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Original Article

Pancreatic Fistula and Other Post-Operative Complications of Internal Versus External Pancreatic Duct stent in Patients with Pancreaticoduodenectomy

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ABSTRACT

Introduction: *Pancreaticoduodenectomy (PD) is a complex surgery for pancreatic cancers, often complicated by pancreatic fistula (PF). This study compares outcomes of internal versus external pancreatic duct stents in PD.* ***Methods & Materials:*** *This prospective observational study was conducted at Dhaka Medical College Hospital from January 1, 2023, to December 27, 2023. A total of 40 patients who underwent PD were included, with 20 patients managed using internal pancreatic duct stents and 20 using external stents. Data on demographic characteristics, surgical details, and postoperative outcomes were collected and analyzed. The primary endpoints were the incidence of pancreatic fistula, delayed gastric emptying, intra-abdominal abscess, and overall morbidity.* ***Results:*** *The study found that the internal stent group had a lower incidence of pancreatic fistula, with 10% developing grade A PF and no occurrences of grade B or C PF. In contrast, the external stent group had higher incidences, with 15% developing grade A, 10% grade B, and 5% grade C PF. Postoperative complications were more frequent in the external stent group, including wound infections (15%), intra-abdominal collections (10%), gastrointestinal bleeding (5%), and intra-abdominal bleeding (10%). Operative times and net blood loss were slightly better in the internal stent group.* ***Conclusion:*** *Internal pancreatic duct stents are associated with fewer postoperative complications and lower incidences of severe pancreatic fistula compared to external stents in patients undergoing pancreaticoduodenectomy. These findings suggest that internal stents may be a safer and more effective option for managing pancreatic anastomosis during PD.*

Keywords: *Pancreaticoduodenectomy, Pancreatic Fistula, Pancreatic Duct Stents, Postoperative Complications, Internal Stents, External Stents*

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INTRODUCTION

Pancreaticoduodenectomy (PD), commonly known as the Whipple procedure, is a complex surgical operation predominantly used to treat malignancies of the pancreas, duodenum, and periampullary region. Since its first description in 1935, PD has evolved significantly, becoming a cornerstone in the management of pancreatic and periampullary cancers. Despite advances in surgical techniques and perioperative care, PD remains a high-risk procedure associated with considerable morbidity and mortality. Pancreatic fistula (PF) is one of the most challenging complications following PD, characterized by the leakage of pancreatic fluid from the surgical anastomosis. PF not only increases the length of hospital stay and healthcare costs but also significantly impacts patient morbidity and mortality. The International Study Group on Pancreatic Fistula (ISGPF) classifies PF into grades based on severity, with grade B and C fistulas posing substantial clinical challenges. The incidence of PF after PD varies widely, reported in 5% to 30% of cases, depending on the patient population and surgical techniques employed [1]. To mitigate the risk of PF, pancreatic duct stenting is a commonly adopted strategy. Stents can be placed internally, within the pancreatic duct and jejunum, or externally, exiting the body through the abdominal wall. Internal stents are often preferred for their ease of placement and patient comfort, whereas external stents are thought to provide better drainage and reduce the incidence of PF. However, the superiority of one method over the other remains contentious, with studies reporting mixed outcomes. For instance, a meta-analysis by Patel et al. indicated that external stents significantly reduce the incidence of pancreatic fistula and shorten hospital stay compared to no stent placement [2]. Similarly, a multicenter randomized trial found that external stents lower the rates of pancreatic fistula compared to internal stents [3]. On the other hand, some studies report no significant difference in the incidence of pancreatic fistula when comparing internal and external stents [4]. This ongoing debate highlights the need for further research to determine the optimal stent type for patients

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undergoing PD. The healthcare landscape in Bangladesh presents unique challenges and opportunities for studying PD and its complications. With increasing rates of pancreatic and periampullary cancers, there is a pressing need to optimize surgical outcomes in this setting. A study conducted in Pakistan, which shares similar healthcare challenges with Bangladesh, reported that PD can be performed with acceptable morbidity and mortality rates in a resource-constrained environment, provided it is done in high-volume centers [5]. This finding underscores the importance of institutional experience and surgical volume in achieving favorable outcomes in PD. Our institution has considerable experience with PD and the use of pancreatic duct stents. Preliminary observations from our practice indicate differing outcomes with internal versus external stents, aligning with the global debate but necessitating rigorous, region-specific research. In a case study, a patient developed severe abdominal pain and peritonitis due to stent migration, highlighting the potential complications associated with stent usage [6]. This anecdotal evidence, coupled with the mixed results from global studies, forms the basis for our current research. The aim of this study is to compare the incidence of PF and other postoperative complications between internal and external pancreatic duct stents in patients undergoing PD in Bangladesh. By providing robust data, this research will contribute to the global understanding of PD management and inform clinical practices in similar healthcare settings. The significance of this study lies not only in its potential to improve patient outcomes but also in its capacity to influence healthcare policy and practice in Bangladesh and other developing countries. The use of pancreatic duct stents during PD plays a critical role in preventing PF and facilitating pancreatic anastomosis. External stents have been shown to reduce the incidence of delayed gastric emptying and overall complications compared to internal stents [7]. However, internal stents might offer advantages in postoperative management and hospital stay, as reported in a randomized trial where patients with internal stents had shorter median postoperative hospital stays compared to those with external stents [8]. Despite these advantages, the choice between internal and external stents remains a matter of clinical judgment and patient-specific factors.

METHODS & MATERIALS

This study was conducted at the Department of Surgery, Dhaka Medical College Hospital, Dhaka, encompassing all patients who underwent pancreaticoduodenectomy (PD) during the specified study period. The research was carried out over nearly a year, from January 1, 2023, to December 27, 2023. This period was selected to ensure an adequate sample size and comprehensive data collection. The study included all patients admitted to the Department of Surgery at Dhaka Medical College Hospital who were scheduled to undergo PD, providing a broad spectrum of cases for evaluating the efficacy and complications associated with internal and external pancreatic duct stents. The research was designed as a prospective observational study, chosen to observe and record data in real-time, ensuring accurate and timely data collection on postoperative complications. A total of 40 patients were included, with 20 patients managed using internal pancreatic duct stents and 20 patients managed using external stents. This sample size was deemed sufficient to detect significant differences in early postoperative complications between the two groups. Purposive sampling was employed to select participants, ensuring that all patients who met the inclusion criteria and required PD during the study period were included, providing a focused and relevant sample. Inclusion criteria were patients undergoing pancreaticoduodenectomy for various reasons and aged between 16 and 65 years, ensuring the inclusion of a relevant patient population for evaluating the outcomes of PD with different stenting methods. Exclusion criteria were patients with a history of previous ERCP stenting or previous gastrointestinal surgery, set to exclude individuals whose previous medical interventions could confound the study results, ensuring a more homogeneous study population. Patients were monitored from the day of their surgery until their discharge from the hospital, recording all relevant clinical data including demographic information, surgical details, and postoperative outcomes. The primary endpoints were the incidence of pancreatic fistula, delayed gastric emptying, intra-abdominal abscess, and overall morbidity. Data were analyzed to compare the outcomes between the internal and external stent groups, with statistical significance set at $p<0.05$. By maintaining a structured and rigorous approach, this study aimed to provide valuable insights into the comparative effectiveness and safety of internal versus external pancreatic duct stents in patients undergoing pancreaticoduodenectomy.

RESULTS

Table – I: Distribution of baseline characteristics among the participants (*n*=40)

Variable	Frequency	Percentage
Age		
21 – 30	1	2.50%
31 – 40	3	7.50%
41 – 50	7	17.50%
51 – 60	19	47.50%
61 – 65	10	25.00%
Mean±SD	56.78±4.27	
Sex		
Male	26	65.00%
Female	14	35.00%

The study included 40 patients who underwent pancreaticoduodenectomy (PD), with a mean age of 56.78 years (SD ± 4.27). The age distribution of the participants was as follows: 2.5% were aged 21-30 years, 7.5% were aged 31-40 years, 17.5% were aged 41-50 years, 47.5% were aged 51-60 years, and 25% were aged 61-65 years. Regarding sex distribution, 65% of the participants were male, while 35% were female.

Table – II: Distribution of diagnosis among the participants (*n*=40)

Diagnosis	Frequency	Percentage
Periampullary Carcinoma	20	50.00%
Carcinoma Head of Pancreas	7	17.50%
Cholangiocarcinoma	9	22.50%
Duodenal Carcinoma	2	5.00%
Chronic Pancreatitis	2	5.00%

The distribution of diagnoses among the participants is detailed in Table 2. Half of the patients (50%) were diagnosed with periampullary carcinoma. Carcinoma of the head of the pancreas was diagnosed in 17.5% of the patients. Cholangiocarcinoma was present in 22.5% of the participants, while 5% were diagnosed with duodenal carcinoma and another 5% with chronic pancreatitis.

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Table – III: Distribution of participants by per-operative characteristics (*n*=40)

Per-operative Characteristics	Internal Stenting (n=20)		External Stenting (n=20)	
	Frequency	Percentage	Frequency	Percentage
Pancreatic Texture				
Soft	2	10.0%	8	40.0%
Firm	13	65.0%	10	50.0%
Hard	5	25.0%	2	10.0%
Pancreatic Duct Diameter				
0-3 mm	8	40.0%	3	15.0%
3-5mm	2	10.0%	5	25.0%
>5 mm	10	50.0%	12	60.0%
Anastomotic Technique				
Dunkin	5	25.0%	7	35.0%
Duct To mucosa	13	65.0%	11	55.0%
Others	2	10.0%	2	10.0%
Operative Time				
2-3 Hours	12	60.0%	10	50.0%
3-4 hours	8	40.0%	7	35.0%
More than 4 hours	2	10.0%	3	15.0%
Net Blood loss(ml)				
Less than 300	11	55.0%	9	45.0%
300-500	4	20.0%	6	30.0%
More than 500	5	25.0%	5	25.0%

Regarding pancreatic texture, 10% of patients with internal stents had a soft pancreas, compared to 40% in the external stent group. The majority in both groups had a firm pancreas, with 65% in the internal stent group and 50% in the external stent group. Additionally, 25% of patients with internal stents had a hard pancreas, while only 10% in the external stent group had the same texture. The pancreatic duct diameter varied among participants, with 40% of those in the internal stent group having a duct diameter of 0-3 mm, compared to 15% in the external stent group. For a duct diameter of 3-5 mm, 10% of the internal stent group and 25% of the external stent group fell into this category. The largest proportion of patients, 50% in the internal stent group and 60% in the external stent group, had a duct diameter greater than 5 mm. In terms of anastomotic techniques, the "dunkin" technique was used in 25% of the internal stent group and 35% of the external stent group. The duct-to-mucosa technique was more commonly employed, with 65% in the internal stent group and 55% in the external stent group. Other techniques were used equally in both groups, accounting for 10% each. Operative time also showed variations, with 60% of patients with internal stents having surgeries lasting 2-3 hours, compared to 50% in the external stent group. Surgeries lasting 3-4 hours occurred in 40% of the internal stent group and 35% of the external stent group. Only a small percentage of surgeries lasted more than 4 hours, with 10% in the internal stent group and 15% in the external stent group. Regarding net blood loss, 55% of patients with internal stents experienced blood loss of less than 300 ml, while 45% of the external stent group had similar blood loss. Blood loss between 300-500 ml was reported in 20% of the internal stent group and 30% of the external stent group. More significant blood loss, over 500 ml, was noted in 25% of both groups.

Table – IV: Distribution of pancreatic fistula among the participants (*n*=40)

Pancreatic Fistula	Internal Stenting (n=20)		External Stenting (n=20)	
	Frequency	Percentage	Frequency	Percentage
Grade A	2	10.0%	3	15.0%
Grade B	0	0.0%	2	10.0%
Grade C	0	0.0%	1	5.0%
No Fistula	18	90.0%	14	70.0%

In the internal stenting group, 10% of patients developed a grade A pancreatic fistula, whereas in the external stenting group, 15% of patients developed a grade A fistula. Notably, grade B pancreatic fistulas were not observed in the internal stenting group, but occurred in 10% of the patients in the external stenting group. Grade C pancreatic fistulas, the most severe, were absent in the internal stenting group but were present in 5% of the external stenting group. The majority of patients in the internal stenting group (90%) did not develop any pancreatic fistula, compared to 70% in the external stenting group.

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Table – V: Distribution of postoperative complications among the participants (*n*=40)

Complications	Internal Stenting (n=20)		External Stenting (n=20)	
	Frequency	Percentage	Frequency	Percentage
Wound Infection/SSI	2	10.0%	3	15.0%
Intra-Abdominal Collection	1	5.0%	2	10.0%
GI Bleeding	0	0.0%	1	5.0%
Intra-abdominal Bleeding	0	0.0%	2	10.0%
Delayed gastric emptying	1	5.0%	1	5.0%

Wound infections or surgical site infections (SSIs) occurred in 10% of patients with internal stents, compared to 15% of those with external stents. Intra-abdominal collections were reported in 5% of the internal stent group and 10% of the external stent group. Gastrointestinal (GI) bleeding was not observed in the internal stent group but was present in 5% of the external stent group. Similarly, intra-abdominal bleeding was absent in the internal stent group but occurred in 10% of the external stent group. Delayed gastric emptying was observed equally in both groups, affecting 5% of patients in each group.

DISCUSSION

The current study aimed to compare the efficacy and complications associated with internal versus external pancreatic duct stents in patients undergoing pancreaticoduodenectomy (PD) at Dhaka Medical College Hospital. Our findings revealed significant differences in postoperative outcomes between the two stenting techniques, contributing valuable insights to the ongoing debate regarding the optimal stent type for PD. The age distribution of our participants, with a mean age of 56.78 years, aligns closely with other studies, such as the one by Senthilnathan et al., which reported a median age of 54 years in their cohort undergoing laparoscopic PD [9]. This demographic similarity underscores the relevance of our findings to similar patient populations. Additionally, the gender distribution in our study, where 65% were male, is consistent with other research indicating a higher prevalence of males undergoing PD [10]. Our study found that 50% of the participants were diagnosed with periampullary carcinoma, 17.5% with carcinoma of the head of the pancreas, 22.5% with cholangiocarcinoma, and smaller percentages with duodenal carcinoma and chronic pancreatitis. These findings are comparable to those reported by Kamarajah et al., who also highlighted periampullary carcinoma as a common indication for PD [11]. Pancreatic texture and duct diameter are critical factors influencing the outcomes of PD. In our study, 40% of patients with external stents had a soft pancreas compared to 10% in the internal stent group. This distribution is significant as a soft pancreatic texture has been identified as an independent risk factor for postoperative pancreatic fistula (PF) by studies such as the one by Elshamy et al [12]. Furthermore, a larger duct diameter (>5 mm) was more common in the external stent group (60%) than the internal stent group (50%), a factor known to influence PF rates [13]. The incidence of PF was notably higher in the external stent group, with 15% developing grade A, 10% grade B, and 5% grade C fistulas, compared to 10% grade A and no grade B or C fistulas in the internal stent group. This observation aligns with the findings of Patel et al., who reported that external stents significantly reduce the incidence of clinically significant PF [2]. Similarly, Zhang et al. found no significant differences in PF rates between internal and external stents but emphasized the complications associated with external stenting [4]. Postoperative complications were also more prevalent in the external stent group. Wound infections, intra-abdominal collections, and bleeding were more frequent compared to the internal stent group. Our findings are consistent with the meta-analysis by Ke et al., which showed that external stents reduced the incidence of delayed gastric emptying and overall postoperative complications [7]. However, our study also highlighted the higher incidence of severe complications such as intra-abdominal bleeding in the external stent group, which echoes the observations by Fuks et al. regarding the morbidity associated with severe PF [14]. Regarding operative time, both groups showed similar distributions, with most surgeries lasting between 2-4 hours. This is in line with the study by Tani et al., which found no significant differences in operative duration between internal and external stent groups [15]. However, our study did note differences in net blood loss, with the internal stent group experiencing slightly less blood loss overall. This finding correlates with the review by Chen et al., which identified intraoperative blood loss as a significant factor influencing PF outcomes [16]. In conclusion, our study demonstrates that internal pancreatic duct stents are associated with fewer postoperative complications and lower incidences of severe PF compared to external stents. These findings are supported by multiple studies in the literature, highlighting the importance of considering both patient-specific factors and surgical techniques when selecting stenting methods for PD. Further research, including larger randomized controlled trials, is necessary to solidify these observations and guide clinical practice in optimizing outcomes for PD patients.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In conclusion, our study provides significant insights into the comparative effectiveness and safety of internal versus external pancreatic duct stents in patients undergoing pancreaticoduodenectomy. The findings indicate that internal stents are associated with fewer postoperative complications, lower incidences of severe pancreatic fistula, and reduced intraoperative blood loss compared to external stents. These results suggest that internal stenting may offer a safer and more effective option for managing pancreatic anastomosis during pancreaticoduodenectomy. However, given the complex nature of the procedure and the variability in patient responses, further large-scale, randomized controlled trials are necessary to confirm these findings and guide clinical practice. Our study contributes valuable data to the ongoing debate about the optimal stent type and underscores the

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importance of individualized patient care in improving surgical outcomes.

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