

Second-Generation Distal Attachment Cuff for Adenoma Detection in Screening Colonoscopy

A Randomized Multicenter Study

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Conclusion

A distal attachment cap with side arms significantly increased the ADR in patients undergoing primary colonoscopic screening. Because of the correlation of ADR and interval cancer, its use should be encouraged, especially in this setting.

Objective

To evaluate the impact of the ENDOCUFF VISION™ (ECV) device in a primary colonoscopy screening program.

Design

Multicenter randomized controlled trial (Evidence Level 2, according to Oxford Center Evidence based Medicine [2011])

Primary Outcome

Adenoma Detection Rate (ADR) using ECV device versus standard colonoscopy (SC)

Colonoscopy

- Patients over age 55 years undergoing screening colonoscopy in 9 German private offices in Berlin and Hamburg were randomized to either the study group (using ECV device) or the SC group.
- The colonoscopies were performed by 23 experienced examiners, each with more than 1,000 lifetime colonoscopy examinations.

Participant Characteristics

- A total of 1416 patients were included in the study (51.8% women; mean age, 61.1 years).
- Of 1416 patients, with a median of 41 examinations per examiner (n = 23; interquartile range, 12-81), 700 were examined using ECV device, and 716 were examined without it.

Results

- Adjusting for the effects of the colonoscopies, ADR was 39.5% in the ECV device group versus 32.2% in the SC group, which results in an increase of 7.2% (95%-CI: 2.3-12.2%; p=0.004). The polyp detection rate (PDR) was 47.2% in the ECV device group and 39.2% in the SC group, with a significant difference (p<0.002). (See **Figure 1** on next page).
- Adenomas per colonoscopy (APC) was also higher in the ECV device group (0.57 ECV vs 0.51 SC, p=0.045).
- ADR for adenomas <10 mm was 33.3% in the ECV device group and 24.0% in the SC group, a significant difference (p<0.001). In adenomas ≥10 mm there was no significant difference between the ECV device group and the SC group (See **Figure 2** on next page).
- No adverse events were reported in this study.

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Note

- This is the first study to include only patients undergoing primary colonoscopy screening, which in general has lower basal ADR rates than colonoscopies done within a FIT-based colorectal cancer screening program.
- The study has the following limitations:
 - **Lack of Blinding:** Endoscopists were not blinded to the intervention, which may introduce performance bias.
 - **Variability in Bowel Preparation:** Different bowel preparation regimens were used across centers, which could influence ADR, although this reflects real-world practice.
 - **Population Variability:** While the study was conducted in Germany, the findings might not be universally applicable to different populations or settings.

Figure 1: Overall Adjusted ADR and PDR

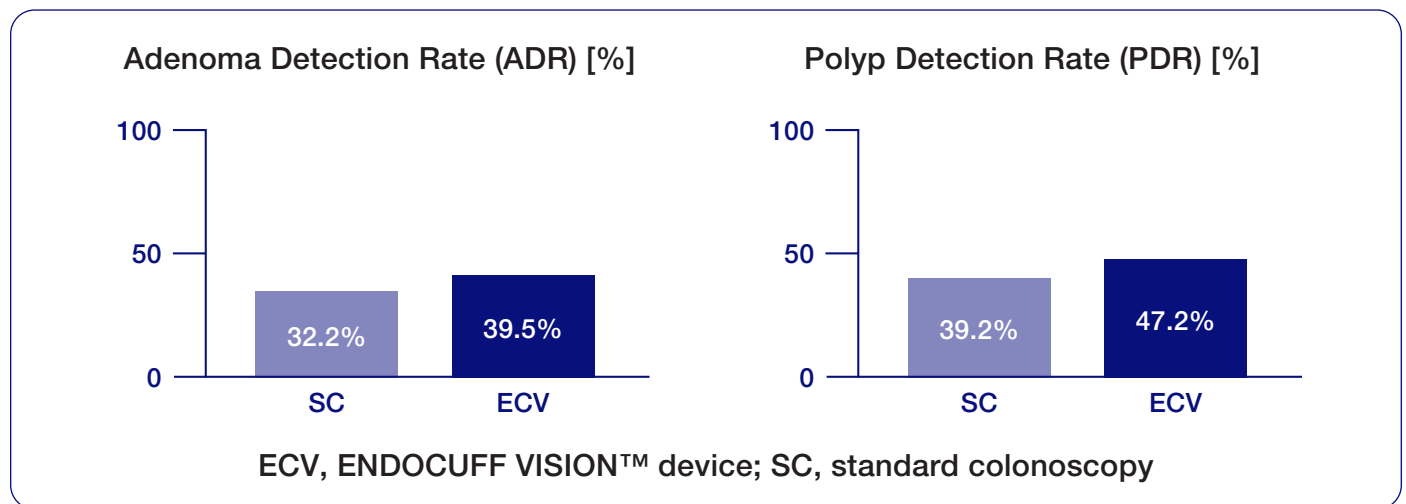
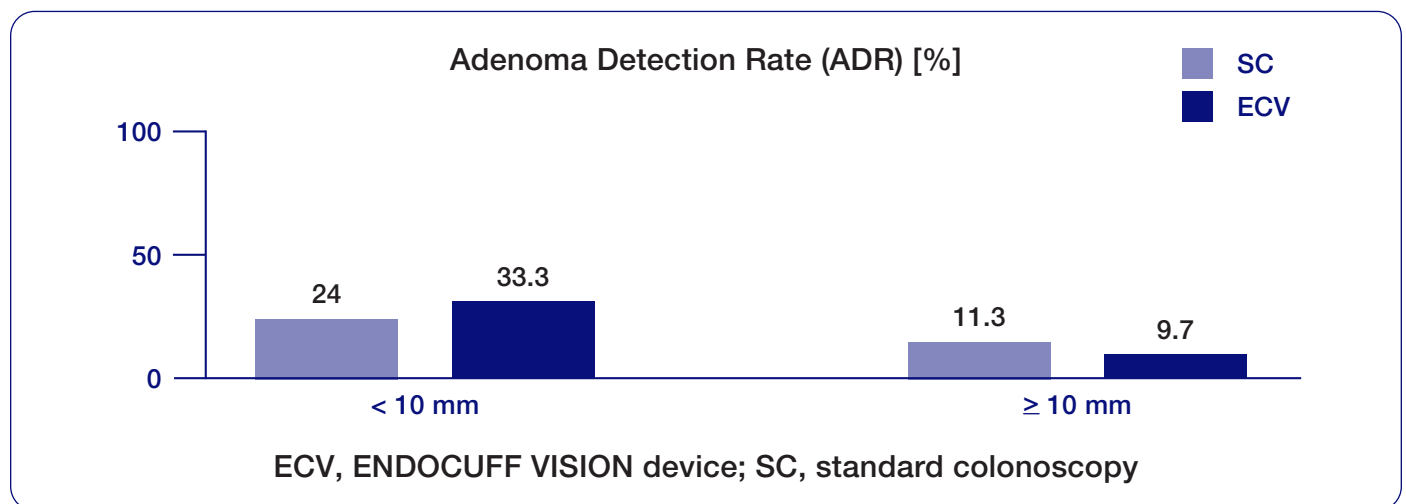


Figure 2: Adjusted ADR by Size of Adenoma



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