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Safety and Feasibility of Simultaneous Transcarotid Revascularization with Flow Reversal and Coronary Artery Bypass Grafting for Concomitant Carotid Artery Stenosis and Coronary Artery Disease

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Abstract

Objective: The management of patients with combined severe carotid artery and coronary artery disease (CAD) is controversial. Transcarotid stenting with flow reversal (TCAR) is a novel hybrid technique for carotid revascularization. We sought to investigate the safety and feasibility of simultaneous TCAR and coronary artery bypass grafting (CABG) for concomitant carotid and coronary artery disease.

Methods: A single-institution, retrospective study of patients with critical carotid artery stenosis and symptomatic CAD who underwent simultaneous TCAR-CABG was completed. The primary outcomes were technical success, perioperative stroke, death, and hemorrhage.

Results: Four patients underwent TCAR-CABG. All patients were male with a mean age of 64. Technical success was achieved in all cases. There were no perioperative strokes or deaths. There were no re-explorations for hemorrhage.

Conclusions: TCAR-CABG is a technically feasible hybrid approach for simultaneous carotid and coronary revascularization. It should be part of the vascular surgeon's armamentarium for coexisting carotid and coronary disease. Further research focused on patient selection and perioperative antiplatelet management is warranted prior to the widespread adoption of this technique.

Keywords

transcarotid artery revascularization (TCAR); coronary artery bypass grafting (CABG); coronary artery disease (CAD); carotid artery disease; combined severe carotid; coronary artery disease

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Introduction

Atherosclerosis is a systemic pathologic process; hence, carotid artery disease and coronary disease frequently coexist. Carotid artery stenosis is a risk factor for the development of ischemic strokes following coronary artery bypass grafting (CABG).¹ In patients undergoing CABG, an estimated 12% will have severe carotid artery stenosis (> 80%).^{2,3} Similarly, among patients undergoing carotid artery endarterectomy (CEA), up to a third have clinically significant coronary artery disease.⁴

The management of concomitant coronary and carotid disease, however, remains controversial. Historically, there exist three treatment strategies: (1) simultaneous CEA-CABG, (2) staged CEA followed by CABG, and (3) staged CABG followed by CEA.^{2, 4-6} Recent studies have investigated the role of carotid artery stenting at the time of coronary revascularization or in a staged fashion.⁷⁻⁹ While there are advantages and disadvantages to each of the aforementioned approaches, there is no consensus on the optimal management of these patients.

Transcarotid artery revascularization (TCAR) with the ENROUTE Transcarotid Neuroprotection System (Silk Road Medical, Sunnyvale, Calif.) with flow reversal is an emerging hybrid strategy for carotid artery revascularization. TCAR involves direct common carotid artery (CCA) access followed by temporary CCA occlusion coupled with flow reversal. TCAR mitigates embolic events by eliminating endovascular manipulation within the aortic arch and by utilizing flow reversal during lesion crossing and stenting. The initial results with TCAR have been promising. In fact, the perioperative stroke rate of 1.4% in the ROADSTER trial was the lowest reported in any carotid stenting clinical trial.¹⁰ TCAR has the potential to merge the morbidity benefits of carotid artery stenting with the robust neuroprotection of carotid endarterectomy.

In this study, we sought to investigate the safety and feasibility of simultaneous TCAR-CABG for patients with concomitant carotid artery stenosis and coronary artery disease.

Methods

Patient Population

After obtaining approval from the Duke University Health System Institutional Review Board, our institutional carotid stenting database was reviewed and a total of four patients who underwent simultaneous TCAR-CABG from February 2018 through January 2019 were identified. All patients considered for TCAR-CABG presented with symptomatic coronary disease and symptomatic carotid artery stenosis or asymptomatic carotid artery stenosis with a stenosis > 85%.

TCAR Procedure

Following induction of general anesthesia, all patients underwent a median sternotomy, and the cardiothoracic surgery team harvested the left internal mammary artery. Next, the vascular surgery team exposed the proximal common carotid in the mediastinum via the sternotomy (Figure 1). Percutaneous access to the femoral vein was obtained and the

ENROUTE NPS Venous sheath was placed. Heparin was given to obtain an activated clotting time greater than 250 seconds. The CCA was accessed with a micropuncture kit, and angiography performed via the micropuncture sheath revealed the CCA bifurcation. The ENROUTE NPS Arterial sheath was advanced into the CCA. Flow reversal was initiated by connecting both the arterial and venous sheaths to the flow controller. The CCA was occluded proximally with an atraumatic vascular clamp. The lesions were crossed with a steerable 0.014-inch wire and stented with an open-cell, self-expanding stent. Pre- and post-dilation maneuvers were performed at the discretion of the vascular surgeon. The arterial sheath was removed and the arteriotomy closed primarily. CABG was performed by the cardiothoracic surgery team. Heparin was reversed with protamine. All patients received a Plavix load via a nasogastric tube at the completion of the case. All patients were managed with aspirin 81 mg daily preoperatively.

Outcomes

The primary outcomes were technical success, perioperative stroke, death, and hemorrhage. Perioperative stroke was defined as a stroke occurring within 30 days of the procedure. Secondary outcomes included length of stay and flow reversal time.

Results

Four patients underwent TCAR-CABG at our institution from February 2018 to January 2019. All patients were male with a mean age of 64. All patients had symptomatic coronary artery disease, and two had symptomatic carotid artery stenosis. The other two patients had critical carotid lesions that were > 85% and 90% stenosed, respectively. In addition, two of the four patients had contralateral carotid artery occlusion (Table 1).

The procedural success rate, defined as successful revascularization of both vascular beds, was 100%. There were no perioperative strokes, re-explorations for hemorrhage, or perioperative deaths (Table 2).

The average postoperative length of stay was 10 days and the mean flow reversal time for TCAR was 10.5 minutes (Table 3).

Discussion

Our findings demonstrate the safety and feasibility of simultaneous TCAR and CABG in highly selected patients with concomitant coronary and carotid disease. All cases resulted in successful revascularization of both vascular beds with no neurologic or bleeding complications.

The appropriate management of patients with clinically significant carotid and coronary artery disease remains quite controversial, partly because of a dearth of randomized controlled data and numerous institutional experiences reporting disparate findings. The argument for a staged approach hinges on increased morbidity and mortality with concomitant procedures.^{5,6} However, a staged approach also invariably places one vascular bed at risk during the interim period prior to the second revascularization. Wang and

colleagues recently evaluated the outcomes of CEA in the setting of unrevascularized severe coronary disease with the Vascular Quality Initiative database.^{11,12} This study identified 2582 patients who underwent CEA in the setting of unrevascularized severe CAD. The postoperative myocardial infarction (MI) rate was 1.9%, which is double the nationally reported rates for post-CEA MI. A large meta-analysis of 97 studies similarly demonstrated that a staged CEA-CABG strategy was associated with the highest MI rate (6.5%), while a staged CABG-CEA approach had the highest stroke rate (6.3%).¹³

Transfemoral carotid artery stenting (TF-CAS) is a minimally invasive alternative to CEA. Recent studies have investigated the efficacy of TF-CAS as a modality for carotid artery revascularization in the setting of CABG.⁷ The appeal of TF-CAS lies in the ability to provide effective carotid revascularization without the added morbidity and mortality of CEA. However, TF-CAS is not equivalent to CEA. In randomized controlled trials, it has invariably been associated with a higher stroke rate.^{14–16} Furthermore, in the setting of concomitant coronary and carotid revascularization, a staged TF-CAS-CABG approach was associated with a higher stroke risk, despite having a lower overall mortality compared to simultaneous CEA-CABG and staged CEA-CABG.¹⁷

Patients with significant atherosclerotic disease in the coronary and carotid vascular beds are at increased risk for cardiovascular sequelae.^{18–20} The ideal approach to treating these challenging patients would be a low morbidity, simultaneous revascularization. A simultaneous approach is critical because it eliminates the need to place either vascular bed at risk for ischemic complications, which is requisite in a staged approach. TCAR has the potential to serve as a low morbidity, effective carotid artery revascularization strategy in the setting of CABG. TCAR involves direct carotid access; in the setting of CABG, this can be achieved via the median sternotomy incision. In fact, mediastinal carotid access eliminates one of the anatomic limitations of TCAR, which is > 5 cm from clavicle to carotid bifurcation. Moreover, the initial results of TCAR have been favorable, reporting a 1.4% 30-day stroke rate and 0.6% 1-year stroke rate.²¹ A limitation to this strategy is the deviation from standard antiplatelet management. Preoperative dual antiplatelet administration is standard of care for carotid artery stenting.²² In our series, all four patients were maintained on aspirin preoperatively, anticoagulated with heparin intra-operatively, and loaded with Plavix at the completion of the procedure. The onset of action of Plavix is two hours; therefore, the carotid stent is unprotected for a period. Given this limitation, simultaneous TCAR-CABG should be reserved for highly selected patients who are invariably considered high risk for perioperative cardiac and cerebrovascular complications.

This study has several other limitations that warrant discussion. First, this was a small retrospective study; no conclusions regarding the efficacy of this technique can be made from a case series with four patients and no control group. Second, the decision to perform TCAR-CABG was made at the discretion of the vascular and cardiothoracic surgeon; therefore, there is selection bias in our study.

Conclusion

The results from this study demonstrate that simultaneous TCAR-CABG is a technically feasible procedure that can be performed safely in highly selected patients with excellent short-term neurologic outcomes. TCAR should be part of the armamentarium for vascular surgeons when managing patients with concomitant coronary and carotid disease. Further research is warranted to evaluate outcomes in a larger patient population and best determine which patients would benefit from this novel hybrid technique.

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Figure 1:
Intraoperative view of (A) proximal control of the common carotid artery via median sternotomy and (B) ENROUTE Transcarotid Neuroprotection and Stent system in place.

Table 1 –

Patient Characteristics

Case No.	Age	Gender	Exertional Angina	Unstable Angina	LVEF (%)	Symptomatic Carotid Disease	Extent of Carotid Stenosis (%)	Contralateral Carotid Disease
1	61	Male	Yes	Yes	55	Yes	>90	No
2	75	Male	Yes	Yes	25–30	No	85	Patent Prior ICA Stent
3	57	Male	Yes	No	55	No	>90	Yes
4	63	Male	Yes	No	40	Yes	>90	ICA Occlusion

Table 2 –

Adverse Procedural Outcomes

Outcome Measure	N = 4 (%)
Technical Success	4 (100%)
Ipsilateral Stroke	0 (0%)
Death	0 (0%)
Re-Exploration Hemorrhage	0 (0%)
30-Day Stroke Rate	0 (0%)

Table 3 –

Patient Operative Details

Case No	Flow Reversal Time	Stent Size (mm)	No. Bypass Grafts	LIMA	Postoperative Length of Stay (Days)
1	10	7×40	3	Yes	12
2	14	7×40	3	Yes	11
3	10	7×30	3	Yes	10
4	8	7×40	3	Yes	7