Article

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Larger Circular Staplers Improve Anastomotic Alignment and Reduce Leakage Risk in Esophagectomy

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Background: Circular stapling is the most commonly used anastomosis method after esophagectomy. However, it is unclear to what extent the diameter of the stapler affects the occurrence of postoperative anastomotic leakage, given the elasticity of gastrointestinal tissues that can adapt to a range of stapler sizes. This study aimed to observe and evaluate the possible effects of various diameters of circular staplers on anastomotic efficacy in gastroesophageal anastomoses of the same diameter.
Methods: Four circular staplers with different diameters from the same series were used to investigate the anastomotic effect on eight groups of fresh porcine esophagogastric tissues, with 32 anastomoses being tested. Anastomotic seepage was inspected using normal saline diluted with methylene blue.
Results: No stapling failure was observed in any of the 32 anastomoses; however, two anastomoses in the 21 mm stapler group showed deviation in staple line approximation and mild fluid leakage. This issue was corrected by intensive tissue trimming at the root of the stapler's base.
Conclusion: A smaller circular stapler may cause poor anastomotic alignment and seepage of the digestive juices due to the thicker esophageal tissue remaining at the base of the stapler. It is recommended that the internal diameter of the esophagus be tested in clinical practice using a valve-size tester, similar to that used in valve surgery, to select a larger circular stapler whenever possible.

Keywords: circular stapler; esophagectomy; anastomotic leakage

Introduction

The anastomotic technique used after esophagectomy is linked to several complications, such as anastomotic fistula and anastomotic stenosis. Fistula refers to an abnormal postoperative channel at the anastomotic site, often associated with infection or tissue necrosis; leakage indicates a noticeable outflow of fluid observed postoperatively or during the experiment; and seepage denotes a minor extravasation of fluid during the experiment, usually related to poor anastomotic alignment. Among these, anastomotic fistula is considered the most serious postoperative complication, leading to prolonged hospital stay, increased costs, higher postoperative mortality, and reduced long-term survival rates [1].

Esophagectomy is a complex surgical procedure with a lengthy learning curve. The circular stapler has become the most frequently used anastomotic technique owing to its safety, short time consumption, and ease of mastery [2]. The relationship between circular stapler diameter and postoperative anastomotic leakage and stenosis has been widely investigated [3–6]. Staplers with diameters of 21, 25, and 28–29 mm, and even more than 33 mm, have been used; however, whether to choose a larger- or smaller-diameter stapler remains debatable.

Considering the variations in ethnicity and patient size, selecting a larger or smaller circular stapler based on an individual's anatomical characteristics may offer a more scientifically sound approach [6]. Since it is not feasible to intraoperatively compare the anastomotic efficacy of different circular stapler sizes on the same esophageal internal diameter, this study was conducted using porcine upper gastrointestinal tract to evaluate the impact of varying stapler diameters on the outcomes of esophagogastric anastomosis.

Materials and Methods

Materials

Four different circular stapler diameters (21, 25, 29, and 33 mm) from the same series and company (Proximate circular stapler, Johnson & Johnson) were used in this study. All staplers have two rows of nails, but the number of nails varies with the model, as detailed in Table 1. Complete esophageal and gastric tissues from eight groups of experimental pigs (male, approximately 6 months old, each weighing 60–75 kg) were selected. All pigs were housed under standard laboratory conditions, with controlled temperature and a 12 h light/dark cycle, and were provided free access to food and water in accordance with

Table 1. Characteristics of circular staplers.

Circular stapler	CDH21A	CDH25A	CDH29A	CDH33A
Head diameter (mm)	21	25	29	33
Rows of staples	2	2	2	2
Number of staples	16	20	24	28

Fig. 1. Photograph of the experimental pig esophagus placed on a sterile surface, showing a uniform thickness along its length, prepared for anastomosis with a circular stapler.

the Chinese National Standard Regulation on the Management of Experimental Animals (GB 14925-2019). Animals were first sedated by intramuscular injection of ketamine (15 mg/kg; Yichang Humanwell Pharmaceutical Co., Ltd., China; Approval No. H20244192) combined with diazepam (2 mg/kg; Shandong Xinhua Pharmaceutical Co., Ltd., China; Approval No. H14022569). After intravenous access was established, anesthesia was induced with propofol (3.5 mg/kg; Fresenius Kabi, China; Approval No. H20233666) and fentanyl (0.5 µg/kg; Yichang Humanwell Pharmaceutical Co., Ltd., China; Approval No. H20203712). Deep anesthesia was confirmed by the absence of responses to painful stimuli, sufficient muscular relaxation, and stable respiratory and heart rates. Animals were then humanely euthanized by intravenous administration of potassium chloride (40 mL, 150 mg/mL; China Resources Double-Crane Pharmaceutical Co., Ltd., China; Approval No. H20153283). A random sequence generated using a random number table was employed to allocate the porcine esophageal and gastric tissues randomly into groups corresponding to different circular stapler diameters. These tissues were washed and prepared with saline at room temperature, refrigerated at 4 °C after removing the surface adipose tissue, fascia, and contents, and then rewarmed to room temperature after 24 h. The animal experiments conducted in this study were approved by the Animal Experimental Ethical Inspection of the First Affiliated Hospital, Zhejiang University School of Medicine (2023 Experimental Animal Fast-Review No.1082).

Gastroesophageal Anastomosis

As depicted in Fig. 1, the experimental pig esophagus was roughly similar in thickness. A standard set of gastric and esophageal tissues, along with circular staplers of various diameters from the same series, was used in this study. A continuous purse-string suture technique was employed to place 3-0 non-absorbable polypropylene sutures evenly around the circumference of the esophageal stump with an inter-stitch distance of approximately 2–3 mm. A purse-string clamp was used during suturing to ensure complete enclosure of the circular stapler anvil by the esophageal tissue, and the suture was secured by tying the knot firmly at the base of the anvil. Esophagogastric end-to-end anastomoses were performed using circular staplers of various diameters, following the same procedures (Fig. 2). All experiments were performed in a third-party laboratory qualified for animal experimentation by the same surgeon skilled in esophageal surgical techniques and the use of circular staplers. The evaluations were performed independently by two experienced esophageal surgeons, both of whom were blinded to the stapler diameter and experimental group assignments.

Anastomosis Effect and Pressure Test

The inner and outer stapling effects, as well as the alignment of the anastomoses, were carefully assessed. Any signs of incomplete stapling or poor alignment were recorded. After anastomosis, the esophageal stump was sutured and inverted. A total of 1000 mL of saline containing methylene blue (Jichuan Pharmaceutical Group, National Drug Approval Number H32024827) was infused into the gastric cavity. All anastomoses were positioned at the same

Fig. 2. The esophagogastric end-to-end anastomoses were performed using circular staplers of various diameters (21 mm, 25 mm, 29 mm, and 33 mm) with a continuous purse-string suture technique.

level, and the setup was left undisturbed for 30 min to allow potential leakage to fully manifest. To further quantify anastomotic leakage, a pressure test was conducted under controlled conditions. The anastomotic site was subjected to a pressure of approximately 350 mmH_2O (equivalent to 3.43 kPa), selected to approximate the median lower esophageal sphincter pressure in healthy individuals (3.23 kPa) as a physiological reference. The pressure was applied using a calibrated infusion system connected to the esophageal lumen, with the gastric end sealed. Seepage was defined as the visible leakage of methylene blue-stained saline at the anastomotic site under this pressure. The presence and extent of seepage were recorded for each stapler diameter group to assess anastomotic efficacy.

Results

Following a 30-min resting period, all anastomoses were examined for signs of leakage. Seepage was identified in two anastomoses from the 21 mm stapler group, which also exhibited poor alignment. No incomplete stapling was observed in any of the 32 anastomoses tested (Figs. 3,4). This was attributed to the esophageal tissue remaining at the root of the stapler base being extruded into the anastomosis due to the small diameter of the stapler, forming a sandwich layer (Fig. 5). To address this issue, the 21 mm circular stapler was heavily trimmed by removing excess tissue, specifically by excising the excess tissue entrapment, ensuring no excess tissue remained within the stapler's alignment edges (Figs. 6,7). This adjustment prevented the issue from recurring in subsequent anastomoses.

Discussion

Anastomotic fistula remains a critical complication following esophageal surgery, serving as a key indicator

Fig. 3. Photograph of an esophagogastric anastomosis after 30 min, showing methylene leakage in 21 mm stapler.

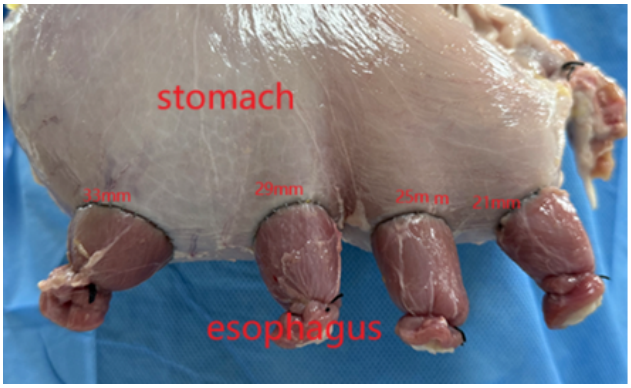

Fig. 4. Photograph of esophagogastric anastomoses after a 30-min resting period, showing the stomach and esophagus anastomosed with staplers of various diameters (21 mm, 25 mm, 29 mm, 33 mm). Appearance of no incomplete stapling and no leakage.

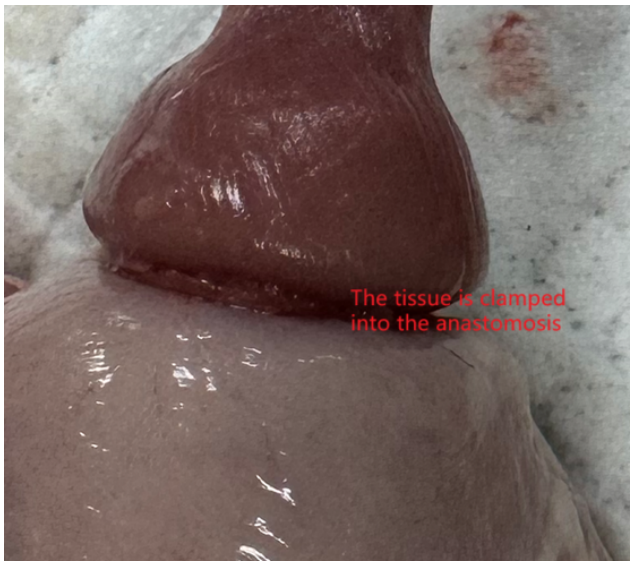

Fig. 5. The esophageal tissue is clamped into the anastomosis, forming a sandwich-like layer due to the small stapler diameter.

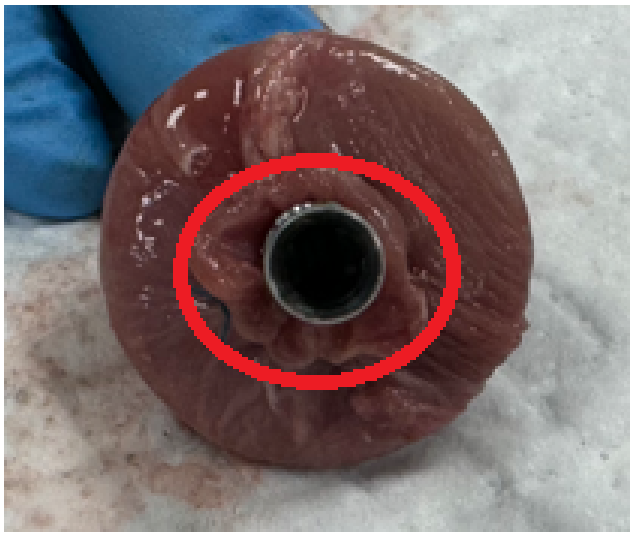

Fig. 6. Excess esophageal tissue (circled in red) remained within the stapler base, contributing to misalignment and tissue entrapment in the anastomosis.

of surgical quality [7]. The present study investigates the impact of circular stapler diameter on anastomotic efficacy using an *ex vitro* porcine model. Our findings suggest that smaller staplers (e.g., 21 mm) may lead to poor anastomotic alignment and increased seepage of digestive juices due to thicker esophageal tissue accumulating at the stapler base, forming a sandwich-like structure. This issue was mitigated in our experiments through intensive tissue trimming, particularly in the 21 mm stapler group. However, this intervention introduces a potential confounding variable, as the trimming was not standardized across all groups.

Fig. 7. After trimming the excess tissue, the anastomosis showed no evidence of tissue entrapment, indicating improved alignment.

A significant limitation of this study is the lack of quantitative measurements of esophageal diameter and wall thickness. These tissue characteristics are critical for ensuring comparability when tested with various stapler sizes, as variations may influence anastomotic outcomes. Additionally, the non-standardized tissue trimming in the 21 mm group may have affected the results' consistency. Furthermore, the *ex vitro* nature of this study precludes follow-up evaluation, making it impossible to assess long-term outcomes such as anastomotic healing, fistula formation, or stenosis development over time. Future studies should incorporate standardized measurements of tissue properties, uniform surgical techniques, and longitudinal clinical follow-up to minimize such confounders and enhance result reliability.

The use of larger circular staplers (e.g., 29 mm or 33 mm) was associated with improved anastomotic alignment and reduced seepage in our model. This may be attributed to the larger anastomotic area and increased number of staples, which allow better distribution of tissue and potentially more secure closure [8]. However, the relationship between stapler size and anastomotic tensile strength remains complex, as tensile strength depends on multiple factors beyond staple count [9]. While larger staplers may reduce the risk of anastomotic fistula [6,10], our *ex vitro* model cannot assess dynamic factors such as mucosal blood supply or microcirculation, which are critical for anastomotic healing *in vivo* [11,12]. Therefore, further clinical studies are needed to evaluate the impact of stapler size on these physiological factors.

Another important consideration is the risk of anastomotic stenosis, which, according to existing literature, may be reduced by using larger circular staplers [5,13]. Our findings align with this, as larger staplers created more spacious anastomoses in the porcine model. However, the *ex vitro*

setting does not account for anatomical constraints, such as limited mediastinal or cervical space, which may restrict stapler size selection during surgery [14].

To optimize stapler size selection in clinical practice, we propose exploring the use of a "valve-size tester" to measure esophageal internal diameter intraoperatively, similar to tools used in valve surgery. This concept, while promising, was not tested or modeled in the present study and requires further development. Future research should focus on designing and piloting such a tool to validate its feasibility and accuracy in guiding stapler selection.

Our study highlights the potential benefits of larger circular staplers in achieving better anastomotic alignment and reducing seepage *ex vitro*. However, limitations such as unquantified tissue characteristics and non-standardized trimming, and the absence of follow-up data, necessitate cautious interpretation of our findings. Standardized protocols, *in vivo* studies, and longitudinal clinical evaluations are essential to confirm these findings and explore the clinical utility of tools like the valve-size tester.

Conclusion

The findings of this study indicate that smaller circular staplers may cause poor anastomotic alignment and seepage of digestive fluids due to the thicker esophageal tissue remaining at the base of the stapler. Conversely, larger circular staplers can create more spacious anastomoses. Based on these observations, it is recommended to test the esophageal internal diameter in clinical practice using a "valve-size tester", similar to those used in valve surgery. This approach can help in selecting a larger circular stapler whenever feasible.

Availability of Data and Materials

The data and materials in the current study are available from the corresponding author on reasonable request.

Author Contributions

HM, HJ, and XT contributed to the study design. HM conducted the literature search. XL and HM acquired the data. HJ wrote the article and performed data analysis. All authors contributed to important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was approved by the Animal Experimental Ethical Inspection of the First Affiliated Hospital, Zhejiang University School of Medicine (2023 Experimental Animal Fast-Review No.1082).

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Conflict of Interest

The authors declare no conflict of interest.

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