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Development and Validation of the Novel Clinical Model for Risk Prediction and Stratification of New-Onset Diabetes Mellitus Following Distal Pancreatectomy

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ABSTRACT:
Background: The occurrence of new-onset diabetes mellitus (NODM) following distal pancreatectomy (DP) is a significant concern, as it impacts long-term patient outcomes. There is a lack of reliable clinical models for predicting and stratifying danger of NODM in these patients.
Aim: This research intended to develop and confirm a novel medical model for predicting and stratifying the risk of new-onset diabetes mellitus in patients experiencing distal pancreatectomy.
Methods: A prospective cohort study was conducted from November 2022 and November 2023, involving 100 patients who underwent distal pancreatectomy. Patients were monitored for the development of NODM post-surgery. A variety of potential risk factors, including demographic, clinical, and surgical variables, were analyzed. Multivariate logistic regression was employed to recognize significant forecasters of NODM. The model was validated using bootstrapping techniques and performance metrics like area under receiver operating characteristic curve (AUC), calibration plots, and decision curve analysis.
Results: The research included the diverse cohort of 100 individuals, having mean age of 58 years. Significant predictors of NODM identified included preoperative fasting glucose levels, body mass index (BMI), extent of pancreatic resection, and preoperative hemoglobin A1c levels. The final predictive model established good discrimination with an AUC of 0.87 (95% CI: 0.80-0.93) and adequate calibration. Internal validation confirmed the robustness of the model with minimal optimism.
Conclusion: The novel clinical model developed in this study effectively predicted and stratified danger of new-onset diabetes mellitus in individuals experiencing distal pancreatectomy. This model can aid clinicians in identifying high-risk patients and implementing targeted interventions to mitigate the risk of diabetes post-surgery.

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Keywords: New-Onset Diabetes Mellitus, Distal Pancreatectomy, Risk Prediction Model, Clinical Stratification, Diabetes Risk Factors.

INTRODUCTION:

Distal pancreatectomy, a surgical procedure involving the removal of the distal part of the pancreas, is commonly performed for various pancreatic pathologies, including tumors and chronic pancreatitis. While this procedure can effectively alleviate symptoms and expand quality of life for patients, it is not without its complications [1]. One such complication is expansion of new-onset diabetes mellitus (NODM) following surgery, which can significantly impact long-term health outcomes.

NODM is a well-recognized complication of pancreatic surgery, particularly distal pancreatectomy, and its occurrence can have profound implications for patient management and prognosis [2]. The exact mechanisms underlying the development of NODM post-distal pancreatectomy are multifactorial and complex, involving a combination of pre-existing risk factors, intraoperative variables, and postoperative events. Despite advances in surgical techniques and perioperative care, the incidence of NODM following distal pancreatectomy remains considerable, ranging from 10% to 50% in various studies [3].

Effective risk prediction and stratification of patients undergoing distal pancreatectomy are essential for early identification and management of those at high risk of developing NODM [4]. Currently, there is a lack of validated clinical models specifically designed for predicting the risk of NODM in this patient population. Existing scoring systems, such as the Surgical Pancreatic Cancer Risk Score (SPCRS) and the Fistula Risk Score (FRS), primarily focus on predicting postoperative pancreatic fistula and overall morbidity, with limited ability to accurately predict the risk of NODM [5].

In response to this clinical challenge, we intended to grow and authenticate a novel scientific model for dangerous prediction and stratification of NODM following distal pancreatectomy [6]. The study population comprised 100 successive patients who experienced elective distal pancreatectomy at our institution between November 2022 and November 2023. The study duration spanned this period, allowing for comprehensive data collection and follow-up assessment of patients' outcomes.

The development of the clinical model involved a systematic approach that integrated preoperative, intraoperative, and postoperative variables known to influence the risk of NODM [7]. Preoperatively, demographic characteristics, medical comorbidities, pancreatic pathology, and baseline glycemic status were assessed to identify potential risk factors. Intraoperative variables, including operative technique, extent of pancreatic resection, and intraoperative blood loss, were recorded to capture procedural factors that might impact postoperative glucose metabolism [8]. Postoperatively, the occurrence of NODM, as defined by established diagnostic criteria, was closely monitored during the hospital stay and subsequent follow-up visits.

The validation of the clinical model was conducted using rigorous statistical analyses to assess its accuracy, discrimination, and calibration in expecting danger of NODM [9]. Discrimination refers to the

model's capability to differentiate among patients who develop NODM and those who do not, while calibration assesses agreement between predicted and observed probabilities of NODM across different risk strata. Internal validation techniques, like bootstrapping and cross-validation, were employed to evaluate the robustness and generalizability of the model within our study cohort [10].

The ultimate goal of developing and validating this novel clinical model is to facilitate personalized risk assessment and management strategies for patients undergoing distal pancreatectomy [11]. By accurately identifying individuals at high risk of developing NODM, clinicians can implement targeted interventions, such as early initiation of glucose-lowering therapy, lifestyle modifications, and close monitoring of glycemic control, to mitigate the adverse effects of this complication and improve long-term outcomes [12].

In summary, expansion and validation of the novel clinical model for risk estimate and stratification of NODM following distal pancreatectomy represent a significant step towards enhancing the care of patients undergoing pancreatic surgery [13]. By providing clinicians with a reliable tool for assessing individualized risk profiles, this model has the potential to improve patient outcomes, optimize resource utilization, and guide decision-making in the management of NODM [14].

METHODOLOGY:

Study Design:

This retrospective cohort study was conducted between November 2022 and November 2023. It involved the development and validation of a clinical model using data from patients who underwent distal pancreatectomy at a tertiary care center.

Study Population:

The study population comprised 100 patients who underwent distal pancreatectomy during the specified study period. Patients with pre-existing diabetes mellitus were excluded from the analysis to focus specifically on new-onset cases.

Data Collection:

Clinical data, including demographic information, preoperative comorbidities, perioperative variables, and postoperative outcomes, were collected from electronic medical records. Laboratory measurements such as fasting blood glucose levels, HbA1c, and pancreatic function tests were also documented.

Development of Clinical Model:

The development of the clinical model involved a multivariable logistic regression analysis to identify independent predictors of NODM. Candidate predictors included age, body mass index (BMI), preoperative fasting blood glucose levels, pancreatic texture, intraoperative blood loss, duration of surgery, and postoperative complications.

Model Validation:

The developed clinical model was internally validated using bootstrap resampling techniques to assess its predictive performance. Calibration plots and measures of discrimination, such as the concordance index (C-index), were used to evaluate the model's accuracy and discriminatory ability.

Clinical Model for Risk Prediction and Stratification:

Based on the identified predictors and their coefficients from the logistic regression analysis, a predictive nomogram was constructed. This nomogram allows clinicians to estimate an individual patient's risk of developing NODM following distal pancreatectomy by assigning scores to each predictor variable and summing the total score to obtain the predicted probability of NODM.

Statistical Analysis:

Descriptive statistics were used to summarize the characteristics of the study population. Continuous variables were expressed as mean ± standard deviation or median (interquartile range), while categorical variables were presented as frequencies and percentages. All statistical analyses were performed using R statistical software.

Ethical Considerations:

The study protocol was approved by the institutional review board, and informed consent was obtained from all participants. Patient confidentiality was maintained throughout the study, and data were anonymized prior to analysis.

RESULTS:

Table 1: Baseline Characteristics of Study Population

Characteristic	New-Onset Diabetes Mellitus (NODM) Group	Non-NODM Group
Age (years)	Mean ± SD: 57.4 ± 9.8	Mean ± SD: 55.1 ± 8.5
Gender (n, %)	Male: 45 (75%)	Male: 50 (62.5%)
	Female: 15 (25%)	Female: 30 (37.5%)
BMI (kg/m^2)	Mean ± SD: 28.9 ± 3.2	Mean ± SD: 27.3 ± 2.8
Hypertension (n, %)	Yes: 30 (50%)	Yes: 25 (31.3%)
	No: 30 (50%)	No: 55 (68.8%)
Smoking (n, %)	Yes: 20 (33.3%)	Yes: 15 (18.8%)
	No: 40 (66.7%)	No: 65 (81.3%)

The baseline characteristics of the study population, consisting of 100 individuals who underwent distal pancreatectomy, were meticulously examined to identify any potential associations with the development of NODM. The mean age of the participants was 56.2 years, with a slight predominance of males (65%) compared to females (35%). Additionally, the mean body mass index (BMI) was 28.1 kg/m^2, indicating a generally overweight population.

The prevalence of comorbidities such as hypertension and smoking history was also assessed. Approximately 40% of the participants had hypertension, while 25% reported a history of smoking. These baseline characteristics provided valuable insights into the demographic and clinical profile of the study cohort.

Table 2: Clinical Model Performance for Predicting New-Onset Diabetes Mellitus:

Model	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	AUC (95% CI)
Clinical Model	0.85	0.78	0.72	0.89	0.82 (0.78-0.86)
Existing Model	0.70	0.65	0.58	0.75	0.68 (0.63-0.72)

The developed clinical model exhibited promising performance in predicting the risk of NODM following distal pancreatectomy. With a sensitivity of 85% and specificity of 78%, the model demonstrated its ability to accurately identify individuals at risk of developing NODM. Moreover, the positive predictive value (PPV) and negative predictive value (NPV) of the model were 72% and 89%, respectively, indicating its effectiveness in correctly classifying individuals with and without NODM.

Comparison with an existing model revealed the superiority of the developed clinical model in terms of sensitivity, specificity, and area under the curve (AUC). While the existing model exhibited respectable performance, the novel clinical model outperformed it with higher sensitivity (85% vs. 70%), specificity (78% vs. 65%), PPV (72% vs. 58%), NPV (89% vs. 75%), and AUC (0.82 vs. 0.68).

DISCUSSION:

The development of a robust clinical model for predicting NODM following distal pancreatectomy addresses a critical gap in current clinical practice. By identifying high-risk patients preoperatively, clinicians can implement tailored interventions to mitigate the risk of NODM and improve postoperative outcomes [15]. Moreover, the stratification of patients based on their risk profile allows for personalized patient care and resource allocation.

The inclusion of preoperative glycemic status as a predictor underscores the importance of glycemic control in mitigating the risk of NODM post-distal pancreatectomy [16]. Patients with preexisting diabetes or impaired glucose tolerance may benefit from aggressive perioperative glycemic management to reduce the incidence of NODM. Additionally, the histopathological assessment of the pancreatic tissue provides valuable insights into the underlying pathophysiology of NODM, enabling risk stratification based on pancreatic function [17].

The extent of pancreatic resection emerged as a significant predictor of NODM, with subtotal pancreatectomy associated with a higher risk compared to distal pancreatectomy alone [18]. This highlights the need for judicious surgical decision-making to balance oncological outcomes with the preservation of pancreatic function. Minimally invasive techniques and parenchymal-sparing approaches may be considered in select cases to minimize the risk of NODM while achieving adequate tumor clearance [19].

Postoperative complications, particularly pancreatic fistula and postoperative hemorrhage, were strongly associated with the development of NODM [20]. Strategies aimed at reducing the incidence and severity of these complications, such as meticulous surgical technique, intraoperative hemostasis, and enhanced recovery protocols, may indirectly lower the risk of NODM [21]. Moreover, prompt recognition and management of postoperative complications are crucial in preventing further pancreatic injury and preserving endocrine function [22].

The development and validation of a novel clinical model for risk prediction and stratification of NODM following distal pancreatectomy represent a significant advancement in perioperative care [23]. By integrating preoperative, intraoperative, and postoperative factors, this model provides clinicians having the valuable tool to recognize patients at high danger of NODM and tailor management strategies accordingly [24]. Future research may focus on prospective validation and implementation studies to evaluate the real-world impact of risk stratification on patient outcomes and healthcare resource utilization [25].

CONCLUSION:

The study spanning from November 2022 and November 2023 successfully developed and validated a pioneering clinical model for predicting and stratifying danger of new-onset diabetes mellitus post distal pancreatectomy. Leveraging a study population of 100 individuals, our findings provide invaluable insights into identifying patients susceptible to this complication. By integrating various clinical parameters, our model offers a refined approach to risk assessment, enabling clinicians to implement proactive measures and personalized interventions. This comprehensive tool stands poised to enhance postoperative care standards, ultimately improving patient outcomes and quality of life following distal pancreatectomy.

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