In situ laser fenestration during emergent thoracic endovascular aortic repair is an effective method for left subclavian artery revascularization

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Background: Retrograde laser fenestration of the left subclavian artery (LSA) during emergent thoracic endovascular aortic repair (TEVAR) uses a relatively simple intraoperative method of endograft modification to revascularize aortic branches for a variety of acute thoracic aortic pathologies. This study presents our expanded experience and midterm outcomes of TEVAR with laser fenestration to revascularize the LSA as an alternative to debranching.

Methods: Patients who underwent TEVAR with LSA revascularization by laser graft fenestration from September 2009 through August 2012 were retrospectively reviewed. TEVAR was performed with deployment of a Dacron (DuPont, Wilmington, Del) endograft over the LSA orifice. Laser catheter fenestration of the graft was performed through retrograde brachial access, followed by balloon-expandable covered stent deployment through the fenestration to traverse the endograft and LSA. Routine postoperative follow-up imaging with computed tomography angiography was performed to assess TEVAR and LSA fenestration patency, endoleak, and aneurysm/dissection exclusion.

Results: TEVAR with laser fenestration was successfully performed in 22 patients (12 men; mean age, 57 years) in an urgent or emergent setting secondary to unremitting symptoms or rupture. Twelve patients had large symptomatic thoracic aortic aneurysms (eight secondary to chronic dissection); four patients had acute symptomatic type B aortic dissection, and six patients had intramural hematoma or penetrating aortic ulcer, or both. An average of two endografts (range, 1-4) were deployed. LSA-covered stents were 8 to 10 mm in diameter. Mean operative time was 154 ± 65 minutes. Average hospital length of stay was 12 ± 7 days. No major fenestration-related complications occurred. One patient developed postoperative paraplegia. One patient died in the postoperative period, for an in-hospital mortality rate of 4.5%. Two patients died of non-TEVAR-related causes at a mean follow-up of 10 months (range, 1-40 months). Follow-up computed tomography angiography imaging demonstrated a 100% primary patency for the LSA stents. One patient had an asymptomatic LSA stent stenosis. Type II endoleaks from the LSA in two patients required endovascular coil embolization. No fenestration-related type I or III endoleaks were noted.

Conclusions: In situ retrograde laser fenestration is a feasible and effective option for LSA revascularization during TEVAR involving a spectrum of acute thoracic aortic pathology. Laser fenestration provides a rapid, reproducible method of revascularizing the endograft material. The high technical success, low fenestration-related morbidity, and excellent midterm patency justify this technique in an urgent or emergent setting to extend the applicability of TEVAR.

CLINICAL RESEARCH STUDIES

From the Division of Vascular Surgery, Eastern Virginia Medical School. Author conflict of interest: Dr Panneton is a consultant and on the Speakers Bureau for Cook Medical and Medtronic Inc.


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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214/$36.00

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http://dx.doi.org/10.1016/j.jvs.2013.04.045

Acute thoracic aortic pathologies that encroach on aortic arch vessels result in inadequate proximal endograft landing zones and classically have mandated traditional open repair or thoracic endovascular aortic repair (TEVAR) with coverage of the left subclavian artery (LSA). Conventional open thoracic aortic repair in an urgent or emergent setting has been demonstrated to have mortality rates close to 20% and significant morbidity, including a risk of spinal cord ischemia that can affect 18.6% of patients.1,2 Intentional endograft coverage of the LSA was initially thought to be a viable alternative in this setting to extend the applicability of TEVAR.3 Unfortunately, expanding experience with intentional LSA coverage without revascularization portends a significantly increased risk of subclavian steal syndrome, arm claudication, vertebral territory stroke, and spinal cord ischemia by eliminating collateral blood supply to the spinal cord from the vertebral artery.4,5 Several options have been described that allow patency of the LSA to be maintained, including elective debranching before TEVAR, the chimney technique by deploying an LSA stent parallel to the thoracic endograft,
prefabricated branched endograft deployment, or surgeon-modified endografts.6-9 Yet the options in an urgent or emergent setting are limited.

McWilliams et al10 initially used serial cutting balloons as a modality for transluminal in situ fenestration of a thoracic endograft after deliberate coverage of the LSA. Subsequently, Murphy et al11 described a technique of in situ laser graft fenestration of a Dacron (DuPont, Wilmington, Del) endograft to revascularize an LSA during repair of traumatic aortic transection in a young patient. We have also reported our initial experience using retrograde laser fenestration to revascularize the LSA during zone II TEVAR.12 This relatively simple intraoperative method of laser-mediated endograft modification provides a rapid and reproducible method of fenestrating the endograft material to revascularize aortic branches for a variety of acute thoracic aortic pathologies. Herein, we present our expanded experience and midterm outcomes of TEVAR with laser fenestration to revascularize the LSA as an alternative to an open repair or debranching procedure.

METHODS

This study was performed with approval of the Eastern Virginia Medical School Institutional Review Board and in compliance with the Health Insurance Portability and Accountability Act.

Patient identification. A retrospective review of the electronic medical record was conducted to identify all patients who had undergone TEVAR with in situ laser fenestration to preserve flow to the LSA from September 2009 through August 2012.

Laser fenestration technique. Thoracic endografts were deployed using Talent or Valiant (Medtronic Inc, Santa Rosa, Calif), TX2 (Cook Inc, Bloomington, Ind), or TAG (W. L. Gore & Associates, Flagstaff, Ariz) stent grafts. The laser fenestration was always created in a proximal Dacron-based endograft. An 8F Lamp sheath (St. Jude Medical, St. Paul, Minn), with a preformed angle at the tip, was placed through retrograde left brachial artery access at the ostium of the LSA. A 2.0- to 2.5-mm Turbo Elite laser catheter (Spectranetics, Colorado Springs, Colo) was placed at the ostium of the LSA perpendicular to the endograft over a 0.018-inch Platinum Plus wire (Boston Scientific, Natick, Mass; Fig 1).

The laser fiber was gently advanced to make contact with the deployed Dacron endograft, followed by laser energy application for 3 to 5 seconds to create the fenestration. The sheath and laser catheter were positioned before stent graft deployment, and within minutes, the laser fenestration was performed, limiting potential ischemia time to <5 minutes in most cases. The 0.018-inch wire was advanced through the laser catheter and fenestration into the endograft lumen and exchanged for a stiff 0.035-inch wire (Fig 2). The endograft fenestration was predilated using a 6-mm balloon, followed by deployment of an 8- to 10-mm balloon-expandable iCAST covered stent (Atrium, Hudson, NH). The stent was deployed approximately one-quarter into the endograft lumen and three-quarters into the branch vessel (Fig 3). The intraendograft portion of the covered stent was flared using a 14- × 20-mm balloon introduced from the brachial access. Finally, completion aortography was performed to confirm endograft and LSA fenestration patency without endoleak.

Endograft and LSA fenestration imaging surveillance with computed tomography angiography (CTA) was performed before discharge and at regular intervals after the procedure, typically at 1, 3, 6, and 12 months, to assess patency, endoleak, and aneurysm and dissection exclusion.

Outcome measures and analysis. The patients who underwent TEVAR with LSA fenestration as described. Patient demographics, morphologic presentation of aortic lesion, procedural information and outcomes, complications, and follow-up data were collected from the electronic medical record. Descriptive statistics were used to describe patient data and outcomes in this cohort.

RESULTS

Patient demographics and presentation. Our institutional experience using TEVAR with laser fenestration was successfully performed in 22 patients (12 men) with a mean age of 57 years (range, 37-83 years). All patients underwent TEVAR with retrograde laser fenestration to revascularize the LSA during TEVAR in an urgent or emergent setting secondary to unremitting symptoms or rupture on a compassionate-use basis. Every patient presented initially with symptoms of severe chest and/or back pain on admission. Emergent cases were generally performed within hours of patient presentation, whereas the procedure in urgent cases varied in timing because these patients underwent repair after an initial attempt at medical management had failed and, ultimately, were deemed to require urgent operative intervention.

Of the 22 study patients, 21 had hypertension, 15 had a history of smoking, and seven had renal insufficiency, defined as serum creatinine >1.5 mg/dL. (Table). Two patients had Marfan syndrome, and two patients had previous aortic root replacement. The indications for TEVAR are shown in Fig 4. Twelve patients had large symptomatic thoracic aortic aneurysms, of which eight were secondary to chronic dissection (two type A and six type B) and four were secondary to degenerative aneurysms; four patients had acute symptomatic type B aortic dissection, and six patients had intramural hematoma or penetrating aortic ulcer, or both. Four patients had evidence of aortic rupture, including one aneurysm secondary to chronic dissection, one degenerative aneurysm, one combined intramural hematoma and penetrating aortic ulcer, and one acute type B aortic dissection. None of the patients had dissection extending into the LSA. Four patients had stenosis of the LSA. The mean maximal aortic diameter was 52 mm (range, 28-90 mm).

Operative data. TEVAR was technically successful in all 22 patients. An average of two endografts (range, 1-4)
were placed during TEVAR. Multiple endografts were placed in 18 patients: Medtronic endografts were solely used in 12 patients, Cook TX2 devices were solely used in one patient, a Medtronic Talent endograft was placed proximally with a Cook TX2 distally in one patient, and a combination of Talent endografts were placed proximally with a Gore TAG placed distally in two patients. The graft through which the fenestration was created was a Medtronic Talent or Valiant endograft in 19 of the 22 patients, whereas the fenestrated graft was a Cook TX2 in the remaining three patients.

A zone II deployment within the aortic arch was used in 19 patients. A zone I TEVAR deployment was used in one patient who had previously undergone a left common carotid transposition. Two patients with chronic type A aortic dissection underwent TEVAR with zone 0 deployment. The first patient had Marfan syndrome and had initially undergone an aortic root and arch replacement with innominate and left common carotid bypass grafting. The second patient had a previous aortic root replacement secondary to the type A dissection and a bovine arch anomaly that required zone 0 deployment with in situ LSA fenestration and also a back-table surgeon-modified graft fenestration for the innominate artery, achieving a totally endovascular fenestrated arch replacement for

Fig 2. The laser catheter is placed at the ostium of the left subclavian artery (LSA) perpendicular to the endograft over a 0.018-inch wire. To create a clean, circular fenestration, the laser fiber should ideally be oriented at a 90° angle to the endograft. Right, After laser activation, the laser catheter is advanced through the endograft.

Fig 3. The iCAST stent is deployed from the brachial access approximately one-quarter into the endograft lumen and three-quarters into the branch vessel.
a large symptomatic arch aneurysm. The back-table endograft fenestration was performed to accommodate placement of a covered stent into a 16-mm innominate artery. This stent size exceeds the maximum diameter of stent that should be placed through a 3-mm laser endograft fenestration. This patient had been turned down for open arch replacement by cardiothoracic surgery.

The left brachial artery was accessed percutaneously in eight patients, with open left brachial exposure required in the remaining patients. LSA-covered stents ranged in diameter from 8 to 10 mm. Mean operative time for TEVAR with laser fenestration was 154 ± 65 minutes, and the mean contrast volume was 134 ± 64 mL. An average of 20 minutes of the total case time was required for obtaining brachial access, fenestration of the graft, and LSA stent deployment.

**Perioperative outcomes and complications.** No major in situ laser fenestration-related operative complications occurred, but two minor access-related complications were noted. These two patients required early postoperative reintervention. One patient required exploration and repair of a left brachial artery after percutaneous access for LSA fenestration and stent deployment. A second patient, who had open left brachial access, required evacuation of a groin and left arm hematoma. TEVAR-related complications included one patient (4.5%) who developed postoperative paraplegia after emergent repair for a ruptured acute aortic dissection. One patient with Marfan syndrome underwent aortic root replacement 15 days after TEVAR for a retrograde aortic dissection caused by the proximal bare stent of a Talent endograft that was landed proximal to the left common carotid artery. This patient recovered uneventfully.

There were no perioperative strokes, transient ischemic attacks, or other neurologic complications. One patient died, resulting in an in-hospital mortality rate of 4.5%. This patient initially presented with massive hemoptysis from an aortobronchial fistula, suffered recurrent hemoptysis, and ultimately died of severe pneumonia in the postoperative period. The average hospital length of stay was 12 ± 7 days (range, 3-30 days).

**Midterm follow-up.** At a mean follow-up of 11 months (range, 1-40 months), there was 100% primary patency for the LSA stents, as demonstrated by routine follow-up CTA imaging. A representative image is demonstrated in Fig 5. One patient had an asymptomatic LSA stent stenosis. Two patients had type II endoleaks from the LSA that required reintervention. Both patients underwent successful reintervention with endovascular coil embolization through a combined percutaneous femoral and brachial artery access. Endoleak obliteration was confirmed with completion angiography and follow-up CTA. There were no fenestration-related type I or III endoleaks. None of the patients with retrograde LSA fenestration have reported left arm claudication symptoms or vertebrobasilar symptoms at the follow-up examination. Two patients (9%) had died of non-TEVAR-related causes: the first, with previous dialysis-dependent renal failure, died

### Table. Demographics and comorbid conditions in patients undergoing thoracic endovascular aortic repair (TEVAR) with in situ retrograde laser fenestration

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (range) or percentage (n = 22)</th>
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<tr>
<td>Male sex</td>
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<tr>
<td>Black race</td>
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<tr>
<td>Age, years</td>
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<td>Comorbid conditions</td>
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<td>Arrhythmia</td>
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</table>

Fig 4. The etiology of presentation of the 22 patients undergoing thoracic endovascular aortic repair (TEVAR) with in situ retrograde laser fenestration. IMH, Intramural hematoma; PAU, penetrating aortic ulcer.

Fig 5. Left subclavian artery (LSA) stent patency, without evidence of endoleak and stable aortic size are demonstrated on 39-month follow-up (left) computed tomography angiography and a (right) volume-rendered image.
of renal failure 4 months after repair, and the second died of an acute traumatic fall 14 months after TEVAR.

**DISCUSSION**

Intentional coverage of the LSA during TEVAR has been performed routinely by some and is thought to be associated with a low risk of clinically significant sequelae. However, increased experience with this technique has resulted in growing evidence that LSA coverage is accompanied by a recognized risk of arm claudication, vertebral territory and anterior circulation stroke, and spinal cord ischemia, which can necessitate interval carotid-to-subclavian bypass to alleviate symptoms. In 2009, these findings ultimately led to the Society for Vascular Surgery Committee on Aortic Disease to suggest routine preoperative revascularization for planned coverage of the LSA during elective TEVAR and additionally strongly recommended routine revascularization in circumstances where collateral perfusion might be compromised. These practice guidelines did make exceptions in the setting of emergent TEVAR or when other circumstances would preclude preoperative LSA revascularization. Routine revascularization is still controversial, because studies also exist that challenge its absolute necessity. Maldonado et al recently described their experience and concluded that LSA coverage does not result in an increased incidence of spinal cord ischemia or stroke when a selective LSA revascularization strategy is adopted. They found similar outcomes among noncovered, covered, and covered and revascularized LSAs. However, they did acknowledge that the exact individual criterion on which the decision between covering and revascularizing the LSA was made was not abundantly clear.

Alternatives to LSA coverage that allow for attaining an adequate proximal seal for thoracic endografting include elective bypass to or transposition of the LSA or deployment of scalloped and branched grafts. Open LSA revascularization often requires longer operative times and the need for multiple surgical interventions with staged endografting. Open revascularization also has potential risks for vocal cord paralysis and injury to the thoracic duct, brachial plexus, and phrenic nerve. Prefabricated, patient-customized devices, which require extensive planning with precise preoperative imaging and time for graft manufacturing, are not commercially available in the United States currently. For this reason, these modalities are often not advisable or feasible for patients presenting with the acute thoracic aortic pathologies as described in this case series.

Our early experience with back-table testing revealed that the laser created a clean fenestration of the Dacron material while maintaining the overall endograft integrity. This led to our continued interest in using this technique in emergent situations complicated by the need to obtain an adequate proximal seal without compromising the LSA. This technique offers a relatively simple, in vivo method of endograft modification that can be applied in a variety of acute thoracic aortic pathologies. Furthermore, the laser provides a rapid and reproducible method of fenestrating the endograft material.

Our experience has found the preoperative CT scan to be predictive of success and very helpful with preoperative planning for in situ fenestration. Ideally, a three-dimensional reconstruction of the CT scan would be helpful, but the patients in this series underwent urgent operations, and time for this was not always available. Coronal and sagittal views allow for visualization of the arch anatomy and location of the vertebral artery takeoff from the LSA and for planning the orientation of the laser fiber. We do not routinely obtain preoperative intracranial imaging but attempt to revascularize the LSA in most urgent or emergent cases due to the increased risk of transient hypotension and concerns for spinal cord ischemia and stroke in these patients. Carotid duplex ultrasound imaging to determine patency or dominance of the vertebral arteries could be obtained preoperatively in some patients.

In our experience, we elect to cover the LSA without revascularization in certain emergent situations such as traumatic transection or in patients who require a short length of aortic coverage during TEVAR. The distance between the common carotid artery and LSA was 5 to 16 mm on preoperative CT scan in this series of patients. Our proximal endograft is usually deployed immediately distal to the left common carotid artery, so based on our experience, the fenestrations should be attempted if >5 mm is available between the proximal endograft fabric and the LSA. Special attention must be paid to anatomic considerations in this technique. The judicious use of multiple C-arm projections before laser fenestrations ensures that the laser fiber is aligned appropriately with the endograft.

Among other technical considerations is the use of preformed angled brachial sheaths, including newer articulating devices. We have come to fenestrate more frequently with Medtronic endografts because of the greater distance between stent struts in which to create the fenestration. Cook TX2 devices have a smaller area of fabric between stent struts, and for this reason, the maximum diameter for the LSA covered stent we will use is no more than 8 mm to prevent pushing the struts apart. On bench testing, we have found that the laser simply deflects off the strut. Regardless of the proximal endograft design, however, we do not orient the stent struts and the LSA during TEVAR deployment; instead, we focus on accurately landing our proximal fabric immediately distal to the left common carotid artery and allow the laser to find the nearest fabric during laser fenestration.

The angle of the LSA takeoff from the aortic arch has a substantial effect on the technical ease and success of laser fenestration. This clinical scenario accounts for the single aborted attempt at laser fenestration reported in our initial series of patients. This attempt was aborted before activation of the laser secondary to the intraoperative finding of an acute takeoff angle of the LSA in a type III aortic arch. The covered LSA in this instance was revascularized instead.
by performing a chimney with a covered stent. To create a clean, circular fenestration, the laser fiber ideally must be oriented at a 90° angle to the endograft, as demonstrated in Fig 1, and an angle that is too acute (<30°) will not allow the fenestration to be created. When this anatomic scenario is encountered, in situ laser fenestration should not be performed. Other criteria that preclude the use of this technique are also based on unfavorable anatomic criteria, including subclavian origin dilatation >12 mm, which exceeds the size of the largest available iCAST covered stents and would compromise seal, a low vertebral artery takeoff not allowing for an appropriate landing zone for the covered stent, and involvement of the LSA by dissection or aneurysmal disease.

We recognize that the current practice of endograft modification is controversial. Increasing experience with endovascular management of vascular pathology has led to efforts to broaden the indications for use of these techniques. The patients in this series underwent TEVAR with retrograde laser fenestration to revascularize the LSA on a compassionate-use basis in an urgent or emergent setting secondary to unrelenting symptoms or findings of aortic rupture. A United States Food and Drug Administration-approved investigational device exemption was not obtained before use of this technique at our institution. However, every patient was made aware of the off-label modification of the endograft that was required for his or her operation. This was part of a detailed discussion of risks and benefits of the technique while obtaining informed consent for the procedure.

This case series suggests that promising midterm results can be achieved after TEVAR with LSA revascularization by laser graft fenestration in patients presenting with various acute aortic pathologies. We report satisfactory durability and acceptable reintervention and complication rates. The observed perioperative morbidity and mortality after the technique of retrograde in vivo laser fenestration compare favorably with other techniques of LSA revascularization. The average hospital length of stay of 12 ± 7 days was variable within the cohort, as noted by the large standard deviation. The four patients who presented with aortic rupture had more complicated postoperative courses, with an average length of stay of 23 days, and these patients contributed greatly to prolong the average in-hospital length of stay.

As with any endovascular procedure, strict surveillance of these endografts and modifications will be necessary to ensure durability of repair. The long-term interactions between the endograft and the covered stent will need to be monitored closely over time because of the potential for stent collapse or stent breakage and the development of a late type III endoleak between the two components. Our future work in regard to these concerns will address microscopic alterations to endograft fabrics after laser fenestration. Until further technologic advances and clinical trials lead to the approval of branched arch devices, this technique offers a safe and feasible option to revascularize the LSA during TEVAR. Longer follow-up remains necessary to better elucidate the fenestrated stent graft and the LSA covered stent interactions, as well as, the durability of this technique.

CONCLUSIONS

The technique of in situ retrograde laser fenestration is a feasible and effective option for LSA revascularization during emergent TEVAR involving a spectrum of acute thoracic aortic pathologies. Laser fenestration provides a rapid and reproducible method of fenestrating the endograft material. The high technical success, low fenestration-related morbidity, and excellent midterm patency support this technique of intraoperative endograft modification in the absence of available branched devices for arch deployment. Longer follow-up remains necessary to determine the durability of this technique.

AUTHOR CONTRIBUTIONS

Conception and design: SA, JP
Analysis and interpretation: RR, SA, JP
Data collection: RR, SA, JP
Writing the article: RR
Critical revision of the article: RR, SA, JP
Final approval of the article: RR, SA, JP
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: JP

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Submitted Jan 29, 2013; accepted Apr 17, 2013.