FOUNDATION FOR INTERVENTIONAL & THERAPEUTIC ENDOSCOPY

FITE RESEARCH REVIEW

2025 APRIL

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

ADVERSE EVENTS ASSOCIATED WITH ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY: SYSTEMATIC REVIEW AND META-ANALYSIS

Frances Dang • March Gastroenterology

Bishay, Kirles et al. "Adverse Events Associated With Endoscopic Retrograde Cholangiopancreatography: Systematic Review and Meta-Analysis." Gastroenterology vol. 168, 3 (2025): 568-586. doi:10.1053/j.gastro.2024.10.033

Summary: This meta-analysis systematically reviewed and analyzed adverse events associated with ERCP using contemporary data from 380 studies (136 observational and 224 RCTs) with over 2 million unique patients. The authors found that rates of post-ERCP pancreatitis (PEP) have remained stable since 2000 with incidence of PEP 4.6% overall, rising to 6.5% in first time ERCP patients. The mortality rate was 0.2% in all ERCP patients. Majority (65.9%) of patients with PEP was classified as mild. Female patients, precut sphincterotomy, inadvertent PD cannulation and PD contrast injection had higher risks of PEP while rectal NSAIDs, placement of prophylactic PD stent and aggressive IV fluid hydration were effective in reducing risk.

Study Design:

- Meta-analysis and systematic review included both RCTs and observational studies from year 2000-2024
- Primary outcome: incidences of adverse events (pancreatitis, bleeding, cholangitis, cholecystitis, perforation, and death).

Key Findings:

- Total of 380 studies were included (136 observational and 244 RCTs) with over 2 million unique patients

Incidence of adverse events

	Incidence All-Comers % (95% CI; total patients)	Incidence first time patients (95% CI; total patients)
Death	**0.2** (95% CI 0.1–0.3, n=47,258)	**0.3** (95% CI 0.2-0.4, n=19,553)
PEP	**4.6** (95% CI 4.0–5.1, n= 293,378)	**6.5** (95% CI 5.9-7.1, n= 293,378)
Bleeding	**1.5** (95% CI 1.2–1.7, n= 229,655)	**1.9** (95% CI 1.6-2.3, n= 54,917)
Cholangitis	**2.5** (95% CI 1.9–3.3, n= 121,619)	**1.9** (95% CI 1.6-2.4, n= 37,837)
Cholecystistis	**0.8** (95% CI 0.5–1.2, n= 7799)	**1.1** (95% CI 0.6-1.9, n= 6,502)
Perforation	**0.5** (95% CI 0.4–0.6, n= 306,378)	**0.6** (95% CI 0.5-0.7, n= 42,238)

- Majority (65.9%) of PEP was classified as mild, 27.9% for moderate and 10.2% for severe.
- Subgroups with highest incidence of PEP based on pre-procedural factors included female patients (10%), patients with suspected/confirmed sphincter of Oddi dysfunction (15%) or patients with planned pancreatic interventions (11.9%).
- For procedural factors with highest incidence of PEP include performance of precut sphincterotomy (14.1%), inadvertent cannulation of PD (14.2%) and any pancreatic duct injection (15.8%).
- Effective preventative strategies for reducing pancreatitis risk include: rectal NSAIDs (RR = 0.49); prophylactic stent placement (RR = 0.56), aggressive IV fluid hydration (RR =0.5)

Implications for Practice:

The incidence of adverse events in ERCP remain high and stable despite advancements in procedure techniques and tools, prevention and recognition. Knowing estimates of ERCP-associated adverse event risk will allow endoscopists to better risk stratify patients and have more personalized and detailed informed consent discussions and provide more evidence-based strategies to reduce risk.

Quality of Evidence:

- Overall, this study has strong methodology with appropriate rationale/justification of data representation and analysis work. Limitations appropriately acknowledged by the authors.
- GRADE analysis:
  - o Certainty of evidence ranged from very low to high depending on the outcome. There was substantial statical heterogeneity in several pooled estimates, imprecision and use of observational type data from RCTs. Attempts made to elucidate heterogeneity by performing several subgroup and sensitivity analyses.
  - o Indirectness: some subgroup analyses limited by differences in study populations, definitions of outcomes, and regional variations.
  - o Risk of bias: majority of studies (68%) were at low risk of bias but 20% had some concerns and 11% had high risk of bias.
  - o Publication bias: Egger's test and funnel plots indicate potential publication bias in most studied outcomes. No inclusion of gray literature.

PREVALENCE OF ENDOSCOPICALLY CURABLE LOW-RISK CANCER AMONG LARGE (≥20 MM) NONPEDUNCULATED POLYPS IN THE RIGHT COLON

Avni Jain • CGH – March 2025

Gauci JL, Whitfield A, Medas R et al. Prevalence of Endoscopically Curable Low-Risk Cancer Among Large (≥20 mm) Nonpedunculated Polyps in the Right Colon. Clinical Gastroenterology and Hepatology. 2025;23:555-563.

Summary: The study investigates the prevalence of endoscopically curable low-risk cancer in large (≥20 mm) nonpedunculated polyps in the right colon (R-LNPCPs). Low-risk cancer is defined as cancers with superficial submucosal invasion without additional high-risk histopathologic features (such as poor differentiation, high tumor budding, presence of lymphovascular invasion). The authors assess whether a universal endoscopic submucosal dissection (ESD) strategy improves oncologic outcomes compared to conventional endoscopic mucosal resection (EMR). The findings suggest that low-risk cancers amenable to endoscopic cure in the right colon are rare, suggesting that universal ESD (a more resource intensive procedure with higher risk of adverse events compared to EMR) for management of these lesions cannot be justified.

Study Design:

- Prospective multicenter cohort study
- Australian Colonic Endoscopic Resection cohort involving 2956 patients with sporadic R-LNPCPs enrolled at seven sites with established advanced resection programs were included
- Primary outcome was proportion of R-LNPCPs with low-risk cancer that could be endoscopically cured

Key Findings:

- Referral to Surgery: 2.1% of patients were sent directly to surgery due to suspected invasive cancer
- Histopathology: Most cases with submucosal invasive cancer (SMIC) exhibited features requiring surgical management
- Cancer Prevalence: 4.4% of R-LNPCPs contained cancer
- Low-Risk Cancer Prevalence: Only 0.78% (23 of 2940) were classified as low-risk cancers, potentially curable via en bloc resection
- ESD vs. EMR Impact: Universal ESD would have little effect on oncologic outcomes but would increase procedural risks and resource use

Outcomes:

- **Endoscopic Cure Rate:** 23 out of 2490 (0.78%) low-risk cancers could have been cured endoscopically, however only four cases of low-risk cancer were successfully treated with en bloc EMR.
- **Need for Surgery:** If a universal ESD strategy were applied, 3.1% of patients would still require surgery, with a high number needed to treat (142 ESD procedures to prevent one additional surgery). Most cases with submucosal invasive cancer (SMIC) exhibited endoscopic features (e.g. non-lifting), ultimately requiring surgical management.
- **Complications:** The study highlights the safety and cost-effectiveness of EMR, given the low proportion of endoscopically curable lesions and the increased cost and resources required for ESD.

Implications for Practice

- A universal ESD approach for R-LNPCPs is difficult to justify due to the low prevalence of low-risk cancers and the associated risks
- EMR remains the preferred technique in Western settings due to its safety, efficacy, and cost-effectiveness for management of R-LNPCPs
- Future efforts should focus on better pre-resection risk assessment and stratification to identify rare cases where ESD may be beneficial
- The study supports a selective, rather than universal, approach to ESD in the right colon.

Quality of Evidence:

- Low; although prospective data collection, quality of evidence is low due to study design being an observational study

MULTICENTRE RANDOMISED CONTROLLED TRIAL OF A SELF-ASSEMBLING HAEMOSTATIC GEL TO PREVENT DELAYED BLEEDING FOLLOWING ENDOSCOPIC MUCOSAL RESECTION (PURPLE TRIAL)

Grace Kim • Gut – March

Drews J, et al. Multicentre randomised controlled trial of a self-assembling haemostatic gel to prevent delayed bleeding following endoscopic mucosal resection (PURPLE Trial). Gut. 2025 Feb 23:gutjnl-2024-334229. doi: 10.1136/gutjnl-2024-334229. Epub ahead of print. PMID: 39988360.

Summary: This was a multicenter, randomized controlled trial evaluating clinical efficacy of prophylactic application of hemostatic gel PuraStat in preventing delayed bleeding after EMRs of duodenal and colorectal polyps.

Study Design:

- Randomized controlled trial
- 15 centers in Germany
- To evaluate clinical significance of prophylactic hemostatic gel on hot snare EMRs of duodenal (>10 mm) and colorectal (>20 mm) polyps
- No clips were allowed for closure or partial closure of the resection field
- Clips were allowed for treatment of intraprocedural bleeding and perforation (without closing the resection edges)
- Primary endpoint: delayed bleeding within 30 days

Key Findings:

- Trial was stopped early after an interim analysis of 232 patients (208 colorectal, 26 duodenal)
- The delayed bleeding rate in the hemostatic gel group was 11.7%, compared to 6.3% in the control group (p=0.227).

Outcomes:

- There was no significant difference in delayed bleeding rates in EMRs with or without the application of hemostatic gel as a prophylaxis

Implications for Practice

- Hemostatic gel itself has not shown to be sufficient or effective in preventing delayed bleeding after hot snare EMRs.
- It may still be useful for intraprocedural bleeding given its ease of use and transparent nature that does not hinder visualization.
- This finding is not generalizable with other resection techniques such as cold snare EMR or ESD.
- Hemostatic gel's efficacy in conjunction with resection closure has not been studied.

Quality of Evidence: high; this study is an RCT

SAFETY AND EFFICACY OF UNDERWATER EMR FOR 10- TO 20-MM COLORECTAL SERRATED LESIONS (SEA CLEAR STUDY)

Vibhu Chittajallu • GIE - March

Tanaka, K., Yabuuchi, Y., Imai, K., Hosotani, K., Morita, S., Takada, K., Kishida, Y., Ito, S., Hotta, K., Mori, K., Inokuma, T., & Ono, H. (2025). Safety and efficacy of underwater EMR for 10- to 20-mm colorectal serrated lesions (SEA CLEAR study). Gastrointestinal endoscopy, 101(3), 632–638. https://doi.org/10.1016/j.gie.2024.08.040

Summary:

- A multi-center prospective observational study evaluating the complete resection rate of 10-20 mm colorectal serrated lesions utilizing underwater endoscopic mucosal resection (UEMR)

Study Design:

- 2-center, prospective, observational study
- Patients aged ≥20 years who had at least 1 SL sized 10 to 20 mm
- UEMR technique included (1) lesion detection, (2) spraying an acetic acid solution over the lesion to identify the margins, (3) completely deflating the intraluminal air, (4) totally immersing the lesion in normal saline, (5) snaring the lesion and surrounding mucosa, and (6) resecting the lesion with an Endo-Cut mode electrical current
    - o When the absence of residual lesions was confirmed, biopsies at the 4 quadrants of the mucosal defect margins were performed and tattooed near mucosal defect
- Primary outcome: Complete resection rate of UEMR (en bloc resection with no serrated tissue in the 4 marginal biopsy specimens and histologically negative margins)
    - o R0 resection was defined as en bloc resection with negative margins upon histologic examination

Key Findings:

- 58 patients included with 65 lesions
- Success rate of UEMR - 65 (100%); En bloc resection rate of UEMR - 57 (87.7%); R0 resection rate of UEMR - 40 (61.5%); Residual lesion rate in the marginal biopsy samples - 1 (1.5%); Complete resection rate of UEMR - 39 (60.0%)
- Adverse events: Immediate bleeding - 1 (1.5%); Delayed bleeding - 0 (0%); Delayed perforation - 1 (1.5%)
- Recurrence rate - 3 (5.3%)

Outcomes:

- This prospective observational study determined a complete resection rate of 60.0% (39 of 65) with UEMR of colonic SLs measuring 10-20 mm, with a recurrence rate of 5.3% (3 of 57) upon surveillance colonoscopy 12 months postoperatively and a low adverse event rate 3% (2 of 65).

Implications for Practice

- Study demonstrates comparable resection and recurrence rates for UEMR compared to conventional EMR (including submucosal injections) with consideration as an alternative approach for the endoscopic management of large SSLs
    - o The rates of en bloc resection, R0 resection, complete resection, and recurrence were 86.5%, 54.7%, 52.4%, and 3.6% for conventional EMR for SSLs ≥10 mm in previous studies, respectively, whereas these were 87.7%, 61.5%, 60.0%, and 5.3% in the present study

Quality of Evidence

- Moderate; multi-institutional prospective study but not randomized controlled trial

CONTACT US

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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