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Can preoperative computed tomography scan predict the occurrence of a pancreatic anastomotic leak: A prospective study with clinical, radiological and pathological co-relation

Adithya V. Naragund, Prabhu R. Y., Hira P., Karegar M. M., Khuroo S. F., Bapat R. D., Kantharia C., Supe A. N.

ABSTRACT

Aims: The pancreatic anastomosis after pancreaticoduodenectomy leaks in 5–30%. The accepted determinants of postoperative pancreatic fistula (POPF) are small pancreatic duct and soft pancreatic texture. Pancreatic fibrosis decreases the risk of POPF as seen in patients undergoing surgery for chronic pancreatitis. Recent studies have attempted to use radiological methods to determine the pancreatic fibrosis and thus indirectly predict the risk of leak. Methods: Patients undergoing Pancreatico-enteric anastomosis underwent a pancreatic protocol CT scan preoperatively. The enhancement ratio expressed as late phase/ early phase ratio (L/E ratio) was calculated as: (hepatic phase – unenhanced phase)/ (pancreatic phase – unenhanced phase) to indicate delayed-phase enhancement. This ratio is used to predict the degree of pancreatic fibrosis. The pancreas was assessed by the surgeon intraoperatively. Pancreatic tissue obtained was analyzed for degree of pancreatic fibrosis. Pancreatic leak was classified as per ISGPF criteria. Results: Thirty-seven patients were included in the study, 21 underwent Frey's/Beger's procedure and 16 patients underwent pancreaticoduodenectomy. The L/E ratio co-related well with the surgeons assessment of the pancreatic texture as well as the degree of pancreatic fibrosis. A ratio of 0.98 could predict leak with sensitivity of 75% and Specificity of 93.1%, P value 0.0231. Surgeon's assessment of the pancreas was also a good predictor of a POPF. Conclusion: L/E ratio calculation is simple and cost effective. The ability to predict a leak may have a significant impact on patient outcome. It helps in pre-operative patient counseling and warns surgeons about the presence of high risk factors for leak. This study validates the ability to co-relate radiology with histological fibrosis and incorporate them into clinical practice.

Keywords: Fibrosis, Leak, Pancreas, Pancreaticoduodenectomy

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INTRODUCTION

Any anastomosis concerning the pancreas and the bowel is considered most tenuous in gastrointestinal surgery. The pancreatic anastomosis after pancreaticoduodenectomy leaks in 5–30% [1, 2] and contributes to significant morbidity i.e., 30–50% [3–5]. A leak cannot be avoided and is best anticipated both by the surgeon and the patient. The impact of a biochemical leak on an individual patient varies and has no relation to the biochemical parameters which define a leak. The International Study Group of Pancreatic fistula (ISGPF) definitions was used to classify pancreatic fistulas [6]. The accepted determinants of postoperative pancreatic fistula (POPF) are anatomic features of pancreatic remnant such as small pancreatic duct and soft pancreatic texture. Pancreatic fibrosis decreases the risk of anastomotic failure as seen in patients undergoing surgery for chronic pancreatitis [7, 8].

Recent studies have attempted using radiological methods to determine the pancreatic fibrosis and thus indirectly predict the risk of POPF [9, 10]. Primary aim of our study was to determine role of preoperative CT scan in determining the degree of pancreatic fibrosis and predicting the occurrence of a POPF following Pancreatico-enteric anastomosis. Secondary aim was to co-relate CT scan findings with intraoperative findings and histopathological degree of pancreatic fibrosis.

MATERIALS AND METHODS

The study was approved by the institutional ethics board. This was a prospective observational study, carried out between Jan 2013 and March 2014. All patients undergoing a pancreatico-enteric anastomosis during the specified period were included in the study. Patients with contra-indications for a preoperative contrast enhanced CT scan or patients not consenting to undergo the procedure were excluded from the study.

COMPUTED TOMPGRAPHY PROTOCOL

A 64 slice Philips CT machine was used. A plain scan of the pancreas was performed to look for pancreatic calcifications. Two ml/kg body weight of iohexol contrast (Omnipaque 300, GE Health care) was injected at a rate of 4 ml/s through an 18 gauge intravenous cannula placed in the ante-cubital vein. Median slice thickness was of 5 mm with post study reconstructions of 2.5 mm. The early-portal phase or the pancreatic phase was taken after a scan-delay of 40–50s. The 'late portal' or hepatic phase has a scan-delay of 70–80 s.

The CT image was analyzed by a single experienced radiologist independently with special interest in gastrointestinal radiology. CT images taken within 30 days before surgery were included in this analysis. Attenuation values were measured on both unenhanced phases and images obtained in the pancreatic (early) and hepatic (late) phases after contrast administration. All attenuation values of the pancreatic parenchyma were quantified by Hounsfield unit thresholds by placing a region of interest (ROI) at six points in two segments of the pancreas (body and tail). The mean value for the two segments was computed for each patient. ROIs in the body were placed over an area unaffected by the tumor usually in the SMA region and in the tail about two-thirds distal from the body–tail transition. In patients with chronic pancreatitis, regions with calcification were carefully avoided. The largest possible spherical ROI was taken, making every effort to avoid the pancreatic duct and structures outside the pancreas.

The CT attenuation values of the liver and spleen were measured on unenhanced images and on images obtained in the pancreatic and hepatic phases.

The enhancement ratio expressed as

Late phase/early phase ratio (L/E ratio) was calculated as:

(Hepatic phase – unenhanced phase)/ (pancreatic phase – unenhanced phase**)** to indicate delayed-phase enhancement.

Normally, the pancreas shows maximum enhancement in the 'early' phase but with increasing fibrosis of the pancreatic parenchyma, there is a delay in the maximum enhancement which tends to coincide with the hepatic phase. This shift in the enhancement pattern is used to predict the degree of pancreatic fibrosis.

The pancreatic duct size was measured in millimeter in the region of the neck of the pancreas for patients planned for pancreaticoduodenectomy. For patients undergoing Frey's procedure, an average of three measurements of the pancreatic duct in the region of the head, neck and mid body of the pancreas was taken for analysis.

PREOPERATIVE EVALUATION

All patients underwent standard preoperative evaluation which included hemoglobin, total and differential counts, liver function tests, renal function tests, chest X-ray and ECG. The preoperative BMI was recorded for each patient. The albumin, bilirubin levels, hemoglobin and BMI were tested for significant association with POPF.

SURGICAL TECHNIQUE

Surgical technique was standardized. All procedures were performed by experienced surgeons. A classical Whipple pancreaticoduodenectomy (PD) procedure with duct-to-mucosa pancreatico-jejunostomy was performed for patients with malignancy or high suspicion of malignancy. No stents were used across the PJ. An end-to-side hepaticojejunostomy and 40 cm distal to the biliary anastomosis, an antecolic, end-to-side gastro-jejunostomy were performed.

For patients with chronic pancreatitis, a standard Frey's procedure with head coring and a side to side Pancreatico-jejunostomy was performed.

Beger's procedure was performed in patients with chronic Pancreatitis with a bulky pancreatic head. All patients had a closed drain placed near the pancreatic anastomosis.

Intraoperatively, the texture of the pancreatic gland was subjectively assessed by surgeon with an experience of more than 10 years in HPB surgery using a 1–10 scale and classified into three grades as "soft" (scale 1–3), "firm" (4–7), or "very firm" (8–10).

HISTOPATHOLOGICAL ANALYSIS

The pancreatic tissue obtained was evaluated by a senior pathologist with special interest in gastrointestinal pathology. Masson's trichrome staining was used to identify the collagen tissue by dyeing them blue for quantitative evaluation of fibrosis in the pancreatic tissue. For quantitative evaluation the proportion of collagenous fiber was determined in 10 views (histological fields ×40) .The degree of fibrosis was calculated as the ratio of stained collagen tissue to total area measured in entire section. The percentage of fibrosis was calculated as the average of multiple sections studied for each patient [10, 11].

Anastomotic Leak definition and Classification

Anastomotic leak was diagnosed and classified based on the ISGPF criteria of any measurable drainage from an operatively placed drain (or a subsequently placed percutaneous drain) on or after postoperative day-3, with amylase content greater than three times the upper limit of normal serum amylase level. All patients below this threshold were considered to have no fistula. Pancreatic fistulas, when detected, were classified into grade A/B/C depending on the clinical manifestations in accordance with the ISGPF criteria [6].

PERIOPERATIVE CARE

All patients were shifted to the ICU postoperatively. Patients were monitored in the ICU for two days and shifted to the general ward on day-3, unless otherwise indicated. Ryles tube was kept in place for three days. Enteral nutrition was started on day-2 and gradually increased as per patient's tolerance. Drain fluid amylase was tested on postoperative day-3. If drain amylase was normal on day-3 with persistent drain output, it was repeated on day five. If normal, no further testing was done and patients were observed for decrease in output. Patients with uneventful recovery were discharged by day 7–9. All patients with suspicion of pancreatic leak were closely observed. Any deviation from normal recovery would prompt urgent imaging with a CT scan. Collections were tackled with radiologically (USG/ CT) guided minimally invasive techniques and surgical intervention was reserved for patients who deteriorated or radiologically guided access was not feasible

STATISTICAL ANALYSIS

Data analysis was done with the help of appropriate statistical software SPSS version 15 and Sigmaplot version 11. Quantitative data is presented with the help of Mean, Standard Deviation, Median and IQR, while the comparison between two study groups was done with the help of unpaired T test or Mann-Whitney test and comparison among three groups was done with one way ANOVA test or Kruskal Wallis test as per results of Normality test. Association among study group was assessed with the help of Pearsons chi-square test and Fisher Exact test was applied for 2x2 tables. The p-value less than 0.05 was taken as significant level.

RESULTS

Forty-three eligible patients presented to us. Six patients who underwent pancreatoduodenectomy were excluded from the study due to inability to perform a CT scan in accordance with the pancreatic protocol due to various reasons,

(Contrast hypersensitivity in 3, renal function compromise in 2 and unwilling to undergo a repeat CT scan as per pancreatic protocol in 1 patient)

A total of 37 patients who underwent Pancreaticojejunostomy were included in the present study (Figure 1).

The age group ranged from 16 to 70 years for patients suffering from chronic pancreatitis (median age 41 years). patients with suspected malignancies ranged from 45 to 70 years of age with a (median of 57.5 years).

All patients underwent a preoperative contrast enhanced CT scan with pancreatic protocol (Figure 2).

Hemoglobin less than 12 g/dL was considered as anemia [8]. A mean hemoglobin was 12.26 g/dL in the study group with a median of 12.05 g/dL (Range 7.9 to16.5 g/dL) 45.95% of patients suffered from anemia in the study group.

Elevated bilirubin levels were detected in nine patients. Eight of these patients were diagnosed with malignancies (Total bilirubin range 8.5–26.5 mg/dL, mean 15.58 mg/dl). One patient with chronic pancreatitis with CBD stricture had a total bilirubin of 3.0 mg/dl. Eleven patients had albumin levels less than 3.5 g/dl (range 1.2–3.4 g/dl). -

The BMI was calculated for all patients. A normal BMI for Indians is between 18.5 and 23. Nineteen patients had a BMI less than 18.5 (51.4%). Of these, six patients (31.57%) suffered from malignancy, one patient (5.2%) had adenomyomatous hyperplasia of distal CBD and 12 (63.15%) suffered from chronic pancreatitis. Four patients had a BMI of > 23 (10.8%). Three patients (75%) had malignancy and 1 patient (25%) had CP.

No significant association was seen between patient characteristics or preoperative investigations and risk of POPF except for an elevated BMI which showed significant association with POPF (Table 1).

MORBIDITY

Five (13.5%) patients out of 37, developed clinically significant leaks (i.e., Grade B and Grade C leaks, ISGPF criteria). This included one patient out of 21 (4.7%) of Frey's/Beger's procedure group and 4 (25%) patients out of 16 in the Whipple procedure group. All grade B leaks were managed by pig tailing of the collection and appropriate antibiotics as per the culture reports. Multiple interventions were done when necessary. Two patients with grade C leaks had to be re-operated and collections were drained after thorough peritoneal lavage. Wound infections were managed by local dressings and DGE was managed by Ryles tube aspiration and nasojejunal feeds till the patient could tolerate oral feeds.

MORTALITY

Two patients out of 37 died (5.4%). Both patients were post Whipple surgery and had developed grade C leaks and died due to sepsis and pulmonary complications resulting in a procedure specific mortality rate of 9.09% (Total Whipple performed - 22 patients - including 6 patients who were excluded from the study).

A significant number of leaks, i.e., 5 (62.5%) out of 8 leaks occurred in patients with malignancy though this value did not attain statistical significance (p-value 0.067). However, it was found that four out of five patients (80%) with a clinically significant leak (ISGPF grade B/C) were suffering from malignancy (p-value 0.024). Patients with chronic pancreatitis were less susceptible to leak with only three leaks out of eight occurring in these patients. Moreover, only one clinically significant leak occurred in these patients (*p*-value 0.144).

COMPUTED TOMOGRAPHY FINDINGS

Pancreatic duct size was considered dilated when it was more than 3 mm. Six out of eight patients who developed a leak had a pancreatic duct size of 3 mm or less (*p*-value 0.001). Out of these, two were grade B and two grade C leaks. One Grade B leak occurred in a patient with dilated duct.

The L/E ratio, described earlier, was tested for association with POPF. Analysis revealed that a L/E ratio less than or equal to 1 was present in six out of eight patients with leak (p-value 0.001).

Furthermore, all five patients (100%) with grade B and C leaks had a L/E ratio less than or equal to 1 (*p*-value of 0.0003, Fisher's exact test). A mean L/E ratio of 0.98 had a sensitivity and specificity of 75% and 93.1% respectively for predicting the occurrence of a leak (Figure 3).

In five out of eight patients with leak (62.5%) and 4 out of five patients (80%) with a clinically significant leak, the consistency of the pancreas was deemed to be soft by the surgeon. The p-value on Pearson chi-square test was 0.001. The L/E ratio also co-related with the surgeon's assessment of the pancreatic texture. The mean L/E ratio was 1.04 for soft pancreas, (*p*-value- 0.001) (Table 3).

HPE AND POPF

Sixty percent of the clinically significant leaks occurred in patients with less than 35% fibrosis (50% when total number of leaks were considered), but this co-relation did not achieve statistical significance, p-value

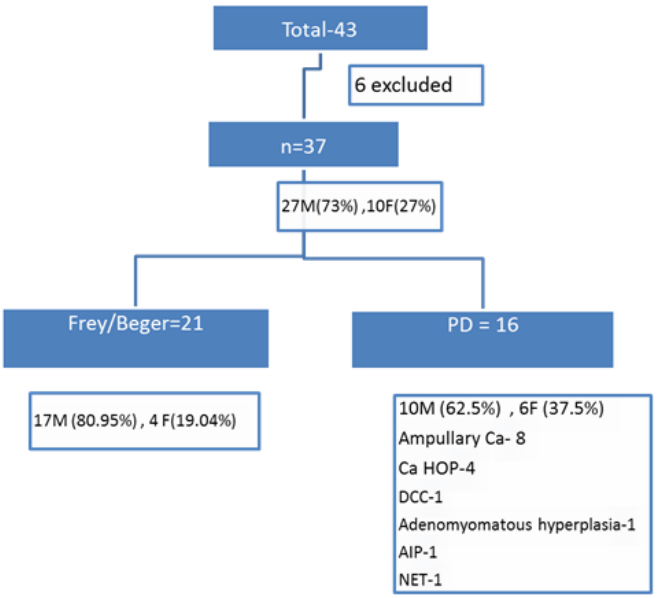

Figure 1: Structure of the study cohort. Out of 43 patients, six were excluded (see text), 37 were included. Twenty-one patients underwent Frey's/Beger's procedure and 16 underwent pancreaticoduodenectomy.

0.084. The receiver operating characteristic (ROC) curve shows that a 35% fibrosis has a sensitivity of 62.5% and a specificity of 86.2% for developing a leak (Figure 4).

The L/E ratio in our study showed excellent co-relation with the degree of pancreatic fibrosis. A mean L/E ratio of 1.48 with a SD of 0.69 showed statistically significant association with a fibrosis of 56% with a p-value 0.002 (Figure 5).

The L/E ratio also co-related with the surgeon's assessment of the pancreatic texture. The mean L/E ratio was 1.04 for soft pancreas, 1.38 for firm and 2.26 for very firm pancreas, (p-value 0.001). Table 3 shows the co-relation between the texture of the pancreas, degree of fibrosis and the mean L/E ratio among the cohort.

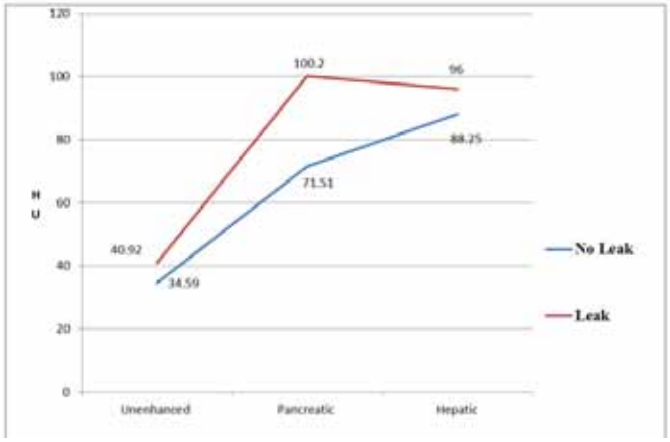

Figure 2: Preoperative contrast enhanced computed tomography (CT) scan, the characteristics of CT enhancement on unenhanced, pancreatic and hepatic phases in patients with and without leak. The No leak group showing an increase in enhancement in the late (hepatic) phase whereas the leak group showing an early (pancreatic) phase enhancement followed by a fall in the HU in the late phase. An average of 102 ml of contrast was used.

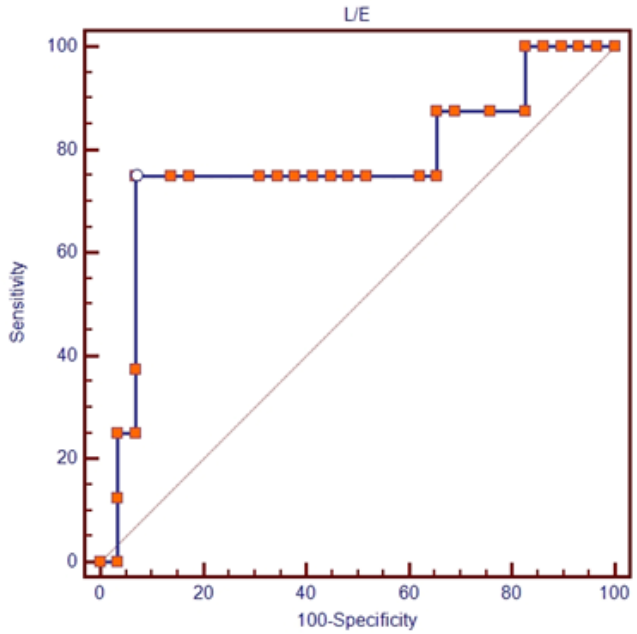

Figure 3: Mean late phase and early phase ratio (L/E ratio) and area under curve (AUC). The above receiver operating characteristic (ROC) curve showing that an L/E ratio of 0.98 has a sensitivity of 75% and a Specificity of 93.1% in predicting the occurrence of a leak (p-value 0.0231).

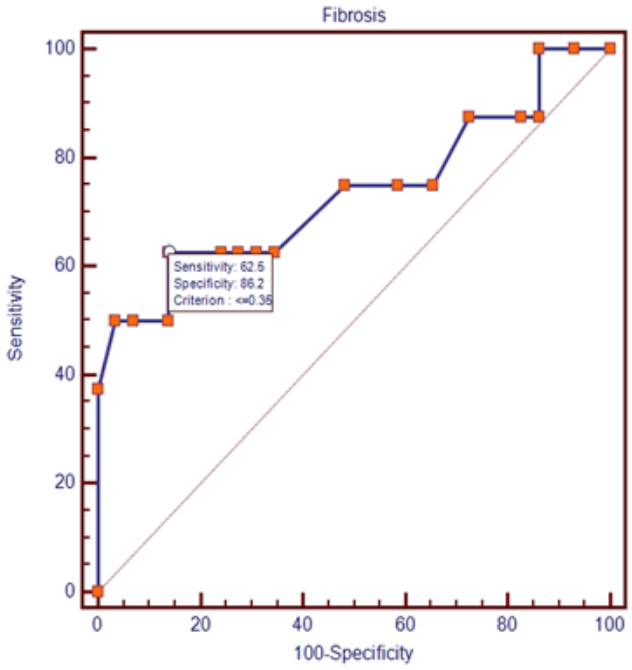

Figure 4: The receiver operating characteristic (ROC) curve showing a 35% pancreatic fibrosis having a sensitivity of 62.5% and a specificity of 86.2% for developing a leak.

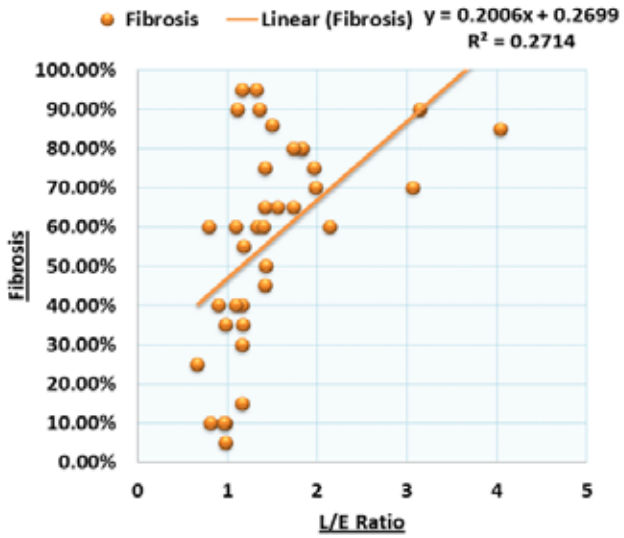

Figure 5: The graph showing the correlation between L/E ratio and the degree of pancreatic fibrosis. A mean L/E ratio of 1.48 with a SD of 0.69 showed statistically significant association with a fibrosis of 0.
56 and SD of 0.27 (p-value 0.002).

DISCUSSION

The need for predicting the occurrence of a pancreatic leak preoperatively has inspired many researchers to explore various diagnostic modalities, prominent among them being CT scan and MRI.

Tajima et al. [12] described the MRI characteristic Time signal intensity curve (TIC) in normal pancreas which showed a rapid rise followed by a rapid decline while a fibrotic pancreas showed a slow rise to the peak followed by a decline or plateau.

Takahasi N et al. [9] described CT enhancement characteristics in normal pancreas, autoimmune pancreatitis, focal AIP and carcinoma. Y Hashimoto et al. [10] also compared the enhancement patterns on CT in patients undergoing PD among those who did and did not develop a POPF. The enhancement pattern observed in our study was similar to earlier studies especially with regards to POPF (Table 4). As the degree of pancreatic fibrosis increases, there is a rise in enhancement of the pancreatic tissue in the late phase as compared to the early phase. In contrast, in normal pancreatic tissue or where the fibrous content is lesser, there is an early rise followed by a fall in the enhancement in delayed phase.

The L/E ratio of less than or equal to 1 was significantly associated with a pancreatic leak (all Grades included) with a *p*-value of 0.001 and it was < 1 in all patients who developed a grade B or grade C leak (*p*-value 0.0003). The mean L/E ratio which was significantly associated with POPF was 1.12 and that among the no leak group was 1.59. The higher mean L/E ratio seen in our study is due to the fact that our study group consisted of patients suffering from chronic pancreatitis who had a significantly higher L/E ratio and developed Grade A leaks which were also included. However, when clinically significant leaks (ISGPF B and C) were considered, the mean L/E ratio was 0.9. These findings corroborate with the findings of Hashimoto et al. [10] who found that the mean L/E ratio among those patients who developed a leak was 0.86 and 1.09 among those who did not. They considered only patients undergoing PD and developing grade B and grade C leaks.

The ROC curve in our study showed that an L/E ratio of 0.98 had a sensitivity and specificity of 76% and 93% respectively for predicting POPF.

It is now accepted that a soft pancreas has a higher chance of leaking. A study determined that 14% of leaks developed in a soft pancreas [13]. Another study reported a leak rate of 32.1% in soft pancreas [14]. An experienced surgeon's assessment of the pancreatic texture intra-operatively can also predict the occurrence of a leak as shown in our study where four out of five patients who developed POPF could be identified by the surgeon as having soft pancreas. This also co-related with the actual degree of fibrosis (Table 5). Thus an experienced surgeon

Table 1: Patient characteristics and postoperative pancreatic fistula

	No POPF (n %)		POPF (n %)		p-value
Age < 65 years	24	82.8%	5	62.5%	0.218
> 65 years	5	17.2%	3	37.5%	
Males	22	75.9%	5	62.5%	0.655
Females	7	24.1%	3	37.5%	
Hemoglobin g/dL (< 12 g/dL)	62.5%		41.4%		0.428
Serum Albumin (<3.5 g/dl)	24.1%		50%		0.203
Serum Bilirubin (>2 mg/dl)	4	13.8%	5	62.5%	0.218
Body Mass Index >23 kg/m²	1	3.4%	3	37.5%	0.006

Table 2: Morbidity

	N = 37		
POPF -	8 (21.62%) Grade A -3 Grade B -3 Grade C -2	PD – 5 • Grade A –1 • Grade B – 2 • Grade C – 2 CP – 3 • Grade A – 2 • Grade B – 1	31.25% (POPF rate for PD) 14.28% (POPF rate for CP)
Wound infection	2	PD – 2	12.5%
DGE	1	PD – 1	6.25%

POPF Postoperative pancreatic fistula, PD Pancreaticoduodenectomy, CP Chronic pancreatitis, DGE Delayed gastric emptying

Table 3: Co-relation between texture of pancreas, percentage of fibrosis and late phase and early phase ratio

N	Texture	Fibrosis (HPE) (Mean+/- SD)	L/E Ratio Mean	POPF Total (B+C)
7	Soft	0.21+/- 0.18	1.04	5 (4)
23	Firm	0.62+/- 0.22	1.38	3 (1)
7	Very firm	0.71+/- 0.21	2.26	0
p-value		0.0009	0.002	

Table 4: Comparison of computed tomography scan enhancement characteristics between studies.

	Hashimoto et al.,		Present study	
Phases on CT	POPF	No POPF	POPF	No POPF
Unenhanced	33.7	31.5	**40.9**	**34.5**
Pancreatic	107	98.3	**100.2**	**71.5**
Hepatic	92.2	101.7	**96**	**88.25**

Table 5: Comparison between studies- Fibrosis and Pancreatic Texture

	Y HASHIMOTO et al. [6]	PRESENT STUDY
Texture (intra-op)	Fibrosis (%) Mean +/- SD	
Soft	16.6+/- 14	21+/-18
Firm	31.5+/- 27.2	62+/-22
Very firm	52+/-28.5	71+/-21
p-value	< 0.001	0.0009

can identify a patient at a high risk of a POPF intra-operatively.

The surgeon's assessment of the pancreatic texture co-relates well with the L/E ratio as calculated on the preoperative CT scan in our study. Thus it is possible to have the same information available preoperatively by calculating the L/E ratio which would have been determined intraoperatively otherwise. This is a significant advantage to the operating surgeon who is mentally prepared for a daunting task ahead.

The ROC for pancreatic fibrosis on Histopathology showed that a pancreas with < 35% fibrosis was 62.5% sensitive and 86.2% specific in predicting the occurrence of a POPF. In our study, we found that 60% of the clinically significant leaks (grades B and C ISGPF), occurred in pancreas with a fibrosis < 35%. This, however, did not achieve statistical significance.

Hashimoto et al. [10] in their study found a significant co-relation between L/E ratio and degree of pancreatic fibrosis with a *p*-value of < 0.001. We in our study found similar association between the two variables with a *p*-value of 0.002. A natural extrapolation of this result would be to use this ratio to predict the outcome of a pancreatico-jejunostomy and there by devising means to avoid a leak in high risk patients.

A BMI more than 23 is considered as abnormal for the Indian population [15]. An elevated BMI is associated with an increased risk of leak from the pancreatic anastomosis probably due to the increased Pancreatic and peripancreatic fat content [16, 17]. Our study found a similar high incidence of POPF in over-weight/obese patients. Age, gender, anemia, preoperative serum albumin levels and elevated bilirubin levels were not significantly associated with POPF. Elevated bilirubin has been found to be a risk for anastomotic failure in some series though [18].

The limitation of this study is probably the smaller number of patients in the study groups. As the study is progressive we are hopeful of presenting a larger series in the future. The strict protocol to be followed while performing the CT scan requires co-ordination with the Radiologist and monitoring and adequate training of the technical staff.

CONCLUSION

The late phase/early phase (L/E) ratio may have a significant impact on our ability to predict a POPF. It is a simple and objective way of assessing the degree of pancreatic fibrosis by a non-invasive test preoperatively. The calculation is simple and does not require much time. The other advantage is that it comes at no additional cost to the patient. It can be calculated for all patients

who undergo a pancreatic surgery and helps in better risk stratification. The ability to predict a leak may have a significant impact on patient outcome. It helps in preoperative patient counseling and warns the surgeons about the presence of high risk factors for leak. This may have an impact in teaching hospitals where patients may be segregated as per the risk and operations planned accordingly. The present study is significant in that, it tested the L/E ratio for chronic pancreatitis as well and found consistent results, which further validates the ability to co-relate radiology with histological fibrosis and incorporate them into clinical application.

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Author Contributions

Adithya V. Naragund – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
Prabhu R. Y. – Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published
Hira P. – Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published
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Supe A. N. – Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published

Guarantor

The corresponding author is the guarantor of submission.

Conflict of Interest

Authors declare no conflict of interest.

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