Prospective, multicenter, international phase 2 trial evaluating ultrasonic energy for pulmonary artery branch sealing in video-assisted thoracoscopic surgery lobectomy

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ABSTRACT

Objectives: The study objectives were to evaluate the immediate, short-, and medium-term efficacy and safety of pulmonary artery branch sealing using an ultrasonic vessel-sealing device in minimally invasive anatomic lung resection.

Methods: This study consists of a prospective, phase 2, multicenter, international clinical trial (clinicaltrials.gov: NCT02719717) that enrolled patients planned for video-assisted thoracoscopic surgery/robotic anatomic lung resection in 7 centers (United States, Canada, United Kingdom). Pulmonary artery branches of 7 mm or less were sealed and divided with an ultrasonic energy vessel-sealing device. The remainder of the lobectomy was performed according to surgeon preference. Intraoperative, in-hospital, and 30-day postoperative bleeding and complications were prospectively recorded.

Results: A total of 150 patients with a minimum of 1 pulmonary artery branch sealed with an ultrasonic vessel-sealing device were prospectively enrolled in the trial. Resections included 139 lobectomies and 11 segmentectomies. A total of 424 pulmonary artery branches were divided: 239 with the ultrasonic vessel-sealing device, 181 with endostaplers, and 4 with endoscopic clips. The mean and median pulmonary artery diameters were 4.7 mm/5.0 mm, 10.3 mm/10.0 mm, and 6.5 mm/6.5 mm for each method, respectively. Three of the pulmonary artery branches divided with the ultrasonic vessel-sealing device (1.3%) and 4 pulmonary artery branches divided with endostaplers (2.2%) bled intraoperatively. Among the patients with seal failures, 1 patient required conversion to thoracotomy. There was no postoperative bleeding from divided pulmonary artery branches with either sealing method. There was no mortality at 30 days.

Conclusions: Pulmonary artery branch sealing with ultrasonic energy during video-assisted thoracoscopic surgery lobectomy is safe for vessels 7 mm or less. The use of an ultrasonic device is a reasonable sealing method for pulmonary artery branches 7 mm or less. (J Thorac Cardiovasc Surg 2020;159:301-11)

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

Perspective
We performed a prospective, phase 2, multicenter, international clinical trial that evaluated ultrasonic PA branch sealing for vessels 7 mm or less. There was no difference in bleeding between ultrasonic-sealed vessels and vessels sealed with endostaplers. PA branch sealing with ultrasonic energy during VATS lobectomy is safe for vessels 7 mm or less.

See Commentaries on pages 312, 314, and 315.
Although video-assisted thoracoscopic surgery (VATS) lobectomy has been proven to be effective and safe in experienced hands, it is not devoid of risk. Intraoperative surgical complications can be catastrophic at times. The most important intraoperative complication is pulmonary vascular injury necessitating urgent conversion to open thoracotomy and even death. Published conversion rates range from 2% to 20%. In a Canadian study published in 2011 analyzing the causes of VATS conversion to thoracotomy in 237 cases, the conversion rate from VATS to open was 13.5%. Pulmonary artery (PA) injury alone constituted 37.5% of all conversions.

Currently, despite being a safe and effective technique in experienced hands, anatomic pulmonary resections amenable to minimally invasive resections are still being performed by thoracotomy. Data from the National Surgical Quality Improvement Program database show that between 2007 and 2015 the incidence of thoracoscopy for lobectomy/segmentectomy or lobectomy by VATS or robotic-assisted thoracic surgery (RATS) were approached for enrollment in this clinical trial. Eligibility criteria were as follows: (1) ability to consent; (2) age more than 18 years; (3) nonhilar tumors; (4) preoperative imaging (chest computed tomography and positron emission tomography–computed tomography), nonsuggestive of hilar or mediastinal nodal disease; (5) invasive mediastinal staging requirement was based on current American College of Chest Physicians lung cancer staging criteria and was performed by any of the following tests, in appropriate patients, alone or in combination based on study site preference in accordance with American College of Chest Physicians guidelines: mediastinoscopy, mediastinotomy, VATS, endobronchial ultrasound, and endoscopic ultrasound.

Exclusion criteria were as follows: (1) previous ipsilateral thoracic surgical procedure or trauma; (2) history of mediastinal or pulmonary irradiation; (3) anticoagulation with inability to stop anticoagulants before surgery; (4) systemic vascular disease or vasculitis; (5) uncorrectable coagulopathy; and (6) use of systemic steroids or immunosuppressive medication. Pulmonary hypertension was not an exclusion criterion because patients with pulmonary hypertension were shown to have higher bursting strength in previous studies.

**Surgical Technique**

The Harmonic ACE+7 Shears with Advanced Hemostasis (ACE+7; Ethicon, Cincinnati, Ohio) was the ultrasonic energy vessel-sealing device evaluated in this trial. Surgeons were instructed to perform the planned anatomic lung resection following their standard technique except for PA division. For the trial, all PA vessels that required division were dissected and measured in vivo using a sterile ruler. PA branches greater than 7 mm in diameter were divided using a vascular endostapler. Division and sealing of the lobar and segmental PA branches 7 mm or less in diameter were performed with the ACE+7 (Video 1). PA vessels with diameters 1 to 5 mm were sealed on the Min setting with generator set at level “3”, and vessels between 5 and 7 mm were sealed using the Advanced Hemosclerization setting. The Harmonic ACE+7 was used in both VATS and RATS approaches with the same technique for PA sealing.

To seal and divide a PA branch with the ultrasonic energy device, surgeons were instructed to verify that the PA would lie flat inside the 2 blades of the instrument without any folding of the vessel wall before instrument activation. Only 1 activation of the instrument was used until the vessel was completely divided. Surgeons were also instructed to avoid putting tension on the vessel being sealed. Finally, surgeons were encouraged to leave a long stump of the PA being divided for safety purposes. No clips or sutures were added for reinforcement on PA stumps divided.

To ensure uniformity of the PA sealing technique with the device, all participating surgeons had to follow a training module outlining all of the steps and technical aspect of the technique. The module also contained several videos with examples of proper sealing technique. The study credentialed surgeon investigator remained responsible to decide the suitability of PA branches for sealing with the device. This was assessed and
decided upon intraoperatively according to anatomy, vascular dissection, and patient-specific factors. Surgeons were not required to seal PA branches less than or equal to 7 mm with the device if they had a reason to believe it was not safe. Of the 15 surgeons participating in the trial, 3 had previous experience with the device for PA branch sealing during minimally invasive lung resections. All other surgeons learned the technique specifically for the trial. All procedures were filmed and recorded during PA manipulation and division for analysis in case of a seal failure and for monitoring purposes.

Patients were included in the study analysis only if they underwent the study intervention: PA branch sealing using ACE+7 of at least 1 PA branch during a minimally invasive anatomic lung resection. Conversion to thoracotomy before sealing a PA branch with the device also excluded patients from study analysis.

Standard postoperative care was provided to all patients according to surgeon practice and preference. No additional monitoring or tests were necessary for patients in the postoperative period.

Study Outcomes

The primary outcome of this trial was intraoperative and postoperative seal failure on a sealed PA branch with the ultrasonic energy device. Immediate seal failure was defined as bleeding from a divided PA branch during the initial operation that required direct intervention, such as compression, clip placement, or suture. Delayed seal failure was defined as bleeding from a PA branch sealed with the device in the first 30 postoperative days. It was assumed that postoperative bleeding from a PA branch would cause hemodynamic instability necessitating prompt investigations and reintervention in a patient, thus allowing study investigators to identify all primary outcomes. Secondary outcomes were overall postoperative complications according to the Clavien-Dindo Classification and 30-day mortality. Safety outcomes in this trial were any seal failure related to the study device, as described earlier, and any complication directly related to the use of the study device, such as a thermal injury.

Efficacy in the trial was defined as the ability of the ACE+7 to seal PA branches 7 mm or less in a practical manner for the surgeons. This was assessed with the ability of surgeons to perform the procedure as described in the protocol.

Postoperative data were recorded prospectively during patient hospital stay. After hospital discharge, patients were followed in the outpatient postoperative clinic or with a phone call.

Surgeon Questionnaire

Immediately after each operation, surgeons were asked to fill out a short questionnaire to evaluate their impression of the use of the energy sealing device.
device during the specific operation. The questionnaire was developed by 
the surgeons who had previous experience with the energy-sealing device. 
The questions were as follows:

1. Compared with your standard technique, did the use of the Harmonic 
   ACE+7 make this procedure (a) much easier, (b) easier, (c) similar level 
   of difficulty, (d) harder, or (e) much harder.
2. For PA branch sealing, the Harmonic ACE+7 was (a) very easy to use, 
   (b) somewhat easy to use, (c) neutral, (d) somewhat difficult to use, or 
   (e) very difficult to use.
3. In your opinion, did the Harmonic ACE+7 Shears avert a conversion to 
thoracotomy in this case? Yes/No.

Statistics

This trial is evaluating precision and does not aim at testing a hypothe-
sis. The sample size has been calculated on the basis of a 2-sided 99% 
confidence interval. We assumed a rate of seal failure of 2% at 30 days. This

363 assessed for eligibility

93 excluded
- Refused to participate (n = 40)
- Not meeting inclusion criteria (n = 28)
- Other reasons (n = 25)

270 allocated to intervention
150 received allocated intervention
120 did not receive allocated intervention:
- All PA branch diameter >7 mm (n = 77)
- Conversion to thoracotomy unrelated to ACE (N = 26)
- Lobectomy not performed because of intraoperative findings (n = 7)
- ACE not used for technical reasons (n = 10)

0 lost to follow-up

150 included in analysis

FIGURE 2. Prospective, multicenter, international phase 2 trial evaluating ultrasonic energy for PA branch sealing in VATS lobectomy consort diagram. PA, Pulmonary artery.

estimate is based on our previous experience with the technique and on published data. On the basis of this assumption, the absolute minimum number of patients was 85. However, allowing for subgroup analyses, we aimed at recruiting 150 patients. nQuery (Statistical Solutions Ltd, Cork, Ireland) was used for sample size calculation, and IBM SPSS Statistics (version 25; New York, NY) was used for descriptive statistics.

RESULTS
Between July 2016 and November 2018, 270 patients were approached and consented for study enrollment (Figure 2). These patients were recruited across 7 sites and were planned for surgery with 1 of 15 board certified general thoracic surgeons with experience in minimally invasive lobectomy/segmentectomy.

A total of 150 patients were included and represent the cohort for study analysis. In these patients, a minimum of 1 PA branch was sealed with the ultrasonic energy sealing device (ACE+7) during VATS or RATS anatomic lung resection. Mean age was 66 years (range, 33-82 years). There were 93 female and 57 male patients. Mean body mass index was 26.6 kg/m² (standard deviation [SD], 5.1; range, 16-42). A total of 46 patients (31%) were receiving aspirin therapy at the time of operation. Ten patients (6.7%) were receiving continuous anticoagulant therapy before surgery. Anticoagulants were stopped before surgery and resumed afterward according to site-specific standard clinical practice.

A total of 139 lobectomies and 11 anatomic segmentectomies were performed in the trial (Table 1). A total of 128 resections were performed using a VATS approach, and 22 were performed using a RATS approach. Tumor stage and pathological findings are detailed in Tables 2 and 3. A total of 424 PA branches were divided: 239 with the ultrasonic vessel-sealing device, 181 with endostaplers, and 4 with endoscopic clips (Table 4). The mean and median PA diameters were 4.7 mm/5.0 mm, 10.3 mm/10.0 mm, and 6.5 mm/6.5 mm for each method, respectively. Twenty-nine branches 7 mm or less in diameter were not divided with the ACE+7; 27 of those were divided with endostaplers and 2 with clips.

Seal failure occurred in 7 cases: 3 after sealing with the ACE+7 device and 4 after division with an endostapler (P = .47). All seal failures occurred intraoperatively, and no patient experienced a bleed from a divided PA stump postoperatively. The first seal failure related to the use of the energy sealing device was on a 5-mm posterior ascending PA branch during a right upper lobectomy (Video 2). The branch had sealed initially; however, the corner of the stump started bleeding at the end of the operation because of suction trauma. A clip was applied on the PA stump to control the bleeding. Blood loss was 300 mL, and no blood transfusion was necessary. The second bleed related to the ACE+7 was on a 5-mm anterior PA branch during a right upper lobectomy. The bleeding was difficult to control.
to control during thoracoscopy; therefore, conversion to thoracotomy was necessary to allow for suture of the PA stump that controlled the bleeding. Blood loss was 550 mL, and no blood transfusion was necessary. The third bleed with ultrasonic sealing was on a 6-mm anterior basal artery during a left lower lobectomy. The bleeding was coming from the corner of the PA stump immediately after the energy device was applied and necessitated a single clip placement. No conversion to thoracotomy was necessary, blood loss was 50 mL, and no transfusion was required.

Bleeding associated with endostaplers occurred on PA branches of 7, 7, 8, and 12 mm. In all cases, the seal failure was partial and visible pulsatile bleeding was seen on a portion of the staple line. All necessitated clip placement to control the bleeding, and no conversion to thoracotomy or blood transfusion was necessary. There was no specific cause for seal failures associated with the endostaplers. In our experience, the mismatch between staple size and vessel wall thickness can explain the incomplete seal of a PA branch with endostaplers.

Two other patients required conversion to thoracotomy after the PA branches had been sealed with the energy sealing device. One conversion was necessary for a bronchoplasty due to left main bronchus injury during left upper lobectomy. The second conversion was during a right lower lobectomy. An angioplasty was necessary because of tumor invasion into the main PA. Neither of these conversions were related to the use of the energy device.

Mean operative time was 126 minutes (SD, 79 minutes). Mean blood loss was 109 mL (SD, 119 mL). Median chest tube removal day was postoperative day 3 (range, 1-21 days). Mean and median length of stay were 4.1 days (SD, 3.1 days) and 3.8 days (range, 1-30 days), respectively.

Table 5 describes the postoperative complications in the trial. One patient required reoperation because of bleeding from a bronchial artery. At the time of reoperation, all the PA stumps were carefully examined, and it was confirmed that no bleeding was coming from any PA branch. All patients were followed up until postoperative day 30. There was no mortality at 30 days.

A total of 148 questionnaires were answered by 15 surgeons with a response rate of 98.7%. Figure 3 demonstrates surgeon perception of the utility of the ultrasonic energy sealing device on the procedure compared with the surgeon’s standard approach. In 74.3% of cases, surgeons declared that the device made the surgical procedure much easier (n = 72) or easier (n = 38) compared with their standard practice. Figure 4 demonstrates surgeon perception regarding the ease of use of the energy sealing device during the procedure. In 91.2% of cases, surgeons declared

<table>
<thead>
<tr>
<th>Complications</th>
<th>No. of cases (%)</th>
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<tbody>
<tr>
<td>Prolonged air leak</td>
<td>23 (15.3)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>10 (6.7)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>9 (6.0)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Delirium</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Hemothorax</td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

Table 3: Histology of resected lung tumors

<table>
<thead>
<tr>
<th>Histology</th>
<th>No. of cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung adenocarcinoma</td>
<td>101 (67)</td>
</tr>
<tr>
<td>Squamous cell lung cancer</td>
<td>16 (11)</td>
</tr>
<tr>
<td>Lung adenocarcinoma and squamous cell lung cancer</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Carcinoid lung tumor</td>
<td>13 (8.7)</td>
</tr>
<tr>
<td>Lung adenocarcinoma and small cell lung cancer</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Colorectal adenocarcinoma</td>
<td>7 (4.7)</td>
</tr>
<tr>
<td>Urothelial carcinoma</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Testicular teratoma</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>B-cell lymphoma</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Benign lung lesion</td>
<td>8 (5.3)</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
</tr>
</tbody>
</table>

Table 4: Divided pulmonary artery characteristics

<table>
<thead>
<tr>
<th>PA division method (no. of PAs)</th>
<th>Mean diameter (mm)</th>
<th>Median diameter (mm)</th>
<th>Range (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic energy (239)</td>
<td>4.7</td>
<td>5.0</td>
<td>1-7</td>
</tr>
<tr>
<td>Endostapler (181)</td>
<td>10.3</td>
<td>10.0</td>
<td>3-24</td>
</tr>
<tr>
<td>Clip (4)</td>
<td>6.5</td>
<td>6.5</td>
<td>3-10</td>
</tr>
</tbody>
</table>

PA, Pulmonary artery.
that the device was very easy to use (n = 112) or somewhat easy to use (n = 23). Finally, in 18% of cases, surgeons subjectively thought that the use of the energy sealing device during minimally invasive anatomic lung resection prevented conversion to thoracotomy.

### DISCUSSION

A minimally invasive approach is the standard of care for anatomic lung resections for stage I and II lung cancer. The incidence of VATS and RATS lobectomy has increased consistently over the last decade. Several factors may have contributed to this increase, including the availability of instruments adapted to VATS/RATS to ease dissection, manipulation, and division of hilar structures. This phase 2 trial aimed specifically at evaluating the safety of an ultrasonic energy sealing device for sealing PA branches during thoracoscopic anatomic lung resections.

The current trial evaluated a device that has already been commercialized; however, there is a lack of safety data for its use on pulmonary vasculature because safety studies on energy devices are typically performed on systemic arteries. Therefore, this trial is the result of a comprehensive step-by-step approach carried out by our group to demonstrate the efficacy and safety of energy sealing for PA vessels 7 mm or less. Ex vivo studies evaluated burst pressures of PA branches sealed with different energy vessel-sealing devices and with standard endostaplers. Results showed that PAs sealed with ultrasonic energy can sustain higher pressures than PAs sealed with advanced bipolar energy devices or endostaplers. Two phase 1 trials evaluated the safety of ultrasonic energy for PA sealing in open and VATS lobectomy. These 2 trials allowed us to obtain safety data to support the current phase 2 multicenter trial.

There were 3 seal failures with the ACE+7. In the first case, the PA stump started bleeding after a suction rubbed the stump. This complication can be avoided by not touching the freshly sealed PA stumps. The second bleed associated with the ACE+7 was during a right upper lobectomy on a 5-mm branch. No specific cause was identified to...
explain the seal failure. The surgeon hypothesized that tension on the PA during activation could have caused premature cutting of the branch. The third case in which bleeding occurred was on a 6-mm branch during a left lower lobectomy. Retrospectively, we believe this seal failure can be explained by the positioning of the PA inside the instrument. The PA branch was wedged into the crotch of the instrument jaws, and sealing at this location is not as effective because the vessel may be folded. The 2 blades do not have full contact in the crotch, and surgeons should avoid placing the PA inside the “V” at the instrument.

The 3 seal failures related to the energy sealing device all occurred intraoperatively and were managed with minimal complications. There was no difference in failure rates between energy sealed vessels and endostaplers in this trial. There were no postoperative seal failures in either group.

We believe that technical details are important to ensure the safe use of this instrument (Table 6). PA dissection is necessary to safely apply the blades of the ACE+7 around the PA branch. This avoids having other tissues (lung, lymph nodes) between the vessel wall and the instrument, which can compromise the quality of the seal. Also, sufficient dissection allows keeping a safe distance between the tip of the instrument and the surrounding tissues. At the end of activation, the tip can reach temperatures up to 200°C. In circumstances where only limited clearance of the main PA (<2 mm) can be obtained, some other form of vascular division should be considered. In the current trial, no thermal injury caused any clinically significant complication. Proper apposition of the PA branch inside the blades of the instrument is important. The vessel needs to lie flat because folds in the vessel wall can compromise the quality of the seal. Also, proper sealing is best achieved in the middle of the blades. Positioning the artery in the crotch of the instrument should be avoided. We recommend leaving at least a few millimeters of stump to allow easier vascular control in case of sealing failure. The ACE+7 has 3 buttons: maximum (Max), minimum (Min), and advanced hemostasis. We do not recommend using the Max function on PA branches because it spends less time sealing the tissue and cuts the tissue faster than other functions. However, some authors suggest the Max function is sufficient for PA sealing. The Min function is the appropriate function to seal and divide named blood vessels of 5 mm or less. This function spends more time sealing tissues before dividing them. Finally, the advanced hemostasis function spends more time sealing vessel walls before dividing the tissue. Advanced hemostasis is appropriate for vessels between 5 and 7 mm. On the basis of our experience, we advise avoiding tension or torsion on the PA branch while the instrument is activated. This avoids premature division of the PA before a complete seal is achieved.

Because of the device profile and small tip size, the surgeon’s stress level when getting around small PA branches may be decreased. In a Japanese study, surgeon stress was evaluated with a visual analog scale and was found to be significantly less when using an energy device compared with an endostapler for PA division. To our knowledge, the current trial is the largest prospective human trial evaluating an ultrasonic energy sealing device for PA sealing. In 2016, White and colleagues performed a retrospective study looking at the use of the Harmonic ACE for PA and vein sealing. They divided 97 pulmonary arteries and 21 veins in 82 lobectomies. There was 1 seal failure. Likewise, for a seal failure in this trial, their explanation for the seal failure seemed to be related to the positioning of the PA branch within the jaws of the instrument. Other publications report on the use of advanced bipolar energy sealing devices. In our opinion, there are not enough safety data available for these devices compared with ultrasonic devices for PA sealing. In 1 ex vivo study evaluating the burst pressures of pulmonary arteries sealed with different devices, some PA stumps did not seal at all with advanced bipolar devices. We advise caution on applying the results of this trial to other energy devices that are commercially available. Sufficient safety data should be obtained for a specific device before its routine use can be recommended for the pulmonary vasculature.

CONCLUSIONS

PA branch sealing with an ultrasonic energy device during VATS lobectomy is safe for vessels 7 mm or less. There was no difference in bleeding between ultrasonic-sealed vessels and vessels sealed with endostaplers. The use of an ultrasonic device is a reasonable sealing method for small PA branches.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://aats.blob.core.windows.net/media/19%20AM/Saturday_May4/203BD/203BD/S14%20-%20Looking%20to%20the%20future/S14_5_webcast_111059219.mp4.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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References

Key Words: pulmonary artery, vessel sealing, ultrasonic energy, VATS lobectomy

Discussion

**Dr Scott J. Swanson** (Boston, Mass). You and your co-investigators should be congratulated for successfully designing and carrying out a prospective phase 2 trial looking at new technology, and you looked at ultrasonic energy to divide PA branches during a lobectomy and a segmentectomy. You showed what we and others have seen, that you can successfully divide 7-mm PA branches using the ultrasonic shears. We did it in animals too and saw the same thing: minimum morbidity and no mortality. It’s a big advance. You did observe several failures, which were immediately remedied at the time and had no significant consequence. I have 3 questions.

You mentioned in your article it’s hard to know exactly how many of these branches that could be divided were divided by each surgeon, but do you have any idea if, say, 6 or 7 or smaller, if 3 were done or 2 were done, and how those decisions were made? Do you have any insight on that?

**Dr Moishe Liberman** (Montreal, Quebec, Canada). We have all those data. Every vessel had to be measured, even if you were going to staple it or put a clip on it, so we know which vessels were sealed with energy and which were not. And I would say in the trial I think, I could be wrong, but I think except for the 9 or 10 vessels that were 7 mm and less, they were all sealed with the ultrasonic device.

The reasons reported by the surgeons who had not sealed those smaller vessels, some of them were due to anatomy or I guess the vessel probably was very, very short, and some were at the beginning of the trial when surgeons were a little less comfortable and were in their learning curve, sort of getting used to seeing that this actually works. I think at the end of the trial, almost every size
appropriate vessel is being sealed with energy. So it’s a small percentage.

Dr Swanson. We have seen, shown, and observed that you can use it on veins, no problem, same size, 7 mm. Any reason not to look at that or did you just want to keep it as a pure study?

Dr Liberman. Good point, and I agree with that 100%. We also use it in anatomic segments, on veins and middle lobe veins. In reality, when you are doing a lobectomy, it is rare to find a very small vein that drains an actual lobe. The trial was really designed for the PA. It would have been confusing, for the sample size calculation, to have added veins to it, especially because we had a small percentage of segments. But I think there is no hesitation to use it on veins. The worry with veins is not the same as with arteries, because systemic veins and pulmonary veins are pretty much the same. This has already been well shown in the belly to work on veins, so I’m not worried about it. But it’s a good question.

Dr Swanson. I think the economics of these things are important, and the more you use it and the less you use other devices the better.

The other thing is, I think the 7-mm size is based on the size of the probe, it’s about an 11- to 12-mm probe, and when you flatten out the vessel, you want no wrinkling, as you have mentioned in your article, and that’s where 7 mm comes in. So my guess is when probes get bigger, we will be able to do bigger vessels.

The last question is really around the technique, and I have a bit of difference in your sort of interpretation about what setting to use, and I think it showed up well in the videos. I think the longer you have to pull the vessel, the more likely you can sometimes tear or be under tension, and tension is really the problem here. With the fast speed, you need less time and you get less tension, and in our animal model and in our practice the fast speed worked. And 1 of the vessels that didn’t work out, you mentioned maybe because it was under some tension. So I wonder if you have data as to why you think the fast setting is worse than the slow setting, because we found the opposite, and I think you would avoid some of that tension. But it was a great study. I really appreciate it.

Dr Liberman. The answer is, I don’t know. I would say that in our animal studies we found that the slow setting for larger vessels was better, and that was, again, we were just at 5 mm, we weren’t going to 7 mm at that time. When you have a very small 2-mm vessel, yes, I think the fast is great. When you are at 6 to 7 mm, we were using advanced hemostasis; when you are at 5, I’m not sure the fast setting is enough. We tried to keep it standard for the trial. We haven’t had problems. We have done more than 500 cases now without a problem using these settings. And I’m not saying the other way is wrong, it’s just that’s the way we do it, and we wanted everyone in the trial to do it the same way.
Dr Liberman. A good question. It is exactly as we said, don’t put it in the crotch, it should really lie flat, because the problem with the crotch is that the tension is not evenly distributed and the vessel often folds, even a minor bit that you don’t see, and we have seen that when we have done ex vivo studies looking under the electron microscope at what happens to those vessels.

Dr Gunda Leschber (Berlin, Germany). I would like to return to the length of the stump. On a PA, I don’t think that’s so much of a problem because it is relatively long, although I was at least trained to have a very short stump only. But I would caution if you do this on a vein, because don’t you think it could be where an embolism could develop and then you end up having systemic emboli?

Dr Liberman. Again, when we see a longer stump, we’re talking about 5 mm, maybe 4 mm. When you use an endostapler, you are usually leaving 5 or 4 mm on each side anyway for the artery. I’m not saying in terms of the stump. If you leave a 5-mm stump on a venous branch, I don’t know that that is actually a problem. That’s a good question, can that cause an embolism? We haven’t seen it, but I’m not saying it’s not possible. It’s a good question and a concern. Again, we are really only using it on segments and not for lobectomies.

Dr Thomas A. D’Amico (Durham, NC). It’s reported in the literature for lobectomies.