Advances in balloon endoscopes

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Received: 19 March 2014 / Accepted: 25 March 2014 / Published online: 23 April 2014
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Abstract In September 2003, a double-balloon endoscope (DBE) composed of balloons attached to a scope and an overtube was released in Japan prior to becoming available in other parts of the world. The DBE was developed by Dr. Yamamoto (1), and 5 different types of scopes with different uses have already been marketed. In April 2007, a single-balloon small intestinal endoscope was released with a balloon attached only to the overtube as a subsequent model. This article presents a detailed account of the development of these scopes up to the present time.

Keywords Double-balloon endoscopy · Single-operator method · Treatment · Double overtube · Continuous infusion · Single-balloon endoscopy · DBERCP · DBECS · Dilatation

Introduction

In September 2003, a double-balloon endoscope (DBE) composed of balloons attached to a scope and an overtube was released in Japan prior to becoming available in other parts of the world. The DBE was developed by Dr. Yamamoto [1], and 5 different types of scopes with different uses have already been marketed. We present a detailed account of the development of these scopes up to the present time.

Types of DBE and changes

There are 2 DBE models—one with a working length of 2 m that is designed to reach deep into the small intestine and the other with a working length of 1.5 m that is designed in consideration of operability in the bile duct/large intestine or for reaching treatment tools.

Endoscopes with a small forceps channel diameter of 2.2 mm and with a large forceps channel diameter of 2.8 have also been released, and an endoscope with a larger diameter of 3.2 mm has recently been released. The difference in the forceps channel diameter also reflects the difference in the outside diameter. Large endoscopes are used when treatment is performed or when image quality is given priority. Small endoscopes are used when deep insertion is attempted or when it is necessary to reduce the examination burden on a patient (Table 1; Fig. 1).

First DBE P5 for observation of the small intestine. This is a small long-type endoscope used for the small intestine, large intestine, stomach, and duodenum.

Second DBE T5 for treatment of the small intestine. This is a large long-type endoscope with good image quality used for the small intestine, large intestine, stomach, and duodenum.

Third DBE BI5 for the large intestine (bile duct). This is a large short-type endoscope with good image quality used for the large intestine as stipulated by the Japanese National Health Insurance program.

Fourth DBE EI530B for the bile duct. This is a large short-type endoscope with especially good image quality used for the esophagus, stomach, duodenum, small intestine, and large intestine as stipulated by the Japanese National Health Insurance program.

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Table 1 DBE specification

Body	Model	EN-450P5	EN-450T5	EC-450BI5	EI-530B	EN-580T
	Release date	2003.11	2004.7	2005.11	2011.6	2013.12
	Field of view	1,201	1,401	1,401	1,401	1,401
	Observation range (mm)	5–100	5–100	3–100	3–100	2–100
	Forceps channel diameter (mm)	2.2	2.8	2.8	2.8	3.2
	Working length (mm)	2,000	2,000	1,520	1,520	2,000
	Total length (mm)	2,300	2,300	1,820	1,820	2,300
	Distal end diameter (mm)	8.5	9.4	9.4	9.4	9.4
	Flexible portion diameter (mm)	8.5	9.4	9.3	9.3	9.3
Overtube	Compatible model	TS-12140	TS-13140	TS-13101	TS-13101	TS-13102
	Outside diameter (mm)	12.2	13.2	13.2	13.2	13.2
	Inside diameter (mm)	10	10.8	10.8	10.8	10.8
	Total length (mm)	1,450	1,450	1,050	1,050	1,450

Fig. 1 P5 and T5

Fifth DBE EN580T for the small intestine, large intestine, stomach, and duodenum (successor model to T5). This is a large long-type endoscope with especially good image quality used for the esophagus, stomach, duodenum, small intestine, and large intestine as stipulated by the Japanese National Health Insurance program. A large forceps channel diameter (3.2 mm).

Changes in overtubes

Early first-generation overtube—the surface around the insertion port was clearly uneven, which facilitated hooking fingers on the overtube in the dual-operator method.

The second-generation overtube with a modified insertion port—because the uneven surface around the insertion

Fig. 2 Appearance of overtube

port was smoothed, insertion by the single-operator method became slightly more difficult.

The third-generation overtube with a modified insertion port—the form of the insertion port was modified to allow fingers to be hooked on the overtube even in the single-operator method. This modification allowed an assistant to easily hook the fingers even in the dual-operator method, and either method became relatively easy to perform. Simultaneously, the form of the anti-leakage film was also changed from extended to plate-like (Fig. 2).

At present, 3 types of overtubes are available, and all 3 are compatible with the 5 types of DBE according to outside diameter and length.

Changes in the balloon at the tip

The balloon at the tip of the endoscope is called the ‘tip balloon’.

Because the inflated diameter of the tip balloon SB-1 was rather small at first, it was difficult to fix the balloon in the large intestine in some cases. This prompted the development of SB-2, a slightly larger balloon for the lower gastrointestinal tract. Subsequently, the use of this balloon became standard and production of the earlier balloon with the small diameter (SB-1) was stopped.

Changes in the hood

Although only black hoods used for observation were available at first, transparent hoods for treatment have also been released.

Hoods manufactured by other companies may also be usable. At our hospital, the adhesive part of band-aids is sometimes used for attaching the hood. In terms of water-resistant properties and adhesiveness, band-aids are often found to be more durable than other methods.

Changes in balloon controllers

In the early PB-10 model, the end of the tube was exposed to the full-size panel. With the successor model designated PB-20, handling of the tube became simpler, and the controller was equipped with an indicator showing balloon status. Furthermore, balloons could be displayed on an observation monitor.

Changes in light sources

When DBEs became commercially available, the light source system was the 4400 Sapientia Series.

Later, light sources improved and the 4450 Advancia HD Series was used. DBE becoming compatible with the LASEREO Series, which uses a laser light source, is eagerly anticipated. Ten patterns from the Fujinon intelligent chromoendoscopy (FICE) system are available for installation and can be used with any of the current types of endoscopes.

Insertion methods

Dual-operator method

The standard method is the dual-operator method. The operator controls the endoscope, while the assistant operates an overtube and a balloon controller.

Single-operator method (with tools)

A method of double-balloon endoscopy to be performed by a single operator was investigated, and methods using

Fig. 3 Layout of equipment

specifically designed tools were developed at 3 institutions. These methods were reported at symposia of the 71st and 72nd Congresses of the Japan Gastroenterological Endoscopy Society [2] —(1) Yamamoto et al., Jichi Medical University: drip-stand type; (2) Abe et al., Osaka Police Hospital: Iron-Arm; and (3) Araki et al., Tokyo Medical and Dental University: small grasping device.

Single-operator method (without tool)

We previously reported a single-operator method that does not require the use of any type of tool. It was reported in Japan in 2006 and at Digestive Disease Week (DDW) in the United States in 2007. In *Endoscopy*, the official journal of the European Society of Gastrointestinal Endoscopy, this method was introduced as a key reference. It was suggested in the journal that only personnel who monitor the condition of a patient are needed because no assistant is required [3].

DBE insertion method: details for the single-operator method

We originally introduced double-balloon endoscopy in September 2004. Although 2 operators are generally required for this test, we developed a single-operator method which allows one operator to perform the test; we reported this method in Japan before it was known throughout the rest of the world [4–6]. Based on our studies, there is no difference in the completion rate of total small intestinal observation or in total observation time between the single- and dual-operator methods. In the dual-operator method, the operator who controls the endoscope cannot obtain delicate sensation at the tip of the endoscope. However, we consider the single-operator method to be better in terms of operability because the sole operator obtains all the information. We recommend

Fig. 4 Keep and slide technique

implementation of the single-operator method from the time of DBE introduction. Even if the dual-operator method has already been introduced, the transition to the single-operator method can be carried out by training whereby the single-operator method is first performed and then converted to the dual-operator method when the endoscopic procedure cannot be continued using the single-operator method.

Because we have also carried out conversion of colonoscopy from the dual-operator method to the single-operator method, we recommend introducing double-balloon endoscopy by the single-operator method from the beginning.

For preparation, the layout of an endoscopy room should be changed to facilitate performance of the procedure. For example, placement of a stand for an endoscope is necessary (Fig. 3).

Actual insertion method

We were able to successfully carry out a solo performance of double-balloon endoscopy by using the following techniques. The single-operator method is composed of the following 5 techniques (2 main techniques and 3 sub-techniques).

The main techniques are (1) grip and pinch technique; and (2) keep and slide technique.

The sub-techniques are (3) abdominal support technique, (4) hooking technique; and (5) pull back and advance technique.

The single-operator method that we invented is performed according to the following procedure:

(1) The operator inserts an endoscope. (2) The operator inflates and fixes the tip balloon. (3) The operator slides an overtube to the tip of the endoscope. The operator holds the

Fig. 5 Grip and pinch technique

endoscope control unit with the left hand in the same manner as in the ordinary endoscopic operation. Simultaneously, the overtube is held and inserted by the right hand (keep and slide technique) (Fig. 4). (4) The operator inflates and fixes the balloon at the tip of the overtube (the ‘overtube balloon’). (5) The operator holds and pulls back the overtube and the endoscope with the right hand. (6) The operator deflates the tip balloon and inserts the endoscope into the overtube held by the operator. While holding the endoscope control unit with the left hand in the same manner as in the ordinary endoscopic operation, the operator manipulates the dial. Simultaneously, the endoscope is gripped by the fourth finger, fifth finger, and palm of the right hand and the overtube is then pinched with the first and second fingers of the right hand. While the overtube is held, the operator inserts and pulls back the endoscope by flexing and extending the first finger, second finger, and palm (grip and pinch technique) (Fig. 5).

In the event of no or inadequate force being transmitted or of strong resistance from the overtube, the operator should slightly bend the endoscope shaft with the right hand at the outside of the overtube while performing the grip and pinch technique. Then, the operator should push the curved section with his/her abdomen to prevent the endoscope from sliding backwards through the overtube (abdominal support technique).

Alternatively, the operator should hold the overtube with the fourth and fifth fingers of the left hand and insert the endoscope with the right hand toward the overtube (hooking technique).

When the tip of the endoscope is not adequately advanced, it may also be effective to advance the endoscope with tension applied to the intestine by inflating the overtube balloon and pulling it back slightly. The operator should perform the grip and pinch technique while slightly pulling back the overtube fixed to the intestine (pull back and advance technique).

Fig. 6 Double overtube technique

Innovation for smoother performance of double-balloon endoscopy

Double overtube method

When an endoscope is inserted from the mouth (insertion via the upper gastrointestinal tract), we perform the double overtube method (second overtube method), our own innovation. In this method, an overtube is covered with a second overtube (flexible overtube; Sumitomo Bakelite Co., Ltd), in order to prevent aspiration and to reduce discomfort due to the back-and-forth passage of an endoscope through the subject's throat (Fig. 6). Insertion of the first flexible overtube requires meticulous technique and high skill. The esophageal mucosa is drawn between the flexible overtube and a double-balloon overtube employing a rather cumbersome operation, which is associated with a risk of perforation. In an interview survey conducted on 10 subjects, all 10 reported that discomfort was lower during use of the double overtube method.

Continuous drip infusion method

The overtube used for DBE is lined with a hydrophilic coating. If the lumen of the overtube is wet, the endoscope can be inserted very smoothly. Thus, it is necessary to frequently inject water from the water injection port of the overtube with a syringe. Because this process is time-consuming and also cumbersome, the lumen is kept irrigated by continuous infusion of physiological saline from the water injection port of the overtube. This is called the continuous overtube injection technique. It reduced the mean duration from insertion to observation from 100 min in the single-operator method without injection to 83.8 min in the method with injection. Although tap water can be injected into the overtube instead of physiological saline,

we prefer physiological saline for risk management in the event of incorrect connection to the drip infusion line.

Treatment

Endoscopic ultrasound (EUS)

With models with a forceps channel diameter of 2.8 mm, such as therapeutic DBE, an EUS miniature probe can be used. The previous model of the EUS system manufactured by Fujifilm can also be used if the protective cover at the base of the probe is removed (the operator is held personally responsible for making sure this is performed). Meanwhile, the probe of the new model SP702, which is designed in consideration of possible use with the DBE, can be used without any particular modifications. The tip balloon is inflated at the area proximal to a lesion, and water is delivered from the forceps channel port or by pressing the water-delivery button to immerse the lesion. A miniature probe is then inserted from the forceps channel port to perform a test.

Argon plasma coagulation (APC)

APC can be performed with a reusable probe for the large intestine (reusable flexible APC probe 3000 A, direct irradiation, with a diameter of 2.3 mm and length of 3 m) if the therapeutic DBE is equipped with a forceps channel port with a diameter of 2.8 mm. With the observation DBE model with a forceps channel diameter of 2.2 mm, a small, long-type disposable probe that is available on the market can be used (disposable flexible APC probe 3000 A, direct irradiation, with a diameter of 1.5 mm and length of 3 m). At institutions where observation DBE model P-5 is used, this APC probe should always be kept prepared for prompt use because treatment can become difficult in the event of bleeding, for example, at the time of biopsy or local injection. Recently, manufacturers have stopped selling reusable probes, and all currently available probes are disposable.

Clip

Olympus: Rotating Clip Device HX-110UR. Sheath length: 2,300 mm; applicable channel diameter: 2.8 mm or more.

Boston Scientific: ResolutionTM Clip Device. Sheath length: 2350 mm; applicable channel diameter: 2.8 mm.

Both devices described above can be used with models with a forceps channel diameter of 2.8 mm. When the devices are inserted deep into the gastrointestinal tract through a 2-m endoscope, they can be manipulated more

easily using an endoscope with a forceps channel diameter of 3.2 mm.

Retrieval

A retained capsule endoscope must be surgically retrieved if no DBE is available. Tanaka et al. [7] reported on retrieval of a capsule endoscope by DBE. For retrieval of endoscopically resected polyps and foreign bodies, retrieval baskets manufactured by US Endoscopy are commercially available. They can be used with a DBE with a forceps channel diameter of 2.8 mm. The total length of the control unit is 230 mm, and the maximum width of the basket is 30 mm.

Super-selective double-contrast small bowel series with a tip balloon

In order to confirm a lesion, a small bowel series using contrast medium may need to be performed after insertion deep into a portion of the gastrointestinal tract. In such an event, DBE allows super-selective contrast series to be performed by occluding the intestine with the tip balloon. If the target site fails to be reached, the lesion can still be confirmed by this contrast series.

Dilatation of intestinal strictures

Due to the advent of DBE, it has become possible to dilate strictures caused by nonsteroidal anti-inflammatory drugs (NSAIDs)-induced ulcers or Crohn's disease with a balloon, even when deep in the small intestine. Membrane-like strictures caused by NSAIDs are a good indication for balloon dilatation. In the case of Crohn's disease, balloon dilatation is well indicated for a stricture with a major axis of ≤ 2 cm that is not accompanied by ulceration.

A literature search using 'DBE' and 'dilatation' as key words yielded 10 articles [8–17].

With a DBE, stenotic lesions can be dilated in both the large and small intestines. Fukumoto et al. detected a stricture in 179 of 1,035 patients undergoing double-balloon endoscopy at 7 Japanese institutions and attempted dilatation of these lesions. The long-term patency success rates were 73.9 % in patients with Crohn's disease and 75 % in those with NSAIDs-induced ulcers [8].

Ohmiya et al. performed dilatation of 47 lesions in 22 patients using a DBE. They used 8- and 20-mm balloons manufactured by Boston Scientific (CRE Wireguided Balloon Dilators, for the upper and the lower gastrointestinal tract). After the lesions had been dilated with the smaller balloon, they were dilated again with the larger balloon. The success rate was reported to be 96 % [9].

A literature search using 'single-balloon endoscope (SBE) dilatation' as the key word yielded 4 articles [18–20]. None reported any data on dilatation of the gastrointestinal tract using SBE.

Double-balloon endoscopic retrograde cholangiopancreatography (DBERCP), double-balloon endoscopic sphincterotomy (DBEST), double-balloon endoscopic papillary balloon dilatation (DPEPBD)

T-5 was used for approaching the bile duct before specialized devices for the bile duct became commercially available. In the early days, because no device with a working length of > 2 m was available, the approach using T-5 was performed in the following manner—the orifice of the bile duct was approached with the T-5, and an overtube was placed. The proximal section of the overtube outside of the body was then cut by approximately 50 cm without cutting the tube for balloons. The subsequent procedures were performed under fluoroscopic guidance or by replacing the T-5 with a smaller endoscope or a conventional upper gastrointestinal endoscope. Later, the short BI-5 was released, and all conventional devices have been usable since then. At institutions not equipped with a BI-5, a combination of T-5 and the overtube for BI-5 followed by replacement of T-5 with a conventional endoscope allows the procedure to be performed without cutting the overtube. Due to restrictions mandated by the National Health Insurance program in Japan, it will be necessary to use the EI530B for approaching the bile duct in the future. Since 2004, there have been reports by Sunada et al., Sugano et al., Endo et al., and Shimatani et al. in Japanese [21–24].

For dilatation of the bile duct, a balloon for the bile duct is used (CRE WG, Boston Scientific). After dilatation, a crusher is used, and the balloon is retrieved by a retriever balloon. A Xemex Crusher Catheter (Zeon Medical) which can be used with an endoscope with a forceps channel diameter of 2.8 mm is used as the crusher. Recently, at our department, we have also been using balloons 12–15 mm in diameter (CRE Biliary Dilation Balloon, 10–20 mm, available in 4 types, Boston Scientific) that are larger than those for the bile duct in some cases. Because lithotripsy is often unnecessary, the use of larger balloons allows endoscopic papillary large balloon dilatation (EPLBD) to be carried out smoothly. Moreover, in some patients with a preserved papilla, insertion is difficult because the papilla is vertically aligned. However, insertion can be achieved by using a sphincterotome, an endoscopic sphincterotomy (EST) knife (Autotome RX; Boston Scientific).

A literature search in PubMed using 'DBE endoscopic retrograde cholangiopancreatography (ERCP)' as the key word yielded 47 articles [25–63]. May et al. [25] published

a report in 2007, and there is also a report on short DBEs published in 2010 [26] by Shimatani et al.

A literature search using ‘SBE ERCP’ as the key word yielded 14 articles [64–78]. Aktas and Mensink [64] published a report in 2008. There are also reports published by Dellon et al. [65], by Neumann et al. [66], and by Itoi et al. [67] in 2009.

Double-balloon endoscopic colonoscope (DBECS)

DBE is not only applied to the small intestinal region but also in cases where it is difficult to insert a colonoscope. A literature search in PubMed using ‘DBE colonoscopy’ as the key word yielded 53 articles [79–131]. Araki et al. [79] retrospectively examined 33 patients undergoing double-balloon endoscopy using the dual-operator method and 151 patients undergoing the procedure using the single-operator method at one institution between 2007 and 2009, reporting the rates of reaching the cecum to be 100 % for both methods. In 2012, Hotta et al. [80] performed DBECS in 110 patients in whom insertion of a colonoscope was difficult, reporting that the rate of insertion to the cecum was 100 % (multicenter/prospective study). Regarding studies on single-balloon endoscopy performed in patients in whom insertion of a colonoscope was difficult, a literature search using ‘SBE colonoscopy’ as the key word yielded 9 articles [132–141]. In 2010, Teshima et al. [132] performed single-balloon endoscopic colonoscope (SBECS) in 22 patients in whom insertion was difficult, reporting that the rate of insertion to the cecum was 96 %.

SBE

In April 2007, Olympus released a single-balloon small intestinal endoscope with a balloon attached only to the overtube as a subsequent model. Its advantage is considered to be the ability to perform narrow-band imaging (NBI). Spraying with 0.3 % crystal violet solution for marking allows preparation in the event of dislocation during insertion. At present, one model is available on the market, and its endoscope specifications are similar to those of the DBE model T5. Because there is no tip balloon, the insertion method for the SBE is different from that for the DBE. The SBE tip is bent and hooked on the intestine to be fixed. Future reports on assessment of NBI of the small intestine are awaited. There are also articles comparing insertability between the SBE and the DBE. May et al. [142] who removed the tip balloon from the DBE to use it as an SBE and compared it with the conventional DBE, reported that the completion rates of total small intestinal observation were 66 % for the DBE and

22 % for the SBE, showing a significant difference. Takano et al. [143], who compared completion rates of total small intestinal observation between commercially available DBEs and commercially available SBEs, reported that the rates were 57 % for the DBE and 0 % for the SBE, showing a significant difference.

Conclusion

We have described the changes in DBEs and SBEs, peripheral devices, and operating methods. Balloon endoscopy as a form of small intestinal endoscopy may contribute to elucidation of small intestinal lesions, as well as their causes and treatments. Moreover, because parts of the gastrointestinal tract that had been inaccessible to previous endoscopes have now become accessible, the DBE as an ultimate endoscope due to its range of applications may especially contribute to treating postoperative intestinal conditions and cases in which insertion of a colonoscope is difficult.

Disclosures

Conflict of Interest: Akihiro Araki and Kiichiro Tsuchiya declare that they have no conflict of interest. Mamoru Watanabe have served as consultants for and received speaker’s fee and research grants from the following. AbbVie GK, Eisai Co., Ltd, Kyorin Pharmaceutical Co., Ltd, Mitsubishi Tanabe Pharma Co., Ltd, DAIICHI SANKYO Co., Ltd, Ono Pharmaceutical Co., Ltd, Gene Care Research Institute Co., Ltd, Astellas Pharma Inc., Asahi Kasei Kuraray Medical Co., Ltd, MSD K.K., Mitsubishi Tanabe Pharma Co., Ltd, Chugai Pharmaceutical Co., Ltd, Takeda Pharmaceutical Co., Ltd, Ajinomoto Pharma Co., Ltd, Otsuka Pharma Co., Ltd, Kyowa Hakko Kirin Co., Ltd, JIMRO Co., Ltd, Zeria Pharmaceutical Co., Ltd, UCB Japan Co., Ltd, Dainippon Sumitomo Pharma Co., Ltd, Toray Industries Inc., Bristol-Myers K.K.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008(5).

Informed Consent: Informed consent was obtained from all patients for being included in the study.

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