EUS evaluation should be always performed to exclude recurrence and properly assess the lymph node status.

OC.09.6

SURGERY VERSUS ENDOSCOPIC THERAPY FOR MIRIZZI SYNDROME (SEIZE)-STUDY: A MULTICENTRE INTERNATIONAL EXPERIENCE

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Background and aim: The management of Mirizzi syndrome has been primarily surgical, involving hepatico-jejunostomy for advanced Csendes types. Small series have highlighted the feasibility of digital single-operator cholangioscopy (dSOC) for ductal clearance in patients with Mirizzi syndrome, despite no comprehensive comparisons with surgery. The objective of the current study is to compare the outcomes and safety of dSOC-guided lithotripsy with the surgical approach.
Material and methods: A large multicenter international retrospective analysis was conducted on dSOC and surgical procedures in patients with type II–IV Mirizzi syndrome between 2005–2022. Patients with postsurgical anatomy, Mirizzi type I, or a history of pre-dSOC cholecystectomy were excluded. Technical success was defined as the successful and complete clearance of the duct using either dSOC or surgery. The AGREE classification was employed for adverse event (AE) grading.
Results: In total, 290 patients were included, with 176 undergoing dSOC and 114 undergoing surgery. At baseline, patients undergoing dSOC were older (61.3 years [SD16.4] vs. 56.0 [SD14.8]), experienced jaundice more frequently (79.4% vs. 61.9%, $p = 0.001$), and had higher Charlson Comorbidity Index (3 [IQR 1–9] vs. 1 [0–3], $p < 0.001$) and ASA scores ($p < 0.001$).
While technical success was lower in the dSOC group compared to surgery (89.2% vs. 96.5%, $p = 0.025$), the need for reinterventions and the median number of interventions were similar after a median follow-up duration of 741.5 days (IQR 320–1781) vs. 346 (IQR 67–1220) days ($p = 0.009$). Overall adverse events (AE) occurred less frequently in the dSOC group (10.2% vs. 41.2%, $p < 0.001$), including mild AE (4.0% vs. 13.1%, $p = 0.008$), and severe AE (1.7% vs. 15.8%, $p < 0.001$). Three fatal complications occurred in the surgical group (0.0% vs. 2.6%, $p = 0.060$). Patients undergoing elective cholecystectomy following dSOC had a lower need for hepaticojejunostomy than those undergoing primary surgery (6.6% vs. 26.1%, $p = 0.002$).
Conclusions: The use of dSOC for the removal of intraductal stones in Mirizzi syndrome showed superior safety than surgery despite treating patients with more underlying comorbidity. Digital single-operator cholangioscopy may prevent the need for subsequent cholecystectomy and, if still required, downgrade the extent of surgery, potentially reducing the need for a hepaticojejunostomy. Consequently, we advocate for dSOC as the primary modality in the management of Mirizzi syndrome.

OC.09.7

MAGNETIC BALLOON-ASSISTED COLONOSCOPY IN PATIENTS WITH PROLONGED CECAL INTUBATION TIME: A SINGLE-ARM EUROPEAN MULTICENTER CLINICAL INVESTIGATION

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Background and aim: Incomplete colonoscopy has been associated with higher risk of post-colonoscopy interval cancer. Colon loop formation is the main risk factor for incomplete colonoscopies. To address these challenges, a marked magnetic balloon technology add-on device was developed to facilitate colonoscope unlooping and progression. This study aims to assess the safety and efficacy of magnetic balloon-assisted colonoscopy in completing prolonged procedures.
Material and methods: We conducted an open-label, single-arm, prospective, post-market, multicenter study in Italy, Belgium, and Germany. Outpatients undergoing diagnostic or surveillance colonoscopy were eligible if cecal intubation was not achieved within 10 minutes. Patients with angulated and fixed colon curves were excluded. Study technology consists of a balloon catheter that can be inserted on demand in the colonoscope tool channel, filled with a syringe of ferromagnetic fluid, and anchored with an external permanent magnet. Magnetic balloon anchorage stabilizes the scope tip and facilitates easy straightening. Primary endpoint was an incompletion rate $\leq 10\%$. Rate of serious adverse events was also collected.
Results: Between January and May 2023, a total of 38 patients who experienced an insertion time $\geq$10 minutes with incompleteness of colonoscopy, were included for the interim analysis. Technical

success of the magnetic balloon technology was 100%. The cecum was successfully intubated in all 38, achieving a colonoscopy completion rate of 100%, also corresponding to a 0% incompleteness rate (95% CI: 0%–7.6%). Polyp detection rate was 45% (95% CI: 26%–71%).
Conclusions: This clinical investigation provides evidence that magnetic balloon-assisted colonoscopy is both safe and effective in completing prolonged colonoscopies. This on-demand technology has the potential to serve as a useful tool for large-scale solution for facilitating colonoscopy completion in a subset of patients at a higher risk of incomplete procedures or adverse events.

OC.09.8

PREMEDICATION WITH A NOVEL CLEANSING SOLUTION CONTAINING SIMETHICONE, N-ACETYLCYSTEINE AND ACETIC ACID IMPROVES VISUALIZATION DURING UPPER GI ENDOSCOPY: A DOUBLE-BLIND, MULTICENTER, RANDOMIZED CONTROLLED TRIAL

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Background and aim: Esophagogastroduodenoscopy (EGDS) is the gold standard examination for upper gastrointestinal (GI) disease diagnosis.Intraluminal presence of bubbles and mucus may reduce visibility and potentially impair lesion detection.It has been shown that the administration of mucolytic and tensioactive agents before EGDS can improve gastric visualization.Hence,we performed a randomized controlled trial (RCT) testing the effect of premedication with a novel solution containing simethicone,N-acetylcysteine and acetic acid on upper GI tract visualization.
Material and methods: We conducted a multicenter,prospective, double-blind RCT on consecutive adult outpatients undergoing EGDS.Between 12/2022 and 11/2023,patients were randomized 1:1 to drink a 50 ml cleansing solution containing simethicone 150 mg, N-acetylcysteine 250 mg and 10% acetic acid (Lumevis™, Biofarmatec srl,Palermo,Italy) 30 minutes before EGDS or to fasting. The primary outcome was vision quality (VQ) in the whole upper GI tract,defined as the sum of 1–10 visual analogic scale (VAS, 0 = no visualization — 10 = perfect mucosal visualization) scores for each segment (esophagus, stomach, duodenum) before washing. Secondary outcomes included VQ in each upper GI segment,EGDS duration and adverse event rate.
Results: 120 patients were enrolled and randomized to cleansing solution (n = 60) or fasting (n = 60). Patients' characteristics are shown in Table 1. Administration of cleansing solution before EGDS was associated with a significantly (p = 0.001) higher VQ in the upper GI tract compared to no intervention (median VAS score 23 [range 21–25] vs 19 [range 16–23], respectively).Regarding each segment,cleansing solution premedication was associated with a significantly higher VQ compared to fasting only for both stomach (p = 0.001, median VAS score 7 [range 6–8] vs 5 [range 4–7] respectively) and duodenum (p = 0.001, median VAS score 9 [range 8–10] vs 7 [range 5–9] respectively), but not for esophagus (p = 0.130, median VAS score 7 [range 6–9] vs 7 [range 6–8] respectively). No significant difference was observed in EGDS duration between the two groups (p = 0.272, 6.1 vs 6.5 minutes).No adverse events were reported in both groups.

RESULTS

Table 1. Clinical characteristics of the two groups

Variable	Cleansing solution (n=60)	Fasting (n=60)
Age (years)	54 (44, 66)	58 (42, 68)
Age >65 years	16 (26.7%)	16 (26.7%)
Male	27 (45.0%)	27 (45.0%)
Center		
#1	31 (51.7%)	31 (51.7%)
#2	29 (48.3%)	29 (48.3%)
Body mass index (Kg/m²)	24.2 (21.5, 27.4)	24.2 (22.2, 27.5)
Normal weight	25 (41.7%)	25 (41.7%)
Overweight or obese	35 (58.3%)	35 (58.3%)
High-definition endoscope	29 (48.3%)	29 (48.3%)
Reason for EGDS		
Dyspepsia or abdominal discomfort	30 (50.0%)	33 (55.0%)
Screening or follow-up	12 (20.0%)	12 (20.0%)
Esophageal reflux	10 (16.7%)	10 (16.7%)
Celiac disease	3 (5.0%)	2 (3.3%)
Inflammatory bowel disease	2 (3.3%)	2 (3.3%)
Other	3 (5.0%)	1 (1.7%)

Continuous variables were reported as median and quartiles (25^{th}, 75^{th})

Conclusions: Compared to fasting only, the administration of a novel cleansing solution containing simethicone, N-acetylcysteine and acetic acid before EGDS was associated with overall improved mucosal visualization of the upper GI tract. Our results suggest that cleansing solution premedication improves quality and potentially diagnostic yield of EGDS.

OC.10 ENDOSCOPY AND IMAGING 2

OC.10.1

TOTALLY RETROGRADE ENDOSCOPIC THERAPY TO TREAT STRASBERG TYPE C BILE LEAKS: A RETROSPECTIVE SINGLE CENTER EXPERIENCE

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Background and aim: Endoscopic therapy is the treatment of choice for most external biliary fistulas except for those originating from isolated/disconnected ducts, as in Strasberg type C lesions. We propose a totally retrograde endoscopic access to treat Strasberg type C bile leaks. The aim of the study is to evaluate its technical and clinical success.
Material and methods: The proposed intervention consists in cannulating the isolated duct by passing from the cystic duct's or from the bile duct's stump using a hydrophilic guidewire and subsequently placing fc-SEMS or plastic stents to reconnect it to the biliary tree. Before stenting, a mechanical or pneumatic dilation is performed. If cannulating the isolated duct is not technically possible ("single-step direct cannulation"), a "step-up approach" is used: a stent is placed with the proximal edge in the subhepatic intrabdominal space as near as possible to the transected duct and the distal edge transpapillary into the duodenum. After 4–6 weeks, a second ERCP is performed to directly stent the transected duct. Plastic stenting is used to drain the residual biliary tree in all the cases.
Results: 29 consecutive patients (12 M, 19 F; mean age: 55.4 y.o.) were retrospectively enrolled from March 2012 to March 2023. The access to the transected biliary radicle was obtained by opening the