Original Article

The Efficacy of Cap-Assisted Colonoscopy as Compared to Conventional in a Pediatric Population: A Randomized Controlled Trial

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Background: The use of cap-assisted colonoscopy (CAC) in adults reportedly shortens cecal and ileal intubation times (CIT and IIT, respectively) and improves cecal and ileal intubation rates (CIR and IIR, respectively) as compared with the standard colonoscopy (SC). However, no study to date has assessed the efficacy of CAC in children.

Materials and Methods: Thirty-nine children were randomized to CAC (n=22) or SC (n=17) and 22 colonoscopy procedure were done per group. Quality indicators were evaluated.

Results: The median ages of the CAC and SC groups were 9.5 years (range 4.3 to 16.0) and 9.7 years (range 3.9 to 13.5), respectively. The most common indication was hematochezia (38.6%). The median CIT in the CAC and SC groups were 13.5 (range 8 to 19) and 13.7 (range 10 to 18) minutes, respectively (p=0.621). The IIT in the CAC and SC group were 60 (range 55 to 95) and 59 (range 35 to 95) seconds, respectively (p=0.438). The overall CIR was 100% and did not differ between groups. The IIR of the CAC and SC groups were 100% and 95.5%, respectively (p>0.999). Good CIR and IIR were achieved and no complications occurred in either group.

Conclusion: There were no intergroup differences in quality indicators.

Keywords: Cap-assisted colonoscopy, Quality indicators for colonoscopy, Pediatric

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Pediatric endoscopy has developed over the past 30 years as a technique to aid in diagnostics and therapeutics[1]. The two most common methods are esophagogastroduodenoscopy (EGD) and (ileo) colonoscopy. EGD is the most useful method for evaluating and treating pediatric conditions such as variceal bleeding, allergic or infectious esophagitis, and inflammatory gastritis[2]. In addition, colonoscopies are routinely performed by most pediatric gastroenterologists[3] in the diagnosis and treatment of lower gastrointestinal conditions including abdominal pain, hematochezia, chronic diarrhea, weight loss, unexplained anemia with iron deficiency, and rectal bleeding[4-7].

In adults, colonoscopy is a common endoscopic technique and a standard strategy for the screening and follow-up of colorectal cancer[8-10]. However, pediatric colonoscopy differs from adults in most respects including its indications, disease etiologies, anesthetic management, sedatives used, and the fact that biopsies are often obtained in cases with

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unremarkable macroscopic findings[1-3,11,12]. Almost all adult endoscopic societies recommended the assessment of greater than 90% of the cecum[13]. However, as it is a difficult procedure, even experienced endoscopists face challenges and limitations in up to 30% of the cases[10,14] such as an unsatisfactory cecal or ileal approach[15,16], failure to visualize the entire colonic mucosal surface[17], and the overlooking of some small lesions or polyps[9]. There are no quality indicators for pediatric colonoscopy, but some indicators such as cecal and ileal intubation are very challenging yet essential to establishing a histological diagnosis[3,18]. In pediatric endoscopy, EGD is performed twice as frequently as colonoscopy[5]; thus, pediatric endoscopists perform relatively fewer procedures (19 to 30 per year)[5,19,20] than surgeons or adult gastroenterologists, who may be consulted in pediatric cases requiring difficult or advanced procedures. A previous study of a pediatric population revealed that the success rates of cecal and ileal intubation are 52% to 100% and 32% to 100%, respectively[4,5,7,20-25]. Several techniques have been developed to aid the complete colonoscopy success rate including simple maneuvers (position changes, abdominal pressure[10], and low or minimal air insufflation), water immersion techniques, carbon dioxide insufflation in lieu of air, non-standard colonoscopy techniques (gastroscopy or thin colonoscopy), and auxiliary devices such as cap-assisted colonoscopy (CAC)[26]. A CAC or transparent hood is a simple plastic device that is inexpensive and effectively depresses the semilunar fold, improving the visual field[26,27]. It is also helpful in detecting polyps[9], improving cecal intubation rates (CIR), and reducing cecal intubation time (CIT), particularly among trainees[10].

Many trials of adult patients have compared standard colonoscopy (SC) and CAC in terms of CIR and CIT, polyp detection rates (PDR), and adenoma miss rate (AMR) among endoscopists and trainees[8,10,28-31]. As mentioned above, several articles have reported that CAC is associated with higher CIR and ileal intubation rates (IIR) among trainees and reduces CIT, ileal intubation times (IIT), patient discomfort[9,29], and sedative drug dosages[10], and improves PDR[8,30,32,33]. CAC is not associated with cap displacement or any other adverse events[9,10,34]. However, no studies to date have compared CAC with SC in children. Thus, the present study was the first study to compare the efficacy of CAC versus SC in terms of CIR, CIT, ITR, IIT, and complications in a pediatric population.

Materials and Methods

The present study was a prospective randomized controlled trial conducted between May 2017 and May 2019 and was approved by the Ethical Committee of the Faculty of Medicine, Khon Kaen University. The present trial was registered in the Thai Clinical Trial Registry (TCTR20190804001). Informed consents were obtained from the participants' guardians prior to their enrollment.

Patients

All patients under 18 years of age scheduled for colonoscopy at a tertiary referral endoscopic center were invited to participate in the present study. Children with a history of colon resection, fulminant colitis, or severe medical conditions were excluded.

Colonoscopy procedures

The patients were randomly assigned to the CAC or SC group by computer-generated random numbers (blinded blocks of four), and all colonoscopies were performed by one pediatric endoscopist (Charoenwat B). All participants underwent bowel preparation before the procedure that consisted of a clear liquid diet and sodium picosulfate the day before the operation. A standard adult gastroscope (GIF-HQ190; Olympus Optical Co., Ltd., Tokyo, Japan) with an insertion tube length of 1,030 mm and diameter of 9.9 mm was used in children weighing less than 10 kg. A pediatric colonoscope (PCF-H190L/I; Olympus Optical Co., Ltd.) with an insertion tube length of 1,330 mm and diameter of 11.5 mm was used in children weighing 10 kg or more. Data collected during the procedures included CIT, CIR, IIT, IIR, and complications. CIT was recorded in minutes and counted from the start of the procedure until the tip of the colonoscope was placed at the cecum and the ileocecal valve and appendix orifice were identified. IIT, on the other hand, was recorded in seconds from the beginning of the ileal intubation until the tip of the colonoscope was placed in the terminal ileum.

Cap-assisted colonoscopy

In the CAC group, a soft plastic cap was attached to the tip of the colonoscope. Due to resource limitations, the cap from a ligation kit (SKL-6 SmartBand; Intelligent Endoscopy, USA) was used. The cap had an outer diameter of 12.0 mm, inner diameter of 10.0 mm, and depth of 9.0 mm with approximately 4.0 mm of the cap ahead of the tip (Figure 1).

A cap attached to the tip of colonoscope with

Figure 1. Cap-assisted colonoscopy.

approximately 4 mm ahead of the tip with outer diameter of 12.0 mm, inner diameter of 10.0 mm, and depth of 9 mm.

Outcome measurement

The primary outcomes of the present study were CIT, CIR, IIT, and IIR, while the secondary outcomes were complications during and after the procedure.

Statistical methods

In the literature, the mean times required to assess the cecum and ileum in the CAC and SC groups were 4.6 and 6.8 minutes, respectively[10]. The sample size was calculated based on a 5% risk of an alpha error and 80% power. The sample size was calculated from adult data, knowing that in pediatric patients, there are fewer colonoscopies relatively to adults. In the present study, 39 patients were enrolled and 44 colonoscopic procedures were done. Continuous and categorical variables were described as median (interquartile range) or mean ± standard deviation (SD) as appropriate and frequency (%), respectively. The IIR were compared between the two groups using Fisher's exact test, while CIT and IIT were compared using a Mann-Whitney U test. A p-value of less than 0.05 was considered significant. The data were analyzed using Stata, version 10.1 (StataCorp LP, College Station, TX, USA).

Results

Baseline demographics, clinical characteristics, and indications for colonoscopy

Thirty-nine patients were randomly assigned to the CAC (n=22) and SC (n=19) groups. The median ages of the CAC (72.7% male) and SC (70.6% male) groups were 9.5 years (range 4.3 to 16.0) and 9.7 years (range 3.9 to 13.5), respectively. There were no intergroup differences in age, gender, height, or weight. The most common indications for colonoscopy were hematochezia [n=17 (38.6%)] and chronic diarrhea [n=14 (31.8%)]. Polyposis syndrome [n=11 (25%)] including juvenile polyposis syndrome [n=6 (13.4%)], and Peutz-Jeghers syndrome [n=5 (11.4%)] were the most common diagnoses (Table 1).

Colonoscopy quality indicators

The cecal intubation was successful in all 39 patients (100%) and did not differ between the two groups. The median CIT was 13.5 minutes (range 8 to 19) in the CAC group and 13.7 minutes (range 10 to 18) in the SC group, showing no significant intergroup difference (p=0.621).

The overall IIR was 97.7%, and there was no significant intergroup difference (CAC 100% versus SC 95.5%, p>0.999). One test failed to reach the ileum due to technical difficulty. The IIT was similar in both groups. The median time was 60 seconds (range 55 to 95) and 59 seconds (range 35 to 95) in CAC and SC group, respectively (p=0.438).

No cap-associated complications occurred during the study period (Table 2).

Discussion

Pediatric colonoscopy was initially reported during the late 1970s[3,7]. It has since gradually evolved step by step for both diagnostic and therapeutic procedures. According to the American Society for Gastrointestinal Endoscopy and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition, colonoscopy is now routinely performed by pediatric gastroenterologists in the evaluation and treatment of bowel diseases including chronic diarrhea, chronic abdominal pain, weight loss, unexplained iron-deficiency anemia, and rectal bleeding[2]. A total colonoscopy is technically challenging even in expert hands. The factors that impact the lower colonoscopy completion rate are female gender, extremely old (older than 80 years) or young (younger than 5 years) age, diverticulosis, and inadequate bowel preparation[5,16,35,36]. Pediatric procedures are more complex due to a lack of endoscopist experience, inadequate bowel preparation, and smaller anatomy[3,5]. Moreover, pediatric colonoscopy differs from adult colonoscopy in many aspects, in particular, a complete ileal examination is strongly recommended to optimize its diagnostic yield[1-3,11,12].

In recent studies, the success of colonoscopy depended on its quality. There are several quality indicators for adults, such as CIT, CIR, IIT, IIR, PDR, AMR, and withdrawal time[10,30,31]. However, few studies have examined the quality indicators in pediatric patients. Singh et al[5] stated that IIR should be considered a major indicator for pediatric colonoscopy to investigate inflammatory bowel disease. Many adult studies have reported the benefit of an auxiliary device "cap or hood" attached to the tip of

Table 1. Baseline demographics, clinical characteristics, and indications for colonoscopy

	CAC (n=22) n (%)	SC (n=17) n (%)	p-value
Baseline data			
Sex: male	16 (72.7)	12 (70.6)	0.999
Age (year); median (IQR)	9.5 (4.3 to 16.0)	9.7 (3.9 to 13.5)	0.865
Height (m); median (IQR)	129.5 (89 to 158)	118 (95 to 151)	0.723
Weight (kg); median (IQR)	24 (15 to 41)	23.7 (15 to 35)	0.733
Indications for colonoscopy			0.558
Hematochezia	10 (45.5)	7 (31.8)	
Chronic diarrhea	6 (27.3)	8 (36.4)	
Chronic abdominal pain	2 (9.1)	4 (18.2)	
Iron-deficiency anemia	2 (9.1)	0 (0.0)	
Protein losing enteropathy	2 (9.1)	3 (13.6)	
Diagnosis			0.270
Polyposis syndrome			
• Juvenile polyposis syndrome	4 (18.2)	2 (9.1)	
• Peutz-Jeghers syndrome	3 (13.6)	2 (9.1)	
Inflammatory bowel disease			
• Crohn's disease	3 (13.6)	4 (18.2)	
• Ulcerative colitis	2 (9.1)	1 (4.5)	
Non-specific colitis	1 (4.5)	7 (31.8)	
Normal	4 (18.2)	1 (4.5)	
Other	5 (22.7)	5 (22.7)	

CAC=cap-assisted colonoscopy; SC=standard colonoscopy; IQR=interquartile range

Table 2. Primary and secondary outcomes

	CAC (n=22)	SC (n=17)	p-value
Primary outcomes			
CIT (minute); median (IQR)	13.5 (8 to 19)	13.7 (10 to 18)	0.621
IIT (second); median (IQR)	60 (55 to 95)	59 (35 to 95)	0.438
IIR; n (%)	22 (100)	21 (95.45)	0.999
Secondary outcomes			
Complications	No	No	-

CAC=cap-assisted colonoscopy; SC=standard colonoscopy; CIT=cecal intubation time; IIT=ileal intubation time; IIR=ileal intubation rate; IQR=interquartile range

the colonoscope to improve procedural quality[5,8,10,29]. Conversely, other studies[30,31,35] reported no difference between the CAC and SC groups. To our knowledge, no previous study has examined the effect of cap use in pediatric colonoscopy. Thus, the authors report the first study on these points.

The present study revealed CIT and IIT are slightly longer in CAC group but no statistically significant difference was seen between the CAC and SC groups in terms of CIT, CIR, IIT, IIR, or complications. However, the cecal and ileal intubation success rates were near 100% (overall CIR and IIR, 100% and 97.7%, respectively). These favorable results were not inferior to the previous studies[4,5,7,20-24]. The five possible drawbacks of CAC include 1) pediatric gastroenterologists have no experience with CAC, 2) uncooperative patients may experience inadequate bowel preparation, 3) subsequent difficulty cleaning

the lens if fecal matter becomes trapped in the cap, 4) small pediatric anatomy relative to endoscopy equipment and cap sizes, and 5) the present study conducted by single experience endoscopist and cannot be blinded so the result cannot be generalized to trainee or inexperience endoscopist. Even if there were no differences of CAC and SC in terms of quality indicators, the cap allowed a good field of view, enabling a more thorough inspection of blind areas. The success rates of cecal and ileal intubation were approximately 100%. Therefore, CAC should be reserved for selected cases, particularly those of a difficult or failed initial intubation[30]. Further large well-design randomized studies focusing on the benefit of CAC in children are warranted. Despite the present study being a randomized controlled trial conducted in a tertiary center, it has several limitations such as a small sample size and not being double-blinded. However, it was conducted by a single pediatric gastroenterologist (Charoenwat B), which prevents interoperator bias.

Conclusion

CAC effectively improves quality indicators of colonoscopy in adult but not in pediatric populations. Additional studies are warranted to fully assess its efficacy in children.

What is already known on this topic?

Quality indicators of colonoscopy are very crucial and may be difficult in some situations. CAC has been studied to improve its indicators.

What this study adds?

This is the first study to compare the efficacy of CAC to that of SC in pediatric patients. The authors found no differences in indicators between the two groups. A large number of patients are required to validate the present results.

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Conflicts of interest

The authors declare no conflict of interest.

References

1. Thomson M, Tringali A, Dumonceau JM, Tavares M, Tabbers MM, Furlano R, et al. Paediatric gastrointestinal endoscopy: European Society for Paediatric Gastroenterology Hepatology and Nutrition and European Society of Gastrointestinal Endoscopy Guidelines. J Pediatr Gastroenterol Nutr 2017;64: 133-53.
2. Lightdale JR, Acosta R, Shergill AK, Chandrasekhara V, Chathadi K, Early D, et al. Modifications in endoscopic practice for pediatric patients. Gastrointest Endosc 2014;79:699-710.
3. Park JH. Role of colonoscopy in the diagnosis and treatment of pediatric lower gastrointestinal disorders. Korean J Pediatr 2010;53:824-9.
4. Yoshioka S, Takedatsu H, Fukunaga S, Kuwaki K, Yamasaki H, Yamauchi R, et al. Study to determine guidelines for pediatric colonoscopy. World J Gastroenterol 2017;23:5773-9.
5. Singh HK, Withers GD, Ee LC. Quality indicators in pediatric colonoscopy: an Australian tertiary center experience. Scand J Gastroenterol 2017;52:1453-6.
6. Barth BA, Banerjee S, Bhat YM, Desilets DJ, Gottlieb KT, Maple JT, et al. Equipment for pediatric endoscopy. Gastrointest Endosc 2012;76:8-17.
7. Kawada PS, O'Loughlin EV, Stormon MO, Dutt S, Lee CH, Gaskin KJ. Are We Overdoing pediatric lower gastrointestinal endoscopy? J Pediatr Gastroenterol Nutr 2017;64:898-902.
8. Kondo S, Yamaji Y, Watabe H, Yamada A, Sugimoto T, Ohta M, et al. A randomized controlled trial evaluating the usefulness of a transparent hood attached to the tip of the colonoscope. Am J Gastroenterol 2007;102: 75-81.
9. Park SY, Kim HS, Yoon KW, Cho SB, Lee WS, Park CH, et al. Usefulness of cap-assisted colonoscopy during colonoscopic EMR: a randomized, controlled trial. Gastrointest Endosc 2011;74:869-75.
10. Prachayakul V, Aswakul P, Limsrivilai J, Anuchapreeda S, Bhanthumkomol P, Sripongpun P, et al. Benefit of "transparent soft-short-hood on the scope" for colonoscopy among experienced gastroenterologists and gastroenterologist trainee: a randomized, controlled trial. Surg Endosc 2012;26:1041-6.
11. Park JH. Pediatric Colonoscopy: The Changing Patterns and Single Institutional Experience Over a Decade. Clin Endosc 2018;51:137-41.
12. Walsh CM. Assessment of competence in pediatric gastrointestinal endoscopy. Curr Gastroenterol Rep 2014;16:401.
13. Gilger MA, Gold BD. Pediatric endoscopy: new information from the PEDS-CORI project. Curr Gastroenterol Rep 2005;7:234-9.
14. Westwood DA, Alexakis N, Connor SJ. Transparent cap-assisted colonoscopy versus standard adult colonoscopy: a systematic review and meta-analysis. Dis Colon Rectum 2012;55:218-25.

15. Bowles CJ, Leicester R, Romaya C, Swarbrick E, Williams CB, Epstein O. A prospective study of colonoscopy practice in the UK today: are we adequately prepared for national colorectal cancer screening tomorrow? Gut 2004;53:277-83.
16. Dafnis G, Granath F, Pahlman L, Ekbom A, Blomqvist P. Patient factors influencing the completion rate in colonoscopy. Dig Liver Dis 2005;37:113-8.
17. East JE, Saunders BP, Burling D, Boone D, Halligan S, Taylor SA. Surface visualization at CT colonography simulated colonoscopy: effect of varying field of view and retrograde view. Am J Gastroenterol 2007;102:2529-35.
18. Sawczenko A, Sandhu BK. Presenting features of inflammatory bowel disease in Great Britain and Ireland. Arch Dis Child 2003;88:995-1000.
19. Thakkar K, Holub JL, Gilger MA, Shub MD, McOmber M, Tsou M, et al. Quality indicators for pediatric colonoscopy: results from a multicenter consortium. Gastrointest Endosc 2016;83:533-41.
20. Lee WS, Tee CW, Koay ZL, Wong TS, Zahraq F, Foo HW, et al. Quality indicators in pediatric colonoscopy in a low-volume center: Implications for training. World J Gastroenterol 2018;24:1013-21.
21. Tam YH, Lee KH, Chan KW, Sihoe JD, Cheung ST, Mou JW. Colonoscopy in Hong Kong Chinese children. World J Gastroenterol 2010;16:1119-22.
22. Kalaoui M, Radhakrishnan S, al Shamali M, Hasan F, al Nakib B. Findings of colonoscopy in children: experience from Kuwait. J Trop Pediatr 1998;44:371-5.
23. Wu CT, Chen CA, Yang YJ. Characteristics and diagnostic yield of pediatric colonoscopy in Taiwan. Pediatr Neonatol 2015;56:334-8.
24. Thomson M, Eltumi M, Singh C, Eyles M, Shah N, Vadamalayan B, et al. Sub-10-minute high-quality diagnostic colonoscopy with terminal ileum intubation in children is feasible and safe. J Pediatr Gastroenterol Nutr 2019;69:6-12.
25. Ng S, Lau JYW. Technical advances in getting to the cecum. Curr Colorectal Cancer Rep 2011;7:16-23.
26. Urita Y, Nishino M, Ariki H, Ozaki M, Naruki Y, Otsuka S. A transparent hood simplifies magnifying observation of the colonic mucosa by colonoscopy. Gastrointest Endosc 1997;46:170-2.
27. Matsushita M, Danbara N, Fukui T, Matsumoto T, Omiya M, Uchida K, et al. Much colonic surface visualization by a standard colonoscope with a transparent hood. Am J Gastroenterol 2008;103:1568-9.
28. Shida T, Katsuura Y, Teramoto O, Kaiho M, Takano S, Yoshidome H, et al. Transparent hood attached to the colonoscope: does it really work for all types of colonoscopes? Surg Endosc 2008;22:2654-8.
29. Harada Y, Hirasawa D, Fujita N, Noda Y, Kobayashi G, Ishida K, et al. Impact of a transparent hood on the performance of total colonoscopy: a randomized controlled trial. Gastrointest Endosc 2009;69:637-44.
30. Lee YT, Lai LH, Hui AJ, Wong VW, Ching JY, Wong GL, et al. Efficacy of cap-assisted colonoscopy in comparison with regular colonoscopy: a randomized controlled trial. Am J Gastroenterol 2009;104:41-6.
31. Tee HP, Corte C, Al Ghamdi H, Prakoso E, Darke J, Chettiar R, et al. Prospective randomized controlled trial evaluating cap-assisted colonoscopy vs standard colonoscopy. World J Gastroenterol 2010;16:3905-10.
32. Hewett DG, Rex DK. Cap-fitted colonoscopy: a randomized, tandem colonoscopy study of adenoma miss rates. Gastrointest Endosc 2010;72:775-81.
33. Takeuchi Y, Inoue T, Hanaoka N, Higashino K, Iishi H, Chatani R, et al. Autofluorescence imaging with a transparent hood for detection of colorectal neoplasms: a prospective, randomized trial. Gastrointest Endosc 2010;72:1006-13.
34. Kim DJ, Kim HW, Park SB, Kang DH, Choi CW, Hong JB, et al. Efficacy of cap-assisted colonoscopy according to lesion location and endoscopist training level. World J Gastroenterol 2015;21:6261-70.
35. Church JM. Complete colonoscopy: how often? And if not, why not? Am J Gastroenterol 1994;89:556-60.
36. Anderson JC, Gonzalez JD, Messina CR, Pollack BJ. Factors that predict incomplete colonoscopy: thinner is not always better. Am J Gastroenterol 2000;95:2784-7.