Pancreatology 21 (2021) 1291–1298

Contents lists available at ScienceDirect

Pancreatology

journal homepage: www.elsevier.com/locate/pan

Endoscopic transmural drainage tailored to quantity of necrotic debris versus laparoscopic transmural internal drainage for walled-off necrosis in acute pancreatitis: A randomized controlled trial

Suryalok Angadi [a, 1], Soumya Jagannath Mahapatra [b, 1], Rahul Sethia [b], Anshuman Elhence [b], Asuri Krishna [a], Deepak Gunjan [b], Om Prakash Prajapati [a], Subodh Kumar [a], Virinder Kumar Bansal [a, **], Pramod Kumar Garg [b, *]

[a] Departments of Surgical Disciplines, All India Institute of Medical Sciences, New Delhi, India
[b] Gastroenterology, All India Institute of Medical Sciences, New Delhi, India

ARTICLE INFO

Article history:
Received 31 December 2020
Received in revised form
15 June 2021
Accepted 17 June 2021
Available online 21 June 2021

Keywords:
Cystogastrostomy
Acute pancreatitis
Walled-off necrosis
Pancreatic fluid collection
Lumen apposing metal stents

ABSTRACT

Background and aims: Both endoscopic and laparoscopic transmural internal drainage are practiced for drainage of walled-off necrosis (WON) following acute pancreatitis (AP) but the superiority of either is not established. Our aim was to compare transperitoneal laparoscopic drainage with endoscopic drainage using either lumen apposing metal stents (LAMS) or plastic stents tailored to the amount of necrotic debris in WON.

Methods: In a randomized controlled trial, adequately powered to exclude the null hypothesis, patients with symptomatic WON were randomized to either endoscopic or laparoscopic drainage. In the endoscopy group, two plastic stents were placed if the WON contained <1/3rd necrotic debris and a LAMS was placed if it was >1/3rd. Primary outcome was resolution of WON within 4 weeks without re-intervention for secondary infection. Secondary outcome was overall success (resolution of WON at 6 months) and adverse events.

Results: Forty patients were randomized: 20 to each group. Baseline characteristics were comparable between the groups. Primary outcome was similar between the groups [16 (80%) in laparoscopy and 15 (75%) in endoscopy group; $p = 0.89$]. The overall success was similar [18 (90%) in laparoscopy vs. 17 (85%) in endoscopy; $p = 0.9$]. Median duration of hospital stay was shorter in endoscopy group [4 (4–8) vs. 6 days (5–9); $p = 0.03$]. Adverse events were comparable between the groups.

Conclusion: Laparoscopic drainage was not superior to endoscopic transmural drainage with placement of multiple plastic stent or LAMS depending on the amount of necrotic debris for symptomatic WON in AP. The hospital stay was shorter with the endoscopic approach.

(Trial registration number: CTRI/2018/05/13573).

Introduction

Acute pancreatitis (AP) may be associated with both local and systemic complications [1,2]. Local inflammation and (peri) pancreatic necrosis may result in acute (peri) pancreatic fluid collections (PFCs). Fluid collections may persist as pseudocysts or walled-off necrosis (WON) in necrotizing pancreatitis[3]. Given the proximity of PFCs located in the lesser sac to either the stomach and/or duodenum, transmural internal drainage of the PFCs is preferred over percutaneous external drainage [4–6]. For laterally placed collections, there are different percutaneous approaches and minimal access retroperitoneal pancreatic necrosectomy (MARPAN) is the preferred method [7].

Transmural internal drainage can be achieved both by surgical and endoscopic techniques. Endoscopic drainage (ED) is reported to have technical and treatment success rates of 89–100% and 82–100% respectively and <1% mortality over a 22–24 months

* Corresponding author.
** Corresponding author. All India Institute of Medical Sciences, New Delhi, India.
E-mail addresses: drvkbansal@gmail.com (V.K. Bansal), pkgarg@aiims.ac.in (P.K. Garg).
[1] These authors contributed equally to the work and are joint first authors.

https://doi.org/10.1016/j.pan.2021.06.006
1424-3903/

follow up [8–11]. Open surgical drainage is associated with a longer hospital stay and higher costs compared to endoscopic drainage [8]. Laparoscopic drainage (LD) is minimally invasive with a technical success rate >90% and a mortality rate of <1% over 12–16 months follow up, but it is performed less commonly [12–14].

Recently, two randomized controlled trials (RCT) have compared endoscopic with laparoscopic drainage in patients with PFCs. In the MISER trial, Bang et al. [15] showed that endoscopic drainage was associated with significantly lesser adverse events compared with laparoscopic drainage in patients with infected WON. In another RCT, we have shown that both ED and LD were similar in terms of success but superadded infection was more common in the ED group requiring re-intervention [16]. This was attributed to the use of plastic stents in patients with significant necrotic debris within the WON as has been shown earlier if the necrotic debris is >30% [16,17]. Lumen apposing metal stents (LAMS) provide better drainage owing to their large diameter. In an RCT, LAMS and plastic stents were shown to have similar efficacy in patients with WON [18]. However, 2 meta-analyses have shown that metal stents provide better drainage compared with plastic stents with a decreased need for re-intervention [19,20].

Theoretically, the need for a metal stent should depend on the amount of necrotic debris within the PFC. Thus, the aim of the present RCT was to compare laparoscopic drainage with endoscopic drainage by using either plastic stents or LAMS depending on the amount of necrotic debris for transmural internal drainage of WON following AP.

Methods

Study design

The study was an open label randomized controlled trial conducted at the All India Institute of Medical Sciences, New Delhi, a tertiary care academic center. The study was conducted after obtaining clearance from Institute Ethics Committee of All India Institute of Medical Sciences, New Delhi. The study followed the CONSORT guidelines for randomized trials. The trial was registered retrospectively at clinical trial registry (www.ctri.nic.in; CTRI/2018/05/013573).

Patients

All consecutive patients with WON following AP were evaluated for inclusion in the study.

Inclusion criteria

- Patient with WON >4 weeks duration with size >6 cm in diameter and having good interface with the stomach or duodenum. The waiting period of 4 weeks duration was taken so that the wall of WON is matured enough.

AND one or more of the following conditions:

- Patients with suspected infected pancreatic necrosis as suggested by fever with elevated leukocyte count
- Patients who were symptomatic with either abdominal pain or symptoms suggestive of gastric outlet obstruction
- Patents with biliary obstruction due to compression by the collection

Patients meeting both the inclusion criteria were included in the study. The patients were admitted from the out-patient department or inpatient ward (37 from the outpatient and 3 from inpatient).

Exclusion criteria

1. Patients with chronic pancreatitis
2. Distance between the WON and gastric wall >1 cm.
3. Arterial pseudoaneurysm, portal hypertension and/or uncontrolled bleeding diathesis.
4. Significant co-morbidities such as renal failure and congestive heart failure.
5. Obstructive jaundice with serum bilirubin >5 mg/dL.
6. Prior intervention such as percutaneous drainage
7. Extensive necrotic debris present in the WON with minimal liquified content
8. Patients with American society of Anesthesiologists (ASA) class 3 or more
9. Patients refusing consent

An informed written consent was taken from all the patients before inclusion in the study.

Definitions

Diagnosis of AP

The diagnosis of AP was made as per revised Atlanta classification [3] if any two of the following 3 criteria were present: i) abdominal pain suggestive of AP ii) serum lipase and/or amylase activity >3 times the upper limit of normal iii) characteristic findings of AP on imaging i.e. either a contrast-enhanced computed tomography (CECT) or magnetic resonance imaging (MRI) or transabdominal ultrasonography.

Characterization of acute pancreatitis

AP was characterized either as interstitial edematous pancreatitis if there was no necrosis or as necrotizing pancreatitis when there was evidence of pancreatic and/or peripancreatic necrosis on a CECT scan.

Pancreatic necrosis: Pancreatic necrosis was diagnosed as non-enhancing areas of the pancreas on a CECT scan. The amount of pancreatic necrosis was graded as <30%, 30–50% and >50%. A CT severity score was calculated according to Balthazar et al. [21] If a CECT scan was not done in a patient, presence of WON on abdominal ultrasound (showing necrotic debris within a fluid collection) was taken as evidence of necrotizing pancreatitis.

Infected pancreatic necrosis (IPN) was suspected when a patient with necrotizing pancreatitis developed persistent fever of >38 °C without any other focus of sepsis along with leukocytosis and deterioration in clinical condition. The diagnosis of IPN was confirmed when pancreatic necrotic tissue/fluid showed presence of bacteria on Gram's stain or when it grew an organism on culture or if there was presence of extra-intestinal gas in the pancreatic bed on a CT scan.

Pancreatic fluid collections were defined and categorized as per revised Atlanta classification [3]. WON was defined as a mature encapsulated collection of pancreatic and/or peripancreatic necrosis that has developed a well defined inflammatory wall. The CECT criteria of WON were (a) heterogeneous liquid and nonliquid density with varying degrees of loculations (b) a well defined wall, that is, completely encapsulated.

Pre-intervention evaluation

The demographic profile and clinical characteristics of patients i.e. age, sex, etiology of the AP, and duration of illness were recorded. Preoperative investigations included complete blood count,

liver and renal function tests, serum electrolytes, serum amylase, prothrombin time, chest X-ray and electrocardiogram. Abdominal ultrasound (USG), contrast enhanced computed tomography (CECT) and/or magnetic resonance imaging (MRI) scan were done for proper characterization of the PFC including its location, size, wall thickness, presence of debris, closeness to gastric/duodenal wall, and presence of pseudoaneurysm and venous thrombosis. The quantity of necrotic debris within the PFC was assessed by USG and/or MRI. Peripancreatic necrosis was also looked for and diagnosed on the CECT scan whenever we had the CECT scan during the initial presentation. Patients with both pancreatic and peripancreatic necrosis were included. An esophagogastroduodenoscopy was done for assessing bulge in the stomach and varices, if any. The decision for intervention was taken by a team of gastroenterologists and surgeons.

Randomization

Patients were randomized using computer-generated random numbers into one of the two groups for transmural internal drainage of the WON and sequentially numbered opaque sealed envelope technique was used to ensure concealed allocation. Random numbers were generated by a person not involved in the study. Patients were evaluated and enrolled by a gastroenterologist and patients were randomized by another person. Blinding was not done in view of the nature of the intervention.

Group I (Laparoscopic Drainage)- Laparoscopic cystogastrostomy.

Group II (Endoscopic Drainage)- Endoscopic Ultrasonography (EUS) guided endoscopic cystogastrostomy.

Interventions were performed within 2–5 days of randomization.

Intervention technique

Transperitoneal laparoscopic cystogastrostomy

Laparoscopic cystogastrostomy was performed under general anaesthesia as described previously [16]. (Video 1) Briefly, after creation of pneumoperitoneum, an anterior gastrostomy was made over the most prominent part of the collection. A *trans*-gastric trocar guided cystogastrostomy was made with the help of ultrasonic harmonic shears/monopolar hook using a stapler (Echelon™ 60 ENDOPATH, Ethicon Endo-surgery, Cincinnati, USA). Loose necrotic debris was removed from the cyst cavity and anterior gastrostomy was closed. In patients with gallstones pancreatitis, laparoscopic cholecystectomy was performed in the same session.

Intra-operative details including operation time, necrosectomy, adverse events, and conversion to open surgery were recorded in a pre-structured pro forma.

Endoscopic cystogastrostomy

Endoscopic cystogastrostomy was performed under general anaesthesia as described previously [16]. A transmural tract was created between the stomach and WON under EUS guidance using a 19 G needle (Boston Scientific, India). The tract was dilated by a 6 Fr cystotome (Bona, South Korea). Subsequently, a stent was placed across the tract between the stomach and WON lumen to facilitate continuous drainage. The choice of the stent was determined by the amount of necrotic debris present inside the collection. If the necrotic debris was assessed to be >1/3rd of the collection, a self-expandable lumen apposing biflanged metal stent [16 mm diameter, 3 cm length, 1 cm saddle length (Ottomed, J Mitra & Co., New Delhi, India)] was placed (video 2). If the amount of necrotic debris was <1/3rd of the collection, 2 double pigtail plastic stents (7 and 10 Fr) were placed after the cystogastrostomy tract was dilated to 12–15 mm with a wire-guided balloon (CRE balloon, Boston Scientific, India). The distinction of <1/3rd and >1/3rd was based on the observation of our previous study [16] that patients with >1/3rd necrotic debris in WON had a higher need of endoscopic re-intervention for post procedure secondary infection. The metal stent was removed after 2–3 weeks and replaced by a 10 F double pigtail plastic stent. No attempt was made to remove necrotic debris at the index procedure. Plastic stents were removed at 6 months after the procedure.

Post intervention evaluation and care

Broad spectrum antibiotics such as third generation cephalosporin was given post-procedure for 3 days. Patients were discharged if they didn't develop fever and advised oral antibiotics for 5 days. Data regarding post-operative recovery and adverse events such as bleeding, wound infection, hematemesis, fever, intra-abdominal collection and any other drainage performed were collected. Imaging in the form of USG and/or CT scan were done as indicated clinically.

Re-intervention

In case of development of fever and leukocytosis suggestive of secondary infection following cystogastrostomy in either group, a repeat endoscopic procedure was done. A forward viewing endoscope (GIF 180, Olympus, India) was used to enter the WON cavity with or without repeat balloon dilation of the tract. The fluid was aspirated and lavage was done with normal saline. Loose necrotic tissue was removed with a snare or a basket. The procedure was repeated till the signs of sepsis resolved and the cavity was cleared off the necrotic debris.

If required, additional percutaneous drainage of other undrained collections was undertaken in both the groups.

Follow up

All patients were followed for at least 6 months. The follow-up was at 7 days, 4 weeks, 3 months and 6 months after the index procedure. Patients were evaluated for resolution of symptoms and a complete clinical examination. An abdominal ultrasound was done at each follow-up visit to look for residual PFC or recurrence and if indicated a CECT scan was also done.

Resolution

Resolution was defined if there was no significant collection (size of 2 cm or less) on imaging and relief of symptoms after treatment at 4 weeks.

Recurrence

Recurrence was defined as reappearance of collection on imaging with or without reappearance of symptoms after documenting resolution.

Primary outcome measure

Primary success was defined as resolution of the WON at 4 weeks by the intended modality after the index intervention and no need for re-intervention (either endoscopic, radiological or percutaneous) for secondary infection.

Secondary outcome measures

1. Adverse Events: Major adverse events included the following:
   A. Secondary infection: Development of fever after the index intervention which was not present prior to the intervention
   B. Bleeding: Peri-procedure bleeding with a (i) fall in Hb $\geq$ 2 gm/dl or (ii) requiring packed red blood cell

transfusion or (iii) radiological, endoscopic or surgical intervention for hemostasis
C. Perforation of hollow viscus resulting in peritonitis requiring radiological, endoscopic or surgical intervention

Adverse events were classified according to the Clavien-Dindo classification [22].

2. Overall success: Complete resolution of collection at 6 months by the intended modality after index intervention
3. Total number of procedures performed
4. Total duration of hospitalization in days: It was calculated from the day of intervention till the day of discharge.
5. Procedural time of either intervention in minutes
6. Recurrence rate during a follow-up of 6 months
7. Conversion to the other mode of drainage i.e. conversion to surgical drainage in endoscopic group and vice versa.

Statistical analysis

Sample size: Our previous study [16] showed that 6% patients in the laparoscopic group and 50% patients in endoscopic group required re-intervention due to secondary infection after cystogastrostomy and before successful resolution of the collection. Taking the secondary infection rate as 6% in laparoscopic group and 50% in endoscopic group, 5% α-error, 90% power a sample size of 34 was calculated for a superiority trial for laparoscopic cystogastrostomy. Considering a 10% drop out rate the sample size came out to be 38 but we included a total of 40 patients with 20 patients in each group.

Descriptive data are presented as mean (SD) or median (interquartile range) and categorical data as number and percentages as applicable. Unpaired Student's *t*-test and chi square or Fisher's exact test were applied for comparing inter-group quantitative and categorical data, respectively. For not normally distributed data, we applied Wilcoxson rank sum test. 95% confidence interval (CI) of the difference in proportion was calculated. Intention-to-treat analysis was done. A two-sided p-value of <0.05 was taken as significant.

Results

A total of 145 patients with acute pancreatitis and WON were assessed for eligibility from May 2016 to June 2018. Of these, 105 patients were excluded: 42 patiets had spontaneous resolution of the WON, 52 patients were asymptomatic, 9 patients had prior intervention such as percutaneous catheter drainage and 2 patients had extensive necrotic debris on imaging (Fig. 1). Forty patients were thus randomized; 20 to the laparoscopic group and 20 to the endoscopic group. Thirty-two of these patients were referred to our center from other hospitals, our being a tertiary care academic center.

Demographic and clinical profile of patients

The median age of the patients was 32 (16–60) years in the laparoscopic group and 36 (21–51) years in the endoscopic group. Both the groups were similar with respect to age of the patients, sex, etiology of acute pancreatitis and baseline laboratory parameters (Table 1). Four patients each in endoscopic and laparoscopic arms had organ failure initially which resolved with conservative therapy. Sixteen patients in each group had moderately severe acute pancreatitis. Suspected infected necrosis was the indication in two patients in the laparoscopic group and one patient in the endoscopic group. The characteristics of WON are provided in Table 2. The amount of necrotic debris in WON was <1/3rd of the volume of collection in 15/20 (75%) patients in the laparoscopic group and 12/20 (60%) patients in the endoscopic group. Eight out of 20 patients in the endoscopic group had >1/3rd necrotic debris and a LAMS was placed in them.

Assessment of outcomes

Primary outcome, which was resolution of WON at 4 weeks and no need for re-intervention for secondary infection was documented in 16 (80%) patients in the LD group and 15 (75%) patients in the ED group ($p = 0.89$). Three patients in the LD group and three patients in ED group required additional endoscopic interventions with lavage and/or necrosectomy due to fever and evidence of sepsis after index intervention which was attributed to secondary infection of WON. Two patients in the laparoscopic group underwent open drainage: one due to large WON occupying whole of the abdomen and no space for creation of capnoperitoneum and one patient without visible bulge in the stomach for puncture. Two patients in the endoscopic group underwent open surgical drainage: one due to presence of multiseptated WON identified on EUS and other due to bleeding during deployment of a metal stent.

Overall success, defined as successful resolution of the peripancreatic fluid collections by the intended procedure at the end of 6 months, was achieved in 18 (90%) patients in the laparoscopic group and 17 (85%) patients in the endoscopic group ($p = 0.90$) [Table 3]. The duration of hospitalization was shorter in the endoscopic group compared with the laparoscopic group [median (IQR): 4 (4–8) days vs. 6 (5–9) days, $p = 0.037$]. The procedure time was shorter in the endoscopic compared to the laparoscopic drainage [mean ± SD: 31 ± 19 vs. 101 ± 23 min; $p < 0.001$].

Secondary infection developed in five patients in LD group: two responded to antibiotics and two patients needed endoscopic intervention with endoscopic lavage and one patient required endoscopic necrosectomy. Secondary infection developed in four patients in ED group: One responded to antibiotics and two required additional endoscopic intervention with lavage and one patient required endoscopic necrosectomy. Two patients in LD group and 3 patients in ED group required additional percutaneous catheter drainage of separate paracolic collections. One patient each in both groups had bleeding. The patient in LD group had post-operative bleeding from gastric varices due to splenic vein thrombosis, which was managed with endoscopic therapy. The patient in the ED group had bleeding during deployment of LAMS into the WON as described above. One patient in the LD group had iatrogenic colonic injury necessitating conversion to open surgery for repair and diversion ileostomy. One patient died in the ED group who had developed sepsis after discharge due to infected paracolic collection. The patient underwent percutaneous catheter drainage and later surgical necrosectomy for continuing sepsis but could not be salvaged.

We did a subgroup analysis in the ED group between LAMS and plastic stent for primary and secondary outcomes. The differences between the groups were not statistically significant.

Discussion

In the present study, we have demonstrated that laparoscopic transmural drainage is not superior to endoscopic transmural drainage in terms of resolution of WON and adverse events. However, the endoscopic drainage is associated with a shorter hospital stay. Our *a priori* hypothesis based on our previous study was that laparoscopic drainage was superior to endoscopic drainage in terms of lesser re-intervention rates by providing a wider stoma for better drainage.

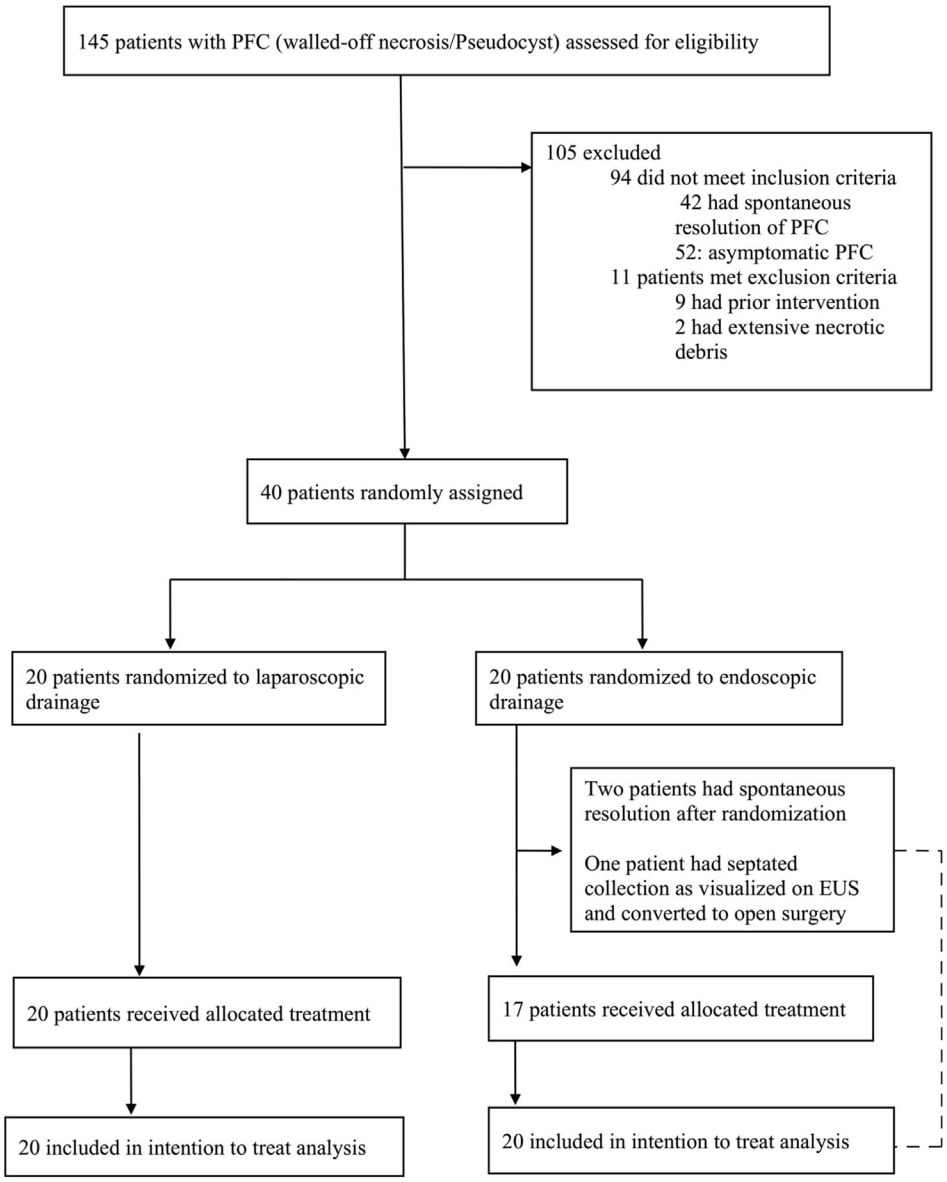

Fig. 1. CONSORT diagram.

The present study has confirmed previous observations in our earlier RCT in terms of similar rates of successful drainage of WON with both the endoscopic and laparoscopic techniques [16]. In our previous RCT which included patients with pseudocyst and WON, the re-intervention rates were higher in the ED compared to the LD group (63.3% vs. 30%, $p < 0.001$) due to post-intervention infection and sepsis. The reasons for the higher rate of post-drainage infection were proposed to be smaller size stoma and use of plastic stents in the endoscopy drainage which were probably inadequate for patients with WON. To overcome this limitation, we chose the stent type depending on the amount of necrotic debris in WON i.e. we placed two plastic stents (7–10 French) for necrotic debris <1/3rd of the volume of WON and LAMS if it was >1/3rd. The volume of WON was found to be an important factor for secondary infection and we addressed this issue by choosing the type of stent based on the necrotic debris as prior studies have shown contradictory results on the superiority of metal over plastic stents in the management of WON [18–20]. We found that the rate of post-drainage infection was similar in the endoscopic and laparoscopic groups. There were no adverse events related to LAMS except bleeding in one patient. We removed LAMS in all the patients at 2–3 weeks and replaced it with a plastic stent if feasible. Seven out of the 8 patients in whom LAMS was placed improved with drainage alone and only one patient required endoscopic necrosectomy suggesting that better drainage through a wider stent might alleviate the need for necrosectomy in WON with significant necrotic debris as was suggested in other studies as well [15,17]. That was perhaps the reason why the need for necrosectomy was lower in our patients compared to some other studies. The need for necrosectomy is however, higher in patients with infected necrosis [15,17].

Endoscopic transmural drainage was better than laparoscopic drainage on account of 2 secondary outcomes: (i) shorter procedure time and thus the general anaesthesia time and (ii) duration of

Table 1
Baseline characteristics of patients in both the groups.

Parameter	Laparoscopic group N = 20	Endoscopic group N = 20	P value
Age, in years Median (Range)	32 (16–60)	36 (21–51)	0.38
Male, Female	18, 2	17, 3	0.58
Etiology of AP, n (%)			
Gall stone	2 (10)	3 (15)	0.86
Alcohol	8 (40)	5 (25)	
Idiopathic	9 (45)	9 (45)	
Others	1 (5)	3 (15)	
Severity of AP			
Mild	0	0	0.96
Moderately severe	16 (80)	16 (80)	
Severe	4 (20)[a]	4 (20)[b]	
Hemoglobin, (g/dL) (Mean ± SD)	11.9 ± 1.7	11.8 ± 1.9	
Total leukocyte count (thousands/cmm) (Mean ± SD)	7.5 ± 1.4	7.9 ± 2.6	0.54
Total bilirubin (mg/dL) (Mean ± SD)	0.6 ± 0.5	0.6 ± 0.3	0.83
ALT (IU/ml) (Mean ± SD)	27.0 ± 19.0	29.5 ± 16.1	0.85
Serum albumin (g/dL) (Mean ± SD)	4.0 ± 0.6	3.9 ± 0.7	0.43
Indication of drainage, n (%)			
Pain	19 (95)	20 (100)	0.92
Fever	2 (10)	1 (5)	
Gastric outlet obstruction	1 (5)	0	
Biliary obstruction	0	0	
Early satiety and weight loss	11 (55)	15 (75)	

SD- Standard Deviation, ALT- Alanine aminotransferase, AP- acute pancreatitis.
[a] Three patients had single organ failure (respiratory) and one patient had multi-organ failure (respiratory and renal). The organ failures improved with supportive management.
[b] Two patients had single organ failure (respiratory) and two patients had multi-organ failure (respiratory and renal). The organ failures improved with supportive management.

Table 2
Baseline characteristics of WON in both the groups.

Parameter	Laparoscopic group N = 20	Endoscopic group N = 20	P value
Amount of necrotic debris in WON, n (%)			
<1/3rd of the volume	15 (75)	12 (60)	0.31
>1/3rd of the volume	5 (25)	8 (40)[a]	
Size of collection (ml) Mean ± SD	1229.4 ± 751.2	1586.5 ± 505.2	0.12
Wall Thickness (mm) Mean ± SD	0.57 ± 0.17	0.56 ± 0.15	0.9
Location of collection, n (%)			
Whole pancreas	9 (45)	11 (55)	0.44
Head & Body	2 (10)	1 (5)	
Body & Tail	9 (45)	8 (40)	
Duration from onset of AP (months) Median (IQR)	3.5 (2–8)	9.0 (2–11)	0.20
ASA class Median (IQR)	2 (1–2)	2 (1–2)	1.0

SD- Standard Deviation, IQR- Interquartile range, ASA- American Society of Anesthesiology.
[a] LAMS placed.

hospital stay was shorter which was in agreement with one prior RCT [8]. We have summarized previous studies which have compared endoscopy and surgery for management of pancreatic fluid collections in AP (Table 4).

There were some limitations of the present study. First, the follow up duration was six months to assess recurrence of collection. A longer follow up could show difference in the recurrence rates between the 2 groups. Second, the sample size was modest but it was adequately powered to test the null hypothesis. Third, one could question the patient tailored endoscopic drainage method with plastic or metal stent rather than a fixed protocol of drainage. However, we feel that it is a strength of the study rather than a limitation as endoscopic drainage should be individualized as per the characteristics of the PFC [23]. A selective use of LAMS could be more cost-effective. Another limitation was that we did not do a formal cost-effective analysis. The reason is that treatment is provided free in our federal government-funded hospital and it was difficult to calculate direct and indirect costs. Another issue is that our patients were much younger as compared to other studies [15,17] and this has been a consistent observation in our patient population as reported in a large series of 1333 patients but the reasons are not clear [22].

Besides per-oral endoscopic and laparoscopic drainage, percutaneous drainage and minimally invasive approaches such VARD, MARPN and percutaneous endoscopic necrosectomy have been used successfully but these are primarily recommended for acute infected necrotic collections particularly those that are predominantly laterally placed [23]. VARD and MARPN are generally done

Table 3
Outcomes in both the groups.

	Laparoscopic group N = 20	Endoscopic group N = 20	P value
Primary outcome			
Resolution of WON without need of re-intervention, n (%)	16 (80)	15 (75)	0.89
Secondary outcomes			
Overall Success, n (%)	18 (90)	17 (85)	0.90
Total duration of hospitalization (days) Median (IQR)	6 (5–9)	4 (4–8)	0.037[b]
Procedure duration, (minutes) Mean ± SD	101 ± 23.0	31 ± 19.0	<0.001[b]
Adverse Events			
Clavein Dindo class I			
Surgical site infection	0	NA	
Enterocutaneous fistula	0	NA	
Stent migration	NA	0	
Clavien Dindo class II			0.14
Bleeding	1[a]	1[b]	
Secondary Infection	5	4	
Clavien Dindo class III			
Perforation of hollow viscus	1[c]	0	
Clavien Dindo Class IV	0	0	
Clavien Dindo Class V			
Mortality	0	1[f]	
Recurrence of collection, n	0	1	
Need for additional procedures	2 (10)	3 (15)	0.23
Percutaneous drainage of additional collections			
Endoscopic intervention	3 (15)	3 (15)	
Surgical intervention	3[d]	3[e]	

SD- Standard Deviation, IQR- Interquartile range, ERCP- Endoscopic Retrograde Cholangiopancreatography.
[a] One patient in Laparoscopy Drainage group had variceal bleeding.
[b] One patient in ED had bleeding during deployment of LAMS into WON.
[c] One patient had iatrogenic colonic injury during laparoscopic cystogastrostomy.
[d] Three patients underwent open surgery in LD: one patient had colonic injury during cystogastrostomy, one had too large collection to give space for pneumoperitoneum and one had no visible bulge in stomach.
[e] Three patients underwent open surgery in ED: one had bleed during deployment of LAMS, one had multiseptated WON and one had WON extending to paracolic gutter with extensive necrotic debris.
[f] One patient died in ED who had WON extending to paracolic gutter with infected pancreatic necrosis.

Table 4
Comparison of endoscopy versus surgery for peripancreatic fluid collections in acute pancreatitis.

Study, Year	Number of patients	Study type and patient population	Efficacy	Adverse events
Bakker et al. [24], 2012	22	RCT; endoscopic transgastric necrosectomy (n = 10) vs surgical necrosectomy, (n = 12) for necrotizing pancreatitis	Composite clinical outcome (major complication or death) was 20% in endoscopic necrosectomy and 80% in surgical necrosectomy (p = 0.03). Post procedure IL-6 level was lower in endoscopic necrosetcomy group.	No new onset multiple organ failure and lesser pancreatic fistula in endoscopic group.
Varadarajulu et al. [8], 2013	40	RCT; Open surgical versus endoscopic cystogastrostomy for sterile pancreatic pseudocyst	Success rate was 95% and 100% in endoscopic and surgical arm. Hospital stay and cost was lower in endoscopic arm.	Two in surgical arm: wound infection and gastrointestinal bleed None in endoscopic arm
Van Brunschot et al. [17], 2017	98	RCT; endoscopic step-up approach (n = 51) versus surgical step-up approach (n = 47) for infected necrotizing pancreatitis	Procedure could be performed in 49/51 (96%) patients in endoscopic arm and 46/47 (98%) in the surgical arm	The primary end point which was a composite of major complication or death at 6-month follow-up was in 22 (43%) of 51 patients in endoscopic group and 21 (45%) of 47 in surgical group. Pancreatic fistula was lower in endoscopic group.
Bang JY et al. [15], 2019	66	RCT; Endoscopic step-up approach (n = 32) versus minimally invasive surgery, laparoscopy or VARD (n = 34) for necrotizing pancreatitis	Procedure could be performed in 100% of patients in both the groups	The primary end point which was a composite of major complication (including fistula) or death at 6-month follow-up was 11.8% in endoscopic group and 40.6% in surgical group (p = 0.007). Pancreatic fistula was lower in endoscopic group.
Garg et al. [16], 2019	60	RCT; Endoscopic (n = 30) versus laparoscopic (n = 30) drainage of sterile pseudocyst and walled-off necrosis	Success rate was 93.3% in laparoscopic and 90% in endoscopic group.	Higher post procedure infection in endoscopic group (19/30 vs 9/30) requiring re-intervention

as a step-up therapy for infected necrosis after percutaneous external drainage.

In conclusion, the efficacy of laparoscopic and endoscopic transmural internal drainage of symptomatic WON in AP was similar with placement of multiple plastic stents or LAMS depending on the amount of necrotic debris, except for a shorter hospital stay with the endoscopic approach.

Author contributions

Suryalok Angadi: Study concept and design, acquisition of data, analysis and interpretation of data, supervision of the study, drafting of the manuscript, critical revision and final approval of the manuscript; Soumya Jagannath Mahapatra: Study concept and design, acquisition of data, analysis and interpretation of data, supervision of the study, drafting of the manuscript, critical revision and final approval of the manuscript; Virinder Kumar Bansal: Study concept and design, acquisition of data, analysis and interpretation of data, supervision of the study, drafting of the manuscript, critical revision and final approval of the manuscript; Pramod Kumar Garg: Study concept and design, acquisition of data, analysis and interpretation of data, supervision of the study, drafting of the manuscript, critical revision and final approval of the manuscript; Rahul Sethia: Acquisition of data, analysis and interpretation of data, critical revision and final approval of the manuscript; Anshuman Elhence: Acquisition of data, analysis and interpretation of data, critical revision and final approval of the manuscript; SJ, SB, SG: Acquisition of data, analysis and interpretation of data, critical revision and final approval of the manuscript; Asuri Krishna: Study design, interpretation of data, critical revision and final approval of the manuscript; Om Prakash Prajapati: Study design, interpretation of data, critical revision and final approval of the manuscript; Deepak Gunjan: Study design, interpretation of data, critical revision and final approval of the manuscript; Subodh Kumar: Study design, interpretation of data, critical revision and final approval of the manuscript.

Grant support

It was an investigator-initiated study.

Declaration of competing interest

None of the authors have any conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pan.2021.06.006.

References

[1] Schepers NJ, Bakker OJ, Besselink MG, et al. Impact of characteristics of organ failure and infected necrosis on mortality in necrotising pancreatitis. Gut 2019;68:1044–51.
[2] Padhan RK, Jain S, Agarwal S, et al. Primary and secondary organ failures cause mortality differentially in acute pancreatitis and should be distinguished. Pancreas 2018;47:302–7.
[3] Banks PA, Bollen TL, Dervenis C, et al. Classification of acute pancreatitis–2012: revision of the Atlanta classification and definitions by international consensus. Gut 2013;62:102–11.
[4] Yang D, Amin S, Gonzalez S, et al. Transpapillary drainage has no added benefit on treatment outcomes in patients undergoing EUS-guided transmural drainage of pancreatic pseudocysts: a large multicenter study. Gastrointest Endosc 2016;83:720–9.
[5] Jagannath S, Bopanna S, Dhingra R, et al. Sa1442 endoscopic cystogastrostomy without transpapillary pancreatic ductal stenting provides long-term success for pseudocysts/walled-off necrosis following acute pancreatitis: a single centre experience. Gastrointest Endosc 2017;85:AB243.
[6] Akshintala VS, Saxena P, Zaheer A, et al. A comparative evaluation of outcomes of endoscopic versus percutaneous drainage for symptomatic pancreatic pseudocysts. Gastrointest Endosc 2014;79:921–8. quiz 983.e2, 983.e5.
[7] Gomatos IP, Halloran CM, Ghaneh P, et al. Outcomes from minimal access retroperitoneal and open pancreatic necrosectomy in 394 patients with necrotizing pancreatitis. Ann Surg 2016;263:992–1001.
[8] Varadarajulu S, Bang JY, Sutton BS, et al. Equal efficacy of endoscopic and surgical cystogastrostomy for pancreatic pseudocyst drainage in a randomized trial. Gastroenterology 2013;145:583–590.e1.
[9] Binmoeller KF, Seifert H, Walter A, et al. Transpapillary and transmural drainage of pancreatic pseudocysts. Gastrointest Endosc 1995;42:219–24.
[10] Ahn JY, Seo DW, Eum J, et al. Single-step EUS-guided transmural drainage of pancreatic pseudocysts: analysis of technical feasibility, efficacy, and safety. Gut Liver 2010;4:524–9.
[11] Kahaleh M, Shami VM, Conaway MR, et al. Endoscopic ultrasound drainage of pancreatic pseudocyst: a prospective comparison with conventional endoscopic drainage. Endoscopy 2006;38:355–9.
[12] Melman L, Azar R, Beddow K, et al. Primary and overall success rates for clinical outcomes after laparoscopic, endoscopic, and open pancreatic cystgastrostomy for pancreatic pseudocysts. Surg Endosc 2009;23:267–71.
[13] Johnson MD, Walsh RM, Henderson JM, et al. Surgical versus nonsurgical management of pancreatic pseudocysts. J Clin Gastroenterol 2009;43:586–90.
[14] Khaled YS, Malde DJ, Packer J, et al. Laparoscopic versus open cystgastrostomy for pancreatic pseudocysts: a case-matched comparative study. J Hepato-Biliary-Pancreatic Sci 2014;21:818–23.
[15] Bang JY, Arnoletti JP, Holt BA, et al. An endoscopic transluminal approach, compared with minimally invasive surgery, reduces complications and costs for patients with necrotizing pancreatitis. Gastroenterology 2019;156:1027–1040.e3.
[16] Garg PK, Meena D, Babu D, et al. Endoscopic versus laparoscopic drainage of pseudocyst and walled-off necrosis following acute pancreatitis: a randomized trial. Surg Endosc 2020;34:1157–66.
[17] Brunschot S van, Grinsven J van, Santvoort HC van, et al. Endoscopic or surgical step-up approach for infected necrotising pancreatitis: a multicentre randomised trial. Lancet 2018;391:51–8.
[18] Bang JY, Navaneethan U, Hasan MK, et al. Non-superiority of lumen-apposing metal stents over plastic stents for drainage of walled-off necrosis in a randomised trial. Gut 2019;68:1200–9.
[19] Bazerbachi F, Sawas T, Vargas EJ, et al. Metal stents versus plastic stents for the management of pancreatic walled-off necrosis: a systematic review and meta-analysis. Gastrointest Endosc 2018;87:30–42. e15.
[20] Saunders R, Ramesh J, Cicconi S, et al. A systematic review and meta-analysis of metal versus plastic stents for drainage of pancreatic fluid collections: metal stents are advantageous. Surg Endosc 2019;33:1412–25.
[21] Balthazar EJ, Ranson JH, Naidich DP, et al. Acute pancreatitis: prognostic value of CT. Radiology 1985;156:767–72.
[22] Agarwal S, George J, Padhan RK, et al. Reduction in mortality in severe acute pancreatitis: a time trend analysis over 16 years. Pancreatology 2016;16:194–9.
[23] Jain S, Padhan R, Bopanna S, et al. Percutaneous endoscopic step-up therapy is an effective minimally invasive approach for infected necrotizing pancreatitis. Dig Dis Sci 2020;65:615–22.
[24] Bakker OJ, van Santvoort HC, van Brunschot S, Geskus RB, Besselink MG, Bollen TL, et al. Endoscopic transgastric vs surgical necrosectomy for infected necrotizing pancreatitis: a randomized trial. J Am Med Assoc 2012;307:1053–61.