

# Standard Carotid Endarterectomy with Dacron Patch Angioplasty, Risks and Outcomes

*Salah-Eldien Altarabsheh MD\*, J. Michael Duncan MD\*\**

## ABSTRACT

**Objective:** The aim of this study was to assess the different risk factors and their impact on the final outcome of standard carotid endarterectomy with dacron patch angioplasty.

**Methods:** From January 1998 to December 2002, 805 (488 males, 317 females) patients underwent standard carotid endarterectomy with dacron patch angioplasty at Texas Heart Institute. The mean age was 69.5 years (range 34-93 years). The primary outcomes were combined same-admission stroke/death and 30-day mortality rate. While the secondary outcomes were same-admission perioperative transient ischemic attack, cranial nerve injuries, myocardial infarction and take back to secure hemostasis.

**Results:** There were 13 (1.6%) cases of same-admission stroke/death, and a total of 5 (0.6%) 30-day deaths. Ten (1.2%) patients had postoperative transient ischemic attack. Furthermore, 7(0.9%) patients had cranial nerve injury. Two patients experienced acute myocardial infarction, and 14 (1.7%) patients were taken back to the operating theater to secure hemostasis.

**Conclusions:** Standard carotid endarterectomy with dacron patch angioplasty is associated with low rates of morbidity and death, with reasonable outcomes in most patients.

**Key words:** Carotid endarterectomy, Carotid stenosis, Dacron Patch, Transient ischemic attack, Stroke

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## Introduction

Extra cranial internal carotid artery stenosis accounts for 15-20% of ischemic strokes, and carotid endarterectomy (CEA) is the most frequently performed surgical intervention in stroke prevention.<sup>(1)</sup> The era of surgical prevention of stroke goes back half a century, when the first carotid endarterectomy was performed in 1953.<sup>(2)</sup> After the initial endorsement of carotid endarterectomy, confusion arose as to the appropriate selection of patients and the allowable risk from the procedure.<sup>(3)</sup>

Since the publication of positive findings from several large randomized controlled clinical trials, including the North American Symptomatic Carotid Endarterectomy Trial (NASCET), European Carotid Surgery Trial (ECST), Asymptomatic Carotid Atherosclerosis Study (ACAS), and Asymptomatic Carotid Atherosclerosis Surgery Trial (ACST), rates of CEA have increased dramatically as a method for preventing stroke in patients with high grade carotid artery stenosis.<sup>(4-6)</sup> However, the development of perioperative complications such as stroke or death is still a major concern because these complications may negate the benefits of the procedure. Identification of risk factors for adverse outcomes

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From the Departments of Cardiovascular Surgery

\* Queen Alia Heart Institute, King Hussein Medical Center, (KHMC), Amman-Jordan

\*\*Texas Heart Institute, Houston-Texas, USA

Correspondence should be addressed to Dr. J. Michael Duncan, Department of Cardiovascular Surgery, Texas Heart Institute, MC 1-162, P.O. Box 20345, Houston, TX 77225-0345. E-mail: [mduncan@heart.thi.tmc.edu](mailto:mduncan@heart.thi.tmc.edu)

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**Table I.** Base line characteristics of patients

Characteristic	No.	%
Sex		
Male	488	61
Female	317	39
Age		
< 80 yr	700	87
≥ 80 yr	105	13

**Table III.** Cerebral and cerebrovascular risk status at base line

Risk	No.	%
Symptomatic		
Stroke only	89	11
Transient ischemic attack only	208	26
Both	72	9
Asymptomatic	436	54
Previous carotid endarterectomy		
Ipsilateral	30	4
Contralateral	137	17
Contralateral occlusion	49	6
History of neck irradiation	16	2

**Table II.** Coronary artery and cardiac risk status at base line

Risk	No.	%
Coronary artery disease	113	14
MI* during 6 months	16	2
Previous coronary revascularization	24	3
NYHA** functional class		
I	469	58
II	301	37
III	35	5
Canadian Cardiovascular Society Class		
0	467	58
1	209	26
2	89	11
3	32	4
4	8	1

\*MI= Myocardial Infarction; \*\*NYHA= New York Heart Association

**Table IV.** Medical risk at base line

Risk	No.	%
History of pulmonary disease	196	24
History of renal impairment	32	3.9
Cigarette Smoking (past or present)	402	50
Hypertension	652	81
Diabetes Mellitus		
Type 1	48	6
Type 2	145	18
Hyperlipidemia	402	50

after carotid surgery is very important in surgical patient selection and patient counseling.

Standard Carotid endarterectomy with dacron patch angioplasty is an effective operation designed to prevent stroke, several large multicenter studies have demonstrated that endarterectomy is superior to the best medical management of high grade symptomatic or asymptomatic carotid artery stenosis.<sup>(6-8)</sup> Nonetheless, some physicians have argued that carotid angioplasty and stenting may be preferable to CEA because it is less invasive, entails a shorter recovery period, and may be less likely to produce adverse outcomes in high risk patients.<sup>(9)</sup>

In this overview, we report the operative outcomes in the management of patients with carotid artery stenosis using standard carotid endarterectomy with dacron patch angioplasty, and we examined the frequency of different outcomes and the possible contribution of various risk factors to those outcomes.

## Methods

The medical records of all patients who underwent standard CEA with dacron patch angioplasty, at Texas Heart Institute (THI), between January 1998 and December 2002 were retrospectively reviewed.

Carotid endarterectomy was performed if carotid artery stenosis was significant i.e. ≥70% narrowing of its internal diameter. The methods used to diagnose and quantify the degree of carotid artery stenosis were: duplex Doppler ultrasound, magnetic resonance angiography, and carotid arteriogram.

All the CEA procedures were performed under general endotracheal anesthesia, with the head of the patient being extended slightly and turned away from the operative site. The incision was typically longitudinally placed along the anterior portion of the sternocleidomastoid muscle and centered over the carotid bifurcation, as best judged from the preoperative angiogram. Heparin was given before clamping of the carotid artery in a dose-weight

standard of 1mg/kg. Shunts were used according to the surgeon preference; the plaque was dissected free using a free elevator, or any other convenient instrument. Closure of the arteriotomy proceeded next, using the dacron patch, which was fashioned to the length of the vessel opening. Protamine sulfate was given at the completion of angioplasty in a protamine-heparin ratio of 1-2/1 ratio. Patients spent 3-4 hours in the recovery intensive care unit before being sent to the surgical ward.

Exclusion criteria included patients with concomitant CEA and coronary artery bypass, and patients in whom dacron was used as an interposition graft rather than a patch.

We assessed the association between the various patient characteristics, preoperative risk factors, and the outcomes. These included (Tables I-IV): age, sex, previous CEA in the same artery, previous neck irradiation, occlusion of the contralateral artery, Canadian Cardiovascular Society (CCS) classification of functional limitation related to angina, New York Heart Association (NYHA) classification of functional limitation related to heart disease, previous Coronary Artery Bypass Grafting(CABG) surgery, symptoms of carotid artery stenosis (stroke, Transient Ischemic Attack(TIA) or both) within six weeks before surgery, hypertension (blood pressure > 140/90 mmHg), Coronary Artery Disease (CAD), cigarette smoking, Diabetes Mellitus(DM), hyperlipidemia, pulmonary disease (including Chronic Obstructive Pulmonary Disease (COPD), asthma, emphysema, pulmonary embolism) and renal impairment.

The rates of in hospital same-admission stroke and death were relatively low, and so these were combined into a single outcome (same-admission stroke/death) for the purpose of analysis. TIA or other neurological events that had short periods i.e. < one day were not classified as strokes. A stroke was defined as a permanent neurological deficit confirmed by the surgeon and the neurologist, with a brain computed tomography findings supporting the diagnosis.

The other outcomes were: 30-day mortality rate (the only outcome for which 30-day follow up data were available for each patient), same-admission rate of post operative TIA, cranial nerve injury, myocardial infarction and take back for hemostasis.

We used  $\chi^2$  analysis and the Fisher exact test with categorical variables. A 2-tailed  $P < 0.05$  was considered statistically significant for each outcome.

## Results

Medical records of 805 (488 male, 317 female) patients, who underwent standard CEA with dacron patch angioplasty in the period between January 1998 and December 2002 were reviewed. Mean age of the patients was 69.5 years (range 34-93 yrs). Of the 805 procedures 370 (46%) were performed on patients who had experienced symptoms of carotid stenosis within the six weeks before surgery. Shunts were used in 713 (89%). The median time from surgery to discharge was two days (range 1-112 days).

Twelve (1.5%) patients had stroke during the CEA procedure or the in-hospital recovery period. Ten patients had strokes (one fatal) in the cerebral hemisphere ipsilateral to the operated artery, one patient had a stroke in the contralateral hemisphere, and one patient had multiple infarcts in both brain hemispheres. There was one additional death from acute myocardial infarction after an emergency aortocoronary bypass surgery two days after CEA. There was a total same-admission mortality of two (0.2%) patients, and a total of five (0.6%) 30-day deaths. The total incidence of combined same-admission stroke/death was 13 (1.6%) (Table V).

Ten (1.2%) patients experienced TIA during the perioperative period. Seven (0.9%) patients were found to have transient postoperative cranial nerve injury, 14 (1.7%) were taken back to the operating theater for bleeding issues after CEA was completed. Only two (0.2%) patients experienced perioperative myocardial infarction, one of which was fatal. (Table VI)

## Discussion

This study showed that 12 (1.5%) patients had stroke during the CEA procedure or in the in-hospital recovery period, one of them died, and an additional death was from an acute myocardial infarction two days after CEA, so the total same admission mortality was two (0.2%), and the total combined same-admission stroke/death was 13 (1.6%). Univariate analysis showed that five factors were associated with increased risk of same-admission stroke/death: NYHA functional class III ( $p=0.02$ ), angina with CCS classification of 2-4 ( $p=0.01$ ), TIA within six weeks prior to surgery ( $p=0.02$ ), contralateral carotid artery occlusion ( $p=0.04$ ), and past or present history of cigarette smoking ( $p=0.01$ ) (Table V).

**Table V.** Univariate predictors of primary adverse outcomes in standard carotid endarterectomy with dacron patch angioplasty (No. = 805):

Primary outcome	No. (%)	Factor		Rate (%)	P-value	
Same-admission stroke/death	13 (1.6)	NYHA* classification	I	7/469 (1.5)	0.02	
			II	4/301 (1.3)		
			III	2/35 (5.7)		
		2-4	CCS** classification	0-1	7/676 (1.0)	0.01
				6/129 (4.7)		
		Previous TIA‡ (past 6 wks)	No	4/525 (0.8)	0.02	
			Yes	9/280 (3.2)		
		Contralateral occlusion	No	10/756 (1.3)	0.04	
			Yes	3/49(6.1)		
		Cigarette smoking (past or present)	No	2/403 (0.5)	0.01	
Yes	11/402(2.7)					
30-Day death	5 (0.6)	CAD† (any history)	No	2/692 (0.3)	0.02	
			Yes	3/113 (2.7)		
		Creatinine ≥ 2.0 mg/dl	No	4/773 (0.5)	0.01	
			Yes	1/32 (3.1)		
		Pulmonary disease (any)	No	1/609 (0.2)	0.01	
			Yes	4/196 (2.0)		

\*NYHA = New York Heart Association; \*\*CCS = Canadian Cardiovascular Society; ‡TIA = Transient Ischemic Attack; †CAD = Coronary Artery Disease.

**Table VI.** Univariate predictors of secondary adverse outcomes in standard carotid endarterectomy with dacron patch angioplasty (No. = 805):

Primary outcome	No. (%)	Factor		Rate (%)	P-value
Postoperative TIA*	10 (1.2)	Previous TIA* (past 6 wk)	No	3/525 (0.6)	0.04
			Yes	7/280 (2.5)	
		Operated side	Right	1/383 (0.3)	0.02
			Left	9/422 (2.1)	
Cranial-nerve injury	7 (0.9)	Previous ipsilateral CEA**	No	5/775 (0.6)	0.03
			Yes	2/30 (6.7)	
Reoperation for hemostasis	14 (1.7)	Sex	Male	13/488 (2.7)	0.01
			Female	1/317 (0.3)	

Three patients died after hospital discharge but within 30 days of surgery, so the total 30-day mortality rate was five (0.7%). In univariate analysis, risk of death within 30 days of CEA was associated with history of CAD ( $p=0.02$ ), serum creatinine  $\geq 2\text{mg/dl}$  ( $p=0.01$ ), and history of pulmonary disease ( $p=0.01$ ) (table V).

There are obvious difficulties in trying to compare a series of patients from different institutions, with no reliable way of equating differences in indications for operation, variations in population base, and surgical expertise. Nevertheless, aware of these potential variables, our results were comparable to those of large multi-institutional studies, such as: NASCET, ECST, ACAS, and ACST. The 30-day mortality rate shown in this study (0.6%), was not substantially different from that observed in ACAS (0.1%)(10), ECST(1.0%),<sup>(11)</sup> NASCET(1.1%),<sup>(12)</sup> and ACST (1.1%).<sup>(13)</sup>

The ACAS and ACST, which included only asymptomatic (and, therefore, lower risk) patients, each found a (1.4%) rate of stroke,<sup>(10,13)</sup> whereas NASCET and ECST which included only

symptomatic (higher-risk) patients found rates of (2.4%) and (3.2%) respectively.<sup>(11,12)</sup> Our (1.5%) stroke rate seems to fit in between these estimates, since about half (46%) of our patients were symptomatic before going to surgery.

Contralateral internal carotid artery occlusion is an important factor in consideration when performing CEA. However, whether patients with internal carotid artery stenosis and contralateral internal carotid artery occlusion have a higher risk of perioperative stroke or stroke related death than patients with unilateral internal carotid artery lesion with patent contralateral internal carotid artery remains a controversial issue.<sup>(14,15)</sup> Moreover several studies have found an increased stroke risk in patients with contralateral internal carotid artery occlusion.<sup>(16,17)</sup> Not surprisingly, this study showed that approximately (6.1%) of patients with contralateral carotid artery occlusion had strokes or died in the post operative period, but only (1.3%) of patients without contralateral occlusion had these adverse outcomes ( $p=0.02$ ).

External irradiation to the neck area, poses a

special challenge to the surgeon, because the lesion may not be closely accessible and the plaque may be closely adherent, leading to difficulty in achieving an adequate cleavage plane for endarterectomy, making avoidance of cranial nerve injury more difficult, added to that the carotid plaque in the irradiated neck contains more lipids and less fibrous tissue than the typical plaques, this feature makes the plaque less stable and more prone to move to the brain and causing stroke.<sup>(18)</sup> It was of interest to note that there were no strokes or cranial nerve injuries among the 16 patients who had previous neck irradiation before CEA. However, because this subgroup of patients was relatively small (16 out of 805), these findings did not show definitively that previous neck irradiation is not a risk factor in CEA. Re-operation on a previously endarterectomized carotid artery makes it difficult to identify the right plane of cleavage in the scar tissue.<sup>(18,19)</sup> This study showed an increase in the incidence of cranial nerve injury in patients with previous CEA (6.7%), compared to (0.6%) in patients with primary CEA. Actually previous ipsilateral CEA was the sole predictor of cranial nerve injury in univariate analysis ( $p=0.03$ ) (Table VI). However it did not show any significant effect of previous CEA on perioperative stroke/death or on 30 day death rate. One notable difference between our findings and those of some multi-institutional studies is in the rate of postoperative cranial nerve injury. Reported rates of postoperative cranial nerve injury were considerably higher in both NASCET (8.6%)<sup>(18)</sup> and ECST (5.1%)<sup>(20)</sup> than it was in this study (0.9%). This finding could be explained by the follow up protocols. In NASCET, all patients underwent a neurological assessment on admission, and at regular periods after CEA, regardless the patients are having symptoms of cranial nerve injury or not.<sup>(21)</sup> The follow up protocol in ECST was also similar, and included a detailed neurological examination.<sup>(22)</sup> In our study, a neurologist assessed patients only if they had symptoms of cranial nerve injury, thus the transient cranial nerve injury, which constitute the majority of cranial nerve injuries, found in NASCET and ECST, were undetected in our study.

Ten (1.2%) patients experienced TIA in the postoperative recovery period, however univariate analysis showed that post operative TIA was most likely to occur in patients who had TIA in the preoperative period( $p=0.04$ ), or had CEA undertaken on the left side. ( $p=0.02$ ) (Table VI).

Fourteen (1.7%) patients were taken back to the operating theater to secure bleeding issues after the completion of CEA, this was predicted only by male sex ( $p=0.01$ ) (Table VI).

## Limitations of the Study

Some potential limitations of the present study must be acknowledged. There was no regular, detailed preoperative or postoperative neurologic assessment, nor was there a systematic effort to identify myocardial infarction, such as by routine measuring postoperative troponin or creatine kinase levels.

## Conclusion

Our experience with CEA with dacron patch angioplasty showed that it is a procedure with low morbidity and mortality. The number of patients studied and the variety of risk factors in its population made data a good basis for comparison between different studies.

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