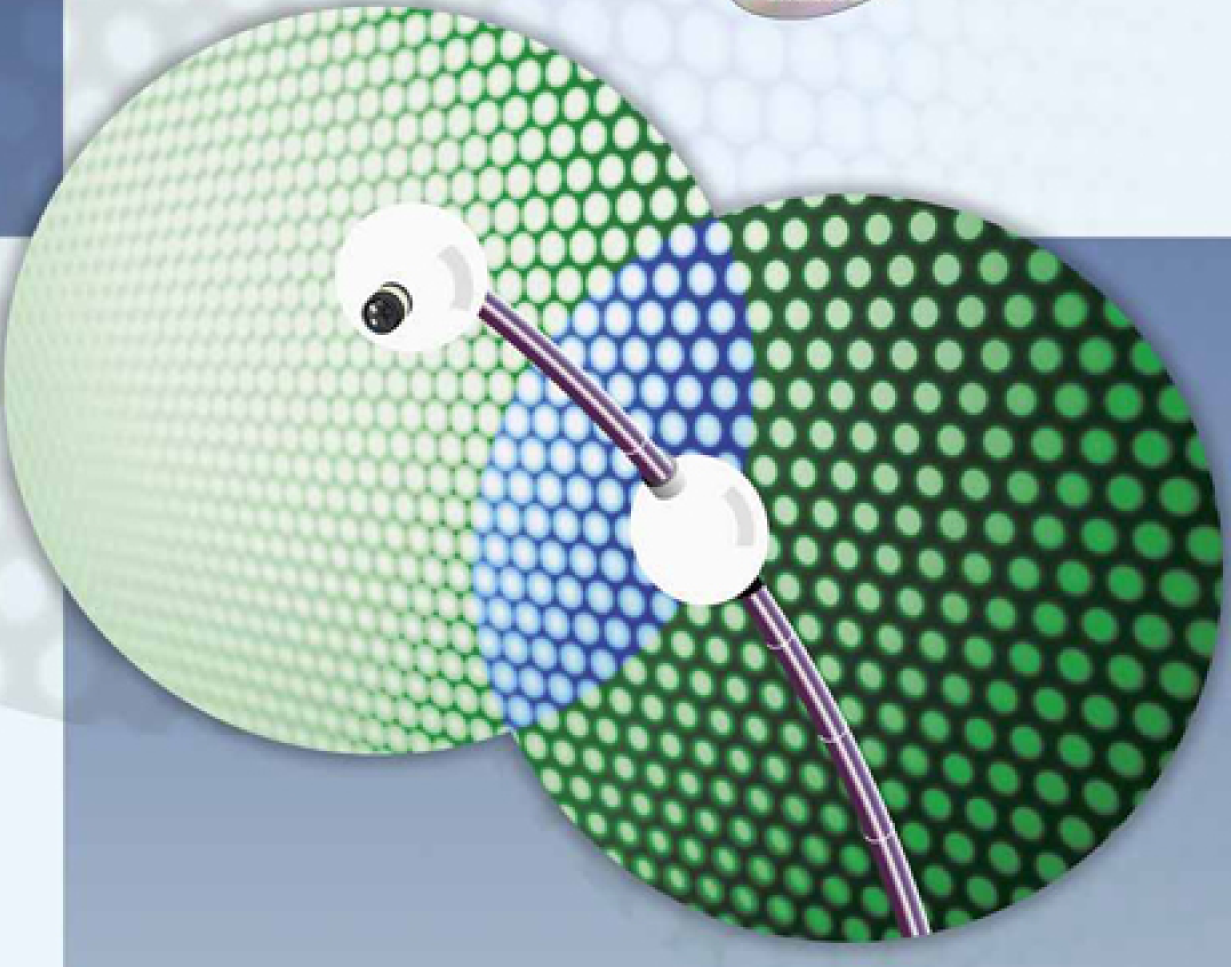
K. Sugano (Editor in Chief)
H. Yamamoto • H. Kita (Eds.)

Double-Balloon Endoscopy

Theory and Practice

DVD with video clips enclosed



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With 109 Figures, Mostly in Color

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Preface

The double-balloon endoscope came about as the combined result of a brilliant idea and tenacious effort by Hironori Yamamoto, an associate professor in our department. The first clinical application of the double-balloon method was made for diagnosis of hemangioma in the small intestine of a patient with Maffucci's syndrome, as described in this book. Dr. Yamamoto attached a handmade balloon to an upper gastrointestinal endoscope and manually inflated and deflated the balloon, with a sphygmomanometer monitoring the pressure. The maneuverability and the time required for examination appeared to be similar to those in the procedure using a conventional enteroscope, although I was impressed by the fact that double-balloon endoscopy actually revealed hemangioma previously suspected by contrast radiogram, validating the concept of the double-balloon method. However, there were various problems with the handmade device, including balloon damage, dropout, and air leakage, as well as the patience required on the part of the assistant doctors, all of which made its practical application difficult. Despite these circumstances, Dr. Yamamoto clearly identified and solved the problems one by one. As he describes in chapter 1 of this book, the cooperation of manufacturers such as Nisco and Fujinon was a great help, and many medical staff in our department who continuously assisted him in time-consuming examinations also contributed significantly to the practical application of this novel modality of endoscopy. Through the development of this procedure, we directly observed many previously unrecognized lesions and performed endoscopic treatments that had been possible only by surgical operation, and we found that the procedure was tremendously useful for a variety of disorders. Now the double-balloon endoscopy system distributed by Fujinon is in clinical use worldwide and contributes to the diagnosis and treatment of disorders in the small intestine and other regions of the gastrointestinal tract that were not easily accessible by conventional approaches. However, there was no guidebook for systematic training in this procedure, and we believed it was important to provide an opportunity for many clinicians to learn the procedure and perform it properly; thus we decided to publish this book. Consequently, the book provides a range of techniques and tips developed through trial and error by Dr. Yamamoto and our colleagues, who are co-authors of the book. A DVD is included to provide a visual presentation of specific manipulations.

As described in the book, the double-balloon method was initially intended for use in enteroscopy; however, the double-balloon endoscope allows observation of the entire gastrointestinal tract, including the stomach and the large intestine. In addition, the endoscope allows shortening and straightening of the intestinal tract and is suitable for examination of a reconstituted intestine after Roux-en-Y anastomosis and colonoscopy in which insertion is difficult. Thus, we have changed the initially planned title *Double-Balloon Enteroscopy* to *Double-Balloon Endoscopy*.

Some people were skeptical of the clinical significance of the procedure, because intestinal diseases were previously considered to be uncommon and the development of the double-balloon endoscope paralleled that of the capsule endoscope. As evidenced by our short-term experience described in this book, however, we realized that a variety of lesions, hitherto unrecognized because of their limited accessibility, were present in the small intestine as well as in the blind loop. Compared with the capsule endoscope, the double-balloon endoscope produces images with much higher resolution, provides maneuverability that allows retrograde examination, and permits concomitant use of a variety of diagnostic techniques such as biopsy, dye spraying, and contrast-enhanced examination. It should also be noted that the double-balloon endoscope is compatible with almost all procedures for endoscopic treatment. In combination with those procedures, double-balloon endoscopy now appears to be far superior to capsule endoscopy with respect to diagnostic and therapeutic performance.

This book is intended to be useful as a technical manual and does not include details of individual diseases and the basis for their diagnosis. It may be somewhat difficult for complete novices to understand the initial settings and other technical details that we are accustomed to. In the future, we will make revisions in response to questions and criticisms from readers. We hope, however, that the book will contribute to the elucidation of the pathophysiological mechanisms of intestinal diseases and their treatments, which we believe will evolve dramatically in the twenty-first century with the general availability of double-balloon endoscopy.

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Contents of Attachment DVD

The DVD that comes with this book, *Procedure Manual for Inserting the Double-Ballon Endoscope*, was provided by Fujinon Corporation. Contents are as follows.

1. Introduction	Introduction of the products, preparation, explanation of operation
2. Clinical Examples	How to operate the products
3. Interviews	Interviews with Dr. Hironori Yamamoto

DVD Planning and creative work : Fujinon Corporation

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1 What Is a Double-Balloon Endoscope?

The double-balloon endoscope is an endoscope that is used in a novel insertion method developed to ensure smooth insertion into the distal small intestine. Its principle came to my mind in 1997. I was involved in community health care after graduating from Jichi Medical University and was not familiar with endoscopic expertise, such as enteroscopy, until I went back to my alma mater 11 years after graduation. My thoughts resulted in a novel idea. In community health care settings, the lack of advice from instructors often required ingenuity to solve problems. Over the 10 years following graduation, I developed critical thinking skills instead of being content with the status quo.

To be honest, I thought enteroscopy was an awful examination when I first witnessed an enteroscopic examination. During push enteroscopy, a long endoscope was inserted through the mouth while the patient complained of discomfort. On the fluoroscopic monitor, I found the endoscope forming a loop, stretching the intestine, but advancing little. Efforts to advance the endoscope farther made it form a larger loop with the tip stalled, which caused more discomfort to the patient. Despite the prolonged examination, the endoscope tip reached only 50 cm distal to the ligament of Treitz, and the examination was discontinued with no elucidation of pathologic conditions.

The examination left a deep impression on me, and I wondered why the endoscope had not advanced despite such an effort. A few days later, while driving, I was still wondering and suddenly realized that stretching the intestine prevents insertion. It was well known at the time that straightening the intestinal tract helped insertion of a colonoscope, and a semi-rigid overtube was used to prevent the straightened intestine from forming a loop again. Such an overtube was also used with a push enteroscope, but it was very difficult to straighten an intricately curved small intestine. Thus, my new idea was not to straighten the intestine but to use a balloon-attached flexible overtube to prevent stretching the curved intestine. Furthermore, another balloon was attached to the endoscope tip to prevent the deeply inserted endoscope from slipping out while advancing the overtube — and a prototype of the double-balloon endoscope was thus developed.

The double-balloon endoscope is often described as a type of “measuring worm” and the procedure as achieving “with balloon support, shortening the intestine and endoscope insertion.” Each description is close to but not exactly the same as my concept. The primary objective is to prevent stretching the intestine. The intestine is shortened only to make the best use of the working length of the endoscope and facilitate its insertion. Accordingly, I believed from the beginning that this approach would be useful in colonoscopy as well, especially in patients with adhesions, which make insertion of a colonoscope difficult.

I asked endoscope manufacturers for their cooperation as soon as the principle of insertion occurred to me, but they turned me down. They had convincing reasons, and it could not be helped. However, it was good not to abandon my idea. They told me that the principle was merely an armchair theory and unlikely to be substantiated in the clinical setting; moreover, the endoscope, if practicable, would be unprofitable from the viewpoint of the enteroscope market.

Because endoscope manufacturers declined to cooperate, I had no choice but to do it myself. A balloon was attached to the tip of a plastic tube purchased at a hardware store and this concoction was used in combination with an endoscope. Because of the lack of an air route for the balloon at the endoscope tip, it was attached in a retrograde direction so the air route came out the forceps channel (Fig. 1.1). I could not test the initial prototype clinically and asked Dr. Yukihiro Sato, one of my fellows, for cooperation. He willingly agreed to be a study volunteer. The first trial was conducted with a prototype overtube that had an outer diameter of 14 mm. The volunteer was given pharyngeal anesthesia only, without sedation, and the procedure was not tolerated because the vomiting reflex manifested before the tube reached the small intestine, failing to test the principle. Next, we took turns being the operator and the study volunteer, and the procedure was tested on me. I was unable to tolerate the examination either and gave it up.

I therefore concluded that the safety and usefulness should be demonstrated in animal studies before clinical application, so I tested the procedure in dogs. The procedure was then approved by our institutional ethics committee and used in the clinical setting.

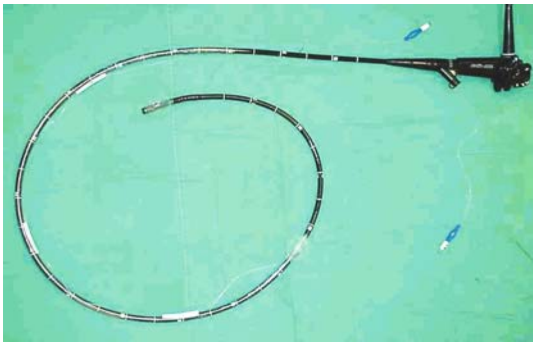

Fig. 1.1. Prototype double-balloon endoscope equipped with a handmade balloon-attached overtube

The first three patients were examined with an upper endoscope that had an outer diameter of 7.7 mm and a working length of 103 cm together with a balloon-attached overtube with an outer diameter of 12 mm and a length of 75 cm. The fourth patient was examined with an enteroscope with a working length of 200 cm in combination with a 140-cm overtube. All examinations were successful; and total enteroscopy was completed with the endoscope tip advanced into the large intestine in the fourth patient. The results were reported at scientific meetings in Japan and other countries and published in *Gastrointestinal Endoscopy* [1].

A few questions remained concerning the clinical safety and effectiveness of this method. One was whether the balloon would grip the less robust small intestine safely and adequately without patient discomfort; thus, an endoscope was inserted with the supporting point as a fulcrum. I believed that appropriate selection of balloon materials, pressure that ensured a wide margin of safety, and a soft balloon with lower pressure and a larger contact area would provide a satisfactory grip. The luminal diameter of the small intestine varies among individuals, and the diameter differs between the jejunum and the ileum. Moreover, some regions are dilated in response to stenosis; and conditions are, of course, totally different in the large intestine. With these factors taken into consideration, inflation of the balloon was specified in terms of inflation pressure, not air content. This approach allowed a balloon to grip intestinal tracts that have different luminal diameters with the same intensity. To demonstrate the safety and determine the optimal pressure, the following experiment was performed in the small intestine of dogs.

Laparotomy was performed under general anesthesia. A silicon or latex balloon attached to the tip of a rod, with a diameter of 10 mm and an approximate length of 15 cm, was inserted from an incision made in the jejunum to investigate the relation between inflation pressure and resistance to withdrawal.

1. The relation between inflation pressure and grip was measured with two types of balloon (Table 1.1; grip 1 and grip 2 represent two measurements).
2. Withdrawal of the latex balloon with an inflation pressure of 100 mm Hg produced no gross mucosal damage.

These results suggested that a soft latex balloon with an inflation pressure of 40–100 mm Hg was suitable for enteroscopy, and the minimum required pressure was determined to be 45 mm Hg.

Table 1.1. Relation between inflation pressure and grip measured with two types of balloon

Balloon pressure (mm Hg)	Grip 1 (g)	Grip 2 (g)
Latex balloon (made from condoms)		
0	0	0
10	0	0
20	20	0
30	30	20
40	70	20
50	80	70
60	120	70
70	200	80
80	200	120
90	220	180
100	100	140
120	180	
140	210	
160	500	
Silicon balloon		
0	0	0
10	0	0
20	0	10
30	10	0
40	10	0
50	20	20
60	20	20
70	20	20
80	20	20
90	20	20
100	20	20
120	30	30
140	60	30
160	60	40
180	60	60
200	80	70
240	360	

Another concern was friction between the overtube and the endoscope. Controlling an endoscope through a long overtube requires eliminating any influence of friction, thereby allowing the endoscope to slide smoothly, even through a curved overtube. The handmade overtube was therefore equipped with a lubricant inlet around one-third the distance from the tip of the overtube so olive oil could be applied during the examination. Currently, the overtube distributed by Fujinon has a convenient internal and external hydrophilic coating by which water injection alone ensures smooth sliding.

Initially, a syringe was used to inflate and deflate a balloon while the internal pressure was being measured with a sphygmomanometer. For marketed devices, a balloon pump controller allows accurate monitoring of the balloon pressure and automatic inflation and deflation of the balloon with the touch of a button, which reduces the time required for the examination.

Tsuneo Nishiguchi, the president of Nisco, cooperated to an extraordinary extent in developing the double-balloon endoscope. Prototypes of a balloon-attached overtube, a balloon at the endoscope tip, and a balloon pump controller were made in cooperation with Nishiguchi. He introduced me to Fuji Photo Optical (currently Fujinon), which made prototypes of dedicated endoscopes. The clinical study results of prototypes demonstrated their usefulness, and the Fujinon double-balloon electronic endoscopy system was put on the market in November 2003 [2, 3]. Engineers at Fujinon made a great contribution to commercializing this endoscopy system. I must especially express my gratitude to Shuichi Yamataka, director of the Medical Equipment Department of Fujinon, and Tetsuo Udagawa, president of Fujinon Toshiba ES Systems.

The development of the double-balloon endoscope paralleled that of the capsule endoscope. Many people expressed concern that practical application of capsule endoscopes in the near future would make the new method of enteroscope insertion obsolete. I insisted, however, that the widespread use of capsule endoscopes would not eliminate but increase the need for enteroscopes that allowed access to the entire area of the small intestine. I believed that capsule endoscopes that could reveal abnormalities would increase the need for a thorough examination by enteroscopy. My belief is now being proven [4].

The widespread use of double-balloon endoscopes and capsule endoscopes will increase interest in intestinal diseases and the need for enteroscopy. I hope this book helps popularize the technique for safe and appropriate insertion of the double-balloon endoscope.

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2 Equipment

Double-Balloon

2.1 Configuration

The double-balloon endoscopy system (Fig. 2.1) consists of a dedicated endoscope that can have a balloon mounted at its tip, a balloon attached to the endoscope, a balloon attached to the overtube, and a balloon pump controller to inflate and deflate the balloons (Fig. 2.2).

2.2 Devices

This subsection describes the characteristics and principle of the double-balloon endoscope distributed by Fujinon.

2.2.1 *Scope (EN-450P5, EN-450T5)*

Table 2.1 shows the specifications of the EN-450P5 and EN-450T5 scopes. Two types of dedicated scope are available. One is a standard scope with better insertability; it has a working length of 2000 mm, outer diameter of 8.5 mm, and forceps channel diameter of 2.2 mm. The other is a treatment scope with more therapeutic capabilities; it has a working length of 2000 mm, outer diameter of 9.4 mm, and forceps channel diameter of 2.8 mm

Fig. 2.1. Double-balloon endoscope

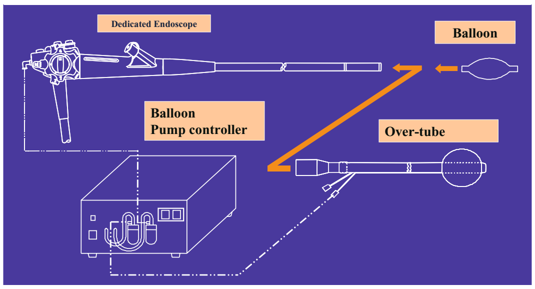


Fig. 2.2. System configuration

Table 2.1. Specifications of dedicated scopes

Variable	EN-450P5	EN-450T5
Observation range (mm)	4–100	4–100
Field of view	120°	140°
Outer diameter (mm)	8.5	9.4
Forceps channel (mm)	2.2	2.8
Working length (mm)	2000	2000

(Fig. 2.3). Each has a built-in air route to inflate and deflate the balloon attached to the tip (Fig. 2.4).

Fig. 2.3. Comparison of EN-450P5 and EN-450T5

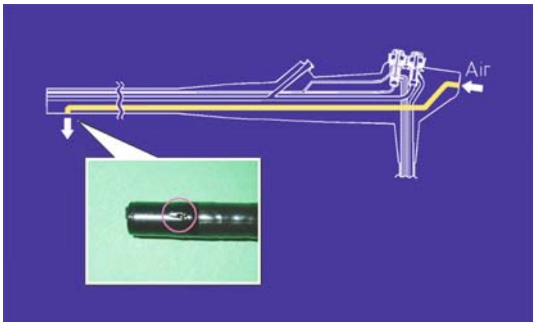


Fig. 2.4. Air route built into the scope

2.2.2 *Overtube (TS-12140, TS-13140)*

Two types of overtube are available. One is the TS-12140 (outer diameter 12.2 mm, length 1450 mm) for use with the EN-450P5, and the other is the TS-13140 (outer diameter 13.2 mm, length 1450 mm) for use with the EN-450T5. Both are flexible tubes. A latex balloon is mounted on the distal end of the overtube. Wetting the inner and outer surfaces of the overtube dramatically improves lubricity, which allows smooth insertion of a scope by reducing friction between the overtube and the scope and the overtube and the intestine.

As shown in Fig. 2.5, the overtube has two connection ports. The white one is connected to the balloon at the tip of the overtube through a built-in route used to inflate and deflate the balloon at the tip using a balloon pump controller, as described later. A syringe is connected to the blue connection port to inject water into the overtube, which ensures lubricity. In addition, a metal ring is embedded at the far end of the overtube with which the position of the balloon can be identified fluoroscopically.

Fig. 2.5. Overtube

2.2.3 *Scope Balloon (BS-1)*

After the scope is passed through the overtube, a dedicated balloon (BS-1) is attached to the distal end of the scope. The balloon is made of latex and has a thickness of approximately 0.1 mm; it is designed to hold the intestine securely at the lowest possible pressure. A specifically designed device (jig) is used to attach a balloon at the distal end of the scope, and both ends of the balloon are secured with fixing rubbers. This makes the balloon ready to be inflated and deflated with a balloon pump controller that supplies and withdraws air, as shown in Fig. 2.6. Attachment procedures are detailed in Chapter 7, and illustrated in the attached DVD (digital videodisc). As needed, an ancillary dedicated hood may be attached to the distal end of the scope. Figure 2.7 shows the devices ready for use.

Fig. 2.6. Balloon at the scope tip

Fig. 2.7. Configuration of the scope, overtube, and balloon

2.2.4 *Balloon Pump Controller (PB-20)*

The balloon pump controller (Fig. 2.8) controls the air in the balloons on the scope and the overtube by either supplying or withdrawing air. The controller has two tubes. A transparent tube for the scope is connected to the connector on the top of the scope control head, and a white tube for the overtube is connected to the white connection port of the overtube. Air can be supplied by pushing two green buttons, one for the scope balloon and the other for the overtube balloon, on the remote switch box (inflation, LED lights up); or it can be withdrawn (deflation, LED lights off). The white buttons below the green buttons function as a pause switch to stop the air supply or withdrawal temporarily. A digital pressure monitor is on the front of the pump for monitoring balloon pressure. The balloon pressure is maintained constant at approximately 5.6 kPa (42 mm Hg) by a pressure sensing and feedback mechanism. The "level" is the minimum pressure required to anchor the intestine; a balloon inflated at such a low pressure is unlikely to cause pain or discomfort to patients.

To ensure safety, the controller is designed to activate an alarm when peristaltic movement or back-and-forth manipulation of the scope elevates the balloon pressure above a set

Fig. 2.8. Balloon pump controller

pressure of 8.2 kPa for 5 s or longer. The controller is also designed to sense balloon damage and air leakage from the connection, whereupon it activates an alarm. It is equipped with a filter to prevent inflow of body fluids in case of balloon damage, and due consideration is given to safety during use.

3 Indications, Contraindications, and Preoperative Examination

3.1 Indications and Contraindications

3.1.1 *Indications*

Double-balloon endoscopy is indicated for enteroscopy in patients who have a suspected intestinal disease and require a thorough examination to determine the treatment strategy. It is also indicated in patients who have had a confirmed diagnosis of intestinal disease and in whom endoscopic treatment is required and feasible. In addition to problems of the small intestine, double-balloon endoscopy is also indicated for examination of the entire gastrointestinal tract, which is not accessible by conventional endoscopy. The specific indications are as follows.

1. *Examination following capsule endoscopy*
   - Diagnostic endoscopy including histological examination is done for a thorough examination of suspected lesions found by capsule endoscopy.
2. *Bleeding*
   - Gastrointestinal bleeding of unknown cause (“obscure” gastrointestinal bleeding): Double-balloon endoscopy is indicated in patients with a suspected bleeding source in the small intestine that has not been identified by conventional upper gastrointestinal endoscopy or colonoscopy. Possible sites of “obscure” gastrointestinal bleeding are preferably examined carefully by skilled endoscopists because such bleeding has been reported to be attributable to lesions located within the reach of a conventional upper gastrointestinal endoscope or colonoscope in 20% of patients. If applicable, gastrointestinal bleeding scintigraphy or capsule endoscopy may be useful before undertaking double-balloon endoscopy.
   - Overt small-intestinal bleeding: Double-balloon endoscopy is indicated in patients with overt bleeding in whom bleeding sources are not identified by upper gastrointestinal endoscopy or colonoscopy. Gastrointestinal bleeding scintigraphy is preferably performed in advance to estimate the location of the bleeding site. Whether the oral or anal route is preferable is determined before enteroscopy for efficient examination on the basis of potential bleeding sites estimated by gastrointestinal bleeding scintigraphy. Where it is difficult to estimate the location of bleeding sites, one strategy is to examine most of the intestine through the anus and the remainder through the mouth because the transanal approach usually causes less discomfort (total enteroscopy is performed by using the combination). By contrast, it is often useful to select a transoral approach as a first procedure in patients with active ongoing bleeding. It is easier to identify bleeding points with the transoral approach in cases of ongoing bleeding because blood flows anally from the bleeding point in the small intestine. For hemostasis, injection and high-frequency cauterization can be performed with the EN-

450P5 enteroscope. High-frequency cauterization can be performed with the tip of a snare in the argon plasma coagulation (APC) mode (spray mode) or a hemostatic forceps in the soft coagulation mode to treat tumor bleeding, as well as hemostasis with a coagulator to treat angiectasia (angiodysplasia). The treatment-type EN-450T5 has a forceps channel with a diameter of 2.8 mm, which allows almost all endoscopic hemostasis procedures, including clips, APC probes, and other accessories. Because of the thin intestinal wall and high risk of perforation, it is deemed safe and effective to perform high-frequency cauterization after injection.

- Postoperative disorders of the gastrointestinal tract: Double-balloon endoscopy is indicated in patients with protein loss and bleeding who are suspected of having blind loop syndrome. Abdominal computed tomography, gastrointestinal bleeding scintigraphy, or albumin scintigraphy should also be performed if indicated. A capsule endoscope usually cannot access the blind loop. Multiple ulcers may occur in the afferent loop or the blind loop after gastrointestinal surgery, such as Roux-en-Y anastomosis and intestinal bypass surgery.

3. *Endoscopic diagnosis and treatment of stenosis*
   - Stenosis is a contraindication to capsule endoscopy but a good indication for double-balloon endoscopy.
   - An endoscopic or pathological diagnosis in patients with stenosis or other abnormalities revealed by small bowel series indicates the need for double-balloon endoscopy.
   - Balloon dilatation for the treatment of benign stenosis associated with Crohn's disease or other inflammatory disorders. A through-the-scope (TTS) balloon dilator is available with the EN-450T5 enteroscope.
   - Metallic stenting for palliative treatment of malignant stenosis of the small intestine. A commercially available metallic stent delivery system may require modification to ensure an adequate working length.
4. *Tumors and masses*
   - Endoscopic or pathological diagnosis of tumors or masses suspected by contrast-enhanced studies, abdominal computed tomography, or other modalities.
   - Preoperative marking in patients who are scheduled to undergo surgical resection (tattooing).
   - Hemostasis for bleeding from tumors, such as gastrointestinal stromal tumors (GISTs) or malignant lymphomas.
   - Endoscopic mucosal resection (EMR) for an intraepithelial neoplasm of the small intestine. A short overtube may be used with a double-balloon endoscope, which is replaced with another endoscope with a large channel diameter by leaving the overtube in place, thereby allowing the use of conventional therapeutic devices, although the indication is restricted by the location of lesions. The EN-450T5 allows clipping and safe EMR without changing endoscopes.
   - Polypectomy of polyps of the small intestine.
5. *Pancreatic and biliary diseases*
   - Endoscopic retrograde cholangiopancreatography (ERCP) after a Billroth II or Roux-en-Y operation.
   - Stenting or other endoscopic biliary treatment in patients with bile duct stones or tumors that are not easily accessible to a conventional endoscope because of previous intestinal reconstruction, such as a Roux-en-Y anastomosis.
6. *Crohn's disease*
   - Balloon dilatation for stenosis of the small intestine.
   - Endoscopic and histological diagnosis of Crohn's disease involving the small intestine and subsequent follow-up (contrast-enhanced studies may be sufficient). With respect to endoscopic diagnosis, capsule endoscopy may be performed as a screening method

in individuals with suspected Crohn's disease, although there is a possibility of capsule retention in the case of stenosis.

7. *Removal of a foreign body from the small intestine*
    - Removal of a foreign body from the small intestine with a basket forceps or three-pronged forceps.
    - Retrieval of a retained capsule endoscope.
    - Removal of parasites.
8. *Identification of the cause of intestinal obstruction*
    - After decompression with a long decompression tube, an overtube is inserted using a long decompression tube as a guide. After the overtube is fixed with the balloon at the tip, a long decompression tube is removed and an enteroscope is inserted. This procedure allows advancement of the enteroscope to the stenotic site within a few minutes.
    - The procedure described above allows endoscopic observation and tissue sampling through the mouth if a long decompression tube is advanced close to the lesion in patients with intestinal obstruction in whom the diagnosis is difficult to make with a colonoscope.
9. *Intussusception*
    - The anal approach allows endoscopic and histological diagnosis of the lesion inducing the intussusception. The intussuscepted intestine may be reduced or corrected by a combination of the following procedures: anchoring the intestine in place with a balloon, exerting manual pressure, and injecting contrast medium. The possibility of intestinal ischemia should be excluded before attempting the correction.
10. *Difficult colonoscopy*
    - Double-balloon endoscopy is applicable in patients who have undergone a difficult colonoscopy especially due to adhesions that precluded straightening the sigmoid or transverse colon. Dolichocolon without adhesions or other conditions for which total colonoscopy is technically difficult is also a good indication. Supporting the sagged intestinal tract with the balloon-attached overtube allows deep insertion of the endoscope while preventing it from further stretching the intestine.

3.1.2 *Contraindications*

Contraindications to the use of the double-balloon endoscope are essentially similar to those for the use of conventional upper gastrointestinal endoscopes and colonoscopes. Endoscopy is indicated only if the potential benefit outweighs the potential risk in patients in poor general condition, those with a risk of gastrointestinal perforation, or patients with significant respiratory or cardiovascular disease. Endoscopy should not be performed in individuals who refuse to undergo the procedure after giving fully informed consent. Meticulous care should be exercised when the endoscope is advanced beyond lesions such as strictures, deep ulcers, or large tumors, although these conditions are not absolute contraindications. It should be noted that there is still a possibility that balloon inflation as well as stretching and shortening operations during endoscopy might result in perforation of fragile, affected regions of the intestine, although the pressure of the balloon is controlled at less than 45 mm Hg during the whole procedure. Deeper insertion of the endoscope should not be forced, especially in these cases.

3.2 Preoperative Examination

Preoperative interviews and examinations should include the following: a review of stool color (by interview or rectal examination); body weight (to determine the sedatives' doses);

medical history, such as past history (previous abdominal surgery, trauma, accident); the presence or absence of previous anesthesia and its related complications; previous drug allergies; the presence or absence of contraindications to anticholinergic agents, such as ischemic heart disease, glaucoma, prostatic hypertrophy; review of oral medications [use of anticoagulants or nonsteroidal antiinflammatory drugs (NSAIDs)]; blood coagulation tests; thoracic and abdominal radiography; and electrocardiography.

It is particularly important to interview patients regarding their use of NSAIDs. Many of the patients taking NSAIDs are older individuals who are unaware of the name and action of medications. These drugs have often been prescribed at multiple medical institutions, and some patients take their medications without knowing that they are "painkillers." Their medications should therefore be reviewed by contacting the medical institutions at which the patients have undergone outpatient treatment. In patients with current or previous use of NSAIDs, NSAID-induced enterocolitis should be taken into consideration at the examination. Etodolac, meloxicam, and other agents with high selectivity for cyclooxygenase-2 are preferentially prescribed for orthopedic disorders, and their unlimited use may lead to iron deficiency anemia or hypoproteinemia "unknown cause". Recently developed capsule endoscopy has shown that patients taking NSAIDs are more likely to have lesions in the small intestine compared with a control group; and it is preferable that endoscopists and gastroenterologists enlighten other physicians on possible NSAID-induced small-intestinal disorders. Patients with intestinal stenosis should be interviewed about previous abdominal contusions associated with traffic accidents or falls, which may have caused mesenteric injury and subsequent ischemic stenosis. The type of abdominal surgery and the procedure should be reviewed, particularly when the surgery involves the intestine. Blind loop syndrome should be taken into consideration in patients with previous intestinal surgery. Thus, the medical interview often helps identify lesions in the small intestine.

Conventional modalities that are potentially useful for diagnosis should also be considered, depending on the case. Such modalities include upper gastrointestinal endoscopy, colonoscopy, contrast-enhanced studies of the gastrointestinal tract (double-contrast examination of the small intestine), abdominal computed tomography (plain and contrast-enhanced), abdominal magnetic resonance imaging (MRI), α_1-antitrypsin test of feces, nuclear medicine examinations (including gastrointestinal bleeding scintigraphy, albumin scintigraphy, Meckel's scintigraphy, gallium scintigraphy, positron emission tomography), and abdominal angiography.

Review of previous films is also important. Particularly, a diagnosis using double-contrast examination of the small intestine is difficult, and abnormalities may be overlooked. To prevent an oversight, the diagnosis is preferably made by multiple physicians.

To identify a source of bleeding, ^{99m}Tc-labeled red blood cell scintigraphy can reveal persistent bleeding of as little as 0.1 ml/min, and abdominal angiography can detect as little as 0.5 ml/min. Although double-balloon endoscopy is relatively minimally invasive, a thorough examination of the entire small intestine requires considerable effort, and thus information on a rough estimation about the location of the abnormality helps improve the accuracy of the examination. Therefore, in a patient with gastrointestinal bleeding, scintigraphy, capsule endoscopy, or other procedures should be considered before double-balloon endoscopy is undertaken.

Effective examinations can be performed by narrowing the choice of possible locations of lesions and by determining the approach route based on the results of these examinations. When no factors are available to determine whether the oral or anal approach is better, the anal approach should be selected because the patient is less likely to experience discomfort. An enteroscope is inserted through the anus, and tattooing is performed at the deepest site reached; the subsequent examination may be done through the mouth.

Reference

1. The Japan Gastroenterological Endoscopy Society (2002) Guidelines for gastroenterological endoscopy, 2nd edn. Igaku-Shoin, Tokyo

4 Informed Consent

Informed consent means understanding and consenting to a procedure on the basis of an adequate explanation. It is a process by which health care providers give the patient easy-to-understand information about the nature and necessity of the examination and treatment, allow the patient to choose among alternatives, and obtain consent from the patient to perform the procedure. In the field of gastrointestinal endoscopy, it is now common practice to obtain informed consent and maintain written consent for relatively invasive operations, including endoscopic retrograde cholangiopancreatography, polypectomy, and endoscopic mucosal resection. Moreover, an increasing number of institutions also obtain written consent for routine upper or lower endoscopy. An increase in the number of endoscopic examinations is associated with more complications during the examination and treatment, greater public interest, and an increase in medical lawsuits. The role of informed consent should be well understood in the context of these circumstances.

4.1 Informed Consent Procedures

Informed consent procedures may include an oral explanation and documentation on the patient's chart. It is advisable to prepare written information about the examination in advance to provide patients with easy-to-understand information in busy clinical settings. Information may be provided with the use of illustrated written information, videotapes of the examination, or presentation software and a computer monitor. Our institution uses written information that simply illustrates the principle of endoscope insertion into the distal small intestine (Fig. 4.1).

4.2 Details of Informed Consent

The primary information provided during informed consent procedures should include the objectives, procedures, complications, and the patient's human rights.

4.2.1 *Objective*

The reason the examination is to be performed should be clearly presented. It is necessary to describe the advantages of double-balloon endoscopy over other modalities. Double-balloon endoscopy allows relatively easy access to lesions located deep in the small intestine, which is not accessible with the conventional push method. It also allows treatment of emergencies, such as small-intestinal bleeding, in a timely manner. It enables not only observation but also biopsy and treatment of lesions. These potential advantages should be explained in association with patients' current conditions.

• Information on insertion of an enteroscope with two balloons (double-balloon enteroscopy)

1. ***Objective.***
Double-balloon enteroscopy is an examination in which an endoscope is inserted through the mouth or the anus into the small intestine for the diagnosis of diseases in the small intestine. The examination is performed to diagnose bleeding, inflammation (enterocolitis), tumors, and narrowing of the small intestine. The examination may be accompanied by treatment to stop bleeding or to dilate a narrowing. This procedure may be performed as colonoscopy in patients in whom a conventional colonoscope failed to advance far enough.

2. ***Procedures.***
The endoscope (at right) used has a structure similar to that of conventional gastroscopes and colonoscopes, but it is longer than gastroscopes and colonoscopes because of the distance of the small intestine from the mouth and the anus. We have developed a method for inserting an endoscope with two balloons, a type of "measuring worm," to insert the endoscope more safely and reliably into the entire small intestine. We have performed the procedure in many patients. This endoscopic system consists of an endoscope with a balloon at its tip and a balloon-attached overtube. The endoscope advances into the small intestine like a "measuring worm" while the distance between the balloon of the endoscope and that of the covering overtube is increased and decreased (see an attached information sheet for specific insertion procedures). Sedative and pain-killing medications are used to reduce pain during the examination, which takes about 1–2 h.

Double-balloon endoscope is on the *right*

a

3. ***Complications.***
Complications of conventional endoscopy may occur, such as pain, nausea, vomiting, and bleeding. In particular, patients with prior abdominal surgery, including gynecologic surgery, may experience pain during endoscopy. Rarely, gastrointestinal perforation (a hole in the gastrointestinal tract) may require emergency surgery. Extremely rarely, the use of sedatives may be associated with complications of aspiration (inhalation of saliva or vomit into the lungs) and resultant aspiration pneumonia, respiratory arrest, and cardiac arrest (in the event of these complications, emergency measures are available).
Between September 25, 2000 and January 31, 2004 we performed 178 double-balloon endoscopic examinations on 123 patients, none of whom experienced respiratory or cardiac arrest during the examination.

4. ***Patients may refuse to undergo the examination or treatment without penalty.***
Patients have the choice of whether to undergo this examination. Patients refusing the examination are allowed to receive other treatments without penalty at our hospital.

5. ***Patients consenting to the examination or treatment are free to withdraw their consent at any time.***

6. ***Other considerations required to protect patients' rights.***
This treatment must be voluntary, and patients' willingness is the first priority in regard to performing the treatment. Please feel free to ask any questions about the procedures.

Left Radiograph showing an enteroscope inserted through the mouth
Right Radiograph showing an enteroscope inserted through the anus

b

• Informed consent form for double-balloon endoscopy

☐Enteroscopy ☐Colonoscopy

I have been fully informed by Dr. ______ and understand the objective, procedures, expected benefits, and complications of double-balloon endoscopy as well as the availability, benefits, and complications of other procedures. I voluntarily consent to undergo this examination. I also understand that I may withdraw my consent at any time without penalty.

Date: ______________

Patient: ____________________ (seal)

Address: ________________________

____

Relative (relationship): _________ (seal)

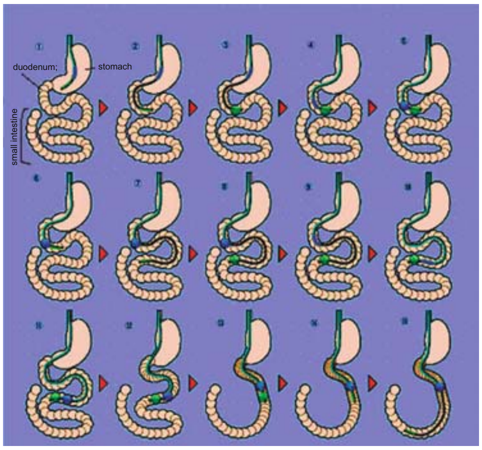
Address: ________________________

____

Jichi Medical University, Department of Gastroenterology

c

• Insertion of the double-balloon enteroscope through the mouth



1. The endoscope is inserted into the stomach.
2. The endoscope tip is inserted into the duodenum. These procedures are similar to those for the gastroscope.
3. The balloon (*green*) at the endoscope tip inserted into the duodenum is inflated to anchor the intestine from the inside.
4. Along the endoscope, the overtube tip is advanced close to the endoscope tip.
5. The overtube balloon (*blue*) is inflated.
6. The balloon (*green*) at the endoscope tip is deflated.
7. The endoscope is moved more deeply. The overtube balloon anchoring the intestinal tract from inside allows smooth insertion of the endoscope to a deeper point.

d

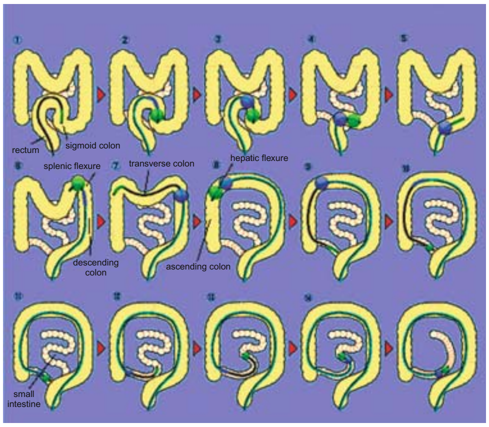
Fig. 4.1a–g. Information to be given to patients to obtain informed consent for double-balloon endoscopy (Jichi Medical University)

8. After the endoscope is advanced more deeply, the endoscope balloon (*green*) is inflated again to anchor the intestinal tract from the inside.
9. The overtube balloon (*blue*) is deflated.
10. Along the endoscope, the overtube tip is again advanced close to the endoscope tip.
11. The overtube balloon (*blue*) is inflated.
12, 13. Both balloons are inflated to anchor the intestinal tract from the inside, and the entire endoscope is pulled back to shorten the small intestine.
14, 15. The balloon (*green*) at the endoscope tip is again deflated, and the endoscope is inserted more deeply.
16. Steps 8–15 are then repeated to insert the endoscope farther into the small intestine.

Radiograph showing an endoscope inserted through the mouth into the middle of the small intestine for a total distance of 7–8 m

e

• Insertion of the double-balloon enteroscope or colonoscope through the anus



1. The endoscope is inserted into the rectum or the sigmoid colon. This procedure is similar to that for conventional colonoscopy.
2. The balloon (*green*) at the endoscope tip is inflated to anchor the intestine from the inside.
3. With the endoscope as a guide, the overtube tip is advanced close to the endoscope tip, and the overtube balloon (*blue*) is also inflated.
4. Both the endoscope and the overtube are pulled back to reduce bends and straighten the rectum and sigmoid colon.
5. The balloon (*green*) at the endoscope tip is deflated, and the endoscope tip is moved more deeply.
6. The balloon (*green*) at the endoscope tip is inflated to secure the endoscope tip in the splenic flexure. The overtube balloon is deflated, and the overtube alone is advanced along the endoscope until it reaches the endoscope tip.

f

7. The overtube balloon (*blue*) is inflated, the balloon (*green*) at the endoscope tip is deflated, and the endoscope tip is moved more deeply. The overtube balloon (*blue*) anchoring the intestinal tract from the inside allows smooth insertion of the endoscope farther into the small intestine.
8. When the endoscope tip reaches the hepatic flexure, the balloon (*green*) at the endoscope tip is inflated. The overtube balloon (*blue*) is deflated, the overtube is again advanced to the endoscope tip, and the balloon (*blue*) is reinflated. With both balloons inflated, the endoscope and the overtube are pulled back simultaneously to reduce the bends and loops of the transverse colon and to straighten it.
9. The balloon (*green*) at the endoscope tip is deflated, and the endoscope tip is advanced farther into the small intestine.
10. The balloon (*green*) at the endoscope tip is inflated to secure the endoscope tip.
11. After the balloon (*blue*) at the overtube tip is deflated, the overtube tip is again advanced close to the endoscope tip with the endoscope as a guide, and the balloon (*blue*) at the overtube tip is reinflated.
12. The balloon (*green*) at the endoscope tip is deflated, and the endoscope tip is inserted more deeply into the small intestine.
13. The balloon (*green*) at the endoscope tip is inflated to anchor the intestinal tract.
14. After the balloon (*blue*) at the overtube tip is deflated, the overtube tip is again advanced close to the endoscope tip with the endoscope as a guide, and the balloon at the overtube tip is reinflated.
15. Both balloons are inflated to anchor the intestinal tract from the inside, and the entire endoscope is pulled back to shorten the small intestine.
16. Steps 12–15 are repeated to insert the endoscope more deeply.

Radiograph showing an endoscope inserted through the anus into the middle of the small intestine for a total distance of 7–8 m

g

4.2.2 *Procedures*

First, the principle of insertion should be described in plain language. Illustrations are preferable for showing the structure of the endoscope and the anatomy. It is desirable that patients understand how the double-balloon endoscope is inserted into the deep small intestine. Next, actual examination procedures are described step by step. Technical terms are avoided to ensure that patients get the whole picture of the examination procedure, including the use of sedatives, positioning for the examination, use of fluoroscopy, the time required for the examination, and safety monitoring procedures.

4.2.3 *Complications*

There is an increasing demand for disclosure of specific information about complications. *Guidelines for Gastroenterological Endoscopy*, developed by the Japanese Society of Gastroenterology [1], indicate that physicians should consider it essential to provide information about complications, including their nature and frequency, the possible need for surgery, and the associated mortality. Double-balloon endoscopy is a newly developed procedure, and evaluation of its safety must await the accrual of patients undergoing the procedure. The lack of nationwide statistics on complications makes it difficult to describe complications on the basis of specific figures. Patients should be well informed of foreseeable complications, including bleeding, gastrointestinal perforation, and those related to such medications as anesthetics for the throat and sedatives, as well as specific emergency treatments.

4.2.4 *Patients' Human Rights*

It should be stipulated that patients who do not consent to undergo the examination still have a right to alternative examinations or treatments without penalty, and due consideration must be given to the patients' human rights. Patients must be allowed to have the choice, and the examination must be voluntary.

4.3 Details of Written Consent

Written consent is required that demonstrates the patient's full understanding of the nature of the examination and his or her consent. Written consent forms typically come with written information that describes the objectives, procedures, and complications. Entries on the form should include the date and time that information is provided and the names of the physicians and others present, the patient giving consent, and a member of his or her family. The written consent consists of two sheets of paper; one is filed in the patient's chart and the other is for the patient.

Adequate information provides patients with a sense of security, resulting in a safe examination. Informed consent represents not only the physician's accountability but also an important process by which a trustful relationship develops between the physician and the patient.

Reference

1. The Japan Gastroenterological Endoscopy Society (2002) Guidelines for gastroenterological endoscopy, 2nd edn. Igaku-Shoin, Tokyo

5 Principle of Insertion and Characteristics

5.1 Principle of Insertion of the Double-Balloon Endoscope

In general, the most important factor when inserting an endoscope is to transmit the force applied to the endoscope shaft effectively to the endoscope tip. When the endoscope bends intricately or forms a loop, the force applied to the endoscope shaft is not transmitted to the endoscope tip, and thus the endoscope tip does not advance. When an enteroscope is inserted by the push method (the most commonly used technique for enteroscope insertion), the enteroscope may bend intricately or form a loop. Attempts were made to straighten the intestine with an inflexible overtube to prevent bend and loop formation and to insert an endoscope into the distal small intestine. However, it is impossible to straighten the entire small intestine, and it is harmful to straighten the intestine forcibly.

In fact, insertion is difficult not because of the bends and loops of an endoscope but because of stretching that part of the intestinal tract that forms a bend or a loop. Insertion of the endoscope shaft stretches the intestine, but the force is not effectively transmitted to the endoscope tip, thereby failing to advance the tip (Fig. 5.1). Unless this problem is solved, a simple endoscope with a long working length cannot reach the deep small intestine.

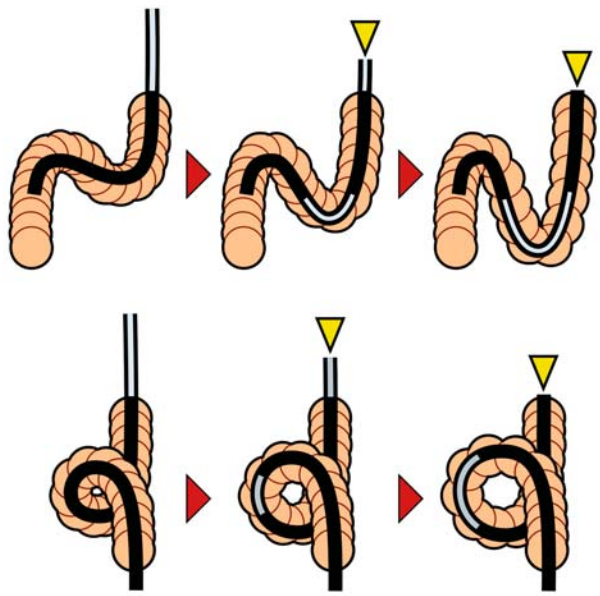


Fig. 5.1. Stretching a curved or looped intestine

This problem can be solved by avoiding stretching of the intestinal tract through which the endoscope tip has passed. Double-balloon endoscopy uses a flexible overtube with a balloon at its tip to prevent the stretching. The inflated balloon at the tip of the overtube anchors the intestine in place from inside and prevents the tip of the overtube from slipping. The overtube can bend flexibly but not stretch. The overtube does not stretch even in the presence of bends or loops, and neither does the intestinal tract that is being anchored by the balloon at the tip of the overtube. Consequently, insertion of the endoscope shaft does not stretch the intestine, and the force is effectively transmitted to the endoscope tip. Thus, the endoscope can be advanced into the deep portion of the small intestine, with the balloon at the tip of the overtube as a fixed support (Fig. 5.2).

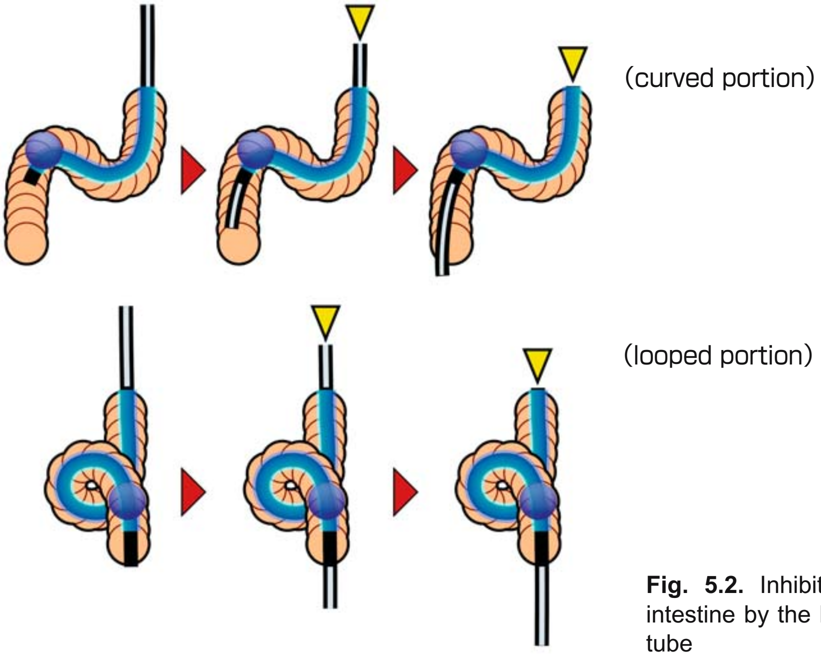


Fig. 5.2. Inhibition of stretching the intestine by the balloon-attached overtube

During double-balloon endoscopy the endoscope is advanced as deeply as possible; the balloon at the tip of the overtube is then deflated, and the overtube is slid distally onto the endoscope. During the procedure, the balloon at the endoscope tip is inflated to grip the intestine from inside, preventing the endoscope tip from slipping. After deflating the balloon at the tip of the overtube and sliding the overtube to the deep position, the balloon at the tip of the overtube is inflated, and the endoscope and the overtube are withdrawn with the two balloons inflated. Through this procedure the inserted intestinal tract is pleated over the overtube and thus shortened (Fig. 5.3). The procedures are repeated to make the best use of the endoscope's working length and shorten the intestine of a total length of 6–7 m, enabling observation of the intestine with the endoscope with a working length of 200 cm. Moreover, the shortening procedure simplifies the curved intestine ahead as well as the subsequent insertion procedure (Fig. 5.4).

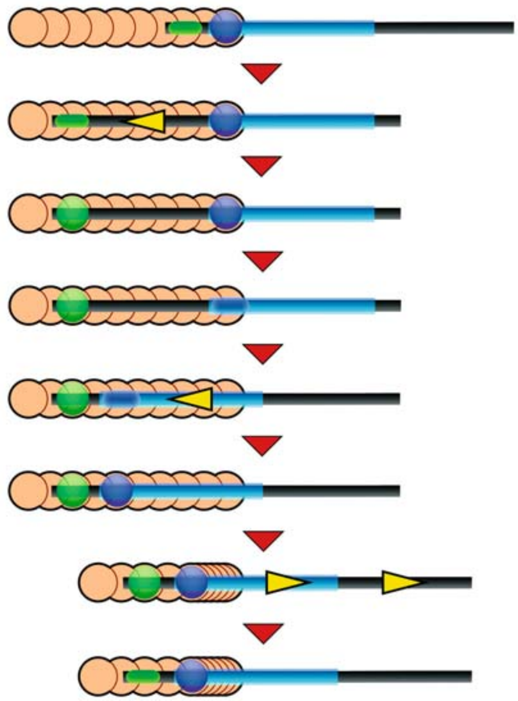


Fig. 5.3. Shortening the intestine with two balloons

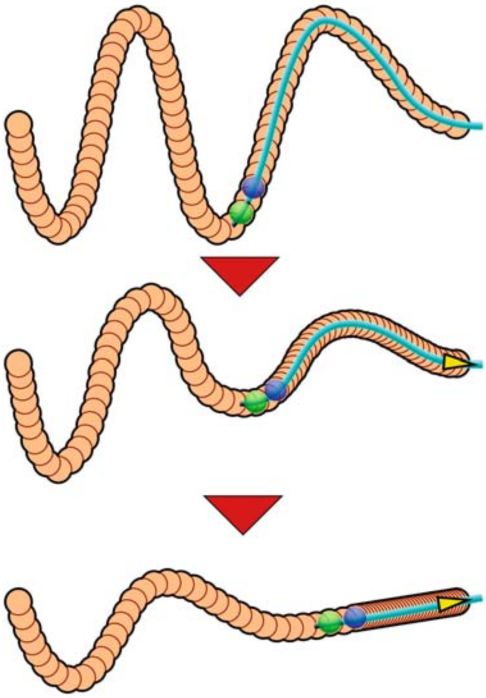


Fig. 5.4. Simplifying the shape of the intestine ahead

In short, double-balloon endoscopy takes advantage of the free mobility of the small intestine (which is not fixed in the abdominal cavity), shortens the small intestine, and simplifies the shape of the small intestine ahead. The endoscope is inserted deeper into the small intestine while the fixed support established by the balloon at the tip of the overtube is moved step by step.

5.2 Characteristics of the Double-Balloon Endoscope

Although a conventional endoscope with a long working length generates concern about maneuverability, the tip of the double-balloon endoscope can be manipulated with the help of a fixed point supported by the balloon at the tip of the overtube. This enables free back-and-forth observation without sacrifice of maneuverability no matter how deeply the endoscope is inserted. Moreover, this method allows insertion from both the mouth and the anus because insertion does not depend on peristalsis of the intestine. Observation of a surgically bypassed segment of the intestine is not possible by the ropeway method, sonde method, or even capsule endoscopy; but it is possible with the double-balloon endoscope.

The tip of the double-balloon endoscope has bending capability (up and down, left and right) and a forceps channel; and it allows directed biopsy, which cannot be performed by the ropeway method or the sonde method. Endoscopic treatment can be performed with a therapeutic device. A therapeutic device with a large diameter may be used without being restricted by the forceps channel diameter after removal of the endoscope with the overtube left in place. The use of a double-balloon endoscope allows endoscopic treatment of lesions in any portion of the small intestine.

It should be noted that this procedure dramatically reduces the patient's discomfort related to endoscopy compared with the push method. Most endoscopy-related discomfort is due to stretching the curved or looped portion of the intestine. Double-balloon endoscopy causes less discomfort due to stretching of the intestine because the method, in principle, allows insertion while inhibiting stretching of the intestine.