

# Controversies in Advanced Endoscopy

## ERCP-DDW 2018

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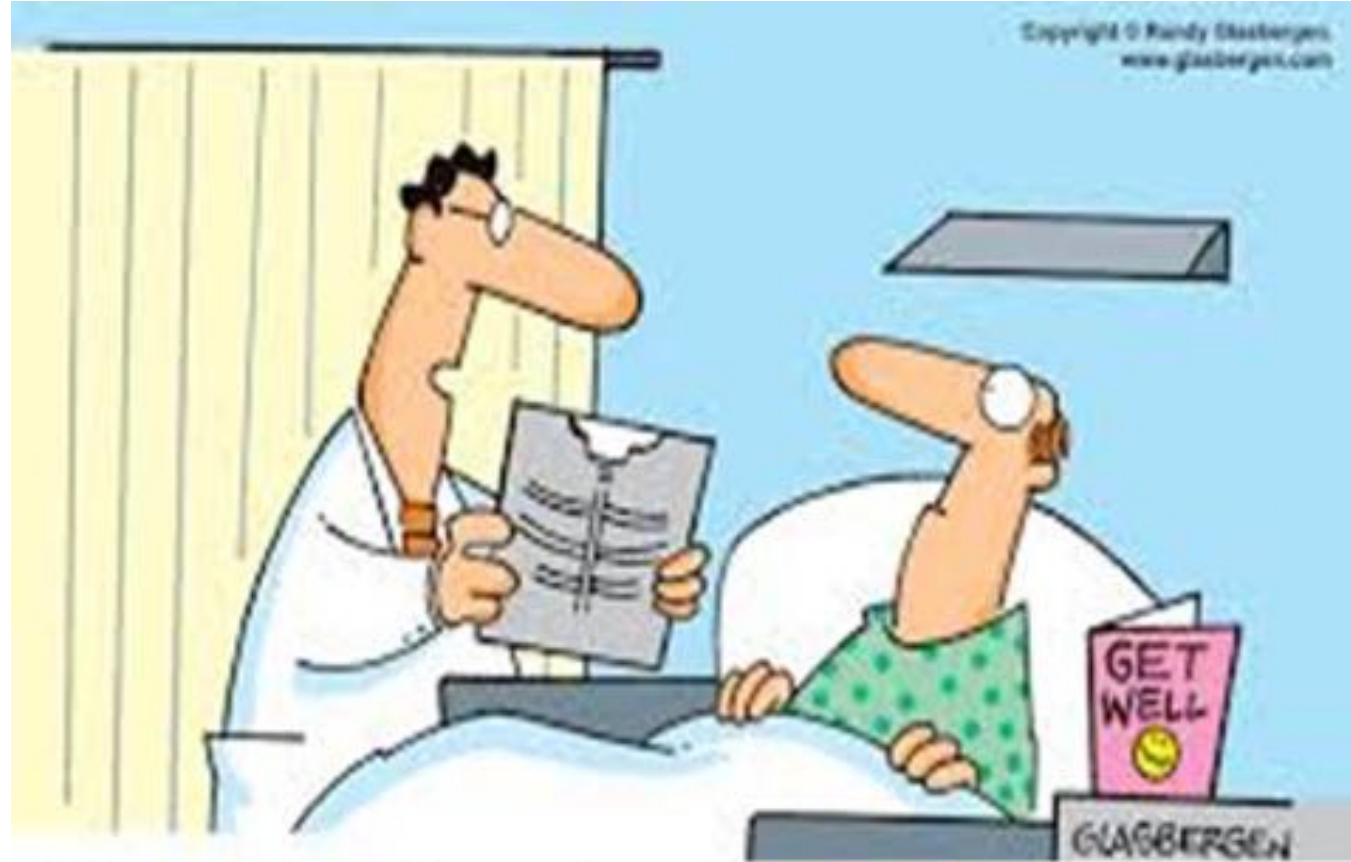
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# Outline

- Stones and cholangitis
- New techniques in ERCP
- ERCP sedation

# Stones and Cholangitis



**“Your x-ray showed gallstones, but we fixed it with Photoshop”**

## **Efficacy of Digital Cholangioscopy-guided Laser vs Mechanical Lithotripsy in Patients with Very Large CBD Stone(s) Who Failed Papillary Large Balloon Dilation**

- Aim: Cholangioscopy guided laser lithotripsy (CL) vs mechanical lithotripsy (ML) in patients with large CBD stones that failed large papillary balloon dilation
- Study Design: Randomized controlled trial in 32 patients.
- Outcomes Measures: Success rates, clearance time, adverse events, radiation exposure
- Results: CL success 100% vs 63%. Less radiation exposure, no difference in adverse events, less ERCP sessions
- Why Important:
  - Pertinent question
  - Direct clinical implications

## Performance Characteristics of the ASGE High-Risk Criteria for Diagnosing CBD Stones

- Aim: To determine the accuracy of the ASGE guideline in high-risk patients for CBD stones
- Study Design: Prospective cohort
- Population: 147 patients stratified as high risk per the ASGE guidelines

TABLE 2. A proposed strategy to assign risk of choledocholithiasis in patients with symptomatic cholelithiasis based on clinical predictors

Predictors of choledocholithiasis<sup>13,14,29,31,32</sup>

Very strong

CBD stone on transabdominal US

Clinical ascending cholangitis

Bilirubin >4 mg/dL

Strong

Dilated CBD on US (>6 mm with gallbladder in situ)

Bilirubin level 1.8-4 mg/dL

Moderate

Abnormal liver biochemical test other than bilirubin

Age older than 55 y

Clinical gallstone pancreatitis

Assigning a likelihood of choledocholithiasis based on clinical predictors<sup>12-14,28,29,31,32</sup>

Presence of any very strong predictor      High

Presence of both strong predictors      High

No predictors present      Low

All other patients      Intermediate

or

Hi Risk for CBD Stone

predictors

- Intervention: ERCP
- Outcome Measures: Presence of stone
- Results: 69% of patients had a stone
- Why Important:
  - Prior studies evaluated the moderate risk group
  - Room for improvement in guidelines for therapeutic ERCP even in high risk patient population



# Mass production



- National Inpatient Sample Database
- National Readmission Database



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

# Outcomes of Early vs Late ERCP in Hospitalized Patients with Acute Cholangitis: A Nationwide Analysis

- Aim: To assess the effect of early vs late ERCP
- Study Design: Database study
- Population: Adult hospitalizations in 2010-2014 National Readmission Database
- Intervention: Early ERCP (1<sup>st</sup> or 2<sup>nd</sup> hospital day)
- Outcome Measures: In-hospital mortality, 30 day readmission mortality, all cause 30-day readmission mortality

- Results: Early ERCP resulted in significantly less in hospital mortality (0.52), 30 day readmission mortality (0.50), 30 day all cause readmission (0.57). Similar benefit of early ERCP for those with and without severe cholangitis.
- Why Important:
  - Large study
  - Mortality benefit
  - Hospitals should have available resources to perform early ERCP in acute cholangitis

# New Techniques in ERCP

## International Multicenter Study on Digital Single Operator Pancreatoscopy (DSOP) for the Management of Pancreatic Stones

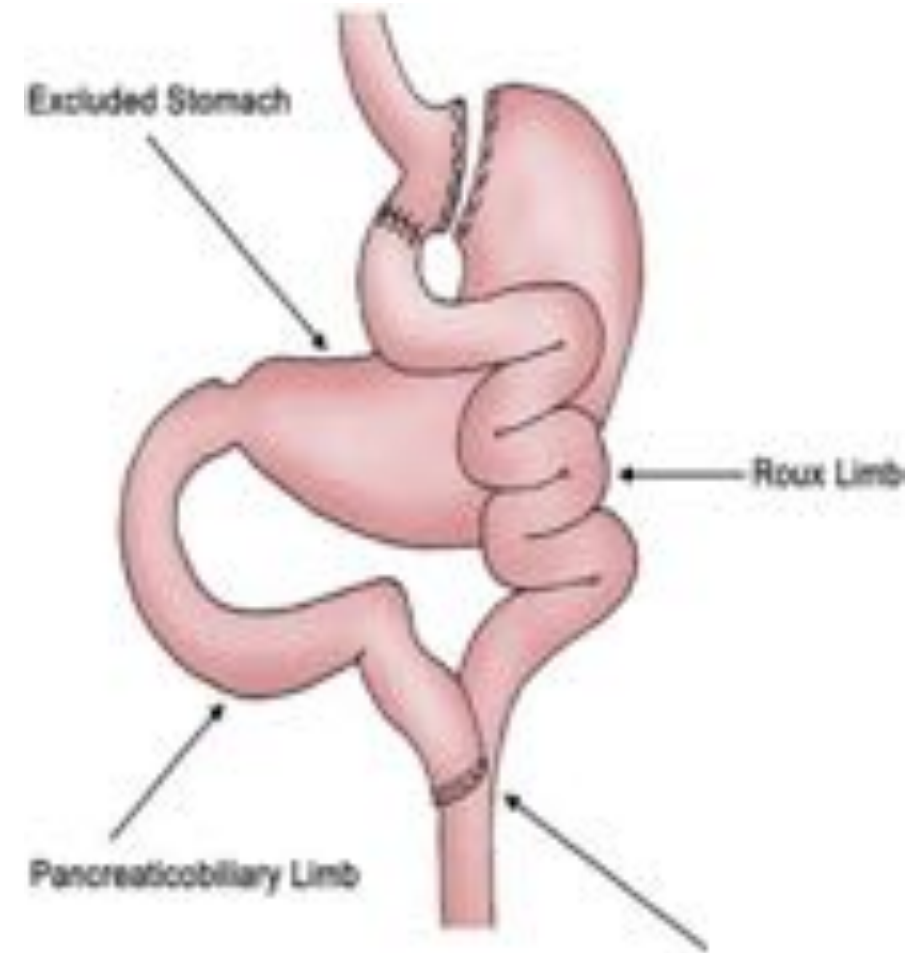
- Aim: To study the technical success and safety of DSOP with EHL or LL
- Study Design: International, multicenter, retrospective study at 17 tertiary centers
- Population: 103 patients
- Intervention: DSOP with EHL or LL
- Outcome Measures: Technical success (complete ductal clearance) and safety

- Results: 103 - 59 EHL and 44 LL
  - 87% previous failed ERCP attempts
  - Stone location: head 51%, neck 22%, body 15%, tail 4%, and multifocal 8%.
  - Mean main PD diameter - 9.19 mm
  - Technical success
    - Overall - 89%
    - Success in a single session - 75%
    - Success in 2-3 sessions - 22%
    - Success in more than 3 sessions - 3%
    - Failure - 11%
  - Adverse events - 8.7%
- Why Important:
  - First, largest , multicenter trial on DSOP for treatment of PD stones
  - ESWL not easily available in the US



# ERCP in Roux-en-Y Gastric Bypass

- Peroral
  - Overtube-assisted enteroscopy
- EUS guided access to the stomach (EDGE)
- Percutaneous access to the remnant stomach
  - PEG
  - Metal stent
  - Lap-assisted ERCP



## Impact of EUS Directed Transgastric ERCP (EDGE procedure) on Technical Success and Adverse Events: A Multi-center Experience

- Aim: Evaluate EDGE and the difference in complications between transjejunal or transgastric access route of LAMS deployment in RYGB patients
- Study Design: retrospective
- Population: 7 centers, 66 patients
- Intervention: EDGE via efferent jejunal limb or transgastrically
- Outcome Measures: complications between transjejunal or transgastric access

- Results:
  - Technical success - 92%
  - Overall complications - 20%
    - Bleeding 7.6%
    - LAMS malposition - 4.5%
    - LAMS migration - 4.5%
    - Perforation- 1.5%
    - 10/13 complications occurred with transgastric access
- Why Important:
  - RYGB is common altered upper GI tract anatomy
  - Common clinical challenge
  - EDGE procedure gaining popularity
  - Multicenter safety data
  - Retrospective data

## **A Randomized Trial Comparing Fully Covered (FC) and Uncovered (UC) Metal Stents for Pre-operative Drainage During Neoadjuvant Therapy in Patients with Pancreatic Cancer**

- Aim: Compare UC SEMS to FC SEMS for management of preoperative biliary obstruction in the setting of neoadjuvant chemotherapy
- Study Design: RCT 9 centers, 6 countries
- Population: 120 patient with borderline resectable pancreatic Ca
- Intervention: FC SEMS or UC SEMS
- Outcome Measures: Successful pancreatobiliary drainage defined as absence of reinterventions up to Whipple or transition to palliative care

- Results: 58 pts in UC and 59 pts in FC group
- Successful PBD was 83% in both UC and FC groups.
- Kaplan-Meier analysis of the time to reintervention until end follow-up showed no significant difference between UC and FC groups ( $p=0.93$ )
- Why Important:
  - Large multicenter RCT
  - Confirms prior findings

## The Majority of Patients Remain Stent-free 5 Years After Temporary Indwelling Stent for Treatment for Benign Biliary Strictures Secondary to Chronic Pancreatitis

- Aim: To report first, MC results of long term (5 year follow up) stricture resolution after FCSEMS therapy for CP induced biliary strictures
- Study Design: prospective, 13 centers, 11 countries
- Population: 118 patients
- Intervention:
  - FCSEMS 10-12 months
  - 5 year follow up after stent removal
- Outcome Measures: Ability to remove the stent, stricture resolution at stent removal, time to re-stenting, long-term stricture recurrence, and serious adverse events (SAEs)

- Results:
  - Endoscopic FCSEMS removal was successful in 100%
  - Stricture resolution at stent removal - 80% [95% CI 71%-87%]
  - Pts who had stricture resolution at removal, likelihood of remaining stent-free at 5 years post FCSEMS indwell was 78% [95% CI 69%-87%]
- Why Important:
  - Large multicenter prospective study
  - Long term data

# ERCP Sedation



As soon as the anesthesiologist gets here, we'll get started.



# Mode of Sedation and Serious Adverse Events During ERCP: Analysis of the Clinical Outcomes Research Initiative National Endoscopic Database (CORI-NED)

- Aim: assess whether mode of sedation was associated with the occurrence of serious adverse events during ERCP
- Study Design: Retrospective cohort
- Population: 26,698 ERCPs
- Intervention ERCP with Endoscopist sedation, MAC or GA
- Main Outcome Measure: Serious adverse events
- Results: Endoscopist sedation associated with higher risk of serious adverse events (OR 1.86, 95% CI 1.44-2.42).
- Why Important:
  - pertinent topic, large sample
  - Retrospective data
  - Selection bias

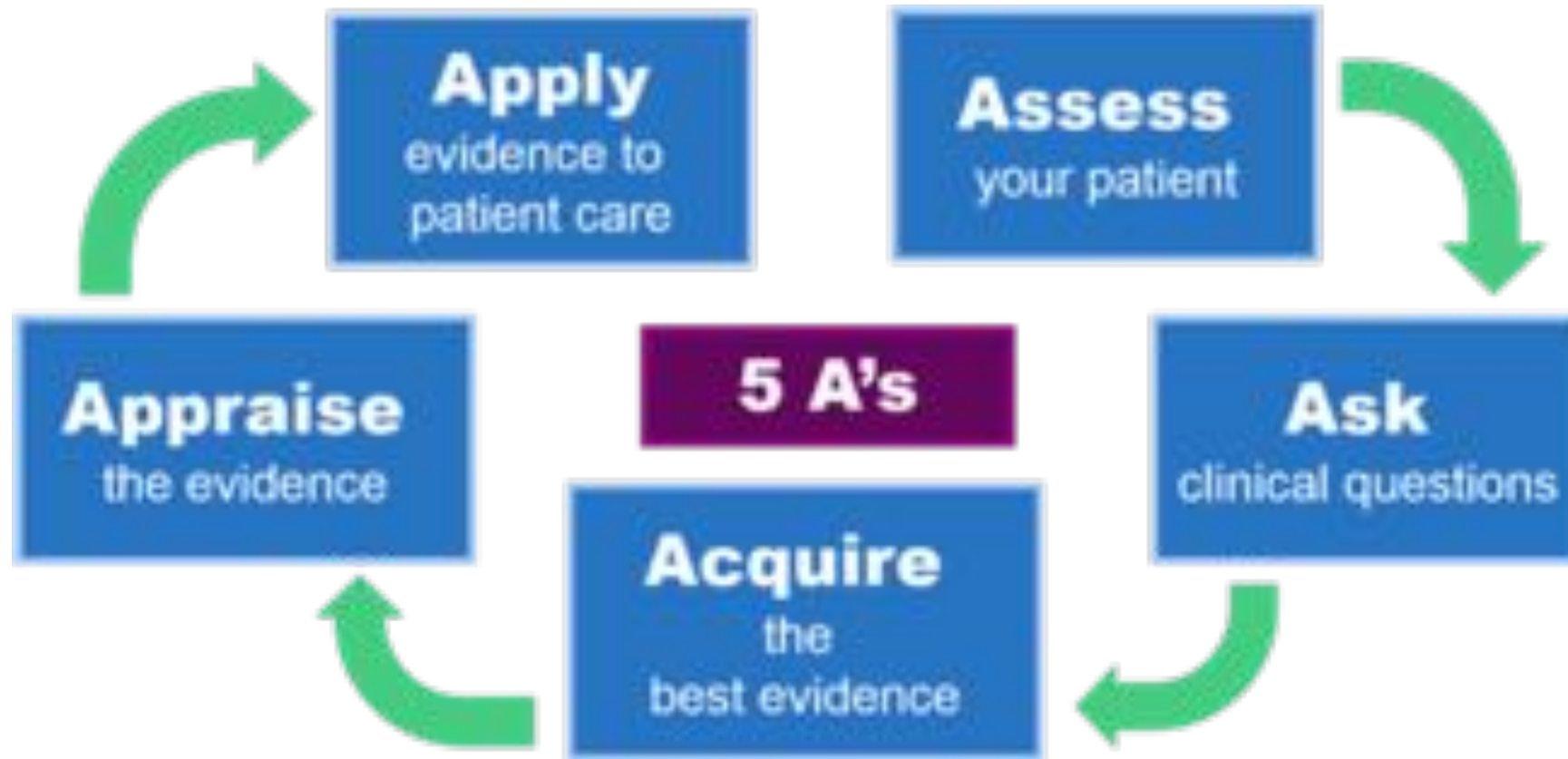
## General Anesthesia vs Moderate Conscious Sedation: A Prospective Study on Outcomes with Selective Sedation in ERCP

- Aim: Compare moderate conscious sedation (MCS) vs GA
- Study Design: Prospective cohort
- Population: 502 ERCPs
- Intervention: MCS or GA
- Outcome Measures: success rates, complications
- Results: No difference in ERCP success but shorter procedure time and AE with MSC
- Why Important:
  - Prospective but not randomized data
  - selection bias for low risk patients done with MSC
  - Nevertheless the utilized “selective sedation protocol” works and lower risk patients can be successfully managed by MCS

## Randomized-Controlled Trial of General Endotracheal Anesthesia Compared with Monitored Anesthesia Care and the Incidence of Sedation-related Adverse Events during ERCP in High-risk Patients

- Aim: Compare ERCP with MAC or GA in high risk patients
- Study Design: RCT in 200 patients
- Outcome Measures: Sedation-related adverse events
- Results: MAC 51% vs GA 9.1%
- Why Important: Multiple issues
  - Patients at high risk for sedation – not pertinent to practice
  - Study outcome of little relevance (chin lift, jaw thrust, nasal trumpet, oral airway)

# Evidence Based Medicine



# How Things are Usually Done

- The four great reasons:
  - Someone told me to do it
  - Everyone else is doing it
  - It seemed like a good idea at the time
  - That's the way we've always done it

# Take Home Messages DDW 2018

- Cholangioscopy may be better than mechanical lithotripsy in patients who had failed large balloon dilation of the papilla
- “High risk for CBD stone” ASGE criteria are good but 1/3 of patients will not have a stone
- Pancreatoscopy should be consider for PD stones
- For RYGB patients EDGE is feasible but
  - Two stage procedure
  - Expensive
  - High complications
  - Jejunal access may be better

# Take Home Messages DDW 2018

- 2/3 of patients with chronic pancreatitis bile duct stricture can be managed by endoscopy with fully covered metal stents
- Metal stents are preferred in the setting of borderline resectable pancreatic Ca in patients undergoing neoadjuvant therapy. There is no difference between uncovered and fully covered stents
- The optimal mode of anesthesia for ERCP remains to be determined
  - Low risk patient Endoscopist guided sedation or MAC
  - High risk patient GA