

A Systematic Review of Contemporary Outcomes from Aortic Arch In Situ Laser Fenestration During Thoracic Endovascular Aortic Repair

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Background: In situ laser fenestrated endovascular aortic repair (L-FEVAR) is a novel and creative solution for complex aortic pathologies in the urgent and emergency setting. Outcomes of this technique, however, are poorly reported. We sought to evaluate the efficacy, safety, and outcomes of L-FEVAR in aortic arch pathologies.

Methods: A systematic literature review and analysis were conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses and Cochrane guidelines. A search was conducted using Google, PubMed, and Scopus to identify studies evaluating L-FEVAR. Two independent reviewers determined study inclusion. Case reports and series including < 10 patients were excluded. Reviewers also assessed the methodological quality and extracted data regarding outcomes. A meta-analysis of endoleak event rates was conducted using a fixed-effect model due to small sample size.

Results: Eight studies met inclusion criteria between 2013 and 2021. Most studies were retrospective (87.5%) with median follow-up duration of 12.5 months (range 10–42). There were 440 patients included (range 15–148), mostly men (64%). Mean age was 61 years (range 53–68). Included patients were all symptomatic with L-FEVAR being technically successful in 93.3% of cases. The main indication for aortic arch intervention was aortic dissection. Single fenestrations occurred most frequently (68%), followed by triple (22%) then double fenestrations (9%). Meta-analysis of 8 studies ($n = 440$) demonstrated an endoleak event rate of 0.06 (95% confidence interval 0.04–0.09, $P < 0.001$) with no observed statistically significant heterogeneity of effects ($Q = 7.91$, $P = 0.34$). The median operative time was 162 min (range 53–252) with median length of stay of 10 days (range 7–17). Primary branch patency was 96.6%. Secondary patency rate was 97%. Pooled complication rates such as endoleak occurred in 4.8%, stroke in 2.0%, spinal cord ischemia in 0.2%, retrograde dissection in 0.9%, and 30-day death in 2.0%. Access complications occurred in 0.4%. Antiplatelet regimen was poorly reported in the study cohort.

Conclusions: In situ laser fenestration is a feasible, safe, and effective approach to treat aortic arch disease in patients who are unsuitable for open or custom-made endovascular means. High technical success and excellent short-term branch patency can be achieved. These single-institution series exhibit promising short-term outcomes. In a similar paradigm to investigational device exemptions studies for custom-made and physician modified endografts, these preliminary data make a persuasive argument for larger long-term multi-institutional prospective study of this promising technique.

The authors declare no conflicts of interest.

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INTRODUCTION

Treatment of aortic dissection has migrated from open surgical repair for Type B aortic dissection (TBAD) to thoracic endovascular aortic repair (TEVAR) with a significant benefit in terms of patient outcomes.¹ The increased use of TEVAR for TBAD has led to new challenges with respect to extent of coverage of the thoracic aorta and aortic arch vessels. The most notable example of this concerns the left subclavian artery (LSA). The optimal strategy for managing the LSA is still a topic for debate, with mounting evidence and consensus guidelines to suggest that routine coverage in both elective and emergency settings can be performed but is associated with a higher risk of overall stroke.^{2,3}

Further evidence exists drawing an association with temporary paraparesis and even permanent paralysis with subclavian artery coverage without revascularization as this artery forms part of an important and fragile collateral network supplying perfusion to the spinal cord.^{4,5} Methods of left subclavian revascularization include surgical options such as subclavian-carotid transposition and carotid-subclavian bypass (CSB). These procedures, however, do have associated and defined complications and therefore add not only time and additional surgical stress to an already complex operation but also risks of mortality and phrenic nerve palsy (25%), recurrent laryngeal nerve palsy (5%), axillary nerve palsy (2%), neck hematoma requiring re-exploration (1%), significant postoperative bleeding (11.4%), peripheral nervous system complications (9%) including ipsilateral recurrent laryngeal nerve paresis and Horner's Syndrome and upper extremity paresis, paresthesia and facial nerve paresis, cutaneous chylous fistula (3.8%), and local wound infection (2.4%) with wound complication rate of 4% necessitating graft explantation in 2.8% of cases.^{6,7}

Other options for left subclavian revascularization include endovascular options such as snorkel or chimney approaches, physician-modified and custom-manufactured endografts, and laser fenestrated approaches, which avoid many of the complications associated with open surgical repair but are complicated by stroke, stent occlusion, endoleak, and need for aortic and left subclavian stent reintervention.^{8–10}

McWilliams et al. were the first to describe in situ stent graft fenestration in 2004 where they used serial cutting balloons to maintain LSA flow in a patient undergoing endograft repair for a saccular

thoracic aneurysm with planned LSA coverage.¹¹ Murphy et al. was the first to describe the concept of in-situ laser-assisted endograft fenestration during TEVAR for traumatic acute aortic transection just distal to the takeoff of the LSA.¹² Since then, few single-center studies have been published reporting their experience using this novel and creative technique for complex aortic pathologies in urgent and emergent setting.^{9,10,13}

Following on from initial experience with laser fenestration to the subclavian artery during TEVAR, published small series reports of laser fenestration to the visceral arteries during complex EVAR surfaced demonstrating some preliminary safety and efficacy of this technique in patients unfit for open repair and who could not undergo a custom-made device.^{14,15} Outcomes of these novel and untested techniques, however, are poorly reported. In this study, we sought to evaluate the efficacy, safety, and short-term outcomes of laser fenestrated endovascular aortic repair (L-FEVAR) in aortic arch pathologies.

METHODS

Search Methodology

The databases PubMed, Scopus, [ClinicalTrials.gov](https://www.clinicaltrials.gov/), and IEEE Explore were searched by a medical librarian (C.S.). Search results were downloaded on August 11, 2021. Searches were limited to English. The general search strategy included the following concepts in combination: (laser* AND fenestrat* AND [aort* OR endovascular OR endograft* OR stent*]). The approach to the systematic review followed the preferred reporting items for systematic reviews and meta-analyses statements and the Cochrane guidelines.^{16,17} In addition, we followed the stepwise approach for systematic reviews for endovascular intervention reported by Antoniou et al.¹⁸

Article Selection. Figure 1 demonstrates the stepwise approach to identification of studies. Two independent reviewers (J.B. and S.T.) determined study inclusion. Case reports and case series including less than 10 patients were excluded. Studies published before 2010 were also excluded. We excluded studies which did not report endoleak rate as it is a primary outcome of interest. Reviewers also assessed the methodological quality and extracted data regarding outcomes for statistical analysis. All

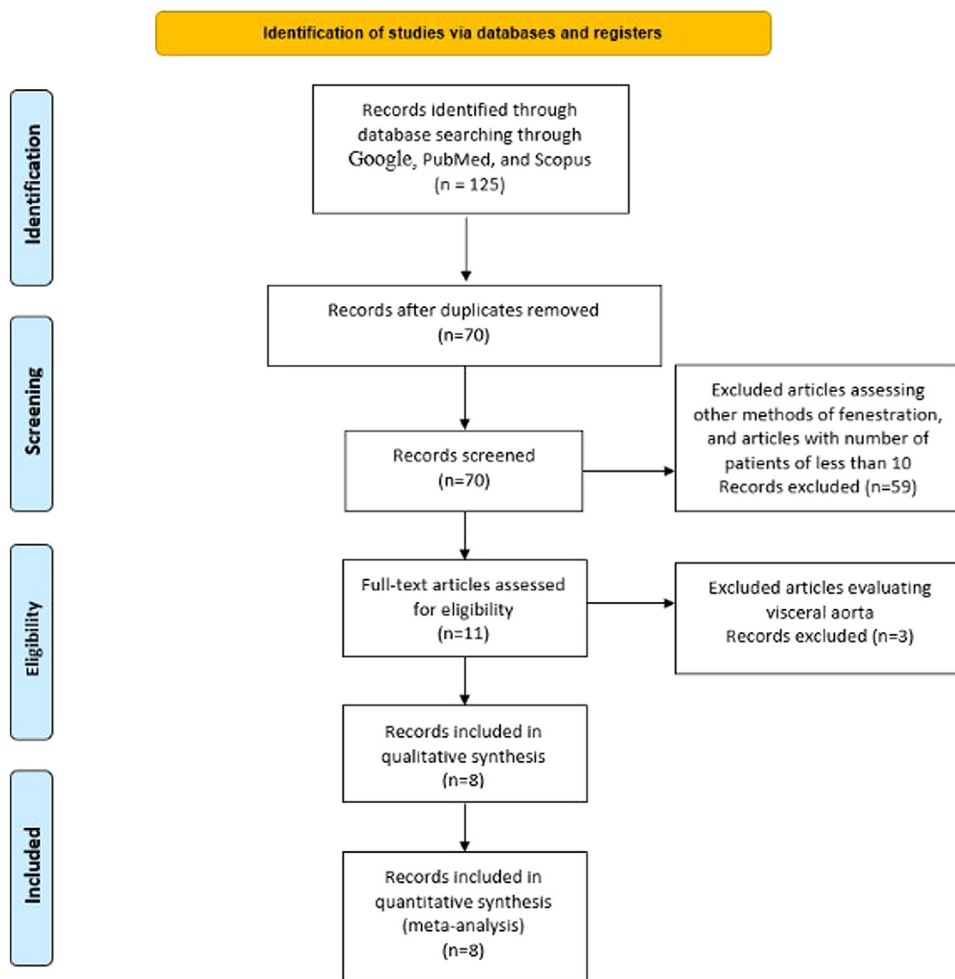


Fig. 1. Flow chart of literature search using the PRISMA template.

results that were compatible with each outcome domain in each study were sought for analysis.

Statistical Analysis and Follow-Up. Medians and weighted average percentages were calculated to take into account the weight of each study sample. A meta-analysis of endoleak event rate was conducted using a fixed-effect model due to small sample size (Fig. 2). A continuity correction factor of 0.5 was applied for studies with zero events.¹⁹ Homogeneity of effects was assessed using Cochrane's Q and I^2 .

Follow-up was rendered in these 8 studies with clinical examination and computed tomography angiographic (CTA) imaging in all cases. This was described in the methods section of the studies. The follow-up schedule was a 1-month, 6-month, and annual follow-up with CTA. Additional 3-month and 6-month visits with imaging were also described in 2 of the studies. Duplex was not

described as a follow-up modality given the adequacy of the CTA imaging for follow-up.

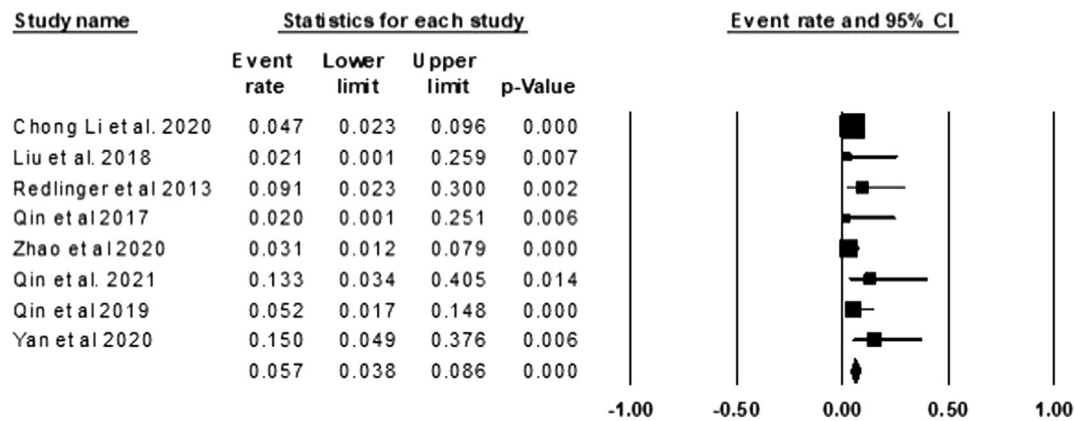
RESULTS

Included Studies and Patient Demographics

Eight studies published between 2013 and 2020 met our inclusion criteria and were included in our analysis.^{9,10,20–25} Indications for the procedure included rupture or unremitting symptoms, Type A aortic dissection, Acute and chronic TBAD, Thoracic aortic aneurysm, penetrating aortic ulcer, intramural hematoma, and mural thrombus.

Overall, 440 patients were included in this study (Table I) with the total number of branches treated being 661; a pooled mean of 1.5 branches treated per patient. Among those patients, 280 (64%)

Meta-Analysis of Endoleak Event Rate



*Fixed-effect model was used. Homogeneity of effects was assessed using Cochrane's Q and I

Fig. 2. Meta-analysis of endoleak.

Table I. Demographics^a

	N/%
N = 440 patients	
Age (y/range)	61 [53–68]
Male	280 (64)
Female	160 (36)
Symptomatic aortic arch disease	440 (100)
HTN	267 (60.6)
Smoking	182 (41.4)
Diabetes Mellitus	187 (42.5)
Coronary Artery Disease	125 (28.4)
Peripheral arterial disease	102 (23.1)
Renal insufficiency	27 (6.2)

^aWeighted average percentages. Median was calculated for age.

were males and 160 (36%) were females. Hundred percent of the patients had symptomatic aortic arch disease at the time of the repair and 267 (60.6%) had hypertension, 182 (41.4%) were smokers, 187 (42.5%) had diabetes mellitus, 125 (28.4%) had coronary artery disease, 102 (23.1%) had peripheral vascular disease, and 27 (6.2%) had renal insufficiency.

The 810 nm laser was the most commonly used to establish fenestrations in 268 (61%) patients followed by the 980 nm laser in 150 (34%) and 308 nm laser in 22 (5%). Single fenestration was most commonly performed in 299 (68%) of patients followed by triple fenestrations, which were

performed in 97 (22%) patients. Double fenestrations were least commonly performed in 40 (9%) cases. Median operative time was 162 min (range 53–252) and the median contrast used was 164 mL (range 134–204). Table II demonstrates these findings. The types of graft used for laser fenestration were as follows: Talent (Medtronic PLC, Dublin), Zenith (Cook Medical, Bloomington), TAG (Gore Medical, Flagstaff), Endurant (Medtronic PLC, Dublin), Ankura (Lifetech Scientific, China), TX2 (Cook Medical, Bloomington), Hercules (Lombard Medical, United Kingdom), and E-vita (Jotec, Germany). For the bridging stents the types of stent-grafts used were as follows: Fluency (BD Medical, New Jersey), Advanta V12 (Getinge Group, Sweden) and iCAST (Atrium Medical, St. Louis), BeGRAFT (Bentley Global, Germany), Via-bahn and VBX (Gore Medical, Flagstaff), and Omni-link (Abbott, Chicago).

Outcomes

Technical success was achieved in 410 (93.3%) patients (Table III). The reported primary and secondary patency rates were 96.6% and 97%, respectively, at a mean follow-up of 12.5 months (range 10–42). Endoleak was seen in 18 patients (4.8%) and a meta-analysis of all 8 studies ($n = 440$) demonstrated there was no statistically significant heterogeneity of effects observed across

Table II. Operative characteristics^a

<i>N</i> = 440 patients	<i>N</i> /%
980 nm laser	150 (34)
810 nm laser	268 (61)
308 nm laser	22 (5)
Number of fenestrations	
Single fenestration	299 (68)
Double fenestration	40 (9)
Triple fenestration	97 (22)
Operative time and contrast volume	
Average contrast volume in mL	164 (134–204)
Operative time in minutes	162 (53–252)

^aWeighted average percentages were calculated to report type of laser and number of fenestrations. Median was reported for operative time and contrast volume.

studies ($Q = 7.9$, $P = 0.34$, $I^2 = 11.5\%$) (Fig. 2). Reintervention was undertaken in 5 patients (1.1%) during the mean follow-up period of 12.5 months, of which there was 1 branch reintervention (0.22%) and 4 aortic reinterventions (0.9%). Access complications were reported in 7 of the 8 studies and occurred in 3 patients overall (0.68%). Retrograde dissection rate was 0.9% (4 patients) with spinal cord ischemia reported in 1 patient (0.2%) and stroke in 9 patients (2%). Reported 30-day mortality rate was 2% (9 patients). The average hospital length of stay was 10 days (range 7–17).

Table IV provides a summary of the included studies from 2017 to 2021.

DISCUSSION

In situ laser fenestration is a relatively new endovascular approach that has emerged over the past decade to provide an additional option for endovascular repair of aortic arch pathologies. The advantage of L-FEVAR is that it is rapid to perform and avoids the morbidity and mortality associated with sternotomy and ascending aortic debranching or a more complex aortic procedure.¹² Despite the technical complexity of the procedure, these current presented data suggest that it is a safe and feasible method to treat aortic arch pathology with high reported technical success rates and favorable mid-term outcomes such as low stroke, retrograde dissection, endoleak, and patency rates.

Open and Hybrid Surgical Techniques for Aortic Arch Repair

Traditional methods of left subclavian revascularization include surgical options such as subclavian-carotid transposition and CSB, which have been

Table III. Outcomes of in-situ laser fenestration^a

Primary outcomes	<i>N</i> /%
Endoleak rate	18 (4.8)
Technical success rate	410 (93.3)
Primary patency rate	425 (96.6)
Secondary patency rate	427 (97)
Secondary outcomes	
Retrograde dissection rate	4 (0.9)
Spinal cord ischemia rate	1 (0.2)
Stroke	9 (2)
30-day mortality rate	9 (2)
Hospital length of stay (d)	10 (7–17)
Follow-up (m)	12.5 (10–42)

^aWeighted average percentages were calculated for primary and secondary outcomes. Median is reported for hospital length of stay and follow-up.

associated with a short-term complication rate of 29%. These complications include phrenic nerve palsy in 25%, recurrent laryngeal nerve palsy in 5%, axillary nerve palsy in 2%, neck hematoma requiring re-exploration in 1% and extremity ischemia, thrombosis, hemorrhage, stroke, thoracic duct leak, surgical site infection, and graft infection.^{6,7,26}

Although elective LSA occlusion has been reported to be well tolerated in the absence of stenotic carotid arteries and intact vertebrobasilar vasculature,²⁷ there is a significant rate of stroke and spinal cord injury that occurs with coverage of the LSA without revascularization.^{3,28} Moving further towards zone 0 of the aortic arch increases the overall risk of the procedure including the risk of stroke. The most aggressive surgical options for arch disorders involve ascending aortic repair, hemiarch repair, or total arch replacement and use deep hypothermic circulatory arrest with a significant morbidity and mortality.^{29,30} Frozen elephant trunk techniques straddle the bridge between true open and endovascular surgical repair of the arch and descending thoracic aorta.^{31–33} Other hybrid approaches have arisen, borne out of a need to reduce the overall risk of this procedure, and include aortoinnominate and aortocarotid bypass with CSB for total arch debranching prior to TEVAR or supra-aortic debranching based upon the innominate artery with carotid-carotid bypass and carotid to subclavian bypass.^{34,35}

Endovascular Techniques for Aortic Arch Repair

Custom-made devices for the aortic arch are moving from trial to commercial use including branched

Table IV. Summary of included studies

Author	Year	Country	Indication	Branches	Laser used	Single fenestration	Double fenestration	Triple fenestration	Patients	LOS (d)	Mean F/U (m)	Technical success %
Chong Li et al. ¹⁰	2020	China	TAAD (13) TBAD (107) TAA (17) PAU (11)	183	980 nm	124	13	11	148	NA	15	97.3%
Liu et al. ¹⁶	2018	China	TAA (12) IMH (11)	36	810 nm	9	11	3	23	7	10.5	100%
Redlinger et al. ⁸	2013	USA	Rupture or unremitent symptoms (22)	22	308 nm	22	0	0	22	12	11	100%
Qin et al. ¹⁹	2017	China	TAAD (4) TBAD (7) TAA (2) MT (7)	24	810 nm	16	6	2	24	17	10	95.8%
Zhao et al. ¹⁸	2020	China	Acute TBAD (109) Chronic TBAD (21)	130	810 nm	130	0	0	130	9	42	96.9%
Qin et al. ¹⁷	2021	China	Retrograde TAAD (15)	34	810 nm	1	9	5	15	10	13	86.7%
Yan et al. ²⁰	2020	China	TAAD (20)	58	810 nm	0	2	18	20	13	16	100%
Qin et al. ²¹	2019	China	TAAD (58)	174	810 nm	0	0	58	58	10	12	91.4%

TAAD, type A aortic dissection; TBAD, type B aortic dissection; TAA, thoracic aortic aneurysm; PAU, penetrating aortic ulcer; IMH, intramural hematoma; MT, mural thrombus; NA, not applicable.

TEVAR (bTEVAR), most commonly targeting innominate artery and left common carotid artery, and fenestrated TEVAR (fTEVAR).^{36–39} These devices, however, are still plagued by a significant stroke rate and limited availability outside of specialized centers and therefore creative solutions have been employed to treat patients in a minimally invasive fashion without exposing them to risks and morbidity of open surgery.

Total endovascular revascularization of the supra-aortic branches can be achieved with chimney, snorkel, and periscope techniques.^{27,38–41} Although the chimney technique remains an elegant solution to address the thoracic aortic lesion while reconstructing supra-aortic branches, the main disadvantage is the elevated endoleak rate compared to other approaches. This has been attributed to the gutter between the chimney and the aortic stent.⁴⁰ Wang et al. reported a rate of 10.7% and 4.9% for type I and type II endoleak, respectively.⁴⁰ In another study by Guo et al., evaluating parallel stent grafting techniques in aortic arch repair, they reported a 12.9% rate for endoleak.⁴² This review demonstrated a 4.8% endoleak rate associated with L-FEVAR and compares favorably against these other endovascular debranching techniques.

In this systematic review, we found that three-vessel laser fenestration was undertaken at a higher frequency than two-vessel laser fenestration. Most of the laser fenestration procedures were performed for aortic dissection. In addition, many of these repairs were performed for Type A patients who were not candidates for repair, acute or symptomatic Type B dissections, and higher risk for retrograde type A dissection. With this in mind, although it cannot be definitively stated, we postulate that the approach would warrant coverage to a healthier margin of aortic tissue and therefore more likely to involve a total arch approach, that is, 3-vessel fenestration rather than 2 vessels.

Laser Fenestrated Endovascular Aortic Repair Techniques for Aortic Arch Repair

L-FEVAR has been used to manage a wide array of aortic arch pathologies in both elective and urgent settings including acute Type A aortic dissection, acute and chronic TBAD, aortic arch aneurysms, penetrating ulcers, and intramural hematomas or thrombus. A number of techniques have been described for fenestration, including needle and radiofrequency, used to establish successful in situ fenestrations.⁴¹ Qin et al. reported multiple

advantages, however, to using laser with the first being a rapid, repeatable, and reproducible method during TEVAR that prevents overt damage to the polytetrafluoroethylene or Dacron endografts.^{21,25} Second, the diode laser has been developed to allow for more safe and selective action for branch vessel fenestration as it has a tissue penetration of ~0.3 mm. The third advantage would be the laser fiber flexibility and ability to pass through anatomically challenging routes which makes it an optimal method for aortic arch pathologies considering anatomic variations and complexity.^{21,25}

Technical Challenges during Laser Fenestrated Endovascular Aortic Repair for Aortic Arch Repair

Maintaining cerebral blood flow during the operation is a key component and protecting against stroke from high-energy laser-induced air bubbles or plaque/tissue debris that can potentially cause intraoperative cerebral ischemia.²⁰ Although in the hands of an experienced team, a bypass is not usually necessary, the utility of temporary bypass has been suggested by intraoperative doppler monitoring to maintain adequate cerebral blood flow during the operation, and prevent extended hypoperfusion episodes and cerebral ischemia. Temporary bypass has been achieved by an extracorporeal shunt between the proximal aorta and bilateral carotid arteries.²⁴ If an external bypass has not been established and the fenestration cannot be achieved in a timely manner to prevent < 5 min ischemic time, alternative endovascular techniques can be used as a bailout strategy, like chimney grafting.²⁵ Alternative strategies that have also been described in total endovascular arch fenestration include using the retrograde in-situ branched stent-graft technique; employing a balloon to create a temporary gutter between the TEVAR graft and the aortic wall to maintain antegrade cerebral perfusion to the innominate artery during left common carotid artery fenestration.⁴³ To avoid ischemia due to air embolus, the use of high pressure balloons is advised to avoid bursting of the balloons due to overinflation.²³ The low 30-day mortality rate of 2% associated with L-FEVAR along with low short-term neurologic complication rate of 0.2% and 2% for spinal cord ischemia and stroke, respectively, are lower than many reported trials for branched thoracic devices and suggest safety of this approach despite initial concerns regarding laser debris and additional arch manipulation for the L-FEVAR procedure.^{44–46}

Laser fenestration is a new technique using existing technology, which was borne out of an unmet need to treat complex aortic arch disorders without resorting to invasive techniques such as sternotomy and supra-aortic debranching or deep hypothermic circulatory arrest and aortic repair. Resultantly, the majority of the literature has been published on patients who are at a very high risk for complication, acute or symptomatic Type B dissections or patients unfit for open surgery with Type A dissections. The excellent results in terms of outcome from these techniques should pave the way, in our opinion, to a registry-based multicenter retrospective study of these techniques to further advance understanding of the applicability, specific technique, and outcomes from these high-risk procedures in high-risk patients. Once a solid body of patients and adequate mid-term and long-term follow-up has been collected, then the second stage would be the consideration to a small prospective Food and Drug Administration–approved trial at certain centers with experience with these techniques, under the auspices of an investigational-device exemption.

The authors believe that laser fenestration is a viable option in patients who are not surgical candidates and who are not appropriate for a commercially available approved device. This is especially true in the paravisceral aorta, in the author's opinions, but also for the thoracic aorta in cases where the combined risks of hybrid treatment are higher. The authors do stress that these techniques are experimental and not approved for use in this manner and therefore should be best studied through a Food and Drug Administration–approved investigational-device exemption.

Limitations

The retrospective nonrandomized design allows for reporting bias to occur in that negative results might not be published for an experimental procedure such as L-FEVAR. Small and heterogenous patient mix and reporting of outcomes is an issue with systematic reviews where the literature is scant and in an effort to minimize this effect, heterogeneity statistics were performed suggesting a consistent finding for endoleak, as an example of an outcome, across studies. Also, the lack of control arm prohibits direct comparison with open or other endovascular approaches in managing aortic arch pathologies. Technically, the use of in situ laser fenestration in aortic disease remains “off-label”. Available data are dominated by single-institution results, which raise concerns of generalizability. The existing

literature also lacks long-term follow-up, therefore precluding the evaluation of long-term outcomes.

CONCLUSION

This review suggests that *in-situ* laser fenestration is a feasible, safe, and effective approach to treat aortic arch disease in patients who are unsuitable for open or custom-made endovascular means. High technical success, even for triple L-FEVAR and excellent short-term branch patency can be achieved. In a similar paradigm to investigational device exemptions studies for custom-made and physician-modified endografts, these preliminary data make a persuasive argument for larger long-term multi-institutional prospective study of this creative technique. Similarly, very limited data are available on L-FEVAR for visceral aortic pathologies. This necessitates the need for multi-institutional effort to create registries that allow for retrospective evaluation of outcomes to pave the road for future prospective trials.

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