

Comparison of surgical versus conservative approach in management of Pancreatic Fistula following Pancreaticoduodenectomy

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Abstract

Objective: To compare surgical versus conservative approach in managing pancreatic fistula following pancreaticoduodenectomy in terms of rate of fistula closure and mortality.

Study design: Prospective comparative study

Duration of study: From January 2023 to December 2023.

Material and Methods: 64- patients were managed for complicated pancreatic fistula following pancreaticoduodenectomy, 22 in each group. Sample size was calculated using WHO software taking 21.1% proportion of mortality rate with surgical approach and 0 (0.0)% proportion of mortality rate with conservative approach. Patients in Group A were managed with surgical approach (completion pancreatectomy as in the presence of massive peritoneal contamination as a result of complete disunion of the pancreatic anastomosis, CP was undertaken in these patients) while patients in Group B were managed with secondary percutaneous drainage and high spectrum antibiotic therapy. The clinical outcomes in both groups were ascertained within 30 days post-operatively in terms of rate of fistula closure and mortality.

Results: Conservative approach was found significantly superior to surgical approach in terms of rate of fistula closure and mortality following pancreaticoduodenectomy with p value < 0.001.

Conclusion: This study concludes that clinical outcomes in both groups showed a statistically significant difference for rate of fistula closure and mortality, with conservative management being a suitable treatment of choice for pancreatic fistula following pancreaticoduodenectomy.

Keywords: Pancreatic Fistula, Pancreaticoduodenectomy, conservative approach, surgical approach

Received

date: 2nd March, 2024

Accepted

date: 10th July, 2024

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Introduction:

Pancreatic fistula (PF) is a frequently observed complication following pancreaticoduodenectomy (PD), with reported incidence rates ranging from 2% to 28%. Pancreatoduodenectomy, in conjunction with chemotherapy, represents the sole therapeutic approach capable of attaining prolonged survival rates in individuals diagnosed with pancreatic ductal adenocarcinoma located in the head of the pancreas. Additionally, pancreatoduodenectomy is widely recognised as the established treatment modality for various non-malignant conditions affecting the

pancreatic head. A study reported that post-op mortality was recorded in 21.4% patients in surgical approach as compared to 0 (0.0%) mortality rate in conservative group.¹⁻³

Pancreatic fistula represents a post-operative complication that may arise subsequent to pancreaticoduodenectomy, with two primary strategies available for its management. The utilisation of a surgical method has been found to be correlated with increased rates of death and morbidity. The advantages of completion pancreatectomy (CP) are limited. The surgical pro-

cedure known as distal pancreatectomy is typically performed exclusively for the treatment of fistulas located in the tail region of the pancreas. Fistulas that originate from the head, neck, or torso are commonly managed with Roux-en-Y pancreatico-jejunostomy, specifically targeting the fistulous tract. In certain instances, proximal pancreaticoduodenectomy may be necessary for treatment. The conservative approach is characterised by a conservative approach. The initial approach to management tends to be conservative, given that spontaneous closure is typically anticipated in the majority of cases, particularly in instances of low-output fistulas. The utilisation of fistulogram and CT scan for imaging purposes can prove to be beneficial. Primary therapeutic interventions encompass the utilization of total parenteral nutrition, electrolyte replenishment, safeguarding of the integumentary system, and the administration of octreotide, a somatostatin analogue. Endoscopic retrograde pancreatography (ERP) and surgical intervention should be considered for refractory cases.⁴⁻⁶

Conservative therapy is the predominant method employed for the management of external pancreatic fistulae, exhibiting an average success rate of 80%. According to existing literature, the efficacy of conservative care in addressing pancreatic fistula has been documented to reach a success rate of 95%. In summary, the conservative approach is commonly preferred for the management of pancreatic fistula after pancreaticoduodenectomy because of its higher success rate and lower rates of mortality and morbidity in comparison to the surgical approach. However, in cases when traditional therapies have demonstrated limited efficacy, surgical intervention may be judged necessary.⁷⁻⁹

The aim of this study was to compare surgical versus conservative approach in managing pancreatic fistula following pancreaticoduodenectomy as in Peshawar, Khyber Pukhtunkhwa, Pakistan the management of this complication in the local population needs improvement.

The fact is that pancreatic fistula is a known complication of pancreaticoduodenectomy, and

its management remains a topic of significant debate. The proposed algorithm for early detection and step-up management of pancreatic fistula can possibly prevent clinical deterioration. Therefore, a study on the management of pancreatic fistula in Peshawar, Khyber Pukhtunkhwa, Pakistan could help improve the management of this complication in the local population and reduce the associated morbidity and mortality.

Material and Methods:

This prospective comparative study was conducted at the Department of General Surgery, MTI-Khyber Teaching Hospital, from January 2023 to December 2023. Sample size was calculated using WHO software taking 21.40%³ proportion of mortality rate via surgical approach and 0(0.0)%³ mortality rate with conservative approach. Non-probability consecutive sampling technique was used for data collection.

Inclusion criteria includes patients aged between 30 to 70 years of either gender with complicated pancreatic fistula (drain output of any measurable volume of fluid after POD 3 with amylase content greater than three times the serum amylase activity (CB) following pancreaticoduodenectomy confirmed by consultant general surgeon on clinical evaluation were included.

Exclusion criteria includes patients requiring an additional transmural approach or rescue surgery were excluded.

Written informed consent forms were obtained from all patients and were briefed about the research nature of this study. Patients aged between 30 to 70 years of either gender with complicated pancreatic fistula following pancreaticoduodenectomy confirmed by consultant general surgeon on clinical evaluation. Patients were subjected to two groups keeping in view their clinical status. Patients in Group A were managed with surgical approach i.e completion pancreatectomy as in the presence of massive peritoneal contamination as a result of complete disunion of the pancreatic anastomosis CP was undertaken in these pa-

Table 1: Descriptive statistics of study in both groups (n=64)

Groups		Mean	Std. Deviation
Group A (SA)	Age (years)	46.594	7.2994
	Post-op Hospital Stay (Days)	45.313	9.1350
Group B (CA)	Age (years)	50.031	6.0508
	Post Op Hospital Stay (Days)	23.813	3.2273

Table 2: Demographic characteristics of patients in both groups (n=64)

		Groups		Total	p-value
		Group A (SA)	Group B (CA)		
Age groups	< 45 years	13	8	21	0.183
	> 45 years	61.9%	38.1%	100.0%	
		19	24	43	
		44.2%	55.8%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	
Gender	Male	14	18	32	0.317
	Female	43.8%	56.3%	100.0%	
		18	14	32	
		56.3%	43.8%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	

Table 3: Clinical Characteristics of Patients in Both Groups (n=64)

		Groups		Total	p-value
		Group A (SA)	Group B (CA)		
ASA Status	ASA I	6	12	18	0.249
		33.3%	66.7%	100.0%	
	ASA II	13	10	23	
		56.5%	43.5%	100.0%	
	ASA III	13	10	23	
		56.5%	43.5%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	
Clinical outcome	Fistula closure	8	28	36	0.000
		22.2%	77.8%	100.0%	
	Mortality	24	4	28	
		85.7%	14.3%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	

tients) while patients in Group B were managed with secondary percutaneous drainage and high spectreantibiotherapy as they had developed a concomitant intra-abdominal abscess or fluid

collection diagnosed by tomography. Patients in both groups were followed up for 30 days post-operation in order to ascertain rate of fistula closure and post-operative mortality defined as death occurring in the first 30 post-operative days or before discharge from the hospital.

Data was entered and analyzed using SPSS (Statistical package for the social sciences) version 23.0. Mean±SD were calculated for quantitative variables like age and post-op Hospital stay. Frequencies and percentages were calculated for qualitative variables like gender, ASA, and clinical outcomes. Chi-Square test was applied keeping p value < 0.05 as significance level.

Results:

A total of 64 patients (32 patients in each group) as per our sample size were included in this study. In Group A, mean±SD for age and post-op hospital stay was 46.59±7.29 years and 45.31 days respectively. Similarly, in Group B, mean±SD for age and post-op hospital stay was 50.03±6.05 years and 23.81±3.22 days respectively as shown in table I.

Statistically insignificant association was found between the groups in terms of age and gender with p-value 0.183 and 0.317 respectively as shown in table- II.

Statistically insignificant association was found between the groups for ASA status of patients with p value 0.249, however, conservative approach was found significantly superior to surgical approach in terms of rate of fistula closure and mortality following pancreaticoduodenectomy with p value < 0.001 as shown in table III.

Discussion:

This study compared surgical and conservative approaches in managing pancreatic fistula following pancreaticoduodenectomy. The study included 64 patients, with 32 patients in each group. Several studies have been conducted on the management of pancreatic fistula.

Conservative management of pancreatic fistula

is successful in 95% of cases.¹² External pancreatic fistulas are managed primarily by conservative treatment with a success rate of approximately 80%.¹³ Failure of conservative treatment has traditionally been dealt with using surgery; however, significant morbidity and mortality are associated with operative management.¹⁴

Using a non-restrictive definition of pancreatic fistula, one study found that conservative management was the treatment of choice.⁶ Overall, these studies suggest that conservative management can be successful in treating pancreatic fistula, with surgery being reserved for cases where conservative treatment fails. This study supports this finding, as a statistically significant difference was recorded for fistula closure and mortality between the surgical and conservative groups.¹⁰

This study compared surgical versus conservative approaches in managing pancreatic fistula following pancreaticoduodenectomy. The study included 64 patients, with 32 patients in each group. The mean age and post-op hospital stay for Group A were 46.59 ± 7.29 years and 45.31 days, respectively. For Group B, the mean age and post-op hospital stay were 50.03 ± 6.05 years and 23.81 ± 3.22 days, respectively. This study found no statistically significant association between the groups for age and gender. However, a statistically significant difference was recorded for fistula closure and mortality between the two groups. This study could not find any studies that directly compared surgical versus conservative approaches in managing pancreatic fistula following pancreaticoduodenectomy. However, some related studies were found that compared different surgical approaches for pancreaticoduodenectomy and the management of pancreatic fistula.

A systematic review and meta-analysis comparing pylorus-preserving pancreaticoduodenectomy versus classic Whipple procedure showed no difference in overall outcomes.¹⁶ A case-match study compared posterior approach pancreaticoduodenectomy (paPD) technique with the standard Whipple procedure (sPD) and found

that paPD was associated with less blood loss, shorter hospital stay, and fewer complications.¹⁷

A retrospective study compared open, laparoscopic, and robotic pancreaticoduodenectomy and found that robotic pancreaticoduodenectomy was associated with longer operative time, but similar post-operative outcomes compared to open and laparoscopic approaches.¹⁸ A study compared surgical versus conservative approaches in managing pancreatic fistula after pancreaticoduodenectomy and found that the conservative approach was associated with lower mortality and morbidity rates compared to the surgical approach.¹⁹ A study compared laparoscopic and open pancreaticoduodenectomy for the treatment of non-pancreatic periampullary adenocarcinomas and found that laparoscopic pancreaticoduodenectomy had less intraoperative bleeding and faster post-operative recovery compared to open pancreaticoduodenectomy.²⁰

Another study compared surgical versus conservative approaches in managing pancreatic fistula after pancreaticoduodenectomy and found that the conservative approach was associated with lower mortality and morbidity rates compared to the surgical approach²¹ thus in agreement to the findings of this study. Overall, the related studies suggest that different surgical approaches for pancreaticoduodenectomy may have different outcomes, and that conservative management may be associated with lower morbidity and mortality rates compared to surgical management for pancreatic fistula as proved in this study.

Conclusion:

In conclusion, based on the findings of this study, it can be concluded that while there were no significant differences in age, gender, or ASA status between the surgical and conservative management groups, there were significant differences in clinical outcomes. Specifically, the conservative approach showed a significant advantage and superiority in terms of rate of fistula closure and lower mortality rates compared to the surgical approach following pancreaticoduodenectomy.

This suggests that the conservative approach is a more effective and safer option for managing pancreatic fistula in this patient population. However, further research and larger studies may be needed to confirm these findings and establish the most appropriate approach for managing pancreatic fistula post-pancreaticoduodenectomy.

Conflict of interest: None

Funding source: None

Role and contribution of authors:

Muhammad Amin, conception, study design, drafting the manuscript, approval of the final version to be published.

Misbahullah, data analysis, data interpretation, critical review, approval of the final version to be published.

Maryam Munir, data acquisition, critical review, approval of the final version to be published.

Ishfaqullah, proof readings, write-up, approval of the final version to be published.

Limitations of study:

The main limitations of this study were its small sample size of 64 patients, with 32 patients in each group. A small sample size limits the generalizability of findings and increases the risk of type II error (false negative).²² This study was conducted in a single center, which may limit the external validity of findings. Different centers have different patient populations, surgical techniques, and post-operative care protocols that could affect the outcomes.²³ Moreover, there was lack of blinding as blinding is important to minimize bias and ensure that the outcomes are measured objectively.²⁴ Finally, due to paucity of time, there was lack of long follow-up as long-term follow-up is important to assess the durability of the outcomes and the potential long-term complications.²⁵

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