DDW Update 2016: Endoscopic Ultrasound

June 2016 Walt Coyle

No Disclosures to Declare

Review of topics

- Treatment of pancreatic fluid collections:
 - Plastic, SEMS, or LAMS???
- Acquiring Pancreas Tissue
 - FNA, FNB and Next Gen Sequencing
- Portal Vein Access by EUS
 - Delivery of chemotherapy
 - Detection of Circulating tumor cells
 - Portal pressure measurement
- LAMS: Any space and any fluid? (? Time)

ORIGINAL ARTICLE

Classification of acute pancreatitis—2012: revision of the Atlanta classification and definitions by international consensus

Peter A Banks,¹ Thomas L Bollen,² Christos Dervenis,³ Hein G Gooszen,⁴ Colin D Johnson,⁵ Michael G Sarr,⁶ Gregory G Tsiotos,⁷ Santhi Swaroop Vege,⁸ Acute Pancreatitis Classification Working Group

- Update of the 1992 classification
- Defined early and late phases
- Described the different fluid collections resulting from pancreatitis

Gut 2013;62:102–111

Revised Atlanta Classification

Acute Peripancreatic Collection

- < 4 weeks</p>
- In interstitial pancreatitis
- Homogeneous fluid density
- No fully definable wall
- Adjacent to pancreas
- Confined by normal fascial planes

Pseudocyst

- > 4 weeks
- In interstitial pancreatitis
- Homogeneous fluid density
- Well defined wall
- Adjacent to pancreas
- No non-liquid component

Acute Necrotic Collection

- < 4 weeks</p>
- In necrotizing pancreatitis
- Heterogeneous collection
- No fully definable wall
- Intra- or extrapancreatic

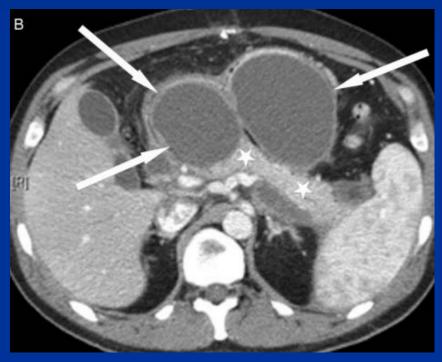
Walled-off Necrosis

- > 4 weeks
- In necrotizing pancreatitis
- Heterogeneous collection
- Well-defined wall
- Intra- or extrapancreatic

Two different fluid collections

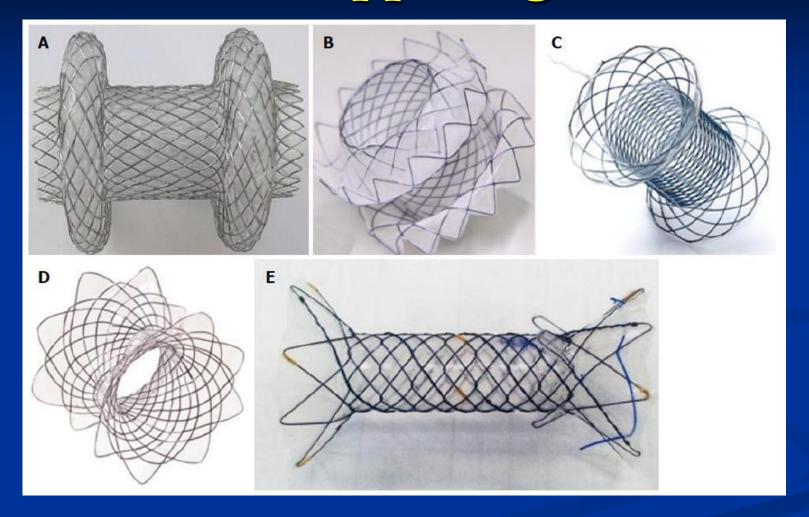
Pseudocyst

WOPN





LAMS: Lumen apposing metal stents



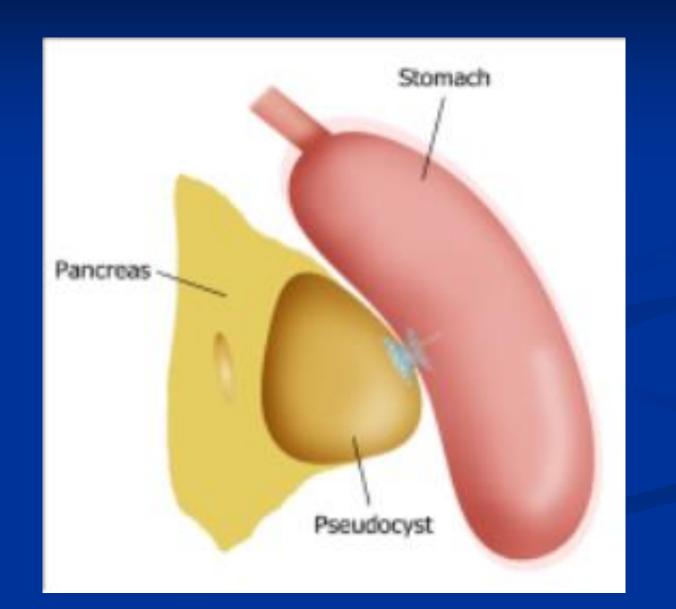
A. Axios, B. Spaxus, C. Nagi, D. Aix, E. BCF

LAMS: Lumen apposing metal stents

Table 5 Technical characteristics of the lumen apposing metal stents

Producer	Model	Internal diameter (mm)	Length (mm)	Flange diameter (mm)
Boston Scientific	Axios	10, 15	10	21, 24
Leufen Medical	Aix	10, 14	20	14/16, 18/20
M.I. Tech	Hanarostent BCF	10, 12	30, 40	25
TaeWoong Medical	Spaxus	8, 10, 16	20	25
TaeWoong Medical	Nagi	10, 12, 14, 16	10, 20, 30	22, 24, 26, 28

World J Gastrointest Endosc. Feb 10, 2016; 8(3): 143-156 Published online Feb 10, 2016. doi: 10.4253/wjge.v8.i3.143



Lumen Apposing Metal Stents in Pancreatic Fluid Collections: An International, Multicenter Experience



Presentation Number: 880

Author Block: Nikhil A. Kumta¹, Amy Tyberg¹, Ali A. Siddiqui², Thomas E. Kowalski², David E. Loren², Amit P. Desai¹, Alex M. Sarkisian¹, Elizabeth Brown¹, Kunal Karia¹, Monica Gaidhane¹, Laura Isby¹, Prashant Kedia³, Paul R. Tarnasky³, Umangi Patel³, Douglas Adler⁴, Linda J. Taylor⁴, Maria Petrone⁵, Patrick S. Yachimski⁶, Pierre H. Deprez⁷, Christina Mouradides⁷, Sammy Ho⁸, Safeera Javed⁸, Jeffrey J. Easler⁹, Isaac Raijman¹⁰, Enrique Vazquez-Sequeiros¹¹, Mandeep Sawhney¹², Tyler M. Berzin¹², Reem Z. Sharaiha¹, Michel Kahaleh¹ Gastroenterology, New York Presbyterian Hospital - Weill Cornell Medicine, New York, New York, United States; ¹⁰ St. Luke's Episcopal Hospital, Houston, Texas, United States; ¹¹ Hospital Universitario Ramón y Cajal, Madrid, Spain; ¹² BIDMC, Boston, Massachusetts, United States; ² Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, United States; ³ Methodist Dallas Medical Center, Dallas, Texas, United States; ⁴ University of Utah School of Medicine, Salt Lake City, Utah, United States; ⁵ San Raffaele Scientific Institute, Milan, Italy; ⁶ Vanderbilt University Medical Center, Nashville, Tennessee, United States; ⁷ Saint Luc Clinics, Brussels, Belgium; ⁸ Montefiore Medical Center, NEW YORK, New York, United States; ⁹ Indiana University School of Medicine, Indianapolis, Indiana, United States

- Retrospective, prosp database 2011-15
- Tech Success: stent deployment
- Clin Success: complete resolution in 3 months
- All AEs documented
- 192 patients, mean f/u 4.2 months

LAMS for PFCs

- Technical success: 189/192 patients (98.4%)
- Clinical success: 125/135 patients (92.6%)
 - ? other 37 patients (125/192= 65%)
- WOPN: *H2O2*-assisted necrosectomy (7) and nasocystic irrigation (28)
- AEs: bleeding (11, 5.7%) 3 with IR Rx, infection (n=2, 1%), perforation (n=2, 1%), managed endoscopically. No deaths
- Only RF for AEs: # of sessions

LAMS in PFCs

Lumen Apposing Metal Stents in Pancreatic Fluid Collections

Predictors of Adverse Events				
	OR	p-value		
PFC resolution	2.5 (0.41-15.4)	0.231		
Number of sessions	1.4 (1.14-1.81)	0.002		
Age	1.0 (0.96-1.04)	0.80		
Sex	2.1 (0.42-10.2)	0.36		
PFC length	0.9 (0.98-1.01)	0.71		

LAMS for PFCs

Conclusions: LAMS represent promising technology for drainage of pancreatic fluid collections and WOPN

Coyle Comments: Mix of PC and WOPN, large # of patients not accounted for in abstract. Many of the complications are major: perforation and bleeding.

Fully Covered Self-Expanding Metal Stents Versus Lumen-Apposing Fully Covered Self-Expanding Metal Stent Versus Plastic Stents for Endoscopic Drainage of Pancreatic Walled-off Necrosis: Clinical Outcomes and Success

View Session Detail

Presentation Number: 272

Author Block: Ali A. Siddiqui¹, Thomas E. Kowalski¹, David E. Loren¹, Ammara Khalid¹, Ayesha Soomro¹, Syed M. Mazhar¹, Laura Isby², Michel Kahaleh², Kunal Karia², Joseph Yoo¹, Andrew Ofosu¹, Beverly Ng¹, Reem Z. Sharaiha²

- Consec patients at 3 centers with WOPN
- Compared FCSEMS, LAMS, DP
- Evaluated for tech and clinical success (6 m)
- Assess for AEs
- 313 pts: 121-FCSEMS, 86-LAMS, 106-DP

¹ Gastroenterology, Thomas Jefferson University, Philadelphia, Pennsylvania, United States; ² Weil Cornell University, New York, New York, United States

Which Stent is Best?

- 76% women, etiology similar (GS and EtOH)
- Mean size: 102 mm (20mm-510)
- Mean # sessions: 2.5 (1-13)
- Tech success: 99% all groups
- □ Clinical success: 89.6% (95 vs 90 vs 81 P=.001)
- AEs: SEMS-1.6% vs LAMS-9.3% vs PS-7.5%)
 - P <.01 Most early AEs were in LAMS group
- # Sessions: SEMS-3.0,LAMS-2.2, PS-3.6 P=.04

Which Stent is Best?

Predictors for success	Odds Ratio (95% CI)	P value
Stent type FCSEMS	Ref	
LAMS Plastic	0.43 (0.13-1.44) 0.18 (0.06-0.53)	0.18 0.002
Age	0.99 (0.97-1.01)	0.65
Sex	1.5 (0.67-3.54)	0.31
WON Size (mm)	0.99 (0.99-1.01)	0.81
Procedure Adverse Events	2.2 (0.48-10.1)	0.31

Early AEs: 27 patients (8.6%)

6-perforation

8-bleeding

9-suprainfection

7-other

Which Stent is Best?

Conclusion: For WOPN, both metal stents have a higher clinical success. FCSEMS has less AEs but LAMS requires less sessions

Coyle Comments: Not randomized, for WOPN larger stents with easier access makes sense, bleeding and migration with LAMS needs to be better defined

Treatment of PC and WOPN

- Individualize treatment: PC vs WOPN
- DPPS safe and less \$\$ for PC
- WOPN: major undertaking, timing critical
 - ? SEMS vs LAMS
 - Long term relationship with patient
 - Multidisciplinary team
 - Be prepared for complications
 - More info on timing, stent removal, late bleeding
 - Need rand, prospective trials

Malignant Gastric Outlet Obstruction

SEMS

LAMS

Lap gastro-jejunostomy

EUS-Guided Gastroenterostomy Is Comparable to Enteral Stenting in Terms of Technical Feasibility and Clinical Success With Lower Rates of Reintervention: A Multicenter Comparative Study

to.

View Session Detail

Presentation Number: 714

Author Block: Mouen A. Khashab¹, Yen-I Chen¹, Yamile Haito Chavez¹, Todd H. Baron², Ian S. Grimm², Jose Nieto⁴, Saowanee Ngamruengphong¹, Majidah Bukhari¹, Gulara Hajiyeva¹, Amr Ismail¹, Vivek Kumbhari¹, Ahmad S. Alawad¹, Takao Itoi³

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- Malignant gastric outlet obstruction common with gastric cancer and panc CA (up to 15%)
- Enteral stenting (ES): effective
- EUS created gastroentero (EUS-GE): LAMS
- EUS-GE: Direct, balloon assisted, Double balloon
- Retrospective, MC comparison of ES to EUS-GE

Double Balloon Method of EUS-GE



ES vs EUS-GE

- 4 centers (3 US/1 Asia): 2008-2015
- 90 subjects: 60 had ES and 30 had EUS-GE
 - Demographics and Dx similar
 - Length of f/u similar (105-108 days)
- <u>Tech Success</u>: 96.7% ES vs. 86.7% EUS-GE, p=0.07
- □ Clin Success: 70.0% ES vs. 86.7% EUS-GE, p=0.08
- Reintervention rate higher with ES
 - 43.3% vs. 3.4%, OR 21.4, p<0.001
 - Tumor ingrowth, food, distended bowel

ES vs EUS-GE

- AEs: ES group: 18.3% p=0.5
 - 5 perforation, 4 cholangitis, and 2 stent malposition
- AEs: EUS-GE: 13.3%
 - Missed deployment or abdominal pain
- After confounding variables controlled
 - Need for reintervention (OR 25.7, p=0.004)

ES vs EUS-GE

Conclusion: ES and EUS-GE comparable for malignant GOO. Reintervention much higher with ES in this study.

Coyle Comments: Initial Cost \$\$, the 43% reintervention rate very high (makes ES more costly), prospective data needed especially with new enteral stent technology (2008-11 vs 2013-2015)



View Session Detail

Presentation Number: 876

Author Block: Manuel Perez-Miranda², Amy Tyberg¹, Reem Z. Sharaiha¹, Ernesto Toscano², Monica Gaidhane¹, Amit P. Desai¹, Nikhil A. Kumta¹, Jose Nieto¹, Marc Barthet⁴, Raj Shah³, Brian C. Brauer³, Michel Kahaleh¹

¹ Division of Gastroenterology and Hepatology, Weill Cornell Medical College, New York, New York, United States; ² Gastroenterology, Valladolid Hospital, Valladolid, Spain; ³ Gastroenterology, Denver, Denver, Colorado, United States; ⁴ Gastroenterology, MArseille University, Marseille, France

- Retrospective comparison EUS-GJ vs Lap=GJ
- 54 pts: 25 vs 29 pts
- Length of stay similar
- Tech and clin success evaluated
- No cost analysis
- See Graph

EUS-GJ vs Lap-GJ

EUS guided Gastrojejunostomy versus Laparoscopic Gastrojejunostomy

	EUS-GJ	Lap-GJ	p Value
Number of patients	25	29	
Sex (M)	11	22	
Malignant GOO	17 (68%)	29 (100%)	
Symptomatic GOO	25 (100%)	10 (34%)	
Altered Anatomy	7(28%)	0	p=0.06
Technical Success	23 (88%)	29 (100%)	
*Conversion to open		2 (7%)	
*Stent Dislodgement	9(36%)		
	*6 successfully salvaged with bridging stent		
	*3 unsalvaged		
Clinical Success	21 (84%)	28 (90%)	p=0.11
Adverse Events	3 (12%)	12 (41%)	p=0.03

EUS-GJ vs Lap-GJ

EUS-GJ is a safe and efficacious, minimally invasive option for patients with GOO

Coyle Comments: Not randomized or controlled, few patients in EUS-GJ arm not accounted for, need prospective study but EUS-GJ may be the best choice in some patients (but stent vs EUS-GJ???)

EUS Tissue Acquisition







Original article

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A meta-analysis comparing ProCore and standard fine-needle aspiration needles for endoscopic ultrasound-guided tissue acquisition

Ji Young Bang¹, Robert Hawes², Shyam Varadarajulu²

- Systematic analysis of all studies with ProCore
- 576 subjects from nine studies
- No difference in dx accuracy, quality of tissue
- Less passes required for ProCore

Endoscopy 2016; 48(04): 339-349

EUS Tissue Acquisition

- Over a dozen studies of tissue acquisition
 - New needles, comparison of FNA to FNB
 - Use of Rapid Onsite Evaluation (ROSE) or not
 - Many retrospective and small numbers
 - These small studies suggest core biopsy needles are superior to FNA needles for amount of tissue obtained
 - Slightly more AEs, bleeding and pancreatitis

Two Prospective Needle Studies

FNA vs FNB (Su1985)

- 3 passes each needle
- No ROSE, 89 patients
- Overall yield:
 - 76% FNB vs 61% FNA
- Panc Mass: 85% vs 69%
- Both slightly significant
- One pancreatitis
- FNB superior to FNA

FNA vs FNB (Mo2072)

- 2 passes each needle
- ROSE; 23 patients
- Overall yield:
 - 95% FNA vs 78% FNB
- No difference in cellularity
- No AEs reported
- FNA in experienced hands superior to FNB
- ROSE is important



- Tissue acquisition will move from dx alone
- Now need dx AND adequate tissue for DNA sequencing of tumor
- Directed and personalized chemo and immunotherapy is here
- Will be especially important in pancreas cancer
 - Survival remains poor
 - Many tumors resistant to standard therapy



日本語要約

Virtual microdissection identifies distinct tumor- and stroma-specific subtypes of pancreatic ductal adenocarcinoma

Richard A Moffitt, Raoud Marayati, Elizabeth L Flate, Keith E Volmar, S Gabriela Herrera Loeza, Katherine A Hoadley, Naim U Rashid, Lindsay A Williams, Samuel C Eaton, Alexander H Chung, Jadwiga K Smyla, Judy M Anderson, Hong Jin Kim, David J Bentrem, Mark S Talamonti, Christine A Iacobuzio-Donahue, Michael A Hollingsworth & Jen Jen Yeh

Affiliations | Contributions | Corresponding author

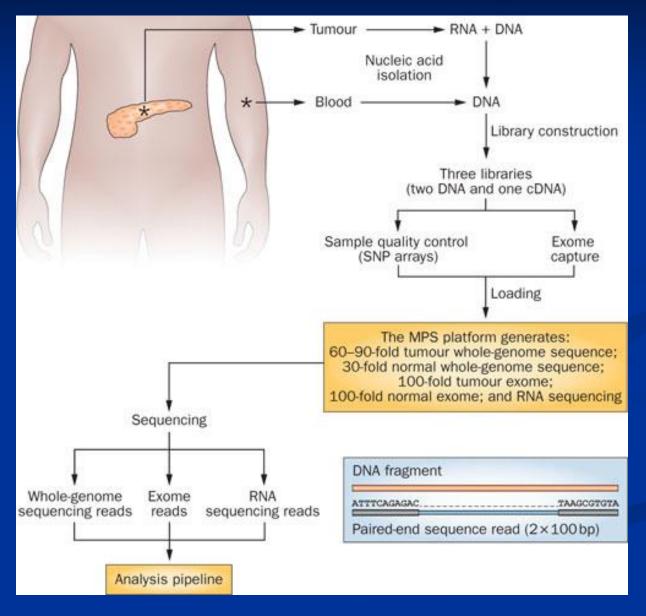
- Describe four subtypes of pancreatic cancer
- May open avenues for treatment in future

Some key pancreatic tumors genes

Table 1: Frequently mutated genes in pancreatic cancer tumour subgroups detected by sequencing.

Pancreatic tumour type	Driver gene	Approximate proportion of mutated samples	Reference
Ductal adenocarcinoma	KRAS	>90	5-8
	TP53	74-86	5,7
	SMAD4	36-43	5,7,8
	CDKN2A	30-41	5,7,8
Intraductal papillary-mucinous	KRAS	62-74	9
neoplasm (IPMN)	GNAS	40-61	9,10
Acinar cell carcinoma	TP53	13-31	11
Pancreatic neuroendocrine tumours	MEN1	44	12
	DAXX/ATRX	43	12
	MTOR pathway genes	15	12

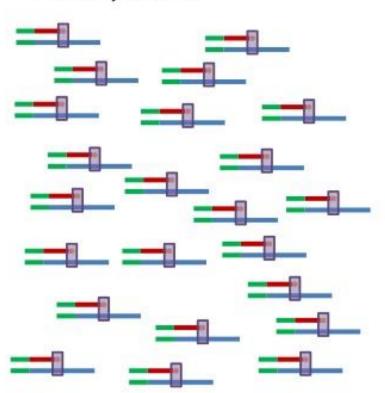
Next Generation Sequencing



Next Generation Sequencing

What is "next-generation" sequencing?

Massively Parallel:



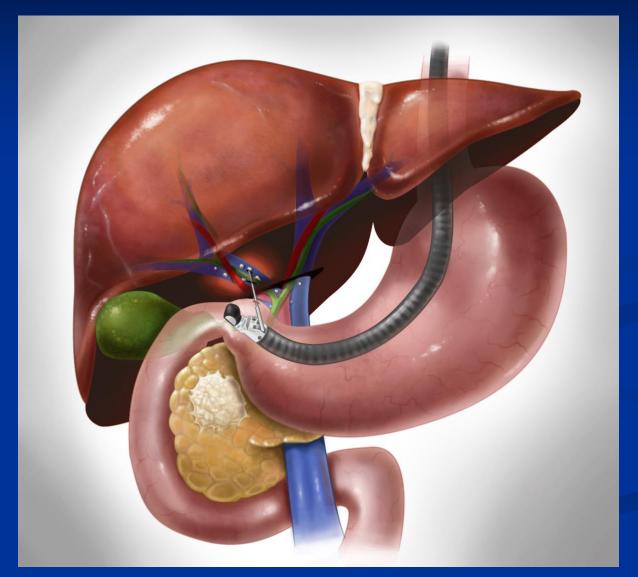
-- first-generation sequencers: -

Sanger sequencer: 384 samples per single batch

-- next-generation sequencers: --

Illumina, SOLiD sequencer: billions per single batch, ~3 million fold increase in throughput!

Portal Vein Access





Presentation Number: 477

Author Block: Douglas O. Faigel¹, Toufic Kachaamy³, Douglas Lake², Alaa El Chami¹, Krutika Patel¹, Catherine Kelman⁴, Tracy L. Landreth⁴, Ronald Marler⁴

Gastroenterology, Mayo Clinic in Arizona, Scottsdale, Arizona, United States; ² School of Life Sciences, Arizona State University, Tempe, Arizona, United States; ³ Cancer Treatment Centers of America, Goodyear, Arizona, United States; ⁴ Center for Procedural Innovation, Mayo Clinic, Scottsdale, Arizona, United States

- EPIC may be a new means to deliver chemoRx to liver metastasis
 - High liver levels of drug with very low systemic levels
 - Important with doxorubicin (no cardiac toxicity)
 - Prior studies with pigs showed safety at 24 hours
- This study assesses long term safety in porcine model

EPIC

- 16 pigs; received either irinotecan or doxorubicin loaded into microbeads injected into PV or similar agent without beads injected into IVC as control
- Animals observed for 7 days then autopsied
- No adverse events. Similar liver drug levels between groups. Significantly lower cardiac drug levels in study group vs control.
- Human trials to begin soon.

EPIC

- May be new area of therapeutic EUS
- Potential delivery of drug, antibody, DNA, or other biologic directly to liver with little systemic effect or toxicity
- Much more to come from this technique.

Endoscopic Ultrasound Guided Portal Pressure Gradient Measurement With a Simple Novel Device - First Human-Pilot Study

View Session Detail

Presentation Number: 717

Author Block: Jason B. Samarasena¹, Jason Y. Huang¹, Takeshi Tsujino¹, Ke-Qin Hu¹, Jimin Han¹, John G. Lee¹, Kenneth J. Chang¹
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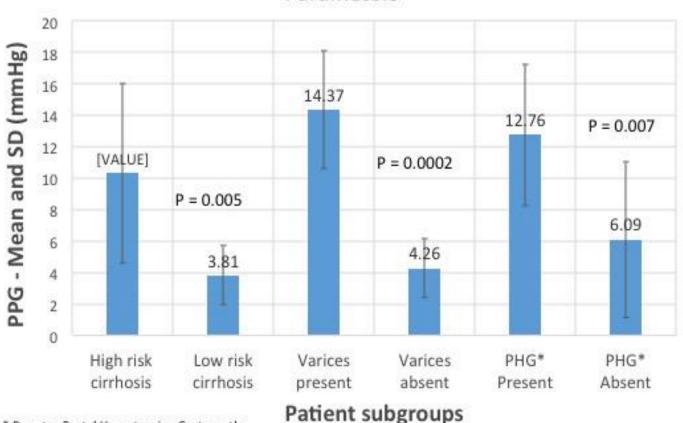
- Portal HTN important problem with cirrhosis
- IR directed measure of portal pressures only widespread option
- UCI group showed PPG by EUS via FNA was safe and feasible in porcine model
- This is first data on human portal pressure determination by EUS FNA

EUS PPG Measurement

- 28 subjects, 25 guage FNA, non-compressible tubing and a small manometer used.
- Pressure measured via hepatic veins (transgastric) and PV (transduodenal).
- Data collected and AEs documented

EUS PPG Measurement

Figure 1: EUS PPG Measurement based on Clinical Parameters



* Denotes Portal Hypertensive Gastropathy

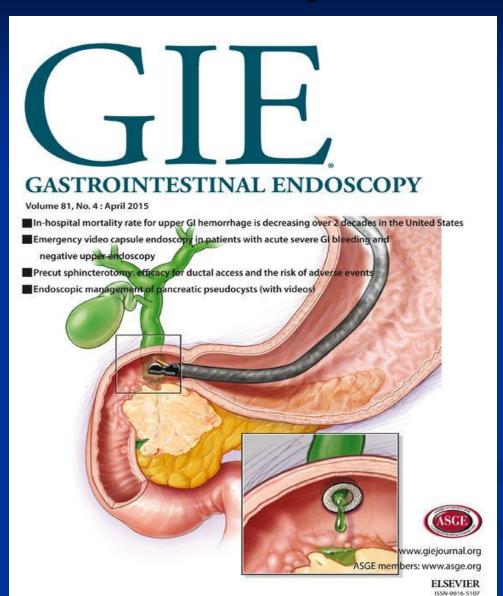
EUS PPG Measurement

- Safe and feasible with good clinical correlation
- Will be useful technique in portal hypertensive patients.

Coyle Comments: May be helpful to assess efficacy of treatment of PTH, especially for drug therapies like beta blockers and nitrates.

Questions?

LAMS Everywhere



Endoscopic Ultrasound-Guided Gallbladder Drainage Versus Endoscopic Transpapillary Gallbladder Drainage for Acute Cholecystitis in High Risk Surgical Patients: Which is Better?

View Session Detail

Presentation Number: 271

Author Block: Dongwook Oh¹, Sang Soo Lee¹, Dong Hui Cho¹, Tae Jun Song¹, Do Hyun Park¹, Dong Wan Seo¹, Sung Koo Lee¹, Myung-Hwan Kim¹

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- **EUS-GBD (LAMS) vs ETGBD, 2010-14**
- Retrospective, prosp database; 179 patients
- Tech success: 98.8% (82/83) vs. 83% (80/96), P<0.05
- □ Clin success: 95.2% (79/83) vs. 83% (80/96), P<0.05
- AEs: EUS: pneumoperitoneum (3/83, 3.6%), abdominal pain (3/83, 3.6%), and duodenal perforation (1/83, 1.2%)
- AEs: ERCP: pancreatitis 8/96 (8.3%)

EUS-GBD vs ETGBD

- Reintervention: 7.2%(6/83) vs17.7%(17/96), P=.02
 - All due to recurrent cholecystitis
- Conclusion: In ill patients with acute cholecystitis EUS-GBD might be more useful treatment method than ETGBD
- Coyle Comments: Not randomized, only severe AE in EUS arm, will require individualized Tx

Lumen Apposing Metal Stents for All Endoscopic Indications: An International, Multicenter Experience



View Session Detail

Presentation Number: 879

Author Block: Nikhil A. Kumta¹, Amy Tyberg¹, Ali A. Siddiqui², Thomas E. Kowalski², David E. Loren², Amit P. Desai¹, Alex M. Sarkisian¹, Elizabeth Brown¹, Prashant Kedia³, Paul R. Tarnasky³, Umangi Patel³, Douglas Adler⁴, Linda J. Taylor⁴, Laura Isby¹, Kunal Karia¹, Monica Gaidhane¹, Maria Petrone⁵, Patrick S. Yachimski⁶, Pierre H. Deprez⁷, Christina Mouradides⁷, Sammy Ho⁸, Safeera Javed⁸, Jeffrey J. Easler⁹, Isaac Raijman¹⁰, Enrique Vazquez-Sequeiros¹¹, Jose Nieto¹², Mandeep Sawhney¹³, Tyler M. Berzin¹³, Brian C. Brauer¹⁴, Raj Shah¹⁴, Peter Vilmann¹⁵, Reem Z. Sharaiha¹, Michel Kahaleh¹

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■ All LAMS use from 2014-15, US and Europe

- 15 centers; retrospective review
- All indications included
- Data collected on success and AEs
- 256 patients: SEE TABLE

LAMS: all indications

Lumen Apposing Metal Stents for All Endoscopic Indications

Indication	Technical Success	Adverse Events
Pancreatic Fluid Collection n=192	98.4%	Bleeding n=11 Infection n=2 Perforation n=2
Biliary Obstruction n=17	100%	Bleeding n=1
Luminal Obstruction n=14	100%	Perforation n=1
Cholecystitis in non-surgical patients n=14	92.9%	*
Ampullary Access in Altered Anatomy n=10	90	Perforation n=1
Non-pancreatic Fluid Collection n=9	100%	Infection n=2
Overall n=256	98%	n=20

^{*3} cases of LAMS migration

LAMS: all indications

High technical success rates in high risk patients for a variety of indications.

Coyle Comments: ALL AEs were immediate. No data on long term issues: stent removal, migration, late bleeding, etc... Great tool, not sure if ready for prime time.

LAMS in PFCs

Lumen Apposing Metal Stents in Pancreatic Fluid Collections

Predictors of Success		
	OR	p-value
Adverse Events	3.01 (0.47-19.1)	0.24
Number of sessions	0.78 (0.63-0.97)	0.03
Age	0.99 (0.96-1.02)	0.71
Sex	1.68 (0.64-4.41)	0.28
PFC length	1.00 (0.99-1.01)	0.64
Axios diameter	0.53 (0.16-1.78)	0.31