World J Surg
https://doi.org/10.1007/s00268-022-06572-3

SCIENTIFIC REVIEW

Using a Reinforced Stapler Decreases the Incidence of Postoperative Pancreatic Fistula After Distal Pancreatectomy: A Systematic Review and Meta-Analysis

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Accepted: 11 April 2022

Abstract

Background There is no consensus on the pancreatic transection during distal pancreatectomy (DP) to reduce postoperative pancreatic fistula (POPF). This meta-analysis aimed to evaluate the effects of a reinforced stapler on the postoperative outcomes of DP.

Methods We systematically searched electronic databases and bibliographic reference lists in The PubMed/MEDLINE, Google Scholar, Cochrane Library's Controlled Trials Registry and Database of Systematic Reviews, Embase, and Scopus. Review Manager Software was used for pooled estimates.

Results Seven eligible studies published between 2007 and 2021 were included with 553 patients (267 patients in the reinforced stapler group and 286 patients in the standard stapler group). The reinforced stapler reduced the POPF grade B and C (OR = 0.33; 95% CI [0.19, 0.57], $p < 0.01$). There was no difference between the reinforced stapler group and standard stapler group in terms of mortality rate (OR = 0.39; 95% CI [0.04, 3.57], $p = 0.40$), postoperative haemorrhage (OR = 0.53; 95% CI [0.20, 1.43], $p = 0.21$), and reoperation rate (OR = 0.91; 95% CI [0.40, 2.06], $p = 0.82$).

Conclusions Reinforced stapling in DP is safe and seems to reduce POPF grade B/C with similar mortality rates, postoperative bleeding, and reoperation rate. The protocol of this systematic review with meta-analysis was registered in PROSPERO (ID: CRD42021286849).

Introduction

Although distal pancreatectomy (DP) is considered a minor procedure compared to pancreaticoduodenectomy, its morbidity remains high, ranging between 32 and 40% [1, 2]. This morbidity is essentially due to postoperative pancreatic fistula (POPF) [3]. The incidence of POPF after DP varies between 0 and 61% [4], leading to substantial morbidity and delayed or cancelled chemotherapy [5, 6]. Various risk factors for POPF after DP have been recognized, such as high body mass index (BMI), "soft" pancreatic parenchyma, prolonged operative time, and blood loss [7, 8]. However, these are non-modifiable factors; this highlights the importance of surgical measures to improve postoperative outcomes. Surgical techniques and patient

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Published online: 07 May 2022

management improvements ensure better postoperative outcomes after DP. One such surgical technique is laparoscopic pancreatic surgery; staplers are increasingly used because of their easy, fast, and reproducible mechanism. According to to DIStal PAnCreatecTomy (DISPACT) trial, a multicentre randomized clinical trial, staplers provide a POPF rate similar to hand-sewn closure [9]. Moreover, standard stapling seems insufficient to provide better postoperative outcomes than hand-sewn closure. However, staple line reinforcement during surgery could decrease the risk of staple line complications. Currently, there exists a debate regarding the harms and benefits of stapler reinforcement. Jensen et al. [10] published a meta-analysis in 2013 that included five retrospective reviews and five prospective case series published between 2007 and 2009. They did not find a difference in the overall relative risk of developing a POPF after using either reinforced stapling or standard pancreatic stapling,. Recently, a new category of reinforced staplers has been introduced, and several clinical trials have investigated the benefits and harms of these staplers [11–14], and the results were controversial.

We performed this systematic review with meta-analysis to evaluate the effects of the reinforced staplers on the postoperative outcomes after DP.

Methods

We conducted a systematic review with meta-analysis according to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines 2020 [15] and Assessing the methodological quality of systematic reviews (AMSTAR 2) guidelines [16]. We registered the protocol of this systematic review with meta-analysis in PROSPERO (ID: CRD42021286849).

Electronic database search

We conducted a comprehensive and extensive electronic database search of the relevant literature using the following databases: The Cochrane Library's Controlled Trials Registry and Database of Systematic Reviews, PubMed/MEDLINE of the United States National Library of Medicine, Google Scholar, Embase, and Scopus. The keywords used were "pancreatic fistula", "distal pancreatectomy", "postoperative pancreatic fistula", "staple closure", "reinforced stapler", "stapler", "stump closure", "prevention", "reinforcement", and "morbidity". We used Boolean operators "or" and "and". Further, we checked the references of included articles eligible for clinical trials.

Inclusion criteria and data extraction

Studies search: Two authors independently searched for the clinical trials assessing the outcomes after pancreas division using staplers for DP. All randomized controlled trials (RCTs) and controlled clinical trials (CCTs) reporting a comparison between the reinforced stapler and standard stapler or a subgroup comparison between the two kinds of staplers were considered. Only articles published in peer-reviewed journals were considered**.** Studies were required to include at least 20 patients to ensure that data were representative of an established practice. Non-comparative studies, studies were in only abstracts were available, case series (fewer than 10 cases), editorials, and letters to editors, were not considered. Studies with articles written in a language other than English, redundant patient populations, or no original data were also excluded.

Data extraction: Data were extracted based on the first author, year of publication, country, journal, study design, sample size for each group (reinforced stapler and standard stapler) sorted by sex, surgical approach, age, BMI, spleen preservation, indication for distal splenectomy, and pancreatic texture. Moreover, the POPF rate and grade were categorized as A, B, and C according to the International Study Group for Pancreatic Surgery (ISGPS) criteria [17, 18].

Participants: Adults (aged 18 or older) of either sex undergoing open or laparoscopic DP for benign or malignant pancreatic tumours with or without splenectomy were included**.** In both groups (reinforced stapler and standard stapler), we included only studies using mechanical staplers; the studies that used a sealing patch to reinforce staplers were excluded.

Outcome measures

The primary outcome measure was POPF grade B/C, which, according to ISGPS criteria [17, 18], is defined as a drain output of any measurable volume of fluid on or after postoperative day 3 with an amylase content greater than three times the serum amylase activity. The secondary outcomes were mortality, postoperative bleeding, and reoperations.

Data collection and analysis

Study selection: Two authors independently reviewed the abstracts of the retrieved studies. Moreover, RCTs and CCTs were considered, and full texts were checked.

Missing data: We contacted authors via e-mail in the case of unclear bias domains or missing primary outcomes information. If data were not reported numerically, we extracted it from figures.

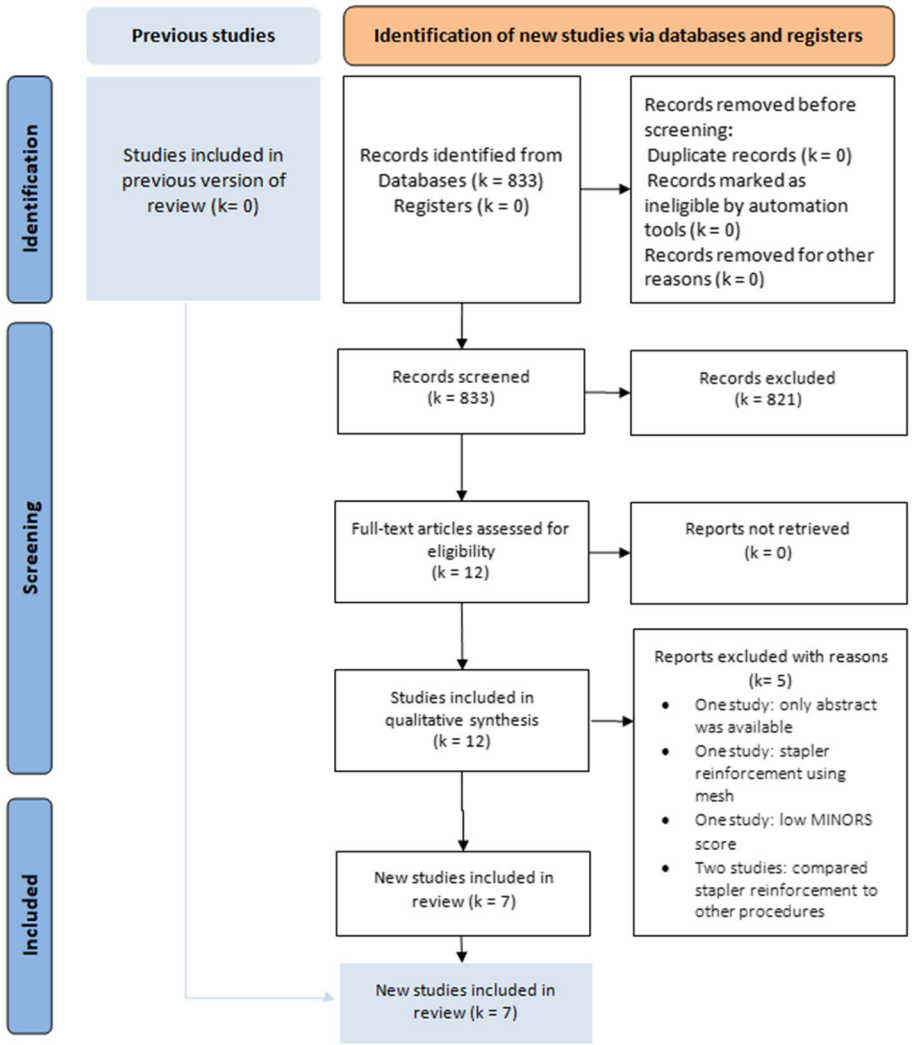

Fig. 1 PRISMA 2020 flow-diagram of the included studies

Assessment of the studies' quality: The CCTs that met the inclusion criteria were independently appraised by two authors according to the Methodological Index for Non-randomized Studies (MINORS) [19] and the risk of bias using the Newcastle–Ottawa Scale (NOS) [20]**.** For the RCTs, we used the Consolidated Standards of Reporting Trials (CONSORT) for quality assessment [21] and version 2 of the Cochrane risk-of-bias tool (RoB2) [22]. We evaluated the bias in five distinct domains: randomization process, deviations from intended interventions, bias in the measurement of outcome, bias to missing outcome data, bias in selecting the reported results, and overall bias. Within each domain, one or more signalling questions led to judgments of "low risk of bias", "some concerns", or "high risk of bias".

Data extraction: Two authors independently extracted the data from the retained studies. Disparities were settled after a discussion with a senior author (OS). If studies presented the results as the median and interquartile range (IQR) or range, we converted the values to mean and standard deviation (SD), as suggested by Hozo et al. [23] or the Cochrane Handbook 7.7.3.5 [24], as appropriate.

Evaluation of effect size: We used the Review Manager 5.3 software for the meta-analysis. Mean difference (MD) was selected as an effective measure for continuous data. For dichotomous variables, odds ratio (OR) with 95% confidence interval (CI) was calculated. Further, we used the random-effects model and set the statistical significance threshold at 0.05.

Assessment of heterogeneity: The studies responsible for heterogeneity were identified by funnel plots. We used the Cochrane Chi^2 test (Q-test), I^2 statistic, and variance Tau^2 to estimate the degree of heterogeneity [25]. We used the random-effects model. When I^2 was between 51 and 100%, we tested for interactions between relevant factors and effect size estimates.

Summary of findings: Two authors independently assessed the certainty of the evidence using the Grading of

Table 1 List of the included studies

First author	Year of publication	Country	Study period	Type of study	Number of patient (reinforced/control)	Reinforced stapler	Compared to	Number of POPF B and C (reinforced/control)	MINORS	CONSORT
Goh	2021	Singapore	2014–2019	CCT	90 (25/65)	Echelon laparoscopic stapler (Ethicon)EndoGIA (Covidien/ Medtronic) reinforced with Neoveil	Echelon laparoscopic stapler (Ethicon)/ EndoGIA (Covidien/ Medtronic)	1/16	18/24	–
Jimenez	2007	USA	September 2003–May 2006	CCT	31 (13/18)	Stapler gun with Gore Bioabsorbable Seamguard® Reinforcement	Stapler gun	0/7	14/24	–
Kawaida	2019	Japan	April 2013–March 2018	CCT	93 (56/37)	Endo GIA™ Reinforced Reload with Tri-Staple™ Technology 60 mm; COVIDIEN	Endo GIA™ Reloads with Tri-Staple™ Technology 60 mm; COVIDIEN	2/5	20/24	–
Kondo	2019	Japan	July 2016–December 2017	RCT	120 (61/59)	Endo GIA tri-staple (Covidien) with Neoveil® (Gunze)	Endo GIA tri-staple (Covidien)	10/16	–	20/25
Miyamoto	2019	Japan	January 2007–May 2018	CCT	59 (20/39)	Endo GIA™ Reinforced Reload with Tri-Staple™; black reload; 60-mm long; Medtronic plc, in conjunction with a reinforcing mesh of Neoveil® (Gunze)	Endo GIA™ Reinforced Reload with Tri-Staple™; black reload; 60-mm long; Medtronic plc	2/14	16/24	–
Wallace	2013	Georgia—USA	September 2003–August 2010	CCT	54 (36/18)	Gore Bioabsorbable Seamguard® Reinforcement	Standard stapler	3/5	16/24	–
Wennerblom	2021	Sweden	May 2014–February 2016	RCT	106 (50/56)	EchelonTM, Ethicon Endo-Surgery	Standard stapler (EndoGIATM, Medtronic)	6/8	–	23/25

RCT randomized controlled study; *CCT* controlled clinical trial; *MINORS* Methodological index for non-randomized studies; *CONSORT* Consolidated Standards of Reporting Trials; *NOS* Newcastle–Ottawa Scale; *control* standard stapler group; *reinforced* reinforced stapler group

Table 2 Characteristics of the retained studies in the meta-analysis

First author	Sex (F/M)		Surgical approach (reinforced/control)		Age		BMI		Spleen preservation (Yes/No)	
	Reinforced stapler	Control group	Open	Laparoscopy	Reinforced stapler	Control group	Reinforced stapler	Control group	Reinforced stapler	Control group
Goh	11/14	41/24	0	90/90	–	–	23.3 ± 6.8	23.7 ± 5.7	5/25	12/65
Jimenez	10/3	7/11	–	–	63	63	–	–	–	–
Kawaida	38/18	18/19	24/32	9/28	62.9 ± 2	66.1 ± 2.5	–	–	–	–
Kondo	30/31	34/25	47/14	45/14	70 (62–76)	73 (67–78)	22.1 (19.9–25)	20.8 (19.6–23.9)	2/59	5/54
Miyamoto	9/11	19/20	–	–	59 (39–82	58 (34–86)	22.6 ± 2.16	23.7 ± 2.25	3/20	8/39
Wallace	20/16	7/11	32/16	4/2	62	63	–	–	–	–
Wennerblom	29/27	23/27	43/41	13/9	67 (35–84)	68 (28–89)	26.7 (18.7–47.3)	26.8 (18.9–37.6)	14/56	13/50

First author	ASA score (reinforced/control)				Indication (reinforced/control)				Pancreatic texture (hard/soft)	
	1	2	3	4	Adk	NET	IPMN and cystic lesion	Other	Reinforced stapler	Control group
Goh	6/1	48/17	11/7	0	4/19	–	–	–	–	–
Jimenez	–	–	–	–	3/5	3/5	4/3	3/5	7/6	N/A
Kawaida	–	–	–	–	–	–	–	–	–	–
Kondo	–	–	–	–	28/35	9/6	12/10	12/8	56/5	55/4
Miyamoto	–	–	–	–	9/18	2/3	4/6	6/12	17/3	32/7
Wallace	–	–	–	–	12/5	7/5	10/3	7/5	–	–
Wennerblom	8/6	31/30	16/13	1/1	21/22	7/5	16/16	12/7	21/15	–

F female, *M* male, *control* standard stapler group, *reinforced* reinforced stapler group, *BMI* body mass index, *ASA* American society of anesthesiologist score, *Adk* adenocarcinoma, *NET* neuroendocrine tumor, *IPMN* intraductal papillary mucinous neoplasm

Table 3 Cochrane tool for bias assessment to assess the risk of bias in randomized trials (RoB2)

First author	Randomization process	Deviations from intended interventions	Bias in measurement of outcome	Bias to missing outcome data	Bias in selecting the reported results	overall bias
Kondo	Low risk	Some concerns	Low risk	Low risk	Low risk	Some concerns
Wennerblom	Low risk	High risk	Low risk	Low risk	Low risk	High risk

Table 4 Newcastle–Ottawa Scale for Risk of bias assessment of the included non-randomized trials

Study	Selection	Comparability	Outcome
Goh	***	**	**
Jimenez	***	**	**
Kawaida	***	**	**
Miyamoto	**	*	*
Wallace	***	**	**

Recommendations Assessment, Development, and Evaluation (GRADE) [26]. We used the five GRADE considerations: study limitations constancy of effect, imprecision, indirectness, and publication bias. Moreover, the GRADEpro GDT (Guideline Development Tool) was used to prepare the summary of findings tables, and the reasons for downgrading or upgrading the certainly of included studies were explained using footnotes. We assessed the certainty of evidence as high, moderate, low, or very low and used the methods and recommendations described in Sects. 8.5 and 8.7 and chapters 11 and 12 of the Cochrane Handbook for Systematic Reviews of Interventions.

Results

Literature search results

We retrieved seven eligible studies (Fig. 1 and Table 1) published between 2007 and 2021 [13, 14, 27–31] of which two RCTs [13, 14] and five were CCTs [27–31]. Five studies were excluded for the following reasons: one study was available only as an abstract [32], one study was excluded due to a MINORS score inferior to 13 [12], one study compared reinforced stapler to ultrasonic dissector [33], and two studies compared reinforced stapler to ultrasonically parenchyma transection and transfixed pancreatic duct closure or pancreaticogastrostomy [34]. The seven retained studies comprised 553 patients (267 patients in the reinforced stapler group and286 in the standard stapler group).

The characteristics of the included patients, in this meta-analysis, are reported in Table 2. The sex ratio was 0.86 with 257 males (46.4%) and 296 females (53.6%). The mean age and BMI ranged from 58 to 73 years and 20.8 to 26.8 kg/m^2, respectively. Moreover, the DP was performed using the laparoscopic approach in 55% and the open approach in 45% of the cases. Spleen preservation was adopted in 14.41% of the cases. The pancreatic texture was hard in 57% and soft in 43% of the cases. In addition, a POPF grade B/C was reported in 91 patients (16.45%) in 23 out of 257 patients (8.61%) and 68 out of 268 patients (25.37%) in the standard stapler group.

The quality assessment based on CONSORT and MINORS scores and details of the included studies is summarized in Table I. The RoB 2 is presented in Table 3, and the NOS is presented in Table 4. The summary of evidence-based findings for the different outcomes is reported in Table 5.

Outcome measures

POPF B/C: Six studies reported the POPF according to ISGPF criteria [13, 14, 27, 29–31]. We found 23 out of 257 patients and 68 out of 268 patients in the reinforced stapler group and the standard stapler group, respectively. Thus, significantly lower number of patients displayed POPF grade B/C in the reinforced stapler group (OR = 0.33; 95% CI [0.19, 0.57], $p < 0.01$) (Fig. 2).

Mortality: Data on mortality rates were available in six studies [13, 14, 27–29, 31]. Two studies reported this outcome [14, 27]. Three patients among 247 patients were dead in the standard stapler group. There was no mortality in the reinforced stapler group. There was no difference between the two groups in terms of mortality rate (OR = 0.39; 95% CI [0.04, 3.57], $p = 0.40$) (Fig. 3).

Postoperative bleeding: Five studies reported this outcome [13, 14, 27, 29, 30]. Seven out of 222 patients in the reinforced stapler group and 17 out of 247 patients in the standard stapler group reported postoperative bleeding. There was no difference between the two groups in terms of bleeding complications (OR = 0.53; 95% CI [0.20, 1.43], $p = 0.21$) (Fig. 4).

Table 5 Summary of findings table

Reinforced stapler compared to a standard stapler for distal pancreatectomy						
Patient or population: distal pancreatectomy Setting: Intervention (reinforced stapler); Comparison (standard stapler)						
Outcomes	Nº of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects		Comments
				The risk with a standard stapler	Risk difference with Reinforced stapler	
POPF B/C	525 (4 CCTs + 2 RCTs)	⊕◯◯◯ Very low[a]	OR 0.49 (0.20 to 1.18)	209 per 1000	94 fewer per 1000 (159 fewer to 29 more)	The evidence is very uncertain that reinforced stapler reduces POPF B/C grade, mortality, bleeding, reoperation, and blood loss
Mortality	494 (4 CCTs + 2 RCTs)	⊕◯◯◯ Very low[a]	OR 0.39 (0.04 to 3.57)	12 per 1000	7 fewer per 1000 (12 fewer to 30 more)	
Bleeding	469 (3 CCTs + 2 RCTs)	⊕◯◯◯ Very low[a]	OR 0.53 (0.20 to 1.43)	69 per 1000	31 fewer per 1000 (54 fewer to 27 more)	
Reoperation	347 (2 CCTs + 2 RCTs)	⊕◯◯◯ Very low[a]	OR 0.91 (0.40 to 2.06)	73 per 1000	6 fewer per 1000 (42 fewer to 67 more)	
Blood loss	471 (3 CCTs + 2 RCTs)	⊕◯◯◯ Very low[b,c]	RR 42.12 (-78.08 to 162.33)	Low		

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)

CI confidence interval; *OR* odds ratio; *RR* risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the effect estimate

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

[a]Small sample size and number of events

[b]I^2 superior to 50%

[c]Small sample sizes

Reoperation rate: The reoperation rate was reported in four studies [13, 14, 27, 28]. Thirteen out of 155 patients were operated in the reinforced stapler group and 14 out of 192 patients in the standard stapler group. There was no difference between the two groups in terms of reoperation rate (OR = 0.91; 95% CI [0.40, 2.06], $p = 0.82$) (Fig. 5).

Discussion

The current systematic review with meta-analysis concluded that the reinforced stapler group presented lower POPF grade B/C and similar mortality rates, postoperative bleeding, blood loss, and reoperation rate.

POPF can lead to various clinically significant and sometimes life-threatening consequences, including intra-abdominal abscess, intra-abdominal bleeding, wound infection, and longer hospital stay. Thus, the risk of POPF must be minimized. Pancreatic stump leak is a major source of morbidity following DP. For years, the literature has widely discussed the surgical care of the pancreatic stump, with the bulk of comparative trials failing to show that one procedure is superior to the other [9, 35, 36]. However, few studies have focused on stump closure management, particularly in the soft pancreas, which is one of the most critical topics. This complication depends on intrinsic characteristics such as pancreatic parenchyma [37], pancreatic duct size [38], and pasireotide use [39]. Several surgeons have suggested a variety of intraoperative procedures to reduce the POPF rate. A simple pancreatic transection with a standard stapler has been proven safe with results similar to hand-sewn closure [9, 40]. In addition, reinforcement of the staple line has been suggested as a tool to minimize staple line complications and avoid over-sewing and using additional running sutures. Several

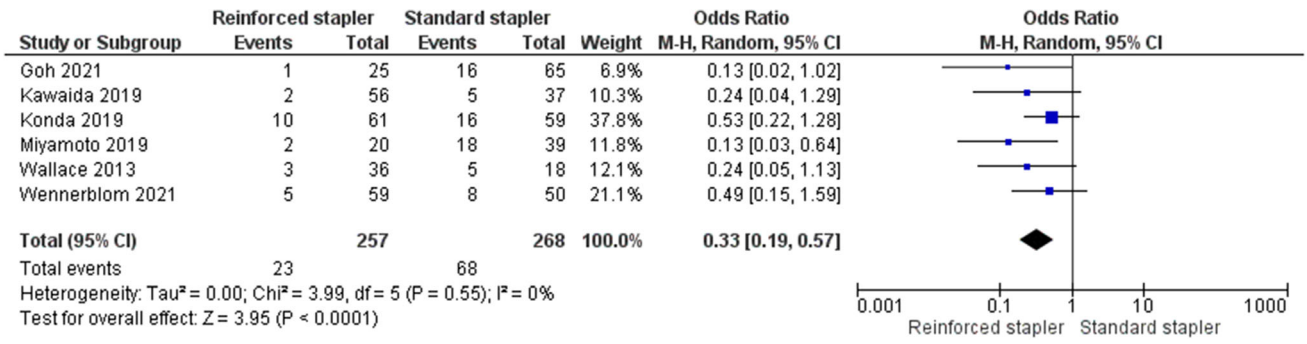

Fig. 2 Forest plot of grade B and C postoperative pancreatic fistula

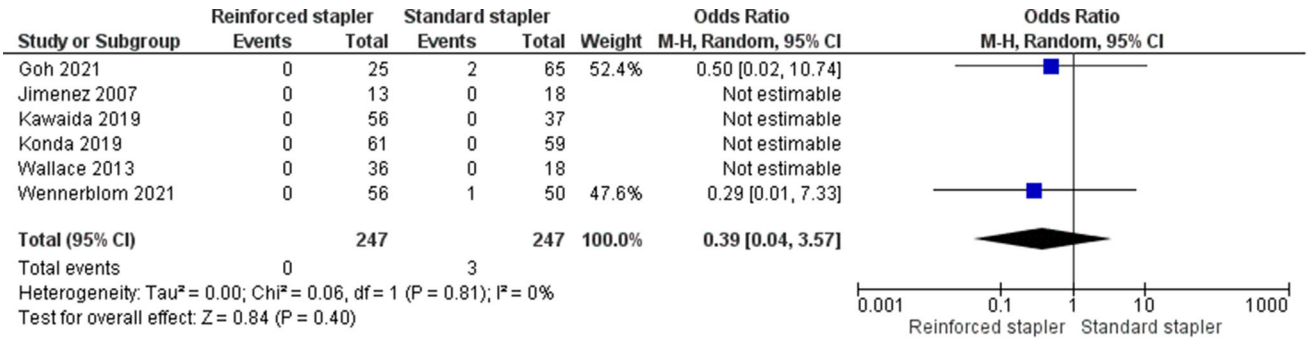

Fig. 3 Forest plot of mortality

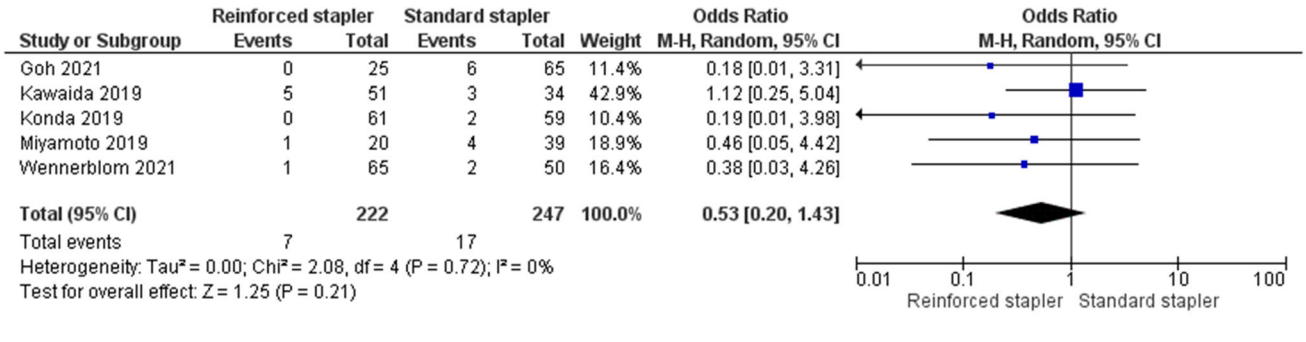

Fig. 4 Forest plot of bleeding

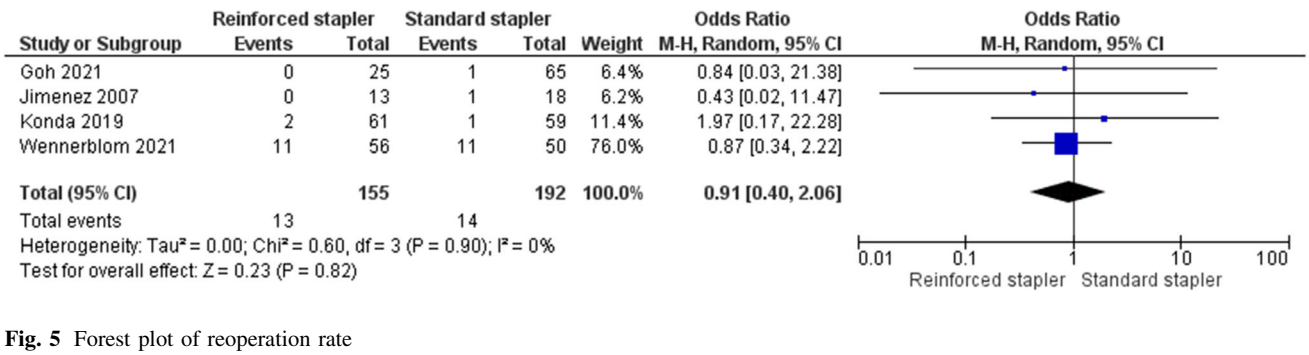

Fig. 5 Forest plot of reoperation rate

methods of reinforcement have been reported: Neoveil, Seamguard, and triple line staplers.

Neoveil is an absorbable reinforcement material made from polyglycolic acid absorbed for about 15 weeks [41]. Seamguard® is a bioabsorbable mesh of trimethylene carbonate microporous structure and polyglycolic acid; it is absorbed in 6 months after surgery [42]. Triple line staplers provided graduated compression profile and varied height staples allow greater perfusion into the staple line [43]. The material used in the reinforced stapler includes synthetic copolymer-based product or collagen [40]. Moreover, first bolsters used for staple lines were non-absorbable, semi absorbable, and bioabsorbable materials. Each method may provide different degrees of efficacy on fistula, leak, and bleeding. Currently, the efficacy of staple line reinforcement and heterogeneity in some outcomes in our review are subject to debate in the literature. The problem has always been to find the optimal material that yields the greatest advantages in terms of POPF grade B/C.

This systematic review with meta-analysis assessed the efficacy of reinforced stapler to reduce the POPF rate. The use of reinforced staplers is safe in the pooled analysis and significantly reduces the pancreatic fistula rate. However, despite the ISGPS criteria standardizing the diagnosis of clinically relevant POPF, the diagnosis remains difficult. Our study supports the continued use of reinforced staplers for DP. In the selected RCTs [13, 14], we found that the incidence of POPF grade B/C after reinforced staplers pancreatic transection was statistically significantly decreased. This finding was relevant since the previous two meta-analyses [10, 44] published on this topic concluded the absence of POPF rate in the reinforced stapler group compared with the non-reinforced stapler group. However, here, it is noteworthy that these two studies included works that had used both ISGPS and non-ISGPS definitions of POPF.

The 30-day postoperative mortality rate showed no difference between the two groups. There was no mortality in the reinforced stapler group, and for the three cases of postoperative death in the standard stapler group, the reasons behind the deaths were not linked to the use of standard staplers. There was no difference between the two groups in terms of mortality rate [45]. Concerning morbidity, the reinforced staplers provided results similar to standard staplers in terms of postoperative bleeding and reoperation rate. These findings highlight the safety and efficacy of reinforced staplers.

In face of technological advances in pancreatic surgery, the treatment of the pancreatic stump remains a matter of debate. We presented this meta-analysis of only those clinical trials that had compared reinforced stapler to standard stapler in the context of DP. Here, it is imperative to consider several limitations of this study. We retained a limited number of clinical trials. We found only two RCTs [13, 14], and it was impossible to perform the meta-analysis with such a small sample size. Additional CCTs were included to increase the population. This inclusion could have contributed to a selection bias. To overcome this deficiency, the risk of bias was assessed using the five piece Cochrane RoB 2 for randomized trials and the NOS for the observational trials [20, 46]. In addition, the retained studies were rigorously assessed and scored using the MINORS and CONSORT statements [19, 21]. Furthermore, when heterogeneity existed among the studies, it was impossible to perform subgroup analyses. Therefore, these findings of the study should be considered with caution and require confirmation of further additional RCTs.

Conclusion

Identifying the best pancreatic remnant stump closure techniques was the main focus of the current research. We can conclude that using a reinforced stapler instead of a standard stapler reduced the POPF rate. However, this superiority of reinforced staplers remains uncertain and further studies with larger sample sizes are needed to prove this superiority. Thus, our study's overall level of evidence can be graded 2a with a recommendation grade of B [47].

Acknowledgements None

Authors' contributions All authors participated in the study on the conception, design of the research, acquisition of the data, analysis and interpretation of the data.

Funding None.

Availability of data and materials All data generated or analysed during this study are included in this published article.No conflicts of interests or disclosures.

Declarations

Conflict of interest No conflict of interest to disclose.

Ethical approval Ethics approval and consent to participate in this retrospective research that involves Human participants are not applicable in this review.

Human or animal participants This research involves Human participants. It is a retrospective analysis of published cases and did not require informed consent. Ethics approval and consent to participate were not applicable in this review.

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