

Did Wrapping Falciform Ligament Pedicle Flap Around Pancreaticojejunostomy Reduce the Incidence of Pancreatic Fistula in Pancreaticoduodenectomy? Randomized Control Trial

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Abstract

Background: Pancreatic leakage and secondary hemorrhage are the most important source of morbidity and mortality after PD. After Blumgart anastomosis has reported a reduction in the rate of PF after PD, adjuvant use of the falciform ligament around PJ was introduced as an augmentation to PJ.

Aim of Study: To evaluate the effectiveness of wrapping the PJ by falciform flap in reducing pancreatic fistula.

Patients and Methods: This is a prospective 2-center RCT that was carried out in the period from 2019 to 2021. It includes 50 patients that were randomized into 2 groups, PJ with falciform wrapping and PJ without falciform wrapping. All patients were compared regarding risk factors and post-operative complications.

Results: The two groups were comparable regarding patients', operative and pathological factors. The post-operative complications were less in the falciform group but without statistical significance.

Conclusion: Wrapping the Blumgart PJ with a falciform flap can reduce pancreatic leak incidence and/or severity.

Key Words: Falciform – Wrapping – Leak – Hemorrhage.

Introduction

PANCREATODUODENECTOMY (PD) remains a standard procedure for pancreatic head and periampullary neoplasms [1]. But unfortunately, PD is still a complex and technically challenging process. In fact, many global medical records have almost achieved a zero mortality rate [2-4]. However, postoperative morbidity rates may reach up to 30-50 percent [5,6], even in high-volume facilities. The big concern during the reconstructive stage of PD is the management of the pancreatic stump [7,8].

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Leakage from the pancreatic stump after PD, with subsequent hemorrhage, abdominal collection, abscess formation, delayed gastric emptying, pleural effusion, wound infection, bacteremia, and septic shock, the single most important source of morbidity and death after PD [8-10].

Several risk factors for pancreatic fistula (PF) have been mentioned in the literature, these can be classified as patient, surgeon, and pancreas related [11,12]; the two most reported risk factors are a small caliber pancreatic duct and a soft pancreatic texture with studies reporting a rate of 42% of PF after PD when these two factors are present [10,11,13].

To prevent this complication, several prophylactic pharmacological approaches, as well as various surgical techniques and modifications of pancreatic-enteric reconstruction, have been proposed [14]. However, the pancreatic fistula may be inevitable, even in experienced hands [15-17].

In 2003, a new standardized U-suture technique for PJ was introduced, this U-suture technique was termed the Blumgart anastomosis (BA) [18]. In their study, they reported a reduction of POPF from 13% with the conventional Cattle Warren technique to 4% only when they started using the Blumgart technique. Thereafter multiple studies were conducted for assessment of the BA technique with major diversities in results regarding the clinically relevant postoperative pancreatic fistula (CR-POPF) ranging from 0% up to 30% [19-24].

To reduce the PF and its sequelae post-PD, Wrapping of the PJ and the retroperitoneum was described using the falciform ligament or the omentum, and this was first described in 1994 by Moriura

et al., [25]. This technique was used a lot in Asian centers, but its use is limited in US and Europe. Although the use of omentum protects the skeletonized vessels and may reduce the PF, it was speculated to affect the drainage of pancreatic fluid rich in amylase with subsequent panniculitis and intra-abdominal abscess. There were no randomized studies addressing this technique and no standard technique for wrapping.

The use of falciform ligament in the setting of PD was mainly to cover the exposed vessels and protect against the PPH (post pancreatectomy hemorrhage) and several retrospective studies have shown its effectiveness in minimizing the PHH [26], while others have not [27], but its role in minimizing the PF was controversy and its wrapping around Blumgart anastomosis never been tested in a prospective study also.

In this study, we use the falciform ligament flap as an integral part of the Blumgart technique as the U sutures pass through the pancreas and falciform and we test the effectiveness of adding a falciform ligament flap around the Blumgart anastomosis in reducing the pancreatic fistula and postoperative hemorrhage.

Patients and Methods

Study design:

This is a prospective randomized controlled 2-center study that includes all patients who underwent PD at NCI, and Damietta cancer center from 2019 to 2021. Patients were randomly divided into 2 groups, group A, PD with falciform ligament flap around the Blumgart anastomosis while group B, PD without flap with conventional Blumgart, the endpoint of the study reached fifty patients, and patients were assigned equally and randomly both groups.

These groups were prospectively compared regarding operative factors and postoperative complications, pathological factors, and all risk factors for the pancreatic leak (texture of the pancreas, size of the duct).

Surgical technique:

The operation starts with a bilateral subcostal abdominal incision with identification of the falciform ligament which was followed to the umbilicus and fully mobilized from the upper surface of the liver to gain much length as we can to be free only attached to the left portal vein from which the flap gains its blood supply. After the end of resection, when we start Blumgart anastomosis, the falciform ligament spread over the CHA behind the pancreas

(it acts as a capsule for the pancreas) then the 4 vertical PDS 3/0 passing through the pancreas and the posterior leaflet of the falciform then into the jejunum then back to falciform and pancreas again. After the end of the duct to mucosa using proline 6/0 interrupted sutures, the 4 PDS vertical sutures were passed through the anterior leaflet of the falciform and sutured in the jejunum and tied over the falciform. So, we use the falciform to cover the CHA and GDA, and acts as a capsule for the pancreas and holds the sutures. The omentum was mobilized from the transverse colon and elevated as a flap and passed behind the bile duct to cover the retroperitoneum used to cover the retroperitoneum in all cases in both groups.

Inclusion criteria:

The study included all patients who underwent PD for pancreatic head and periampullary cancer. Patients with radiological evidence of SMV-PV involvement were candidates for exploration and vascular resection, patients who received neoadjuvant treatment also are included.

Exclusion criteria:

Patients whose data were incomplete or who lost follow-up were excluded. Also, patients with reconstruction other than Blumgart or done by another surgical team were excluded.

Data collection:

All data were collected for each group and were divided into Patient factors, intraoperative and postoperative factors. Patients' factors included patients' demographics, co-morbidities, neoadjuvant treatment, Pathology, and Biliary drainage. Intra-operative factors included type of PD (Whether classic or pylorus-preserving), Operative time in hours and estimated blood loss in ML, size of the pancreatic duct, and texture of pancreas. Post-operative factors included the short-term postoperative course which was divided into specific complications (pancreatic leakage, biliary leakage, DGE, 2ry HGE, intra-abdominal collection, sepsis, deep wound infection, PV-SMV thrombosis) and general surgical complications (DVT, cardio-pulmonary, Liver failure, renal failure, patients requiring re-laparotomy and mortality).

Results

A total number of 50 patients with operable pancreatic head cancer were treated in this study. All were subjected to PD, 25 patients in group A had falciform flap around the Blumgart anastomosis, and 25 patients without flap.

Patients' factors:

Patients' Factors including age, sex, co-morbidities, and neo-adjuvant treatment are pre-

sented in (Table 1). There was no significant statistical difference between the falciform flap group A and group B regarding these factors.

Table (1): Patient and operative factors.

	Group				P-value
	Group A		Group B		
	Count	%	Count	%	
<i>Gender:</i>					
Male	20	80.0	18	72.0	0.508
Female	5	20.0	7	28.0	
<i>DM:</i>					
Yes	19	76.0	16	64.0	0.538
<i>HTN:</i>					
Yes	9	36.0	9	36.0	1
<i>Neoadjuvant:</i>					
Yes	4	16.0	4	16.0	1
<i>Perioperative biliary drainage:</i>					
Yes	19	76.0	21	84.0	0.480
<i>Vascular resection:</i>					
Yes	6	24.0	5	20.0	0.473
<i>Pylorus -preserving or not:</i>					
Yes	21	84.0	24	96.0	0.349
<i>Pancreas texture:</i>					
Hard	7	28.0	5	20.0	0.757
Intermediate (firm)	10	40.0	10	40.0	
Soft	8	32.0	10	40.0	

	Group A			Group B			p-value
	Mean	Minimum	Maximum	Mean	Minimum	Maximum	
Age	60.28	45.00	73.00	54.72	24.00	87.00	0.101
Blood transfusion by ml	460.00	300	1500.00	460.0	200	500.00	0.465
Operative time (hours)	6.04	5.00	7.00	6.08	4.00	6.00	0.862
Pancreatic duct (ml)	4.36	1.00	9.00	4.16	1.00	8.00	0.768

Table (2): Pathological outcome.

	Group				P-value
	Flap Group		No Flap Group		
	Count	%	Count	%	
<i>T:</i>					
T1	1	4.0	1	4.0	0.778
T2	11	44.0	14	56.0	
T3	13	52.0	10	40.0	
<i>N:</i>					
N0	19	76.0	11	44.0	0.073
N1	4	16.0	10	40.0	
N2	2	8.0	4	16.0	

Table (3): Post-operative complications.

	Group				P-value
	Group A		Group B		
	Count	%	Count	%	
Pancreatic leak	2	8.0	6	24	0.231
Pancreatic leak GRADE A	1	4.0	2	8.0	0.781
Pancreatic leak GRADE B	1	4.0	3	12.0	0.609
Pancreatic leak GRADE C	0	0.0	1	4.0	1
DGE	3	12.0	4	16.0	1
Bile leak	0	0.0	1	4.0	1
Enteric leak	0	0.0	0	0.0	
Hemorrhage	0	0.0	1	4.0	0.490
Wound infection	1	4.0	0	0.0	1
Re-laparotomy	1	4.0	1	4.0	1
General complication	3	12.0	3	12.0	1
Postoperative mortality	1	4.0	2	8.0	1



Fig. (1): Mobilization of falciform ligament.



Fig. (2): Suturing the falciform posteriorly.



Fig. (3): Suturing the flap anteriorly.



Fig. (4): After the end of wrapping.

Discussion

The pancreas was devoid of peritoneal covering, and when the texture is soft the leak from the pancreatic stump is an unavoidable complication in PD. Until now no single technique in pancreatic anastomosis has proven to be superior in preventing a pancreatic leak. The falciform ligament flap around the anastomosis adds a peritoneal covering to the anastomosis and allows coverage of the exposed vessels behind the anastomosis to protect against secondary hemorrhage. Its role in wrapping the anastomosis had unclear results in the literature but seems to reduce the rate of PPH [26] most of the published studies address the use of omentum over the anastomosis and falciform over the vessels.

In our centers we used to use the Blumgart technique in PD with the accepted outcome, the ad of falciform ligament had been discussed in reducing leak from the pancreatic stump in left pancreatectomy and to cover the vessels, we discuss its use around the Blumgart technique aiming to add a peritoneum around the anastomosis to be

incorporated in the vertical sutures of Blumgart also to cover the CHA and GDA.

We had 2 cases with leaks in group A and 6 cases in group B, but the difference wasn't statistically different due to the small sample size. Also, we had a difference in the grade of the pancreatic leak, in group A (1 case grade A and 1 case grade B) while in group B, half of the leak cases were grade B. We expect the flap around the anastomosis provide a peritoneum helping in healing and provide support to sutures in the weak pancreas, but the results were insignificant due to small sample size and more studies are needed to address these issues.

We had also 1 patient in group B who developed post pancreatectomy hemorrhage (PPH) which is fatal and consequently the patient died, and this was a result of severe pancreatic leak.

In 2020, A systematic review and meta-analysis were conducted by Andreasi et al., [26] on the role of omental or falciform ligament wrapping during PD. This systematic review discussed 9 studies

involving more than 4000 patients, but unfortunately, this meta-analysis reported several limitations in all the included studies. The most important limitation is the absence of randomized control studies, and all studies were retrospective, other limitations include non uniform intra and post-operative management among the studies, different wrapping techniques among different centers, different definitions of outcome parameters were used so, the conclusions from this experience should therefore be interpreted with the utmost care.

In this meta-analysis Patients who underwent PD with either PJ or PG, the two procedures that are used for reconstruction after PD, were included. It's worth noting that the subgroup study, which only included patients who had had PD with PJ anastomosis, showed that the wrapping group had a lower rate of CR-POPF. Although only two trials were considered in this subgroup analysis, it is possible to speculate that omental wrapping around the PJ anastomosis site would aid in anastomosis healing by encouraging adhesion and the development of granulation tissue.

The other important outcome parameter that was addressed in this meta-analysis was PPH, A potentially fatal possible consequence of CR-POPF which is due to the erosion of peripancreatic arteries, particularly the gastroduodenal artery (GDA), by pancreatic enzymes. Omental or falciform ligament flaps have been suggested in several publications to cover the skeletonized arteries and keep them away from the pancreatic anastomosis site.

The fact that wrapping appears to be a safe practice was another intriguing outcome of the recent analysis. Regarding this, several controlled studies that were part of the previous review as well as a few single-arm series reported that no complications relating to the omental or falciform ligament flap, such as intestinal obstruction, portal vein compression, necrosis of the flap, or infection, took place. Despite these promising results, no definite conclusions can be drawn due to the low methodological quality of the included studies and the significant limitations of the available data. To understand the function of omental or falciform ligament wrapping during PD, well-designed randomized prospective studies are required.

In our study, we did our best to overcome all these limiting factors to provide a better-designed study that can help judge this technique. We conducted a prospective randomized controlled study that was done by the same team of surgeons after

standardization of the technique and provide a uniform intra and post-operative management plan. The CHA, GDA, and Blumgart anastomosis were covered with the falciform ligament, which also serves as a capsule for the pancreas. In every case in both groups, the retroperitoneum was covered with an omental flap.

Also, we uniformed the outcome measures and definitions of complications as we followed the globally recognized criteria established by the International Study Group on Pancreatic Surgery (ISGPS).

By comparing our results with previous studies, we can find that we studied a total number of 50 patients (25 patients in each arm of the study), which is considered a small number when compared to other previous retrospective studies which are attributed to the prospective nature of the study. In previous studies, the omentum was used for wrapping the PJ anastomosis in most of the cases except for a very small number of cases in which the falciform was used. Most of the studies reported the wrapping of the peripancreatic vessels using omentum or falciform ligament (57%), the lesser number reported the use of omentum for wrapping the pancreatic anastomosis (41%), and a very small number (2%) underwent wrapping of both PG and peripancreatic vessels. In all cases of our study, we used the omentum to cover the peripancreatic vessels, and in 25 cases we additionally used the falciform ligament wrapping around the PJ anastomosis, in this way we can assess the isolated effect of using the falciform ligament for covering the pancreatic anastomosis after elimination of other factors that may affect the results.

Pancreatic fistula:

Andreasi et al., [26] stated that in 6 studies including 3127 cases, Patients who had omental wrapping experienced a similar rate of total POPF (33%) as compared to patients who did not (35%). The rate of POPF was lower in the PD-W group (18%) compared to the PD-nW group (30%) when only studies involving patients who had undergone PD with PJ were considered. Again, the lack of standardization in these previous studies precludes the ability to accurately compare the results, here we can consider our two groups as wrapping as we routinely used the omentum to wrap the peripancreatic vessels, furthermore we added the falciform wrapping in 25 cases to study its effect. It is noteworthy to mention that in both of our groups, the rate of POPF was less than in previous similar studies, overall (16%) in our cases Vs (18%) in the wrapping group in previous studies and (33%)

in the literature non-wrapping group, we attribute this difference to the standardization of the technique and single team performing the same technique with high experience in the operation.

When specifically considering cases of CR-POPF, four previous studies addressed this outcome, and the results were favoring the wrapping technique in cases of PD as the rate of CR-POPF was significantly lower in the PD-W group (2%) compared to the PD-nW group (22%), in our study also the results showed a better outcome in falciform wrapping group regarding POPF (4%) vs (16%) in the non-wrapping group, these results specifically emphasize on the effect of adding falciform wrapping around PJ with the wrapping of the omentum over the peripancreatic vessels.

Extra luminal PPH:

Regarding this outcome, previous studies demonstrated the protective effect of wrapping the peripancreatic vessels (2.6%) when compared to the non-wrapping group (4.2%), but when comparing the wrapping of the PJ anastomosis alone with the non-wrapping group, no significant difference was detected (5% in both groups). In our series, we reported a single case of PPH (2%) which was in the non-wrapping group. This is almost like the wrapping group in literature (2.6%). It to be noted again that in our (non-wrapping) group we used the omentum to cover the peripancreatic vessels, this may explain the similar outcome with the wrapping group of literature.

Conclusion:

The falciform flap wrapping around the Blumgart technique was introduced in our study as an adjuvant procedure to augment the PJ integrity and to reduce the frequency of pancreatic leak and its severity. However, more prospective studies and meta-analyses are needed to prove it.

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هل تغليف توصيله البنكرياس مع الصائم بسديله الرباط المنجلي فيما بعد استئصال الاثنى عشر ورأس البنكرياس تقلل تجربة عشوائية خاضعة للسيطرة؟ حدوث ناسور البنكرياس

يعتبر تسريب عصارة البنكرياس والنزيف الثانوي من أهم المضاعفات وأسباب الوفاة بعد عملية استئصال الاثنى عشر. ورأس البنكرياس بعد ظهور طريقة بلومجارت لتوصيل البنكرياس بالصائم وحدث تحسن في نسب التسريب والناسور كانت هناك الحاجة لتقوية هذه التوصيلة باستخدام سديله الرباط المنجلي. تمت هذه الدراسة المستقبلية في مركزين للأورام في الفترة من ٢٠١٩ إلى ٢٠٢١ وضمنت هذه التجربة خمسون مريض بسرطان رأس البنكرياس تم تقسيمهم مجموعتين كل مجموعة تحتوى على ٢٥ مريض. فى المجموعة الأولى تم تغليف سديله الرباط المنجلي حول توصيلها لبنكرياس بالصائم. وكانت المجموعة الثانية بدون عمل مقارنة بين المجموعتين من حيث عوامل المرض واللاجرعات التى تمت داخل الجراحة كما تم عمل مقارنة من حيث المضاعفات الخاصة بالعملية والمضاعفات العامة بعد العمليات.

كانت نتائج المجموعة الأولى أفضل من حيث ناسور البنكرياس والنزيف لكن لم تصل لحد الدلالة الإحصائية ومن الممكن أن يكون هذا بسبب قلة عدد الحالات مما يستوجب إجراء هذه التجربة على عدد أكبر من المرضى فى المستقبل.