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Original Research Article

Postoperative Day 1 Serum Lipase for Early Prediction of Pancreatic Leak Following Pancreaticoduodenectomy: A Prospective Observational Study

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Conflict of interest: Nil

Abstract:

Background: Postoperative pancreatic fistula remains a major source of morbidity after pancreaticoduodenectomy. This study assessed postoperative day 1 (POD1) serum lipase as an early predictor of postoperative pancreatic leak and compared its diagnostic performance with POD1 serum amylase.

Methods: In this prospective observational study, 52 consecutive adults undergoing classical pancreaticoduodenectomy or pylorus-preserving pancreaticoduodenectomy were enrolled between December 2024 and June 2026. POD1 serum lipase and amylase were measured, and drain fluid amylase was assessed on postoperative days 3, 5, and 7. Pancreatic leak was classified using the 2016 International Study Group of Pancreatic Surgery criteria. Receiver operating characteristic analysis and logistic regression were used to evaluate predictive performance.

Results: Pancreatic leak occurred in 30 patients (57.7%): 19 biochemical leaks (36.5%) and 11 grade B postoperative pancreatic fistulas (21.2%). No grade C fistula occurred. POD1 serum lipase was markedly higher in patients with pancreatic leak than in those without leak (665.03 ± 509.87 vs 43.18 ± 41.17 U/L; $p<0.001$). Its area under the receiver operating characteristic curve was 0.958 (95% confidence interval, 0.895-1.000). A cut-off of 137 U/L yielded 90.0% sensitivity, 100% specificity, 100% positive predictive value, 88.0% negative predictive value, and 94.2% overall accuracy. POD1 serum amylase showed lower discrimination (area under the curve, 0.827; cut-off, 223 U/L; sensitivity, 73.3%; specificity, 95.5%). Soft pancreatic texture and preoperative diagnosis were also associated with leak.

Conclusion: POD1 serum lipase showed excellent accuracy for early identification of pancreatic leak after pancreaticoduodenectomy and outperformed POD1 serum amylase in this cohort. Larger multicentre studies should validate the proposed cut-off before routine clinical adoption.

Keywords: Pancreaticoduodenectomy; Postoperative Pancreatic Fistula; Pancreatic Leak; Serum Lipase; Serum Amylase; Diagnostic Accuracy.

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Introduction

Pancreaticoduodenectomy is the standard potentially curative operation for resectable malignant and selected benign lesions of the pancreatic head and periampullary region. Although perioperative mortality has declined in specialised centres, morbidity remains substantial, and postoperative pancreatic fistula (POPF) continues to be one of the most consequential complications because it can precipitate intra-abdominal collections, sepsis, delayed gastric emptying, post-pancreatectomy haemorrhage, reintervention, prolonged hospitalisation, and death [1,2].

The International Study Group of Pancreatic Surgery (ISGPS) revised its definition in 2016, replacing the former grade A fistula with the term biochemical leak and restricting clinically relevant POPF to grades B and C [1]. This distinction improved comparability across studies and emphasised that elevated drain amylase alone does not necessarily represent clinically important anastomotic failure. Nevertheless, early recognition of pancreatic enzyme leakage remains clinically useful because it may identify patients who require prolonged drainage, closer surveillance, cross-sectional imaging, or timely intervention.

Several intraoperative factors are consistently associated with POPF, including a soft pancreatic gland, small main pancreatic duct, non-pancreatic ductal adenocarcinoma pathology, and greater blood loss. These variables form the basis of the original Fistula Risk Score and subsequent alternative models [3-5]. Such scores estimate baseline operative risk but do not capture the evolving biological response during the immediate postoperative period. A readily available serum biomarker could therefore provide complementary dynamic information.

Drain fluid amylase remains central to the diagnosis of POPF, but its usefulness depends on the presence and position of surgical drains and on institutional drain-management protocols. Serum enzymes are attractive because they are inexpensive, minimally invasive, and widely available. Serum amylase has been investigated as an early marker of pancreatic injury after pancreaticoduodenectomy [6,7]. More recent studies suggest that postoperative serum lipase may be at least as informative, and in some cohorts superior, for predicting clinically relevant POPF [8-11]. However, reported thresholds vary, and conflicting evidence regarding the relative performance of amylase and lipase remains [12].

The present prospective observational study therefore evaluated postoperative day 1 (POD1) serum lipase as an early predictor of pancreatic leak after pancreaticoduodenectomy. The secondary objectives were to compare its diagnostic performance with POD1 serum amylase, identify clinicopathological factors associated with leak, and assess the relationship between pancreatic leak and duration of drain retention.

Methods

Study design and setting: This prospective observational analytical study was conducted in the Department of Surgical Oncology, Kidwai Memorial Institute of Oncology, Bengaluru, India, between December 2024 and June 2026. Consecutive eligible patients undergoing pancreaticoduodenectomy were enrolled prospectively and followed throughout the index hospital admission. The manuscript was prepared in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.

Participants and eligibility: Adults aged 18 years or older undergoing classical pancreaticoduodenectomy or pylorus-preserving pancreaticoduodenectomy (PPPD) for malignant or selected benign pancreatic or periampullary lesions were screened. Patients undergoing distal pancreatectomy, total pancreatectomy, palliative bypass, or another non-pancreaticoduodenectomy procedure were excluded. Further exclusions were incomplete perioperative biochemical data, death before POD1 blood sampling, refusal of written informed consent, or withdrawal of consent. Consecutive recruitment was used to reduce selection bias.

Preoperative Assessment: All patients underwent standard clinical assessment, laboratory investigations, cross-sectional imaging, anaesthetic evaluation, and multidisciplinary review according to institutional practice. Recorded preoperative variables included age, sex, body mass index, diabetes mellitus, preoperative biliary drainage, American Society of Anesthesiologists (ASA) physical status, serum albumin, and the preoperative diagnostic category.

Operative technique and intraoperative assessment: Operations were performed by surgical oncology teams experienced in pancreatic surgery. The choice between classical pancreaticoduodenectomy and PPPD was determined by tumour location, oncological considerations, and operating-surgeon judgement. After resection, reconstruction consisted of pancreaticojejunostomy, hepaticojejunostomy, and either gastrojejunostomy after classical pancreaticoduodenectomy or duodenojejunostomy after PPPD. The pancreatic anastomosis was fashioned using the surgeon's standard technique. Closed drains were placed adjacent to the pancreaticojejunostomy and hepaticojejunostomy. Pancreatic texture was assessed intraoperatively and categorised as soft or firm. Main pancreatic duct diameter was measured at the transection margin, and estimated blood loss was recorded from the anaesthesia and operative records.

Postoperative management and biochemical measurements: Postoperative care followed a standard institutional pathway. Venous blood was collected on POD1 for serum amylase and serum lipase measurement. Samples were analysed in the institutional central biochemistry laboratory using automated enzymatic assays and the manufacturer's quality-control procedures. Laboratory personnel were not provided with subsequent clinical outcome information at the time of analysis. Drain fluid was collected separately from the pancreatic and biliary anastomotic drains, and drain fluid amylase was measured on postoperative days 3, 5, and 7, or until drain removal. Decisions regarding drain retention or removal were based on the patient's clinical condition, drain volume and character, biochemical results, and treating-team judgement.

Definitions and outcome measures: POPF was classified according to the 2016 ISGPS definition [1]. A biochemical leak was defined as elevated drain fluid amylase without a clinically relevant change in postoperative management. Grade B POPF required a clinically relevant alteration in

management, whereas grade C POPF was associated with severe clinical consequences such as organ failure, reoperation, or death attributable to the fistula. The prespecified primary outcome was a composite pancreatic-leak endpoint comprising biochemical leak and grade B or C POPF. Clinically relevant POPF (grades B/C) was additionally reported as a separate outcome to permit comparison with contemporary literature.

Secondary outcomes were the diagnostic performance of POD1 serum lipase and POD1 serum amylase for the composite pancreatic-leak endpoint, associations between demographic or operative factors and pancreatic leak, and the duration of postoperative drain retention. Variables collected prospectively included age, sex, body mass index, diabetes mellitus, biliary drainage, ASA grade, serum albumin, operative procedure, pancreatic texture, duct diameter, blood loss, POD1 serum enzymes, serial drain fluid amylase, drain-removal day, and final histopathology.

Sample Size and Missing Data: All consecutive eligible patients operated during the predefined 18-month study period were included; no formal a priori sample-size calculation was performed. The analysis was therefore exploratory. Completeness of the case-record form was checked before database lock. Patients with missing primary-outcome or POD1 biomarker data were excluded according to the prespecified eligibility criteria, and no statistical imputation was undertaken.

Statistical Analysis: Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics for Windows. Continuous variables were assessed for distribution and summarised as mean ± standard deviation or median with range, as appropriate. Categorical variables were presented as frequency and percentage. Between-group comparisons used the independent-samples t test for approximately normally distributed continuous data and the Mann-Whitney U test for non-normally distributed data. Categorical variables were compared using the chi-square test or Fisher exact test, as appropriate.

Receiver operating characteristic curves were constructed for POD1 serum lipase and POD1 serum amylase. Discrimination was quantified using the area under the curve (AUC) with 95% confidence intervals. Optimal thresholds were selected using the Youden index. Sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy were calculated from two-by-two tables. Binary logistic regression was used to examine associations between candidate variables and pancreatic leak, with effect estimates reported as odds ratios and 95% confidence intervals. Given the limited sample and event count, regression findings were interpreted as exploratory and no overfitted multivariable prediction model was developed. All tests were two-sided, and $p<0.05$ was considered statistically significant.

Ethics: The Institutional Ethics Committee of Kidwai Memorial Institute of Oncology approved the study (KMIO/MEC/2024/12/PG/MO-40; 7 December 2024). Written informed consent was obtained from all participants. Data were de-identified before analysis, and the study was conducted in accordance with the Declaration of Helsinki and applicable national ethical guidance.

Results

Patient and operative characteristics: Fifty-two patients were included. Mean age was 55.69 ± 11.87 years, 36 patients (69.2%) were male, and mean body mass index was 22.88 ± 2.23 kg/m². Diabetes mellitus was present in 10 patients (19.2%), and 2 (3.8%) had undergone preoperative biliary drainage. Thirty-one patients (59.6%) underwent classical pancreaticoduodenectomy and 21 (40.4%) underwent pylorus-preserving pancreaticoduodenectomy. The gland was soft in 21 patients (40.4%) and firm in 31 (59.6%). Mean main pancreatic duct diameter was 5.75 ± 1.43 mm and mean estimated blood loss was 518.75 ± 267.98 mL (Table 1).

Pancreatic leak and associated factors: Pancreatic leak occurred in 30 patients (57.7%): 19 biochemical leaks (36.5%) and 11 grade B postoperative pancreatic fistulas (21.2%). No grade C fistula occurred. Therefore, the rate of clinically relevant postoperative pancreatic fistula was 21.2%. Preoperative diagnosis ($p=0.006$) and soft pancreatic texture ($p=0.044$) were associated with pancreatic leak. Age, sex, body mass index, albumin, diabetes, biliary drainage, American Society of Anesthesiologists grade, type of pancreaticoduodenectomy, duct diameter, blood loss, and final histopathology were not significantly associated with leak.

POD1 serum lipase was substantially higher in patients with pancreatic leak than in those without leak (665.03 ± 509.87 vs 43.18 ± 41.17 U/L; $p<0.001$). POD1 serum amylase was also higher (331.63 ± 262.18 vs 118.18 ± 192.82 U/L; $p<0.001$). Drain removal occurred later in patients with leak (17.47 ± 5.49 vs 7.73 ± 0.83 days; $p<0.001$) (Table 2).

Predictive performance: On logistic regression, POD1 serum lipase (odds ratio per 1 U/L increase, 1.020; 95% confidence interval, 1.005-1.035; $p=0.007$) and POD1 serum amylase (odds ratio per 1 U/L increase, 1.006; 95% confidence interval, 1.001-1.011; $p=0.010$) were significantly associated with pancreatic leak. These effect estimates should be interpreted cautiously because they are expressed

per 1 U/L increment and were derived from a small cohort (Table 3).

POD1 serum lipase showed excellent discrimination, with an area under the curve of 0.958 (95% confidence interval, 0.895-1.000; p<0.001). At the Youden-derived cut-off of 137 U/L, sensitivity was 90.0%, specificity 100%, positive predictive value 100%, negative predictive value 88.0%, and overall accuracy 94.2%. POD1 serum amylase had an area under the curve of 0.827. A cut-off of 223 U/L yielded 73.3% sensitivity and 95.5% specificity (Table 4).

Table 1: Baseline and operative characteristics (N=52)

Characteristic	Value
Age, years	55.69 ± 11.87
Male sex	36 (69.2%)
Female sex	16 (30.8%)
Body mass index, kg/m²	22.88 ± 2.23
Serum albumin, g/dL	3.68 ± 0.17
Diabetes mellitus	10 (19.2%)
Preoperative biliary drainage	2 (3.8%)
ASA II	32 (61.5%)
ASA III	20 (38.5%)
Classical pancreaticoduodenectomy	31 (59.6%)
Pylorus-preserving pancreaticoduodenectomy	21 (40.4%)
Soft pancreas	21 (40.4%)
Firm pancreas	31 (59.6%)
Main pancreatic duct diameter, mm	5.75 ± 1.43
Estimated blood loss, mL	518.75 ± 267.98

Table 2: Comparison of patients with and without pancreatic leak

Variable	No leak (n=22)	Leak (n=30)	p value
Age, years	53.64 ± 11.80	57.20 ± 11.89	0.299
Body mass index, kg/m²	22.80 ± 1.30	22.94 ± 2.75	0.687
Albumin, g/dL	3.64 ± 0.18	3.71 ± 0.16	0.157
Main pancreatic duct, mm	5.95 ± 1.00	5.60 ± 1.67	0.151
Estimated blood loss, mL	502.27 ± 180.26	530.83 ± 320.00	1.000
POD1 serum amylase, U/L	118.18 ± 192.82	331.63 ± 262.18	<0.001
POD1 serum lipase, U/L	43.18 ± 41.17	665.03 ± 509.87	<0.001
Drain-removal day	7.73 ± 0.83	17.47 ± 5.49	<0.001

Table 3: Logistic regression for postoperative pancreatic leak

Variable	Odds ratio	95% confidence interval	p value
Age	1.03	0.98-1.08	0.284
Body mass index	1.03	0.80-1.32	0.828
Albumin	12.75	0.42-388.18	0.144
Main pancreatic duct diameter	0.84	0.56-1.24	0.377
Estimated blood loss	1.0004	0.9982-1.0026	0.704
POD1 serum amylase	1.006	1.001-1.011	0.010
POD1 serum lipase	1.020	1.005-1.035	0.007

Table 4: Diagnostic performance of POD1 serum lipase and amylase

Parameter	Serum lipase	Serum amylase
Area under the curve	0.958	0.827
95% confidence interval	0.895-1.000	Not reported
Optimal cut-off	137 U/L	223 U/L
Sensitivity	90.0%	73.3%
Specificity	100.0%	95.5%
Positive predictive value	100.0%	Not reported
Negative predictive value	88.0%	Not reported
Overall accuracy	94.2%	Not reported

Discussion

In this prospective cohort, POD1 serum lipase showed excellent discrimination for the composite pancreatic-leak endpoint after pancreaticoduodenectomy. A threshold of 137 U/L yielded 90.0% sensitivity and 100% specificity, and its AUC was higher than that of POD1 serum amylase. The principal interpretation is that serum lipase may provide useful early postoperative information in addition to conventional intraoperative risk assessment. However, the threshold was derived and evaluated in the same small dataset and should not be considered ready for routine adoption without external validation.

The overall pancreatic-leak rate was 57.7%, but 19 of the 30 events were biochemical leaks. The clinically relevant grade B/C POPF rate was 21.2%, with no grade C events. This distinction is important because the revised ISGPS framework no longer considers biochemical leak a true fistula [1]. Consequently, our primary analysis predicts a broader composite endpoint and may yield greater apparent accuracy than studies restricted to clinically relevant POPF. Future validation should use grade B/C POPF as the primary endpoint.

Soft pancreatic texture was significantly associated with leak, in keeping with the biological and technical basis of established risk scores. The original Fistula Risk Score combines gland texture, duct diameter, pathology, and blood loss [3], while the alternative score simplifies prediction using body mass index, duct diameter, and texture [4]. Large multicentre analyses have also confirmed the importance of gland characteristics and pathology [5]. The association between preoperative diagnosis and leak in our cohort is therefore plausible, as periampullary and other non-pancreatic ductal adenocarcinoma lesions are often accompanied by a softer, less obstructed gland with preserved exocrine secretion.

Our biomarker findings are broadly consistent with previous reports. Chen and colleagues found that POD1 serum lipase was strongly associated with clinically relevant POPF and had better discrimination than serum amylase in a cohort of 212 patients [8]. Honselmann et al. incorporated early postoperative serum lipase into a nomogram for clinically relevant POPF, supporting the concept that postoperative laboratory markers can refine operative risk estimates [9]. An earlier study also suggested that low early serum lipase could help rule out clinically significant fistula after pancreaticoduodenectomy [10]. More recently, Tang et al. reported that POD1 serum lipase outperformed serum amylase and that a normal lipase level identified a lower-risk subgroup [11].

Nevertheless, the literature is not uniform. A 2023 study reported superior performance of POD1 serum amylase compared with lipase after partial pancreaticoduodenectomy [12]. Serum amylase has also been associated with POPF in earlier series [6,7]. Differences in assay reference ranges, timing of blood collection, surgical technique, case mix, definitions of POPF, and whether biochemical leak is included may account for the varying findings. These discrepancies reinforce the need to validate institution-specific thresholds and to avoid assuming that one absolute enzyme value will apply universally.

Serum lipase has practical advantages. It is widely available, independent of drain placement, and more pancreas-specific than amylase. Its longer elevation after pancreatic injury may provide a more stable signal during the first postoperative day. In the present cohort, the separation between lipase values in patients with and without leak was marked, whereas serum amylase showed greater overlap. Even so, a serum marker cannot diagnose POPF by itself and should not replace clinical assessment, drain fluid amylase, imaging, or established risk scores.

Clinically, POD1 serum lipase could be used as one component of a staged pathway. A low value might support standard recovery and consideration of early drain removal when other clinical and biochemical criteria are favourable. An elevated value could justify closer observation, repeat laboratory testing, delayed drain removal, and selective imaging when accompanied by concerning clinical findings. Such a strategy requires prospective evaluation because diagnostic accuracy alone does not establish that biomarker-guided management improves outcomes.

The strengths of this study include prospective consecutive enrolment, standardised POD1 sampling, collection of relevant operative variables, and use of the revised ISGPS classification. The main limitations are the single-centre design, small sample, absence of grade C POPF, and use of a composite endpoint that included biochemical leak. The limited number of clinically relevant events restricted reliable multivariable modelling. In addition, the cut-off was selected by the Youden index without internal resampling or an independent validation cohort, making the estimates of specificity and positive predictive value susceptible to optimism. Confidence intervals were not available for all diagnostic indices.

A larger prospective multicentre study should validate the 137 U/L threshold and directly compare serum lipase with serum amylase, drain fluid amylase, inflammatory markers, and validated fistula risk scores. Analysis should be centred on grade B/C POPF, with prespecified thresholds, calibration assessment, and decision-curve or

pathway analyses to determine whether incorporating serum lipase improves drain management, complications, length of stay, and cost.

Conclusion

POD1 serum lipase was strongly associated with postoperative pancreatic leak after pancreaticoduodenectomy and showed better discrimination than POD1 serum amylase in this prospective single-centre cohort. A threshold of 137 U/L achieved high sensitivity and specificity for the composite endpoint of biochemical leak or grade B/C POPF. These findings support serum lipase as a simple, inexpensive, and widely available adjunct to clinical assessment, drain fluid amylase, and established intraoperative risk scores. The result should be considered hypothesis-generating , larger prospective multi centre studies should validate the cut-off value for appropriate clinical management.

Declarations

Ethics approval and consent to participate: The Institutional Ethics Committee of Kidwai Memorial Institute of Oncology approved the study (KMIO/MEC/2024/12/PG/MO-40; 7 December 2024). Written informed consent was obtained from all participants.

Availability of data and materials: De-identified study data may be made available by the corresponding author on reasonable request and subject to approval by the institution and ethics committee.

Author contributions:

Arun HN: conceptualisation, methodology, investigation, data curation, formal analysis, and drafting of the manuscript. Pradeep S: methodology, investigation, clinical supervision, and critical revision of the manuscript. Vikas Pandurangappa: conceptualisation, methodology, project administration, supervision, interpretation of data, and critical revision of the manuscript. Prakash BV: investigation, resources, surgical and clinical supervision, and critical revision of the manuscript. Srinivas C: supervision, validation, interpretation of findings, and critical revision of the manuscript. All authors reviewed and approved the final manuscript and agree to be accountable for the integrity of the work.

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