2018

NCSCG 15TH ANNUAL POST-DDW SYMPOSIUM

Rehoboth McKinley Christian Health Care Services

Northern California Society for Clinical Gastroenterology

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2018 NCSCG 15TH ANNUAL POST-DDW SYMPOSIUM

Advanced Endoscopy Updates

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Disclosures

- Boston Scientific – Consultant
- Off-label use of devices

EUS and ERCP Updates

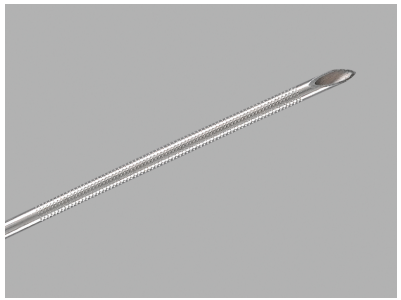
- Diagnostic EUS
  - Tissue acquisition (FNA vs FNB)
  - Liver Biopsy
- ERCP
  - Cannulation
  - Cholangioscopy for CBD/pancreatic stones
  - Metal stents in distal malignant biliary obstruction
- Necrotizing pancreatitis
  - Endoscopic Approach vs Surgery
- Therapeutic EUS
  - Lumen apposing stents (CBD, Gallbladder, Gastro-jejunal anastomosis RYGB-ERCP)

#1 Diagnostic EUS

- Fine needle biopsy vs fine needle aspiration
- EUS guided liver biopsy

EUS Needles

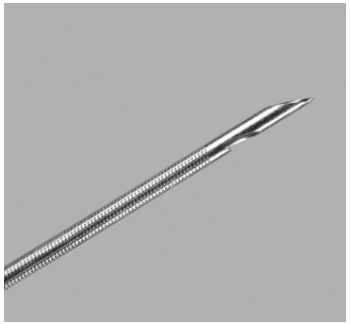
FNA Needles



FNB Needles

Fork tip

Franseen tip



Reverse bevel

A MULTICENTER RANDOMIZED TRIAL COMPARING A 25G EUS FINE NEEDLE ASPIRATION DEVICE WITH A 20G EUS FINE NEEDLE BIOPSY DEVICE

Presentation Number: Su1406

AuthorBlock: *Priscilla Anita van Riet[1], Alberto Larghi[2], Fabia Attili et al*

BACKGROUND AND AIM

Most studies comparing fine needle aspiration (FNA) to fine needle biopsy (FNB) were underpowered, limited to a single indication, or performed in a single center. Accuracy of diagnosis, but also, procurement of sufficient tissue quantity is becoming increasingly important in the era of personalized medicine. This global prospective randomized multicenter study compared the performance of a large-bore 20G FNB (ProCore) to a small-caliber 25G FNA (Echotip) needle (both Cook Medical).

METHODS

The study was conducted in 13 EUS-centers across the world. Consecutive patients with a solid pancreatic lesion, lymph node, or other solid lesion ≥1 cm in size were enrolled between February 2015 and September 2016. Patients were randomized 1:1 for ≥3 passes with FNA or FNB. Primarily, we compared diagnostic accuracy for malignancy and the diagnosis according to the Bethesda classification (non-diagnostic, benign, atypical, malignant). The final diagnosis was based on surgical resection specimens or, in non-operated patients on more than 9 months of follow-up. Secondly, we assessed needle safety, yield per pass, sample sufficiency, cellularity, and histological tissue core yield. Multivariable analysis was performed adjusting for indication, lesion size, number of passes, and presence of an on-site pathologist. Supplementary analysis was done to assess variation of diagnostic accuracy between centers.

RESULTS

608 consecutive patients were randomized to FNA (n=306) or FNB (n=302) biopsy of 312 pancreatic lesions (51%), 147 lymph nodes (24%), and 149 other solid lesions (25%). Diagnosis of malignancy was established in 463 (76%) cases. Sampling was technically feasible in all FNA, and all but four FNB (99%) cases (p=0.043), with no difference in adverse events (3 in FNA and 2 in FNB). Sample sufficiency was equally good for FNA and FNB (82% versus 87%, p=0.062), as was sample cellularity (62% vs 62%, p=0.733). FNB resulted in a higher histological yield (77% versus 44%, p<0.001) and showed a higher diagnostic accuracy for malignancy (87% vs 78%, p=0.002), and for the Bethesda classification (82% versus 72%, p=0.002, table 1). This difference in accuracy was independent of indication, lesion size, number of passes, and presence of an on-site pathologist (OR 3.53, 95% CI 1.51-8.26, p=0.004, table 2). Diagnostic accuracy differed between the centers, but this did not affect the difference in diagnostic accuracy between the needles (p=0.836).

CONCLUSION

The 20G ProCore FNB needle out-performed the widely used 25G FNA needle, in terms of histological yield and diagnostic accuracy, in pancreatic as well as non-pancreatic lesions, independent of the number of passes or presence of an on-site pathologist. The observation that these findings were consistent amongst 13 centers from all over the world supports the general applicability of our findings.

A MULTICENTER RANDOMIZED TRIAL COMPARING A 25G EUS FINE NEEDLE ASPIRATION DEVICE WITH A 20G EUS FINE NEEDLE BIOPSY DEVICE

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Table 1. Performance characteristics for final diagnosis

Diagnostic outcome parameters	FNB n=302	FNA n=306	p-value
Accuracy for malignancy			
1st pass	72% (218/302)	65% (200/306)	0.069
1-3 passes	86% (261/302)	76% (232/306)	0.001
4th and additional passes	86% (24/28)	77% (47/61)	0.345
Overall	87% (263/302)	78% (237/306)	0.002
Accuracy for Bethesda classification			
1st pass	65% (197/302)	60% (182/306)	0.143
1-3 passes	81% (245/302)	70% (215/306)	0.002
4th and additional passes	79% (22/28)	72% (44/61)	0.519
Overall	82% (248/302)	72% (219/306)	0.002

A MULTICENTER RANDOMIZED TRIAL COMPARING A 25G EUS FINE NEEDLE ASPIRATION DEVICE WITH A 20G EUS FINE NEEDLE BIOPSY DEVICE

Presentation Number: Su1406

Table 2. Multivariable analysis of factors influencing diagnostic accuracy for malignancy.

Variables	Correct diagnosis, % (n/n)	Odds ratio (95% CI)	P-value
Needle type			
FNB FNA	87 (263/302) 78 (233/306)	3.53 (1.51-8.26)	0.004
Indication			
Pancreas Lymph node Submucosal and other solid lesions	86 (268/312) 82 (121/147) 75 (111/149)	2.89 (1.47-5.67) 2.20 (1.02-4.75) *	0.002 0.044 0.008
Lesion size			
1-3 cm ≥3 cm	79 (237/299) 85 (232/273)	1.47 (0.92-2.36)	0.106
Needle passes			
1-3 >3	82 (419/514) 89 (78/88)	2.41 (1.05-5.57)	0.039
Presence of ROSE			
Yes No	83 (83/100) 83 (415/502)	0.92 (0.52-1.79)	0.917

Tu 2016: COMPARISON OF FNA AND FINE-NEEDLE BIOPSY FOR EUS-GUIDED SAMPLING OF SOLID TUMORS: PROSPECTIVE, MULTICENTER, RANDOMIZED, CONTROLLED STUDY

Malignancy	FNA（n=168） （95%CI）	FNB（n=168） （95%CI）
Sensitivity	91.02(85.62-94.89)	94.61(90.02-97.51)
Specificity	95.45(77.16-99.88)	89.47(66.86-98.7)
PPV	99.35(96.41-99.98)	98.75(95.56-99.85)
NPV	58.33(40.76-74.49)	65.38(44.33-82.79)
Accuracy	91.53(86.62-95.08)	94.09(89.66-97.01)

EUS Guided Liver Biopsy

- A PROSPECTIVE RANDOMIZED TRIAL OF 19-GAUGE (G) ASPIRATION NEEDLE VERSUS 19G CORE BIOPSY NEEDLE FOR ENDOSCOPIC ULTRASOUND-GUIDED LIVER BIOPSY
- EUS GUIDED LIVER BIOPSY IS MORE COST-EFFECTIVE THAN PERCUTANEOUS LIVER BIOPSY IN PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE(NAFLD)
- META-ANALYSIS OF EUS GUIDED LIVER BIOPSY IN COMPARISON WITH PERCUTANEOUS AND TRANSJUGULAR LIVER BIOPSY FOR THE DIAGNOSIS OF PARENCHYMAL LIVER D...
- ENDOSCOPIC ULTRASOUND GUIDED LIVER BIOPSY USING A 22 GUAGE FINE NEEDLE BIOPSY NEEDLE: A PROSPECTIVE STUDY.
- EUS-GUIDED CORE LIVER BIOPSY USING A 22G FORK-TIP NEEDLE WITH STANDARD SUCTION TECHNIQUE OFFERS A SAFE AND RELIABLE CORE LIVER TISSUE ACQUISITION:...
- ENDOSCOPIC ULTRASOUND-GUIDED LIVER BIOPSY USING WET-HEPARINIZED SUCTION IMPROVED TISSUE ADEQUACY AND SPECIMEN YIELDS: A PROSPECTIVE CROSS-OVE...
- ENDOSCOPIC ULTRASOUND-GUIDED LIVER BIOPSY: A TERTIARY CENTER EXPERIENCE
- DIRECT COMPARISON OF ENDOSCOPIC ULTRASOUND AND COMPUTER TOMOGRAPH-GUIDED BIOPSY OF THE LIVER MASSES.

EUS Liver Biopsy - Summary

- EUS-LB vs Perutaneous-LB:
  - Comparable in one meta-analysis, superior to transjugular
  - Superior in one meta-analysis
  - More cost-effective in modeling study
- Type of needle
  - 19G FNA vs 19 G Franseen FNB – Franseen superior (both adequate)
  - 19G Franseen/Fork-tip, 34 pts (8 post-LT pts),all adequate, pain in 3, hematoma in 1 pt
  - 22G FNB needle – adequate in all (17 pts, 8 to 65 CPTs, 3 pain)
  - 22G Fork tip – adequate in all (36 pts, 17-35 CPTs, 2 pain)
- Needle preparation
  - Two studies, heparin vs dry needle, higher yield with heparin prepped needles

#2 ERCP

- Biliary cannulation
- Large bile duct stones: Basket vs EHL
- Timing of ERCP in acute cholangitis
- Pancreatic stones: Laser vs EHL
- Biliary drainage in malignant distal biliary obstruction

PRIMARY NEEDLE-KNIFE FISTULOTOMY VERSUS CONVENTIONAL CANNULATION METHOD IN HIGH RISK COHORT OF POST-ENDOSCOPIC RESTROGRADE CHOLANGIOPANCREATOGRAPHY PANCREATITIS: A MULTICENTER RANDOMIZED CONTROLLED TRIAL

Presentation Number: 169

- **AuthorBlock:** *Sung Ill Jang[1], Dong Uk Kim[2], Jae Hee Cho[3], Chang Il Kwon[4], Dong Hee Koh[5], Se Woo Park[5], Tae Hoon Lee[6], Jin-Seok Park[7], Seok Jeong[7]*

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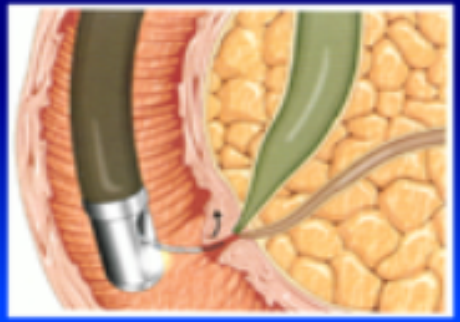
- **Background and aims**: The aims of this study are to evaluate the usefulness of needle knife fistulotomy (NKF) as a procedure for primary biliary access in patients who are at increased risk for post-endoscopic retrograde endoscopic retrograde cholangiopancreatography pancreatitis (PEP) and to assess PEP and other complications between NKF and conventional cannulation methods (CCM).

  Method: Two hundred seven patients with biliary disease were prospectively enrolled and randomly allocated into NKF and CCM group. They underwent ERCP with NKF or CCM in 7 Korean tertiary referral centers between September 2016 and November 2017. They had one or more of the following risk factors for PEP: suspected biliary sphincter of Oddi dysfunction, age (< 50 years), female, normal CBD diameter (≤ 9 mm), normal serum bilirubin level, obesity (body mass index > 30), or past history of acute pancreatitis. The incidence of adverse events including PEP and the success rate of biliary cannulation and CBD stone removal were assessed.

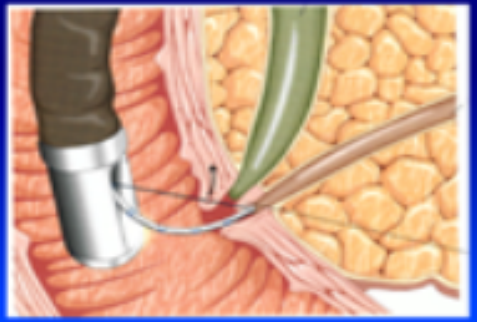
  Results: The mean number of risk factors for PEP was not different between two groups (NKF group: 2.2±1.0, CCM group 2.2±0.9). Eight patients in CCM group experienced PEP but none of patients in NKF group experienced PEP (9.2% vs 0%, p<0.001). The rate of other complications was not different between two groups. The success rate of biliary cannulation of NKF group was higher than that of CCM group (97.9% vs 89.7%, p=0.005). The mean cannulation time and total procedure time were longer in NKF group than CCM group. However, the CBD stone removal or stent insertion after cannulation was all successful in both groups except one patient.

  Conclusions: NKF as a procedure of primary biliary access could prevent PEP in high-risk patients of PEP.

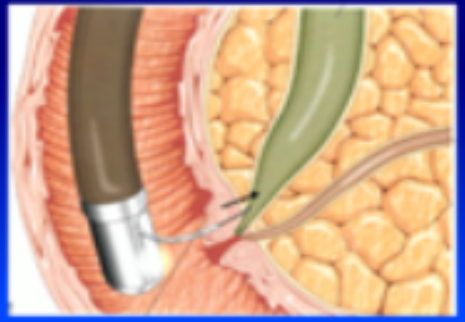
Introduction



needle-knife sphincterotomy



transpancreatic pre-cut papillotomy



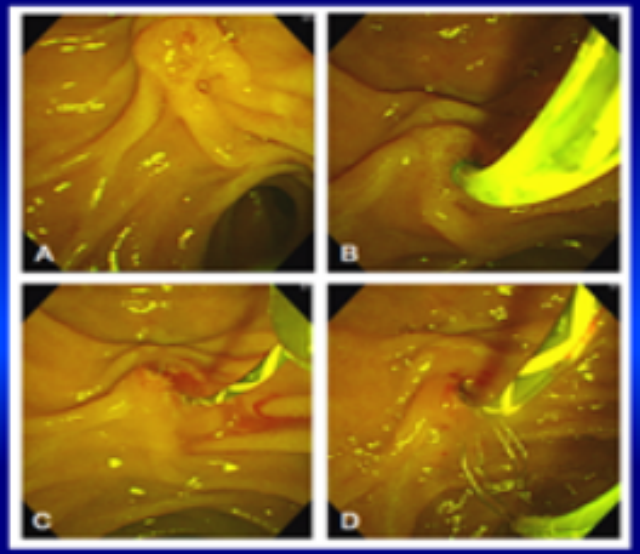
needle-knife fistulotomy

Touch the papillary orifice
Incise sphincter muscle

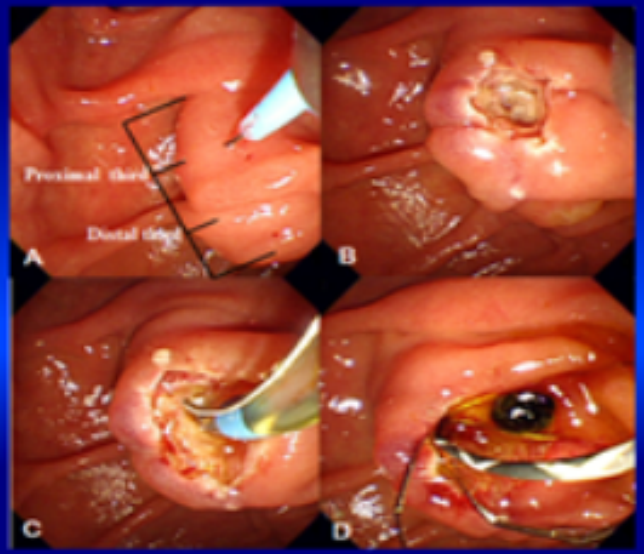
No touch the papillary orifice
Preserve sphincter muscle

Loperfido S, GIE (1998)
Freeman ML, NEJM (1996)
Masci E, Endoscopy (2003)

Methods



Conventional cannulation method
(CCM group)



Needle Knife Fistulotomy
(NKF group)

Variables	CCM group (n=87)	NKF group (n=96)	P value
Primary method (n, success cases/total trials)			
NKF	0	96/98	
CCM	87/97	0	
Technical success rate (%)	89.7	97.9	0.005
Secondary method (n)			
NKF	10	0	
CCM	0	1	
PTBD	0	1	
No. of papillary contact (mean±SD)	2.9±2.3	0.34±0.7	0.001
Pancreatic duct cannulation, n (%)	18 (20.7)	8 (8.3)	0.017
Contrast injection to pancreatic duct, n (%)	4 (4.6)	3 (3.1)	0.606
Stent insertion (pancreatic duct), n (%)	6 (6.9)	1 (1.0)	0.048
Total cannulation time (mean±SD, s)	171.5±173.9	257.2±219.6	0.004
Total procedure time (mean±SD, s)	766.9±375.2	907.6±458.8	0.025
Post-ERCP adverse events (n,%)			
Pancreatitis	8 (9.2)	0 (0)	0.001
Bleeding	1 (1.1)	3 (3.1)	0.363
Perforation	0 (0)	0 (0)	>0.999
Cholangitis	2 (2.3)	3 (3.1)	0.733
Cholecystitis	0 (0)	0 (0)	>0.999
Asymptomatic hyperamylsemia	15 (17.2)	13 (13.5)	0.489

EFFICACY OF DIGITAL CHOLANGIOSCOPY-GUIDED LASER LITHOTRIPSY VERSUS MECHANICAL LITHOTRIPSY IN PATIENTS WITH VERY LARGE COMMON BILE DUCT STONE(S) WHO FAILED PAPILLARY LARGE BALLOON DILATION: A RANDOMIZED CONTROLLED STUDY

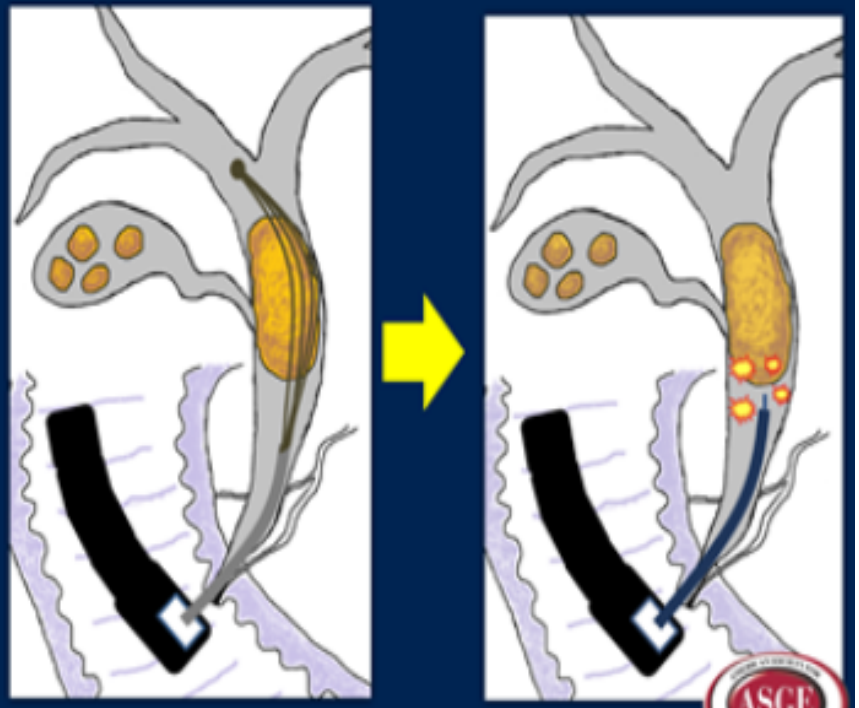
Presentation Number: 165

- **AuthorBlock:** *Santi Kulpatcharapong[1], Wiriyaporn Ridtitid[1], Phonthep Angsuwatcharakon[1], Panida Piyachaturawat[1], Pradermchai Kongkam[1], Chaloemphon Boonmee[2], Wattana Pareesri[2], Thawee Ratanachu-ek[3], Rungsun Rerknimitr[1]*
[1]Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital, Bangkok, Thailand, Bangkok, Thailand; [2]Surgery, Thabo Crown Prince Hospital, Nongkhai, Thailand; [3]Surgery, Rajavithi Hospital, Bangkok, Thailand;

- **Backgrounds:** Endoscopic papillary large balloon dilation (EPLBD) is an effective tool to remove large common bile duct stones (CBDS). However, the very large CBDS or CBDS in distal tapering bile duct, EPLBD alone may fail and additional mechanical lithotripsy (ML) is required. Recently, cholangioscopy-guided laser lithotripsy (CL) has been a new option with promising efficacy for large CBDS. Unlike ML, CL requires less fluoroscopic guidance during lithotripsy. This study therefore aimed to compare the efficacy of CL versus ML in patients with large CBDS that failed EPLBD.
Methods: Of 476 patients who underwent ERCP with CBDS removal, 32 consecutive patients with large CBDS who failed EPLBD were enrolled during September 2016-October 2017. Patients were randomized into CL (n=16) vs. ML (n=16) groups (figure 1). CL was performed using a digital cholangioscope (SpyGlass™ DS, Boston Scientific, Marlborough, Mass, USA) with holmium laser system (Dornier Medilas H Solvo, Dornier MedTech, Wessling, Germany), while ML was done using a basket mechanical lithotriptor (BML; LithoCrush V, Olympus, Tokyo, Japan). CBDS clearance time was defined as the number of minutes between lithotriptor placement and complete CBDS removal. Unsuccessful CL and ML were defined as either failure to initiate fragmentation CBDS during the first 15 minutes or procedure time was longer than 2 hours. The success rates, CBDS clearance time, radiation exposure, and adverse events were compared.
Results: Patients' demographic data were not different between CL and ML group (table 1). In CL group, complete CBDS clearance rate in single ERCP session was significantly higher than the ML group (100% vs. 63); p=0.002). Of those 6 patients with unsuccessful ML (failure to capture the stone) underwent CL as a crossover, 4 patients achieved successful CBDS clearance in one session, one had CL through EUS-guided choledochoduodenostomy tract and another required multiple ERCP sessions to complete CBDS clearance (figure 1). There was a trend of shorter CBDS clearance time in CL group than ML group (39 min vs. 53 min, p=0.26), mean fluoroscopic time and radiation dose in CL group were significantly lower than those of in the ML group (11 min vs. 22 min; p=0.008 and dose area product (DAP) (20,989 mGycm^2 vs. 40,745 mGycm^2; p=0.04, respectively). There were no differences in rate of adverse events and length of hospital stay between the two groups. One patient from each group developed mild post ERCP pancreatitis. Post sphincterotomy bleeding occurred in 1 patient in ML group and stopped spontaneously. No death was reported.
Conclusions: In patients with large stones who failed EPLBD, CL is the preferred option over ML because the better efficacy of stone clearance and lower radiation exposure. Future study should focus on the cost effectiveness between the two treatments.

Limitations of ML

- Stone larger than basket
- Stone impaction
- Associated stricture



Mechanical vs Cholangioscopic lithortripsy (ML vs CL) if large balloon dilation fails in large CBD stones

Methods:

- RCT, 32 pts – 16 in each arm
- Successful clearance in single session

Results

- Complete clearance: CL= 100% 63%, p=0.002
  - ML 6 failures: 4 CL, 1 EUS guided choledochoduodenostomy, 1 multiple ERCPs
  - Clearance time: CL: 39 min vs. ML: 53 min, p=0.26
  - Fluoroscopic time 11 min vs. 22 min; p=0.008
  - Radiation dose (20,989 mGycm^2 vs. 40,745 mGycm^2; p=0.04
- Adverse events and LOS, no difference

Conclusions:

- Large stones with failed LBD, CL is the preferred option over ML because the better efficacy of stone clearance and lower radiation exposure

OUTCOMES OF EARLY VERSUS LATE ERCP IN HOSPITALIZED PATIENTS WITH ACUTE CHOLANGITIS: A NATIONWIDE ANALYSIS

Presentation Number: 167

AuthorBlock: *Ramzi Mulki[1], Rushikesh Shah[1], Emad S. Qayed[1]*

Background: The impact of the timing of endoscopic retrograde cholangiopancreatography (ERCP) on outcomes in patients with acute cholangitis is unclear. In addition, the severity of disease may affect this association. The aim of this study is to assess the effect of early versus late ERCP on mortality in acute cholangitis, using a nationally representative sample.

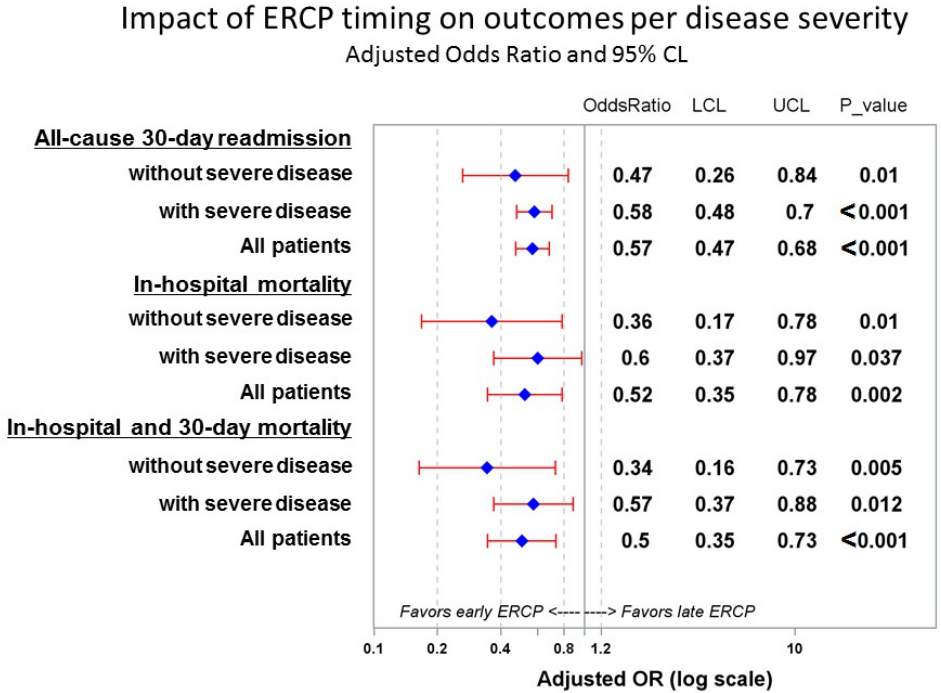
Methods: We identified all adult hospitalizations with a diagnosis of acute cholangitis in the 2010-2014 National Readmissions Database. We excluded patients who did not have an ERCP during the index admission. Timing of ERCP was defined as early (first two days of admission) and late (third day of admission or later). Patients with severe cholangitis had any of the following additional diagnoses: severe sepsis, septic shock, systemic inflammatory response syndrome with acute organ dysfunction, acute renal failure, acute respiratory failure, or thrombocytopenia. Multivariate logistic regression was used to calculate the adjusted odds of association of ERCP timing with in-hospital mortality, composite in-hospital or 30-day readmission mortality, and 30-day readmissions.

Results: A total of 4,592 patients satisfied the inclusion criteria; 65.9% had early ERCP, while 34.1% had late ERCP. Table 1 shows the patient demographics, hospital characteristics, and outcomes comparing early vs late ERCP. Patients who had early ERCP were younger (mean age 63.6 vs. 65.6) and had a lower Elixhauser comorbidity index (mean, 4.6 days vs. 7 days; p <0.0001) compared to those in the late ERCP group. In addition, Early ERCP was associated with a shorter length of stay (mean, 4.6 vs. 7.7; p <0.0001) and lower total cost of hospitalization ($23,723 vs. $17,193, p<0.0001). After controlling for age, sex and Elixhauser mortality index, early ERCP was associated with a lower in-hospital mortality (adjusted odds ratio, 95% CI, p value) (0.52, 0.35-0.78, 0.002), in-hospital or 30-day readmission mortality (0.5, 0.35-0.73, <0.001), and all-cause 30-day readmission (0.57, 0.47-0.68, <0.001) compared to the late group (Figure 1). When stratified by severity, there was a similar benefit of early ERCP on all outcomes in those with and without severe disease (Figure 1).

Conclusion: In this large, nationally representative sample of patients with acute cholangitis, early ERCP (within two days from admission) was associated with lower in-hospital and 30-day readmission mortality. This benefit was demonstrated in those with or without severe cholangitis. Our findings suggest that hospitals should have available resources to perform early ERCP in acute cholangitis to improve outcomes and decrease length of stay and costs.

OUTCOMES OF EARLY VERSUS LATE ERCP IN HOSPITALIZED PATIENTS WITH ACUTE CHOLANGITIS: A NATIONWIDE ANALYSIS

Presentation Number: 167



OUTCOMES OF EARLY VERSUS LATE ERCP IN HOSPITALIZED PATIENTS WITH ACUTE CHOLANGITIS: A NATIONWIDE ANALYSIS

Presentation Number: 167

Results- Length of Stay and Costs

Outcome	Late ERCP 1528 (33.4%)	Early ERCP 3042 (66.6%)	Adjusted Mean difference, early vs late ERCP (95% CI)	*P*
Length of stay in days, mean (SD)	6.9 (5.4)	4.5 (3.9)	-2.1 days (1.9-2.4)	<.0001
Hospitalization costs, mean	$21,459	$16,939	-$3760 ($2803-$4718)	<.0001

Adjusted mean difference and P value obtained from multivariable linear regression controlling for age, sex, severe disease, and mortality score

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Conclusion

- In this large, nationally representative sample of patients with acute cholangitis, we demonstrated that ERCP within 48 hours of admission, was associated with reduced mortality, 30-day readmissions, length of stay, and hospitalization costs.
  - ➢ This association was observed regardless of cholangitis severity.
- We recommend performing ERCP within 48 hours of admission in patients with acute cholangitis regardless of disease severity.

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Pancreatoscopy – Pancreatic stone EHL

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

Presentation Number: 336

AuthorBlock: *Olaya I. Brewer Gutierrez[1], Isaac Raijman[2] et al.*

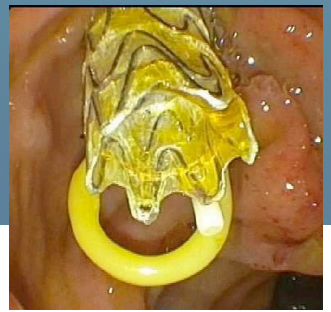
Background: The role of the digital single-operator cholangioscopy (D-SOC) system for the treatment of pancreatic ductal (PD) stones in patients with chronic pancreatitis (CP), using electrohydraulic (EHL) and laser lithotripsy (LL), is not well known. **Aims:** (1)To study the technical success (complete 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.

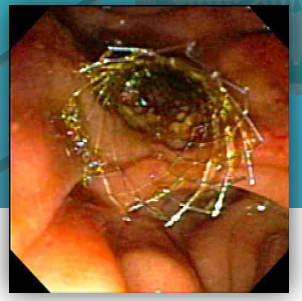
Results: 103 (30% F, mean age 54 yr.) patients were included. Most frequent cause of CP was alcohol (60%), 96% had abdominal pain, 49% diabetes, 77% were on narcotics and 45% on pancreatic enzymes. Overall, 12% of patients had previous extracorporeal shock wave lithotripsy (ESWL), 87% previous failed 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
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



Metal Stents: Covered vs Uncovered



Advantages of covered stents

- Decreased tumor ingrowth into the stent
- Removable - benign conditions/indeterminate strictures

Disadvantages of covered stents

- Migration out of position
- Sludge formation within the stent
- Risk of cholecystitis

A RANDOMIZED TRIAL COMPARING FULLY COVERED AND UNCOVERED BILIARY SELF EXPANDING METAL STENTS FOR PRE-OPERATIVE DRAINAGE DURING NEOADJUVANT THERAPY IN PATIENTS WITH PANCREATIC CANCER

Presentation Number: Tu1394

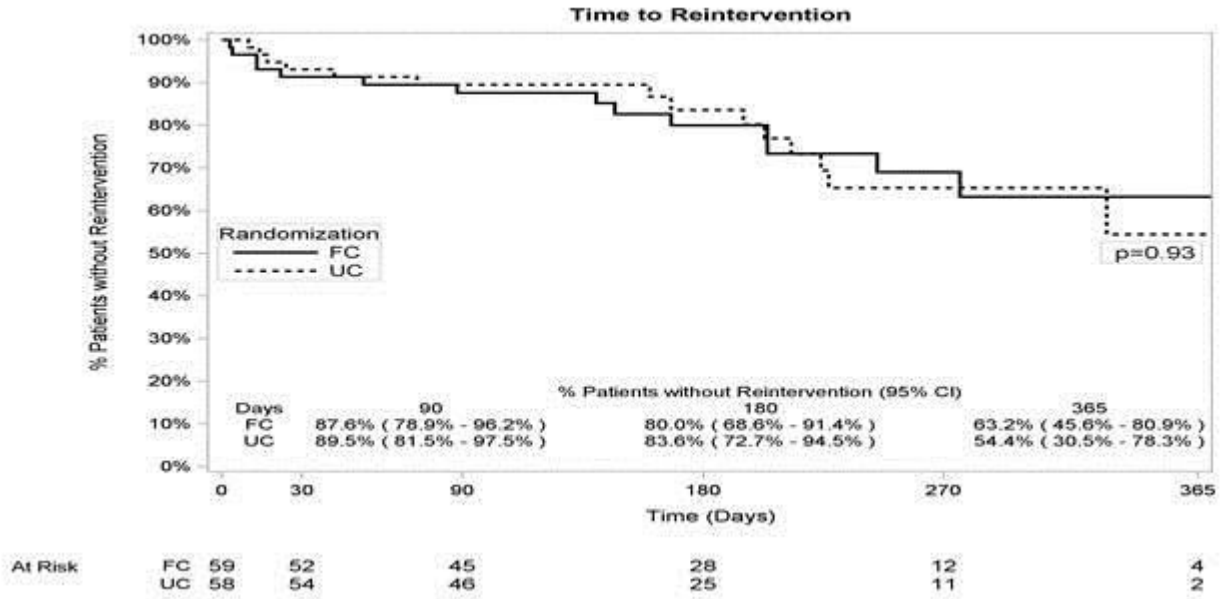
AuthorBlock: *Dong Wan Seo[1], Kulwinder S. Dua et al*

BACKGROUND & AIMS:Concerns have been raised about tissue ingrowth requiring reintervention when using uncovered (UC) SEMS, and of migration and acute cholecystitis (AC) when using fully covered (FC) SEMS. This randomized controlled trial (RCT) compares UC SEMS to FC SEMS for management of preoperative biliary obstruction in PCA pts in the setting of NATX.

METHODS: RCT at 9 centers in 6 countries comparing PBD using UC SEMS and FC SEMS (WallFlex™ RX Biliary Stent, Boston Scientific Corp, Marlborough, MA, USA) in pts with resectable or borderline resectable PCA during NATX. Primary endpoint was successful PBD defined as absence of reinterventions for the management of biliary obstructive symptoms up to PD or transition to palliative care (PAL). Pts followed till 30 days after surgery in PD cohort or 12 month after SEMS placement in PAL cohort. Final data will be presented.

RESULTS: Of 120 enrolled pts 117 pts (mean age 66 years, 57% male) reached primary endpoint eligibility. Randomization to 58 pts in UC and 59 pts in FC group. PD in 52% of UC pts and 48% of FC pts. PD per schedule in 93% of cases. Median time to PD or transition to PAL was not different between groups (100 days in UC and 142 days in FC group (p=0.14)). Primary endpoint of successful PBD was 83% of pts in both UC and FC groups. Kaplan-Meier analysis of the time to reintervention until end follow-up demonstrated no significant difference between UC and FC groups (p=0.93) with 28 pts needing one or more interventions consisting of SEMS removal and replacement by another SEMS or placement of SEMS in SEMS (20), cholecystostomy tube (3), sludge removal (3), cholecystectomy (2), plastic stents (2), percutaneous transhepatic biliary drain (1), and radiofrequency ablation (1). Reason for reintervention was tumor ingrowth (9 UC), AC (4 FC, 1 UC), complete or partial distal SEMS migration (4 FC), sludge (2 FC, 1 UC), and cholangitis or other biliary obstructive symptoms not associated with one of the prior causes (4 FC, 3UC). 1 case in the FC SEMS group stent dysfunction caused NATX not being completed.

CONCLUSION: No significant difference was observed in rate of successful PBD and timing of reintervention between UC and FC SEMS in resectable or borderline resectable PCA pts undergoing NATX, however the reason for intervention differed between groups. Both types of stents are effective for this indication and selection of stent type should be made on a pt by pt basis.



Reintervention:

- Tumor ingrowth (9 UC)
- Acute cholecystitis (4 FC, 1 UC)
- Migration (4 FC)

Summary:
UC: More ingrowth
FC: Migration/cholecystitis

SELF-EXPANDING METAL STENTS IN MALIGNANT BILIARY OBSTRUCTION – RESULTS FROM A LARGE PROSPECTIVE MULTI-CENTRE CANADIAN REGISTRY

Presentation Number: Sa1345

AuthorBlock: *Gurpal Singh Sandha[1], Andre Roy et al.*

Aim: To document per standard of practice biliary SEMS stent type selection and functionality for malignant biliary obstruction.
Methods: Prospective, open-label study at 12 centers in Canada. Consecutive data was collected for biliary SEMS (WallFlex®, Boston Scientific Corp, Marlborough, MA) in UC, PC and FC versions. SEMS were placed for palliation (Group A) or pre-operative drainage with neoadjuvant therapy (Group B). Outcomes measured were technical success (defined as satisfactory stent deployment), stent functionality (defined as the absence of unscheduled re-intervention after initial placement) and significant adverse events (SAEs: post-ERCP pancreatitis [PEP], cholangitis, cholecystitis, stent migration, stent occlusion and procedure related mortality).
Results: A total of 314 pts (52% male, mean age 69±12 yrs.) were enrolled (260 Group A, 54 Group B). Indications included pancreatic cancer in 166 pts (53%), bile duct cancer in 57 pts (18%), metastatic cancer in 33 pts (11%), ampullary cancer in 20 pts (6%), and other reasons in 38 pts (12%). Technical success was achieved in 312/314 pts (99%). UC SEMS were placed in 163 pts (52%), FC in 111 pts (36%) and PC in 40 pts (13%). Stent functionalitywas observed in 232/258 (90%) for Group A and 46/54 (85%) for Group B. In Group B, 25/43 pts (58%) had curative intent surgery whereas 18/43 pts (42%) transitioned to palliation (data for 11/54 patients is still pending). SAEs were reported in 7/260 (3%) Group A pts [cholangitis in 5 pts (3 UC, 2 FC) and PEP in 2 pts (2 PC)] and none in Group B. There was no procedure-related mortality. Stent migration was seen in 5/111 (5%) FC and none with UC or PC stents. Re-intervention with metal stent placement was performed in 4 pts whereas 1 required no intervention. Stent occlusion was seen in 25/163 (15%) UC, 4/111 (4%) FC and 1/40 (3%) PC requiring re-intervention with stenting in 21/25 UC, 3/4 FC and 1/1 PC stent groups at a mean of 140 days (range 3-342 days) after initial SEMS placement. There were no reported cases of acute cholecystitis.
Conclusions: In this large, multi-centre prospective cohort, FC and UC SEMS performed similarly for patients with malignant biliary obstruction, whether placed for palliation or prior to curative intent surgery. However, the need for re-intervention for occlusion of UC stents appears to be substantially greater than that for migration seen with FC stents.
Funding Agency: Sponsored by Boston Scientific Corporation.

Necrotizing Pancreatitis

- Endoscopic therapy vs minimally invasive surgery
- New necrosectomy device

TIME FOR CHANGING OF GUARD: FROM MINIMALLY INVASIVE SURGERY TO ENDOSCOPIC DRAINAGE FOR MANAGEMENT OF WALLED-OFF PANCREATIC NECROSIS

Presentation Number: Mo1334

AuthorBlock: *Muhammad Ali Khan[1], Michel Kahaleh[4] et al*

Background: About 20% of patients with acute pancreatitis develop necrosis of the pancreatic parenchyma and peripancreatic tissue leading to prolonged course along with a high risk of complications, organ failure and death. Endoscopic drainage (ED) with or without necrosectomy, and minimally invasive surgical necrosectomy (MISN) have been increasingly utilized for treatment of symptomatic sterile and infected walled-off pancreatic necrosis (WON).

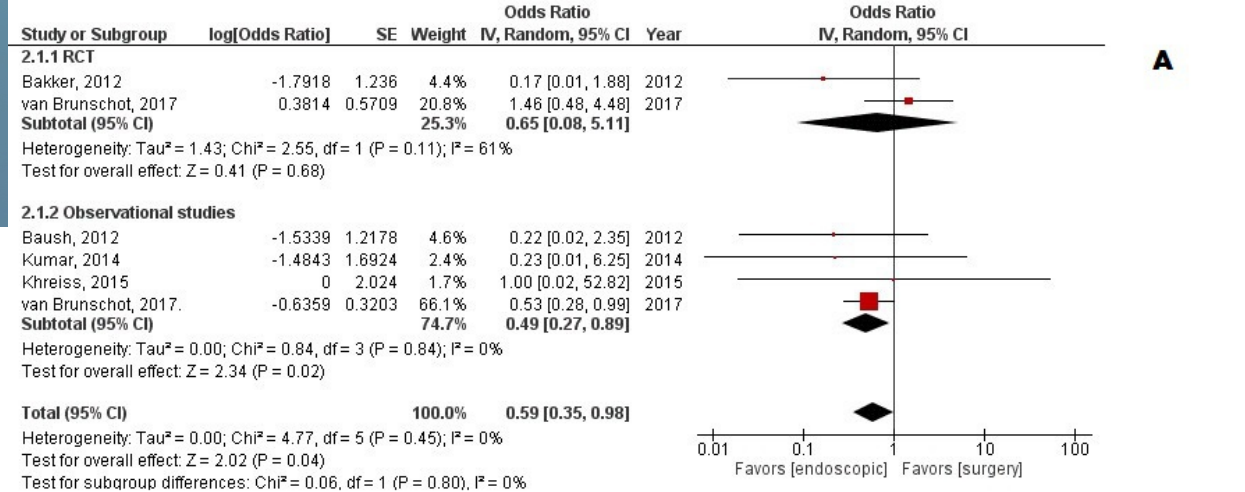
Aims : We conducted this systematic review to compare the safety of ED with MISN for management of WON.

Methods: We searched several databases from inception through November 9, 2017 to identify comparative studies evaluating the safety of ED versus MISN for management of WON. MISN could be done using video-assisted retroperitoneal debridement (VARD) or laparoscopy. Our primary outcome of interest was difference in mortality. Secondary outcomes included major organ failure, adverse events and length of hospital stay. Pooled odds ratios (OR) and mean difference (MD) were calculated for categorical and continuous outcomes, respectively. Subgroup analysis was done based on type of study and type of MISN.

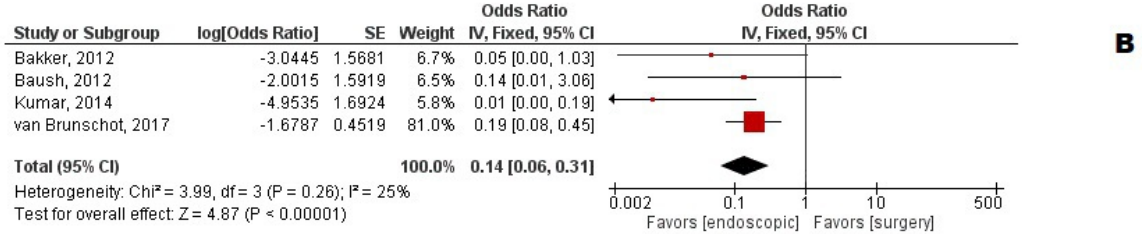
Results: Six studies (2 RCTs & 4 observational studies) with 641 patients (326 ED & 315 MISN) were included in this meta-analysis. Both RCTs had low risk of selection, detection, attrition and reporting biases using Cochrane tool for risk of bias. Three observational studies were rated as high quality and one was rated as moderate quality on Newcastle Ottawa Scale assessment. Rates of mortality for ED and MISN were 8.5% and 14.2%, respectively. Pooled OR with 95% confidence interval (CI) was 0.59 (0.35, 0.98), I^2=0% in favor of ED. On subgroup analysis: no difference in mortality was seen based on RCTs OR 0.65 (0.08, 5.11), while ED had improved survival in observational studies OR 0.49 (0.27, 0.89). No difference in mortality was seen when subgroup analysis was done based on type of surgery i.e. laparoscopy or VARD, OR 0.42 (0.03, 5.32) and 0.60 (0.36, 1.01). Development of new major organ failure rates after interventions were 12% and 54% for ED and MISN, respectively. Pooled OR was 0.12 (0.06, 0.26), I^2=26% in favor of ED. For adverse events, pooled OR was 0.25 (0.10, 0.67), I^2=70% in favor of ED. Data from RCTs were also in favor of ED with pooled OR 0.07 (0.01, 0.85). There was no difference in risk of bleeding, OR 0.68 (0.44, 1.05), while ED was associated with a significantly lower rate of pancreatic fistula formation OR 0.20 (0.11, 0.37), I^2=0%. Length of stay was also lower with ED, pooled MD was -21.07(-36.97, -5.18) days.

Conclusions:When expertise is available, ED is the preferred invasive management strategy over MISN for management of WON as it is associated with lower mortality, risk of major organ failure, adverse events and length of hospital stay.

Mortality



Morbidity



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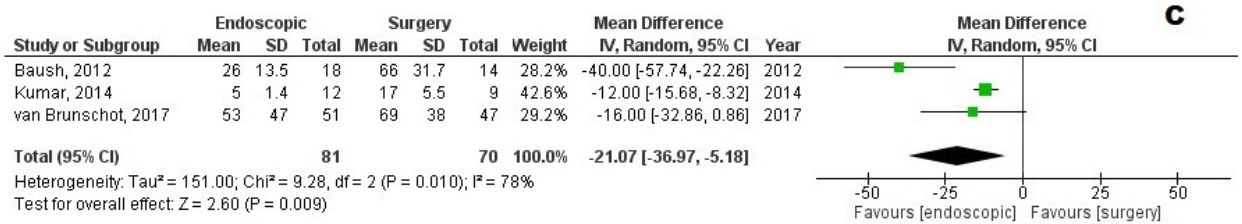

A NOVEL TOOL FOR FAST AND EFFECTIVE ENDOSCOPIC REMOVAL OF PANCREATIC NECROSIS

Presentation Number: Tu1440

AuthorBlock: *Sophia Elisabeth van der Wiel[1], Jan-Werner Poley[1], M.J.A.L. Grubben[1], Marco J. Bruno[1], Arjun D. Koch[1]*
[1]Gastroenterology and Hepatology, Erasmus Medical Center, Rotterdam, Netherlands;

Introduction: Acute pancreatitis may run a severe course when pancreatic necrosis becomes infected. Invasive treatment of these patients is virtually always necessary and over the last decade the treatment has changed dramatically towards less invasive treatments. Endoscopic drainage and ensuing necrosectomy have been shown to be effective in the management of pancreatic necrosis. One of the main limitations during endoscopic management is the lack of dedicated and effective instruments to remove pancreatic necrotic tissue, resulting in time consuming procedures with marginal results and often necessitating multiple procedures. We aimed to evaluate the technical feasibility, safety and clinical outcome of the EndoRotor®, a novel automated mechanical endoscopic resection system to suck, cut and remove small pieces of tissue in patients with necrotizing pancreatitis.
Methods: Subjects with infected walled-off pancreatic necrosis were endoscopically treated using the EndoRotor® device. Procedures were performed under conscious or propofol sedation by four endoscopists with a broad experience in advanced endoscopic procedures including conventional endoscopic necrosectomy. Endoscopists were additionally asked to fill out a short questionnaire about their experience using the EndoRotor®.
Results: Six patients have been endoscopically treated for pancreatic necrosis, five patients were men and the median age was 61.7 years (range 43-71). Imaging data of the pancreas revealed a mean necrotic collection size of 114.7mm diameter (range 50-180mm). Transgastric drainage was performed in all patients, four patients received plastic stents and two a fully covered lumen apposing stent. Three patients were previously treated unsuccessfully with conventional tools with a median of two procedures (range 1-3). Additionally, the EndoRotor® was used in six patients with a total of 16 procedures, the average procedure length was 46.5 minutes (range 32-80). To achieve complete removal of pancreatic necrosis, the median number of required procedures was two per patient (range 1-7). No procedure-related adverse events occurred. Endoscopists agree on the ease of use and effective removal of necrotic tissue with the EndoRotor®, rating both 8.3 on a 10-point scale. They are especially satisfied by the ability to manage the removal of necrotic tissue in a controlled way (8.6 on a 10-point scale). Moreover, they are convinced that this device is of additional value in the management of pancreatic necrosis (8.6) and are willing to use it again (9.3 on a 10-point scale).**Conclusion**: Initial experience with the EndoRotor® suggests that this device can safely, quickly and effectively remove pancreatic necrosis.

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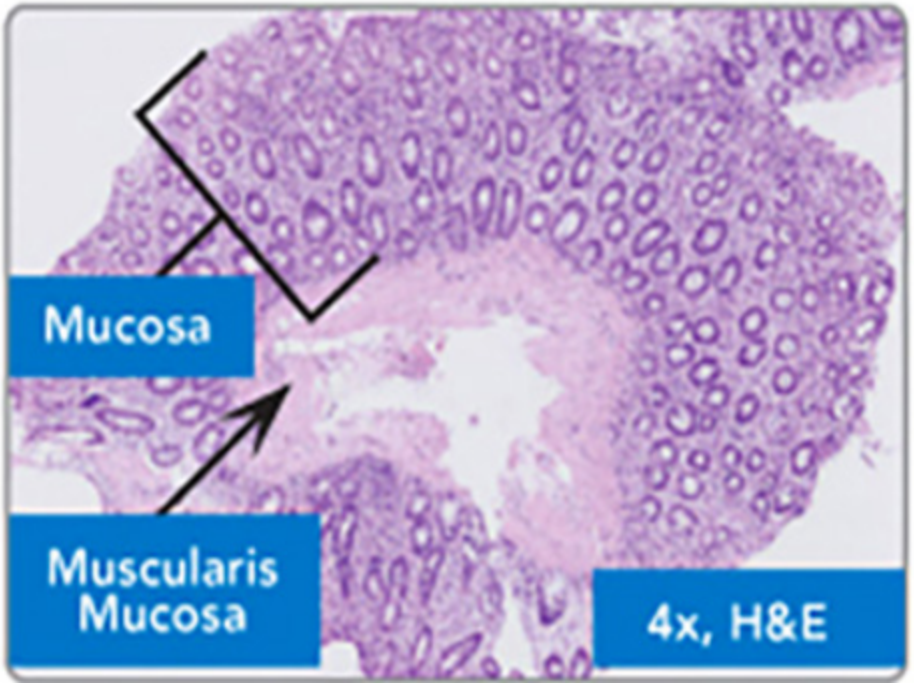
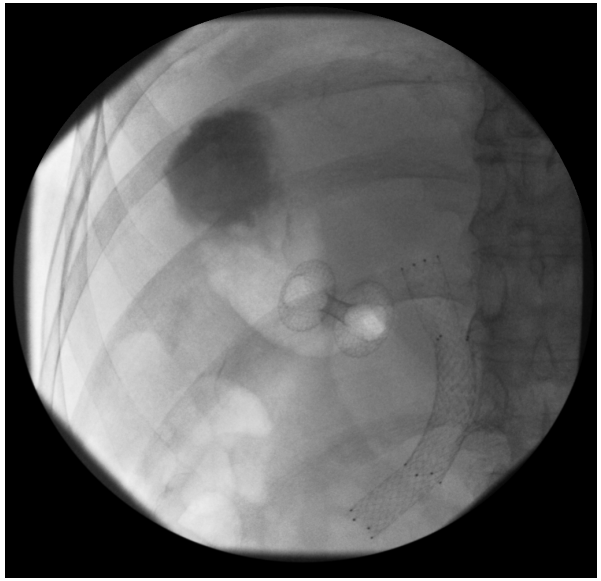


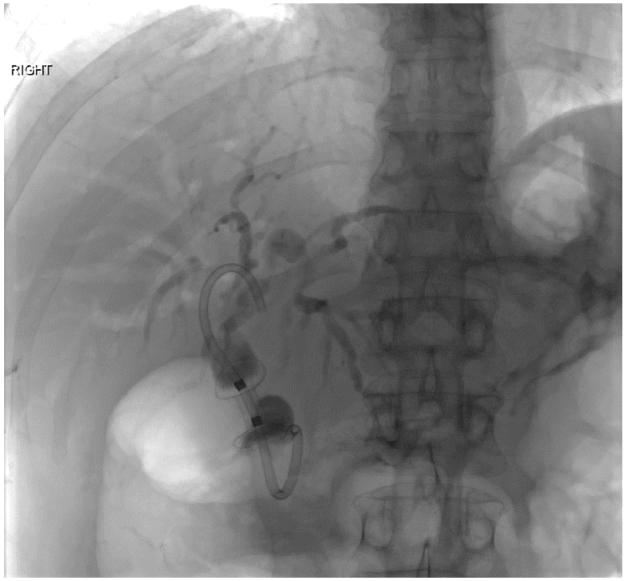
#4 Therapeutic EUS

- Lumen apposing metal stents (LAMS)
  - Bile duct drainage
  - Gallbladder drainage
  - Gastrojejunal Anastomosis
  - Reversal of gastric bypass for ERCP

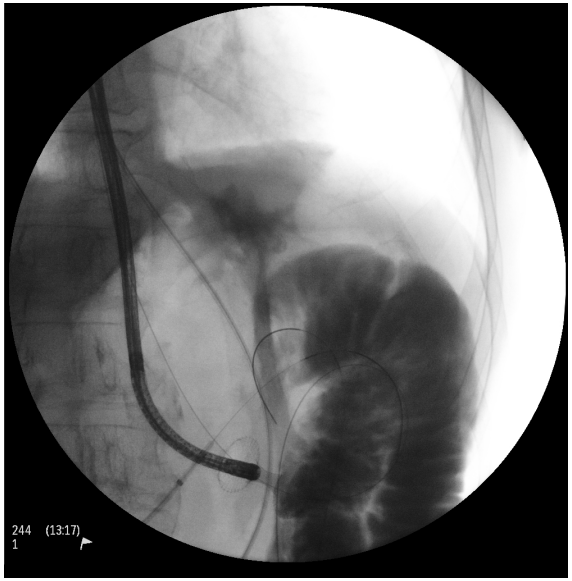
LAMS – Transmural drainage/anastomosis



Gallbladder drainage



Bile duct drainage



Gastro-jejunostomy

EUS-GUIDED TRANSMURAL STENTING VS. CONVENTIONAL ERCP ASSISTED TRANSPAPILLARY STENTING FOR PRIMARY PALLIATION OF MALIGNANT DISTAL BILIARY OBSTRUCTION: A RANDOMIZED CLINICAL TRIAL

Presentation Number: 171

AuthorBlock: Woo Hyun Paik1, Tae Hoon Lee et al

BACKGROUND/AIM: Although ERCP assisted transpapillary stenting for the palliation of malignant biliary obstruction is the standard care, post-procedure pancreatitis and stent dysfunctions are not uncommon. While EUS-guided transmural stenting has garnered interest as a viable alternative when transpapillary stenting is impossible, its role as a primary palliation of malignant distal biliary obstruction is yet to be proven. The aim of this study was to determine whether transmural stenting is comparable to conventional transpapillary stenting in the primary palliation of malignant distal biliary obstruction.

METHODS: A multicenter, randomized, noninferiority trial was conducted at 4 tertiary academic referral centers in South Korea from May 2015 to January 2017; patients were followed up through July 2017. A total of 125 patients with unresectable malignant distal biliary obstruction were included. Participants were randomly assigned to the transmural stenting (n = 64) or transpapillary stenting group (n = 61). We performed random allocation to endoscopic ultrasound-guided transmural or conventional endoscopic transpapillary stenting. Primary outcome was the technical success rates, while the secondary outcomes were the rates of clinical success, adverse events, stent patency, reintervention, and quality of life (QOL).

RESULTS: Technical success rates were 93.8% (60/64) for transmural stenting and 90.2% (55/61) for transpapillary stenting (difference 3.6%, 95% 1-sided confidence interval lower limit -4.4%, P = .003 for noninferiority margin of 10%). Clinical success rates were similar (84.4% vs. 85.2%, P = .89). Lower rates of overall adverse events (6.3% vs 19.7%, P = .03) including the rates of post-procedure pancreatitis (0 vs 14.8%, P = .001), reintervention (15.6% vs. 42.6%, P = .001), and higher rate of stent patency (63.1% vs. 36.5%, P = .001) were observed with transmural stenting at the study end. The transmural stenting was associated with more preserved QOL than transpapillary stenting after 12 weeks of the procedure regrading global (4.17 vs -9.03, P = .001), and parts of functional (emotional, 1.62 vs -9.72, P = .001; cognitive, 0.93 vs -11.11, P = .003) and symptom scale (fatigue, -3.40 vs 8.02, P = .02; pain, -17.59 vs 4.63, P = .01; financial difficulties, 2.78 vs 18.52, P = .01).

CONCLUSIONS: This is the first prospective randomized study reporting comparable success rates between EUS-guided transmural stenting and ERCP assisted transpapillary stenting in relief of malignant distal biliary obstruction. In addition, transmural stenting was associated with fewer adverse events, longer stent patency with a less reintervention rate, and more preserved QOL. (Cris.nih.go.kr number, KCT0001396)

EUS-GUIDED TRANSMURAL STENTING VS. CONVENTIONAL ERCP ASSISTED TRANSPAPILLARY STENTING FOR PRIMARY PALLIATION OF MALIGNANT DISTAL BILIARY OBSTRUCTION: A RANDOMIZED CLINICAL TRIAL

Presentation Number: 171

RCT, 125 pts, transmural stenting (n = 64) or transpapillary stenting group (n = 61)

Transmural vs Transpapillary:

- Technical success 93.8% (60/64) vs 90.2% (55/61)
- Clinical success rates 84.4% vs. 85.2%, P = .89
- Adverse events 6.3% vs 19.7%, P = .03
    - Post-procedure pancreatitis (0 vs 14.8%, P = .001)
    - Reintervention (15.6% vs. 42.6%, P = .001
    - Higher rate of stent patency (63.1% vs. 36.5%, P = .001)
- Better QOL

Comparable success rate and fewer adverse events, longer stent patency with a less reintervention rate, and more preserved QOL

OUTCOMES OF AN INTERNATIONAL MULTI-CENTERED REGISTRY ON EUS-GUIDED GALLBLADDER DRAINAGE IN PATIENTS THAT ARE UNFIT FOR CHOLECYSTECTOMY

Presentation Number: 173

AuthorBlock: *Anthony Y.B. Teoh[1], Manuel Perez-Miranda et al.*

Background: EUS-guided gallbladder drainage (EGBD) is gaining popularity as a means of achieving gallbladder drainage in patients suffering from acute cholecystitis that are unfit for cholecystectomy. However, most of the published studies only included small number of patients using one type of stent with a short follow-up. Hence, the aim of the current study is to review the outcomes of a large scale international registry on EUS-guided gallbladder drainage that encompasses different stent systems.

Methods: This was a retrospective international multi-centred cohort study conducted in 12 institutions. Consecutive patients that received EGBD for symptomatic gallstones, acute cholecystitis or conversion of PC were included. EGBD was performed with a variety of stents including HOT AXIOS (Boston Scientific, Marlborough, USA), SPAXUS (Niti-S, Taewoong Medical, Korea), BONA-AL stent (Standard Sci Tech Inc., Seoul, Korea) and the Microtech stent (Nan Jing Co. Ltd., China). Outcomes reviewed include technical and clinical success, adverse events, mortality, re-interventions rates, recurrence rates and learning curve of the procedure.

Results: Between June 2011 and November 2017, 371 patients were recruited to the study. The mean (S.D.) age was 73.6 (15.1) years old and 51.1% patients were male. The mean (S.D.) age-adjusted Charlson comorbidity index was 5.6 (3.2). The types of stents used were AXIOS (70.1%), SPAXUS (8%) and others (17.7%). The overall technical success and clinical success rates were 92.3% and 88.4% respectively. Unplanned procedural events occurred in 10.6% patients. The mean follow-up duration was 490.9 (542.1) days. The 30-day adverse event rate was 13.5% and 30-day mortality was 9%. The risk of unplanned procedural events was significantly higher in patients that received EGBD performed for symptomatic gallstones and conversion of PC ($P < 0.001$). When comparing between different stent systems, significant differences were noted in endoscopist experience ($P < 0.001$) and 30-day adverse events ($P = 0.026$). The unplanned procedural events ($P = 0.043$), clinical success ($P = 0.037$) and mortality ($P = 0.057$) were significantly worst with experience of less than 25 procedures. On multinominal regression analysis, both endoscopist experience ($P = 0.027$) and clinical success ($P = 0.003$) were predictors to 30-day adverse events, whilst clinical success ($P < 0.001$) was the only significant predictor to mortality.

Conclusion: EGBD was effective for treatment of acute cholecystitis that are at high-risk for cholecystectomy. EGBD done for other indications were technically more difficult. Outcomes of different stent systems were similar. The endoscopist experience is an important parameter to outcomes and the number of cases required to gain competency of the technique is 25 patients.

Table 1. The predictors to 30-day adverse events by multinominal regression analysis

	Multinominal analysis	
Parameter	P value	RR (95% CI)
Age >75	0.75	1.15 (0.48 – 2.74)
Sex = M	0.54	1.3 (0.58 – 2.80)
ASA grading	0.84	1.31 (0.10 – 17.21)
Age-adjusted charlson comorbidity index > 6	0.53	0.76 (0.32 – 1.80)
Indications for EGBD	0.31	1.87 (0.56 – 6.25)
Technical success	0.41	1.93 (0.40 – 9.30)
Clinical success	0.003*	0.18 (0.58 – 0.55)
Unplanned procedural events	0.83	1.14 (0.36 – 3.62)
Endoscopist experience < 25	0.027*	6.2 (1.22 – 31.00)

EUS-GUIDED GASTROJEJUNOSTOMY WITH LUMEN APPOSING METAL STENT VERSUS ENTERAL STENT PLACEMENT FOR PALLIATION OF MALIGNANT GASTRIC OUTLET OBSTRUCTION

Presentation Number: 68

AuthorBlock: *Phillip Ge[1], Joyce Y. Young[1], William Dong[1], Christopher C. Thompson[1]*

Background: Enteral stent placement is commonly performed for palliation of obstructive symptoms caused by malignant gastric outlet obstruction (GOO). EUS-guided gastrojejunostomy (EUS-GJ) with placement of a lumen-apposing metal stent (LAMS) is a novel procedure that may offer long lasting patency with fewer incidence of stent failure, however there is limited data comparing EUS-GJ to enteral stent placement.

Aim: To compare clinical outcomes and adverse events between EUS-GJ and enteral stent placement in the endoscopic palliation of malignant GOO.

Methods: A prospectively collected university health care system registry was queried for LAMS, enteral stents, and GOO, and a retrospective analysis was performed. Patients who underwent EUS-GJ and enteral stent placement for the palliation of malignant GOO from 2014-2017 were included. Patients with benign GOO, gastroparesis, or surgically altered anatomy were excluded. Demographics, procedural and technical characteristics, and relevant clinical outcomes were recorded. Adverse events were assessed. Characteristics and clinical outcomes were compared using Fisher's exact test and Student's *t* test when appropriate.

Results: A total of 100 consecutive patients who underwent endoscopic palliation of malignant GOO during the study period were analyzed, of which 78 patients underwent enteral stent placement, and and 22 patients underwent EUS-GJ. Mean age was 65.9 ± 11.9 years, and 44.0% of patients were female. A total of 121 stents were placed, including 24 LAMS in the EUS-GJ group and 97 uncovered self expanding metal stents in the enteral stent group. When comparing EUS-GJ and enteral stent cases, technical success was achieved in 100% in both groups, however higher clinical success was attained in the EUS-GJ group compared to enteral stent group (91.7% vs 69.1%, p= 0.036). Mean length of hospital stay following stent placement was similar between the two groups (p = 0.821). The rate of stent failure requiring repeat intervention was significantly higher in the enteral stent group (31.6% vs 8.0%, p = 0.021). The enteral stent group had greater number of adverse events (40.2% vs 20.8%, p = 0.098) and incidence of stent ingrowth (16.5% vs 4.2%, p = 0.189), however this did not reach statistical significance. Misdeployment resulting in perforation occurred in two cases of EUS-GJ, however both cases were managed endoscopically with subsequent successful LAMS deployment in the same session, and neither case required surgery.

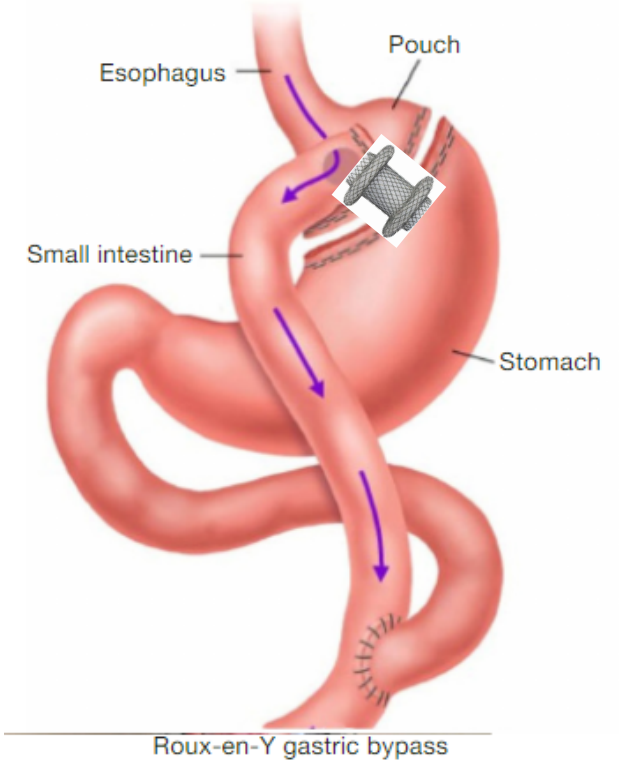
Conclusions: When compared to enteral stent placement, EUS-GJ has higher rate of initial clinical success and lower rate of stent failure requiring repeat intervention. EUS-GJ should be offered as a minimally invasive alternative for selected patients with malignant GOO in centers with extensive experience.

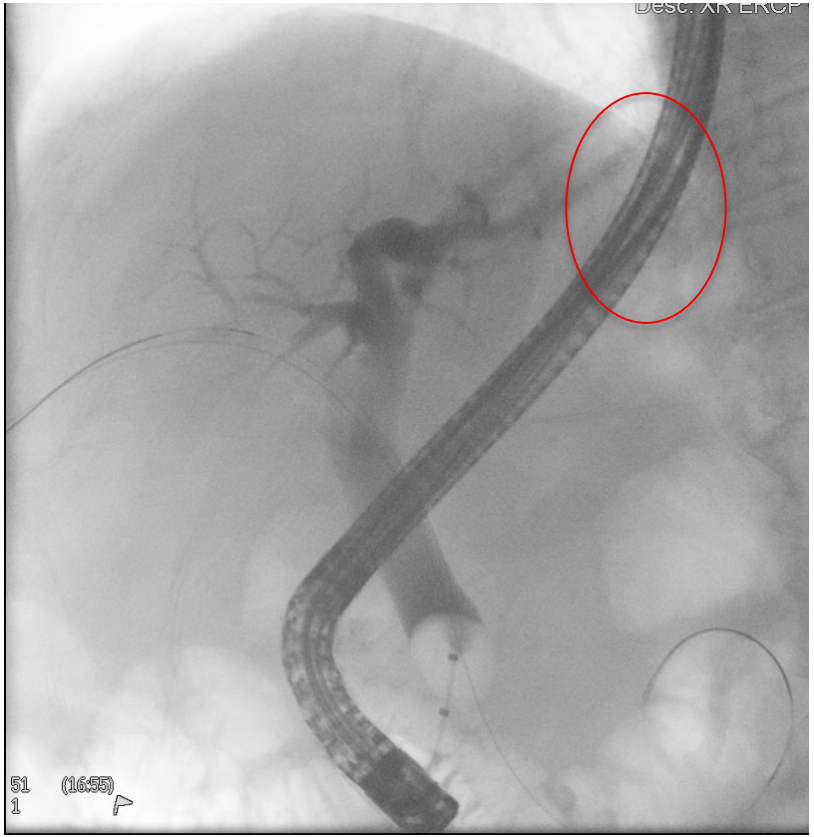
EUS-GUIDED GASTROJEJUNOSTOMY WITH LUMEN APPOSING METAL STENT VERSUS ENTERAL STENT PLACEMENT FOR PALLIATION OF MALIGNANT GASTRIC OUTLET OBSTRUCTION

Presentation Number: 68

	EUS-GJ (n, %)	Enteral Stent (n, %)	p value
Patients	22 (22.0)	78 (78.0)	---
Stents Placed	24 (19.8)	97 (80.2)	---
Technical Success	24 (100.0)	97 (100.0)	1.000
Clinical Success	22 (91.7)	67 (69.1)	0.036
Length of Hospital Stay Following Stent Placement (± SD, days)	7.4 (9.1)	7.9 (8.2)	0.821
Stent Failure Requiring Re-Intervention	2 (8.0)	31 (31.6)	0.021
Time to Re-Intervention (± SD, days)	128 (157.0)	99.2 (166.5)	0.812
Total Adverse Events	5 (20.8)	39 (40.2)	0.098
Stent Ingrowth	1 (4.2)	16 (16.5)	0.189
Stent Obstruction (not including ingrowth)	0 (0.0)	7 (7.2)	0.342
Stent Migration	0 (0.0)	2 (2.1)	1.000

LAMS in RYGB


Esophagus
Pouch
Small intestine
Stomach
Roux-en-Y gastric bypass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IMPACT OF EUS-DIRECTED TRANSGASTRIC ERCP (EDGE PROCEDURE) ACCESS ROUTE ON TECHNICAL SUCCESS AND ADVERSE EVENTS: A MULTI-CENTER EXPERIENCE

Presentation Number: 338

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Background: Endoscopic ultrasound (EUS) directed transgastric ERCP (EDGE) is an alternative method of accessing the remnant stomach to perform transpapillary ERCP in patients with Roux-en-Y gastric bypass. In EDGE, the distal flange of a lumen-apposing metal stent (LAMS) is placed in the remnant stomach and the proximal flange theoretically in the gastric pouch. Due to anatomic considerations, better visualization of the remnant stomach may lead to inadvertent or volitional transjejunal LAMS deployment. LAMS access route and its potential effects on adverse outcomes have not been studied. We hypothesize that increased fibrosis, distance between apposed lumens, and neo-vascularity may be encountered with the transgastric approach could impact visualization and adverse events as compared to the transjejunal approach.

Aim: To determine whether complications differed between transjejunal or transgastric access route of LAMS deployment. Secondary outcome was to identify predictors for technical success and adverse events in patients undergoing EDGE.

Methods: Patients who underwent EDGE for various indications between December 2014 and November 2017 at 7 academic centers were included in a retrospective database. Demographic, procedural, and outcomes data were recorded. Transjejunal approach included proximal flange deployment of the LAMS in the blind or efferent jejunal limb. Fisher's exact test was used to compare complications at placement between transgastric and transjejunal LAMS access routes. Logistic regression was then used to determine independent predictors for technical success and adverse events.

Results: A total of 66 patients underwent EDGE. All had wire-guided placement of LAMS of 15mm diameter. Transgastric and transjejunal access routes via the blind or efferent limb were used in 45.5%, 35.8%, and 16.7% of patients, respectively. Technical success was achieved in 92% of patients. At placement, 13 complications were noted including bleeding (7.6%), LAMS malposition (4.5%), LAMS migration (4.5%), perforation (1.5%), and pancreatitis (1.5%). Ten out of 13 complications occurred after using transgastric access. A significant difference was observed between transgastric vs. transjejunal approaches (combined blind limb and efferent limb) for complications during placement (15.2% vs. 4.5% respectively, p=0.027). On multivariate regression adjusting for co-variates, access route was not found to be a significant predictor for technical success or complications at time of LAMS placement (both p>0.05).

Conclusion: The EDGE procedure via transjejunal access is safe, and in this retrospective study may be possibly associated with fewer complications than transgastric LAMS placement. Access route should therefore be guided by optimal visualization of the remnant stomach rather than predetermined location of stent delivery.

EDGE: Transgastric vs Transjejunal for ERCP

Aim:

- Complications between transjejunal (TJ) or transgastric (TG) access route of LAMS deployment.
- Secondary outcomes: Technical success and adverse events.

Methods:

- December 2014 and November 2017 at 7 academic centers were included in a retrospective database.

Results:

- 66 pts, 15 mm LAMS, TG and TJ (via blind or efferent limb): 45.5% vs 54.5% respectively, technical success: 92%
- 13 complications - bleeding (7.6%), LAMS malposition (4.5%), LAMS migration (4.5%), perforation (1.5%)
- 10/13 complications using transgastric access.
- TG vs. TJ complications, **15.2% vs. 4.5% respectively, p=0.027**.
- Multivariate regression adjusting for co-variates, no difference technical success or complications (both $p>0.05$)

Conclusion:

- EDGE procedure via TJ is safe, possibly associated with fewer complications than transgastric LAMS placement

COST UTILITY ANALYSIS OF ENDOSCOPIC APPROACHES TO ERCP IN GASTRIC BYPASS ANATOMY: ERCP VIA LUMEN-APPOSING METAL STENT SHOULD BE THE INITIAL CHOICE

Presentation Number: Su1364

AuthorBlock: *Thomas Wang[1], Christopher C. Thompson[1], Marvin Ryou[1],* Brigham & Women's Hospital, Boston, Massachusetts, United States

Background

Performing ERCP in patients with Roux-en-Y gastric bypass (RYGB) anatomy is often difficult. Historical options include device-assisted enteroscopy (DAE), which has up to a 50 % reported failure rate, and surgically-assisted transgastric access, which is more invasive, logistically demanding, and often used to rescue failed DAE. Recently, a new endoscopic approach has been described (EUS-Guided transGastric ERCP [EDGE] or Gastric Access Temporary for Endoscopy [GATE]) which involves EUS-guided placement of a lumen apposing metal stent (LAMS) to temporarily re-establish foregut continuity and allow passage of a duodenoscope.

Aim

To compare costs of two endoscopic approaches to ERCP (DAE versus GATE) in patients with RYGB anatomy, including the costs of surgically-assisted transgastric ERCP for failed endoscopic cases

Methods

This was a retrospective chart review of 22 post-RYGB patients who underwent ERCP at a single tertiary referral center during 2012-2017. We developed a cost analysis model to measure and compare costs associated with DAE and GATE, accounting for established failure rates. The model consists of Time-Driven Activity Based Costing (TDABC), a highly validated cost analysis tool within the literature for medical procedures that accounts for both human and material resources, and facility costs estimated from institutional billing information, Medicare reimbursement rates, and expert opinion. Post-operative stay and revision procedures are included.

Results

A total of 27 ERCP cases were analyzed. 12 patients started with DAE, and 10 patients started with GATE. Procedural success (defined by cannulation) was achieved in 7/12 (58%) DAE versus 10/10 (100%) GATE patients ($p<0.001$). The 5 failed DAE patients subsequently underwent successful surgically-assisted ERCP (5/5, 100% successful). **[FIG 1]**

The cumulative costs of successful DAE and GATE procedures, including peri-operative care, totaled $7188.78 ±1455.34 and $13,210.04±966.34 respectively (Δ= -$6021.26, $p<0.0001$). Average procedural time was 148.2±50.1 min for DAE and 164.7±16.2 min for GATE ($p=0.33$). GATE procedures required between 1-3 revisions (mean 1.8) post-procedure, which on average took 50.1±30.5 min per revision.

When taking into account failure rates for DAE, cumulative costs totaled $16937.60±2073.20 ($\Delta$= +$3727.56 when compared to GATE, which exhibited no failures in our cohort, $p<0.0001$). To reach the same cumulative cost for DAE, failure rates for GATE would have to reach 20.3%.

Conclusion:

In centers with expertise in LAMS placement, Gastric Access Temporary for Endoscopy (GATE) should be considered the preferred endoscopic approach to ERCP. In our experience GATE had a significantly lower failure rate (0%) than DAE (42%). The failure rate of GATE would have to reach 20.3% to consider both endoscopic techniques as cost equivalent.

Cost comparison of device assisted enteroscopy (aka balloon enteroscopy) vs EGDE (aka GATE)

Aim

- Compare costs of ERCP (DAE vs GATE), including the costs of surgically-assisted transgastric ERCP for failures

Methods

- 22 post-RYGB pts, single tertiary referral center, 2012-2017
- Cost analysis model, Time-Driven Activity Based Costing (TDABC) – validated tool human/material, facility costs, Medicare reimbursement, post-op stay and revision procedures are included

Results

- 27 cases, Procedural success (defined by cannulation)
- **DAE: 7/12 (58%) vs 10/10 (100%) GATE pts (p<0.001)**, 5/5 (100%) DAE had successful surgical access
  DAE vs GATE costs: **$7188.78** ±1455.34 vs $**13,210.04**±966.34 respectively (**Δ= -$6021.26, p<0.0001**)
- Cumulative costs for **DAE $16937.60±2073.20** (Δ= +$3727.5, p<0.0001).

Conclusion:

- GATE significantly lower failure rate (0%) than DAE (42%)
- To reach the same cumulative cost for DAE, failure rates for GATE would have to reach 20.3%.
- In centers with expertise in LAMS placement, GATE should be considered the preferred endoscopic approach to ERCP

Summary

- EUS-FNB – first line approach for tissue acquisition and has a potential role for liver biopsy
- ERCP – early fistulotomy access, early in acute cholangitis, cholangioscopy for difficult CBD stones and early for pancreatic stones, metal stents (tissue ingrowth vs migration/cholecystitis)
- Necrotizing pancreaititis – endotherapy, possibley an endoscopic tool that works?
- LAMS – Transmural drainage/bowel anastomosis/access in RYGB

"Now, keep in mind that these numbers are only as accurate as the fictitious data, ludicrous assumptions and wishful thinking they're based upon!"

Sp***H***incterotomy for ***A***cute ***R***ecurrent ***P***ancreatitis
SHARP Trial

- Obstruction at the level of minor papilla is one cause of RAP in pancreas divisum
- Minor papilla endoscopic sphincterotomy (miES) will relieve the obstruction, thereby reducing the risk of a recurrent attack of acute pancreatitis.
- NIH funded RCT, miES vs sham procedure to evaluate response (recurrence of pancreatitis) and disease progession

SpHincterotomy for Acute Recurrent Pancreatitis
SHARP Trial

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4	University of Alabama-Birmingham, Birmingham, AB	Wilcox, CM
5	Methodist Health System, Dallas, TX	Tarnasky, P
6	University of Manitoba, Winnipeg, Canada	Moffatt, D
7	Dartmouth School of Medicine, Hanover, NH	Gardner, T
8	Indiana University School of Medicine, Indianapolis, IN	Fogel, E
9	University of Missouri – Kansas City, Kansas City, MO	Jonnalagadda, S
10	Virginia Mason Medical Center, Seattle, Washington	Ross, A
11	Royal Wolverhampton NHS Trust, Wolverhampton, United Kingdom	Menon, S
12	University of Southern California, Los Angeles, CA	Buxbaum, J
13	Ohio State University, Columbus, OH	Conwell, D
14	University of Virginia, Charlottesville, VA	Wang, A
15	Northwestern University, Chicago, IL	Keswani, R
16	University of California – SF, – San Francisco, CA	Arain, M
17	Radboud University, The Netherlands	Van Geenan, E