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A Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis analysis to evaluate the quality of reporting of postoperative pancreatic fistula prediction models after pancreatoduodenectomy: A systematic review

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ABSTRACT

Background: Postoperative pancreatic fistula is a frequent and potentially lethal complication after pancreatoduodenectomy. Several models have been developed to predict postoperative pancreatic fistula risk. This study was performed to evaluate the quality of reporting of postoperative pancreatic fistula prediction models after pancreatoduodenectomy using the Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) checklist that provides guidelines on reporting prediction models to enhance transparency and to help in the decision-making regarding the implementation of the appropriate risk models into clinical practice.

Methods: Studies that described prediction models to predict postoperative pancreatic fistula after pancreatoduodenectomy were searched according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The TRIPOD checklist was used to evaluate the adherence rate. The area under the curve and other performance measures were extracted if reported. A quadrant matrix chart is created to plot the area under the curve against TRIPOD adherence rate to find models with a combination of above-average TRIPOD adherence and area under the curve.

Results: In total, 52 predictive models were included (23 development, 15 external validation, 4 incremental value, and 10 development and external validation). No risk model achieved 100% adherence to the TRIPOD. The mean adherence rate was 65%. Most authors failed to report on missing data and actions to blind assessment of predictors. Thirteen models had an above-average performance for TRIPOD checklist adherence and area under the curve.

Conclusion: Although the average TRIPOD adherence rate for postoperative pancreatic fistula models after pancreatoduodenectomy was 65%, higher compared to other published models, it does not meet TRIPOD standards for transparency. This study identified 13 models that performed above average in TRIPOD adherence and area under the curve, which could be the appropriate models to be used in clinical practice.

Introduction

Pancreatoduodenectomy (PD) is a complex procedure usually performed in case of malignant tumors of the pancreatic head or periampullary region. Over the past decades, the mortality of pancreatic resections has been reduced to <5% as an effect of centralization of care. However, the overall morbidity of pancreatic resections is still high, ranging from 30% to 60%.[1–3] The most serious complications after pancreatic resection originate from anastomotic leakage, especially of the pancreatic anastomosis, also known as a postoperative pancreatic fistula (POPF). A POPF has a high prevalence rate that ranges from 5% to 30%.[4,5] The International Study Group for Pancreatic Surgery developed a definition and grading for POPF. Type A pancreatic fistula, also known as biochemical leakage, according to the updated International Study Group for Pancreatic

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Surgery definition, has no clinical symptoms or consequences. Type B and C pancreatic fistula are known as clinically relevant POPF.[6] A POPF is a serious complication that can lead to increased postoperative morbidity and may prolong hospital stays and increase medical costs.[7–9] A POPF can be a potentially life-threatening complication in the case of postpancreatectomy hemorrhage.[10,11] There are many risk factors for POPF described in the literature, such as a small pancreatic duct diameter <3 mm, soft pancreatic texture, nonpancreatic cancer pathology, obesity in combination with cardiovascular diseases, intraoperative blood loss, male sex, age above 60 years, and diabetes mellitus.[5,12–15]

Over the past decade, several fistula risk models have been developed to predict POPF to optimize individual treatment decisions (such as drain placement and the use of somatostatin analogs), improve postoperative management, and reduce complication rates.[16] Furthermore, individual risk estimation could provide a solid basis for shared decision-making. The most cited and most used model for predicting POPF is the validated Fistula Risk Score (FRS) by Callery et al.[17]

The FRS predicts POPF based on pancreatic texture, pancreatic duct diameter, intraoperative blood loss, and definitive pathology.[17] Other fistula risk models use different input parameters; some include preoperative variables, whereas others use intraoperative variables. To be able to judge individual risk models on their merits and identify the best-performing models for clinical implementation, it is important to evaluate the quality of reporting and assess model performance through external validation.[18] The general guidelines of the Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) checklist were published in 2014 to enhance the transparency of the reporting of prediction models. With respect to POPF, there are many prediction models developed and validated, many of which have fair to good performance upon internal and/or external validation, and this was mainly represented as an area under the curve (AUC). However, the quality of reporting of prediction models on POPF is not investigated yet. Therefore, the current study was performed to evaluate the quality of reporting of prediction models on POPF after pancreatoduodenectomy using the TRIPOD checklist in relation to models' performance (AUC) and to find the best-performing models in both AUC and TRIPOD adherence to guide decision-making regarding the implementation of the appropriate prediction models into clinical practice.

Material and methods

Search strategy

This systematic review study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The following databases were searched for relevant articles: PubMed, Embase, Scopus, Web of Science, and Cochrane. Additionally, the reference sections of the included articles were cross-checked to find additional relevant articles. The search terms used were pancreatoduodenectomy, prediction, risk model, calculator, score, pancreatic fistula, and Whipple. The last search was conducted on December 29, 2022. Figure 1 shows a flow chart of the search strategy and the included articles. There was no need for approval from the ethics committee due to the nature of this study. The reference list of the included studies can be found in Table I.

Inclusion and exclusion criteria

Studies that describe the development and/or validation of a multivariable prediction model as well as diagnosis or prognosis outcomes for POPF after open or laparoscopic PD or pylorus-preserving PD were included in this study. Publications that did not meet this inclusion criteria were excluded. Risk models developed for other types of pancreatic resections and studies that investigated only risk factors with no calculator were excluded. Articles that were not written in English, abstract only, comments, and posters were excluded. One study was excluded from the analysis due to the lack of AUC. There was no exclusion of articles based on the publishing date.

Data extraction

All extracted articles were directly imported into EndNote 20.4 software. Next, duplicates were generated and removed automatically by this software. After that, inclusion and exclusion criteria were applied to the remaining articles. The following data were extracted from the relevant articles: year of publishing, study type, AUC, and additional performance measure. The relevant studies were divided into 4 main categories: development, incremental value, external validation, or both development and external validation. The TRIPOD checklist with 22 items, as indicated in Supplementary Appendix S1, was used to evaluate the adherence rate. The 22 main items were divided into subitems. The maximum score of the main and subitems was 30 points for the development studies, 35 points for the validation and incremental value studies, and 36 points for the combined development and validation studies.

TRIPOD analysis

All 52 studies were divided into the 4 main subcategories: development. external validation, incremental value, and both development and external validation. Each study was evaluated using the TRIPOD checklist. Checklist scoring was performed separately by different investigators (Z.A., L.D., and R.L.). During the analysis when the study type is both development and external validation, the AUC that was extracted was for the external validation cohort, whereas in the studies that evaluated multiple risk models or all variants of the Fistula Risk Scores, the highest AUC or the AUC of the ua-FRS were extracted, respectively. Some TRIPOD items designed to evaluate a specific type of study, for example, items 10a, 10b, 14a, 15a, and 15b, are unsuitable for evaluating external validation studies. The same applies to items 10c, 10e, 12, 13c, 17, and 19a, which are not relevant for development studies. Item 21 concerning supplementary information is not included in the overall score. The results were compared, and the items scored differently by the investigators were re-evaluated until a consensus was reached.

Statistics

Statistical analysis was performed using SPSS Statistics version 28 (IBM SPSS, Inc, Armonk, NY). Descriptive statistics were calculated as percentages, median, or mean as appropriate. The IQR and SD were calculated as appropriate. A 2-tailed t test was used to calculate the P value. The AUC was extracted from each study to measure predictive multivariable model performance. In addition, clinically relevant performance measures such as model calibration and assessment of clinical usefulness were extracted if reported. A quadrant matrix chart was created to plot AUC against TRIPOD adherence using Microsoft Office Excel, version 16.69 (Microsoft, Corp, Redmond, WA).

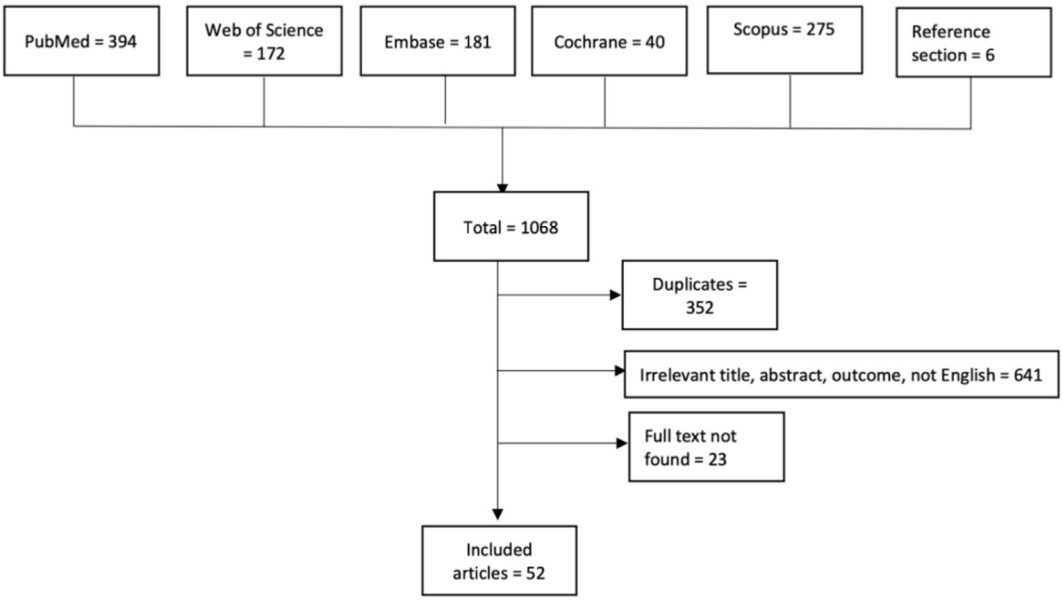

Figure 1. Flow chart of the search strategy.

Results

Through our electronic search, we identified 52 studies reporting the development and/or validation of prediction models for POPF after PD. Twenty-three of these studies reported the development of a fistula risk model. Fifteen studies reported the external validation of an existing fistula prediction model. Four studies were incremental value studies and investigated the impact of adding a particular variable on the model performance. Ten studies reported both the development and the external validation of a prediction model for pancreatic fistula.

The overall adherence to the TRIPOD items ranged between 38% and 90%, with both a mean and median adherence rate of 65% (SD of 10% and IQR of 60%–70%) (Tables I and II). The adherence rate for the development studies ranged between 48% and 77%, with both mean and median adherence rates of 63% (SD of 7% and IQR of 57%–68%). For the validation studies, the adherence rates ranged between 47% and 90%, with a mean and median adherence rate of 66% and 67%, respectively (SD of 10% and IQR of 60%–73%). Incremental studies had a TRIPOD adherence range between 38% and 77% with a mean and median adherence rate of 61% and 64%, respectively (SD 17% and IQR of 43%–75%). The adherence rates for the development and validation studies ranged between 61% and 89%, with a mean and median adherence rate of 72% and 68%, respectively (SD of 10%, IQR of 64%–82%) (Table II).

Of all evaluated studies, 3 had an adherence rate lower than 50%. Twelve studies had an adherence rate of 51% to 60%, and most studies ($n = 31$) had an adherence rate of 61% to 75%. Only 6 studies had an adherence rate higher than 75% (Figure 2).

An adherence rate of 100% was achieved on items 5c and 19a, meaning that all authors specified the treatment participants received. Furthermore, all authors gave an overall interpretation of the results and discussed the results with reference to performance in the development and/or validation data. The lowest adherence rate of 10% was achieved on item 7b and 17% on items 6b and 2, meaning that most authors failed to report whether any actions were done to a blind assessment of predictors and failed to provide a complete abstract of the study. In total, 92% of the studies described the study design and source of data (item 4a), and 92% of the studies explained how the study size was reached (item 8). In total, 81% of the 52 studies gave adequate instructions on using the model in clinical practice (item 20). The performance of the prediction model (item 16) was described in 35% of the studies. Limitations of the study were described in 90% of the studies (item 18) (Figure 3).

The AUC of the prediction model of each study was extracted from the article. In 1 study, the AUC was missing, and this study was excluded from the analysis (Table I). The reported AUC value of each study was plotted against its TRIPOD adherence rate on a quadrant matrix chart (Figure 4). We identified 13 prediction models with a combination of above-average adherence to the TRIPOD checklist and performance (AUC), 4 of which were published in high-impact factor journals (Table I). The reporting of prediction models was poor for both the adherence to the TRIPOD checklist and performance (AUC) in 11 studies (Figure 4).

The TRIPOD checklist was published in May 2014. The current analysis involved 6 studies published before this period with a mean adherence rate to the TRIPOD items of 67%. The rest of the included studies were published after this period with a mean adherence rate of 65%. We did not observe a trend toward improvement in the quality of reporting in the studies that were published after the introduction of the TRIPOD guidelines. Furthermore, 4% ($n = 2$) of the included studies reported the net clinical benefit of the model and only 25% ($n = 13$) of studies reported on model calibration.

Discussion

The aim of this study was to evaluate the quality of reporting of prediction models on POPF after PD using the TRIPOD checklist. In the selected 52 studies, the mean adherence rate to the TRIPOD checklist was 65%. No model achieved 100% adherence. Most studies failed to report whether any actions were done to a blind assessment of predictors and failed to provide a complete abstract of the study. Among the 52 selected studies, we identified 13 prediction models with a combination of above-average TRIPOD adherence rate and performance (AUC).

The quality of reporting is important to enable clinicians to judge prediction models on their merits and select the best-performing models for clinical implementation. Information

Table I
Detailed description for all studies

Study ID	Year of publishing	Type of study	Performance measure*	Impact factor†	AUC	Adherence rate
Yamamoto Y et al[4]	2011	Development	Not reported	3.282	0.83	0.60
Xingjun G et al[24]	2019	Development and external validation	Not reported	2.030	0.89	0.75
Xia W et al[25]	2018	Development	Not reported	3.386	0.81	0.63
Wellner UF et al[26]	2010	Development	Not reported	3.842	Not reported	0.73
Shubert CR et al[27]	2015	External validation	Not reported	6.532	0.73	0.70
Roberts K et al[28]	2015	External validation	Calibration curve	13.787	0.76	0.47
Roberts K et al[29]	2014	Development	Calibration curve	3.842	0.75	0.77
Mungroop et al[30]	2019	External validation	Calibration curve	13.787	0.75	0.90
Mungroop et al[16]	2019	Development and external validation	Calibration curve	13.787	0.78	0.89
Miller BC et al[31]	2014	External validation	Not reported	3.267	0.72	0.53
Li Y et al[32]	2019	Development	Not reported	5.374	0.84	0.67
Grendar J et al[33]	2017	External validation	Not reported	3.842	0.72	0.60
Gaujoux et al[34]	2010	Development	Hosmer-Lemeshow test	4.348	0.78	0.67
Chen J et al[35]	2015	Development	Not reported	5.374	0.81	0.63
Casadei R et al[36]	2017	External validation	Not reported	13.400	0.66	0.73
Callery M et al[17]	2013	Development	Not reported	6.532	0.94	0.73
Lin Z et al[37]	2021	Development and external validation	Calibration curve	4.531	0.87	0.61
Lao M et al[38]	2020	External validation	Not reported	3.842	0.74	0.74
Box EW et al[39]	2021	Development	Not reported	3.125	0.84	0.55
Perri G et al[40]	2021	Development and external validation	Not reported	4.348	0.65	0.65
Guilbaud T et al[41]	2021	Development	Not reported	4.348	0.83	0.69
Petrova E et al[42]	2019	Development and internal validation	Calibration slope and Intercept	3.977	0.65	0.57
Shinde RS et al[43]	2020	External validation	Calibration curve	3.977	0.70	0.67
Lapshyn H et al[44]	2021	Development and internal validation	Not reported	3.977	0.76	0.63
Shi Y et al[45]	2020	Development and external validation	Not reported	11.205	0.81	0.82
Mohamed A et al[46]	2021	Development	Not reported	3.125	0.72	0.60
Guo CX et al[47]	2020	Development and internal validation	Calibration curve	1.740	0.82	0.69
You Y et al[48]	2019	Development and internal validation	Not reported	3.842	0.65	0.64
Yoon SJ et al[49]	2022	External validation	Not reported	1.740	0.67	0.69
Yu J et al[50]	2021	Development and external validation	Hosmer-Lemeshow test and calibration curve	3.253	0.85	0.66
Yin J et al[51]	2022	Development, internal and external validation	Calibration curve	2.160	0.62	0.82
Ryu Y et al[52]	2019	External validation	Not reported	3.149	0.62	0.74
Tang B et al[53]	2021	Incremental value	Not reported	3.842	0.82	0.69
Lucassen CJ et al[54]	2022	Incremental value	Hosmer- Lemeshow test	3.842	0.81	0.77
Zhang JY et al[55]	2021	Development	Not reported	2.853	0.92	0.54
Suzuki S et al[56]	2021	Development	Not reported	3.282	0.81	0.55
Honselmann KC et al[57]	2021	Development and internal validation	Not reported	2.895	0.90	0.69
Maqueda González R et al[58]	2022	Development	Not reported	2.895	0.78	0.60
Lee B et al[59]	2022	External validation	Not reported	3.453	0.68	0.70
Akgul O et al[60]	2019	Development and internal validation	Not reported	3.267	0.67	0.48
Kantor O et al[61]	2017	Development, internal and external validation	Not reported	6.532	0.62	0.64
Han IW et al[62]	2020	Development and internal validation	Not reported	5.374	0.74	0.66
Long ZD et al[63]	2022	Development and internal validation	Decision curve	1.168	0.90	0.56
Angrisani M et al[64]	2020	Incremental value	Not reported	3.977	0.77	0.59
Liu R et al[65]	2021	Development	Not reported	2.030	0.90	0.66
Tabchouri N et al[66]	2021	Development and external validation	Not reported	3.267	0.73	0.70
Huang XT et al[67]	2021	Development, internal and external validation	Calibration curve Decision Curve	3.282	0.74	0.64
Gupta, V et al[68]	2022	External validation	Not reported	0.437	0.80	0.63
Kang JS et al[69]	2019	External validation	Not reported	8.265	0.64	0.62
Hayashi H et al[70]	2021	Incremental value	Not reported	2.808	0.67	0.38
Niu C et al[71]	2022	External validation	Not reported	4.348	0.72	0.63
Blunck CK et al[72]	2022	External validation	Not reported	3.125	0.82	0.56
Median					0.76	0.65
Mean					0.76	0.65
IQR					70%–80%	60%–70%
SD					8%	10%

* Additional to the AUC.
† Impact factor of the publishing journal based on the latest rank.

needed for a proper judgment extends beyond model performance measures alone, including relevant aspects such as the risk of bias and composition of the derivation cohort, as covered by the TRIPOD checklist. Inadequacies or low-quality reporting of potentially powerful prediction models may still result in limited usability in a clinical setting. It appears that the reporting of postoperative pancreatic fistula prediction models is better than prediction models in general, with a median adherence rate of 44% based on a study evaluating 170 models.[19] Notably, these 170 models were published before the TRIPOD era, which may explain this low adherence rate. A recent TRIPOD analysis study for melanoma prediction models showed an adherence rate of 61%.[20] In this study, there was no exclusion of studies based on the publishing date. The TRIPOD checklist does not explicitly mention specific performance

Table II
Mean and median adherence rate per type of study

Type of study	Range of adherence	Mean adherence rate (SD)	Median adherence rate (IQR)
Overall ($n = 51$)	38%–90%	65% (10%)	65% (60%–70%)
Development ($n = 22$)	48%–77%	63% (7%)	63% (57%–68%)
External validation ($n = 15$)	47%–90%	66% (10%)	67% (60%–73%)
Development and external validation ($n = 10$)	61%–89%	72% (10%)	68% (64%–82%)
Incremental value ($n = 4$)	38%–77%	61% (17%)	64% (43%–75%)

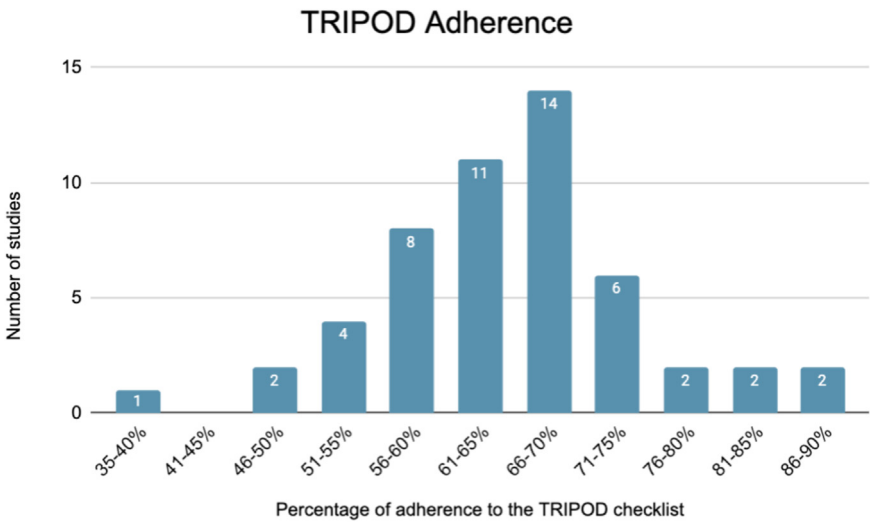

Figure 2. The adherence of studies to TRIPOD. *TRIPOD*, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis.

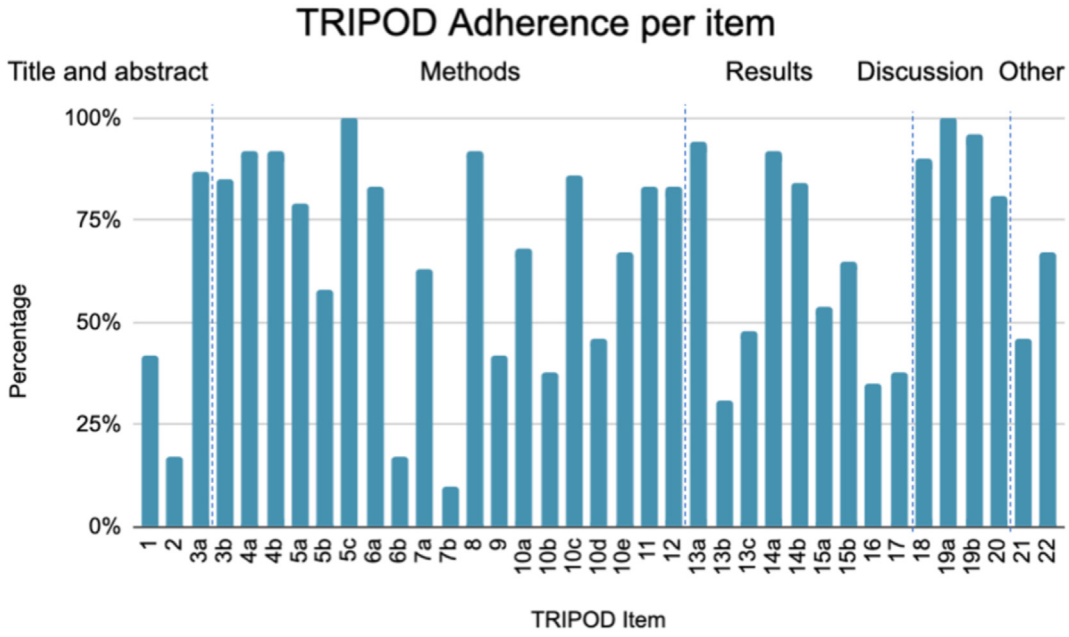

Figure 3. TRIPOD adherence per item. *TRIPOD*, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis.

measures (checklist item 16). However, there is international consensus on the importance of model calibration and net clinical benefit.[21–23] Only 13 of the included studies have assessed the calibration of the model in addition to the AUC performance measure, and 2 of the included studies have assessed the clinical usefulness.

In total, 81% of the studies gave adequate instructions on how to use the model in clinical practice. Providing information on how to use the prediction model is crucial, as the absence of an unequivocal intended use can easily lead to errors with potentially severe consequences. In POPF prediction models, instructions on how to use the model were explained in 81% of the studies, whereas in

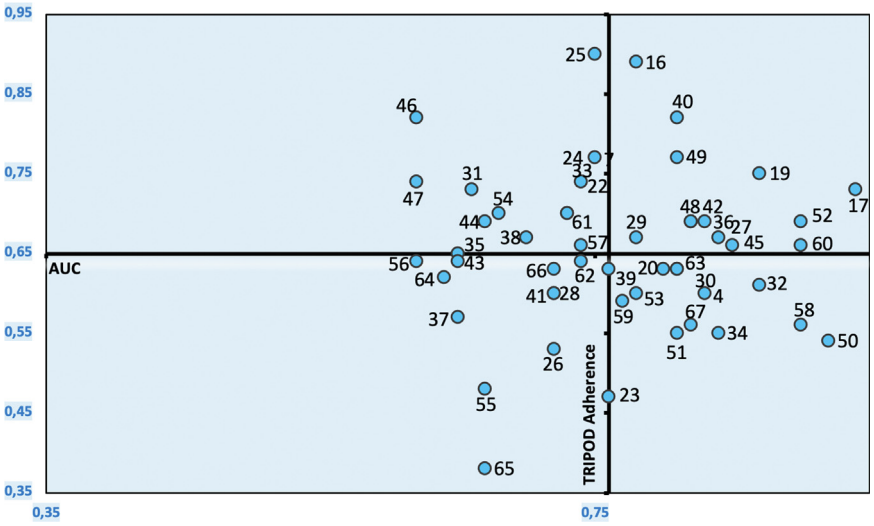

Figure 4. X-axis performance of the studies (area under the curve) is plotted against Y-axis Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis adherence with the means (0.76–0.65) in the center; recommended models are in the upper right top of the graph. (Numbers represent the IDs of the included studies, complete references can be found in the reference list). *TRIPOD*, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis.

melanoma prediction models, only 54% of the studies explained how to use the model.[20]

This systematic review study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. To our knowledge, this is the first study to investigate the relationship between model performance based on the AUC and the TRIPOD checklist for POPF risk models. Moreover, the evaluation of TRIPOD items was performed independently by 3 investigators, and the results were then compared, and the items that were scored differently were re-evaluated until a consensus was reached to acquire trustworthy outcomes.

Study limitations

Our study has several limitations. First, the TRIPOD checklist can be overly stringent on certain items not impacting the performance of the evaluated models. This may lead to the possibility that the TRIPOD checklist scoring system exaggerates gaps in reporting. Second, all TRIPOD items are each equally weighed to calculate the TRIPOD adherence rate, whereas certain items may feel less important to the individual reader who encounters a study on a fistula prediction model than others. For example, the title or abstract of a fistula prediction model study can miss certain aspects listed in the TRIPOD checklist, but this does not necessarily have to impact the quality and utility of the prediction model itself. On the other hand, a study can properly report the title and abstract according to the TRIPOD checklist but can lack information on missing data or the model's performance, or the model itself can be poorly executed. Both of the above-mentioned examples can have a similar TRIPOD adherence rate, but, rationally speaking, the poorly reported items in the second example have a bigger impact on the quality and utility of the prediction model. It would be ideal for future studies to report according to the TRIPOD standards, but alternating the TRIPOD checklist and balancing/outweighing certain important aspects of the checklist more than others might also ensure optimizing the quality and utility of reporting of the prediction models.

In conclusion, the overall mean and median TRIPOD adherence rate for reporting postoperative pancreatic fistula prediction models after PD was 65%. Model discrimination was reported by all the studies except one, and yet only a minority reported on clinically relevant performance measures such as model calibration and clinical usefulness. Although higher than comparable prediction models and prediction models in general, it does not meet TRIPOD standards for transparency. We identified 13 prediction models that combined both above-average TRIPOD checklist adherence and performance (AUC), which could be the appropriate models to be used in clinical practice.

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Conflict of interest/Disclosure

The authors have no conflicts of interests or disclosures to report.

Supplementary materials

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