

The efficacy of cap-assisted colonoscopy performed by a single endoscopist in patients after colorectal resection

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Abstract

Background: The use of a transparent cap is regarded as a simple method to obtain better outcomes compared with standard colonoscopy. In this study, we investigated whether cap-assisted colonoscopy can improve the quality of procedure-related outcomes in patients with a history of colorectal resection.

Methods: This study was designed as a prospective, randomized, controlled trial conducted at a single tertiary center by a single endoscopist (Kang J.). A total 183 patients after colorectal resection due to primary colorectal cancer were enrolled and 1:1 randomized to undergo either cap-assisted colonoscopy (CAP group) or standard colonoscopy (non-CAP group). The primary endpoint was the comparison of cecal intubation time between the 2 groups.

Results: The mean cecal intubation time of the CAP group (n=89) was significantly shorter than that of the non-CAP group (n=89) (538 seconds vs 677 seconds, $P=0.024$). In the CAP group, the endoscopist performed faster intubation than average more often compared with the non-CAP group (71.9% vs 57.3%). In regard to moving average curve, the CAP group showed a gentle slope during the learning period, while the non-CAP group showed a steep decrease.

Conclusion: The cap-assisted colonoscopy could reduce cecal intubation time and achieve more frequent faster intubation compared with standard colonoscopy in patients after colorectal resection.

Abbreviations: BMI = body mass index, MIS = minimally invasive surgery, SD = standard deviation, WT = withdrawal time.

Keywords: cap, cecal intubation, colonoscopy, colorectal resection

1. Introduction

Colonoscopy has been widely recommended as the standard diagnostic tool for detection of malignant or precancerous lesions in the colorectum.^[1,2] In patients who previously underwent colorectal resection due to primary cancers, regular colonoscopic surveillance is even more essential because of their higher risk of developing metachronous neoplasia^[3,4] with an annual incidence of 0.35%.^[5]

Despite the benefits, colonoscopy is still a difficult technique because of patient's intolerance and the endoscopists feel

overwhelmed by pressure of successful cecal intubation. Even for well-trained endoscopists, failure rates up to 10% have been reported.^[6–8] Several factors are known to cause failed or delayed complete colonoscopic exams, including female sex, old age, poor bowel cleanliness, low body mass index (BMI), a history of abdominopelvic surgery, complicated diverticular disease, and peritonitis.^[9–17]

The use of a transparent cap is a simple method to obtain better outcomes with relatively low cost and no additional procedure. In previous studies, this cap-assisted colonoscopy method was shown to shorten cecal intubation time and perform better as a rescue method both for experienced and inexperienced endoscopists.^[18–20] Even though it is unclear that cap-assisted colonoscopy can enhance polyp detection,^[21–23] most recent studies have demonstrated faster cecal intubation time with cap-assisted colonoscopy than standard colonoscopy.^[19,21,24] However, most previous randomized studies investigating the impact of cap-assisted colonoscopy excluded patients who underwent colorectal resections. Therefore, little is known about the impact of cap-assisted colonoscopy in this patient population.

In this study, we aimed to investigate whether cap-assisted colonoscopy can improve the quality of procedure-related outcomes in patients with a history of colorectal resection.

2. Materials and methods

2.1. Study design

This study was designed as a prospective, randomized, controlled trial conducted at a single tertiary center (Gangnam Severance

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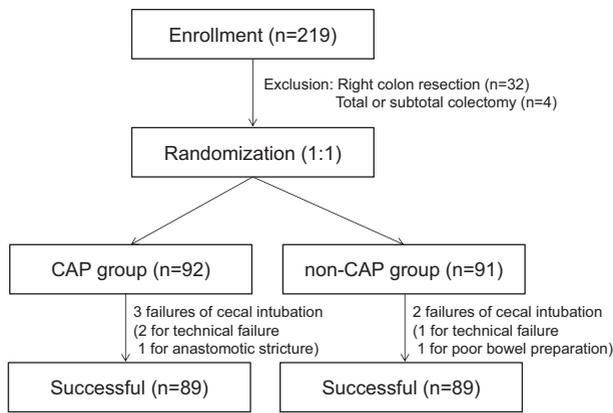


Figure 1. Flow diagram demonstrating enrollment of the patients.

Hospital, Yonsei University College of Medicine) by a single endoscopist (Kang J.) from October 2012 to August 2013. The study was approved by the local institutional review board.

A total of 183 patients with history of an operation to treat primary colorectal cancer were enrolled in this study and randomly assigned to undergo cap-assisted colonoscopy (CAP group) or standard colonoscopy (non-CAP group) based on computer-generated random sequences (Fig. 1). The endoscopist performed about 70 colonoscopies under supervision and an additional 50 colonoscopies without any supervision, and had no experience in the use of CAP before onset of this trial. Considering technical convenience, patients who underwent right-sided colon resection, subtotal colectomy, or total proctocolectomy were excluded before randomization. Colonoscopy was performed for postoperative surveillance. Written informed consent was obtained from all participants.

2.2. Procedures and outcome measurement

Before their procedures, all participants received standard bowel preparation including a one-day low-residue diet followed by 4L of polyethylene glycol-containing lavage solution. Sedation was not induced during procedures, and patients were given only a single intramuscular analgesic injection (pethidine 50mg for males, 25 mg for females). One colonoscope (CF-H260 AL/I, Olympus, Tokyo, Japan) was used for the examination, and a transparent cap (D-201-14305, Olympus, Tokyo, Japan) was fitted to the tip of the colonoscope in the CAP group.

During the insertion phase, the endoscopist intended to intubate the cecal base as quickly as possible without any effort to detect polyps. When cecal intubation was confirmed, photo documentation with stopwatch was performed to show the appendiceal orifice and cecal valve, or intubation of the terminal ileum. During the withdrawal phase, the colonic mucosa was

observed carefully, and all detected polyps were removed for pathologic assessment.

After the procedure, quality of bowel preparation was assessed by the endoscopist using the 5-grading system of Aronchick bowel preparation scale.^[25] In this study, results of the quality of bowel preparation were defined as excellent (Aronchick scale “excellent”), fair (Aronchick scale “good,” “fair”), and poor (Aronchick scale “poor,” “inadequate”).

The primary endpoint of this study was the comparison of cecal intubation time between the 2 groups. As secondary outcomes, total colonoscopy time, faster intubation rate (defined as a cecal intubation time shorter than mean value), polyp detection rate, and complication rate were assessed.

2.3. Sample size calculation and statistical analysis

At least 182 subjects were required to have 90% power with a type I error rate of 0.05 and a dropout rate of 20%. Incremental difference between the 2 groups was based on a previous national result,^[26] reporting a shortened mean cecal intubation time of 2.1 minutes in the CAP group. We used the moving average method to represent the cecal intubation time. To filter the variation caused by variation of individual values, averaging of past values was used to clarify the trend of the cecal intubation time. A moving average order of 10 was defined as the mean of the previous 10 data points.

$$\text{Simple moving average(SMA)}_{(10)}(n) = X_n + X_{n-1} + \dots + X_{n-9} / 10$$

All statistical analyses were performed using SPSS software, version 20.0 (SPSS, Chicago, IL). χ^2 test or Fisher exact test was used for analysis of categorical variables, and continuous variables were analyzed using Student’s *t*-test. Univariate and multivariate analyses were performed using logistic regression. A value of $P < 0.05$ was considered statistically significant.

3. Results

Among the 183 participants, 92 patients were randomized into the CAP group, and 91 patients were randomized into the non-CAP group. The endoscopist failed to reach the cecum in 3 cases due to technical difficulty, in 1 case due to anastomosis site stricture, and in 1 case due to poor bowel preparation (Table 1). Demographic data including sex, BMI, length of resected colon, and bowel cleanliness were comparable between the 2 groups (Table 2).

3.1. Procedure-related outcomes

There were no procedure-associated complications to report. There was no significant difference in polyp detection rate between the 2 groups.

Table 1 Analysis of intubation failure among the initially enrolled patients (N = 183).

	CAP	Non-CAP	P
Failure rate	3/92 (3.2%)	2/91 (2.1%)	1.0*
Reason of intubation failure	2, technical failure 1, anastomosis site stricture	1, technical failure 1, hard stool in transverse colon	

* Fisher exact test.

Table 2**Baseline characteristics of patients (N=178).**

		CAP (N=89), n (%)	Non-CAP (N=89), n (%)	P
Sex	Male	66 (74.2)	65 (73.0)	0.865
	Female	23 (25.8)	24 (27.0)	
Age, y (mean ± SD)		61.1 ± 9.8	60.2 ± 10.8	0.573
BMI, kg/m ² (mean ± SD)		24.2 ± 2.8	23.8 ± 3.0	0.276
Length of resected colon, cm (mean ± SD)		17.8 ± 6.1	19.0 ± 7.2	0.240
Duration from operation, d (mean ± SD)		1034 ± 697	903 ± 712	0.217
Operation method	MIS*	71 (79.8)	72 (80.9)	0.850
	Open	18 (20.2)	17 (19.1)	
Bowel cleanliness	Excellent and fair	66 (74.2)	67 (75.3)	0.863
	Poor	23 (25.8)	22 (24.7)	

BMI=Body Mass Index, SD=standard deviation.

* MIS: minimally invasive surgery included a laparoscopic surgery and a robotic surgery.

The mean cecal intubation time of the CAP group was significantly shorter than that of the non-CAP group (538 seconds vs 677 seconds, $P=0.024$). Also, there was a statistical difference in total colonoscopy time and a faster intubation rate. In the CAP group, the endoscopist performed faster intubation than average more often compared with the non-CAP group (71.9% vs 57.3%) (Table 3). When we compared the outcomes of cecal intubation and colonoscopy time according to bowel preparation grade, the CAP group showed shorter cecal intubation time and higher faster intubation rate in well-prepared patients. However, in patients with poor preparation, there was no significant difference between the 2 groups (Table 4). In multivariate analysis, female sex and attachment of cap were significantly associated with faster intubation (Table 5).

In regard to moving average curve, the CAP group showed a gentle slope during the learning period, while the non-CAP group demonstrated a steep decrease before maintaining a steady state. The learning period to reach steady state was achieved after 40 cases in both groups (Fig. 2).

4. Discussion

This study revealed that cap-assisted colonoscopy reduced cecal intubation time and achieved faster intubation than average more often compared with standard colonoscopy.

Diverse opinions have been reported whether prior abdominal or pelvic surgery can cause difficulties in complete colonoscopy or not. Most have agreed that a history of hysterectomy is significantly related to procedure incompleteness and prolonged cecal intubation time.^[10-12,16] Also, it is generally believed that previous pelvic surgery results in poor cooperation during

passage of the sigmoid colon, and upper abdominal surgery, such as gastrectomy, usually causes discomfort during passage of the transverse colon or hepatic flexure. This phenomenon seems to be developed from parts of colon trapped in adhesions,^[27] however; analyzing the effect of previous abdominal surgery on procedure completeness is not simple, due to multiple surgical types and approaches

Although there is room for controversy, cap-assisted colonoscopy has been considered as a useful tool for successful colonoscopy. Especially in specific situations including older patients, those with previous abdominal surgery, or females with low BMI, cap-assisted colonoscopy has displayed a shorter cecal intubation time.^[19,21,24] Although the efficacy of cap-assisted colonoscopy has been demonstrated in randomized, controlled trials,^[19-21,28,29] most previous studies comparing cap-assisted colonoscopy and conventional colonoscopy did not include patients who previously underwent colorectal resection. Thus, to the best of our knowledge, this is the first prospective, randomized, controlled trial to compare cecal intubation time during cap-assisted and standard colonoscopy in patients who had previously undergone colorectal resection due to primary cancers.

Only one previous study reported the factors affecting cecal intubation time after colorectal resection.^[30] The researchers demonstrated that right-sided colon resection was an independent predictor for prolonged insertion time and that colonoscopy was easier in patients with sigmoid colon resection. They explained this conclusion by assuming that resected sigmoid colon resulted in less looping or angling during the procedure. In the present study, we reduced possible sources of error resulting from different surgical types by excluding patients with previous right-sided, subtotal, or total colon resection.

Another unique part of our study was that only one endoscopist participated. Park et al^[29] demonstrated that cap-assisted colonoscopies might help increase the rate of cecal intubation (80.7% in the cap group vs 63.3% in the non-cap group, $P<0.001$) and reduce cecal intubation time (13.7 minutes in the cap group vs 18.7 minutes in the non-cap group, $P<0.001$) for trainees. However, all 6 participating endoscopists in their study were assigned to only one group and performed only one procedure (cap-assisted or standard) during the study periods. Therefore, they could not rule out the possibility that the difference in individual abilities of trainees had an influence on the overall results. In our study, one endoscopist performed both cap-assisted and standard colonoscopy with serial sequencing.

Table 3**Outcomes of intubation between the 2 groups.**

	CAP (N=89), n (%)	Non-CAP (N=89), n (%)	P
Complications	0	0	N/A
Polyp detection rate	24 (27)	26 (29.2)	0.739
Cecal intubation time, s (mean ± SD)	539 ± 348	677 ± 454	0.024
Total colonoscopy time, s (mean ± SD)	1300 ± 476	1470 ± 553	0.030
Faster intubation* rate	64 (71.9)	51 (57.3)	0.042

SD=standard deviation.

* Faster intubation: shorter than mean of cecal intubation time.

Table 4

Outcomes of intubation according to bowel preparation grade between the 2 groups.

Grade of bowel preparation	Excellent and fair (N=133), n (%)			Poor (N=45), n (%)		
	CAP (N=66)	Non-CAP (N=67)	P	CAP (N=23)	Non-CAP (N=22)	P
Cecal intubation time, s (mean ± SD)	516 ± 309	691 ± 483	0.014	605 ± 442	636 ± 357	0.796
Total colonoscopy time, s (mean ± SD)	1310 ± 460	1497 ± 575	0.041	1272 ± 532	1390 ± 484	0.441
Faster intubation* rate	48 (72.7)	37 (55.2)	0.036	16 (69.6)	14 (63.6)	0.673

SD=standard deviation.

*Faster intubation: shorter than mean of cecal intubation time.

Table 5

Factors associated with faster intubation.

		OR	95% CI	P
Sex	Male	1		
	Female	0.4	0.2–0.9	0.035
Age	<70	1		
	≥70	1.2	0.5–2.7	0.532
BMI, kg/m ²	<25	1		
	≥25	0.8	0.4–1.7	0.743
Operation	Open	1		
	MIS*	0.9	0.4–1.8	0.807
Bowel cleanliness	Excellent and fair	1		
	Poor	1.5	0.7–3.2	0.267
CAP	(+)	1		
	(-)	0.5	0.2–0.9	0.043

*MIS: minimally invasive surgery included a laparoscopic surgery and a robotic surgery.

Thus, our study design minimized interendoscopist bias resulting from individual abilities.

However, this advantage may also be a limitation. All procedures were performed by one endoscopist (Kang J.) who had performed about 120 colonoscopies before the start of this study. From the results of a prospective, multicenter trial evaluating the adequate level of training required for technical competence in screening and diagnostic colonoscopy,^[31] more than 150 cases of experience were recommended for efficient colonoscopy in accordance with previous reports of at least 100 to 200 procedures.^[32,33] According to these criteria, the endoscopist in this study had either just completed his learning curve or was still in his learning period. Considering the earlier learning

periods of the endoscopist, however, the cecal intubation rate of 97.2% in this study is comparable with the average cecal intubation rate, ranging from 94.6% to 99.0% performed by experienced hands.^[19–21]

Interestingly, when we inspect the moving average curve demonstrated in Fig. 2, we found that the learning curve did not achieve steady state until an additional 40 cases. Comparing the moving average curve on cecal intubation time between the 2 groups, the CAP group showed a gentle slope to the steady state after an additional 40 cases, while the non-CAP group demonstrated a steep decrease before maintaining steady state. Although this may be a reflection that cap-assisted colonoscopy during inexperienced periods might be beneficial in overcoming the difficulties met during the learning periods, further studies are warranted to confirm our preliminary result.

In addition to successful cecal intubation, adenoma detection rate has been proposed as a reliable indicator to assess the quality of colonoscopic exams. Among postoperative-surveillance group, previous data^[30,34] showed that metachronous adenomas were detected in 35.0% to 36.1% of patients after curative resection of colorectal cancer during the follow-up period. Polyp detection rate in this study was not different between the cap-assisted group and conventional colonoscopy group (27.0% in the CAP group vs 29.6% in the non-CAP group). Even though these might be somewhat lower than those reported, if we take into account the specific study cohort with mean follow-up period of 3-year postoperative-surveillance, repeated colonoscopies and polyp removal had already been performed. Moreover, this study showed similar withdrawal time (WT) (more than 10 minutes) between the CAP and non-CAP groups (data not shown). It is generally accepted that WT of more than 6 minutes is required for complete colonoscopic examinations that result in significantly higher adenoma detection rate.^[35,36] Gromski et al^[37] supported this trend by reporting that adenoma detection rate was significantly higher among first-year trainees with WT more than 10 minutes. These outcomes demonstrate that the qualities of this randomized trial were with acceptable range.

In conclusion, cap-assisted colonoscopy could reduce cecal intubation time and achieve more frequent faster intubation compared with standard colonoscopy in patients with a history of colorectal resection.

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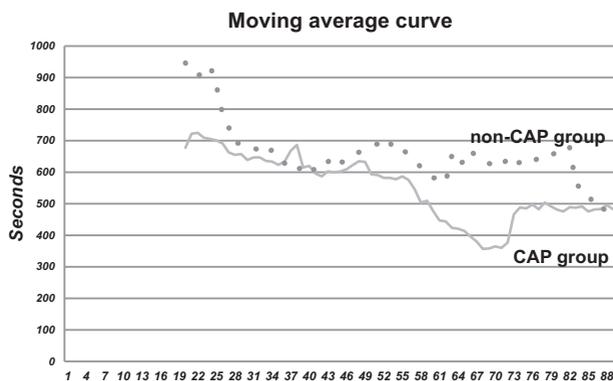


Figure 2. Moving average curve in both groups.

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