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Original Research Article

Post operative pancreatic fistula rate following pancreaticojejunostomy with Heidelberg technique versus classical duct to mucosa technique: a comparative study

Sumanth Subhramaniyam*, Bharghav J. Kalariya, Guruprasath S., Arul Jothi R. D. R.

Department of Surgical Gastroenterology, Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur, Tamil Nadu, India

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***Correspondence:**
Dr. Sumanth Subhramaniyam,
E-mail: Subramaniam.sumanth@gmail.com

ABSTRACT

Background: The best technique for pancreatic anastomosis is still a debate and unanswered by multiple RCTs and meta-analyses, done over past two decades. This study intends to compare the outcomes of pancreatico-jejunostomy (PJ) using Heidelberg technique vs classical duct to mucosa technique
Methods: All patients who underwent pancreaticoduodenectomy meeting criteria were included in study. Outcome of PJ done by Heidelberg technique evaluated by occurrence of POPF, as defined by ISGPF and results were compared to historical cohort of patients who had underwent PJ by classical duct to mucosa technique in our institution,
Results: PJ reconstruction was done with Heidelberg and classical duct to mucosa technique in 20 patients each. POPF rates in Heidelberg and duct to mucosa techniques when calculated using ISGPS-2005 definition (30% vs. 40%, p=0.677 and 10% vs. 10%, p=0.514 respectively) and ISGPS-2016 definitions (10% vs. 10%, p=0.514). There is no statistical difference between the two techniques in terms of DGE, infection, and days of hospital stay or duration of drain requirement. But Heidelberg technique is superior to DM technique with respect to shorter operating time (p=0.0001) and lower Clavien-Dindo morbidity grades (p=0.0004). Though a statistical significance could not be reached, there is an increased tendency of higher grade POPF with respect to increased age (>57 years), softer texture and smaller duct size (<3 mm).
Conclusions: There is no significant difference of CR-POPF rates between Heidelberg and classical duct to mucosa techniques of PJ. However, Heidelberg technique is better in terms of simplicity, reduced operating time and lower post-operative morbidity when compared to duct to mucosa technique.

Keywords: Postoperative pancreatic fistula, Heidelberg technique, Mucosa technique

INTRODUCTION

The pancreatic anastomotic leak is the Achilles heel of pancreaticoduodenectomy and the resulting pancreatic fistula may turn into intra-abdominal collections, abscess, peritonitis, sepsis, erosion of adjacent vessel walls that may result in pseudoaneurysm and contribute to post-operative haemorrhage, endangers other anastomoses-predisposing to biliary leak, delayed gastric emptying, prolonged paralytic ileus, wound infections and in worst cases contributes to mortality. These complications contribute to increased ICU stay, ventilator dependency, and prolonged hospital stay, causing significant emotional and financial burden. First successful resection of periampullary carcinoma was done as a two-stage procedure-6 weeks apart, by Kaush in 1909.[1] Later in 1942 Allan Whipple described a single stage operation for pancreatic head cancers that included PJ. That

procedure was modified by Waugh and Clagett in 1946 to the current single staged procedure.[2] Initial mortality rates where upto 33% which declined to less than 5% over time. Despite refinements in the surgical technique and advancements in postoperative management, surgical morbidity remains between 40% and 50%.[3] The three most common complications were delayed gastric emptying in 14%, wound infection in 7% and pancreatic fistula in 5%.[4] Though hemorrahge occurs in 8% of cases, it accounts for 11 to 38% of mortality.

According to ISGPF (Table 1 and 2), POPF is defined as inclusive of all peripancreatic fluid collections, abscesses, leaks, or fistulas and diagnosed and graded by virtue of drain amylase, output, imaging, and clinical picture. POPF is diagnosed when the amylase concentration in the drain fluid on or after post-operative day 3 is more than three times the upper limit of the normal serum level.

Grade A fistulas-now classified as biochemical leaks, comprise nearly half of all POPF, does not affect outcome. However, grade B and C fistulas occur in 40% and 11% respectively, are clinically relevant and adversely affect the outcome.[5]

Many pancreatic anastomotic techniques and modifications have been described, but regardless of the technique used many large studies describe a POPF rate of more than 10%. Buchler et al described the Heidelberg technique with reported POPF rate of 2% in 331 patients who underwent PD.[6] Best technique for pancreatic anastomosis is still a debate and unanswered by multiple RCTs and meta-analyses, done over past two decades.[6]

Heidelberg end to side PJ technique

Originally propagated by Buchler et al this technique involves 4-layer anastomosis. In their original series a POPF rate of 2% was observed in 331 patients. In separate study done by Shrikhande et al POPF rate of 3.2% documented in 123 patients who underwent PD (Figure 1).[6]

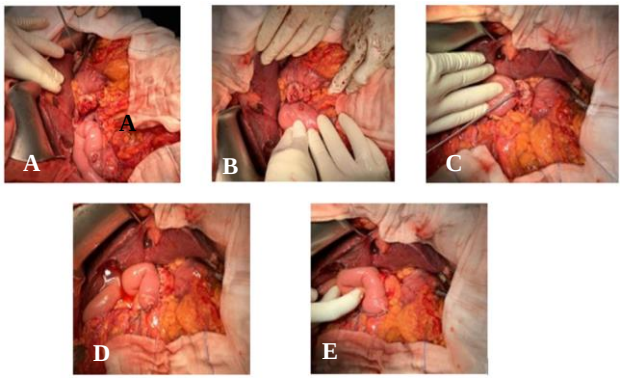

Figure 1: Heidelberg technique. (A) Preplaced sutures, (B) posterior outer layer, (C) posterior inner layer, (D) anterior inner layer, (E) anterior outer layer.

After completion of the pancreaticoduodenectomy and the specimen is delivered out, the proximal jejunal loop is brought in to the supra-colic compartment through a separate rent in the mesocolon. PJ is done 5 cm proximal to the stapled line of jejunal end and at least 15 cm from the planned hepaticojejunostomy site.

Duct to mucosa technique

Originally described by Warren and Cattell done in single, two- and three-layer sutures (Figure 2).

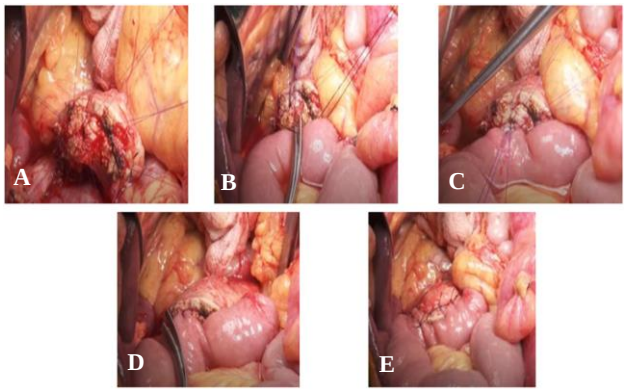

Figure 2: Duct to mucosa technique. (A) Preplaced duct sutures, (B) posterior outer, (C) posterior duct to mucosa, (D) anterior duct to mucosa, (E) DM completed.

Sutures are placed between the posterior edge of the seromuscular jejunal wall and the posterior pancreatic capsule to form the posterior part of the outer suture-row.

A small opening is made in the centre of the jejunal loop with a diameter that matches the diameter of the main pancreatic duct. Consequently, the jejunal mucosa is exposed at a point exactly opposite main the pancreatic duct.

The inner suture-row forms the actual duct-to-mucosa anastomosis: to this purpose, the pancreatic duct is sutured to the jejunal mucosa in all directions. To complete the outer suture-row anteriorly, the anterior part of the seromuscular jejunal wall is anastomosed to the anterior pancreatic capsule. Interrupted sutures are commonly preferred because of ability to place accurate sutures. Mobilisation of the pancreatic stump is not necessary as required in dunking method. Usual modification is with / without pancreatic stent. Leak rates of around 12-24%.

The objective of this study is to compare the outcomes of POPF rates following PJ using Heidelberg technique vs classical duct to mucosa technique.

Table 1: ISGPF definition of POPF grades.[19]

Criteria	Grade A	Grade B	Grade C
Clinical condition	Well	Often well	Ill appearing/ bad
Specific treatment*	No	Yes/No	Yes
US/CT (if obtained)	Negative	Negative/ positive	Positive
Persistent drainage (after 3 weeks)^	No	Usually yes	Yes
Reoperation	No	No	Yes
Death related to POPF	No	No	Possibly yes
Signs of infection	No	Yes	Yes
Sepsis	No	No	Yes
Readmission	No	Yes/No	Yes/No

*Partial peripheral or total parenteral nutrition, antibiotics, enteral nutrition, somatostatin analogue, minimal invasive drainage /with or without drain *in situ*.

Table 2: ISGPS-2016 update.[20]

Event	Biochemical leak	Grade B POPF	Grade C POPF
Drain amylase concentration > 3x upper limit of normal	Yes	Yes	Yes
Persisting peripancreatic drainage > 3 weeks	No	Yes	Yes
Clinically relevant change in management of POPF	No	Yes	Yes
Percutaneous or endoscopic drainage of POPF associated collection	No	Yes	Yes
Angiographic procedures for POPF – Associated bleeding	No	Yes	Yes
Reoperation for POPF	No	No	Yes
Signs of infection related to POPF	No	Yes (Without organ failure)	Yes (With organ failure)
POPF Related organ failure	No	No	Yes
POPF related death	No	No	Yes

METHODS

Study area

Study carried out at Dhanalakshmi Srinivasan medical college.

Study duration and design

It is a comparative study-a retrospective and prospective analysis of data collected from period between July 2020 to May 2023.

Study sample

Prospective cohort of all patients undergoing PD at Dhanalakshmi Srinivasan hospital (From September 2020 to May 2023). Patients who underwent PD in past 2 years (From July 2018 to July 2020) as Retrospective controls

Inclusion criteria (Figure 3)

All patients above 18 years of age undergoing PD and PJ by Heidelberg technique-from September 2020 to May 2023. Historical cohort of patients who underwent PD and PJ by classical DM technique in past 2 years-data obtained from EMR were included in the study.

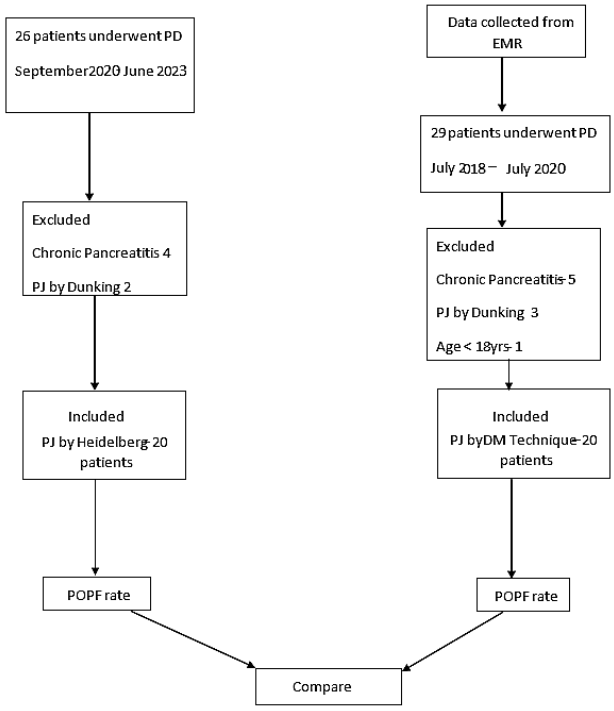

Figure 3: Inclusion criteria.

Exclusion criteria

Patients with chronic pancreatitis and patients below 18 years of age were excluded.

Sample size

Required sample size (n),

$N=Z_1^2-\frac{\alpha}{2}p(1-p)/d^2$

Z= 1.96 (for 95% confidence interval), p=3.2% (rate of POPF in patients who underwent pancreatico-duodenectomy),

q=1-p.

Allowable error, d=10%

Then, n =$(1.96)^2$ ×0.032× (1-0.032)/0.01

Required sample size, n=12

Accordingly, 20 patients should be included in the study.

Data collection

Data was collected as per a preformed questionnaire

RESULTS

PJ reconstruction was done with Heidelberg and classical duct to mucosa technique in 20 patients each. Of the 40 patients included in the study.

POPF rates calculated for both the techniques with respect to ISGPS-2005 (Old) and ISGPS-2016 (New) definitions and grading.

POPF rates according to ISGPS-2005

Eight of the 20 patients (30%) developed POPF. Six patients developed grade A POPF (30%) and 2 patients developed grade B POPF (10%). There was no grade C POPF in the Heidelberg group. CR-POPF rate in Heidelberg group was 10% (Table 3).

Ten of the 20 patients (50%) developed POPF. Eight patients developed grade A POPF (40%), 1 patient had grade B POPF (5%), 1 patient had grade C POPF (5%) in the DM group. CR-POPF rate in DM group was 10%.

POPF rates according to ISGPS-2016

Two of the 20 patients (10%) developed POPF. Six patients developed biochemical leak (30%) and 2 patients developed grade B POPF (10%). There was no grade C POPF in the Heidelberg group. CR-POPF rate in Heidelberg group was 10% (Figure 4).

Two of the 20 patients (50%) developed POPF. Eight patients developed biochemical leak (40%), 1 patient had grade B POPF (5%), 1 patient had grade C POPF (5%) in the DM group. CR-POPF rate in DM group was 10%.

There was no statistical difference between the occurrence of POPF and CR-POPF rates in Heidelberg and duct to mucosa techniques when calculated using ISGPS2005 definition (30% vs. 40%, p=0.677 and 10% vs. 10%, p=0.514 respectively) (Figure 5) and ISGPS-2016 definitions (10% vs. 10%, p=0.514).

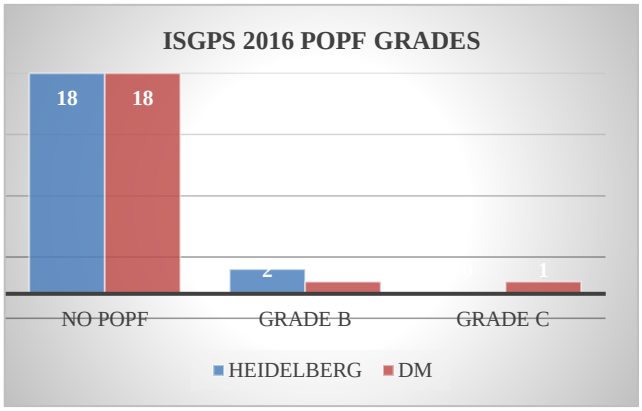

Figure 4: ISGPS 2016 POPF grades.

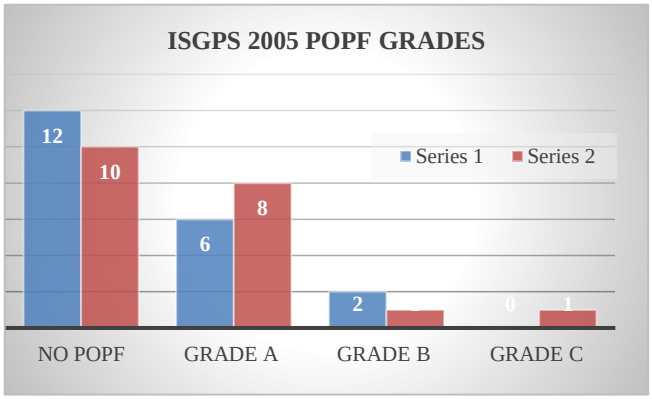

Figure 5: ISGPS 2005 POPF grades.

Subset analysis

Duration of surgery, duration of hospital stays, duration of drain requirement, post-operative morbidity based on Clavien-Dindo grading, other complications like DGE, POPH and infection rates are evaluated with respect to both techniques (Table 4).

There is no statistical difference between the two techniques in terms of DGE, Infection, and days of hospital stay or duration of drain requirement. But Heidelberg technique is superior to DM technique with respect to shorter operating time (p=0.0001) and lower Calvien Dindo morbidity grades (p=0.0004). Two patients in Heidelberg group had grade 2 POPH and were managed conservatively with ICU admission and blood

transfusions. There was no incidence of POPH in DM group. This could be explained by exposure of some pancreatic cut surface in Heidelberg technique.

Risk factors for POPF

Age of the patient, CEA, CA 19-9, total bilirubin and albumin levels, presence of pre-operative cholangitis and biliary drainage, duct size and T stage of the lesion were analysed to assess association with occurrence of POPF. Only pre-op albumin level, presence of cholangitis and biliary drainage were found to have near close association with POPF occurrence. Though a statistical significance could not be reached, there is an increased tendency of higher grade POPF with respect to increased age (>57 years), softer texture and smaller duct size (<3 mm).

Table 3: Heidelberg versus DM.

Heidelberg vs DM	ISGPS-2005	ISGPS-2016
P value and statistical significance		
Test	Chi-square	Chi-square
Chi-square, df	1.801, 3	1.333, 2
P value	0.6147	0.5134
P value summary	NS	NS
One or two sided	NA	NA
Statistically significant (p<0.05)	No	No
Data analysed		
Number of rows	2	2
Number of columns	4	3

Table 4: Heidelberg vs DM - other parameters.

Parameters		Heidelberg, n (%)	DM, n (%)	P value
DGE	Grade A	3 (15)	7 (35)	0.337
	Grade B	1 (5)	1 (5)	
	Grade C	0	0	
POPH	Grade A	0	0	
	Grade B	2 (10)	0	
	Grade C	0	0	
Infection	Superficial	4 (20)	3 (15)	0.5647
	Deep	0	0	
	Organ space	0	1 (5)	
Days of hospital stay	Median	11 days	12 days	0.3479
Drain removal	Median	2-3 weeks	2-3 weeks	0.7875
Duration of surgery	Median	600 min	720 min	<0.0001
Clavien-Dindo grade	Grade 1	14 (70)	3 (15)	0.0004
	Grade 2	5 (25)	16 (80)	
	Grade 3A	0	0	
	Grade 3B	0	0	
	Grade 4	1 (5)	0	
	Grade 5	0	1 (5)	

Table 5: Risk factors for POPF.

Parameters		P value
Age (In years)	56.1±11.5	0.5901
CEA	5.69±8.31	0.8611
CA 19-9	726±3670	0.4067
Total bilirubin	6.69±4.8	0.4062
Albumin	3.89±0.41	0.0858
Pre-op cholangitis	9 (22.5%)	0.0583
Pre-op bile drainage	14 (35%)	0.0962
Texture of pancreas	Firm-13 (32.5), soft-27 (67.5)	0.1702
Pancreatic duct diameter	3.65 mm	0.1818

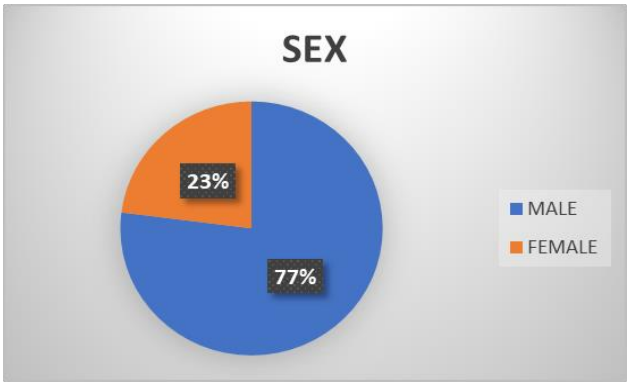

Figure 6: Sex.

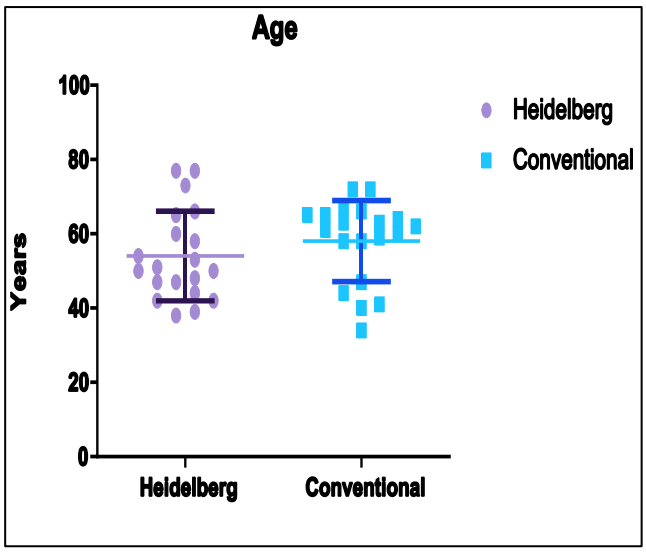

Figure 7: Age.

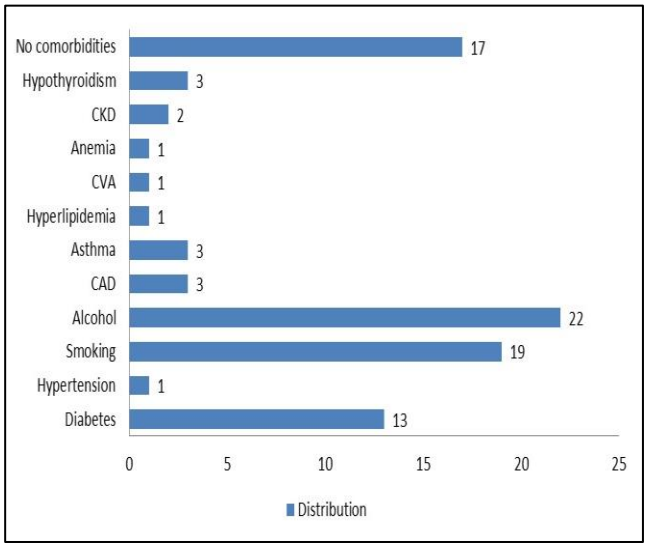

Figure 8: Comorbids.

DISCUSSION

The study aimed to determine and compare the POPF rates after PJ in Heidelberg and classical duct to mucosa technique. There was no difference in POPF rates between the techniques, though the Heidelberg technique required less time to construct PJ and had less post-operative morbidity when compared with classical technique.

In the present study occurrence of grade A POPF or biochemical leak was 35% and clinically relevant POPF (CR-POPF) which includes grades B and C were 5%. In a multicentre study by McMillan et al reported an overall POPF rate of 19.2% of which 42.3% were biochemical leaks and 11.1% were CR-POPF.[18]

Since the ISGPF-2016 update did not include grade A fistulas or biochemical leaks as POPF, only the grade B and C POPF or CR-POPF are considered for further discussion. The primary objective of the study was to determine the POPF when PJ was done using Heidelberg technique. The occurrence of CR-POPF with Heidelberg technique was 5%. There was no mortality in the Heidelberg group. There are only a handful of studies reported on Heidelberg technique. In the first prospective study describing Heidelberg technique, Buchler et al evaluated the perioperative and postoperative data of 331 consecutive patients. In that study the prevalence of POPF was found to be 2.1%. But there was a mortality rate of 2.1% in Buchler's study.[6]

Following the study by Buchler, Shrikande et al published a prospective study of pancreatic fistula after PD in 2007. He reported a POPF rate of 3.2% and a mortality rate of 0.8% due to POPF.[7]

In the present study Heidelberg technique was executed as described by Shrikande.[7]As is the norm with every original technique undergoing modifications by various surgeons according to their adaptation, Heidelberg technique has also been modified, like using continuous sutures for outer layers, use of stent etc. There are two studies which has published the outcome of Torres et al published their study outcomes of a modified Heidelberg technique for PJ in 17 patients. Their modification included a continuous suture on outer seromuscular and pancreatic capsule layer and use of 20cm long plastic stent placed in pancreatic duct and in jejunum across the anastomosis. None of their patients developed CR-POPF but 23.5% developed grade A POPF.[8]

Chowdappa et al studied pancreatic anastomosis following pancreaticoduodenectomy using modified Heidelberg technique in 208 patients over 10 years. In that study the incidence of grade B and C POPF were 1.4% each and a 30-day mortality of 0.4%.[9]

There is no study till date that compared Heidelberg technique with classical duct to mucosa techniques. Two patients in Heidelberg group and one patient in DM group had grade B POPF because of extended requirement of drains for more than 3 weeks. Otherwise, these patients did not have any deviation from expected post-operative course requiring any form of intervention. There was only one mortality in DM technique.

With respect to duration of surgery, performing Heidelberg technique took less time when compared to that of DM technique. Shorter duration of surgery translates shorter anaesthesia time with resultant reduction in morbidity related to duration of surgery and anaesthesia.

Post-operative morbidity was assessed with Clavien-Dindo score and the Heidelberg group had significantly lower morbidity grades when compared with DM group. The difference was due to higher number of grade 2 morbidity in DM group.

There was no significant difference with respect to occurrence of other complications (DGE, infection), duration of hospital stays, duration of drain requirement. However, 2 patients in Heidelberg group had grade B POPH and were managed conservatively with ICU admission and blood transfusions.

Though not the primary intention of the study, as a subset analysis, factors like age of patient, comorbidities, total bilirubin, albumin, CEA, CA 19-9, pre-operative cholangitis, pre-operative biliary drainage, texture of gland, duct size, intraoperative blood loss, T-stage of tumor were correlated with occurrence of CR-POPF. A near close association between the Preoperative cholangitis, biliary drainage and albumin <3.8 and CR-POPF could be seen. Though softer gland, duct <3 mm, higher T stage of tumor, age >57 years correlated to higher grade POPF. It was found that with each additional risk factor the odds of developing a clinically relevant fistula increased by 52%.[10]

A highly predictive 10-point Fistula Risk Score was proposed by Callery et al.[8] In their internal validation study patients with scores of 0 points never developed a CR-POPF, while fistulas occurred in all patients with scores of 9 or 10.

Many modifications have been proposed in literature as ways to reduce the occurrence of CR-POPF like use of stents, both internal and external, use of somatostatin analogues, dual limb with isolated PJ, prophylactic drainage, tissue sealants etc. In a French RCT comparing stented versus no stent group, the CR-POPF rate was 25% and 36% respectively.[9] In another recent study by Zhang et al found no difference in the incidence of complications according to the Clavien-Dindo grades or the rate of CR-POPF after PD.[10] A recent Cochrane systematic review found the role of stents in decreasing CR-POPF after PD was uncertain due the fact that benefit of stenting in pancreatic anastomosis is not supported by high quality evidence.[11]

There were inconsistent results with respect to use of somatostatin analogues for reducing CR-POPF.[10,11] In a recent Cochrane analysis, 21 trials were studied by Guruswamy et al concluded though there was evidence that somatostatin analogues reduced incidence of CR-POPF, there was no significant difference in perioperative mortality.[12] Role of dual Roux limbs with isolated PJ was studied in a RCT involving 90 patients found that isolated PJ was not associated with a decreased CR-POPF rate.[13] A recent meta-analysis also was unable to demonstrate any statistically significant difference between a single Roux limb and a double Roux limb.[14]

Routine placement of drains after PD has remained highly controversial although drains often aid in the detection of complications after pancreatic resections. In an early RCT involving 179 patients, showed that drain failed to reduce the complications after pancreatic resection. But, in a recent, multicentre RCT involving 137 patients were randomized to no drain versus drain. No drain group was associated with greater morbidity and mortality. The study was terminated early in view of an unacceptable increase in mortality from 3% to 12%, and concluded that elimination of drainage increased severity of complications.[15] There are studies which claimed that prolonged retention of a drain was associated with an increase in complications, hospital stay, and cost.[16]

In an RCT involving 125 patients to study the role of tissue fibrin sealants, there was no difference in the rate of a fistula with no significant difference in morbidity and duration of hospital stay.[17] Currently there is no high-level evidence in favour of Fibrin.

To add up to never ending debates of superiority of open and laparoscopic PD, the new entrant Robotic surgery and its influence on morbidity and mortality following PD has also been studied. The precise, fine movement in various axes along with its magnified 3-dimensional visual has also been claimed to decrease the incidence of POPF after pancreatic reconstruction when using the robot.

Nine RCTs and 17 meta-analyses have been done comparing PJ versus PG in the past. But the results of the studies were variable. In the RECOPANC trial, Keck et al randomised 320 patients to PJ and PG. There was no significant difference in the rate of CR-POPF after PG versus PJ (20% vs 22%, p=0.617). Compared with PJ, PG was associated with an increased rate of grade A and B bleeding events, less enzyme supplementation at 6 months, and improved results in some quality-of-life parameters.

The authors suggested that although the incidence of CR-POPF was not different after a PG, it may be technically easier for novice surgeons to construct a secure, invaginated PG especially with a soft pancreas.[18]

This study substantiates the effectiveness of Heidelberg technique in reducing CR-POPF, at par with classical DM technique in concordance with similar studies. The advantages of Heidelberg over DM technique are the technical simplicity, faster operating time and lower post-op morbidity.

Limitations

The study is not a true randomised control study. The study lacks adequate sample strength to evaluate risk factors for POPF

Strength

There is no study till date to compare Heidelberg technique with classical duct to mucosa technique for PJ. This is the first study to compare both techniques.

CONCLUSION

There is no significant difference of CR-POPF rates between Heidelberg and classical duct to mucosa techniques of PJ. However, Heidelberg technique is better in terms of simplicity, reduced operating time and lower post-operative morbidity when compared to Duct to Mucosa technique. A near close association between the pre-operative cholangitis, biliary drainage and albumin <3.8 and CR-POPF was seen. Though softer gland, duct<3 mm, higher T stage of tumor, Age >57 years correlated to higher grade POPF, a statistical significance is not achieved.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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