Early results after synchronous carotid stent placement and coronary artery bypass graft in patients with asymptomatic carotid stenosis

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Background: **The optimal management of patients with combined carotid and coronary artery disease requiring cardiac surgery is still unknown. Staged carotid endarterectomy and carotid artery stenting (CAS), each followed by coronary artery bypass graft (CABG), are options frequently employed. However, for patients with severe carotid artery disease in urgent need of open cardiac revascularization, staged operations may not be the most appropriate alternative. The aim of this study was to describe our experience using a synchronous CAS-CABG method with minimal interprocedural time. We used this synchronous combination of procedures in patients with combined carotid and coronary artery disease admitted for urgent CABG.**
Methods: **Patients with concomitant severe carotid and coronary artery disease scheduled for synchronous CAS and urgent CABG between December 2006 and January 2010 were included in the study. All procedures were performed at a single center: the Cardiovascular Foundation of Colombia, in Floridablanca, Santander, Colombia. The study cohort was characterized according to demographic and clinical characteristics, which included degree of carotid stenosis, presence/absence of preoperative neurological symptoms, and cardiac operative risk profile. All patients underwent CAS under embolic protection devices and then CABG within the next 2 hours. Patients received aspirin pre- and postprocedure but were started on clopidogrel only after CABG. The primary end point of the study was the composite incidence rate of myocardial infarction, stroke, and death 30 days after CAS-CABG.**
Results: **Fifteen patients with concomitant severe carotid and coronary artery disease underwent synchronous CAS-CABG. Most patients (60%) were men, and mean (± standard deviation) age was 65.2 (± 8.4) years. Most patients (93%) were neurologically asymptomatic. The median (interquartile range) ejection fraction and logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) for the cohort were 55% (36%-62%) and 9.7% (4.6%-14.8%), respectively. There were no deaths, major strokes, minor strokes, or myocardial infarctions during the procedure or within 30 days of CAS-CABG. One patient experienced neurological symptoms likely as a result of transient ischemic attack ipsilateral to the CAS procedure. None of the patients required cardiac or carotid reinterventions, and there were no cases of postoperative bleeding requiring reoperation.**
Conclusions: **Synchronous CAS-CABG, when CABG is performed within the 2 hours of the CAS procedure, may be a viable alternative to the more generally accepted staged combination, particularly among patients for whom CABG cannot be postponed. We hope that this strategy will be further evaluated in larger prospective studies and adequately powered randomized clinical trials. (J Vasc Surg 2013;57:58S-63S.)**

Cerebrovascular accident, or stroke, is a well-recognized complication of cardiac surgery. The incidence of perioperative stroke after coronary artery bypass graft (CABG) procedures has been reported to increase among patients with concurrent severe carotid artery stenosis,[1-4] and the staged or simultaneous use of CEA and CABG has been associated with combined rates of postoperative stroke, myocardial infarction (MI), and death in the range of 10% to 12%, particularly among patients aged 75 years and older and those with bilateral carotid stenosis.[5] Carotid stenosis may, in fact, be found in up to 62% of patients who are scheduled to receive a CABG, although severe unilateral and bilateral carotid stenosis occur in 10% and 2% of these patients, respectively.[6] Severe carotid stenosis is also found in as many as 30% of early strokes occurring post-CABG.[7]

To lower perioperative neurological morbidity, patients with severe carotid stenosis scheduled for cardiac surgery are frequently advised to undergo prophylactic carotid revascularization. In this setting, frequent indications for carotid interventions include symptomatic neurological status (recent history of stroke, amaurosis fugax, or transient ischemic attack [TIA]), contralateral carotid artery occlusion, and severe concomitant vertebral artery stenosis.[8] The optimal management of patients with combined carotid and coronary artery disease requiring cardiac surgery is, however, still unknown.[1,9-11]

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Carotid endarterectomy (CEA) has been the traditional approach to treatment of carotid artery disease in patients in need of CABG. Although this approach has been helpful in reducing the incidence of post-CABG stroke, carotid artery stenting (CAS) has emerged as a suitable and less invasive alternative for the treatment of patients with combined coronary and carotid disease.[12-16] Current evidence reveals that CAS may be an alternative to CEA for the treatment of isolated carotid artery disease in some standard- and high-surgical-risk patients, although the individual outcomes of stroke, MI, and death may vary. In addition, some studies suggest that CAS might be a safer alternative to prophylactic CEA in patients in need of CABG.[12-20] Nevertheless, optimal timing of the two procedures, that is, whether CAS and CABG should be performed in a staged or synchronous fashion, remains controversial.

For those patients with a clinical indication for coronary artery revascularization during the index admission, planning a staged CAS-CABG process with weeks between procedures was not an option because of the necessity of prompt coronary revascularization. Very little data exist in the literature describing the outcomes of patients undergoing synchronous CAS with urgent CABG. We report our experience employing synchronous CAS-CABG with a minimal interprocedural time less than 2 hours in patients with combined carotid and coronary artery disease admitted for urgent CABG.

METHODS

Patient population. All consecutive patients with concomitant severe carotid and coronary artery disease scheduled at our center, the Fundación Cardiovascular de Colombia, for synchronous CAS and urgent CABG between December 2006 and January 2010 were included. Standard institutional eligibility criteria for CAS in patients requiring CABG include common or internal carotid stenosis greater than 50% in symptomatic patients and greater than 80% in asymptomatic patients. Eligibility was assessed by carotid duplex scanning and confirmed with intraoperative catheter angiography. All pre-CABG carotid duplex scanning and clinical screening were performed by a physician member of the Division of Vascular Surgery, after which the patient was considered eligible for pre-CABG stent placement. The degree of carotid artery stenosis was assessed according to the North American Symptomatic Endarterectomy Trial (NASCET) criteria.[10] Patients were deemed ineligible for CAS if they had femoral artery disease that precluded femoral artery access, severe proximal carotid tortuosity, presence of thrombus within the lesion, severe intracranial stenosis (greater than that of the target vessel), long near-occlusive lesions ("string sign" lesions), and major residual neurological deficit from a previous disabling ipsilateral hemispheric stroke. Some of these patients underwent CEA instead of CAS, which was a decision made by the patient's attending vascular surgeon. All patients underwent neurological evaluation on admission, and patients with lateralizing neurological symptoms attributable to the carotid territory or history of stroke underwent a formal evaluation by neurology. Patients were also considered symptomatic if they had a history of TIA, stroke, or amaurosis fugax within 6 months prior to admission. Indications for CABG were based on standard American College of Cardiology/American Heart Association guidelines.[21] The study was reviewed and approved by our institutional ethics committee.

The necessity for prompt CAS and CABG was determined by a team of interventional cardiologists, cardiovascular surgeons, and peripheral vascular surgeons. It was based on several factors that include European System for Cardiac Operative Risk Evaluation (EuroSCORE) calculations, severity of symptoms and hemodynamic status, anatomic severity of the disease, as well as sociodemographic conditions. For instance, staged procedures may not be a feasible option for some patients in our region because of limited resources and transportation.

Carotid stenting technique. To facilitate immediate progression to CABG after stenting, all patients underwent the procedure under general anesthesia. All patients received aspirin prior to the procedure and postoperatively. None of the patients received antiplatelet therapy with clopidogrel before CAS. However, there were patients who were on clopidogrel prior to admission, which did not represent a reason to delay their treatment. CAS procedures were performed using a fixed angiographic unit (INNOVA 2000S; General Electric, Waukesha, Wisc). Unfractionated heparin intravenous (IV) bolus (100 U/kg) was given to achieve a target activated clotting time of 250 to 300 seconds. Additional heparin was administered approximately every 30 minutes to maintain the ACT within this range. Intracranial views were obtained during angiography to determine complete circle of Willis anatomy and to rule out arterial intracranial lesions. Distal protection devices were used for cerebral embolic protection in all patients. Deployment of an appropriately sized self-expanding stent was followed by balloon postdilatation (5 mm) when necessary. A bolus of intravenous atropine (0.5 mg) was administered per institutional protocol to prevent bradycardia and hypotension. Ipsilateral carotid and intracranial angiography was performed after stent deployment. Procedural success was defined as successful stent deployment with residual diameter stenosis $\leq$30%.

After CAS and with the assistance of experienced hemodynamic and surgical ward staff, all patients were immediately transported to the catheterization laboratory next door to the operating room where CABG was performed according to standard practice. The transportation between rooms did not exceed 15 minutes. Aspirin and clopidogrel were started after CABG once the possibility of major bleeding was ruled out, usually on postoperative day 2.

End point definition. The primary end point of the study was the composite incidence rate of MI, stroke, and death 30 days after CAS-CABG. Stroke was defined as any focal acute neurological event lasting at least 24

hours. Fatal stroke was defined as death attributed to an ischemic or hemorrhagic stroke. Stroke was classified as major stroke if patients had new neurologic deficits with a modified Rankin score ≥3 (moderate to severe disability that restricts or impairs lifestyle) lasting more than 7 days. A minor stroke was defined as a new neurological deficit with a Rankin score of ≤3 (slight or no significant disability in performing activities of daily living) resolving completely within 7 days. TIA was defined as a focal neurological deficit lasting less than 24 hours. Predicted operative mortality from cardiac surgery was calculated using the standard EuroSCORE.[22] Our institution uses the EuroSCORE, a risk stratification system for the prediction of hospital mortality and the assessment of quality of care, as a prognostic score for patients undergoing cardiovascular surgical procedures.[22]

Neurological evaluations using the National Institutes of Health Stroke Scale were performed at baseline, within 72 hours postprocedure and at the 30-day follow-up. If any suspicion of a neurological event existed, a formal neurological consultation was immediately obtained.

Statistical analysis. Continuous variables are described as means and standard deviations (SD) for normally distributed variables and as medians and interquartile ranges (IQRs) for non-normally distributed variables. Categorical variables are described as frequencies and percentages.

For this small series with an expected low rate of adverse events, an a priori decision was made to perform only descriptive statistics. The SAS 9.2 (SAS Institute, Cary, NC) and MedCalc 11.1.1.0 (MedCalc Software, Mariakerke, Belgium) software programs were used for data analyses.

Table I. Baseline demographic and clinical characteristics of patients (n = 15)[a]

Characteristic	*No. (%)*
Age, years	65.2 (8.4)[a]
Female sex	6 (40.0%)
Neurological symptomatic status	1 (6.6%)
Comorbidities	
Hypertension	13 (18.6%)
Diabetes mellitus	4 (26.6%)
Dyslipidemia	9 (60.0%)
Smoking	11 (73.3%)
Previous MI	4 (26.7%)
Congestive heart failure	1 (6.6%)
Unstable angina pectoris	11 (73.3%)
Previous percutaneous coronary intervention	2 (13.3%)
Previous CAS	2 (13.3%)
Renal failure	2 (13.3%)
Contralateral carotid artery stenosis	
No stenosis	7 (46.6%)
Stenosis <50%	3 (20.0%)
Stenosis 50%-80%	5 (33.3%)
Stenosis >80%	0 (0%)
Contralateral carotid artery occlusion	0 (0%)
Ejection fraction	
<35%	3 (20.0%)
35%-50%	4 (26.7%)
>50%	8 (53.3%)
Logistic cardiac EuroSCORE	
<10%	9 (60.0%)
10%-20%	5 (33.3%)
>20%	1 (6.6%)
Body mass index, kg/m^2	23.1 (3.7)[a]

CAS, Carotid artery stenting; *EuroSCORE,* European System for Cardiac Operative Risk Evaluation; *MI,* myocardial infarction.
[a]Mean (standard deviation).

RESULTS

A total of 15 patients with combined severe carotid and coronary artery disease underwent synchronous CAS and urgent CABG during the study period. All of the patients had unilateral CAS procedures. Nine (60%) were performed on the right internal carotid artery, and six (40%) on the left internal carotid artery. Baseline characteristics of the study cohort are described in Table I. Most patients (60%) were men. Mean (SD) age was 65.2 (± 8.4) years, and there were no octogenarians in the study cohort. The patient cohort possessed a high prevalence of comorbidities, which included hypertension (86.6%), smoking (73.3%), unstable angina pectoris (73.3%), and previous MI (26.7%). All patients were thus high surgical risk for CEA. Of note, none of the patients had a history of chronic obstructive pulmonary disease or previous CEA procedure. One of the patients was neurologically symptomatic, with a left brachial monoparesis caused by stroke within the previous 6 months. Another patient had a history of stroke 7 years prior to the hospitalization for CAS-CABG. Before arriving at our hospital, 12 (80%) patients were on antiplatelet treatment with aspirin and five (33.3%) were on clopidogrel. In addition, 13 (86.6%) patients were on cholesterol-lowering therapy with statins. Two patients had a history of CAS in the contralateral carotid artery. Although 53% of the patients had contralateral carotid artery disease, the degree of stenosis in the contralateral side was not >70% in any of the patients, and none of them had contralateral carotid occlusion. The median (IQR) ejection fraction and logistic EuroSCORE for the cohort were 55% (36%-62%) and 9.7% (4.6%-14.8%), respectively. Preoperative coronary angiography revealed left main coronary disease in eight (53.3%), three-vessel disease in seven (47%), and four-vessel disease in four (26.7%) patients.

All of the CAS procedures were performed under cerebral embolic protection with filter devices. Spider (EV3, Plymouth, Minn) was used in 40%, FilterWire (Boston Scientific, Natick, Mass) in 26%, EmboShield (Abbott Vascular, Santa Clara, Calif) in 20%, and EPI Filter Wire (Boston Scientific) in 13% of the cases. All of the distal protection devices were successfully deployed and positioned. The following carotid stent devices were used: Protege (EV3; 47% of patients), Wallstent (Boston Scientific; 47%), and Precise (Cordis, Miami, Fla; 6%). Technical success was achieved in 100% of the CAS procedures.

In the present series, all patients immediately underwent CABG within 2 hours of CAS. The median (IQR) number of coronary vessels undergoing revascularization was 3

Table II. Thirty-day outcomes after synchronous CAS-CABG (n = 15)

Event	*No. (%)*
Death	0 (0.0%)
Major stroke	0 (0.0%)
Minor stroke	0 (0.0%)
Death or any stroke	0 (0.0%)
TIA	1 (6.7%)
MI	0 (0.0%)
Acute renal failure	1 (6.7%)
Postoperative cardiac arrest	1 (6.7%)
Cerebral hypoxic encephalopathy	1 (6.7%)
Pneumonia	1 (6.7%)
Pleural effusion	3 (20.0%)
Postoperative blood transfusion	8 (53.3%)

CABG, Coronary artery bypass graft; *CAS,* carotid artery stenting; *MI,* myocardial infarction; *TIA,* transient ischemic attack.

(3-4), and CABG was performed without cardiopulmonary bypass (off-pump) in 40% of the cases. The median (IQR) time on bypass for patients undergoing on-pump CABG was 117 (110-128) minutes, and median clamp time was 82 (68-100) minutes. Mean (SD) postoperative length of stay in the intensive care unit was 4.3 (±2.5) days, and median (IQR) length of hospital stay was 9 (6-12) days.

Table II summarizes postprocedural event rates within 30 days of the synchronous CAS-CABG. There were no deaths, major strokes, minor strokes, or MIs periprocedurally or within 30 days post-CABG. Only one patient experienced a TIA episode ipsilateral to the CAS procedure. The event occurred 24 hours post-CABG and was described as paresis of the left upper limb lasting less than 1 hour. The stent was later determined to still be patent by duplex sonography. One patient with a 30% preoperative ejection fraction endured cardiac arrest 3 hours post-CABG, resulting in hypoxic encephalopathy confirmed by magnetic resonance imaging and leading to eventual total dependency. Another patient developed nonoliguric renal failure with a creatinine level of 2.1 and eventual resolution and discharge in the week following the procedure. The patient did not require dialysis and recovered without any other complications. None of the patients required cardiac or carotid reinterventions. There were no cases of postoperative bleeding requiring reoperations. However, almost all the patients (93%) received red blood cell transfusions intraoperatively or within the first 24 hours post-CABG. The median (IQR) number of red blood cell units transfused was 3 (2-6) for the whole cohort. Of note, the number of red blood cell units received by patients taking clopidogrel prior to admission was not significantly higher than that of patients who were not on this antiplatelet medication (median [IQR], 2.0 [1.5-7.2] and 3.5 [2.0-5.0] units, respectively; P [Mann-Whitney test] = .76). Aspirin was started at 2.2 ± 2.9 (1-12) days and clopidogrel at 3.2 ± 2.5 (1-11) days post-CABG.

Median (IQR) long-term follow-up time was 48 (31-293) days. No strokes or MIs were captured during this period. However, two deaths were identified, one 60 days and the other 2 years post-CABG. The investigators were not able to verify the cause of death in either of the two patients.

DISCUSSION

We report our experience with a series of patients with combined severe coronary and carotid artery disease necessitating carotid stenting with immediate open coronary vascularization. Our study adds valuable information to the scant literature on CAS performed during the same hospitalization with minimal delay before CABG.[4,23-25] In our series, the 30-day incidence of postoperative death, stroke, and MI was 0%, suggesting that the synchronous hybrid approach CAS-CABG is feasible and safe. Our results are comparable to those of the few published studies on synchronous CAS-CABG, which have reported 30-day cumulative incidence rates of stroke, MI, and death in the range of 0% to 6%.[4,23-27]

Most previous studies on synchronous CAS-CABG are small case series. However, their results consistently suggest that the outcomes of this combined treatment approach may be superior to those of alternative management strategies for concurrent carotid and coronary disease. Alternative management options frequently employed include synchronous CEA plus CABG, staged CEA-CABG, reverse-staged CABG-CEA, synchronous CEA plus CABG off bypass, and staged CAS followed by CABG. Current evidence reveals that the cumulative risk of stroke and death and of any stroke, death, or MI for any of those alternatives lies between 6.1% to 9.1% and 5.0% to 11.5%, respectively.[12] From currently available data, it is impossible to ascertain whether the improved outcomes from the synchronous management approach represent a true treatment effect or are the result of bias and insufficient power of the studies.

Recently, Illuminati et al[28] published the results of a randomized clinical trial that assessed the timing of CEA in patients with severe asymptomatic unilateral carotid stenosis undergoing CABG. This study supports our current approach to the management of patients with combined carotid and cardiac disease in that we always perform the carotid intervention immediately before CABG. As suggested by the authors, delayed staged CEA may not prove to be a safe alternative because of the increased risk of stroke. Whether CEA or CAS is used for the treatment of patients undergoing CABG depends on experience and preference. Only a randomized clinical trial could validate if CAS or CEA is superior, but such a trial would be logistically difficult to perform and, to our knowledge, has not been designed or developed.

Our group has adopted CAS as the method of choice for carotid revascularization in high-risk patients because of our experience and low rate of complications with this procedure. Moreover, CAS may indeed be an excellent option for patients at high risk of MI, that is, those who need CABG, as long as stroke and death rates after the procedure are maintained low and within the American Heart Association guidelines.[22]

We can speculate that our improved outcomes are explained by several theoretical advantages of the synchronous CAS-CABG approach when compared with staged revascularization. First, the synchronous approach provides shorter procedure time with less surgical trauma when compared with combined surgical revascularization. This is particularly important in the cases of high-risk patients. Second, by eliminating the time interval between CAS and CABG, the risk of acute MI between the two procedures is expected to significantly decrease. This effect is more evident when staged CAS-CABG is compared with staged CEA-CABG. In fact, data from systematic reviews demonstrate that the 30-day incidence of MI is 6.5% after staged CEA-CABG and only 1.8% after staged CAS-CABG.[29,30] Furthermore, the results of the Carotid Revascularization Endarterectomy Versus Stenting Trial revealed a significantly increased incidence of MI after CEA as compared with CAS (1.1% vs 2.3%; $P = .03$), highlighting the inferiority of CEA as compared with CAS with respect to acute coronary events, even in non-high-coronary-risk populations.[17] Although the risk of MI seems to be low when the staged CAS-CABG approach is used, it is not known if the benefit after synchronous CAS-CABG is similarly low, as the combined baroreceptor-mediated hemodynamic effect of CAS and the inflammatory response to CABG on perioperative coronary adverse events are still to be determined.

Despite the potential advantages, the synchronous CAS-CABG approach is not exempt from important limitations. The need for perioperative antiplatelet therapy to prevent in-stent thrombosis and stroke after CAS is of the utmost concern. In addition to aspirin, current guidelines recommend preoperative use of clopidogrel either as continuous therapy or as a loading dose at least a few hours pre-CAS, continued at least 30 days postprocedure.[31] When synchronous CAS-CABG is planned, several factors need to be considered regarding the type of antiplatelet therapy to be used. These include the potential increase in risk of interprocedural complications by increasing the delay between CAS and CABG until antiplatelet therapy post-CAS is completed, the increased risk of bleeding during or after CABG in patients on clopidogrel, and the increased risk of stroke if CAS is performed without dual-antiplatelet protection. In our series, 33% of the patients were on clopidogrel before CAS-CABG, although none of these patients received it as a premedication for CAS. The rates of stroke, MI, and death did not differ between patients undergoing CAS-CABG with and those undergoing CAS-CABG without preoperative antiplatelet therapy. In addition, none of the patients on preoperative clopidogrel experienced a reoperation because of bleeding, and the number of perioperative blood transfusions did not differ between the groups. Other studies on synchronous CAS-CABG in which patients did not receive pretreatment with clopidogrel have shown similar low rates of postoperative stroke.[23-26] Nevertheless, whether the benefits of synchronous CAS-CABG without pretreatment with dual-antiplatelet therapy outweigh the risk of periprocedural stroke remains to be determined.

Our study has some important limitations. First, it is a single-center small case series without a control group. Second, most patients in our study cohort were neurologically asymptomatic, and most of them did not have severe contralateral carotid artery stenosis. This might limit the generalizability of our results and partially explain the low rates of postoperative stroke observed in this series. Furthermore, the mean follow-up of our study was 48 days, and more long-term follow-up would be helpful in the data analysis. Finally, general anesthesia was used for all CAS procedures, limiting our ability to assess the neurological function of patients during CAS and through the short interval between CAS and CABG. Although we were unable to detect any neurological event occurring during this period, all of our patients were neurologically intact after CAS-CABG.

CONCLUSIONS

In this series of patients with concomitant severe carotid and coronary artery disease in need of urgent open coronary revascularization, synchronous CAS-CABG was performed without any periprocedural occurrences of stroke, MI, or death. These findings suggest that synchronous CAS-CABG may be a viable alternative to the more frequently used staged CEA-CABG or CAS-CABG. This strategy should be further evaluated in larger prospective studies and adequately powered randomized clinical trials.

AUTHOR CONTRIBUTIONS

Conception and design: JB
Analysis and interpretation: JB, KR, CB, CE, JS, SM
Data collection: JB, KR, CB, CE, AF, AM
Writing the article: JB, KR, CB, CE, AF, AM
Critical revision of the article: JB, KR, CB, CE, AF, AM
Final approval of the article: JB, KR, CB, CE, AF, AM
Statistical analysis: JB
Obtaining funding: JB
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JB and KR contributed equally to this work.

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