Staged Carotid Artery Stenting and Coronary Artery Bypass Surgery Versus Isolated Coronary Artery Bypass Surgery in Concomitant Coronary and Carotid Disease

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ABSTRACT: Background. We aimed to compare the outcomes of patients who underwent carotid artery stenting (CAS) followed by coronary artery bypass grafting (CABG) with the outcomes of those who underwent isolated CABG without carotid intervention. Methods. In this prospective cohort study, conducted between March 2007 and February 2010, all patients who had significant carotid artery stenosis (>70%) and were candidates for CABG were included. The outcome measures, including 30-day post-stenting complications, cardiac surgery neurological complications, myocardial infarction (MI), and mortality rates, were assessed. Results. A total of 112 patients underwent CABG without carotid artery intervention and 62 patients were scheduled for CAS + CABG. The death and MI or stroke rates in the CAS + CABG patients and isolated CABG group were 9.7% and 6.3%, respectively (P=.18). In the CAS + CABG group, 4 patients (6.4%) were complicated by ipsilateral stroke, 2 (3.2%) by MI, and 3 (4.8%) by death; 2 deaths had neurological causes and 1 death had a cardiac cause. In the isolated CABG group, 4 stroke cases (3.6%) were diagnosed in the postoperative period, 2 of them (1.8%) being ipsilateral. Also, 1 MI case (0.9%) and 4 deaths (3.6%) occurred after cardiac surgery; 2 deaths had neurological causes and the remaining 2 deaths resulted from other postoperative complications (mediastinitis and arrhythmia). Conclusion. The risk of ipsilateral stroke in the isolated CABG approach in patients with concomitant coronary and carotid stenosis is small, and there is no evidence that this risk is lessened by prophylactic CAS. Staged CAS + CABG may become the preferred option in patients with symptomatic bilateral carotid stenosis with stable cardiac status if it is conducted in a high-volume center by experienced operators.

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Key words: carotid stenosis, coronary artery bypass graft, outcome

Perioperative stroke after coronary artery bypass grafting (CABG) is an issue of paramount importance, particularly in patients with significant carotid artery stenosis. Numerous studies have found that patients with significant carotid disease have an increased risk of stroke after CABG,1-8 and protocols have been developed to recommend carotid endarterectomy (CEA) as a prophylactic treatment to prevent stroke in patients scheduled for CABG. The existing literature abounds with registries and systematic reviews presenting evidence both for and against this treatment modality;9-18 however, there is no controlled randomized or prospective non-randomized study into a comparison between CEA in tandem with CABG and CABG alone, much less one that would demonstrate the superiority of the former over the latter.

A 10%-12% cumulative risk of death, stroke, or myocardial infarction (MI) following staged or synchronous surgery has been previously reported,9 and the results of large studies such as the SAPPHIRE trial19 have led to the consideration of coronary artery stenting (CAS) as a preferred revascularization modality for CABG candidates with significant carotid stenosis on account of the fact that the majority of them have high operative risk factors for CEA. In the interim, an increasing number of studies have been published regarding the outcome of staged CAS in tandem with CABG,20-25 All of these studies enrolled small target populations, without a control group, to investigate whether the risk of perioperative stroke was lessened by prophylactic CAS. Indeed, there is no compelling evidence that staged CAS + CABG is preferable to isolated CABG. It is, nevertheless, worthy of note that there are other papers that have reported low risk of ipsilateral stroke in patients with significant carotid stenosis who underwent isolated CABG.26-28

Because there are no conclusive data to determine whether either strategy is appropriate, there remains unease regarding advice to give patients and colleagues alike. Although the final decision lies with the physician, the treatment strategy in our hospital is that patients with symptomatic and/or bilateral carotid stenosis who have stable coronary artery disease are predominantly scheduled for staged CAS + CABG and patients who have asymptomatic carotid stenosis and/or unstable coronary artery disease are mostly scheduled for isolated CABG. We sought to evaluate the appropriateness of the said treatment approach in a prospective manner and compare the outcomes of the patients who underwent CAS followed by open-heart surgery with the outcomes of those who underwent isolated open-heart surgery without carotid intervention.

Methods

Patient population. This prospective cohort study, conducted between March 2007 and February 2010, included all patients who had significant carotid artery stenosis (>70%)
and were candidates for CABG. The eligibility for CABG was at the discretion of the responsible cardiologist or the treating surgeon based on the standard American College of Cardiology/American Heart Association guidelines. In our center, screening for carotid artery stenosis is performed by Duplex ultrasound imaging in all CABG candidates. The eligibility for CAS followed by CABG or isolated CABG without carotid intervention was determined based on the joint decision of the interventional cardiologist, cardiac surgeon, and neurologist. Few patients who were suggested concomitant carotid endarterectomy and CABG were excluded. All patients gave written informed consent. The indications for CABG were established before the stenting procedure. Patients were excluded if any of the following was applicable: history of major stroke within the previous week, intracranial tumor or arteriovenous malformation, severe disability as a result of stroke or dementia, and intracranial stenosis that exceeded the severity of the extracranial stenosis. Patients were considered to be symptomatic if they had suffered a transient ischemic attack, amaurosis fugax, and minor or major disabling stroke involving the study carotid artery within a 6-month period prior to the procedure, as well as patients who had ischemic or infarct defects in their cerebral imaging without an obvious history of neurological event. Neurological evaluation was performed at baseline, the day after the stenting procedure, and 2-3 days after CABG (depending on the time of the patient’s recovery after CABG) by an experienced neurologist, who evaluated the patients using the National Institutes of Health (NIH) stroke scale.39 In the CAS group, the patients received a combination of clopidogrel 75 mg and aspirin 325 mg for 5 days before CAS or, alternatively, loading doses of clopidogrel (600 mg) and aspirin (325 mg) at least 4 hours before the procedure. The technical details of CAS in our institution are mentioned in a previously published report.30 If the neurological examination was unchanged and the procedure was uncomplicated, the patients were discharged 2 days after the procedure on a regimen that included aspirin (325 mg daily) and clopidogrel (75 mg daily) for 4 weeks.

Our institution is a high-volume cardiovascular referral center with 8 cardiothoracic surgeons and 9 interventional cardiologists. It also operates as a training center for cardiologists, cardiac interventionists, and cardiovascular surgeons. Each year, up to 3500 cardiac surgery procedures and 3000 percutaneous interventions are performed in our center. During the period of enrollment, 155 CAS, 9464 CABG, and 2625 valve surgery procedures were carried out.

All demographic, clinical, and procedural details as well as any periprocedural complications were prospectively recorded on standard forms by a physician. Additionally, the baseline and outcome data for all consecutive patients with carotid artery stenosis (>70%) scheduled for CABG without carotid intervention within the same period were collected by the same physician so as to constitute a comparison group. If the procedure was uncomplicated, the patients were discharged 2 days after CAS and 5-7 days after CABG. In the CAS group, coronary artery bypass was usually scheduled 5-6 weeks after CAS and clopidogrel was discontinued 7 days before CABG. The CAS + CABG patients were followed up from the day of carotid stenting and for 30 days after CABG. The isolated CABG patients were followed up for 30 days after CABG. The adverse events included death, myocardial infarction (MI), and stroke. MI was defined as a serum creatine kinase-MB level more than twice the upper limit of the normal range.

Table 1. Demographic and clinical characteristics in the two groups of patients.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Isolated CABG (n = 112)</th>
<th>CAS + CABG (n = 63)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>65 ± 8</td>
<td>66 ± 8</td>
<td>.45</td>
</tr>
<tr>
<td>Male</td>
<td>59%</td>
<td>57%</td>
<td>.75</td>
</tr>
<tr>
<td>Hypertension</td>
<td>68%</td>
<td>69%</td>
<td>.86</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>55%</td>
<td>56%</td>
<td>1</td>
</tr>
<tr>
<td>Current or quitted smoker</td>
<td>35%</td>
<td>18%</td>
<td>.02</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>76%</td>
<td>76%</td>
<td>1</td>
</tr>
<tr>
<td>Symptom within a 6-month period</td>
<td>5%</td>
<td>29%</td>
<td>.001</td>
</tr>
<tr>
<td>Hx of neurological event</td>
<td>10%</td>
<td>45%</td>
<td>.001</td>
</tr>
<tr>
<td>Recent acute coronary syndrome</td>
<td>16%</td>
<td>13%</td>
<td>.66</td>
</tr>
<tr>
<td>Creatinin &gt;2 mg/dl</td>
<td>1.8%</td>
<td>1.6%</td>
<td>1</td>
</tr>
<tr>
<td>Moderate to severe valvular heart disease</td>
<td>18%</td>
<td>24%</td>
<td>.53</td>
</tr>
<tr>
<td>Three-vessel disease</td>
<td>80%</td>
<td>82%</td>
<td>.84</td>
</tr>
<tr>
<td>Left main &gt;50% stenosis</td>
<td>20%</td>
<td>21%</td>
<td>1</td>
</tr>
<tr>
<td>Bilateral carotid stenosis (&gt;50%)</td>
<td>10%</td>
<td>23%</td>
<td>.02</td>
</tr>
<tr>
<td>Carotid stenosis in Doppler (%)</td>
<td>81 ± 16</td>
<td>79 ± 10</td>
<td>.34</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>49 ± 10</td>
<td>50 ± 11</td>
<td>.55</td>
</tr>
<tr>
<td>Coronary artery bypass grafting + valvular surgery</td>
<td>7%</td>
<td>9%</td>
<td>.75</td>
</tr>
</tbody>
</table>
and stroke was defined as a new focal neurological deficit that persisted longer than 24 hours. Neurological deficits that were fully resolved within 24 hours were classified as a transient ischemic attack (TIA). Fatal stroke was defined as death attributed to an ischemic or hemorrhagic stroke. All analyses were performed using SPSS software, version 17.1.

### Results

**Patient population.** This prospective clinical study, performed between March 2007 and February 2010, included all 174 consecutive patients who had significant carotid artery stenosis and were candidates for CABG. During this period, 112 patients underwent CABG without carotid artery intervention and 62 patients were scheduled for CAS + CABG. Table 1 lists the baseline patient characteristics in the two groups, demonstrating a higher prevalence of a history of neurological event at any time, symptomatic patients, and bilateral carotid artery stenosis in the planned CAS + CABG group. After CAS, 5 patients were prevented from undergoing the planned CABG by complications related to the carotid stenting procedure; the other 57 patients in this group underwent CABG after carotid stenting. The median (1st quartile, 3rd quartile) interval between CAS and CABG was 1.8 (1.5, 2.8) months.

**Carotid stenting procedure.** CAS was technically successful in all 62 patients (100%). Forty-four percent of the procedures were done on the left side and 50% on the right side, and 6% of the patients underwent staged, bilateral CAS. In the aortic angiogram, 64% of the treated patients had aortic arch type I, 33% type II, and 3% type III. Sixty-six stents were implanted in the 62 patients: 32 (48%) Precise (Cordis Corporation); 27 (41%) Carotid Wallstent (Boston Scientific); 5 (8%) Xact (Abbott Vascular); 1 (1.5%) Cristallo Ideal (Invatec); and 1 (1.5%) Acculink (Guidant Corporation). Embolic protection devices were used in all the procedures, and they included 52 (79%) EZ (Boston Scientific); 12 (18%) Emboshield (Abbott Vascular); and 2 (3%) MOMA (Invatec). Also, postdilation was done in 97% of the procedures with a mean balloon length of 20.78 ± 2.70 mm, mean balloon diameter of 5.10 ± 0.25 mm, and mean pressure of 6.60 ± 1.75 atm. The mean angiographic degree of stenosis was reduced from 85 ± 8% to 12 ± 4%.

### Periprocedural outcome and 30-day follow-up.

The 30-day incidence rates of death, stroke, and MI are listed in Table 2. In the CAS + CABG group, 4 patients (6.4%) were complicated by stroke, which was fatal in 2 cases: both of the fatal strokes were hemorrhagic, 1 of them developing 2–3 hours after stenting and 1 occurring 4 days after CAS. The other 2 strokes were nonfatal and occurred within 24 hours after CAS. All fatal and nonfatal strokes (6.4%) in this group were ipsilateral. There were 2 cases (3.2%) of MI in the CAS + CABG group; the first occurred 25 days after CAS and the other happened 15 days after CABG. In total, 3 deaths (4.8%) occurred in this group: 2 deaths had neurological causes (CVA) and 1 death had a cardiac cause (MI). There were 2 deaths in the waiting period (the time between CAS discharge and CABG): 1 was due to MI 25 days after CAS and 1 happened after hemorrhagic CVA 4 days after CAS. In the isolated CABG group, 2 fatal and 2 nonfatal strokes (3.6%) were diagnosed in the postoperative period by clinical documentation of neurological deficits, substantiated by brain imaging. In both fatal and nonfatal stroke groups, 1 of the 2 strokes was contralateral (1.8%) and 1 was ipsilateral (1.8%). The remaining 2 deaths resulted from other postoperative complications (mediastinitis and arrhythmia).

As there was a higher prevalence of symptomatic patients and bilateral carotid artery stenosis in the planned CAS + CABG group, we also compared the 30-day outcomes in the patients with an asymptomatic unilateral carotid stenosis between the two groups of patients. A total of 129 patients were included in this selection: 35 CABG + CAS cases and 94 isolated CABG patients. The 30-day incidence rate of death was 2 (5.7%) and 4 (4.3%), respectively ($P = .66$). Although the CAS + CABG strategy was associated with a higher incidence of stroke in asymptomatic unilateral carotid stenosis, 2 (5.7%) vs 3 (3.2%), this association did not reach statistical significance ($P = .61$).

### Discussion

To our knowledge, this is the first study to prospectively compare the outcomes of the two treatment approaches of planned CAS + CABG versus isolated CABG in candidates for CABG with significant carotid artery stenosis. The majority of the studies in this field are single arm without any comparison group in the same data set.

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Isolated CABG (n = 112)</th>
<th>CABG + CAS (n = 62)</th>
<th>Total Patients (n = 174)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial infarction</td>
<td>1 (0.9%)</td>
<td>2 (3.2%)</td>
<td>3 (1.7%)</td>
<td>.29</td>
</tr>
<tr>
<td>Stroke</td>
<td>4 (3.6%)</td>
<td>4 (6.4%)</td>
<td>8 (4.6%)</td>
<td>.45</td>
</tr>
<tr>
<td>Ipsilateral stroke</td>
<td>2 (1.8%)</td>
<td>4 (6.4%)</td>
<td>6 (3.5%)</td>
<td>.18</td>
</tr>
<tr>
<td>Contralateral stroke</td>
<td>2 (1.8%)</td>
<td>0</td>
<td>2 (1.2%)</td>
<td>.53</td>
</tr>
<tr>
<td>Myocardial infarction or stroke</td>
<td>5 (4.5%)</td>
<td>6 (9.7%)</td>
<td>11 (6.4%)</td>
<td>.20</td>
</tr>
<tr>
<td>Death</td>
<td>4 (3.6%)</td>
<td>3 (4.8%)</td>
<td>7 (4%)</td>
<td>.70</td>
</tr>
<tr>
<td>Death or stroke</td>
<td>6 (5.4%)</td>
<td>5 (8.1%)</td>
<td>11 (6.4%)</td>
<td>.52</td>
</tr>
<tr>
<td>Death, myocardial infarction, or stroke</td>
<td>7 (6.3%)</td>
<td>6 (9.7%)</td>
<td>13 (7.5%)</td>
<td>.18</td>
</tr>
</tbody>
</table>
The patients in the CAS + CABG group had a higher risk of composite endpoint of death, MI, or stroke compared with the isolated CABG patients. These results were achieved despite a significantly worse baseline risk profile in terms of symptomatic patients, history of neurological events, and bilateral carotid stenosis in the CAS + CABG patients. After the exclusion of symptomatic or bilateral carotid stenosis, the difference between the outcomes of the two treatment approaches remained statistically non-significant.

A noticeable finding in the current study is that our approach suggests a favorable ipsilateral stroke of 1.1% in patients with asymptomatic unilateral carotid artery stenosis who underwent isolated CABG. Few studies have published outcome data in patients undergoing isolated CABG in the presence of significant carotid disease and then stratified them also for symptom status.32,33

D’Agostino et al reported a post-CABG stroke incidence of 2.9% in asymptomatic patients with a unilateral carotid stenosis.2 In the Schwartz et al study, the risk of ipsilateral stroke in asymptomatic patients with 50%-99% carotid stenosis was 2.5%.34

In a recent systematic review of 11 published studies, Nayler et al reported data on 760 CAS + CABG procedures. Most of the patients (87%) were neurologically asymptomatic and 82% had unilateral carotid stenoses. Given the 30-day risk of death/any stroke of 9.1% in their observation, they reported that most CABG patients with an asymptomatic, unilateral carotid stenosis could probably undergo their CABG procedure without any prophylactic carotid intervention.35 These data may reveal that in neurologically asymptomatic patients with combined unilateral carotid and coronary stenosis, isolated CABG exhibits a similar safety profile to the staged CAS + CABG. It seems that less manipulation would become an attractive alternative, especially in neurologically asymptomatic individuals in whom a delay in performing CABG is less acceptable.

The rates of ipsilateral and contralateral stroke after isolated CABG in our study were the same (1.8%). The similar incidence of ipsilateral and contralateral stroke after isolated CABG in our finding highlights the concept that the etiology of stroke after CABG is multifactorial and not merely related to the presence of carotid artery disease. It is important to note that 60% of brain infarctions cannot be attributed to carotid disease and 85% of all CABG patients destined to suffer a procedural stroke will not have any evidence of carotid disease.8,9 These two observations in conjunction with our results are sufficient to cast significant doubt on the assumption that asymptomatic unilateral carotid stenosis is an important cause of post-CABG stroke.

A second finding to emerge from our study is that the risk of composite endpoint of death, MI, or stroke in staged CAS + CABG was lower (9.7%) compared to previous studies.9,21,24,31 Randall et al assessed the outcome of staged CAS + CABG in 52 patients:21 the prevalence of 30-day stroke/death in that study was 13.5%. As their report shows, they used distal protection devices (69%) or dual-antiplatelet therapy (83%) for their patients less often. Compared with our study, the Randall et al study included a smaller percentage of neurologically symptomatic patients.

Lopes et al presented their experience in 49 patients with concomitant carotid and coronary artery disease who underwent CAS before CABG.36 All of their patients had grade III or IV New York Heart Association functional classification and 59% had severe stenosis of the left main coronary artery. Seeking to avoid death in the interval between CAS and CABG, they performed CABG as soon as possible without interrupting antiplatelet therapy. In our study, 13% of the patients had recent (≤2 months) acute coronary syndrome and 21% had severe stenosis of the left main coronary artery. Furthermore, CABG was scheduled 5-6 weeks after CAS and the majority of our patients stopped receiving antiplatelet therapy at least 7 days before CABG. Lopes and colleagues showed an 8% death rate (4/49), 2% major stroke rate (1/49), and 6% minor stroke rate (3/49), with a combined incidence of complications of at least 16.3%. No information is provided about the use of distal protection devices in their study. In our study, the overall rate of death, any stroke, and MI was 9.7%, which compares favorably with the series by Lopes et al.

Kovacic et al described 20 patients who underwent CAS followed by CABG.20 They reported 5% MI (1/20), 5% minor stroke (1/20), and no cardiac death and major stroke. Compared to our study, the size of their study is too small to permit a meaningful statistical temporal analysis.

The extraordinarily poor outcomes seen in some of the above-mentioned studies highlight the importance of the interventionist’s experience in the appropriate selection of patients when performing CAS. It seems that the adoption of the staged CAS + CABG strategy should be limited to high-volume centers where experienced interventionists are available.37

We had 2 deaths (2.2%) in the waiting period (after CAS discharge and before CABG) in the CAS + CABG group: 1 of them was cardiac related and 1 had a neurological cause. Randall et al reported 3 deaths (5.7%) in the waiting period; all of them were considered cardiac-related deaths.21 The low incidence of events within the waiting period in our study may have been affected by our center’s treatment strategy, whereby patients with unstable coronary artery disease are predominantly candidates for isolated CABG.

**Study limitations.** Although our study is the first prospective study with a control group in the debate of managing concomitant carotid and coronary artery disease, this is a non-randomized single-center study and there are some differences in the baseline characteristics between the two groups of patients. Also, the relatively small number of patients in each group denied us adequate power for a more robust analysis of all the predictors of adverse events. A large prospective trial with randomization, be it for staged CAS + CABG or isolated CABG in a study population, would demonstrate the optimal therapeutic strategy.

**Conclusions**

The risk of ipsilateral stroke in the isolated CABG approach in patients with concomitant coronary and carotid stenosis is small and there is no evidence that this risk is lessened by
prophylactic CAS. On the other hand, staged CAS + CABG may become the preferred option in patients with symptom-
omatic bilateral carotid stenosis who have stable cardiac status if done in a high-volume center by experienced operators who have previously proven low adverse outcomes in this case. In
the meantime, the best approach for patients with advanced coronary and carotid disease should be suggested based on the
decision involving neurologists, surgeons, and interventionists who would take into account the neurological symptoms, bi-
lateral or unilateral carotid disease, urgency of cardiac surgery, local expertise, degree of stenosis, and all the comorbidities of the
patient.

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