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RESEARCH ARTICLE

Complication Rate After Carotid Endarterectomy Comparing Patch Angioplasty and Primary Closure: Long-Term Outcome

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ABSTRACT

Objective: In patients with symptomatic or asymptomatic severe internal carotid artery stenosis, carotid endarterectomy (CEA) has been shown to reduce risk for stroke. The optimal surgical technique remains subject of debate. In the latest European Society of Vascular Surgery (ESVS) guidelines on the management of atherosclerotic carotid disease, routine patching is preferred to routine primary closure. However, there are no RCT's evaluating selective patching strategies. This follow-up study aimed to assess long term complication rate and restenosis after carotid endarterectomy with selective patching.

Methods: Two hundred thirteen consecutive carotid endarterectomies over a 3-year period from January 5th 2011 to December 19th 2013 were prospectively analyzed in a follow-up study over 5 years (mean 4.6, range 3.17-6.17). Patient population consisted of 141 procedures on males and 72 on females with mean age 73 years at the time of surgery (standard deviation (SD) 8.57, range 53-95). There was a follow-up of 89%. Postoperative risk factors were assessed such as hypertension, diabetes mellitus, coronary artery disease and smoking. Postoperative symptoms of cranial nerve injury, transient ischemic events, cerebrovascular events and mortality were evaluated. Duplex ultrasound was performed by a radiologist blinded to the operative technique to evaluate patency of the carotid artery after carotid endarterectomy.

Results: Primary closure was used in 110 operations, and patch angioplasty in 103 procedures (Dacron patch). Primary closure was performed when the carotid artery had a diameter above 5 mm, when there was a high carotid bifurcation or when the contralateral carotid artery was occluded. There were no significant differences among groups' baseline characteristics at the time of surgery. Primary closure was performed significantly more in male patients (P= .02). Overall complication rate was 3.76% postoperatively (1.8% after primary closure, 5.8% after patch angioplasty) and after 5 years 5.29% (2.0% after primary closure, 9.1% after patch angioplasty). There are no significant differences in results between the two groups (P= .09 and P= .05).

In four cases patients experienced symptoms of cranial nerve damage postoperatively, two in each group. In one of the two cases in each group, the patient fully recovered and the other had persistent complaints (P-value= 1). None of the patients experienced amaurosis fugax during the 5-year follow up period. In five cases a patient had an ipsilateral cerebrovascular thrombosis in the group after patch angioplasty compared to zero in the primary closure group (P-value= .02). In the group of primary closure there was a mortality of 26 patients (23.6%) compared to 26 (25.2%) patients after patch angioplasty (P-value = .70). One was caused by cerebral hyperperfusion syndrome within one month postoperative after patch angioplasty and none were caused by an ipsilateral ischemic stroke. Objective duplex ultrasound showed no significant difference comparing restenosis in both groups (P-value= .43). In twelve cases patients showed a restenosis between 50-70% (6 primary closure and 6 patch angioplasty), none of the patients had high grade restenosis of more than 70%. Patient characteristics did not show a significant effect on long term outcomes. There was a correlation between postoperative use of antihypertensive medication and long-term stroke (P-value= .006), restenosis (P-value= .01) and mortality (P-value= .003).

Conclusion: After long-term follow-up we found primary closure and patch angioplasty to be equivalent with respect to complication rate and restenosis when used in selected cases. Best medical treatment and especially the use of antihypertensive medication should be emphasized.

Keywords: Carotid stenosis, carotid endarterectomy, primary closure, patch closure, best medical treatment.

Introduction

Carotid endarterectomy (CEA) reduces the risk of cerebrovascular and long-term ischemic events in patients with symptomatic or high grade (> 70%) asymptomatic internal carotid artery stenosis.[1,2] The risk for adverse events caused by this intervention depends upon achieving a smooth endarterectomized surface with gradually tapered distal endpoint and precise closure of the artery. An accurate closure technique contributes to optimal hemodynamics of the vessel; however, the ideal surgical closure technique during carotid endarterectomy remains a subject of debate.

The use of patch angioplasty has been suggested to improve hemodynamic flow in the artery by increasing the carotid artery diameter. [3,4] However, this positive influence of patch closure on the hemodynamic profile has been under discussion and recent studies question the routine use of patch angioplasty. Harrison et al. found no favorable flow dynamics after patching, since incorporation of a patch increases areas of low wall shear stress and high oscillatory shear index at the bifurcation.[5] Domanin et al. found no negative hemodynamic conditions after primary closure, in particular when the ICA diameter is greater than 5mm. [6] In addition, an American study found no difference in restenosis and post-operative stroke rate within 30 days.[7] The clinical impact of these hemodynamic changes on patient's outcome has been studied. Early restenosis (3-6 months postoperatively) is usually secondary to neo-intima hyperplasia, whereas, late restenosis, developing after 24 months, is caused by recurrent atherosclerosis. Influencing factors are smoking, female gender, small carotid diameter, hypertension, diabetes and primary closure.[8] Some studies indicate that carotid patch angioplasty reduces the risk of immediate postoperative complications, and significantly lowers vessel restenosis and occlusion rates.[9] However, patch angioplasty has also been associated with rare patch specific complications, such as patch rupture, false aneurysm formation, and thrombo-embolism stemming from the dilated, aneurismal carotid bifurcation. Especially saphenous vein patch angioplasty has been shown to be prone to aneurysmal dilation, but provide a lower risk of infection and bleeding.[10,11] Patch rupture, though rare, requires further intervention with additional morbidity and cost.[12] Also, there is an increased cross-clamp time that may cause a greater neurocognitive decline, especially in the elderly population.[13]

Primary closure has the advantage of eliminating graft-specific complications and reducing cross-clamp times in comparison with patch angioplasty.[13,14] In addition, large published series of carotid endarterectomy showed excellent results when primary closure was used.[15,16]

Recently, there is a trend suggesting primary closure is an equivalent closure technique compared to patch angioplasty when used in selective cases. Patch angioplasty is mostly used in cases where there is tortuosity of the vessel and narrow vessel diameter.[16] A large retrospective trial by Avgerinos et al. found that closure technique does not affect perioperative and long term outcomes.[17] These considerations have led many surgeons to recommend selective use of patch closure.[15]

Previous research showed that primary closure appears to be an equivalent closure technique compared to patch angioplasty when used in selected patients with broad carotid artery (diameter above 5 mm), a high carotid bifurcation or occlusion of the contralateral carotid artery.[18] However, most literature still suggests patch closure to be superior in the longer term in terms of restenosis.[4,19] A Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) secondary analysis demonstrated a significant reduction of 2-year restenosis rates with the use of patch (P-value (P) = .06).[20] In contrast, other studies have shown that the occurrence of restenosis may be independent of primary or patch closure.[14,18]

This follow-up study aims to assess long-term complication rate and restenosis after CEA with selective patching.

Methods

STUDY POPULATION

Two-hundred and thirteen consecutive CEA procedures (115 left, 98 right) carried out at Sint-Lucas Hospital, Ghent, Belgium over a period of 3 years from January 2011 to December 2013, have been enrolled in this prospective 5-year follow up study. No subjects were excluded. All patients signed an informed consent approved by the Ethical Committee of AZ Sint Lucas Ghent. Indications for surgery were asymptomatic high-grade carotid stenosis (> 80%) and symptomatic carotid artery stenosis, categorized into transient ischemic attack, cerebrovascular attack and amaurosis fugax. Individual patient characteristics were registered, including preoperative ipsilateral and contralateral stenosis on carotid color duplex ultrasound scans and angiographic studies. Preoperative risk factors were listed, including hypertension, diabetes mellitus, coronary artery disease, smoking status and preoperative use of aspirin and/or anticoagulants.[21] Renal function was classified by the estimated glomerular filtration rate (GFR) at the

time of surgery as normal (GFR ≥ 60 mL/min), moderate (GFR 30-59) and severe (GFR < 30). A detailed study design and short term results have been reported previously. [18]

After 5 years patients were asked to complete a questionnaire to see if the cardiovascular risk factors had changed. An ultrasound duplex was performed by an objective radiologist, blinded to the technique used in surgery. Restenosis was categorized as none or mild restenosis <50% (internal carotid artery (ICA)/common carotid artery (CCA) peak systolic velocity (PSV) 0.1-1.9); PSV < 125) moderate between 50-69% (ICA/CCA PSV 2.0-4.0; PSV 125-230) and severe between 70-99% (ICA/CCA PSV, >4; PSV >230). The threshold of 70% was chosen because few surgeons or interventionists would adopt a lower threshold for re-intervening in asymptomatic patients and very few published outcome data used a restenosis threshold of 80%. Five-year morbidity and mortality data were registered.

CAROTID ENDARTERECTOMY TECHNIQUE

All CEA procedures were performed under general anesthesia with administration of systemic heparin. No shunting technique was used.[22] The decision to perform patch angioplasty or primary closure was made by the primary operator during surgery, based upon patient characteristics and experience of the surgeon. The carotid diameter was measured before surgery using the preoperative computed tomography (CT) or magnetic resonance (MR) scan. Primary closure was performed when the carotid artery had a diameter above 5 mm, when there was a high carotid bifurcation or when the contralateral carotid artery was occluded.

Primary closure was performed using 7-0 polypropylene suture material (Prolene; Ethicon, Inc, Somerville, NJ). For patch closure, a polyethylene terephthalate patch (Dacron; Vascutek, UK) was tapered to the appropriate size to reconstruct the shape of the carotid artery. The patch was sewn into place with 6-0 Prolene suture material.

To obtain hemostasis, an absorbable hemostat and digital pressure were applied before skin closure (Surgicel® Fibrillar™ Absorbable Hemostat; Ethicon, Inc, US). Protamine was given at the end of each procedure. Postoperative care included application of closed suction drainage and aspirin therapy. If patients were not under aspirin therapy, aspirin was started at least 24 hours before surgery (Asaflow 80mg daily). All procedures were carried out by two vascular surgeons, both using the same techniques and decision-making criteria to perform primary or patch closure.

STATISTICAL ANALYSIS

Patients were grouped according to primary closure or patch closure during the CEA procedure. Vagal and hypoglossal nerve injuries, cerebrovascular incidents and mortality were evaluated during a follow up period of 5 years.

Mann-Whitney U test was used to compare both groups (primary closure versus patch angioplasty). Risk differences were calculated between the patch angioplasty and primary closure groups together with 95% confidence intervals (CI) using Newcomb's method based on Wilson score confidence intervals for single proportions. The equivalence margin was set at 10%. The equivalence hypothesis is accepted if the 95% CI of the difference between proportions falls entirely within this predefined range of equivalency.

Kaplan-Meier estimates of survival were plotted together with 95% pointwise confidence intervals (calculated using the log - log approach) for the overall population and stratified according to surgical technique. Estimates for 1-year and 5-year survival are reported. The log rank test was used to compare survival between the patch angioplasty and primary closure groups (superiority test).
Analyses were performed in R version 3.5.2 using the "PropCIs" and "survival" packages.

Results

One-hundred and forty-one procedures on males and 72 on females were included in this study with a mean age of 73 years at the time of surgery (SD 9, range 53-95). A total of 213 procedures were performed. Primary closure was used in 110 operations and patch angioplasty in 103 procedures. Primary closure was more frequently used in male patients than female patients (81 vs. 29; P-value (P) = .02). Additionally, there was a significant association between the surgeon and the used surgical technique (P = .006).

There was a follow-up of 89%, including 101/110 (92%) in the group after primary closure and 88/103 (85%) after patch angioplasty (P = .19). Causes for loss to follow-up include unavailability (8.2%) and refusal to participate in the follow-up study (2.8%).

Gender and nicotine abuse are significantly different in both groups. Demographic data are described in Table 1.

Table I: Demographic data.

	Closure technique		P-value*
	Primary closure N = 110	Patch angioplasty N = 103	
Age (median)	74.6 (67.4-78.3)	73.6 (67.1-79.4)	0.82
Sex (male)	81	60	0.02
Smoker (yes)	22	37	0.004
Hypertension (yes)	91	78	0.24
Hypercholesterolemia (yes)	85	76	0.63
Diabetes (yes)	42	31	0.25
Coronary artery disease (yes)	34	32	0.61
Anti-platelet (yes)	84	85	0.31
Anti-coagulantia (yes)	9	7	0.80
Operation side (right)	49	49	0.68
Stenosis ICA (median %)	80	80	0.33
Stenosis contralateral ICA (median %)	50	40	0.07
Symptomatic lesion (yes)	45	36	0.40

*P-values were measured by Fisher's Exact test

Patient characteristics did not show a significant effect on long term outcome. There was an association between postoperative use of antihypertensive medication and long-term stroke (P= .006), restenosis (P= .01) and mortality (P= .003).

Overall postoperative complication rate was 3.76% (1.82% after primary closure, 5.82% after patch angioplasty, as reported previously.[18] After 5 years the overall complication rate was 5.29 % (2.0% after primary closure, 9.1% after patch angioplasty). These results are not significantly different between the two groups (P= .05).

Complications are summarized in Table II. In four cases patients experienced symptoms of vagal or hypoglossal nerve injury obtained during dissection postoperatively, 2 in each group. In both groups, 1 of the two fully recovered and the other had persistent complaints. None of the patients experienced amaurosis fugax during the 5-year follow up period. The results show no higher overall complication risk when using primary closure compared to patch closure. The risk for ischemic attack within 5 years after surgery is 6% higher in the patch angioplasty group compared to the primary closure group (P= .02).

Table II: Outcomes stratified by carotid endarterectomy (CEA) technique during a 5-year follow-up period.

	Closure technique		Risk difference with 95% CI	P-value*
	Primary closure N = 101	Patch angioplasty N = 88		
Total complications	2 (2.0%)	8 (9.1%)	-7%(-15.2% to -0.8%)	0.05
Cerebrovascular event	0	5 (5.7%)	-6%(-12.6% to -1.9%)	0.02
Nerve damage	2 (2.0%)	2 (2.3%)	0%(-6.2% to 5.0%)	1
Cerebral hyperperfusion	0	1 (1.0%)	-1%(-5.4% to 2.4%)	0.48

*P-value's were measured by Fisher's Exact test

Objective duplex ultrasound showed no significant difference in restenosis (P= .76) between closure groups. In twelve cases patients had a restenosis between 50-70% (6 primary closure and 6 patch angioplasty, P= .76), however none of the patients had high grade restenosis of more than 70%. Of all patients with restenosis 6 (7.41%) were symptomatic and 6 (4.55%) were asymptomatic at baseline.

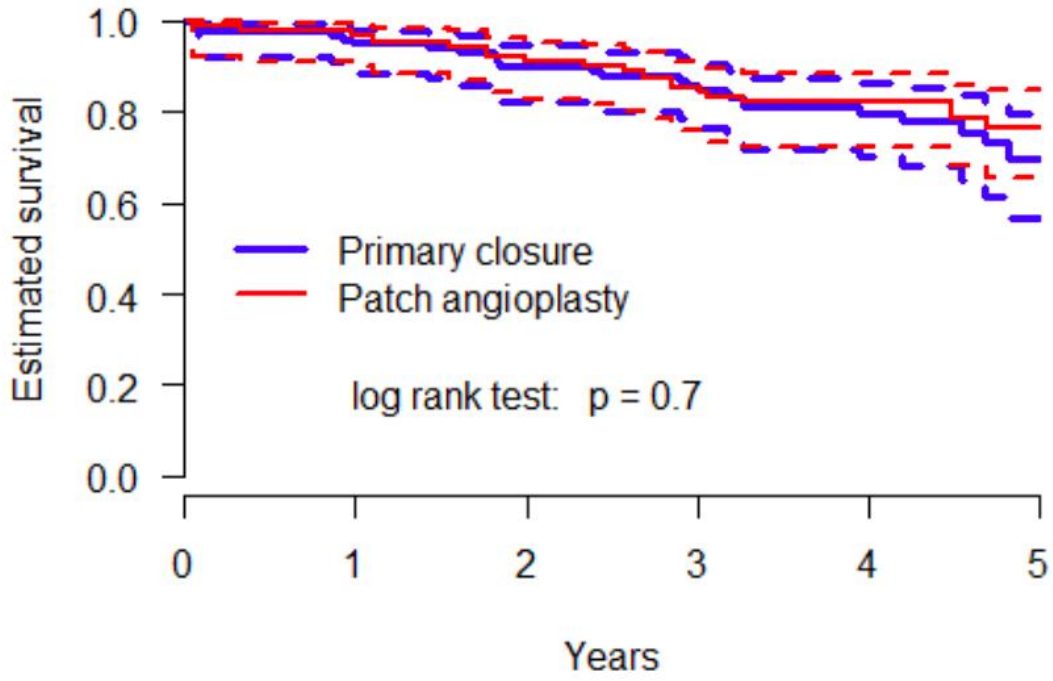
From the 213 procedures performed in this study, 50 patients died during follow-up and 163 procedures were censored for the survival analysis. The smallest time interval at which at least 25% of patients had died was 5.3 years. After primary closure, the estimated 1-year and 5-year survival probability was 95% (95% CI 89% - 98%) and 70% (95% CI 56% - 80%) respectively. After patch angioplasty, the estimated 1-year and 5-year survival probability was 97% (95% CI 90% - 99%) and 77% (95% CI 65% - 85%) respectively. The log-rank test indicated no significant difference in survival curves between both surgical techniques (P= .70; Figure 1). Causes of mortality are

summarized in Table III. Survival curves did not differ according to kidney function (P = 0.42).

Table III: Mortality causes according to carotid endarterectomy (CEA) technique during a 5-year follow-up period (P = 1)

	Closure technique	
	Primary closure	**Patch angioplasty**
Overall mortality	26 (23.64%)	26 (25.24%)
Cerebral hyperperfusion	0	1 (0.97 %)
Cardiac death	5 (4.55%)	5 (4.85%)
Gastro-intestinal death	4 (3.64%)	3 (2.91%)
Pulmonary death	5 (4.55%)	9 (8.74%)
Cancer	5 (4.55%)	2 (1.94%)
Neurological death	2 (1.82%)	3 (2.91%)
Unknown	5 (4.55%)	3 (2.91%)

Figure 1: Kaplan Meier curve. There is no overall difference in estimated survival between carotid endarterectomy (CEA) techniques according to the log rank test.



Discussion

In literature, overall evidence in support of the benefits of patch angioplasty versus primary closure after CEA is conflicting and there is no general consensus among surgeons regarding the ideal closure technique during surgery. Current ESVS guidelines suggest routine patch closure is the technique of preference in comparison to routine primary closure. However, there is no recommendation on a selective patching strategy.[8] Closure technique in clinical practice mainly depends on the individual surgeon's experience and preference. [23] The decision seems to depend on vessel size and in certain studies mode of anesthesia. Vascular surgeons agree that carotid artery patching is positively desirable in patients with very narrow internal carotid arteries or long plaques needing extended arteriotomy.[24] Primary closure can lead to equivalent patient outcomes while avoiding the risks associated with patch angioplasty.[7,16,18,25] Primary closure was performed when the carotid artery measured a diameter above 5 mm. This is an arbitrary limit, based on thresholds used in literature.[17,23,25,26] Primary closure was also used when the contralateral carotid artery was occluded to reduce clamp time and possible ischemic time. This explains why we found significantly more primary closure in patients with contralateral stenosis in our sample. Also, when there was a high carotid bifurcation primary closure was preferred because of the technically challenging and time-consuming patch placement in these cases.

A meta-analysis of 10 randomized controlled trials (RCT) comparing routine patching with routine primary closure observed that routine patching was associated with significant reductions in perioperative ipsilateral stroke and routine patching was associated with significant reduction in 30-day internal carotid artery thrombosis. There was no significant difference between routine patching and routine primary closure regarding perioperative death and fatal stroke. Long-term outcomes show significant reduction in late stroke and restenosis after routine patching. However, no RCT's have compared routine patching with selective patching and there is no consensus on criteria for selective patching.[8]

In this prospective follow-up study 213 CEA procedures with a selective patching strategy were analyzed over a follow-up period of 5 years. The aim of the study was to observe the incidence of overall complications and restenosis after carotid endarterectomy with selective patching.[27] Overall complications were not significantly different in both groups. The risk for ischemic attack within 5 years after surgery seems to be 5-7% higher in the patch angioplasty group compared to the primary closure group. A 5.7% risk of developing a cerebrovascular accident in the patch angioplasty group is consistent with stroke rates reported literature.[28] We suspect the low number of ischemic attacks in the primary closure group can be explained by patient selection.

Objective duplex ultrasound after 5 years showed no significant difference comparing restenosis in both groups. These results are consistent with the study from Chung at al. using propensity score matching.[14] In literature the prevalence of restenosis > 70% over 47 months is 5.8% (6% for any type of CEA and 4% for patched CEA).[29] It is still under discussion which closure technique shows less recurrent carotid disease. Recurrent stenosis after surgery is reported in 3%-36% of cases.[30] Restenosis tends to develop in the first 6-12 months after CEA and is usually due to neointimal hyperplasia. Lesions developing after 24-36 months tend to represent recurrence of the atherosclerotic process.[31] Mannheim et al. found reduced restenosis rates after patching.[32] Similarly, Eikelboom et al. showed significantly higher restenosis after primary closure (21%) compared with patch closure (3.5%).[24] Two studies with a 5-year follow-up showed no statistical difference between the two techniques in men, but there was a higher risk of restenosis in women after primary closure.[33,34] A CREST secondary analysis demonstrated a significant reduction of 2-year restenosis rates with the use of patch angioplasty (P = .06).[20] However the follow-up period was only 2 years and there was no difference in clinical outcome regarding stroke rates. In contrast, Clagett et al. found that the incidence of recurrent carotid disease was unexpectedly higher in the group with patch closure (12.9%), than in patients with primary closure (1.7%). However, it should be taking into account that venous patch material was used in this study. It seems that patch procedures using autologous vein have shown to be inferior to bovine pericardium or polytetrafluoroethylene (PTFE). [35]

These results suggest that the cause of restenosis after CEA is rather defined by multiple factors than by closure technique only. Characteristics of calcified carotid plaque and the disease's natural course may have an impact on restenosis risk. It was shown that carotid plaque calcification may be inversely associated with recurrent stenosis 1 year after CEA, indicating a relationship between characteristics of calcified carotid plaque and recurrent stenosis after CEA, as well as the disease's natural course.[36] Therefore, another important factor seems to be best medical treatment (BMT). Prior evidence favoring a patch closure technique was based on studies at a time that BMT, including perioperative use of aspirin and statins, was not as prevalent as they are nowadays.[4] During the last decade there has been a dramatic improvement in BMT for patients with vascular disease. Literature suggests BMT, particularly statins, reduce the long-term morbidity and mortality associated with CEA.[16,17,37-39] In the Asymptomatic Carotid Surgery Trial, the use of lipid-lowering therapy reduced the risk of stroke after 10 years to 9.6% for patients on statins compared to 21.2% for patients not using statins.[1] In contrast to some studies[17], this study showed no association between renal insufficiency and restenosis. However, a significant association between postoperative use of antihypertensive medication and long-term stroke, restenosis and mortality were found. Postoperative hypertension has indeed been associated with intracerebral hemorrhage and stroke due to hyperperfusion syndrome.[40-42] This is also consistent with results published by Avgerinos et al. indicating that restenosis was predicted by hypertension (P=.027), female gender (P=.042) and age less than 65 years (P=.016) but not by statins or surgical technique.[28] Also, an RCT of Chinese hypertensive patients without history of stroke showed a reduced risk of first stroke in patients using enalapril and folic acid.[43] A meta-analysis of 25 RCT's in patients with no prior vascular disease reported significant reductions in late stroke.[44] BMT seems to detract the clinical significance of CEA technique in short-term and longer term outcomes. A recent systematic review and network meta-analysis suggests that

modern BMT and CEA with BMT in asymptomatic patients showed equivalent efficacy in reducing major stroke, combined stroke and mortality. [39]

In contrast, use of antiplatelet medication does not correlate with late stroke in this study. This is consistent with the results of Boysen et al. and Hause et al. reporting that starting antiplatelet therapy after CEA did not reduce late stroke.[42,45] However, an RCT by Lindblad et al. demonstrated that starting antiplatelet therapy prior to CEA reduces the risk of disabling stroke without increasing bleeding complications.[46] One study even shows significant better long-term survival when long-term aspirin therapy is given after CEA.[47] There is increasing evidence that dual antiplatelet therapy significantly reduces stroke due to early postoperative carotid thrombosis.[40]

Also, there was no significant long-term effect of use of statins in this study. In contrast, several studies have reported that statin therapy was associated with significant reductions in mortality and stroke rate.[37,40,48]

Current literature suggests some benefit performing carotid patch angioplasty to reduce the long-term risk of restenosis compared to primary closure [8,49]; however clinical significance is questionable as there is no higher incidence of ipsilateral stroke. [49] The tendency of restenosis to cause stroke appears to be highly variable in literature, ranging between 0.1% and 10%.[50] In this study we found no high-grade restenosis > 70% during the follow-up period. A meta-analysis showed significantly higher risk of 5% for late ipsilateral stroke in patients after CEA with untreated asymptomatic > 70% restenosis at 37 months[29]. However, most late ipsilateral strokes occurred in patients without evidence of significant restenosis.[29,49] In general, postoperative stroke during the 5-year follow-up was found to be rare in both groups and mortality seems mostly unrelated to the present carotid artery disease. This is similar to a study published by Avgerinos et al., showing a low rate of disease progression and associated clinical events.[17]

This study has a number of limitations. It was a single center study and the results may not be generalizable. The low number of complications may not be sensitive enough to find significant differences in complication rate among both groups. Finally, the effect of statin use and use of anti-hypertensive medication cannot be fully ascertained, since patients were assumed to be under these medications if they were prescribed to them, not taking in account the possibility of poor compliance.

Conclusion

Long-term results support the conclusion that primary closure appears to be an equivalent closure technique compared to patch angioplasty when used in selected patients with broad carotid artery (diameter > 5 mm), a high carotid bifurcation or occlusion of the contralateral carotid artery. Best medical treatment and especially the use of antihypertensive medication should be emphasized.

Additional research is needed to further investigate the validity of a selective patching strategy when performing a carotid endarterectomy as there are no randomized controlled trials available on this topic. An RCT comparing a selective patching strategy versus routine patch angioplasty could bring more clarity.

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