

# CLINICAL AND ENDOSCOPIC PREDICTORS FOR RECURRENT CHOLEDOCHOLITHIASIS AFTER NORMAL CHOLANGIOGRAPHY OR ENDOSCOPIC BILE DUCT CLEARANCE

Presentation Number: Sa1310

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**Background:** Recurrent choledocholithiasis after endoscopic bile duct clearance is seen in clinical practice yet is infrequently described in the literature. The aim of this study is to determine the clinical and endoscopic predictors of recurrent symptomatic choledocholithiasis after normal cholangiography or endoscopic bile duct clearance in patients who present with choledocholithiasis.

**Methods:** Patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) for suspected choledocholithiasis from January 2007 to July 2017 at the University of Vermont Medical Center were identified through the electronic medical record. The control group consisted of patients who had documented clearance of the bile duct on cholangiogram during an initial or subsequent ERCP without a future recurrence. A recurrence was defined by the presence of a biliary stone on subsequent ERCP after confirmation of bile duct clearance on prior ERCP. Demographic, clinical, laboratory, and endoscopic data were collected for each group. In the recurrence group, time to recurrence, need for surgery, and all-cause mortality were also collected. Group differences in patient characteristics were evaluated using the Chi-square test except for the continuous variables (total bilirubin and bile duct diameter) which were tested using the Kruskal-Wallis test.

**Results:** A total of 687 patients were included in this study. There were 628 patients in the control group and 59 (8.6%) in the recurrence group. Baseline characteristics between the two groups were similar, including age, gender, and history of a prior cholecystectomy. Variables that were associated with a recurrence included presence of a perampullary diverticulum ( $p=0.01$ ), placement of a biliary stent during initial ERCP ( $p=0.005$ ), and larger bile duct diameter (10.4 mm in recurrence group vs. 9.3 mm in control group,  $p=0.03$ ). There were 13 patients (22%) in the recurrence group who did not have a confirmed biliary stone on initial ERCP. The median time to recurrence was 19 weeks. Factors not associated with a recurrence included presence of a biliary stricture, performance of endoscopic ultrasound (EUS) or magnetic resonance cholangiopancreatography (MRCP) before initial ERCP, biliary sludge or debris, multiple stones, presence of pancreatitis or cholangitis, and total bilirubin level. In patients with a recurrence, 36% presented with cholangitis, and the all-cause mortality was 10%.

**Conclusion:** Factors associated with biliary stone recurrence after endoscopic bile duct clearance include bile duct diameter, placement of a biliary stent, and the presence of a perampullary diverticulum. These results can be used to select patients at higher risk of recurrence and potentially determine the need for ancillary imaging of the bile duct (e.g. cholangioscopy) to confirm bile duct clearance.

# EVALUATION OF ASPIRATION FLUID CYTOLOGY AS AN ADJUNCT WITH SINGLE OPERATOR CHOLANGIOSCOPY AND TARGETED BIOPSY TO IMPROVE THE DIAGNOSTIC YIELD IN INDETERMINATE BILIARY STRICTURES.

Presentation Number: Tu1401

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## Background:

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) with Digital Single Operator Cholangioscopy (dSOC) has been shown to increase the sensitivity of detecting malignancy in indeterminate biliary strictures (IBS). However, IBS remain a diagnostic challenge. Water irrigation is commonly used during dSOC to improve duct visualization. We hypothesize that fluid aspiration of water used to irrigate the common bile duct (CBD) during dSOC could increase the diagnostic yield in IBS.

The aim of this study is to evaluate whether the addition of aspiration fluid cytology (AFC) collected during water irrigation of the CBD before and after dSOC targeted biopsy (CBx) could improve the diagnostic sensitivity of detecting malignancy in IBS.

**Methods:** We conducted a retrospective analysis of all patients at a tertiary medical center who underwent ERCP with dSOC and CBx for evaluation of biliary strictures. We included patients who had aspiration of fluid from the CBD during water irrigation before and after the CBx and was sent for cytology from January to October 2017. Diagnosis was made on the basis of final pathology or follow up over 6-8 months. The comparison of sensitivities of CBx alone and CBx with AFC in diagnosing malignancy was performed using McNemar (chi-square) test.

**Results:** 56 patients had ERCP with dSOC for biliary stricture in the study time period. 35 patients satisfied the inclusion criteria. 22 (62%) patients were male and the average age was 65 years. Two patients with malignant biliary stricture had only atypical cells on CBx but AFC showed malignant cells. One patient had benign cells on CBx where AFC showed malignant cells. On considering atypical cells as benign; the sensitivity, specificity, positive and negative predictive values (PPV, NPV) for CBx were 66.66%, 100%, 100% and 80 % respectively. When combined with AFC the above values increased to 80%, 100%, 100% and 86.95% respectively. When atypical cells were considered as malignant, the sensitivity, specificity, PPV and NPV for CBx were 80%, 80%, 75%, 84.2% and increased to 86.6%, 70%, 68.4% and 87.5% respectively after adding AFC to the biopsies. CBx with AFC had significantly improved sensitivity when compared with CBx alone with a p-value of 0.014 (for both when atypical is used as benign or malignant).

Conclusion:

For patients undergoing ERCP with dSOC for indication of biliary stricture, the addition of aspiration fluid cytology to dSOC targeted biopsies significantly improves the sensitivity for detecting malignancy. Irrigation during cholangioscopy is done routinely for visualization of the duct and aspirating the fluid for cytology can be done without increasing the length of the procedure and significantly enhancing the diagnostic sensitivity.

Baseline Characteristics (n=35)	
Average age (years)	65 (25 – 97)
Male	22 (62%)
Primary sclerosing cholangitis (PSC)	7 (20%)
Location of stricture	Common bile duct – 25 (71.4%) Common hepatic duct – 4 (11.4%) Hilar – 2 (5.7%) Pancreatic duct – 1 (2.9%) Intrahepatic ducts – 3 (8.6%)
Diagnosis	Benign – 13 (37.5%) PSC – 7 (20%) Cholangiocarcinoma – 8 (22.9%) Pancreatic adenocarcinoma – 4 (11.4%) Gall bladder carcinoma – 2 (5.7%) Hemangio-endothelioma – 1 (2.9%)

<b>Atypical cells as benign</b>	Cholangioscopic biopsy with Aspiration fluid cytology (n= 35)	Brush cytology (n=9)	Cholangioscopic biopsy (n=35)
Sensitivity	80%	66.6%	66.6%
Specificity	100%	100%	100%
PPV	100%	100%	100%
NPV	86.95%	85.7%	80%
<b>Atypical cells as malignant</b>	Cholangioscopic biopsy+ Aspiration cytology (n= 35)	Brush cytology (n=9)	Cholangioscopic biopsy (n=35)
Sensitivity	86.6%	66.6%	80%
Specificity	70%	66.6%	80%
PPV	68.4%	50%	75%
NPV	87.5%	80%	84.2%

# INTERNATIONAL MULTICENTER STUDY ON DIGITAL SINGLE OPERATOR PANCREATOSCOPY FOR THE MANAGEMENT OF PANCREATIC STONES

Presentation Number: 336

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**Background:** The role of the digital single-operator cholangioscopy (D-SOC) system for the treatment of pancreatic ductal (PD) stones in patients with chronic pancreatitis (CP), using electrohydraulic (EHL) and laser lithotripsy (LL), is not well known. **Aims:** (1) To study the technical success (complete ductal clearance) and safety (rate/severity of adverse events (AE) per ASGE lexicon) of D-SOC system with EHL/LL in the treatment of pancreatic stones; (2) To compare the performance of EHL vs. LL. **Methods:** International, multicenter, retrospective study at 17 tertiary centers between 02/2015 and 09/2017. All patients who underwent D-SOC with EHL/LL for the treatment of PD stones were included. Logistic regression analysis was performed to identify factors associated with technical failure and the need for more than one D-SOC EHL/LL session. **Results:** 103 (30% F, mean age 54 yr.) patients were included. Most frequent cause of CP was alcohol (60%), 96% had abdominal pain, 49% diabetes, 77% were on narcotics and 45% on pancreatic enzymes. Overall, 12% of patients had previous extracorporeal shock wave lithotripsy (ESWL), 87% previous failed ERCP attempts to clear the PD, and 67% prior indwelling stents. Location of stones was: head 51%, neck 22%, body 15%, tail 4%, and multifocal 8%. The mean main PD diameter was 9.19±3.17 mm. A total of 59 patients were treated with EHL and 44 with LL. The mean procedure time was 64.2±23.2 min. Technical success was achieved in 92 (89%)

patients, in a single session in 69 (75%) of patients, whereas 20 (21.7%) required 2-3 sessions and only 3 (3.3%) required more than 3 sessions. A total of 11 (11%) patients failed EHL/LL and were treated with ESWL (n=6), surgery (n=1), combined treatment (n=1) or other (n=3). Nine (8.7%) AEs occurred, 3 pancreatitis, 3 abdominal pain, 1 pancreatic duct perforation, 1 fever and 1 bleeding (mild 6 and moderate 3). Incomplete pancreatic stone removal/stone recurrence occurred in 7 (8%) patients during a median follow-up time of 214 days (IQR 66-403). Technical success was significantly higher in the LL group (81% vs 100%, p=0.002) and procedure time was shorter (55min vs. 74min, p<0.001). AEs (8% vs 9%, p=1) were similar between the two groups. On univariable analysis, the only factor associated with technical failure was the presence of a PD stricture (OR 3.68 (1.00-13.47), p=0.05). There were no significant predictors of the need for more than one D-SOC EHL/LL on logistic regression analysis **Conclusion:** D-SOC using EHL or LL is highly effective and safe in treating PD stones, although LL appears to be more effective and efficient when compared to EHL. Only a minority of patients will require additional treatment with ESWL or surgery to achieve ductal clearance. This is the first large multicenter study on D-SOC for PD stones and suggests its major role in the treatment of PD stones.

	Total (N=103)	EHL (N=59)	LL (N=44)	P value
Female sex; n (%)	31 (30.1)	23 (39)	8 (18.2)	0.02
Mean age (mean $\pm$ SD)	54.8 $\pm$ 14.89	56 $\pm$ 2	53.2 $\pm$ 2	0.34
<b>Symptoms</b>				
o Abdominal pain; n (%)	99 (96.1)	56 (94.9)	43 (97.7)	0.46
o Weight loss; n (%)	55 (53.4)	16 (27.1)	39 (88.6)	< 0.001
o On pancreatic enzymes; n (%)	79 (76.7)	37 (62.7)	42 (95.5)	< 0.001
o Pancreatic insufficiency; n (%)	46 (44.7)	15 (25.4)	31 (70.5)	< 0.001
o Diabetes; n (%)	51 (49.5)	20 (33.9)	31 (70.5)	< 0.001
Prior ESWL	12 (11.7)	10 (16.9)	2 (4.5)	0.05
Prior ERCP with failed stone extraction; n (%)	90 (87.4)	46 (78)	44 (100)	0.001
Indwelling pancreatic stent; n (%)	69 (67)	42 (71.2)	27 (61.4)	0.29
Main pancreatic duct size; (mean $\pm$ SD) (mm)	9.19 $\pm$ 3.17	8.39 $\pm$ 2.89	10.27 $\pm$ 3.23	0.003
<b>Stone location</b>				0.07
o Head; n (%)	53 (51.5)	35 (59.3)	18 (40.9)	
o Neck; n (%)	23 (22.3)	10 (16.9)	13 (29.5)	
o Body; n (%)	15 (14.6)	6 (10.2)	9 (20.5)	
o Tail; n (%)	4 (3.9)	4 (6.8)	0 (0)	
o Multifocal; n (%)	8 (7.8)	4 (6.8)	4 (9.1)	
<b>Stone size (largest)</b>				0.02
o 1-9 mm; n (%)	58 (56.3)	40 (67.8)	18 (40.9)	
o 10-19 mm; n (%)	30 (29.1)	13 (22)	17 (38.6)	
o >20 mm; n (%)	15 (14.6)	6 (10.2)	9 (20.5)	
Stone impaction; n (%)	66 (64.1)	26 (44.1)	40 (90.9)	<0.001
Main pancreatic duct stricture; n (%)	81 (78.6)	39 (66.1)	42 (95.5)	<0.001

	Total (N=103)	EHL (N=59)	LL (N=44)	p value
Technical success (pancreatic duct clearance); n (%)	92 (89.3)	48 (81.4)	44 (100)	0.002
Number of EHL/LL sessions to clear pancreatic duct; n (%) (n=92)				0.7
o 1	69 (75)	37 (77.1)	32 (72.7)	
o 2-3	20 (21.7)	9 (18.8)	11 (25)	
o More than 3	3 (3.3)	2 (4.2)	1 (2.3)	
Number of additional ERCPs for dilation/removing stents; n (%) (n=90)				0.03
o None	12	12 (21.8)	0 (0)	
o 1	50	24 (43.6)	26 (74.3)	
o 2-3	20	13 (23.6)	7 (20)	
o More than 3	8	6 (10.9)	5 (5.7)	
Need for ESWL; n (%)	6 (5.8)	6 (10.2)	0 (0)	0.04
Need for surgery; n (%)	1 (1)	1 (1.7)	0 (0)	1
Other treatment	3 (2.9)			
Combined treatment	1(1)			
Stone incomplete stone removal/recurrence; n (%) (n=89)	7 (7.9)	6 (11.1)	1 (2.9)	0.24
Procedure time (min) (mean ± SD) 24 patients no recorded times (n=79)	64.2±23.2	74.4±25.5	55.1±16.6	<0.001
Adverse events	9 (8.7)	5 (8.5)	4 (9.1)	1
Median follow up time; days median (IQR)	214 (66-403)	157 (63-353)	324.5 (158-416)	0.004
Median time to recurrence; days (IQR)	96 (84-495)	91 (76.25-205.5)	561 (n=1)	0.24

# PERORAL CHOLANGIOSCOPY WITH CHOLANGIOSCOPY DIRECTED BIOPSIES IN THE DIAGNOSIS OF BILIARY MALIGNANCY: A META-ANALYSIS

Presentation Number: Sa1321

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**Aim:** To evaluate the efficacy of cholangioscopy directed biopsies in differentiating biliary intraductal malignancies from benign lesions.

**Method:** Articles were searched in Medline, Pubmed, and Ovid journals. Pooling was conducted by both fixed and random effects models. Only studies from which a 2 X 2 table could be constructed for true positive, false negative, false positive and true negative values were included.

**Results:** Initial search identified 211 reference articles for peroral cholangioscopy, of these 26 relevant articles were selected and reviewed. Data was extracted from 15 studies (N = 539) which met the inclusion criteria. Pooled sensitivity of cholangioscopy directed biopsies in diagnosing malignancy was 71.9 % (95 % CI: 66.1 - 77.1) and pooled specificity was 99.1% (95% CI: 96.9 - 99.9). The positive likelihood ratio of cholangioscopy directed biopsies was 18.1 (95 % CI: 9.1 - 35.8) and the negative likelihood ratio was 0.3 (95% CI: 0.2 - 0.4). The pooled diagnostic odds ratio, the odds of having the correct histologic etiology of a lesion in positive as compared to negative peroral cholangioscopy directed biopsies was 71.6 (95% CI: 32.8 - 156.4). All the pooled estimates calculated by fixed and random effect models were similar. SROC curves showed an area under the curve of 0.98. The p for chi-squared heterogeneity for all the pooled accuracy estimates was > 0.10.

**Conclusion:** Peroral cholangioscopy with cholangioscopy directed biopsies has a high specificity in differentiating intraductal malignancies from benign lesions. Cholangioscopy directed biopsies should be strongly considered for biliary stricture evaluation.

# PERORAL CHOLANGIOSCOPIC VISUAL IMPRESSION IN THE DIAGNOSIS OF BILIARY MALIGNANCY: A META-ANALYSIS

Presentation Number: Tu1433

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**Aim:** To evaluate the efficacy of cholangioscopic visual impression to differentiate intraductal malignancies from benign lesions.

**Method:** Articles were searched in Medline, Pubmed, and Ovid journals. Pooling was conducted by both fixed and random effects models. Only studies from which a 2 X 2 table could be constructed for true positive, false negative, false positive and true negative values were included.

**Results:** Initial search identified 211 reference articles for peroral cholangioscopy, of these 18 relevant articles were selected and reviewed. Data was extracted from 8 studies (N = 323) which met the inclusion criteria. Pooled sensitivity of cholangioscopic visual impression alone in diagnosing malignancy was 90.3 % (95 % CI: 84.4 - 94.5) and pooled specificity was 87.4% (95% CI: 81.2 - 92.1). The positive likelihood ratio of cholangioscopic visual impression alone was 5.2 (95 % CI: 3.5 - 7.7) and the negative likelihood ratio was 0.13 (95% CI: 0.06 - 0.25). The pooled diagnostic odds ratio, the odds of having the correct etiology of a lesion in positive as compared to negative peroral cholangioscopic visual impression was 64.5 (95% CI: 23.1 - 180.3). All the pooled estimates calculated by fixed and random effect models were similar. SROC curves showed an area under the curve of 0.95. The p for chi-squared heterogeneity for all the pooled accuracy estimates was > 0.10.

**Conclusion:** Peroral cholangioscopy with cholangioscopic visual impression alone may be a useful tool in detecting malignancy, and has a high sensitivity for differentiating intraductal malignancies from benign lesions.

# DIGITAL PANCREATOSCOPY IN THE EVALUATION OF MAIN DUCT INTRADUCTAL PAPILLARY MUCINOUS NEOPLASM: A MULTI-CENTER STUDY

Presentation Number: Tu1423

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**Background and Aims:** Single operator digital pancreatoscopy has become commercially available. The aims of this study are to look at the outcomes of digital pancreatoscopy in main duct intraductal papillary mucinous neoplasms.

**Methods:** This is a multi-center retrospective study. Outcomes analyzed were technical success, safety, incremental pathology yield compared to prior cross-sectional/echoendoscopic imaging, and utility (if the device changed surgical management).

**Results:** A total of 31 patients were enrolled from six tertiary care centers. Patient and procedure characteristics are listed in Table 1. Forty-two percent had a diffusely dilated duct while the rest had a focally dilated duct. Visual findings on pancreatoscopy were fronds/papillary projections (87%), a mass/nodule (32%), and fish-egg like protrusions (29%) (FIGURE 1). Technical success was achieved in 100% of cases ( $p < 0.001$ ). Forty-two percent of cases had findings seen on pancreatoscopy that were not seen on cross-sectional imaging or EUS ( $p = 0.21$ ). Overall, digital pancreatoscopy dictated the type of surgery performed in 45% (13) of the cases that underwent surgery ( $p = 0.6$ ). However, when the patient had a diffusely dilated pancreatic duct greater than 10 mm, the pancreatoscopy dictated the type of surgery 77% of the time (10/13,  $p = 0.007$ ). Patients with a diffusely dilated duct were less likely to develop post-ERCP pancreatitis than those with a focally dilated duct. One patient out of 13 (8%) with a diffusely dilated duct developed PEP while 7 out of 18 (39%) patients with a focally dilated duct developed PEP (8% vs 39%;  $p = 0.05$ ).

**Conclusion:** Digital pancreatoscopy should be considered in the diagnostic algorithm of main duct IPMN, especially for patients with a diffusely dilated pancreatic duct diameter of  $>10$  mm, and without any focal lesions seen on cross-sectional imaging.

TABLE 1: PATIENT AND PROCEDURE CHARACTERISTICS

PATIENT CHARACTERISTICS
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Female	17 (55%)
Median Age	67
Median Pancreatic Duct Diameter	10 mm
Diffusely Dilated Pancreatic Duct	13 (42%)
Fish mouth appearance of the pancreatic duct	25 (81%)
PROCEDURE CHARACTERISTICS	
Deep Cannulation Achieved	31 (100%)
Antibiotics Given	31 (100%)
Pancreatic Sphincterotomy Performed	18 (58%)
Pancreatic Duct Stent Placed	18 (58%)
Pancreatoscopy Scope Advanced To:	
Head/Neck of Pancreatic Duct	17 (55%)
Body/Tail of Pancreatic Duct	14 (45%)
Changes of IPMN Seen:	
Head/Neck	21 (68%)
Body/Tail	6 (19%)
Diffuse	4 (13%)
Pancreatoscopy Directed Biopsies Taken	28 (90%)
Pancreatoscopy Findings:	
Fronds/Papillary Projections	27 (87%)
Mass/Nodule	10 (32%)
Fish-egg like Protrusions	9 (29%)
Histology from Pancreatoscopy Directed Biopsies:	
IPMN with LGD	22 (79%)

IPMN with HGD	5 (16%)
IPMN with adenocarcinoma	1 (4%)



# DIGITAL SINGLE OPERATOR PANCREATOSCOPY IN THE DETECTION OF EARLY HIGH-RISK LESIONS

Presentation Number: Tu1407

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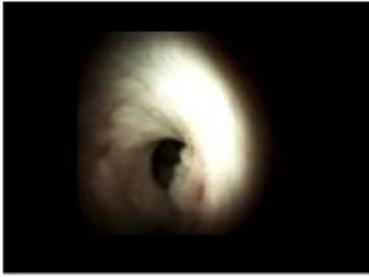
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**Introduction:** Digital single operator pancreatoscopy (DSOP) is used mainly for therapeutic interventions in performing lithotripsy. Its use in diagnostic purposes has been mostly limited to the pre-operative assessment of existing intraductal papillary mucinous tumors (IPMNs). There are little data on the use of DSOP in the diagnosis of early high-risk lesions. IPMNs and pancreatic intraepithelial neoplasia (PanIN) are both precancerous lesions, which can co-exist. The purpose of this study was to determine the capacity of diagnostic DSOP (dDSOP) in the diagnosis of early IPMNs and PanINs.

**Methods:** All patients undergoing endoscopic retrograde pancreatography (ERP) since April 2015 to August 2017 were included. All procedures were performed under monitored anesthesia, the majority on an outpatient basis, and all received prophylactic pre-procedure intra-rectal indomethacin. All patients received a post-procedure pancreatic stent, 47 for therapy and 30 for prophylaxis. The patients with visible IPMN were not included as all had an advanced lesion for which dDSOP was being performed for local staging/mapping. Patients with Dilated duct (DD) included those with a duct >5 mm with otherwise negative EUS and other imaging. Categorical data were presented as proportions. Continuous data were presented with mean and standard deviation..

**Findings:** There were 106 patients, 78 men, with a mean age of 61 years (31 to 88). Indications for ERP included stones (PS) in 61 (57.5%), IPMN in 21 (19.8%), dilated duct (DD) in 22 (20.7%) and filling defect (FD) in 2 (2%). Diagnostic DSOP was performed in 32 of the patients with pancreatic stones who were deemed high risk for pancreatic cancer for a total of 56 dDSOP. Of the 32 patients with PS, dDSOP was performed after stone clearance. PanINs were found in 7 patients (21.8%), IPMN and PanIN in 13 of the 22 patients with DD (59%) and in 1 of the 2 patients with FD (50%). Surgery was performed in 5 patients with PS and PanIN, corroborating the DSOP findings but in addition, 2 had high dysplasia and one had a carcinoma in situ. Three of the 13 patients with DD and PanIN/IPMN underwent surgery finding high-grade dysplasia in 4 and carcinoma in situ in 1. The patient with FD and PanIN had high-grade dysplasia. Overall, 21/56 (37.5 %) of patients undergoing dDSOP were found to have an early high-risk pancreatic lesion..

**Conclusion:** dDSOP is of value in the diagnosis of early high-risk lesions in patients with a variety of pancreatic disorders, with significant impact on patient's management and prognosis. This study is limited by selection bias and it is a single center experience. Confirmation of these findings in larger, multicenter studies would be of value



# PER ORAL PANCREATOSCOPY WITH INTRADUCTAL LITHOTRIPSY COMPARED TO ERCP WITHOUT PANCREATOSCOPY FOR THE MANAGEMENT OF PANCREATIC DUCT STONES IN PATIENTS WITH CHRONIC PANCREATITIS

Presentation Number: Tu1406

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## **Background:**

Peroral pancreatoscopy (POP) permits targeted intraductal lithotripsy which remains an unapproved indication for POP. Limited data exists regarding the efficacy and safety of POP with laser (LL) or electrohydraulic (EHL) lithotripsy. The aim of this study is to compare the technical success and adverse event (AE) rate in patients with symptomatic calcific chronic pancreatitis undergoing ERCP with and without POP for the treatment of PD stones.

## **Methods:**

This is a single-center retrospective review of ERCPs performed for PD stones from January 2000 to January 2017. POP type was recorded in addition to specific interventions, AEs, and demographic data. Definitions: Technical Success - partial or complete clearance of PD stones; Clinical Success - absence of surgery, emergency room visits or hospitalizations for chronic pancreatitis; Recurrence: return of PD stones after complete clearance. Adverse events were graded per ASGE guidelines. Multivariate analysis was used to identify associations with technical and clinical success.

## **Results:**

A total of 223 patients [mean age 51.2 years, 52% males, 40% current smokers] received 549 ERCPs for the treatment of PD stones. POP was used in 94/223 (42.2%) patients for 160/549 (29.1%) of cases with 3 methods of POP (**Table 1**). The cumulative complete stone clearance rate was 165/223 (74.3%) patients after a mean of 1.7 ( $\pm$  0.47) POP and 2.5 ( $\pm$  3.1) ERCPs per patient. Follow-up of 7.2 years ( $\pm$  3.9) was obtained in 141/223 (63.2%) patients. Clinical success was 76.6% (95% CI: 0.69, 0.83) with a recurrence rate of 53.2% (95% CI: 0.44, 0.63) at a mean of 243 days ( $\pm$  353). Of the 160 POP cases, EHL and LL achieved a 99% (95% CI: 0.95, 1) and 100% (95% CI: 0.86, 1) per-procedure technical success rate, respectively. Per procedure, ERCP with POP had a higher technical success rate (96.3% vs. 78.2%,  $p=0.001$ ) and was used for larger stones (8.9 vs. 6.1 mm,  $p=0.001$ ) and greater number of stones (6+ stones: 33.8% vs. 19.8%,  $p=0.002$ ) than ERCP without POP (**Table 2**). There was no difference in AE rates [6.3% (POP) vs. 11.3% (non-POP),  $p=0.07$ ], including post-ERCP pancreatitis (0.6% vs. 1.3%) or abdominal pain requiring admission (3.1% vs. 6.7%). Multivariate regression revealed that only POP was significantly associated with improving technical success ( $r^2=0.14$ ,  $p=0.02$ )

## **Conclusions:**

1) In our referral center patient cohort, 165/223 (74.3%) patients achieved complete stone clearance

after a mean of 2.5 procedures and mild AEs. 2) PD stones were larger in POP cases with EHL or LL compared to ERCP procedures without POP and achieved a higher technical success. 3) While cumulative clearance of stones is similar between ERCP with and without POP, POP was used in cases with larger and more numerous stones.

Table 2: Comparison of ERCP with and without Pancreatoscopy for Treatment of Pancreatic Duct Stones (per procedure analysis)

	<b>Total Procedures (n=549)</b>	<b>ERCP with Pancreatoscopy (n=160)</b>	<b>ERCP without Pancreatoscopy (n=389)</b>	<b>P value</b>
<b>Per Procedure Technical Success</b>				0.001
Failure	56 (10.2%)	6 (3.8%)	50 (12.9%)	
Partial	204 (37.2%)	115 (71.9%)	89 (22.9%)	
Complete Clearance	289 (52.6%)	39 (24.4%)	250 (64.3%)	
Technical Success (partial or complete clearance)	493 (89.8%)	154 (96.3%)	339 (87.2%)	0.001
Cumulative complete clearance of stones per patient	165 (74.3%)	69 (73.4%)	96 (75%)	0.79
Recurrence Rate per patient	58 (45.5)	26 (52%)	32 (54.2%)	0.8
Time to Recurrence (days)	242.9 ± 352.8	228.3 ± 386.7	254.83 ± 328.6	0.78
Stone Size (mm)	7.33 ± 4.5	8.9 ± 5.3	6.1 ± 3.1	0.001
6+ stones	131 (23.9%)	54 (33.8%)	6.1 ± 3.1	0.001
Adverse Events	54 (9.8%)	10 (6.3%)	44 (11.3%)	0.07
<b>ASGE Adverse Event Severity</b>				0.36
Grade 1	47 (87%)	10 (100%)	36 (84.1%)	
Grade 2	4 (7.4%)	0 (0%)	4 (9.3%)	
Grade 3	3 (5.6%)	0 (0%)	3 (7%)	

Post-ERCP Pancreatitis	6 (1.1%)	1 (0.6%)	5 (1.4%)	0.47
Number of ERCPs per patient	2.5 ± 3.1	2.3 ± 2.2	2.8 ± 3.6	0.38

Table 1: Clinical and Endoscopic Features

Clinical and Endoscopy Variables	Mean (SD), n (%) N=223 patients
PD Cannulation Success (deep access with wire into PD)	542 (98.7%)
PD Stone Location (Main duct)	512 (93.3%)
<b>Number of Stones</b> One stone Multiple (2-5 stones) Many (6+ stones)	88 (16%) 330 (60.1%) 131 (23.9%)
Impacted Stone (unable to pass guidewire past stone)	75 (13.7%)
<b>Pancreatoscopy Types</b>	
Pancreatoscope (Olympus)	43 (26.9%)
Fiber-optic single-operator pancreatoscope (Boston Scientific)	80 (50%)
Digital single-operator pancreatoscope (Boston Scientific)	37 (23.1%)
<b>Sphincterotomy</b> Major Papilla	118 (21.5%) 101 (85.6%)
<b>Sphincterotomy with Pancreatoscopy</b> Major Papilla	61 (38.1%) 53 (86.9%)
<b>Dilation</b> Balloon Size (mm)	309 (56.3%) 288 (93.2%) 5.8 ± 1.7
<b>Stenting</b> Diameter of stent(s) (french) Duration Interval (days)	421 (76.7%) 9.0 ± 3.2 52.7 ± 28.6

General Anesthesia	527 (96%)
ESWL after Index ERCP	16 (7.2%)
Hospitalizations and ER visits after technical success achieved	0.5 ± 1.8
Follow-up (years)	5.1 ± 4.4

Table 1: PD: pancreatic duct; ESWL: extracorporeal shock wave lithotripsy; ER: