

Comparison of Surgical versus Conservative Approach in Management of Pancreatic Fistula Following Pancreaticoduodenectomy

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Received: 13-09-2025

Revised: 30-10-2025

Accepted: 13-11-2025

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 April 2024 to March 2025.

Methodology: Sixty-four patients were managed for complicated pancreatic fistula following pancreaticoduodenectomy, thirty-two 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

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.^{1,2,3}

Pancreatic fistula represents a postoperative 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 procedure 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.^{4,5,6}

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.^{7,8,9}

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.

METHODOLOGY

This Prospective Comparative Study was conducted at the Department of General Surgery, MTI-Khyber Teaching Hospital, from April 2024 to March 2025. 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. Nonprobability consecutive sampling technique was used for data collection.

Inclusion Criteria

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

Patients requiring an additional transmurial 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 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 patients) while patients in Group B were managed with secondary percutaneous

drainage and high spectre antibiotherapy 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 $\pm$ 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 $\pm$ SD for age and post op hospital stay was 46.59 $\pm$ 7.29 years and 45.31 days respectively. Similarly, in Group B, mean+SD for age and post op hospital stay was 50.03 $\pm$ 6.05 years and 23.81 $\pm$ 3.22 days respectively. (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. (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 . (Table III).

**Table-I: 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-II: 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
		61.9%	38.1%	100.0%	
	> 45 Years	19	24	43	
		44.2%	55.8%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	
		Groups		Total	p-value
		Group A (SA)	Group B (CA)		
Gender	Male	14	18	32	0.317
		43.8%	56.3%	100.0%	
	Female	18	14	32	
		56.3%	43.8%	100.0%	
Total		32	32	64	
		50.0%	50.0%	100.0%	

**Table-III: 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%	
		Groups		Total	

		Group A (SA)	Group B (CA)		p-value
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%	

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. Your 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 outcomes¹⁶. A case-match study compared posterior approach pancreatoduodenectomy (paPD) technique with the standard Whipple procedure (sPD) and found that paPD was associated with less blood loss, shorter hospital stay, and fewer complications¹⁷.

A retrospective study compared open, laparoscopic, and robotic pancreatoduodenectomy and found that robotic pancreatoduodenectomy was associated with longer operative time, but similar postoperative outcomes compared to open and laparoscopic approaches¹⁸. 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 approach¹⁹. A study compared laparoscopic and open pancreaticoduodenectomy for the treatment of nonpancreatic periampullary

adenocarcinomas and found that laparoscopic pancreaticoduodenectomy had less intraoperative bleeding and faster postoperative recovery compared to open pancreaticoduodenectomy²⁰. 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.

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 postoperative care protocols that could affect the outcomes²³. Moreover, there was lack of blinding as blinding is important to minimize bias and ensure that the outcomes are measured objectively²⁴. 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 complications²⁵.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

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

Najam ud Din, Hafeezullah: Data analysis, data interpretation, critical review, approval of the final version to be published.

Irshad Ahmed, Habibullah: Data acquisition, critical review, approval of the final version to be published.

Ishtiaque Ali Langah, Jamshed Khan: Proof readings, write-up, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

None.

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