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REVIEW ARTICLE

A comparison of the postoperative outcomes between intraoperative leak testing and no intraoperative leak testing for gastric cancer surgery: a systematic review and meta-analysis

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Abstract

Background Postoperative anastomotic leakage (PAL) is a serious complication of gastric cancer surgery. Although perioperative management has made considerable progress, anastomotic leakage (AL) cannot always be avoided. The purpose of this study is to evaluate whether intraoperative leak testing (IOLT) can reduce the incidence of PAL and other postoperative outcomes in gastric cancer surgery.

Materials and methods In this meta-analysis, we searched the PubMed, Embase, and Cochrane Library databases for clinical trials to assess the application of IOLT in gastric cancer surgery. All patients underwent laparoscopic radical gastrectomy for gastric cancer surgery. Studies comparing the postoperative outcomes of IOLT and no intraoperative leak testing (NIOLT) were included. Quality assessment, heterogeneity, risk of bias, and the level of evidence of the included studies were evaluated. PAL, anastomotic-related complications, 30-day mortality, and reoperation rates were compared between the IOLT and NIOLT group.

Results Our literature search returned 721 results, from which six trials (a total of 1,666 patients) were included in our meta-analysis. Statistical heterogeneity was low. The primary outcome was PAL. IOLT reduced the incidence of PAL [2.09% vs 6.68%; (RR = 0.31, 95% Cl 0.19–0.53, $P < 0.0001$]. Anastomotic-related complications, which included bleeding, leakage, and stricture, were significantly higher in the NIOLT group than in the IOLT group [3.24% VS 10.85%; RR = 0.30, 95% Cl 0.18–0.53, $P < 0.0001$]. Moreover, IOLT was associated with lower reoperation rates [0.94% vs 6.83%; RR = 0.18, 95% CI 0.07–0.43, $P = 0.0002$].

Conclusion Considering the observed lower incidence of postoperative anastomotic leakage (PAL), anastomotic-related complications, and reoperation rates, IOLT appears to be a promising option for gastric cancer surgery. It warrants further study before potential inclusion in future clinical guidelines.

Keywords Anastomotic leak · Prevention · Gastric cancer · Gastroscopy · Postoperative complications

Gastric cancer is the fifth most commonly diagnosed cancer with over one million patients worldwide diagnosed each year [1, 2]. Approximately, one out of every twelve oncologic deaths can be attributed to gastric cancer [3]. Surgery is often the only curative treatment option for gastric cancer [4]. Although progress has been made in perioperative management, postoperative complication rates remain high following gastric cancer surgery, especially in low-volume centers [5]. Postoperative anastomotic leak (PAL) is a critical complication, with an incidence ranging from 2.1 to 14.6% in patients who underwent gastric cancer surgery [6–9]. These complications have far-reaching consequences, such as prolonged hospitalization, escalated healthcare costs, compromised quality of life, or even death [10–12].

Currently, detection of anastomotic continuity is performed through air or methylene blue testing, with or without gastroscopy. Intraoperative leak testing (IOLT) may be one of the most important preventive methods that can be performed during gastric cancer surgery [13]. If the IOLT is positive, the leak can be fixed during the operation to minimize the possibility of PAL. However, previous studies have shown controversial results with the use of IOLT. Some studies suggest that IOLT can reduce PAL [14–16], while

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other studies suggest that IOLT has no significant impact on PAL [17, 18]. Furthermore, IOLT may cause trauma in the anastomosis, or methylene blue may contaminate the area, leading to adverse reactions or necrosis [19]. Thus, the potential of IOLT for risk reduction remains a topic of debate in the literature.

IOLT is widely used in colorectal and bariatric surgery [20–23]. Limited studies evaluate the safety and feasibility of the anastomotic procedure with IOLT after gastric cancer surgery [24–30]. The aim of this study was to compare postoperative outcome of IOLT with no intraoperative leak testing (NIOLT) in gastric cancer surgery, which included PAL, anastomotic-related complications, 30-day mortality, and reoperation rates.

Materials and methods

This systemic review was registered at PROSPERO (CRD42023453854) and followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA)2020.

Literature search strategy

We performed a literature search for clinical studies using the PubMed, Embase, and Cochrane Library databases. Our search was focused on human studies. The following search strategy was used in PubMed and conducted in other databases accordingly: ((stomach neoplasms) and (endoscopy) and (intraoperative) and (anastomotic Leak)) or ((stomach neoplasms) and (stomach tube) and (intraoperative) and (anastomotic Leak)) or ((stomach neoplasms) and (endoscopy) and (intraoperative leak testing)) or ((stomach neoplasms) and (stomach tube) and (intraoperative leak testing)) or ((Gastrectomy) and (stomach tube) and (intraoperative leak testing)) or ((Gastrectomy) and (endoscopy) and (intraoperative) and (anastomotic Leak)) or ((Gastrectomy) and (stomach tube) and (intraoperative) and (anastomotic Leak)) or ((Gastrectomy) and (stomach tube) and (intraoperative) and (anastomotic Leak)) or ((endoscopy) and (intraoperative) and (anastomotic Leak)) or ((stomach tube) and (intraoperative) and (anastomotic Leak)) or ((endoscopy) and (intraoperative leak testing)) or ((stomach tube) and (intraoperative leak testing)). Studies including both an IOLT group and a NIOLT group were included. Clinical studies published before June 2023 were included. Moreover, we attempted to find all relevant literature by looking through the references of the included articles. In addition, we searched gray and unpublished literature through the PubMed, Embase, and Cochrane Library databases and the references attached to the relevant literature. We then analyzed the full text to find eligible studies.

Study selection

Studies were included in the meta-analysis if they met these criteria: (1) The clinical trials comparing the postoperative outcomes of IOLT with NIOLT in patients with gastric cancer who underwent radical gastrectomy. (2) PAL is a study outcome and the study also reported at least one of the following clinical outcomes: postoperative anastomotic-related complications, 30-Day mortality rates, or reoperation rates. (3) The study was published as a full text in English language. (4) Valid data and a full text of the study could be obtained successfully.

Exclusion criteria

Studies were excluded from our analysis for the following reasons: unavailable data, duplicate studies, only abstract available, animal experiments, reviews, case reports, and letters.

Data extraction

Articles were screened independently by two reviewers according to title and abstract. Disputes were resolved by a third reviewer. This process was then repeated with a full-text review for data extraction. The first author, publication year and origin country, number of subjects, mean age, BMI, tumor pathological stage, mode of operation, type of reconstruction, type and number of positive result on the intraoperative leak test, PAL, anastomotic-related complications, 30-day mortality, and reoperation rates were extracted. PAL can be diagnosed if patient met one of the following conditions: (1) Drainage of gastrointestinal or bile contents from the abdominal drainage tube; (2) Leakage of contrast medium from the drainage tube was observed on gastrointestinal radiography; (3) Extraction of methylene blue from the abdominal drainage tube after oral administration of methylene blue; (4) Incomplete gastrointestinal wall on abdominal CT examination and revealing gas and fluid leaks around the anastomosis; and (5) Identification of anastomotic leaks under endoscopy after surgery. We categorized anastomotic-related complications into three types: PAL, postoperative anastomotic bleeding, and postoperative anastomotic stricture.

Study quality and assessment of risk of bias

Two reviewers independently rated the risk of bias of the randomized control trials (RCTs) using the revised Cochrane risk of bias, version 2 (ROB 2) tool. The risk of bias in cohort studies was assessed by Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I).

Statistical analysis

Risk ratio (RR) and 95% confidence intervals (CIs) were calculated on pooled effects for dichotomous variables with a fixed-effect model. I^2 was used to evaluate statistical heterogeneity with a value < 30% representing low heterogeneity, a value between 30 and 50% representing intermediate heterogeneity and > 50% representing high heterogeneity. Sensitivity, subgroup, and meta-regression analyses were performed to investigate potential sources of heterogeneity if necessary and possible. Begg's and Egger's tests were used to assess publication bias. $P < 0.05$ was regarded as statistically significant. Discrepancies were discussed and consensus was reached with an arbitrator. Stata software (version 17.0; Stata Corporation; College Station, TX) was used to perform all analysis.

Results

Literature search results

The systematic search revealed a total of 721 publications for possible inclusion (Fig. 1). Irrelevant publications, duplicate publications, or those not fitting our inclusion criteria were excluded based on title and abstract review. 129 publications were excluded based on the full text. Finally, six studies, including one prospective cohort study, four retrospective cohort studies, and one RCT were included [25–30].

Study characteristics

Our study included 1666 patients with 813 in the IOLT group and 853 in the NIOLT group. Four published studies [25, 27, 28, 30] implemented endoscopy for IOLT, while two studies adopted nasogastric tube for IOLT [26, 29]. Table 1 shows features of the included studies. Table 2 presents patient characteristics of the included studies.

Study quality

The risk of bias of the included studies are evaluated and listed in Fig. 2.

Intraoperative characteristics

There were 61 positive events including 11 air leakage, 20 venous bleeding, 8 mucosal tearing, 17 anastomotic leak, three arterial bleeding, and two anastomotic stricture events. Table 3 shows the types and number of positive events, which is identified by IOLT. Furthermore, additional reinforcing suturing was performed in 41 cases, endoscopic hemostasis in 16 cases, and re-anastomotic in three cases. After all repairs were completed, the leak test was conducted again until IOLT became negative.

Primary outcome-postoperative anastomotic leakage

Six studies reported PAL (Fig. 3). The PAL rates were 2.09% (17/813) in the IOLT group and 6.68% (57/853) in the NIOLT group. There was no significant heterogeneity ($I^2 = 0.0\%$, $p = 0.95$) when a fixed-effect model was used. PAL was significantly lower in the IOLT group than that in the NIOLT group (RR = 0.31, 95% Cl 0.19–0.53, $P < 0.0001$). No bias of publication was found with Begg's ($P = 1.000$) and Egger's ($P = 0.494$) tests.

Subgroup analysis

We performed subgroup analyses based on the different methods of intraoperative leak testing. Two studies employed air and methylene blue testing through the orogastric tube (OG group), while four studies used intraoperative endoscopy for leak testing (EN group). The PAL rate was 1.5% in patients with IOLT in the EN group, which was lower than the PAL rate of 4.1% in the OG group ($P = 0.043$). Furthermore, in the four studies with the EN group, PAL rate was lower in the IOLT group than in the NIOLT group (RR: 0.37, 95% CI 0.19–0.72, $P = 0.004$). Meanwhile, the two studies with an OG group, PAL rate was lower in the IOLT group than in the NIOLT group (RR: 0.24, 95% CI 0.10–0.58, $P = 0.001$) (Fig. 4).

Secondary outcomes

Postoperative anastomotic-related complications.

Four studies involving 955 patients evaluated the incidence of postoperative anastomotic-related complications. The incidence rates were 3.24% (15/494) in the IOLT group and 10.85% (51/461) in the NIOLT group. A fixed-effect model was used with no heterogeneity ($I^2 = 0.0\%$, $P = 0.75$). No bias of publication was found with Begg's ($P = 0.734$) and Egger's tests ($P = 0.373$). There was a statistically significant decrease in postoperative anastomotic-related complications rates in the IOLT group, when compared with that in the NIOLT group (RR = 0.30, 95% Cl 0.18–0.53, $P < 0.0001$) (Fig. 5).

30-Day mortality rates

Five studies included 30-Day mortality rates. The 30-day mortality rates were 0.13% (1/743) in the IOLT group and 0.64% (5/785) in the NIOLT group. Due to the lack of inter-study heterogeneity ($I^2 = 0.0\%$, $P = 0.74$), a fixed-effect

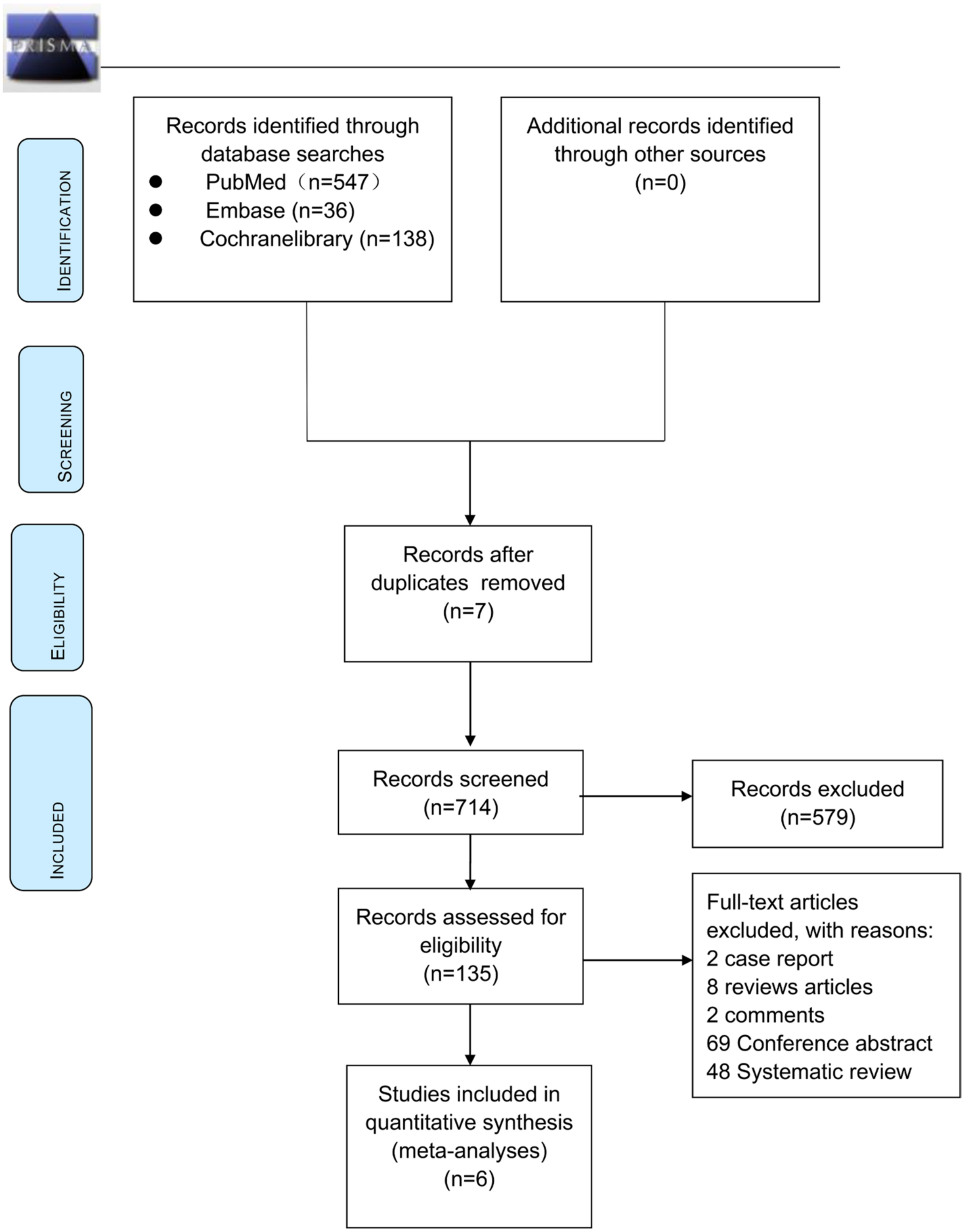

Fig. 1 PRISMA flowchart of trials

model was used. The meta-analysis showed no significant difference in 30-day mortality rates between the two groups (RR = 0.33, 95% Cl0.06–1.73, $P = 0.19$) (Fig. 6).

Reoperation rates

Four studies involving 1,015 patients compared the incidence of reoperation rates. We found that IOLT was associated with a lower rate of reoperation (0.94% vs 6.83%;

Table 1 Characteristics of included studies

First author, year	County	Type of study	Study period	Number of patients (IOLT/NIOLT)	Number of patients with IOLT(+)[c]	Postoperative anastomotic leakage		Postoperative anastomotic-related complications		30-Day mortality		Reoperation		Method of IOLT	Surgical Approach
						IOLT[a]	NIOLT[b]	IOLT	IOLT	IOLT	NIOLT	IOLT	NIOLT		
Lieto (2011) [25]	Italy	Prospective study	2005–2006	62/80	8	3	14	4	22	0	3	0	21	EN[e]	Open
Celik (2016) [26]	Turkey	Retrospective study	2007–2014	108/90	8	4	13	NR	NR	1	1	0	0	OG[d]	NR
Ji-Ho Park (2019) [27]	South Korea	Retrospective study	2013–2016	319/270	26	8	15	11	24	0	1	5	11	EN	Open/ laparoscopy
Alemdar (2021) [28]	Turkey	Retrospective study	2017–2020	43/43	7	0	1	0	1	0	0	0	1	EN	NR
Deng (2022) [29]	China	Retrospective study	2017–2019	211/302	7	2	13	NR	NR	0	0	NR	NR	OG	Laparoscopy
Gao (2023) [30]	China	randomized controlled trial	2018–2022	70/68	5	0	1	0	4	NR	NR	NR	NR	GAM[f]	Laparoscopy

[a]IOLT: intraoperative leak testing

[b]NIOLT: no intraoperative leak testing

[c]IOLT(+): positive events which is identified by IOLT

[d]OG: air and methylene blue testing through the orogastric tube

[e]EN: intraoperative endoscopy for leak testing;

[f]GAM: a comprehensive leak testing procedure which combines gastroscopy, air, and methylene blue leak testing

NR no report

Table 2 Patient characteristics from included studies

Study		Age (mean ± SD)	Sex (n)		BMI[b]	Tumor pathological stage[a]			Mode of operation			Type of reconstruction
			Male	Female		I	II	III	TLTG[c]	TLDG[d]	TLPG[e]	
Lieto [25]	IOLT	57 ± 14	35	27	23 ± 2	9	19	34	62	–	–	RY[f]
	NIOLT	54 ± 15	46	34	22 ± 3	11	33	36	80	–	–	
Celik [26]	IOLT	55.1 ± 10.8	49	59	NR	2	46	59	108	–	–	RY
	NIOLT	56.93 ± 12.3	51	39	NR	3	43	40	90	–	–	
Park [27]	IOLT	61.7	124	42	22.8	225	33	61	87	224	8	BI[g]\BII[h]\RY\Esophago-gastrostomy\DT[i]
	NIOLT	62.4	196	74	22.9	190	40	40	57	198	15	
Alemdar [28]	IOLT	63.1 ± 12.5	30	13	26.46	11	15	16	43	–	–	RY
	NIOLT	60.1 ± 13.5	30	13	25.69	11	10	20	43	–	–	
Deng [29]	IOLT	NR	130	81	NR	32	62	117	100	141	–	Esophagojejunostmy\BII
	NIOLT	NR	182	120	NR	62	94	146	146	156	–	
Gao [30]	IOLT	62.1 ± 9.3	51	19	22.4 ± 2.8	NR	NR	NR	70	–	–	RY
	NIOLT	61.7 ± 9.2	55	13	22.3 ± 2.7	NR	NR	NR	68	–	–	

[a]According to the 8thAJCC TNM staging system for gastric cancer

[b]BMI body mass index NR: no report

[c]TLTG: totally laparoscopic total gastrectomy

[d]TLDG: totally laparoscopic distal gastrectomy

[e]TLPG: totally laparoscopic proximal gastrectomy

[f]RY: Roux-en-Y g:BI: Billroth I. h: BII: Billroth II i: DT: Double tract reconstruction

RR = 0.18, 95% CI 0.07–0.43, $P = 0.0002$) (Fig. 7). No bias of publication was found with Begg's ($P = 0.734$) and Egger's ($P = 0.868$) tests. Intermediate heterogeneity was detected ($I^2 = 48.5\%$, $P = 0.14$). Thus, a sensitivity analysis was conducted. For reoperation rates, heterogeneity primarily originated from the study conducted by Park et al. (Fig. 8). Statistical heterogeneity decreased in the three remaining studies and Park's study was excluded ($I^2 = 32\%$, $P = 0.23$). A meta-analysis of the three trials demonstrated that the incidence of reoperation in the IOLT group is lower in the NIOLT group (RR: 0.05, 95% CI 0.01–0.40, $P = 0.005$).

Discussion

PAL is recognized as one of the most common and severe complications following gastric cancer surgery, with the potential to lead to hemodynamic instability, sepsis, multi-organ failure, and even mortality [18, 31]. It also associated with increased medical cost, length of hospital stay, and reoperation rate [12, 32]. PAL rate is an indication for the quality of gastric cancer surgery. IOLT, however, has the potential to reduce surgical complication in gastric cancer surgery [13]. To the best of our knowledge, this is the first meta-analysis, which compares the postoperative outcomes with or without IOLT in gastric cancer surgery. The main results of this study are as follows: (1) IOLT can reduce the incidence of PAL. (2) IOLT was associated with a reduction in anastomotic-related complications. (3) IOLT can reduce reoperation rate. (4) IOLT conducted by gastroscopy is better than that by oral gastric tube.

In this study, we found that IOLT can reduce the incidence of PAL. One study demonstrates that IOLT can successfully detect anastomotic leakage and allow for the repair of defects intraoperatively, which resulted in a reduction in PAL rates [24]. The result is consistent with our study. While some researchers found that IOLT cannot prevent all anastomotic leakage, such as late leakage and leakage caused by other factors, such as age, anemia, diabetes, malnutrition, or preoperative comorbidities [33, 34]. Our study demonstrates that IOLT has the ability to timely address anastomotic defects through additional suturing or re-anastomotic, which reduces anastomotic leakage. However, in this study, we also observed cases of PAL in patients showing negative results during intraoperative leak testing. This finding suggests that the etiology of anastomotic leakage is multifactorial and complex. Leak testing can address technical issues; it cannot prevent all risk factors associated with anastomotic leakage.

We also found that the implementation of intraoperative leak testing was associated with a reduction in anastomotic-related complications. Previous studies have suggested that intraoperative leak testing can reduce postoperative complications, such as anastomotic leakage, intraluminal bleeding, and anastomotic stricture [35, 36]. These findings are

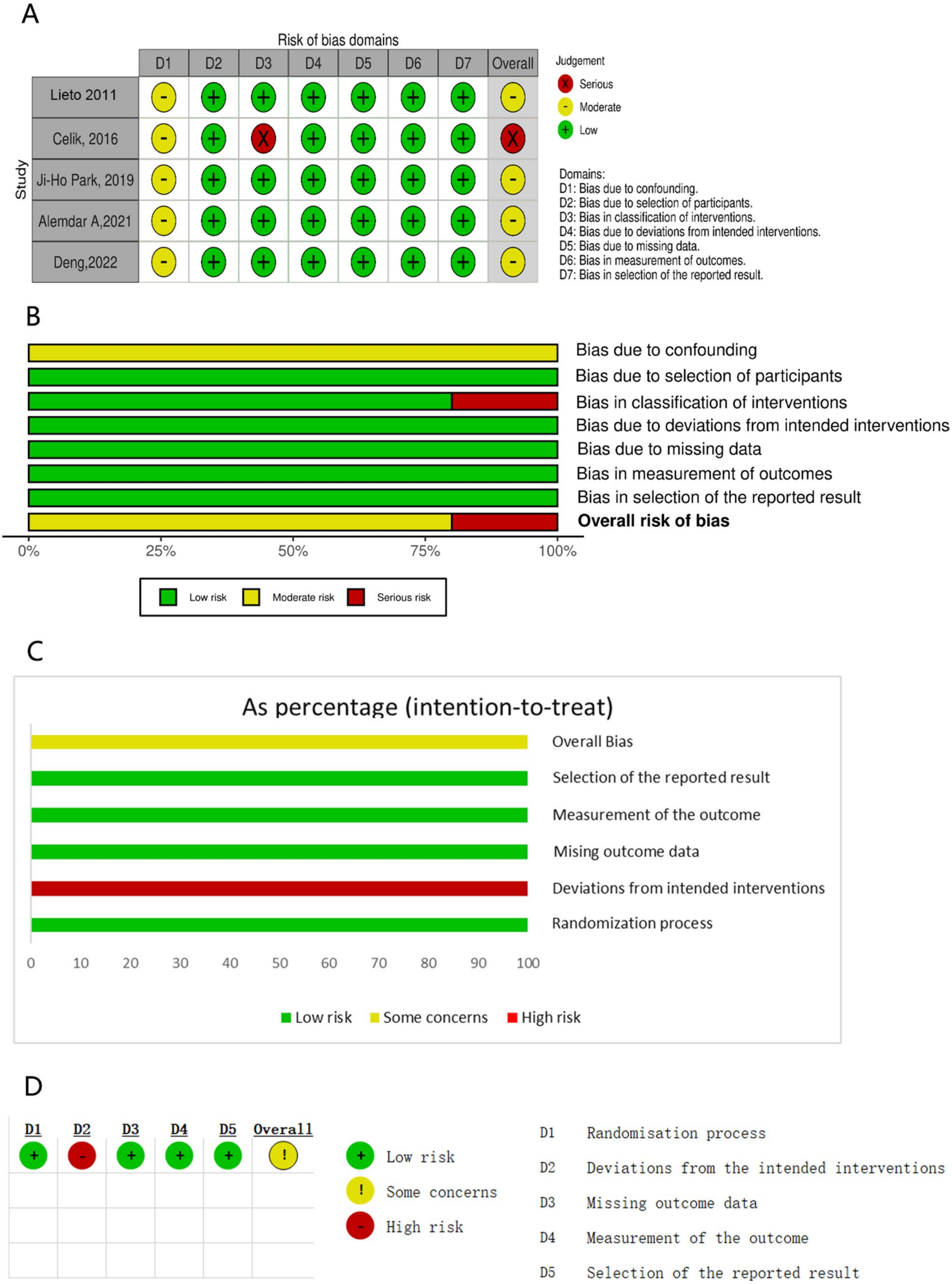

Fig. 2 Quality assessment of included five cohort studies and one randomized controlled trial. **A**, **D** Risk of bias summary. **B**, **C** Risk of bias graph

Table 3 Cases with a positive result on the intraoperative leak test

Study	Arterial bleeding	Venous bleeding	Air leakage	Mucosal tearing	Anastomotic stricture	Anastomoses bleeding	Anastomoses leak	Intervention			
								Endoscopic hemostasis	Reinforce suture	Re-anastomotic	prolonged anastomotic compression
Ji-Ho Park [27]	1	20	2	7	1	NR	NR	13	13	2	NR
Lieto [25]	NR	NR	5	NR	NR	3	NR	NR	5	NR	NR
Celik [26]	NR	NR	NR	NR	NR	NR	8	NR	8	NR	NR
Deng [29]	NR	NR	NR	NR	NR	NR	7	NR	7	NR	NR
Alemdar [28]	NR	NR	4	1	NR	2	NR	3	4	NR	NR
Gao [30]	2	NR	NR	NR	1	NR	2	NR	4	1	NR

consistent with our study. IOLT allows direct visualization and repeated assessment of anastomoses, which enable the identification of potential defects and allow for timely repair, thereby improving postoperative outcomes. However, some studies have reported that intraoperative leak testing does not decrease postoperative anastomotic-related complications [17, 18]. In their opinion, insufflation and over-distention of the anastomosis have a negative impact on the newly constructed anastomosis. Gastroscopy or an oral gastric tube may injure the anastomosis. These factors potentially leading to anastomotic-related complications.

In this study, we found that IOLT could reduce reoperation rate, which may be attributed to the reduction of PAL, anastomotic bleeding, anastomotic stricture, etc. It is worth noting that in the study by Park et al., there were still five (1.6%) patients in the IOLT group who underwent reoperation after surgery. The possible reason for reoperation in the IOLT group was that while IOLT may aid in the early detection of anastomotic defects, it cannot address all factors leading to reoperation, such as diffuse peritonitis, sepsis with one or multi-organ failure, intraabdominal bleeding, or small bowel obstruction [31, 37, 38]. Further studies are needed to explore the impact of IOLT on reoperation rate in gastric cancer surgery.

The technique of IOLT has been applied in various ways in clinical practice. Some surgeons adopted air testing, while others use methylene blue testing with or without gastroscopy. Researchers found that IOLT performed with gastroscopy had a significantly lower incidence of PAL rates than that in IOLT performed with gastric tubes [39, 40]. These conclusions are consistent with our study findings. The difference in PAL rates between IOLT, conducted via gastroscopy or gastric tubes, could potentially be attributed to the following factors: Firstly, the direct visualization provided by gastroscopy during IOLT enables a more accurate assessment of anastomotic integrity. Secondly, the inherent properties of gastroscopy, such as its flexibility and ability to navigate intricate anatomic structures, which could contribute to its effectiveness in detecting even subtle abnormalities in the anastomotic site. It may be challenging to perform the procedure with the relatively rigid structure of gastric tubes, which may miss potential defects in the anastomosis. Thirdly, the utilization of gastroscopy allows for real-time adjustments and interventions, such as additional suturing or reinforcement to be performed. It is worth noting that the choice of IOLT technique may also be influenced by the availability of endoscopist, intraoperative gastroscopy equipment, as well as the surgeon's experience and familiarity. Further comprehensive studies and standardized protocols are needed to establish the optimal approach for IOLT. We recommend the GAM procedure, which combines gastroscopy, air testing, and methylene blue testing for IOLT in

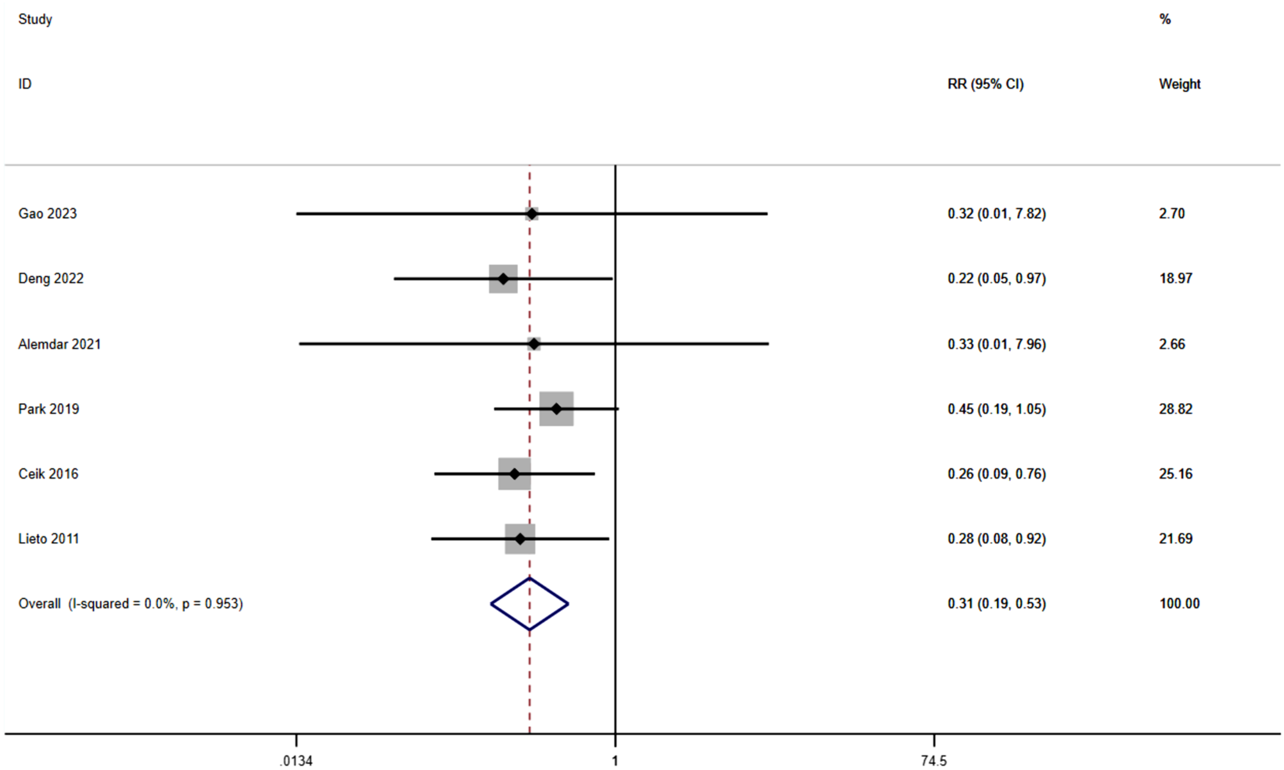

Fig. 3 Postoperative anastomotic leakage

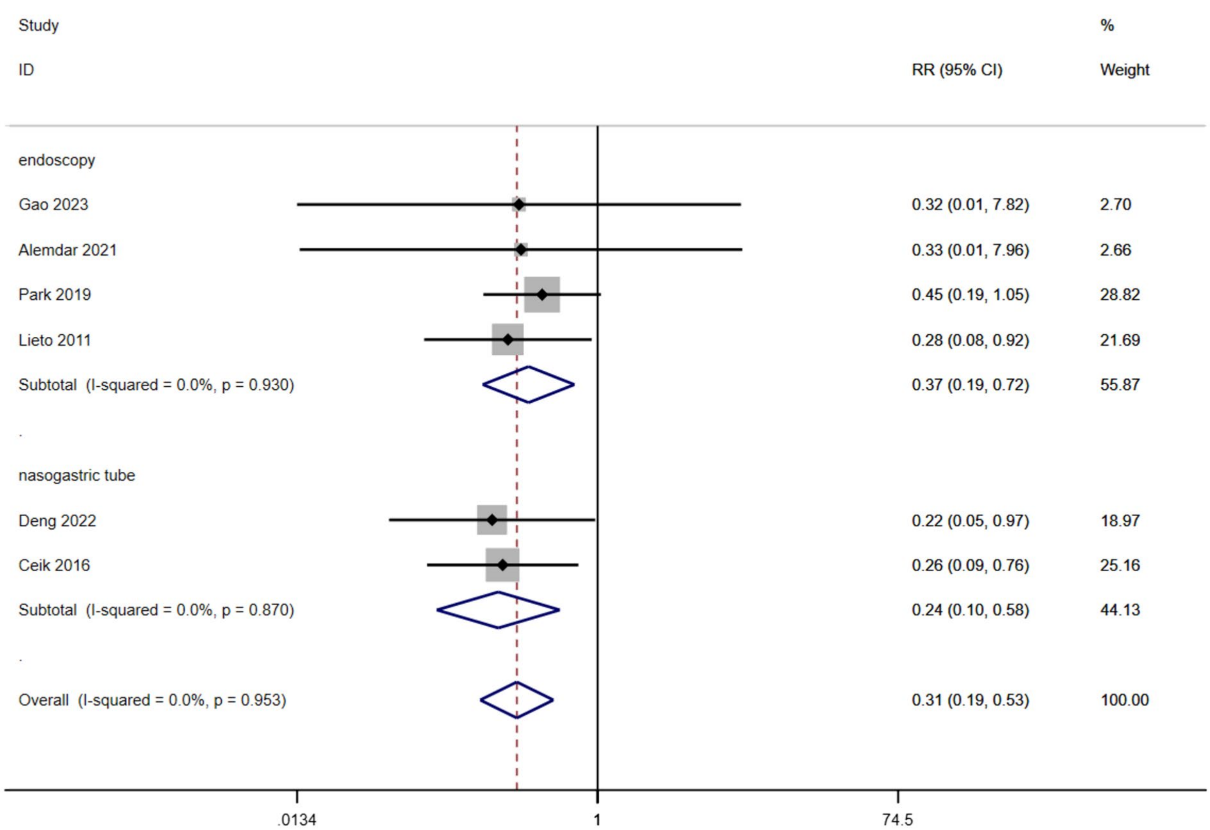

Fig. 4 Subgroup Analysis

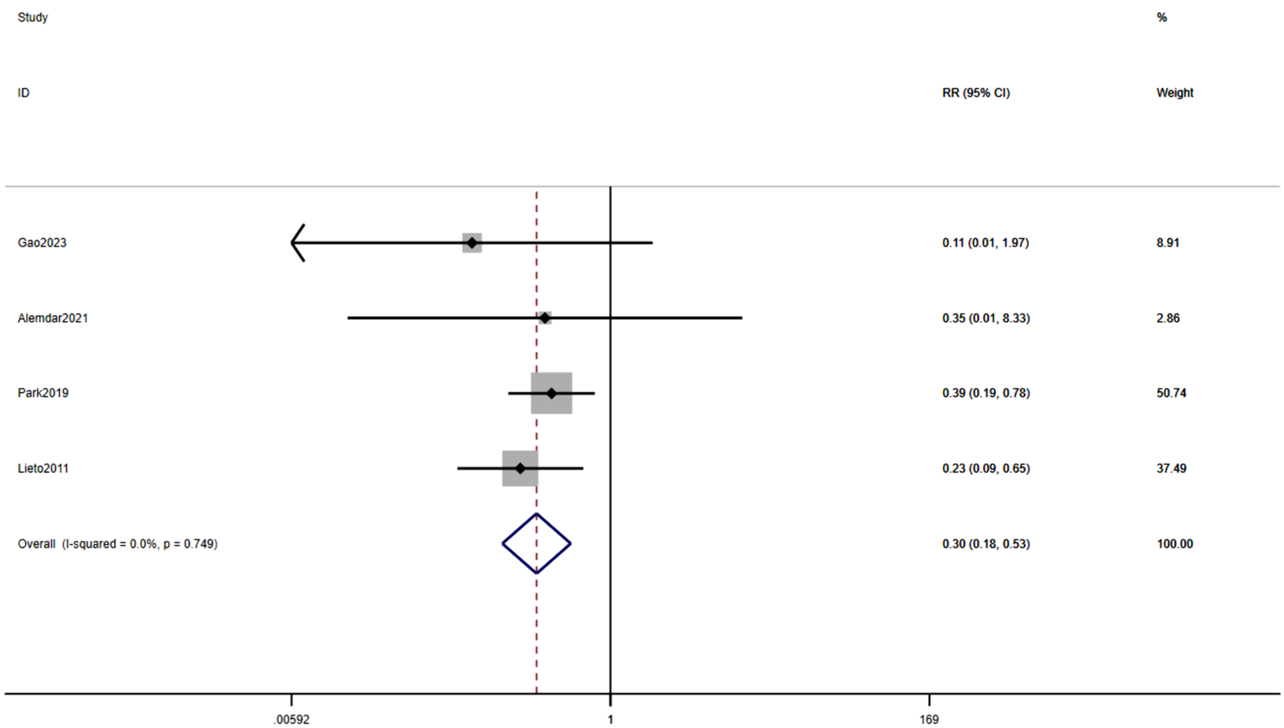

Fig. 5 Postoperative anastomotic-related complications

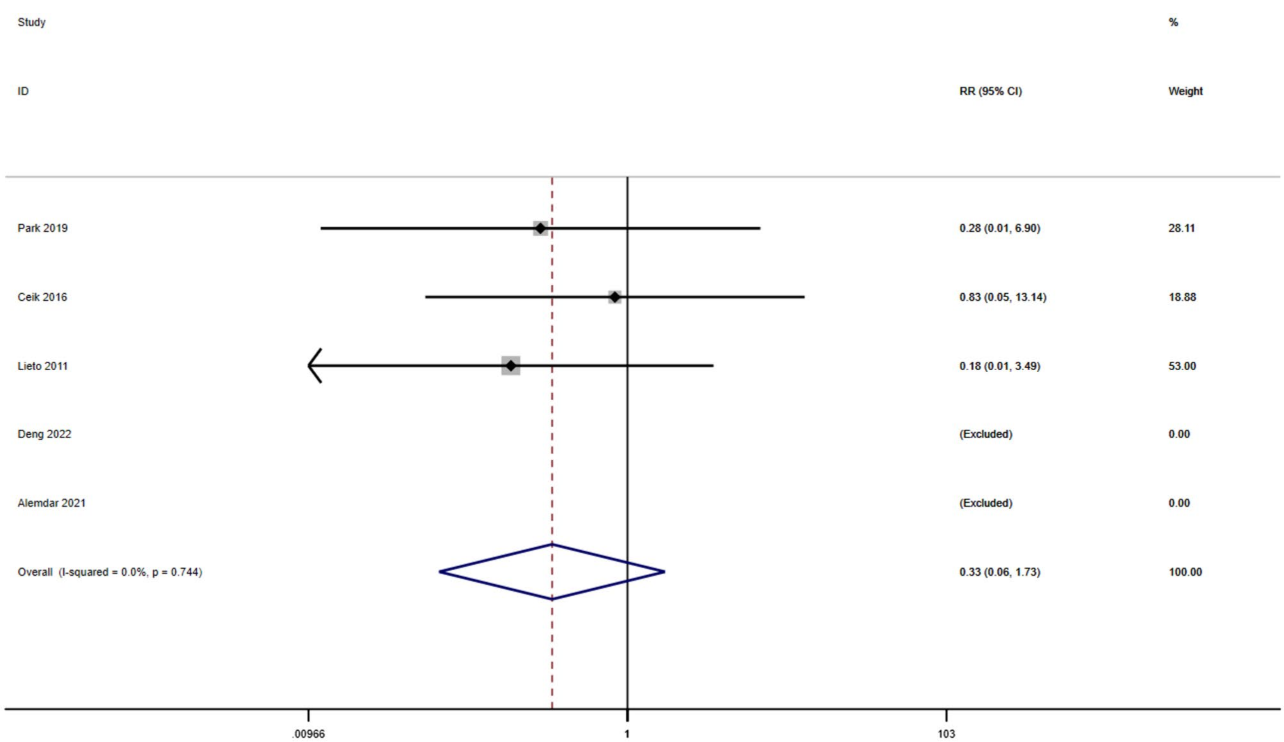

Fig. 6 30-Day mortality rates

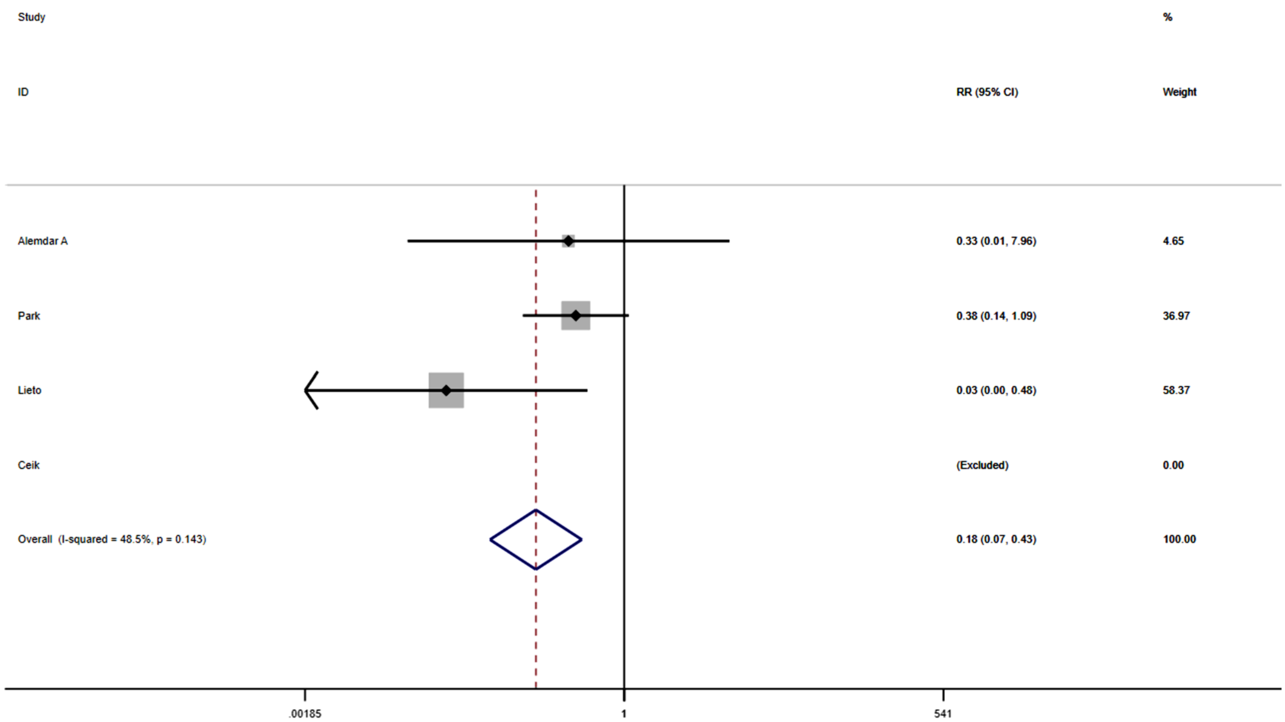

Fig. 7 Reoperation rates

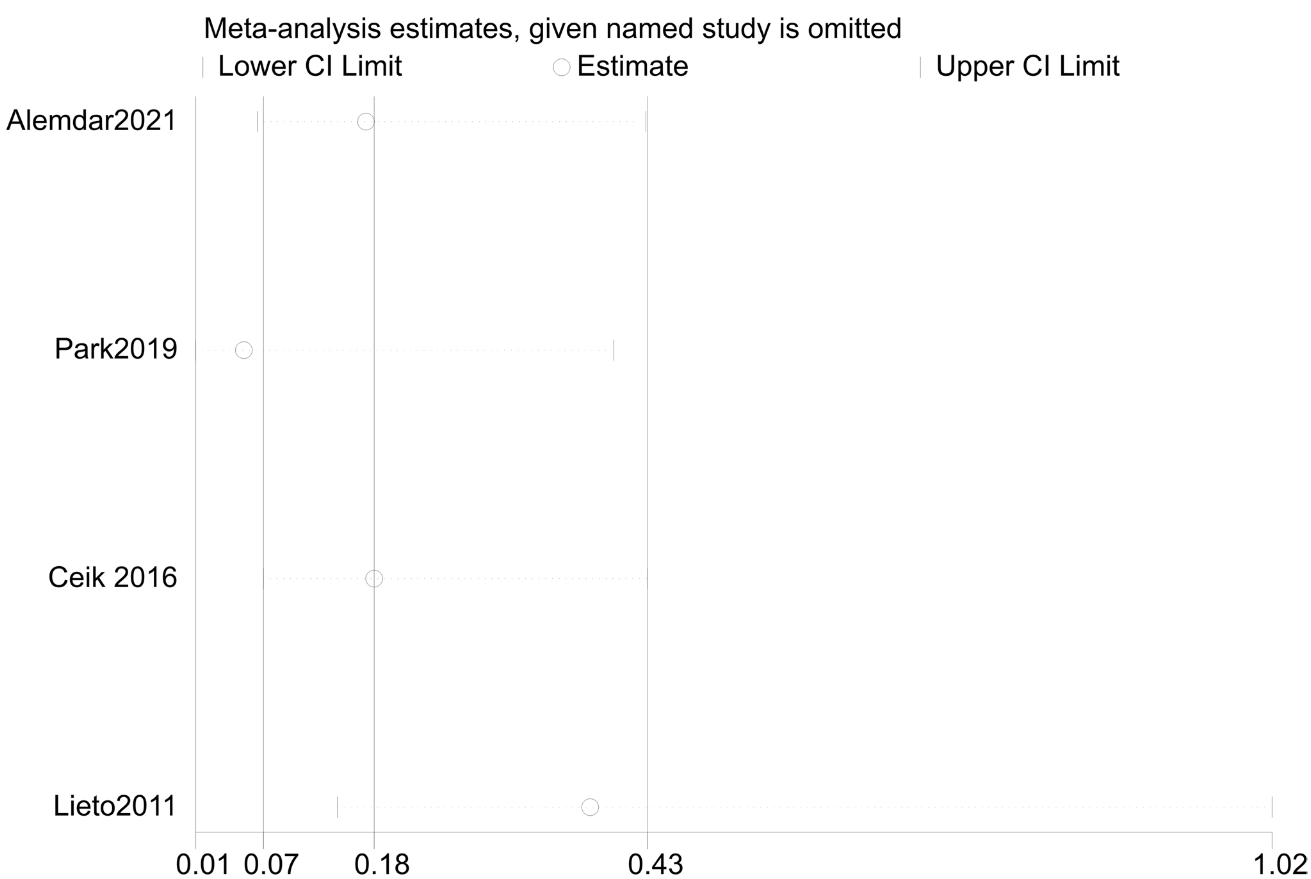

Fig. 8 Sensitivity analysis of Reoperation rate

gastric cancer surgery due to its comprehensive nature and superior results [41].

There are three limitations of our study. First, most of the included studies were retrospectively conducted, only one RCT was included, which may result in a high risk of bias in our study. Second, incomplete information of preoperative patient characteristics and intraoperative data were described, such as preoperative comorbidity, intraoperative gastrointestinal reconstruction methods, and surgical duration. Lastly, the lack of standardization of leak testing procedure may be a confounding factor in our study.

Conclusion

Considering the observed lower incidence of postoperative anastomotic leakage (PAL), anastomotic-related complications, and reoperation rates, IOLT appears to be a promising option for gastric cancer surgery. It warrants further study before potential inclusion in future clinical guidelines.

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Author contributions YT, LH, and SL have made substantial contributions to the design of the work. YL and BL interpreted the patients' data. LH, SL, and TH were major contributors in writing the manuscript. YT, LH, and LW have drafted the work or substantively revised it. All authors read and approved the final manuscript.

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Data availability The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Disclosures Heng Luo, Shunying Liu, Wentao Huang, Yu Lei, Yan Xing, Luke Wesemann, Binyu Luo, Wenjing Li, Jiani Hu, and Yunhong Tian have no conflicts of interest to disclose.

Ethical approval and consent to participate This is a meta-analysis on anonymized data so ethical approval is considered unnecessary.

Consent for publication No individual person's data is included in this study.

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