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Effectiveness of Ultrasound-guided Percutaneous Catheter Drainage for Pancreatic Fluid Collections: An Interventional Study

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ABSTRACT

Introduction: Pancreatic Fluid Collections (PFCs) are accumulations of pancreatic fluid or debris contained within a granulation tissue wall. Unlike true cysts, they arise as complications of various conditions like acute pancreatitis, abdominal trauma, pancreatic surgery, or chronic pancreatic duct obstruction. While smaller PFCs (under 4 cm) often resolve on their own without intervention, larger collections exceeding 6 cm or those causing symptoms like infection or bile duct obstruction have significantly lower rates of spontaneous resolution. In such cases, drainage intervention is typically recommended.

Aim: To assess the treatment effectiveness of Percutaneous Catheter Drainage (PCD) for PFCs using ultrasound guidance.

Materials and Methods: A prospective interventional study was conducted in the Department of Radiodiagnosis, Government Stanley Medical College and Hospital, Chennai, Tamil Nadu, India, from September 2021 to August 2022. The study focused on patients (N=73) with PFC as a complication of acute pancreatitis necessitating ultrasound-guided PCD. The study outcomes were clinical effectiveness, reinterventions, and mortality rates.

Additionally, authors investigated the impact of various drainage factors, such as indication, PFC type, location relative to the pancreas, PFC size, Modified Computed Tomography (CT) Severity Index (CTSI), duration between symptom onset and PCD initiation, total catheter dwell time, and duration between symptom onset and reintervention. Statistical analyses employed International Business Machine (IBM) Statistical Packages for Social Sciences (SPSS) Statistics. Descriptive statistics and independent samples t-test for continuous variables; Chi-square test for categorical data (p<0.05).

Results: In present study, the mean age of the subjects was 47 years. PCD in terms of clinical success was 63% (n=46) and clinical failure was 37% (n=27). Open necrosectomy was performed on 15 patients (20.5%) and open cystogastrostomy was performed on 11 patients (15.1%).

Conclusion: The utilisation of ultrasound-guided PCD for PFCs represents a technique associated with relatively low morbidity and mortality rates. This approach can serve as either definitive treatment or a transitional measure before resorting to open surgery.

Keywords: Catheter dwell time, Mortality, Open cystogastrostomy, Pancreatitis

INTRODUCTION

The Pancreatic Fluild Collections (PFCs) refer to accumulations of pancreatic fluid or debris encapsulated within a granulation tissue wall, distinguishing them from true cysts [1]. They can arise as complications of various conditions such as acute pancreatitis, abdominal trauma, pancreatic surgery, or chronic pancreatic duct obstruction (e.g., due to pancreatic malignancy). While many PFCs tend to resolve spontaneously, particularly if their size is under 4 cm, and can be managed without drainage intervention, larger collections exceeding 6 cm in size or those causing symptoms such as infection or bile duct obstruction have significantly lower rates of spontaneous resolution [2]. In such cases, drainage intervention is often recommended. PFCs can be managed through various drainage methods, including surgical drainage, percutaneous drainage guided by imaging techniques such as ultrasound or Computed Tomography (CT), endoscopic transmural drainage, as well as surgical approaches such as open surgery or laparoscopy [1]. Ultrasound-guided PCD has emerged as a preferred technique for managing PFCs due to its minimally invasive nature and efficacy. The rationale behind study stems from the need to evaluate the treatment effectiveness of PCD for PFCs. The novelty of present study lies in its focus on the comprehensive evaluation of treatment outcomes associated with PCD for PFCs in this context. The present study aimed to assess the effectiveness of ultrasoundguided PCD for managing PFC arising as a complication of acute pancreatitis regardless of the underlying cause and gauge the

clinical outcomes, distinguishing between success and failure, associated with this drainage procedure.

MATERIALS AND METHODS

A prospective interventional study was conducted in the Department of Radiodiagnosis, Government Stanley Medical College and Hospital, Chennai, Tamil Nadu, India, from September 2021 to August 2022 following approval from the Ethical Committee (Number: GSMCH/IEC/29122020/002). The study focused on patients with PFC as a complication of acute pancreatitis necessitating ultrasound-guided PCD, with written consent obtained from all participants.

Sample size calculation: The sample size (n) for present study was determined using the formula $n=Z\times Z\times p\times q/d\times d$, where n represents the sample size, Z denotes the statistical significant constant for a 95% Confidence Interval (CI), 'p' represents the lower limit of the prevalence of PFCs in acute pancreatitis (set at 5%), 'q' represents the complementary probability to 'p' (95%), and d signifies the absolute precision (5%). Upon substituting the given values into the formula, the calculated sample size (n) was 73. The sampling method employed was consecutive sampling.

Inclusion and Exclusion criteria: Inclusion criteria encompassed patients meeting the Revised Atlanta Criteria for PFC from acute pancreatitis requiring ultrasound-guided PCD, while patients under 18 years old, unwilling participants, those treated through Endoscopic Retrograde Cholangiopancreatography (ERCP)

transpapillary drainage, endoscopic-guided drainage, or surgical drainage were excluded from the study.

Study Procedure

The study utilised a predesigned proforma to collect patients' clinical details and employed a Standard Ultrasound Machine (Mindray Resona 19, Mindray DC60, and Aloka Prosound Alpha 5SX) for guidance for PCD of PFC. Confirmation of entry was done using an 18-gauge needle aspiration, followed by the insertion of an all-purpose pigtail catheter 8-12 Fr under ultrasound guidance. The catheter's position was reconfirmed using ultrasound or CT, and patients were reimaged once, approximately four weeks after the drainage procedure, to assess the status of the PFC.

Before the procedure, the coagulation profile was done and proceeded only if the international normalised ratio was less than 1.5. Contrast-enhanced Computed Tomography (CECT) images were analysed for the optimal site of entry. Prophylactic administration of broad-spectrum antibiotics preceded the procedure. Employing stringent aseptic measures, and guided by real-time ultrasound using a curvilinear probe (2-5 MHz), the Interventional Radiologist percutaneously inserted an 18-gauge needle into the PFC for fluid aspiration. Subsequently, a 0.035-inch guidewire was advanced into the collection, followed by dilation of the tract as necessary, and insertion of a catheter. The catheter size ranged from 8-12 Fr, depending on the collection's dimensions, with its placement confirmed under ultrasound guidance. Additional catheter exchanges and upsizing were performed based on persistent fluid collection on imaging, clinical presentation, catheter drain output volume, and any catheter malfunction. Decisions regarding catheter removal were jointly made by the treating surgeon and the interventional radiologist. The study's endpoint, or success was defined as a reduction in the collection's size by more than 50% from the initial measurement or a collection size less than 2 cm on follow-up imaging conducted at least four weeks post-drainage. Failure was defined as the absence of these criteria.

The study focused on assessing treatment outcomes, including clinical effectiveness, reinterventions, and mortality rates. Additionally, authors investigated the impact of various drainage factors, such as PFC type, location relative to the pancreas, total catheter dwell time, and duration between symptom onset and reintervention.

STATISTICAL ANALYSIS

The gathered data underwent analysis using IBM SPSS Statistics for Windows, version 23.0 (Armonk, NY: IBM Corp). Descriptive statistics, including frequency and percentage analyses, were utilised to characterize categorical variables, while mean and Standard Deviation (SD) were employed for continuous variables. The independent samples t-test was used to identify significant differences between bivariate samples in independent groups. The Chi-square test was applied to categorical data to assess significance. In both statistical methods, a probability value of 0.05 was considered statistically significant.

RESULTS

In the study population, the age distribution revealed that patients aged <30 years constituted 6 (8.2%) individuals, 16 (21.9%) were aged 31- 40 years, 17 (23.3%) were aged 41-50 years, 16 (21.9%) were aged 51-60 years, and 18 (24.7%) were aged >60 years. Gender distribution indicated that 11 (15.1%) were female, while 62 (84.9%) were male. Regarding aetiology, alcohol-related factors accounted for 25 cases (34.2%), followed by biliary causes with 25 cases (34.2%), idiopathic factors with 18 cases (24.7%), and traumatic causes with 5 cases (6.8%) [Table/Fig-1]. CT findings for the location of PFC in relation to the pancreas demonstrated distribution in the head/uncinate process region at 53.4%, body at 38.4%, and tail at 8.2% [Table/Fig-2]. The distribution of types of PFC included Acute

Peripancreatic Collection (APC) at 5.5%, Acute Necrotic Collection (ANC) at 2.7%, Walled-off Pancreatic Necrosis (WOPN) at 52.1%, and Pseudocyst at 39.7% [Table/Fig-3]. Indications for intervention comprised infected cases at 53.4%, rapidly enlarging size at 13.7%, persistent pain at 20.5%, compression causing obstructive jaundice at 5.5%, and rupture at 6.8% [Table/Fig-4].

Aetiology	Frequency	Percentage (%)					
Alcohol	25	34.2					
Biliary	25	34.2					
Idiopathic	18	24.7					
Traumatic	5	6.8					
Total	73	100.0					
[Table/Fig-1]: Actiology distribution							

Frequency	Percentage (%)
39	53.4
28	38.4
6	8.2
73	100.0
	39 28 6

[Table/Fig-2]: Location of fluid collection in relation to pancreas.

Type of fluid collection	Frequency	Percentage (%)	
Acute peripancreatic collection	4	5.5	
Acute necrotic collection	2	2.7	
Walled off pancreatic necrosis	38	52.1	
Pseudocyst	29	39.7	
Total	73	100.0	

[Table/Fig-3]: Type of fluid collection distribution.

Indication	Frequency	Percentage (%)
Infected	39	53.4
Rapidly enlarging size	10	13.7
Persistent pain	15	20.5
Compression causing obstructive jaundice	4	5.5
Rupture	5	6.8
Total	73	100.0

[Table/Fig-4]: Indication distribution.

In terms of treatment response, clinical success was achieved in 63.0%, while 37.0% experienced failure [Table/Fig-5]. Among the 27 cases classified as treatment failures, one case did not necessitate reintervention despite the lack of clinical success. The present particular case exhibited a stable clinical condition and resolution of symptoms without intervention. The patient's condition was closely monitored, and supportive measures including intravenous hydration and pain management were provided. Despite the absence of further intervention, the patient showed significant improvement in symptoms and reduction in PFC size during follow-up. The present unique case highlights the potential variability in response to PCD and underscores the importance of individualised patient management strategies.

Response	Frequency	Percentage (%)		
Failure	27	37.0		
Success	46	63.0		
Total	73	100.0		

[Table/Fig-5]: Treatment response- clinical success/failure distribution

In present study, the average duration from symptom onset to drainage initiation was 35.2 days, with a range of 17 to 52 days. Additionally, patients undergoing drainage had an average modified CTSI of 6.6. Reintervention or further treatment was not necessary for 64.4%, with open necrosectomy required in 20.5%, and

open cystogastrostomy in 15.1% [Table/Fig-6]. The overall status distribution indicated that 64 patients (89.0%) were alive, while nine patients (11.0%) succumbed to the condition. Statistical analyses revealed no significant associations between CT findings for the location of PFC in relation to the pancreas and treatment response (χ^2 =2.074, p=0.354) [Table/Fig-7] or between the type of PFC and treatment response (χ^2 =3.960, p=0.266) [Table/Fig-8].

Reintervention/Further treatment	Frequency	Percentage (%)
Nil	47	64.4
Open necrosectomy	15	20.5
Open cystogastrostomy	11	15.1
Total	73	100.0

[Table/Fig-6]: Reintervention/Further treatment distribution.

			Treatment response			χ²-	p-
CT findings		Yes	No	Total	value	value	
	Head/	Count	22	17	39		
For the location	Uncinate process	%	47.8%	63.0%	53.4%		
of PFC in	Dodu	Count	19	9	28		
relation to the	Body	%	41.3%	33.3%	38.4%	2.074	0.354#
pancreas	Toil	Count	5	1	6	2.07 1	0.001
Tail		%	10.9%	3.7%	8.2%		
Total		Count	46	27	73		
TOTAL		%	100.0%	100.0%	100.0%		

[Table/Fig-7]: Comparison of CT findings for the location of PFC in relation to the pancreas with treatment response by Pearson's Chi-square test. #No statistical significance

			ment				
Variab	Variables		Yes	No	Total	χ²-value	p-value
	APC	Count	4	0	4		
	APC	%	8.7%	0.0%	5.5%		
	ANIO	Count	2	0	2		
Type	ANC	%	4.3%	0.0%	2.7%		
of PFC	MODNI	Count	22	16	38	0.000	0.000 !!
	WOPN	%	47.8%	59.3%	52.1%	3.960	0.266 #
	Describe	Count	18	11	29		
	Pseudocyst	%	39.1%	40.7%	39.7%		
Total		Count	46	27	73		
Total		%	100.0%	100.0%	100.0%		

[Table/Fig-8]: Comparison of type of PFC with treatment response by Pearson's Chi-square test.

*No statistical significance; APC: Acute peripancreatic collection; ANC: Acute necrotic collection; WOPN: Walled-off nancreatic necrosis

Additionally, no statistically significant differences were observed in treatment response concerning the time of drainage from onset (days) (t=0.335, p=0.738) [Table/Fig-9], and catheter indwelling days (t=0.305, p=0.761) [Table/Fig-10] based-on independent samples t-tests. The comparison between CT findings regarding size (largest dimension in centimeters) and treatment response, conducted through an independent sample t-test, yielded a t-value of 0.783 and a p-value of 0.436, indicating no statistically significant difference

Variable	Treatment response	N	Mean	SD	t-value	p-value
Time of drainage, from	Yes	46	35.02	8.47	0.335	0.738#
onset (days)	No	27	35.63	5.34	0.333	0.736"

[Table/Fig-9]: Comparison of time of drainage, from onset (days) with treatment response by independent sample t-test.

*No statistical significance at p>0.05 level

[Table/Fig-11]. Predrainage and post-drainage ultrasonography and Computed Tomography (CT) images for ultrasound-guided PCD of PFCs in few illustrative cases are shown in [Table/Fig-12-14].

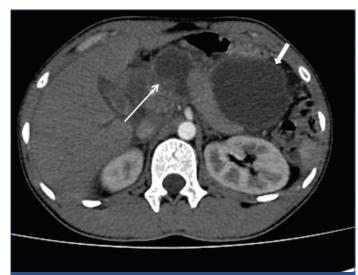
Variable	Treatment response	N	Mean	SD	t-value	p-value
Catheter	Yes	46	19.46	3.27	0.305	0.761#
indwelling days	No	27	19.70	3.46	0.305	0.761"

[Table/Fig-10]: Comparison of catheter indwelling days with treatment response by independent sample t-test.

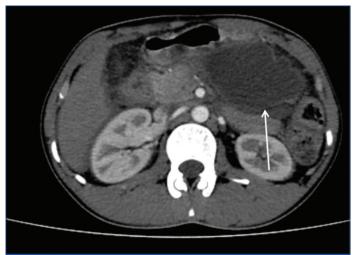
*No statistical sig	anificance
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Variable	Treatment response	N	Mean	SD	t-value	p-value
CT findings-size	Yes	46	10.52	2.26	0.700	0.436#
(largest dimension in centimeters)	No	27	10.07	2.52	0.783	0.436

[Table/Fig-11]: Comparison of CT findings- size (largest dimension in centimeters) with treatment response by independent sample t-test. *No statistical significance



[Table/Fig-12a]: A 27-year-old male sustained blunt trauma injury to the abdomen and was referred from elsewhere for traumatic pancreatic injury. CECT abdomen shows near total transection of pancreas (thin white arrow) in the region of neck, right of superior mesenteric vessels. There is also a well-defined collection in the lesser sac noted (thick white arrow).



[Table/Fig-12b]: A 27-year-old male sustained blunt trauma injury to the abdomen and was referred from elsewhere for traumatic pancreatic injury. A more inferior section of the CECT abdomen shows a well-defined collection in the lesser sac (white arrow)

DISCUSSION

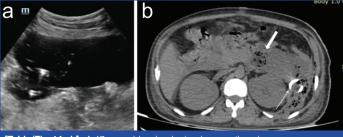
The natural course of pancreatic necrosis is gradual liquefaction of solid debris that ultimately forms a well-defined pseudocyst or resorbable liquefied necrotic mass [3]. This process can be complicated at any time by superinfection of necrotic tissue,



[Table/Fig-12c]: A 27-year-old male sustained blunt trauma injury to the abdomen and was referred from elsewhere for traumatic pancreatic injury. USG abdomen shows a well-defined collection in the lesser sac (thick white arrow) with the catheter tip inside the collection (thin white arrow).



[Table/Fig-13]: A 47-year-old male who is a known ethanol consumer, presented to the Emergency Department for acute abdominal pain. Serum amylase was elevated and acute pancreatitis was diagnosed. Axial CT images show a well-defined encapsulated collection (thin white arrow) in the left-side, tracking along the left paracolic gutter. Multiple air pockets noted within the collection (thick white arrow) suggestive of infection



[Table/Fig-14a,b]: A 47-year-old male who is a known ethanol consumer, presented to the emergency department for acute abdominal pain. Serum amylase was elevated and acute pancreatitis was diagnosed. Post-procedural ultrasound (left) shows a catheter within the collection and axial CT (right) shows infected fluid collection (thick white arrow) and radiodense pigtail catheter tip within the collection (thin white arrow).

rapid enlargement of collection, rupture of pseudocyst, and compression of adjacent structures causing obstructive jaundice and pain, usually requiring surgical or radiological intervention [3]. The step-up approach has gained widespread acceptance as the contemporary strategy for managing acute pancreatitis accompanied by fluid collection [4]. Typically, ultrasound-guided PCD serves as the initial treatment, often serving as a temporary measure to manage sepsis and postpone surgery [5]. If the fluid collection does not respond adequately to catheter drainage, the subsequent step involves either open necrosectomy or open cystogastrostomy, chosen based on the type of fluid collection. Bruennler T et al., showed the aetiology in 80 patients presenting with acute pancreatitis were biliary (32.5%), alcohol (32%), post-traumatic (1.3%), and idiopathic (18.8%) [6]. In present study, it was biliary (34.2%), alcohol (34.2%), idiopathic (24.7%), and traumatic (5%). In the literature review, the time of drainage from admission varies widely. Gambiez LP et al., in their study of 10 patients, showed the mean time of drainage from admission was 17 days ranging from 10-25 days [7]. Cheung MT et al., showed the mean time of drainage from admission was 55 days ranging from 21- 154 days [8]. van Santvoort HC et al., in their study of 43 patients showed the mean time of drainage from admission was 30 days ranging from 11-17 days [9]. The present study in 73 patients showed the mean time of drainage from onset was 35.2 days ranging from 17 to 52 days. In present study, the mean modified CTSI of patients undergoing drainage was 6.6. van Santvoort HC et al., in their study [9], showed mean CTSI was eight and Bruennler T et al., showed the mean CTSI was six [6].

The most common indication for percutaneous drainage was infected collections. In Mortele KJ et al.'s study of 35 patients, 37% had infected collections that underwent drainage [10]. Bruennler T et al., found that 65% of their fluid collections were infected [6]. Cheung MT et al., reported that 50% of patients who underwent drainage were infected [8]. In present study, 53.4% of the collections were infected, followed by persistent pain at 20.5%.

Notably, for patients who did not respond to Percutaneous Drainage (PCD), the mean time between catheter drainage and open surgery was 55.7 days in present study, significantly exceeding the study's chosen endpoint of four weeks. Mortele KJ et al., reported a mean time of 69 days between catheter drainage and open surgery [10]. Cheung MT et al., showed a mean time of 70 days between catheter drainage and open surgery [8].

In present study, the clinical success rate of PCD was 63%, and the mortality rate was 11%. This was comparable to Navalho M et al., who reported a successful PCD rate of 63% and a mortality rate of 17% in their study of 30 patients [11]. Lee JK et al., demonstrated a successful PCD rate of 78% and a mortality rate of 6% [12]. Mortele KJ et al., showed a successful PCD rate of 49% and a mortality rate of 17% [10].

Gupta P et al., examined 33 patients with Peripancreatic Fluid Collections (PFC) admitted to the Intensive Care Unit (ICU) who received bedside PCD. PCD was successful in 40% of patients, while six individuals (18.1%) subsequently underwent necrosectomy. Hospital mortality was observed in sixteen patients (48.5%) [13]. An analysis of 11 studies encompassing 384 patients revealed that employing PCD as the primary drainage method in individuals with infected collections yielded an overall success rate of 56% [14].

The present study highlights the effectiveness of ultrasound-guided PCD as a valuable intervention for managing PFCs in patients with acute pancreatitis. The robust sample size, prospective design, and adherence to standardised procedures enhance the reliability and validity of our findings. Moving forward, future research could explore comparative effectiveness studies between different drainage modalities, such as endoscopic versus percutaneous approaches, and evaluate the long-term outcomes and cost-effectiveness of these interventions. Additionally, efforts should be directed towards refining prognostic models to better stratify patients based-on their likelihood of treatment success and guide personalised management strategies. By addressing these areas, authors can further optimise the care of patients with PFCs, ultimately improving clinical outcomes and enhancing patient care.

The present study provides valuable insights into the effectiveness of ultrasound-guided PCD for managing PFCs in patients with acute pancreatitis. The findings highlight the importance of this minimally invasive intervention as a viable treatment option, offering clinicians an effective alternative to open surgery. By incorporating percutaneous drainage into clinical practice, healthcare providers can expedite patient recovery, minimise morbidity and mortality, and enhance overall treatment outcomes.

Limitation(s)

The present study presents several limitations that should be acknowledged. Firstly, we did not conduct a comparative analysis of treatment outcomes with endoscopic-guided drainage, open, or minimally invasive surgical methods. This absence of comparison limits ability to assess the relative efficacy and advantages of different intervention strategies for PFCs. Secondly, present study did not include an evaluation of severity prediction scores such as Ranson's or Modified Glasgow scores in relation to treatment outcomes. The incorporation of these scores could have provided valuable insights into their prognostic utility and their correlation with the success or failure of various treatment modalities. Additionally, we did not document the number of catheter exchanges during the drainage procedure. This oversight hinders a comprehensive understanding of the procedural aspects and potential complications associated with catheter management in percutaneous drainage [15]. Furthermore, present study lacked long-term follow-up of patients to monitor PCD-related complications like pancreatic-cutaneous fistula [16]. This limited follow-up period prevents us from assessing the durability of treatment outcomes and the occurrence of late complications associated with percutaneous drainage procedures.

CONCLUSION(S)

The management of PFCs has changed in the last two decades. From conventional open surgery for every PFC, the treatment has moved to a step-up approach. Careful selection of patients for minimally invasive therapy can be beneficial in avoiding the morbidity and complications of open surgery. Ultrasound-guided PCD plays a crucial role in the management of PFCs, which is widely used as the first line of management when the patient needs drainage of these fluid collections.

Author contributions: AH: study design, collection of data, data analysis, and writing of the manuscript. AF: writing of the manuscript, sourcing and editing of clinical images, critical review, and investigation results. VR: sourcing and editing clinical images, investigation results, critical review, and revision. All authors have critically reviewed and approved the final draft and are responsible for the manuscript's content and similarity index.

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