Assessing implementation strategy and learning curve for transoral incisionless fundoplication as a new technique

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We read with great interest the article by Bomman et al. regarding the transition to transoral incisionless fundoplication (TIF) in an outpatient setting. TIF is a minimally-invasive endoscopic fundoplication technique used for gastroesophageal reflux disease (GERD). It was first introduced in 2005, approved by the Food and Drug Administration in 2007, and is performed using an EsophyX device (EndoGastric Solutions Inc., Redmond, WA, USA). The procedure and the device to perform TIF have evolved over the years. TIF procedures currently in practice include TIF 2.0 and cTIF (concomitant TIF with hiatal hernia repair). TIF 2.0 is reserved for patients with hiatal hernia size of ≤2 cm or Hill grade ≤2; cTIF is performed in patients with hiatal hernia size >2 cm or Hill grade >2, similar to the surgical fundoplication performed in this patient population. The technique aims to create a full-thickness, 270° to 300° circumference esophagogastric fundoplication with the device, elongating the intra-abdominal esophagus by 2 to 4 cm. There is growing evidence of the safety and efficacy of this procedure.

In a previous issue of Clinical Endoscopy, Bomman et al. reported their experience with 30 cases, where TIF (TIF 2.0) was adapted as a new procedure at a tertiary U.S. center in a stepwise approach from an inpatient operating room to a fully outpatient procedure. As the first step, three procedure sessions (nine cases) were performed in the operating room with overnight admission and esophagography. In the second step, TIF was transitioned to being performed in an endoscopy suite as a complete outpatient procedure with same-day discharge. The technical success rate of the procedure was 97%; no major adverse events were reported. There was no difference in the 30-day readmission rates between the two groups (one case in each group). The procedure time decreased with more experience and as it transitioned from the operating room to the outpatient endoscopic suite.

Only one technical failure occurred in a patient who had undergone prior sleeve gastrectomy. Performing full-thickness esophagogastric fundoplication using TIF after sleeve gastrectomy can be challenging. Even with a skilled endoscopist, this may not be technically feasible, given that the left fundus may not be adequate for TIF. Unfortunately, data on such cases are limited. An alternative option of performing TIF procedure before bariatric surgery is yet to be supported with evidence. Shah et al. successfully demonstrated a case of same-session TIF followed by endoscopic sleeve gastroplasty in 2020 in a patient with GERD and obesity. Bomman et al. demonstrated that TIF was technically successful in four patients with prior altered anatomy (hernia repair, hernial repair with partial fundoplication). In addition, TIF was successfully performed in
patients after peroral endoscopic myotomy. Finally, the authors also assessed the impact of experience and training on the duration of the procedure during the transition. Bomman et al. reported a consistently lower procedure time after 20 procedures, with an average time of 65 min; however, we would have appreciated a more thorough assessment of the learning curve. In 2021, Dbouk et al. assessed the learning curve for TIF in 72 procedures performed with clearly defined endpoints for proficiency (defined as the creation of TIF ≥270° in circumference and >2 cm in length), minimum mean time for plication (placing a set of two fasteners), and efficiency (minimum number of TIF procedures to achieve the minimum mean TIF duration). The study results showed that proficiency was achieved after 18 to 20 TIF procedures, efficiency for performing plications after 26, and maximum efficiency for the whole procedure after 44; the time decreased significantly to 39.4 minutes. It would be interesting to compare the proficiency and efficiency endpoints for performing TIF in different settings and specialties, such as foregut surgeons, general gastroenterologists, or therapeutic endoscopists.

In conclusion, TIF is a minimally-invasive endoscopic fundoplication technique with growing evidence of its efficacy and safety in selected patients with GERD. This study demonstrated that TIF can be safely and successfully transitioned to an outpatient endoscopic suite after standardized training of new users. However, an experienced and skilled endoscopist should be consulted for anatomically challenging cases, such as sleeve gastrectomy, to assess the feasibility of the procedure.

Conflicts of Interest
Dr. Thompson has served as a consultant for Apollo Endosurgery, Boston Scientific, Enterasense, EnVision Endoscopy, Fractyl, USGI Medical, Medtronic/Covidien, Fractyl, Fujifilm, Lumendi, Xenter, Olympus/Spiration, and GI Dynamics; has served as an advisory board member for USGI Medical and Fractyl; has received research grants and support from USGI Medical, Apollo Endosurgery, Boston Scientific, ERBE, Fujifilm, Lumendi Olympus/Spiration, Aspire Bariatrics, and GI Dynamics; has served as a general partner for Blueframe Healthcare; has served as a founder for Enterasense, EnVision Endoscopy, and GI Windows; and holds stock and royalties for GI Windows. Dr. Haseeb has no conflicts of interest to declare.

Author Contributions
Conceptualization: MH, CCT; Data curation: MH; Formal analysis: MH; Supervision: CCT; Validation: MH, CCT; Visualization: MH, CCT; Writing—original draft: MH; Writing—review & editing: MH, CCT.

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