Medical Physicists' Role in IAC Carotid Stenting Accreditation

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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)

Learning Objectives

1) Review the IAC accreditation process.
2) Review clinical carotid stenting procedures.
3) Outline relevant Medical Physics processes and responsibilities.
4) Outline physics and related requirements for a carotid stenting program.

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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

IAC

- Vascular Testing | ICAVL - 1990
- Echocardiography | ICAEL- 1996
- Nuclear/PET | ICANL - 1997
- MRI | ICAMRL - 2000
- CT | ICACTL – 2007
- Dental CT | ICACTL - 2011
- Carotid Stenting | ICACSF - 2009
- Vein Center - 2013

IAC INTERSOCIETAL ACCREDITATION COMMISSION

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)

Improving health care through accreditation

Why these sessions?

"Physics" reports submitted in good faith to IAC-CS did not respond to the standard.

- Facility administration not have noticed or understood than enhanced "physics" requirements are needed for IAC accreditation.
- Physicists may not have been aware accreditation or that physics is part of the application.
- Routine physics QA reports were submitted to IAC by facility administration.
  - Testing and evaluation usually included only the minimum regulatory requirements (some irrelevant).
  - These reports had been accepted by regulators.

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Process improvement

- Technical information in this presentation is for your consideration
  - Not prescriptive
  - Starting point for implementing a facility's program
- Medical physicists add value by understanding and appropriately contributing to relevant processes.
- You are professionals ! !

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Accreditationθ

- Ensure high quality care by encouraging and recognizing the provision of quality imaging diagnostic evaluations.
- Facilities assess every aspect of daily operation and its impact on the quality of health care provided to patients.
- Facilities often identify and correct potential problems, revise protocols and validate QI Programs.
- Accreditation is renewed every three years; a long-term commitment to quality and self-assessment is developed and maintained.
- Reimbursement directives that require accreditation of the facility have been instituted by Medicare carriers as well as private insurers.

θ Adapted from IAC statement

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Carotid Stenting Physics

Goal is to bring medical physics related activities up to the level of best practices.

- Carotid stenting should be performed using equipment that meets IEC interventional standards.
- Patient and staff radiation management using best practices.
- All staff should have appropriate initial and continuing radiation safety training.

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Physicists' Clinical Knowledge

- Some first hand knowledge of clinical practice provides essential background information that will improve consultations with administrative and clinical staff.
- IAC Standard recommends observation of at least one procedure per year.

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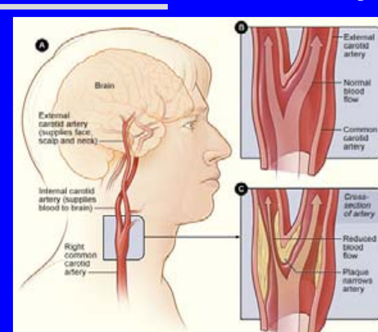
Cartotid Stenosis - Anatomy



http://www.nhlbi.nih.gov/health/health-topics/topics/catd

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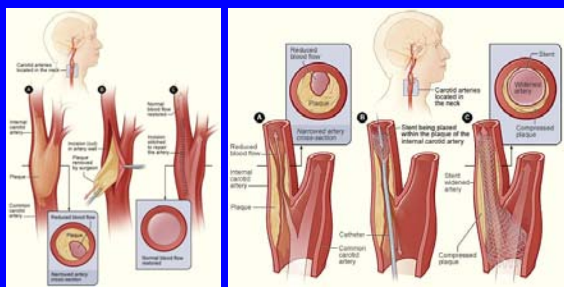
Cartotid Stenosis - Therapy



http://www.nhlbi.nih.gov/health/health-topics/topics/catd

Predictors of Acute and Persisting Ischemic Brain Lesions in Patients Randomized to Carotid Stenting or Endarterectomy

ICSS imaging substudy of patients with recently symptomatic carotid artery stenosis randomized to CAS (n = 124) or CEA (n = 107).

- CAS patients had more acute lesions than CEA patients (0.5 vs. 0; RR 8.8; 95% CI 4.4-17.5; *P* < 0.001)
- CAS patients had more persisting lesions (27-33 days post treatment) than CEA patients (RR 4.2; 95% CI 1.6-11.1; *P* = 0.005)
- Likelihood of conversion from acute (1-3 days post treatment) to persisting lesions was lower in the CAS group (RR 0.4; 95% CI 0.2-0.8; *P* = 0.007)

Implications: Acute and persisting ischemic brain lesions are more likely to occur after CAS than after CEA.

Bonati LH, et al. *Stroke.* 2013;Epub ahead of print.

Procedure

Initial Stenosis | Stent Deployment | Result

Physics topics

- Training
- Facility Design
- Equipment Selection
- Equipment QA
- Patient Dose Monitoring
- Staff Radiation Protection

IAC Carotid Stenting Program Data Summary: Complications

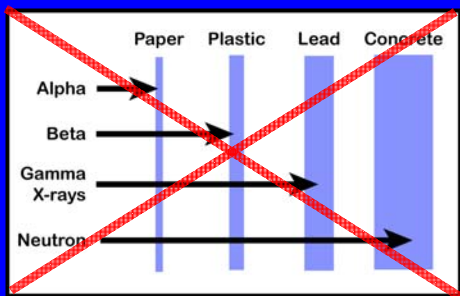
- Stroke and death complication rate
  - 1.99% Asymptomatic
  - 2.49% Symptomatic
- All complications
  - 3.52% Asymptomatic
  - 7.88% Symptomatic

Goal is to reduce probability of future strokes

Training: Radiation Safety

- All individuals participating in carotid stent procedures must be trained.
- Initial training is not specified by IAC.
- Recurrent training of at least 1 CME every three years.
- Documentation of training is required for accreditation.

Training – what not to present



NEVER GIVE THE SAME LECTURE TWICE

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Training – Useful topics

- Radiation risks
  - Patient
  - Staff
- Equipment configuration and function.
- Relevant image formation.
- Operational radiation safety.
- Review of facility radiation data.

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Medical Physicist's Qualifications

- Qualified Medical Physicist
  - Usual pathways for initial qualification
  - Eventual board certification
- Recurrent training per CAMPEP
- Recurrent clinical
  - observing one procedure per year (at each facility)

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Facility Design

- Interventional procedures attract a large number of participants and observers.
- Adequate space is needed in both the procedure and control rooms.
  - Control room should be designed to accommodate observers who do not have to be in the procedure room.
  - Control room should be shielded for full time occupancy by the general public.
- Clinical emergencies happen.

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Fluoroscopic Equipment

- Should (substantially) conform to IEC 60601-2-43 (Interventional Fluoroscopes)
  - Reference point air kerma and KAP monitoring
  - Structured Dose Report Export (2nd Ed. – 2010)
  - Many other important features
- Newer systems will eventually comply with NEMA XR-27 (QA mode)
  - Manual control of system parameters during testing.
  - Output of configuration details
  - Output of "for processing" images

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Equipment QA

- NY State regulatory on IAC website
  - Sample regulatory minimum
- Additional items may be added
  - Configuration documentation
  - Collimation limited to less than FOV
  - Maximum acquisition outputs
  - SID tracking
  - Integrated dosimeter accuracy
  - Effects of magnification

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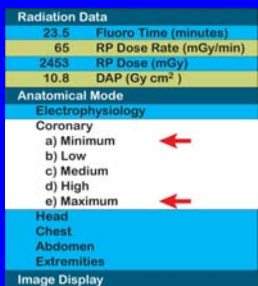
Clinical Configuration & Selection



Control Panel

Table Side

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Collimator Limits

- Restricting the maximum field size to less than the full active FOV permits continuous monitoring.
  - Most frequent QA failure
  - Service can set to approx. 95% in most systems.
  - Clinicians never comment on the small unused margin.

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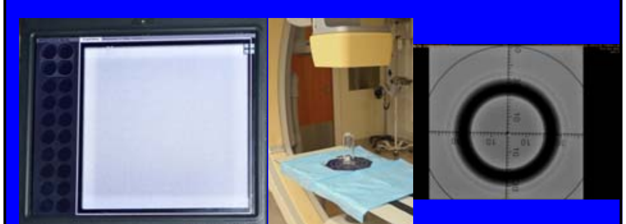
Beam confinement and alignment



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NY State Output Protocol

	19 mm Al	38 mm Al	38 mm Al + 0.5 mm Cu	38 mm Al + 2 mm Cu	38 mm Al + Pb or Cu
Fluoro	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
Acquisition	XXXXX	XXXXX	XXXXX	XXXXX	

- Testing should correspond to the most common clinical mode for CS
- Max output for acquisition mode is not required – typically 2 – 4 times the 2 mm Cu value
- What happens at the table-top when the SID is increased?

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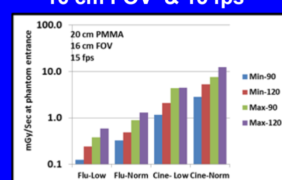
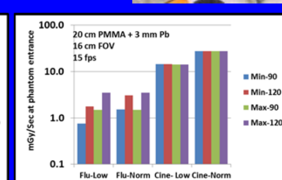
Patient Size & SID (Info not for application)

- Clinical interventional Fluoroscope very busy clinical system
- IEC 60601-2-43 compliant Installed 2010
- 16 cm FOV & 15 fps





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Integrated dose monitor testing

- Reliable values are the basis of dose management QA
  - Clinical decision making
  - Dosimetry review
  - Evaluation of structured dose reports.
- TG-190 protocol nearly complete

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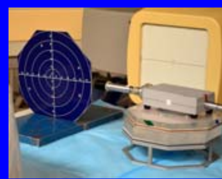
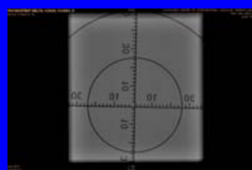
Partial procedure (AAPM TG-190 wip)

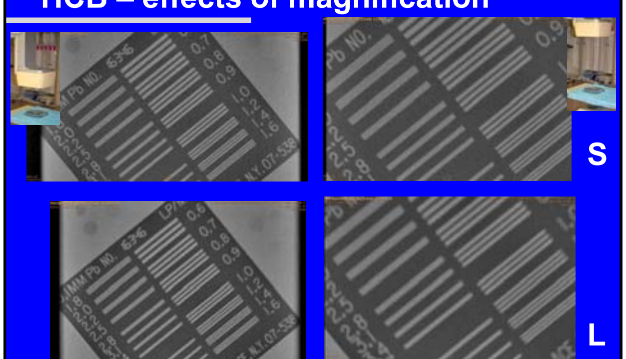
≈ 100 kV (≈ 8 mm Cu)
FS at isocenter ≈ 70 cm^2
Integrate 50 – 100 mGy
Test with different dose-rates



Geometric Effects

- Resolution vs FOV
- Resolution vs mode
- Resolution vs magnification

HCB – effects of magnification



Patient Radiation Management

- Essentially per published guidelines
  - NCRP – 168
  - SIR / CIRSE
- Integration into periodic QA
  - Clinical dose logs
  - Periodic MP statistical analysis
  - Periodic reports to clinical QA team

Staff Radiation Management

- Monitoring results
- Work habits
  based on observed procedures

Situational awareness

(photo taken at monitor location)

Medical Physics goals

- Contribute to optimizing procedures.
- Staff safety
  - My camera is my best dosimeter.
- Patient safety
  - Optimized equipment configuration and performance.
  - Improved physician knowledge.
- *Many CS physicians do not know who their physicist is!!!*

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Wrap-up

- Measurements and surveys
  -- tools to gather information
  -- not an end point
- Use professional judgment
  – not generic protocols
- Medical Physicists are consultants
  -- to facility administration
  -- to clinical staff (have you met them?)

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