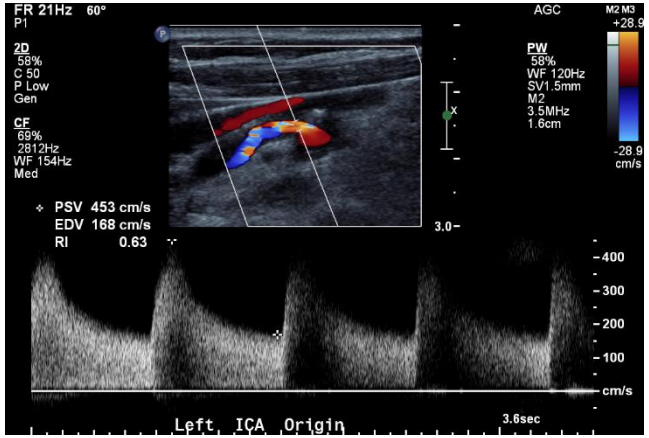
The Latest Word On The IAC Carotid Criteria Project



Heather L. Gornik, MD, RVT, RPVI

On behalf of the

IAC Carotid Diagnostic Criteria Committee

IAC INTERSOCIETAL ACCREDITATION COMMISSION
VASCULAR TESTING

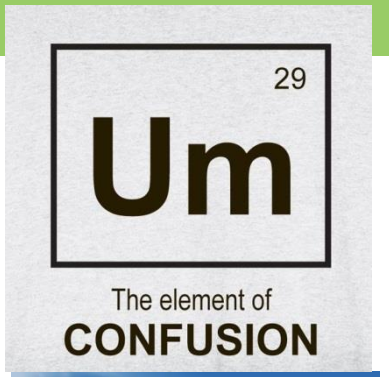
DISCLOSURE

Heather Gornik, MD, RVT, RPVI

Royalty: Flexlife Health/Zin Medical
Research Grants: CVR Global
Board Member: IAC Vascular Testing;
FMD Society of America

STRANDNESS SYMPOSIUM

The Carotid Criteria Crisis



- There are no universal standard criteria for ICA stenosis
  - IAC has historically been OK with this, as long as each lab **validates** the criteria it uses
- Criteria for ICA stenosis vary from lab to lab
  - *Even within the same institution sometimes!*
- 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

2010 IC
152 Va

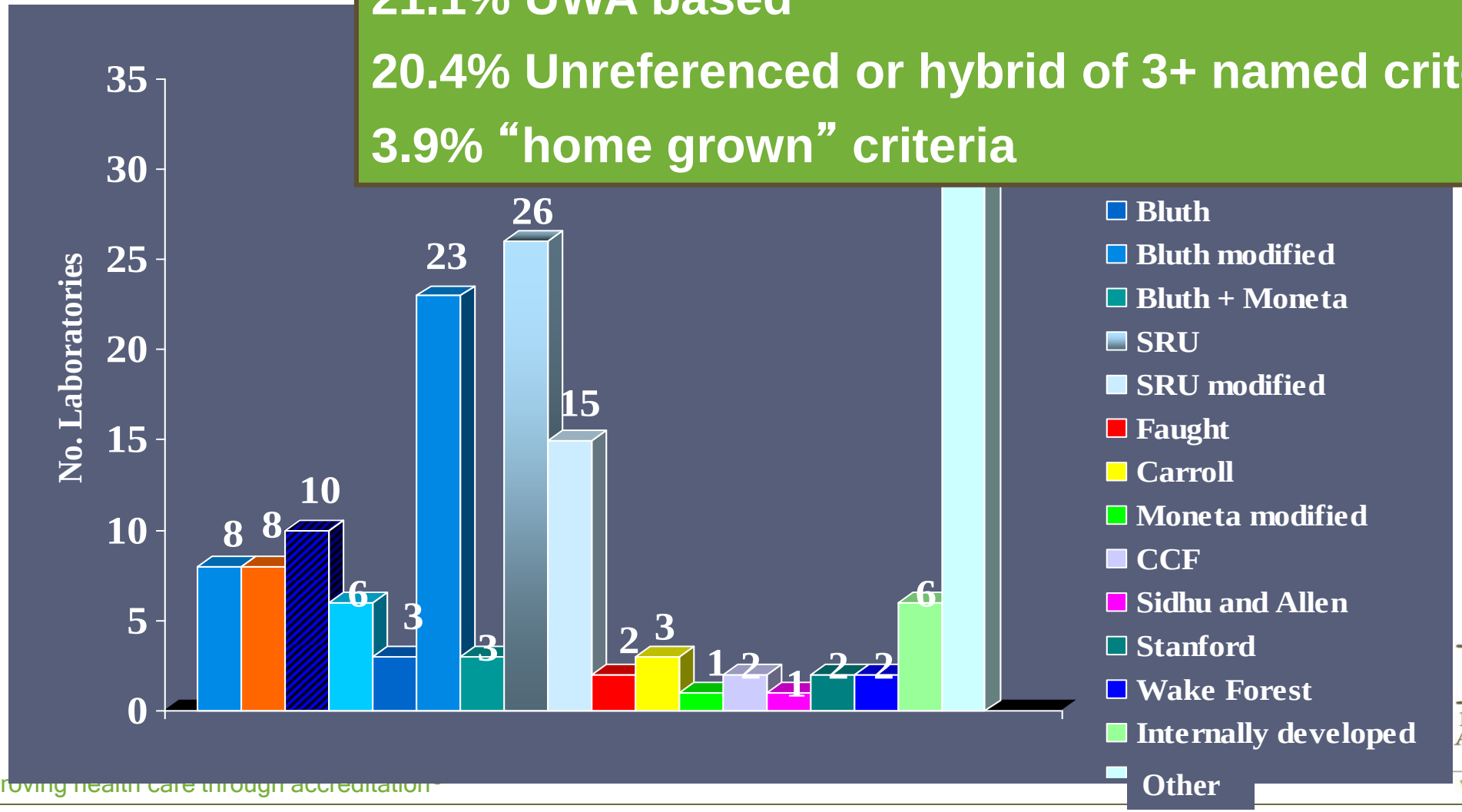
27.0% SRU consensus based

23.0% Bluth based

21.1% UWA based

20.4% Unreferenced or hybrid of 3+ named criteria

3.9% “home grown” criteria

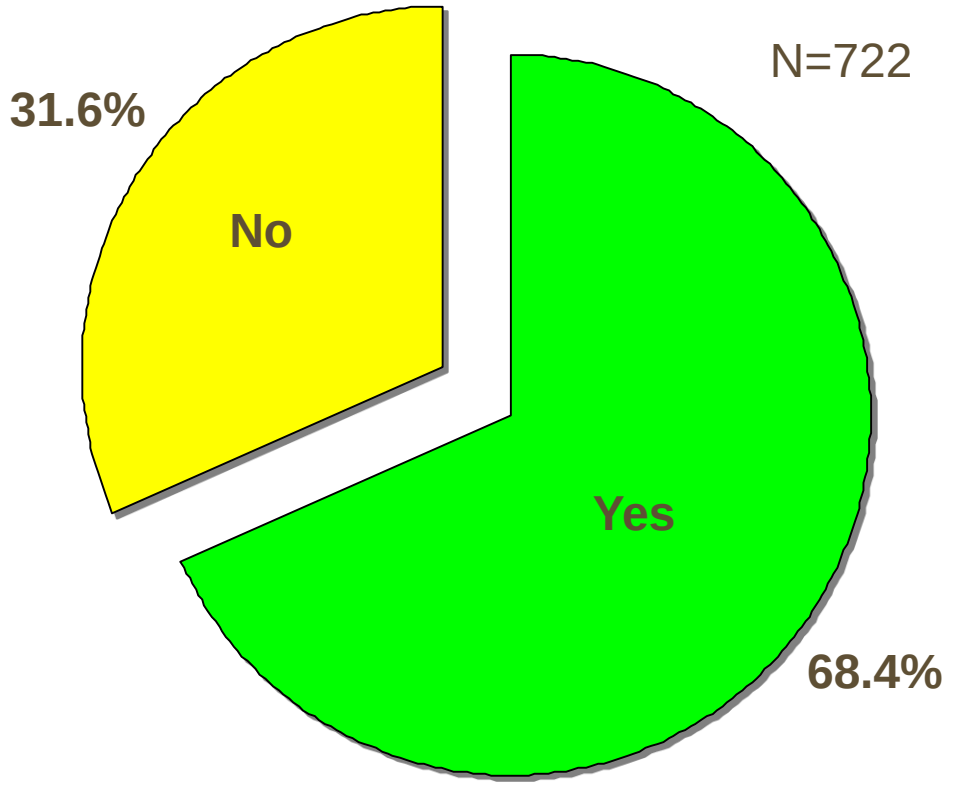


IAC INTERSOCIETAL ACCREDITATION COMMISSION VASCULAR TESTING

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

2012 IAC-VT Carotid Survey

Q9: In your opinion, if IAC Vascular Testing (ICAVL) developed one set of standardized diagnostic criteria that were researched and validated should laboratories be <u>required</u> to incorporate their use for accreditation?



Improving health care through accreditation®

INTERSOCIETAL ACCREDITATION COMMISSION
VASCULAR TESTING

Gornik H, Needleman L, et al. Presented at ACC 2013.

A Long Journey

2014 IAC-VT white paper on carotid criteria[1]

- 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*

2014-2018 More work than we ever imagined

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

2019 Complete results anticipated

[1]www.intersocietal.org/vascular/forms/IACCarotidCriteriaWhitePaper1-2014.pdf

Carotid Stenosis Diagnostic Criteria Committee

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

Study Methods I

- Traditional ultrasound – angiogram validation study
  - Gold standard catheter-based DSA (**not** CTA or MRA) chosen after extensive committee discussion
- Study investigators: IAC-VT Board members (current and former) representing all IAC-VT specialties
- De-identified materials collected from participating study sites:
  - Complete bilateral carotid duplex studies (performed between 1/1/2009 – 12/31/2015)
  - Digital subtraction catheter based angiograms performed within 3 months of duplex (at least 2 ICA diagnostic views)
  - Limited demographic and clinical data for each case submitted

Study Methods II

- Technical data abstraction: velocities, rating of technical quality of case, cursor alignment, angle of insonation
- Ultrasound and angiogram interpretation by blinded co-investigators
  - U/S reviewers analyzed complete ultrasound cases and assigned a diagnostic category according to SRU Consensus Criteria (2 independent reviews/case)
    - Interpretive discrepancies sent to 2 additional reviewers
    - If 3 of 4 reviewers did not agree, a panel review “tiebreaker” was performed for final interpretation
  - Angiogram reviewers interpreted angiograms using electronic calipers and NASCET methodology
    - Angiogram review panel
- Ultrasounds and angiogram images of poor quality were excluded from the analysis dataset
  - Single ICA side could remain in dataset if good quality

Analysis Plan

- Evaluate the sensitivity, specificity, and accuracy of SRU Consensus Criteria (SRUCC) for diagnosis of ICA stenosis compared to angiography
- Determine optimal ultrasound velocity cut points for diagnostic parameters (PSV, EDV, ICA/CCA ratio, others) using ROC AUC analysis compared to angiography.
- Additional analyses to determine whether a single parameter or combinations of the optimal parameter values provide best predictors of % ICA stenosis
- Additional analyses
  - Inter-reader agreement (% ICA stenosis using SRUCC by duplex)
  - Analysis of individual interpretive reader implementation of SRUCC criteria elements and diagnostic performance

Participating Sites

1. Novant Health [Charlotte, NC] (K. Estes)
2. Cleveland Clinic (H. Gornik, A. Grattan)
3. Univ. of Southern California (S. Parese)
4. Univ. of Pittsburgh (S. Leers)
5. Tri-Health [Cincinatti, OH] (J. Lohr)
6. Univ. of Miami (T. Rundek)
7. University Hospital and Clinics [Lafayette, LA] (M. Comeaux)
8. Univ. at Buffalo (A. Siddiqui)
9. Univ. of Washington (R.E. Zierler)
10. Riverside Radiology [Columbus, OH] (L. Laperna)
11. University of Maryland (M. Lilly)

PROGRESS AND PRELIMINARY DATA PREVIEW

Case Study Disposition

224 cases/448 sides submitted and uploaded for review

299 sides (from 167 patients) in final analysis dataset

Reasons for exclusion (149 sides, **~33% excluded**)

▪ Inclusion/exclusion	Dates, unilateral case, stents/CEA, non-athero disease
▪ Poor image quality	Duplex or angiogram
▪ Incomplete imaging	Inadequate angio views, duplex images, or velocities
▪ Media formatting issues	Images could not be reviewed
▪ Bilateral ICA occlusions	No informative duplex data
▪ Tandem lesions	CCA stenosis >> ICA stenosis on angio

Study Population (N=167 pts)

60% male; mean age 69.9 ± 10.3 years

50% symptomatic prior to duplex (TIA/stroke/retinal ischemia)

Atherosclerotic risk factors

- HTN 87%
- ↑ Chol 78%
- Tobacco (100+ cigs) 60%
- Diabetes 31%

U/S study clinical indications (more than 1 possible)

- Hemispheric sx 46%
- F/u known stenosis 31%
- Cervical bruit 13%
- Athero elsewhere 12%
- Preop exam 13%
- Other 6%

U/S manufacturers: 76% Philips, 22% GE, 2% Other

Agreement of U/S Readers for ICA Stenosis Severity (SRU Consensus)

- N=299 U/S sides reviewed by MD Reviewers
- For purposes of agreement, *normal* and *< 50% stenosis* combined into *<50% stenosis* category
- 90.3% Agreement Reviewers 1,2 on % ICA stenosis using SRUCC
- 6.7% Agreement with Reviewers 3,4
- 3.0% Required tie-breaker/panel adjudication of % ICA stenosis using SRUCC

Distribution of ICA Stenosis Severity (N=299 sides)

Stenosis Category	"Gold Std" Angiogram (NASCET)	Ultrasound Reviewers (SRUCC)
<50%*	67.2%	43.5%
50-69%	18.7%	29.1%
≥70%	11.0%	24.4%
Near total occlusion	1.0%	1.3%
Occlusion	2.0%	1.7%

Note: relatively small # of sides in dataset with > 70% stenosis by angio (11.0%, N=33); fewer with > 80%

*Normal and plaque with < 50% stenosis combined

Angiogram Gold Standard vs. U/S Reviewers (SRUCC) for ICA Stenosis

% ICA Stenosis By Angio (NASCET)

% ICA Stenosis By U/S (SRUCC)	<50%*	50-69%	≥70%	Near total occlusion	Occlusion
<50%*	64.2%	1.8%	0	0	0
50-69%	29.9%	42.9%	6.1%	33.3%	0
≥70%	6.0%	53.6%	90.9%	0	16.7%
Near total occlusion	0	1.8%	3.0%	66.7%	0
Occlusion	0	0	0	0	83.3%
	100%	100%	100%	100%	100%

Kappa=0.42 (moderate agreement)

*Normal and plaque with < 50% stenosis combined

Observations

- Agreement of expert physician U/S interpretation (using SRUCC) vs. angiography for determination of % ICA stenosis is **moderate at best**
- Carotid U/S interpretation by expert physician reviewers using SRUCC tends to overcall degree of ICA stenosis for both <50% vs. 50-69% lesions (as determined by angiography)
- Agreement is good for ≥ 70% stenosis (by angio)
- These general findings are consistent with those of AbuRahma A et al. for SRUCC vs. CTA (*J Vasc Surg* 2011;53: 53.)
- ROC analysis of SENS/SPEC for various components of SRUCC (PSV, ICA/CCA ratio, EDV) is being finalized

Next Steps

- ROC analysis to determine optimized # thresholds for individual ultrasound parameters (PSV, ICA/CCA ratio, EDV) to be incorporated into a single set of IAC carotid diagnostic criteria
- Multiple additional sub-analyses of dataset planned
- It is likely that the IAC carotid diagnostic criteria will look ***somewhat different*** than the SRU Consensus Criteria
  - Higher velocity thresholds for ≥ 50% and ≥70% stenosis than SRUCC
- Full publication of findings is anticipated in 2019
- Next steps in term of implementation to be determined by the IAC BOT

Stay tuned and thank you for your patience!

Photo from Betakit.com