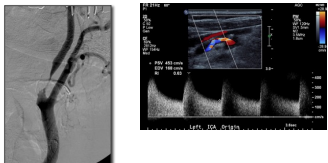



A Review of the IAC Consensus Criteria: How To Transition And Incorporate It Into Your Practice




Heather Gornik, MD, RVT, RPVI



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Disclosure



- Heather Gornik, MD – former Board member IAC Vascular Testing (IAC-VT), IAC
- Have been on the carotid diagnostic criteria journey with my IAC compadres for nearly 15 years



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The ICA Criteria Crisis

- Historically there have been no universal standard criteria for ICA stenosis
 - IAC had historically been OK with this, as long as each lab **validates** the criteria it uses
- Criteria for ICA stenosis vary from lab to lab
- Methods of angiographic correlation for ultrasound criteria vary (ECST vs. NASCET)
- This situation is confusing for technologists, interpreting physicians, referring doctors (who read reports), and patients
 - “My carotid went from 50-69% to 60-79% blocked in a few months!”
 - Problem more relevant in this era of patient direct access to EMRs and their own medical reports

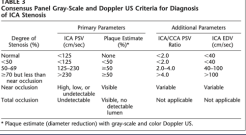



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2002 Society of Radiologists in Ultrasound Consensus Conference (SRUCC)

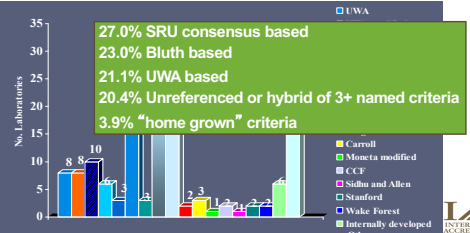
Carotid Artery Stenosis: Gray Scale and Doppler US Diagnosis—Society of Radiologists in Ultrasound Consensus Conference¹

- Seminal paper in vascular ultrasound
- Addressed many topics beyond diagnostic criteria (e.g., scanning technique, sample volume placement, angle correction, recommends NASCET-based methods for angio correlations, QI)
- Proposed SRUCC criteria were an amalgam of individual validated parameters for ICA stenosis from other published diagnostic criteria (Strandness/UWa, NASCET, Bluth), not validated together vs. angiography
 - Some of these parameters were developed in studies that used ECST-based angiogram measurements




Grant E. et al. Radiology. 2003;229:340.

2010 ICAVL Survey 152 Vascular Labs; >16 Diagnostic Criteria



27.0% SRU consensus based
23.0% Bluth based
21.1% UWA based
20.4% Unreferenced or hybrid of 3+ named criteria
3.9% “home grown” criteria



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Gornik H, Hutchisson, M, et al. Presented at AHA 2011.

The Long Journey

2014 IAC-VT white paper on carotid criteria¹


- Use of SRU Consensus criteria recommended by IAC unless labs have internally validated their own criteria
- IAC Carotid Diagnostic Criteria Committee formed to *internally validate and make recommendations for specific ICA diagnostic criteria to be used by all facilities applying for accreditation. The future recommended diagnostic criteria may or not be identical to the SRU consensus criteria*

2014-2020 More work than we ever imagined

- Research protocol development, site recruitment, contracts and IRBs, database development, case study collection and uploading, image review, data analysis, committee discussion

5.2021 Complete study results published *Vascular Medicine*

www.intersocietal.org/Vascular/forms/IACCarotidCriteriaWhitePaper1-2014.pdf



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IAC-VT Carotid Diagnostic Criteria Committee

- Jim Benenati
- Nirvikar Dahiya
- Heather Gornik
- Naomi Hamburg
- Anne Marie Kupinski
- Steve Leers
- Mike Lilly
- Joann Lohr
- Larry Needleman
- John Pellerito
- Ken Rholl
- Tatjana Rundek
- Melissa Vickery
- Marge Hutchisson (IAC)
- Hannah Gardener, PhD, study statistician

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11 Sites and Investigators Contributing Case Materials

- Cleveland Clinic, Cleveland, Ohio (Heather L Gornik, Alia Grattan)
- Novant Health Heart and Vascular Institute, Charlotte, North Carolina (Kelly Hicks)
- Riverside Radiology, Columbus, Ohio (Lucy LaPerna)
- TriHealth, Cincinnati, Ohio (Joann M Lohr)
- University at Buffalo, Buffalo, New York (Adnan Siddiqui)
- University Hospitals and Clinics, Lafayette, Louisiana (Michel Comeaux)
- University of Maryland, Baltimore, Maryland (Michael P Lilly)
- University of Miami, Miami, Florida (Tatjana Rundek)
- University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania (Steven A Leers)
- University of Southern California, Los Angeles California (Susana Robison)
- University of Washington, Seattle, Washington (R Eugene Zierler)

Gornik HL, et al. Vasc Med. 2021.26:515.

5.2021 IAC Carotid Diagnostic Criteria Study

Optimal Aorta

VASCULAR MEDICINE

Optimization of duplex velocity criteria for diagnosis of internal carotid artery (ICA) stenosis. A report of the International Accreditation Commission (IAC) Vascular Testing Division Carotid Diagnostic Criteria Committee

Heather L Gornik¹, Tatjana Rundek², Hannah Gardener³, James P Benenati⁴, Nirvikar Dahiya⁵, Naomi H Homburg⁶, Alan Rhee Agapay⁷, Steven A Leers⁸, Michael P Lilly⁹, Joann M Lohr¹⁰, John S Pellerito¹¹, Kenneth S Rhee¹², Melissa A Zierler¹³, Rong S Hershenson¹⁴

and Kenneth Homburg¹⁵ on behalf of the IAC Vascular Testing Division Carotid Diagnostic Criteria Committee

- Multi-center validation study of original SRU consensus criteria vs. catheter angiography (NASCET)
- N=167 patients; 299 ICA sides
- Physician interpretation (2+ expert reviewers) using SRUCC vs. catheter angiography (NASCET)
- Only moderate agreement of categorization of ICA stenosis by SRUCC vs. angiography (kappa = 0.42).
- SRUCC **overestimated** degree of ICA stenosis compared to angiography (NASCET)
 - For ICA lesions of < 50% stenosis by angiography, % ICA stenosis **overestimated** by SRUCC 36% of time
 - Among ICA lesions interpreted as 50–69% stenosis by SRUCC, 69% had < 50% stenosis by angiography
 - For ICA lesions of 50–69% by angiography, overestimation of severity of stenosis (> 70% ICA) by SRUCC 54% of time

Gornik HL, et al. Vasc Med. 2021.26:515.

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5.2021 IAC Carotid Diagnostic Criteria Study

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Table 4. ROC analysis – sensitivity, specificity, PPV, and accuracy of duplex ultrasound velocity parameters as specific values for prediction of ≥ 50% versus < 50% ICA stenosis by catheter angiography (NASCET)

Velocity parameter threshold	Sensitivity	Specificity	PPV	NPV	Accuracy
Flow: SRUCC					
PSV ≥ 125 cm/sec	0.978	0.642	0.547	0.985	0.745
PSV ≥ 125 cm/sec + 2	0.964	0.640	0.528	0.976	0.689
PSV ≥ 125 cm/sec + 2 ratio ≥ 2	0.945	0.645	0.724	0.971	0.675
Health parameters					
PSV ≥ 125 cm/sec	0.978	0.642	0.547	0.985	0.745
PSV ≥ 140 cm/sec	0.964	0.702	0.688	0.979	0.761
PSV ≥ 140 cm/sec	0.952	0.771	0.649	0.975	0.828
PSV ≥ 150 cm/sec	0.944	0.791	0.647	0.970	0.828
PSV ≥ 180 cm/sec	0.931	0.816	0.682	0.965	0.852
PSV ≥ 180 cm/sec	0.899	0.849	0.708	0.949	0.851
PSV ≥ 180 cm/sec + 2	0.901	0.845	0.728	0.971	0.841
PSV ≥ 140 cm/sec + 2	0.931	0.823	0.726	0.944	0.824
PSV ≥ 140 cm/sec + 2 ratio ≥ 2	0.920	0.820	0.741	0.941	0.829
PSV ≥ 175 cm/sec + 2	0.908	0.865	0.776	0.956	0.875
PSV ≥ 180 cm/sec + 2	0.897	0.870	0.750	0.951	0.879

- Extensive ROC velocity analyses
- Goal: identify parameters that met prespecified requirements for > 90% SENS, > 80% SPEC, **and** > 80% Accuracy
- Raising PSV threshold from 125 to 180 cm/sec increased diagnostic performance of duplex for ≥ 50% ICA stenosis
- Combination PSV ≥ 125 cm/sec **plus** ICA/CCA PSV ratio ≥ 2 also met prespecified requirements
- Study underpowered to validate/further refine SRUCC for ≥ 70% ICA stenosis
- Modification to SRUCC subsequently proposed by IAC

Gornik HL, et al. Vasc Med. 2021.26:515.

10.2021 IAC Carotid Diagnostic Criteria Communication

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IAC Vascular Testing Communication
Updated Recommendation for Carotid Stenosis Interpretation Criteria

Recommended Modification of the SRU Consensus Conference Criteria for Internal Carotid Artery Stenosis for Implementation in IAC-Accredited Vascular Laboratories

Degree of Stenosis, %	Primary Parameters		Additional Parameters	
	ICA PSV, cm/sec	Plaque Estimate, % ^a	ICA/CCA PSV Ratio	ICA/CCA PSV, cm/sec
Normal	< 120	None	< 2.0	< 40
1-49%	120-149	None	< 2.0	< 40
50-69%	150-199	< 25%	< 2.0	< 40
≥ 70% (no stenosis exclusion)	≥ 200	< 25%	< 2.0	< 40
≥ 70% (stenosis exclusion)	≥ 200	> 25%	< 2.0	< 40
≥ 70% (stenosis exclusion)	≥ 200	> 25%	> 2.0	> 40
≥ 70% (stenosis exclusion)	≥ 200	> 25%	> 2.0	> 40
≥ 70% (stenosis exclusion)	≥ 200	> 25%	> 2.0	> 40

- IAC VT now recommends general adoption of modified SRU criteria incorporating the higher PSV threshold value of 180 cm/sec for 50% diameter reducing ICA stenosis.
- IAC Vascular Testing recognizes there may be selected cases with 50-69% ICA stenosis in which PSV < 180 cm/sec, but there is elevated ICA/CCA PSV ratio > 2.0 with significant plaque and other features of stenosis (e.g., post-stenotic turbulence).
- IAC Vascular Testing recommends the use of these modified criteria for carotid interpretation at this time.
- Broad acceptance of this recommendation will enhance the accuracy of the detection of clinically-relevant ICA stenoses and further reduce the variability in grading of ICA stenosis on duplex studies by IAC-accredited vascular labs.

<https://intersocietal.org/vascular-testing/>

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Journey to the Present: 2024 Standard Revision

- Summer-fall, 2023 IAC-VT Board reviewed past 10+ years of progress and 2023 survey results
- Updated communication on carotid criteria released by IAC November, 2023:
 - Based upon these data...IAC Vascular Testing now strongly recommends general adoption of modified SRU criteria incorporating the higher PSV threshold value of 180 cm/sec for 50% diameter reducing ICA stenosis.
 - IAC Vascular Testing strongly recommends the use of these modified criteria for carotid interpretation at this time.

Strongly Recommended Modification of the SRU Consensus Conference Criteria for Internal Carotid Artery Stenosis for Implementation in IAC-Accredited Vascular Laboratories

Degree of Stenosis, %	Primary Parameters		Additional Parameters	
	ICA PSV, cm/sec	Plaque Estimate, % ^a	ICA/CCA PSV Ratio	ICA/CCA PSV, cm/sec
Normal	< 180	None	< 2.0	< 40
1-49%	180-209	None	< 2.0	< 40
50-69%	210-249	< 25%	< 2.0	< 40
≥ 70% (no stenosis exclusion)	≥ 250	< 25%	< 2.0	< 40
≥ 70% (stenosis exclusion)	≥ 250	> 25%	< 2.0	< 40
≥ 70% (stenosis exclusion)	≥ 250	> 25%	> 2.0	> 40

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2024 EC Standard Revision


IAC-VT Extracranial Carotid standards posted for public comment and ultimately implemented in February, 2024

1.6B Abnormalities will require additional images and waveforms that demonstrate the severity, location, extent and whenever possible etiology of the abnormality present.

Internal Carotid Artery (ICA) Stenosis/Disease – These criteria must state how velocity measurements, ICA/CCA peak-systolic velocity ratio, spectral Doppler waveform analysis and imaging are used to document the severity, location, extent and whenever possible etiology.

Comment: IAC strongly recommends use of the **IAC-modification to the SRU Consensus Criteria for Interpretation of Internal Carotid Artery Stenosis.**


<https://intersocietal.org/wp-content/uploads/2024/03/IACVascularTestingStandards2024.pdf>



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Preparing For Implementation: Expect Reclassification


- Tafreshi S, et al. RSNA 2002
- “Real world” data from Northwell Health (J. Pellerito lab)
- Retrospective analysis of 2 years of carotid duplex scans; 15,810 studies in 7905 patients
- Using original SRUCC criteria, 1311 50-69% ICA stenoses identified
- Of these 1311, only 615 met updated IAC SRUCC criteria for 50-69% stenosis
 - 1. PSV > 180 cm/sec or 2. PSV 125-180 cm/sec + ICA/ICA PSV ratio ≥ 2
- IAC modified SRUCC reclassified **53% (696/1311)** of 50-69% ICA stenoses to < 50% stenosis category



Tafreshi S, et al. RSNA 2002

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IMPLEMENTATION: LESSONS LEARNED FROM THOSE WHO HAVE DONE IT



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2023 IAC Carotid Diagnostic Criteria Lab Survey

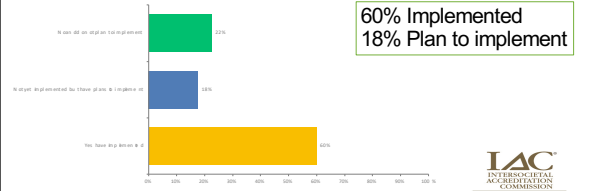

- Objective: to assess awareness of research paper and 10.2021 communication; to **assess uptake** of criteria among accredited labs and **experience of those who have implemented**
- Survey of medical and technical directors of all vascular laboratories accredited in EC testing as of 12.2022
- 2,307 email surveys sent from 1,262 accredited labs in January 2023
- N=581 respondents, 25.2% response rate
 - 173 Medical Directors (~30%)
 - 408 (~70%) Technical Directors
 - TD and MD from same lab may have responded (estimated 55 pairs from same lab)
 - Estimate 526 labs represented (~42% representation of EC accredited labs)

Hutchisson, M. et al. Presented at SVU 2023.

As of today, has your facility implemented the 2021 IAC recommended carotid stenosis interpretation criteria (a modification of the SRU Consensus Criteria) into daily practice?

Answered: 489 respondents *familiar* with criteria

60% Implemented
18% Plan to implement

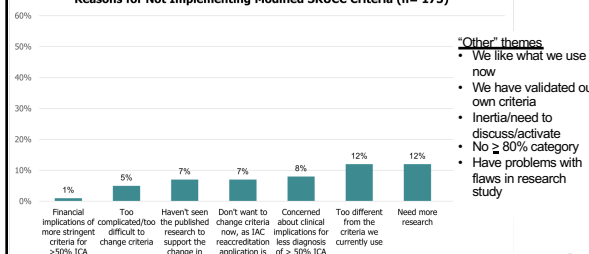



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Hutchisson, M. et al. Presented at SVU 2023.

Reasons for Not Implementing Modified SRUCC

Reasons for Not Implementing Modified SRUCC Criteria (n= 173)



Other themes:

- We like what we use now
- We have validated our own criteria
- Inertia/need to discuss/activate
- No $\geq 80\%$ category
- Have problems with flaws in research study

Gornik HL, et al. Presented at SVM 2023.

LESSONS LEARNED FROM IMPLEMENTING LABS

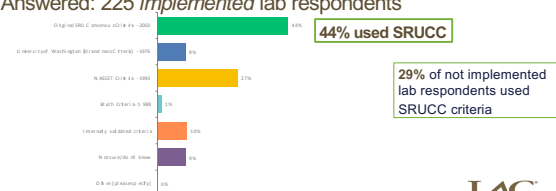
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Prior to the 2021 IAC Vascular Testing communication, what diagnostic criteria did your vascular facility use for determining internal carotid artery (ICA) stenosis?

Answered: 225 *implemented* lab respondents



Diagnostic Criteria	Percentage
Original ICA criteria (2014 to 2020)	44%
Modified ICA criteria (2021-2023)	27%
Internally developed criteria	12%
Other criteria (e.g., B-mode)	15%
Other (e.g., Doppler)	2%

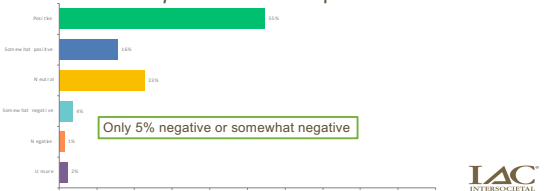
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Hutchisson, M. et al. Presented at SVU 2023.

How has your facility's experience been implementing the 2021 IAC Recommended Modified SRU Consensus Interpretation Criteria?

Answered: 225 *implemented* lab respondents



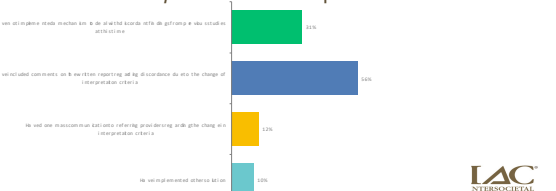
Experience	Percentage
Positive	51%
Somewhat positive	23%
Negative	5%
Somewhat negative	15%
Not sure	6%

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Hutchisson, M. et al. Presented at SVU 2023.


How has your facility managed discordant interpretations from previous carotid studies that may come after implementing the 2021 IAC Recommended Modified SRU Consensus Interpretation Criteria?

Answered: 225 *implemented* lab respondents



Management Method	Percentage
Use of comments on the description reporting the degree of stenosis due to the change of interpretation criteria	44%
Use of discussion with referring physician regarding the change of interpretation criteria	23%
Use of education (e.g., E-blast, or other mass communication)	15%
Other (e.g., Mailer or fax)	18%

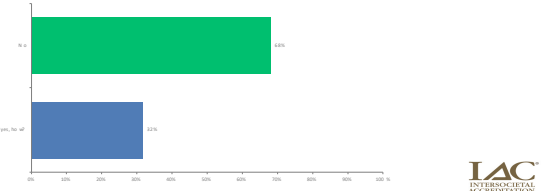
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Hutchisson, M. et al. Presented at SVU 2023.


Have you taken any steps to educate your referring providers regarding implementation of the 2021 IAC Recommended Modified SRU Consensus Interpretation Criteria?

Answered: 220 *implemented* lab respondents



Response	Percentage
Yes	55%
No	45%

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Steps to Educate Referring Providers (Themes from Physician and Sonographer Verbatim Responses)

- Providing education by email, E-blast, or other mass communication
- Mailer or fax
- Comments on duplex reports with reference of new guideline publications (what my lab has done)
- Discussed at staff meetings
- Mini-education sessions
- Personal communication on an individual basis
- *Prior to implementation, we provided the new criteria to them for review. They were supportive of moving forward since this had been studied by multiple institutions over several years.*
- Through our recently published book
- They are not familiar with or interested in learning vascular ultrasound

Do You Have Any Suggestions/Helpful Hints for Other Facilities When They Implement the Criteria (Selected *Physician* Responses)?

- Be careful.
- Bite the bullet and do it.
- I recommend a statement about the interpretation guideline changes for follow-up studies that do not correlate.
- Internal validation (old school, I know).
- It's not difficult to change.
- It's really not that different...our surgeon only concerned with 70% and symptomatic.
- Just dive right in!
- Just do it.
- No it was a smooth transition.
- Sending a mass email is a great idea, but often missed by some. I think adding a comment universally to the bottom of the carotid reports to explain the discordance has more impact/attention.
- We shared the white paper with all of our interpreting physicians and they had no problem adopting the new criteria.
- When implementing any criteria, be flexible with the velocity values and mindful towards the images. I think stressing the importance of looking at the images, rather than connecting the dots of the velocity criteria, would be most beneficial to patients.

Do You Have Any Suggestions/Helpful Hints for Other Facilities When They Implement the Criteria (Selected *Sonographer* Responses)?

- Educate your referring providers as to the need for the new criteria.
- Ensure buy-ins from your interpreter panel so there is consensus in interpretation of degree of stenosis.
- Get confirmatory imaging.
- I would say that many of the previous criteria for ICA stenosis were overcalling the 50-69% stenosis category and this update will bring a more accurate depiction of the level of ICA disease and is closer to the gold standard of diagnosis ICA pathology.
- Read the article, analyze the data table, and make a choice that fits your lab's needs
- Revert back to older criteria
- Just do it (x2)


The Time is Now

- The IAC modification to the SRUCC is an evidence-based refinement of the original SRUCC which is associated with overdiagnosis of ICA stenosis
- IAC-VT now *strongly recommends* use of these criteria for labs applying for accreditation in EC testing
- Per Marge Hutchisson, IAC-VT ~40% of applications for EC carotid accreditation in 2024 are using these criteria
- Implementing labs reported straightforward, largely positive process and used different strategies to communicate the transition and manage discrepancies
 - Expect ~ 1/2 of 50-69% stenosis to be reclassified/downgraded
- Labs using original SRUCC criteria more likely to have implemented
- There is more work to be done, but some progress has been made toward standardization and quality improvement in the field of carotid diagnostic testing
- Standardization will be accomplished one lab at a time

STANDARDIZATION WILL BE ACCOMPLISHED ONE LAB AT A TIME

IF YOU HAVEN'T ALREADY... JUST DO IT!

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Thank You

- IAC-VT Carotid Diagnostic Criteria Committee
- IAC-VT Board of Directors
- IAC leadership and staff
- Mary Beth Farrell, EdD, CNMT
- Marge Hutchisson, RVT
- The vascular ultrasound community for its patience, tough questions, and general support



Photo from [Befakit.com](https://www.befakit.com)

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