Stent First, Then Heart Surgery, for Patients With Severe Carotid/Coronary Disease

Michael O’Riordan  |  Aug 02, 2013

CLEVELAND, OH — With the absence of randomized, controlled clinical trials to address the optimal management of patients with severe carotid and coronary artery disease, a new retrospective study suggests the best tactic is a staged approach that sees the patient undergo carotid artery stenting (CAS) followed by coronary artery bypass graft (CABG) surgery or non-CABG cardiac surgery.1

Investigators report that a combined approach that includes carotid endarterectomy (CEA) and open-heart surgery (OHS) is equivalent in terms of short-term outcomes with the staged CAS-OHS procedure. Beyond one year, however, the staged CAS-OHS approach resulted in the lowest risk of all-cause mortality, stroke, and MI when compared with a combined CEA-OHS procedure and staged CEA-OHS.

"The surgeons get very worried about doing operations on these patients because they don’t want to do a beautiful job on the bypass only to have the patient have a stroke," lead investigator Dr Mehdi Shishehbor (Cleveland Clinic, OH) told heartwire.

Shishehbor said that when patients are undergoing open-heart surgery, whether it’s CABG or valve surgery, they are screened for carotid artery disease, given the heightened risk of stroke when undergoing heart surgery. As a result, various teams from neurology, vascular surgery, and interventional cardiology are called to address the safety of the surgery in the setting of severe carotid disease, said Shishehbor.

"These patients are the sickest of the sick in the sense that they have two conditions that are occurring concomitantly," he said. "These are not patients who just have carotid disease. There are many patients who have moderate or mild carotid disease who undergo open-heart surgery with no problem. These are people with severe disease, those with more than 80% stenosis in one of their carotid arteries or maybe both. They also have severe coronary artery disease. These are people with left-main or three-vessel disease who are destined to undergo bypass."

The Whole Point Is to Prevent Stroke

In the study, published this week in the Journal of the American College Cardiology, the investigators reported data on 350 patients who underwent carotid revascularization and cardiac surgery. These included 45 patients who were treated with a staged CEA-OHS approach (OHS performed a median of 14 days after CEA), 110 who were treated with a staged CAS-OHS procedure (OHS performed a median of 47 days after CEA), and 195 patients treated with a combined CEA-OHS procedure. OHS is defined as CABG, CABG plus other cardiac procedures, or non-CABG cardiac surgery (isolated valve or aortic-repair surgery). In total, just 8% of procedures were non-CABG surgeries.

In a propensity-adjusted analysis analyzed by intention-to-treat, the 30-day risk of death, stroke, and MI was similar between the staged CAS-OHS and combined CEA-OHS procedures. The highest risk of the composite end point was observed in patients who underwent staged CEA-OHS.

At one year and beyond (median follow-up was 3.7 years), the staged CAS-OHS patients had the lowest risk of death, stroke, and MI. Compared with staged CEA-OHS, those treated with CAS-OHS had a 67% lower risk of death, stroke, and MI and a 65% lower risk compared with combined CEA-OHS.
### Unadjusted Comparison of Primary/Secondary End Points

<table>
<thead>
<tr>
<th>Event</th>
<th>Staged CEA-OHS, n=45 (%)</th>
<th>Combined CEA-OHS, n=195 (%)</th>
<th>Staged CAS-OHS, n=110 (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall 30-d risk post-OHS</td>
<td>31</td>
<td>10</td>
<td>10</td>
<td>0.003</td>
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<tr>
<td>Death</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>0.75</td>
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<tr>
<td>Stroke</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>0.11</td>
</tr>
<tr>
<td>MI</td>
<td>24</td>
<td>0.5</td>
<td>3</td>
<td>&lt;0.001</td>
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<tr>
<td>Overall composite risk 1 y and beyond</td>
<td>27</td>
<td>39</td>
<td>12</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death</td>
<td>38</td>
<td>39</td>
<td>11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>2.2</td>
<td>1.5</td>
<td>0</td>
<td>0.37</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
<td>3.1</td>
<td>2.7</td>
<td>0.5</td>
</tr>
</tbody>
</table>

"In the long term, stenting [followed by OHS] definitely did better than the combined approach," said Shishehbor. "What's also important is that with the combined approach, the reason they didn't do very well is because they had a higher rate of stroke in the perioperative period. . . . Remember the whole point of doing this is to prevent stroke. This is why we feel the combined approach is a little bit inferior to the staged CAS/open-heart-surgery approach. If you have a 7% risk of stroke in the 30-day perioperative period, that doesn't appear to be the best option for the majority of patients."

To heartwire, Shishehbor said that while the patients were well matched, the patients undergoing stenting tended to be sicker. For example, they were more likely to have symptomatic carotid stenosis and were more likely to have undergone a previous carotid revascularization. Shishehbor also said that clinical events occurring between the initial carotid artery revascularization procedure and OHS were included in the analysis. These deaths, strokes, and MIs were identified and accounted for in the data.

In an editorial accompanying the study[2], Drs Ehtisham Mahmud and Ryan Reeves (University of California, San Diego) say the work by the Cleveland Clinic group is strengthened by the propensity-adjusted analysis and long follow-up beyond the perioperative period. Most important, they say the study provides clarity for the management of patients with carotid and coronary disease.

"For patients presenting with an acute coronary syndrome requiring urgent coronary revascularization in whom waiting three to four weeks is not safe, combined CEA-OHS is the optimum revascularization strategy, though associated with higher neurological ischemic events," write Mahmud and Reeves. "However, for patients with a stable or an accelerating anginal syndrome who can wait three to four weeks to complete dual antiplatelet therapy [DAPT] after carotid stenting, staged CAS followed by OHS leads to superior early and long-term outcomes."

Since completing the analysis, Shishehbor said there have been discussions with colleagues in vascular surgery, vascular medicine, cardiac surgery, and cardiology to establish the optimum way to treat patients with severe carotid and coronary disease. "The bottom line is that there will never be a randomized, clinical trial in this setting," he told heartwire. "I hope there would be, but I doubt it. So I think papers like this are critical because we're doing these procedures to prevent stroke. It's important that we pick the right procedure for the right patient."

Confounded by Registry Requirements

Shishehbor is also concerned about the scrutiny carotid stenting is under from the Centers for Medicare & Medicaid Services (CMS). Currently, the CMS reimburses procedures for asymptomatic patients only if they are included in one of the industry-funded and -maintained registries. He believes the scrutiny has led to a dwindling number of clinicians with the expertise capable of doing the procedure, and this is concerning, since the present analysis shows there are cohorts of asymptomatic patients who would benefit from the treatment.

In addition, to be included in a registry, an asymptomatic patient must receive DAPT with aspirin and clopidogrel for four weeks. If the patient does not meet the DAPT requirements, they can't be included in the registry. However, Shishehbor said, many of these patients have significant coronary disease and can't wait four weeks. As a result, they are treated with a combined CEA-OHS approach, an approach that is associated with a higher risk of stroke.

Shishehbor reports serving as a speaker and consultant for Abbot Vascular, Medtronic, and Gore but waives all compensation for his work. Mahmud reports trial support from Boston Scientific and Abbott Vascular. In addition, he consults for Cordis and the Medicines Company and serves on the speaker's bureau for Medtronic. Disclosures for the coauthors are listed in the paper.

References


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