STATEMENT

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Use of device-assisted enteroscopy in small bowel disease: an expert consensus statement by the Korean Association for the Study of Intestinal Diseases

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The introduction of device-assisted enteroscopy (DAE) in the beginning of 21st century has revolutionized the diagnosis and treatment of diseases of the small intestine. In contrast to capsule endoscopy, the other main diagnostic modality of the small bowel diseases, DAE has the unique advantages of observing the region of interest in detail and enabling tissue acquisition and therapeutic intervention. As DAE becomes an essential procedure in daily clinical practice, there is an increasing need for correct guidelines on when and how to perform it and what technical factors should be considered. In response to these needs, the Korean Association for the Study of Intestinal Diseases developed an expert consensus statement on the performance of DAE by reviewing the current evidence. This expert consensus statement particularly focuses on the indications, choice of insertion route, therapeutic intervention, complications, and relevant technical points. **(Intest Res 2023;21:3-19)**

Key Words: Device-assisted enteroscopy; Balloon enteroscopy; Intestine, small; Consensus statement

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INTRODUCTION

Evaluation of the small bowel (SB) has long been a challenge for endoscopists because of its location and length. Endoscopic instruments have made remarkable progress in overcoming this challenge, with 2 revolutionary enteroscopic procedures, capsule endoscopy (CE) and device-assisted enteroscopy (DAE), which appeared at the beginning of the 21st century, completely changing the paradigm of managing SB diseases.[1,2]

Unlike CE, DAE has both diagnostic and therapeutic abili-

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ties and has a unique advantage in situations such as small bowel bleeding (SBB). Three types of DAE are currently available: double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), and spiral enteroscopy. The main technical and performance parameters, such as depth of insertion, learning curve, complications, diagnostic yield, and therapeutic yield, are known to be comparable among the 3 methods.[3]

In Korea, DAE has been reimbursed by the National Health Insurance since August 2014. Although DAE has been incorporated into daily practice, there are no proper recommendations providing useful guidance for the DAE procedure. For this reason, the Small Intestine Research Group of the Korean Association for the Study of Intestinal Diseases (KASID) decided to develop a set of consensus statements for DAE to ensure that it is performed properly in clinical practice.

We intended to draw up these statements by placing greater emphasis on the following 3 purposes: First, the statements should provide guidance regarding the indication, timing, and performance of DAE for various clinical situations. Second, it is necessary to suggest what should be considered for a successful procedure. Third, DAE-related complications and how to manage them should be informed. These statements consist of 3 sections: Preprocedure, Intraprocedure, and Postprocedure. These statements do not have precedence over clinical evaluations made by physicians that consider various factors related to the patients and health care environment in actual clinical practice. Therefore, these statements must not be used to restrict the medical practice of clinicians or to make legal judgments regarding DAE procedures or treatments performed on a particular patient. Nevertheless, these statements are expected to serve as a useful and complementary reference in clinical settings.

METHODS

The expert statement committee consisted of the president (Seung-Jae Myung) and committee members of the Small Intestine Research Group of KASID, which comprised 16 expert endoscopists in the field of DAE in July 2020. The committee reviewed published articles and guidelines regarding DAE for SB diseases and developed the initial statements. Sixteen statements were drafted after discussion and revision. The statements were grouped into 3 parts: Preprocedure, Intraprocedure, and Postprocedure.

The modified Delphi method was applied to establish an expert statement.[4,5] A 9-point Likert scale questionnaire (range 1–9; 1 = strongly disagree, 9 = strongly agree) with a literature review of supporting data was provided by e-mail to the panel of 17 endoscopists with expertise in DAE and SB diseases. A statement was accepted if the coefficient of variation was less than 0.5. Initially, all 16 statements met the criteria for the coefficient of variation. However, if a small number of panelists requested correction, the development committee reviewed and revised the statements according to the panelists' comments and then requested a review of the revised statements from the panelists. Two rounds of modified Delphi exercises were conducted, a final draft of 15 statements was made after revision based on this process. Table 1 summarizes the statements with strength of agreement among panelists.

The current statements for use in clinical settings will be subject to revision by systematic review in the future.

RESULTS

1. Preprocedure

1) Preprocedural Indications

(1) Small bowel bleeding

Statement 1
Diagnostic yield can be increased by performing DAE after CE in overt and occult suspected small bowel bleeding (SSBB). DAE can be considered following CE or contrast-enhanced computed tomography (CT) in overt and occult SSBB.

Obscure gastrointestinal bleeding is defined as gastrointestinal bleeding of unknown cause even after upper and lower gastrointestinal endoscopy. Obscure gastrointestinal bleeding accounts for approximately 5% of gastrointestinal bleeding and is usually due to SBB.[6] CE is useful for the detection of a source of SSBB, except for hemodynamically unstable patients with massive bleeding requiring emergency angiography.[7,8] Contrast-enhanced CT can be considered instead of CE in patients with suspected obstruction.[7,8] The most common indication for DAE is diagnostic evaluation of and therapeutic procedures for SSBB. DAE could be indicated as a diagnostic procedure for negative/positive results of CE or contrast-enhanced CT and as the first-line therapeutic procedure for positive results of CE or contrast-enhanced CT.[7,8]

Overt SBB

Overt SBB patients presenting with either melena or hematochezia require definitive diagnosis because of morbidity and mortality with ongoing bleeding.[9] In a meta-analysis, the diag-

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Table 1. Consensus Statements on the Use of Device-Assisted Enteroscopy by KASID

Accepted statements	Strength of agreement (mean)	SD	CV
1. Diagnostic yield can be increased by performing DAE after CE in overt and occult suspected small bowel bleeding (SSBB). DAE can be considered following CE or contrast-enhanced computed tomography (CT) in overt and occult SSBB.	8.3	0.59	0.07
2. In cases of overt SSBB, early DAE can be considered after CE or contrast-enhanced CT to improve diagnostic yield and provide a chance for therapeutic intervention.	7.9	0.75	0.09
3. DAE is not a routine diagnostic test in patients with clinically suspected Crohn's disease (CD). However, if there is no specific finding in the ileo-colonoscopy or other imaging studies, and results of laboratory tests alone are insufficient to diagnose CD in patients with suspected SB CD, SB tissue biopsy through DAE can be considered for enhancing confirmative diagnosis.	7.9	0.86	0.11
4. DAE can be considered for the localization and characterization of SB tumors along with other imaging modalities.	7.6	0.70	0.09
5. DAE may be used in symptomatic patients with intestinal polyposis causing obstruction and bleeding. Also, DAE may be used for the diagnosis and follow-up of some intestinal polyposis syndromes, particularly Peutz-Jeghers syndrome (PJS) rather than familial adenomatous polyposis (FAP).	7.8	0.88	0.11
6. In patients with suspected SB tumors, DAE can be considered for definite histologic diagnosis, identification of the extent and location of SB tumors, and therapeutic interventions to tailor appropriate treatment strategies.	7.9	0.86	0.11
7. In surgically altered anatomy, DAE enables examinations of parts of the intestinal lumen that are inaccessible to conventional and CE approaches and facilitates endoscopic retrograde cholangiopancreatography (ERCP).	7.9	0.78	0.10
8. The use of carbon dioxide insufflation rather than air insufflation improves intubation depth and increases patient convenience.	8.2	0.75	0.09
9. Although the majority of patients with SB lesions can be diagnosed without TE, TE could be considered in patients with negative CE findings and high clinical suspicion for a significant SB lesion, or in patients with lesions that are difficult to detect by a single approach.	7.6	0.62	0.08
10. The results of diagnostic studies prior to DAE and the clinical presentation should be considered in determining the insertion route.	8.4	0.80	0.09
11. Generally, the transoral approach is the preferred insertion route if the location of the lesion is uncertain from the previous diagnostic investigations. However, the insertion route should be determined considering the overall clinical situation.	7.8	0.66	0.09
12. Endoscopic hemostasis is recommended for achieving bleeding control and the hemostatic method should be selected according to the bleeding lesion.	7.9	0.83	0.10
13. Endoscopic balloon dilatation (EBD) using DAE in symptomatic benign SB stricture is reasonably safe and effective.	7.5	0.72	0.10
14. Enteroscopic polypectomy is recommended for the removal of large SB polyps to prevent polyp-related complications.	7.9	0.70	0.09
15. Although caution is required according to the patient's condition and indications, DAE is considered a safe procedure.	7.7	0.69	0.09

The response scale is a 9-Likert scale, ranging from 1 point (strongly disagree) to 9 points (strongly agree), and the closer the score is to 9, the higher the strength of agreement.
KASID, Korean Association for the Study of Intestinal Diseases; DAE, device-assisted enteroscopy; CE, capsule endoscopy; SB, small bowel; TE, total enteroscopy; SD, standard deviation; CV, coefficient of variation (SD/mean).

nostic yield of CE was higher than that of DAE, and could be increased by performing DAE after CE.[10] The diagnostic yield of DAE in overt SBB patients has been reported at 68.5% to 100%.[11-18] The diagnostic yield of DAE in ongoing overt SBB patients is higher compared to those with previous overt SBB or occult SBB.[11-14,19] Therefore, if ongoing overt SBB is suspected, DAE should be considered as the preferred therapeutic procedure following CE with a positive result. The therapeutic yield of DAE in overt SBB patients has been reported at 33.3% to 77.8%.[17,18,20-23] Following endoscopic therapy with DAE, the absolute rebleeding rates of SBB are high, reported to be 33.1% to 60.0%.[24-26] The long-term rebleeding outcome of overt SBB patients after DAE at 12 months has been found to be 34% compared with 13% in occult SBB patients ($P=0.06$).[13]

Occult SBB

Occult SBB patients usually visit hospitals for positive fecal occult blood tests or anemia caused by chronic gastrointestinal blood loss.[8,27] The diagnostic yield of DAE in occult SBB ranges from 52.4% to 75.0%,[28-30] which increases when DAE is performed after a positive CE.[29] The most frequently identified lesions are angioectasias, and occasionally, erosions, ulcers, and tumors.[29,30] Although previous studies did not comparatively evaluate therapeutic yields between overt and occult SBB, therapeutic yields of SBB, defined as improved hemoglobin levels and decreased transfusion needs after hemostatic procedures during DAE, were reported as substantial.[31-33] Liver cirrhosis, female sex, Osler-Weber syndrome, and cardiac disease were reported to be factors associated with rebleeding.[33,34]

Statement 2
In cases of overt SSBB, early DAE can be considered after CE or contrast-enhanced CT to improve diagnostic yield and provide a chance for therapeutic intervention.

Until now, there has been no consensus regarding the most appropriate timing of DAE in overt SBB.[8] In most clinical practice, CE or contrast-enhanced CT precedes DAE unless there is massive hemorrhage, and if the bleeding lesion is identified, DAE is recommended to confirm and treat the lesion.[6,7] Previous guidelines recommended CT enterography (CTE) as a proper imaging study for SSBB,[6-8] but contrast-enhanced CT could also be acceptable for the initial evaluation of SSBB in general situations.[35] Like the proper timing of CE in SSBB,[36] proper timing of DAE after bleeding episodes is important to increase diagnostic and therapeutic performance. In a previous study, diagnostic yield for SSBB was found to be higher when CE was performed within 7 to 15 days compared to CE performed after 7 to 15 days, and within 1 month compared to that after 1 month.[35] Urgent DAE, which is performed within 72 hours from the onset of SSBB, showed not only higher diagnostic yield compared to non-urgent intervention (70%–90% vs. 30%–50%, respectively), but also higher therapeutic performance (28.6%–57.5% vs. 13.0%–50.0%, respectively).[37] Another study reported that DAE within 24 hours in overt SBB showed a higher diagnostic (70%) and therapeutic yield (90%).[20] In a recent meta-analysis of DAE in overt bleeding, early DAE was associated with a significantly higher diagnostic yield (odds ratio, 3.2; 95% confidence interval, 1.9–5.3; $P=0.002$), although the definition of early intervention varies among the studies (from during ongoing bleeding to 1 week).[38] These studies suggest that early DAE may increase diagnostic yield and improve treatment outcomes, although the definition of early or urgent intervention is not unified. The reason for the increase in the diagnostic yield in early DAE is hypothesized as follows. Vascular lesions, such as angioectasia or Dieulafoy lesions in the SB, are usually too small to be detected during enteroscopic procedures. If such a lesion shows active bleeding during the procedure, it can more easily be found and the opportunity is presented to treat endoscopic hemostasis. However, if bleeding temporarily stops, it is difficult to identify the definite site of bleeding. Yin et al.[18] reported a study of emergency enteroscopy, supporting this hypothesis. They divided the enrolled patients (n=265) into 3 groups according to the timing of the procedure: less than 3 days (n=32), between 3 and 7 days (n=146), and >7 days (n=87). The reasons for bleeding included angioectasia, diverticulum, tumor, ulceration/erosion, and polyps. The ratio of diagnostic findings between the 3 groups was not different except for angioectasia, which showed increased yield in the emergency setting (<3 days) compared to the other groups (3–7 days or >7 days). Considering the bleeding pattern of vascular lesions in the SB, emergency enteroscopy could increase the diagnostic yield, which gives endoscopists more opportunities to perform endoscopic hemostasis. Considering the above results, in the case of overt SSBB, early DAE could increase the diagnostic yield and provide a chance for therapeutic intervention.

(2) Crohn's disease

Statement 3
DAE is not a routine diagnostic test in patients with clinically suspected Crohn's disease (CD). However, if there is no specific finding in the ileo-colonoscopy or other imaging studies, and results of laboratory tests alone are insufficient to diagnose CD in patients with suspected SB CD, SB tissue biopsy through DAE can be considered for enhancing confirmative diagnosis.

Thirty to sixty percent of patients with CD have SB lesions, and 10% to 30% of patients show isolated SB disease. Isolated SB CD is difficult to diagnose because the lesion cannot be identified using duodenoscopy and colonoscopy only, which are standard endoscopy methods.[39,40] Since SB CD often progresses to complicated diseases such as stenosis and can lead to poor clinical outcomes that require surgery, early diagnosis and appropriate management of this SB disease are important.

Although most studies on DAE in CD are small studies, some

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studies reported that the diagnostic yield in patients with suspected SB CD was low in the early days of DAE introduction, but recently reached 80%.[41,42] Common indications for DAE in patients with suspected CD were abnormal CE or other imaging studies. It is reported that the diagnostic sensitivity of DAE for suspected SB CD is higher than that of other imaging tests such as SB barium contrast studies, CT, or magnetic resonance enterography (MRE).[6,42,43] The diagnosis of SB mucosal changes by radiographic examination can be misleading, especially in mild forms of SB disease.[41] Although CE is convenient and widely available to detect SB lesions, the statement by the European Crohn's and Colitis Organisation and the World Endoscopy Organization recommended that a diagnosis of CD should not be based on CE findings alone because there are no validated criteria for CE-based diagnosis of SB CD.[44] A poor correlation between CE and DBE in suspected CD patients has also been reported.[41] Therefore, not only when no specific findings are observed, but even if there is a positive CE finding in patients with known or clinically suspected CD, caution is still needed when interpreting the results. Regardless of CE findings, DAE can be considered as an additional diagnostic tool when it is judged that various imaging tests and laboratory findings are insufficient to diagnose clinically suspected small intestine CD.

Unlike other imaging modalities such as CT or MRE and CE, the advantage of DAE in patients with suspected CD is that it is possible to obtain tissue samples for pathologic diagnosis. Furthermore, it is possible to perform endoscopic therapeutic interventions such as stricture dilation and landmarks or tattooing of lesions, as well as avoiding the risk of capsule retention.[45] The rate of granuloma diagnosis has been reported as 6.3% to 39% in SB pathology results obtained by DAE.[41,42,46]

However, despite these advantages to increase the diagnostic yield, it is difficult to routinely perform DAE in all patients with suspected SB CD. This is because DAE is an invasive examination, requires advanced skills, and is a time-consuming study, in addition to the fact that DAE availability (examination environment and expertise of the examiners) varies by institution.[47] In some cases, the clinical condition of the patient or the location of the lesion does not permit this invasive procedure.

Complications are known to be rare and occur in <1% of diagnostic DAE cases; however, they may be higher in patients with active CD.[6,48] In a systematic review, the per-procedure perforation rate of diagnostic DAE in CD was similar to diagnostic DAE for all indications.[49] However, the perforation risk was higher if an intervention was carried out. Balloon dilation of strictures has a reported perforation risk of up to 3%.[45,49,50] If the patient has fixed bowel secondary to active CD or adhesions from previous surgeries as well as strictures, the procedure becomes more difficult, and deep intubation of the scope is limited. In 17% of CD patients the DAE procedure was unable to reach the target area.[41] In addition, it should be noted that the predicted complication rates from endoscopists with less experience might be higher since most of the reported complication rates use data from experienced endoscopists.[51]

In conclusion, although DAE is not a routine diagnostic tool in patients with clinically suspected CD, it can be considered for histologic confirmation of suspected CD imaging findings or CD observed only in the SB without lesions in the gastrocolorectal area. DAE can also be reserved for potential therapeutic interventions, such as dilation of stenosis.

(3) SB tumor

> **Statement 4**
> DAE can be considered for the localization and characterization of SB tumors along with other imaging modalities.

Previously, the barium SB series was the initial screening method to detect SB tumors, with a diagnostic rate of only 30% to 44%.[52,53] This modality is no longer preferred due to the introduction of newer technologies. A combination of contrast-enhanced CT and CE is useful for detecting SB tumors.[54] CTE in particular allows intraluminal visualization, which can help determine the stage of SB tumors. However, CT has a low diagnostic yield for epithelial tumors in the SB, and CE could miss tumors located in the distal duodenum and proximal jejunum (because CE passes quickly through this area).[54-56] MRE could also be a useful tool for detecting SB tumors, but this modality has some limitations, including high costs, lack of availability, and contraindications in patients with metal devices such as pacemakers.[57]

The diagnostic yield of DAE for SB tumors is comparable to that of a combination of CT and CE.[58,59] The overwhelming advantage of DAE is that it can be used for histologic diagnosis and endoscopic treatment. A multicenter retrospective analysis in Japan described that SB tumors were identified by DAE in 61 of 144 subjects (42.4%) who suspected the presence of SB tumors for 5 years; malignant lymphoma was most frequent (31/144, 21.5%) and gastrointestinal stromal tumor (GIST) was the second most frequent (27/144, 18.8%).[60,61]

Based on these results, we suggest that DAE can be considered a useful tool for the detection and characterization of SB tumors along with other imaging modalities.

Statement 5
DAE may be used in symptomatic patients with intestinal polyposis causing obstruction and bleeding. Also, DAE may be used for the diagnosis and follow-up of some intestinal polyposis syndromes, particularly Peutz-Jeghers syndrome (PJS) rather than familial adenomatous polyposis (FAP).

Intestinal polyposis syndromes are relatively rare and can be classified into hamartomatous polyposis syndromes, FAP, and other rare polyposis syndromes such as hereditary mixed polyposis syndrome. SB polyps occur in 90% of PJS patients characterized by hamartomatous polyposis, and in more than 75% of those with FAP.[62] FAP patients with duodenal polyps are at significantly higher risk to exhibit additional polyps in more distal parts of the SB.

A retrospective study analyzing the correlation between CE and DAE in 25 patients with SB polyps showed that the agreement between CE and DAE was good for both the location and size of polyps, but DAE was better than CE in defining the number of polyps.[63] Another retrospective study including 18 patients with PJS who underwent fluoroscopic enteroclysis showed that the polyp detection rate of DAE was better than that of fluoroscopic enteroclysis and similar to that of CE.[64] A prospective study of 15 patients with PJS who underwent both MRE and DAE showed that MRE and DAE have a comparable diagnostic yield for detecting clinically relevant SB polyps (≥15 mm), but DAE allows for direct interventions such as immediate polypectomy, tattooing, and biopsy, and was preferred over MRE by most patients.[65]

In patients with PJS, large polyps (10–15 mm) or symptomatic or rapidly growing polyps should be removed because these polyps are risk factors for SB intussusception.[66] DAE proved to be safe and effective in the treatment of SB polyps in patients with PJS in various studies, and the resection of SB polyps through DAE resulted in a significant decrease in the mean number and mean maximum size of resected polyps in periodic enteroscopies.[67-69] Additionally, a multicenter retrospective cohort study of 25 patients with PJS reported that there were no SB polyp-related complications at a median follow-up of 56.5 months after polypectomy of SB polyps by DAE.[68] However, the effect of DAE therapy on cancer reduction remains unknown.

There is still insufficient evidence regarding the indications for or role of DAE in patients with FAP. A study on the prevalence of SB adenomas in 41 patients with FAP reported that DAE is equal to intraoperative endoscopy in terms of diagnostic yield for SB adenomas in FAP.[70] A prospective study of 62 patients with FAP showed that screening and surveillance with DAE could be useful in FAP patients with advanced duodenal polyposis. However, another study of 18 FAP patients with advanced duodenal polyposis reported that routine DAE is not warranted in patients with FAP because the malignant potential of these lesions is unknown.[71,72]

Statement 6
In patients with suspected SB tumors, DAE can be considered for definite histologic diagnosis, identification of the extent and location of SB tumors, and therapeutic interventions to tailor appropriate treatment strategies.

If there is uncertainty about the diagnosis and therapeutic strategies for SB tumors, or subepithelial tumors are detected in CE or other imaging modalities, DAE is a useful procedure to elucidate definite histologic diagnosis through direct visualization of SB mucosa.[73-75] Previous studies showed that DAE enables histologic diagnosis in the majority of patients with SB tumors and the diagnostic yield is high for adenocarcinoma, lymphoma, and neuroendocrine tumor (NET).[54,60,76] However, in patients with highly suspicious GIST, histologic confirmation through tissue biopsy should be chosen with care because 50% to 80% of the DAE biopsies for GIST missed the diagnosis and the hypervascular nature increased bleeding risk after biopsy.[58,60,77] Therefore, in the case of GIST, tissue biopsy at the internal margin of ulceration and prophylactic procedures to prevent significant bleeding are recommended.[78]

DAE helps identify tumor extent through direct exploration of the entire SB and precisely localizing SB tumors with tattooing. Gangi et al.[79] reported bidirectional DAE found additional NETs in 51.1% of patients who were already diagnosed with SB NETs. In addition, DAE can identify multiple lesions in more than half of patients with metastatic SB tumors and preoperative tattooing effectively marks target lesions and assists in deciding on the most suitable type of operation, facilitating removal of all metastatic SB tumors.[80] DAE is also used to perform other therapeutic interventions, including polypectomy for epithelial tumors within the mucosal layer or subepithelial tumors confined to the submucosal layer, hemostasis for tumor bleeding, and dilatation or stenting for SB obstruction.[35,60,81,82]

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This is despite some hurdles including limited working channel of the enteroscope and the requirement for high-level technical skills. These procedures revised therapeutic strategies in 25% to 65% of patients with SB tumors by reducing emergent surgery or by modifying the surgical approaches, which suggested beneficial impacts on clinical practice for SB tumors.[73,83]

2) Preprocedural Considerations

Surgically altered anatomy

Statement 7
In surgically altered anatomy, DAE enables examinations of parts of the intestinal lumen that are inaccessible to conventional and CE approaches and facilitates endoscopic retrograde cholangiopancreatography (ERCP).

Although CE is recommended as the first diagnostic option for SBB, CE cannot reach the bypassed parts of the gastrointestinal tract (e.g., Roux-en-Y gastrojejunostomy) in patients with surgically altered anatomy. In such cases, DAE has the advantage that it can be advanced to a bypassed lumen of the postoperative reconstructed intestine.[84-86] DAE also can be used when SB stricture or obstruction is suspected, for which CE is contraindicated. For this reason, it is recommended that DAE be considered as the initial SB diagnostic procedure in patients with SSBB and possible obstruction or surgically altered anatomy.[8]

DAE has increased the success rate of ERCP in patients with anatomical alterations that do not allow access to the pancreaticobiliary system with conventional endoscopy due to upper gastrointestinal surgery.[87] In a systematic review that analyzed the efficacy and safety of DAE-assisted ERCP, the overall ERCP success rate for various post-surgical upper gastrointestinal anatomical configurations was 74%.[88] The success rates were highest at 90% in patients with Billroth II anatomy and lowest at 70% in patients with Roux-en-Y gastric bypass anatomy.

Despite these advantages, it should be cautioned that the risk of perforation might be increased in patients with surgically altered anatomy. In a retrospective study analyzing 2,478 DBE examinations in 9 U.S. centers, the perforation rate was 0.4% (11/2,478).[89] On the other hand, in the subset of 219 examinations performed in patients with surgically altered anatomy, perforations occurred in 3% (7/219), which was significantly higher compared with those without surgically altered anatomy. Six of the seven perforations occurred during transanal DBEs.

2. Intraprocedure

1) Insufflation

Statement 8
The use of carbon dioxide insufflation rather than air insufflation improves intubation depth and increases patient convenience.

Insufflation with carbon dioxide (CO_2) is reportedly effective in enteroscopic examinations and procedures. An excessive amount of air in the bowel prevents the shortening procedure, making it difficult to insert the endoscope deeper and increasing patient inconvenience. CO_2 insufflation dissolves in water at a rate more than 100-fold higher than air and is rapidly absorbed and exhaled through the breath.[35] A randomized, controlled, double-blind trial showed that compared with air insufflation, CO_2 insufflation significantly increased intubation depth of transoral enteroscopy in DBE.[90] Another randomized, controlled, double-blind trial reported that CO_2 insufflation improves the intubation depth and total enteroscopy (TE) rate in SBE.[91] However, a systematic review and meta-analysis showed that intubation depth of transanal enteroscopy was not significantly different between the CO_2 group and the air group.[92] Therefore, CO_2 insufflation allows for deeper intubation of transoral DAE and increases the TE rate.[90-92] In addition, compared with air insufflation, CO_2 insufflation significantly reduced the sedation dosage during DAE and the degree of abdominal pain after DAE.[92,93] In terms of CO_2 retention, 2 randomized controlled trials confirmed that partial pressure of CO_2 in the blood did not differ significantly between the CO_2 group and the air group.[91,93]

Therefore, insufflation with CO_2 may lead to a higher diagnostic and therapeutic yield of DAE with reduced patient discomfort and increased safety.

2) Complete Rate

Statement 9
Although the majority of patients with SB lesions can be diagnosed without TE, TE could be considered in patients with negative CE findings and high clinical suspicion for a significant SB lesion, or in patients with lesions that are difficult to detect by a single approach.

TE is defined as the complete visualization of the SB with either a single approach alone or combined transoral and transanal approaches. Usually, a combination of transoral and trans-

anal approaches to achieve TE is required.[2] If TE is needed, tattooing or clipping should be performed at the deepest point that can be reached by a single approach.[37] Then, the marked sites can be accessed by the other route.

In a randomized control trial in Japan, the TE rate of DBE was significantly higher than that of SBE (57.1% vs. 0%, $P=0.002$).[94] The result of another randomized control trial performed in Germany was similar (DBE vs. SBE, 66% vs. 22%, $P<0.0001$).[95] A systematic review conducted from 2001 to 2010 reported that TE rate for DBE was 44.0% and TE by transoral approach alone was achieved in 1.6%.[96] In 2 studies comparing DBE and SBE, the TE rate for DBE was significantly higher than that for SBE.[97,98] The recently developed motorized spiral enteroscopy increased capability for complete visualization of the SB in a single approach. TE was achieved in spiral enteroscopy using a transoral approach alone (16.6%) and in a combined approach (53.4%).[99]

Although TE rates vary in different DAE techniques, the clinical impact of TE rate remains controversial.[100-102] This suggests that TE rate does not guarantee increased diagnostic or therapeutic yields, as SBE, DBE and spiral enteroscopy have comparable diagnostic and therapeutic yields according to results of previous studies.[3,95,103] In patients with SBB, if a bleeding focus is identified by DAE from either the transoral or transanal approach, TE is not required.[104-106] However, in a study performed in patients with SBB, CE had a significantly lower yield as compared with DBE by combined approaches (odds ratio, 0.12; 95% confidence interval, 0.03–0.52).[107] The false-negative rate of CE was reported as 11% for all SB lesions and approximately 19% for SB tumors.[7] This suggests that TE can be useful when an SB lesion is strongly suspected. Although the majority of patients with SB lesions can be diagnosed without TE, physicians should consider whether TE should be attempted based on clinical judgment. TE could be considered in patients with a negative CE and a high clinical suspicion of a significant SB lesion.[59] In patients with SB lesions that are difficult to detect by a single approach, TE could also be pursued. In cases of massive SBB where the bleeding site cannot be identified by TE or DAE with combined approaches, radiologic intervention or intraoperative enteroscopy can be considered.[108]

3) Insertion Route Choice

Statement 10
The results of diagnostic studies prior to DAE and the clinical presentation should be considered in determining the insertion route.

Statement 11
Generally, the transoral approach is the preferred insertion route if the location of the lesion is uncertain from the previous diagnostic investigations. However, the insertion route should be determined considering the overall clinical situation.

DAE is commonly performed following less invasive SB evaluations, such as CE, SB barium contrast studies, CTE, and MRE. Therefore, the results of imaging studies prior to DAE should be considered in the choice of insertion route.[8,109,110] CE transit time has been known to be helpful in determining the insertion route.[6] The transoral approach is preferred due to the deeper intubation and higher success rate if the lesions are suspected to be located in the proximal 2/3 of the SB. Several CE time-based indexes have been suggested; the cutoff value of 0.75 has been proposed which is calculated by the transit time between the ingestion of the capsule and the first image of the lesion divided by the time between ingestion and the first image of the cecum; or the cutoff value of 0.6 has been suggested which is calculated by the time from the pylorus to the lesion divided by the time from the pylorus to the ileocecal valve.[7,111-113] In addition, clinical presentation can be considered in determining the insertion route in case of obscure-overt gastrointestinal bleeding.[111] The transoral approach is preferred in patients with black stool or melena, and the transanal approach is preferred in patients with bright or dark red stool.[11,35,37] In case of massive bleeding, the transoral approach is preferred because of the poor visibility and excessive friction between the scope and overtube by blood and clots in the transanal approach.[113]

If no pathology was found through the first insertion route and a whole bowel evaluation is required, approach through the other route after clipping or tattooing the maximal insertion point is recommended in a following session rather than the same session because of the increased insertion depths achieved in a separate session.[113,114] However, in the case of gastrointestinal bleeding, the other route can be tried immediately or as soon as possible, because the diagnostic yield decreases progressively with time.[20,35,115]

If the location of the lesion is not revealed by previous examinations, the transoral approach is preferred because of the higher success rate in identifying lesions, especially in patients with SBB.[113,116,117] However, the transanal approach can be considered first in patients with CD or NETs considering the distribution of SB involvement.[113]

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4) Therapeutic Intervention

(1) Hemostasis

Statement 12
Endoscopic hemostasis is recommended for achieving bleeding control and the hemostatic method should be selected according to the bleeding lesion.

DAE has a relatively high therapeutic yield for SBB. A previous prospective study of 60 patients with SBB reported a therapeutic yield of 57%.[118] A recent multicenter retrospective cohort study reported a 67.4% therapeutic yield.[119] In another study considering the timing of endoscopy, earlier enteroscopy had a higher therapeutic yield (100%, 76.9%, and 57.7% at ≤24, ≤48, and ≤72 hours, respectively).[120] Therefore, endoscopic hemostasis is recommended for various SB lesions such as bleeding lesions (ulcers or erosions), vascular lesions (angioectasia or Dieulafoy lesions), tumors, and diverticula. In addition, there is evidence that endoscopic hemostasis improves clinical outcomes by decreasing transfusion requirements.[26,121]

The endoscopic hemostasis method for upper or lower gastrointestinal bleeding can be applied to SBB. The method of endoscopic hemostasis should be selected based on the type of lesion or available treatment tools. Endoscopic hemostasis includes injection therapy with epinephrine, mechanical therapy with hemoclips and band ligation, thermal therapy with argon plasma coagulation, and monopolar or bipolar coagulation.[121-123] As the SB wall is very thin and has a high risk of iatrogenic perforation, argon plasma coagulation or mechanical therapy with hemoclips is recommended for hemostasis of SBB. For bleeding SB polyps, hemostasis can be achieved by endoscopic mucosal resection or polypectomy.[123,124] When endoscopic hemostasis is unsuccessful, surgical treatment or interventional radiology is indicated for ongoing bleeding.

(2) Stricture dilatation

Statement 13
Endoscopic balloon dilatation (EBD) using DAE in symptomatic benign SB stricture is reasonably safe and effective.

SB strictures occur in cases of CD, nonsteroidal anti-inflammatory drug enteropathy, and post-surgical, idiopathic, and neoplastic lesions. To date, most stricture dilatation procedures using enteroscopy have been performed for CD. Approximately 70% to 80% of patients with CD require surgery due to obstructive symptoms within 20 years after diagnosis, with approximately 30% requiring repeat surgeries within 10 years due to recurrence of symptoms.[125] Repeated surgical treatment can cause short bowel syndrome with other various complications such as fistulae, leaks, and abscesses.[126,127] To prevent such complications, EBD has been used as an alternative procedure to postpone surgery and has shown favorable outcomes with 89% technical success and perforation rates as low as 3%.[128] The usual candidates for EBD are strictures without deep ulceration, without adjacent fistula, and with short segment involvement (≤5 cm).[128] Until recently, most of the studies were conducted on dilatation of primary strictures (colon and terminal ileum) and anastomotic strictures which were within reach of conventional colonoscopy. However, there are relatively few studies on EBD of SB strictures using DAE. Fukumoto et al.[129] reported a study on the diagnosis and treatment of SB strictures using DAE. EBD using DAE was performed in 23 patients with CD, with a long-term success rate of 73.9% (17/23). In a retrospective cohort study by Sunada et al.,[130] 473 stricture EBD procedures using DAE were performed in 85 patients. The surgery-free rates after the stricture dilatation were 87.3% at 1 year, 78.1% at 3 years, and 74.2% at 5 years. In terms of complications, perforations occurred in 4.5% of patients (4/85), and postprocedure bleeding requiring transfusion occurred in 1 patient, which was controlled by endoscopic hemostasis. In the first patient with perforation, mechanical damage after passage of the enteroscope or overtube through the stricture may have been implicated. In the second patient, perforation occurred beyond the reach of the enteroscope, which may be related to increased luminal pressure. In the third patient, dilatation occurred up to 12 mm (stricture diameter before EBD was 5 mm), and in the fourth patient, dilatation occurred up to 15 mm (stricture diameter before EBD was 9 mm). The above complication cases suggest that the maximal or optimal diameter of dilatation usually depends on stricture diameter before EBD, and overtube or enteroscopic mechanical damage should be kept in mind during passage through the dilated stricture. The optimal EBD diameter for SB strictures is still unclear, and further research is needed to draw firm conclusions.

The first multicenter prospective study on the efficacy and safety of EBD using DAE for SB CD strictures was reported by Hirai et al. in 2018.[131] In this study, a total of 112 patients from 23 institutions were enrolled, and EBD was technically successful in 93.7% of patients (89/95). Short-term success, defined as improvement of symptoms related to stricture within 4 weeks, was achieved in 66 patients (69.5%), while adverse events were

low and well-managed with conservative treatment. Recently, a systematic review and meta-analysis were published.[132] In the pooled analysis, the technical success rate was 94.8%, clinical efficacy was 83.3%, and major complications occurred at 1.82% per dilatation and 3.21% per patient. In terms of long-term outcomes, the rate of symptom recurrence was 24.8%, 46.8%, and 67.2% at 6, 12, and 24 months after EBD respectively. Endoscopic redilatation after EBD was observed in 31.2%, 45.7%, and 55.4% of patients within 6, 12, and 24 months respectively. The rate of surgical management after EBD was 22.0% and 24.9% at 12 and 24 months respectively. Considering the above results, EBD using DAE in SB CD strictures is a reasonably safe and effective procedure and postpones the need for surgery when it is applied in cases with appropriate indications.

(3) Polypectomy

Statement 14
Enteroscopic polypectomy is recommended for the removal of large SB polyps to prevent polyp-related complications.

SB polyps larger than 10 to 15 mm may cause bleeding, intussusception, or obstruction.[133] Additionally, in polyposis syndromes such as PJS or FAP, polyps larger than 10 mm are recommended to be resected to prevent malignant transformation.[66,134,135] Before the introduction of enteroscopy, intestinal resection with laparotomy or intraoperative enteroscopy were used for removal of large symptomatic or asymptomatic SB polyps. However, intestinal resection can ultimately result in short bowel syndrome or adhesion, which is more crucial in polyposis syndromes requiring repeated polyp removal. With the development of CE and DAE, the diagnostic and therapeutic efficacy for SB polyps has been reported in a few studies. As most SB polyps arise from polyposis syndrome rather than sporadic polyps, most studies have been conducted in patients with polyposis syndromes. In terms of efficacy, Perrod et al.[136] analyzed 274 polyps that were endoscopically resected by 50 DAEs in 25 patients with PJS. Complete resection was achieved in 76% of cases, and intraoperative enteroscopy and surgical resection were performed in 4 and 2 patients respectively, due to incomplete resection. In a study by Wang et al.,[69] after 320 polypectomies in 97 PJS patients, complications occurred in 14 cases (4.4%) including 8 cases of delayed bleeding, 4 perforations, 1 transmural syndrome, and 1 intussusception due to a detained polyp. Mensink et al.[137] conducted a multicenter survey of 2,362 DAE cases, wherein polypectomy-related complications were reported in 12 of 364 polypectomies. In another study by Wang et al.,[138] polypectomy-associated complications were reported in 11 of 84 procedures. Considering the results of other small studies, the incidence of complications after enteroscopic polypectomy is reported to be 0% to 13%.[67,139-142] As represented in these studies, most of the complications were minor or moderate bleeding, pancreatitis, and few perforations which could managed by endoscopic or conservative treatment. However, the SB wall is thin and polypectomy during DAE is technically demanding. Therefore, considering the lack of data comparing various endoscopic polypectomy modalities in the SB, it has been suggested that submucosal injection with a dilute solution is required to prevent bleeding or perforation.[113]

3. Postprocedure

Complications

Statement 15
Although caution is required according to the patient's condition and indications, DAE is considered a safe procedure.

The overall complication risk of DAE has been reported as 0.8% to 1%,[89,137,143-146] making it a safe procedure. Mortality associated with DAE appears extremely rare.[24] In the case of therapeutic procedures such as dilation, polypectomy, and electrocoagulation, the risk of complications from DAE increases by 1% to 4%.[130,144,147] No difference in complication rate according to patient age or DAE type has been observed.[115,148-152] Major complications of DAE include perforation, bleeding, mucosal injury, and acute pancreatitis. Other minor complications include sore throat, abdominal discomfort, and minimal mucosal injuries.

The incidence of acute pancreatitis in reported studies were 0.3% to 0.5% and almost all cases were in transoral DAE.[89,96,137] Post-DAE pancreatitis is thought to be associated with a long procedure time.[153,154] This might be caused by the physical force applied to the duodenum and pancreas, so balloon inflation and mechanical stress should be minimized in the proximal duodenum during the procedure.[155,156] As described above, the incidence of post-DAE pancreatitis increases in transoral DAE, so caution is needed.

Perforation was generally reported in 0.3% to 0.4% of patients.[89,137,156] However, as mentioned earlier, it should be noted that the perforation risk seems to be higher in patients with al-

tered anatomy due to abdominal surgery, resection of polyps larger than 30 mm, and SB stricture, so more attention should be paid to these patients.[89,113,140]

CONCLUSIONS

At the beginning of the 21st century, DBE was introduced as the first form of DAE. Based on technological advances and accumulating evidence of its efficacy, DAE has since gained widespread acceptance.

DAE has multiple diagnostic and therapeutic applications, the most common being the evaluation of overt and occult SSBB, suspected SB CD, and SB tumors. To increase diagnostic and therapeutic yields while performing DAE safely and effectively, selection of an appropriate insertion route based on the results of antecedent diagnostic studies and insufflation with CO_2 are needed. Most endoscopic therapeutic interventions performed in duodenoscopy and colonoscopy, including hemostasis, balloon dilatation, and polypectomy, can be safely and effectively performed in DAE.

We have made our best efforts to provide the most appropriate recommendations for the real practice of DAE based on the available evidence at the time of review. These expert statements should be interpreted considering specific clinical situations and available resources. In addition, these statements might be revised as technical innovations emerge, and further controlled clinical studies should be conducted.

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