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Zhang, J¹; You JY².**ADMINISTRATIVE INFORMATION****Support -** No.**Review Stage at time of this submission -** Data extraction.**Conflicts of interest -** None declared.**INPLASY registration number:** INPLASY202390017**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 September 2023 and was last updated on 06 September 2023.**INTRODUCTION**

Review question / Objective Risk of bias of existing pancreatic fistula prediction models. The practicability and effectiveness of the prediction model were evaluated.

Condition being studied Pancreatic fistula is the most common complication after pancreatic surgery and one of the reasons for the increased mortality after pancreaticoduodenectomy. At present, there are many prediction models for the risk of pancreatic fistula in patients after pancreatic surgery, but the risk of bias in the process of model establishment and validation has not been known. In this study, PROBAST was used to evaluate the bias line of these related literatures, and to evaluate the feasibility and applicability of these prediction models for pancreatic fistula.

METHODS

Search strategy ((risk scale) OR (prediction model)) OR (prognostic model)) AND (pancreaticoduodenectomy) AND (postoperative pancreatic fistula).

Participant or population Patients who underwent pancreaticoduodenectomy or laparoscopic pancreaticoduodenectomy.

Intervention No intervention.

Comparator No.

Study designs to be included To build up the forecast model on the pancreatic fistula and validation studies.

Eligibility criteria Inclusion criteria: (1) existence of prediction model; (2) after pancreaticoduodenectomy or laparoscopic pancreaticoduodenectomy; (3) Full text of paper; (8) English papers. **Exclusion criteria:** (1) lack of prediction model; (2) systematic review; (3) descriptive/narrative review; (4) previous meta-analysis; (5) the paper without full text; (6) lack of abstracts; (7) research do not belong to the development and validation of models, such as: explore the forecasting model of clinical practical value of research.no.

Information sources We systematically searched PubMed, web of science library databases from their inception to August 31, 2023 for relevant articles.

Main outcome(s) PROBAST was used to assess the risk of bias of existing fistula risk score(FRS) models.

Additional outcome(s) Existing validity and the practicability of the FRS.

Data management For each relevant publication, two reviewers extracted information through a piloted standardized form based on the recommendations in the CHARMS checklist. The key items to be extracted from each primary study were grouped within 11 domains, including source of data, participants, outcome(s) to be predicted, candidate predictors, sample size, missing data, model development, model performance, model evaluation, results, interpretation, and discussion. In addition, we extracted the general characteristics of the studies, including title, author, publication year, and specific objective (i.e., to develop or to validate or both). Model performance is typically evaluated using measures of calibration and discrimination. Calibration reflects the disparity between predictions and observed outcomes.

Quality assessment / Risk of bias analysis The PROBAST was used to assess the risk of bias (ROB) of each prognostic model identified from the included studies. Two investigators assessed ROB for each model independently.

Strategy of data synthesis We conducted a descriptive analysis of the characteristics of models and reported mean or median for continuous variables, with differences calculated using t-test or Kruskal–Wallis test, or percentages for categorical variables, with differences calculated using χ^2 test or Fisher's exact test. We compared the number of sample size and events

and the proportion of methodological items and predictors used in the models across three categories.

Subgroup analysis To explore the source of heterogeneity from the perspective of clinical heterogeneity and methodological heterogeneity, and fundamentally solve the problem that only homogeneity can be used to combine the effect size. Subgroup analysis can be performed according to age, disease severity, gender, design, etc.

Sensitivity analysis Certain ambiguous studies were included or excluded, regardless of whether they met the inclusion criteria. Data were reanalyzed using certain study estimates with less definitive outcomes. Data were reanalyzed after reasonable estimation of missing data. Data were reanalyzed with different statistical methods, such as random-effects models instead of fixed-effects models. After the literatures with poor quality were proposed from the included studies, Meta-analysis was performed again to compare whether there was a significant difference between the combined effects before and after. A stratified Meta-analysis was conducted according to different study characteristics, such as different statistical methods, methodological quality of the study, sample size, and whether unpublished studies were included.

Language restriction English, Chinese.

Country(ies) involved China.

Keywords Pancreatic fistula, predictive model, risk of bias.

Contributions of each author

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