reviewers performed the data collection (AI and ZA), and any discrepancy was discussed and resolved. The primary outcomes of our analysis were the rates of technical success and overall adverse effects of EUS-AG and BE-ERCP. Secondary outcomes included clinical success rates, and rates of pancreatitis, perforation and bile peritonitis. Data were collected and tabulated in Microsoft Excel (Microsoft, Redmond, Wash, USA) by 2 independent reviewers (AI and ZA). Any discrepancy in data collection was resolved through mutual discussion.

Study definitions

Technical success of the procedure was defined as achieving successful biliary access and intervention, including the successful placement of biliary drainage and/or performance of stone removal procedures. Clinical success of the procedure was

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defined as clearance of all stones, confirmed by cholangiogram, intraductal US, or direct visualization by cholangioscopy, either on its own or with adjunctive techniques, such as repeating the procedure, percutaneous transhepatic biliary drainage or surgery.

Statistical analysis

We performed a meta-analysis of the included studies using Review Manager 5.3 (Cochrane Collaboration, Copenhagen, The Nordic Cochrane Centre). The random-effects model was used to calculate the weighted pooled risk ratio (RR) and mean difference (MD), with the corresponding 95% confidence intervals (CI) of our desired outcome. A P-value <0.05 was considered statistically significant. The heterogeneity of the effect size estimates across the studies was quantified using the Q statistic and I^2 (P<0.10 was considered significant). A value of I^2<50% was chosen to indicate low heterogeneity, and ≥50% for substantial heterogeneity [10].

Bias assessment

The bias assessment for included studies was evaluated using Newcastle--Ottawa scale for observational studies and the Cochrane Risk of Bias Tool for RCTs [11]. Publication bias was assessed visually, using funnel plots, as well as quantitatively, using Egger's regression analysis. A P-value <0.05 was indicative of substantial publication bias.

Results

Systematic review

Using the search strategy above, 33 studies were screened, duplicates were removed, and 3 were included (Fig. 1) [12-14]. All included studies were observational. A total of 795 patients were included, which also corresponded to the total number of procedures performed, including EUS-AG and BE-ERCP.

The mean age of participants included in the study was 65±15 years, with 610 (74%) males. Table 1 shows the demographic details and outcomes for each study. A total of 95 EUS-AG and 700 BE-ERCP procedures were performed in patients with RYGB.

Primary outcomes

The technical success rates of EUS-AG and BE-ERCP were similar (RR 1.08, 95%CI 0.84-1.38; P=0.57; I^2=56%; Fig. 2A). The overall rate of adverse effects was higher in the BE-ERCP group than in the EUS-AG group (RR 1.95, 95%CI 1.21-3.15; P=0.006; I^2=0%; Fig. 2B).

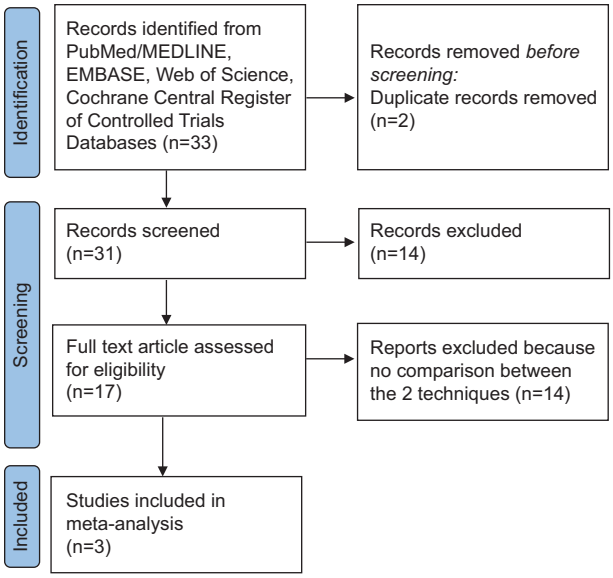

Figure 1 PRISMA flow diagram for selection of studies [9]

Secondary outcomes

The clinical success rate of EUS-AG was similar to that of BE-ERCP (RR 0.95, 95%CI 0.75-1.18; P=0.62; I^2=33%; Fig. 2C).

Adverse events

The 2 groups were similar in terms of pancreatitis (RR 0.34, 95%CI 0.04-2.55; P=0.29; I^2=0%; Fig. 2D), perforation (RR 0.38, 95%CI 0.05-2.80; P=0.34; I^2=0%; Fig. 2E), and bile peritonitis (RR 7.66, 95%CI 0.54-108.94; P=0.13; I^2=37%; Fig. 2F).

Bias assessment

The bias assessment of the included observational studies using the Newcastle--Ottawa scale showed a score of 5-8 for all studies (Supplementary Table 2). The publication bias was difficult to assess both qualitatively and quantitatively, as the number of studies was insufficient.

Discussion

To the best of our knowledge, this study represents the first systematic review and meta-analysis to compare EUS-AG and BE-ERCP specifically in the context of RYGB patients. Based on this meta-analysis, the technical and clinical success rates were comparable between EUS-AG and BE-ERCP, as were the incidences of pancreatitis, perforation and bile leak, suggesting a similar safety profile. However, it is noteworthy that the overall rate of adverse effects was found to be higher in the BE-ERCP group compared to the EUS-AG group. This observation

Table 1 Baseline study demographics and outcomes for each study

Characteristics	Iwashita, 2023 [12]	Sato, 2024 [13]	Takasaki, 2021 [14]
Age, years (SD)			
EUS-AG group	80 (71-84)	77 (72-82)	65.3±17.5
BE-ERCP group	76 (72-81)	76 (70-81)	67.4±16.8
Male, n (%)			
EUS-AG group	18 (78.3)	39 (66)	10 (43.5)
BE-ERCP group	74 (77.1)	445 (75.6)	24 (77.4)
Total Procedures (n)			
EUS-AG group	23	59	13
BE-ERCP group	96	588	16
Technical success, n			
EUS-AG group	15	49	12
BE-ERCP group	67	492	9
Clinical success, n			
EUS-AG group	15	40	9
BE-ERCP group	67	459	7
Overall adverse effects, n			
EUS-AG group	4	11	5
BE-ERCP group	7	60	3
Pancreatitis, n			
EUS-AG group	0	0	
BE-ERCP group	3	23	
Perforation, n			
EUS-AG group	0	0	
BE-ERCP group	4	15	
Bile peritonitis, n			
EUS-AG group	3	0	
BE-ERCP group	0	2	

SD, standard deviation; EUS-AG, EUSendoscopic ultrasound antegrade; BE-ERCP, balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography

may influence the choice of technique, favoring EUS-AG over BE-ERCP for its potentially lower risk of adverse effects.

ERCP in patients with surgically altered anatomy is difficult, and requires an experienced endoscopist, a good understanding of the length of afferent limb, the type of endoscope used with choice of approach, and compatible ERCP accessories with various endoscopic types [15].

Device-assisted enteroscopy (DAE) procedures are currently considered the first-line approach for patients with Roux-en-Y anatomy, because of their lower costs and risks compared to surgery [16]. DAE can be performed with BE-ERCP or spiral enteroscopy. Recently, alternative access techniques, including LA-ERCP and EDGE, have been gaining importance through improving efficacy and success rates. Studies report that LA-ERCP and EDGE show greater technical, cannulation and therapeutic success compared to enteroscopy-assisted ERCP, though they are also associated with more adverse events [17].

The core of our findings indicates that there is no significant difference in the technical and clinical success rates between EUS-AG and BE-ERCP. This outcome suggests that both techniques are equally viable options for endoscopic intervention in RYGB, allowing for flexibility in clinical decision-making based on the practitioner's expertise and the specific circumstances of each case [12-14]. Itoi *et al*, in a recent case series of patients with surgically altered anatomy and choledocholithiasis, report a technical success rate of 60% with the EUS-AG technique [18]. Iwashita *et al* also reported the results of a prospective study of AG stenting in 20 patients with surgically altered anatomy. In their study, the technical and clinical success rates of EUS-AG treatment were both 95% [19].

Our meta-analysis showed a higher overall adverse event rate in the BE-ERCP group as compared to EUS-AG, and our results are on a par with what has been reported in the literature. A recent retrospective analysis by Gerson *et al* demonstrated that double BE is associated with a higher complication rate compared with standard endoscopic procedures. The perforation rate was significantly elevated in patients with altered surgical anatomy undergoing diagnostic retrograde double BE procedures [20]. Inamdar *et al* also reported an overall 32 adverse events, mainly involving pancreatitis, bleeding, perforation and death from embolic stroke [21]. Sato *et al* reported aspiration pneumonia in 4 patients, respiratory failure in 2 patients, pulmonary embolism in 1 and bradycardia in 1 patient in BE-ERCP patients, compared to none of these adverse effects in patients undergoing EUS-AG [13]. Differences in the pooled safety of these procedures are a key finding of this study.

We acknowledge the limitations associated with our study. First, the sample size is small, with only 795 patients. No RCTs were available comparing EUS-AG and BE-ERCP, and our

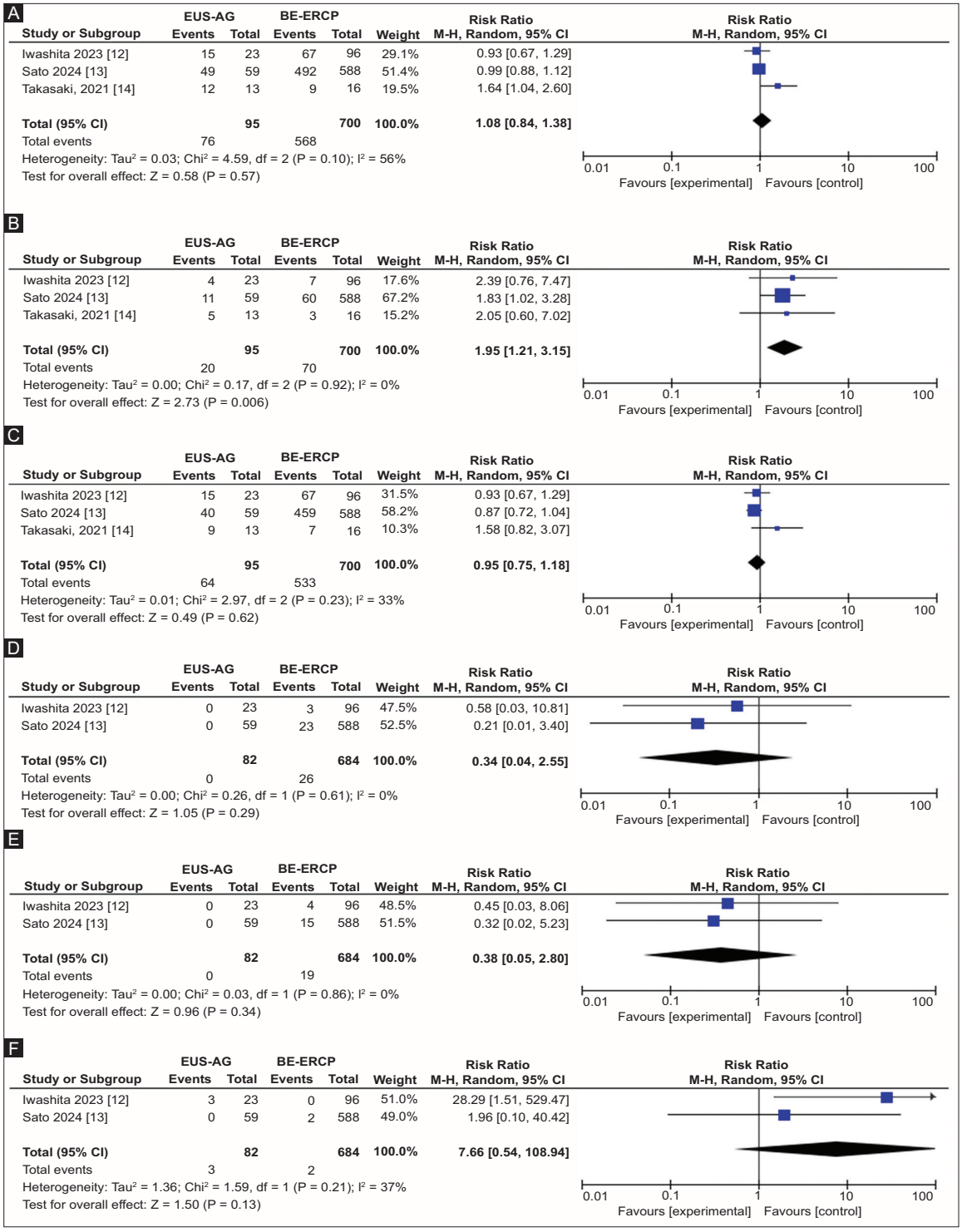

Figure 2 EUS guided antegrade treatment vs Balloon enteroscopy ERCP for biliary disease in patients with Roux en Y gastrectomy. (A) Forest plot comparing technical success of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy. (B) Forest plot comparing overall adverse effects of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy. (C) Forest plot comparing clinical success of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy. (D) Forest plot comparing rate of pancreatitis of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy. (E) Forest plot comparing rate of perforation of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy. (F) Forest plot comparing rate of bile peritonitis of EUS-AG vs BE-ERCP for biliary disease in Roux en Y gastrectomy

EUS-AG, endoscopic ultrasound-guided antegrade; BE-ERCP, balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography; CI, confidence interval

results were based on observational studies, with their inherent bias. Hence, we advocate for the need for high-quality RCTs comparing both techniques in terms of their efficacy, risks and complications. Third, given the low number of full studies reporting all possible adverse effects, we cannot fully evaluate the adverse effects profile for each procedure. Fourth, the experience of endoscopists cannot be disregarded. Lastly, the procedures were performed in high volume tertiary centers, limiting generalizability. However, despite these limitations we performed a robust systematic review with stringent inclusion and exclusion criteria. Moreover, as it is the only meta-analysis focusing on this topic, the findings of this study add valuable information to the current literature.

In conclusion, we noted no statistical difference in the rates of technical success, clinical success, pancreatitis, perforation or bile peritonitis between the 2 endoscopic techniques. The overall rate of adverse effects was higher in the BE-ERCP group than in the EUS-AG group. Future well-conducted studies are needed to validate our findings.

Summary Box

What is already known:

- Endoscopic ultrasound (EUS)-directed transgastric (EDGE) and laparoscopic-assisted (LA) endoscopic retrograde cholangiopancreatography (ERCP) are increasingly used for the management of choledocholithiasis in patients with Roux-en-Y gastric bypass (RYGB)
- Balloon enteroscopy-assisted ERCP (BE-ERCP) is associated with more adverse effects and less technical success compared to LA-ERCP and EDGE

What the new findings are:

- EUS-antegrade treatment is a newer technique for the management of choledocholithiasis in RYGB
- EUS-antegrade treatment is associated with fewer overall adverse effects compared to BE-ERCP

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Supplementary material

Section and Topic	Item #	Checklist item	Location where item is reported
		TITLE	
Title	1	Identify the report as a systematic review.	Title
		ABSTRACT	
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 3
		INTRODUCTION	
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 4, 5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 4, 5
		METHODS	
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Page 5, 22
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 6
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 6
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 8
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 7
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 18
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	None
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Page 6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 7
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	None
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	None

(*Contd...*)

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 8
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	None
		RESULTS	
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 19
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	None
Study characteristics	17	Cite each included study and present its characteristics.	Page 8, 18
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 23
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Page 20, 21
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 18, 23
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Page 8, 9
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Page 11
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	None
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	None
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	None
		DISCUSSION	
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Page 9, 10
	23b	Discuss any limitations of the evidence included in the review.	Page 11
	23c	Discuss any limitations of the review processes used.	None
	23d	Discuss implications of the results for practice, policy, and future research.	Page 12, 13
		OTHER INFORMATION	
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	None
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Not prepared
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	None
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	None
Competing interests	26	Declare any competing interests of review authors.	None
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Page 18

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Supplementary Table 1 Keyword searches: (Web of Science, KCI, SciELO, etc.)

Roux-en-y AND (gastric* OR gastrect* OR stomach* OR altered-anatom* OR surgical-anatom* OR surgically-alter*)
endoscopic-retrograde-cholangiopancreatograph* OR "e.r.c.p." OR endoscopic-cholangiograph* OR endoscopic-cholangiopancreatograph* OR endoscopic-pancreatocholangiograph* OR endoscopic-pancreatograph* OR endoscopic-retrograde-cholangiograph* OR endoscopic-retrograde-pancreaticocholangiograph* OR ERCP* OR retrograde-cholangiopancreatograph* OR retrograde-endoscopic-cholangiograph* OR retrograde-endoscopic-cholangiopancreatograph*
balloon*
antegrad* OR anterograd*
(echoendoscop* OR endoscopic-echograph* OR endoscopic-ultrasonograph* OR endoscopic-ultrasound* OR endosonograph* OR "eus" OR interventional-ultrasonograph* OR interventional-ultrasound* OR intravascular-ultrasonograph* OR echo-endoscop* OR ultrasonic-endoscop*)
Embase.com Searches (with Emtree Search headings). Do not use subheadings unless you intend to exclude Conference Abstracts
'Roux-en-Y gastric bypass'/syn
'endoscopic retrograde cholangiopancreatography'/syn
'balloon enteroscopy'/syn
'interventional ultrasonography'/exp OR 'endoscopic ultrasonography'/exp
NOT ([animals]/lim NOT [humans]/lim)
NOT ('conference review'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it OR 'review'/it OR 'short survey'/it OR 'tombstone'/it OR 'case report'/de OR 'meta analysis'/de OR 'meta analysis topic'/de OR 'systematic review'/de OR 'systematic review topic'/de)
MEDLINE in PubMed (with MeSH headings). Use OVID MEDLINE if you are using proximity operators.
"Gastric Bypass"[Mesh]
"Cholangiopancreatography, Endoscopic Retrograde"[Mesh]
"Balloon Enteroscopy"[Mesh]
"Ultrasonography, Interventional"[Mesh] OR "Endosonography"[Mesh]
NOT ("animals"[mesh] NOT "humans"[mesh])
NOT ("case reports"[Publication Type] OR "comment"[Publication Type] OR "editorial"[Publication Type] OR "guideline"[Publication Type] OR "introductory journal article"[Publication Type] OR "meta analysis"[Publication Type] OR "news"[Publication Type] OR "retracted publication"[Publication Type] OR "review"[Publication Type] OR "systematic review"[Publication Type])
Cochrane Central Register of Controlled Trials. Use MEDLINE search but "Term"[MeSH] > [mh "Term"]
Keywords for Global Index Medicus – remove truncation from keyword phrases. Use "" around phrases

Supplementary Table 2 Newcastle–-Ottawa scale

Study	Selection				Comparability	Outcome			
	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that the current outcome of interest was not present at the start of the study	Comparability of cohorts on the basis of design or analysis	Assessment of outcome	Was follow up long enough for outcomes to occur	Adequacy of follow up of cohorts	Quality score
Iwashita, 2023 [12]	*	*	*	*	*	*	*	*	8
Sato, 2024 [13]	*	*	*	*	*	*	*	*	8
Takasaki, 2021 [14]	*	*	*	*	0	*	0	0	5