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Suture versus stapler in distal pancreatectomy and its impact on postoperative pancreatic fistula

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Postoperative pancreatic fistula is a critical complication after distal pancreatectomy. The aim of this systematic review is to assess new reports on the main pancreatic stump closure techniques (stapler and hand-sewn suture) in distal pancreatectomy, to define their influence on postoperative pancreatic fistula rates. A literature review was performed following PRISMA guidelines (PROSPERO: CRD42023408181). The survey was conducted in Medline (via PubMed) and EMBASE. Clinical trials and cohorts were included if they assessed pancreatic fistula rates after distal pancreatectomy, and excluded if they used a fistula rating system other than the ISGPF one. The risk of bias was assessed using the Study Quality Assessment Tools | NHLBI, NIH. A meta-analysis was presented as forest-plots. Eleven articles were included, representing 1498 patients. No significant difference was found between Suture and Bare stapler (95% CI 0.91–1.68) or Bare stapler and Reinforced stapler for A-graded fistula rates (95% CI 0.78–1.28) and B-graded fistula rates (I-squared = 0.0%, p = 0.784). Most articles showed unclear risk of detection bias. This meta-analysis found no difference in fistula rates between stump closure techniques. This choice should be made by surgeons' and hospital administration's preferences.

Keywords Pancreatectomy, Surgical suture, Surgical staplers, Fistula

Pancreas surgery has been one of the most relevant and studied procedures in Medicine, ever since the first successful tumor removal in 1867[1]. More than 150 years later, the art of pancreatectomy has evolved beyond recognition, with increasingly more advanced techniques, cutting-edge devices and technology, laparoscopic and robotic surgeries. Unfortunately, one critical complication still captures surgeons' attention and concern: the Postoperative Pancreatic Fistula (POPF).

Affecting up to 40% of patients, POPF is a risk factor for other complications (including sepsis and organ failure), increasing morbidity and mortality in individuals who already had their quality of life worsened by conditions such as cancer and chronic pancreatitis[2,3]. A recent cohort study showed that 19,4% of the patients undergoing laparoscopic distal pancreatectomy developed pancreatic fistulas grade B/C[4], an astounding number, considering the seriousness of this condition.

Succinctly, POPF is formed by a pancreatic duct disruption. This complication causes pancreatic fluid leakage, which leads to erosion of the tissue around it and, ultimately, the fistula development[5]. One of the most alarming consequences is artery erosion, which can evolve into significant hemorrhage and eventual death. Thus, many of the techniques developed to reduce its occurrence focus on pancreatic stump closure.

Currently, two main approaches are used worldwide: hand-sewn suture closure or stapler closure (both bare and reinforced versions). The last systematic review on this theme was published in 2019 and the present study included 3 new clinical trials that were published since the last systematic review.

The aim of this systematic review is to assess new findings and reports on the main pancreatic stump closure techniques, stapler and hand-sewn suture, in human distal pancreatectomy (DP), to define their influence on postoperative pancreatic fistula (POPF) rate.

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Materials and methods

This systematic review was carried out in accordance with the items of Preferred Reports for Systematic Reviews and Protocol Meta-Analysis (PRISMA-P)[6]. This study was registered by the Prospective Register of Systematic Reviews (PROSPERO, identification code CRD42023408181) before the research was carried out.

Drafting of the research question was based on the PICO strategy[7], considering: patients undergoing DP, under the risk of developing POPF (Patient or Problem); pancreatic stump closure performed by hand-sewn suture (Intervention or Assessment); pancreatic stump closure performed with the use of stapler (Control or Comparison); effects on POPF rate (Outcome).

Eligibility criteria

Inclusion criteria

Types of studies Articles were selected from their titles and abstracts according to their data relevance and regardless of their publication status.

The following study designs were considered: randomized controlled clinical trials, non-randomized controlled clinical trials, prospective and retrospective cohorts, case–control and cross-sectional. Reports and case series, reviews, letters to the editors, research protocols, and congress proceedings were not included. Finally, articles which full text were not accessible to the authors were excluded from the analysis.

Types of participants Study participants were adult patients undergoing distal pancreatectomy, for the resection of tumors (malignant, benign or metastasis), pseudocysts or chronic pancreatitis, susceptible to developing POPF.

Types of intervention First and foremost, three stump closure techniques, the main subject of the present study, were contemplated in the analysis: bare staplers, reinforced staplers and hand-sewn sutures. Open, laparoscopic, and robotic procedures were considered in this review.

Exclusion criteria

Studies were be excluded if: (1) included patients whose indication to DP was trauma related; (2) included procedures other than DP; (3) assessed techniques related to pancreatic stump closure other than suture and stapler; (4) analyzed procedures performed on animals, children or teenagers; (5) used a postoperative pancreatic fistula grading system other than the International Study Group of Pancreatic Fistula (ISGPS) definition[8]; (6) were not related to the question proposed by this review; (7) were in a language other than English; (8) were incomplete, unpublished or inaccessible to the authors.

Types of variables/parameters analyzed

Data were collected and arranged in tables, including the authors, date and country of publication, type of study, number of participants analyzed, sex, age, body mass index (BMI), comorbidities, and grade of pancreatic fistula developed after surgery (according to ISGPS classification[9]).

Literature revision

The survey was conducted on January 15th 2024, without language or date restrictions, in the following databases: Medline (via PubMed) and EMBASE.

Using the search tool, we selected MeSH terms from the most relevant publications to conduct a new search, in order to obtain articles that could be included in this systematic review.

In addition, a manual search of theses, meetings, references, study records, and contact with experts in the field was carried out.

Search strategy

The same keywords were used in all databases, respecting their heterogeneities (for example, Emtree terms and MeSH terms were mapped in Embase and Medline, respectively).

The keywords used were: "Pancreatectomy"; "Surgical Suture"; "Surgical Staplers"; "Fistula".

The complete Search Strategy can be found in Supplementary Material 1.

Data extraction

The data for each study were extracted independently by 5 authors (AN, OD, BN, IB, and CB). Disagreements were resolved by consensus. If no consensus was reached, a 6th author (AM) would be consulted. Data extraction was carried out using the Rayyan tool—https://www.rayyan.ai/ [10].

All eligible studies were analyzed according to their titles and abstracts, according to inclusion and exclusion criteria. If the eligibility criteria were met, the full text would be extracted. All studies eligible for qualitative analysis were described in the "Results" section.

Missing data were clarified by contacting the authors directly.

Data validation

5 authors (AN, OD, BN, IB, and CB) carried out the data validation through the discussion of the selected works. If no consensus was reached, a 6th author (AM) would be consulted.

The risks of bias for the studies were assessed using the Study Quality Assessment Tools | National Heart, Lung, and Blood Institute (NHLBI)[11].

Statistical analysis

The studies' socio-demographic and clinical characteristics were presented by frequencies and percentages for qualitative variables and mean or median and standard deviation for quantitative variables.

The meta-analysis was made following Random Effects Models. The studies' heterogeneity was assessed by I2% value (heterogeneity index). The results were presented by forest plot, with relative risk and 95% confidence intervals. The analysis was performed in the software Stata MP 14.0 for Windows.

Results

Research flow

The search strategy resulted in 1083 articles. After removing duplicate articles, 791 remained. After abstract analysis, 119 were found to be potentially eligible studies and were sought for retrieval. Only 1 article was inaccessible to the authors. Of those selected, 107 were not included for not meeting the inclusion criteria: 5 studies included patients whose indications to surgery were trauma related; 2 did not provide complete data; 23 used techniques that will not be discussed in this review (such as fibrin glue, ultrasonic, and radiofrequency transection); 67 had study designs that will not be included in this review (such as letters, other reviews, conference abstracts, and commentaries); 8 did not use ISGPS fistula grade classification or did not include a "biochemical leak/grade A fistula" group; and 2 articles were unrelated to the review question In the end, 11 studies were selected for qualitative analysis[8,12–21] (Fig. 1).

Limitations and methodologies of studies

Among the limitations reported in the studies, small sample sizes and groups not being randomized were the most frequent. Staple heights and drain removal time varying according to surgeon's preference were also mentioned. Two out of 11 articles did not report any limitations.

Quality of evidence

The articles selected for this review compared the main pancreatic stump closure techniques (bare stapler, hand-sewn suture, and reinforced stapler) in human DP regarding their influence on POPF rate and fistula grade according to the ISGPS guideline. After analyzing the studies, the selection, detection, reporting, information, and loss biases were observed to define the quality of the evidence found, with the classification displayed in Figs. 2 and 3.

The studies included in this review show mostly low selection bias. Among the unclear retrospective observational studies, Watanabe et al. cohort determines the number of participants and separates the patients by age, sex, and etiology, but does not show the eligibility criteria. Chikhladz et al. cohort also presents unclear selection bias, since the article did not specify exclusion or inclusion criteria. The cohorts by Tian et al. and Murata et al. show both low selection bias, given that the articles specify eligibility criteria and apply it uniformly throughout all participants, and also identify the patients by their demographic characteristics. The clinical trials by Kondo et al., Diener et al., Merdrignac et al., Wennerblom et al., and Aoki et al., and the phase 2 single arm study by Kawai et al., all show low selection bias. Wallace et al. prospective cohort also presents low selection bias[8,12–21].

Furthermore, the studies selected show mostly unclear detection bias, except Diener et al. clinical trial, which shows low detection bias, since outcome assessors were blinded to participants' group assignments[16].

Analyzing and categorizing POPF according to ISGPS guidelines is a task that needs to be performed by the medical team due to its technical complexity and does not involve information provided by the patients, hence the low reporting bias shown by all the studies analyzed[9].

All of the studies analyzed presented low information bias. This low risk of bias was attained by the observational studies, clinical trials, and the phase 2 single arm study analyzed by correctly following the ISGPS guidelines for pancreatic fistula grading[9].

Lastly, the low loss bias is directly related to the type of intervention being analyzed by the studies. As the patients underwent a complex surgery, it is required that they remain hospitalized after the procedure. This situation decreases the drop-out rate because the participants are under medical care during the whole research, making it easier to implement the protocols designed by each study.

All included articles and their study type can be seen in Table 1.

Characteristics of the studies

The demographic characteristics collected are displayed in Table 2.

11 articles were included, with a total of 1498 participants. The minimum number of participants in a study subgroup was 10 (Reinforced stapler subgroup for Aoki et al.[19]) and the maximum was 232 (Hand-sewn suture subgroup for Chikhladze et al.[12]), 50% of the studies subgroups had at least 59 participants. Considering the total number of participants in a study, the minimum was 22[19] and the maximum was 352[16], 50% of the studies had at least 106 participants.

The mean age of participants was 60.7 years. Most participants were female (51.5%). The results are shown in Table 2.

The most listed comorbidity among the articles was diabetes (5 out of 11 studies reported this information[13–15,18,20]). Hypertension[13], cardiovascular disease[13,17,18], abdominal or back pain[13], lung disease[17,18], neurological disease[17], cerebrovascular disease[13] and hyperlipidemia[13] were also cited.

The selected articles were published between 2007[8] and 2023[14]. These articles were conducted in the following countries: China[13], France[17], Germany[12,16], Japan[8,14,15,19,20], Sweden[18], and USA[21].

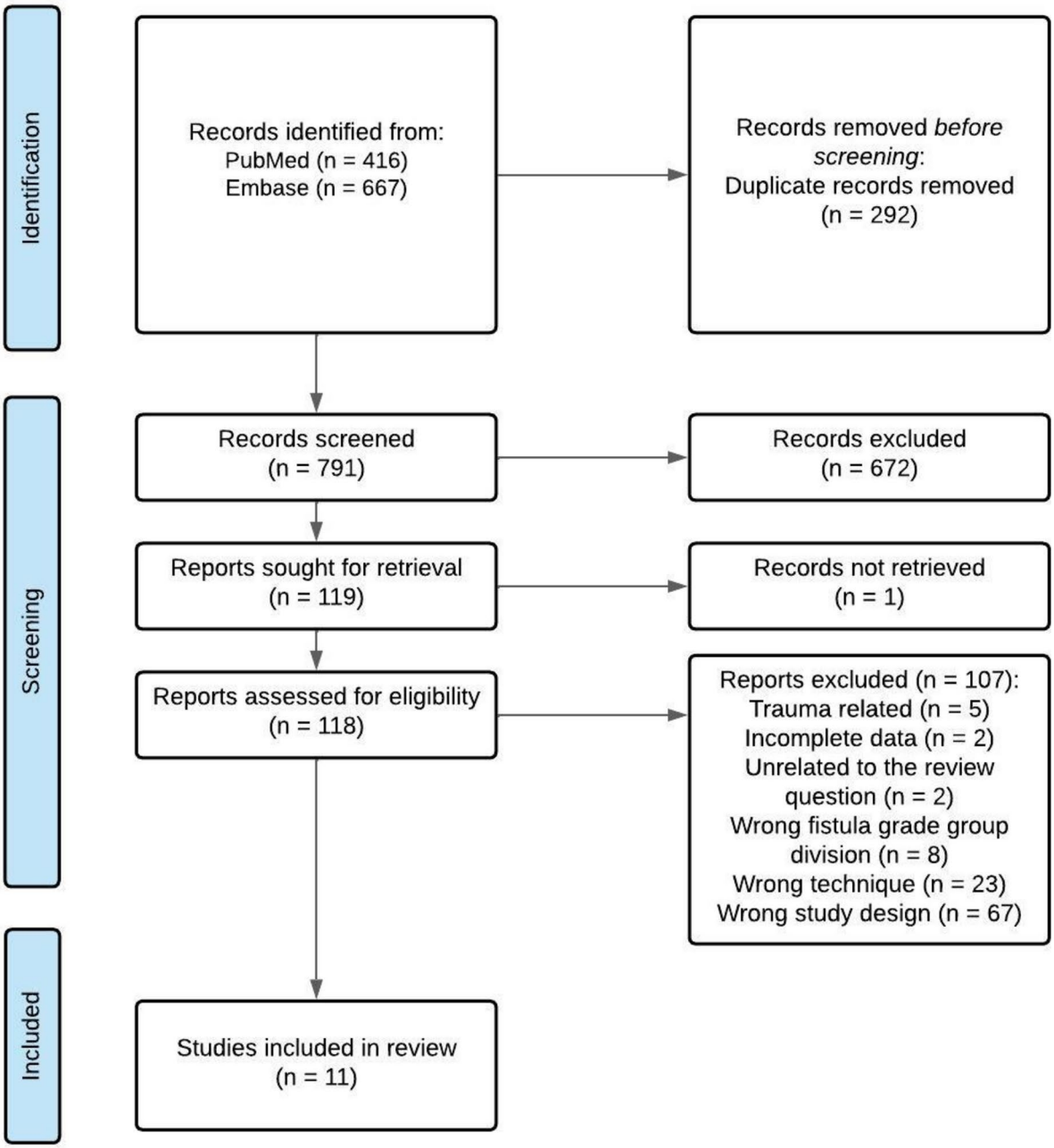

Fig. 1. Research flow.

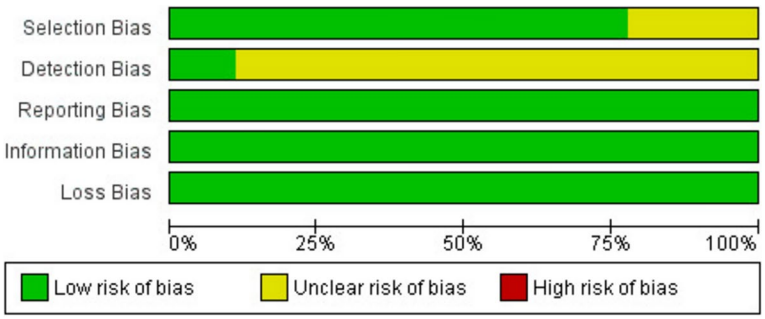

Fig. 2. Graph of risk analysis of general bias in articles.

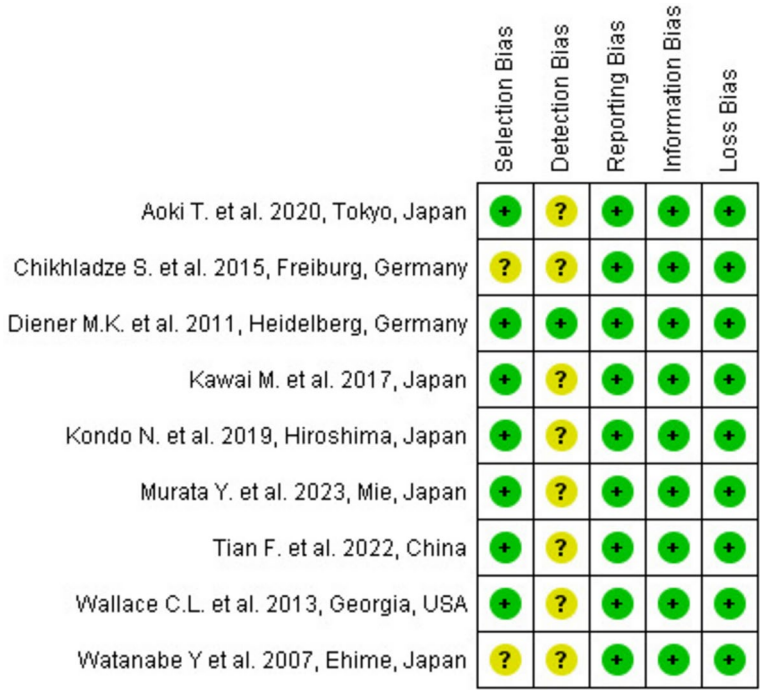

Fig. 3. Summary of risk analysis of general articles bias.

Authors	Year of publication	Type of study
Murata et al. (2023), Mie, Japan	2023	Retrospective observational study
Kawai et al. (2017), Japan	2017	Non-randomized single-arm trial
Watanabe et al. (2007), Ehime, Japan	2007	Observational study
Wallace et al. (2013), Georgia, USA	2013	Prospective cohort
Wennerblom et al. (2021), Sweden	2021	Randomized clinical trial
Kondo et al. (2019), Hiroshima, Japan	2019	Randomized clinical trial
Tian et al. (2022), China	2022	Retrospective observational study
Diener et al. (2011), Heidelberg, Baden-Württemberg,Germany	2011	Randomized clinical trial
Aoki et al. (2020), Tokyo, Japan	2020	Clinical trial
Merdrignac et al. (2022), Lyon, Villejuif, Paris, France	2022	Randomized clinical trial
Chikhladze et al. (2015), Freiburg, Germany	2020	Retrospective observational study

Table 1. Included articles in the Systematic Review and Meta-analysis.

Outcomes

As biochemical leaks are not as clinically significant as grades A, B and C POPF, we did not perform an analysis about this group.

Comparing fistula grade A rates between group "Suture" (control) and "Bare Stapler", revealed no association between type of procedure and fistula rates (relative risk RR 1.24; 95% CI 0.91–1.68). However, only three articles could be included in this analysis and 42.6% of heterogeneity was observed between the studies (Fig. 4).

While also comparing fistula grade A rates for groups "Bare stapler" (control group) and "Reinforced stapler", no difference was found either (relative risk RR 1.00; 95% CI 0.78–1.28) (Fig. 5).

Finally, in regards to fistula grade B/C rates, while comparing "Bare stapler" (control group) and "Reinforced stapler", no significant difference was found again (I-squared = 0.0%, p = 0.784) (Fig. 6).

A comparison of fistula grade B/C rates for "Bare stapler" and "Suture" was not possible, as only one article would be included for this analysis.

This set of results shows a tendency to reveal no difference in fistula rates regardless of the method used for stump closure.

Discussion

Postoperative pancreatic fistula is, without a doubt, one of the most important and grim complications secondary to distal pancreatectomy of our time. This systematic review and meta-analysis compared and identified which stump closure method is responsible for minimum fistula rates.

	Total	Bare Stapler	Reinforced Stapler	Suture
Number of studies	11	9	8	4
Sample size	1498	551	491	456
Age (years)				
Mean (median)	60.7 (61.9)	62.5 (62.6)	58.8 (64.1)	59.0 (59.0)
Minimum–maximum	32.0–73.0	54.5–73.0	32.0–70.0	58.2– 59.8
Sex				
Male	717 (48.5%)	266 (48.3%)	229 (48.6%)	222 (48.7%)
Female	761 (51.5%)	285 (51.7%)	242 (51.4%)	234 (51.3%)
BMI (kg/m^2)				
Mean (median)	23.6 (23.2)	23.6 (23.6)	23.4 (22.9)	24.0 (24.0)
Minimum–maximum	20.8–26.8	20.8–26.8	21.5–26.7	22.5–25.4
Spleen-preserving/splenectomy				
Spleen-preserving	381 (26.8%)	156 (29.9%)	119 (26.7%)	106 (23.2%)
Splenectomy	1041 (73.2%)	365 (70.1%)	326 (73.3%)	350 (76.8%)
Type of surgical approach				
Open	702 (60.9%)	256 (64.4%)	137 (41.9%)	309 (72.2%)
Laparoscopic	450 (39.0%)	141 (35.5%)	190 (58.1%)	119 (27.8%)

Table 2. Demographic description of studies included in the systematic review. *BMI* Body Mass Index.

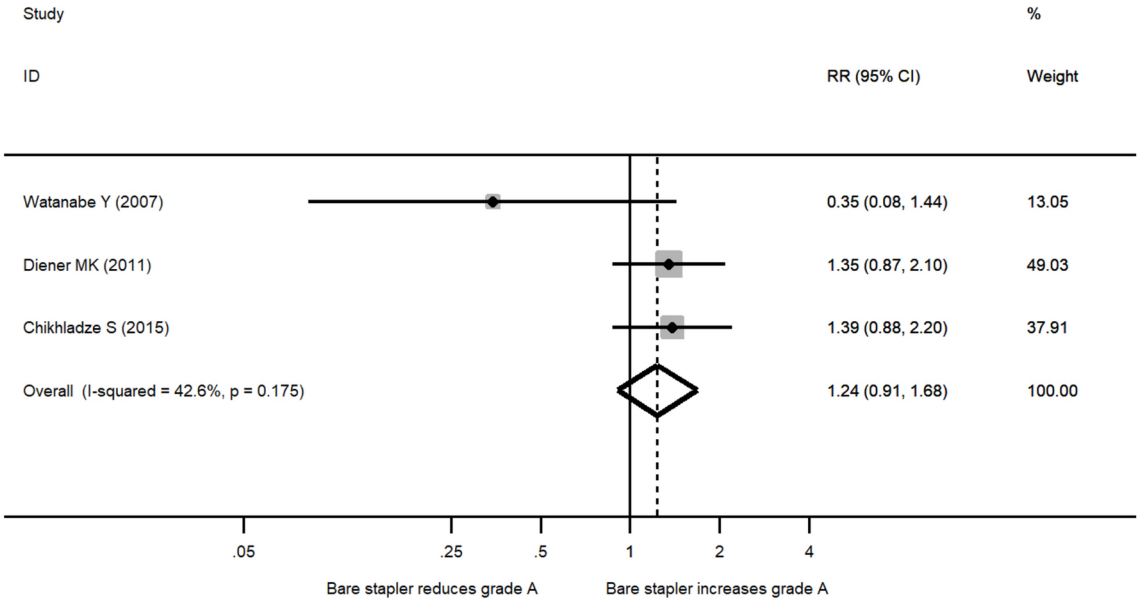

Fig. 4. Forest Plot for fistula grade A rate for Suture (control group) vs Bare Stapler.

Although numerous techniques have been cited to try to reduce fistula rates, such as methods of pancreas transection and reconstruction, we exclusively focused on stump closure strategies. This is the reason why approaches like harmonic scalpel transection, radiofrequency ablation, fibrin glue, ligament patches, and different types of anastomosis were not included in this review.

The last two meta-analyses assessing this subject were published in 2018 (Tiefrunk et. al.[22]) and 2019 (Ratnayake et. al.[23]). Both of them had a different methodology, comparing multiple strategies to reduce fistula rates, not only stapler and suture. Also, neither of these articles compared bare stapler and reinforced stapler as distinct techniques, combining these two different types of patients in the same group. Tiefrunk et al.[22], when comparing suture and stapler, included two randomized clinical trials (totaling 381 patients), finding no difference between these two groups of interest. Ratnayake et al.[23] included the same RCTs and also found the same results. Our review included five clinical trials, four of these being multicenter randomized ones, updating the literature with new valuable information.

Our analysis found no significant differences between suture, bare stapler, and reinforced stapler in fistula rates. This conclusion confirms the tendency found in the last meta-analyses, but with a higher number of

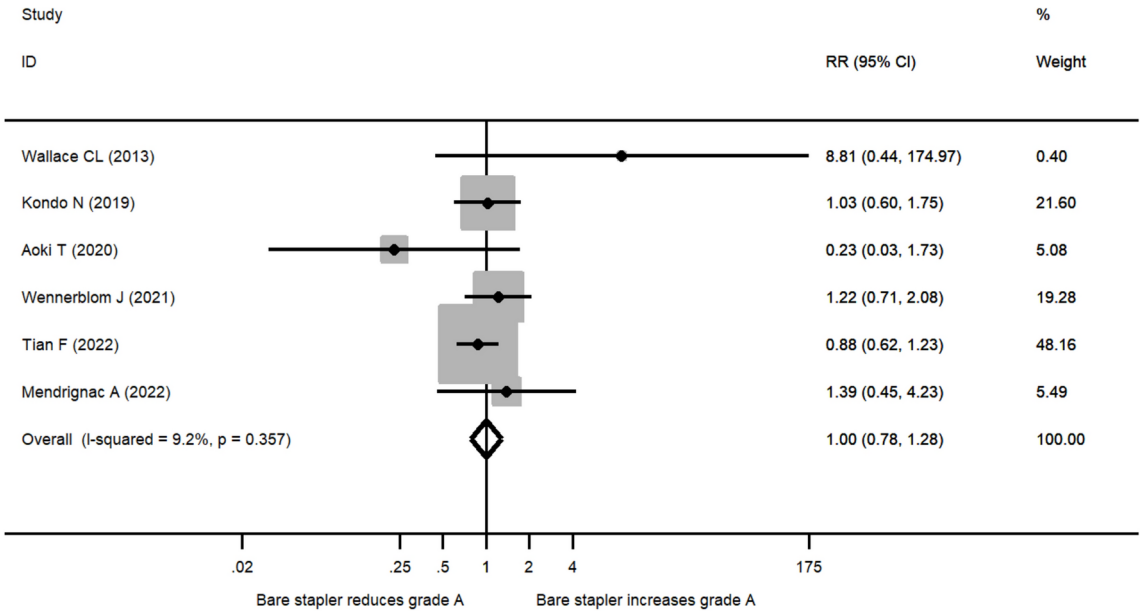

Fig. 5. Forest Plot for fistula grade A rate for Bare Stapler (control group) vs Reinforced Stapler.

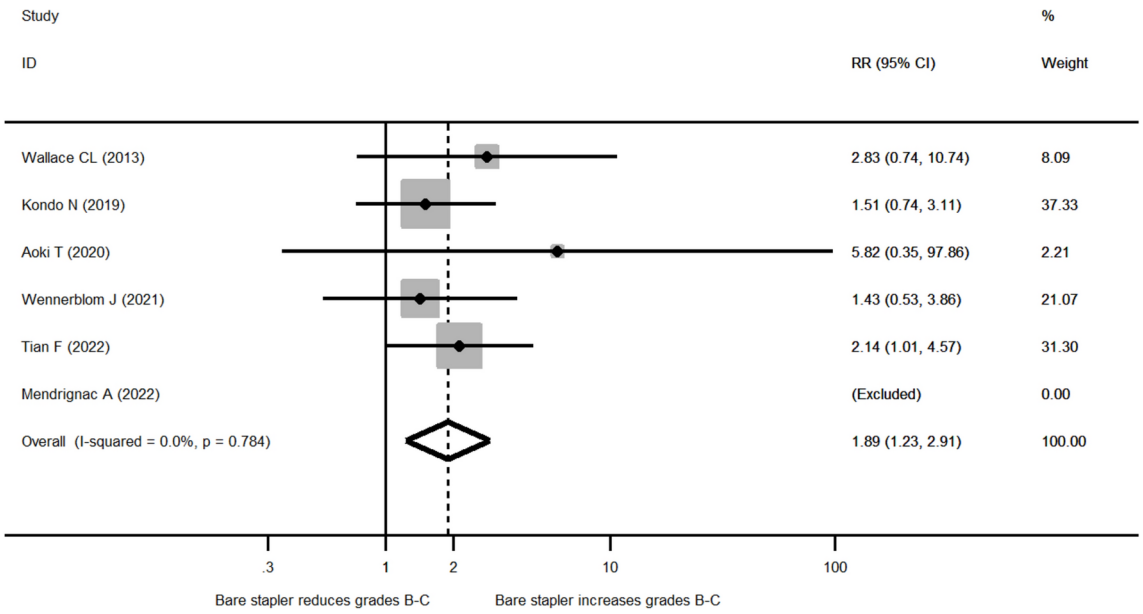

Fig. 6. Forest Plot for fistula grade B/C rate for Bare Stapler (control group) vs Reinforced Stapler.

patients in clinical trials (799 in this review when compared to the 381 patients in the previous one) and double the number of randomized clinical trials[22].

On the subject of study types and their results, an interesting contrast was found. Most observational studies (3 out of 4) concluded that staplers led to lower fistula rates, while clinical trials (5 out of 6) determined that there was no difference between suture and staplers. This happened because of the intrinsic differences in methodology between various study types.

It is relevant to note that reinforced staplers are sold at higher prices than their bare counterparts. An unit of bare stapler 60 mm cartridge costs approximately $260.00[24], while its reinforced counterpart is sold at $350.00[25], an approximately 35% higher price. Based on this review's results, usage of bare stapler could help to cut expenses without risking postoperative results. This reasoning is especially important for medical centers with limited resources, where the price discrepancy between types of staplers may culminate in supply shortage in other situations.

In regard to the choice of stapler or suture, the insignificant difference suggests that the surgeon in charge should choose the method which they feel most comfortable performing. Suture is more ability-based and

requires more training to be executed satisfactorily. However, different surgeons have different skills and should choose the technique they are more comfortable or proficient performing. This meta-analysis shows that this choice should not interfere with the operation outcome.

Many authors have proposed fistula risk scores after distal pancreatectomy. The most recent and distinguished ones are Distal Pancreatectomy Fistula Risk Score (D-FRS) by Pastena et al., and DISPAIR Fistula Risk Score (DISPAIR-FRS) by Bonsdorff et al.[26,27]. A 2024 retrospective analysis of these scores concluded that they both accurately predict POPF occurrence after DP[28]. These scores consider factors such as pancreatic duct size, pancreatic neck thickness, BMI, operating time and diagnosis of diabetes mellitus. Most articles we included in this review did not present many of these variables, so it was not possible to perform an analysis on this matter. We suggest future articles to include this information, as it provides an interesting perspective on risk factors to POPF development, other than surgery technique.

It is also important to comment on the 2024 PANDORINA multicenter randomized trial, which concluded a no-drain policy after DP reduced POPF development[29]. This should be considered by surgeons just as much as stump closure technique.

Our systematic review does have some limitations. We initially intended to perform comparisons about postoperative complications other than POPF rates, such as blood loss and intra-abdominal abscess, other demographic characteristics, as transection level and ASA score. However, this analysis was not possible because the articles included this information in small sample sizes and/or few articles included this information at all. Another difficulty found was POPF categorization between articles. We aimed to make a high value analysis, only including those that followed the ISGPS classification. Many studies were excluded during full text screening because they grouped patients with no fistula and those with grade A fistula in their analysis. Although biochemical leak is less severe than clinical relevant fistula, it should not be considered the same as developing no fistula at all, when discussing methods to prevent fistula development[2].

We suggest that the next studies assessing this theme report about postoperative complications and intraoperative variables, as an analysis about the impact of the stump closure methods in operative time, intraoperative blood loss, hospital stay, mortality rate, pancreatic neck thickness and pancreatic duct size would be appealing for pancreas surgery research.

In conclusion, our systematic review and meta-analysis found that there is no statistically significant difference in fistula rates in stump closure performed using suture, bare stapler or reinforced stapler. This choice should be made by the surgeon in charge, considering their expertise and abilities, and hospital administration, when evaluating expenses and resources.

Data availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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Author contributions

Authors' Contributions were classified according to the Contributor Roles Taxonomy (CRediT), as following: AOSN: Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Writing—Original Draft; ODCS, BND, ICBB, CMOB: Data Curation, Formal Analysis, Investigation, Writing—Original Draft; JVT, LZP: Formal Analysis, Validation, Writing—Review & Editing; LRI, WTH, LACD, WA: Methodology, Project administration, Supervision, Writing—Review & Editing; AM: Conceptualization, Investigation, Methodology, Project administration, Supervision, Writing—Review & Editing. All authors have approved the submitted version and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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