To Study the Biochemical Markers for the Prediction of Fistula Formation after Pancreatic Resection Surgery in the Post Operative Period

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Abstract

Background: To study and assess the potential laboratory biomarkers for foreseeing postoperative pancreatic fistula (POPF) after pancreatic resection medical procedures. **Subjects and Methods:** 64 patients were studied from Jan 2008 to Dec 2018. All patients undergoing Pancreatic resection surgeries like Pancreaticoduodenectomy (PD), distal Pancreatectomy (DP) for tumors of the periampullary region, Pancreatic body or chronic pancreatitis Clinical data of the patients, surgical approach, pancreatic parenchymal tissue consistency, histopathology of the specimen, white blood cell count and blood amylase levels tube Drain fluid amylase were recorded and analyzed. Correlations between these parameters and postoperative pancreatic fistula (POPF) were assessed. **Results :** 22 out of the 64 (34.37%) patients developed POPF. The fistula was graded according to the ISPG classification. It was Grade An of every 10 (45.45%) patients, grade B in 8 (36.36%), and grade C in 4 (18.18%),.On univariate and multivariate strategic relapse investigations, higher amylase levels in the stomach waste liquid on a postoperative day (POD)1 and higher serum amylase levels on POD4 indicated a critical relationship with fistula arrangement in the post-operation period (POPF) (P < 0.05). On ROC (recipient working trademark bend) examination, amylase cut-off degree of 2270.67 U/L in the stomach waste liquid was related with a 76.6% affectability and 82% particularity [area under the bend (AUC): 0.844; P = 0.009]. A cut-off serum amylase level of 53.2 U/L was related with a 74.6% affectability and 72.9% explicitness (AUC: 0.784; P = 0.05). **Conclusion:** Post-operative channel liquid amylase levels on day 1 and serum amylase level on day 4 speak to interesting biomarkers related to POPF improvement after the pancreatic medical procedure.

Keywords: Pancreatic fistula, Pancreaticoduodenectomy

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Introduction

Pancreaticoduodenectomy (PD) is a typical employable methodology for the treatment of different dangerous infections of the distal biliary pipe, the head of the pancreas, and the peri-ampullar district. It is an extremely perplexing surgery conveying a critical dreariness and mortality. PD is related with significant perioperative mortality (2%-5% even in high-volume focuses) and bleakness (30%-50%). [1,2] Postoperative pancreatic fistula (POPF) is one of the main complexities of the method of PD; detailed occurrence rates range from 2% to 25%. [3] This confusion may additionally prompt intra stomach draining boil development which expands the expense and emergency clinic remain of the patients. [3,4] POPF and other PD-related complexities are as yet uncontrolled postoperatively in spite of the improvement of more current strategies of pancreatic gut anastomosis. [5] Various pre-usable and intra-employable components, for example, preoperative jaundice Fatty pancreas and lower measurement of the pancreatic channel, are related with higher paces of POPF; in any case, these elements are not dependable indicators of POPF. [6,7] Bio-chemical markers in serum and waste liquid may mirror the infection movement, and it is exceptionally critical to research their connection with clinical attributes and their expected incentive as indicators of fistula danger in post-operation

period POPF. In this examination, we explore to recognize possible indicators of POPF improvement, which may help enhance the treatment of these patients in clinical practice.

Subjects and Methods

64 patients were tentatively remembered for this investigation. Preoperative, Intraoperative and postoperative information was gathered for every patient. Preoperative factors of interest included age, sex, history of diabetes, jaundice, serum protein levels Intraoperative factors included pancreatic surface/consistency, breadth of pancreatic pipe, and the procedure utilized for pancreatic anastomosis. Postoperative information included histopathology of the example, tube channel liquid volume, and post usable confusions, for example, intra stomach draining, intense pancreatitis, deferred gastric exhausting (DGE), pancreatic and biliary fistula [Table 1]. The seriousness of POPF has delegated grade A, B, or C, as characterized by the International Study Group of Pancreatic Fistula. [8] Composed educated assent was acquired from all patients. Postoperative serological and biochemical investigations along with the surgical outcome were recorded.

Procedure

48 patients underwent Pancreaticoduodenectomy (Whipple's procedure, Six patients were operated on for chronic pancreatitis and 10 patients had distal pancreatic resections. Pancreato-jejunostomy was performed by the same surgeon in all patients as follows. A retrocolic jejunal limb was brought into the lesser sac through a window in the transverse colon, an end to side pancreatic-jejunal anastomosis was fashioned in two layers; a duct to mucosa anastomosis was made using PDS interrupted sutures. Abdominal drains two in number were used; one without suction was kept in a subhepatic location, the second adjacent to the pancreatic anastomosis A single drain was used for patients undergoing distal Pancreatectomy DP and was placed adjacent to the pancreatic stump. The drain withdrawal was influenced by levels of amylase recorded postoperatively, the color of the abdominal fluid and the general clinical condition of the patient. Broad-spectrum antibiotics were used in the intial period of 72-96 hrs. The upper limit of the reference range of amylase in our laboratory was 100 IU/L.

Statistical Analysis

Data were analyzed on IBM SPSS 22. Receiver operating characteristic (ROC) curve analysis was performed to assess the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the identified variables. A P value of < 0.05 was considered as significant. Univariate and

Table 1: Complications

Complication	Definition
Pancreatic Fistula POPF	Amylase activity of fluid in the drain is at least three times the upper limit of normal on or after postoperative day 3
Free fluid in Peritoneum (Ascites)	> 5 cm of fluid depth on USG abdomen
Post-op Bleeding Hemorrhage	The requirement of > 2 units of whole blood
Biliary fistula	Bilious drainage of > 50 ml post-op

multivariate analyses were performed to identify factors significantly related to fistula formation POPF.

Results

Out of 64 patients, 22 (34.7%) created POPF. The seriousness of POPF was delegated grade an of every 10 (45.45%) patients, grade B in 8 (36.36%) and grade C in 4 (18.18%) [Table 2]. Division of patients was made into fistulous gatherings (POPF) and non-fistulous gatherings (non-pop gatherings) and afterward looked at the degrees of various boundaries between the two gatherings [Table 3]. On univariate investigation, amylase level in the stomach seepage liquid on post-operation day 1 and serum amylase level on day 1 and day 4 postoperatively was connected with pancreatic fistula arrangement (POPF) (P < 0.05) [Table 4]. Multivariate strategic relapse investigation affirmed that amylase level in stomach seepage liquid on post-operation day 1 and serum amylase level on day 4 were autonomous indicators of POPF [Table 5]. On Receiver Operating Curve (ROC) investigation, a cut-off amylase level of 2365.5 U/L in the stomach seepage liquid on post-operation day 1 as an indicator of POPF was related with 78.6% affectability, the particularity of 80%, 66.7% positive prescient worth (PPV) and 88% negative prescient worth (NPV); P = 0.009] [Figure 1]. Essentially, a cut-off serum amylase level of 44.2 U/L on post-operation day 4 was related with a 78.6% affectability and 70.9% particularity [AUC: 0.784; P = 0.05; Figure 2]. The explicitness of these affiliations was additionally featured by the perception that neither one of the whites platelet (WBC) tallies nor egg whites levels related with post-operation fistula arrangement POPF advancement.

Discussion

"Whipple method" for Pancreaticoduodenectomy (PD) for the treatment of threatening tumors in the head of the pancreas

Table 2: Complications

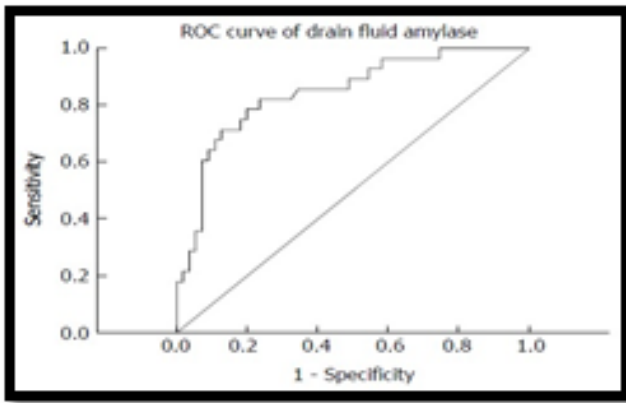| Complication	Cases n = 26	Incidence %
Post-op Fistula	22	34.37
Grade A	10	45.45
Grade B	8	36.36
Grade C	4	18.18
Free Fluid in Peritoneal cavity (Ascites)	6	27.27
Bleeding	4	18.18
Post-op Biliary leak	2	9.99
Paralytic ileus	6	27.27

Figure 1: ROC curve analysis of amylase activity in tube drain fluid. 2365.5 U/L was associated with 78.6% sensitivity, 80% specificity, 66.7% positive predictive value and 88% negative predictive value for risk of fistula formation.

and the peri-ampullar locale is one of the most unpredictable and progressed surgery of fluctuating inconveniences and delayed activity time.[9,10] Postoperative difficulties following PD range from 30%-70%, and a death pace of 5% or all the more even in high-volume centers.[11] POPF represents 2%-25% of all entanglements of methodology.[12] More up to date careful methods for Pancreaticojejunostomy like conduit mucosa or pancreatic channel stent implantation have not brought about any significant improvement in diminishing the fistula rates.

As such early discovery of POPF and ideal mediation is imperative to improve careful results.[13–17] Different instruments and procedures have been concentrated to recognize patients who are in danger of the advancement of fistula POPF. This investigation distinguished possible indicators of POPF and the outcomes recommend that cylinder channel liquid amylase
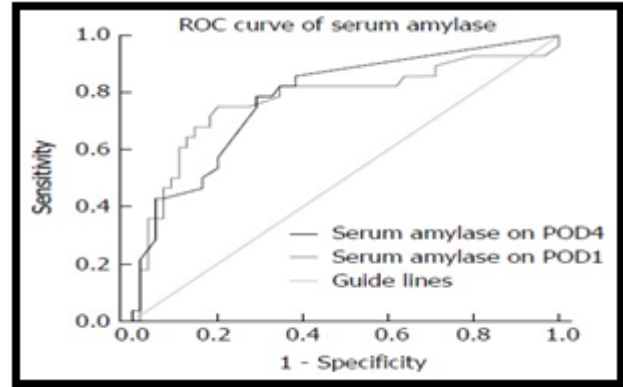

Figure 2: Serum amylase ROC curve analysis activity. Post op day 4 value of 44.2 U/L on has a 78.6% sensitivity and 70.9% specificity for post op fistula risks.

(DFA) levels and serum amylase levels can serve as clinical biomarkers and its measurement is simple and promising. Factors assigned fistula formation include pancreatic parenchymal texture, Pancreatic duct diameter, Histopathology of the specimen and comorbidities associated;[18–23] however, the prescient worth has been demonstrated to be generally poor and conflicting. In the current investigation, we noticed a conspicuous connection between's amylase levels in the cylinder channel liquid on POD1 and the serum amylase level on POD4 with the event of POPF. Recently published data (Popiela et al; Kawai et al,[24–26] show that drainage fluid amylase levels on post-op Day 1 (> 350 U/L) predicts post of the fistula with a 79% specificity and a sensitivity of 100 %. A positive prescient estimation of 41% PPV, and a negative prescient of 100%. The aftereffects of this investigation show that post-operation day 1 amylase level in channel liquid and blood amylase on day 4 could foresee the chance of pancreatic fistula development in the post usable period after pancreatic medical procedure Leukocyte tallies and protein levels (albumen) were not seen to have any relationship with fistula arrangement.[27–29] Our results were consistent with the published reports. A cut-off amylase level in tube drain of 2365.5 was associated with a prediction of fistula formation in 78.6 % and a specificity of 80 %; It has a positive predictive value of 66.7% and a negative predictive value of 88 %. Our conclusion from the study is that in patients with the post of pancreatic fistula POPF, increased levels of amylase in tube drain on post-op day 1 comes from the disruption in the pancreatic and bowel anastomosis causing leaks and fistula formation. S Amylase levels in serum on post-op day 4 as high as 100 u/l have a prediction of fistula formation with a sensitivity of 42.9% and a specificity of 55% having a positive predictive value of 75% with a negative value of 76.1%. Intraoperative and postoperative hypovolemia and compression injury to pancreatic vessels during the

Table 3: Risk Factors for Pancreatic Leakage Variable POPF

Variables	POPF (22)	Non-POPF (42)	χ^2	P Value
Patients Age (yrs)	52.7	51.4	0.07	0.94
Gender Male Female	12 (54.5) 10 (45.5)	22 (52.38) 20 (47.61)		
Operative blood loss (ml)	325 (250-570)	300 (200-450)	1.25	0.2
Pancreatic duct diameter Less than 3mm More than 3mm	8 14	13 29	3.18	0.13
Pre-op Jaundice Yes No	9 13	14 28	0.17	0.78
Pre-op Biliary drainage Yes No	3 19	4 24	0.46	0.47
ERC Drainage External Internal	8 14		0.28	0.78
Procedure time	270 (240-380)	285 (235-370)	-0.08	0.97
Hospital stay (Days)	15 (12-21)	9 (7-17)	-2.29	0.91
Comorbidity Diabetes Yes No	4 18	8 34	4.29	0.89
Drainage fluid amylase level on POD1 in U/L	6085 (2395-10800)	654 (400-972)	-4.9	<0.001
Serum amylase level in U/L Post op D1 D4	340 (168-690) 40 (30-74)	100 (50-190) 30 (25-52)	-5.01	<0.00
Albumen D1 D3 D5	2.9 (2.5-3.8) 3.1 (2.9-3.9) 3.1 (2.8-4.0)	3.1 (2.4-4.2) 3.0 (2.8-4.0) 3-1 (2.7-4.1)	-0.12	0.97
White Blood Cell Count (TLC)t D1 D3 D5	14.7 (10.8-18.7) 14.90 (11.7-18.64) 11.99 (9.65, 15.5)	15.4 (12.4-18.5) 13.5 (10.8-16.7) 11.2 (9.8-14.6)	-0.7 -1.12 0.75	0.4 0.2 0.6
Specimen Histopathology Results Adenoma Pancreas PeriampullaryCa CholingioCa Others	8 6 4 4	18 14 4 6		

surgery cause ischemic injury to pancreatic tissues which leads to elevation of serum enzyme amylase. [30,31] No factually huge relationship was seen between serum amylase level in post-operation day 1 and pancreatic spillage, and no connection was found between serum amylase levels on day 4 mirrors the foundation of the pancreatic anastomosis. The disruptive effect of

Table 4: Results of Univariate Analysis Showing Risk Factors For Postoperative Pancreatic Fistula

Variabales	β	SE	Wald χ^2	0R	" P "value
Patient Age (yrs)	0.023	0.03	0.39	1.02	0.52
Gender ; female/male	-0.58	0.5	0.5	0.56	0.27
Operative Blood loss in mL	0.00	0.01	1.35	1.00	0.61
Duct diameter,	0.83	0.4	3.13	0.45	0.07
More than 3 mm Or < 3 mm					
Plasma protein low, yes/no	0.17	0.7	0.16	1.19	0.77
Jaundice Relieved, yes/no	0.75	0.5	1.01	2.12	0.43
Comorbidity of Jaundice, yes/no	0.10	0.4	0.04	1.11	0.82
Drainage of Pancreas	0.23	0.4	0.28	1.26	0.56
Comorbidity; Diabetes, yes/no	21.9	26450.8	0.000	3.67	0.99
Histopathology result, Ampullary carcinoma	0.24	0.1	1.74	2.34	0.18
Pancreatic carci-noma/cholangiocarcinoma					
Intraoperative Time in min	0.00	0.01	0.008	1.00	0.98
Amylase levels in drain fluid, POD1 > 5000 U/L	0.00	0.00	8.93	1.00	0.001
Blood amylase level	0.004	0.01	6.94	1.00	0.002
Day 1 > 140 U/L	0.013	0.03	7.75	1.01	0.005
Day 4 > 140 U/L					
Post op albumin	0.00	0.04	0.00	1.00	0.99
Day 1	-0.006	0.04	0.02	0.99	0.08
Day 3	-0.023	0.04	0.27	0.98	0.58
Day 5					
Post-op TLC count	0.00	0.00	1.15	1.00	0.28
Day 1	0.00	0.00	1.25	1.00	0.25
Day 3	0.00	0.00	2.20	1.00	0.15
Day 5					

Table 5: Results of Multivariate Logistic Regression Analysis Showing Risk Factors for Postoperative Pancreatic Fistula

Parameter	β	Se	Wald χ^2	Or	P value
Post op amylase level, Day 1 > 5000 U/L	0.000	0.000	6.27	1.000	0.009
Post Op Day 1 > 140 U/L	0.001	0.002	0.34	1.001	0.624
Levels on Day 4 > 140 U/L	0.007	0.004	3.82	1.008	0.050

pancreatic enzymes on the anastomotic site and the vasculature increases the absorption of amylase causing the rise in serum amylase levels. Therefore day 4 blood amylase level is of sure prescient incentive for the event of post-operation fistula. In our examination, we found that amylase movement in waste liquid on day1 and serum amylase action on day 4 could precisely foresee post of pancreatic fistula POPF. Protein levels (albumen) leukocyte counts did not show a significant prediction for fist ululation. Amylase levels in tube drain on post-op day 1 and blood amylase level on day 4 is a comparatively easy and economical method in clinical practice. This study supports the use of tube drain amylase levels to predict pancreatic fistula formation. This may help for timely interventions (percutaneous drainage/exploration), increased hospitalization prolonged use of antibiotics and octreotide.

Treatments, that may help forestall POPF and consider convenient danger correspondence to the patient. It is additionally another method in the preparing did in our clinical focus.

Conclusion

Post-operative channel liquid amylase levels on day 1 and serum amylase level on day 4 speak to interesting biomarkers related to POPF improvement after the pancreatic medical procedure,

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