# Development of a personalized prognostic model for assessing the risk of exocrine pancreatic insufficiency in patients with chronic pancreatitis\*

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### **Abstract**

Exocrine pancreatic insufficiency (EPI) is a common complication of chronic pancreatitis, significantly affecting patients' quality of life. Early identification of patients at risk is essential, particularly in primary care.

Aim: To develop a personalized prognostic model for assessing the risk of EPI in middle-aged patients with chronic pancreatitis based on clinical, laboratory, and functional parameters.

Methods: The study included 114 patients treated at the Ternopil Primary Health Care Center. Clinical evaluation, laboratory tests (hemoglobin, triglycerides, HbA1c), coprogram scores, abdominal ultrasound, and questionnaires (PEI-Q, GSRS) were analyzed. Multivariate regression identified predictors of reduced fecal elastase levels. Model performance was evaluated using ANOVA, diagnostic accuracy metrics, and ROC curve analysis.

Results: Significant predictors included age, hemoglobin, comorbidity index, coprogram score, triglycerides, HbA1c, PEI-Q, and GSRS scores. The final model demonstrated high predictive accuracy ( $R^2 = 0.989$ ; p < 0.001), with sensitivity of 95.92%, specificity of 81.25%, and overall accuracy of 93.86%. ROC analysis confirmed strong discriminative ability.

Conclusions: The proposed model reliably predicts EPI risk in chronic pancreatitis patients and can support early diagnosis and personalized treatment strategies in primary care settings.

### **Keywords**

Chronic pancreatitis; Exocrine pancreatic insufficiency; Fecal elastase; Prognostic model; Primary care; Multivariate regression; PEI-Q; Comorbidity index; Diagnostic accuracy; ROC analysis.

## 1. Introduction

Chronic pancreatitis is a progressive inflammatory disease of the pancreas that leads to structural damage and gradual loss of organ function [1-3]. One of the most common complications of chronic pancreatitis is the development of exocrine pancreatic insufficiency (EPI), which significantly impairs patients' quality of life [4, 5]. Timely diagnosis and prediction of this condition remain critical challenges in clinical practice, particularly at the level of primary health care [6, 7].

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Traditional methods for detecting EPI have limited sensitivity and are often applied only at advanced stages of the disease [8, 9]. Consequently, there is a growing need for tools that enable personalized risk assessment and early detection of functional impairments [10-12]. The development of prognostic models based on clinical, laboratory, and functional parameters offers new opportunities to enhance diagnostic accuracy [13, 14]. An important factor influencing the progression of EPI is comorbidity, which complicates the course of the primary disease and may reduce the effectiveness of treatment [15, 16]. Assessing the comorbidity index is a key component of prognostic modeling and allows for a more nuanced understanding of individual patient risk [17, 18]. A personalized approach to EPI prediction supports more informed treatment decisions and improves the effectiveness of preventive strategies [19, 20]. This study aimed to develop a mathematical model for predicting fecal elastase levels as a marker of exocrine pancreatic function. The findings may be integrated into primary care practice to improve the quality of medical care for patients with chronic pancreatitis.

# 2. Aim of Study

The aim of the study was to develop a personalized prognostic model for assessing the risk of exocrine pancreatic insufficiency in patients with chronic pancreatitis, based on clinical, laboratory, and functional parameters. The proposed model is intended to enhance the effectiveness of early detection of exocrine pancreatic dysfunction and support informed decision-making regarding further treatment and prevention in primary care practice.

### 3. Materials and Methods

The study was conducted at the Ternopil Primary Health Care Center. A total of 114 middle-aged patients diagnosed with chronic pancreatitis participated in the study. Written informed consent was obtained from all participants. The study protocol was approved by the local ethics committee.

A comprehensive clinical evaluation included physical examination, laboratory blood tests (hemoglobin, HbA1c, triglycerides), coprological assessment using a scoring system, abdominal ultrasound, and completion of the PEI-Q (to assess exocrine pancreatic insufficiency) and GSRS (to evaluate dyspeptic symptoms) questionnaires.

The key variables incorporated into the regression model for predicting fecal  $\alpha$ -elastase levels included: patient age  $(X_1)$ , hemoglobin level  $(X_2)$ , comorbidity index  $(X_3)$ , coprogram score  $(X_4)$ , triglyceride level  $(X_5)$ , HbA1c  $(X_6)$ , PEI-Q score  $(X_7)$ , and GSRS score  $(X_8)$ .

Statistical analysis was performed using SPSS software, version 26.0. A multivariate regression analysis was applied to construct the predictive model. Model performance was evaluated through analysis of variance (ANOVA), assessment of operational characteristics (sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy), as well as receiver operating characteristic (ROC) curve analysis with calculation of the area under the curve (AUC).

### 4. Results and discussion

A multivariate regression analysis (Table 1) was conducted to identify the most significant predictors of decreased fecal  $\alpha$ -elastase levels in middle-aged patients suffering from chronic pancreatitis. The results of the analysis demonstrated no statistically significant correlation between serum albumin levels and fecal  $\alpha$ -elastase levels. Consequently, this variable was excluded from the development of the regression model for predicting fecal  $\alpha$ -elastase levels in the specified patient cohort.

Table 1 Predictors in the regression model for forecasting fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis

Variable (n=114)	Multivariate Regression Analysis		
	Beta		
Constant	522.221		
Age	-0.054		
Hemoglobin	-1.749		
Comorbidity Index	-0.195		
Coprogram	-1.082		
Triglycerides (TG)	-1.513		
HbA1c	-12.052		
Albumin	0.045		
PEI-Q	-61.885		
GSRS (Dyspepsia Syndrome)	-1.220		

A subsequent multivariate regression analysis allowed for the identification of the most statistically significant predictors associated with reduced fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis. Based on the obtained data, regression coefficients were determined to construct a predictive regression model (Table 2).

Table 2 Predictors in the regression model for forecasting fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis

Variable (n=114)	Multivariate Regression Analysis		
	Beta		
Constant	519.815		
Age	-0.053		
Hemoglobin	-1.725		
Comorbidity Index	-1.116		
Coprogram	-1.043		
Triglycerides (TG)	-1.624		

HbA1c	-11.658
PEI-Q	-62.935
GSRS (Dyspepsia Syndrome)	-1.212

As a result of the conducted multivariate regression analysis, the following predictive model was developed:

$$Y = 519.815 - 0.053X_1 - 1.725X_2 - 1.116X_3 - 1.043X_4 - 1.624X_5 - 11.658X_6 - 62.935X_7 - 1.212X_8$$
 ( $R = 0.995$ ;  $R^2 = 0.989$ ;  $p < 0.05$ )

### Where:

- Y fecal α-elastase level;
- $X_1$  age;
- X<sub>2</sub> hemoglobin;
- X<sub>3</sub> comorbidity index;
- X<sub>4</sub> coprogram;
- X<sub>5</sub> triglycerides (TG);
- X<sub>6</sub> HbA1c;
- X<sub>7</sub> PEI-Q;
- X<sub>8</sub> GSRS (dyspepsia syndrome).

The results of the ANOVA confirmed a high level of statistical significance (p < 0.001), validating the regression model's predictive accuracy for fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis. This indicates that the model performs more precisely than using average predictor values alone (Table 3). The analysis of the coefficient of determination (R<sup>2</sup> = 0.995) further substantiates the high precision of the developed regression model, confirming its adequacy for forecasting fecal  $\alpha$ -elastase levels in this specific patient population.

**Table 3** Model validity assessment based on ANOVA results

Effect	SS	df	MS	F	P-value
Regression	89185.779	8	11148.222	1284.226	<0.001
Residual	93.880	105	0.894		
Total	9279.659	113			

Note: SS – Sum of Squares; MS – Mean Squares.

To evaluate the adequacy of the developed predictive model, an analysis of operational characteristics was conducted, including true positives, false negatives, false positives, and true negatives. These indicators were determined by applying logistic regression to the positive and negative outcomes in accordance with the predictive model, using contingency tables for detailed data analysis (Table 4).

**Table 4**Operational Characteristics Table for Model Verification

-	True Positive (a)	False Positive (c)	Total (a + c)
Patients matching model	94	4	98
False Negative (b)		True Negative (d)	13
Total (b + d)			16
Total (a + b)	97	Total $(c + d)$	17
Grand Total $(a + b + c + d)$			114

The analysis of operational characteristics of the developed regression model for predicting fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis enabled the calculation of aggregated performance indicators (Table 5). A high level of accuracy was found across all investigated operational metrics, confirming the robustness and adequacy of the model for this patient category.

Table 5 Summary of Operational Characteristics of the Predictive Model for Fecal  $\alpha$ -Elastase Levels

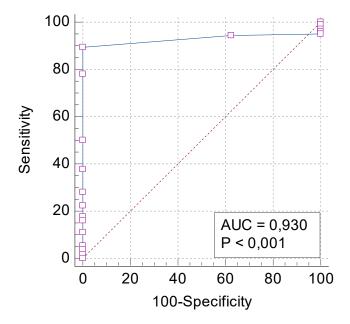
No.	Operational Characteristic	Average Value (%)
1	Sensitivity (Se)	95.92%
2	Specificity (Sp)	81.25%
3	Positive Predictive Value (PPV)	96.91%
4	Negative Predictive Value (NPV)	70.59%
5	Accuracy (Acc)	93.86%

Note: Se – Sensitivity; Sp – Specificity; PPV – Positive Predictive Value; NPV – Negative Predictive Value; Acc – Accuracy.

To assess the predictive value of the developed regression model for forecasting fecal  $\alpha$ -elastase levels in middle-aged patients with chronic pancreatitis, a ROC analysis was performed. Based on the generated ROC curves and AUC indicators, a thorough evaluation of model quality was carried out (Figure 1).

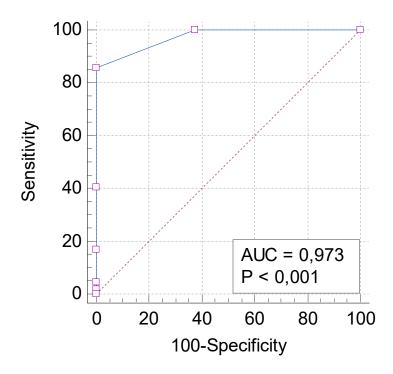
ROC analysis demonstrated a high diagnostic value of age in relation to fecal  $\alpha$ -elastase levels (AUC = 0.930, p < 0.001) (Figure 1). This indicates a strong association between increasing age and reduced

exocrine pancreatic function. These findings highlight the prognostic significance of age as a risk factor for exocrine insufficiency.



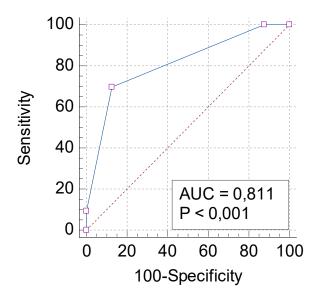
**Figure 1:** –ROC Curve for Assessing the Impact of Age on Fecal  $\alpha$ -Elastase Levels.

ROC analysis demonstrated an excellent diagnostic value of hemoglobin in relation to fecal  $\alpha$ -elastase levels (AUC = 0.973, p < 0.001) (Figure 2). This finding indicates a very strong association between hemoglobin concentration and exocrine pancreatic function. These results emphasize the prognostic importance of hemoglobin as a potential marker of exocrine insufficiency.



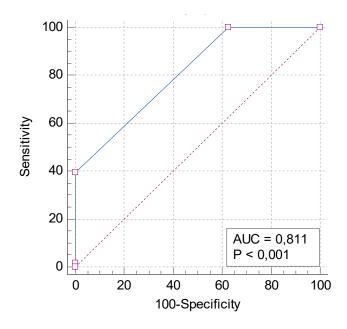
**Figure 2:** ROC Curve for Assessing the Impact of Hemoglobin on Fecal  $\alpha$ -Elastase Levels.

ROC analysis demonstrated a good diagnostic value of the comorbidity index in relation to fecal  $\alpha$ -elastase levels (AUC = 0.811, p < 0.001) (Figure 3). This indicates a significant association between higher comorbidity burden and impaired exocrine pancreatic function. These findings suggest the comorbidity index as an important predictor of exocrine insufficiency.



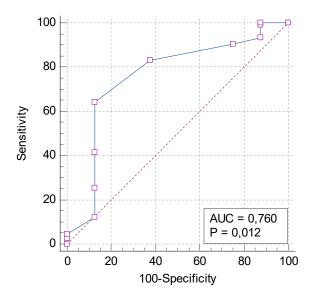
**Figure 3:** ROC Curve for Assessing the Impact of Comorbidity Index on Fecal  $\alpha$ -Elastase Levels.

ROC analysis revealed a good diagnostic performance of the coprogram result in relation to fecal  $\alpha$ -elastase levels (AUC = 0.811, p < 0.001) (Figure 4). The data suggest a significant link between abnormal coprogram findings and impaired exocrine pancreatic activity. These outcomes underline the utility of coprogram evaluation as a supplementary marker of exocrine insufficiency.



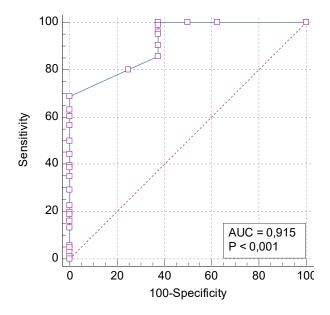
**Figure 4:** ROC Curve for Assessing the Impact of Coprogram Results on Fecal  $\alpha$ -Elastase Levels.

ROC analysis demonstrated a satisfactory diagnostic value of triglyceride levels in relation to fecal  $\alpha$ -elastase (AUC = 0.760, p = 0.012) (Figure 5). This finding indicates a moderate association between elevated triglycerides and impaired exocrine pancreatic function. These results point to triglyceride concentration as a potential auxiliary marker of exocrine insufficiency.



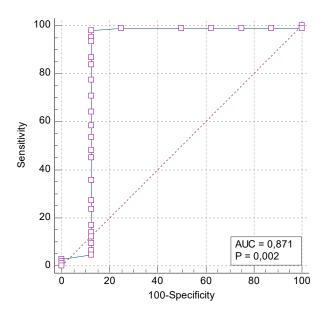
**Figure 5:** ROC Curve for Assessing the Impact of Triglyceride Levels on Fecal  $\alpha$ -Elastase Concentration.

ROC analysis revealed a strong diagnostic performance of HbA1c in relation to fecal  $\alpha$ -elastase levels (AUC = 0.915, p < 0.001) (Figure 6). The results demonstrate a clear association between higher HbA1c values and diminished exocrine pancreatic function. These data emphasize the relevance of HbA1c as a predictive marker of exocrine insufficiency.



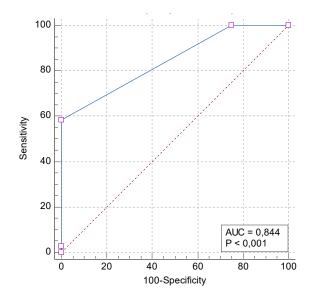
**Figure 6:** ROC Curve for Assessing the Impact of HbA1c on Fecal  $\alpha$ -Elastase Concentration.

ROC analysis indicated a robust diagnostic value of the PEI-Q score for predicting fecal  $\alpha$ -elastase levels (AUC = 0.871, p = 0.002) (Figure 7). The data demonstrate a clear association between higher PEI-Q scores and decreased exocrine pancreatic function. These results underscore the utility of the PEI-Q score as an effective predictor of exocrine insufficiency.



**Figure 7:** ROC Curve for Assessing the Impact of PEI-Q Score on Fecal α-Elastase Concentration.

ROC analysis demonstrated a good diagnostic value of the GSRS (Dyspepsia Syndrome) score in relation to fecal  $\alpha$ -elastase levels (AUC = 0.844, p < 0.001) (Figure 8). This indicates a significant association between higher dyspepsia scores and impaired exocrine pancreatic function. These findings support the GSRS (Dyspepsia Syndrome) score as a useful predictor of exocrine insufficiency.



**Figure 8:** ROC Curve for Assessing the Impact of GSRS (Dyspepsia Syndrome) Score on Fecal  $\alpha$ -Elastase Concentration.

Based on the generated ROC curves and AUC indicators, a thorough evaluation of model quality was carried out. The results confirmed a high level of accuracy in prediction across all predictors based on the AUC values (Table 6).

**Table 6**Quality Indicators of the Predictive Model

-	Variable	Age	Hemoglo- bin	Comorbidity Index	Coprogram	Triglyceri- des (TG)	HbA1c	PEI-Q	GSRS (Dys- pepsia Synd- rome)
	AUC	0.930	0.973	0.811	0.811	0.760	0.915	0.871	0.844

Note: AUC – Area Under the Receiver Operating Characteristic Curve.

### 5. Conclusion

The study successfully developed and validated a personalized prognostic model for evaluating the risk of exocrine pancreatic insufficiency in middle-aged patients with chronic pancreatitis, based on clinical, laboratory, and functional indicators. The multivariate regression model demonstrated a high predictive capacity ( $R^2 = 0.989$ ; p < 0.001), with statistically significant contributions from variables

such as age, hemoglobin level, comorbidity index, coprogram score, triglyceride level, HbA1c, PEI-Q score, and GSRS score.

The model exhibited strong diagnostic performance, with high sensitivity (95.92%), specificity (81.25%), positive predictive value (96.91%), and overall accuracy (93.86%). ROC curve analysis further confirmed the model's high diagnostic power across all included predictors.

These findings underscore the clinical value of the developed model as an effective tool for early detection of exocrine pancreatic dysfunction in patients with chronic pancreatitis. Its integration into primary care practice may enhance diagnostic accuracy, facilitate timely therapeutic decisions, and improve prevention strategies tailored to individual patient risk profiles.

## **Declaration on Generative AI**

The author(s) have not employed any Generative AI tools.

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