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Operative Intervention for Carotid Restenosis is Safe and Effective

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Carotid stenting has been proposed as an alternative to reoperative carotid endarterectomy (rCEA) for recurrent carotid stenosis. The purpose of this study is to prove the safety, effectiveness and durability of reoperation in long term follow up of 18 years in a community hospital setting. From March 1988 to April 2005 80 patients, 46 men and 34 women (mean age: 64.1 years) underwent a total of 83 operations. Symptomatic recurrent stenosis (>70%) was the indication in 32, asymptomatic high-grade stenosis (>80%) in 49, intimal flap in one and fibromuscular dysplasia (F.M.D), in one.

The initial operation was carotid endarterectomy with primary closure in 60 and prosthetic patch in 23. The mean recurrences were at 23.3 months in 33 with myointimal hyperplasia, 105.4 months in 29 with recurrent atherosclerosis, 61.4 months in 19 with both hyperplasia and atherosclerosis, 2 months in one with intimal flap and 8 months in one with F.M.D bands. Reoperation utilized primary closure (3), vein patch (14), prosthetic patch (55), Gore-Tex interposition grafts (7), vein interposition grafts (3) and intraoperative dilation (1).

No perioperative strokes or deaths occurred. One patient died from cardiac complications following combined rCEA and coronary artery bypass grafting. Operative morbidity consisted of reversible nerve injury (5), irreversible recurrent laryngeal nerve injury (1) and hematoma requiring evacuation (3). During follow up (3–153 months; mean: 50.9) carotid occlusion resulted in mild ipsilateral stroke in one patient, and one non-hemispheric stroke. There were 26 late deaths due to all causes, one due to CVA. Eight patients required reoperation (mean 53.4 months). Seven of these were hypertensive.

Kaplan-Meier analysis of long-term follow up shows relatively high stroke free rates; at 153 months (12.75 years) the hemispheric stroke free rate was 98.67% and the all-stroke free rate was 95.85%. The survival estimate following redo surgery was 69.97% at 5 years and 40.23% at 10 years. We found that individuals on statin therapy (p-value = 0.0042), and those on combination of statin and aspirin (p-value = 0.0320), had significantly increased interval between primary and secondary operation. Increased age was correlated to a decreased time to redo surgery (p-value = <0.0001).

We conclude that reoperation for recurrent carotid stenosis using standard vascular techniques is safe, effective, durable and cost effective. It should continue to be the mainstay of treatment when secondary intervention is required. Statins have a salutary effect on durability of the procedure and should be used when indicated.

Keywords: Carotid endarterectomy; Recurrent stenosis; Cerebrovascular disease; Carotid stent; Long term; Follow up.

Introduction

Carotid endarterectomy is the gold standard for treatment of symptomatic and asymptomatic flow limiting carotid artery disease as compared to medical treatment for prevention of stroke.[1–3] This is supported by the results of the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS) clinical trials.[1,2] CEA is not only durable, but has been shown to have low operative risks. The perioperative risks are clearly defined.[4,5] However the increase in CEA's performed has also resulted in an increase in the number of patients presenting with a recurrent stenosis as reflected in the approximate 2% to 5% incidence of reoperation.[6–10]

It has been suggested that local anatomic complications such as nerve damage occur frequently in patients undergoing operation for restenosis, and with the added difficulty of redissection in the prior operative field, new treatment modalities such as carotid artery stenting have been proposed as safer alternatives to rCEA.[11,12] As a result, most carotid artery stenting trials classify rCEA among the high-risk inclusion criteria. In the NASCET trial the recurrent carotid artery stenosis was one of the exclusion criteria. This has also resulted in categorization of recurrent stenosis in the high risk group by the proponents of carotid stenting. In the trial, Stenting and Angioplasty with protection in patients at High Risk for Endarterctomy (SAPPHIRE) it has been documented that carotid stenting is not inferior to

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CEA.[13] The results of this trial continue to be debated because of the study design.

In 1998 we had published our 10 year experience in performing CEA for recurrent stenosis.[14] In the current study our purpose is to prove the safety, effectiveness and durability of rCEA as seen in long term follow up of 18 years. This is especially pertinent as the patients continue to present with recurrent stenosis to various specialists and in the days of evidence based medicine we should be able to advise patients appropriately from both a clinical and an economic perspective.

Methods

Patient selection and data collection

In this retrospective study a review was performed of all patients who underwent an operation for recurrent carotid stenosis between March 1988 and May 2005 by our group of three board certified vascular surgeons in a community hospital setting. The original operations were not always performed by the group. Patient demographics were obtained from patient charts and indications and technique for the original operation were identified when possible in a retrospective manner. All of the original operative notes were not available. The temporal relationship from primary CEA and type of reconstruction (type of patch or primary closure) and the technique in treating the recurrent carotid stenosis was documented. Patients' clinical and laboratory data, operative details, post operative carotid noninvasive studies and clinical course for those undergoing rCEA were obtained. Clinical criteria determination made at time of rCEA included: hypertension, diabetes mellitus, coronary artery disease, history of cigarette smoking, high cholesterol as determined by lab values, family history of coronary disease, and the use of aspirin or statins. Carotid stenosis symptoms including hemispheric and non-hemispheric TIA and amaurosis fugax were documented. In asymptomatic patients, a second operation was performed in patients who displayed greater than 80% restenosis, intimal flap causing hemodynamically significant stenosis or fibromuscular dysplasia. No patient was rejected because of underlying co-morbidities.

All operations were carried out under general anesthesia. A shunt was routinely used unless it could not be placed for technical reasons. Various techniques were used for reconstruction. When intimal hyperplasia is identified, an attempt is made to perform an intimectomy, however it is not always possible to do a complete removal of thickened intima. A patch is routinely used in either circumstance. If indicated a bypass is performed. Hospital and patient office records were screened for any adverse events during the hospitalization that was associated with surgical procedures. Particular weight was placed on postoperative cardiovascular and neurologic status as documented on record. A perioperative stroke was defined as a central neurologic deficit ipsilateral to the operative side. Other complications examined included hematoma requiring drainage and reversible or irreversible laryngeal nerve injury which was determined clinically.

Follow up included clinical exam and duplex interrogation of the operative site at 6 weeks, 6, and 12 months after discharge, and annually thereafter. The primary end point was stroke. Secondary end points included death or lost to follow up. Review of cause of death was performed to determine if it was due to carotid disease. An attempt was made to call the families when the patient was lost to follow up or died in another facility. Patients who were lost to follow up usually moved out of state to warmer climates or could not return for follow up because of socioeconomic reasons.

Recurrent (tertiary) stenosis: Follow up continued anywhere from 3 to 153 months (mean 50.9 months) unless evidence of another restenosis developed as was the case after eight reoperations. These tertiary surgeries took place from 5 to 147 months after the second operation for restenosis with a mean of 53.4 and a median of 46.5 months. The time between the primary and tertiary operations ranged from 12 to 153 months with a mean of 88.3 and a median of 84 months. The original criteria for reoperation were used. Seven of the patients were asymptomatic and had >80% stenosis, one patient had TIA and >70% stenosis.

Statistical analysis: Data were tabulated and Kaplan-Meier analysis was performed on survival and stroke free interval. A multivariate analysis was carried out to see if any of the risk factors had a significant impact on long term result. T-tests were performed when appropriate.

Results

Between 1988 and 2005, 80 patients, (mean age: 64.1 years) underwent a total of 83 rCEAs. Of these patients, 32 underwent the second operation due to symptomatic recurrent stenosis (>70%), 49 presented with asymptomatic high-grade stenosis (>80%), one with an intimal flap and one with F.M.D. In these asymptomatic patients, 22 had intimal hyperplasia, 16 had recurrent atherosclerosis and 11 had a combination of intimal hyperplasia and recurrent

atherosclerosis. Patients were followed by serial ultrasound and operated on when the stenosis became greater than 80%, even if the patient was asymptomatic. Primary closure was used in 60 of the primary cases, and prosthetic patch in 23 (Table 1). Of the 60 procedures in which the original operation was primary closure, findings at the time of second operation included; 24 intimal hyperplasia 21 atherosclerosis, 14 combined atherosclerosis and intimal hyperplasia and 1 intimal flap. Of the 23 original prosthetic patch procedures, findings at the time of second operation were: 9 intimal hyperplasia, 9 atherosclerosis, 4 atherosclerosis and intimal hyperplasia and one fibromuscular dysplasia.

There were no patients in the symptomatic category who had less than 70% stenosis. The average time from primary CEA to recurrence was 23.3 months in the 33 patients who presented with myointimal hyperplasia, 105.4 months in the 29 with recurrent atherosclerosis, 61.4 months in the 19 presenting with both problems as determined intraoperatively and on histology, two months in the patient with an intimal flap, and 8 months for the patient with symptomatic fibromuscular dysplasia beyond the site of the original carotid endarterectomy. The patient had magnetic resonance angiography before the initial endarterectomy and fibromuscular dysplasia was not identified. The average time from primary CEA to recurrence in symptomatic patients was 64.9 months with a median of 56.5. In asymptomatic patients the average time between surgeries was 56.1 months with a median of 49.5. Recurrent stenosis was identified preoperatively by ultrasonic examination in all patients. A comparison of the mean time to restenosis between symptomatic and asymptomatic patients was analyzed using a t-test and was found not to be statistically significant. Our lab uses a peak systolic velocity of 250 cm/sec, a peak diastolic velocity of 100 cm/sec and a systolic velocity ratio of 3.7 to diagnose a stenosis of greater than 80%. MRA or arteriography was performed rarely to confirm the ultrasonic diagnosis.

All patients received general anesthesia. Reoperation utilized primary closures in three, fourteen vein patches, 55 prosthetic patches, seven Gore-Tex interposition grafts, three vein interposition grafts and one intraoperative dilation for the patient with fibromuscular dysplasia (Table 2).

No perioperative strokes occurred (Table 3). There was one perioperative death unrelated to the rCEA in a patient who underwent combined coronary artery bypass grafting with rCEA and died from cardiac complications. Operative morbidity consisted of reversible recurrent laryngeal nerve injury in five, irreversible recurrent laryngeal nerve injury in one and hematoma requiring evacuation in three. During follow up, carotid occlusion resulted in mild ipsilateral stroke in one patient. This patient was operated on for asymptomatic stenosis which was caused by a long segment of intimal hyperplasia. The stroke occurred three months after the redo operation. One patient had non-hemispheric stroke due to small vessel disease. There were 26 late deaths due to all causes including one due to cerebrovascular accident as

Table 1. Demographics and risk factors

	N	%
Men	46	57.5
Women	34	42.5
Age at first operation	64.1 ± 1.0	
Tobacco use (any history)	52	65
Hypertension	65	81.25
Diabetes	19	23.75
High cholesterol	54	67.5
Family History of stroke	30	37.5
Coronary artery disease	39	48.75
Statin therapy	46	57.5
Aspirin therapy	72	90
Reasons for redo-operation		
Symptomatic		
AF	3	3.61
TIA − HEMI	22	26.50
TIA − NON HEMI	7	8.43
Asymptomatic	49	59.03
Intimal Flap	1	1.20
FMD	1	1.20
Initial Operation		
Primary closure	60	
Prosthetic	23	

FMD, Fibromuscular dysplasia; *AF*, Amarousis fugax; *TIA*, Transient ischemic attack; *Hemi*, Hemispheric; *Non-Hemi*, Non Hemispheric.

Table 2. Surgical characteristics

	N	%
General		
Total Redo Procedures	83	100
Average time from first CEA (2 to 218 months)	59.7 ± 5.9	–
Contralateral CEA	34	41
Bilateral Redo CEA	3	3.6
Redo-Operation Procedure		
Primary Closure	3	3.6
Intraoperative dilation	1	1.2
Interposition Graft		
Gortex	7	8.4
Vein	3	3.6
Total Patches		
Dacron patch	4	3.6
Hemashield patch	22	26.5
Acuseal patch	22	26.5
Goretex patch	7	8.4
Vein patch	14	16.9

CEA, Carotid endarterectomy.

Table 3. Operative complications and follow up

	N	%
Complication		
Perioperative CVA	0	0
Perioperative death	1	1.2
Hematoma requiring drainage	3	3.6
Reversible nerve injury	5	6
Irreversible recurrent laryngeal nerve injury	1	1.2
Follow-up 3 to 153 months (mean: 50.9 months)		
Recurrent stenosis requiring tertiary operation	8	9.6
Average time between second and third operation	53.4 ± 16 months	
Stroke on operative side	1	1.3
Stroke, nonhemispheric	1	1.3
Death due to CVA (nonhemispheric)	1	1.3
Death due to other causes	25	31.3
Lost to follow-up (mean: 21.4 months)	18	22.5
Recurrence of symptoms after redo (TIA) resulting in tertiary operation	1	

CVA, Cerebrovascular accident.

determined by hospital records. The cause of death could not always be determined. Only eight operations were performed for tertiary restenosis at 5, 10, 49, 58, 82, 32, 44 and 147 months (mean: 53.4 months). Seven of these patients were hypertensive. Seven operations were carried out in asymptomatic patients and one patient had a TIA.

Follow up ranged from 3 to 153 months (mean 50.9 months, median 42 months). Kaplan-Meier analysis of long-term follow up shows relatively high stroke free rate. At 153 months (12.75 years) the hemispheric stroke free rate was 98.67% (Fig. 1, Table 4) and the all-stroke free rate was 95.85% (Fig. 2, Table 5). The survival estimate following redo operation was 69.97% at 5 years and 40.23% at 10 years (Fig. 3, Table 6). We found that individuals on statin therapy (mean: 67.38 months; p-value = 0.0042), and those on a combination of statin and aspirin (mean: 62.32 months; p-value = 0.0320), had significantly increased time to redo operation. Those on just aspirin (mean: 52.12 months) and those on neither statin nor aspirin (mean: 25 months) (Table 7) are likely to have earlier recurrence. Using a Pearson product correlation, an increased age was correlated to a decreased time to redo operation (p-value = <0.0001). We did not find a significant correlation between risk factors (single and paired) or gender and cause for restenosis (intimal hyperplasia, atherosclerotic plaque or both). Risk factors included hypertension, family history, diabetes mellitus, coronary artery disease, tobacco use and hypercholesterolemia. There also did not seem to be a correlation between risk factors or gender and the need for third operation.

Discussion

Carotid Endarterectomy has been shown to be safe and effective in various randomized trials both in the United States in the NASCET and ACAS trials,[1,2] and in Europe in the ECST and ACST trials.[34,35] However, the role of surgery for recurrent carotid artery stenosis has become controversial in the recent past due to the advent of endovascular techniques. Various authors

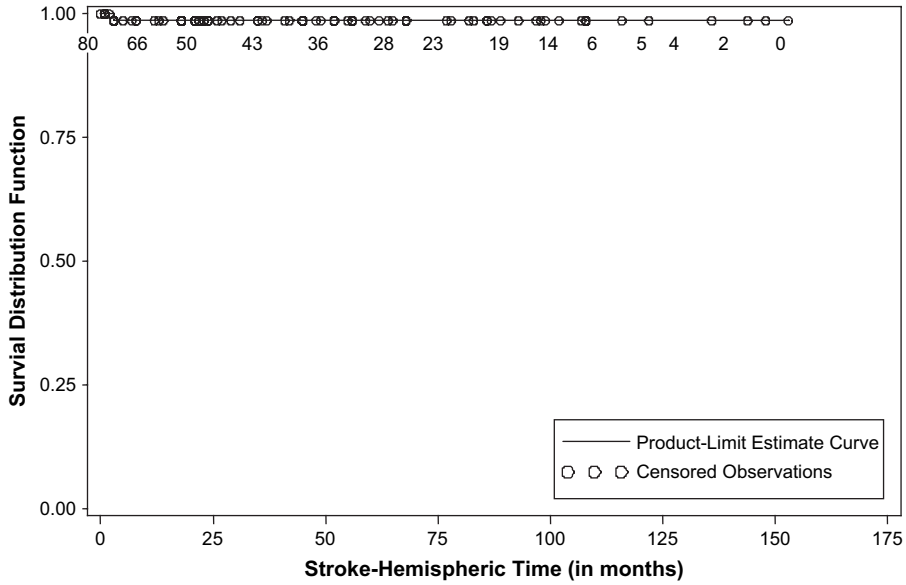

Fig. 1. Hemispheric Stroke Free Survival using Kaplan-Meier curve from the time of reoperation. Numbers in graph represent patients being followed at 12 month intervals.

Table 4. Hemispheric stroke free survival rate

Total	Failed	Censored	Percent Censored
80	1	79	98.75

Summary of the Number of Censored and Uncensored Values. Only one survival time has failed and 79 were censored. Failure were observed at 3 months (S(t) = 0.9867; Std. Error = 0.0132).

have reported stroke/mortality rates with surgery to be less than 5%. This is within the guidelines recommended by NASCET and the Ad Hoc Committees of the American Heart Association on Carotid Surgery Standards.[14–16] In guidelines presented by American Heart Association, the stroke/death rate of <6% for symptomatic patients, and <3% for asymptomatic patients is acceptable and for rCEA the acceptable rate is <10%.[17] Our results are well within these guidelines. We believe that the low rate of major adverse outcomes in this study, which has also been echoed by other reoperative series with stroke/death rates noted between 0% and 7%, make the redo operation very safe[18,19] Many studies, ours included, indicate the operative risk of rCEA is similar to that of first-time operation.[6–8] The operation is durable as seen by our long term clinical and ultrasonic follow up of the carotid arteries.

Our group's approach has been to recommend reoperation in otherwise good-risk patients with asymptomatic high-grade stenosis greater than 80% or for symptomatic stenosis greater than 70%. The choice of operation depends on several factors and the procedures include endarterectomy, patch angioplasty and resection/grafting. The procedure used depends on the operative findings. If the artery has a thin web of intimal hyperplasia, this can often be peeled off and the artery is then closed with a patch. Recurrent atherosclerosis can be removed along a plane as in the first operation. Long segment smooth stenosis sometimes only requires a patch. In patients with severely thickened arteries, or those without an easily established plane of dissection, resection and grafting is the procedure of choice.[14] We follow a similar practice.

The reason to carry out the reoperation is to prevent strokes. In our study, during follow-up, carotid occlusion resulted in a mild ipsilateral stroke in one patient which compares favorably with long-term results shown in the NASCET report. One patient had a non-hemispheric stroke which is within the 13% 5-year ''risk of any stroke or perioperative death'' reported in the ACAS study.[14] Of 26 late deaths, one was due to CVA as determined by hospital records. Our results show a 98.7% hemispheric stroke free survival and 95.85% all stroke free survival. These results are similar to the results published by Stoner *et al.* who reported a stroke free rate of 96% during a mean follow up of 4.4 years.[20] Since we did not know the cause of death for all the patients, it is possible that some patients may have died as a result of stroke.

Another concern of reoperative carotid operation is the possibility of injuring an adjacent structure (e.g.

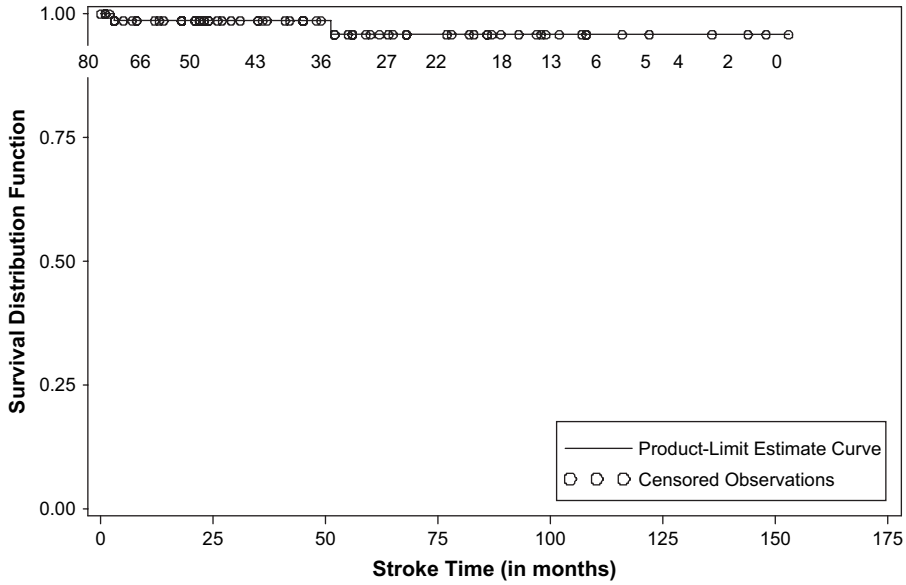

Fig. 2. All Stroke Free Survival using Kaplan-Meier curve from the time of reoperation. Numbers in graph represent patients being followed at 12 month intervals.

Table 5. All stroke free survival rate

Total	Failed	Censored	Percent Censored
80	2	78	97.50

Summary of the Number of Censored and Uncensored Values. Only two survival time has failed and 78 were censored. Failure were observed at 3 months (S(t) = 0.9867; Std. Error = 0.0132) and 51 months (S(t) = 0.9585; Std. Error = 0.0306).

cranial nerves or internal jugular vein). It seems to be the natural tendency for these structures to become adherent to the planes of previous dissection.[21] However, the use of blue monofilament suture makes reoperation fairly straightforward if patience and due diligence are exercised. The color of the suture makes it easy to go down to the previous suture line. The dissection is also often surprisingly easy the further in time one gets after the original operation.[14] In our study there were only six nerve injuries which were clinically apparent, five of which were reversible. One patient had persistent vocal cord paralysis. Cranial nerve injury is recorded in the 0% to 7% range in several publications for reoperative carotid operation.[22–24] These are within ranges suggested for first-time carotid surgery.[25] There was no attempt made to do routine independent neurogical or laryngoscope evaluation if not clinically warranted. Occasionally, reoperation for neck hematoma is required. We do not routinely take patients off aspirin prior to the operation. Heparin is always reversed. Occasionally low molecular weight Dextran is used intraoperatively and postoperatively but there was no correlation found between the use of Dextran and postoperative bleeding. Currently patients are taken off Clopidogrel for two weeks prior to an operation. In our study neck hematoma requiring operation rate was 4% (three cases) which is consistent with previously published and acceptable rates as defined by randomized trials.[1,17,20] These results demonstrate that meticulous surgical technique can yield excellent results, despite the presence of a reoperative field.[20]

Studies have shown the salutary effect of HMG-Co A reductase inhibitors on the progression of vascular disease. We had 46 patients on statins after the primary operation. We found a significant delay in developing recurrent stenosis requiring operation when the patients were on statins or statins and aspirin. We would recommend the use of statins post carotid endarterectomy as also reported by LaMuraglia *et al.*[26]

The effect of age on CEA needs further attention. We noticed that increased age at the time of carotid endarterctomy has a negative impact on developing restenosis. In a study of nonagenarians published by our group we showed that vascular operation can be safely carried out when appropriate measures are taken.[27] We continue to offer the operation to patients at any age if they are functional.

We have low recurrence rates, as is also seen in other reports.[20,28,29] Long term follow-up in our patients displays good results with only eight incidences of tertiary stenosis requiring operation. The recurrence rate after redo endarterectomy of ten percent

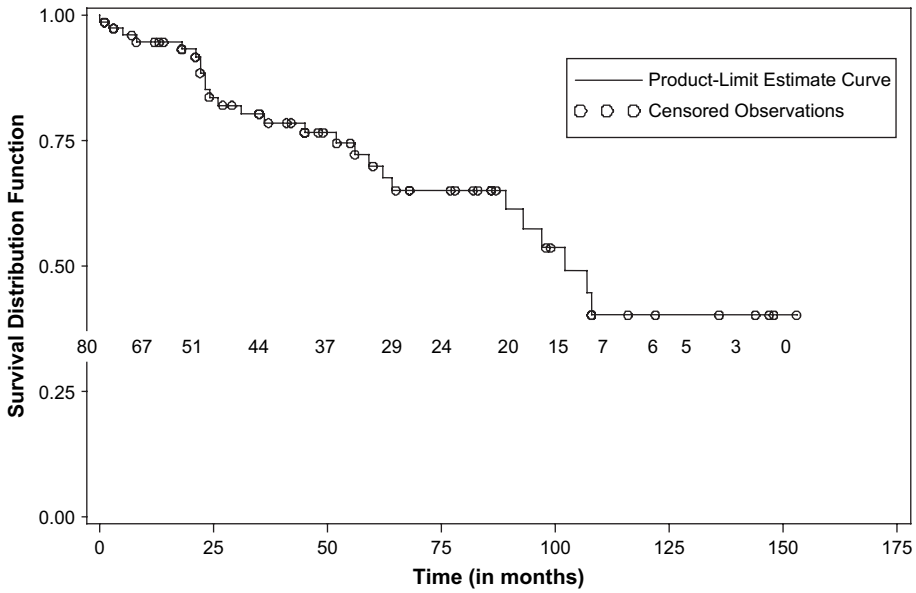

Fig. 3. Survival using Kaplan-Meier curve from the time of reoperation. Numbers in graph represent patients being followed at 12 month intervals.

Table 6. Long term survival

Total	Failed	Censored	Percent Censored
80	26	54	67.50

Summary of the Number of Censored and Uncensored Values.

in this series may be considered by some to be high however this is one of the very few reports looking at a long term follow up in this population. Modifying their risk factors may help to decrease recurrent stenosis. Seven of these patients had hypertension. This was not found to be statistically significant. This may be because of sample size. Other authors have shown a higher incidence of hypertension in patients presenting with recurrent stenosis.[30,31] This finding should promote physicians to better control hypertension in this group of patients. We did not find any other risk factor to correlate with recurrent stenosis as reported by other authors. Once again it may be due to sample size. A meta analysis of various studies may show a better relationship between various risk factors and recurrent stenosis.

Outcomes with carotid stenting performed as the reoperative intervention have shown a comparable incidence of complications including TIA, stroke, restenosis and death in the 30 day period following the procedure.[32] In the data being presented we were able to carry out the operation without procedure related stroke or death. There was only one perioperative death due to cardiac complications following combined rCEA and coronary artery bypass grafting. The results of combined operation tend to be different as compared to CEA alone. However, for the sake of completion we have included this patient in this series. Patients having carotid stenting for recurrent carotid stenosis have been shown to have higher stroke rate, restenosis rate, and lower stroke free survival rate[32,33] as compared to our data.

We recognize there are inherent weaknesses to our study as with any retrospective review or report.

Table 7. Multivariate analysis of risk factors associated with progression to recurrent carotid artery stenosis

Variable	Hazard Ratio	95% CI	*p*-value
Hypertension	0.7517	[0.4972, 9.0451]	0.3097
Family History	1.715	[0.7789, 3.7720]	0.1806
Diabetes Mellitus	1.021	[0.3801, 2.7420]	0.9672
Coronary artery disease	1.845	[0.8217, 4.1445]	0.1377
Smoking	0.543	[0.2417, 1.2184]	0.1385
Hypercholesterolemia	0.435	[0.1979, 0.9559]	0.0382
Gender	1.447	[0.6565, 3.1889]	0.3595
Aspirin	1.121	[0.3241, 3.8758]	0.8570
Statin	0.302	[0.1330, 0.6850]	0.0042*
Aspirin and statin	0.396	[0.1698, 0.9233]	0.0320*

* $p < 0.05$.

Occasionally the follow up is incomplete because patients died at another facility or did not return for follow up visits. The primary operation was not always performed by our group resulting in variable surgical techniques. Since the incidence of recurrent stenosis requiring intervention is low, it is difficult to have a prospective study for this group of patients.

Conclusions

Reoperation for recurrent carotid stenosis, using standard vascular techniques, is safe, effective and durable. In patients with symptomatic 70% stenosis and asymptomatic 80% stenosis the operation can be carried out with low risk and long stroke free survival. Statins should be diligently used when indicated. The operation can be safely carried out in a community hospital setting when performed by board certified vascular surgeons. Carotid endarterctomy should continue to be the mainstay of treatment when secondary intervention is required.

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