Incompleteness of the Circle of Willis is Related to EEG-based Shunting During Carotid Endarterectomy

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WHAT DOES THIS STUDY/REVIEW ADD TO THE EXISTING LITERATURE AND HOW WILL IT INFLUENCE FUTURE CLINICAL PRACTICE PAPER ADDS

With the current study we have identified independent predictors and we have developed a prediction model for the likelihood of shunt use during carotid endarterectomy that is based on the configuration of the circle of Willis (CoW) assessed by magnetic resonance angiography. Because with our model discrimination can be improved to a likelihood of about 5% for the group with a risk of 10% or lower and about 51% for the group with a risk of 30% or higher, this model can potentially be of help in clinical decision-making regarding surgical strategy and in the design of future studies on prediction models for shunt use in carotid revascularization.

Objectives: The occurrence of cerebral ischemia during carotid endarterectomy (CEA) can be prevented by (selective) placement of an intraluminal shunt during cross-clamping. We set out to develop a rule to predict the likelihood for shunting during CEA based on preoperative assessment of collateral cerebral circulation and patient characteristics.

Methods: Patients who underwent CEA between 2004 and 2010 were included. Patients without preoperative magnetic resonance angiography (MRA) or computed tomography angiography (CTA) were excluded. The primary endpoint was intraluminal shunt placement based on electroencephalography changes. Age, sex, cardiovascular risk factors peripheral artery disease, symptomatic status, degree of ipsilateral and contralateral carotid, status of the vertebral arteries, and morphology of the CoW were studied as potential predictors for shunt use. A prediction model was derived from a multivariable regression model using discrimination, calibration, and bootstrapping approaches and transformed into a clinical prediction model.

Results: A total of 431 patients were included, of which 65 patients (15%) received an intraluminal shunt. In the MRA group (n = 285) factors related to shunt use in multivariate analysis were ipsilateral carotid stenosis 90–99% (odds ratio [OR] 0.15, 95% CI 0.04–0.53), contralateral carotid occlusion (OR 4.29, 95% CI 1.68–10.95) and any not-visible anterior (OR 4.96, 95% CI 1.95–12.58) or ipsilateral posterior segment of the CoW (OR 5.08, 95% CI 2.10–12.32). In the CT group none of the factors were independently related to shunt use; therefore, only predictors describing morphology of CoW derived from MRA findings were included in our model. The c-statistic of this model was 0.79 (95% CI 0.72–0.86). Among patients with an estimated chance of needing a shunt of under 10% (49% of the population), the likelihood of shunting was 5%. In those in whom this chance was estimated higher than 30% (13% of the population) the likelihood was 51%.

Conclusions: Among patients scheduled for CEA, assessment of cerebral arteries and of the configuration of the CoW based on MRA-derived images can help to identify patients with low and high likelihood of the need of shunt use during surgery.

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INTRODUCTION

During carotid endarterectomy (CEA), cross-clamping (CC) may induce intraoperative cerebral ischemia. This can be grossly prevented or diminished by placement of an intraluminal shunt during CC. Furthermore, sufficient collateral circulation is important to maintain adequate blood supply to the brain in case of interruption of one of the principle blood suppliers by CC. The circle of Willis (CoW) plays an important role in the collateral circulation, both by the anterior communicating artery (A-com), which connects the right and left anterior cerebral arteries (A1 segments) and by the posterior cerebral arteries (P1 segments) and posterior communicating arteries (P-com), which link the carotids with the basilar artery (Fig. 1).

Considerable variability exists in the configuration of the different arteries of the CoW, which can be large, hypoplastic, or even absent. Based on post-mortem studies anomalies of the CoW are present in approximately 50—80% of individuals.1,2 Previous studies have demonstrated that both computed tomography angiography (CTA) and magnetic resonance angiography (MRA) are sensitive and minimal invasive modalities that can be used to examine the configuration of the CoW.3,4 Besides the status of the CoW, the risk of cerebral ischemia requiring shunt placement is determined by several other factors, including

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**Figure 1.** Diagram of the circle of Willis and score model.

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<table>
<thead>
<tr>
<th>Artery</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-com</td>
<td>Not visible</td>
</tr>
<tr>
<td>A1 Right/ Left</td>
<td>Not visible</td>
</tr>
<tr>
<td>P-Com Right/ Left</td>
<td>Not visible</td>
</tr>
</tbody>
</table>

**Anterior segment**

A-com: anterior communicating artery
- [not-visible]: if flow was not visualized between the left and right A1 segments
- [present]: if flow was visualized between the left and right A1 segments

A1 (right/left): proximal segment of the anterior cerebral artery (ACA)
- [normal]: at least 0.8 mm in diameter
- [hypoplastic]: less than 0.8 mm in diameter
- [not-visible]: if one of the component vessel segments was not-visible

**Posterior segment**

P-com (right/left): posterior communicating arteries

P1: Proximal part of the posterior cerebral artery (PCA)
- [not-visible]: not seen
- [<P1]: smaller than P1 ('normal' circle)
- [=P1]: of the same size as P1 (transitional configuration)
- [>P1]: larger than P1 (partial fetal variant)
- [not-visible P1]: P1 was not seen (full fetal variant)
clinical characteristics and the degree of stenosis in the contralateral carotid artery and the bilateral vertebral artery. We set out to develop a clinical prediction rule to assess the likelihood of the need for shunting during CEA based on routine clinical information and preoperative assessment of the collateral cerebral circulation.

**METHODS**

**Patients**

Patients who underwent CEA between January 2004 and August 2010 in University Medical Center Utrecht, The Netherlands, were eligible for this cohort study. Indications for CEA were symptomatic or asymptomatic carotid stenosis >70% as discussed by a multidisciplinary team. All patients were seen by a stroke neurologist confirming and grading the presenting neurological symptoms (non-disabling ischemic stroke defined as modified Rankin scale (MRS) ≤2, and disabling stroke as MRS ≥3). The severity of the carotid artery stenosis was assessed by color Doppler-assisted duplex ultrasound and confirmed by MRA or CTA and categorized on a four-point scale: <50%, 50–70%, 70–99% stenosis, or occlusion. Patients without reliable preoperative MRA or CTA of the CoW were excluded. We performed a subgroup analysis of these excluded patients confirming that no important information was lost for the purpose of this study.

All patients were operated under general anesthesia and intraoperative monitoring included both electroencephalography (EEG; Inc., Treviso, Italy) and transcranial Doppler (TCD; DWL Multidop X4, Sipplingen, Germany). An intraluminal Javid shunt was placed selectively based on the occurrence of new delta or theta activity on the EEG, during a period of at least 2 minutes of test-clamping, as described in detail previously. TCD monitoring was used for detection of intraoperative embolism and identification of patients at risk for the development of cerebral hyperperfusion syndrome. After surgery, patients remained for 6 hours at the recovery ward for continuous invasive radial artery blood pressure monitoring. All patients underwent neurological examination before and after surgery.

**Outcome parameter and potential predictors**

The primary outcome parameter was the need of an intraluminal shunt. Age, sex, cardiovascular risk factors, peripheral artery disease, statin use, symptomatic status, degree of ipsilateral and contralateral carotid stenosis, status of the vertebral arteries (VA), and morphology of the CoW based on contrast-enhanced CTA or contrast-enhanced MRA images were considered as potential predictors. The CoW morphology for each individual patient was assessed by two experienced radiologists (JH, PJvL), unaware of clinical outcome, patient characteristics and whether or not a shunt was used. The anterior CoW segments were considered as (a) normal (at least 0.8 mm in diameter), (b) hypoplastic (diameters measuring < 0.8 mm), or (c) not-visible (Fig. 1). For the posterior CoW the classification was based on the comparison of the relative size of the P1 segment of the posterior cerebral artery with the connected P-com.

Subsequently, per individual patient, the not-visible segments were grouped into anterior CoW (A-com, ipsilateral A1 and contralateral A1), ipsilateral posterior CoW (not visible ipsilateral P1 or Pcom), and contralateral posterior CoW (not visible contralateral P1 or Pcom).

**Statistical analysis**

After the selection of all potential predictors, identification of missing values was performed. Since the percentage of missing values was below 5%, we did not impute missing values. Continuous variables were presented as mean ± SD and categorical variables as absolute number combined with percentage. Baseline variables between shunt and non-shunt groups were compared using the χ² test or Student t test when appropriate.

The relation between potential predictors and shunt use was examined by multivariable logistic regression models using a backward stepwise approach with ρ = .20 for removal. Patients that underwent either MRA or CTA were analyzed separately. Prediction models derived with multivariable regression analysis are known for overestimated regression coefficients, which results in too extreme predictions when applied in new patients. Therefore, we internally validated our model with bootstrapping techniques where in each bootstrap sample the entire modeling process was repeated. This resulted in a shrinkage factor for the regression coefficients. The bootstrap procedure was also used to estimate a value of the area under the receiver operating characteristic curve (AUC) that was corrected for overoptimism to provide an estimate of discriminative ability that is expected in future similar patients.

To study the performance of the final prediction model, we assessed its discrimination and calibration. Discrimination is the ability of the model to distinguish between patients that did and did not receive a shunt, and was quantified with the AUC. An AUC ranges from 0.5 (no discrimination; same as flipping a coin) to 1.0 (perfect discrimination). Calibration refers to the agreement between the predicted probabilities and observed frequencies. This was tested with the Hosmer–Lemeshow statistic where a significant test result implies insufficient calibration.

To facilitate practical application of the model based on all patient data, the regression coefficients of the predictors in the model were converted into points on a score chart (by dividing the coefficients of all variables by the lowest coefficient observed). The total points (sum scores) were linked to the likelihood of receiving a shunt during surgery. Finally, various cut-off values were introduced in the predicted probabilities, categorizing patients as having a low risk, moderate risk and high risk to receiving a shunt. Data were analyzed using SPSS for Windows (SPSS 20.0, SPSS Inc, Chicago, IL, USA).
RESULTS

Patient characteristics

Of all 582 patients who underwent CEA in the study period, 431 patients were included (Table 1).

The majority of patients (n = 381, 88%) were symptomatic (stroke n = 104, transient ischemic attack n = 277). In 65 patients (15%) an intraluminal shunt was used. An ipsilateral high-degree stenosis of the internal carotid artery of 90—99% was less often present in patients who required placement of an intraluminal shunt than in patients who could be operated without shunting (n = 9 [14%] vs. n = 119 [33%]; p < .01), whereas a contralateral occlusion was more often seen in the shunt group (n = 16 [28%] vs. n = 52 [14%]; p = .01). Of all 431 patients, 14 patients (3%) suffered from stroke and three patients (0.7%) died. The overall 30-day rate of death/stroke was 4%. Both death and stroke occurred more in the shunted group than the non-shunted group, that is n = 2 (3%) vs. n = 1 (0.3%) p = .01, and n = 5 (8%) vs. n = 9 (3%), p = .03, respectively.

The excluded patients did not significantly differ from the study population regarding clinical outcome.

Circle of Willis on MRA/CTA

In 284 patients (67%), MRA was performed and in 140 patients (33%) CTA. The number of patients that underwent MRA instead of CTA did not differ between shunted and non-shunted patients (71% vs. 66%; p = .49). Any deviation from the normal anatomy of the CoW was seen in 394 patients (91%) (Fig. 2; Table 2). A normal A-com was found in most patients (88%), as well as a normal ipsilateral (82%) and contralateral A1 segment (87%). Posteriorly, the most observed abnormality was a not-visible P-coms (47% and 45% for the ipsilateral and contralateral P-com, respectively).

Model development and performance

None of the clinical variables were related to the likelihood of shunting (Table 1). In the MRA group carotid stenosis 90—99% (OR 0.15, 95% CI 0.04—0.53), contralateral carotid occlusion (OR 4.29, 95% CI 1.68—10.95), and any not-visible anterior (OR 4.96, 95% CI 1.95—12.58) or ipsilateral posterior segment of the CoW (OR 5.08, 95% CI 2.10—12.32) were independently related to the need of shunt use during CEA.

Table 1. Candidate predictors of shunt use during carotid endarterectomy. Values are shown as mean (±standard deviation) or number of patients (%).

<table>
<thead>
<tr>
<th>Candidate predictors</th>
<th>All (n = 431)</th>
<th>Shunt (n = 65)</th>
<th>No shunt (n = 366)</th>
<th>p</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr</td>
<td>69 (±9)</td>
<td>69 ± 8</td>
<td>69 ± 9</td>
<td>.51</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Gender, male</td>
<td>289 (67%)</td>
<td>46 (71%)</td>
<td>243 (66%)</td>
<td>.49</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>96 (22%)</td>
<td>13 (20%)</td>
<td>82 (22%)</td>
<td>.78</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>376 (87%)</td>
<td>56 (86%)</td>
<td>323 (88%)</td>
<td>.68</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Current smoking</td>
<td>144 (33%)</td>
<td>22 (34%)</td>
<td>118 (32%)</td>
<td>.87</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26.5 (±3.8)</td>
<td>25.8 (±3.6)</td>
<td>26.6 (±3.8)</td>
<td>.21</td>
<td>5 (1.2%)</td>
</tr>
<tr>
<td>Statin use</td>
<td>346 (84%)</td>
<td>50 (81%)</td>
<td>296 (84%)</td>
<td>.47</td>
<td>18 (4%)</td>
</tr>
<tr>
<td>Peripheral artery disease</td>
<td>79 (19%)</td>
<td>9 (14%)</td>
<td>70 (19%)</td>
<td>.31</td>
<td>7 (1.6%)</td>
</tr>
<tr>
<td>CEA-related factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical presentation (symptomatic)</td>
<td>383 (88%)</td>
<td>56 (86%)</td>
<td>327 (89%)</td>
<td>.44</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>104 (24%)</td>
<td>17 (26%)</td>
<td>87 (24%)</td>
<td>.68</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>279 (65%)</td>
<td>39 (60%)</td>
<td>240 (66%)</td>
<td>.35</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Ipsilateral carotid stenosis 90—99%</td>
<td>129 (30%)</td>
<td>9 (14%)</td>
<td>119 (33%)</td>
<td>&lt;.01*</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Contralateral occlusion</td>
<td>70 (16%)</td>
<td>18 (28%)</td>
<td>52 (14%)</td>
<td>.01*</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Reversal flow/occlusion/gracile ipsilateral vertebral artery</td>
<td>48 (11%)</td>
<td>8 (13%)</td>
<td>40 (11%)</td>
<td>.73</td>
<td>10 (2.3%)</td>
</tr>
<tr>
<td>Reversal flow/occlusion/gracile contralateral vertebral artery</td>
<td>45 (11%)</td>
<td>5 (8%)</td>
<td>40 (11%)</td>
<td>.49</td>
<td>19 (4.4%)</td>
</tr>
<tr>
<td>Circle of Willis morphology CT or MR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not visible anterior segment (any)</td>
<td>76 (18%)</td>
<td>21 (32%)</td>
<td>55 (15%)</td>
<td>&lt;.01*</td>
<td>8 (1.9%)</td>
</tr>
<tr>
<td>Not visible posterior segment ipsilateral (any)</td>
<td>216 (50%)</td>
<td>43 (75%)</td>
<td>173 (53%)</td>
<td>&lt;.01*</td>
<td>7 (1.6%)</td>
</tr>
<tr>
<td>Not visible posterior segment contralateral (any)</td>
<td>207 (48%)</td>
<td>30 (49%)</td>
<td>177 (52%)</td>
<td>.73</td>
<td>7 (1.6%)</td>
</tr>
<tr>
<td>Circle of Willis morphology MR</td>
<td>n = 284</td>
<td>n = 46</td>
<td>n = 238</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not visible anterior segment (any)</td>
<td>48 (17%)</td>
<td>14 (31%)</td>
<td>34 (14%)</td>
<td>&lt;.01*</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Not visible posterior segment ipsilateral (any)</td>
<td>136 (48%)</td>
<td>34 (74%)</td>
<td>102 (43%)</td>
<td>&lt;.01*</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Not visible posterior segment contralateral (any)</td>
<td>123 (43%)</td>
<td>19 (41%)</td>
<td>104 (44%)</td>
<td>.76</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Circle of Willis morphology CT</td>
<td>n = 140</td>
<td>n = 19</td>
<td>n = 121</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not visible anterior segment (any)</td>
<td>28 (20%)</td>
<td>7 (37%)</td>
<td>21 (17%)</td>
<td>.05</td>
<td>0</td>
</tr>
<tr>
<td>Not visible posterior segment ipsilateral (any)</td>
<td>78 (55%)</td>
<td>9 (47%)</td>
<td>69 (57%)</td>
<td>.43</td>
<td>0</td>
</tr>
<tr>
<td>Not visible posterior segment contralateral (any)</td>
<td>81 (57%)</td>
<td>11 (58%)</td>
<td>70 (58%)</td>
<td>1.00</td>
<td>0</td>
</tr>
</tbody>
</table>

Statistically significant differences are indicated by an asterisk (*).
CEA. While in the CT group none of the factors were independently related to the need of shunt use during CEA. Therefore, only predictors describing morphology of CoW derived from MRA findings were included in our model. The calibration of the model was good, confirmed by a non-significant Hosmer–Lemeshow test ($p = .66$). The model discriminated well between patient who did receive and who did not receive a shunt, with an AUC after correction for optimism of 0.79 (95% CI 0.72–0.86).

Subsequently, the bootstrapped betas of the predictors in the final model were used for constructing a risk score for shunt use during CEA (Table 3). Patients were categorized according to their model-derived likelihood of shunt use into low-risk (<10%, $n = 141$), medium risk (10–30%, $n = 104$), or high risk (>30%, $n = 36$). The observed incidence of shunt use in the low-risk, medium-risk and high-risk groups was 5%, 17%, and 51% (Table 4).

**DISCUSSION**

The present study suggests that preoperative MRA of the cerebral arteries and the basal arteries of the CoW, but not clinical characteristics, can help to identify preoperatively which patients are at increased risk for cerebral ischemia during CC and thus need a shunt during CEA surgery. Our main finding is that three abnormalities in the cerebral circulation seen on MRA predict a higher risk of shunt use: an occluded contralateral carotid artery, any not-visible segments of the anterior part of the CoW, and any not-visible segments of the ipsilateral posterior part of the CoW.
CoW. The relation between these factors and shunt use may be explained by the lack of a sufficient collateral circulation. A preocclusive (near-total) stenosis of the ipsilateral carotid artery predicts lower risk of shunt use, probably because adequate collateral circulation has been developed already to sustain adequate cerebral blood flow.

The association between CoW abnormalities and failing collateral circulation in case of diminished supply through the internal carotid artery has been described previously. Based on unselected post-mortem studies variation of the CoW exists in approximately 50% and several configurations of the CoW have been extensively described. Moreover, a higher incidence in abnormalities has been found in patients with an internal carotid artery stenosis or occlusion (64%) than in control subjects (45%). Furthermore, the observation that the need for a shunt is high in patients with failure of both the anterior and the posterior segments is in line with previous studies. However, we could not confirm that only in patients without contralateral internal carotid artery occlusion shunt placement is predicted by MRA measured incompleteness of the CoW. Moreover, in our cohort 89% of all patients with an intact A1 segment required shunt insertion, whereas either an intact anterior or the posterior pathway on the ipsilateral or contralateral site on digital subtraction angiography (DSA) has been associated with stable intraoperative EEG recordings. These contrasting results might be explained by the limited number of events in the study described by Schwartz et al. Although the number of shunts in the current study is still relatively small, the number of events is higher than in previous studies evaluating the value of imaging the CoW prior to carotid endarterectomy. In agreement with previous reports, our study indicated that clinical patient characteristics are not related to the likelihood of receiving a shunt. However, despite internally validating the model by means of bootstrapping methods, external validation in different CEA populations is warranted.

**Clinical implications**

Our model enables identification of a group of patients that have either a high or a low likelihood of receiving a shunt. In our group of patients 15% received a shunt, and with our model discrimination can be improved to a likelihood of about 4% for the risk of 10% or lower and about 56% for the group with a risk of 30% or higher. Although the current implications for current clinical practice are limited, our findings may guide us to future projects which might eventually lead to accurate decision-making and identification of patients that can surely be operated without shunt use.

**Limitations**

This study should been seen in context of its design. First, all included patients were operated under general anesthesia, and EEG was used to detect cerebral ischemia, while locoregional anesthesia allows awake patient monitoring of neurological function and can be regarded as the accepted standard for detection of cerebral ischemia during CC. If patients are operated under general anesthesia, however, as in our center, EEG is the most commonly applied technique to decide whether a shunt is needed, with a high positive and high negative predictive value.

Moreover, our results might be hampered by the methods used to visualize the anatomy of the CoW. DSA, which is the best method, is not commonly performed anymore due to the inherent risk of this invasive technique. Both CTA and MRA have previously been shown reliable tools for the assessment of the CoW. Apparently in the current study we found that anomalies seen on MRA increased the likelihood of the development of cerebral ischemia during CEA more than anomalies seen on CTA. Studies performing both CT and MR in all patients are required to compare the accuracy of both modalities for assessment of the CoW morphology in patients undergoing CEA. Nevertheless, some segments of the CoW may have been present, but not detected because the signal intensity may be below the threshold. Moreover, from post-mortem studies it appears that a complete CoW is present in most individuals. An absent P-com was only found in 5% of the cases. Their contribution to the blood flow, however, depends on the vessel diameter, which vary among individuals. Even a complete CoW may therefore be functionally insufficient as a collateral pathway during CC. Unfortunately we had to exclude several patients, however, as the outcome results within these two cohorts were similar and reasons for exclusion were not clinically driven we believe this has not influenced our results. Missing data concerning the status of the secondary collateral pathways, such as the ophthalmic arteries and leptomeningeal collaterals, may have affected our results as these vessels are able to compensate in case of a failing primary collateral network (CoW).

The presence of flow in the leptomeningeal vessels is linked to a better outcome after stroke, but the association with CEA is unknown.

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**Table 4.** Predicted and observed incidence of shunt use during cross-clamping divided into three risk categories.

<table>
<thead>
<tr>
<th>Risk score (sum of points)</th>
<th>Score category</th>
<th>Predicted shunt risk (mean ± SD)</th>
<th>Observed incidence of shunt (95% CI)</th>
<th>Patients within score category (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0</td>
<td>Low (&lt;10%)</td>
<td>3.3 ± 1.8</td>
<td>5.0% (n = 7)</td>
<td>141 (50%)</td>
</tr>
<tr>
<td>0–1</td>
<td>Medium (10–30%)</td>
<td>18.6 ± 4.7</td>
<td>17.1% (n = 18)</td>
<td>105 (37%)</td>
</tr>
<tr>
<td>&gt;1</td>
<td>High (&gt;30%)</td>
<td>54.2 ± 11.5</td>
<td>56% (n = 20)</td>
<td>36 (13%)</td>
</tr>
</tbody>
</table>

SD: standard deviation, CI: confidence interval.
In conclusion, in the current study we have identified independent predictors and we have developed a prediction model for the likelihood of shunt use during CEA that is based on the configuration of the CoW assessed with MRA. This may be useful in clinical decision-making regarding surgical strategy. However, despite internally validating the model by means of bootstrapping methods, external validation in different CEA populations is warranted.

CONFLICT OF INTEREST
None.

FUNDING
None.

REFERENCES