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Does A Contralateral Carotid Occlusion Adversely Impact CAS Outcomes?

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Abstract

Background—Carotid artery stenting (CAS) has grown as a possible alternative for the treatment of extracranial cerebrovascular disease in the past decade. A pre-existing contralateral carotid artery occlusion has been described as a risk factor for inferior outcomes following carotid endarterectomy (CEA), yet its impact on CAS outcomes is less understood.

Methods—Retrospective review of 417 CAS procedures from May 2001 through July 2010 at a single center using self-expanding nitinol stents and mechanical embolic protection devices. Patients were divided into those with a pre-existing contralateral carotid occlusion (Group A, n=39) versus those without a contralateral occlusion (Group B, n=378). Patient demographics and co-morbidities as well as 30-day and late death, stroke, and myocardial infarction (MI) rates were analyzed. Mean follow-up was 4.0 years (range 0–9.4 years).

Results—Overall mean age of the 314 men and 103 women was 70.5 years. In Group A there were 2 (5.1%) octogenarians and 9 patients (23.1%) with symptomatic disease as compared to Group B with 53 (14.0%) octogenarians and 121 (32.0%) patients with symptomatic disease. The overall 30-day death, stroke, and MI rates were 0.5%, 1.9%, and 0.7%. When comparing Group A to Group B these results were not significantly different: death (0% vs 0.5%), stroke (2.6% vs 1.9%), and MI (0% vs 0.8%). Long-term outcomes for Groups A and B were not significantly different: death (25.6% vs 22.2%), stroke (5.3% vs 3.4%), and MI (15.4% vs 14.0%) (p=NS).

Conclusion—A pre-existing contralateral carotid artery occlusion does not appear to adversely impact CAS outcomes.

Introduction

Carotid artery stenting (CAS) has grown as a possible alternative for the treatment of extracranial cerebrovascular disease and stroke prevention. A pre-existing contralateral carotid artery occlusion has been described as a risk factor for inferior outcomes following carotid endarterectomy (CEA).^{1–3} The impact of a contralateral carotid occlusion among patients treated with CAS is less well understood. Interestingly, the presence of contralateral carotid occlusion has been designated as a high-risk factor for enrollment in many CAS trials and registries despite a lack of evidence to support the hypothesis.

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This paper aims to address this question by retrospectively reviewing the outcomes of CAS among patients with and without a contralateral occlusion, treated at a single institution. The purpose is to better understand whether CAS is the preferred choice for patients undergoing carotid revascularization with contralateral occlusion compared to the gold standard therapy of CEA.

Methods

Institutional Review Board (IRB) approval was obtained prior to initiation of this retrospective study. Between May 1, 2001 and July 31, 2010, 417 CAS procedures were performed in our vascular division. CAS is preferred over CEA in patients with history of neck radiation, re-stenosis post CEA, open wounds near a proposed neck incision, and high lesions. Patients were also considered for CAS based on the inclusion criteria of ongoing institutional clinical trials or registries. All patients were educated on CAS vs CEA, if they were able to receive either, the decision was ultimately left to the patient. Neurologic status of patients was classified as either asymptomatic or symptomatic based on commonly accepted definitions. Symptomatic patients had one of the following in order to classify as a symptomatic neurologic event: stroke, transient ischemic attack (TIA), or amaurosis fugax. All patients underwent preoperative bilateral carotid artery duplex examination. CAS or CEA was recommended for patients with $\geq 50\%$ stenosis and symptomatic disease or $\geq 80\%$ stenosis and asymptomatic disease. Symptomatic patients underwent either a computed tomographic (CT) scan or a magnetic resonance imaging (MRI) scan to assess for the presence, location, and size of an infarct. Daily life-long aspirin (81 or 325 mg) therapy was implemented pre-operatively if not already active. Clopidogrel 75 mg daily antiplatelet therapy was also implemented post procedure for a minimum of four weeks in addition to a 300 mg pre-procedure load.

CAS procedures were performed in the operating room angiosuite with high-quality fluoroscopic imaging as previously described.⁴ Local anesthesia and percutaneous femoral artery access was routinely used with placement of a 6-French standard sheath. A diagnostic arch aortogram was performed in a left anterior oblique (LAO) projection to easily identify each of the arch vessels. The appropriate common carotid artery was then cannulated using a 4- or 5-French simple curved diagnostic catheter. Extracranial imaging was performed with this catheter in place. A stiff wire was then placed into the external carotid artery and over this a long 6-French sheath was advanced from the common femoral artery to the common carotid artery. Systemic intravenous heparin sulfate was given to achieve an activated clotting time of at least 300 seconds. The internal carotid artery stenosis was then crossed with the embolic protection system and deployed beyond the stenosis in a more distal segment of normal, straight internal carotid artery. Angioplasty was typically performed to dilate the lesion. A self-expanding nitinol stent was then deployed. Post-stent deployment angioplasty was routinely performed. Completion angiogram of the extracranial carotid system and two-view (anterior-posterior and lateral) intracranial angiographic imaging was performed to confirm no evidence of distal embolization. Filter and sheath removal completed the procedure. Closure device or manual compression was used for hemostasis.

Patient demographics and co-morbidities as well as 30-day and long-term death, stroke, and myocardial infarction (MI) rates were analyzed. Myocardial infarction was defined by at least two of the following criteria: typical chest pain lasting 20 minutes or more; serum levels of creatine kinase, creatine kinase MB, or troponin at least twice the upper limit of the normal range; and EKG changes. Mortality data was verified against the Social Security Death Index, accessed on September 15, 2010. Baseline and outcome comparisons of groups were performed using Student's t-test or Fisher's exact test, as appropriate. Survival curves

were estimated using the product-limit method and compared using the log-rank test. Univariate Cox proportional-hazards analyses were also performed.

Results

Demographics

A total of 417 CAS procedures were performed over a nine year period. The overall mean age of the 314 men and 103 women was 70.5 years. Patients were divided into those with a pre-existing contralateral carotid occlusion (Group A, n=39) versus those without a contralateral occlusion (Group B, n=378). In Group A there were 2 (5.1%) octogenarians and 9 patients (23.1%) with symptomatic disease as compared to group B with 53 (14.0%) octogenarians and 121 (32.0%) patients with symptomatic disease. In both groups, there was approximately the same proportion in sidedness of lesions and intervention being performed for recurrent carotid stenosis. Group A had a larger proportion of patients with COPD, tobacco use, and prior stroke. Group B had a larger proportion of patients with renal dysfunction, symptomatic disease, and octogenarians. However, tobacco use and presence of prior stroke were the only two variables that held statistical significance. (Table I)

30-day outcomes

The overall 30-day death, stroke, and MI rates were 0.5%, 1.9%, and 0.7%. When comparing Group A to Group B these results were not statistically significantly different: death (0% vs 0.5%), stroke (2.6% vs 1.9%), and MI (0% vs 0.8 %). Event rates within 30-days were low in both groups. Group A had only one stroke within 30 days. This patient underwent CAS for asymptomatic disease and suffered an intra-operative stroke resulting in mild neurologic impairment. Group B had seven strokes within 30 days. Table II shows there to be no statistically significant differences in the rates of death, stroke, and myocardial infarction (MI) between the groups.

Long-term outcomes

Long-term outcomes for Groups A and B were comparable: death (25.6% vs 22.2%), stroke (5.3% vs 3.4%), and MI (15.4% vs 14.0%). For overall death, there are some patients that have recently been lost to follow-up. In these situations, death was investigated by searching the social security database. Frequency of events long-term increased from the 30-day data. Both groups have approximately the same proportion of outcomes (Table II). Univariate data analysis shows a statistically significant difference in long-term death and stroke rates in the COPD and re-stenosis subsets (Table III). All cause mortality and Kaplan-Meier curves appeared similar in both groups (Table II and Figure I). We used a Cox regression model on patient mortality and the presence of chronic obstructive pulmonary disease (COPD), diabetes mellitus, and history of radiation therapy were found to be statistically significant indicators of survival. A history of MI and neurologic symptoms approached statistical significance as predictors in the Cox regression (Table IV).

Discussion

Carotid surgery remains the gold standard for stroke prevention among patients with extracranial carotid artery disease. While various factors may influence the periprocedural outcomes of CEA, clear-cut data is often lacking or conflicting. The impact of a pre-existing contralateral carotid occlusion is one such factor. For instance, data from the Asymptomatic Carotid Atherosclerosis Study (ACAS) reported by Baker et al, showed that a contralateral occlusion did not increase the risk of CEA among asymptomatic patients.⁵ Pulli et al from Italy reported that contralateral occlusion results in an increased usage of intraoperative shunt with the selective shunt technique, but did not increase the risk of perioperative

stroke.⁶ However, the many recent large published series and meta-analyses do report an increased perioperative risk in CEA patients who have a contralateral occlusion, especially in symptomatic patient cohorts.¹⁻³

Based on these recent large series and meta-analyses, many surgeons accept that a contralateral occlusion does increase the perioperative stroke risk following CEA. It is not clear how this translates to CAS outcomes. Over the last several years, the yearly volume of CAS procedures has risen rapidly.⁷ This is in part due to the fact that multiple specialists are able to perform CAS: vascular surgeons, interventional cardiologists, and interventional radiologists. Interestingly, a pre-existing contralateral carotid occlusion has been designated a “high-risk” inclusion criterion for many CAS trials and registries. In 1998, Mathur et al reported their series of 26 patients with a contralateral occlusion who underwent CAS with low incidence of procedural neurologic complications and late stroke.⁸ While a small series, this report initiated a more thorough investigation of the impact of a contralateral occlusion on CAS outcomes. Other studies followed from Germany and France in recent years. One group of German investigators analyzed the subgroup of 5,341 symptomatic and asymptomatic CAS patients (Pro-CAS Data). They did not find that patients had a statistically significant difference in outcomes following CAS with a contralateral occlusion.⁹ This group reports ‘contralateral occlusion’ in their abstract but in the results section, complete occlusions were combined with severe stenosis (>90%). Another German group reported their symptomatic and asymptomatic CAS data on 3,137 patients (ALKK-CAS Registry). This group also concluded that there was no statistical significance in the differences seen in outcomes for CAS procedures with contralateral occlusions. The authors did report that all adverse events occurred in the symptomatic cohort, none in the asymptomatic cohort.¹⁰ Two meta-analysis studies were published in Europe recently, supporting the above claims that there is not an increase in CAS procedural risk in patients with contralateral occlusion. The investigators concluded that CAS should be considered first line therapy for carotid revascularization in this subgroup, with the exception of the elderly (≥80 years of age) who tend to do poorly with CAS.^{11,12}

The current study has several limitations inherent to any single-center retrospective review. First, the small sample size makes it difficult to make definitive conclusions. In particular, with small numbers of patients in each cohort, very few patients (2 patients with a contralateral carotid occlusion and 12 with a patent contralateral carotid) developed a stroke beyond 30 days from the procedure, precluding time-dependent analysis for long-term stroke. However, a pre-existing contralateral carotid occlusion does not appear to adversely impact CAS outcomes. Second, a number of other factors are known to impact CAS outcomes: 1) interventionalist experience; 2) use and choice of embolic protection device; 3) stent design; 4) pre-procedural neurologic status; 5) age; and 6) vascular anatomy (access vessels and target lesion). Lastly, roughly 6% of patients have been lost to long-term follow-up. Despite these short-comings, our data does show both groups A and B have acceptable outcomes. Moreover, our data appears to be consistent with recently published European data on CAS with contralateral occlusion.

Conclusion

While the role of CAS remains to be clearly defined, certain anatomic conditions may make this approach a more suitable therapeutic option than CEA for stroke prevention. A pre-existing contralateral carotid artery occlusion may be one such circumstance. The current literature, including this report, suggests that a contralateral occlusion does not adversely impact CAS outcomes.

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Kaplan-Meier Survival Curves

Figure 1.
Kaplan Meyer survival curves.

Time (Years)	0	1	2	3	4	5	6	7	8	9
Group A (# alive)	31	36	33	22	17	12	7	1	0	0
Group B (# alive)	378	331	295	238	190	132	75	32	13	2

Table I

Demographics and co-morbidities

Demographic & Risk factor	Contralateral Occlusion										P value
	Total (n=417)		Yes (n=39)		No (n=378)						
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Age	70.5	9.14	68.1	7.36	70.7	9.28	70.7	9.28	70.7	9.28	0.09
	N	%	N	%	N	%	N	%	N	%	
Gender (male)	314	75.3	29	74.4	285	75.4	285	75.4	285	75.4	0.89
COPD	70	16.8	10	25.6	60	15.9	60	15.9	60	15.9	0.12
HTN	373	89.5	34	87.2	339	89.7	339	89.7	339	89.7	0.59
HL	299	71.7	24	61.5	275	72.8	275	72.8	275	72.8	0.14
Tobacco	211	50.6	26	66.7	185	48.9	185	48.9	185	48.9	0.04
DM	134	32.1	10	25.6	124	32.8	124	32.8	124	32.8	0.36
MI (n=411)	58	14.1	6	15.4	52	14.0	52	14.0	52	14.0	0.81
Old stroke (n=415)	138	33.3	19	48.7	119	31.7	119	31.7	119	31.7	0.03
PTCA	84	20.1	8	20.5	76	20.1	76	20.1	76	20.1	0.95
Renal dysfunction	41	9.8	1	2.6	40	10.6	40	10.6	40	10.6	0.16
Stratification											
Side (Left)	215	51.6	22	56.4	193	51.1	193	51.1	193	51.1	0.52
Symptoms	130	31.2	9	23.1	121	32.0	121	32.0	121	32.0	0.28
Octogenarian	55	13.2	2	5.1	53	14.0	53	14.0	53	14.0	0.14
XRT	57	13.7	6	15.4	51	13.5	51	13.5	51	13.5	0.81
Restenosis	81	19.4	6	15.4	75	19.8	75	19.8	75	19.8	0.67

* COPD: chronic obstructive pulmonary disease, HTN: hypertension, HL: hyperlipidemia, DM: diabetes mellitus, MI: myocardial infarction, PTCA: Percutaneous transluminal coronary angioplasty, XRT: radiation therapy

Table II

Post-operative outcomes

Post-operative outcome	Contralateral Occlusion				P value
	Yes (n=39)		No (n=378)		
	N	%	N	%	
Death < 30 days	0	0.0	2	0.5	0.99
Stroke < 30 days	1	2.6	7	1.9	0.55
MI < 30 days	0	0.0	3	0.8	0.99
Overall death	10	25.6	84	22.2	0.63
Overall stroke (n=392)	2	5.3	12	3.4	0.64
Overall MI (n=411)	6	15.4	52	14.0	0.81

* MI: myocardial infarction

Table III

Univariate relationships between long-term death and stroke

Demographic & Risk factor	Death				Ipsilateral stroke			
	No		Yes		No		Yes	
	n	%	n	%	n	%	n	%
<u>Gender</u>								
female	84	81.6	19	18.5	92	96.8	3.00	3.2
male	239	76.1	75	23.9	286	96.3	11.00	3.7
<u>COPD</u>								
None	279	80.4	68	19.6	315	97.2	9	2.8
Yes	44	62.9	26	37.1	63	92.7	5	7.4
<u>HTN</u>								
None	35	79.6	9	20.5	38	97.4	1	2.6
Yes	288	77.2	85	22.8	340	96.3	13	3.7
<u>HL</u>								
None	87	73.7	31	26.3	106	97.3	3	2.8
Yes	236	78.9	63	21.1	272	96.1	11	3.9
<u>TOB</u>								
None	161	78.2	45	21.8	187	97.9	4	2.1
Yes	162	76.8	49	23.2	191	95.0	10	5.0
<u>DM</u>								
None	226	79.9	57	20.1	258	96.6	9	3.4
Yes	97	72.4	37	27.6	120	96.0	5	4.0
<u>MI (n=411)</u>								
None	277	78.5	76	21.5	320	96.4	12	3.6
Yes	40	69.0	18	31.0	54	96.4	2	3.6
<u>Stroke (n=415)</u>								
None	208	75.1	69	24.9	252	96.9	8	3.1
Yes	113	81.9	25	18.1	126	95.5	6	4.6
<u>PTCA</u>								

Death										Ipsilateral stroke							
No										Yes							
Demographic & Risk factor										No				Yes			
										P value				P value			
n										n				n			
%										%				%			
n										n				n			
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77.5										95.8				4.2			
22.5										4.2				1.3			
75										79				1			
19										98.8				0.64			
22.6										0.28				3.4			
79										340				2			
98.8										95.0				5.0			
1.3										0.50				0.37			
294										340				266			
78.2										96.6				97.1			
21.8										3.4				2.9			
82										38				112			
12										95.0				94.9			
29.3										0.21				3.5			
38										49				2			
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70.9										98.7				95.9			
2.9										3.5				4.1			
0.11										0.08				0.49			
328										304				74			
97.0										95.9				98.7			
10										13				1			
3.0										4.1				1.3			
7.4										0.50				0.70			
2.9										3.5				0.70			
5.1										0.21				0.11			
0.11										0.08				0.49			
284										329				328			
78.5										96.5				97.0			
21.6										3.5				3.0			
78										49				50			
16										96.1				92.6			
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0.1																	

* COPD: chronic obstructive pulmonary disease, HTN: hypertension, HL: hyperlipidemia, MI: myocardial infarction, PTCA: Percutaneous transluminal coronary angioplasty, XRT: radiation therapy

Table IV

Cox regression model on patient mortality

Predictor	Hazard Ratio	95% CI	P value
Contralateral Occlusion	0.676	0.34–1.35	0.27
Age	1.012	0.98–1.04	0.44
Gender (female vs. male)	0.749	0.43–1.31	0.31
COPD	2.068	1.28–3.35	0.00
HTN	1.206	0.59–2.46	0.61
HL	0.807	0.51–1.28	0.36
Tobacco	0.967	0.59–1.59	0.89
DM	1.628	1.05–2.54	0.03
MI	1.82	0.96–3.45	0.07
Old stroke	0.675	0.39–1.17	0.16
PTCA	0.829	0.48–1.43	0.50
Renal dysfunction	1.553	0.77–3.14	0.22
Side (left vs. right)	0.748	0.49–1.14	0.17
Symptoms	1.546	0.96–2.49	0.07
Octogenarian	1.646	0.81–3.36	0.17
XRT	2.645	1.48–4.72	0.00
Restenosis	0.639	0.33–1.26	0.19

* COPD: chronic obstructive pulmonary disease, HTN: hypertension, HL: hyperlipidemia, DM: diabetes mellitus, MI: myocardial infarction, PTCA: Percutaneous transluminal coronary angioplasty, XRT: radiation therapy