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Angioplasty Alone: May Be the Best Endovascular Treatment for ICAS

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Why did PTAS fail in SAMMPRIS?

- Aggressive medical management was too effective in the SAMMPRIS population
- Angioplasty and Stenting with the Gateway-Wingspan system created too many (severe) complications in the SAMMPRIS population

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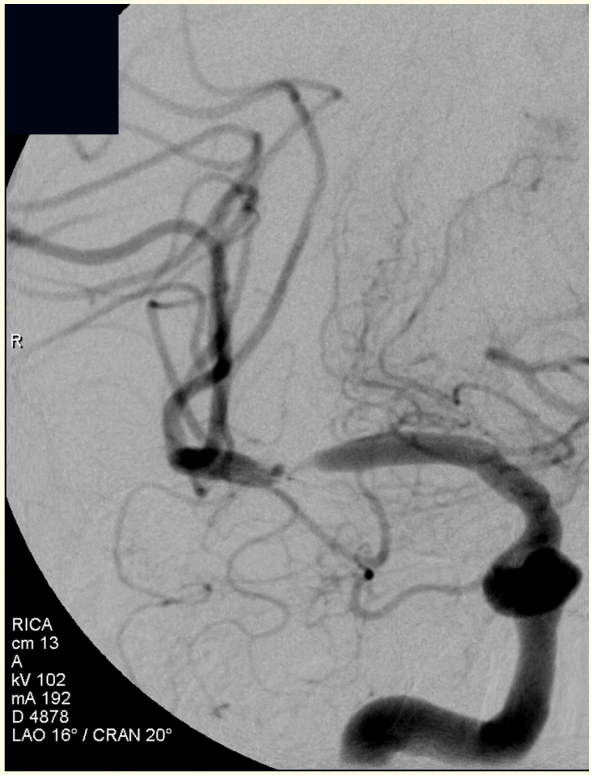
Estimated Event Rate in SAMMPRIS population

- >70% stenosis, symptomatic within 30d with stroke or TIA
  - Projected medical event rate: 24.9%



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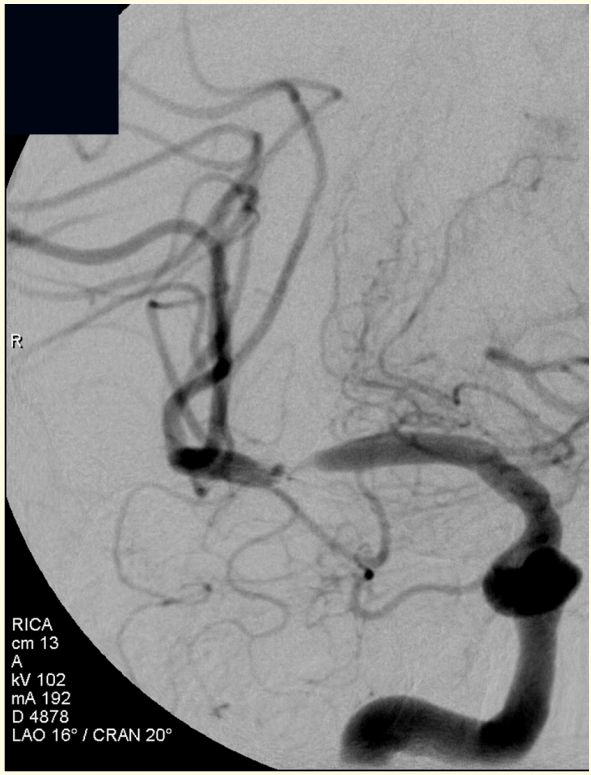
Actual Event Rate in SAMMPRIS population

- >70% stenosis, symptomatic within 30d with stroke or TIA
  - Projected medical event rate: 24.9%
  - Actual medical event rate: 12.2%



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Estimated Event Rate in the Stenting Population

- PTAS with the Wingspan-Gateway System
  - Registry Data: 5 - 10% major event rate

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Actual Event Rate in the Stenting Population

- PTAS with the Wingspan-Gateway System
  - Registry Data: 5 - 10% major event rate
  - SAMMPRIS
    - 14.7%: 30d event rate
    - 20.0%: 1 year event rate

PTAS is too invasive

- Need to target a 5% rate of peri-procedural complications
- ~10% 1- year risk of composite neurological events

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PTAS is too invasive

- Strategy: Need the “lightest touch” intervention possible which will improve flow

PTAS is too invasive

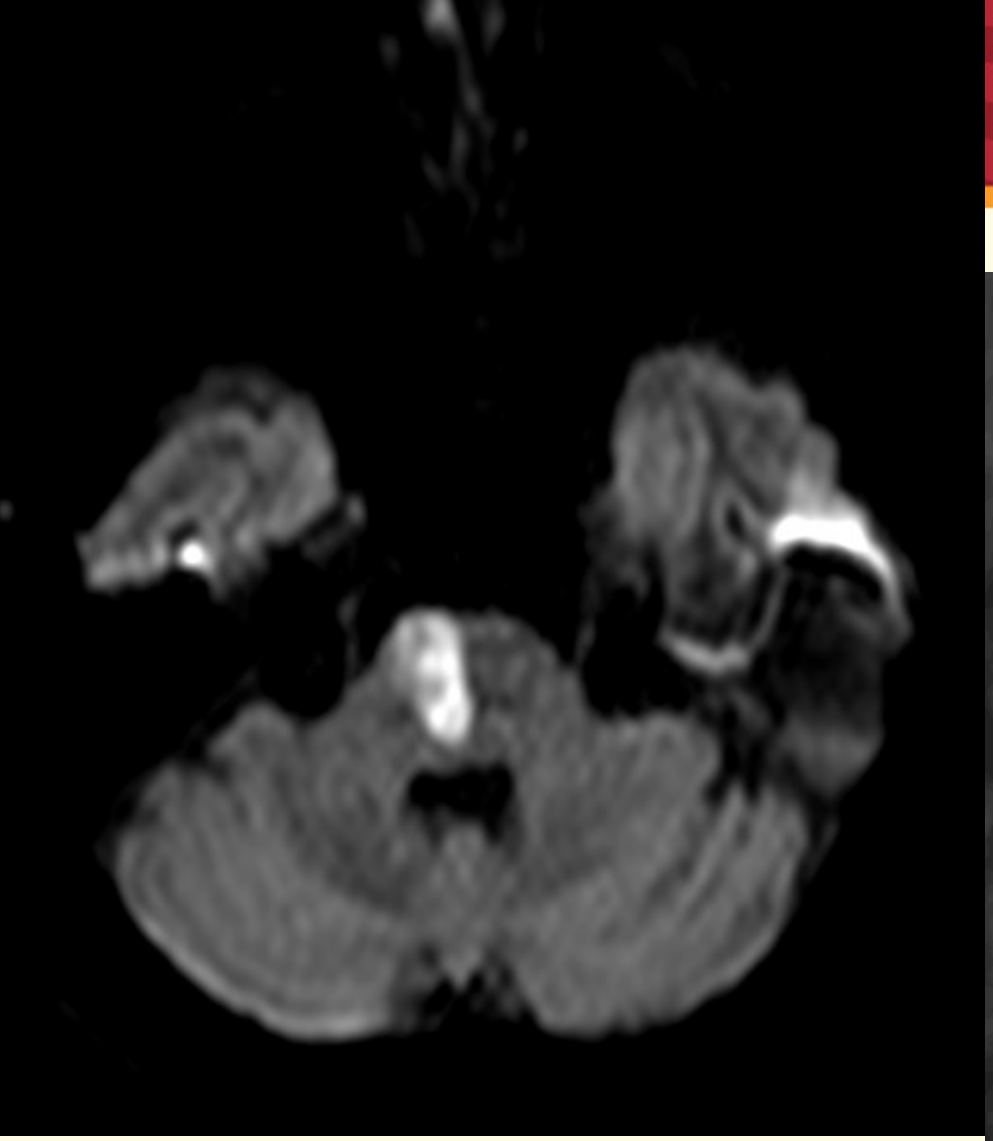
- Best Potential Candidate: Submaximal PTA alone
  - Stenting reserved for bailout
    - Flow limiting dissection
    - Stenosis worsened after PTA

Concept SM-PTA

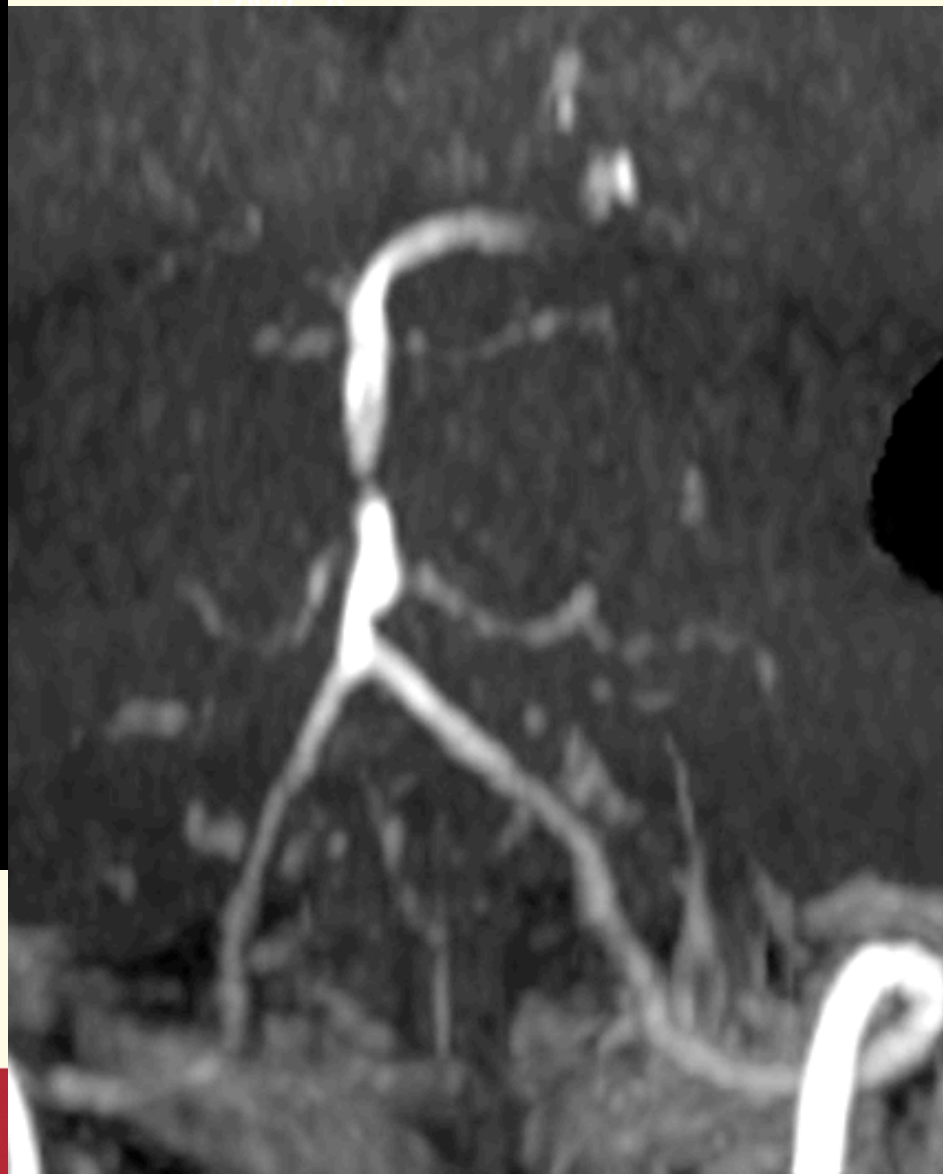
- PTA performed with balloon sized to 80% of the estimated normal parent vessel diameter
  - Slow inflation over 1-2 minutes or longer
  - Often requires pressures of only ~4-8 ATM

Concept SM-PTA

- Leaves considerable residual stenosis (~40%)
  - Flow proportional to radius^4
    - Small increases in diameter can dramatically increase flow



5 mm



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5 mm
RMCA

Medical Management

- Initially heparinized, then converted to ASA and plavix (with loading dose)
- Progressed to complete left HP 48 hours later

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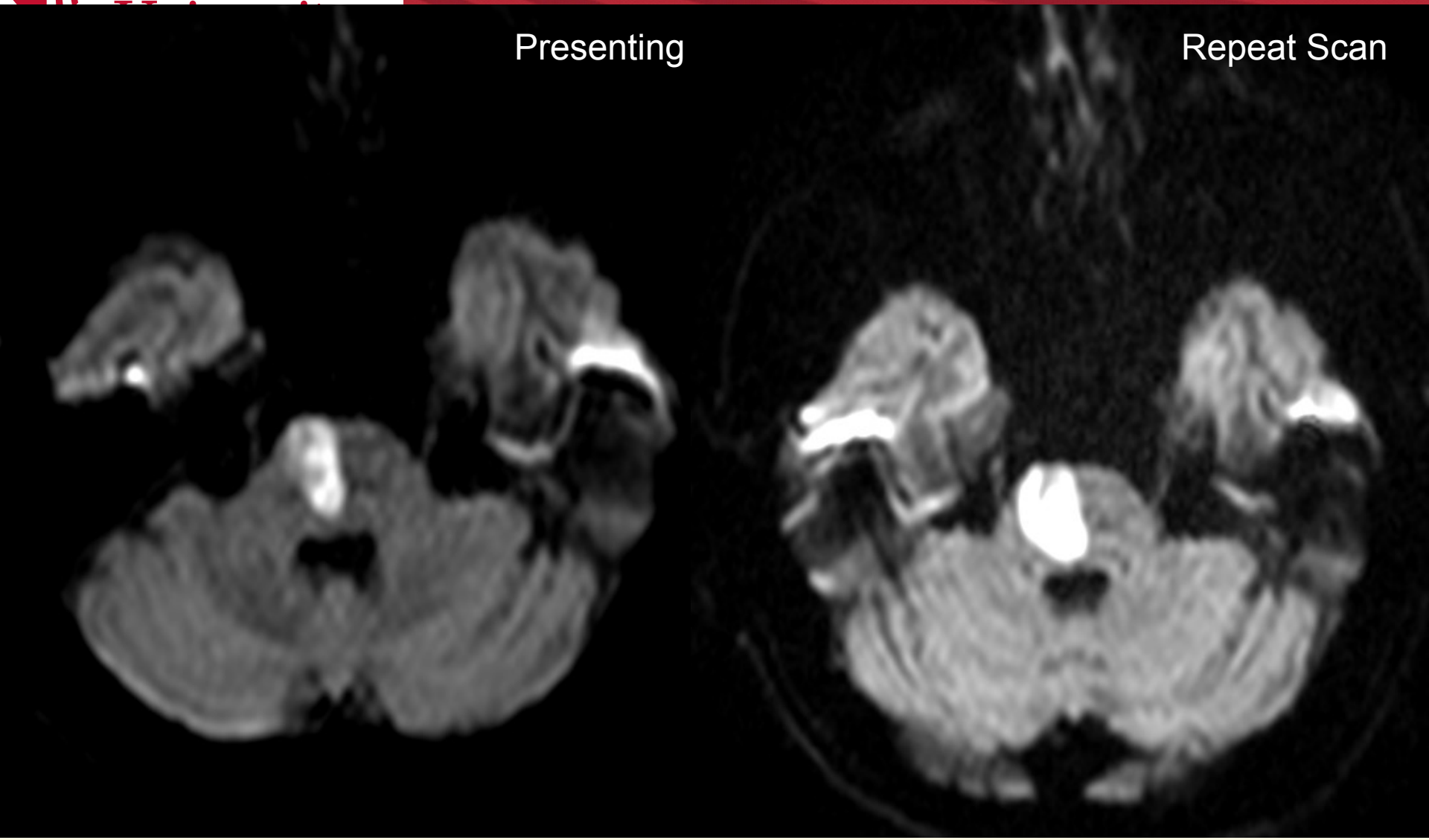
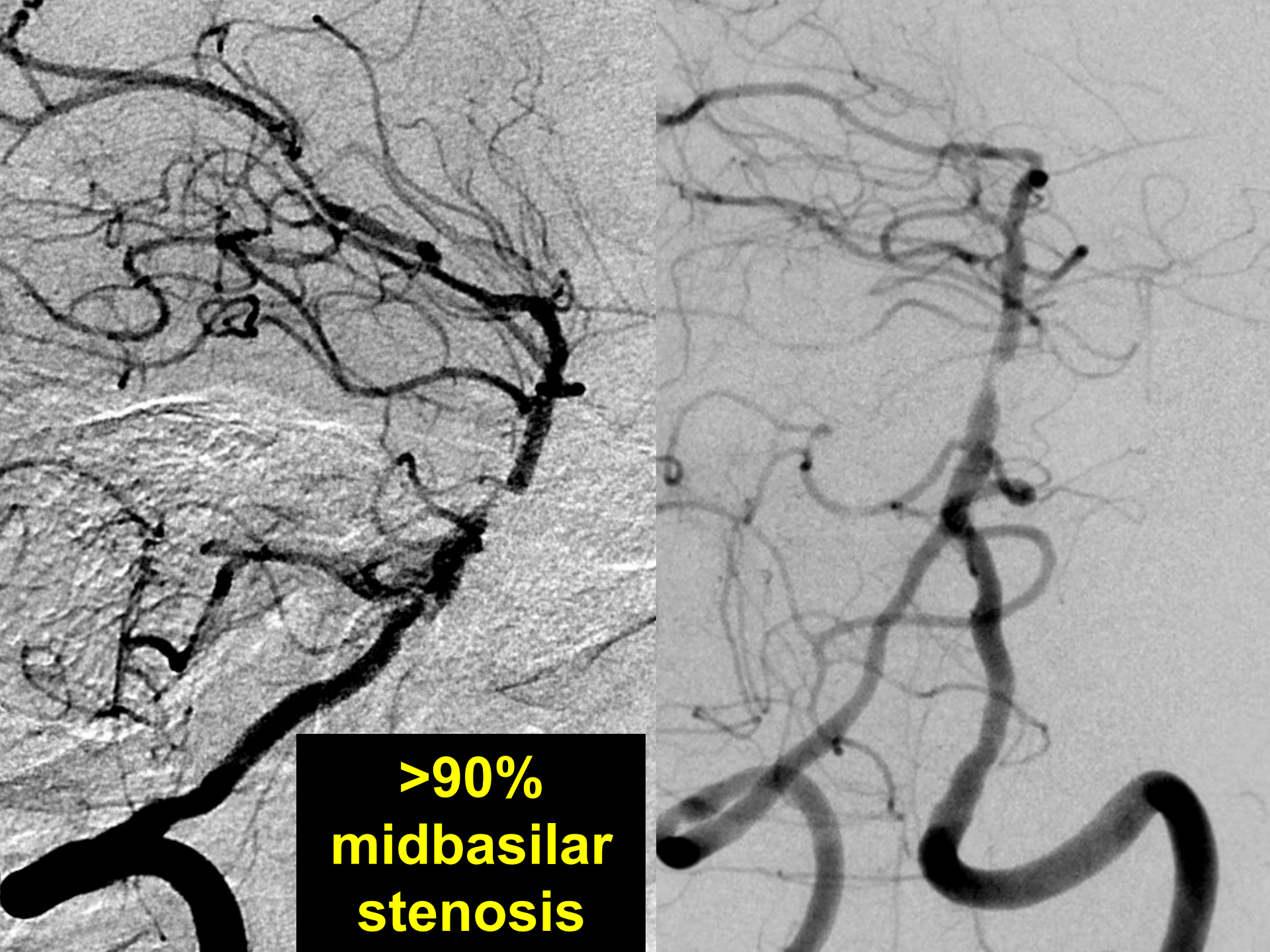
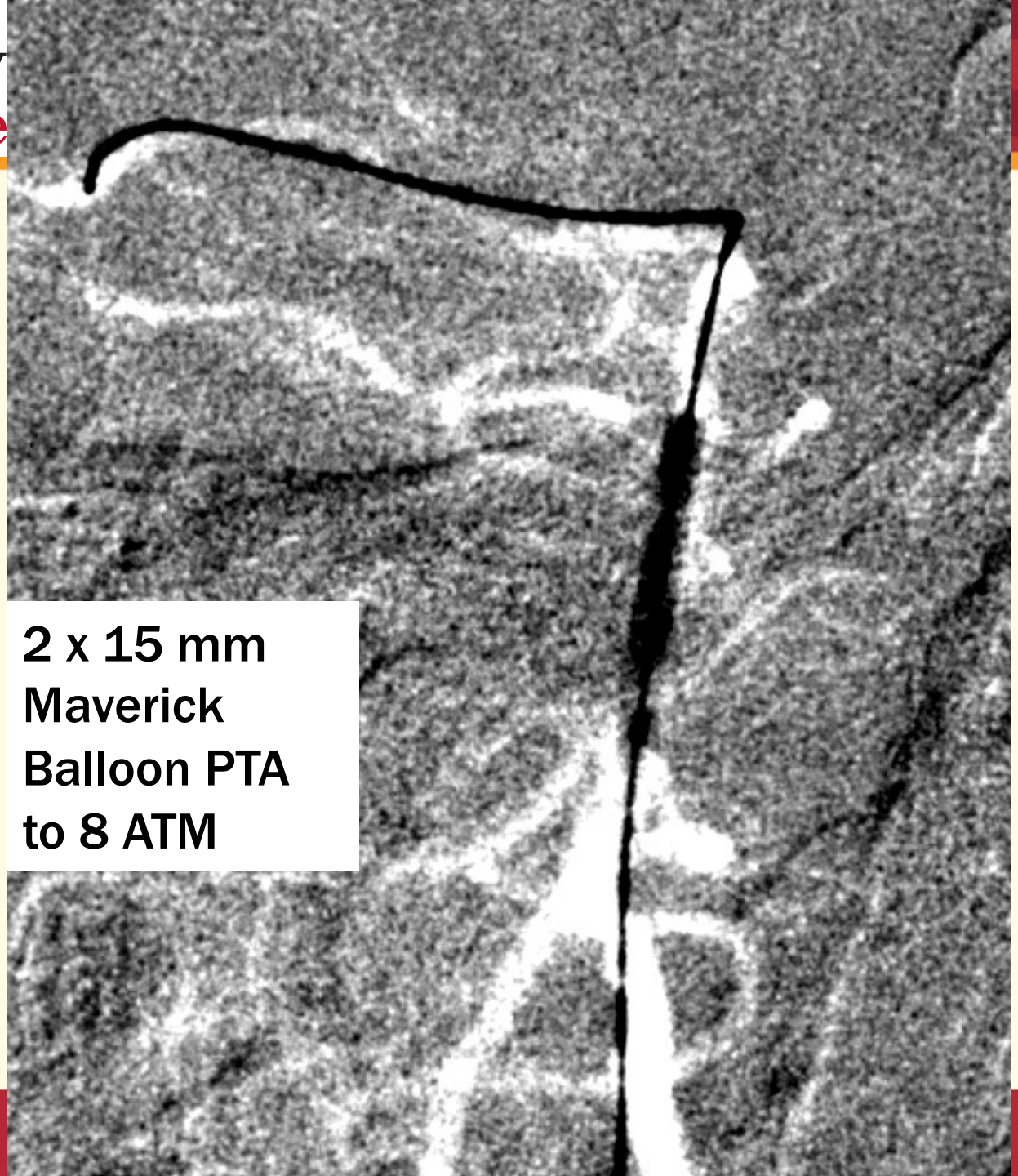
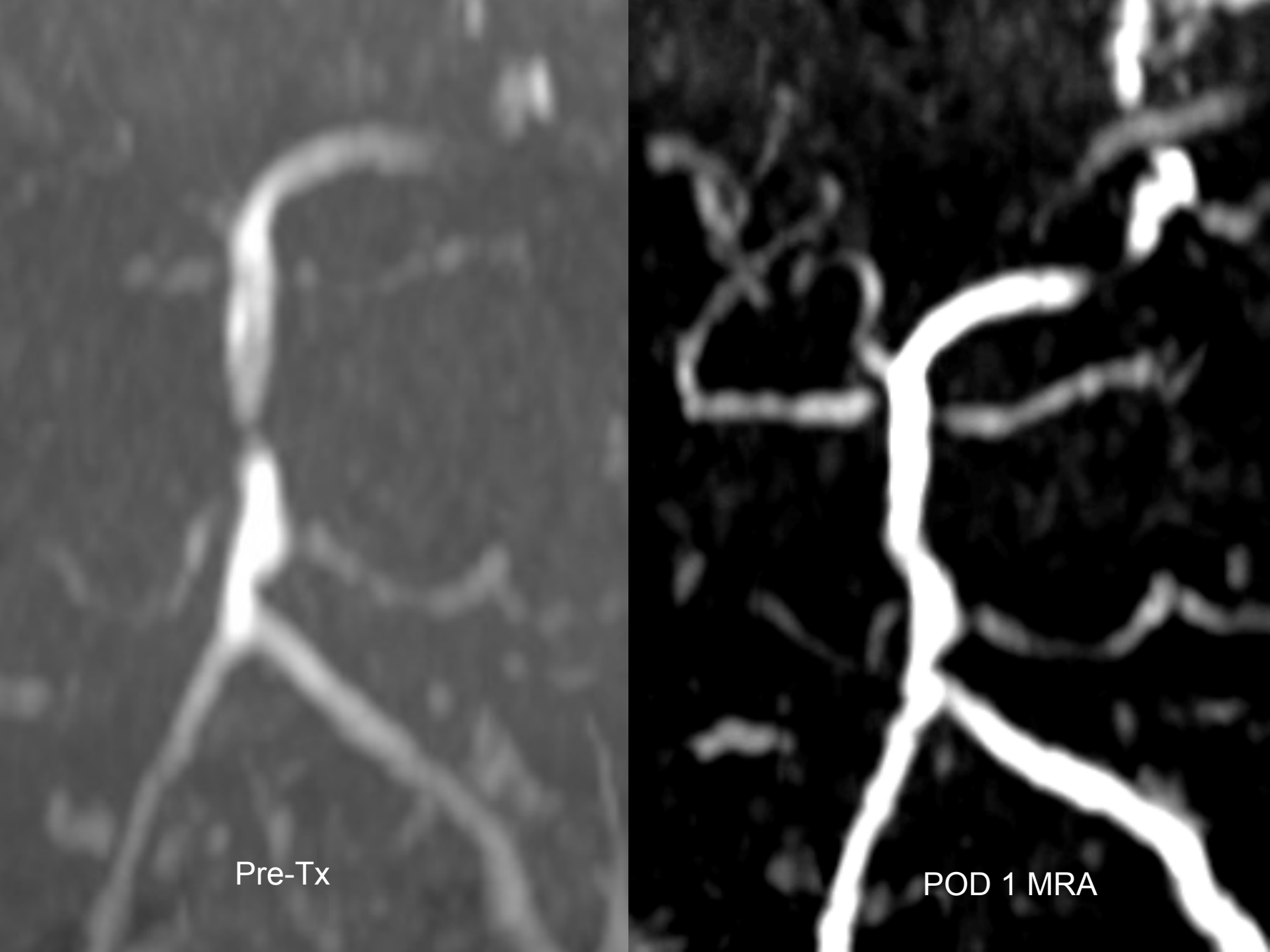



>90%
midbasilar
stenosis



2 x 15 mm
Maverick
Balloon PTA
to 8 ATM


Pre-Tx
POD 1 MRA

Potential Advantages of SM-PTA

- "Least Invasive" Intervention
  - Lowest profile, most flexible devices
  - Single-step procedure
  - No/few microwire exchanges

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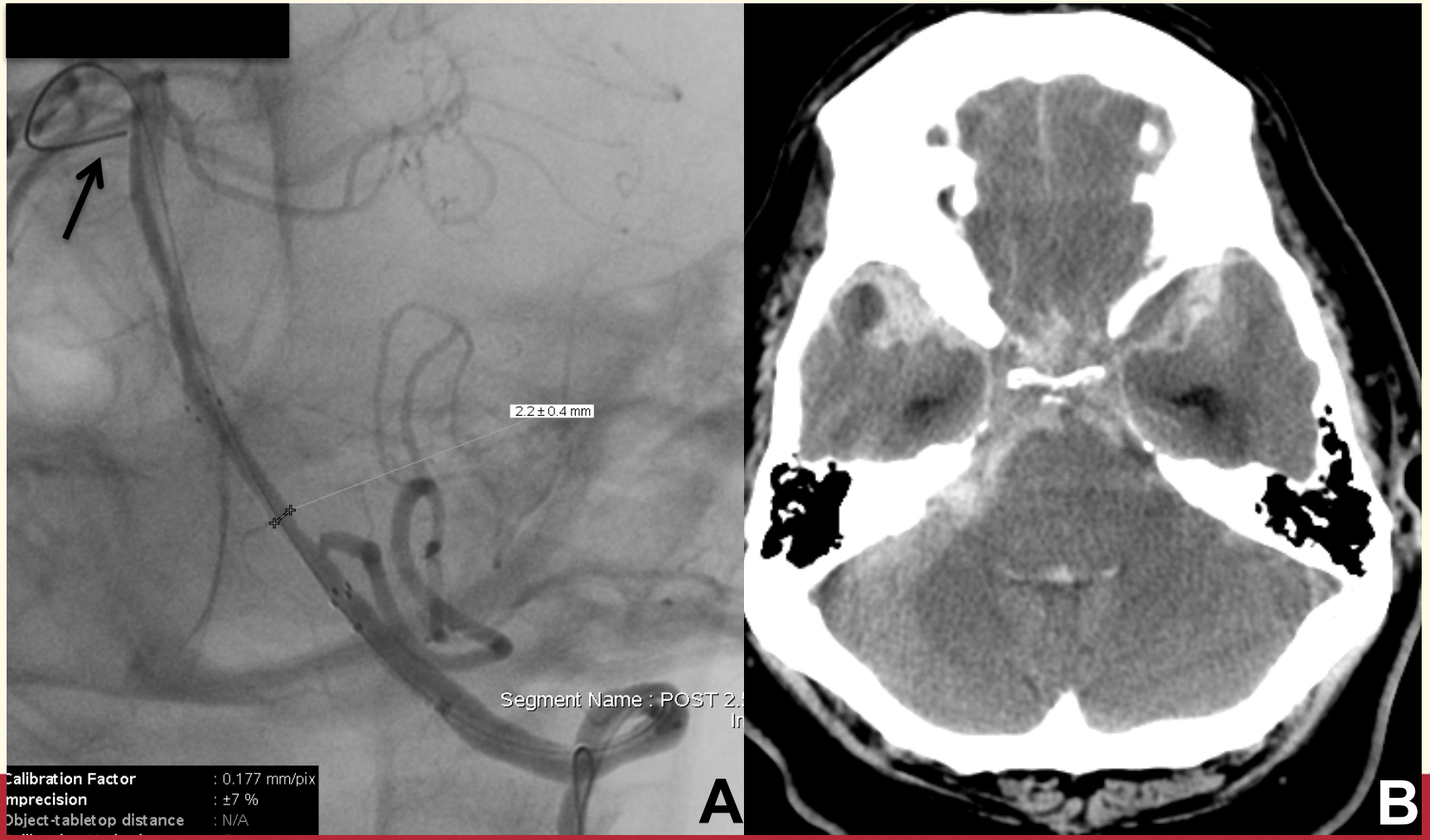
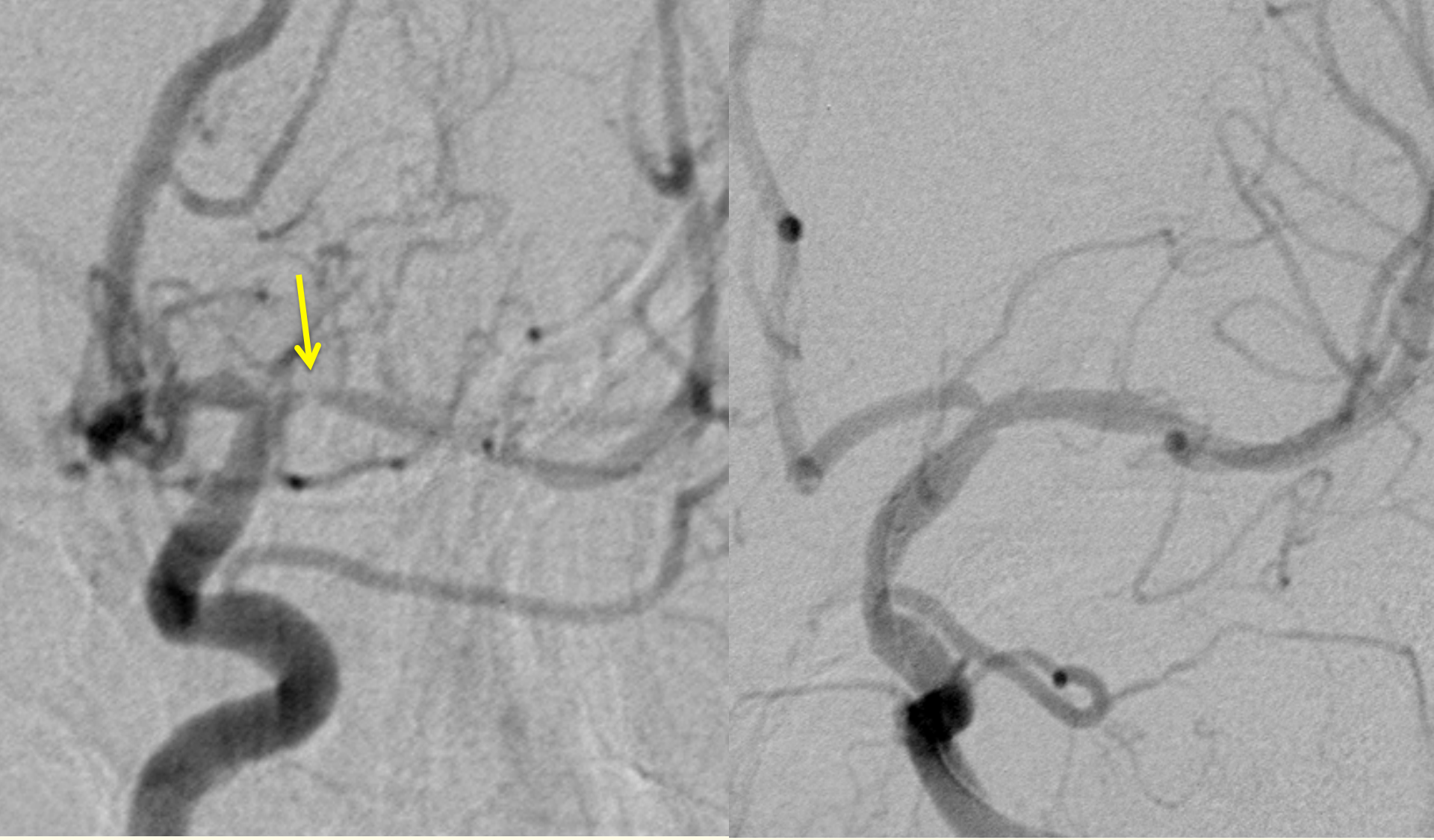
Potential Advantages of SM-PTA



Potential Advantages of SM-PTA

- Reduces trauma to plaque with potential for
  - Lower risk of distal emboli
  - Lower risk of vessel rupture
- Less aggressive luminal restoration
  - May reduce reperfusion hemorrhage



Hemorrhagic Complications in SAMMPRIS

- 11 Total Hemorrhages
  - 5 SAH (2.3%)
  - 6 IPH (2.8%)
    - 4 fatal, 1 mRS 5

Potential Advantages of SM-PTA

- Less plaque disruption
  - Less snow-plowing over regional perforators
- No Stent
  - ?Less likely to pin dislodged plaque over perforator origins
  - ?Less (and shorter lived) thrombogenicity at the revascularization site
  - ?Less stimulus for in-stent stenosis

SM-PTA: Perforator Infarction

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  - Less "snow-plowing" over regional perforators
- No Stent
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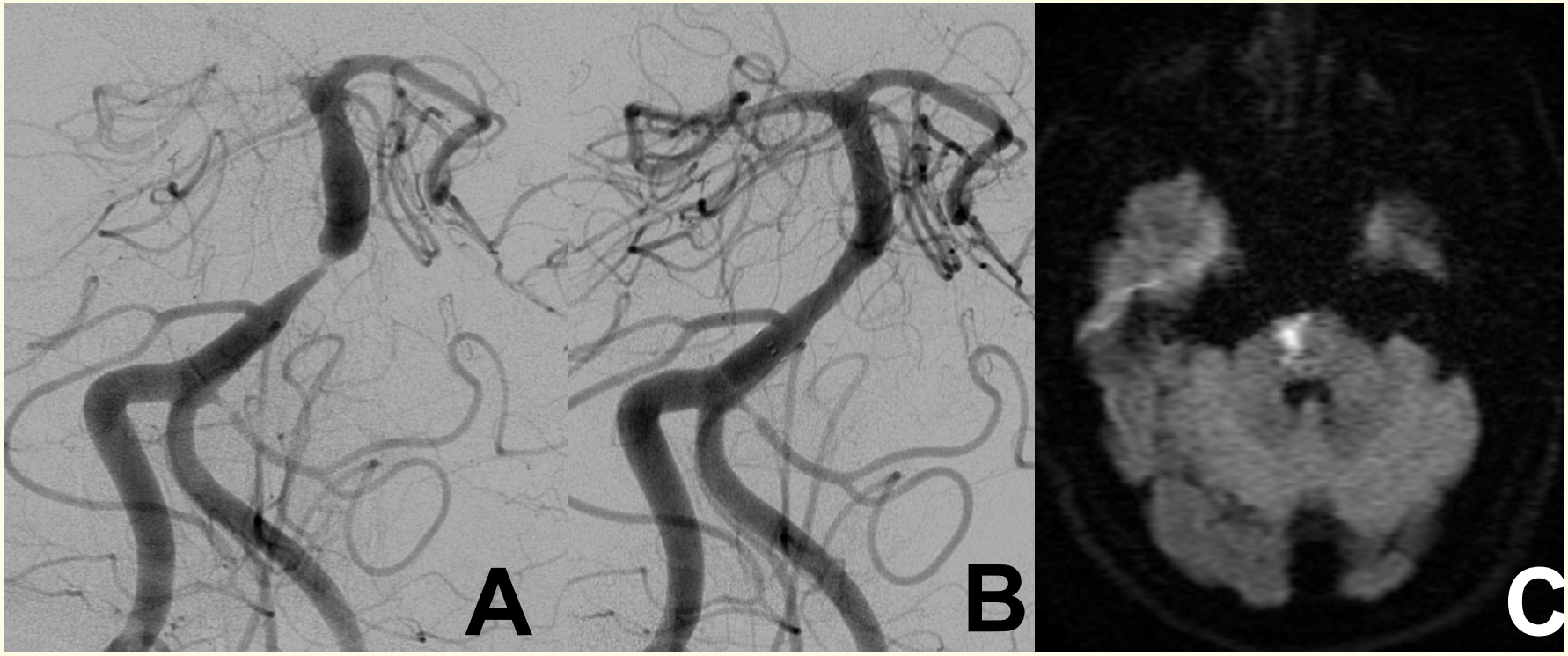
Potential advantages of SM-PTA

- **Perforator Infarction:** Most common single complication related to PTAS in SAMMPRIS
  - Accounted for ~1/2 of all stenting complications in SAMMPRIS
    - 15 of 21 ischemic complications


A
B
C

Existing Clinical Series of PTA Alone

- Dumont et al., Neurosurgery 2012 (4.9%)
  - 41 patients
    - 1 vessel perforation, 1 reperfusion hemorrhage
- Nguyen et al. 2011 (5.0%)
  - 74 patients
    - 2 strokes, 2 deaths (1 ischemic, 1 hemorrhagic)
- Marks et al., 2006 (5.8%)
  - 120 patients
    - 3 strokes, 4 deaths

Existing Clinical Series of PTA Alone

- Low levels of complications (5%)
  - Self-adjudicated, retrospective series
  - Not necessarily a high risk population for recurrent stroke on AMM

Potential Disadvantages of PTA

- Dissection may worsen stenosis
  - Requires stent bailout
- Suboptimal luminal restoration
  - May affect durability of treatment
    - Requires Re-treatment

Post-Treatment Percent Stenosis

- Dumont et al., Neurosurgery 2012 (45%, range 17-70%)
  - 41 patients
- Nguyen et al. 2011 (34% +/- 18%)
  - 74 patients
- Marks et al., 2006 (36% +/- 20%)
  - 120 patients

Post-Treatment Percent Stenosis

- Residual Stenosis after PTA alone
  - ~35%, ranging from 20 – 60%
- Considerations
  - Not core lab adjudicated
  - May represent sufficient flow (r^4)
  - May be safer to have less than full restoration of vessel size
    - Lower perforation rate
    - Lower reperfusion hemorrhage rates

Retreatment Rate after PTA

- Dumont et al., Neurosurgery 2012 (24.4%)
  - 41 patients (median 19M FU)
    - 10 re-PTA, only one for TIA symptoms
    - No complications

Retreatment Rate after PTA

- Nguyen et al., 2011 (2.8%)
  - 71 patients w 3M FU
    - 2 re-treatments, 1 stroke, 1 TIA
    - No complications reported
- Marks et al., 2006 (12.1%)
  - 120 patients w 14 re-treatments (reasons not stated)
  - No complications

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Retreatment Rate after PTA

- Rates of retreatment highly variable: 3 – 25%
  - Non-protocolized operator decision
    - Appearance vs. Symptomatic
- Complications during retreatment appear to be relatively infrequent
  - Small numbers
  - Self-adjudicated

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How to evaluate the theoretical advantages of SM-PTA?

- Single arm, prospective, pilot study of PTA for the treatment of a sub-selected “high risk” cohort from the SAMMPRIS population

How to evaluate the theoretical advantages of SM-PTA?

- Define safety (and efficacy) of PTA
- Determine feasibility of a randomized trial vs. AMM in this population