Japanese Journal of Gastroenterology and Hepatology

Clinical Paper

ISSN: 2435-1210 | Volume 8

Endocuff-Assisted Colonoscopy Demonstrates High Ileal Intubation and Adenoma Detection Rates in Trainees

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Received: 02 Jun 2022
Accepted: 14 Jun 2022
Published: 20 Jun 2022
J Short Name: JJGH

Citation:

Sawatzki M. Endocuff-Assisted Colonoscopy Demonstrates High Ileal Intubation and Adenoma Detection Rates in Trainees. J Gstro Hepato. V8(20): 1-7

Keywords:

Endocuff, ileum intubation, adenoma detection rate, colorectal cancer screening, quality measurements

Abbreviations:

ADR: Adenoma detection rate; CRC: Colorectal cancer; EC: Endocuff; ESGE: European Society of Gastrointestinal Endoscopy; IBD: Inflammatory bowel disease; IIR: Ileum intubation rate; PDR: Polyp detection rate; SC: Standard colonoscopy; SSL: Sessile serrated lesion; TI: Terminal ileum

1. Abstract

1.1. Introduction: The Endocuff (EC) significantly improves the Adenoma Detection Rate (ADR). Whereas cecal intubation and cost-effectiveness using the EC have been studied repeatedly, evidence regarding the Ileum Intubation Rate (IIR) remains scarce. This study investigates the IRR and ADR in EC-assisted colonoscopy compared with standard colonoscopy in patients undergoing screening and/or surveillance colonoscopy.

1.2. Materials and Methods: Patients referred for screening colonoscopy between January 2018 and August 2020 were prospectively included. Colonoscopies were performed by three experienced gastroenterologists and four trainees. EC was used at the discretion of the endoscopist. Primary outcome parameter was the IIR in both EC-assisted colonoscopy and standard colonoscopy; secondary outcome parameters were the ADR and factors associated with successful terminal ileum intubation.

1.3. Results: During the study period 971 colonoscopies were included (median age 60 years (IQR 54-68), 56% male). EC was used in 766 patients (85%). The IRR was comparable in EC-assisted and standard colonoscopy (79.4% vs. 76.0%, p=0.358), irrespective of the endoscopists' experience. Overall ADR was 55.1%. Particularly in trainees, the ADR significantly improved with the use of the EC (ADR standard colonoscopy 35%, ADR EC 52%, p=0.010). Experienced endoscopists detected more SSL's compared with trainees (13.2% vs. 7.4%, p=0.003). No adverse events were reported.

1.4. Conclusion: Terminal ileum intubation in EC-assisted colonoscopy is feasible and was achieved at a rate comparable to standard colonoscopy, irrespective of the endoscopists' experience. A significantly increased ADR in trainees performing EC-assisted colonoscopy may support the participation of less-experienced endoscopists in colorectal cancer screening programs.

2. Introduction

Colonoscopy is the primary or follow-up screening test to detect colorectal adenomas and cancer [1, 2], the second most common cancer in Europe and the United States [3, 4]. The most important quality indicator in screening colonoscopy is the Adenoma Detection Rate (ADR), which is inversely associated with the risk for developing interval Colorectal Cancer (CRC) [5, 6]. An ADR >25% is therefore crucial for the effectiveness of CRC screening programs, and consequently screening colonoscopy should be performed only by experienced endoscopists. However, trainees are part of many CRC screening programs because of an increasing number of procedures. Thus, especially in low-detectors an increase of the ADR is mandatory. In the past years, evidence was rising that add-on devices such as the Endocuff (EC) can improve the ADR. Next to an 7% increase in detecting adenomas compared with Standard Colonoscopy (SC), a

faster cecum intubation and a decreased withdrawal time emphasize the value of EC-assisted colonoscopy in a CRC screening population [7-11]. In the most recent guidelines, add-on devices are also recommended in average risk patients to increase ADR [12], and recent data indicate cost-effectiveness using the EC [13]. Despite these advantages, concerns were raised against the routine use of EC. The larger diameter of the tip of the colonoscope due to the attached cap can complicate the passage of narrowed colonic segments, especially in patients with diverticulosis. EC-assisted colonoscopy may be contraindicated in patients requiring terminal ileum intubation, for example in Crohn's disease. Additionally, a lower terminal Ileum Intubation Rate (IIR) compared with standard colonoscopy has been described [14], and only one study investigated the IIR as a primary endpoint [15]. However, many endoscopists prefer to routinely intubate the terminal ileum in terms of a quality indicator and the need to increase the ADR especially in trainees are reasons to suggest EC-assisted colonoscopy as a standard in screening and surveillance colonoscopy.

The aim of this study was to prospectively evaluate the rate of ileum intubation and the ADR in EC-assisted compared with standard colonoscopy in a population undergoing screening colonoscopy by experienced endoscopists and trainees.

3. Methods

3.1. Patient Population

This prospective study was conducted at the outpatient clinic of the Kantonsspital St. Gallen, a tertiary referral center in Switzerland. All patients undergoing screening or surveillance colonoscopy between January 2018 and August 2020 were prospectively included. The decision to perform colonoscopy with or without the use of EC was at the discretion of the endoscopist. Patients <18 years were excluded from the analysis.

The anonymized database contains information regarding gender, experience of the endoscopist, EC use (yes/no), indication of the endoscopy, presence of polyps, and the corresponding histological diagnosis. Data analysis was conducted in accordance with the ethical guidelines of the Helsinki Declaration 1975 and approved by the Ethics Committee of Eastern Switzerland (EKOS 20/036).

3.2. Histopathological Analysis

The histopathological analysis of all specimens was performed at one centralized pathology center (Institute of Pathology, Kantonsspital St. Gallen). Specimens were classified as hyperplastic polyp, sessile serrated lesion, tubular, tubulovillous or villous adenoma or colorectal carcinoma. Dysplasia was graded according to the Vienna classification into non-dysplastic, indefinite for dysplasia, low-grade dysplasia, high-grade dysplasia or invasive carcinoma (16).

3.3. Endoscopy Procedure

The colon was cleansed with a split dose of Macrogol® over two days. The colonoscopy was performed under conscious propofol sedation in left lateral position and with CO2 insufflation. Cecal intubation was documented on the base of the appendix. The intubation of the terminal ileum was attempted in every colonoscopy, irrespective of the indication and the use of the EC. The colonoscopies were performed by three experienced endoscopists (>4000 colonoscopies) and four less-experienced trainees (<400 colonoscopies). The examinations were performed using standard of care Olympus® endoscopes (CF H-180, CF-HQ190L and PCF-H190L).

3.4. Definitions

Ileum intubation was defined as documented intubation of the ileal valve by a peri-procedural image of the ileal mucosa. ADR was defined as biopsy or endoscopic resection of at least one histopathological confirmed adenoma (excluding hyperplastic polyps) per endoscopy. Polyp detection rate (PDR) was defined as the prevalence of at least one polyp (including sessile serrated lesions/hyperplastic polyps) per endoscopy.

3.5. Endocuff

Endocuff Vision® (Arc Medical Design Ltd, Leeds England) is a CE-certified and FDA-approved device that is attached cap-like to the distal tip of the colonoscope. The eight flexible branches flatten the folds of the colon during the withdrawal, improving the visibility behind the folds and consecutively the detection of hidden adenomas.

3.6. Outcome Measures

The primary endpoint was the IIR in both EC-assisted colonoscopy and standard colonoscopy. Secondary endpoints were factors associated with an increased IIR (ie the use/absence of EC, experience of the endoscopist), the ADR and the PDR for both EC-assisted and standard colonoscopy and the rate of colonoscopy related complications.

3.7. Statistical Analysis

Mean and SD were used for normally distributed continuous variables. Median and IQR were used for continuous variables with a skewed distribution. We performed a binary logistic regression and a linear regression to estimate the effect of clinical and procedural factors on successful TI intubation. Statistical calculations were performed using SPSS, version 24.0 (IBM Corp, Armonk, NY).

4. Results

4.1. Patient Characteristics

Between January 2018 and August 2020, 971 patients underwent a screening or surveillance colonoscopy at the outpatient clinic of the Kantonsspital Sankt Gallen. Median age was 60 years (IQR 54-68), and 42.2% were male. EC-assisted colonoscopy was performed in 825 patients (85%), whereas 146 patients (15%) underwent standard colonoscopy. Four-hundred fifty-five (46.9%) of the colonoscopies were performed by experienced endoscopists, and 516 (53%) by trainees. Baseline characteristics are shown in Table 1.

Table 1: Baseline characteristics

	Included patients *(n=971)*
Median age, years (IQR)	60 (54-68)
Male sex, n (%)	410 (42.2)
Colonoscopy performed by experienced endosocopist, n (%)	455 (46.9)
Indication, n (%) - Screening - Surveillance	 637 (65.6) 334 (36.4)
EC-assisted colonoscopy, n (%)	825 (85%)

EC=Endocuff-assisted, IQR=Interquartile range

4.2. Terminal Ileum Intubation Rate

In 655 out of 825 patients undergoing EC-assisted colonoscopy, TI intubation was successful, whereas in 111 out of 146 patients undergoing standard colonoscopy the TI was successfully intubated (79.4% vs. 76.0%, p=0.358). Experienced endoscopists had a similar IIR with and without the EC (78.4% vs 81.2%, p=0.552). In trainees, IIR in EC-assisted colonoscopy was 77.9% compared with an IRR of 72.4% in standard colonoscopy (p=0.343) (Table 2). Overall IIR was comparable between experienced endoscopists and trainees (80.7% vs. 77.3%, p=0.204). Figure 1 illustrates successful TI intubation in EC-assisted colonoscopy.

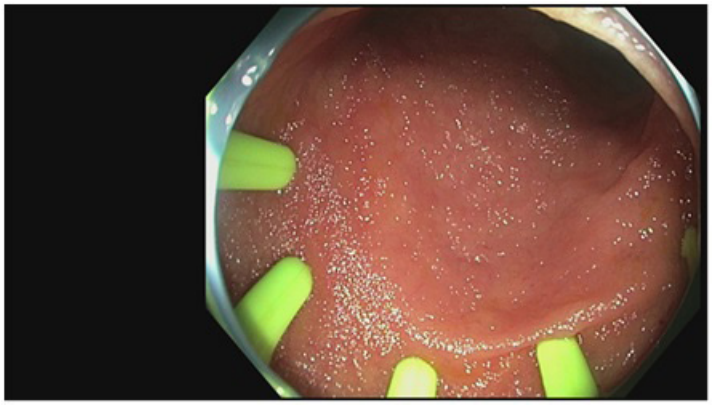

Figure 1: Example of terminal ileum intubation in Endocuff-assisted colonoscopy

Table 2a: Terminal ileum intubation rate (IIR).

	EC-assisted colonoscopy n=825	Standard colonoscopy n=146	p-value
Overall IIR, n (%)	655 (79.4)	111 (76.0)	ns
IIR in experienced endoscopists, n (%)	298 (81.2)	69 (78.4)	ns
IIR in trainees, n (%)	357 (77.9)	42 (72.4)	ns

Table 2b: Univariable analysis* of TI intubation success

Variable	Events, n (%)	OR (95% CI)
Endocuff		
No	111/146 (79.4)	1 (referent)
Yes	655/825 (76.0)	1.22 (0.80-1.84)
Sex		
Female	246/316 (77.8)	1 (referent)
Male	328/410 (80.0)	1.14 (0.80-1.63)
Experience		
Trainee	399/516 (77.3)	1 (referent)
Experienced endoscopist	367/455 (80.7)	1.22 (0.90-1.67)

CI=Confidence Interval; IRR=Terminal Ileum Intubation Rate; OR=Odds Ratio; TI='Terminal ileum

* Binary logistic regression using the enter method

4.3. Factors Associated with Increased Ileocecal Intubation Rate

Neither the presence/absence of the EC device (OR 1.22 (95%CI 0.80-1.84)) nor the level of endoscopist's experience (OR 1.22 (95%CI 0.9-1.67)) were associated with a successful TI intubation (Table 2b).

4.4. Adenoma and Polyp Detection Rate

In 535 out of 971 patients, at least one adenoma was detected, resulting in an ADR of 55.1%. A higher ADR was achieved in the EC-assisted colonoscopy compared with patients undergoing standard colonoscopy; however, this difference was statistically not significant (56.1% vs. 49.3%, p=0.120). Similar results were observed if the ADR in EC-assisted and standard colonoscopy was compared in the subgroup of experienced endoscopists (60.8% vs. 59.1%, p=0.809).

In contrast, in trainees a significant increase of the ADR could be observed in EC-assisted colonoscopy compared to standard colonoscopy (52.4% vs. 34.4%, p=0.010). Details regarding the number and type of adenomas detected are shown in Table 3.

Table 3a: ADR and PDR in all included patients

	Included patients (n=971)
ADR, n (%)	535 (55.1)
PDR, n (%)	668 (68.8)

Table 3b: ADR and PDR in the subsets of EC-assisted and SC

	EC-assisted colonoscopy n=825	Standard colonoscopy n=146	p-value
ADR, n (%)	463 (56.1)	72 (49.3)	ns
PDR, n (%)	582 (70.5)	86 (58.9)	0.005
ADR			
- Trainee	240 (52.4)	20 (34.4)	0.012
- Experienced endoscopist	223 (60.8)	52 (59.1)	ns
Advanced adenoma, n (%)	115 (13.9)	22 (15.0)	ns
Adenoma <10mm, n (%)	400 (48.5)	60 (41.1)	ns
Histology adenoma, n (%)			
- Sessile serrated lesion	83 (10.0)	15 (10.3)	ns
- Tubular	378 (45.8)	56 (38.4)	ns
- Tubulovillous	2 (0.2)	2 (1.4)	NA*
- HGD/carcinoma	2 (0.2)	1 (0.7)	NA*

* Numbers too small for statistical analysis

ADR=Adenoma detection rate; EC=Endocuff; IQR=Interquartile range; HGD=high-grade dysplasia NA=Not available, PDR=Polyp detection rate

4.5. Sessile Serrated Lesion Detection Rate

In 98 out of 971 (10.1%) colonoscopies, sessile serrated lesions (SSL) were detected. Experienced endoscopists diagnosed SSL in 13.1% of the EC-assisted colonoscopies compared with 13.6% in standard colonoscopy (p=0.890). Trainees had an SSL detection rate of 5.2% (standard colonoscopy) and 7.6% using EC (p=0.498). Overall, experienced endoscopists detected significantly more SSL compared with trainees (13.2% vs. 7.4%, p=0.003). Figure 2 shows a SSL detected in EC-assisted colonoscopy.

4.6. Complications in EC-assisted and standard colonoscopy

No complications occurred in EC-assisted or in standard colonoscopy.

5. Discussion

In this prospective single center study, we investigated the IIR and ADR in EC-assisted and standard colonoscopy in patients undergoing screening or surveillance colonoscopy. We demonstrated an IIR of 79.4% in EC-assisted colonoscopy, comparable with an IIR of 76.0% in standard colonoscopy. A similar IIR with or without EC was observed in experienced endoscopists and trainees, with the latter having a significantly higher ADR in EC-assisted colonoscopy compared with standard colonoscopy. Experienced endoscopists had a significant higher SSL detection rate compared with trainees, irrespective whether the EC was used or not.

In our prospective single-center study, we observed an IIR of almost 80% in EC-assisted colonoscopy. This is higher than the majority of the 10 previously published studies, which report a highly variable IIR in EC-assisted colonoscopy ranging from 7.7 to 83% (Table 4 summarizes the 10 published studies reporting the IIR in EC-assisted colonoscopy). Three factors may contribute to our high IIR. First, in contrast to the majority of published studies we attempted to intubate the ileocecal valve in every colonoscopy in terms of a quality feature. In contrast, in the study of Sola-Vera et al. the intubation of the ileocecal valve was not forced, resulting in a very low IIR of 7.7% [11]. Second, and again in contrast to the majority of published studies [7, 11, 17-21], we included only screening and surveillance colonoscopies. In a screening colonoscopy, one may expect a normal configuration of the ileocecal valve. In patients with inflammatory bowel disease, a stenotic ileocecal valve due to inflammation and consecutive fibrosis is more difficult to pass due to the attached EC at the tip of the endoscope and the consecutively increased diameter of the scope. This was demonstrated by a lower IIR in EC-assisted colonoscopy in several studies evaluating the EC in patients undergoing diagnostic colonoscopy [11, 17-20] including patients with inflammatory bowel disease. Third, a minimum number of EC-assisted colonoscopies rather than the absolute number of performed colonoscopies (with or without EC) seems to be crucial for a successful intubation of the terminal ileum in EC-assisted colonoscopy. In our outpatient clinic, the EC is recommended in all screening and surveillance colonoscopies. Thus, trainees use the EC already in the beginning of their training programme. This probably contributes to their comparable IIR in EC-assisted and standard colonoscopy. The fact that both trainees and experienced endoscopists achieved a high and similar IIR in EC-assisted and standard colonoscopy indicates a steep learning curve, particularly in less-experienced endoscopists. This learning curve is also demonstrated by an absolute increase of 14.6% regarding the IIR when our first experience using the EC in our pilot study from 2015 is compared with the results of the current study [22].

Based on our data, we were not able to identify factors associated with a successful intubation of the terminal ileum. Vemulapalli et al. described recently an increased IIR if the cecum was filled with

water instead of gas [21]. Additionally, they identified an association between the use of a pediatric scope and successful intubation of the terminal ileum in a multivariable logistic regression model [21]. These results are promising and may further contribute to establish the use of the EC in screening colonoscopy.

Overall, we observed a high ADR in EC-assisted colonoscopy, which is in line with previously published studies (Table 4). The additional value of EC-assisted colonoscopy becomes evident especially in trainees, where the use of the EC resulted in an absolute increase of the ADR of 17%. The high ADR in trainees indicates that the EC has the potential to partially compensate for the lack of experience regarding the ADR.

Table 4: Summary of published studies reporting the terminal ileum intubation rate in EC-assisted colonoscopy.

Reference	Study Setting	Study population	EC:SC	Experience	IIR	ADR	Limitations
					EC vs. SC	EC vs. SC	
2014 (18) Floer	Multi-center RCT EC vs. SC	Screening/ Surveillance Diagnostic	252:248	10 experienced	66% vs. 71% p=0.239	35% vs. 21% p=<0.0001	Diagnostic Experienced only
2014 (27) Lenze	Retrospective Cohort	Screening/Surveillance	50:00:00	NA	65-83%	34%	Only EC Retrospective
2015 (7) Biecker	Multi-center RCT EC vs. SC	Screening/ Surveillance Diagnostic	239:247	6 experienced	71% vs. 70% p=0.741	NA	Diagnostic Experienced only
2015 (22) Sawatzki	Multi-center RCT Single-arm	Screening/Surveillance	104:00:00	5 endoscopists (4x>2500, 1x>1000 colonoscopies)	64%	47%	Single-arm Experienced only
2017 (14) González-Fernández	Single-center RCT EC vs. SC	Screening	174:163	6 experienced 12 trainees	73% vs. 78% p=<0.001	22% vs. 13% p=0.02	Single-center
2019 (17) Fang	Single-center Single-arm	Screening in UC	25:00:00	2 experienced	44%	NA	Single-arm Ulcerative colitis Experienced only
2019 (11) Sola Vera	Single-center RCT EC vs. CAC	Screening/ Surveillance Diagnostic	357:354	8 experienced	7.7% vs. 9.8%* p=0.32	50% vs. 51% p=0.97	IIR not force Diagnostic Experienced only
2019 (19) Jacob	Single-center RCT EC vs. SC	Screening/ Surveillance Diagnostic	182:138	Surgeons	52% vs. 52% p=0.905	37% vs. 29% p=ns	Surgeons Single-center Diagnostic
2020 (20) Karsenti	Single-center RCT EC vs. SC	Screening/ Surveillance Diagnostic	1026:1032	22 endoscopists Experience NA	28% vs. 40% p=<0.001	39% vs. 29% p=<0.001	Diagnostic Experience NA
2020 (21) Vemulapalli	Single-center RCT EC vs. SC	Screening/ Surveillance Diagnostic	149:55:00	NA	65% vs. 91% p=<0.001	NA	Diagnostic Experience NA
2021 Current study	Single-center EC vs. SC	Screening/Surveillance	766:205	3 experienced 4 trainees	79.4% vs. 76% p=0.552	56% vs. 49% p=0.120	Single-center

CAC=Cap-assisted colonoscopy; EC=Endocuff; IRR= Ileum intubation rate; NA=not available; SC=standard colonoscopy; RCT=Randomized controlled trial,

* Cap-assisted colonoscopy

However, the EC increased only the detection rate of tubular adenomas with a size of less than 10 mm, whereas the detection rate of advanced adenomas (including a size of >10 mm, tubulo-villous and high-grade dysplasia/carcinoma) was comparable between EC-assisted and standard colonoscopy. This can be considered as plausible, since the EC facilitates visualization of smaller lesions with flattening the mucosa. Interestingly, the detection rate of SSL did not improve with the use of the EC. This is in contrast with a recent study published by Rex et al. [15] who found a significantly increased serrated polyp detection rate of 19.8% in EC-assisted colonoscopy compared with 11.1% in standard colonoscopy. A potential explanation might be the relatively low number of patients included into this study. Although our study showed a trend toward a higher SSL detection rate in EC-assisted colonoscopy particularly in trainees, the difference did not reach statistical significance. Additionally, we observed a significantly higher overall SSL detection rate in experienced endoscopists compared to trainees. If this is of clinical relevance remains debatable, since the trainees in our study achieved a SSL detection rate of 7.4% in EC-assisted colonoscopy, which is comparable with the SSL rate in other studies using standard colonoscopy only [23, 24]. However, an excellent ADR in EC-assisted colonoscopy may support the participation of trainees in colorectal cancer screening programs. Future studies need to address if the lower SSL rate in trainees using EC-assisted colonoscopy have an adverse effect on the number of interval cancer in the setting of colorectal cancer screening.

A limitation of our study is the lack of randomisation (EC-assisted versus standard colonoscopy), which may lead to a selection bias in favour of EC-assisted colonoscopy. However, in the included patients undergoing screening and surveillance colonoscopies, the anatomy of the ileocecal valve can be expected to be normal, and intubation of the terminal ileum was attempted irrespective whether the EC was used or not. Furthermore, with the exclusion of patients undergoing diagnostic colonoscopy, data regarding the IIR in pa-

tients with inflammatory bowel disease remains scarce. Demonstrating that intubation of the terminal ileum is feasible and safe at a rate comparable with standard colonoscopy in a screening setting, our results support additional studies evaluating the EC for CRC screening colonoscopies in patients with Crohn's disease or ulcerative colitis. One may criticize that an IRR of 76% in standard colonoscopy is low if compared to international references, but we feel that our success rate reflects the real world intubation rate if less-experienced endoscopists are included in the analysis. In addition, all endoscopies were performed in a routine screening setting, allowing not for additional endoscopy time for forced ileum intubation. Given these time constraints, additional maneuvers such as switching the left-lateral position of the patient to a supine or right-lateral position were not routinely used. In addition, the high ADR (and the consecutively required time for polypectomy) in this study further limited the "extra" time for ileum intubation. Other studies showed in similar settings a much lower or comparable IIR [25, 26], respectively.

However, factors such as length and type of endoscopes, lateral versus supine position and external manual splitting were not routinely assessed in our study, which could have increased the IIR particularly in EC-assisted colonoscopy. Last, the trainees participating in our study (and especially their high ADR) may not be comparable with trainees in other countries, since we motivate fellows to start using the EC device early in their training program. Despite a steep learning curve, future studies are needed to investigate the minimum number of EC-assisted colonoscopy to achieve a high IIR in combination with an ADR >25%.

In summary, ileum intubation in EC-assisted colonoscopy was high and achieved at a rate comparable with standard colonoscopy, irrespective of the experience of the endoscopist. A significantly increased ADR in trainees performing EC-assisted colonoscopy may support the participation of less-experienced endoscopists in CRC screening programs. Future studies need to address if the lower SSL rate in trainees using EC-assisted colonoscopy have an adverse effect on the number of interval cancers.

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