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What does it take to seal the deal?

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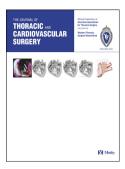
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I disclose no potential conflicts of interest.

In this issue, Goudie and coauthors report on prospective Phase I study using an ultrasonic energy device (Harmonic ACE® +7, Ethicon Cincinnati, OH) for pulmonary artery sealing and division during lobectomy. The authors designed a safe clinical trial using an open lobectomy technique, which would provide rapid control of any bleeding, and limited division of pulmonary branch vessels to diameters of 7 mm or less. The author's ultimate stated goal is use of this device during VATS lobectomy with a potential advantage over endostaplers in situations involving division of small, short segmental pulmonary arteries in "tight" spaces where endostaplers may not be utilized safely. While all vessels were successfully sealed and divided without bleeding in this prospective trial, the authors conclude that further study of this device is needed before 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 may not be possible, there is little doubt such a device would be quickly placed in the armamentaria of many thoracic surgeons. And 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. (1-4) 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 are or conceptual appeal may be, prospectively collected data is more convincing. The authors of this publication are therefore to be congratulated 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 to the device itself. As a brief initial thought, the authors disclose that this study did not receive any funding from industry yet the primary investigator discloses research and educational grants from Ethicon Endosurgery (Cincinnati, OH). These two statements perhaps leave only the reader conflicted as to the presence or absence of any underlying interest conflict. That aside, the authors have well defined the limitations of this study, including a very small sample size. By design however Phase I trials are preliminary feasibility

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