

# High Complete Defect Closure Rate and Low Delayed Bleeding Using an Anchor-Pronged Through-the-Scope Clip After Endoscopic Resection of Large Gastrointestinal Lesions

D. VON RENTELN<sup>1</sup>, D. REX<sup>2</sup>, H. POHL<sup>3</sup>, N. KUMTA<sup>4</sup>, S. CHAN<sup>5</sup>, M. RYOU<sup>6</sup>, Z. NABI<sup>7</sup>, P-H. ZHOU<sup>8</sup>, H. INOUE<sup>9</sup>, J. PEETERMANS<sup>10</sup>, M. ROUSSEAU<sup>10</sup>, J. MOSKO<sup>11</sup>

<sup>1</sup>Centre hospitalier de l'Université de Montréal (CHUM), Canada; <sup>2</sup>Indiana University School of Medicine, Indianapolis, USA; <sup>3</sup>Dartmouth Hitchcock Medical Center, Lebanon, USA; <sup>4</sup>NYU Langone Health, New York, USA; <sup>5</sup>Prince of Wales Hospital, New Territories, Hong Kong <sup>6</sup>Brigham and Women's Hospital, Boston, USA; <sup>7</sup>Asian Institute of Gastroenterology, Hyderabad, India; <sup>8</sup>Shanghai Zhongshan Hospital, Shanghai, China; <sup>9</sup>Showa University Koto Toyosu Hospital, Tokyo, Japan; <sup>10</sup>Boston Scientific Corporation, Marlborough, USA; <sup>11</sup>St. Michael's Hospital, Toronto, Canada

## INTRODUCTION

- Delayed bleeding is a significant clinical challenge after endoscopic resection of large gastrointestinal (GI) lesions.
- Prophylactic defect closure with through-the-scope (TTS) clips mitigates risk but is technically challenging for larger lesions.
- A novel rotatable, anchor-pronged TTS clip was introduced in 2022, offering improved tissue approximation for defect closure.

## AIM

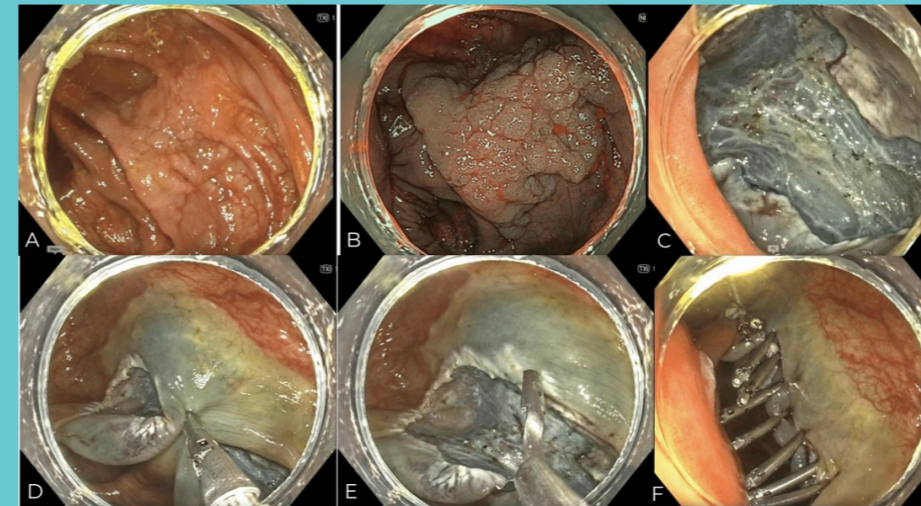
This study aimed to evaluate the efficacy of the new clip in preventing delayed bleeding after endoscopic mucosal resection (EMR), polypectomy, or endoscopic submucosal dissection (ESD).

## METHODS

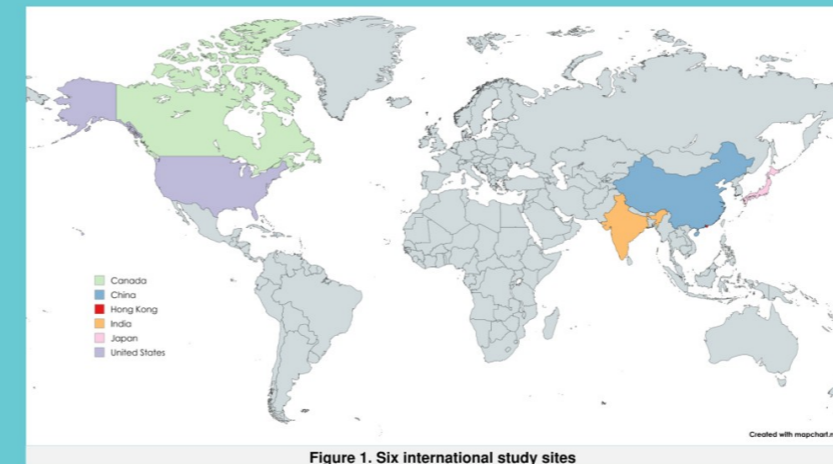
- Multicenter prospective cohort study across 10 centers in 6 countries, including patients undergoing prophylactic clipping with the MANTIS™ clip (Boston Scientific Corporation, Marlborough, Massachusetts, USA) after lesion resection by EMR, polypectomy, or ESD. (**Figure 1**).
- **Primary endpoint**
  - Incidence of delayed bleeding, defined as bleeding requiring hospitalization, blood transfusion or invasive intervention within 30 days.
- **Secondary endpoints**
  - Rate of complete defect closure
  - Device- or procedure-related serious adverse events (SAEs)
- Trial registered with ClinicalTrials.gov, number NCT05653843

## RESULTS

- **191 participants**
  - Mean age 65.4±12.2 (range 23-89) years
  - 110 (57.6%) male
- **199 lesions**
  - 172 lesions removed by EMR (**Figure 2**), 27 by ESD
  - 74.9% lesions colorectal
  - Median maximum lesion diameter 25.0 (IQR 18.0-40.0; max 100) mm
    - 148 (74.4%) lesions ≥20 mm
    - 89 (44.7%) ≥30 mm
    - 54 (27.1%) ≥40 mm
    - 27 (13.6%) ≥50 mm
- **Mean 4.2±2.9 total clips per procedure**
  - 2.7±2.2 study clips
  - 1.5±2.3 non-study clips
- **191 (96.0%) defects had complete closure**
  - 95.9% for EMR/polypectomy vs 96.3% for ESD (**Table**)
  - 96.0% for both colonic and noncolonic sites
  - 100% in lesions <20 mm vs 94.6% in lesions ≥20 mm
- **Delayed bleeding in 2 (1.0%) patients**
  - Bleeding at the ascending colon resection site in one patient (**Table**)
  - Bleeding at unspecified site in second patient
  - Both events began on day 1, resolved on day 2 postprocedure
- **3 (1.6%) patients had reinterventions for procedure-related SAEs**
  - 2 colonoscopies for the bleeding SAEs mentioned in "Delayed bleeding"
  - 1 surgery for a cecal perforation
- **8 (4.2%) patients had ≥ 1 procedure-related SAE**
  - Bleeding (2 patients), perforation (1), microperforation (1), aspiration (1), nausea (1), postpolypectomy syndrome (1), left lower abdominal pain (1)
  - No SAEs considered device-related



**Figure 2. Endoscopic mucosal resection (EMR).** (A) Granular, Paris Ila, JNET Ila, large non-pedunculated colorectal polyps in the cecum. (B) No concerning areas noted on narrow-band imaging. (C) Post-EMR defect following snare tip soft coagulation to the margin. (D) MANTIS clip closure of center of defect (open position). (E) MANTIS clip closure of center of defect (closed position). (F) Complete endoscopic clip closure.



**Figure 1. Six international study sites**

| Table. Main outcomes (N=199 lesions in 191 patients)             |                              |             |
|--|------------------------------|-------------|
|  | Lesions or patients, % (n/N) | 95% CI      |
| <b>Complete closure</b>  | 96.0% (191/199 lesions)      | 92.2%-98.2% |
| <b>By procedure type</b>   |                              |             |
| EMR/large polypectomy - prophylaxis                              | 95.9% (165/172 lesions)      | 91.8%-98.3% |
| ESD  | 96.3% (26/27 lesions)        | 81.0%-99.9% |
| <b>By anatomical site</b>  |                              |             |
| Colorectal EMR/ESD   | 96.0% (143/149 lesions)      | 91.4%-98.5% |
| Noncolonic EMR/ESD*  | 96.0% (48/50 lesions)        | 86.3%-99.5% |
| <b>By lesion size</b>  |                              |             |
| Lesion <20 mm  | 100.0% (51/51 lesions)       | 93.0%-100%  |
| Lesion ≥ 20 mm   | 93.9% (139/148 lesions)      | 88.8%-97.2% |
| Lesion <30 mm  | 97.3% (107/110 lesions)      | 92.2%-99.4% |
| Lesion ≥ 30 mm   | 93.3% (83/89 lesions)        | 85.9%-97.5% |
| Lesion <40 mm  | 97.2% (141/145 lesions)      | 93.1%-93.2% |
| Lesion ≥ 40 mm   | 90.7% (49/54 lesions)        | 79.7%-96.9% |
| Lesion <50 mm  | 97.1% (167/172 lesions)      | 93.3%-99.0% |
| Lesion ≥ 50 mm   | 88.9% (24/27 lesions)        | 70.8%-97.6% |
| <b>Delayed bleeding</b>  | 1.0% (2/191 patients)        | 0.1%-3.7%   |
| <b>Any serious adverse event related to endoscopic procedure</b> | 4.2% (8/191 patients)        | 1.8%-8.1%   |

\*Noncolonic sites included the esophagus, stomach, duodenum, ileoanal pouch (2), jejunum, appendiceal orifice (s/p appendectomy), gastric body

## CONCLUSIONS

Prophylactic use of the anchor-pronged TTS clip achieved high rates of complete defect closure and was associated with a low rate of delayed bleeding after resection of large GI lesions.

## REFERENCES

Guardiola JJ, Rex DK, Thompson CC, et al. A new through-the-scope clip with anchor prongs is safe and successful for a variety of endoscopic uses. *Endosc Int Open* 2024;12(6):E812-E817.

## ACKNOWLEDGEMENTS

Funded by Boston Scientific Corporation

## CONTACT INFORMATION

E-mail Dr. Jeffrey Mosko at [jeff.mosko@unityhealth.to](mailto:jeff.mosko@unityhealth.to)

