

2015

ACE Standards

for Carotid Artery Stenting Accreditation



Accreditation for Cardiovascular Excellence

Quality in Invasive Cardiovascular Care

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1. STANDARDS: Facility

- 1.1. Each hospital department or section (cath lab, operating room, radiology suite, etc) performing carotid artery stenting (CAS) must document that they have the resources to perform the procedure in a safe manner.
- 1.2. Equipment
 - 1.2.1. Digital subtraction angiography (> 12-in image intensifier preferred) with on-line image storage and retrieval capabilities.
 - 1.2.2. Advanced physiologic monitoring with real-time and archived physiologic, hemodynamic and rhythm monitoring equipment with support staff capable of interpreting results and responding appropriately.
 - 1.2.3. Large inventory of disposable supplies for vascular access management, cervico-cerebral angiography, carotid intervention with embolic protection, and intra-cranial thrombus retrieval devices.
 - 1.2.3.1. The inventory should include devices and drugs to assist in the management of complications including allergic reactions, arterial thrombosis, thromboembolism or vessel rupture and dissection.
 - 1.2.3.2. All staff should be trained in the appropriate use of these devices.
 - 1.2.4. Emergency management equipment and systems must be readily available in the interventional location performing carotid stenting. This includes resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation, and personnel familiar with their indications and use.
 - 1.2.5. There must be a process documenting routine preventive maintenance and testing of laboratory equipment, including a comprehensive radiation safety program such as outlined by The Society for Cardiovascular Angiography and Interventions. Rather than an inclusive document, this is to serve as a topic summary with recommendations for best practice. This will provide a framework for evaluating current compliance with these recommendations. Over time, these standards may become requirements for accreditation.

2. STANDARDS: Personnel Related

- 2.1. Each Department within the Institution (ie. cath lab, radiology, and surgery) performing CAS must have:
 - 2.1.1. A licensed, board-certified physician in an appropriate specialty and/or sub-specialty as a Medical Director. There may be a single Medical Director responsible for performance in all areas where CAS is performed.
 - 2.1.2. A Technical Director (licensed technologist or registered nurse) with a minimum of 5 years of experience working in an invasive angiographic imaging laboratory.
 - 2.1.3. A clearly delineated program for the initial granting of carotid stent privileges with physician operators meeting one of the peer-reviewed national societal training standards appropriate for the individual's specialty. The initial granting of privileges should be free of conflict of interest.
 - 2.1.4. A designated individual responsible for coordination of quality assurance activities. This may be the Medical Director or his/her designee.
 - 2.1.5. A standard operating procedure for monitoring peri-procedural, in-hospital and 30-day outcomes.
 - 2.1.6. Peri-procedural, in-hospital and 30 day outcomes-monitoring should include an independent neurological stroke evaluation by an NIH certified provider not directly involved in care of the patient and not a member of the interventional team.
 - 2.1.6.1. Follow up monitoring compliance for stroke, MI, Death should be reported at >90% for periprocedural and in-hospital period. Failure to achieve a minimum of 80% compliance with follow up will result in remedial action less than 80% follow up may result in denial of accreditation.
 - 2.1.6.2. 30 day outcomes for stroke, MI, Death monitoring should be no less than 50% compliance and corrective action will result if follow up is between 30-50%.
 - 2.1.6.3. Patient follow up that includes independent neurologic evaluation that occurs less than 30% of the time not acceptable and may result in denial of accreditation.
- 2.2. Maintenance of physician privileges
 - 2.2.1. Physicians must obtain 20 hours of Category 1 continuing medical education credits over a 3-year period in the field of endovascular therapy of peripheral or cerebrovascular diseases (i.e. non-coronary, non-cardiac vascular diseases). At least 10 of these hours must be in the field of cervico-cerebral vascular disease management including carotid, vertebral, and intracranial endovascular therapy.
 - 2.2.2. The institution must have a defined process for re-credentialing which should be based on volume, outcomes, fulfillment of CME requirements and other quality parameters. There are currently no accepted standards for re-credentialing. These may develop over time and be implemented in a later version of these standards.
 - 2.2.3. Recertification criteria for individual practitioners should be decided by each institution but guidelines should include documentation for fulfillment of CME requirements as outlined in 2.2.1 and participation in at least 50% of M and M and/or case review meetings.

- 2.2.4. The operator's complications should not exceed delineated thresholds.
 - 2.2.4.1. Mortality < 3% asymptomatic, < 6% symptomatic
 - 2.2.4.2. Stroke <3% asymptomatic, < 6% symptomatic
 - 2.2.4.3. Death < 3% asymptomatic, < 6% symptomatic
- 2.2.5. Hospital privileges and state licensing should be maintained throughout the period of certification for all operators. Any loss of either hospital privileges or state license shall be reported to ACE with an explanation from the Medical Director, CEO, CMO or institutional leader at the facility.
- 2.2.6. For adult laboratories, physicians must maintain ACLS certification and follow facility standards for radiation safety.
- 2.3. Other Health Care Professionals
 - 2.3.1. Skilled allied health professionals in the laboratory (nurses and technicians) must be trained and experienced in evaluating patients before and after catheter-based interventional procedure. State requirements for performance and roles of personnel must be supplied and facilities will be reviewed for compliance based on these standards.
 - 2.3.2. Documentation of training of nursing personnel in the recognition and management of acute neurological syndromes is required.
 - 2.3.3. Documentation of training of support staff to interpret results from physiologic, hemodynamic and rhythm monitoring equipment.
 - 2.3.4. All personnel with direct patient care responsibilities should be ACLS certified
 - 2.3.5. Facilities should have policies regarding the supervising role of the primary operating physician during the procedure when secondary operators are performing the procedure and direct the non-physician provider or fellow in addition to providing all clinical decision making.
- 2.4. There must be a process in place for providing acute neuro-rescue or stroke intervention in the event of a complication. Documentation of this policy must be provided.

3. STANDARDS: Quality Assurance

- 3.1. A quality monitoring program must include a peer-review conference with randomly selected CAS procedures reviewed for their indications, imaging quality, documentation, complications and a quality oversight committee to review outcomes and make privileging recommendations.
 - 3.1.1. All major complications should be reviewed.
- 3.2. A regularly scheduled quality monitoring conference must occur no less than quarterly. Attendance at a majority (50%) of the meetings is a requirement for CAS privileges for individual practitioners.
- 3.3. The oversight committee for this program should be representative of the individual specialties involved, and the Chair of the committee should rotate on an annual basis and not be a member of any of the carotid interventional teams.
- 3.4. A cath lab/OR/endovascular specific quality assurance (QA) monitoring program must be present and integrated with the facility quality improvement program (CQI) effort.
 - 3.4.1. A QA program should include structural, process and outcomes indicators.
 - 3.4.2. Structural indicators may include: a) credentialing and re-credentialing criteria, b) completion of accurate and informative reports, c) documentation of CME participation.
 - 3.4.3. Process indicators may include: a) quality of angiographic studies, b) completion of accurate and informative reports, c) emergency response times, d) total procedure and fluoroscopy times, e) contrast usage, f) radiation dose, and g) other criteria.
 - 3.4.4. Outcome indicators assessed should be part of an overall QA program.
- 3.5. The quality assurance program must include a peer-review process with randomly selected diagnostic and interventional procedures representing all operators performing cases. These should be reviewed for their indications and complications, and include a periodic review of all major laboratory/OR/endovascular complication rates.
- 3.6. The QA program must include an assessment of: a) an assessment of overall and vascular complication rates for all types of procedures performed, and b) an assessment of the diagnostic accuracy and adequacy of angiograms.
- 3.7. The oversight committee should be empowered to identify the minimum case volume for primary operators to maintain privileges, as well as a threshold complication rate to trigger suspension of privileges or activation of measures for remediation.
- 3.8. Major events such as 30 Day Death and Major Stroke rate should not exceed 3% for asymptomatic and should not exceed 6% for symptomatic patients.

4. STANDARDS: Radiation Safety

- 4.1. There must be a procedure in place to document radiation exposure of the patients and staff.
 - 4.1.1. The radiation safety program should be considered a component of the overall carotid artery stenting facility quality assurance (QA) process with the Carotid Artery Stenting program QA individual(s) actively involved with this process.
 - 4.1.2. Each carotid stent facility must establish a radiation safety education program either in conjunction with the hospital Health Physics Department/Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial. Documentation of this training must be provided. This program should have the following mandated components: a) initial training or verification of prior training for all physicians and staff using fluoroscopy in the carotid stent facility; b) annual updates on radiation safety; c) hands on training for new operators in a facility and existing operators on newly purchased equipment.
- 4.2. Patient radiation dose needs to be monitored and recorded.
 - 4.2.1. This should include the Fluoroscopic Time (FT, min), and Total Air Kerma at the Interventional Reference Point ($K_{a,r}$, Gy) and/or Air Kerma Area Product (PKA, Gyc). Peak Skin Dose (PSD, Gy) should be included if technology permits its measurement.
 - 4.2.2. A program should be in place for patients whose recorded Total Air Kerma at the Interventional Reference Point ($K_{a,r}$) is 5 Gy or greater and/or fluoroscopy doses that exceed 60 minutes. This should include what dose and a reason for this dose, patient notification, medical physicist/health physics involvement for $K_{a,r} > 10\text{Gy}$, and a mechanism for patient follow up of potential adverse effects from radiation.

5. STANDARDS: Reporting of Results

- 5.1. The reporting standards of The Joint Commission (TJC) for operative procedures must be followed. These include:
 - 5.1.1. Preliminary procedure reports must be written or dictated immediately after the procedure. Final should be posted to the medical record within 72 hours.
 - 5.1.2. There must be enough information in the record immediately after the procedure to manage the patient throughout the post-procedure period. This information could be entered as the procedure report or as a hand-written operative progress note.
 - 5.1.3. If the procedure report is not placed in the medical record immediately after the procedure due to transcription or filing delay, then a progress note should be entered in the medical record immediately after the procedure to provide pertinent information for anyone required to attend the patient. Immediately after the procedure is defined as "upon completion of procedure, before the patient is transferred to the next level of care."

- 5.1.4. The procedure progress note should contain at a minimum information including: a) name of the operator, b) procedures performed and description of each procedure, c) findings, d) estimated blood loss, e) specimens removed if appropriate, f) complications, g) post-operative diagnosis, and h) recommendations.
- 5.2. All procedure reports at a facility should be individualized to the institution but be consistent with the HPS (23) for structured reporting, standardized among operators and contain relevant content on each of the following topics:
 - 5.2.1. Patient demographics, primary and assisting operator(s) and supporting staff present and procedures performed.
 - 5.2.2. Indications for each component of the procedure (i.e. carotid and/or cerebral angiography, etc.)
 - 5.2.3. Appropriate supporting pertinent history, physical findings, and laboratory findings.
 - 5.2.4. The time frame and procedural events with technical comments; for example, Interventional procedures performed and any issues of concern.
 - 5.2.5. Access site information and closure method.
 - 5.2.6. All catheters, sheaths, guide wires, and interventional equipment used should be reported in a procedural section.
 - 5.2.7. Drugs and doses given during the procedure, type and amount of radiographic contrast used, and estimation of radiation exposure should be included in the procedure report.
 - 5.2.8. A clear description of any complications or a positive statement that there were no apparent complications.
 - 5.2.9. Minimum requirements for reporting the carotid diagnostic angiography are: 1) a description of the aortic arch and the vessels selected for arteriography, 2) a notation of the size, extent of distribution, tortuosity, and visual estimate of the degree of any narrowing, 3) patency of runoff vessels, 4) anatomic variations, 5) presence and severity of calcification, 6) presence and description of collaterals.
 - 5.2.10. For interventional procedures a complete description of the procedure, key equipment used (including types of devices used and embolic protection used), in lab results such as point-of-care ACT measurements, complications occurring and outcome of the intervention. Technical comments are helpful should future interventions be necessary.
- 5.3. Summary of major findings or diagnosis.
- 5.4. Disposition of the patient as a result of the procedure and comments, including plans for follow-up care including medical therapy, imaging, and anticipated further interventions.

6. STANDARDS: Patient Indications

- 6.1. The indication for carotid artery stenting (CAS) must be documented according to accepted societal standards and be consistent with published guidelines, expert consensus documents. Interventions for asymptomatic or non-threatening conditions is generally not warranted and must be fully supported by documented justification for performing the procedure.
 - 6.1.1. There must be sufficient clinical information available in the procedure report and medical record to determine the indication for the procedure.
- 6.2. Symptomatic vs. asymptomatic
 - 6.2.1. Symptomatic Defined as: focal neurologic findings such as TIA persisting < 24 hours, Non-Disabling stroke: Modified Rankin Scale, Transient monocular blindness: amaurosis fugax occurring within the previous 180 days (Services, 2010)
- 6.3. Severity of carotid artery stenosis
 - 6.3.1. By ultrasound
 - 6.3.2. By MRA/CTA
 - 6.3.3. By Digital Subtraction Angiography (DSA)
 - 6.3.3.1. The degree of CAS stenosis shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient's medical record. If the degree of stenosis is measured by the ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. Angiography using the NASCET criteria for measurement, is the gold standard for determination of the severity of stenosis. If the stenosis is determined to be <70% by angiography in a symptomatic patient, then CAS should not proceed. If the stenosis is <80% in an asymptomatic patient, CAS should not proceed. (Services, 2010)
- 6.4. All patients shall have an angiogram clearly documenting pre and post lesion assessment.
 - 6.4.1. NASCET Criteria shall be used to calculate % stenosis
 - 6.4.1.1. The North American Symptomatic Carotid Endarterectomy Trial (NASCET) is a method of quantifying internal carotid artery stenosis. The diameter of the stenotic segment is divided by the diameter of a normal, distal segment of internal carotid artery (where walls are parallel) and subtracted from 1 and expressed as a percentage of the distal segment diameter.
- 6.5. ≥90% of determinations should meet these criteria for stenosis depending on symptomatic status. Failure to achieve a minimum of 75% compliance with stenosis severity will result in remedial action less than 75% compliance with stenosis severity may result in denial of accreditation.
- 6.6. All treated patients shall have a post procedure cerebral angiogram to evaluate flow and evaluate for distal embolization
 - 6.6.1. Pre-treatment cerebral anatomy may be evaluated by DSA but if so documentation of these findings should be included as part of the pre procedure evaluation. Otherwise, pre stenting cerebral angiography should be performed as part of the initial angiographic lesion and anatomic assessment.

6.7. High surgical risk (CMS criteria) vs. average surgical risk

6.7.1. Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e. recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include but are not limited to: (Services, 2010)

- Congestive Heart Failure (CHF) class III/IV
- Left ventricular ejection fraction (LVEF) < 30%
- Unstable Angina
- Contralateral carotid occlusion
- Recent myocardial infarction (MI)
- Prior radiation treatment to the neck
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies such as ARCHER, CABERNET, SAPPHIRE, BEACH, MAVERIC II

6.8. Lesion location: common carotid vs. internal carotid artery

7. STANDARDS: Patient Outcomes

7.1. Primary outcomes to 30 days (3 to 6 weeks post procedure)

7.1.1. All stroke and all death for elective carotid artery stent cases.

7.1.1.1. Stratify by symptom status (www.cms.hhs.gov/Transmittals/Downloads/R98NCD.pdf - 2009-08-19)

7.1.1.1.1. Symptomatic benchmark = 6%

7.1.1.1.2. Asymptomatic benchmark = 3%

7.1.1.2. Stratify by CEA risk status (www.cms.hhs.gov/Transmittals/Downloads/R98NCD.pdf - 2009-08-19)

7.1.1.2.1. High Surgical Risk

7.1.1.2.1.1. Comorbid

7.1.1.2.1.2. Anatomic

7.1.1.2.2. Average Surgical Risk

7.1.2. $\geq 90\%$ of all elective CAS patients must have a documented NIH stroke scale by an NIHSS certified examiner, who is not a member of the interventional team.

7.1.2.1. Pre-procedure; within 4 weeks prior to the procedure

7.1.2.2. Post-procedure; within 72 hrs post procedure

7.1.2.3. 1 month follow-up; 3 to 6 weeks post-procedure

7.2. Secondary outcomes for elective cases.

7.2.1. Angiographic success rate $\geq 90\%$: $\leq 50\%$ residual target lesion stenosis determined by NASCET methodology at the conclusion of the procedure.

7.2.2. Procedural success rate $\geq 90\%$: Angiographic success without a major complication at hospital discharge.

7.2.2.1. Major Complications

7.2.2.1.1. Death

7.2.2.1.2. Stroke

7.2.2.1.3. TIA

7.2.2.1.4. Hyperperfusion syndrome

7.2.2.1.5. Acute MI (STEMI and NSTEMI)

7.2.2.1.6. Decompensated heart failure

7.2.2.1.7. Severe contrast reaction

7.2.2.1.8. Respiratory arrest requiring intubation

7.2.2.1.9. Cardiac arrest requiring defibrillator or pacemaker therapy

7.2.2.1.10. CAS procedure failure requiring urgent/emergent surgery.

7.2.2.1.10.1. Requires re-intervention or surgical correction.

7.2.2.1.10.2. Thromboembolism

7.2.2.1.10.3. Infection requiring antibiotics or drainage.

7.2.2.1.10.4. Results in prolonged hospital stay

7.2.2.1.10.5. Requires any transfusion of PRBC's or platelets.

7.2.2.1.11. Bleeding (any blood product transfusion).

7.2.2.1.12. Renal failure (i.e. need for dialysis, doubling serum Cr)

7.2.2.2. Minor Complications

7.2.2.2.1. Access site complication not requiring intervention

7.2.2.2.1.1. Hematoma

7.2.2.2.1.2. Percutaneous repair (i.e. thrombin injection, ultrasound-guided compression) of pseudoaneurysm

7.2.2.2.1.3. AV fistula not requiring further treatment

7.2.2.2.2. Hypotension (periprocedural) requiring ≥ 24 hours of intravenous pharmacologic support.

7.2.2.2.3. Jaw claudication due to external carotid compression. Non MAE complication rates will be compared to benchmark data. If rates exceed 2 standard deviations from the mean value, corrective action will be required.

7.2.3. One year outcomes:

7.2.3.1. 30 day all stroke and death plus 31 days to 1 year ipsilateral stroke and neurologic death.

7.2.3.2. Restenosis:

7.2.3.1.1. Symptoms (hemispheric or retinal ischemia (TIA or Stroke)).

7.2.3.2.2. Imaging study demonstrating $\geq 70\%$ in-stent restenosis.

7.2.3.2.3. Target vessel revascularization.

8. Performance Metrics

As part of the ACE application, performance metrics from the PVI Registry Executive Summary will be reviewed. The specific performance metrics examined and their source are shown in the table below.

CAS Process Metrics	Source	Line
Proportion of procedures performed upon patients at high surgical risk	PVI	1
Proportion of patients with an embolic protection device successfully deployed	PVI	2
Proportion of patients with dual antiplatelet therapy prescribed at discharge	PVI	3
Proportion of patients with a stain prescribed at discharge	PVI	4
CAS Outcome Metrics		
Incidence of new stroke not resolved 24 hrs post procedure in symptomatic patients	PVI	5
Incidence of new stroke not resolved 24 hrs post procedure in asymptomatic patients	PVI	6
Incidence of death or stroke in symptomatic patients	PVI	7
Incidence of death or stroke in asymptomatic patients	PVI	8
Incidence of death, stroke or MI for symptomatic patients	PVI	9
Incidence of death, stroke or MI for asymptomatic patients	PVI	10
Risk adjusted stroke or mortality (RASM)	PVI	11
CAS Utilization/Data Quality Metrics		
Proportion of patients with the NIH stroke scale performed by an accredited individual	PVI	12
Post-procedure length of stay	PVI	13
Proportion of patients with a follow up visit conducted	PVI	14
Proportion of patients with a follow up visit involving the use of the NIH stroke scale for evaluation	PVI	15

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