

# Complications of double balloon enteroscopy: a multicenter survey

## Author

P. B. F. Mensink<sup>1</sup>, J. Haringsma<sup>1</sup>, T. Kucharzik<sup>2</sup>, C. Cellier<sup>3</sup>, E. Pérez-Cuadrado<sup>4</sup>, K. Mönkemüller<sup>5</sup>, A. Gasbarrini<sup>6</sup>, A. J. Kaffes<sup>7</sup>, K. Nakamura<sup>8</sup>, H. H. Yen<sup>9</sup>, H. Yamamoto<sup>10</sup>

## Institution

Institutions are listed at the end of article.

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## Corresponding author

**P. B. F. Mensink, MD, PhD**

Erasmus MC – University

Medical Center

Department of Gastro-

enterology and Hepatology

Dr. Molewaterplein 40

3015 GD Rotterdam

The Netherlands

Fax: +31-10-4634680

p.mensink@erasmusmc.nl

**Background and study aims:** Double balloon enteroscopy (DBE) is a new technique for the visualization of the small bowel. Although the technique is widely used, little is known about the complications. A few complications have been reported in the literature, mainly in case reports. The aim of this study was to establish the complication rate of both diagnostic and therapeutic DBE.

**Patients and methods:** A total of 10 centers (nine academic centers and one teaching hospital) across four continents participated in the study. Complications were defined according to the literature. A therapeutic DBE was defined as a DBE with use of argon plasma coagulation, a polypectomy snare, injection of fluids (other than ink for marking), removal of foreign body, or balloon dilation.

**Results:** A total 85 adverse events were reported in 2362 DBE procedures. In all, 40 events fulfilled the definition of a complication, 13 in 1728 diagnostic DBE (0.8%) and 27 during 634 therapeutic procedures (4.3%). The complications were rated minor in 21 (0.9%), moderate in 6 (0.3%) and severe in 13 procedures (0.6%). No fatal complications were reported. Seven cases of pancreatitis were reported, six after diagnostic (0.3%) and one after therapeutic (0.2%) DBE.

**Conclusions:** Diagnostic DBE is safe with a low complication rate. The complication rate of therapeutic DBE is high compared with therapeutic colonoscopy. The reason for this is unclear. The incidence of pancreatitis after DBE is low (0.3%), but has to be considered in patients with persistent abdominal complaints after a DBE procedure.

## Introduction

Double balloon enteroscopy (DBE) is a novel technique for the visualization of the small bowel. The procedure is based on the combined use of a balloon-loaded enteroscope and overtube. Alternately inflating and deflating the two balloons and straightening the endoscope with the overtube achieves a stepwise progression of the enteroscope throughout the small intestine. With a combined oral and rectal approach a complete small bowel exam can be achieved in up to 86% of patients [1]. The technique was developed by Yamamoto, and first described in 2001 [2]. Within 5 years DBE has become the new standard for detection of small bowel pathology [2–4]. Endoscopic interventions can also be performed, such as mucosal biopsy, coagulation, snare polypectomy, injection therapy, tattooing, and balloon dilation.

Complications are relatively rare in the small series published to date [4–7]. One publication reported mild self-limiting mucosal bleeding in

15% of patients [4]. Two cases of perforation were reported during rectal insertion and after contact diathermy in two series of respectively 50 and 40 DBE procedures [5,6]. One case of intestinal infarction after epinephrine injection using DBE was recently published [8]. Most striking is the reported occurrence of acute pancreatitis and hyperamylasemia after DBE [9–11]. Three recent publications reported absence of major complications in respectively 147, 70, and 89 DBE procedures [12–14]. This article presents the results of a large international survey on complications and DBE.

## Patients and methods

A total of 14 endoscopy units across different continents and with a large practice of DBE were invited to participate in this survey. A standard questionnaire was sent to these centres. The questionnaire consisted of three subject categories: 1) general information about the center; 2)

**Table 1** Complications after double balloon enteroscopy – diagnostic and therapeutic procedures

	Procedures n	Complications n (%)	Pancreatitis n (%)	Bleeding n (%)	Perforation n (%)	Other n (%)
Total	2362	40 (1.7)	7 (0.3)	19 (0.8)	6 (0.3)	8 (0.3)
Diagnostic	1728	13 (0.8)	6 (0.3)	1 (0.1)	1 (0.1)	5 (0.3)
Therapeutic	634	27 (4.3)	1 (0.2)	18 (3.0)	5 (0.8)	3 (0.5)

Intervention	n	Bleeding			Perforation n (%)
		Minor n (%)	Moderate n (%)	Major n (%)	
Polypectomy	364	5 (1.4)	7 (1.9)	0	0
APC	253	0	1 (0.4)	0	3 (1.2)
Dilation	70	0	0	0	2 (2.9)

APC, argon plasma coagulation.

**Table 2** Complication rate per double balloon enteroscopy intervention

specific information about the DBE performed in the center; 3) specific information about complications and DBE. The data provided were classified and entered into a database.

A complication was defined as any event that changed the health status of a patient negatively, and that occurred during the 30-day period after DBE. Complications were categorized as minor (requiring up to 3 days of hospitalization), moderate (requiring 3–10 days of hospitalization) and major (requiring > 10 days of hospitalization, and/or an endoscopic, radiological or surgical intervention, and/or contributing to the death of the patient), as published by Cotton et al. [15]. The definition of pancreatitis was defined according to the literature as newly developed or worsened abdominal pain after the procedure, a serum amylase  $\geq 3$  upper limits 24 hours after the procedure and at least 2 days of unplanned hospitalization after the procedure (American Society for Gastrointestinal Endoscopy [ASGE] guidelines) [16]. Procedure-related mortality was defined as mortality within 30 days after DBE. A therapeutic DBE was defined as a DBE with the use of argon plasma coagulation (APC), a polypectomy snare, injection of fluids (other than ink for marking), and balloon dilation.

## Results

The questionnaire was completed and returned by 10 of the selected 14 centers. The 10 centers consisted of nine university centers and one teaching hospital. The mean annual total number of endoscopic procedures performed in these centres was 7500 (range 5000–11 425) by a mean number of 11.3 endoscopists (range 4–31). The mean annual number of DBE procedures was 202 (range 20–711) by a mean number of 3.2 endoscopists (range 1–7).

The DBE endoscopes used were the 8.5 mm Fujinon EN-450P5 with a 2.2 mm working channel in two centers, and the 9.4 mm Fujinon EN-450T5 with a 2.8 mm working channel in two centers. Both endoscope types were used in six centers. The DBE procedure was performed using conscious sedation with midazolam and/or a morphine analog in five centres, propofol sedation or anesthesia in three centers, and either midazolam or propofol in two centers.

Data on a total of 2362 DBE procedures were submitted. Of these, 1728 (73%) were diagnostic, and 634 (27%) were therapeutic.

Oral intubation was performed in 1207 procedures (51%), anal intubation in 412 (17%), and dual intubation (both oral and anal) was performed in 743 (32%). Visualization of the entire small bowel was achieved in 15% (range 0%–41%) of all procedures.

In eight of the 10 centers a complication registration system was actively used. The majority of DBE procedures, 2047/2362 (87%), were performed on an inpatient basis. In this series no fatal complications occurred. Of the total 85 adverse events reported, only 40 fitted the definition of a complication, accounting for an overall complication rate of 1.7%. The complications were rated minor in 21 (0.9%), moderate in 6 (0.3%) and severe in 13 procedures (0.6%). The 45 adverse events not fulfilling the criteria of a complication were: abdominal discomfort (n=26), sore throat (n=10), admission for observation (n=6), fever (n=2), and balloon dislocation (n=1).

In the diagnostic DBE procedures, 13 complications (0.8%) occurred. In one patient injection therapy with adrenalin was complicated by intestinal necrosis [7]. Pancreatitis or hyperamylasemia was reported in six patients (0.3%) after diagnostic DBE. Therapeutic DBE was associated with 27 complications (4.3%, **Table 1**). In the therapeutic group, pancreatitis was observed only once. This occurred after papillotomy using DBE for cannulation of the blind loop in a patient with a Roux-en-Y reconstruction. Of the seven patients with acute pancreatitis, six (86%) presented with symptoms immediately after the DBE procedure; one patient presented with persistent pain after a 24-hour interval. The location of the pancreatitis was body and/or tail in four patients, pancreatic head in one patient, and the entire pancreas in two patients. In four patients presenting with pancreatitis after DBE, the diagnostic (P5) endoscope was used, and in three cases the therapeutic (T5) endoscope.

Detailed information of the therapeutic interventions and complications was available from seven of the 10 centers (70%) (**Table 2**). A total of 364 polypectomies were performed in 59 procedures. Twelve postpolypectomy bleeds were reported, accounting for an overall postpolypectomy bleeding rate of 3.3%. Of these, five were categorized as minor (1.4%) and seven (1.9%) as moderate, no major bleeding was reported. No postpolypectomy perforations were reported.

Treatment with APC was reported at 253 DBE procedures, mainly for angiodysplasia. Three cases of perforation were reported in

conjunction with APC, accounting for a complication rate of 1.2%. All three patients underwent laparotomy. A total of 70 balloon dilations were reported during DBE. Two perforations were reported after dilation, accounting for a perforation rate of 2.9%.

## Discussion

This is the first international survey on complications of DBE covering a vast number of procedures. The data of this survey were gathered from centers in various parts of the world. Although all included centers were academic centers or teaching hospitals, the centers should be considered representative of current general practice given the range in annual volume of endoscopies. As the questionnaires were filled in retrospectively by the endoscopists in the selected centers, under-reporting of complications could occur. However, as eight out of the 10 centers used an active complication registration system, this bias is likely to be limited. As the majority of procedures (almost 90%) were performed on an inpatient basis, the chance of having missed early complications, like acute pancreatitis, is small.

From the data gathered by this survey, it emerges that DBE is a safe procedure. Also in the literature few severe and no fatal complications have been published to date. The overall complication rate we found in diagnostic DBE is 0.8%. This is comparable with complication rates observed in diagnostic colonoscopy (0.02%–2.4%) [17–19]. The complication rate in therapeutic DBE procedures (4.3%) is considerably higher than that associated with therapeutic colonoscopy (1.2%–2.0%) [20–22]. The thin wall of the small bowel might in part explain this, but data are lacking to support this theory.

Pancreatitis complicating DBE was initially reported by the Rotterdam group [9]. This survey confirms that acute pancreatitis is of major concern in patients undergoing DBE. Therefore, in all patients with persistent abdominal pain after DBE, a diagnosis of acute pancreatitis should be considered and treatment should be timely and adequate, as in ERCP-induced pancreatitis. Polypectomy and balloon dilation carry the highest complication rates. APC, often used for treatment of angiodysplasia in the small bowel and one of the most common findings during DBE, seems relatively safe. However, all centers in this survey used diminished APC power settings to account for the small bowel wall thickness. In summary, from this survey one can conclude that double balloon enteroscopy is a safe procedure. However, small bowel therapy seems to carry a considerably higher risk than interventional colonoscopy. Acute pancreatitis is the most common complication seen after diagnostic DBE, justifying added caution in patients with persistent abdominal complaints after a DBE procedure.

**Competing interests:** None

## Institutions

- 1 Department of Gastroenterology and Hepatology, Erasmus MC – University Medical Center, Rotterdam, The Netherlands
- 2 Department of Medicine B, University of Muenster, Muenster, Germany
- 3 Department of Gastroenterology, Georges Pompidou European Hospital, Paris, France
- 4 Unit of Small Bowel, Section of Digestive Diseases, Hospital General Universitario Morales Meseguer, Murcia, Spain
- 5 Division of Gastroenterology, Hepatology and Infectious Diseases, Otto von Guericke University, Magdeburg University Hospital, Magdeburg, Germany
- 6 Department of Internal Medicine and Endoscopy, Gemelli Hospital, Catholic University, Rome, Italy
- 7 Department of Gastroenterology and Hepatology, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia

- 8 Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan
- 9 Department of Gastroenterology, Changhua Christian Medical Center, Changhua, Taiwan
- 10 Department of Internal Medicine, Division of Gastroenterology, Jichi Medical University, Shimotsuke, Tochigi, Japan

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