Carotid Stenting Certification

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Disclosures

• Founding Board Member ICACSF
• SVIN Representative to ICACSF
• No financial interest
Intersocietal Accreditation Commission (IAC)

• Accreditation is IAC’s only business for 23 years
• Over 15,000 sites accredited
• One non profit 501(c)(6) organization with seven divisions
  – Five diagnostic imaging modalities (vascular testing, echo, nuclear/PET, MR and CT)
  – Two therapeutic (carotid stent; vein center)
• Overall organization directed by IAC board
  – Composed of 2 representatives from each division
  – Responsible for strategic direction and financial oversight
• Primary division responsibility – review and revise modality specific standards
IAC Carotid Stenting | ICACSF
Sponsoring Organizations

- American Academy of Neurology (AAN)
- American Association of Neurological Surgeons/Cerebrovascular Section
- American Association of Physicists in Medicine (AAPM)
- American Society of Neuroradiology (ASNR)
- Neurocritical Care Society (NCS)
- Society for Vascular Medicine (SVM)
- Society for Vascular Surgery (SVS)
- Society of Interventional Radiology (SIR)
- Society of NeuroInterventional Surgery (SNIS)
- Society of Vascular and Interventional Neurology (SVIN)
ACE- Accreditation for Cardiovascular Excellence

- Cath/PCI and Diagnostic Catheterization Accreditation
- CAS is newest
- Sponsors
  - SCAI
  - ACC
- 3 Centers Accredited
IAC Standards for Carotid Stenting Accreditation

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IAC Requirements

- Volume criteria (25 facility; 15 individual physician)
- Medical and technical staff training and experience
- Procedure Log (3 years)
- Outcome data analysis
- Quality Improvement program (minimum 6 month review)
- Physicist report of the angiographic equipment
- Safety processes
- 5 procedures to include continuum of care processes and imaging

Improving health care through accreditation
QI program requirements

• Review at a minimum every 6 months
• Outcome Measures (risk category/indications and technical)
• Administrative Processes
• Technical (equipment)
• Physician Performance
• Patient and Staff Exposure
• Medical and Technical Staff Training and Experience Requirements
• A process/protocol for the performance of CAS procedures (recommended)
Procedure data elements

- Patient identifier
- Date of procedure
- Clinical Indication
- Symptomatic or asymptomatic
- Right or left procedure
- 30-day outcome for stroke and/or death for each patient
- Name of the primary operator
- Department or specialty of primary operator
- Use of embolic protection
Benchmark Outcome Analysis
Criteria

- Only patients treated with CAS for indications of carotid bifurcation disease $2^\circ$ due to atherosclerosis, post CEA restenosis, or radiation induced stenosis included in the benchmark analysis.

- Emergent procedures combined with intracranial acute ischemic stroke revascularization, CAS for trauma or dissection not included in the benchmark analysis but included in the overall QI program.
Benchmarks: Technical Outcomes

• **Successful Deployment**
  – Benchmark = > 95% of the cases have successful stent deployment (if the stent has been deployed across the target lesion per the IFU)

• **Improvement in the degree of Stenosis** - percentage angiographic stenosis using NASCET criteria
  – Benchmark = > 95% of the cases have improvement in the degree of stenosis.
Benchmarks: Technical Outcomes

• **Independent neurological exam**
  
  Benchmark: 100% at 24 hours for pre and post procedure measurement of NIHSS and mRS
  (if a change > 2 a neurological consult is required)

• **30 day follow up**
  
  Benchmark: 80% of patients will have 30-day outcomes follow-up data
  
  -- Imaging of stent must be performed at 30 days +/-10 days) for patency. Duplex ultrasound is the recommended imaging study.
  
  -- Measurement of neurological outcome mRS; NIHSS
Benchmark: Complications

- **Asymptomatic**
  < 3% all stroke and death within 30 days of the procedure

- **Symptomatic**
  < 6% all stroke and death within 30 days of the procedure
Procedure Image Review

• Pre-procedure stenosis measurement and documentation using electronic calipers and image capture of the measurement is requested.

• Pre-stent frontal (AP) and Lateral subtracted views of the arterial phase of the intracranial vasculature to extend from the top to base of skull. The frontal view should extend to the lateral margin of the skull on the side of the angiogram.

• Post-stent frontal (AP) and Lateral subtracted views of the arterial phase of the intracranial vasculature to extend from the top of the skull to the base of skull. The frontal view should extend to the lateral margin of the skull on the side of the angiogram.

• The degree of stenosis post procedure.
Procedure Documentation

Requirements

• Indication for intervention
• Noninvasive diagnostic exam reports (duplex, CTA, MRA)
• Invasive exam pre procedure report (cerebral angiography)
• H&P documentation
• Carotid stent procedure report
• Nurse and anesthesia monitoring report during the procedure
• Neurologic assessment (NIHSS and mRS) documentation pre and post procedure
• Patient 30-day follow-up results including NIHSS, mRS and neurological assessment
• Reports from imaging test performed at 30 day follow up
Program Data Summary

- 8 facilities (35 procedures reviewed)
- Asymptomatic reported volume: 653
- Symptomatic reported volume: 321
- Physician specialties (as reported)
  - Interventional Radiology
  - Cardiology
  - Interventional Cardiology
  - Vascular Surgery
  - Neuro-Interventional Radiology
  - Radiology
  - Surgery
Program Data Summary

Complications

• Stroke and death complication rate
  ▪ 1.99% Asymptomatic
  ▪ 2.49% Symptomatic

• All complications
  ▪ 3.52% Asymptomatic
  ▪ 7.88% Symptomatic
Deficiencies

35 procedures reviewed

- 18 asymptomatic; 17 symptomatic
- Over estimation of stenosis (subjective vs. quantitative)
- NIHSS and mRS not consistently performed
- Patients not returning for 30 day follow up
- Neurological assessment not performed at 30 days
- Analysis performed incorrectly – including other studies that do not meet benchmark criteria
- Percentage of complications not calculated correctly
Program Summary Data
Deficiencies

• CAS not part of overall QI program
• Procedure log issues – total calculations not accurate; some missing all items requested (clinical indication, designation asymp vs. symp)
• Radiation safety/image quality issues
Lessons Learned

The IAC accreditation program assesses not only outcomes but appropriateness of intervention and accuracy of measurement of stenosis

Findings:
• The degree of stenosis is frequently overcalled in routine and even research practice
• Raises concerns about the appropriateness of patient selection and overuse of intervention
• Raises concerns that outcomes may look misleadingly good if pts with 50% stenosis are being called 80-90% and being treated, since lower degrees of stenosis are usually associated with lower complication rates
Baseline ipsilateral carotid and cerebral angiography must be performed

- The percent of carotid artery stenosis should be measured using NASCET criteria.
- The use of electronic calipers, (if available on the system) is required to quantitatively measure the percent of the stenosis to validate the clinical necessity for the procedure.
IAC Standards
% Stenosis

- A process to confirm the accuracy of the percentage of stenosis reported for symptomatic and asymptomatic patients warranting the intervention must be in place.
- If electronic calipers are used to measure the stenosis percentage, there must be a process to assess differences between subjectively reported and the electronic measurement.
- The quantitative (electronic) and subjective measures of stenosis severity should be very similar or identical.
- If subjective measurements are used to determine the need for treatment, deviations between the subjective and electronic measurement warrant a documented explanation and where appropriate, documented corrective action.
- **Benchmark:** 90% of patients should meet facility defined clinical and degree of stenosis indications as defined in the QI program.
## Comparison of IAC & ACE

<table>
<thead>
<tr>
<th>Quality Measure</th>
<th>ACE</th>
<th>IAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIHSS/mRS certification</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Independent Neuro exam</td>
<td>&gt; 50% compliance</td>
<td>100% compliance</td>
</tr>
<tr>
<td>NIHSS pre/peri/ 30 days</td>
<td>90% compliance</td>
<td>100% compliance</td>
</tr>
<tr>
<td>Neurologist exam for changes</td>
<td>No</td>
<td>Yes (if NIHSS &gt; 2)</td>
</tr>
</tbody>
</table>
# Comparison of IAC & ACE

## Quality Measure

### Outcomes
- **Pre discharge**
- **30 day**
- **1 year**
- **S/D benchmark**

### Tech/Nurse Credentials

<table>
<thead>
<tr>
<th>ACE</th>
<th>IAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/D/MI 80%</td>
<td>NIHSS/mRS</td>
</tr>
<tr>
<td>S/D/MI 50%</td>
<td>S/D 80%</td>
</tr>
<tr>
<td>Yes, not threshold</td>
<td>no</td>
</tr>
<tr>
<td>3/6% ? All vs. major</td>
<td>3/6 % all strokes</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
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</table>
### Comparison of IAC & ACE

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<thead>
<tr>
<th>Quality Measure</th>
<th>ACE</th>
<th>IAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation safety</td>
<td>air kerma &lt;5 Gy</td>
<td>DAP, fluorotime</td>
</tr>
<tr>
<td>Mechanism for low volume</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>On Site visit</td>
<td>Yes, nurse MD for outliers</td>
<td>Clinical staff/MD available</td>
</tr>
<tr>
<td>Accreditation cycle</td>
<td>2 years</td>
<td>3 years (mid site visit)</td>
</tr>
<tr>
<td>Fee</td>
<td>$15,000</td>
<td>$6000</td>
</tr>
</tbody>
</table>
## Comparison of IAC & ACE

<table>
<thead>
<tr>
<th>Quality Measure</th>
<th>ACE</th>
<th>IAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Credentials</td>
<td>Societal</td>
<td>Societal</td>
</tr>
<tr>
<td>Indications</td>
<td>CMS 90%</td>
<td>use CMS criteria</td>
</tr>
<tr>
<td>QI meetings</td>
<td>Monthly; 75%</td>
<td>Every 6 mos(min)</td>
</tr>
<tr>
<td>Detector size (min)</td>
<td>12 inches</td>
<td>9 inches</td>
</tr>
<tr>
<td>Angio success</td>
<td>&lt;50% residual; 90%</td>
<td>improvement; 95%</td>
</tr>
<tr>
<td>Stroke rescue</td>
<td>Require process</td>
<td>Require process</td>
</tr>
<tr>
<td>Procedure success</td>
<td>No comp; 90%</td>
<td>no</td>
</tr>
</tbody>
</table>
BENEFITS OF ACCREDITATION
Accreditation means the facility:

- Has undergone a thorough review of its operational and technical components by a panel of experts.
- Has standards in place for patient and personnel safety.
- Upholds processes that are in compliance with national standards.
- Has successfully passed a comprehensive site visit and facility audit.
Accreditation Benefits

• Provides a standard of care for patients comparing one facility to another
  – Provides independent, unbiased, outcome-based evidence to patients and their families that they are receiving the highest quality care
• Certifies to insurers that their beneficiaries are getting the best possible care
• Establishes the evidence necessary to support the image facilities would like to promote to the public
• Validates facility’s position, voice, and influence in government policy-making circles
Accreditation Benefits

• Potentially minimizes liability by encouraging best practices and early identification and resolution of problems and offering evidence of meeting best practice standards in the event of a lawsuit.

• Reduces costs by supporting more effective and efficient operation based on uniform standards.

• Minimizes complications, which in turn benefits payors, patients, and society by reducing costs.
**Press Release**

**Date:** xxx

**Contact:** Tamara Stoker (tstoker@intersocietal.org)

**XXX receives Carotid Stenting accreditation by the IAC**

Cardiovascular diseases are the No. 1 cause of death in the United States. On average, one American dies every 40 seconds of cardiovascular disease — a result of the heart and blood vessels. According to the American Heart Association, the total direct and indirect cost of cardiovascular disease and stroke in the U.S. for 2018 was an estimated $330.2 billion.

Specifically, Decreased blood flow to the brain caused by plaque on the inside of the carotid arteries is a common cardiovascular condition that may lead to stroke. Carotid Stenting is a therapeutic procedure used to open the site of the blockage to provide support to keep the artery open. Carotid Stenting, a minimally invasive procedure, may be considered as an alternative to carotid surgery in some patients. While Carotid Stenting can be extremely beneficial in reducing the risk of stroke due to carotid artery disease, the effectiveness of the procedure is significantly impacted by the performing facility’s adherence to benchmarks related to standards defining optimal resources, training and education.

Accreditation by the IAC means that programs that comply with the published standards are found in substantial compliance in all areas of the IAC’s comprehensive application for accreditation. Accreditation is widely recognized as an operation that is of significant value in the medical community. It is also an assurance of quality care for patients and their families. Accreditation is valid for a period of 3 years, after which it must be re-applied for in order to maintain the designation.

The Certification of Accreditation indicates that the hospital’s carotid stenting program has met the standards established by the Intersocietal Accreditation Commission for Carotid Stenting (ICACSF). The hospital will be accredited until September 30, 2020.
Contact Information

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ACE Accreditation

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