



Endoscopic Management of Pancreatic Fluid Collections: Guidelines of Society of Gastrointestinal Endoscopy of India and Indian EUS Club

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Introduction

The endoscopic management of pancreatic fluid collections (PFC) is in flux due to changes in how we classify them, as well as rapid advances in technology. The revised Atlanta classification of PFC¹ clearly distinguished pseudocysts from walled-off necrosis (WON) and acute peri PFC from acute necrotic collections, based upon presence of necrosis, time since the onset of attack of pancreatitis and formation of a mature wall around the fluid collection. The literature prior to this had both, a mix of WON and pseudocyst, usually labeled as pseudocysts.^{1,2} The subsequent publications have clearly demonstrated that the management issues are different for pseudocyst and WON, although clarity still eludes several areas. Another major development has been the application of biflanged metal (BFMS) and lumen apposing

metal stents (LAMS) for PFC. Despite a lot of literature available for BFMS and LAMS, controversies still exist about their appropriate role. The Society of Gastrointestinal Endoscopy of India and Indian endoscopic ultrasound (EUS) club developed these guidelines to conduct an updated literature review, and provide recommendations based upon strength of available evidence.³

Methods

We invited 19 experts who had publications in peer-reviewed journals on PFCs to participate. Due to coronavirus disease-2019 pandemic, a physical participation and face-to-face meeting were not possible and hence email and online meetings were conducted. An initial email was first sent to all the experts to formulate important questions regarding

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endoscopic management of PFCs. Experts were asked to focus on specific areas of current research on the definition, diagnosis, treatment, and technical aspects of PFC drainage. Sixty-one questions were received initially that were merged into eighteen questions after mutual discussions. The experts were then divided into teams of two, and each team was given two questions each for an exhaustive literature review, and subsequent formulation of a statement. Fourteen statements were thus compiled, and a summary of relevant literature was added. The level of evidence and strength of recommendation for each statement were added utilizing the evidence levelling system³ (►Table 1). The statements were circulated among the experts once more and any discordance was discussed and clarified.

Statement 1

Endoscopic Drainage Is Recommended for Symptomatic Pancreatic Fluid Collections (Walled-Off Necrosis or Pseudocyst) Located within Close Vicinity of Stomach or Duodenum

Level of Evidence: IIA, Grade of Recommendation: B

Endoscopic drainage should be considered for symptomatic PFC. The usual symptoms include abdominal pain, obstruction to the gastric outlet (vomiting), or bile duct (jaundice). Patients with suspected or proven infection should also be considered for endoscopic drainage. Infected WON can be

Table 1 Classification of evidence levels and recommendation grades

Level/Grade Evidence level	Description
I-A	Evidence from meta-analysis of RCTs
I-B	Evidence from at least 1 RCT
II-A	Evidence from at least 1 controlled study without randomization
II-B	Evidence from at least 1 other type of quasi-experimental study
III	Evidence from nonexperimental descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities or both
Recommendation grade	
A	Directly based on category I evidence
B	Directly based on category II evidence or extrapolated recommendation from category I evidence
C	Directly based on category III evidence or extrapolated recommendation from category I or II evidence
D	Directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

Abbreviation: RCT, randomized controlled trial.
Source: Adopted from Shekelle et al.³

suspected clinically by fever, leucocytosis, presence of gas in the collection on cross-sectional imaging, or can be proven by fluid aspiration and culture.⁴⁻⁶ Fluid collections are only amenable to endoscopic drainage if they are in close vicinity of stomach or duodenum.^{1,7-9}

Statement 2

Endoscopic Transmural Drainage of Symptomatic PFC Should Be Performed When the Collections Have a Well-Formed Encapsulating Wall

Level of Evidence: III, Recommendation Grade: C

Endoscopic drainage of PFC in absence of well-formed wall can result in pneumoperitoneum or pneumo-retroperitoneum and its consequent infective complications. Therefore, PFC are usually drained >4 weeks after the onset of acute pancreatitis when these collections have got encapsulated. It seems appropriate to delay the endoscopic drainage as long as possible because the solid debris in WON tends to liquefy over time thereby, making endoscopic transluminal drainage easier.^{1,10-16}

Statement 3

Early (<4 Weeks of Onset of Acute Pancreatitis) Intervention as Compared with Delayed (>4 Weeks after Onset of Acute Pancreatitis) Intervention Is Technically Feasible and Effective but May Be Associated with Higher Incidence of Adverse Events, Need for Surgery, and Longer Hospital Stay

Level of Evidence: III, Recommendation Grade: C

Few recently published studies have demonstrated the safety and efficacy of early transmural drainage during early phase (<4 weeks) of acute necrotizing pancreatitis (ANP), thus expanding the role of endoscopic drainage in ANP.¹⁰⁻¹³ However, the data on efficacy and safety of early endoscopic drainage of PFC is limited and is from highly experienced tertiary care centers with extensive experience in pancreatic endotherapy. Therefore, we need to establish the safety and efficacy of early (<4 weeks) endoscopic drainage of PFC before it can be routinely recommended.¹⁴⁻¹⁶

Statement 4

EUS-Guided Access Is Preferred Over Conventional Endoscopic-Guided Access

Level of Evidence: 1B, Grade of Recommendation: B

EUS defines the PFC morphology and its contents including percentage of debris and also allows accurate assessment of wall maturity and interposing vessels. It helps to differentiate from other cystic lesions of the pancreas. It facilitates drainage of PFC that are not bulging into the lumen, a distinct advantage over conventional endoscopic drainage. Two randomized controlled trials (RCTs) showed the superior technical success of EUS-guided drainage over conventional endoscopic drainage for pancreatic pseudocysts with similar clinical success and complications.^{7-9,17-19}

Statement 5

A Cross-Sectional Imaging Prior to Drainage Provides Useful Information

Level of Evidence: III, Strength of Recommendation: Grade C

Preprocedure imaging assesses the maturity of cyst wall, proximity to gut lumen, size of the cyst, necrotic contents within the cyst, presence of pseudoaneurysms, and pancreatic ductal disruption. A contrast-enhanced computed tomography (CECT) or magnetic resonance imaging (MRI) examination is performed for assessing a PFC. T2-weighted MRI scan is better than CECT scan in assessing the necrotic contents of the cyst and the integrity of pancreatic duct. CECT scan is better in delineating venous thrombosis, collaterals, and pseudoaneurysms.²⁰

Statement 6

Antibiotic Prophylaxis Is Recommended Prior to Drainage of Pancreatic Fluid Collection

Level of Evidence: IV, Strength of Recommendation: D

- EUS-guided drainage of PFC potentially increases the risk of infection of the PFC due to instrumentation and possibility of inadequate drainage. Although multiple randomized controlled studies have tested the role of prophylactic antibiotics in prevention of infected pancreatic necrosis, there is paucity of data on the role of antibiotic prophylaxis prior to drainage of PFC.^{21,22} Current recommendations from expert consensus guidelines suggest the use of prophylactic intravenous antibiotics having broad spectrum coverage but the duration of antibiotic therapy is unclear.

Statement 7

A 19 Gauge Needle Is Used for Puncture of Cyst Cavity, Followed by Passage of 0.025" or 0.035" Guidewire. Tract Dilation Is to Be Done with a Cystotome or a Balloon. Hot Stents May Not Need Any of These Steps

Level of Evidence: IV, Strength of Recommendation: D

The technique of PFC drainage involves cyst puncture, guidewire passage, tract dilation, and stent placement. There are no comparative studies regarding the needle used to puncture the cavity, although 19-gauge needle seems preferable as there is need to pass a stiff 0.025" 0.035" guidewire. Tract dilation is done with a coaxial cautery dilator (6F cystotome) or a 6 or 8 mm balloon dilator, or a combination of the two. Balloon dilation up to 15 mm may be needed if multiple plastic stent (PS) placement followed by necrosectomy is planned.²³ There is no evidence that cautery dilators increase the incidence of bleeding. Noncoaxial cautery instruments like precut-papillotome should be avoided. Hot stents are one step devices incorporating a cautery dilator and thus do not need prior track dilation.

Statement 8

Double Pigtail Plastic Stents Provide Adequate Drainage with Acceptable Safety Profile for Both Pseudocysts and WON

Level of Evidence: I B, Strength of Recommendation: B

Double pigtail PS are safe, economic, and effective. The treatment success rates of endoscopic drainage of PFC using PS have ranged from 69.7 to 96.6%.²⁴ The caliber of double pig tail stent used ranges from 7 to 10F and the median number of stents used varies from 1 to 4.²⁵⁻²⁹

Till date no randomized studies have addressed the optimal number of PS that should be inserted for drainage of a PFC. In a retrospective study of 122 patients, no difference in the number of interventions required for treatment success was found with respect to the caliber of stents (7 Fr vs. 10 Fr: one intervention required in 87.7 vs. 90.5%; $p = 0.76$) or the number of stents (1 vs. >1 stent: one intervention required in 88.9 vs. 88.6%, $p = 0.99$).³⁰ On multiple logistic regression analysis, the stent size and number were also not predictors of the number of interventions required for treatment success.

In another multicentric study from China, in all patients who achieved technical success, the clinical success for single-stent drainage versus multiple-stent drainage was 93.9 (46/49) versus 97.4% (37/38) ($p = 0.799$).²⁵ There was no significant difference in secondary infection between the single-stent and multiple-stent placement groups (9/49 vs. 2/38, respectively; $p = 0.134$).

In a RCT of plastic versus metal stent for drainage of walled-off pancreatic necrosis, the authors used the size of WON as the criterion for deciding the number of PS. They inserted at least one or more PS if size of WON was less than 10 cm and at least 2 or more if the WON size was more than 10 cm.²⁴

In a RCT comparing endoscopic versus laparoscopy drainage, a single 10F PS resulted in overall clinical success rate of 91% in the endoscopy group, although 50% of the patients required re-endoscopic lavage or necrosectomy for secondary infection.^{6,17,31,32}

As a general recommendation, two stents (7–10 F) should be placed (► Table 2).

Statement 9

Lumen Apposing Metal Stents or Biflanged Metal Stents Are Safe and Effective in Patients with WON

Level of Evidence: IB, Strength of Recommendation: B

WON with large amounts of necrotic debris may not be drained adequately by single or multiple PS due to their smaller diameter, thereby leading to possibility of infection. Large-bore metal stents provide the advantage of efficient drainage of thick WON contents and also enable subsequent necrosectomy if required, thus reducing the overall need for surgical intervention. Three designs of metal stents are available, BFMS (Nagi, Taewoong, South Korea), LAMS (Spaxus, Taewoong, South Korea, and Axios, Boston Scientific) and

Table 2 Prospective studies of EUS-guided drainage of pseudocysts and walled-off necrosis utilizing LAMS, BFMS, or PS since 2012*

Study	Type of study	Type of PFC	Type of stent	Number of patients (n)	Clinical success (%)	Technical success (%)	Mortality (%)	Adverse events (%)	Number of DEN (mean)
Bang et al ³³ 2019	RCT	WON	LAMS PS	31 29	93.5 96.6	100 100	0	41.9 20.6	2.8 3.2
van Brunschot et al ⁴⁶ 2018	RCT	WON	PS Surgery	51 47	73	96	43	30	3
Garg et al ¹⁷ 2020	RCT	WON 25 PP 5	PS Surgery	30 30	90	96.6	0	10	NA
Dhir et al ⁵⁵ 2018	Prospective	WON	BFMS	88	87	100	1.1	25	1.7
Dhir et al ⁵⁶ 2015	Prospective	PP	BFMS	47	91.4	95.3	0	4.2	0
Wang et al ⁶⁵ 2016	Prospective	WON 46 PP 15	LAMS	61	93	98	0	33.3	NA
Thompson et al ³² 2016	Prospective	WON	PS	60	86.7	98.3	0	3.3	1.58

Abbreviations: BFMS, biflanged metal stents; DEN, direct endoscopic necrosectomy; EUS, endoscopic ultrasound; LAMS, lumen apposing metal stents; "n," number; PP, pseudocysts; PS, plastic stents; RCT, randomized control trial; WON, walled-off necrosis.

* 2012 was chosen as cutoff as the revised Atlanta classification was published that year.

lumen apposing stents with cautery enhanced tip (Hot Spaxus, Taewoong, South Korea, and Hot Axios Boston Scientific, United States)

Choosing plastic or metal stent for EUS-guided drainage of WON is a subject of ongoing debate. A recent RCT concluded that apart from shorter procedure duration, there was no significant difference in treatment outcomes between LAMS and PS.³³ A meta-analysis found no difference between LAMS and PS in the clinical success of WON drainage (88.5% with LAMS vs. 88.1% with PS, $p = 0.93$). However, the resolution of WON with LAMS was achieved with lesser mean number of procedures (mean: 1.5–2.8) as compared with PS (mean: 2.7–4.0). The rates for bleeding, sepsis, perforation, and stent-migration were similar between LAMS and PS, contrary to higher bleeding rates reported in LAMS group by another study.^{34–36}

Another recent meta-analysis reported that the use of metal stents for drainage of PFC was associated with improved clinical success, fewer adverse events, and reduced bleeding compared with PS.^{29,37} Although LAMS have increased cost at index procedure, they provide easier access to perform direct endoscopic necrosectomy (DEN) and lead to reduced total number of procedures. Another three meta-analyses concluded that metal stents were superior to PS for endoscopic transmural drainage of PFC because they had a higher clinical success rate and lower rate of adverse events in particular infection and occlusion^{29,38,39} (► **Table 2**). In a prospective international multicenter study, use of LAMS facilitated DEN with low adverse events.⁴⁰

Statement 10

The Addition of a Coaxial DPS Inside a LAMS/BFMS May Be Associated with a Lower Adverse Events, Need for Necrosectomy, and Lower Rates of Stent Migration

Level of Evidence: IIA, Strength of Recommendation: C

Adding a coaxial short double pigtail PS within the metal stent is primarily intended to prevent migration of BFMS. Other benefits have led to their use in LAMS as well.

A prospective study showed that there was a trend toward higher pseudocyst infection with LAMS alone, and placing a DPS across the LAMS minimized this risk.⁴¹ Another retrospective study reported lower adverse events with concurrent coaxial DPT insertion. In a retrospective study, a total of 41 patients were treated (21 LAMS alone; 20 LAMS plus DPS). The LAMS alone group had a significantly higher rate of adverse events than the LAMS plus DPS group (42.9 vs. 10.0%; $p = 0.04$). Bleeding was the most frequent adverse event observed.⁴² On the contrary, another study reported no significant difference in fluid collection resolution or adverse events between patients drained by LAMSs alone versus those with LAMS plus DPS.⁴³

Statement 11

Symptoms Suggestive of PFC Infection after Stent Placement for Walled-Off Pancreatic Necrosis (WON) Indicates the Need for Endoscopic Necrosectomy
Level of Evidence: II A, Strength of Recommendation: Grade B

DEN has evolved as an important tool for the management of walled-off pancreatic necrosis, particularly after advent of LAMS with wider diameters. DEN can either be done in the same sitting as LAMS deployment (primary) or after a few days after index drainage (secondary). There is no clarity over which approach is better. A step-up approach was shown to reduce the need for necrosectomy. However, a large recent study showed that early necrosectomy may reduce the number of necrosectomy sessions. A variety of approaches are utilized for reducing the need for necrosectomy. These include utilizing a 20 mm LAMS, hydrogen peroxide irrigation, and continuous nasocystic saline irrigation. Better data are needed for each of these approaches. Endoscopic necrosectomy utilizing current devices is a slow and cumbersome technique and may require several sessions. The latter is considered in symptomatic patients with persistent or new onset symptoms such as fever or lack of significant resolution of PFC on imaging studies.^{44–52}

Statement 12

- a. For PFC drained with PS, long-term indwelling of transluminal stents should be kept in patients with proven disconnected pancreatic duct syndrome (DPDS).

Level of Evidence: IB; Strength of Recommendation: Grade A

- b. For PFC drained with LAMS/BFMS, stent retrieval should be done within 4 to 6 weeks, with long-term indwelling PS to be placed in patients with DPDS.

Level of Evidence: IIB; Strength of Recommendation: Grade B

DPD is a potential risk factor for recurrent PFC, to prevent recurrence of PFC; one of the strategies proposed is to place transluminal PS at index drainage and leave them in situ indefinitely. If endoscopic drainage of PFC has been performed in a patient with a confirmed DPD diagnosed by magnetic resonance cholangiopancreatography (MRCP) and/or endoscopic retrograde cholangiopancreatography (ERCP), long-term indwelling of transluminal PS is indicated.^{53,54} This approach has been based on a small RCT that included 28 patients with pseudocysts as predominant PFC having DPD in half of them.⁵³ There was a significant reduction in recurrence in patients where the stent was left in situ compared with patients in whom the stent was removed after resolution (0 vs. 38%).⁵⁰ Since then, several retrospective studies have reported similar results of low recurrence of PFC having permanent indwelling PS along with low rate of spontaneous stent migration.⁵⁴ Adverse events associated with long-term indwelling PS complications are few; however, data are inhomogeneous. In one series, two serious adverse events occurred due to small-bowel obstruction as a consequence of spontaneous stent migration.⁵⁴ Infectious complications due to permanent indwelling stent have not been reported.

The strategy of permanent indwelling stents may be considered when the index drainage is done with PS. But in case where index drainage is done with metal stents, including LAMS, that cannot be kept for long-term due to adverse events

like bleeding, an early removal has been recommended by 3 to 4 weeks.^{55,56} In such a scenario, replacement of metal stents by PS in residual PFC cavity has been proposed when there is associated DPD. However, it is often technically challenging to exchange a PS in a WON that is complete or has near completely resolved. In a recent prospective study, comparing plastic with metal stent, recurrent PFC was observed in 5 out of 24 patients (20%) where PS could not be replaced with metal stents. None of the patient with PS replacement developed recurrent PFC⁵⁷⁻⁵⁹ (► **Table 3**).

Statement 13**In Patients with Partial Disruption of the Main Pancreatic Duct, Placement of a Transpapillary Stent, Bridging the Disruption May Be Considered. Stenting of the Pancreatic Duct Has No Role in Complete Disruption of Pancreatic Duct or DPDS****Level of Evidence: II; Strength of Recommendation: Grade C**

ERCP may be considered in patients with recurrence of PFC after removal of stents to evaluate for any pancreatic ductal disruption and to place transpapillary pancreatic ductal stenting if possible. In general, ERCP is not recommended if there is no recurrence or there is asymptomatic recurrence of small PFC. Pancreatic ductal disruptions following ANP can be partial or complete. Dynamic MRCP using secretin (s-MRCP) may suggest pancreatic ductal disruption. In patients with “partial ductal disruption” confirmed on ERP, a transpapillary pancreatic ductal stent bridging the leak should be done wherever it is possible. Whereas in “complete disruptions” that also known as DPD, bridging stent is not possible. Placing the stents in downstream pancreatic duct alone may not be effective. Another retrospective study observed that pancreatic ductal stent bridging the partial disruption leads to successful outcome.^{59,60} Similar observations were reported in another large retrospective study.⁶¹ The advantage of pancreatic ductal stenting was also reported in a retrospective study of patients with WON where they suggested combining transluminal drainage with transpapillary stenting to

Table 3 Recurrence and transpapillary stenting in patients with DPDS

	Author	Type of study	Number of patients (n)	DPDS (%)	Permanent indwelling stents (%)	ERCP+ plastic stent (%)	Overall recurrence (%)	Recurrence in DPDS
1	Arvanitakis et al ⁵³ 2007	RCT	28	50	13	0	38.4	13.4
3	Basha et al ⁵⁸ 2021	Retrospective	274	74	0	12.5	13.2	17.4
4	Dhir et al ⁵⁵ 2018	Prospective	88	61	0	63.6	9.1	13.2
5	Bang et al ⁵⁷ 2020	Prospective	188	50	70	0	3.6	25
6	Wang et al ⁶⁵ 2020	Retrospective	141	40	28	0	9	9

Abbreviations: DPDS, disconnected pancreatic duct syndrome; ERCP, endoscopic retrograde cholangiopancreatography; n, number; RCT, randomized controlled trial.

improve outcome.⁶² In a large study of 375 patients, there was no benefit of ERCP and transpapillary stenting in addition to transmural drainage in terms of long-term recurrence of PFC.⁶³ A meta-analysis of nine studies also did not find any benefit of combined transmural and transpapillary drainage.⁶⁴ In surgical series, transpapillary stenting has been reported after surgical cystogastrostomy with excellent long-term results. A RCT comparing endoscopic and laparoscopic cystogastrostomy without transpapillary stenting did not find any significant recurrence in either group.¹⁷ In another study, DPDS frequently occurs in patients with PFCs but does not negatively impact successful resolution.⁶⁵ DPDS is associated with increased PFC recurrence after stent removal.⁶⁷ ERCP carries a risk of post-ERCP pancreatitis and should be used judiciously. A distinction should be made between PFC following acute pancreatitis and PFC due to chronic pancreatitis. The risk of recurrence is higher in patients with PFC associated with chronic pancreatitis in whom a transpapillary stenting is often required.

Conflict of Interest

None declared.

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