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Original Article

Success and Safety of Plastic Stent for Endoscopic Ultrasound Guided Pancreatic Pseudocyst Drainage - A Tertiary Single Centre Experience

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ABSTRACT

Objective: To determine the success and safety of plastic stent for endoscopic ultrasound (EUS) guided pancreatic pseudocyst (PP) drainage.

Study design: Quasi-experimental study

Place and duration: Pak-Emirates Military Hospital Rawalpindi, Pakistan from Jan 2018 to Jan 2021

Methodology: This study was conducted on seventy three participants with 20-80 years age, both genders, and symptomatic PP. Cases having small asymptomatic PP (<5cm), neoplastic cysts, multiloculated pseudocysts, coagulation profile derangement were excluded. EUS -guided drainage of PP was done. Success and safety of the procedure and post procedure compression related problems (PPCRP) were recorded at 24 hours, and at 4, 8, 12 and 24 weeks. Chi-square test was used to determine the association of PPCRP with biochemical and cytological parameters.

Results: The mean age was 45.38±12.79 years and 44 (60.27%) were males. In all participants, there was a 50.00% regression in cyst size at 4, 8, 12, and 24 weeks. Significant factors affecting PPCRP at 8 weeks were complicated pancreatic pseudocysts (PP), cystic haemorrhage, portal hypertension (on CT), and cystic location (on EUS). At 8 weeks, no resolution of compression-related problems was found in cases of complicated cysts (0%), and the results were statistically significant ($p<0.001$). The highest resolution in compression-related problems at 8 weeks was found when the cyst was located in the head (n=19, 61.29%) followed by the pancreatic body (n=4, 12.90%), and the difference was statistically significant ($p<0.001$).

Conclusion: Endoscopic ultrasound guided drainage of PP is an effective treatment modality having 50% regression in size after one month in all patients. Clinician should adopt EUS-guided rather than surgical drainage of PP to minimize complications and cost due its effectiveness.

Keywords: Endoscopic drainage, Pancreatic Pseudocyst, Pancreatic cyst

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INTRODUCTION

The pancreatic pseudocyst (PP) is a cavity filled with inflammatory fluid surrounded by a capsule having minimal or no necrosis.[1] The origin of PP is due to complication of chronic pancreatitis, acute pancreatitis or complication of pancreatic surgery.[2] In recent era, the incidence of detection of PP has increased due to availability of advanced diagnostic tools which aid in early diagnosis.[3] The common cystic lesions of pancreas are PP and pancreatic cystic neoplasm (PCN) in which PP has prevalence of 70% and PCN up to 15%.[4]

In most of the times the PPs are symptomless and undergo resolution without treatment. When these are symptomatic, have size more than 6cm, grow rapidly in size or have infection or bleeding, the drainage is warranted.[5,6] Treatment modality of PP with symptoms or complications is Ultrasound guided endoscopic (UGE), percutaneous or surgical drainage. UGE drainage of PP is a relatively new procedure having minimal risk of bleeding and perforation due to visualization of the cyst along with its feeding vasculature.[7,8]

In addition, the evidence shows that UGE-guided drainage is far better than blind approach, specifically in patients where no external compression was found during endoscopy.[9] Usual practice for UGE-guided procedure is the placement of multiple 7 or 10 French double pigtail stents after punctured tract is dilated.[10]

A meta-analysis showed that the success and complication rate is equal whether the PP is drained with UGE or surgically. Duration of hospitalization and cost of treatment is much lower in endoscopic than surgical drainage.[4]

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This procedure is done in many tertiary care hospitals in Pakistan, but we have little published data regarding this procedure. This study aimed to establish the success and safety of plastic stent for endoscopic ultrasound guided pancreatic pseudocyst drainage based on locally performed procedures.

METHODOLOGY

This Quasi-experimental study was conducted on 73 participants, from January 2018 to January 2021, at Department of Gastroenterology, Pak-Emirates Military Hospital, Rawalpindi, Pakistan. Patients were recruited through non-probability consecutive sampling technique. The sample size was 73, calculated with WHO software at confidence level of 95%, anticipated prevalence of success for EUS-guided (Endoscopic ultrasound-guided) drainage of pancreatic pseudocysts to be 75% and at 10% margin of error.[11]

After a detailed explanation about the study, a verbal informed consent was obtained from all participants. All participants were assured that their records will be confidential and will be solely used for research purpose. Ethical approval was obtained from the PEMH. **Inclusion Criteria:** Patients aged 20 to 80 years of both genders presenting with symptomatic pancreatic pseudocysts were included in the study.

Exclusion Criteria: Patients having small asymptomatic pseudocysts (less than five centimetres), neoplastic cysts, multi-loculated pseudocysts and coagulation profile derangement were excluded.

The clinical procedure for EUS-guided drainage of PP was done as follows: the advancement of EUS was carried out to the duodenum or stomach. The delineation of pancreas and PP was done by endoscopic ultrasound and favourable location to puncture the PP was chosen. For avoiding any sort of interposing vasculature, doppler imaging was used for assistance. The puncture of pseudocyst was performed using Giovannini needle or aspiration needle (19gauge). Guide wire was advanced over the needle and coiled within the pseudocyst and the needle was retracted. The tract was enlarged using a dilation catheter of 10mm. Either one or two stents were inserted subsequently.

The success of the procedure was defined as complete absence of compression related problems with at least 50% reduction or full resolution of PP. The procedure was labelled as safe if no procedure related bleed, gut perforation or infection was found.

Data analysis was done using R programming version 4.1.2 in RStudio. Continuous data was computed as mean and SD while categorical as percentages and frequencies. Frequency of success and safety was calculated. Confounders for success and safety were controlled using Chi-square test. A p value of $p \leq 0.05$ was considered significant.

RESULTS

Of total 73 patients, females were 29(39.73%) and males were 44(60.27%). The mean age was 45.38 ±12.79 years. The mean size of pancreas was 111.56±22.28mm on pre-treatment CT scan and was 111 ±20.98 mm on endoscopic ultrasound. The ERCP procedures were 'CBD (common bile duct) and PD (pancreatic duct) stents placement' in 1(1.37%), 'CBD stent placement' in 3(4.11%) and 'PD stent placement' in 10(13.70%). 'Gastro-esophageal varices/ esophageal varices banding' was done in 2(2.74%), 'Isolated type 1 gastric varices' were seen in 7(9.59%) while 'Oesophago-gastro duodenoscopy was not done' in 64(87.67%). (Table-I)

Table-I: Descriptive Statistics of Gender, Age, Pre-Treatment Cyst Size (on CT Scan and EUS), ERCP Findings and Oesophago-Gastro-Duodenoscopy Procedures (n=73)

Variable(s)	Characteristic(s)	value
Gender	Female	29(39.73%)
	Male	44(60.27%)
Age (years)	Mean±SD	45.38±12.79
Pre-treatment size (in mm) of PP on CT scan	Mean±SD	111.56±22.28
Pre-treatment size (in mm) of PP on EUS	Mean±SD	111.00±20.98
Endoscopic Retrograde Cholangiopancreatography (ERCP)	CBD and PD stents placed	1(1.37%)
	CBD stent placed	3(4.11%)
	Not done	59(80.82%)
	PD stent placed	10(13.70%)
Oesophago-gastro duodenoscopy (OGD)	Gastro-esophageal varices - esophageal varices banded	2(2.74%)
	Isolated type 1 gastric varices	7(9.59%)
	Not done	64(87.67%)

Frequency of complicated PP was 31(42.47%), infected PP were 3(4.11%), cyst hemorrhage was seen in 12(16.44%) and gastric outlet obstruction was seen in 13(17.81%). Cyst location was in the body of pancreas in 23(31.51%), in the body and tail in 7(9.59%), in pancreatic head in 19 (26.03%) and in pancreatic tail in 17(23.29). Homogenous fluid density

was observed on EUS in 70 (95.89%). Non-liquid component within the fluid was seen on EUS in 3(4.11%). Main pancreatic duct connection was seen on EUS in 11(15.07%). (Table-II)

Table-II: Frequencies of Features of PP on Pre-treatment CT scan and Endoscopic Ultrasound (n=73)

Variable(s)	Characteristic(s)	Frequency (%)
Complicated PP on pre-treatment CT scan	Absent	42(57.53)
	Present	31(42.47)
Infected PP on pre-treatment CT scan	Absent	70(95.89)
	Present	3(4.11)
Cyst migration on pre-treatment CT scan	Absent	73(100.00)
Bile duct blockage on pre-treatment CT scan	Absent	73(100.00)
Cyst hemorrhage on pre-treatment CT scan	Absent	61(83.56)
	Present	12(16.44)
Gastric outlet obstruction on pre-treatment CT scan	Absent	60(82.19)
	Present	13(17.81)
Portal hypertension on pre-treatment CT scan	Absent	43(58.90)
Cyst rupture on pre-treatment CT scan	Absent	73(100.00)
Cyst location on EUS	Pancreatic body	23(31.51)
	Pancreatic body and tail	7(9.59)
	Pancreatic head	19(26.03)
	Pancreatic head and body	7(9.59)
	Pancreatic tail	17(23.29)
Cyst vascularity on EUS	Nil	73(100.00)
Homogenous fluid density on EUS	Absent	3(4.11)
	Present	70(95.89)
Non-liquid component within fluid on EUS	Absent	70 (95.89)
	Present	3(4.11)
Main PD connection on EUS	Absent	62(84.93)
	Present	11(15.07)

EUD: Endoscopic Ultrasound, PD: pancreatic Duct

Pseudocyst fluid viscosity on EUS on fine needle aspiration was raised in 3(4.11%). All cases had raised fluid amylase on EUS on fine needle aspiration (FNA). Pseudocyst fluid culture on EUS FNA shows that E. coli was present in 1(1.37%).

In all participants 50% regression in cyst size were found at 4, 8, 12, and 24 weeks. Resolution of compression related problems at 24 weeks was found in all cases (100%). (Table-III)

Significant factors affecting RCRP at 8 weeks were complicated PP, cystic hemorrhage, portal hypertension (on pre-treatment CT) and cyst location (on EUS). No RCRP (Resolution of compression related problem) at 24 weeks was found in case of complicated cyst on pre-treatment CT (0%) and results were statistically significant (p<0.001). Compression related problems were more reduced without cystic hemorrhage 19(61.29%) than with cystic hemorrhage 12(38.71%) and this difference is statistically significant (p<0.001). Highest RCRP at 24 weeks was found when cyst was located in head 19(61.29%) followed by pancreatic body 4(12.90%) and this was statistically significant (p<0.001). (Table-IV)

Table-III: Post procedural related problems, regression by 50% at four, eight twelve and twenty four weeks

Variable	Characteristic	n= 73
Resolution of compression related problems at eight weeks	Absent	42(57.53)
	Present	31(42.47)
Post procedure observation in 24 hrs US abdomen	Unremarkable	73(100.00)
Resolution of compression related problems at 24 weeks	Present	73(100.00)
Regression of cyst size by 50% four weeks US Abdomen	Present	73(100.00)
Regression of cyst size by 50% eight weeks US Abdomen	Present	73(100.00)
Regression of cyst size by 50% twelve weeks US Abdomen	Present	73(100.00)
Regression of cyst size by 80% twenty four weeks US Abdomen	Present	73(100.00)

Association of RCRP at 8 weeks with fluid viscosity, fluid amylase, fluid culture and fluid cytology was not statistically significant (p>0.05). Decrease in size of cyst size by 80% at twenty four weeks seen on US Abdomen was found in all patients (100%). (Table V)

DISCUSSION

This study was aimed to establish the success and safety of plastic stent for endoscopic ultra sound guided pancreatic pseudocyst drainage based on local data. The findings of study showed that plastic stent for endoscopic ultrasound guided pancreatic pseudocyst drainage is effective in the resolution of compression related problems at 24 weeks in around half of all the cases. Regression of cyst size by 50% was found in all cases at 4, 8, 12 and 24 weeks.

A study was conducted by Sousa *et al.*[12] in Brazil on eleven patients having pancreatic pseudocysts and reported that clinical success was 91% for endoscopic ultrasound-guided drainage. They defined success as reduction of cyst diameter below 2mm on CT at 4th week. In our study all cases have reached reduction in size by 50% (success) reduction in size by >80% at 24 weeks. Similarly successful results for endoscopic ultrasound-guided drainage of pancreatic pseudocysts have been reported in other studies.[13,14]

Table-IV: Factors affecting resolution of compression related problems at 24 weeks

Variable	Characteristic	Absent (n = 42) Frequency (%)	Present (n = 31) Frequency (%)	*p*-value*
Complicated PP on pre-treatment CT scan	Absent	11 (26.19)	31 (100.00)	<0.001
	Present	31 (73.81)	0 (0.00)	
Infected PP on pre-treatment CT scan	Absent	39 (92.86)	31 (100.00)	0.356
	Present	3 (7.14)	0 (0.00)	
Cyst migration on pre-treatment CT scan	Absent	42 (100.00)	31 (100.00)	-
Bile duct blockage on pre-treatment CT scan	Absent	42 (100.00)	31 (100.00)	-
Cystic hemorrhage on pre-treatment CT scan	Absent	42 (100.00)	19 (61.29)	<0.001
	Present	0 (0.00)	12 (38.71)	
Gastric outlet obstruction on pre-treatment CT scan	Absent	34 (80.95)	26 (83.87)	0.99
	Present	8 (19.05)	5 (16.13)	
Portal hypertension on pre-treatment CT scan	Absent	42 (100.00)	1 (3.23)	<0.001
	Present	0 (0.00)	30 (96.77)	
Cyst rupture on pre-treatment CT scan	Absent	42 (100.00)	31 (100.00)	-
Cyst location on EUS	Pancreatic body	19 (45.24)	4 (12.90)	<0.001
	Pancreatic body and tail	6 (14.29)	1 (3.23)	
	Pancreatic head	0 (0.00)	19 (61.29)	
	Pancreatic head and body	0 (0.00)	7 (22.58)	
	Pancreatic tail	17 (40.48)	0 (0.00)	
Cyst vascularity on EUS	Nil	42 (100.00)	31 (100.00)	-
Homogenous fluid density on EUS	Absent	3 (7.14)	0 (0.00)	0.356
	Present	39 (92.86)	31 (100.00)	
Non-liquid component within fluid on EUS	Absent	39 (92.86)	31 (100.00)	0.356
	Present	3 (7.14)	0 (0.00)	
Main PD connection on EUS	Absent	37 (88.10)	25 (80.65)	0.583
	Present	5 (11.90)	6 (19.35)	

Another study by Nelson *et al*. including five patients in pancreatic pseudocysts were drained using endoscopic ultrasound-guided technique and reported that after one month two patients had complete resolution of PP and three had significant improvement. These results are supporting our findings. However they used metal stents while in our study we used plastic stents.15 Most of the previous literature on EUS guided drainage of PP reported that success varies between 80 and 100%.[16,17]

In our study size of PP was similar on pre-treatment CT scan (111.56 ±22.28mm) and on endoscopic ultrasound (111 ±20.98 mm). A study by Nelson et al reported that the mean size of PP was 90mm.15 Sousa *et al*. reported the mean size of PP to be 94 ±2.69 mm.[12]

This study found that compression related problems at 24 weeks were resolved in 42.47%. As the PP increase in size, they can lead to compression of related organs resulting in gastric outlet obstruction, stomach compression, duodenal compression, and cholestasis.[18] When the PP was drained under EUS guided procedure, about half of these problems were resolved.

We found that the association of compression related problems at 24 weeks follow up with predictors like viscosity, amylase level in cystic fluid, culture of fluid and cytology of fluid was not statistically significant. The literature shows that

biochemical parameters have less role in diagnosis of PP. Serum amylase level is usually raised in fluid of PP.[19]

The study has limitations like lack of control group and measurement of size regression up to 80%. The strength of this study is that this is the first kind of study performed on calculated sample size on effectiveness of ultrasound guided endoscopic drainage of PP.

Table-V: Association of resolution of compression related problems at 24 weeks with fluid viscosity, fluid amylase, fluid culture and fluid cytology

Variable	Characteristic	Post procedure compression related problems at 8 weeks		*p*-value *
		Absent (n = 42) n(%)	Present (n = 31) n(%)	
EUS FNA Pseudocyst fluid viscosity	Low	39(92.86)	31(100.00)	0.356
	Raised	3 (7.14)	0(0.00)	
EUS FNA Pseudocyst fluid amylase	Raised	42(100.00)	31(100.00)	-
EUS FNA Pseudocyst fluid CEA levels > 400ng/mL	Absent	42(100.00)	31(100.00)	-
EUS FNA Pseudocyst fluid culture	Grew E. coli	1 (2.38)	0(0.00)	0.999
	Negative for any growth	41(97.62)	31(100.00)	
EUS FNA Pseudocyst fluid cytology	Negative for malignant cells	42(100.00)	31(100.00)	-

**Fisher exact test FNA: Fine needle Aspiration, EUS: endoscopic ultrasound, CEA: carcinoembryonic antigen*

CONCLUSION

Endoscopic ultra sound guided drainage of PP is an effective treatment modality having 50% regression in size after one month in all patients. Clinicians should adapt this technique rather than surgical drainage of PP to minimize complications and cost. Regression of cyst size by >80% at twenty four weeks was found in all patients.

Authors Contribution

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

MBK & ZAK: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

UAK & RSAK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

KS & QUAC: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

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

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