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# Facilitating endoscopic submucosal dissection: the suture-pulley method significantly improves procedure time and minimizes technical difficulty compared with conventional technique: an ex vivo study (with video)

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## Abstract

**Background—**The lack of countertraction in endoscopic submucosal dissection (ESD) results in increased technical demand and procedure time. Although the suture-pulley method for countertraction has been reported, its effectiveness compared with the traditional ESD technique remains unclear.

**Objective—**To objectively analyze efficacy of countertraction using the suture-pulley method for ESD.

**Design—**Prospective ex vivo animal study.

**Setting—**Animal laboratory.

**Interventions—**Twenty simulated gastric lesions were created in porcine stomachs by using a standard circular template 30 mm in diameter. In the control arm (n = 10), ESD was performed by using the standard technique. In the suture-pulley arm (N = 10), a circumferential incision was made, and an endoscopic suturing device was used to place the suture pulley.

**Main Outcome Measurements—**The primary outcome of this study was total procedure time.

**Results—**The median total procedure time with the suture-pulley method was significantly shorter than the traditional ESD technique (median, 25% to 75%, interquartile range [IQR]: 531 seconds [474.3–549.3 seconds] vs 845 seconds [656.3–1547.5 seconds], *P* < .001). The median time (IQR) for suture-pulley placement was 160.5 seconds (150.0–168.8 seconds). Although there was a significantly longer procedure time for proximal versus middle/lower stomach lesions with traditional ESD (median, 1601 seconds; IQR, 1547.5–1708.8 seconds vs median, 663 seconds; IQR, 627.5–681.8 seconds; *P* =.01), there was no significant difference in procedure time for



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lesions of various locations when using the suture-pulley method. Compared with traditional ESD, the suture-pulley method was less demanding in all categories evaluated by the NASA Task Load Index.

**Limitations—**Ex vivo study.

**Conclusions—**The suture-pulley method facilitates direct visualization of the submucosal layer during ESD and significantly reduces procedure time and technical difficulty. In addition, the benefit of the suture-pulley method was seen for both simple and more complicated ESDs.

GI cancers are currently among the most common cancers worldwide, with more than 140,000 new diagnoses and more than 75,000 deaths due to esophageal, gastric, and colon cancers combined in the United States in 2013.[1] For laterally spreading early GI cancers in these locations, endoscopic submucosal dissection (ESD) allows curative en bloc resection, which would not be achievable with EMR. The primary component of ESD is dissection of supportive tissue between the mucosal and muscular layers. However, ESD is a technically demanding procedure, in part because of the lack of countertraction that elevates the mucosal flap to expose a dissection plane in the submucosal layer. This allows ESD to be performed safely and reduces the technical complexity of the procedure. In open or laparoscopic surgeries, assistants provide effective countertraction; this is not an option in traditional ESD. To overcome this drawback, the suture-pulley method was developed in 2011.[2] However, its advantages compared with those of the traditional ESD technique have not been studied and remain unclear.

The objective of this study was to assess the potential advantage of this novel assistive technique over the traditional method by evaluating procedure duration and level of technical demand.

## METHODS

### Suturing platform

A U.S. Food and Drug Administration–approved commercially available endoscopic suturing device (Over-Stitch; Apollo Endosurgery, Inc, Austin, Tex) was used for suture-pulley placement (Fig. 1). This device allows placement of a 3-0 polypropylene suture with a detachable anchor. The device includes an end-cap assembly with a curved suturing arm, side-mounted wire actuation cable, a needle-exchange assembly that operates within the endoscope working channel, and a detachable needle tip attached to suture material. All suturing devices used in this study were obtained after previous clinical use and reprocessing.

### Ex vivo study

Resected porcine stomachs were used in this study. A 5-cm incision was created at the greater curvature in the upper body. The stomach was inverted to an inside-out position to expose the mucosal side. After careful lavage, 5 simulated gastric lesions were created by using marking dots around a standard circular template 30 mm in diameter (Fig. 2A). This was performed at the anterior wall in the lower gastric body, the greater curvature in the lower gastric body, the anterior and posterior wall in the upper gastric body, and the greater curvature in the middle gastric body (Fig. 2B). Then stomachs were everted to normal anatomic configuration, and the incision line was closed with running suture. The stomachs were then affixed to the human anatomy platform.[3] During the procedure, the stomach was kept moisturized with continuous immersion in normal saline solution to maintain favorable conditions for electrosurgical current transmission. In both arms, a submucosal injection of saline solution was performed, and a round circumferential incision was made by using standard ESD knives (Flex Knife and IT Knife; Olympus Medical Systems, Tokyo, Japan). In the control arm, submucosal dissection was performed in a traditional method by using repeated injections of saline solution and further dissection. In the suture-pulley arm, after the circumferential incision was completed, the endoscope was replaced with a double-channel endoscope equipped with the endoscopic suturing device (Video 1, available online at www.giejournal.org). The first bite (fulcrum) was taken at the gastric wall opposite the lesion. The second bite (anchor) was placed at the margin of the isolated lesion, and the T-tag anchor was released to serve as a lifting retainer. This was positioned so that the traction force is directed toward the opposite side of the submucosal dissection plain. Therefore, for lesions in the middle and lower gastric body, the pulley was placed at the gastric wall opposite and distal to the lesion, whereas the anchor was placed at the proximal edge of the lesion so that submucosal dissection could be performed in the forward-viewing position. On the other hand, for lesions in the proximal stomach, the pulley was placed at the gastric wall, opposite and proximal to the lesion, whereas the anchor was placed at the distal edge of the lesion so that submucosal dissection could be performed in the retroflex position. The suture tail was withdrawn through the esophagus and was held by an assistant. Tension could then be placed on the suture to provide countertraction as needed during ESD to assist with the dissection. In total, 10 ESDs were performed with the suture-pulley method, and 10 ESDs were performed with the standard technique. A single endoscopist experienced in ESD (H.A.) performed all procedures.

Time was recorded separately for the circumferential incision, suture-pulley placement, and submucosal dissection. Times to perform the circumferential incision and submucosal dissection were recorded from the time when first incision was made to the time when the incision was completed. The time for suture-pulley placement was recorded from the time when the double channel endoscope was inserted until the time when the endoscope was removed after the suture pulley was successfully placed. The maximal diameter of the specimen was determined after resection. The endoscopist’s effort was graded immediately after completion of each ESD by using the validated NASA Task Load Index,[4] which is a multidimensional rating procedure developed and validated by NASA to evaluate the workload in a procedure and consists of the following 7 factors.

- *Mental demand.* How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?
- *Physical demand.* How much physical activity was required? Was the task easy or demanding, slack or strenuous?
- *Temporal demand.* How much time pressure did you feel because of the pace at which the tasks or task elements occurred? Was the pace slow or rapid?

- *Performance.* How successful were you in performing the task? How satisfied were you with your performance?
- *Effort.* How hard did you have to work (mentally and physically) to accomplish your level of performance?
- *Frustration.* How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?
- *Difffficulty*. How much difficulty did you feel that you were experiencing during the procedure?

These factors were rated based on a 10-cm visual analog scale (VAS). The endoscopist specified his level of agreement with a statement by indicating a position along a continuous line between 2 endpoints from 0 (disagree) to 10 (strongly agree).

### Definition of outcomes

The primary outcome measurement of this study was total procedure time. Secondary outcome measurements included the time for to perform ESD, VAS scores in the NASA Task Load Index, and occurrence of adverse events such as perforation.

### Statistical analysis

The Mann-Whitney *U* test was used to compare total procedure time, time for circumferential incision and ESD, as well as VAS and NASA Task Load Index scores. Data are shown as median with 25% to 75% interquartile range (IQR). All statistical analyses were performed by using SAS version 9.3 (SAS Institute Inc, Cary, NC), with results considered significant if $P < .05$.

### Sample-size calculation

In a previous study,[5] the time for ex vivo gastric ESD was normally distributed with a standard deviation of 3.9 minutes. To detect a 15% reduction in time for ESD in the experimental group compared with the control group, 10 cases were anticipated to reject the null hypothesis with a power of 93% and $\alpha = .05$.

## RESULTS

### Endoscopic submucosal dissection

Suture-pulley placements were successful in all 10 cases. Median time was 160.5 seconds (range, 150.0–168.8 seconds). During ESD, the suture-pulley provided the endoscopist with direct visualization of the submucosal layer, and the tension force could be precisely controlled from outside the stomach (Fig. 3). There was no inadvertent tear at the fulcrum or anchor point in any case. All 20 ESDs were completed as previously planned (Table 1). The total procedure time in the suture-pulley group was significantly shorter compared with that in the control group (531 seconds [474.3–549.3 seconds] vs 845 seconds [656.3–1547.5 seconds], $P < .001$) (Fig. 4). When the total procedure time was subdivided into specific steps, the time for ESD with the suture pulley was significantly shorter than for traditional ESD (164 seconds [129.5–221.0 seconds] vs 690 seconds [545.5–1311.3 seconds], $P < .001$)

(Table 1). There was no statistically significant difference between the groups in terms of the time for circumferential incision (192 seconds [156.3–244.3 seconds] vs 215 seconds [110.0–270.0 seconds], *P* = .970).

In the control group, lesions in the proximal stomach required a longer total procedure time compared with lesions in the middle or lower gastric body (1601 seconds [range, 1547.5–1708.8 seconds] vs 663 seconds [627.5–681.8 seconds]. This was largely attributed to the time required for ESD (1390 seconds [1311.3–1487.5 seconds] vs 547 seconds [499.8–576.3 seconds]. However, in the suture-pulley group, the difference was small based on lesion location in terms of the total procedure time (575 seconds [549.3–615.8 seconds] vs 493 seconds [425.5–534.0 seconds] and the time for ESD (238 seconds [221.0–267.5 seconds] vs 214 seconds [178–226 seconds] (Fig. 5).

There was no significant difference in maximal diameter of specimens (34 mm [range, 33.0–35.8 mm] vs 37 mm [34.0–42.0 mm], *P* = .196). There were no perforations or other adverse events in either group.

### Analysis of endoscopist's effort based on the NASA Task Load Index

Each ESD procedure was evaluated by the endoscopist for his effort based on the NASA Task Load Index. The suture-pulley method was less demanding in all categories (Table 2). Specifically, there was a significant reduction in the suture-pulley group compared with the control group in mental demand (3.2 [range, 3.1–3.3] vs 4.9 [4.4–5.3], *P* = .004), physical demand (2.1 [1.8–2.2] vs 6.3 [5.1–6.4], *P* < .001), temporal demand (2.0 [1.9–2.2] vs 5.3 [4.3–5.4], *P* < .001), effort (2.1 [2.0–2.2] vs 5.4 [4.6–5.9], *P* < .001), frustration (2.1 [1.8–2.1] vs 4.4 [3.7–4.6], *P* < .001), and difficulty (2.1 [1.9–2.3] vs 6.3 [6.1–7.2], *P* < .001). Additionally, the VAS score for performance was significantly improved in the suture-pulley group (2.1 [1.9–2.3] vs 6.3 [6.1–7.2], *P* < .001).

## DISCUSSION

ESD is currently not in widespread use in the United States. Most laterally spreading colorectal tumors are still treated with endoscopic piecemeal resection or referred for surgery. However, endoscopic piecemeal resection for such lesions is associated with less R0 resection (68.6%)[6] and a higher local recurrence rate (12%)[7] compared with high R0 resection rate (88%) and low local recurrence rate (0.07%) after en bloc resection with ESD.[8] Although surgical en bloc GI resection could be curative, in many cases, it would be overtreatment from an oncologic, economic, and perhaps ethical point of view. Man-I et al[9] reported that ESD is a favorable treatment for patients with comorbidities. By using a patient risk prediction model for surgery, it was shown that morbidity was halved with ESD with no mortality compared with a predicted death rate of 0.5% to 2% after surgery.

In ESD, endoscopists commonly have difficulty maintaining direct visualization of the submucosal dissection layer. This may result in blind dissection, unexpected bleeding, perforation, and longer procedure time. This aspect of ESD remains challenging. ESD has been facilitated by using a hood attached at the endoscope tip that allows direct visualization of the submucosal dissection plane. However, the operative field yielded by this transparent hood is still limited by its diameter and length and theoretically requires substantial experience. The efficacy of novel devices that provide endoscopists with countertraction and direct visualization of the dissection line have been investigated, including the sinker device[10]; external grasping forceps[11–13]; thin endoscope[14,15]; and internal traction using nylon suture,[16] a spring,[17] and a rubber band[18,19]; percutaneous traction[20]; and peroral traction[21] with a pulley method.[2,22] In addition, injectable reverse-phase polymer has been suggested to assist in ESD by providing mechanical force in transitioning from a liquid to a more solid substance.[23]

The suture-pulley method used in this study provided us with direct visualization of the submucosal space. Perpendicular arrangement of submucosal connective tissue fibers and horizontal arrangement of muscle fibers were easily discriminated. During dissection, we did not see any "burn" injuries around the anchor site, and ESD was successfully performed under the same electrosurgical current settings as in the control group. These findings suggest that the metallic anchor did not act as electrosurgical current sink. The angle of the mucosal flap could be easily controlled by the assistant by increasing and releasing the tensile force on the laterally placed suture. The suture-pulley method has several advantages over the other traction devices. First, compared with the internal traction methods (the sinker device,[10] internal traction using nylon suture,[16] a spring,[17] and a rubber band,[18,19] the assistant can maintain and precisely adjust the tension force in accordance with ESD progression simply by pulling the suture tail. Second, compared with the external traction methods using assistive endoscopic devices (external grasping forceps[11–13] and an additional thin endoscope[14,15]), the working space of therapeutic endoscope is not restricted by the traction device.

Placement of the suture pulley was easily performed and provided effective countertraction. Notably, we avoided the muscularis propria in all cases by placing the edge of mucosal flap between the curved suturing arm and the needle exchange assembly of the suturing device without adding a submucosal dissection at the proximal margin. Thus, stitch placement was always in the tissue flap. We observed a statistically significant difference in the time for submucosal dissection (164 seconds [range, 129.5–221.0 seconds] vs 690 seconds [545.5–1311.3 seconds] as well as in total procedure time (531 seconds [474.3–549.3 seconds] vs 845 seconds [656.3–1547.5 seconds]) even though there was no difference in specimen size between groups. Although each stomach was used for multiple lesions, we did not find any gastric deformities because only the mucosal layer was removed by ESD; the muscularis propria was not affected. Although ESD was performed at various gastric locations in this study, resection time was significantly shorter at all locations. Additionally, in the control group, proximal gastric lesions were noted to be more challenging, consistent with clinical experience.[24,25] However, when using the suture-pulley method, there was no difference in resection time or degree of difficulty with regard to lesion location. This suggests that the suture-pulley method may make the more complicated ESDs more feasible, in addition to making more straightforward ESDs more efficient. In this study, we did not experience any failures of the suture pulley, including misplacement or need for additional sutures. If such situations were encountered, an additional suture pulley could have been placed either by using a new suture or by reusing the suture after its removal from the ESD site. This technique is easiest to use in open areas and may be more challenging in post-pyloric lesions or other confined locations.

In this study, ESD with and without the suture-pulley method was analyzed by using the NASA Task Load Index to compare mental and physical demand. This is a multidimensional rating system that provides an overall workload score based on a weighted average of ratings on multiple 10-cm subscales. The data show that the suture-pulley method reduced mental and physical demand of traditional ESD by improving its performance.

This study has several limitations. First, this was an ex vivo study in which we could not investigate the efficacy of this procedure to reduce unexpected bleeding. We conducted this ex vivo study to facilitate robust comparison of procedure time and technical difficulty by strictly controlling for the size and locations of simulated lesions between 2 groups. We believe that under direct visualization of the submucosal layer, endoscopists can easily identify submucosal thick vessels and coagulate them preemptively. Second, all ESDs were performed by a single endoscopist experienced in ESD, which could limit translation of these results to a broader group of endoscopists. Nevertheless, this allowed robust direct comparison of these techniques, and it is possible that a significant decrease in procedure time and improvement in the NASA Task Load Index score in experts may be even more significant for ESD trainees.

Additionally, there are other potential benefits to using a suturing device during ESD procedures. The device may allow oversewing of large defects or perforations, which could serve as a safety net for endoscopists during their early clinical experience.[26]

In conclusion, this study demonstrates that the suture-pulley method provides the endoscopist with direct visualization of the submucosal dissection line throughout the procedure, which is essential to avoid adverse events such as perforation and bleeding. This technique also results in a significant reduction in ESD time and improves efficiency, with reduced mental and physical workload. The suture-pulley method is effective even for lesions in difficult locations, lessening lesion location as a complicating factor for ESD. Further clinical study is now warranted.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Abbreviations

| | |
|---|---|
| **ESD** | endoscopic submucosal dissection |
| **IQR** | interquartile range |
| **VAS** | visual analog scale |

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**Take-home Message**

- The suture-pulley method provides direct visualization of submucosal dissection layer.
- This countertraction method results in reduction of not only procedure time, but also mental and physical load.

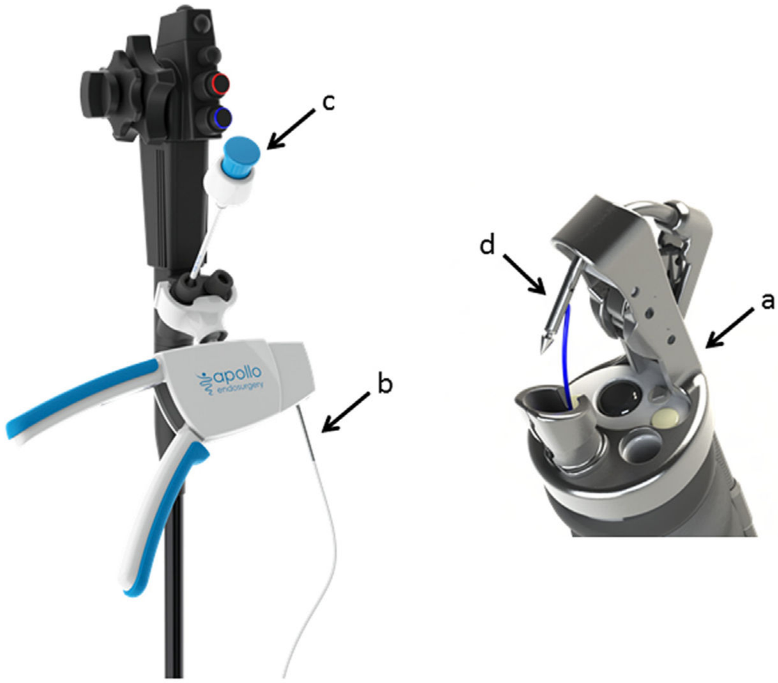


**Figure 1.**

Endoscopic suturing device. **a,** End-cap assembly with a curved suturing arm. **b,** Side-mounted wire actuation cable. **c,** Needle exchange assembly. **d,** Detachable needle attached to a 3-0 polypropylene suture.

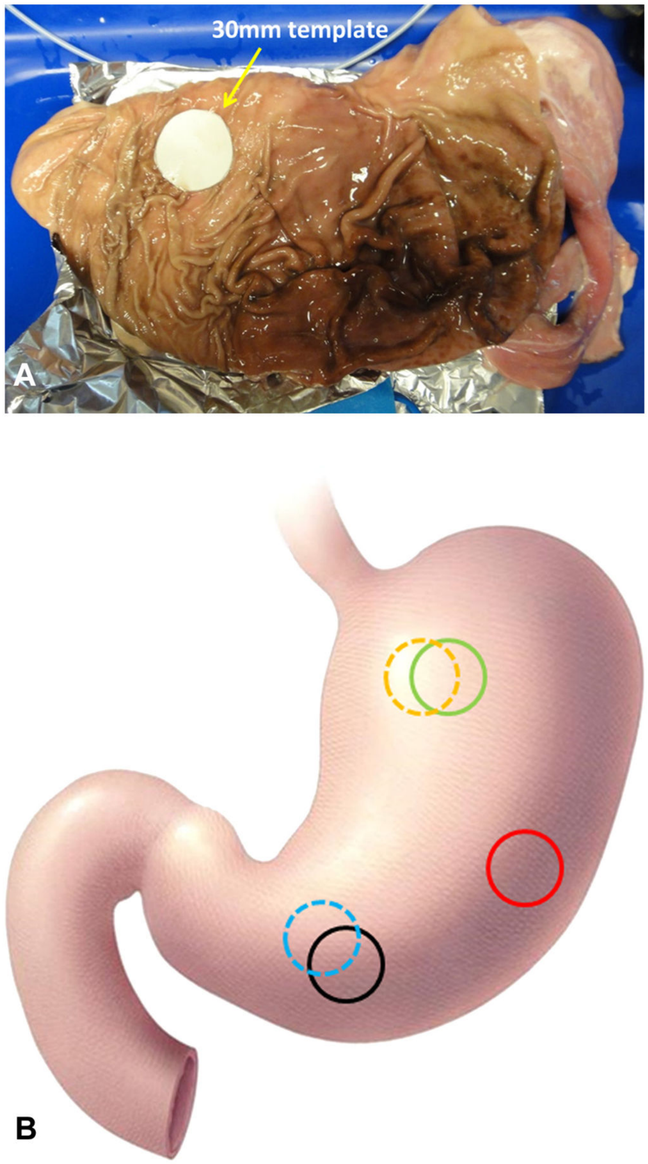


**Figure 2.**
Simulation of gastric lesions in ex vivo porcine stomach. **A,** Gastric lesions were simulated by using a standard circular template 30 mm in diameter and marking dots. **B,** Gastric lesions were simulated at the anterior wall in the upper gastric body (*green*), the posterior wall in the upper gastric body (*yellow*), the greater curvature in the middle gastric body (*red*), the anterior wall in the lower gastric body (*black*), and the posterior wall in the lower gastric body (*blue*).

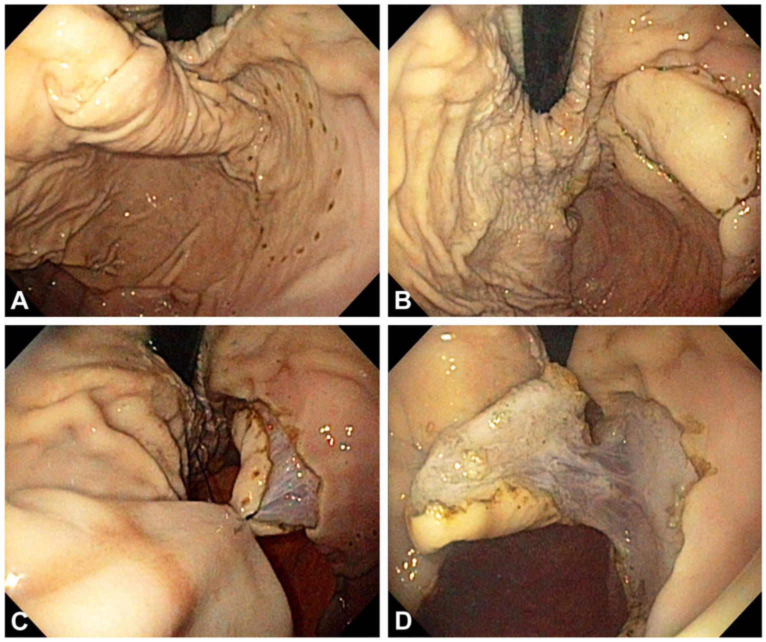


**Figure 3.**

Efficacy of the suture-pulley method. **A,** 3-cm gastric lesion was simulated by marking dots in the upper stomach. **B,** The circumferential incision was completed. **C,** The suture pulley provided direct vision of the submucosal dissection plane at the initiation of submucosal dissection. **D,** Traction force was effective until submucosal dissection was completed.

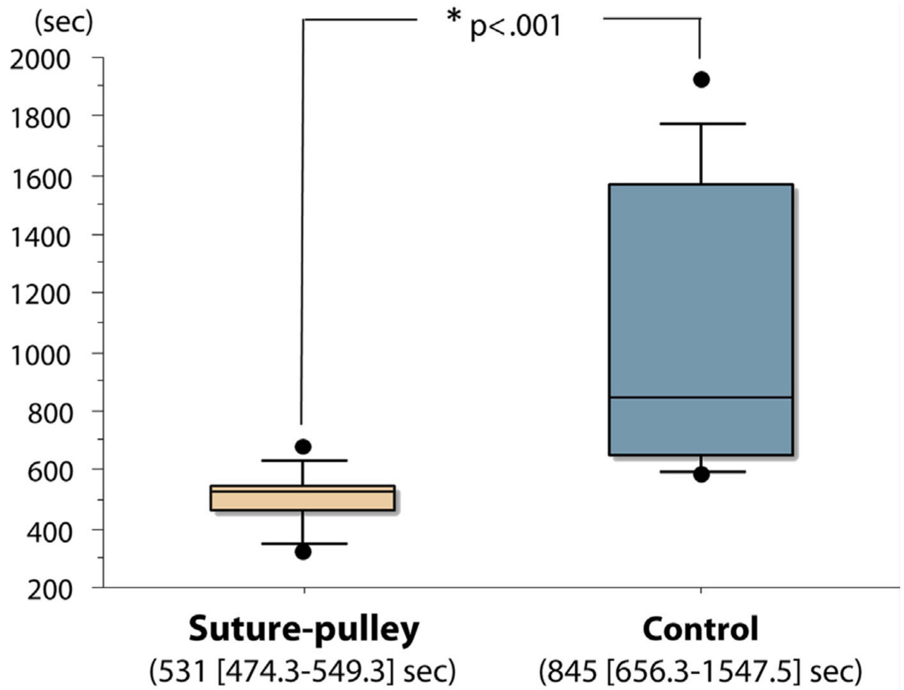


**Figure 4.**

Total procedure time. The suture-pulley method significantly reduced total procedure time compared with the control group (median [interquartile range]), 531 seconds [474.3–549.3 seconds] vs 845 seconds [656.3–1547.5 seconds], $P < .001$, Mann-Whitney *U* test).

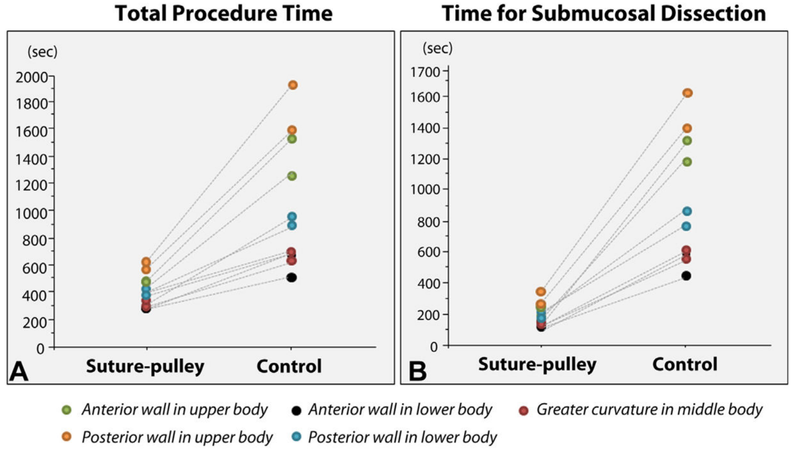


**Figure 5.**
Procedure time based on the lesion location. The suture-pulley method led to a reduction in total procedure time.

## TABLE 1

Procedure time and specimen size

| | Suture-pulley group | Control group | *P* value* |
|---|---|---|---|
| Total procedure time, s | 531 (474.3–549.3) | 845 (656.3–1547.5) | <.001 |
| Circumferential incision, s | 192 (156.3–244.3) | 215 (110.0–270.0) | .970 |
| Suture-pulley | 160.5 (150.0–168.8) | — | |
| Submucosal dissection, s | 164 (129.5–221.0) | 690 (545.5–1311.3) | <.001 |
| Specimen size, mm | 34 (33.0–35.8) | 37 (34.0–42.0) | .196 |

Data shown as median with 25% to 75% interquartile range.

*Mann-Whitney *U* test.

## TABLE 2

NASA Task Load Index for endoscopists's effort in ESD

| | Suture pulley group | Control group | *P* value* |
|---|---|---|---|
| Mental demands | 3.2 (3.1–3.3) | 4.9 (4.4–5.3) | .004 |
| Physical demands | 2.1 (1.8–2.2) | 6.3 (5.2–6.4) | .001 |
| Temporal demands | 2.0 (1.9–22) | 5.3 (4.3–5.4) | .001 |
| Effort | 2.1 (1.8–2.1) | 4.4 (3.7–4.6) | .001 |
| Frustration | 2.1 (1.8–2.1) | 4.4 (3.7–4.6) | .001 |
| Performance | 6.5 (6.2–7.1) | 2.5 (2.1–2.9) | .001 |
| Difficulty | 2.1 (1.9–2.3) | 6.3 (6.1–7.2) | .001 |

*Mann-Whitney *U* test.