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STUDY EXAMINING LARGE-SCALE DATA OF DOUBLE BALLOON ENTEROSCOPY SHOWS IT IS SAFE AND EFFECTIVE

OAK BROOK, Ill. – Sept. 26, 2011 – A large-scale data review by researchers in China of double balloon enteroscopy (DBE) over the last decade showed the endoscopic procedure to be safe and effective for detection of diseases of the small intestine. DBE had a pooled detection rate of 68.1 percent for all small intestinal disease. Suspected mid-gastrointestinal bleeding was found to be the most common indication, with a relatively high detection rate. Inflammatory lesions and vascular lesions were the most common findings in patients with suspected mid-gastrointestinal bleeding. The study appears in the September issue of *GIE: Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).

Balloon assisted or “deep” enteroscopy is a procedure which can allow the advancement of a long endoscope (called an enteroscope) into the small intestine for both diagnostic and therapeutic purposes. Balloon assisted enteroscopy may use a one or two balloon system. The system using two balloons is called double balloon enteroscopy (DBE). The balloon assisted enteroscopy technique advances the endoscope through the small bowel by alternately inflating and deflating balloons, and pleating the small bowel over an insertion tube like a curtain over a rod. The procedure can be performed via the upper gastrointestinal (GI) tract (antegrade) or through the lower GI tract (retrograde). The procedure is indicated for patients who have problems in the small intestine including bleeding, strictures, abnormal tissue, polyps, or tumors. Since the first article introducing DBE was published in *GIE: Gastrointestinal Endoscopy* in 2001, DBE has been widely used in clinical practice worldwide.

Methods

Up until now, there have been many published original articles across the world addressing the technical aspects and positive findings of DBE. However, most of these studies were of small sample size and show inconsistent, if not controversial, data among different settings and in different countries. Therefore, the researchers performed this systematic review of all eligible studies related to diagnostic DBE during the decade of development in order to produce state-of-the-art data on indications, lesion detection rate, total enteroscopy, and complications in examining diseases of the small intestine.

The researchers, led by Zhuan Liao, MD, and Zhao-Shen Li, MD, Department of Internal Medicine, Changhai Hospital, Second Military Medical University, Shanghai, China, searched PubMed between January 1, 2001 and March 31, 2010 for original articles about DBE evaluation of diseases of the small intestine. Data on total number of procedures, distribution of indications, pooled detection rate, pooled total enteroscopy rate, and composition of positive findings were extracted and/or calculated. In addition, the data involving DBE-associated complications were analyzed. Indications were defined as the primary reasons for DBE. DBE findings that could explain the symptoms of the patient and resulted in a change in therapeutic management were considered positive findings, and these included any clinically significant

findings in the entire GI tract. Total enteroscopy was defined when the entire small intestine was successfully visualized. Complications of DBE were defined as any adverse events that occurred during and after the procedures and were divided into minor and major categories. Minor complications included GI symptoms such as nausea, vomiting, abdominal distension, and other transient and self-limiting symptoms. Major complications included any severe adverse events that required hospitalization and/or an endoscopic or surgical intervention and/or contributed to the death of the patient.

Results

A total of 66 English-language original articles involving 12,823 procedures were included. Suspected mid-gastrointestinal bleeding was the most common indication (62.5 percent), followed by symptoms and signs only (7.9 percent), small intestine obstruction (5.8 percent), and Crohn's disease (5.8 percent). The pooled detection rates were as follows: suspected mid-gastrointestinal bleeding (68.1 percent), symptoms and signs only (68 percent), Crohn's disease (53.6 percent), and small intestine obstruction (63.4 percent). The overall detection rate was 85.8 percent. Inflammatory lesions (37.6 percent) and vascular lesions (65.9 percent) were the most common findings, respectively, in suspected mid-gastrointestinal bleeding patients of Eastern and Western countries. The pooled total enteroscopy rate was 44 percent by combined or antegrade-only approach. The pooled minor and major complication rates were 9.1 percent and 0.72 percent, respectively.

The researchers concluded that the detection rate and complication rate of DBE are acceptable. They found that DBE is a valuable modality, with a pooled detection rate of 68.1 percent for all small intestinal disease. Inflammatory lesions and vascular lesions are the most common findings in patients with suspected mid-gastrointestinal bleeding in Eastern and Western countries, respectively, according to DBE. Although DBE failed to identify a proportion of lesions, they consider that the performance of DBE is acceptable because the symptoms of a significant proportion of patients without positive findings would not recur during follow-up. They noted that DBE is considered to be a safe procedure with few complications, most of which are minor.

In an accompanying editorial, Andrew S. Ross, MD, Digestive Disease Institute, Virginia Mason Medical Center, Seattle, Wash., stated, "...we finally have composite large-scale data to support what we have suspected - DBE performed in appropriately selected individuals is a highly useful and extremely safe clinical tool that can be used for a variety of indications for deep enteroscopy. Although it is clearly an improvement over technologies of the past, DBE is not without its limitations and does not provide an answer in every patient. No amount of data can replace clinical vigilance and long-term follow-up. In the case of small-bowel disorders and obscure GI bleeding in particular, it is up to us as endoscopists to selectively choose from the now-myriad selection of devices within our toolbox that can help us to solve what is often a vexing clinical problem."

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About the American Society for Gastrointestinal Endoscopy

Since its founding in 1941, the American Society for Gastrointestinal Endoscopy (ASGE) has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with nearly 12,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit www.asge.org and www.screen4coloncancer.org for more information and to find a qualified doctor in your area.

About Endoscopy

Endoscopy is performed by specially-trained physicians called endoscopists using the most current technology to diagnose and treat diseases of the gastrointestinal tract. Using flexible, thin tubes called endoscopes, endoscopists are able to access the human digestive tract without incisions via natural orifices. Endoscopes are designed with high-intensity lighting and fitted with precision devices that allow viewing and treatment of the gastrointestinal system.