REVIEW REPORT

Title: Double loop reconstruction with isolated gastric limb after pancreaticoduodenectomy

Authors: Md. Emran Ali, Abdullah Md Abu Ayub Ansary, Mohammad Saief Uddin, Muhammad Salauddin, Kamrul Afsar Hillol, Bidhan Chandra Das, Md. Mohsen Chowdhury

Reviewer A: **Anonymous,** **COI:** **None,** **AI disclosure:** **None**

1. Comment The Title was appropriate, but I suggest revising the title to double loop reconstruction with isolated gastric limb after pancreaticoduodenectomy: A Randomised Controlled Trial.

Response: We appreciate the suggestion. However, we addressed the corrections given by Reviewer 3 and keep the title as "Double loop reconstruction with isolated gastric limb after pancreaticoduodenectomy" (Line 2)

3. Comment Methods: The randomisation procedure is not clear

Response: The procedure has been revised under the "Allocation of reconstruction technique"
Now looks like

Following completion of the resection phase and confirmation that PD could be performed, patients were allocated to one of the two reconstruction techniques using a predefined alternating sequence. Patients were assigned consecutively to either conventional single-loop reconstruction or Roux-en-Y double-loop reconstruction with an isolated gastric limb. Once the 1:1 ratio was fulfilled during the study period the recruitment was stopped. (Lines 165-170)

4. Comment References are not sequentially ordered.

Response: We rearranged the references throughout the document as well as updated the references as advised.

Reviewer E: **Kazi Mahzabin Arin,** **ORCID:** **0009-0004-0064-3847,** **COI:** **None,** **AI disclosure:** Artificial intelligence–based tools were used solely for language editing, formatting, and structural refinement of the manuscript. All intellectual content, data interpretation, and scientific conclusions were developed and verified by the authors. The AI tool did not generate or modify any study data or results.

6. Comment Abstract

The study duration is not similar in the abstract and methods section (Lines 49-50, 117). The manuscript states that patients were divided "randomly," while the abstract reports alternate assignment (Lines 50-51, 123). Please specify the outcome variables (Line 51- 52). Patients were enrolled and 5 were excluded later on (as written in the Methods section); so the abstract should match withing. This statement given in lines 60-61 is irrelevant to the study aim.

The conclusion should be more cautious because the sample contains only 15 patients per group. Trial registration is not reported.

Response: Provided "This interventional study" in (Line 44).

We streamlined the study duration (Lines 45 and 129);

The information in abstract and methods section (Line 46-48, 166-170);

Streamlined this allocation throughout the document.

Aim of the study as per the findings (Lines 41-42 and 121-123); and conclusion (Lines 59-61 and 348-353)

We have not taken the trial registration number for this study.

7. Comment Objective: The study aim is not clearly defined (Lines 112-113).

Response: We have revised the objective as advised. Now it looks as – "to evaluate whether Roux-en-Y double-loop reconstruction with an isolated gastric limb reduces the incidence of DGE and influences POPF-related outcomes compared with conventional single-loop reconstruction after pancreaticoduodenectomy"

8. Comment Introduction and Rationale: The Introduction provides a general explanation of DGE and POPF after pancreaticoduodenectomy. However, the rationale should be better focused. Authors need to cite appropriate references to support the statement that no national data are available or qualify it as an observation from the authors' literature search;
The authors need to clearly explain the anatomical or physiological basis by which an isolated gastric limb may reduce DGE

Response: As advised, we have revised the entire introduction with rationale and also provided updated supportive references (Lines 71-123).

9. Comment Methods: CONSORT flow diagram needs to be added. The manuscript states that predefined inclusion criteria were used, but inclusion and exclusion criteria are not presented. These must be added. The Methods section states that patients were divided "randomly," but it provides no information about:

- the random sequence-generation method;
- allocation concealment;
- who generated the sequence;
- who enrolled participants;
- when allocation occurred;
- whether outcome assessors were blinded.

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Response: We have provided the CONSORT flowchart as Figure 1. The inclusion and exclusion criteria have been given in Methods section (Line 145). We have described the subject recruitment process in separate heading (Lines135-145).

10. Comment Alternate allocation is predictable and does not provide adequate allocation concealment. Therefore, the design should be accurately classified according to the procedure actually used.

Response: We tried to stated the design according to the procedure of the study (Lines 165-170).

11. Comment Table 1: Variable name- age group needs to be mentioned; Minimum and maximum are not needed

Table 1 reports a minimum age of 14 years in the double-loop group, although the presented age groups are 30-60 and 61-70 years. The double-loop group column reported 12 patients as 80% and three as 30%; three of 15 should be 20%, not 30%. Please correct this %. The authors need to clarify:

- whether a 14-year-old participant was enrolled; whether paediatric participation was permitted by the eligibility criteria and ethics approval; whether parental consent and participant assent were obtained; why the participant is not represented in the age group categories.

Response: Re-writed as "Age group in years. The percentage calculations were recalculated and are now accurate. It's a typo. It is 24 years.

12. Comment Figure 1: Values must be recalculated from the raw data and reported consistently. The authors should specify whether an independent-samples t-test or Mann-Whitney U test was used and justify the choice based on the distribution.

The figure should also present an informative summary, such as median and interquartile range or mean with confidence interval, rather than unexplained individual points alone.

Response: We have removed the Figure 1 as advised by one reviewer and explained in text only.

13. Comment Results: Varied numerically- what does that mean? (Lines 191-192). Authors did not see prevalence of comorbidities; it is a background clinical variable. It is better to write in one sentence that baseline demographic and clinical characteristics are matched between the two groups (Lines 191). Hospital-stay results are contradictory. Hospital-stay comparisons are reported differently in separate sections: the abstract gives P=0.87; the Results text gives P=0.193; Figure 1 shows P=0.87.

Response: We have revised prevalence as proportion (Lines 255). Thank you for identifying this inconsistency. We have carefully checked the hospital-stay data and corrected the discrepancy to ensure that the Results and Abstract are consistent. Checked and revised the figures (Lines 56, 280).

14. Comment Do not repeat all numerical findings at the beginning of the Discussion. Begin with one concise statement of the main finding. This part of the discussion is irrelevant to the study objectives (Lines 245-250).

Response: Thank you for the suggestion. We have revised the opening of the Discussion to begin with a concise statement of the main finding instead of repeating the numerical results. Thank you for this valuable comment. We agree that the deleted section was not directly relevant to the study objectives. Accordingly, this part of the Discussion section has been removed from the revised manuscript to improve its focus and clarity.

15. Comment Strength and limitations of the study have not been discribed

Response: We mentioned the strength and limitations (Lines 333-346)

16. Comment Conclusion: Make it brief. Do not need to repeat all the results. Please focus on the primary outcome.

Response: We have revised the Conclusion to make it more concise and focused on the primary outcome without repeating the detailed results. (Lines 348–353)

17. Comment References: Line no. 238-241: Reference 15 contradicts the write-up. "Multivariate analysis found relatively high body mass index, laparoscopic surgery, and soft or moderate pancreatic texture independent risk factors for CR-POPF."

Line no. 277-278:Reference 23 is explicitly marked in the reference list as having been retracted, yet it is cited positively in the Discussion to support the benefit of enteral nutrition. A retracted article must not be used as evidence for a clinical claim.

Response: We have revised the relevant statements to accurately reflect the cited evidence and have removed the retracted reference, replacing it with an appropriate, non-retracted reference.

Reviewer F: **Sonjoy Biswas,** **ORCID:** **0009-0005-4077-2894,** **COI:** **None,** **AI disclosure:** **None**

18. Comment The title may sound better using a single clause (i.e. "Double loop reconstruction with isolated gastric limb after pancreaticoduodenectomy"). The short title should be shorter (i.e. "Double-Loop Reconstruction After Pancreaticoduodenectomy") Line 5.

Response: Thank you for your valuable suggestions. We agree with it and revised the title and short title as advised.

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19. Comment

- P-value" might have been replaced by calculation with "95% CI" for better clarification of the analysis (Lines 57, 59).
- The acronyms 'RIGL' and 'POPF' might have been avoided (Line 47).
- Although the objective includes evaluation of postoperative pancreatic fistula (POPF), the results demonstrate no significant difference in POPF incidence (which is not mentioned in the abstract at all), while the conclusion emphasizes easier fistula management without providing supporting data.
- Referring to "keywords", "Whipple procedure" is mentioned; however, in the abstract, this term is not mentioned at all (Line 64).
- "Key message" should be a little elaborated up to 50-60 words as it counts only 26 words.

Response: We have avoided the use of these acronyms at first mention and used the full terms for better clarity. We revised the conclusion. "Whipple procedure" and "pancreaticoduodenectomy (PD)" were used as search terms, as they are synonymous and used interchangeably in literature. We have elaborated the key messages as recommended word limit (Lines 66-70).

20. Comment Objective: Although the objectives have been depicted, it can be clarified and elaborated (Lines 45-47 and 112-113).

Response: We have revised the objective as advised. Now it looks as – "to evaluate whether Roux-en-Y double-loop reconstruction with an isolated gastric limb reduces the incidence of DGE and influences POPF-related outcomes compared with conventional single-loop reconstruction after pancreaticoduodenectomy"

21. Comment Introduction: The rationale for Roux-en-Y reconstruction with an isolated gastric limb (RIGL) is not clearly explained. Therefore, this can be clarified in this context (Lines 108-113).

Response: As advised, we rephrased the rationale and elaborated it (Lines 112-118).

22. Comment Methods: The methods described are satisfactory. But, the sampling technique, sample size and 'randomization' should be to further explanted.

Response: We have given the "Power of the study" under Methods section.

23. Comment The inclusion and exclusion criteria are not mentioned at all (Line 119). It is mentioned as "anti-colic gastro-jejunostomy". I think the term should be "ante-colic" (Line 148). The definitions given by the "ISGPS" an "CDC guidelines" should be explained (Lines 162-169). In the methodology, how the DGE is measured and grading of severity of POPF should be explained.

Response: Given the inclusion and exclusion criteria. We have revised the term. (Lines135-140). Explained in separate sub heading under methods section (Lines 212-219)

24. Comment Appropriate and thorough description of the Statistical methods.
:"....standardized procedure"... please explain (Line 172).
"Post-operative visit in 30-days" is mentioned. But there is no clue about it in the result or discussion parts (Lines 166-169).
Please avoid the acronyms of MPD and CBD.
SLR & DLR ... please avoid the acronyms.
Please explain 95% CI and its significance, if you use later for inference.

Response: Post hoc power analysis has been given in separate heading. Thank you for these helpful suggestions. We have revised the manuscript accordingly by addressing the statement on the 30-day postoperative follow-up aa routin process and replacing the acronyms with the full terms for better clarity.

25. Comment Quality, clarity and appropriateness of the Table(s).
Table 1: Grouping of age does not help in entire study. So, it may be better to avoid. Mean (SD) and Number (%) may be used separately to have a better glance.
Table 2: Mean (SD), median (IQR) and Number (%) may be used separately to have a better glance.
Table 4: This table should be more self-explanatory; i.e. grading of POPF and GDE are to be explained in the footnotes.

Response: We Removed the age groups. We rearranged the variables, we explained in footnote for making the tables self explanatory.

26. Comment Figure 1: This figure is not well-explanatory and does not create much attention. So, it can be omitted and the finding can be merged with previous suitable table.

Response: We removed the figure and explained in the text

28. Comment Table 3 depicts 1 patient was re-admitted in the DLR group. What is the reason? This is neither mentioned in the result part, nor discussed in the discussion part. Line 166-169: Post-operative visit is mentioned. But there is no clue about it in the result, table or discussion parts

Response: We mentioned as it is a routine process of the hospital. However, we have removed this from the discussion.

29. Comment The discussion is comprehensive but overly long and repetitive. It overstates causality ("DLR emerges as a promising alternative") despite likely limited sample size and non-randomized design. Several grammatical errors reduce clarity ("POPF less frequently observed," "there is no perioperative mortality"). Literature review is extensive but sometimes distracts from the study's own findings, and unsupported interpretations (e.g., DLR mitigating high-grade DGE) should be more cautious.

Response: We revised accordingly

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30. Comment The strengths and limitations are not described / explained at all in any part of the discussion.

Response: We added the strength and limitations (Lines 333-346).

31. Comment The conclusion is partially supported by the data. The results demonstrate no significant difference in POPF incidence, while the conclusion emphasises easier fistula management without providing objective supporting data. So, recommendations favouring DLR should be more cautious

Response: Revised the conclusion as advised (Lines 348-353)s

32. Comment As the Vancouver method is used in citations, so the use. Although the references are reasonable, citations #2, 3, 9, 12, 13, and 14 are too old to be cited, as there is an abundance of references regarding this study.

Response: We have updated the reference list by replacing older citations with more recent and relevant references where appropriate. The Vancouver style used throughout texts.

33. Comment Storytelling: The message is simple, but the storytelling can be more palatable by avoiding '....et al. '. The number of paragraphs might have been reduced by making the single paragraph a little longer. Minor grammatical errors and repetitive statements also reduce the overall strength and precision of the storytelling.

Response: We revised the entire manuscript to improve the storytelling and corrected the grammar

34. Comment The "Key message" should be up to 50-60 words (now, it is 26 words).

Response: We have expanded the Key Message to the recommended length (Lines 66-70).