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

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

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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.
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>
<thead>
<tr>
<th>Table 1</th>
<th>Procedure data</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>CC</td>
</tr>
<tr>
<td>No. patients</td>
<td>30</td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
</tr>
<tr>
<td>Post operative patients</td>
<td>16</td>
</tr>
<tr>
<td>Age</td>
<td>63.1 ± 15.3</td>
</tr>
</tbody>
</table>

| 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
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 ± SD. Statistical difference was detected by $\chi^2$ 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 ± SD).
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 patients. For unskilled endoscopists, it is...
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)\(^5,6\), 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 \textit{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 study\(^9\), observation of the entire colon using DBC 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 inexpert 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

<table>
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<tr>
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<td>M</td>
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<tr>
<td>2</td>
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<td>45</td>
<td>F</td>
<td>appendectomy, adnexotomy</td>
<td>hemorrhoids</td>
</tr>
</tbody>
</table>

Table 3: Clinical characteristics of incomplete intubation patients with CC

...
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 overtube\(^1\). 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 world\(^{11-15}\). 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, unedated 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 unit\(^{16}\). 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 responsibility\(^{17,18}\). 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.

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References


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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

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【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られる。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、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。検査中に患者が苦痛を感じ、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思われた。