Endovascular Therapies for Extracranial Vertebral Artery Disease

Description

Vertebral artery diseases, including atherosclerotic stenosis, dissections, and aneurysms, can lead to ischemia of the posterior cerebral circulation. Conventional management of extracranial vertebral artery diseases may include medical therapy (eg, antiplatelet or anticoagulant medications), medications to reduce atherosclerotic disease risk (eg, statins), and/or surgical revascularization. Endovascular therapies have been investigated as an alternative to conventional management.

OBJECTIVE

The objective of this evidence review is to determine whether percutaneous transluminal angioplasty with or without stent implantation improves the net health outcome in individuals who have extracranial vertebral artery stenosis, aneurysm(s), dissection(s), or arteriovenous fistula(e).

POLICY STATEMENT

Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, is considered investigational for the management of extracranial vertebral artery diseases.
POLICY GUIDELINES

The extracranial vertebral artery is considered to be segments V1 to V3 of the vertebral artery from its origin at the subclavian artery until it crosses the dura mater.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Currently, no endovascular therapies have been approved by the U.S. Food and Drug Administration (FDA) specifically for treatment of extracranial vertebral artery disease.

Various stents, approved for use in the carotid or coronary circulation, have been used for extracranial vertebral artery disease. These stents may be self- or balloon-expandable.

Two devices have been approved by the FDA through the humanitarian device exemption process for intracranial atherosclerotic disease. This form of the FDA approval is available for devices used to treat conditions with an incidence of 4000 or less per year; the FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows:

1. Neurolink System (Guidant). "The Neurolink system is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system."

2. Wingspan™ Stent System (Boston Scientific). "The Wingspan Stent System with Gateway PTA [percutaneous transluminal angioplasty] Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system."

RATIONALE

Summary of Evidence

For individuals who have extracranial vertebral artery stenosis who receive PTA with or without stent implantation, the evidence includes RCTs and noncomparative studies. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs, the VIST and the VAST, found no advantage for endovascular intervention compared with best medical therapy alone. Evidence from noncomparative studies has shown that vertebral artery stenting can be performed with high rates of technical success and low periprocedural morbidity and mortality, and that vessel patency can be achieved in a high percentage of cases. However, long-term follow-up has demonstrated high rates of in-stent stenosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), or AV fistula(e) who receive PTA with stent implantation, the evidence includes small case series and reports. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. The available evidence has indicated that endovascular therapy for extracranial vertebral artery disorders other than stenosis is feasible and may be associated with favorable outcomes. However, given the lack of data comparing endovascular therapies to alternatives, the evidence is insufficient to permit conclusions about the efficacy of endovascular therapy for extracranial vertebral artery aneurysms, dissections, or AV fistulae. The evidence is insufficient to determine the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Heart Association and American Stroke Association

The American Heart Association and American Stroke Association (2014) issued joint guidelines on prevention of stroke in patients with stroke and transient ischemic attack, which made the following recommendations about treatment of extracranial vertebrobasilar disease (see Table 2).21.

Table 2. Guidelines on Stroke Prevention in Patients With Stroke and Transient Ischemic Attack

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
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<tr>
<td>&quot;Routine preventive therapy with emphasis on anti-thrombotic therapy, lipid lowering, BP control, and lifestyle optimization is recommended for all patients with recently symptomatic extracranial vertebral artery stenosis&quot;</td>
<td>I</td>
<td>C</td>
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<tr>
<td>&quot;Endovascular stenting of patients with extracranial vertebral stenosis may be considered when patients are having symptoms despite optimal medical treatment.&quot;</td>
<td>IIb</td>
<td>C</td>
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<tr>
<td>&quot;Open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, may be considered when patients are having symptoms despite optimal medical treatment.&quot;</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
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BP: blood pressure; COR: class of recommendation; LOE: level of evidence.

American Stroke Association et al

In 2011, a multi-society task force issued guidelines on the management of extracranial vertebral and carotid artery disease, which made the following statements about catheter-based revascularization of extracranial vertebral artery disease: "Although angioplasty and stenting of the vertebral vessels are technically feasible, as for high-risk patients with carotid disease, there is insufficient evidence from randomized trials to demonstrate that endovascular management is superior to best medical management."22 No specific recommendations were made about endovascular therapies.

European Society for Vascular Surgery

The European Society for Vascular Surgery (2018) made the following recommendation: "Patients with recurrent vertebrobasilar territory symptoms (despite best medical therapy) and who have a a 50 to 99% extracranial vertebral artery stenosis may be considered for revascularisation." The recommendation was based on Level B evidence (data derived from a single randomized controlled trial or large non-randomized studies) and considered Class IIb (i.e., the usefulness/efficacy is less well established).23

U.S. Preventive Services Task Force Recommendations

Not applicable.
Medicare National Coverage

Centers for Medicare & Medicaid Services has a national coverage determination addressing the use of percutaneous transluminal angioplasty in the treatment of atherosclerotic obstructive lesions of the lower or the upper extremities (not including the head or neck vessels), of a single coronary artery, of renal arteries, and of arteriovenous dialysis fistulas and grafts. It also addresses the use of percutaneous transluminal angioplasty concurrent with carotid stent placement in Food and Drug Administration investigational device exemption clinical trials, in Food and Drug Administration-approved post approval studies, and in patients at high-risk for carotid endarterectomy.

The national coverage determination states that all other indications for percutaneous transluminal angioplasty, with or without stenting, to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

REFERENCES


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>June 2015</td>
<td>New policy</td>
<td>Endovascular therapy for extracranial vertebral artery disease considered investigational.</td>
</tr>
<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 28, 2016; reference 5 added and some references removed. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 5, 2018; reference 6 added; some references removed. Policy statement unchanged.</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 6, 2019; References added. Policy statement unchanged.</td>
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