

HARMONIC® Technology on pulmonary vasculature

Evaluation of efficacy of an ultrasonic scalpel for pulmonary vascular ligation in an animal model

Daniel G. Nicastri, MD, Maoxin Wu, MD, PhD, Jaime Yun, MD, and Scott J. Swanson, MD | *J Thorac Cardiovasc Surg.* 2007 Jul;134(1):160-4.

Objective: Dissection to accommodate bulky stapling devices may cause injury to pulmonary arteries in thoracoscopic lobectomies. The Harmonic Ace (Ethicon Endo-Surgery, Inc; Cincinnati, Ohio), a small ultrasonic scalpel used in systemic vessels, was tested on pulmonary vessels in pigs.

Methods: Nine pigs were assigned 1- or 6-week survival. Lobectomies were performed using the device to divide and ligate pulmonary vessels. Vessel diameter was measured, and ligation outcome was recorded. Necropsies were then performed.

Results: Permanent ligation occurred in 76% of arteries and 92% of veins. At the highest power setting, the instrument showed no failure in arteries 5 mm or less and veins 7 mm or less. Necropsies revealed no evidence of postoperative bleeding. Histopathologic analysis revealed acute coagulation necrosis at 1 week. By 6 weeks, the vessel stumps displayed features consistent with normal wound healing.

Conclusions: This device reliably divides pulmonary vessels 4 mm and smaller, typically encountered in pig lobectomies. Higher power settings and operator experience may increase effectiveness. Further testing is necessary to delineate the device's limitations before potential use in human pulmonary vasculature.

Energy-Based Ligation of Pulmonary Vessels: A Six-Year Experience with Ultrasonic Shears in Video-Assisted Thoracoscopic Lobectomy and Segmentectomy

White A, Kucukak S, Lee DN2, Swanson SJ. | *Ann Thorac Surg.* 2016 Apr;101(4):1334-7.

Background: Mechanical staplers are widely employed in minimally invasive anatomic lung resections, but have limitations when managing smaller pulmonary arterial and venous branches. Published data is lacking regarding the safety and efficacy of pulmonary vessel ligation using ultrasonic shears. We describe a single-surgeon experience employing ultrasonic shears for the ligation of pulmonary vasculature during lobectomy and segmentectomy, primarily in the setting of video-assisted thoracic surgery (VATS) resection.

Methods: A retrospective chart review was conducted for all patients, who underwent anatomic resection, between 2008 and 2014. Charts were divided into 2 groups based on method of ligation (energy based or conventional). Dictated operative reports were reviewed and patient demographics, tumor characteristics, and complications were recorded.

Results: Ultrasonic shears were used for pulmonary vessel ligation (5 to 6 mm) in 82 of 283 anatomic resections. A total of 118 vessels were ligated with ultrasonic shears. The majority of patients (83%) in the energy-based ligation group underwent VATS resection. There were fewer complications in the energy-based ligation group (26% vs 38%; $p = 0.05$); however, rates of intraoperative transfusion, prolonged air leak, empyema, and return to the operating room were similar across the 2 groups, and no statistically significant difference was found. There were no postoperative complications directly attributable to ultrasonic vessel ligation.

Conclusions: Energy-based ligation of small-diameter pulmonary vessels is a safe and useful adjunct in anatomic VATS resection and a viable alternative to mechanical stapling. Its narrow profile and thin blades make it ideal for ligation of pulmonary vasculature, particularly where the size and necessary clearance of mechanical staplers prohibit safe dissection.

HARMONIC® Technology in VATS lobectomy

Benchtop & Preclinical Trials

2014

Pilot study of pulmonary arterial branch sealing using energy devices in an ex vivo model

Liberman M, Khoreba M, Goudie E, Kazakov J, Thiffault V, Lafontaine E, Ferraro P. *J Thorac Cardiovasc Surg.* 2014 Dec;148(6):3219-23.

2015

Pulmonary Artery Sealing Using the HARMONIC ACE+ Shears for Video-Assisted Thoracoscopic Surgery Lobectomy

Liberman M, Khoreba M, Nasir B, Goudie E, Danino A, Giot JP, Nizard N, Hadjeres R, Thiffault V, Farrenq N, Ferraro P. *Ann Thorac Surg.* 2015 Sep;100(3):898-903; discussion 903-4.

2016

Pulmonary Artery Sealing With an Ultrasonic Energy Device in Video-Assisted Thoracoscopic Surgery Lobectomy: An Animal Survival Study

Goudie E, Khoreba M, Tahiri M, Hegde P, Thiffault V, Hadjeres R, Berdugo J, Ferraro P, Liberman M. *Ann Thorac Surg.* 2016 Oct;102(4):1088-94.

Clinical Trials

2017

Pulmonary artery sealing with ultrasonic energy in open lobectomy: A phase I clinical trial

HARMONIC ACE+ 7
(no comparator)

Pulmonary artery sealing for vessels with diameter ≤ 7 mm was safely achieved with an ultrasonic energy vessel-sealing device in open lobectomy. The use of ultrasonic energy vessel-sealing devices in video-assisted thoracoscopic surgical lobectomy may have the advantage of making small, short, pulmonary artery branch sealing safer than with vascular endostaplers. Further studies are necessary before widespread application in lobectomy, including video-assisted thoracoscopic surgical lobectomy.

Goudie E, Thiffault V, Jouquan A, Lafontaine E, Ferraro P, Liberman M. *J Thorac Cardiovasc Surg.* 2017 Jun;153(6):1600-1607.

2018

Phase 1 Trial Evaluating Safety of Pulmonary Artery Sealing With Ultrasonic Energy in VATS Lobectomy

HARMONIC ACE+ 7
(no comparator)

PA branch sealing for vessels 7 mm or less was safely achieved using an ultrasonic energy vessel-sealing device in VATS lobectomy. Large-scale, prospective, multi-institutional studies are necessary before widespread clinical application of energy for PA branch sealing in VATS lobectomy.

Ann Thorac Surg. 2018 Jan;105(1):214-220.

Goudie E, Oliveira RL, Thiffault V, Jouquan A, Lafontaine E, Ferraro P, Liberman M.

2019

Prospective, Multi-Center, International Phase 2 Trial Evaluating Ultrasonic Energy for Pulmonary Artery Branch Sealing in VATS Lobectomy

HARMONIC ACE+ 7
(no comparator)

PA branch sealing with ultrasonic energy during VATS lobectomy is safe for vessels of 7mm or less. The use of an ultrasonic device is a reasonable sealing method for PA branches of 7mm or less.

Liberman M, Goudie E, Morse C, Hanna W, Evans N, Yasufuku K, and the VATS PA Study Working Group. 2019 - Manuscript in review

Devices

Conclusion