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Study Summary

Texture and Color Enhancement Imaging (TXI) Plus ENDOCUFF VISION™ Versus TXI Alone for Colorectal Adenoma Detection

A Randomized Controlled Trial

Pattarajierapan, S., Tipmanee, P., Supasiri, T. et al. Texture and color enhancement imaging (TXI) plus ENDOCUFF VISION™ versus TXI alone for colorectal adenoma detection: a randomized controlled trial. Surg Endosc 37, 8340–8348 (2023). https://doi.org/10.1007/s00464-023-10396-0

Conclusion

Adding ENDOCUFF VISION™ (ECV) Device to TXI™ Technology significantly improves Adenoma Detection Rate (ADR) and Adenomas Per Colonoscopy (APC) compared to TXI technology alone.

Objective

To determine if there is an added benefit of using TXI technology in combination with the ENDOCUFF VISION™ (ECV) device versus the use of TXI technology alone.

Design

Randomized controlled trial (Evidence Level 2*, according to Oxford Center Evidence based Medicine (2011)).

Primary Outcome

ADR using TXI technology combined with ECV device and TXI technology alone.

Secondary Outcome

APC, serrated lesion detection rate (SLDR), serrated lesion per colonoscopy, colonoscopy insertion time, and colonoscopy withdrawal time.

Colonoscopy Procedure

- The procedures were conducted at a single site, 9 King Chulalongkorn Memorial Hospital, Thailand. Two experienced endoscopists (≥1,000 colonoscopies per year and ≥5,000 in total) with ADRs ≥40% performed the exams.
- All procedures were performed using 290 or 1500 series HD colonoscopes and the EVIS X1™ video system center (Olympus Corporation, Tokyo, Japan). Half the patients were randomly assigned ENDOCUFF VISION™ Device
- After colonoscope insertion to the cecum, Endoscopists switched on TXI mode 2 for the entire colonoscope withdrawal phase.

* https://www.cebm.ox.ac.uk/resources/levels-of-evidence/ocebm-levels-of-evidence

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Participant Characteristics

Inclusion Criteria

- Age 40 years or more, and…
  - Undergoing colonoscopy for colorectal cancer screening, or…
  - Undergoing colonoscopy for any gastrointestinal symptoms

Exclusion Criteria

- History of colorectal cancer
- Previous colonic resection, known colonic stricture
- Inflammatory bowel disease
- Familial polyposis syndrome
- Refusal to consent to the study

Results

- The ADR of patients in the TXI technology and ECV device group was significantly higher than that of those in the TXI group (65.6% vs. 52.1%, P = 0.007), (Figure 1).
- Mean number of adenomas per colonoscopy (APC) was also higher in the TXI technology and ECV device group (1.6) compared to the TXI technology alone group (1.2, p = 0.02), (Figure 2).
- There was no significant difference in the mean withdrawal time in the TXI technology and ECV device group versus TXI technology alone group (10.1 minutes in both groups, p = 0.849).
- The APC was higher in the TXI technology and ECV device group than the TXI technology alone group for proximal (1.0 vs. 0.7, P = 0.031), diminutive (1.3 vs. 1.0, P =0.045), and non-pedunculated (1.4 vs. 1.1, P = 0.035) adenomas, (Figure 3).
- No difference existed in the APC for distal, small, large, pedunculated or advanced adenomas between the groups.

Note

- This is the first randomized controlled trial to investigate efficacy of Endocuff and TXI technology in combination to detect colorectal neoplasia, this study was conducted at one endoscopy centers in Thailand.
- The study has the following limitations:
  - **Study Design:** As the control group used TXI technology and not white light it was not possible to assess the synergistic benefits of TXI technology and ECV.
  - **Lack of Blinding:** The design used in this cannot be performed blinded (with regards to endoscopists), so that individual endoscopist bias cannot be excluded. Lack of blinding may influence proceduralists' behavior and interpretation of findings (Hawthorne Effect).
  - **Population Variability:** While the study was conducted in Thailand, the findings might not be universally applicable to different populations or settings.
  - **ECV Device Usage:** Against the manufacturer's recommendations the large ARV-140 size ECV was used for all procedures rather than the smaller ARV-120 size. This introduced a risk of loss or reduction of performance, and damage to the ENDOCUFF VISION™ or the colonoscope. In this study, no ECV detachment was observed during the procedure.

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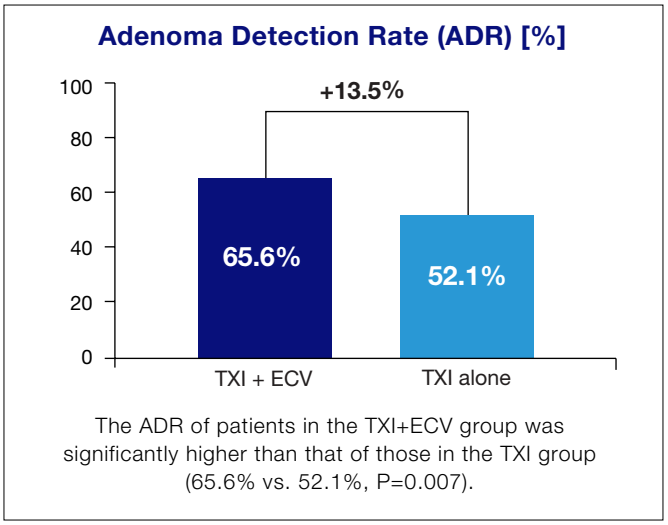
Disclaimer

ENDOCUFF VISION™ Device is 510(k) cleared in the United States. This study is being furnished to provide data results from this study that are related to the use of the ENDOCUFF VISION™ Device. Not all products used in this study, including the 290 and 1500 series colonoscopes, are currently available in all markets, including the United States. There is no time established as to when, or if, these products will be available in these markets, including the United States. The safety and effectiveness for these products and/or the use of some of these products has not yet been established in the United States market.

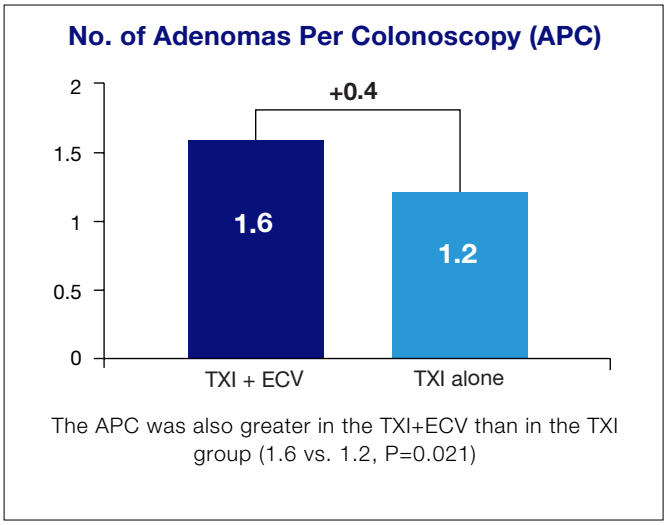
Graphical Results

Figure 1



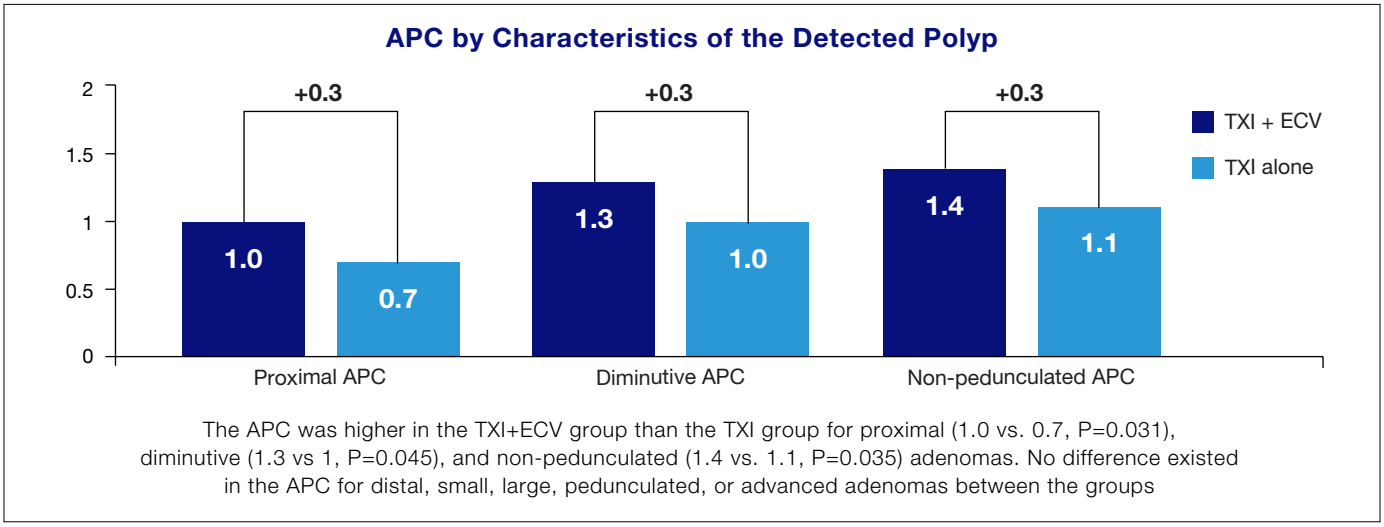
The ADR of patients in the TXI+ECV group was significantly higher than that of those in the TXI group (65.6% vs. 52.1%, P=0.007).

Figure 2



The APC was also greater in the TXI+ECV than in the TXI group (1.6 vs. 1.2, P=0.021)

Figure 3



The APC was higher in the TXI+ECV group than the TXI group for proximal (1.0 vs. 0.7, P=0.031), diminutive (1.3 vs 1, P=0.045), and non-pedunculated (1.4 vs. 1.1, P=0.035) adenomas. No difference existed in the APC for distal, small, large, pedunculated, or advanced adenomas between the groups

TXI technology is not intended to replace histopathological sampling as a means of diagnosis.

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