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Learning curve analysis of endoscopic sleeve gastroplasty in standardized Bama miniature pigs: an animal experiment

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To the Editor: Endoscopic sleeve gastroplasty (ESG) is a recently developed incisionless transoral gastroscopic bariatric procedure that can shrink the gastric cavity into a tubular structure similar to the capacity of surgical sleeve gastrectomy by means of endoscopic full-thickness sutures. Clinical practice has proven its safety, durability, minimal invasiveness, and long-term weight loss effects, which are close to those of bariatric surgery.[1]

The ESG procedure requires the OverStitch system (Apollo Endo-surgery, Austin, TX, USA), a commercially available endoscopic suturing device for full-thickness sutures in the stomach to reduce the length and width of the stomach; however, the operation may be relatively complicated, affecting the promotion of the procedure. Therefore, many endoscopists are reluctant to perform ESG because they believe that ESG requires considerable time-consuming training and a long learning curve. There have been two studies on the ESG learning curve, and the difference in the results from the limited studies is relatively large. The number of introductory cases for the ESG learning curve has been reported as 7–9 and 29–38 in these two studies, respectively,[2,3] which may be related to the basic conditions of different patients. The experience and medical background of the endoscopist also have a great influence. Due to the difficulty of the technique and increasing interest in the implementation of an ESG training program among hospitals, it is necessary to determine the baseline number of procedures necessary for an endoscopist to be considered fully qualified.

We conducted an animal experiment that focused on procedure development, reproducibility, safety, and learning curves. From January 2020 to December 2020, we selected 26 male Bama miniature pigs from the same medical laboratory animal breeding center with similar genetic pedigrees five times to participate in this prospective study. These Bama minipigs were 8–10 months old and weighed 19–24 kg, which is within the healthy weight range. The stomach of Bama minipigs is similar to that of humans in terms of structure, size, and shape. These animals were dewormed and quarantined in a timely manner and reached the qualification standard for laboratory animals.

This study was approved by the Institutional Animal Care and Use Committee of Beijing Friendship Hospital, Capital Medical University (IRB No. 18–7004). All applicable institutional and national guidelines for the care and use of animals were followed.

All ESG procedures were performed by an experienced endoscopist who had performed thousands of advanced endoscopic treatments, including endoscopic submucosal dissection, endoscopic retrograde cholangiopancreatography, and peroral endoscopic myotomy, endoscopic ultrasound-guided fine-needle aspiration. Before performing ESG, he attended one day of dedicated theoretical study on ESG and 2 h of ESG practice on an isolated pig stomach. In addition, the anesthesia and assistant teams were consistent in each process. Members of the assistant team were not familiar with ESG or the OverStitch device before the project started.

ESG was performed in a conventional manner. In brief, a classical triangular pattern was performed where each suture consisted of two rows that traversed the anterior wall, greater curvature, and posterior wall. Each row consisted of 5–6 closely spaced bites depending on the available area and interspace. Each time the stomach wall was sutured to the tissue, we used a cinch to tighten the suture gap and create a fold. On average, each ESG included 3–5 folds. In all cases, the antrum and lesser gastric curvature were not sutured, and no reinforcement sutures were used. Finally, a gastroscopy was performed

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to confirm the final shape of the gastric tube and rule out any potential and immediate complications.

The following variables were prospectively recorded: operative time, the total number of sutures used during each operation, number of stitches for each suture, weight, body length, chest and waist circumferences of each Bama minipig, and whether there were complications or the occurrence of death.

The cumulative sum (CUSUM) technique for the assessment of a learning curve was applied to explore the relationship between operative time and the case number of ESG procedures. The minipigs were divided into two groups according to the cutoff point of the CUSUM score: group 1 (≤cutoff value) represented the early experience group, and group 2 (>cutoff value) represented the late-experience group. Statistical analysis was performed using SPSS Statistics (software version 26.0, IBM Corporation, Armonk, USA), and a P-value <0.05 was considered statistically significant.

A graph of the raw operative times plotted from each case arranged in chronological order is shown in Supplementary Figure 1A, http://links.lww.com/CM9/B222. Once the operative times were arranged, we calculated the CUSUM values for each case to obtain a graph for the learning curve [Supplementary Figure 1B, http://links.lww.com/CM9/B222]. Then, we analyzed the learning curve of the average operative time per suture for each ESG operation [Supplementary Figure 1C, http://links.lww.com/CM9/B222]. The length of the operation and case number of procedures led to a statistically significant cubic equation correlation ($R^2 = 0.891$, $P < 0.001$). We analyzed the learning curve and found that a decreasing point for the total operative time and the average operative time per suture began at the 5th and 8th operations, respectively. There was a relatively flat plateau between the 5th and 8th operations. After the 8th ESG operation, the total operative time and average operation efficiency of each fold showed progressive improvement.

The CUSUM plots revealed that the learning plateau period of ESG was cases 5–8, and the cutoff point of the learning curve was case 8; therefore, we divided animals into group 1 and group 2 according to case 8 [Table 1]. A comparison of the data between the two groups revealed that the total operative time, the total number of stitches, and average operative time per suture all improved, while the total number of sutures was not statistically significant. There were no significant differences in body length, weight, chest circumference, or waist circumference between the two groups of recipients.

The ESG operation went smoothly in all 26 animals. During the perioperative period, we noticed that the Bama miniature pigs were in a good state of mind, and the process of resuming the diet went smoothly. We observed the living conditions of the minipigs and compared the blood test results before and after the ESG operation. No infection, perforation, bleeding, or other complications occurred.

Although systematic procedures and goals have been developed for the ESG procedure, it is still very difficult to provide accurate and stable full-thickness sutures in the gastric cavity with the assistance of the OverStitch suture system.[4] However, taking the first step in learning the new technology and new equipment while performing endoscopic surgery has certain shortcomings. This is referred to as trial-and-error learning; it will not only increase the time of each procedure but may also increase the patient's discomfort and the risk of complications. In particular, in situations of intense working conditions and information overload, it is often difficult for endoscopists to adequately respond to address these limitations. Therefore, it is very meaningful to conduct theoretical training and simulated operations before performing operations on patients to better improve the ESG skill level of endoscopists. For an endoscopist with proficient endoscopy skills, a live animal model such as a pig model provides the most ideal and most realistic clinical scenario for performing ESG and can provide a completely immersive operation experience.[5]

The main limitation of our research may be the fact that the effects of training were evaluated only in animals; therefore, the application ability of this technique to humans by the same endoscopist is not clear. In addition, there are some differences between the stomachs of pigs and humans, which may lead to different complications (i.e., the mucosal layer of the pig's stomach is thicker, and

Table 1: Analysis of ESG operation data from the two groups.

Items	Group 1 (n = 8)	Group 2 (n = 18)	t values	P values
Body length (cm)	66.50 ± 4.04	67.67 ± 2.74	–0.865	0.396
Weight (kg)	21.52 ± 2.10	20.80 ± 1.69	0.930	0.362
Chest circumference (cm)	65.25 ± 2.71	66.00 ± 3.76	–0.506	0.617
Age (months)	9.00 ± 0.83	9.00 ± 0.86	0.115	0.909
Waist circumference (cm)	69.81 ± 2.17	68.78 ± 2.51	1.008	0.324
Total operative time (min)	88.75 ± 47.03	31.78 ± 6.57	3.412	0.011
Total number of sutures	3.50 ± 0.76	3.94 ± 0.64	–1.549	0.134
Total number of stitches	18.63 ± 1.77	21.33 ± 3.01	–2.355	0.027
Average operative time per suture (min)	27.86 ± 13.02	8.49 ± 1.91	4.188	0.004

Group 1 (cutoff value) represented the early experience group, and group 2 (> cutoff value) represented the late experience group. ESG: Endoscopic sleeve gastroplasty.

bleeding may be more infrequent and subtle). This feature is likely to conceal possible complications, such as bleeding, in the human body. A third limitation is that the process of learning and mastering this technology was evaluated only by an experienced endoscopist; therefore, the results cannot be generalized.

Overall, ESG is an endoscopic surgical technique with complex equipment and techniques. Before obese patients are treated, a sufficient preclinical learning process is required. The minipig model seems to be suitable for this purpose, and any center interested in implementing this operation should probably consider having a breeding space capable of accommodating and caring for at least 5–8 minipigs for practicing this procedure. According to the results of this study, for experienced endoscopy experts, we believe that at least 5–8 preclinical ESG procedures are required to master this technique. Although further research is needed to verify the current research results, we believe that the results can be used as guidelines for establishing ESG skills/training programs in centers around the world.

In summary, the learning curve of ESG assisted with the OverStitch device for an experienced endoscopist (thousands of advanced endoscopic treatments) is 5–8 cases. This learning curve can be used as the basis for performance guidance during training.

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Conflicts of interest

None.

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