Double-balloon endoscopy: an effective rescue procedure after incomplete conventional colonoscopy
Marco C. Becx and Abdul Al-Toma

**Objective** A significant percentage of colonoscopies remain incomplete because of a failure to intubate the caecum. By double-balloon endoscopy (DBE), originally developed for deep enteroscopy, an otherwise incomplete examination of the colon might be completed. We evaluated the success rate of caecal intubation, the reasons for its failure and the therapeutic consequences of using DBE after incomplete conventional colonoscopy.

**Methods** We report our single-centre experience of using DBE to complete an otherwise incomplete colonoscopy. A total of 114 consecutive patients, 45 male and 69 female, with a mean age of 64.8 years, who had undergone 116 procedures, were evaluated retrospectively by a review of their medical records.

**Results** The main causes for failed caecal intubation using a conventional colonoscope were loop formation in 70 patients (61.4%) and an adhesive angulated sigmoid in 33 (28.9%). Caecal intubation by DBE was successful in 101 patients (88.6%). The rate of failure was not associated with the cause of failure of the previous colonoscopy. In 55 patients (48.2%) a relevant new diagnosis was made in the previously inaccessible part of the colon: carcinoma (n = 4; 3.5%), one or more adenomas (n = 48; 42.1%) and caecal flat hyperplastic polyps (n = 4; 3.5%). Endoscopic polypectomy was performed in 51 patients (44.7%); two complications occurred, both being mild postpolypectomy bleedings. In seven patients (6.1%) a subsequent surgical resection was performed.

**Conclusion** Colonoscopy by DBE was useful in most patients in whom conventional colonoscopy was incomplete, irrespective of the cause of the failure. In nearly half the patients, a relevant new diagnosis was made with therapeutic consequences. Eur J Gastroenterol Hepatol 00:000–000 © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins.

**Keywords:** caecal intubation, colonoscopy, double-balloon, endoscopy, incomplete colonoscopy, rescue, screening

European Journal of Gastroenterology & Hepatology 2014, 00:000–000

**Introduction** Colonoscopy is the most efficient diagnostic modality for colorectal disease, also providing effective therapeutic possibilities, like endoscopic polypectomy. Caecal intubation is the primary quality index of the examination [1]. Colonoscopy is not always complete: the rate of failed caecal intubation is reported to be 1.6–16.7% [2–4]. Factors associated with failed caecal intubation, other than stenosis, are female sex, older age, prior abdominal or pelvic surgery, low BMI and diverticular disease [2,5]. The anatomical factors most frequently implicated are a sharply angulated sigmoid and loop formation in a redundant colon [6]. In the inaccessible part of the colon, advanced neoplasia were missed in 4.3% of patients [7]; hence, a complete evaluation of the colon is required. Video capsule endoscopy and modern radiological methods like colonography by computed tomography (CT) or MRI are capable of visualizing the entire colon, but histological evaluation or therapeutic interventions are not possible. Hence, endoscopic methods to complete the colonoscopy are more relevant. Repeating conventional colonoscopy can be successful in 50–72% of patients [8,9]. Various other endoscopes were tested to complete the colonoscopy: paediatric colonoscopes [10], gastroscopes [11], variable stiffness colonoscopes [12] and push enteroscopes [13], as well as magnet-imaging-enhanced colonoscopy [14]. In recent years balloon-assisted endoscopy, double balloon as well as single balloon, has also been applied [8,14–23]. The double-balloon endoscope was originally designed to overcome the problem of looping when inserting the endoscope into the small intestine [24]. This endoscope might be useful to complete an otherwise incomplete evaluation of the colon.

Here we report the data of our series of patients in whom we performed double-balloon endoscopy (DBE) of the colon after an incomplete conventional colonoscopy. The aims of the study were: (i) to evaluate the success rate of caecal intubation on DBE, (ii) to compare this success rate in various failed conventional colonoscopies and (iii) to evaluate the findings of relevant pathology and their therapeutic consequences.

**Patients and methods** All consecutive patients who underwent DBE of the colon between January 2007 and March 2013 were evaluated retrospectively by review of their medical records for details on: (i) patient characteristics, (ii) the preceding colonoscopy
(indication, sedative medication administered, reason for failure of caecal intubation and pathological findings) and (iii) the DBE procedure (indication, sedative medication administered, caecal intubation or reason for failure, pathological findings, endoscopic therapy performed, complications, any subsequent surgical treatment based on the findings from DBE and any modality and outcome of subsequent examination of the colon following DBE failure).

Patients were referred for DBE if the previous colonoscopy was incomplete and if a clear indication to complete the colonoscopy was present. Conventional colonoscopy and DBE were considered to have failed if the caecum could not be intubated or no sufficient positioning of the endoscope for caecal polypectomy could be achieved. In the case of failure of DBE because of colonic stenosis or insufficient bowel cleansing, patients were not included for further evaluation. Caecal intubation was documented by a picture of the appendiceal orifice and/or of the terminal ileum.

The index colonoscopies at our teaching hospital were performed by 11 gastroenterologists (80 procedures; 70%), 11 trainee gastroenterologists in various stages of their training (30 procedures; 27%) and two certified nurse endoscopists (four procedures; 3%), all working under direct supervision. Failed colonoscopies by trainees or nurse endoscopists were only labelled incomplete if the supervising gastroenterologist was also unable to complete the procedure. Ten patients were referred for DBE by other institutions.

The DBE procedures were performed by four different gastroenterologists with varying degrees of experience in double-balloon procedures, ranging from 15 to greater than 100 procedures per person. One or two nurses assisted with the endoscopy. Patients were informed about the procedure and gave informed consent. The same bowel cleansing regimen as used for conventional colonoscopy was followed, including administration of 41 of polyethylene glycol solution before 2008 or 21 of polyethylene glycol solution with ascorbic acid since 2008, mostly in split doses. All procedures were performed under conscious sedation with intravenous meperidine and midazolam. Fluoroscopy was not performed. The therapeutic Fujinon EN-450T5/20 double-balloon enteroscope (Fujinon Inc., Saitama, Japan) was used, comprising an endoscope with an overtube, both equipped with a latex balloon at the tip. The endoscope used had a working length of 200 cm and an external diameter of 8.5 mm. The overtube used had a length of 135 cm and an external diameter of 13.2 mm. Both balloons could be inflated, pressure controlled and deflated separately using a double-barostatic pump. The DBE procedure was described by Yamamoto and Sugano [24].

Statistical analysis: Fisher’s exact test was used to assess the statistical significance between variables. A P-value of 0.05 or lower was considered statistically significant.

The local institutional review board judged the study not subject to the Medical Research involving Human Subjects Act (WMO).

Results
A total of 114 patients underwent DBE of the colon. The characteristics of these patients, on whom 116 DBE procedures had been performed, are shown in Table 1. Of these patients 45 were men and 69 were women, with a mean age of 64.8 years (range from 31 to 91 years).

The main indications for total colonoscopy were surveillance and screening because of previous adenomas or a family history of colorectal cancer in 31 patients (27.2%), the finding of one or more newly diagnosed adenomas or carcinomas (in one patient) during the previous incomplete colonoscopy in 26 patients (22.8%) and rectal blood loss or iron deficiency in 20 patients (17.5%).

On DBE, the mean doses of sedative medication administered were comparable with the doses administered at the previous conventional colonoscopies: meperidine 52.6 versus 54.9 mg, midazolam 3.9 versus 4.2 mg.

The results of caecal intubation on DBE are summarized in Table 2. Caecal intubation was achieved in 101 of 114 patients (88.6%), in one of these at a second attempt (first procedure was terminated because of insufficient cleansing of the colon). There was no statistically significant difference in the success rate between women (63/69; 91.3%) and men (38/45; 84.4%; P-value = 0.36). No difference was found between patients with a redundant colon (61/70; 87.1%), those with an adhesive angulated sigmoid (29/33; 87.9%), those with insufficient positioning for caecal polypectomy (9/9; 100%) and those with an unknown cause for failure of the previous colonoscopy.

<table>
<thead>
<tr>
<th>Reason for incomplete CC [n (%)]</th>
<th>n</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Looping</td>
<td>70</td>
<td>0.614</td>
</tr>
<tr>
<td>Adhesive angulated sigmoid</td>
<td>33</td>
<td>0.289</td>
</tr>
<tr>
<td>Failed positioning for caecal polypectomy</td>
<td>9</td>
<td>0.79</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Table 1 Patient characteristics and data of the previous conventional colonoscopy
colonoscopy (2/2; 100%); the P-value ranged from 0.18 to 1.0. DBE failed in 13 patients. The most frequent cause for failure to reach the caecum was looping (n = 6), which also caused failure of conventional colonoscopy. In three patients the failure was caused by insufficient bowel cleansing, among whom in one patient both attempts failed. In four patients the adhesive angulated sigmoid prevented further passage, like in the index conventional colonoscopy.

Table 3 shows the relevant abnormalities that were found in the part of the colon not fully intubated previously, and the therapeutic consequences. In 55 patients (48.2%) a new diagnosis was made, with subsequent treatment. In four patients (3.5%) a carcinoma was found. One or more adenomas were found in 48 patients (42.1%), which were endoscopically removed in all of the cases, in one patient combined with argon plasma coagulation for an angiodysplasia. One patient needed additional surgical resection because a large adenomatous polyp could not be completely removed endoscopically. Four patients (3.5%) underwent endoscopic polypectomy of a flat caecal hyperplastic polyp, combined with polypectomy of an adenoma in one of them. One patient had relapsing diverticulitis and was treated by surgical resection. One patient was surgically treated for a peritoneal pseudomyxoma, suspected at CT-scanning, performed because of an unexplained extrinsic caecal bulging found on DBE.

Two complications (1.8%) occurred, both were postpolypectomy bleedings. One patient was admitted to the hospital, in whom the bleeding on endoscopy stopped spontaneously; in the other patient, no additional procedure was necessary.

Follow-up data ranging from 5 months to 5 years were available from 12/13 patients with DBE failure; one patient was lost to follow-up. In four patients, no additional examination of the colon was performed. In two patients conventional colonoscopy was repeated and in six patients one or two other modalities of examination of the colon were adopted. One of these patients underwent resection for diverticulitis, otherwise no new relevant pathology was found.

Table 2: Caecal intubation at DBE: success rate and reasons for failure

<table>
<thead>
<tr>
<th>Caecal intubation at DBE</th>
<th>Successful</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [n (%)]</td>
<td>101 (88.6)</td>
<td>13 (11.4)</td>
</tr>
<tr>
<td>Male*</td>
<td>38 (84.4)</td>
<td>7 (15.6)</td>
</tr>
<tr>
<td>Female*</td>
<td>63 (91.3)</td>
<td>6 (8.7)</td>
</tr>
<tr>
<td>Reason for failed CC [n (%)]**</td>
<td>Reason for failed DBE</td>
<td></td>
</tr>
<tr>
<td>Looping</td>
<td>61 (87.1)</td>
<td>6 looping</td>
</tr>
<tr>
<td>3 poor cleansing</td>
<td></td>
<td>(twice in 1)</td>
</tr>
<tr>
<td>Adhesive angulated sigmoid</td>
<td>29 (87.9)</td>
<td>4 angulation</td>
</tr>
<tr>
<td>Positioning for caecal polypectomy</td>
<td>9 (100)</td>
<td>–</td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (100)</td>
<td>–</td>
</tr>
</tbody>
</table>

CC, conventional colonoscopy; DBE, double-balloon endoscopy.
*P=0.366.
**P=0.18–1.0.

Table 3: Relevant new diagnoses and therapy on DBE

<table>
<thead>
<tr>
<th>Diagnoses</th>
<th>N (%)</th>
<th>Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with new diagnoses</td>
<td>55 (48.2)</td>
<td>Endoscopic in all; 1 also surgical</td>
</tr>
<tr>
<td>Adenomas (≥ 1)</td>
<td>48 (42.1)</td>
<td>Endoscopic</td>
</tr>
<tr>
<td>Flat caecal hyperplastic polyp</td>
<td>4 (3.5)*</td>
<td>Endoscopic</td>
</tr>
<tr>
<td>Carcinoma</td>
<td>4 (3.5)*</td>
<td>Surgical</td>
</tr>
<tr>
<td>Peritoneal pseudomyxoma</td>
<td>1</td>
<td>Surgical</td>
</tr>
<tr>
<td>(Relapsing) diverticulitis</td>
<td>1</td>
<td>Surgical</td>
</tr>
<tr>
<td>Angiodysplasia</td>
<td>1*</td>
<td>Endoscopic</td>
</tr>
</tbody>
</table>

DBE, double-balloon endoscopy.
*Combined with adenoma: in two patients with carcinoma, in one with flat caecal hyperplastic polyp, in one patient with angiodysplasia.

Discussion

This study demonstrates that in the vast majority of patients it was possible to reach the caecum using a double-balloon endoscope in cases of unsuccessful conventional colonoscopy. Completion of colonoscopy with full intubation of the caecum in greater than 90% of patients is a target in the USA [25] and in the Netherlands [26]. In the previous studies evaluating alternative methods to complete previous incomplete colonoscopies, varying success rates were found with using a gastroscopy, a push enteroscope or a variable stiffness colonoscopy [11–13]. The double-balloon endoscope, originally developed for deep intubation of the small bowel, combines a very flexible endoscope with a more rigid overtube, with inflatable balloons at their tips. The endoscope allows passage through sharp angulations because of its thin calibre and high flexibility, and also through segments of redundant colon because of the stiffness provided by the overtube, whereas it is kept in place by the inflated balloons, if the endoscope is pulled back and the bowel is stretched [24]. This concept proves to be useful in cases in which endoscopy of the colon is difficult, for which a redundant colon with loop formation and an adhesive angulated sigmoid are the most important anatomical causes [6].

Our series is one of the largest thus far on this subject. Conventional colonoscopies were performed by more than 10 different gastroenterologists, and the DBE procedures were performed by four different gastroenterologists with varying degrees of experience. This might better reflect the real common daily practice than other studies reporting the experience of only one or a few performing endoscopists. Our findings on caecal intubation confirm the results of previous retrospective and prospective studies on DBE [14–19,23] with caecal intubation rates of 88–95%. Recently a 100% success rate of caecal intubation using a short double-balloon endoscope in 110 patients was reported [21]. In this study a shorter double-balloon endoscope, with a length of 152 cm, was used to facilitate the handling of the colonoscope. In addition, single-balloon endoscopes have been studied prospectively for colonoscopy [8,22] and retrospectively comparing single-balloon with
double-balloon colonoscopy [23]. The cecal intubation rates ranged from 93 to 100%, comparable with those of DBE.

The tolerance towards DBE procedures and previous colonoscopies was comparable among our patients, as indicated indirectly by the dosage of sedatives administered during both procedures. Besides, the mean dosages of midazolam and meperidine (3.9 and 52.6 mg, respectively) used by us were not higher than the dosages used in a previous prospective series (6 and 50 mg, respectively), in which even general anaesthesia was used for some patients [23].

Cecal intubation was indeed relevant in our patient group, finding significant pathology with therapeutic consequences in the previously inaccessible part of the colon in nearly half the patients. These findings are in line with the results of other studies [7]. Surprisingly, our limited follow-up data on patients with DBE failure showed few relevant abnormalities. Completion of the colonic investigation endoscopically has the advantage of providing histological diagnosis and endoscopic therapeutic possibilities, as compared with video capsule endoscopy and radiological methods like CT or MR colonography. This might be a strong argument to include DBE as a mandatory rescue procedure in colorectal cancer screening programmes, for patients with a positive faecal immune test and an incomplete colonoscopy. Such a nationwide screening programme is scheduled to start in 2014 in the Netherlands [26].

The main limitation of our study is its retrospective nature. We did not record the time taken for the DBE procedure; in other studies, the procedural time ranged 45 to 51 min for the complete procedure [19,23].

Conclusion
DBE appeared to be a very useful method to complete a previously incomplete conventional colonoscopy procedure. In almost 50% of the patients, relevant pathology was found with therapeutic consequences, mainly endoscopic polypectomy, as well as surgical resection.

Acknowledgements
Conflicts of interest
There are no conflicts of interest.

References