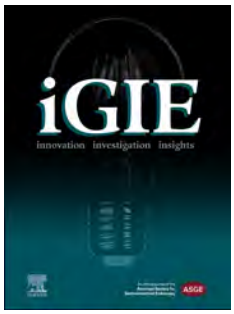

A Novel Approach to Endoluminal Antral Gastroplasty Using a Modified Gastrostomy Tube and Laparoscopic Stapler

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September 23rd, 2023

Christopher C. Thompson, MD, MSc, FASGE, FACG, AGAF, FJES
Editor-in-Chief
iGIE

Dear Dr. Thompson,

We wish to submit an *iNNOVATIONS* manuscript for publication in *iGIE* entitled "**A Novel Approach to Endoluminal Antral Gastroplasty Using a Modified Gastrostomy Tube and Laparoscopic Stapler**," co-authored by Mark Hanscom and Andrew Storm.

The field of bariatric endoscopy continues to evolve with the introduction of new technologies and techniques. Endoscopic sleeve gastroplasty (ESG) results in proven weight loss through the imbrication and reduction of gastric volume; however, long-term durability remains a concern, and as such endoscopic techniques that can more closely mirror surgical outcomes are of interest. Potential solutions include targeting the gastric antrum, which has emerged as a potential novel therapeutic subject, and the use of more durable imbricating devices.

This study demonstrates a novel approach to endoluminal antral gastroplasty using a modified gastrostomy tube (Endo-TAGSS, Shawnee, KS) and laparoscopic stapler. The Endo-TAGSS device is placed similar to a standard, pull-through percutaneous gastrostomy tube and allows for endoluminal access using large caliber laparoscopic instruments, such as a 12 mm surgical stapler.

Our article will be of particular interest to your readers because it highlights a new technology on the cutting-edge of endoluminal surgery. We believe your readers will find our article to be innovative and hypothesis-generating, in its demonstration of a new technology that has the potential to introduce a new suite of tools and endoscopic techniques.

The submitted manuscript was previously presented during the ASGE Video Plenary at DDW 2023. In addition, it was considered for publication in *videoGIE*. It is on the recommendation of their Managing Editor, Dr. Stephanie Kinnan, that we now submit for consideration in *iGIE*. The video has been transferred at their recommendation, and if accepted, we would be pleased to perform any additional revisions needed to meet the standards and requirements of *iGIE*. For full disclosure, we have also included in the submission a copy of the peer reviewers' comments with our point-by-point response.

Thank you for your consideration.

Sincerely,
Mark Hanscom
Mark Hanscom, M.D.

A Novel Approach to Endoluminal Antral Gastroplasty Using a Modified Gastrostomy Tube and Laparoscopic Stapler

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Author Contribution(s): BAD and AS were involved in the conceptualization of the manuscript; MH, LS, and SK in the Data Curation and Investigation; MH, BAD, and AS in performing the procedure; all authors in the Methodology, Writing (Original Draft), Writing (Review & Editing); BAD and AS in the Supervision.

Please see separate “Disclosures” form for a full list of authors’ disclosures and conflicts of interests.

Keywords: obesity, endoscopic antral gastroplasty, combined endoscopic-laparoscopic procedures, percutaneous intragastric trocar, weight gain.

Abstract

Background and Aims: To demonstrate a novel approach to endoluminal antral gastroplasty using a transgastric trocar (Endo-TAGSS, Shawnee, KS) and laparoscopic non-cutting stapler.

Methods: Non-survival study performed successfully in two domestic pigs. Following placement of the Endo-TAGGS device, a laparoscopic stapler was introduced through the trocar and used to place staples along the anterior wall, greater curvature, and posterior wall, resulting in imbrication and reduction of the gastric antrum. Post-procedure, a diagnostic necropsy was performed.

Results: The endoluminal antral gastroplasty was performed successfully without immediate complications.

Conclusions: Endo-TAGSS-assisted endoscopy can overcome limitations of current endoscopic techniques by allowing for use of larger diameter laparoscopic surgical devices in endoscopy, which permitted antral gastroplasty in this study

Introduction: The field of bariatric endoscopy continues to evolve with the introduction of new technology and refinement of endoscopic techniques. Here, we demonstrate a novel, cutting-edge approach to bariatric endoscopy that uses a modified gastrostomy tube or intragastric trocar (Endo-TAGGS, Shawnee, KS) to permit endoluminal access with large caliber laparoscopic devices, specifically a laparoscopic non-cutting stapler. The laparoscopic stapler was introduced through the trocar and used to place staples along the anterior wall, greater curvature, and posterior wall of the stomach, resulting in imbrication and reduction of the gastric antrum. In the future, such techniques could overcome limitations related to current endoscopic technologies.

Background:

The Apollo endoscopic sleeve gastroplasty (ESG) is one technique that results in proven weight loss through the imbrication and reduction of gastric volume, with mean excess weight loss (EWL) and total body weight loss (TBWL) of 49.2% and 13.6%, respectively, at 52 weeks in a pivotal prospective study.[1] More recently, the gastric antrum has gained interest as a potential novel therapeutic target for intraluminal weight loss therapy. The gastric antrum represents the motor function of the stomach, and as such alteration to the antrum could result in changes that impact motor function and result in enhanced satiety and satiation.[2-3] However, long-term durability of ESG remains a concern, with one study showing that just 61% of patients maintained TBWL of 10% at 5 years.[4] Endoscopic techniques for antral reduction through per oral suturing also have limitations with regards to long-term durability, as suture dehiscence has been demonstrated as soon as 8-14 months post procedure.[5] Consequently, endoscopic techniques that more closely mirror surgical outcomes are needed. One potential solution is a combined endoscopic/laparoscopic approach, in which endoscopic access permits the use of surgical

instruments, such as a laparoscopic stapler. This combined approach could theoretically improve durability to approach that of laparoscopic sleeve gastrectomy (LSG), while reducing the risks and recovery of a fully laparoscopic approach. Given access to a novel transgastric trocar (Endo-TAGSS), which permits the use of a surgical stapling device to remodel the stomach, we investigated the use of non-cutting laparoscopic stapler to reduce the gastric antrum.

Methods: We demonstrated a novel approach to endoluminal antral gastroplasty using a modified gastrostomy tube and laparoscopic stapler. The procedure was successfully carried out in two domestic pigs following approval by the Mayo Clinic Institutional Animal Care and Use Committee and in accordance with the American Physiological Society guidelines for the care of animals. The animals were started on a liquid diet 48 hours prior to the procedure, transitioned to a clear liquid diet 24 hours prior, and kept *nil per os* on the day of intervention. Induction was performed with intramuscular telazol (5 mg/kg) and xylazine (2 mg/kg), followed by intubation and mechanical ventilation, with maintenance anesthesia using 2% isofluorane.

First, the Endo-TAGSS device was placed using a technique analogous to pull-through placement of a standard percutaneous endoscopic gastrostomy (PEG) tube (**Figure 1**). It is important to orient the Endo-TAGGS device facing towards the antrum, such that antral mucosa can be pulled easily through the perpendicular jaws of the stapler. The 18-gauge introducer needle can then be inserted, using a gastroscope situated within the stomach lumen to locate a safe and suitable window using palpation and transabdominal illumination, similar to with PEG tube placement. A guidewire is then passed through the introducer, grasped by the gastroscope, removed transorally, and affixed to the Endo-TAGGS device that is then pulled into the stomach and through the abdominal wall

(**Video 1**). The device has a 12 mm inner diameter allowing endoluminal access with 12 mm laparoscopic surgical instruments (**Figure 2**). A 12 mm laparoscopic non-cutting stapler (Ethicon Inc., Raritan, NJ) is then inserted through the trocar and into the stomach (**Figure 3**). Using a transoral gastroscope concurrently situated in the stomach lumen, a helical endoscopic tissue grasper (Apollo Endosurgery, Austin, TX) is used to secure and retract tissue into the jaws of the stapler (**Figure 4**), which is fired to create full-thickness imbrications of the stomach using 45 mm staples (Ethicon-Echelon Flex, Cincinnati, OH, USA). **(Figure 5)**. The procedure was repeated three times along the anterior wall, greater curvature, and posterior wall of the antrum, sparing the lesser curvature, until the stomach was reduced and tubularization achieved. At the end of the procedure, the trocar is removed, and the defect closed using either endoscopic sutures or an over-the-scope-clip.

Results: The endoluminal antral gastroplasty procedure was performed successfully in two porcine models without immediate complications. Endoscopic images demonstrated sequential staple lines leading to effective reduction and tubularization of the antrum (**Figure 6**). During necropsy, full-thickness imbrications were found at the staple sites. There was no evidence of perforation at the staple site or trocar placement (**Figure 7**).

Discussion: In conclusion, we demonstrate a novel approach to endoluminal antral gastroplasty using a transgastric trocar (Endo-TAGSS) and laparoscopic non-cutting stapler. The utility of this trocar has been previously demonstrated in other endoluminal procedures including endoscopic fundoplication.[6-12] The door opened by Endo-TAGSS can overcome limitations of current endoscopic techniques by allowing for use of larger diameter laparoscopic surgical devices in

endoscopy, which permitted antral gastroplasty in this study. Further studies are needed to refine the technique and to explore the weight loss potential which is anticipated through targeted gastric antral reduction procedures.

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Figures

Figure 1. Insertion of the percutaneous intragastric trocar (PIT) using a technique analogous to pull-through placement of a standard percutaneous endoscopic gastrostomy tube. A needle is inserted into the stomach under endoscopic vision (left), which is then grasped with a snare (center), and attached to the PIT, which is then pulled transoral into the stomach and out the abdominal wall (right).

Figure 2. The fully assembled PIT has a 12 mm internal lumen that allows for passage of large diameter instruments.

Figure 3. In a two-operator procedure, one is tasked with controlling the non-cutting stapler passed via the PIT (bottom right), while the other visualizes and guides the stapler using a gastroscope situated in the stomach (top).

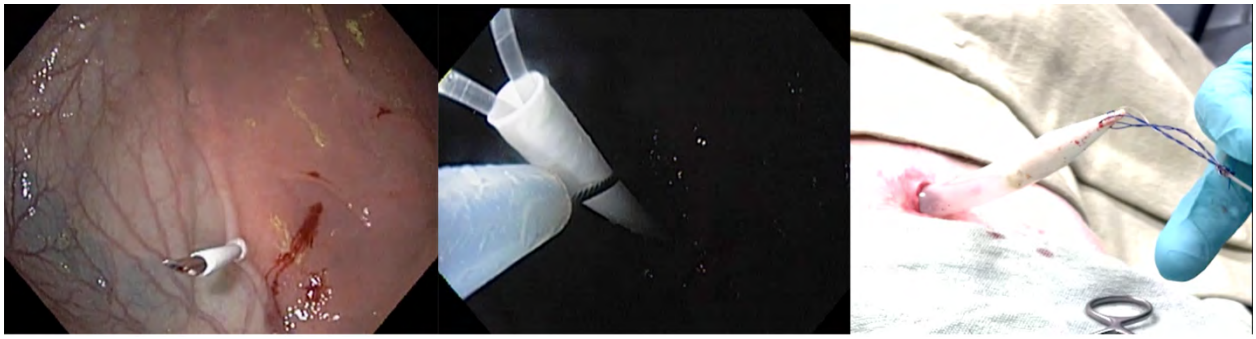
Figure 4. The helical endoscopic tissue grasper is used to secure and retract tissue into the jaws of the non-cutting stapler before firing to create a full-thickness gastric imbrication.

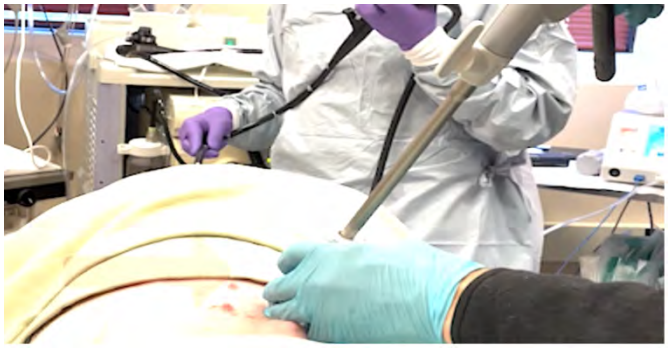
Figure 5. Following stapler firing, a full-thickness imbrication is created in the gastric antrum. The procedure is then repeated multiple times along the anterior wall, greater curvature, and posterior wall of the stomach.

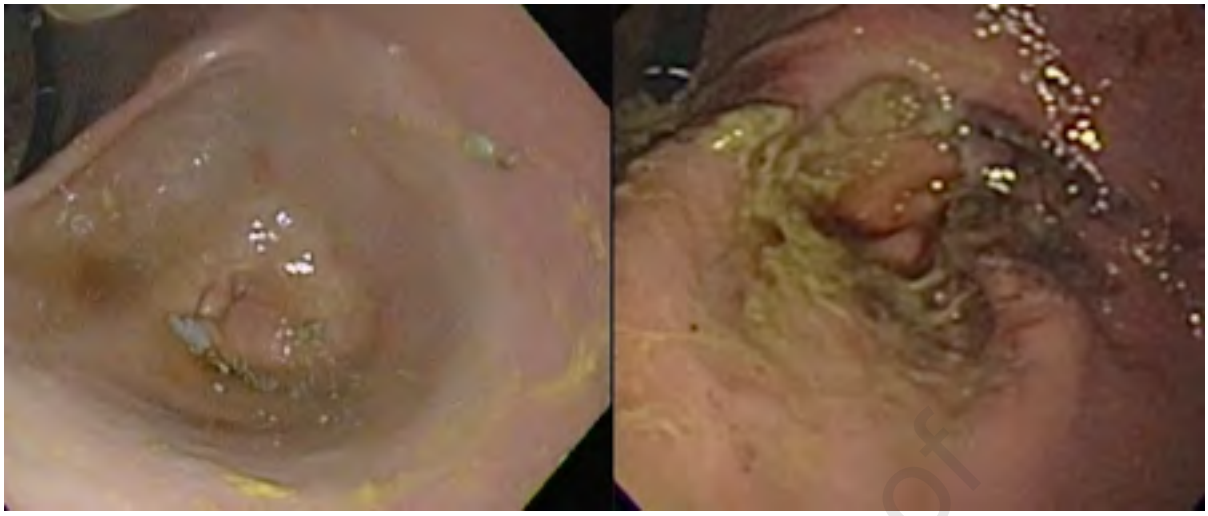
Figure 6. Endoscopic images pre-gastroplasty (left) and post-gastroplasty (right) demonstrating tubularization and reduction of the gastric antrum.

Figure 7. Necropsy findings demonstrating multiple lines of full-thickness staples along the gastric antrum.

Video 1. Endoluminal antral gastroplasty using a modified gastrostomy tube and surgical stapler.







Acronyms and Abbreviations

- ESG = endoscopic sleeve gastroplasty
- EWL = excess weight loss
- PIT = percutaneous intragastric trocar
- TBWL = total body weight loss

AE comments:
We thank the authors for this cutting edge (if not bleeding edge) technology that they presented and we congratulate them for their work. Given the very experimental nature of this device iGIE may be the best podium to present this innovative idea. Congratulations on a video very well made. Given the clearly innovative nature, we think it would be an excellent submission for iGIE.

Reviewer #1: I reviewed the submission on combining a modified gastrostomy tube with a laparoscopic stapler to achieve antroplasty in 2 pig models. Below are my comments/need for clarification:

1- Is it possible for authors to cite a reference supporting the info presented regarding 'alteration to the antrum could result in changes that impact motor function and result in enhanced satiety and satiation'. If not, would start the sentence with: 'We hypothesize...'.
We have added two references supporting this statement as requested (new references 2-3).

2- The dilemma/limitation presented regarding the concern for long term durability of ESG is not well positioned to introduce EndoTAGSS as a potential solution per se. Long term data on EndoTaGSS antroplasty is lacking, unlike data on LSG. Assuming that LSG and EndoTAGSS have comparable durability and outcome remains a hypothesis to be supported by studies that are lacking currently. Would rephrase this part to have a more targeted positioning about the dilemma/limitation of prior techniques that EndoTAGSS might answer.
We agree that long term dating is lacking and have updated the introduction to reflect the more targeted positioning as suggested.

3- The reference 3 cited: 'Runge, Chiang et al. Endoscopic ultrasound-directed transgastric ERCP (EDGE): a retrospective multicenter study. Endoscopy 2021.' Does not support the info presented. Would make sure the right reference is cited to support the info presented.
We thank the reviewer for catching this oversight and have updated the manuscript with the correct refence.

4- How many staples were placed in total? How many of these fired as desired and how many misfired or didn't grab full thickness, if any? and is it possible to comment on the size of the staples used?
For this proof-of-concept study, we placed three rows of staples (anterior wall, greater curvature, and posterior wall). Two of these fired as desired, while one did not capture full-thickness, likely because of too much tissue grasped within the jaws of the stapler. The optimal amount of tissue imbricated at a time remains to be determined. The video was updated to highlight this point. The exact size of the staples is 45 mm and cartridges are Ethicon-Echelon Flex, Cincinnati, OH, USA.

5- In the narration: after 'satiation', it appears that the 'However' was recorded alone and disturbed the flow of narration. Would narrate the whole sentence in synchronous time: 'However, antrum reduction through per oral suturing,...)
We thank the reviewer for catching this inconsistency. This was updated.

6- It is noticeable that the first endoscopic view of the pig stomach shows some bleeding in the stomach. Was a previous trial to introduce the needle made prior to the current one recorded? The possible corresponding first entry point is also seen on the pig abdomen externally next to the gastrostomy tube being inserted, and a possible tear is seen on necropsy at the same site. How easy was it to find a window for insertion? and what is the size of the needle that was inserted?

The bleeding was a consequence of mucosal irritation from pig ingestion of debris prior to the procedure and subsequent endoscopic clearing of the stomach of debris at the start of the procedure. Of note, it was not related to needle introduction and no previous trials were performed during this study. Finding an insertion window was done similar to with placement of a PEG tube using palpation and illumination and was not challenging. Likewise, a standard 18-gauge introducer needle was used, similar to with placement of a PEG tube.

7- Any comment on the angle between the helix handled by the endoscopist and the stapler handled by the 'laparoscopist'? How easy is it to bring the tissue with the helix towards the stapler to ensure a full thickness. And how does the angle of the inserted gastrostomy limit the maneuverability of the device. Would be worth commenting.

The reviewer raises an important point, which was briefly discussed in the video (1:35-1:50). Orienting the stapler perpendicular to the tissue grasped with the helix greatly helps bring the tissue into the jaws of the stapler. This does appear to have a learning curve based on initial experiments and is facilitated by appropriate positioning of the gastrostomy. We have updated the manuscript to make comment.

8- How many helix turns were done? How many staples were fired? What distance was taken between each round of staples?

No set amount of helix turns was performed. Rather, helix turns were made until full thickness tissue was acquired, represented by a “swirling” of the mucosa. Three rows of staples were fired, also described above. No set distance was taken between each round of staples, however, we intended to target the anterior wall, greater curvature, and posterior wall in order to effect tubularization.

9- Two pig models were used. What were the differences in the techniques, any challenges faced in one of the models and not in the other? What lesson was learned from the first model and was applied to the second?

In the second pig model, argon plasma coagulation (APC) was also used to de-epithelialize the antrum mucosa prior to stapling. Otherwise, the technique was the same, with similar challenges. In both models, the importance of orientation was confirmed in order to facilitate pull through of the gastric mucosa into the jaws of the stapler. We did attempt to “bridge” the greater and lesser curvature in the second model, using two forceps with a double channel endoscope to approximate the mucosa, but found the jaws of the stapler too narrow to accommodate both bites at the same time.

10- Is it possible to show an endoscopic view of the scope maneuvered through the stapled antrum into the duodenum ensuring patency?

Unfortunately, we do not have recorded video of this maneuver.

11- At time 4:48: multiple sharp edges of staples could be seen to the right of the screen. Were these misfired staples that didn't capture full thickness? If so would play the video at regular speed and comment on it and what could be done to prevent it. Otherwise please explain the appearance.
The sharp edges do represent misfired staples that did not capture full thickness, because of the amount of tissue in the grasping device that was attempting to be stapled. This highlights the importance of planning when performing the antral gastroplasty, and attention to the size of each bite. The video was paused at this section, with appropriate commentary added.

12- The gastrostomy tube appears to be very close to the liver edge on necropsy. Would mention the precautions taken towards surrounding organs (safety rules for peg tubes) while finding a window and introducing the needle since it is still part of inserting the modified gastrostomy tube.
The manuscript was updated with this information.

13- Would suggest using the term 'Antroplasty' or 'Antral gastroplasty' rather than 'gastroplasty' to highlight the fact that it is limited to the antrum.
The manuscript was updated with the suggested language.

Reviewer #3: The authors present their video case in 2 porcine models of the use of a new, non-FDA approved device called EndoTAGSS, a 12mm inner diameter port/PEG. The authors propose that this may allow for the use of a laparoscopic stapler to perform a stapled gastroplasty of the antrum only.

The technique proposed and the video submitted left me with many questions.

1) In surgical sleeve gastrectomy, some pursue an antrum sparing technique while others do take part of the antrum (which has been shown to increase rates of postoperative GERD after sleeve). In the proposed technique, do the authors propose that patients should undergo this stapled antroplasty followed by traditional ESG with suture? Would that be a two part procedure that occurs after removal of the EndoTAGSS device?
The reviewer raises an excellent question. The most optimal technique using the EndoTAGGS device remains to be determined. Given the current landscape and technical limitations, we do believe a two-stage technique (although both perhaps occurring during the same-session) makes sense, wherein stapled antroplasty is performed to provide additional weight loss and durability, followed by a traditional ESG. The current study is intended to be hypothesis-generating and more studies will be needed to determine effectiveness and safety in a human population. We have updated the language of the introduction to reflect this more targeted positioning of the manuscript.

2) What patients would benefit from this approach that requires a port placement? Given that the staples are full thickness, what is the risk of injury to colon, splenic vessels, or other nearby anatomy? At that point, why not just have the patient undergo a laparoscopic sleeve gastrectomy?

The exact role of a combined endoscopic/laparoscopic approach remains to be determined, and further studies including human studies are needed. One possible scenario would be for patients who desire more weight loss than current endoscopic techniques can provide, where such an approach could better approximate surgical outcomes but lessen the immediate post-operative recovery period. The procedural risks also remain to be determined and are the focus of further survival studies using the Endo-TAGGS device. In this non-survival study, no immediate complications were noted.

3) There was no mention in the manuscript about IACUC approvals or animal protocols related to the use of the porcine models. Please see vGIE requirement around this: https://www.videogie.org/content/authorinfo

The procedure was approved by the Mayo Clinic Institutional Animal Care and Use Committee and in accordance with the American Physiological Society guidelines for the care of animals. Reference is made in lines 48-51 in the manuscript. We would be happy to provide additional information if more specific information is needed.

4) Is the product on market? Close to market? Just started and looking for a use case? Clarity on the intended use of the device would be helpful. Otherwise, it seems that another approach to doing this would be to insufflate the stomach, place T tacks and then use a breakaway sheath to introduce the stapler, followed by endoscopic closure all in one go. It is hard to see what the need for this device is.

The Endo-TAGGS device is not yet cleared by the FDA or offered for sale. It is currently undergoing preclinical trials to establish efficacy and safety in porcine models before its first in human case. The ultimate intent is to provide a safe and streamlined means of transabdominal access to allow for novel methods of treatment of intraabdominal diseases.