



Improving suboptimal bowel prep using a novel on-demand overtube device: an in vivo animal study

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Inadequate bowel preparation for a colonoscopy can occur in more than 25% of cases.¹ This is associated with increased patient cost because of the need for additional examinations, reduced diagnostic yield, and increased risk of interval colorectal cancer.^{2,3} A recently developed, novel overtube (OT) device (IzoScope; IzoMed Inc, Irvine, Calif, USA) can safely and efficiently seal a compartment of the colon to administer targeted fluid lavage (eg, right colonic enema). We performed a proof-of-concept study using a single domestic pig to describe the use of this device to address segmental suboptimal bowel preparation and improve visibility during colonoscopy (Video 1, available online at www.giejournal.org).

The right side of the colon was intubated using a standard adult colonoscope, and poor bowel preparation was seen with opaque liquid stool precluding the visualization of the mucosa, consistent with a Boston Bowel Preparation Scale subscore of 0 (Fig. 1).⁴ The OT device was then deployed. The device consists of a soft, flexible sheet that can be quickly wrapped around and sealed along the axis of the colonoscope, essentially creating an on-demand OT without the need for preloading or scope withdrawal. The device deploys a balloon on the end of the OT, behind the tip of the endoscope, to create an anchor for the OT in the colon (Fig. 2A, *arrow*). A second balloon on a catheter extends beyond the endoscope and can be used to seal the proximal end of the compartment (Fig. 2, *arrowhead*). The maximal balloon diameter is 60 mm and contains a pressure valve set to 60 mm Hg to prevent overdistension of the balloon or colon. The colonoscope was then removed with the OT maintained in the target area of the colon. Fluid was then instilled through the inner lumen of the OT (Fig. 2, *star*) to effectively

perform a right side of the colonic enema. One liter of normal saline was lavaged into the right side of the colon and drained via gravity. The distal balloon catheter was then withdrawn to allow for complete lavage and also provide additional cleansing of the mucosa through a squeegee-like effect (Fig. 3). The colonoscope was then reinserted and mucosa was inspected. Bowel preparation had markedly improved, consistent with a BBPS subscore of 3 (Fig. 4). In this initial experiment, with no prior experience with the device, the total time to complete cleansing was 23 minutes (5 minutes to reach the target area in the colon, 7 minutes to install the device and advance it to the target area, 10 minutes to lavage and drain the colon using gravity, and 1 minute for reinsertion of the colonoscope).

Using the novel OT device presented here, we were able to improve segmental bowel preparation, particularly at the right side of the colon which is not typically accessible to conventional enema. This device has multiple distinct features when compared to currently available over-the-scope cleansing systems, which require removal of the colonoscope and reinsertion.⁵ In addition, the mechanism of these devices is similar to colonoscopic irrigation with a stronger jet of fluid and larger suction port. The device depicted in this video floods and drains the colon through a large port as wide as the colonoscope, allowing clearance of more solid particles. Currently, the OT device is not approved by the U.S. Food and Drug Administration.



Figure 1. Initial examination of the right side of the colon showing inadequate preparation with opaque liquid and stool precluding the visualization of the mucosa.

Abbreviation: OT, overtube.

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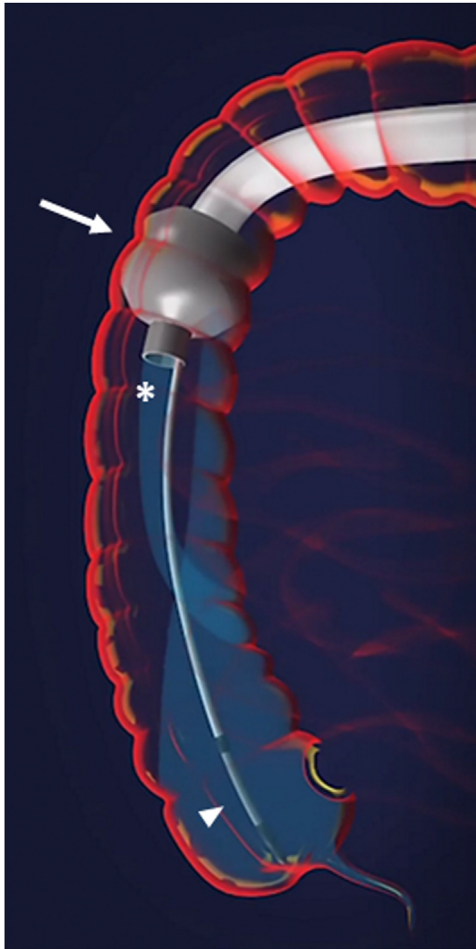


Figure 2. Schematic representation highlighting the structural features of the overtube device, which include a balloon used to secure the overtube (*arrow*), a balloon-tipped catheter that aids in creating a sealed compartment (*arrowhead*), and the inner lumen through which fluid was instilled (*asterisk*).

Our study is limited by a proof-of-concept design and use of a single animal. Data on safety, cost, and learning curve are yet to be determined. While additional studies are needed, this technology of on-demand OT during colonoscopy to optimize mucosal visualization may potentially reduce the need to cancel or reschedule procedures when suboptimal preparation is encountered.

DISCLOSURE

Dr Rajan discloses an intellectual property relationship with Medtronic and is a consultant for Olympus. Dr AbiMansour disclosed no financial relationships. Funding for this work was provided by IzoMed Inc, Irvine, California.

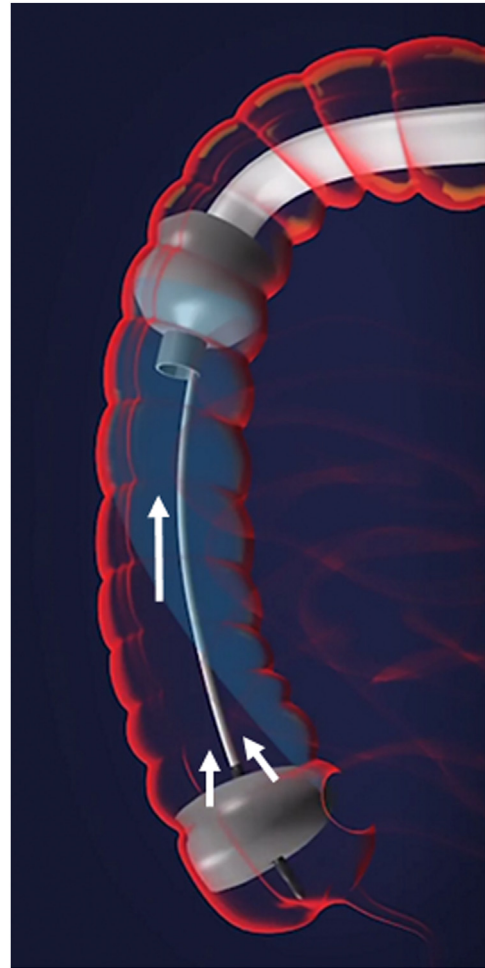


Figure 3. Use of the balloon-tipped catheter to achieve complete lavage and mucosal cleaning via a squeegee effect.



Figure 4. Right side of the colon after enema was performed, showing significantly improved mucosal visualization.

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