Measurement and impact of proximal and distal tortuosity in carotid stenting procedures

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Background: **Proximal and distal carotid tortuosity is considered of paramount importance in carotid artery stenting (CAS) procedures. Specifically, distal internal carotid coiling or kinking is thought to interfere with proper distal protection devices, thus contraindicating CAS. The type of the aortic arch is also considered a key factor in CAS success; however, no standardized method of evaluation of these indicators is available in the literature. We have evaluated the impact of arch angulation and proximal and distal tortuosity in a series of CAS procedures.**

Methods: **In patients undergoing CAS, arch angulation and tortuosity of both common and distal internal carotid arteries were evaluated prospectively by calculating the sum of all angles diverging from the ideal straight axis, considering a 90° ideal angle for the origin from the arch (tortuosity index, TI). All procedures were through a transfemoral approach and with distal protection. Results were correlated with technical procedural success (residual stenosis <30%) and neurologic complication by Student *t* test. Multivariate logistic regression analysis was conducted to identify independent predictors of results.**

Results: **In a group of 298 CAS procedures, the mean proximal TI was 111.9° ± 96.77° and the mean distal TI was 123.4° ± 117.47°. Technical success was obtained in 272 patients (91.2%). Causes for the 26 technical failures were incapacity to obtain stable proximal access in 25 (96.1%), and uncrossable stenosis in one (3.9%). Neurologic protection was achieved with distal filters in all cases. Neurologic complications occurred in 23 patients (7.7%), consisting of 16 transient ischemic attacks and seven minor strokes. The proximal TI was significantly greater in the 26 cases of technical failure (158.4° ± 102.2° vs 107.6° ± 95.3°, *P* = .01). The distal TI was not different in the two groups (89° ± 99.1° vs 126.5° ± 118.6°, *P* = .11). Similarly, the proximal TI was significantly greater in neurologic complications (162.8° ± 111.8° vs 107.6° ± 18.2°, *P* = .03); the distal TI was not different in the two groups (112.6° ± 110.1° vs 124.3° ± 96.1°, *P* = .5) By logistic regression analysis, a proximal TI >150 was an independent predictor of both neurologic complications and technical failure. Age was also independently associated with technical failure. Appropriate distal filter placement was possible in all cases with a crossable stenosis, irrespective of the internal carotid TI.**

Conclusions: **The proximal TI is significantly associated with both technical success and neurologic complications after CAS, whereas the distal TI did not influence either outcome. The presence of distal kinking or coiling should not be considered a contraindication to CAS. (J Vasc Surg 2007;46:1119-24.)**

The role of carotid artery stenting (CAS) in the treatment of both symptomatic and asymptomatic patients with carotid stenosis is yet to be defined with certainty in respect to standard carotid endarterectomy, particularly in the low-surgical-risk patient.[1,2] Thus, identification of characteristics that can improve patient selection could be important in the decision making process. Several clinical and anatomic aspects have been examined in the literature: Other than surgical risk, plaque morphology,[3-5] age,[3-5] type of aortic arch,[6] physician experience, and technical details[7] were correlated with success rate to define possible predictor of success.

Tortuosity has been identified as a possible cause of technical failure to appropriately deliver the distal protection device, the stent itself, or both. Specifically, distal internal carotid artery (ICA) coiling or kinking is thought to possibly interfere with proper deployment of distal protection devices, thus contraindicating CAS.[3-5] The type of aortic arch is also considered a key factor in CAS success.[6,7] Despite these data, to our knowledge, no standardized method for quantifying tortuosity is available in the CAS literature. We have therefore adopted angulation measurement methods used in other anatomic areas to evaluate the impact of proximal and distal tortuosity during CAS.

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METHODS

A series of patients underwent CAS consecutively according to current guidelines for carotid stenting,[8] that is, when an asymptomatic ICA stenosis >80% or a symptomatic stenosis >50% was found by duplex imaging, using European Carotid Surgery Trial (ECST) duplex criteria[9] as described in previous work.[6] Once a patient was evaluated and considered fit for CAS, none was excluded by the study. The complete inclusion and exclusion criteria that were used are summarized in Table I.

In these patients, arch angulation and tortuosity of both common and distal ICAs were evaluated together with a number of other clinical and technical variables summarized in Table II. Plaque was defined as "complicated" if grossly ulcerated at angiography or not homogenous at duplex scanning.

Table I. Inclusion and exclusion criteria

Inclusion criteria
Symptomatic ICA lesion >50% regardless of plaque morphology
Asymptomatic ICA lesion >80% regardless of plaque morphology
Moderate or high surgical risk
Clinically significant cardiac disease (congestive heart failure, abnormal stress test, or need for open heart surgery)
Severe pulmonary disease
Contralateral laryngeal-nerve palsy
Previous radical neck surgery or radiation therapy to the neck
Creatinine <2.0 mg/dL
One patent ileofemoral artery
Exclusion criteria
Recent disabling stroke with large (>1 cm) cerebral lesion
Recent cerebral hemorrhage
Presence of intraluminal thrombus
Total occlusion of target vessel
Aortic or bilateral iliac occlusion or previous bilateral femoral arteries surgery
History of significative bleeding disorder or coagulative disorder
Life expectancy <1 year
Degenerative cerebral disease with reduced collaborative capacity
Severe pulmonary with inability to maintain the supine position

Table II. Preoperative and intraoperative variables considered in logistic regression analysis

Sex
Male
Female
Age
≤65
66-75
76-85
>85
Aortic arch
Normal, type I, type II,
Type III, Abnormal
Tortuosity index
Proximal
>150°
<150°
Distal
>150°
<150°
Type of plaque
Complicated
Not complicated
Contralateral stenosis >80%
Yes
No
Contralateral occlusion
Yes
No
Stenosis
≤70%
75%
80%
>80%
Preoperative symptoms
Yes
No
Preoperative CT or NMR scan
Negative
Positive
Intraprocedural protection system
Concentric filter
Eccentric filter
Stent type
Nitinol
Chromium-cobalt

CT, computed tomography; *NMR,* nuclear magnetic resonance.

The tortuosity index (TI) was defined as the sum of all angles diverging from the ideal straight axis; the ideal origin of the innominate or the left common carotid artery from the arch was considered as a 90° angle from the axis of the carotid and the tangent of the arch, irrespective of the arch type. Two observers calculated TI blindly. If the difference in the result obtained was >10, a third observer recalculated TI; at this point, the mean of the three measurements was taken as TI. A single projection image was used to measure all angles; however, if an angulation in a different plane was suspected or a vessel overlap was present, then the calculation was made also considering the course of the guidewire during the procedure. The proximal TI was defined as TI measured from the arch to the ICA stenosis (Fig 1 and 2), and the distal TI as the TI distal to it up to the target point of protection filter deployment (Fig 2 and 3). Mean time of calculation for each case was 3 minutes 30 seconds (range, 30 seconds to 5 minutes).

Description of carotid artery stenting procedure. No preprocedural study of the supra-aortic vessels origin was performed, and all patients judged to be fit for CAS were taken to the angiographic suite after appropriate informed consent and cardiologic evaluation. The latter was performed for precise operative risk stratification. A computed tomography (CT) or magnetic resonance imaging (MRI) cerebral study was performed in all cases. All patients were medicated with aspirin (100 mg) and clopidogrel (75 mg) for 3 days before the procedure.

All procedures were performed under local anesthesia and systemic heparinization. An 8F groin introducer was used. Common carotid cannulation was achieved with 40° Boston Scientific (Natick, Mass) or Medtronic (Minneapolis, Minn) HS I and II catheters over a Terumo stiff guidewire (Terumo Medical Corporation, Tokyo, Japan). When cannulation was not achievable by these means, several different alternate techniques were used (ie, buddy wire, coaxial). Because of the possibility of straightforward surgical intervention, brachial or carotid access was not attempted in any case. Routine cerebral protection was by Filterwire EZ (Boston Scientific), Angioguard RX (Cordis, Miami Lakes, Fla), or Accunet RX (Guidant, Indianapolis, Ind), and stenting was by Wallstent (Boston Scientific), Precise (Cordis), or Acculink (Guidant).

Technical success was defined as successful treatment of the stenosis with residual stenosis of <30%. Neurologic outcome was evaluated both at the end of the procedure and at 24 hours. All patients who were potentially candidates for CAS and who underwent angiography were con-

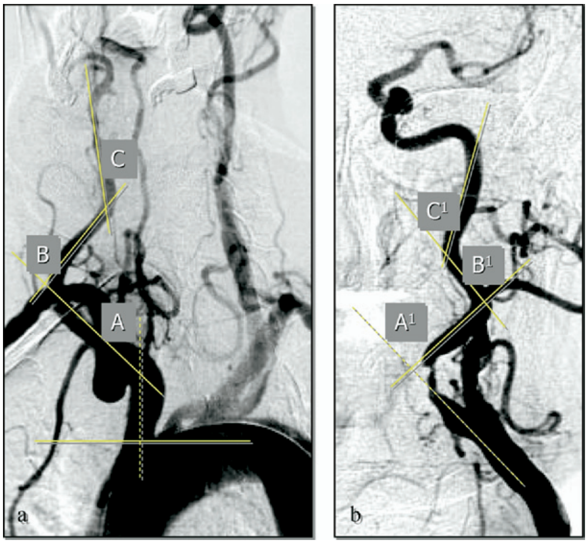

Fig 1. Method of tortuosity index (TI) measurement: **(a)** A + B + C = proximal TI; **(b)** $A^1 + B^1 + C^1$ = distal TI.

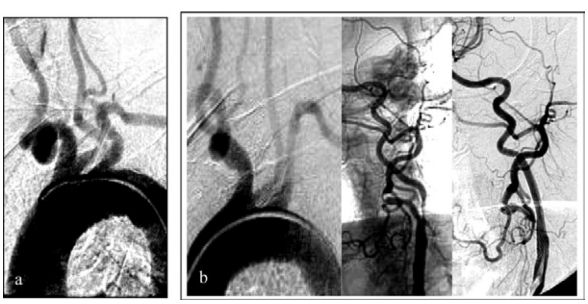

Fig 2. Influence of proximal tortuosity index (TI) in technical failure: **(a)** Technical failure in a bovine arch and severe proximal tortuosity (TI >150°); **(b)** carotid artery stenting is successful in a similar situation (bovine arch) but with TI <150°.

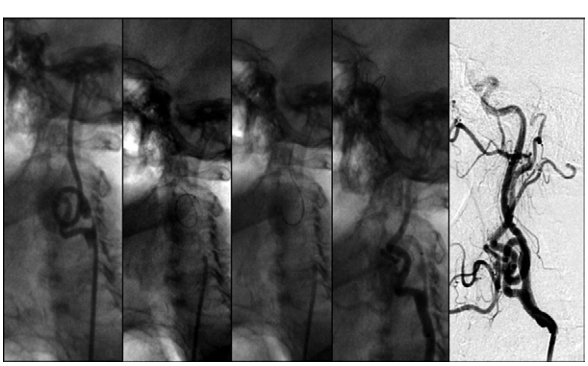

Fig 3. Technical success with coiling in a patient with distal internal carotid artery >150° (coiling).

sidered in the analysis, regardless of arch anatomy, plaque morphology, and presence of proximal and distal carotid tortuosity or disease. Therefore, our results reflect an estimate of the feasibility of CAS in the population of patients with carotid disease and moderate or high surgical risk. Neurologic, general, and technical (duplex imaging) outcome was evaluated at discharge and at 30 days, 6 months, and yearly thereafter.

Table III. Timing of onset of neurologic complications

Timing	*Patients, No.*
Intraprocedural	6
Postprocedural	9
From 10 min to 4 h	
From 4 to 24 h	8
Total	23

Data analysis. Univariate analyses were used to describe the study sample (Table II) and the prevalence of complications. Continuous variables (age and percentage of stenosis) were also categorized and results presented as percentages in addition to means and standard deviation (SD). Differences in the prevalence of complications according to each potential predictor were first examined using the Fisher exact test for categoric variables and Wilcoxon rank sum test for continuous variables. Stepwise forward logistic regression was used to examine the independent association between complication occurrence and each potential determinant. The criteria adopted for the inclusion of variables in the final model were clinical relevance ($P < .2$) and change in the odds ratio of significant predictors >10%.[10] Standard diagnostic procedures were adopted to check final model validity, including influential observation analysis ($\Delta\beta$, change in Pearson χ^2, and similar), multicollinearity, interaction terms, Hosmer-Lemeshow test for the goodness of fit, and C statistic (area under the receiving operator curve).[11] Statistical significance was defined as a two-sided $P < .05$, and all analyses were done using Stata 8.2 software (StataCorp LP, College Station, Tex).

RESULTS

The study examined 298 CAS procedures that were performed from January 2005 to March 2007. The mean proximal TI was 111.9° ± 96.77° and the mean distal TI was 123.4° ± 117.47°. Technical success was obtained in 272 patients (91.2%). Causes for the 26 technical failures were inability to obtain stable proximal access in 25 (96.1%) and uncrossable stenosis in one (3.9%). Neurologic protection was achieved with distal filters in all cases, with the EZ (Boston Scientific) used in 160 (53.6%) and the Accunet (Guidant) in 138 (46.4%). Stenting of the lesion was subsequently performed with the Wallstent (Boston Scientific) in 172 (58.1%) or the Acculink (Guidant) in 126 (41.9%).

Neurologic complications occurred in 23 patients (7.7%): 16 (69.6%) were TIAs and seven (30.4%) were minor strokes. Timing of neurologic symptoms onset varied and is detailed in Table III.

The proximal TI was significantly greater in the 26 cases of technical failure (158.4° ± 102.2° vs 107.6° ± 95.3°, $P = .01$), but the distal TI was not different in the

Table IV. Characteristics of the overall sample by neurologic complications and technical failure (univariate analysis)

Variables	*Total sample, %*	*Neurologic complications, %*	P[a]	*Technical failures, %*	P[a]
Total	298	23 (7.7%)		26 (8.7%)	
Categoric, %					
Sex			.8		.9
Male	63.1	7.4		9.0	
Female	36.9	8.2		8.2	
Age classes, y			.4		.2
≤65	5.0	6.7		0.0	
66-75	36.2	5.6		5.6	
76-85	52.4	8.3		10.9	
>85	6.4	15.8		15.8	
Aortic arch			.3		<.001
III and bovine	20.5	11.5		21.1	
I and II	79.5	6.7		5.5	
Tortuosity index			.018		.023
Proximal†					
≥150°	29.5	13.6		14.8	
<150°	70.5	5.2		6.2	
Distal†			.9		.038
≥150°	42.9	7.8		4.7	
<150°	57.1	7.6		11.8	
Plaque type			.9		.9
Complicated	25.8	7.8		9.1	
Uncomplicated	74.2	7.7		8.6	
Contralateral stenosis >80%			.3		.3
Yes	10.1	13.3		13.3	
No	89.9	7.1		8.2	
Contralateral occlusion			.4		.9
Yes	6.4	0.0		5.3	
No	93.6	8.2		9.0	
Preoperative symptoms			.3		.6
Yes	22.1	10.6		10.6	
No	77.9	6.9		8.2	
Level of stenosis			.5		.6
≤70%	30.9	8.7		8.7	
75%	18.1	3.7		11.1	
80%	29.2	10.3		5.8	
>80%	21.8	6.2		10.8	
Pre-op CT or NMR scan			.9		.9
Positive	24.8	8.1		8.1	
Negative	74.2	7.6		8.9	
Intraprocedural protection system‡			.9		. . .
Concentric	43.6	6.1		0.0	
Eccentric	47.6	7.0		0.0	
Stent type‡			.9		. . .
Chromium-cobalt	52.7	7.0		0.0	
Nitinol	38.6	6.1		0.0	
Continuous variables, mean (SD)					
Age, y	75.5 (6.2)	77.5 (6.7)	.09	79.2 (5.8)	.002
Stenosis, %	78.0 (9.6)	80.0 (10.7)	.9	79.5 (10.5)	.8

CT, Computed tomography; *NMR,* nuclear magnetic resonance.
*Fisher exact test for categoric variables, Wilcoxon rank sum test for continuous variables.
†See text for details on the methodology to derive the score.
‡The sum of these two groups is <100% due to lack of cases with impossible common carotid cannulation.

two groups (89° ± 99.1° vs 126.5° ± 118.6°, P = .11). Similarly, the proximal TI was significantly greater in neurologic complications (162.8° ± 111.8° vs 107.6° ± 18.2°, P = .03), but the distal TI was not statistically different in the two groups (112.6° ± 110.1° vs 124.3° ± 96.1°, P = .5)

By logistic regression analysis, a proximal TI >150 was an independent predictor of neurologic complications and technical failure. Age was also independently associated with technical failure (Table IV and V). Appropriate distal filter placement was possible in all cases with a crossable stenosis, irrespective of the ICA TI. Interestingly, increased distal TI was associated with a statistically significantly lower risk of technical failure; however, a high distal TI was not associated with a significantly different proximal TI or with age.

Table V. Logistic regression analysis of variables associated with results

Variables	*Neurologic complication, OR (95% CI)*	P
Age (1 year increase)	1.05 (0.98-1.13)	.149
Tortuosity index proximal >150°	2.72 (1.14-6.47)	.023
Tortuosity index distal >150°	1.00 (.42-2.37)	.995
	Technical failure, OR (95% CI)	
Age (1-year increase)	1.10 (1.02-1.19)	.009
Tortuosity index, proximal >150°	3.07 (1.259-7.49)	.014
Tortuosity index distal >150°	.32 (.117-.877)	.027

CI, Confidence interval; *OR,* odds ratio.

DISCUSSION

The TI is an objective method of measurement of tortuosity in carotid arteries that appears to correlate with the risk of technical failure and neurologic complications. Interestingly, only proximal tortuosity increases the risk of both neurologic complications and technical failure.

The TI has been used in the iliac arteries to assess the feasibility of endovascular aortic aneurysm repair.[12] Similarly, several authors evaluated carotid tortuosity. Lin et al[5] classified common carotid and internal carotid tortuosity in three categories according to the degree of angulation from the center line of flow.[5] This analysis showed a greater incidence of tortuosity in patients aged older than 80 years; however, no correlation was attempted with CAS results. Indirectly, these data could support a greater neurologic risk in older patients. Chong et al[13] excluded 29 of 177 patients (16.3%) from CAS owing to excessive tortuosity. Choi et al[7] stated that severe tortuosity was a contraindication to CAS but did not provide a precise definition.

We tried to objectively stratify the grade of tortuosity and confirmed its importance in CAS procedures, both for technical success and neurologic outcome. Specifically, increased proximal TI is statistically significantly associated with increased risk of technical success and neurologic complications, thus confirming previous reports that showed increased risk of complications in difficult arch anatomy and in the presence of severe arterial elongation. The reported incidence of severe proximal tortuosity during CAS leading to procedure failure varies from 0.2%[14] to 16.3%[13]; however, it is difficult to extrapolate because patient selection and exclusion criteria differed among the studies (Table VI).[15-23]

Although our results are less favorable in this regard, our policy is to perform CAS in all patients with an indication for carotid revascularization (ie, symptomatic carotid stenosis >50% or asymptomatic carotid stenosis >80%), after appropriate informed consent, if no contraindication to the procedure is present or if the patient is aged younger than 70 years. In this regard, the technical success rate for type I and II arches is 97% in the last 70 cases of our series.

Table VI. Influence of proximal and distal tortuosity in carotid artery stenting results from the literature

First author	*No.*	*Technical failures related to tortuosity*	*Description*
Henry[15] (2000)	290	1 (0.3%)	Excessive tortuosity
Stankovic[16] (2002)	102	3 (2.9%)	CC tortuosity or arch angulation
Sztriha[17] (2004)	260	2 (0.7%)	Vessel tortuosity
Criado[18] (2004)	135	3 (2.2%)	Impossible CC access
Choi[7] (2004)	194	1 (0.5%)	Exclusion for IC tortuosity
Theiss[19] (2004)	3514	13 (0.3%)	Exclusion for arch angulation (n =7) or IC kinking (n =6)
Vitek[20] (2005)	325	1 (0.3%)	Type III arch and CC tortuosity
Lin[5] (2005)	200	4 (2%)	Tortuosity of brachiocephalic or common carotid artery
Chong[13] (2005)	177	29 (16.3%)	Exclusion for CC or IC tortuosity
Setacci[14] (2006)	1222	3 (0.2%)	Impossible access or excessive tortuosity
Safian[21] (2006)	419	6 (1.4%)	Impossible filter delivering for IC tortuosity
Verzini[22] (2006)	627	2 (0.3%)	Impossible CC access
Halabi[23] (2006)	126	2 (1.5%)	Vessel tortuosity

CC, Common carotid; *IC,* internal carotid.

Some authors exclude patients with "carotid tortuosity,"[13,19] and direct carotid access is performed in approximately 3% to 5% of cases in other series.[7,24] In our practice, we avoided cervical and brachial access for a variety of reasons, such as inadequate instrumentation in the angiography suite, risk of peripheral complication, and the possibility of offering a surgical procedure with mortality-morbidity risk <1%, thus our rate of success in this series is our transfemoral success rate. We have already demonstrated an increased risk of neurologic complications in the presence of complex arch anatomy, thus emphasizing the importance of carotid cannulation in determining distal embolization.[6]

Distal tortuosity did not influence either outcome. Apparently a distal TI >150 was associated with a decreased risk of technical failure. Although we do not have definitive explanation for these data, we can speculate that the presence of distal coiling was associated with increased vessel elasticity, with subsequent easier proximal vessel cannulation, irrespective of the proximal TI and other factors. Although some centers perform CAS without routine neurologic protection, we believe that routine embolic prevention is mandatory, and we have been able to properly position a distal filter in all cases. An alternate method of protection in severe distal tortuosity is the use of an ICA exclusion device with reversal of flow, a procedure that was not necessary in any patient in this series. Thus, the presence of distal kinking or coiling should not be considered a contraindication to CAS

CONCLUSION

The results of our study may aid in the selection of patients for CAS. Duplex sonography detection of significant coiling or kinking of the distal ICA should not lead to exclusion of the patient from a CAS program. More important is the study of common carotid anatomy and, particularly, its origin from the arch. Both CT and MRI, however, may fail to detect subtle details if severe tortuosity is present. Thus, procedural angiography may be the gold standard diagnostic tool in this instance, with subsequent immediate CAS, if possible. Evaluation of TI is simple, rapid, and reliable in predicting possible difficulties of the procedure. In this regard, it may be a valuable tool in organizing learning steps for physicians initiating CAS.

AUTHOR CONTRIBUTIONS

Conception and design: GF, AS
Analysis and interpretation: GF, MF, MG, AF, FF, LM
Data collection: MF, FF
Writing the article: GF
Critical revision of the article: MF, MG, AF, LM, AS
Final approval of the article: GF, MF, MG, AF, FF, LM, AS
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Overall responsibility: GF, AS

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