

# Critical appraisal of the Carotid Duplex Consensus criteria in the diagnosis of carotid artery stenosis

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**Background:** Clinicians have relied on published institutional experience for interpreting carotid duplex ultrasound studies (CDUS). This study will validate the ultrasound imaging consensus criteria published in 2003.

**Methods:** The CDUS and angiography results of 376 carotid arteries were analyzed. Receiver-operating characteristic (ROCs) curves were used to compare peak systolic velocities (PSVs), end-diastolic velocities (EDVs) of the internal carotid artery (ICA), and ICA/common carotid (CCA) ratios in detecting <50%, 50% to 69% (ICA PSV of 125-230 cm/s), and 70% to 99% (PSV of  $\geq 230$  cm/s) stenosis according to the consensus criteria.

**Results:** The consensus criteria uses a PSV of 125 to 230 cm/s for detecting angiographic stenosis of 50% to 69%, which has a sensitivity of 93%, specificity of 68%, and overall accuracy of 85%. A PSV of  $\geq 230$  cm/s for  $\geq 70\%$  stenosis had a sensitivity of 99%, specificity of 86%, and overall accuracy of 95%. ROC curves showed that the ICA PSV was significantly better (area under the curve [AUC], 0.97) than EDV (AUC, 0.94) or ICA/CCA ratio (AUC, 0.84;  $P = .036$ ) in detecting  $\geq 70\%$  stenosis and  $\geq 50\%$  stenosis. Pearson correlations showed a statistical difference between the correlation of PSV with angiography (0.833; 95% confidence interval [CI], 0.8-0.86), EDV with angiography (0.755; 95% CI, 0.71-0.80), and ICA/CCA systolic ratio with angiography (0.601; 95% CI, 0.53-0.66;  $P < .0001$ ) in detecting 70% to 99% stenosis. Adding the EDV values or the ratios to the PSV values did not improve accuracy. The consensus criteria for diagnosing 50% to 69% stenosis can be significantly improved by using an ICA PSV of 140 to 230 cm/s, with a sensitivity of 94%, specificity of 92%, and overall accuracy of 92%.

**Conclusions:** The consensus criteria can be accurately used for diagnosing  $\geq 70\%$  stenosis; however, the accuracy can be improved for detecting 50% to 69% stenosis if the ICA PSV is changed to 140 to <230 cm/s. (J Vasc Surg 2011;53: 53-60.)

Color duplex ultrasound imaging has become the method of choice for the noninvasive evaluation of extracranial carotid artery disease.<sup>1,2</sup> The degree of carotid artery stenosis is largely based on an analysis of the peak systolic velocity (PSV) or the end-diastolic velocity (EDV), or both, of the carotid artery. The performance and interpretation of carotid duplex ultrasound results vary considerably from one vascular laboratory to another.<sup>2-4</sup> This, along with increasing reports advocating carotid endarterectomy (CEA) based on carotid duplex results alone, without preoperative arteriography,<sup>1,5,6</sup> makes it imperative to verify that the measurements of stenosis derived from the duplex ultrasound studies are as accurate as possible.

Accreditation of noninvasive vascular laboratories, in general, has resulted in an increased degree of standardization of carotid duplex ultrasound examinations; however, a wide range of practice patterns still exists. Clinicians have

relied on published institutional experience for interpreting carotid duplex ultrasound studies at their institutions. Because of this, a panel of experts from several medical specialties convened in October 2002 in San Francisco, California, under the auspices of the Society of Radiologists in Ultrasound, to arrive at a consensus regarding the performance of Doppler ultrasound imaging to aid in the diagnosis of internal carotid artery (ICA) stenosis. This panel of experts recommended a cutoff PSV of the ICA of  $\geq 125$  cm/s and  $\geq 230$  cm/s for predicting angiographic >50% stenosis and >70% ICA stenosis, respectively.<sup>2</sup> It should be noted that the recommended criteria in the Society of Radiologists in Ultrasound report are based on an analysis of several published studies and the experience of the panelists, and they are not a validated criteria.

The purpose of this study was to validate the ultrasound consensus criteria, published in 2003, used to diagnose various severities of carotid stenosis and to analyze its application at our institution. To our knowledge, only one previous report has specifically analyzed the carotid consensus criteria for the diagnosis of  $\geq 70\%$  carotid stenosis.<sup>4</sup>

## METHODS

This study was approved by the Institutional Review Board of Charleston Area Medical Center/West Virginia University, Charleston Division.

**Patient population.** We analyzed 376 arteries in 197 patients (179 patients with bilateral carotid studies and 18 patients with unilateral carotid studies) who underwent

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Competition of interest: none.

Presented at the 2010 Vascular Annual Meeting, Boston, Mass, June 10-13, 2010.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest.

0741-5214/\$36.00

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doi:10.1016/j.jvs.2010.07.045

carotid color duplex ultrasound scanning and arteriography during a 3-year period. Patients were identified from the angiography procedure log, which was searched using the angiography information system, and a list of patients was generated consisting of patients who underwent carotid angiography. This patient list was cross-referenced with the vascular laboratory report archive, which allowed identification of all patients who had carotid duplex ultrasound imaging and angiography  $\leq 30$  days of the duplex scanning.

Indications for carotid duplex ultrasound scanning included hemispheric transient ischemic attacks (TIAs), hemispheric stroke symptoms, nonhemispheric TIAs, and asymptomatic carotid bruits. Carotid angiography was performed for patients with  $\geq 50\%$  symptomatic carotid stenosis,  $\geq 70\%$  asymptomatic carotid stenosis, and for patients with an interpretation discrepancy between the carotid duplex ultrasound study and other imaging modalities (magnetic resonance angiography or computed tomography angiography).

Carotid color duplex ultrasound imaging was performed using an ATL 5000 instrument (Phillips, Bothell, Wash) using a 7- to 4-MHz linear transducer. The common carotid artery (CCA), external carotid artery, and ICAs were identified, and images were taken. Every effort was made to maintain a Doppler angle of incidence at  $60^\circ$ . Doppler waveforms were obtained along the course of these vessels. PSVs and EDVs were recorded in the CCA, ICA, and external carotid arteries. The ICA/CCA PSV ratio was calculated by dividing the PSV of the ICA, which was selected for analysis by the PSV of the CCA. Specific recordings were also taken proximal to the stenosis, at the stenosis site, and immediately distal to the stenosis in the ICA, as seen on real-time imaging. All duplex scans were interpreted by a single investigator (a board-certified vascular surgeon, RPVI) blinded to the arteriographic findings and confirmed by another investigator who is also a board-certified vascular surgeon with the RPVI credential.

Arteriographic evaluation was performed using selective intra-arterial digital subtraction, four-vessel arch aortography, and carotid arteriography. These were also performed by several board-certified vascular surgeons and a vascular interventionalist. The point of maximal stenosis was measured using calipers and then divided by the diameter of the normal distal ICA to calculate the presence of stenosis, according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET).<sup>7</sup>

The unit of analysis in this study was each individual artery. The data used for analysis included the PSV and the EDV of the ICA, the ICA/CCA PSV ratio, and the ICA/CCA EDV ratio. The following arteries were excluded from the final analysis: previous CEA or carotid artery stenting, carotid artery dissection, total carotid artery occlusion, fibromuscular dysplasia, carotid artery distal to significant brachiocephalic stenosis, and patients with inconclusive carotid duplex ultrasound images.

Because the purpose of this study was to validate the consensus panel criteria,<sup>2</sup> the following is a summary of these criteria:

### Primary parameters

- Normal carotid—an ICA PSV of  $<125$  cm/s with no visible plaques
- $<50\%$  stenosis—an ICA PSV of  $<125$  cm/s with visible plaque of  $<50\%$  diameter reduction
- $50\%$  to  $69\%$  stenosis—an ICA PSV range of  $125$  to  $230$  cm/s with a visible plaque estimate of  $\geq 50\%$  diameter reduction
- $>70\%$  stenosis but less than near occlusion—an ICA PSV of  $>230$  cm/s and a plaque estimate of  $>50\%$  diameter reduction
- Near occlusion—high, low, or undetectable PSVs with visible plaques, variable systolic ratio
- Total occlusion—undetectable flow with visible plaque, no detectable lumen

### Other parameters recommended for use only in borderline data

- Normal carotid—an ICA/CCA PSV ratio of  $<2$  and an ICA EDV of  $<40$  cm/s
- $<50\%$  carotid stenosis—an ICA/CCA ratio of  $<2$  and an ICA EDV of  $<40$  cm/s
- $50\%$  to  $69\%$  stenosis—an ICA/CCA PSV ratio of  $2$  to  $4$  and an ICA EDV of  $40$  to  $100$  cm/s
- $>70\%$  stenosis to near occlusion—an ICA/CCA ratio of  $>4$  and an ICA EDV of  $>100$  cm/s

We also analyzed the performance of our previously published standard criteria.<sup>1</sup> The following is a summary of these criteria:

- Normal carotid—an ICA PSV  $<120$  cm/s
- $<50\%$  carotid stenosis—an ICA PSV  $\geq 120$  to  $139$  cm/s
- $\geq 50\%$  stenosis—an ICA PSV of  $\geq 140$  cm/s
- $\geq 70\%$  stenosis—ICA PSV of  $\geq 150$  and EDV of  $\geq 90$  cm/s

**Statistical analysis.** The data analysis was performed using SAS 9.2 (SAS Institute Cary, NC) and Sigmaplot 10 software (Systat Software Inc, San Jose, Calif). A complete descriptive analysis of all available variables was performed. Receiver-operating characteristic (ROC) curve analyses were used to compare angiographic stenosis with PSV, EDV, systolic ratios, and diastolic ratios to establish optimal criteria for determining significant stenosis. The method of DeLong et al<sup>8</sup> was used to compare ROC areas for the paired data. The difference of each area pair, its standard error, and the 95% confidence interval (CI) were computed. This was followed by the  $\chi^2$  statistic for the area comparison and its associated *P* value. Additional statistical analyses included Pearson correlations among PSV, EDV, systolic ratios, and diastolic ratios with angiographic stenosis.

## RESULTS

This study includes 376 carotid arteries in 197 patients (95 men, 102 women), with a mean age of 67.5 years (range, 23-90 years). There were 43 (11.4%) normal ca-

**Table I.** Validation of consensus criteria for duplex ultrasound vs angiographic stenosis

Consensus	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Overall accuracy (95% CI)
Stenosis					
Normal	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)
<50%	88 (83.6-91.7)	99 (95.6-100)	100 (98.7-100)	68 (58.8-77.3)	90 (84-95.9)
50%-69%	93 (89.3-96.1)	68 (58.5-76.9)	86 (82-90.8)	81 (72.2-89.2)	85 (77.2-92.6)
≥70%	99 (97.7-100)	86 (80-92.8)	93 (89.9-96.5)	98 (95.1-100)	95 (90.2-99.1)

CI, Confidence interval; NPV, negative predictive value; PPV, positive predictive value.

**Table II.** Pearson correlation of the consensus criteria for peak systolic velocity, end-diastolic velocity, systolic ratio, and diastolic ratio to angiography

Duplex variable	Overall correlation (95% CI)	Correlation to ≥70%-99% stenosis (95% CI)
Peak systolic velocity	0.81 (0.77-0.85)	0.833 (0.8-0.86)
End diastolic velocity	0.7 (0.64-0.75)	0.755 (0.71-0.80)
Systolic ratio	0.57 (0.49-0.63)	0.601 (0.53-0.66)
Diastolic ratio	0.54 (0.46-0.61)	0.60 (0.53-0.66)

CI, Confidence interval.

rotid arteries, 113 (30%) with <50% stenosis, 86 (22.9%) with 50% to 69% stenosis, 97 (25.8%) with 70% to 99% stenosis, and 37 (9.8%) with total occlusion based on angiography. Duplex ultrasound imaging detected 36 of 37 carotid occlusions. The remaining 339 carotids were further analyzed according to their PSV, EDV, and ICA/CCA PSV ratio. Of 97 arteries with 70% to 99% stenosis on angiography, 94 were detected on duplex ultrasound imaging; however, in three others with 99% stenosis (near occlusion on angiography), two were felt to have <50% stenosis (PSVs were <125 cm/s), and one had 50% to 69% stenosis (PSV of <230 cm/s).

Fifty-three percent of patients had hemispheric TIA symptoms/stroke, and 47% had nonhemispheric TIA symptoms or asymptomatic carotid bruits, or both. Forty-four percent of patients were diabetics, 88% had hypertension, 78% had hypercholesterolemia, 34% were current smokers, 55% were past smokers, and 72% had coronary artery disease.

Table I reports the validation of the consensus criteria for the diagnosis of normal carotid arteries and various severities of carotid stenosis. The sensitivity, specificity, and overall accuracy for the diagnosis of normal carotid arteries and <50% stenosis were reasonably good. However, the sensitivity for the diagnosis of 50% to 69% stenosis was 93%, with a specificity of 68% and an overall accuracy of 85%; and for the diagnosis of ≥70% to 99% stenosis, the sensitivity was 99%, with a specificity of 86%, and an overall accuracy of 95%.

Table II summarizes the Pearson overall correlation of the consensus criteria to angiographic stenosis and the correlation to 70% to 99% stenosis. As seen in this Table, which shows the four variables considered in the consen-

sus criteria (ICA PSV, ICA EDV, ICA/CCA systolic ratio, and the ICA/CCA diastolic ratio), the PSV has the best overall correlation to angiography (0.813) and also the best correlation for the diagnosis of 70% to 99% stenosis (0.833).

When applying the  $\kappa$  statistic and using the PSV cutoff as defined by the consensus criteria and compared with angiography, the simple  $\kappa$  was 0.6870 (95% CI, 0.623-0.750), with a weighted  $\kappa$  of 0.758 (95% CI, 0.705-0.810). This is in contrast to a simple  $\kappa$  of 0.535 (95% CI, 0.461-0.609), with a weighted  $\kappa$  0.630 (95% CI, 0.565-0.695) when using the EDV cutoff value.

Table III summarizes various PSVs, EDVs, systolic ratios, and diastolic ratios as a single parameter or in combination for detecting ≥70% to 99% stenosis. As noted in this Table, a PSV of >230 cm/s was the most sensitive in diagnosing ≥70% to 99% stenosis. It should also be noted that a PSV >280 cm/s had a better positive predictive value (PPV) of 97% and an overall accuracy of 95%; however, the sensitivity was down to 95% and the negative predictive value (NPV) was 89%. When the PSV was >230 with an EDV >100 or systolic ratio >4, the sensitivity was 91% with a specificity of 97%; however, the PPV was 99% and the NPV was 78%, with an overall accuracy of 93%.

Table IV summarizes the ICA PSV and EDV cutoffs for the diagnosis of ≥50% and ≥70% to 99% stenosis. As noted, if the PSV was increased from ≥125 cm/s (as proposed by the consensus criteria) to ≥140 cm/s, the sensitivity in detecting ≥50% stenosis would decrease from 97% to 94%; however, the specificity would improve from 85% to 91% and the overall accuracy from 89% to 92%. Similarly, if the cutoff were changed to ≥137 cm/s, the sensitivity would be 96%, with a specificity of 91%, and an overall accuracy of 93%. As also noted, when using the 230 cm/s cutoff for detecting ≥70% to 99% stenosis, as recommended by the consensus criteria, the sensitivity was 99%, the specificity was 86%, and the overall accuracy was 94%. A PSV of 252 cm/s had a sensitivity of 97%, specificity of 91%, and overall accuracy of 95%.

**ROC analysis.** Figs 1 to 3 are ROC curves plotting sensitivity against specificity for diagnosing normal carotid arteries, ≥50% stenosis, and ≥70% to 99% stenosis, respectively. As noted in these Figures, the PSV was statistically significantly better than EDVs and ICA/CCA systolic or diastolic ratios in diagnosing normal carotid arteries or ≥50% and ≥70% stenosis. The area under the curve (AUC)

**Table III.** Summary of various velocities and ratios for detecting  $\geq 70$ -99% stenosis

Variable	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Overall accuracy (95% CI)
PSV >230	99 (97-100)	86 (79.8-92.7)	93 (89.9-96.5)	97 (93.5-100)	94 (89.7-98.9)
PSV >240	97 (95-99.4)	87 (80.2-93.2)	94 (90.5-96.9)	94 (89.0-98.6)	94 (88.9-98.5)
PSV >280	95 (92.3-97.9)	93 (88.4-98.5)	97 (95.1-99.4)	89 (82.4-95)	95 (90.2-99.1)
Systolic ratio >2.75	87 (82.8-91.3)	85 (76.6-92.6)	95 (91.6-97.6)	68 (58.8-77.3)	86 (79.7-93.3)
Systolic ratio >3	86 (81.3-90)	91 (84.2-97.9)	97 (95.1-99.4)	63 (53.3-72.5)	87 (80.1-93.5)
Diastolic ratio >3	87 (82.6-91.2)	80 (71.9-89.1)	93 (89.3-96.2)	68 (58.8-77.3)	85 (78.2-92.3)
Diastolic ratio >3.5	86 (81.9-90.5)	89 (81.4-96.1)	96 (93.9-98.8)	65 (55.5-74.4)	87 (80.1-93.5)
PSV >230 and EDV >50	97 (95.0-99.4)	88 (82.2-94.6)	95 (91.6-97.6)	94 (89-98.6)	94 (89.7-98.9)
PSV >230 and/or EDV >90	99 (97-100)	86 (79.8-92.7)	93 (89.9-96.5)	97 (93.5-100)	94 (89.7-98.9)
PSV >220 and diastolic ratio >2.5	88 (84.2-92.4)	87 (80-94.7)	95 (92.7-98.2)	71 (62.1-80.2)	88 (81.6-94.5)
PSV >230 and/or diastolic ratio >5.5	99 (97-100)	86 (79.8-92.7)	93 (89.9-96.5)	97 (93.5-100)	94 (89.7-98.9)
PSV >220 and systolic ratio >2.5	89 (84.8-92.8)	91 (84.5-97.3)	97 (94.5-99.1)	72 (63.3-81.1)	89 (83.2-95.5)
PSV >230 and/or systolic ratio >4.5	99 (96.9-100)	85 (78.9-92)	93 (89.3-96.2)	97 (93.5-100)	94 (89.3-98.7)
EDV >50 and systolic ratio >2.5	88 (84.3-92.4)	88 (81.4-95.6)	96 (93.3-98.5)	71 (62.1-80.2)	88 (82-94.8)
EDV >70 and/or systolic ratio >4	97 (94.2-99.1)	83 (76.3-90.4)	92 (88.3-95.5)	93 (87.6-97.9)	92 (86.8-97.5)
EDV >100 and/or systolic ratio >4	91 (87.6-94.8)	96 (92-100)	99 (97-100)	78 (70-86.6)	92 (87.2-97.7)
PSV >230 and EDV >100 or systolic ratio >4	91 (87.7-94.8)	97 (93.9-100)	99 (97.9-100)	78 (70.2-86.6)	93 (87.6-97.9)
SR >2 and DR >3.5	86 (81.6-90.3)	90 (82.7-97)	97 (94.5-99.1)	64 (54.4-73.5)	87 (80.1-93.5)
SR >3.5 and/or diastolic ratio >3	87 (83.2-91.7)	78 (69.5-86.8)	91 (87.7-95.1)	70 (61-79.2)	85 (77.8-92)

CI, Confidence interval; EDV, end-diastolic velocity; NPV, negative predictive value; PPV, positive predictive value; PSV, peak systolic velocity.

**Table IV.** Sensitivity, specificity, and overall accuracy for velocity cutoffs for the diagnosis of  $\geq 50$ % and 70% to 99% stenosis

Variable	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Overall accuracy (95% CI)
$\geq 50$ % stenosis					
PSV >125	97 (94.2-100)	85 (79.8-89.6)	77 (69.8-83.9)	98 (96.5-100)	89 (84.4-93.6)
PSV >140	94 (89.7-98)	91 (87.5-95.5)	88 (83.1-93.8)	96 (92.5-98.6)	92 (88.6-96.3)
PSV >150	85 (79.7-91)	94 (90.5-97.6)	93 (88.4-97.1)	88 (83-92.6)	90 (85.5-94.3)
PSV >137	96 (92.6-99.4)	91 (86.6-94.8)	87 (81.3-92.6)	97 (94.8-99.6)	93 (89-96.6)
$\geq 70$ -99% stenosis					
PSV >230	99 (97-100)	86 (79.8-92.7)	93 (89.9-96.5)	98 (93.5-100)	94 (89.7-98.9)
PSV >240	97 (95-99.4)	87 (80.2-93.2)	94 (90.5-96.9)	94 (89-98.6)	94 (88.9-98.5)
PSV >252	97 (95.1-99.4)	91 (85.4-96.6)	96 (93.3-98.5)	94 (89-98.6)	95 (91.1-99.5)
PSV >280	95 (92.3-97.9)	93 (88.4-98.5)	97 (95.1-99.4)	89 (82.4-95)	95 (90.2-99.1)
EDV >70	96 (93.1-98.5)	85 (77.7-91.6)	93 (89.3-96.2)	91 (85-96.5)	92 (86.8-97.5)
EDV >87	93 (89.9-96.4)	95 (90.8-99.8)	98 (96.4-100)	84 (76.1-90.9)	94 (88.9-98.5)

CI, Confidence interval; EDV, end-diastolic velocity; NPV, negative predictive value; PPV, positive predictive value; PSV, peak systolic velocity.

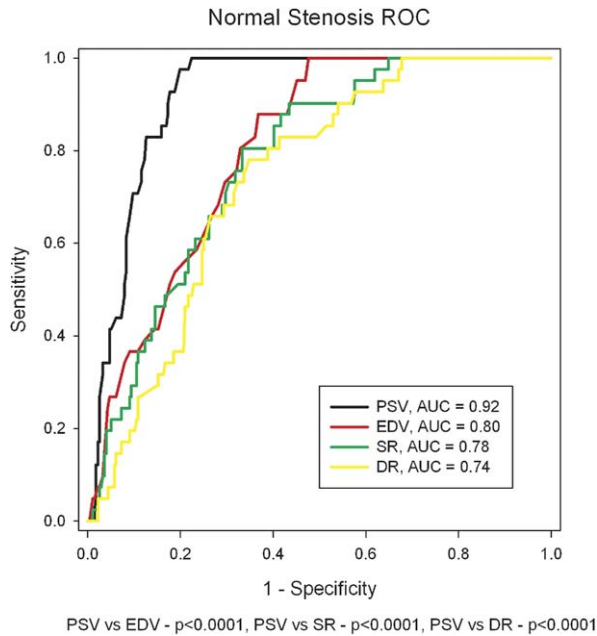
for PSV, EDV, and systolic ratios for normal carotids were 0.92, 0.80, and 0.78, respectively ( $P < .0001$ ). The AUC for PSV, EDV, and systolic ratios for  $\geq 50$ % stenosis were 0.97, 0.88, and 0.84 ( $P < .0001$ ). The AUC for PSV, EDV, and systolic ratios for  $\geq 70$ % stenosis were 0.97, 0.94, and 0.84 ( $P = .0363$ ).

Table V summarizes the performance of our present standard criteria, which we published previously.<sup>1</sup> As noted, the sensitivity, specificity, and overall accuracy for detecting 50% to 69% stenosis were 96%, 82%, and 92%, respectively. The sensitivity, specificity, and overall accuracy for the diagnosis of  $\geq 70$ % to 99% stenosis were 99%, 96%, and 98%, respectively. Our standard criteria were somewhat better than the consensus criteria, specifically for detecting 50% to 69% stenosis.

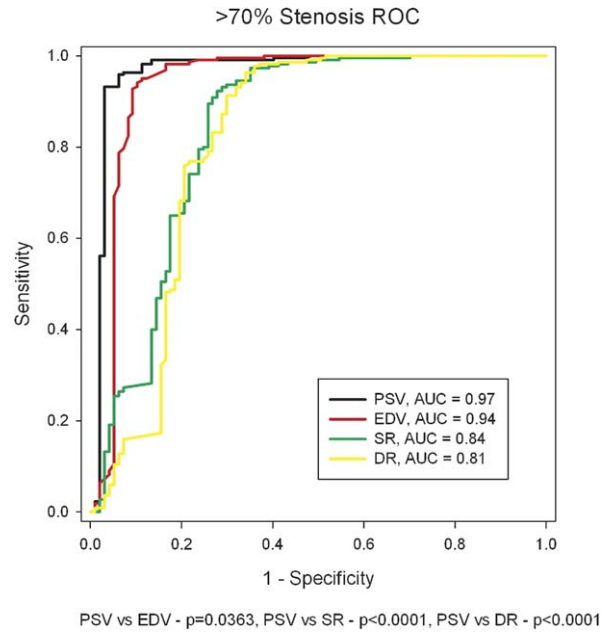
## DISCUSSION

The most common parameters used to describe the percentage of carotid artery stenosis are the PSV, EDV, ICA/CCA PSV ratio, and the description of the plaque itself.<sup>1,2,4,7</sup> In 1997, we published our standard criteria to define stenosis based on these variables. We correlated PSVs and EDVs to the angiographic findings. For the diagnosis of  $\geq 50$ % stenosis, which was the cutoff value used in the NASCET for symptomatic patients, a PSV >140 cm/s of the ICA had a very high sensitivity, specificity, and PPV. A PSV of >150 cm/s with an EDV >90 cm/s was very accurate in detecting >70% to 99% stenosis.<sup>1</sup>

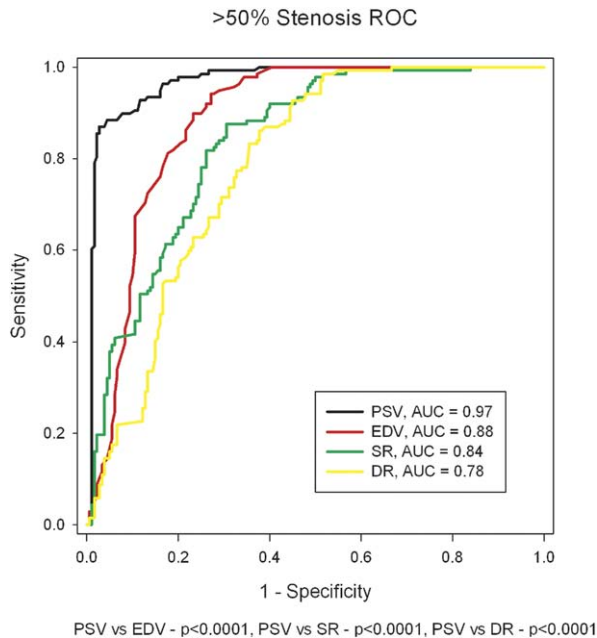
Several other classification systems have been used, offering different carotid velocity threshold numbers to define carotid stenosis<sup>2,3,9-15</sup>; however, no standardized



**Fig 1.** Sensitivity vs specificity receiver-operating characteristic (ROC) curves comparing peak systolic velocity (PSV), end-diastolic velocity (EDV), diastolic ratio (DR), and systolic ratio (SR) for  $\geq 70\%$  to 99% stenosis. AUC, Area under the curve.



**Fig 3.** Receiver-operating characteristic (ROC) curves comparing peak systolic velocity (PSV), end-diastolic velocity (EDV), diastolic ratio (DR), and systolic ratio (SR) for  $\geq 70\%$  to 99% stenosis. AUC, Area under the curve.



**Fig 2.** Sensitivity vs specificity receiver-operating characteristic (ROC) curves comparing peak systolic velocity (PSV), end-diastolic velocity (EDV), diastolic ratio (DR), and systolic ratio (SR) for  $\geq 50\%$  stenosis. AUC, Area under the curve.

system had been established until 2002,<sup>2</sup> when the Carotid Consensus Criteria was developed by a panel of experts in the fields of both radiology and vascular surgery. The panel attempted to review all pertinent articles regarding criteria for defining carotid stenosis to derive a standardized system.<sup>2</sup> The difficulty is that there is no uniformity in interpretation criteria, and different vascular laboratories may report different results for similar Doppler velocity values. Therefore, the objective of the consensus panel was to achieve consistency and provide one system to delineate carotid artery stenosis. It is to be noted that the consensus criteria were not validated and one of its purposes is to serve as a starting point for vascular laboratories that have not validated their own criteria. Therefore, internal validation of carotid duplex interpretation criteria is essential.

The consensus panel recommended that the PSV should be the primary parameter in assessing the percentage of carotid stenosis because it is reproducible and has been found to have high rates of sensitivity, specificity, and PPVs across most studies. They determined that a PSV of  $\geq 125$  to 230 cm/s was consistent with  $\geq 50\%$  to 69% stenosis. They also felt that a PSV  $> 230$  cm/s was consistent with the diagnosis of  $\geq 70\%$  to 99% stenosis. Other parameters that were found to be helpful included the ICA/CCA PSV ratios and the ICA EDVs, both of which could vary depending on different clinical factors and were thus considered to be useful adjuncts; for example, an EDV of  $> 40$  cm/s and an ICA/CCA PSV ratio of  $> 2$  were consistent with 50% to 69% stenosis, and an EDV of  $> 100$  cm/s and a ratio of  $> 4$  were consistent with 70% to 99% stenosis.<sup>2</sup>

**Table V.** Sensitivity, specificity, and overall accuracy validation of our present standard criteria

<i>Standard criteria</i>	<i>Sensitivity (95% CI)</i>	<i>Specificity (95% CI)</i>	<i>PPV (95% CI)</i>	<i>NPV (95% CI)</i>	<i>Overall accuracy (95% CI)</i>
Normal stenosis	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)	100 (100-100)
<50% stenosis	93 (89.8-96.4)	94 (89.2-99.1)	98 (95.8-99.7)	84 (76.1-90.9)	93 (88.4-98.3)
50%-69% stenosis	96 (94.0-98.9)	82 (73.6-89.5)	93 (89.4-96.1)	90 (84-96.7)	92 (86.3-97.9)
>70% stenosis	99 (97.1-100)	96 (91.9-99.8)	98 (96.4-100)	97 (93.4-100)	98 (94.9-100)

CI, Confidence interval; NPV, negative predictive value; PPV, positive predictive value.

To date, only one other published study has applied the consensus criteria to their center's data to determine its true accuracy by correlating it with the angiographic findings. Braun et al<sup>4</sup> examined their own institution's data between 2000 and 2002 and analyzed >400 arteries to determine if the consensus criteria could be used successfully. They primarily analyzed patients with  $\geq 70\%$  stenosis and concluded that when the consensus criteria were used in their patient population, the accuracy was similar to the consensus panel report. A PSV  $>240$  cm/s for their group was slightly more accurate for specificity; however, a cutoff of 230 cm/s was still highly accurate. Other duplex parameters (EDV, ICA/CCA PSV and EDV ratios) were used in their study, but the PSV yielded the highest Pearson correlate. Therefore, they concluded that other parameters should only be used in borderline situations, which was similar to what was recommended by the consensus criteria panel.<sup>4</sup>

Our present study analyzed 376 carotid arteries to assess the validity of the consensus criteria as well. Unlike Braun et al, our group's analysis included a near-equal distribution in our sample size for 50% to 69% stenosis and 70% to 99% stenosis. Our group's analysis also included data sets for medical comorbid conditions that may affect results, including gender, coronary artery disease, hypertension, and diabetes mellitus. Again, our study showed that the parameter with the highest Pearson correlate to angiography was the PSV (0.813), in contrast to both EDV (0.7) and ICA/CCA PSV ratios (0.57,  $P < .0001$ ). A PSV of  $>230$  cm/s was the most sensitive in the diagnosis of 70% to 99% stenosis, and adding other parameters (EDV or ratios) did not improve the overall accuracy. Using a PSV of  $>230$  cm/s with an EDV of  $>100$  cm/s or a systolic ratio of  $>4$  would improve the PPV to 99% and the specificity to 97%; however, the sensitivity would drop to 91%, and the overall accuracy was similar (93%). Meanwhile, having a PSV increase to  $>280$  cm/s will produce an overall accuracy of 95% and a PPV value of 97%; however, the sensitivity would drop to 95%.

In addition, increasing the threshold of the PSV to 252 cm/s improved the specificity from 86% to 91%; however, the sensitivity dropped from 99% to 97%. In regards to  $\geq 50\%$  stenosis, increasing the PSV threshold from 125 to 140 cm/s (137 cm/s being the optimal value) would decrease the sensitivity by 3%; however, it would increase the specificity from 85% to 91% and the PPV value from 77% to 88%, with an accompanying increase in overall accuracy from 89% to 92%.

When we analyzed the performance of our previously published standard criteria,<sup>1</sup> the sensitivity, specificity, and overall accuracy in detecting 50% to 69% stenosis were 96%, 82%, and 92%, respectively. Meanwhile, the sensitivity, specificity, and overall accuracy for the diagnosis of 70% to 99% stenosis were 99%, 96%, and 98%, respectively. It should be noted that these standard criteria were somewhat better than the consensus criteria in our study, particularly in the diagnosis of 50% to 69% stenosis.

Similarly, Shaalan et al<sup>16</sup> recently reported the results of their study on the reappraisal of velocity criteria for carotid bulb/ICA stenosis utilizing high-resolution B-mode ultrasound imaging validated with computed tomography angiography and concluded that substantially higher PSVs (155 vs 125 cm/s) were more accurate for detecting  $\geq 50\%$  bulb/ICA stenosis. The combination of a PSV of  $\geq 155$  cm/s and an ICA/CCA ratio of  $\geq 2$  had excellent predictive values for this category of stenosis. They also concluded that a PSV of  $\geq 370$  cm/s, an EDV of 140 cm/s, and an ICA/CCA ratio of  $\geq 6$  were equally reliable in the diagnosis of  $\geq 80\%$  bulb/ICA stenosis. Although the overall accuracy was better in our previously published study<sup>1</sup> and in the Shaalan study,<sup>16</sup> particularly in the diagnosis of 50% to  $<70\%$  stenosis, we believe application of the consensus criteria is more appropriate for the detection of  $\geq 70\%$  stenosis for the sake of standardization nationwide.

The consensus report also indicated that the ICA/CCA PSV ratio and the ICA EDV are useful parameters when the ICA PSV may not be representative of the extent of carotid disease because of technical or clinical factors, such as the presence of contralateral high-grade stenosis or occlusion, discrepancy between visual assessment of the carotid plaque and the ICA PSV, elevated CCA velocity, low cardiac output, or hyperdynamic cardiac state. It should be noted that patients with low cardiac output would have a low ICA PSV, which is disproportionate when compared with the ICA/CCA PSV ratio. In these situations, the clinician must rely on the presence of the plaque and perhaps the ICA/CCA ratio rather than the absolute ICA PSV. Our present study showed no improvement in the overall accuracy by adding the ICA EDV values or the ICA/CCA ratio, or both, to the PSVs; however, as noted earlier, these must be taken into consideration in certain clinical circumstances.

One limitation of our study is that the patient population may be different from what one may expect when looking to the population as a whole; however, as noted in the distribution of patients, there was a reasonable distribution between normal carotids,  $<50\%$ , 50% to 69%, and

70% to 99% carotid stenosis. Also, as with any other study involving imaging, there will always be some degree of technician-dependent variability. Our practice is to standardize the way in which each test is performed to minimize this variable, but some element will remain.

Finally, the PSV threshold of 230 cm/s for detecting  $\geq 70\%$  stenosis can be used before CEA for symptomatic patients since surgery has been proven to be beneficial, even for  $\geq 50\%$  symptomatic stenosis<sup>7</sup>; however, because the PPV of this threshold is 93% (95% CI, 89.9%-96.5%), its use for asymptomatic patients should be considered with caution. A higher PSV (eg,  $\geq 280$  cm/s), which has a PPV of 97%, or a PSV of  $>230$  cm/s with an EDV of  $>100$  cm/s, or a systolic ratio of  $>4$  (PPV of 99%) may be considered because the benefit/risk ratio in these patients is limited.

It is important to note that the data obtained by individual vascular laboratories will vary across the country. Differences in equipment, abilities, and consistencies of vascular technicians, and reader interpretations, will cause variability from laboratory to laboratory.<sup>1</sup> Therefore, each laboratory must adapt a method that uses the equipment they use and has validated their method when using proposed new duplex criteria.

## CONCLUSIONS

The consensus criteria can be used accurately for the diagnosis of  $\geq 70\%$  stenosis; however, the accuracy in detecting 50% to 69% stenosis can be improved if the ICA PSV is changed to 140 to  $<230$  cm/s.

## AUTHOR CONTRIBUTIONS

Conception and design: AA, MS, AJ, PS, AM, LD, ME  
Analysis and interpretation: AA, LD  
Data collection: MS, AJ, TK  
Writing the article: AA, MS, PS, AM  
Critical revision of the article: AA, LD  
Final approval of the article: AA, MS, AJ, PS, AM, LD, TK, ME  
Statistical analysis: AA, LD  
Obtained funding: Not applicable  
Overall responsibility: AA

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Submitted May 24, 2010; accepted Jul 20, 2010.

## DISCUSSION

**Dr Gregory Moneta** (*Portland, Ore*). Whenever you plot angiographic stenosis vs peak systolic velocities (PSVs), PSVs will tend to increase with increasing angiographic measurements of stenosis, but there will also be a relatively wide range of PSVs correlating with specific severities of angiographic stenosis from one patient to the next. Therefore, what are the confidence intervals around the PSVs that you found correlating with specific levels of internal carotid artery (ICA) angiographic stenosis; specifically those levels of ICA stenosis that are borderline for repair in

asymptomatic patients? Does an isolated PSV of 230 cm/s predict a 70% angiographic ICA stenosis as well as a PSV of say 300 cm/s, and what positive predictive values are acceptable for a specific PSV in predicting a  $>70\%$  angiographic ICA stenosis when selecting asymptomatic patients for prophylactic carotid intervention based on duplex scanning alone?

**Dr Ali F. AbuRahma**. Thanks, Greg, for your question. Based on our analysis, a PSV of  $>230$  cm/s has a PPV of 93% (CI, 89.9-96.5) in detecting  $>70\%$  stenosis. However, for asymptom-

atic stenosis, you may prefer to use a PSV of  $>280$  cm/s, which has a PPV of 97% (CI, 95.1-99.4) or a PSV of  $>230$  cm/s and an EDV of  $>100$  cm/s or a systolic ratio of  $>4$ , which has a PPV of 99% (CI, 97-100).

**Dr Marat Goldenberg** (*Chester, Pa*). How often would you recommend doing corollary studies to confirm the accuracy of

your lab? Would you use a computed tomography (CT) scan or an angiogram to validate the results?

**Dr AbuRahma.** This study looks at conventional angiography, but in your own lab, I would recommend CT instead of magnetic resonance angiography. You have to choose a sample size that you are comfortable with, using data from your own lab.

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