Towards Safer Carotid Artery Stenting
A Scoring System for Anatomic Suitability

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Backgrounds and Purpose—To develop a scoring system to facilitate case selection for carotid artery stenting based on anatomic features.

Methods—Twelve experts comprising a multinational and multispecialty panel were convened. Delphi consensus methodology was applied over 4 “rounds” involving emailed questionnaires, private decision-making, structured interaction and explicit aggregation. In round 1 panelists proposed individual anatomic features that were considered relevant during carotid artery stenting. In round 2 each criterion was scored from 1 (straightforward) to 9 (difficult). Round 3 involved removing some factors based on individual scores to reduce the number of subsequent combination anatomies. The final round involved scoring 96 combination anatomies (representing a “full factorial” design) plus a dichotomous response, ie, whether carotid artery stenting should or should not be advised for a “novice.”

Results—There were 1164 responses, providing a score for 12 individual anatomic features and for 96 combinations of anatomies with good level of agreement between panelists. After derivation of mean (and standard deviation) of the cutting scores for 1152 yes/no responses a scoring system for combination anatomy was produced, comprising broad agreement bands presented as traffic light colors: red for particularly difficult anatomy, amber for moderate difficulty and green for lesser difficulty.

Conclusion—A scoring system has been developed, based on objective expert consensus, which can be used to categorise expected difficulty of carotid artery stenting and aid case selection. (Stroke. 2009;40:1698-1703.)

Key Words: carotid artery disease ■ stents ■ carotid ■ Delphi technique ■ scoring methods

Optimizing risk/benefit for any carotid intervention relies on minimizing procedural hazards. Evidence suggests that medical comorbidities impact on the adverse event rate for carotid endarterectomy but are generally not predictors of procedural risk for carotid stenting (CAS). It has become apparent that anatomic considerations are critical to outcome during CAS. Anatomic factors have not previously been systematically analyzed. We therefore sought to evaluate anatomic features that might increase technical difficulty of CAS and potentially increase the procedural stroke rate. Our aim was to generate a scoring system to grade expected difficulty during CAS and so guide inexperienced operators in case selection.

Materials and Methods
Delphi consensus methodology was used, utilizing emailed questionnaires. Face-to-face interaction was avoided in order to eliminate undue influence from individuals. Carotid interventions are performed by several specialties so panelists were invited from interventional radiology, neuroradiology, interventional cardiology and vascular surgery. Panelists from around the world were approached in order to avoid geographical bias. The 12 panelist are listed in the Appendix.

Panelists were told to assume a robust clinical indication to intervene and that all patients were on dual antiplatelet therapy (level 1 evidence suggest that patients not on dual therapy are at increased risk). The hypothetical procedure was standardized as far as possible with respect to drugs, access (femoral) and use of cerebral protection (filter). Panelists were given explicit instructions that they were to imagine advising a novice, ie, someone with <50 cases personal experience.

The consensus process comprised 4 “rounds”. In round 1 panelists were asked to list all anatomic features which they considered to be relevant during CAS. In round 2 each individual criterion was marked on an integer scale of 1 (straightforward) to 9 (difficult). Consensus among panelists was defined as scores lying within 3 points on the scale. Some anatomic/pathological parameters were only included if they were considered to be severe. Examples of severe tortuosity or steno-occlusive disease were presented in advance for clarity.

In round 3, the list of individual features was reduced by consensus in order to limit the total number of subsequent combinations (it was considered that patients were likely to have some combination of adverse features). In round 4, 96 combination anatomies (representing a “full factorial design”, see results) were scored on an integer scale of 1 (straightforward) to 9 (difficult). Panelists were also asked whether or not they would advise a novice...
to perform CAS in each particular anatomy yielding a dichotomous yes/no response.

A full factorial design, with 12 original features, had 2000 combination anatomies and was considered impractical. A fractional factorial design using all 12 original anatomic features but where a selected proportion of the total number of composites are used was considered. However, there were no feasible factorial designs which did not involve too great an “aliasing” effect.

The order of the 96 slides, each representing a combination anatomy, was scrambled so that the panelists would not “second guess” what score to give successive anatomies based on the preceding image. “Normal” anatomy was presented as slide 1.

Mean cutting scores were derived (the difficulty score at which panelists changed from a “yes” to a “no” response) and subsequently used to inform a scoring system for combination anatomy presented as a table colored in traffic light colors: red for particularly difficult anatomy, amber for moderate difficulty and green for lesser difficulty.

Results

Round 1
The twelve parameters chosen by consensus were subdivided into “Access,” “Arch” or “Target Vessel.” Access: low bifurcation/short CCA, tortuous CCA, diseased CCA, diseased/occluded external carotid artery (ECA); Arch: severe arch atheroma, severe disease at the origin of the great vessels, type III arch (Figure 2), bovine arch (conjoint origin of left CCA and brachiocephalic trunk); Target Vessel: pinhole stenosis (but with flow beyond, ie, not “trickle flow”), angulated internal carotid artery (ICA) origin, angulated distal ICA, circumferential calcification of ICA (>2/3rd the circumference of the vessel at the lesion site).

Round 2
Each anatomic feature, scored individually, was ranked in ascending order from most straightforward (low bifurcation) to most difficult (tortuous CCA) with mean difficulty score (standard deviation) and level of agreement (Table 1). Figure 1 gives an example of the score for angulated ICA origin; the mean difficulty was 7.1 (SD 0.9), with 100% agreement.

Round 3
After agreement between the statistician (R.L.) and the other authors, tortuous CCA was excluded from composite anatomy evaluations. It was considered the most difficult anatomic feature when encountered in isolation and would therefore be graded as very difficult in combination with other anatomic features. Low bifurcation was excluded as it scored as the least difficult of the anatomies. Of the anatomic features pertaining to the ICA, angulated distal ICA was retained in favor of angulated ICA origin (the latter being considered as substantially more difficult) and of the anatomic features pertaining to the lesion, 99% stenosis with flow beyond was retained in favor of circumferential calcification (the latter scoring as substantially more difficult than the former). The full factorial design for round 4 of the Delphi process was based on the following: Access (“normal” access, diseased CCA, diseased/occluded ECA); Arch (Disease) (severe arch atheroma/arch origin disease, “normal” arch); Arch configuration 1 (type III arch, normal arch); Arch configuration 2 (bovine arch, normal arch); Target vessel (angulated distal ICA, normal target vessel); Lesion (pinhole stenosis [flow beyond], “normal” lesion). This gave 96 combination anatomies: \(3 \times 2 \times 2 \times 2 \times 2\).

Round 4
There were 2304 responses in total, in addition to the 12 results from round 2 (1152 difficulty scores ie, 96 combination anatomies provided by 12 panelists), and 1152 yes/no answers. Figure 2 gives an example of combination anatomy.

Statistical Analysis of Round 4 Data
Multiple linear regression was used to determine which anatomic features particularly influenced the level of difficulty. For each of the scenarios the mean response over all experts was used as the dependent variable. Five two-category and one three-category predictive factors were considered: Type III arch (responses no, yes), Bovine arch (no, yes), Arch atheroma (no, yes), Lesion (standard, pinhole...
Table 2. Anatomic Features Influencing Panelists’ Rating of the Level of Difficulty of CAS From Stepwise Linear Regression With Interactions

<table>
<thead>
<tr>
<th>Anatomic Feature</th>
<th>Parameter Estimate (SE)</th>
<th>t Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type III arch</td>
<td>2.19 (0.11)</td>
<td>20.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Angulated distal ICA</td>
<td>0.85 (0.06)</td>
<td>13.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Arch atheroma</td>
<td>1.81 (0.14)</td>
<td>13.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bovine arch</td>
<td>1.19 (0.11)</td>
<td>11.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Access</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease CCA</td>
<td>1.22 (0.11)</td>
<td>11.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ECA problem</td>
<td>1.02 (0.11)</td>
<td>9.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Pinhole stenosis</td>
<td>0.48 (0.06)</td>
<td>7.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Type III arch * Arch atheroma</td>
<td>-0.49 (0.12)</td>
<td>-4.0</td>
<td>0.0001</td>
</tr>
<tr>
<td>Bovine arch * Arch atheroma</td>
<td>-0.44 (0.12)</td>
<td>-3.6</td>
<td>0.0006</td>
</tr>
<tr>
<td>Type III arch * Bovine arch</td>
<td>-0.34 (0.12)</td>
<td>-2.8</td>
<td>0.0065</td>
</tr>
<tr>
<td>Access * Arch atheroma</td>
<td>-0.43 (0.15)</td>
<td>-2.9</td>
<td>0.0053</td>
</tr>
<tr>
<td>Disease CCA &amp; Arch atheroma</td>
<td>0.01 (0.15)</td>
<td>0.0</td>
<td>0.97</td>
</tr>
<tr>
<td>Intercept</td>
<td>2.44 (0.11)</td>
<td>22.0</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Discussion

For CAS, any feature that increases the potential for prolonged catheter/guide wire manipulation in the aortic arch may increase risks of procedural embolization, and any feature that renders more difficult lesion crossing, safe deployment of distal protection devices, and accurate stent placement may also result in increased procedural hazard. We have developed a scoring system, based on objective expert stenosis), Target vessel (normal, angulated distal ICA), and Access (normal, ECA problem, diseased CCA). “Access” was fitted as a categorical variable with 3 categories using 2 dummy variables which were constrained to enter and leave the model together. Stepwise regression was used starting with no variables in the model. Main effect and interaction terms entered and left the model at 5% and 1% significance levels respectively.

All 6 predictive factors entered the final model along with 3 interactions between factors with 2 categories and 1 interaction between a 2-category factor and the 3-category feature. This model explained 96% of the total variability in the mean rating of difficulty. The presence or absence of a Type III arch was the most important anatomic feature and the presence of pinhole stenosis rather than a “standard” lesion the least important. All the interaction terms, except the presence of ECA problems and arch atheroma, had negative parameter estimates so the presence of the 2 anatomic features concerned did not lead to as great an increase in mean level of difficulty as expected from a simple summation of the parameter estimates for each feature. For example, in the absence of arch atheroma the presence of a Type III arch without a Bovine arch increases the mean level of difficulty by 2.19 whereas the presence of a Bovine arch without a Type III arch increases the mean rating of difficulty by 1.19, but the presence of both a Type III and Bovine arch rather than increasing the mean score by 3.38 only increases it by 3.04 (2.19 + 1.19 to 0.34).

Although the interaction terms in the final model were statistically significant their parameter estimates were smaller than the estimates for the individual features involved in the interactions. This implied that there was relatively minor variation in the influence of say a Type III arch according to whether a Bovine arch is present or absent, and vice versa.

The 6 predictive factors all entered a model when interactions were not considered, and this model still explained 93% of the total variability in mean level of difficulty. The most important anatomic feature remained the presence or absence of a Type III arch, followed by the presence or absence of arch atheroma. The influence on the mean score of access difficulties, due to either a diseased CCA or ECA problem, was similar to that from the presence of an angulated distal ICA or the presence of a Bovine arch. The presence of pinhole stenosis rather than a “standard” lesion was still the least important of the features examined.
consensus, which can be used to categorize expected difficulty of CAS and aid case selection. We hope this will reduce complications by identifying higher risk patients.

Stroke resulting from catheterization of the great vessels during CAS cannot be prevented by current protection systems. In an analysis of 627 protected CAS procedures, Verzini et al documented 10 major strokes and 1 cardiac death; 4 major strokes occurred during the catheterization phase (great vessel origin, CCA). Notably, of those “access” features considered to be relevant in our scoring system, tortuous CCA scored as the most difficult anatomic feature of all with a mean score of 8.4.

With regards to features pertaining to arch anatomy (arch atheroma and great vessel origin disease, Type III or bovine arch) our scoring system indicated that arch atheroma and Type III arch were very important predictors of difficulty. The association between aortic arch anomalies and procedural risk was recently explored in 214 consecutive patients who were categorized as having “normal” or abnormal/ anomalous arch anatomy.9 Technical failure was higher and neurological complications occurred more frequently in the arch anomaly group (20% versus 5.3%, \(P=0.039\)). Type of arch was the only variable independently associated with neurological complications (odds ratio =2.01, \(P=0.026\)).

Although we did not include age as a factor in our scoring system, the relationship between patient age, certain anatomic features and outcome after CAS was recently explored.10 Patients over 80 years old had an increased incidence of unfavorable arch elongation (\(P=0.008\)), arch calcification (\(P=0.003\)), common carotid or innominate artery origin stenosis (\(P=0.006\)), common carotid artery tortuosity (\(P=0.0009\)), internal carotid artery tortuosity (\(P=0.019\)), and an increased degree of lesion stenosis (\(P=0.007\)). The combined stroke, myocardial infarction, and death rate was significantly increased in patients aged \(\geq\)80 years old (10.8%) compared with those aged <80 years old (1%, \(P=0.012\)).
The event rate reported in the lead-in phase of the CREST trial increased with age and the effect was not mediated by potential clinical confounding factors. While the safety of CAS in octogenarians is the subject of ongoing debate, with increasing age, atherosclerosis and uncontrolled hypertension, there is elongation and rostral migration of the distal aortic arch and a change in the relative positions of the great vessels resulting in a Type III configuration. Ageing may also be associated with increased aortic arch atheroma. It is interesting to note that Table 4 of our scoring system indicates that the presence of a Type III arch and arch atheroma almost immediately puts the anatomy into the “red zone.”

Multivariate regression analysis of 429 CAS procedures revealed that ostial lesion involvement and lesion length ≥15 mm were independently associated with 30-day stroke rate. The Lenox Hill group considered that the 2 most important anatomic predictors of increased procedural risk in 1500 cases were heavy concentric calcification (≥3 mm in width and deemed in at least 2 orthogonal views to be circumferential) and excessive tortuosity (defined as ≥2 flexion points that exceed 90°, within 5 cm of the lesion, including the takeoff of the ICA from the CCA). They concluded that complex anatomy required special techniques and that the presence of 2 or more anatomic risk factors significantly increased procedural risk. Our findings concord with the Lenox Hill group; we considered significant tortuosity of the CCA to be the single most difficult anatomy for the novice and that angulated ICA origin and circumferential calcification were also very important considerations.

To our knowledge, ours is the only systematic consensus-derived evaluation of anatomic parameters that may impact on procedural stroke during CAS. We have sought to evaluate the interactions between anatomic factors and it would seem that the relationship between number of adverse features and difficulty is not simply linear, ie, the difficulty scores of existing adverse features cannot simply be added. In the assessment of combination anatomy, the presence of a Type III arch was a significant factor in the mean difficulty rating whether or not potential interaction with other variables was considered.

In order to make the scoring of combination anatomies practicable, 12 anatomic parameters were reduced to seven. This was recognized as being a compromise and anyone seeking to use Table 4’s traffic light scoring system will note that tortuous CCA does not feature; this anatomy will automatically appear in the “red zone” as a result of its significance. The presence of a Type III arch and angulated ICA origin is also present and in their place, the reader should look up pinhole stenosis and angulated distal ICA respectively. In each case, it is likely that the resultant score would be less than if calcification and angulated ICA origin did actually occur. In the absence of validated techniques for assessing plaque characteristics, plaque morphology was not considered but it may be appropriate to do so once such techniques are widely available.

Iliac tortuosity was also excluded from analysis although it is clear that if significant, it would hamper the procedure by reducing one-to-one torque of the catheter/guide wire combination and likely increase manipulation in the aortic arch. Moderate disease or tortuosity was excluded although it was accepted that even moderate tortuosity anywhere along the endovascular route to the lesion may cause difficulty. Fresh thrombus and “trickle flow” ie, a subocclusive lesion with significantly reduced flow beyond were also excluded as the panelists were of the opinion that these were generally accepted to be contraindications for CAS. Modified procedural modifications may allow the operator to deal safely with more anatomies. Cutting balloons, for predilatation, may allow safe treatment of circumferentially calcified lesions and proximal protection systems in place of filters may render ICA tortuosity less relevant. However, arguably these procedural modifications are usually the preserve of more experienced operators.

Validation of the scoring system will require correlation with existing or planned CAS datasets in which the mean difficulty score as determined by Table 4 is correlated with outcome during CAS.

Summary
An objective consensus method using experts in carotid stenting has been employed to develop a scoring system which may be used to categorize expected difficulty of CAS and aid case selection with the specific aims of guiding the novice and of reducing procedural stroke.

Appendix

Delphi Carotid Stenting Consensus Panel
Interventional Radiology/Neuroradiology: Peter Gaines, Sheffield, UK, Sumaira Macdonald, Newcastle, UK, Claudio Schönholz, Charleston, USA, Luc Stockx, Genk, Belgium, Jos Van Den Berg, Lugano, Switzerland; Vascular Surgery: Jean-Pierre Becquemin, Paris, France, Marc Bosiers, Dendermond, Belgium, Michel Makaroun, Pittsburgh, USA, Jon Matsumura, Chicago, USA, Peter Schneider, Honolulu, Hawaii; Interventional Cardiology: Alberto Cremonesi, Cottignola, Italy, Robert Fathi, Brisbane, Australia.

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Disclosures
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