FOUNDATION FOR INTERVENTIONAL & THERAPEUTIC ENDOSCOPY FITE () RESEARCH REVEW 2025 JANUARY

Dear FITE members, interventional endoscopy colleagues and fellows,

FITE – the Foundation for Interventional & Therapeutic Endoscopy – founded in 2022 is an organization committed to the education of interventional endoscopists and the promotion of the field through creation of resources, standards, and opportunities which benefit interventional endoscopist and their patients. FITE is committed to its members who are interventional endoscopists, providing them with a sense of community regardless of practice setting.

Our mission statement: To advance healthcare outcomes by enhancing the field of interventional and therapeutic endoscopy to provide cost effective, safe, and minimally invasive procedures.

We are excited to work with the founding group of interventional endoscopists below who have come together around the vision of creating a research review to allow for an accessible and efficient manner for the members of FITE to digest the large volume of literature relevant to interventional endoscopy.

The goal of the FITE Research Review:

- 1. Create a convenient way for FITE members to stay up to date on meaningful interventional endoscopy literature by efficient review of the top impactful articles,
- 2. Grade the articles in a standardized manner to quantify the quality of the published literature to understand its value in enhancing the progress of the field,
- 3. Allow for the busy interventional endoscopists to have a rapid overview of which publications may benefit their practice and care for patients.

We hope that our members and readers will find the research review to be a useful tool in their career and enjoy reading its publication each month.

Lastly, we wholeheartedly thank our FITE Research Review editors for their efforts to support our community.

Sincerely,

The FITE Executive Committee





INCIDENCE, PREDICTORS, AND OUTCOMES OF CLINICALLY SIGNIFICANT POST-ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP) BLEEDING: A CONTEMPORARY MULTICENTER STUDY

Avni Jain reviewing Bishay, K., Ruan, Y., Barkun, A.N., Chen, Y.-I., et al. (2024). Incidence, Predictors, and Outcomes of Clinically Significant Post-Endoscopic Retrograde Cholangiopancreatography Bleeding: A Contemporary Multicenter Study. The American Journal of Gastroenterology, 119(11), pp.2317–2325. doi:https://doi.org/10.14309/ajg.00000000002946.

Summary: A recent multicenter study published in AJG evaluates the contemporary risks of clinically significant post-ERCP bleeding (CSPEB). The study identifies key risk factors and outcomes for CSPEB, defined as overt GI bleeding with hemoglobin drop (\geq 20 g/L), transfusion need, or unplanned healthcare encounters.

Study Design: Multicenter prospective data was analyzed from 9 centers across Canada, the United States and Europe was used between 2018 and 2024, including a total of 8,517 ERCP procedures.

Key Findings:

- Incidence: CSPEB occurred in 1.5% of ERCPs, rising to 2.3% in high-risk cases (sphincterotomy, sphincteroplasty, or needle-knife access).
- Anticoagulants: Bleeding rates were 12.9% for warfarin, 7.3% for DOACs, and 9.3% for P2Y12 inhibitors.
 - Warfarin was held 4 days prior to high-risk ERCP, while DOACs and P2Y12 inhibitors were held for 3 and 4 days, respectively.
- Timing: Bleeding occurred a mean of 3.2 days post-ERCP, with 98% of cases occurring within 7 days.
- Management: Endoscopic intervention was required in 78.3% of cases, radiologic hemostasis in 3.9%, and RBC transfusion in 53.5%.

Outcomes:

- Significant intraprocedural bleeding (OR 2.32) was associated with CSPEB.
- CSPEB (OR 12.71) was associated with increased cardiorespiratory events within 30 days.

Implications for Practice: The findings underscore the heightened bleeding risks with anticoagulants, especially antiplatelet agents, and highlight suboptimal timing of cessation (recommendations are to hold antiplatelet agents 5-7 days prior to high risk ERCP). Adhering to guidelines for anticoagulant management is essential to minimize CSPEB risk. These insights can inform consent discussions and procedural strategies for high-risk ERCP patients.





EFFICACY AND SAFETY OF GASTRIC PERORAL ENDOSCOPIC MYOTOMY ACROSS DIFFERENT ETIOLOGIES OF GASTROPARESIS: SYSTEMATIC REVIEW AND META-ANALYSIS

Sepideh Farzin Moghadam reviewing Malik S, Loganathan P, Khan K, Mohan BP, Adler DG. Efficacy and safety of gastric peroral endoscopic myotomy across different etiologies of gastroparesis: systematic review and meta-analysis. Gastrointest Endosc. 2025 Jan;101(1):54-67.e6. doi: 10.1016/j.gie.2024.08.024. Epub 2024 Aug 23. PMID: 39181473.

Summary: Gastric peroral endoscopic myotomy (G-POEM) has emerged as an effective treatment for refractory gastroparesis, a condition with various causes including diabetes, idiopathic factors, postviral, and postsurgical. Understanding how G-POEM works across different etiologies is essential, as these underlying causes may respond differently to treatment. This systematic review and meta-analysis assess the efficacy and safety of G-POEM in treating gastroparesis across various etiologies to offer insights into more personalized management strategies for patients.

Study Design:

- Systematic review and meta-analysis (8 retrospective, 7 prospective studies) up until October 2023, with 4 studies before 2020 conducted in the USA.
- **Inclusions:** Clinical success and safety of G-POEM based on etiology, including Symptom Index (GCSI) and gastric emptying scintigraphy (GES) scores before and after G-POEM.
- Exclusions: Case reports, case series, studies in non-English languages, and those with combined treatments or initial G-POEM treatment.
- **Definition of clinical success:** A GCSI score decrease of at least 1 point or 25-50% improvement in symptoms, along with improvements in gastric emptying times assessed by GES.

Key Findings:

- Total 982 patients: 290 postsurgical, 287 idiopathic, 286 diabetic, and 52 with other conditions like scleroderma and lupus.
- **Demographics:** Mean age 50.81 years, 67% female, mean BMI 23.53, mean follow-up 21 months.
- Most common prior therapy: Botox injection.
- Adverse Events: Capnoperitoneum, bleeding, perforations, and abdominal pain. Some studies reported no side effects, while others noted complications like mucosectomy closure site disruptions and abscesses.

Meta-Analysis Outcomes:

- Cumulative pooled clinical success rate: 72.6%
- Cumulative GCSI score improvement: 1.79
- Subgroup Analysis:
 - Diabetes: 65% clinical success, with a 1.7 GCSI score improvement.
 - Postsurgical conditions: 70% clinical success, with a 1.34 GCSI score improvement.
 - Idiopathic etiologies: 60% clinical success, with a 1.5 GCSI score improvement.

Analysis of G-POEM Outcomes stratified by GCSI subscales:

- Nausea and vomiting subscale: Sustained improvement at 1, 6, 12, and 18 months.
- Early Satiety: Improvement at 1 and 6 months, but not sustained at 12 months.
- Bloating subscale: No significant improvement.
- **Predictors of success/failure:** High preoperative bloating scores predicted long-term success; high preoperative nausea scores predicted failure.
- **Clinical success:** Highest in postsurgical gastroparesis, greatest GCSI improvement in diabetic gastroparesis.

Implications for Practice:

This study underscores the effectiveness of G-POEM for various types of gastroparesis, particularly for diabetic and postsurgical patients. These findings highlight the potential of G-POEM as a key therapeutic option, supporting more targeted treatment approaches. Further research is needed to define clear criteria for patient selection, leading to better outcomes and more efficient care delivery.





ENDOSCOPIC ULTRASOUND GASTROENTEROSTOMY VERSUS DUODENAL STENTING FOR MALIGNANT GASTRIC OUTLET OBSTRUCTION: A COST EFFECTIVENESS STUDY

Frances Dang reviewing Ramai D, Nelson R, Chaiyakunapruk N et al. Endoscopic Ultrasound Gastroenterostomy versus Duodenal Stenting for Malignant Gastric Outlet Obstruction: A Cost-Effectiveness Study. Endoscopy International Open 2024. doi: 10.1055/a-2509-7671

Summary: There is growing literature to suggest that in the treatment of malignant gastric outlet obstruction, EUS-GE reduces the frequency of reintervention, improve luminal patency, and result in better patient-reported eating habits when compared with duodenal stenting. This study aims to evaluate the cost effectiveness between the two treatment modalities.

Study Design:

Type of Study: cost effectiveness study simulating base-case scenario of a patient undergoing endoscopic management with either EUS-GE or duodenal stenting, with incorporation of procedural mortality, technical success, stent patency, stent occlusion,

and management of occluded stents.

Primary Endpoint: incremental cost-effectiveness ratio (ICER) = (difference in cost between the 2 comparison strategies/difference in QALYs between the 2 strategies).

Key Findings

- EUS-GE was found to be a cost-effective strategy over duodenal stenting (ICER = \$41,994/QALY) at a willingness to pay (WTP) of \$100,000
 - duodenal stenting was associated with a cost of \$22,748 and 0.31 QALYs per patient, whereas an EUS-GE was associated with a cost of \$32,254 and 0.53 QALY
- The model was most sensitive to the probability of mortality events in patients with duodenal stents when compared to EUS-GE
- Monte-Carlo probabilistic sensitivity analysis of 10 000 iterations demonstrates that EUS-GE the most optimal strategy in 62% of iterations at WTP of \$100,000

Implications for Practice

- Based on findings from prospective and randomized studies in addition to this cost effectiveness analysis study, EUS-GE should be the preferred treatment modality in treating malignant GOO where expertise and resources are available
 - In very ill patients with life expectancy ~1 month, duodenal stenting may be reasonable and cost effective with less procedural risk, particularly in centers where EUS-GE expertise is not available





LONG-TERM OUTCOMES OF ADDITIONAL SURGERY AFTER ENDOSCOPIC RESECTION VERSUS PRIMARY SURGERY FOR T1 COLORECTAL CANCER

Avni Jain reviewing Tamaru, Y., Toshio Kuwai, Kajiwara, Y., et al. (2024). Long-term outcomes of additional surgery after endoscopic resection versus primary surgery for T1 colorectal cancer. The American Journal of Gastroenterology. doi:https://doi.org/10.14309/ajg.000000000002879.

Summary: A recent AJG study from Japan assessed whether endoscopic resection (ER) prior to surgical resection for T1 colorectal cancer (CRC) impacts long-term oncologic outcomes. Concerns exist that invasive endoscopic manipulation might influence cancer cell growth, including hematogenous metastasis or microseeding. This study is particularly timely as the detection of T1 CRC continues to rise with improvements in surveillance and detection techniques in colonoscopy.

Study Design: A propensity score-matched analysis was conducted using a multicenter, retrospective cohort of 3,132 patients treated with surgical resection for T1 CRC at high-volume Japanese centers. Of these, 1,407 underwent additional surgery (AS group) following ER, while 1,725 had primary surgery (PS group). Patients with CRC associated with IBD, FAP, or outside the 20–80 age range were excluded.

Key Findings:

- **5-Year Survival Rates:** The AS group showed a 5-year overall survival rate of 97.1%, comparable to 96.0% in the PS group (HR: 0.72; 95% CI 0.4–1.08; p = 0.1070).
- **Recurrence Rates:** No significant difference was found in 5-year cumulative recurrence rates between the groups.
- Long-Term Outcomes: Analysis of 10-year overall survival and cumulative recurrence rates also revealed no significant differences.

Implications for Practice: The study concludes that ER before additional surgery for T1 CRC does not adversely affect long-term oncologic outcomes. These results provide reassurance for endoscopists and surgeons managing patients with T1 CRC and underscore the safety of ER as part of a staged therapeutic approach.





STOOL-BASED TESTING FOR POST-POLYPECTOMY COLORECTAL CANCER SURVEILLANCE SAFELY REDUCES COLONOSCOPIES: THE MOCCAS STUDY

Grace Kim reviewing Carvalho B, et al. Stool-Based Testing for Post-Polypectomy Colorectal Cancer Surveillance Safely Reduces Colonoscopies: The MOCCAS Study. Gastroenterology. 2025 Jan;168(1):121-135.e16. doi: 10.1053/j.gastro.2024.08.022. Epub 2024 Aug 30. PMID: 39218164.

Summary: The study investigates the effectiveness of stoolbased testing as a surveillance method for colorectal cancer in patients who have undergone polypectomy. The findings suggest that utilizing stool-based tests can safely decrease the frequency of follow-up colonoscopies without compromising patient safety in European cohorts.

Study Design

- Prospective, cross-sectional, multicentered observational study in Netherlands
- Individuals 50-75 years of age
- Specifically evaluating those needing surveillance colonoscopies
 - Post-polypectomy
 - Post-CRC
 - Familial risk of CRC
- Three stool-based tests prior to prep: one multitargeted stool DNA test and two FIT
- Model-based analysis with ESGE guidelines and the US Multi Society Task Force guidelines (the earliest surveillance interval was 3 years for both)

Key Findings

- 3453 individuals, 18 centers
- Stool-based tests can lead to a reduction of 15% to 41% in the number of colonoscopies performed, especially with annual FIT tests in European setting with ESGE guidelines.
- This was not seen in US-based setting using US Multi Society Task Force guidelines.
- Multitarget stool DNA-based surveillance was more expensive than colonoscopy
- FIT surveillance was less expensive than colonoscopy

Outcomes

• Stool-based post-polypectomy surveillance can be costeffective and reduce number of colonoscopies by 15%–41%.

Implications for Practice

- Stool-based tests can help reduce healthcare burden and tailor surveillance colonoscopies to those with the highest risk/ likelihood of requiring endoscopic intervention.
- These findings may not be generalizable for patients in the US, and those requiring endoscopic mucosal resections (and a 6-month follow up) were not mentioned in the article.





PRIMARY NEEDLE-KNIFE FISTULOTOMY VERSUS STANDARD TRANSPAPILLARY TECHNIQUE FOR CANNULATION OF LONG-SIZE PAPILLA: A RANDOMIZED CLINICAL TRIAL (PUBLISHED NOV 2024)

Frances Dang reviewing Sadeghi A, Arabpour E, Movassagh-Koolankuh S, Rastegar R, et al (2024). Primary Needle-Knife Fistulotomy Versus Standard Transpapillary Technique for Cannulation of Long-Size Papilla: A Randomized Clinical Trial. Clin Transl Gastroenterol. 2024 Dec 1;15(12):e00788. doi: 10.14309/ctg.000000000000788. PMID: 39626015; PMCID: PMC11671062.

Summary: Traditional ERCP techniques often fail in patients with anatomical anomalies, such as long-sized papilla, leading to potential increased risk of complications. This study evaluates the safety and efficacy of Primary Needle-Knife Fistulotomy (pNKF) to Standard Transpapillary Technique (STP) for cannulation of long-sized papilla.

Study Design:

- Type of Study: Single center, prospective, randomized clinical trial
- Population: 1340 patients with naïve papilla, of which 260 met inclusion criteria of long-sized papilla requiring therapeutic ERCP. Participants were randomized to either pNKF or STP (130 assigned to each arm).
- Endpoints:
 - Primary Endpoint: rate of post-ERCP pancreatitis
 - Secondary Endpoints: biliary cannulation success rates, duration of cannulation, incidence of adverse events.

Key Findings

- 1. Complication Rates:
 - pNKF demonstrated lower rates of post-ERCP pancreatitis compared to STP (2.4% vs. 9.6%, p<0.05).
 - Bleeding more common in STP group (3.5% vs 0, p = 0.05).
- 2. Cannulation Success Rates:
 - pNKF showed significantly higher success rates compared to STP (96.2% vs 87.7%, p<0.01)
 - Faster time to cannulation (187 vs 258 seconds, p<0.01) and less cannulation attempts (1.25 vs 1.72, p<0.01) was achieved with pNKF.
 - Difficult cannulation was significantly less common in pNKF group (11.2% vs 39.5%, p<0.01), and PD was inadvertently cannulated less (4% vs. 13.2%, P<0.01)

Implications for Practice

Given the higher success rate of cannulation and lower adverse events, pNKF could be considered as the initial cannulatio approach in patients with long size papilla undergoing ERCP, provided that it is performed by experienced endoscopists in well-equipped centers.





THE REVISED KYOTO CRITERIA AND RISK OF MALIGNANCY AMONG PATIENTS WITH INTRADUCTAL PAPILLARY MUCINOUS NEOPLASMS

Vibhu Chittajallu reviewing Hamada T, Oyama H, Tange S, Hakuta R, Ishigaki K, Kanai S, Kawaguchi Y, Noguchi K, Saito T, Sato T, Suzuki T, Takahara N, Tanaka M, Hasegawa K, Ushiku T, Nakai Y, Fujishiro M. The Revised Kyoto Criteria and Risk of Malignancy Among Patients With Intraductal Papillary Mucinous Neoplasms. Clin Gastroenterol Hepatol. 2024 Dec;22(12):2413-2423.e18. doi: 10.1016/j.cgh.2024.05.043. Epub 2024 Jun 14. PMID: 38880125.

Summary: The revised Kyoto guidelines 2024 discuss a new list of high-risk stigmata and worrisome features for the risk stratification of intraductal papillary mucinous neoplasms (IPMNs). This retrospective large clinical cohort study in Japan examined the risk profile determined by the revised Kyoto criteria in regard to long- and short-term risk of pancreatic cancer and if there is a multiplicity effect of high-risk stigmata or worrisome features to pancreatic cancer risk.

Study Design

- Retrospective, single institution observational study in Japan
- Includes patients diagnosed with IPMNs between January 1, 2000 and December 31,2021
 - Excluded non-IPMN pancreatic cysts, follow up <6 months, and history of PDAC
- Assessed for high-risk stigmata and worrisome features in addition to multiplicity of each of these characteristics (Table 1)

Key Findings

- 3336 patients with IPMNs, 1 center
 - 3041 (91%), 271 (8.1%), and 24 (0.7%) patients with branch-duct, mixed-type, and main duct IPMNs, respectively
- At IPMN diagnosis, pancreatic carcinomas were predominantly seen in patients with IPMNs with high-risk stigmata.
- Existence of multiple worrisome features was associated with an increased prevalence and incidence of pancreatic carcinoma.

Outcomes

• This study of short- and long-term outcomes confirmed that Kyoto criteria-defined risk factors were correlated with the increased prevalence of pancreatic carcinoma at IPMN diagnosis.

Implications for Practice

 Short- and long-term risks of pancreatic carcinomas can be assessed based on the risk profiles proposed by the revised Kyoto guidelines. This study provides evidence for the risk stratification and personalized management of patients diagnosed with IPMNs.

Table 1:

High-risk stigmata	Worrisome features
Enhancing mural nodule $\geq 5 \text{mm}$	CA19-9 >37
MPD diameter ≥ 10 mm	New-onset or worsening diabetes
Positive or suspicious cytology	Size of IPMNs ≥ 30 mm
Obstructive jaundice	MPD diameter = 5-9.9 mm
	Caliber change of the MPD
	Acute pancreatitis
	IPMN wall thickening
	Lymphadenopathy
	Enhancing mural nodule < 5 mm



At FITE, we are continually striving to educate and empower. We welcome you to reach out with any feedback, questions, or concerns anytime via **support@endofoundation.org.**

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