Quantitation of Lung Sealing in the Survival Swine Model

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Purpose: Small intercostal spaces and limited pleural space significantly limits the use of 12-mm stapling devices in pediatric thoracoscopic surgery. The goal of this study was to compare sealing of lung tissue by the 5-mm Ligasure (Valley Lab, Boulder, CO) device to a standard 12-mm Endo-GIA stapler (US Surgical, Norwalk, CT).

Methods: Institutional Animal Care and Use Committee (IACUC) approval was obtained (#A3-02). Sixteen 10-kg female swine were divided between 2 survival surgical groups. Lung biopsy sections of the lingula were taken by 2 methods: group A, left anterolateral thoracotomy employing a 12-mm Endo-GIA stapler and group B, left thoracoscopy employing the Ligasure 5-mm instrument. After a 7-day survival period, lung burst pressures were measured by flow-controlled insufflation into the trachea.

Results: Burst pressure measurement reflects the first air leak. By Student's *t* test analysis there were no statistically significant differences between the burst pressures, biopsy weights, or operating times. Fifty percent (4 of 8) of the animals in group A (Endo-GIA), and 50% (4 of 8) of the animals in group B (Ligasure) developed the first air leak in the nonoperative lung. Two animals, one from each group, had evidence of intrapleural infections at the time of necropsy. These were asymptomatic and did not appear to affect burst pressure measurement.

Conclusions: After 7 days of healing, lung biopsy sites created with both the Ligasure and the Endo-GIA stapler have burst strengths equal to or greater than that of normal lung tissue in the swine survival model.
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INDEX WORDS: Thoracoscopic surgery, minimally invasive staple devices.

THORACOSCOPY WAS FIRST used by Jacobaeus in the early 1900s.[1-3] Using the crude instruments of the time, he was able to cauterize pleural adhesions that interfered with the implementation of therapeutic pneumothorax for the treatment of tuberculosis.[4] With the discovery of streptomycin, the use of thoracoscopy diminished in the United States. Upon introduction of mechanical ventilation, thoracic surgery became safer, and in the 1960s, there was a resurgence of thoracoscopy for the investigation of pleural effusions.[5,6] Beginning in the late 1970s, thoracoscopy began to be used with increasing frequency in children.[7,8] With the advances in minimally invasive technology of the late 1980s and 1990s, thoracoscopic management of complex surgical procedures became possible.[9-11]

Stapling devices were first used in thoracic surgery to help seal bronchial stumps.[12] Endo-GIA stapling devices opened the door to minimally invasive thoracic surgery.[13] In fact, the Endo-GIA staplers have contributed significantly to both laparoscopic and thoracoscopic surgery. The simultaneous stapling and division of tissues has proved to have a variety of applications from the division of lung tissue to bowel anastamosis.[14-17] In adults, these devices have been utilized widely with great success. Currently, the smallest diameter of these devices is 12 mm. This compromises their usefulness in infants and small children. The 3 limiting factors are narrow intercostal spaces, small size of the intrathoracic space, and limited pulmonary reserves. This makes it either impossible to insert the devices or difficult to manipulate the instruments once they have been inserted into the chest.

Although the stapling devices are not available in smaller diameters, there are a number of commercially available 5-mm energy devices. The Ligasure (Valley Lab: Tyco Health Care, Boulder, CO), an electrothermal bipolar vessel sealer, has been well studied in its ability to seal vessels up to 7 mm in diameter.[18] The Ligasure LS1000 is a 5-mm diameter laparoscopic version of the sealing device. The capacity of energy devises, in particular the Ligasure, to seal lung tissue has never been studied.

The experience in the literature is limited. Shigemura et al[19] described 1 adult case in which a giant bullus was excised, and the remaining lung was sealed with the Ligasure LS1000. Rothenberg[20] described the use of the Ligasure LS1000 for completing pulmonary fissures during thoracoscopic lobectomy with good success. The

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Table 1. Group A, 12-mm Endo-GIA Roticulator (US Surgical)

	Burst Pressure (mm HG)	Burst Hemithorax	Biopsy Weight (g)	Operating Time (min)
	46.9	Left	0.85	40
	74	Right	0.83	28
	74*	Right	0.51	43
	92.7	Right	0.80	35
	78.4	Left	0.45	55
	32.4	Right	1.05	25
	54.7	Left	0.69	29
	66.4	Left	1.06	25
Average	64.9		0.78	35
Standard Deviation	19.3		.22	10

*This animal had evidence of resolving subclinical intrapleural infection at the time of necropsy.

Ligasure has the potential to seal lung tissue well, but its capacity to do this has never been systematically studied.

In this study, we intend to quantitate the lung sealing capacity of both an Endo-GIA 12-mm stapler (US Surgical, Norwalk, CT) and the Ligasure LS1000 in a survival swine model. Ten-kilogram pigs were selected to serve as a model representative of a small child. The Endo-GIA stapler was employed through a thoracotomy incision because it is too large to be used thoracoscopically in an animal this size. The LS1000 was used thoracoscopically using 5-mm ports. The lingula of the left upper lobe was excised to insure that the thickness, length, and amount of lung tissue divided was consistent among the experimental animals. The animals were survived for 1 week, without chest tubes, before they were euthanized for the measurement of burst pressures. The burst pressure was detected by insufflation into the trachea until an airleak was detected. The pressure at which this occurred was recorded as the burst pressure.

MATERIALS AND METHODS

Animal Model

Institutional Animal Care and Use Committee (IACUC) approval was obtained (Docket #A3-02). Ten-kilogram female swine were selected as the animal model. Animals were dosed preoperatively with cefazolin, 20 mg/kg, by intramuscular injection.

Experimental Design

The lingula was amputated from the left upper lobe by dividing the lung tissue with 1 of the 2 experimental devices: group (A) 30-mm to 2.5-mm Endo GIA Roticulator, and Group (B) LS1000 Ligasure Lap vessel sealing instrument.

Surgical Procedures

Group A, 130-2.5 Endo GIA Roticulator (US Surgical), 8 swine. The swine were anesthetized by intramuscular injection of telazol, 25 mg, ketamine, 12.5 mg, and xylazine, 12.5 mg (TKX). Inhalational anesthesia was initiated with isoflurane, 1% to 2.5%, through a #5 cuffed endotracheal tube. A 22-gauge angiocatheter was placed in the lateral auricular vein. An anterolateral thoracotomy was made in the seventh intercostal space. A limited amount of the latissimus dorsi and deep pectoralis muscles were divided with electrocautery. An infant Finochietto was used to obtain exposure. The lingula of the left upper lobe was elevated with a Babcock, distal to the point of resection. The lingula was resected with a single firing of Endo-GIA stapler 30 mm, 2.5 mm. The stapled lung was inspected for air leaks. The specimen was weighed and sent for tissue processing. The ribs were re-approximated with 1-0 PDS. The latissimus dorsi and deep pectoralis muscles were closed with 3-0 Vicryl. Subcutaneous tissues were closed with 3-0 Vicryl. The skin was re-approximated with a running 4-0 Vicryl subcuticular suture and then covered with Nexaband (Abbott Labs, Chicago, IL). At the end of the procedure, the swine were recovered and observed in the facility for 7 days. To assess burst pressures after postoperative day 7, the animals were sedated with an intramuscular injection of TKX and killed with 3 mL of euthanasia solution IV (fatal plus).

Group B, LS1000 Ligasure Lap vessel sealing instrument Valleylab, 8 swine. The swine were anesthetized and positioned in an identical manner to group A. Three 5-mm versaport trocars (US Surgical, Norwalk, CT) were inserted into the fourth, seventh, and tenth intercostal spaces of the left chest triangulated about the position of the lingula. A pneumothorax was created with 5 mm HG pressure of CO_2. A 30°, 5-mm video endoscope (Olympus, Melville, NY) was used for the procedure. The lingula was grasped with an atraumatic grasper distal to the point of resection. The Ligasure LS1000 5-mm instrument was used to seal the base of the lingula, and then the lingula was amputated with the endoscissors (Stryker, San Jose, CA) distal to the seal. The specimen was retrieved after placing it in the finger of a surgical glove. The specimen was weighed. The sealed lung was inspected for any obvious airleak. All trocar sites were closed with 3-0 Vicryl for the intercostal muscle fascia and 4-0 Vicryl subcuticular for the skin. At the end of the procedure the swine were recovered and observed for 7 days. Burst pressures were determined in an identical manner to group A.

Burst Pressure Measurement

On postoperative day 7 immediately after the animal was killed, burst pressures were measured. A mini clam-shell incision was made at the level of the sixth intercostal space, 12 cm long, extending down both sides of the chest and centered about the sternum. The sternum was divided with mayo scissors and spread with an infant Finochietto. Both chest cavities were entered anteriorly and filled with saline. A tracheostomy was performed in which a 5-mm trocar was placed and tied securely in place with an umbilical tape. The trocar was connected to the oxygen flow meter, and the lungs were inflated with oxygen

Table 2. LS1000 Ligasure Lap Vessel Sealing Instrument (Valleylab)

	Burst Pressure (mm HG)	Burst Hemithorax	Biopsy Weight (g)	Operating Time (min)
	41.2†	Left	0.93	20
	59*	Left	1.03	55
	92.3	Right	0.75	22
	68.4	Right	0.80	19
	96.5	Right	0.98	22
	40.5	Left	0.61	11
	46.9	Left	1.20	25
	43†	Right	0.65	15
Average	61		0.87	23
Standard Deviation	22.78		0.2	10

*This animal had evidence of resolving subclinical intrapleural infection at time of necropsy.

†These 2 animals had mild rectal prolapse postoperatively.

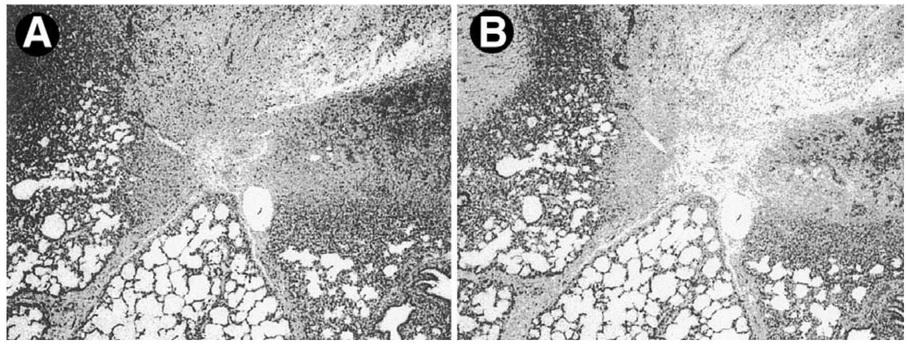

Fig 1. (A) H & E–stained appearance of the Ligasure seal on postoperative day 7. (B) Trichrome-stained appearance of the same seal.

flowing at 1.5 L/min. A pressure transducer was connected inline with the insufflation tubing, and the airway pressures were recorded on a chart recorder during the insufflation process. The burst pressure was noted when air bubbles were seen coming from the chest and confirmed by a sudden drop in the pressure on the chart recorder. The side of the lung that burst (left side operative, right side normal lung control) was noted by the presence of air bubbles. Burst pressures between the experimental groups were compared by Student's *t* test.

Specimen Collection

Once the burst pressures were completed, the clam-shell incision was extended for necropsy. The sealed edge of the left upper lobe was removed sharply, and the seal length was measured. Lung tissue was fixed in 10% neutral buffered formalin at 4°C. Tissues were paraffin embedded, sectioned, and H&E and trichrome stained according to standard protocols.

RESULTS

All 16 swine from the 2 groups had procedures performed without significant complications. At the end of each procedure, the lung was observed to insufflate normally with no gross evidence of air leak before the swine recovered.

For group A, Endo-GIA stapler group, the average lingula biopsy weight was 0.78 g. In 50% (4 of 8) of the swine the normal lung on the nonoperative side burst before the operative side (Table 1). The average burst pressure was 64.9 mm HG (range, 32.4 to 92.7). The average operating time for this procedure was 35 minutes (range, 25 to 55).

In group B (Ligasure LS1000) the average lingual biopsy weight was 0.87 g. Fifty percent (4 of 8) of the swine had the normal lung on the nonoperative side burst before the operative side. The average seal burst pressure was 61 mm HG (range, 40.5 to 96.5). The average operating time for this procedure was 23 minutes (range, 11 to 55). These results are in Table 2. H&E and trichrome staining of the lung tissue showing normal healing and fibrous about the Ligasure seal are shown in Fig 1.

When comparing the Ligasure with the Endo-GIA, there was an average burst pressure difference of 4 mm HG (data tabulated in Table 3). This difference was not statistically significant (P = .71). The average difference in biopsy weight, 0.09 g, was also not statistically significant. Performing a thoracoscopy with the Ligasure had an average decrease in operating time of 12 minutes. This difference was not significant (P = .08). Both groups had minimal blood loss.

There were 2 complications in group A, and 3 complications in group B. This difference was not statistically significant by χ^2. Two swine, one from each group, had evidence of resolving intrapleural infections at the time of necropsy. During burst pressure measurement, one of these 2 swine burst on the operative side and the other on the nonoperative side. Clinically they were asymptomatic. There was no evidence of respiratory difficulty, changes in appetite, or changes in behavior during the 1-week experimental observation. At the time of necropsy, no swine had a pneumothorax. Two swine from group B had mild rectal prolapse postoperatively. This is a common complication in pigs secondary to the stresses of general anesthesia. One swine in group A had a superficial wound infection that did not extend into the chest cavity.

DISCUSSION

Rodgers was one of the first surgeons to describe thoracoscopy as a safe and efficient procedure in children. He described the significant advantage of being able to observe the entire hemithorax when evaluating children with pulmonary or mediastinal lesions.[7] Rogers was limited by the instrumentation of 1979. Today, advances in technology continue to allow thoracoscopic procedures of increasing complexity to be feasible.

A 5-mm instrument is much more functional than a 12-mm instrument in infants and small children. The added maneuverability and dexterity can allow far more technically complicated procedures to be performed by

Table 3. Comparing the LS1000 Ligasure to the Endo-GIA Stapler

	Average Burst Pressure (mm HG)	Average Biopsy Weight (g)	Mean Operating Time (min)
(A) Endo-GIA	64.9	0.78	35
(B) Ligasure	61	0.87	23
t test	P = .71	P = .42	P = .08

thoracoscopy. In the survival swine model we were unable to detect any outcome differences after division of the lingula between the Endo-GIA stapler and the Ligasure LS1000 5-mm instrument. After 7 days of survival, both animal groups had average respiratory burst pressures above any naturally occurring physiologic pressures. In 50% of the animals from both groups, the nonoperative right lung burst before the divided lingula. Thus, we conclude, after 7 days of healing, both seals were at least as strong as normal lung tissue.

The thickness of lung tissue divided varied by respiration but was never thicker than 7 mm by relative size comparison to laparoscopic instrument diameter. Although we had excellent success, this study did not address the thickness of lung tissue that can be divided safely with the Ligasure instrument. In fact, the instrument used was specifically designed for sealing vessels up to 7 mm in diameter. Lung tissues significantly thicker than 10 to 20 mm may tear before a strong seal has been applied. This study serves as a foundation for our gradually expanding experience with the Ligasure instrument. The Ligasure LS1000 offers a promising alternative to the Endo-GIA stapler when dividing lung tissue in the 10-kg swine model. Further investigation needs to be performed to determine its safety and efficacy in humans.

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