What does it take to seal the deal?

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In the June 2017 issue, Goudie and coauthors¹ report on a prospective phase I study using an ultrasonic energy device (Harmonic ACE+7; Ethicon, Cincinnati, Ohio) for pulmonary artery sealing and division during lobectomy. The authors designed a safe clinical trial using an open lobectomy technique to allow for rapid control of any bleeding, and limited division of pulmonary branch vessels to those with a diameter ≤ 7 mm. The authors' ultimate stated goal was to use this device during video-assisted thoracoscopic (VATS) lobectomy, providing a potential advantage over endostaplers in situations involving the division of small, short segmental pulmonary arteries in "tight" spaces where endostapler use might not be safe. Although all vessels were successfully sealed and divided without bleeding in this prospective trial, the authors concluded that further study of this device is warranted before its widespread application, including use during VATS lobectomy.

If a device can demonstrate easy and effective division of smaller branch pulmonary arteries in "tight" spaces where endoscopic stapling might not be possible, there is little doubt that such a device would be promptly included in the armamentaria of many thoracic surgeons. The basis for conducting this prospective trial is on solid footing, including previously published ex vivo human lung specimen studies, animal studies, and a relatively large single-surgeon retrospective series.²⁻⁵ All too often, the surgical community seems willing to accept techniques or technology based on retrospective data or occasionally even conceptual appeal without rigorous scientific validation. As we all know, however, no matter how compelling retrospective data or a conceptual appeal may be, prospectively collected data are more convincing. Thus, Goudie and colleagues¹ are to be commended on their prospective evaluation of an energy device for pulmonary artery sealing and division.

There are inherent limitations to this phase I study, as well as potential limitations of the device itself. As a brief initial thought, the authors disclosed that this study did not receive any funding from industry, yet the primary investigator disclosed research and educational grants from Ethicon. These 2 statements may leave the reader

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Central Message

Goudie and colleagues¹ report on a phase I study using an ultrasonic energy device for branch pulmonary artery sealing and division. The preliminary results are promising; further study would seem warranted.

See Article page 1600 in the June 2017 issue.

unsure of the presence or absence of any underlying conflict of interest. That issue aside, however, the authors clearly defined the limitations of the study, including a very small sample size. By design, however, phase I trials are preliminary feasibility studies, with phase II trials needed to formally assess safety and efficacy.

During lobectomy, pulmonary artery pressures, vessel diameters and lengths, and sizes and angles of tissue gaps available to access vessels for division are variable. Moreover, this device does not appear to be exempt from user error caveats, including choosing the of proper power settings, ensuring that the vessel to be divided flattens in the instrument jaws before applying energy, and allowing the device to cool with gentle rotation before removal to avoid "sticking" after sealing and division. Heat spread from the instrument is an additional concern cited by the authors. These potential issues would seem to merit further study on a larger scale to convincingly accomplish the authors' stated goal. In addition, other techniques that may be more cost-effective with equivalent or even superior efficacy in sealing smaller pulmonary artery branch vessels in tight spaces, such as endoclips, may be available.

What level of evidence does it take to convince surgeons to adopt a new technique or new technology? Is the combination of ex vivo human lung and animal

studies and a relatively large single-surgeon retrospective series cited in this manuscript already sufficient without formal prospective testing? How about multicenter prospective single-arm or even randomized trials? Obviously, these are rhetorical questions with no consensus answers, with answers depending for the most part on the surgeon and the new technique or technology under consideration. Nonetheless, it is fair to say that the bar has not been set particularly high, for various valid (and sometimes maybe not so valid) reasons. For example, as the authors note, the reported failure rate of endostapling during pulmonary branch vessel division is already very low, well under 1%. Studies to identify specific risk factors for endostapler failure are lacking, however. Perhaps endoscopic stapler failures are limited mainly to small, short pulmonary artery branches in tight spaces where the torque of a larger endostapling device may tear fragile pulmonary vessels. If this were the case, then in a perfect world a prospective randomized study controlling for vessel size/location comparing this energy device to endostaplers and perhaps even 3-way randomization using other technology, such as endoclips, would be mandated. Although pharmaceutical manufacturers are held to this standard, such a study would present obvious and unreasonable obstacles to the surgical community. For surgeons, a realistic approach would seem to include striving to obtain as much convincing supporting data as is reasonable, supplemented with a healthy dose of informed consent from the patient when convincing

data are not available, the latter of which tends to be lacking outside of a clinical trial.

In summary, the authors of this prospective phase I trial have demonstrated the feasibility of an energy device for sealing and dividing branch pulmonary arteries during lobectomy, but acknowledge that their data fall short of validating safety and efficacy. The authors are appropriately continuing their efforts by spearheading a multicenter phase II clinical trial ([Clinicaltrials.gov: NCT02719717](https://clinicaltrials.gov/ct2/show/study/NCT02719717)) using this instrument for a planned cohort of 150 patients undergoing VATS lobectomy. Hopefully, one way or another, this prospective study will “seal the deal” for this energy device. Interested surgeons should assist in the accrual effort to help set the evidence level bar high for our specialty.

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