

Is Double-Balloon Colonoscopy a Better Aid to Unskilled Colonoscopists than Conventional Colonoscopy?

Okamoto, Risa
Department of Gastroenterology, Aso Iizuka Hospital

Motomura, Yasuaki
Department of Gastroenterology, Aso Iizuka Hospital

Akahoshi, Kazuya
Department of Gastroenterology, Aso Iizuka Hospital

Kashiwabara, Yumi
Department of Gastroenterology, Aso Iizuka Hospital

他

<https://doi.org/10.15017/20470>

出版情報：福岡醫學雜誌. 102 (12), pp.333-340, 2011-12-25. 福岡医学会
バージョン：
権利関係：

Original Article

Is Double-Balloon Colonoscopy a Better Aid to Unskilled Colonoscopists than Conventional Colonoscopy?

Risa OKAMOTO¹⁾, Yasuaki MOTOMURA¹⁾, Kazuya AKAHOSHI¹⁾, Yumi KASHIWABARA¹⁾, Shingo ENDO¹⁾, Naomi HIGUCHI¹⁾, Manami ODA¹⁾, Masaru KUBOKAWA¹⁾, Noriaki MATSUI¹⁾, Kazuhiko NAKAMURA²⁾ and Ryoichi TAKAYANAGI²⁾

¹⁾Department of Gastroenterology, Aso Iizuka Hospital, Iizuka, 820-8505, Japan

²⁾Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University, Fukuoka 812-8582, Japan.

Abstract Background and study aims : To compare the clinical outcome of double-balloon colonoscopy (DBC) with conventional colonoscopy (CC) for colon evaluation performed by an unskilled colonoscopist.

Patients and methods : Between June 2008 and November 2008, 1544 colonoscopies were performed in our hospital. Fifty-eight patients, (29 male and 29 female ; 19–86 years; mean age, 63 years) involving 60 intubations, were enrolled in this study and were assigned randomly to the DBC or CC group. One first-year GI fellow was enrolled and performed these 60 consecutive colonoscopies (30 DBCs, 30 CCs). Completion rate of colonoscopy, cecal intubation time, and rate of analgesic agent usage were analyzed.

Results : Completion of DBC was 100% (30/30), while completion of CC was 73% (22/30). There was a statistically significant difference ($p < 0.05$). The mean cecal intubation time was 36.2 ± 14.4 minutes (DBC) and 36.5 ± 15.2 minutes (CC). There was no statistically significant difference. Analgesic agent was used with 19 intubations (63%) (DBC) and with 27 intubations (90%) (CC) ($p < 0.05$).

Conclusions : For inexpert endoscopists, using DBC has a higher rate of effectiveness than using CC and can decrease the discomfort of patients during colonoscopic procedures.

Key words : technique, training, double-balloon colonoscopy

Introduction

In our country, Japan, the rate of colon cancer is increasing. To diagnose and treat colon cancer earlier, periodical total colonoscopy is necessary. However, it can be difficult for unskilled colonoscopists to complete colonoscopy using a conventional colonoscope. Even for experienced colonoscopists, it can be difficult to intubate the scope into the cecum if the patients have adhesion

of the bowels caused by abdominal surgery, radiation, or gynecological disease. Double-balloon enteroscopy (DBE), which was developed by Yamamoto *et al.* in 2001¹⁾, is a new endoscopic technique that allows us to get a complete visualization of the entire small intestine and make therapeutic interventions. Recently, double-balloon colonoscopy (DBC), as the short version of DBE, has become commercially available for the purpose of performing total colonoscopy. In this report, we compare the clinical outcome of DBC with conventional colonoscopy (CC) by an unskilled colonoscopist.

Correspondence to :

Dr. Risa OKAMOTO

Department of Gastroenterology, Aso Iizuka Hospital, 3-83 Yoshio-machi, Iizuka 820-8505, Japan.

Tel. : + 81-948-22-3800

Fax : + 81-948-29-8747

E-mail : risapear1015@yahoo.co.jp

Materials and Methods

Patients

Between June 2008 and November 2008, 1544 colonoscopies were performed in Aso Iizuka Hospital. Fifty-eight patients, (29 male and 29 female ; 19–86 years ; mean age, 63 years) involving 60 intubations (60/1544), were enrolled in this study and were assigned randomly (computer assisted randomization) to the DBC or CC group. Two patients (a male and a female) had two intubations and had both DBC intubation and CC intubation respectively by chance. There was no difference in sex, age, or abdominal operative history between the DBC and CC groups (Table 1). All patients in this study consented to the documents of agreement before examination.

Colonoscopes

DBC (EC-450BI5, FUJIFILM, Saitama, Japan) and CC (EC-590MP, FUJIFILM, Saitama, Japan) are used for total colonoscopy (Fig. 1). The DBC system is a high resolution video endoscope with a flexible overtube. The videoendoscope has a

working length of 1520mm, and a detachable balloon at its tip. It is used with a soft overtube measuring 1050mm in length with another balloon at the distal end. The endoscope and overtube balloons are made from latex, which is 0.1mm thick and very soft, and it can be inflated or deflated by a specially designed air pump controller with one-touch controls, while monitoring the air pressure. The balloons are used at 45 mmHg, which is the lowest possible pressure to hold the colon for the endoscope insertion and it is designed not to cause pain or discomfort to the subjects due to balloon dilation (PB-10, FUJIFILM Co, Saitama, Japan)¹⁾. The diameter of the EC-590MP is 11.0mm and the working length is 1330mm.

Endoscopic procedure

Adequate cleansing of the whole colo-rectum was conducted before performing total colonoscopy (TCS). Patients were restricted to a low-fiber diet one day before TCS, and 10mL of 0.75% sodium picosulfate solution (Laxoberon® ; Teijin Pharma Co, Ltd, Tokyo, Japan) was used the night before TCS. Early in the morning of

Table 1 Procedure data

All patients			
	CC	DBC	p value
No. patients	30	30	
Male	16	19	NS
Female	14	11	NS
Post operative patients	16	15	NS
Age	63.1 ± 15.3	63.3 ± 18.8	NS
Post operative patients			
	CC	DBC	p value
Male	7	9	NS
Female	9	6	NS
Age	63.0 ± 11.1	69.9 ± 10.9	NS
Non-post operative patients			
	CC	DBC	p value
Male	9	10	NS
Female	5	5	NS
Age	63.1 ± 19.4	56.7 ± 22.8	NS

NS : Not significant

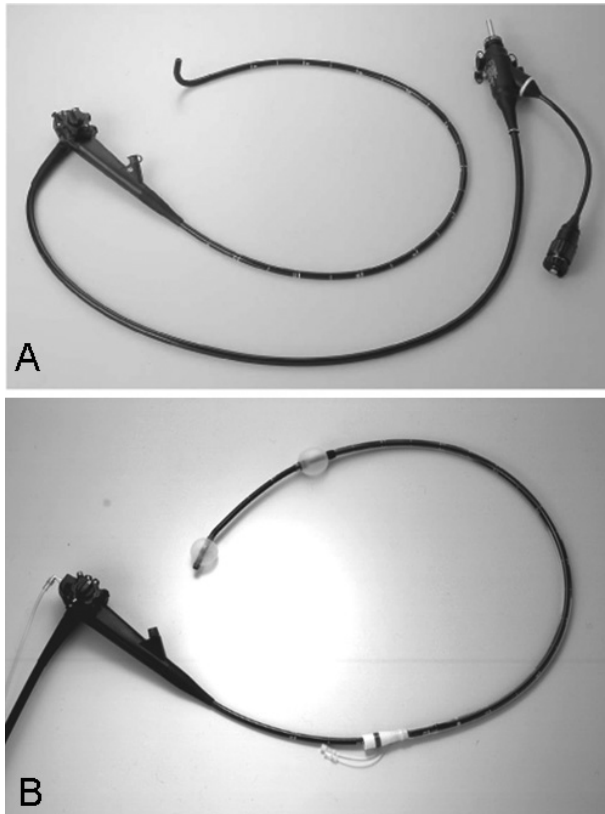


Fig. 1 A) EC-590MP : The diameter of the top is 11.0 mm and the working length is 1330mm.
 B) EC-450BI5 : The diameter is 9.4mm, the working length is 1520mm, and the length of the overtube is 1050mm.

the TCS, 2L of an isotonic polyethylene glycol electrolyte solution (Niflec®; Ajinomoto Pharma Co, Ltd, Tokyo, Japan) were used to achieve good bowel preparation. All procedures were performed by one first year GI fellow (RO), with prior experience of only 29 conventional colonoscopies including sigmoidoscopy. No analgesic agent or anticonvulsant was used during the procedure unless patients complained of pain, in which case pethidine hydrochloride was used. The supervising endoscopist took over when the patients complained extreme pain despite using analgesic agent or the GI fellow could not completed the intubation.

In this study, the completion rate, completion time, discomfort rate of patients, and rate of analgesic agent usage were analyzed.

Statistical analysis

The data were expressed as mean \pm SD. Statistical difference was detected by χ^2 test. $p < 0.05$ was considered to be statistically significant.

Ethical considerations

Each patient was informed of the advantages and disadvantages of DBC or CC. Patients were aware of the experimental nature of the planned procedure. All gave their written informed consent to the designated intervention. This study was reviewed and approved by the ethics committee of Aso Iizuka Hospital. It was conducted in accordance with the ethical principles of the Declaration of Helsinki and in compliance with good clinical practice.

Results

Successful completion (Table 2)

There was a statistically significant difference ($p < 0.01$) in complete intubations between the DBC and CC groups. All patients using DBC (100%) had complete intubations, compared with 22 out of 30 intubations used CC (73%). Fifteen out of 30 intubations of the DBC group and 16 out of 30 intubations of the CC group had a history of abdominal surgery. In the post operative patients, 15 intubations of the DBC group (100%) had complete intubations, as opposed to only 10 intubations in the CC group (62.5%). The successful completion rate of DBC was significantly higher than that of CC in the post operative patient group ($p < 0.01$). In the non-post operative patients, 15 intubations of the DBC group (100%) had complete intubations, compared with 12 intubations of the CC group (85.7%). There was no statistically significant difference between the DBC and CC groups.

Cecal intubation time (Table 2)

There was no statistically significant difference in cecal intubation time between the DBC and CC groups (36.5 ± 15.2 minutes vs. 36.2 ± 14.4 minutes, respectively; mean \pm SD).

Table 2 Technical results of CC and DBC

	CC	DBC	p value
Successful completion	22 (73%)	30 (100%)	p < 0.001
Post operative patients	10 (62.5%)	15 (100%)	p < 0.01
Non-post operative patients	12 (85.7%)	15 (100%)	NS
Insertion time (min)	36.5 ± 15.2	36.2 ± 14.4	NS
Post operative patients	38.3 ± 16.7	39.4 ± 16.1	NS
Non-post operative patients	35.1 ± 14.4	33.1 ± 12.2	NS
Discomfort	30 (100%)	21 (70%)	p < 0.01
Post operative patients	16 (100%)	9 (60%)	p < 0.01
Non-post operative patients	14 (100%)	12 (80%)	NS
Analgesic agent usage	27 (90%)	21 (70%)	p < 0.05
Post operative patients	15 (93.8%)	8 (53.3%)	p < 0.01
Non-post operative patients	12 (85.7%)	11 (73.3%)	NS

NS : Not significant

There was no statistically significant difference in cecal intubation time when we compared non-post operative patients and post operative patients. The cecal intubation time for non-post operative patients was 33.1 ± 12.2 minutes and 35.1 ± 14.4 minutes (DBC vs. CC groups, respectively; mean ± SD). In the post operative patients, the cecal intubation times were 39.4 ± 16.1 minutes and 38.3 ± 16.7 minutes (DBC vs. CC groups, respectively; mean ± SD).

Discomfort rate of patients (Table 2)

The patients' assessments of the procedure are summarized in Table 2. Patients answered written inquiries about discomfort during the procedure. All patients in the CC group felt discomfort, as opposed to 21 out of the 30 patients in the DBC group (p < 0.01).

Analgesic agent usage (Table 2)

When patients requested to reduce their pain during the procedure, pethidine hydrochloride (25–50mg), an analgesic agent, was injected intravenously. CC group patients requested significantly more analgesic agent than the DBC group patients. There was a statistically significant difference between the groups (21 vs. 27 intubations, respectively. p < 0.05). There was

also a statistically significant difference in post operative patients but not in non-post operative patients. In post operative patients, 93.8% of the CC group requested the agents, however only 53.3% of the DBC group did (p < 0.01). On the other hand, in non-post operative patients, 85.7% of the CC group were given the agents, compared to 73.3% of the DBC group.

Incomplete intubation (Table 3)

The clinical characteristics of the patients with incomplete intubation by CC are shown in Table 3. In this study, 6 out of 8 incomplete intubation patients (75%) with CC had prior abdominal surgery. Five out of 6 prior abdominal surgery patients were female, and 3 of them had had gynecologic surgery. Two patients (25%) had diverticular disease. Only one out of 8 patients (12.5%) was neither female nor operative, and had no colonic disease.

Discussion

At present, conventional colonoscopy is the reference standard for evaluating the colon, especially for screening, diagnosis, and treatment of colorectal tumors. However, the entire colon cannot be visualized during colonoscopy in 5–15% of patients²⁾³⁾. For unskilled endoscopists, it is

Table 3 Clinical characteristics of incomplete intubation patients with CC

No	age	sex	surgeries	findings
1	66	M	nephrectomy	colon polyps, melanosis
2	78	F	appendectomy, gynecologic	diverticula, colon polyps
3	71	F	cholecystotomy, herunioplasty	none
4	88	F	none	diverticula, polyps, pseudomembrane
5	79	M	none	anal canal polyp, hemorrhoids
6	58	F	surgery to release ileus	colon polyps
7	56	F	contraceptive surgery	terminal ileitis
8	45	F	appendectomy, adnexotomy	hemorrhoids

more difficult to complete the colonoscopic procedure than it is for experts. Because unskilled endoscopists cannot treat with, such as looped, over extended, spastic, curved, and adherence colon. Therefore, sufficient time is needed to train beginners in intubating the colonoscope into the cecum.

Previous studies about how best to facilitate a complete colon examination evaluated the utility of alternate endoscopic modalities (small-diameter upper endoscope, push enteroscope, pediatric colonoscope, and variable-stiffness colonoscope) compared with the standard adult colonoscope. In patients where colonoscopy failed when using an adult colonoscope, these previous studies found completion rates of 58% (upper endoscope)⁴, 58% to 60% (pediatric colonoscope)^{4,5}, 68.7% (push enteroscope)⁶, and 98.1% (small-caliber, variable-stiffness colonoscope)⁷. A new insertion method of colonoscopy, double balloon colonoscopy (DBC), has made it possible to intubate completely. Double balloon enteroscopy (DBE) was first developed by Yamamoto *et al* in 2001, and DBC was newly released in 2006 by Fujifilm holdings. The previous study with DBC following failure to complete colonoscopy by conventional colonoscope (CC) recorded completion rates of 88%⁸. Furthermore, in our previous study⁹, observation of the entire colon using DBE was possible in 93% of the patients for whom total colonoscopy was unsuccessful using CC. Using the DBE technique, especially via the anal route, it is possible to reach deep portions of the terminal ileum. As a

result, it is considered that DBC is easier than CC to perform total colonoscopy. Therefore, we prospectively compared the clinical outcome of total colonoscopy using DBC and CC by an inexperienced endoscopist.

It is believed that several factors are involved in the failure to complete total colon examination, including angulations or looping particularly in the left side of the colon, spasm, female sex, prior abdominal surgery including hysterectomy, and complicated diverticular disease^{3,10}. In this study (Table 3), 8 patients failed to complete colon examination. All of them used CC. Six out of 8 patients (75%) had had prior abdominal surgery, 6 out of 8 patients (75%) were female, and 2 out of 8 patients (25%) had diverticular disease. Of 8 incomplete intubation patients there was only one (12.5%) patient who was non-operative, male and had no colon disease. It indicates that to complete colon examination is difficult for beginners especially for the situations.

Although the DBC group included 15 post operative patients (50%), all group members were able to receive total evaluation of the colon by DBC without any complications. The balloon of the overtube can fix the motion of the colon and prevent it re-looping and over extending. That balloon feature can make it possible to intubate completely for the beginner. Generally for expert endoscopists, the insertion time of DBC is longer than CC, because the work of ballooning gives some time. But for the beginner endoscopist, the insertion time is no significant difference between CC and DBC in this study. It is

considered that the scoping skill of CC is poor. In addition to evaluation of the colon, DBC allows therapeutic interventions such as biopsy, polypectomy, control of bleeding, and dilation of strictures. These various interventions are enabled by the controlled to-and-fro motion of the scope facilitated by the overtube¹⁾. In our study, even an unskilled endoscopist was able to perform biopsy easily by DBC.

We found that discomfort during insertion was significantly less for DBC than CC. In the CC group, all patients felt discomfort, compared with 70% in the DBC group. Ninety percent of the CC group used analgesic agents, while 63% of the DBC group used them. There was a statistically significant difference ($p < 0.05$). As sedatives reduce anxiety and pain, they are frequently used in colonoscopy throughout the world¹¹⁾⁻¹⁵⁾. When we use sedatives, however, there are a number of risk factors, such as anaphylaxis shock, arrhythmia, hypoxemia, amnesia, and so on. Furthermore, the use of sedatives requires physical monitoring and, at some centers, additional medical staff. Therefore, unsedated colonoscopy contributes to reduce patient recovery time, which means a decrease in the number of recovery beds, nurses, and other support personal needed to operate the endoscopy unit¹⁶⁾. If we have DBC, the patient who have long, looping, curved, or adherence colon can be examined with little discomfort and the unskilled endoscopists can examine them easily. Recently, it has been suggested that nurses can perform diagnostic endoscopy procedures, which traditionally have been a physician's responsibility¹⁷⁾¹⁸⁾. Therefore, an easier and safer endoscopy system to perform total colonoscopy, such as DBC, is necessary.

This study suggests that even inexpert endoscopists using DBC are able to completely intubate and evaluate the colon. In addition, using DBC may be more effective than CC in decreasing the suffering of the patient. It may also help to reduce the cost of drugs and improve safety. Even in a center lacking experts, DBC can make it

possible to evaluate the entire colon and perform necessary treatment.

Acknowledgements

The author thanks Mr. Stephen Cotton for English editing.

References

- 1) Yamamoto H, Yano T, Kita H, Sunada K, Ido K and Sugano K. New system of double-balloon enteroscopy for diagnosis and treatment of small intestinal disorders. *Gastroenterology*. 125 : 1556-1557 ; 2003.
- 2) Marshall JB and Barthel JS. The frequency of total colonoscopy and terminal ileal intubation in the 1990s. *Gastrointest Endosc*. 39 : 518-520 ; 1993.
- 3) Dafnis G, Granath F, Pahlman L, Hannuksela H, Ekblom A and Blomqvist P. The impact of endoscopists' experience and learning curves and interendoscopist variation on colonoscopy completion rates. *Endoscopy*. 33 : 511-517 ; 2001.
- 4) Kozarek RA, Botoman VA and Patterson DJ. Prospective evaluation of a small caliber upper endoscope for colonoscopy after unsuccessful standard examination. *Gastrointest Endosc*. 35 : 333-335 ; 1989.
- 5) Marshall JB. Use of a pediatric colonoscope improves the success of total colonoscopy in selected adult patients. *Gastrointest Endosc*. 44 : 675-678 ; 1996.
- 6) Lichtenstein GR, Park PD, Long WB, Ginsberg GG and Kochman ML. Use of a push enteroscope improves ability to perform total colonoscopy in previously unsuccessful attempts at colonoscopy in adult patients. *Am J Gastroenterol*. 94 : 187-190 ; 1999.
- 7) Horiuchi A, Nakayama Y, Kajiyama M, Fujii H and Tanaka N. Usefulness of a small-caliber, variable-stiffness colonoscope as a backup in patients with difficult or incomplete colonoscopy. *Am J Gastroenterol*. 99 : 1936-1940 ; 2004.
- 8) Pasha SF, Harrison ME, Das A, Corrado CM, Arnell KN and Leighton JA. Utility of double-balloon colonoscopy for completion of colon examination after incomplete colonoscopy with conventional colonoscope. *Gastrointest Endosc*. 65 : 848-853 ; 2007.
- 9) Akahoshi K, Kubokawa M, Matsumoto M, Endo S, Motomura Y, Ouchi J, Kimura M, Murata A and Murayama M. Double-balloon endoscopy in

- the diagnosis and management of GI tract diseases : methodology, indications, safety, and clinical impact. *World J Gastroenterol.* 47 : 7654-7659 ; 2006.
- 10) Cirocco WC and Rusin LC. Factors that predict incomplete colonoscopy. *Dis Colon Rectum.* 38 : 964-968 ; 1995.
 - 11) Baudet JS, Borque P, Borja E, Alarcon-Fernandez O, Sanchez-del-Rio A, Campo R and Aviles J. Use of sedation in gastrointestinal endoscopy : a nationwide survey in Spain. *Eur J Gastroenterol Hepatol.* 21 : 882-888 ; 2009.
 - 12) Keeffe EB and O'Connor KW. 1989 A/S/G/E survey of endoscopic sedation and monitoring practices. *Gastrointest Endosc.* 36 : 13-18 ; 1990.
 - 13) Daneshmend TK, Bell GD and Logan RFA. Sedation for upper gastrointestinal endoscopy : results of a nationwide survey. *Gut.* 32 : 12-15 ; 1991.
 - 14) Quine MA, Bell GD, McCloy RF, Charlton JE, Devlin HB and Hopkins A. Prospective audit of upper gastrointestinal endoscopy in two regions of England : safety, staffing, and sedation methods. *Gut.* 36 : 462-467 ; 1995.
 - 15) Froehlich F, Gonvers JJ and Fried M. Conscious sedation, clinically relevant complications and monitoring of endoscopy : results of a nationwide survey in Switzerland. *Endoscopy.* 26 : 231-234 ; 1994.
 - 16) Dumortier J, Napoleon B, Hedelius F, Pellissier PE, Leprince E, Pujol B and Ponchon T. Unsedated transnasal EGD in daily practice : results with 1100 consecutive patients. *Gastrointest Endosc.* 57 : 198-204 ; 2003.
 - 17) Kruglikova I, Grantcharov TP, Drewes AM and Funch-Jensen P. Assessment of early learning curves among nurses and physicians using a high-fidelity virtual-reality colonoscopy simulator. *Surg Endosc.* 24 : 366-370 ; 2009.
 - 18) Koornstra JJ, Corporaal S, Giezen-Beintema WM, de Vries SE and van Dullemen HM. Colonoscopy training for nurse endoscopists : a feasibility study. *Gastrointest Endosc.* 69 : 688-695 ; 2009.

(Received for publication August 19, 2011)

(和文抄録)

大腸内視鏡初心者における通常内視鏡とダブルバルーン 大腸内視鏡使用時の全大腸挿入成績の比較検討

¹⁾麻生飯塚病院 消化器内科

²⁾九州大学大学院医学研究院 病態制御内科学

岡本梨沙¹⁾, 本村廉明¹⁾, 赤星和也¹⁾, 柏原由美¹⁾, 遠藤伸悟¹⁾, 樋口奈緒美¹⁾,
織田麻奈美¹⁾, 久保川 賢¹⁾, 松井謙明¹⁾, 中村和彦²⁾, 高柳涼一²⁾

【目的】 最近日本では大腸癌の罹患率が急速に増加しており、前癌病変の早期発見早期治療が望まれる。しかし、内視鏡医にとって、通常内視鏡を使用し盲腸まで難なく到達できるようになるまでには、訓練が必要である。又、訓練を積んだ内視鏡医においても、盲腸までの挿入到達率は平均90~95%と言われている。そこで我々は、特定の一人の初心者内視鏡医に、通常大腸内視鏡とダブルバルーン大腸内視鏡の両方を使用させ、挿入成績に関して検討を行った。

【方法】 施行医は、初心者内視鏡医1名。対象は、2008年6月から2008年11月の間に、麻生飯塚病院消化器内科に来院した患者58人60例(男29人, 女29人; 19 - 86歳, 平均年齢63歳)。施行前にコンピューターでランダムに、(A) ダブルバルーン大腸内視鏡 (B) 通常大腸内視鏡、に割付けし、その挿入成績を検討した。

【結果】 各々の内視鏡での盲腸挿入成績は、(A) 100% (30/30例) (B) 73% (22/30例) と両群間に差を認めた。盲腸までの挿入時間は、(A) 平均36.2 ± 14.4分 (B) 平均36.5 ± 15.2分であり、有意差は認めなかった。検査中患者が苦痛を感じ、鎮静剤を使用した場合は、(A) 63% (19/30例) (B) 90% (27/30例) で、両群間に差を認めた。ダブルバルーン大腸内視鏡を使用することで、全例が挿入可能であり、苦痛度の軽減が得られた。全ての症例で偶発症はなかった。

【結論】 ダブルバルーン大腸内視鏡を使用することにより、初心者内視鏡医でも容易に盲腸への到達が可能であり、安全で苦痛の少ない内視鏡検査が可能になると考えられた。