

SVS PRACTICE GUIDELINES

The Society for Vascular Surgery Practice Guidelines: Management of the left subclavian artery with thoracic endovascular aortic repair

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The Society for Vascular Surgery pursued development of clinical practice guidelines for the management of the left subclavian artery with thoracic endovascular aortic repair (TEVAR). In formulating clinical practice guidelines, the society selected a panel of experts and conducted a systematic review and meta-analysis of the literature. They used the grading of recommendations assessment, development, and evaluation (GRADE) method to develop and present their recommendations. The overall quality of evidence was very low. The committee issued three recommendations. **Recommendation 1:** In patients who need elective TEVAR where achievement of a proximal seal necessitates coverage of the left subclavian artery, we suggest routine preoperative revascularization, despite the very low-quality evidence (GRADE 2, level C). **Recommendation 2:** In selected patients who have an anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended, despite the very low-quality evidence (GRADE 1, level C). **Recommendation 3:** In patients who need urgent TEVAR for life-threatening acute aortic syndromes where achievement of a proximal seal necessitates coverage of the left subclavian artery, we suggest that revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C). (J Vasc Surg 2009;50:1155-8.)

Thoracic endovascular aortic repair (TEVAR) is a rapidly evolving new therapy in the treatment of thoracic aneurysms and dissections. TEVAR involves placing an endovascular stent graft into the thoracic aorta from a remote peripheral location under imaging guidance. Be-

cause it is less invasive than traditional thoracotomy with direct operative repair, TEVAR has the potential to revolutionize the treatment of thoracic aneurysms, similar to the development of prosthetic grafts for open repair.

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Reports of patients with large thoracic aneurysms (>6 cm in diameter) show an annual risk of rupture that varies from 10% to 15%, and >90% of these patients do not survive if the aneurysm ruptures.^{1,2} Over the years, surgeons have developed successful techniques to significantly decrease major complications associated with open surgical repair of thoracic aneurysms.³⁻⁶ Although these contributions have resulted in vast improvements in the care of patients with thoracic aneurysms, open repair is still associated with considerable morbidity and mortality. This has led physicians to seek less invasive methods of treatment.⁷⁻¹² TEVAR offers potential for durable aneurysm exclusion while avoiding thoracotomy and aortic cross-clamping. Nevertheless, stroke, spinal cord ischemia, and other complications that are associated with open repair can also occur with TEVAR.

Up 40% of patients undergoing TEVAR have pathology that extends near the left subclavian artery (LSA).⁸ In these situations, currently approved devices are typically placed over the LSA origin, thereby occluding this arch vessel. Some surgeons routinely perform LSA revascularization in these patients, whereas others do in certain circum-

stances, particularly when there is a dominant left vertebral artery (60% of patients), a previous left internal mammary coronary artery bypass graft, or the distal right vertebral segment is absent. Finally, some surgeons do not perform LSA revascularization when this artery is covered unless symptoms develop after TEVAR.¹¹⁻¹⁷ Published reports show the baseline risks of adverse outcomes in patients who have TEVAR and LSA coverage are 6% arm ischemia, 4% spinal cord ischemia, 2% vertebrobasilar ischemia, 5% anterior circulation stroke, and 6% death.¹⁸ Treatments that reduce these risks are important to characterize.

The Society for Vascular Surgery identified several key issues that require the development of clinical practice guidelines to aid surgeons, referring physicians, and patients in the process of decision making. LSA revascularization was one of these areas. In developing these guidelines, the society used similar processes and format to its recently published guidelines:

First, the society selected a committee of experts in the field with knowledge of clinical aspects as well as patients' values and preferences in this regard.

Second, the society commissioned the Knowledge and Encounter Research Unit, Mayo Clinic, Rochester, a third party with expertise in evidence-based medicine, knowledge synthesis, and guideline development to conduct a comprehensive systematic review of the literature and identify the best available evidence. The society acknowledged the value of systematic reviews and meta-analyses because, compared with individual studies, they provide evidence that is more precise and more likely to be applicable to a wider range of patients.

Third, the society used the grading of recommendations assessment, development, and evaluation (GRADE) methods to develop and present its recommendations. The GRADE method provides superior clarity and separates the quality of evidence from the strength of recommendations and allows for the inclusion of patients' values and preferences in recommendations. The GRADE system depicts recommendations as either strong (GRADE 1), denoted by the phrase "we recommend," or weak (GRADE 2), denoted by the phrase "we suggest." Aside from the strength of recommendations, the quality of evidence is graded as high quality (level A, typically derived from well conducted randomized trials), moderate quality (level B, typically derived from less rigorous or inconsistent randomized trials), and low or very low quality (level C, derived from observational studies, case series, and unsystematic observations or expert opinion). See the [Table](#).¹⁹

In this article, the Committee on Aortic Disease presents three recommendations with the aim of clarifying the role of LSA revascularization. Although there is significant diversity of individual opinions, the report reflects the consensus of the committee. The recommendations are followed by the supporting evidence, values statement, and relevant technical remarks. A detailed description of the data analysis is in the accompanying article.¹⁸

Table. Recommendations according to the grading of recommendations assessment, development, and evaluation (GRADE) system¹⁹

The GRADE system categorizes <i>recommendations</i> as	
● strong (GRADE 1) denoted by the phrase "we recommend,"	or
● weak (GRADE 2) denoted by the phrase "we suggest."	
The <i>quality of evidence</i> is graded as	
● high-quality (level A), typically derived from well conducted randomized trials,	
● moderate-quality (level B), typically derived from less rigorous or inconsistent randomized trials,	
● low- or very-low quality, (level C), derived from observational studies, case series, and unsystematic observations or expert opinion.	

RECOMMENDATIONS

Prospective randomized trials directly comparing a selective strategy of LSA revascularization and routine LSA revascularization as well as other techniques of neuroprotection are unavailable and are needed. The following recommendations are based on systematic review of the literature:

- **Recommendation 1:** In patients who need elective TEVAR where achievement of a proximal seal necessitates coverage of the LSA, we suggest routine preoperative revascularization despite the very low-quality evidence (GRADE 2, level C).
- **Recommendation 2:** In selected patients who have an anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended despite the very low-quality evidence (GRADE 1, level C).
- **Recommendation 3:** In patients who need very urgent TEVAR for life-threatening acute aortic syndromes where achievement of a proximal seal necessitates coverage of the LSA, we suggest that revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C).

EVIDENCE

The systematic review commissioned by the society demonstrated that the coverage of the LSA artery is associated with a trend towards an increase in the risk of paraplegia (odds ratio [OR], 2.69; 95% confidence interval [CI], 0.75-9.68) and anterior circulation stroke (OR, 2.58; 95% CI, 0.82-8.09), and a significant increase in the risk of arm ischemia (OR, 47.7; 95% CI, 9.9-229.3) and vertebrobasilar ischemia (OR, 10.8; 95% CI, 3.17-36.7).¹⁸ The incidence of phrenic nerve injury as a complication of primary revascularization was a modest 4.40% (95% CI, 1.60%-12.20%). There was no association with death, myocardial infarction, or transient ischemic attack.

Statistical analysis in this review was robust to sensitivity analysis, and meta-analysis was conducted using the random-effects model, which yields conservative estimates. No significant subgroup interactions were noted by indication

(aneurysm or dissection) or urgency of aortic repair. The tests for subgroup interaction based on the control group in these studies showed no significant interaction for all outcomes except arm ischemia, suggesting that the magnitude of increased risk of arm ischemia due to LSA coverage was greater when coverage was compared with no coverage than when coverage was compared with coverage preceded by primary revascularization.

Several limitations of the literature review deserve comment, because the quality of the evidence was very low. Reporting is not consistent or uniform for potentially relevant confounding factors. Including patency of the vertebral arteries, definitions of hand ischemia, wound complications such as lymphatic leaks, handedness of the patients, presence of reconstructive procedures distal to the LSA origin, and abnormal arch anatomy.²⁰

The evidence supporting TEVAR compared with open repair appears to be associated with lower postoperative mortality and ischemic spinal cord complication rates for patients with traumatic aortic injury. Meta-analysis of retrospective cohort studies demonstrated that endoluminal repair was associated with lower procedurally related mortality (OR, 0.31; 95% CI, 0.15-0.66; $P = .002$), overall 30-day mortality (OR, 0.44; 95% CI, 0.25-0.78; $P = .005$), and postoperative paraplegia (OR, 0.32; 95% CI, 0.1-0.93; $P = .037$). The quality of evidence was also very low in this context.²¹

VALUES STATEMENT

Neurologic events, including stroke and paraplegia, are critical clinical concerns when descending thoracic aneurysm repair is considered. These well-recognized complications occur after open surgical repair and TEVAR, and often lead to the eventual death of the patient.^{7,10} The guideline developers placed a relatively higher value on preventing these catastrophic complications and a relatively lower value on less devastating perioperative complications of LSA revascularization. They also placed a relatively high value on avoiding stroke and paraplegia in the clinical context of decision making with very low-quality evidence, but tempered the strength of the recommendation because of the quality of the evidence. The role of these values was particularly emphasized in the case of selected patients who have an anatomy that compromises perfusion to critical organs. In this case, the committee made a stronger recommendation, despite the paucity of evidence, to prevent these complications.

TECHNICAL REMARKS

The LSA is the primary artery to the left arm and a source of blood flow to the brain and spinal cord. Brain and spinal cord perfusion is particularly relevant when collateral pathways are compromised. In addition, many anatomic situations (discussed below) effectively mandate preservation of antegrade LSA blood flow to avoid a potentially catastrophic outcome.

Neurologic injury with TEVAR. The mechanisms of neurologic injury are multifactorial with TEVAR. Stroke may be caused by (1) systemic factors such as hypotension,

hypertension, and anticoagulation; (2) intracranial changes related to edema, cerebrospinal fluid drainage, or contrast/drug infusion; (3) embolization of air, atheroma, or thrombus from the device or manipulation of devices within the aortic arch; and (4) interruption of forward blood flow from injury or coverage of arch vessels.

The LSA provides blood flow to the upper spinal cord through the vertebral artery to the anterior spinal artery, and collateral perfusion to the left intercostal vessels through the thoracodorsal and other chest wall branch arteries. Paraplegia may be caused by (1) systemic factors such as hypotension, drug-induced vasoconstriction, and embolization; (2) local factors, including intraspinal hematoma, injury due to spinal cord drain placement, and (3) lack of blood flow caused by coverage of intercostal, lumbar, middle sacral, hypogastric, or subclavian arteries. Spinal cord damage after TEVAR may cause complete or partial neurologic deficit. The onset of symptoms can be immediate or delayed, and in some cases the deficit can improve.^{7,10-11}

Arm ischemia and vertebrobasilar ischemia with TEVAR. The LSA normally provides antegrade blood flow to the left vertebral artery and ipsilateral arm. When the LSA origin is acutely occluded, patients may experience left arm ischemia due to inadequate collateral perfusion. Symptoms may exacerbate when the patients exercise the ipsilateral upper extremity. Flow reversal in the left vertebral artery may also occur, resulting in steal of blood from the posterior circulation. At times this can cause a full-blown vertebral steal phenomenon with vertebrobasilar ischemic symptoms manifested as syncope, diplopia, or vertigo. In contrast to stroke and paraplegia, arm and vertebrobasilar ischemia may be addressed on a more elective basis.

LSA REPAIR TECHNIQUES

Traditional LSA revascularization in the setting of chronic occlusive disease has been performed with transposition of the artery to the left common carotid artery or a short bypass originating from the left common carotid artery. In the setting of TEVAR, the technique has evolved to encompass a short bypass from the left common carotid artery to the LSA as well as proximal subclavian ligation or embolization to prevent type II endoleak. Potential complications include stroke, bleeding, and injury to the thoracic duct and left neck nerves, including the phrenic, vagus, sympathetic chain, and brachial plexus. Most nerve injuries are temporary, and only a few are permanent. LSA to carotid transposition may carry lower risk of phrenic nerve injury and does not require use of prosthetic material.^{14,15}

Left carotid to subclavian bypass should be selected when there is an internal mammary artery to coronary artery bypass graft because it allows continuous antegrade perfusion of the coronary artery. Some surgeons prefer the bypass option because it avoids the less familiar medial dissection around the thoracic duct and allows access to the left carotid and LSA from a left brachial approach. Pneumothorax, prosthetic graft infection, and late occlusion are rare after these procedures.

However, long-term outcomes for indications other than occlusive disease have not been published.

In selected patients who have an anatomy that compromises perfusion to the brain, spinal cord, heart, or left arm, routine preoperative LSA revascularization is strongly recommended. Some of these conditions are:

- presence of a patent left internal mammary artery to coronary artery bypass graft,
- termination of the left vertebral artery at the posterior inferior cerebellar artery or other discontinuity of the vertebrobasilar collaterals,
- absent or diminutive or occluded right vertebral artery,
- a functioning arteriovenous shunt in the left arm,
- prior infrarenal aortic repair with ligation of lumbar and middle sacral arteries,
- planned long-segment (≥ 20 cm) coverage of the descending thoracic aorta where critical intercostal arteries originate,
- hypogastric artery occlusion, and
- presence of early aneurysmal changes that may require subsequent therapy involving the distal thoracic aorta.

The increased risk of complications with each of these conditions is not precisely defined in the literature, but these high-risk conditions are ranked by the strength of consensus of guideline developers.

In many circumstances, individualized care must be tailored using clinical judgment. Routine LSA revascularization may not be possible in some patients in whom acute ischemia or hemorrhage requires immediate TEVAR or where local surgical expertise is not available. LSA revascularization can then be considered selectively soon after TEVAR or in a staged approach if symptoms develop. A few patients may have anatomy that makes LSA revascularization difficult, such as previous local operation and scarring or previous radiation treatment. Congenital anomalies such as aberrant arch anatomy or abnormalities of the LSA or vertebral arteries may hinder revascularization of the LSA.

CONCLUSION

Although the quality of evidence is very low, preoperative LSA revascularization is suggested in patients undergoing TEVAR with coverage of the LSA. Preoperative LSA revascularization is strongly recommended in selected patients with compromised collateral circulation. Exceptions include emergency TEVAR where there is no time for LSA revascularization, when anatomic circumstances preclude LSA revascularization, or when expertise in the procedure is not available.

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