



Original Article

Comprehensive comparison of carotid endarterectomy primary closure and patch angioplasty: A single-institution experience

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ABSTRACT

Background: Carotid endarterectomy (CEA) is an effective intervention for the treatment of high-grade carotid stenosis. Technical preferences exist in the operative steps including the use patch for arteriotomy closure. The goals of this study are to compare the rate of postoperative complications and the rate of recurrent stenosis between patients undergoing primary versus patch closure during CEA.

Methods: Retrospective chart review was conducted for patients who underwent CEA at single institution. Vascular surgeons mainly performed patch closure technique while neurosurgeons used primary closure. Patients' baseline characteristics as well as intraprocedural data, periprocedural complications, and postprocedural follow-up outcomes were captured.

Results: Seven hundred and thirteen charts were included for review with mean age of 70.5 years (SD = 10.4) and males representing 64.2% of the cohort. About 49% of patients underwent primary closure while 364 (51%) patients underwent patch closure. Severe stenosis was more prevalent in patients receiving patch closure (94.5% vs. 89.4%; $P = 0.013$). The incidence of overall complications did not differ between the two procedures (odds ratio = 1.23, 95% confidence intervals = 0.82–1.85; $P = 0.353$) with the most common complications being neck hematoma, strokes, and TIA. Doppler ultrasound imaging at 6 months postoperative follow-up showed evidence of recurrent stenosis in 15.7% of the primary closure patients compared to 16% in patch closure cohort.

Conclusion: Both primary closure and patch closure techniques seem to have similar risk profiles and are equally robust techniques to utilize for CEA procedures.

Keywords: Atherosclerosis, Carotid endarterectomy carotid endarterectomy, Carotid stenosis, Patch, Stroke, TIA

INTRODUCTION

Since the first report of successful surgical repair of a stenotic carotid artery, carotid endarterectomy (CEA) has emerged as a pinnacle of standard of care for carotid atherosclerotic disease management.^[15] Landmark prospective, randomized clinical trials with large patient

cohorts have substantiated and advocated for performing CEA in patients with symptomatic and stenotic carotid vascular disease.^[7,16,27,31,33] Overtime, novel surgical approaches, techniques, and procedures have evolved. Two of the most common techniques to perform vascular closure following CEA are conventional primary closure and patch closure.

While primary closure avoids the risk associated with the patch and the double suture line, this procedure may lead to narrowing of the arterial lumen, resulting in an occlusion or restenosis.^[5,21] On the other hand, patch carries the risk of graft rejection and increased risk of thrombosis, and infection.^[6,11,13,29] The patch material can be obtained from a harvested vein or synthetic tissue (e.g., Dacron and polytetrafluoroethylene). A systematic review and meta-analysis of 13 randomized trials did not find a significant difference in complications rate between autologous vein and other synthetic materials.^[36]

Proponents of either closure technique argue for the efficacy and supremacy of each technique over the other for managing patients with high-risk vulnerable carotid plaque.^[1,3,20,32,37] Multiple studies report no differences in outcomes and complications following either closure technique.^[14,24] Further confounding the evidence is studies reporting that perioperative patient risk factors, medical history, and surgical specialty of the surgeon performing CEA are related to CEA outcomes and complications.^[17,18,23,34,39]

The aim of this study is to provide a comprehensive comparison of primary and patch closure on CEA outcomes in a large cohort of patients with carotid stenosis, focusing on postoperative complications, perioperative risk factors, and the impact of primary versus patch closure on vascular disease progression and restenosis at different follow-up intervals.

MATERIALS AND METHODS

Design and patient population

A retrospective analysis was performed for consecutive patients who had previously undergone CEA with primary or patch closure at Hamilton General Hospital, Hamilton, Canada. At this institution, neurosurgeons perform primary closure, while vascular surgeons perform patch closure. Therefore, the decision to perform primary or patch closure was dependent on the surgeon's specialty. This investigation was approved by the Institutional Research Ethics Review Board (Hamilton Integrated Research Ethics Board, Project 1521).

Study inclusion criteria included: (a) the presence of a significant carotid stenosis or symptomatic carotid vascular disease requiring CEA and (b) patient 18 years of age or older. Patients were excluded if they had an incomplete

medical record, such that the necessary data for inclusion in the analysis of this study were not available.

Data collection and definitions

Patient medical records were reviewed for demographic data, cardiovascular risk factors, cerebrovascular symptomatology, history of anticoagulation, and carotid vascular stenosis. Intraprocedural data, periprocedural complications, and postprocedural outcomes were evaluated.

CEA

Vascular surgeons and neurosurgeons performed CEA under general anesthesia using standard surgical approaches and guidelines.^[25] Dependent on preoperative findings and variables such as the patient's history, back pressure measures, and use of electroencephalography, carotid shunting was selectively performed by both specialties, but more frequently by vascular surgeons. At the surgeon's discretion, primary closure or patch angioplasty was performed using XenoSure Biologic Patch (LEMAITRE VASCULAR, INC.). The patch size is 1.5 cm × 10 cm but was trimmed to the length required for the arteriotomy.

Carotid stenosis

Carotid stenosis was defined as symptomatic, when associated with cerebrovascular symptoms, including ipsilateral hemiparesis, transient vision loss, speech deficit, amaurosis fugax, transient ischemic attack, or stroke. Patients were seen and assessed by the surgeon either in the emergency department or the clinic and deemed candidates for surgical intervention.

The patient's medical records were reviewed for the previous multimodality imaging and evaluation of internal carotid artery (ICA) stenosis. Imaging modalities included duplex ultrasound, CT angiography, magnetic resonance imaging, or angiography. ICA stenosis was defined as mild (below 50%), moderate (50–69%), and severe ($\geq 70\%$).

Follow-up

Follow-up Doppler ultrasound imaging for restenosis and evaluation of complications was performed at the following intervals: immediate (within 7-day post-CEA), early (within 1–4 weeks from CEA), and late (2–3 months following CEA) and compared with preoperative stenotic levels. Complications were assessed by operating team as well as stroke neurologist if neurological complications are suspected.

Statistical analysis

Statistical analysis was performed using IBM SPSS (Armonk, NY: IBM Corp.) statistical software. Quantitative data are

presented as mean \pm standard deviation or median with minimum and maximum and compared using independent samples t-test or Mann–Whitney U-test. Qualitative data are reported as counts and percentages and compared using Chi-squared or Fisher's exact test. To adjust for confounding factors, the relationship between complications and type of closure was further assessed with stepwise logistic regression analysis. Odds ratios (ORs) with 95% confidence interval (CI) are reported. For all analyses, $P \leq 0.05$ was predefined for statistical significance.

RESULTS

Study cohort

Between 2008 and 2018, 740 consecutive patients who had undergone CEA at Hamilton General Hospital were retrospectively evaluated for inclusion. Twenty-seven patients were excluded due to an incomplete medical record. Consequently, 713 patients met study inclusion criteria and formulated the study cohort. Males represented 64.2% ($n = 458$) of the study population with a mean age of 70.5 years (SD = 10.4). Of these 713 patients, 349 (49%) patients underwent primary closure while 364 (51%) patients underwent patch closure. Detailed patients' baseline characteristics are provided in [Table 1].

Cardiovascular risk factors did not differ between patients in the two interventions groups [Table 1]. Peripheral vascular disease was more prevalent in patients treated with patch closure (23.9% vs. 11.4% primary closure, $P < 0.001$). In terms of presenting symptomatology, patients with primary closure had greater prevalence of ipsilateral hemiparesis (35.5% vs. 25%, $P = 0.002$), transient vision loss (28% vs. 21.5%, $P = 0.059$), and speech deficit (28% vs. 19%, $P = 0.005$) than patients who underwent patch closure [Table 1]. Furthermore, the radiological degree of mild-to-moderate stenosis was more prevalent in patients undergoing primary closure (10.6% vs. 5.5% patch closure), while severe stenosis was more prevalent in patients receiving patch closure (94.5% vs. 89.4% primary closure), $P = 0.012$ [Table 1].

Perioperative factors and primary versus patch closure

In terms of perioperative procedural factors, the location of CEA differed between the primary and patch closure groups [Table 2]. The left-sided endarterectomy was slightly more common in patients with primary closure (55.3 vs. 49.5%), while the right endarterectomy was more common in patients with patch closure [50.5% vs. 44.7%, $P = 0.118$] and [Table 2]. Intraoperative shunting was performed in 20.9% of patients undergoing primary closure, compared to 85.4% of

Table 1: Baseline characteristics comparison between primary suture closure and patch closure.

Variable	Primary suturing closure (n=349)	Patch closure (n=364)	P-value
Gender			
Male	227 (65.0)	231 (63.5)	0.660
Female	122 (35.0)	133 (36.5)	
Age (mean \pm std. dev.)	70.50 \pm 10.439	70.37 \pm 8.897	0.861
Hypertension	279 (80.0)	306 (84.0)	0.152
Previous TIA/stroke	157 (45.0)	169 (46.5)	0.699
Prior smoking at any time	223 (64.0)	253 (69.5)	0.112
DM	81 (23.0)	95 (26.0)	0.371
Hyperlipidemia	197 (56.5)	219 (60.2)	0.314
CAD (MI, CHF, and atrial fibrillation)	111 (32.0)	135 (37.0)	0.138
Peripheral vascular disease	40 (11.5)	87 (23.9)	<0.001
Ipsilateral amaurosis	41 (11.5)	33 (9.0)	0.240
Severe/chronic renal failure	20 (5.5)	18 (5.0)	0.641
Hx of antiplatelet agent (ASA, Plavix, Ticlid, and Aggrenox)	269 (77.0)	282 (77.5)	0.900
Anticoagulation Agent (Warfarin, Xarelto, and Dabigatran)	29 (8.5)	36 (10.0)	0.464
Antiplatelet/anticoagulation not held before surgery	139/189 (73.5)	132/186 (71.0)	0.752
Symptoms – ipsilateral hemiparesis	124 (35.5)	91 (25.0)	0.002
Symptoms – transient visual loss	97 (28.0)	79 (21.5)	0.059
Symptoms – speech deficit	97 (28.0)	69 (19.0)	0.005
Radiologic degree of occlusion/stenosis			
Mild/moderate	37 (10.6)	20 (5.5)	0.012
Severe (>70)	312 (89.4)	344 (94.5)	
Diagnostic method – US	256/326 (78.5)	267/331 (80.5)	0.497
Diagnostic method CT angiography	195/326 (60.0)	186/331 (56.0)	0.347
Diagnostic method – magnetic resonance imaging	53 (16.5)	21 (6.5)	<0.001
Diagnostic method – angiogram	13 (4.0)	8 (2.5)	0.252

patients who received patch closure [$P < 0.001$] and [Table 2]. In 34.0% of patients with available data, no intraoperative heparin reversal with protamine was performed in primary closure group, compared to only 2.0% of patients with patch closure while complete intraoperative reversal was performed in 17.0% of patients with primary closure and 67.0% in patch closure cohort [$P < 0.001$] and [Table 2].

Complications and primary versus patch closure

Patients' medical records were reviewed for the incidence of complications reported as immediately (within 7-day post-CEA), early (within 1–4 weeks from CEA), and late (2–3 months following CEA). Overall, the incidence of complications did not differ between the two procedures [Table 3]. There were total of 50 (14.7%) complications reported following primary closure, compared to 62 (17.5%) following patch closure [OR 1.23, 95% CI, 0.82–1.85; $P = 0.353$] and [Table 3]. The potential risk factors for complications were related to patient's comorbidities rather than surgical approach and these included previous stroke (OR 2.24; 95% CI 1.40–3.60), diabetes (OR 1.80; 95% CI 1.11–2.93), and presence of ipsilateral hemiparesis (OR 1.62; 95% CI 1.02–2.57). The most common complications were neck hematoma (13 cases following primary closure and 14 cases following patch closure; OR 1.04, CI 0.48–2.24; $P = 0.923$); stroke (17 cases following primary closure and 20 cases following patch closure; OR 1.14, CI 0.58–2.22; $P = 0.697$); and TIA (eight cases following primary closure and nine cases following patch closure; OR 7.08, CI 0.41–2.84; $P = 0.872$). The occurrence of acute occlusion also did not differ between both procedures (nine cases following primary closure and 10 cases following patch closure; OR 1.07, CI 0.43–2.67; $P = 0.881$).

Relationship between postoperative follow-up and primary versus patch closure

The median postoperative length of hospital stay was 2 days (min. 0 days, max. 50 days) following primary closure and

1 day (min. 1 day, max. 186 days) following patch closure ($P = 0.073$) [Table 4]. The time to follow-up with Doppler ultrasound imaging was also compared between both procedures [Table 4]. Follow-up Doppler ultrasound reports were compared to determine whether there was evidence of carotid restenosis of any degree. In the primary closure cohort, carotid restenosis was reported in 12.3% of patients at 3 months and in 3.4% of patients at 6 months. However, in the patch closure cohort, 4.5% of patients had carotid stenosis at 3 months and 11.5% of patients had stenosis at 6 months. Therefore, the occurrence of carotid stenosis linearly differed between both procedures [$P < 0.001$] and [Table 4].

DISCUSSION

In a large single institution, Canadian experience where neurosurgeons strictly performed primary closure and vascular surgeons performed patch closure, we found there to be no relationship between the closure approach utilized and operative complications. Furthermore, despite variance in closure approach and intraoperative techniques such as shunting and reversal with protamine, there was little impact on evidence of carotid stenosis reported at long-term follow-up Doppler ultrasound imaging up to 6 months postoperatively.

Neither primary nor patch closure intervention was related to the occurrence of immediate, early, or late development of neck hematoma, intracranial hemorrhage, CN palsy, pseudoaneurysm formation, TIA, stroke, myocardial infarction, or acute restenosis. These findings parallel studies performed at other institutions where primary closure was compared to patch angioplasty and no significant differences were observed in complication rates, outcomes, and restenosis.^[22,25,38] However, these findings contrast with studies when compared to primary closure, patch closure was found to be related to a heightened risk of restenosis, increased operative time, provided little benefit, and was complicated by graft-specific complications.^[4,9,13,28,41] As discussed by Zenonos *et al.*, a factor not discussed in most CEA surgical comparative studies is neurocognitive decline

Table 2: Perioperative factors comparison between primary suture closure and patch closure.

Variable	Primary suturing closure (n=349)	Patch closure (n=364)	P-value
Location of carotid endarterectomy			
Right	156 (44.7)	184 (50.5)	0.118
Left	193 (55.3)	180 (49.5)	
Was shunting used intraoperative?	73 (20.9)	311 (85.4)	<0.001
Intraoperative reversal with protamine	(n=274)	(n=302)	
No	94 (34.0)	60 (20.0)	
Partial reversal with ½ dose	134 (49.0)	34 (11.0)	<0.001
Complete reversal	46 (17.0)	208 (67.0)	
Intraoperative complications	5 (1.5)	8 (2.2)	0.579
Use of antilipids	244/332 (73.5)	258/339 (76.0)	0.436

Table 3: Complication by the type of procedure.

Type of complication	Primary suturing closure (n=349)	Patch closure (n=364)	OR (95 CI)	P-value (two sided)
Any complication at any time	50 (14.7)	62 (17.5)	1.23 (0.82, 1.85)	0.353
Infection	0 (0)	4 (1.1)	NA	0.124
Immediate	0	0		
Early	0 (0)	4 (1.1)		
Late	0	0		
Neck hematoma	13 (3.8)	14 (4.0)	1.04 (0.48, 2.24)	0.923
Immediate	10 (2.9)	11 (3.1)		
Early	3 (0.9)	3 (0.8)		
Late				
Neck seroma	1 (0.3)	1 (0.3)	0.97 (0.060, 15.55)	1.000
Immediate	0	0		
Early	0 (0)	1 (0.3)		
Late	1 (0.3)	0 (0)		
Intracranial hemorrhage	1 (0.3)	0 (0)	NA	0.491
Immediate	0	0		
Early	1 (0.3)	0 (0)		
Late	0	0		
CN palsy	6 (1.8)	11 (3.1)	1.796 (0.65, 4.91)	0.248
Immediate	0 (0)	2 (0.6)		
Early	6 (1.8)	9 (2.5)		
Late	0	0		
Pseudoaneurysm formation	0 (0)	2 (0.6)	NA	0.499
Immediate	0 (0)	1 (0.3)		
Early	0 (0)	1 (0.3)		
Late	0	0		
TIA	8 (2.3)	9 (2.5)	1.08 (0.41, 2.84)	0.872
Immediate	3 (0.9)	5 (1.4)		
Early	2 (0.6)	3 (0.8)		
Late	3 (0.9)	1 (0.3)		
Stroke	17 (5.0)	20 (5.6)	1.14 (0.58, 2.22)	0.697
Immediate	11 (3.2)	11 (3.1)		
Early	5 (1.5)	4 (1.1)		
Late	1 (0.3)	5 (1.4)		
MI	7 (2.1)	8 (2.3)	1.10 (0.39, 3.07)	0.851
Immediate	5 (1.5)	2 (0.6)		
Early	0 (0)	5 (1.4)		
Late	2 (0.6)	1 (0.3)		
Acute occlusion	9 (2.6)	10 (2.8)	1.07 (0.43, 2.67)	0.881
Immediate	3 (0.9)	9 (2.5)		
Early	3 (0.9)	0(0)		
Late	3 (0.9)	1 (0.3)		

following CEA. This is an important factor since patch angioplasty requires greater clamping time and consequently could be associated with greater neurocognitive decline.^[41] Yet, other studies report that patch angioplasty lowers the occurrence of risk of restenosis and complications, when compared to primary closure.^[1,3,20,32,37] Important variables to consider while discerning an optimal closure technique to utilize include vascular anatomic risk factors^[13] and patch material composition.^[2,10,35]

Our findings show that the specialty of surgeons was related to perioperative procedural techniques utilized

such as the higher use of intraoperative shunting and complete reversal of heparin by vascular surgeons but not postoperative complications. Such procedural differences performed by surgeons heralding from different surgical specialties have been reported by Hannan *et al.* in their retrospective review of 3644 CEA procedures in New York hospitals, vascular surgeons utilized protamine reversal more than neurosurgeons, which are a finding that our work also supports.^[19] They further reported that patients who received CEA performed by vascular surgeons, who predominantly used the patch closure technique, had

Table 4: Relationship between postoperative follow-up and primary versus patch closure.

Variable	Primary suturing closure (n=349)	Patch closure (n=364)	P-value
Postoperative length of hospital stay – median (min., max.)	2.00 (0, 50)	1.00 (1, 186)	0.073
Time of f/u Doppler U/S	(n=207)	(n=202)	<0.001
• Immediate (<7 days postoperative)	18 (8.7)	13 (6.4)	
• 1–4 weeks postoperative	55 (26.6)	22 (11.0)	
• At 2–3 months postoperative	104 (50.2)	31 (15.3)	
• After 3 months	30 (14.5)	136 (67.3)	
Degree of carotid stenosis on postoperative f/u Doppler U/S	(n=203)	(n=199)	<0.001
• No	171 (84.2)	167 (84.0)	
• Yes at 3 months	25 (12.3)	9 (4.5)	
• Yes at 6 months	7 (3.4)	23 (11.5)	

lower odds of experiencing adverse outcomes. This finding differs from our dataset where no differences were found in complications experienced by patients who received primary or patch closure from neurosurgeons or vascular surgeons, respectively. A recent updated systematic review and meta-analysis by Huizing *et al.* that analyzed a total of 23 studies (14 nonrandomized and nine randomized) showed a significantly higher stroke rate in the primary closure group (OR 1.9; 95% CI, 1.2–2.9).^[24] However, no statistically significant difference was found when only randomized studies were pooled (OR 1.8; 95% CI, 0.8–3.9).

The analysis of long-term restenosis in nonrandomized and randomized studies combined showed a statistically significant higher rate of restenosis after primary compared with patch closure (OR, 2.2; 95% CI, 1.4–3.4). Moreover, finally, there was no statistically significant difference between both techniques in the incidence of postoperative bleeding (OR, 1.0; 95% CI, 0.66–1.6). Although these results point to a superiority of the patch technique, the evidence was of moderate quality. The lack of association between surgical specialty and postoperative complications reported in this paper is supported by findings reported by several other reports. Kempczinski *et al.* concluded that the surgical specialty and the annual case load did not lead to significant difference in the complications rate.^[26] Similarly, Brott *et al.* reported comparable rate of complications despite technical differences.^[12]

Despite the more common use of intraoperative shunting and complete heparin reversal performed by vascular surgeons, patients who received those interventions did not benefit from further reduced complications, and there were no statistical differences in the incidence of complications for each study arm. These findings are supported by those of Bennet *et al.*, where in a study cohort of 3153 patients, intraoperative shunting provided no clinical benefit.^[8] Furthermore, Woodworth *et al.* have reported that the use of electrophysiological monitoring and selective shunting reduces the risk of perioperative stroke by 7 times, when compared to patients who nonselectively routinely

undergo shunting during CEA procedures.^[40] With regard to intraoperative protamine reversal, one of the largest meta-analyses on the topic found that the net reduction in bleeding complications is low, and that the use of protamine is not associated with increased risk of stroke, myocardial infarction, and death; however, protamine lowers the incidence of reoperation due to bleeding during a CEA, and thereby significantly reduces the risk of morbidity.^[30] Therefore, the implementation of protamine reversal during CEA acts as a safety measure that does not increase the risk of complications, but rather mitigates bleeding complications.

Finally, our study findings show that there is greater evidence for carotid stenosis in patients who underwent patch closure (11.5%), when compared to primary closure (3.4%) at 6-month postoperatively as evident by Doppler ultrasound. However, more patients were imaged at later time points in the patch closure arm than the primary closure arm. In fact, 67.3% of patients with patch closure received follow-up Doppler vascular imaging at more than 3 months compared to only 14.5% of patients with primary closure. Therefore, a greater incidence of stenosis was noted for the patch closure arm during late follow-up. To unequivocally relate the impact of either primary or patch closure on vascular disease progression, a prospective study with consecutive, linear follow-up imaging would have to be conducted.

The present analysis suffers from inherent limitations of observational designs and the findings should be interpreted with caution. First, the retrospective design of the study makes it prone to inaccuracy and missing data and subsequent biased findings. Second, it is a single-center study with limited generalizability. On the other hand, it has certain strengths. It is a large-scale investigation where a comprehensive rigorous review was conducted of patient cardiovascular risk profiles; perioperative factors including variance in the operative methodology utilized; broad ranged postoperative complications overtime; and postoperative vascular imaging of vascular patency over different time points. The fact that neurosurgeons performed primary and vascular surgeons patch closure provides avoided learning

curve bias mimicking expertise-based design. This, however, may not apply to other centers where neurosurgeons perform both closure types. Other variables such as total clamp time and intraoperative blood loss are probably of importance and could be incorporated in the future studies.

CONCLUSION

In this single-center study, where neurosurgeons strictly performed primary closure and vascular surgeons only performed patch closure, we have shown that the closure technique utilized does not relate to complications, postoperative evidence of carotid stenosis, and patient risk profiles. Overall, our findings suggest that both primary closure and patch closure techniques have similar risk profiles and are equally robust techniques to utilize for CEA procedures. This study was based on a retrospective analysis and warrants the need for a large prospective study multicenter study to properly assess the association between surgical approaches and restenosis and future vascular disease progression.

Declaration of patient consent

The Institutional Review Board (IRB) permission obtained for the study.

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Conflicts of interest

There are no conflicts of interest.

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