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Original Article

A Simplified One-Size-Fits-All Approach to Carotid Stenting

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ABSTRACT: ***Background:*** Carotid artery stenosis causes up to 20% of ischemic strokes. Stenting is used as an alternative to endarterectomy in symptomatic patients. Each commercially available stent offers numerous stent diameters/lengths. Most centers thus carefully match each individual stenosis to a specific stent length/diameter stent size. However, this process can be time-consuming and costly while the relative benefit of a custom stent sizing versus one-size-fits-all approach has not been well evaluated yet. We hypothesized that a 'one-size-fits-all' default approach to carotid stenting results in comparable results to a customized approach. ***Methods:*** We conducted a descriptive retrospective cohort study on 154 patients who presented to our academic carotid revascularization clinic with symptomatic carotid artery stenosis who underwent carotid artery stenting for peri- and postprocedural carotid artery stenting complications. The primary outcomes were periprocedural (within 24 hours of the procedure) or postprocedural (within 30 days of the procedure) TIA, stroke, or death. The secondary outcome was the estimated degree of stenosis on follow-up ultrasound performed within 6 months of the procedure. ***Results:*** The complication rate within the first 24 hours was 4.5% while that during the first 30 days postprocedure was 6.5%. Age over 80 and degree of stenosis on postprocedural cerebral angiogram were associated with an increased risk of complications. Severe restenosis was reported in 16.8% of patients within 6 months postprocedure. ***Conclusion:*** Our study suggests that using a simplified, one-size-fits-all, approach to carotid stenting results in safe and effective outcomes, suggesting an alternative to simplify a complex medical procedure.

RÉSUMÉ : Une approche unique en matière d'utilisation d'endoprothèses carotidiennes : une stratégie simplifiée non-inférieure. ***Contexte :*** La sténose de l'artère carotide est à l'origine d'environ 20 % des AVC ischémiques. À cet égard, la pose d'une endoprothèse (*stenting*) est utilisée comme alternative à l'endartériectomie chez des patients symptomatiques. Chaque endoprothèse (*stent*) disponible sur le marché offre de nombreux diamètres et longueurs. La plupart des établissements de santé essaient donc soigneusement d'adapter chaque sténose individuelle à une longueur ou à un diamètre d'endoprothèse spécifique. Cela dit, ce processus peut être long et coûteux ; de plus, les avantages relatifs d'une dimension personnalisée d'endoprothèse par rapport à une approche unique n'ont pas encore été bien évalués. Nous avons donc émis l'hypothèse qu'une approche par défaut privilégiant une « dimension unique » donne des résultats comparables à ceux d'une approche dite « personnalisée ». ***Méthodes :*** Nous avons mené une étude de cohorte rétrospective descriptive portant sur 154 patients qui se sont présentés à notre clinique universitaire de revascularisation carotidienne avec une sténose symptomatique de l'artère carotide et qui ont bénéficié ensuite de la pose d'une endoprothèse pour des complications péri-procédurales et post-procédurales en lien avec leur sténose. Qu'il s'agisse d'un angle péri-procédural (dans les 24 heures consécutives à l'intervention) ou post-procédural (dans les 30 jours consécutifs à l'intervention), nos principaux résultats ont concerné des cas d'accident ischémique transitoire (AIT) ou d'AVC ainsi que des décès. Un résultat secondaire a aussi porté sur l'estimation du degré de sténose lors d'une échographie de suivi effectuée dans les 6 mois suivant l'intervention. ***Résultats :*** Le taux de complications dans les 24 premières heures était de 4,5 % alors qu'il était de 6,5 % dans les 30 jours suivant l'intervention. Le fait d'avoir plus de 80 ans et le degré de sténose détecté lors d'une angiographie cérébrale post-procédurale ont été associés à un risque accru de complications. Une resténose sévère a par ailleurs été signalée chez 16,8 % des patients dans les 6 mois consécutifs à l'intervention. ***Conclusion :*** Notre étude suggère en somme que l'utilisation d'une approche simplifiée et unique en matière de pose d'endoprothèse carotidienne permet d'obtenir des résultats sécuritaires et efficaces, ce qui laisse entrevoir une alternative permettant de simplifier une procédure médicale complexe.

Keywords: Carotid artery disease; Stroke prevention; Stroke; Interventional neuroradiology

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Introduction

Stroke is the second leading cause of death globally.[1] Up to 20% of ischemic strokes are caused by carotid artery stenosis.[2] Carotid artery stenting (CAS) is a widely used therapeutic alternative to carotid endarterectomy (CEA) in patients with symptomatic carotid artery stenosis.[3,4] Each commercially available stent offers numerous stent lengths/diameters, some even with more complex, varied tapered diameters. Thus, most centers meticulously match each individual stenosis to a specific length/diameter stent size. However, this process is time-consuming and necessitates maintenance of a large stock supply of numerous stent sizes in each neurovascular lab. Maintaining large stocks of these costly items can limit worldwide dissemination of the procedure in resource-constrained health systems. Further, selecting stent sizes can be a time-consuming effort without established relative benefit.

Previous studies have shown a significant direct relationship between length of stenosis and rate of complications within 30 days.[5] Therefore, most centers use customized stent lengths for each patient depending on the length of stenosis. However, to our knowledge, no studies have investigated the effect of stent length. Several studies, using the conventional, customized stent-sizing approach have established normative complication rates in the literature. Most notably, in the CREST trial, a customized approach was used and the periprocedural complication rate was 6.0% within 30 days.[6] Another clinical trial reported a complication rate of 6.5%.[7]

At our large academic tertiary referral site, we use a single size stent for all patients, deviating only when supply chain issues preclude reliable sourcing. Thus, we hypothesize that a simplified 'one-size-fits-all' approach to carotid stenting is comparable to the more complicated, expensive, existing customized practice. As such, we evaluated the efficacy and safety of using a standardized stent length (40 mm) and diameter (8 mm) by reviewing our institutional incidence of periprocedural (within 24 hours) and postprocedural complications defined as TIA, stroke, or death (within 30 days) and comparing our results to standardized outcome metrics utilizing a traditional approach of custom stent lengths and diameters. We also incorporated imaging outcomes for the estimation of restenosis incidence on follow-up ultrasound within 6 months of the procedure.

Methodology

We performed a descriptive, retrospective, cohort study on a total of 154 patients who underwent CAS at London Health Sciences Center (LHSC) in the period from January 2017 to December 2020. The patients were referred for CAS after initial outpatient evaluation in an urgent multidisciplinary, surgical, and endovascular carotid clinic. Decisions as to treatment type (medical vs surgical; stenting vs endarterectomy) were made as per literature-based guidelines and consensus opinion.[8,9] All patients presented with symptomatic (history of ipsilateral stroke, TIA, or retinal TIA) carotid artery stenosis. Degree of carotid stenosis was assessed using computed tomography angiogram (CTA) or ultrasound (US). The Anglo-American criteria were used to define degree of stenosis, namely with $\geq$ 70% stenosis defined as a peak systolic velocity (PSV) > 230 cm/s or a ratio of PSV from the internal to common carotid arteries of > 4.0 or end-diastolic velocity of > 100 cm/s. Similarly, a $\geq$ 50% stenosis was defined by a PSV of > 125 cm/s, or PSV velocity ratio of > 2.0, or EDV > 40cm/s.[10] The study was approved by the local institutional research ethics board. Clinical and angiographic data were collected according to the Canadian Tri-Council policy statement on ethical conduct for research involving the secondary use of data originally collected for health care purposes.

Patients were included if they underwent CAS for symptomatic carotid artery stenosis at LHSC between January 2017 and December 2020. Patients who underwent acute, emergent, CAS during mechanical thrombectomy were excluded. All procedures were performed by one of the fellowship-trained neuro-endovascular staff physicians, with the group comprised of three staff neuro-radiologists and two staff neurosurgeons. Prior to treatment, all patients were placed on a standard dual-antiplatelet regimen of 81 mg aspirin and 75 mg clopidogrel for at least 5 days prior to the procedure. Patients already on anticoagulation therapy were given single antiplatelet therapy only.

In our center, the Cordis Precise Pro 8 x 40 mm open-cell design stent (Cordis, Miami Lakes, FL, USA) was used for all patients. This specific stent was used as it provides the largest diameter stent that is deliverable through an 070 6F guide catheter. Picking a smaller diameter stent would pose the risk of being too small in a distended common carotid artery. Additionally, larger diameter stents (9 mm and above) are not always available across other stent brands and all require a larger delivery platform of an 088 sheath or at least a 7F guide catheter. Finally, the 40-mm length stent was chosen because it is the longest stent available in most product lines.

Data collected included patient age, sex, presenting diagnosis (TIA, retinal TIA, or ischemic stroke), cerebrovascular risk factors including hypertension, diabetes mellitus, dyslipidemia, smoking status, coronary artery disease (CAD), peripheral vascular disease (PVD), atrial fibrillation, previous endarterectomy and timing of initial event to stenting procedure. Imaging variables included the degree of stenosis on CTA or ultrasound, digital subtraction angiogram before and after the procedure where we defined mild, moderate, or severe stenosis as < 50%, 50%–70% and > 70%, respectively, according to North American Symptomatic Carotid Endarterectomy Trial (NASCET) angiographic criteria, presence of ulceration, need for angioplasty, use of cerebral protective device (CPD), date and degree of stenosis on follow-up ultrasound. Type and timing of complications (TIA, stroke, or death) were recorded.

The primary outcome was defined as periprocedural (within 24 hours of the procedure) and postprocedural (within 30 days of the procedure) complications of TIA, stroke, or death. The secondary outcome was the degree of restenosis on follow-up ultrasound which was done within 6 months after the procedure.

Continuous variables were described using median and interquartile range (IQR). Categorical variables were described by count and percentage. We investigated the relationship between the primary outcome and the categorical variables of sex, ulceration, calcification, use of cerebral protective device, time between event to stenting and vascular risk factors using Chi-square test (χ^2 test). Univariate binary logistic regression was used to identify potential predictor variables associated with the primary outcome such as age, degree of stenosis before and after the procedure, presenting diagnosis, and use of protective devices. Significant associations were then tested together by multivariable binary logistic regression to assess predictors of complication rate, adjusting for potential covariates. Statistical significance was set at a two-sided P-value less than 0.05. Our data were analyzed using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

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Results

The study population consisted of 154 symptomatic CAS patients. The mean age was 70 ± 8 years old (mean, IQR). Male to female ratio was 2.75:1. The median time between index event and CAS was 22 days (IQ 11, 43.25), with 37% of patients having the procedure within the first 14 days after the event. The most common vascular risk factor was hypertension 75.3%, followed by history of smoking (active smoker 28.6% and ex-smoker 37.7%), 66.3%, dyslipidemia 59.1%, CAD 31.8%, and diabetes mellites 21.4%. Table 1 lists the baseline patient characteristics for the study sample.

Acute ischemic stroke was the most common presenting diagnosis (69.5%), followed by TIA (21.4%), and retinal TIA (7.8%). Stenosis was classified as mild (0%–49%), moderate (50%–69%), severe (70%–99%), or complete occlusion according to NASCET on initial DSA. Degree of stenosis assessed by conventional digital subtraction cerebral angiogram was severe in 107 (69.5%) patients, moderate in 38 (24.7%), and mild in 9 (5.8%) patients. Notably, all mild cases were associated with ulcerated plaque.

51 (33.1%) of patients underwent pre-stenting balloon angioplasty and 7 (4.5%) underwent post-stenting balloon angioplasty using a monorail sterling balloon angioplasty (Sterling™, Boston Scientific, Natick, MA). A cerebral embolic protection device, the FilterWire EZ Embolic Protection System (Boston Scientific) was used in 50 (32.5%) patients. Table 2 lists the imaging patient characteristics.

Follow-up carotid ultrasound was performed in 110 (71.4%) patients within 6 months to estimate degree of stenosis. Average time from procedure was 129 (SD 173) days. Severe stenosis was defined as an estimated stenosis of greater than 70% by sonographic criteria.

The complication rate within the first 24 hours was 4.5% (7 patients). The overall 30-day stroke rate was 5.8% (9 patients) while death was reported in only one patient. No patients had a TIA during the first 30 days after the procedure. Therefore, the overall complication rate within the first 30 days was 6.5% (10 patients). Rate of complications were not statistically significant different between type of presenting diagnosis (Stroke, TIA, or retinal TIA).

Patients who were 80 years or older had significantly higher complication rate (OR 16.56, 95% CI 1.899–144.44, P-value 0.011). Furthermore, 30-day complication rate was significantly higher in patients who presented with moderate degree of stenosis on postprocedural cerebral angiogram (OR 11.0, 95% CI 2.78–43.4, P-value 0.001). In the adjusted regression analysis, age 80 or older (OR 11.1, 95% CI 1.2–103.6, P-value: 0.033) and degree of stenosis on postprocedural angiogram (OR 7.5, 95% CI 1.7–32.7, P-value 0.007) were also significantly associated with higher rates of complication.

The following were not significantly associated with an increased rate of complication: sex, ulcerated plaque at presentation, degree of stenosis before the procedure, use of angioplasty before or after stenting, degree of stenosis on second day postprocedure ultrasound or on 6 months follow-up ultrasound or vascular risk factors. Also, we did not find a significant difference between those who had the procedure within the first 14 days after initial event versus greater than 14 days post event (OR 0.872, 95% CI 0.235–3.24, P-value 0.838).

Rate of severe restenosis (>70% or occlusion) on the 6 months follow-up ultrasound postprocedure was reported in (16.8%) 18 patients.

Discussion

To the best of our knowledge, our study is the first to investigate the rate of a peri- and postprocedural complications post carotid stent insertion using a standard stent length/diameter approach. Previous trials showed higher 30-day complication rates among patients with longer stent lengths as compared to shorter stent lengths.[7] However, in that trial patients with longer stents also had longer stenoses which could be a confounder. We conducted this review to measure the complication rate in patients who had a uniform 8 x 40 mm stent for different stenosis lengths and/or diameter.

Our complication rate in the first day postprocedure was 4.5% which is comparable to the 5% rate reported in the literature.[7] Our rate of complications within 30 days postprocedure, was 6.5%, which is also comparable to the rate of complications in patients who had stent insertion for symptomatic carotid artery stenosis in several other trials (6%–6.5%).[6,7,11]

More than one-third of our study sample (37%) underwent stenting within 2 weeks post event. This is comparable to previous studies where 20%–43% of patients were stented within 2 weeks of their event.[12–14] Our data showed no significant difference in the complications rate within 30 days after the procedure between patients who had the procedure within or after 14 days post event which is consistent with the results from a previous trial.[14] Most data that suggest optimal timing for carotid revascularization within 14 days were derived from studies of CEA and not carotid stenting.

Patients equal to, or greater than, 80 years of age were more likely to have complications poststenting, which is similar to results from previous studies.[5,15] The CREST trial investigated several potential variables that could mediate a higher complication rate among this age group. Increased plaque length was responsible only for 8% of the estimated age-effect excess risk. Other risk factors, including eccentric plaque, ulcerated plaque, degree of stenosis, PSV, and location of stenosis were not statistically significant.[15] The degree of stenosis, measured using cerebral angiogram, post stent insertion was a significant risk factor for postprocedure early complication rate (29.4% in moderate stenosis vs 3.6% in mild stenosis, P-value 0.001).

Previous studies have evaluated various patient and procedural variables for association with complications in these procedures.[16] One of these procedural variables is the use of a CPD which theoretically may reduce the risk of distal embolization during CAS. In our study, it was not significantly associated with peri or postprocedural complications. Previous studies have shown conflicting results with the use of CPD during CAS. In a study done by Kastrup et al, there was no difference in complications rate in patients where CPD's were, and not, deployed. However, in a large systematic review[17], the use of CPD was found to reduce thromboembolic complications during CAS.

The degree of stenosis on CTA or cerebral angiogram before the procedure was not significantly associated with the risk of complications, a result that is similar to a previous study that included symptomatic and asymptomatic CAS patients.[5] However, our study included only patients with symptomatic stenoses. On the other hand, the degree of stenosis after the procedure was significantly related to the rate of complications which can be explained by more severe flow disturbances serving as a possible source of subsequent emboli. In this particular study, the post-stenosis may be elevated due to an institutional emphasis on simple

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Table 1: Baseline patient characteristics according to event rate within 30 days

	Total n (%)	Event n (%)	No event n (%)	P- value	Odds ratio	CI
	154	10	144			
Age						
< 70	70 (45.5%)	1 (1.4%)	69 (98.6%)	Ref.		
70–79	53 (34.4%)	3 (5.7%)	50 (94.3%)	0.224	4.14	0.418–40.975
> = 80	31 (20.1%)	6 (19.4%)	25 (80.6%)	0.011	16.56	1.899–144.441
Sex						
Male	113 (73.4%)	9 (8%)	104 (92%)	Ref.		
Female	41 (26.6%)	1 (2.4%)	40 (97.6%)	0.246	0.289	0.035–2.354
Presenting diagnosis						
Stroke	107 (69.5%)	7 (6.5%)	100 (93.5%)	Ref.		
TIA	33 (21.4%)	3 (9.1%)	30 (90.9%)	0.621	1.429	0.348–5.867
Retinal Transient Ischemic attack	12 (7.8%)	0	12 (100%)	0.999	–	–
Time from event to stenting						
≤ 14 days	54	4 (7.4%)	50 (92.6%)	Ref.		
> 14 days	92	6 (6.6%)	86 (93.4%)	0.838	0.872	0.235–3.24
Missed data	8	0	8 (100%)			
HTN						
Yes	116 (75.3%)	5 (4.3%)	111 (95.7%)	Ref.		
No	38 (24.7%)	5 (13.2%)	33 (86.8%)	0.067	0.297	0.081–1.090
DM						
Yes	33 (21.4%)	4 (12.1%)	29 (87.9%)	Ref.		
No	121 (78.6%)	6 (5%)	115 (95%)	0.152	2.644	0.700–9.987
Dyslipidemia						
Yes	91 (59.1%)	5 (5.5%)	86 (94.5%)	Ref.		
No	63 (40.9%)	5 (7.9%)	58 (92.1%)	0.548	0.674	0.187–2.434
Smoking status						
Never smoked	52 (33.8%)	5 (9.6%)	47 (90.4%)	Ref.		
Smoker	44 (28.6%)	1 (2.3%)	43 (97.7%)	0.173	0.219	0.025–1.946
Ex-smoker	58 (37.7%)	4 (6.9%)	54 (93.1%)	0.605	0.696	0.177–2.745
PVD						
Yes	14 (9.1%)	2 (14.3%)	12 (85.7%)	Ref.		
No	140 (90.9%)	8 (5.7%)	132 (94.3%)	0.232	2.750	0.524–14.439
CAD						
Yes	49 (31.8%)	6 (12.2%)	43 (87.8%)	Ref.		
No	105 (68.2%)	4 (3.8%)	101 (96.2%)	0.060	3.523	0.946–13.117
Atrial fibrillation						
Yes	16 (10.4%)	2 (12.5%)	14 (87.5%)	Ref.		
No	138 (89.6%)	8 (5.8%)	130 (94.2%)	0.316	2.321	0.448–12.023
Previous Endarterectomy						
Yes	4 (2.6%)	0	4 (100%)	Ref.		
No	150 (97.4%)	10 (6.7%)	140 (93.3%)	–	–	–

CAD = coronary artery disease; CI = confidence interval; DM = diabetes Mellitus; HTN = hypertension; PVD = peripheral vascular disease; Ref = reference.

stenting alone if possible, with avoidance of aggressive post-stent angioplasty out of perceived elevated risk for procedural embolic complications. Still, the relative benefit or risk of this practice requires further prospective investigation.

The rate of severe restenosis or occlusion on follow-up ultrasound was 16.8% which is greater than 5.8% which was found in the SPACE trial.[18] This difference might, in part, be due to differences in measuring the grade of stenosis on ultrasound. In

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Table 2: Patient imaging characteristics according to event rate within 30 days

	Total n (%)	Event n (%)	No Event n (%)	P-value	Odds ratio	CI
	154	10	144			
Pre-stenting degree of stenosis						
Mild	9 (5.8%)	1 (11.1%)	8 (88.9%)	Ref.		
Moderate	38 (24.7%)	0	38 (100%)	0.998	–	–
Severe	107 (69.5%)	9 (8.4%)	98 (91.6%)	0.782	0.735	0.082–6.552
Ulceration						
Yes	52 (33.8%)	3 (5.8%)	49 (94.2%)	Ref.		
No	102 (66.2%)	7 (6.9%)	95 (93.1%)	0.795	0.831	0.206–3.355
Pre-stent Angioplasty						
Yes	51 (33.1%)	3 (5.9%)	48 (94.1%)	Ref.		
No	103 (66.9%)	7 (6.8%)	96 (93.2%)	0.829	0.857	0.212–3.463
Post-stent Angioplasty						
Yes	7 (4.5%)	1 (14.3%)	6 (85.7%)	Ref.		
No	147 (95.5%)	9 (6.1%)	138 (93.9%)	0.408	2.556	0.277–23.572
Post-stenting degree of stenosis						
Mild	135 (88.8%)	5 (3.6%)	130 (96.3%)	Ref.		
Moderate	17 (11.2%)	5 (29.4%)	12 (70.6%)	0.001	11.000	2.786–43.430
Use of CPD						
Yes	50 (32.5%)	4 (8%)	46 (92%)	Ref.		
No	104 (67.5%)	6 (5.8%)	98 (94.2%)	0.600	1.420	0.382–5.278

CPD = cerebral protection device; CI = confidence interval; Ref = reference.

the SPACE trial, they used grading criteria that were evaluated and established in their own ultrasound lab on the basis of hemodynamic parameters, whereas we used the Anglo-American ultrasound criteria in grading.

This study is challenged by several limitations. Namely, the retrospective nature results in difficulty of capturing clinical events and the risk of selection bias. The high rate of incomplete follow up by ultrasound (29%) can also be a potential limitation, though it is also reflective of real-world practice. Further, our study utilizes established complication rates in the existing literature as a comparator cohort. Future, prospective, controlled studies are needed to better clarify this issue. Additionally, although the procedures in this cohort were carried out by several practitioners of differing backgrounds (neuroradiology and neurosurgery), the single-center nature of the study limits the generalizability of our results.

This study suggests that using a simplified, one-size-fits-all approach to carotid stenting may provide comparable results to the more complicated, widespread, customized stent-sizing approach.

Disclosures. Authors declare that they have no financial/personal interest or belief that could affect the results of this study.

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Data analysis and interpretation: AL.
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Critical revision of the article: JM, SP, RK.

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