



To balloon, or not to balloon...

that is the question

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Director of Endovascular Neurosurgery Fellowship Education
Surgical Director of RUSH Comprehensive Stroke Center
Surgical Director of RUSH Interventional Services

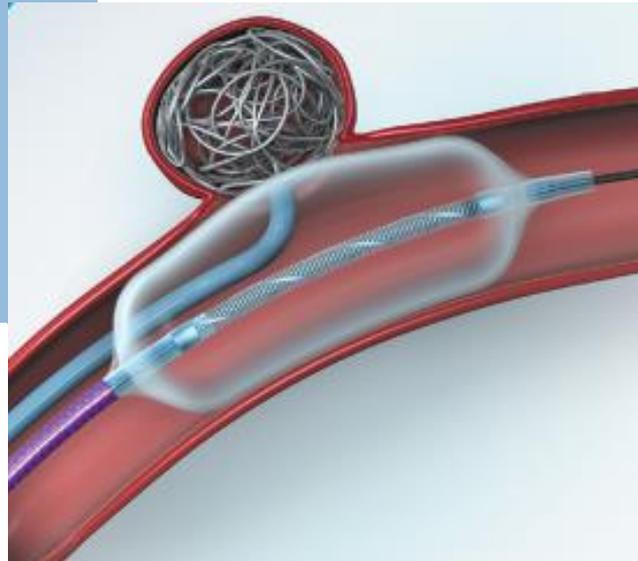
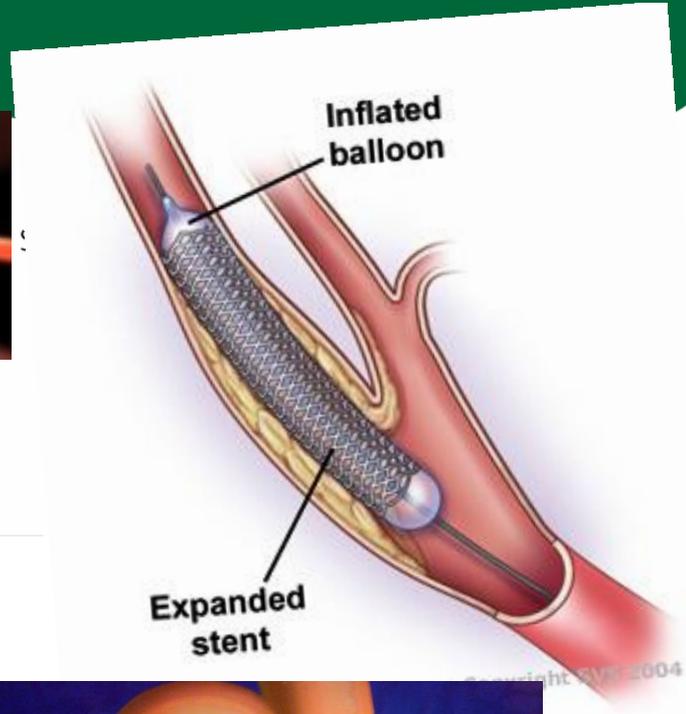
1959 May Day Moscow, USSR



- While watching May Day Parade, Dr. Fedor Serbinenko envisioned small balloons traveling through tortuous arteries
- 1971 (in Russian), 1974 (English) Serbinenko describes balloon test occlusion
 - Temporary occlusion of 304 extracranial and intracranial arteries with 0.7% complication rate



Multiple balloons



Multiple purposes



- Aneurysm
- AVM/AVF
- Vasospasm
- ICAD
- Stroke

Balloon- assisted aneurysm treatment



- Described in 1997 by Moret
- When to consider balloon-assistance
 - Wide neck
 - Parent vessel protection
 - Side branch protection
 - Subarachnoid hemorrhage
 - Avoid antiplatelet medication needed with stent-assistance

Balloon-assisted Coiling



Single-center experience with balloon-assisted coil embolization of intracranial aneurysms: Safety, efficacy and indications

Nohra Chalouhi, Pascal Jabbour, Stavropoula Tjoumakaris, Aaron S. Dumont, Rohan Chitale, Robert H. Rosenwasser, L. Fernando Gonzalez*

- 76 aneurysms
 - 40 ruptured
 - 36 unruptured

	N	Complications	Packing Density	Incomplete Occlusion
Parent vessel protection	56	5 neurologic* 1 groin hematoma	28.09	1
Side-branch protection	12	1 intra-op rupture	28.77	0
Balloon-in-stent technique	8	1 groin hematoma	29.54	0

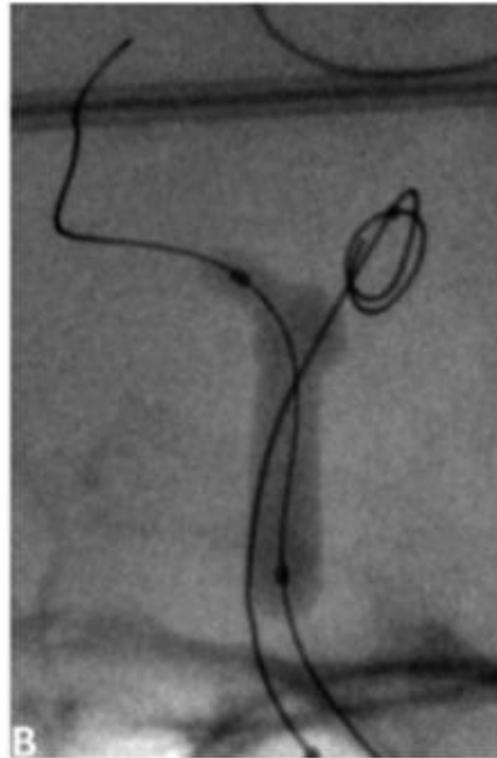
*4 transient; 1 permanent

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- Balloon-assisted embolization was achieved in all, but one case
- Mean total occlusion time = 16 min
- Mean maximum single inflation time = 5.1 min

Criticism of Balloon-assisted Aneurysm Treatment



- **Temporary protection**
 - Coil prolapse after deflation/removal of the balloon
- **Occlusion time**
 - May require multiple cycles of inflation/deflation
- **Brain ischemia**
 - During inflation, potential for downstream ischemia
- **Durability**
 - Long-term assessment of durability ongoing
 - Change to packing density/coil mass following balloon deflation/removal

Balloon-assisted Coiling

INTERVENTIONAL NEURORADIOLOGY



Balloon-assisted coiling of intracranial aneurysms is not associated with a higher complication rate

Boris Lubicz · Florence Lefranc · Michaël Bruneau ·
Danielle Balériaux · Olivier De Witte

- Comparison of 92 BAC-treated aneurysms to 204 aneurysms treated by primary coiling

Indication for BAC	N (%)
Unfavorable dome/neck	65 (70.6)
Branch arising from neck	18 (19.6)
Microcatheter instability	6 (6.5)
Anticipated aneurysm rupture	3 (3.3)

	BAC	Coiling
Morbidity	2.5%	2.3%
Mortality	1.25%	1.15%

“BAC may be an acceptable alternative to coiling for complex aneurysms in the acute phase of SAH”

Balloon-assisted Coiling



ORIGINAL
RESEARCH

Safety and Efficacy of Adjunctive Balloon Remodeling during Endovascular Treatment of Intracranial Aneurysms: A Literature Review

- Meta-analysis of 23 studies
 - 867 aneurysms treated with coiling
 - 273 aneurysms treated with BAC

	BAC	Coiling
Thromboembolic event	8.1%	8.0%
Perforation	1.8%	1.4%
Initial total occlusion	73%	49%
Follow-up total occlusion	72%	54%

Balloon inflation is safe!



An Analysis of Inflation Times During Balloon-Assisted Aneurysm Coil Embolization and Ischemic Complications

Alejandro M. Spiotta, MD; Tarun Bhalla, MD; Muhammad S. Hussain, MD; Thinesh Sivapatham, MD; Ayush Batra, BS; Ferdinand Hui, MD; Peter A. Rasmussen, MD; Shaye I. Moskowitz, MD, PhD

	Balloon	No Balloon
N	81	66
Mean # of inflations	4	NA
Mean inflation time	18 min	NA
Mean single inflation maximum	7 min	NA
Symptomatic DWI	3 (3.8%)	5 (7.6%)
Silent DWI	17 (21.5%)	10 (15.2%)

“...no significant relationship between balloon inflation practices and ischemic events.”

vs. Stent-assistance



- 101 consecutive patients treated at a single institution

	Balloon-assisted	Stent-assisted
N	32	69
Occlusion		
Raymond I	11 (34.4%)	22 (31.9%)
Raymond II	21 (65.6%)	44 (63.8%)
Raymond III	0 (0%)	3 (4.3%)
Packing density*	29.4%	17.5%
Complete occlusion at follow-up*	42.8%	75.4%
Retreatment rate*	15.6%	4.3%

*statistically significant



vs. Stent-assistance



- 84 patients with ruptured aneurysms
 - 40 balloon-assisted
 - 44 stent-assisted
- “procedural complications and clinical outcomes did not differ significantly”

TABLE 2. Results^a

	BAC, n (%)	SAC, n (%)
Initial occlusion rates	38 (95)	40 (91)
Complications		
Hemorrhagic	1 (2.5)	3 (6.8)
Thromboembolic	3 (7.5)	5 (11.4)
Overall	4 (10)	8 (18.2)
Modified Rankin Scale score at discharge		
0	8 (20)	10 (22.7)
1	7 (17.5)	6 (13.6)
2	13 (32.5)	7 (16)
3	3 (7.5)	1 (2.3)
4	5 (12.5)	11 (25)
5	1 (2.5)	2 (4.5)
6	3 (7.5)	7 (15.9)
Modified Rankin Scale score at follow-up		
0	12 (30.8)	11 (26.8)
1	13 (33.3)	8 (19.5)
2	5 (12.8)	6 (14.6)
3	1 (2.6)	5 (12.2)
4	3 (7.7)	1 (2.5)
5	1 (2.6)	2 (4.9)
6	4 (10.2)	8 (19.5)

^aBAC, balloon-assisted coiling; SAC, stent-assisted coiling.

Apples vs. oranges?



Are Aneurysms Treated With Balloon-Assisted Coiling and Stent-Assisted Coiling Different? Morphological Analysis of 113 Unruptured Wide-Necked Aneurysms Treated With Adjunctive Devices

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Brian Hanak, MD‡

Ryan Morton, MD‡

Joshua W. Osbun, MD‡

Michael R. Levitt, MD‡

Louis J. Kim, MD‡

*Department of Neurological Surgery, University of Miami Miller School of Medicine, Miami, Florida; †Department of Neurological Surgery, University of Washington School of Medicine, Harborview Medical Center, Seattle, Washington

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Louis J. Kim, MD

BACKGROUND: In the endovascular treatment of wide-necked unruptured aneurysms, there is controversy over which adjunctive device (stent vs balloon) is appropriate. At the payer level it has been posited that stents and balloons treat the same aneurysms, and, as such, the more expensive stents should not be reimbursed.

OBJECTIVE: We challenge this assertion, and instead hypothesize that aneurysms treated with stent assistance are morphologically different than those selected for balloon assistance.

METHODS: Retrospective review of unruptured aneurysms treated with an adjunctive device between 2008 and 2010. Morphological analysis was performed on the pre-treatment 2-D catheter angiogram. The immediate posttreatment Raymond score was compared with that seen on the 12-month follow-up angiogram.

RESULTS: One hundred six unruptured aneurysms were treated with an adjunctive device and followed for a mean of 24.5 months. Morphological analysis revealed a lower dome-to-neck ratio (1.5 vs 1.2) and aspect ratio (1.44 vs 1.16) in the aneurysms treated

CONCLUSION: We found that unruptured aneurysms selected for treatment with stent-assisted coiling are morphologically different from those selected for treatment with balloon assistance. Despite the more challenging morphology, Raymond scores and re-treatment rates at 1 year were not statistically different between the 2 groups, suggesting an important role for stents in the treatment of unruptured aneurysms.

Apples vs. oranges?

TABLE 2. Comparison of Aneurysms Treated With Balloon Assistance vs Stent Assistance^a

	Stent, %	Balloon, %	P Value
Number	63	34	NA
Aspect ratio	1.16 (IQR 0.7-1.6)	1.44 (IQR 1.05-1.78)	.009 ^b
Dome-to-neck	1.18 (IQR 1.01-1.59)	1.5 (IQR 1.16-1.66)	.01 ^b
Re-treatment rate	8/63 (12.7)	2/35 (5.7)	.233
Major complications	5/71 (7.1)	0/0 (0)	.001 ^b
Minor complications	6/71 (8.5)	3/35 (8.6)	.342

^aNA, not available; IQR, interquartile range.

^bStatistically significant.

Benefits of Balloon-assisted Aneurysm Treatment



- **Reliable parent artery protection**
 - Inflation with contrast reveals exact position and extent of parent artery protection
 - No interstices (like stent) = no microcatheter/coil prolapse
- **Unambiguous parent artery visualization**
 - Balloon conforms to shape of parent vessel, thereby better defining the neck
- **Rupture protection**
 - During inflation, aneurysm isolated from circulation thereby preventing/minimizing extravasation

Benefits of Balloon-assisted Aneurysm Treatment

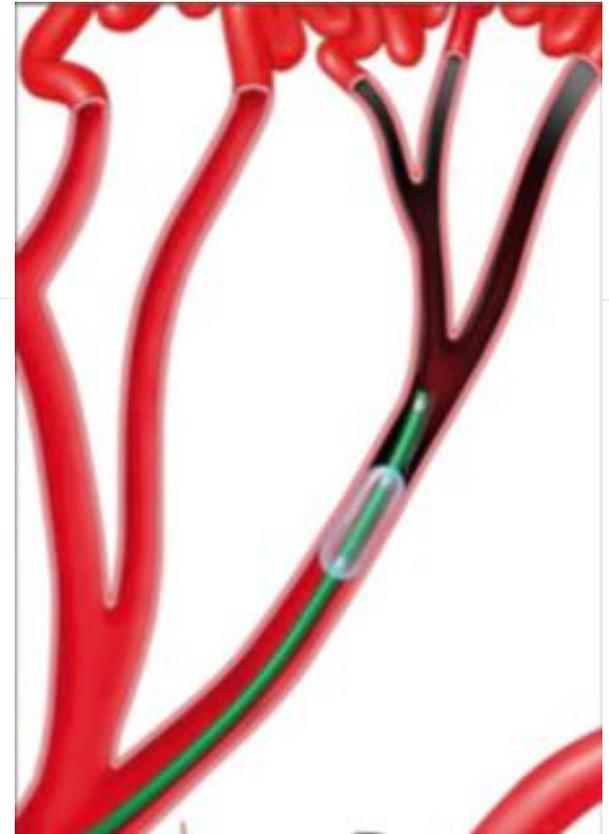


- **Temporary device!**
 - No requirement for dual antiplatelet therapy
- **Improved microcatheter access**
 - Stabilizes microcatheter at aneurysm neck
 - Prevent excessive microcatheter kickback
 - No barrier to re-access of the aneurysm (vs. passing through stent interstices)
- **Improved packing density**

AVMs and AVFs



- Prevents reflux
 - Immediate anterograde embolization → selective nidal penetration
 - Decrease risk of microcatheter retention
- More control of anterograde embolization
 - Particularly helpful when high-flow fistulous component is present



ORIGINAL RESEARCH

Balloon-augmented Onyx embolization of cerebral arteriovenous malformations using a dual-lumen balloon: a multicenter experience

Alejandro M Spiotta,¹ Robert F James,^{2,3} Stephen R Lowe,¹ Jan Vargas,¹ Aquilla S Turk,⁴ M Imran Chaudry,⁴ Tarun Bhalla,⁵ Rashid M Janjua,⁶ John J Delaney,⁷ Stacey Quintero-Wolfe,⁶ Raymond D Turner¹

- 37 arterial pedicles embolized using Scepter C dual lumen balloon microcatheter
- Mean size = 3.3 cm
- Mean fluoroscopy time per procedure = 48 min
- 2 balloon-related complications (8.3%)
 - Rupture of arterial pedicle by inflated balloon
 - Retained Scepter catheter



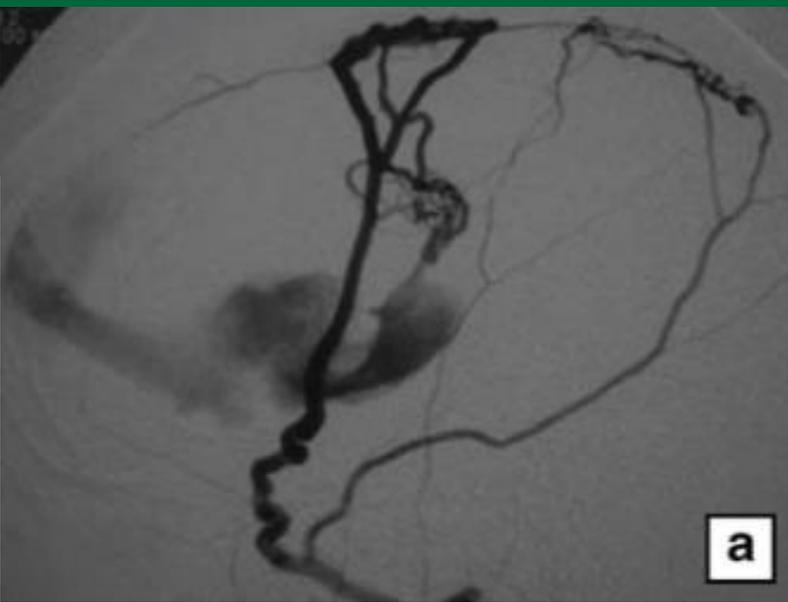
Balloon used to for immediate proximal control and embolization of ruptured vessel

AVMs and AVFs

INTERVENTIONAL NEURORADIOLOGY

Transarterial balloon-assisted glue embolization of high-flow arteriovenous fistulas

Alexander Andreou · Ioannis Ioannidis ·
Nickolaos Nasis



Scepter Balloons



- Flexible, co-axial double-lumen design
- Scepter C (compliant) and XR (extracompliant)
- Navigable over 0.014 in microwire
- Obviates need for proximal Onyx plug
 - Deeper nidal penetration
 - Less fluoroscopy time
 - Faster procedure

Scepter C Compliant Balloon Catheter 

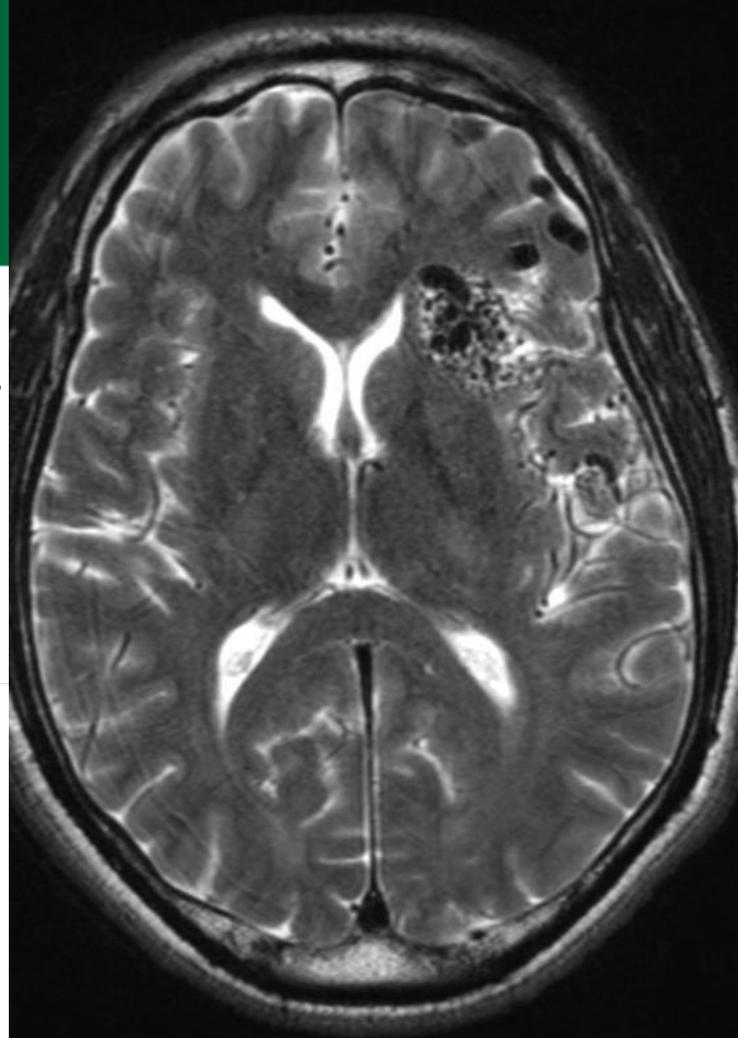
Product Code	Description	Balloon Diameter (mm)	Balloon Length (mm)	Distal Tip Length (mm)
1 balloon catheter, 1 introducer sheath, 1 shaping mandrel per box				
BC0410C	Compliant Occlusion Balloon	4.0	10	5
BC0415C	Compliant Occlusion Balloon	4.0	15	5
BC0420C	Compliant Occlusion Balloon	4.0	20	5

Scepter XC X-tra Compliant Balloon Catheter 

Product Code	Description	Balloon Diameter (mm)	Balloon Length (mm)	Distal Tip Length (mm)
1 balloon catheter, 1 introducer sheath, 1 shaping mandrel per box				
BC0411XC	X-tra Compliant Occlusion Balloon	4.0	11	5



IG •



EGE

35 year old man with new onset seizures

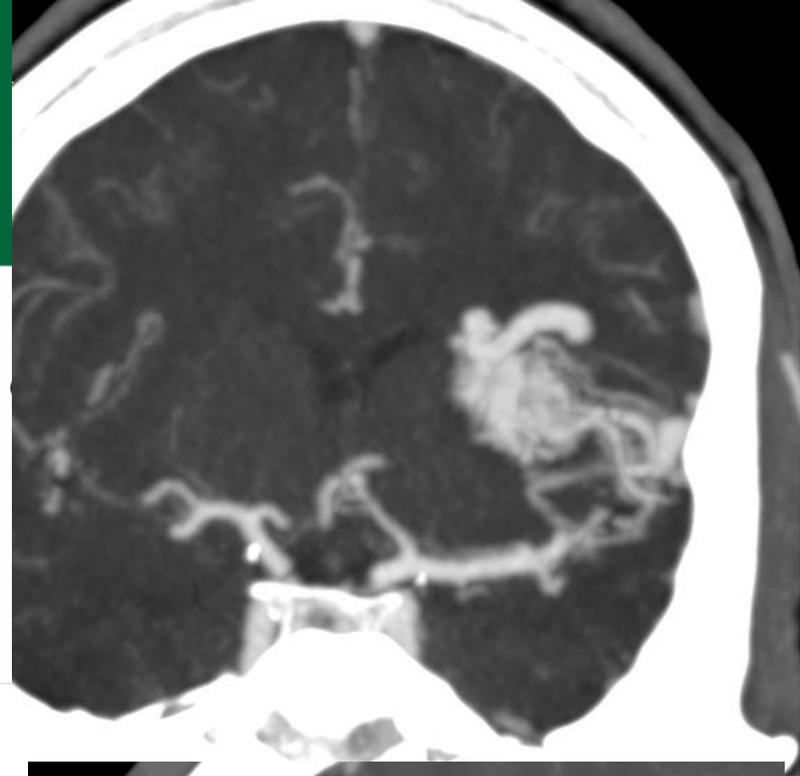
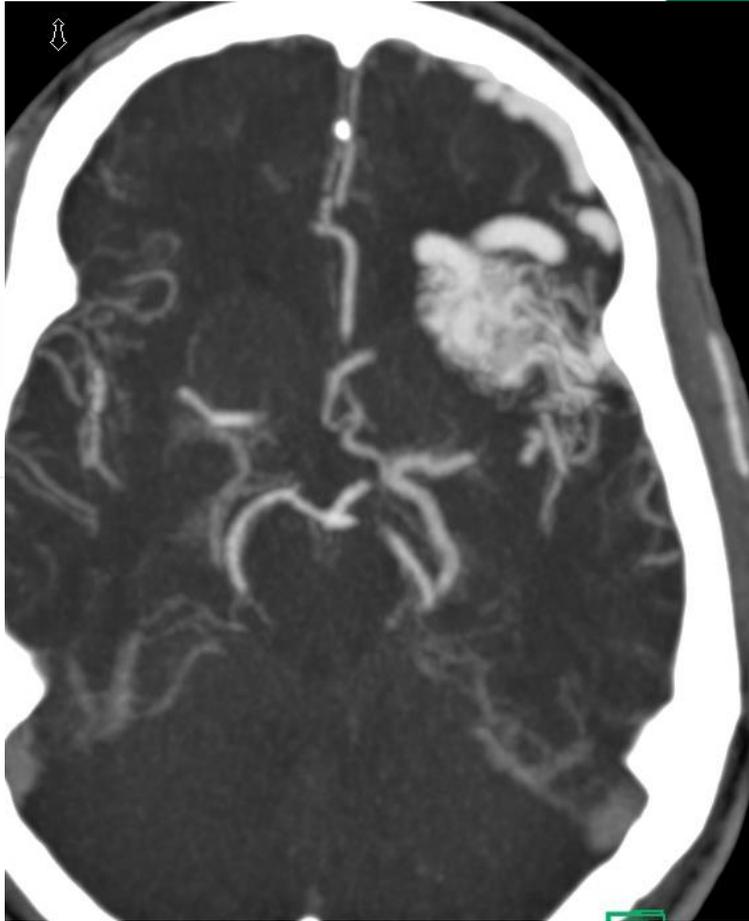
Non contrast head CT

No hemorrhage

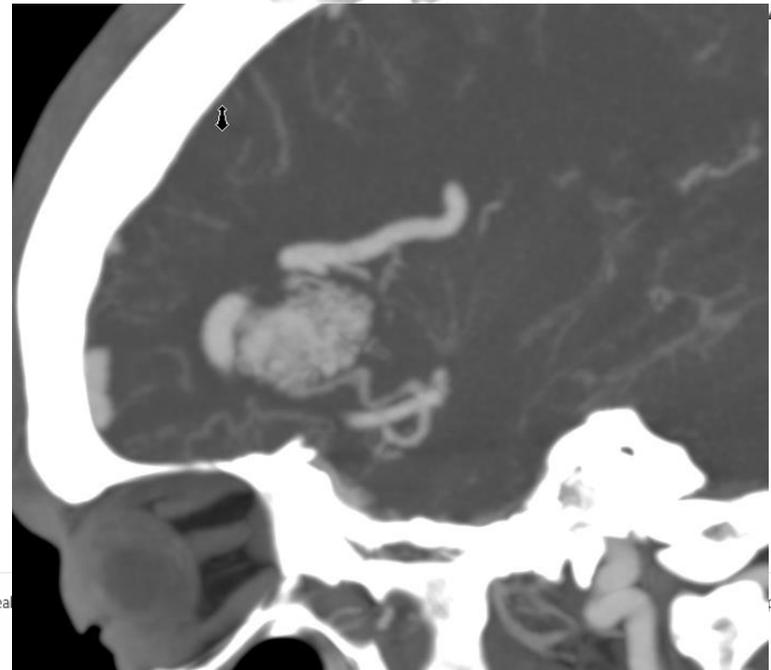
Normal neurologic exam

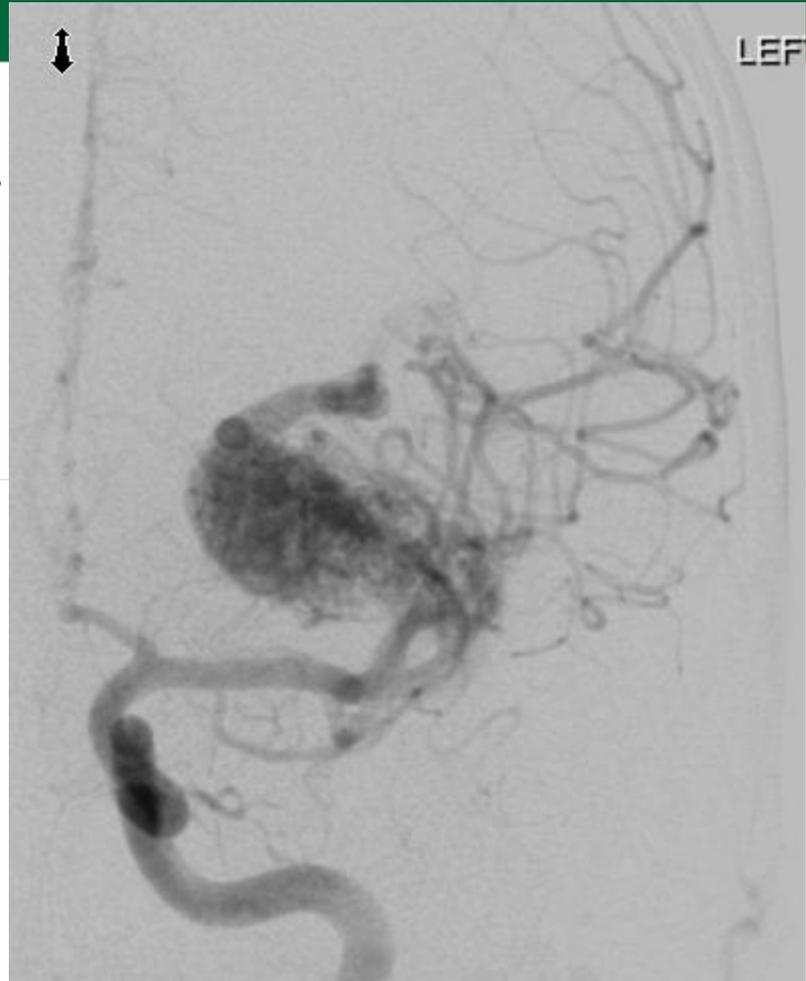


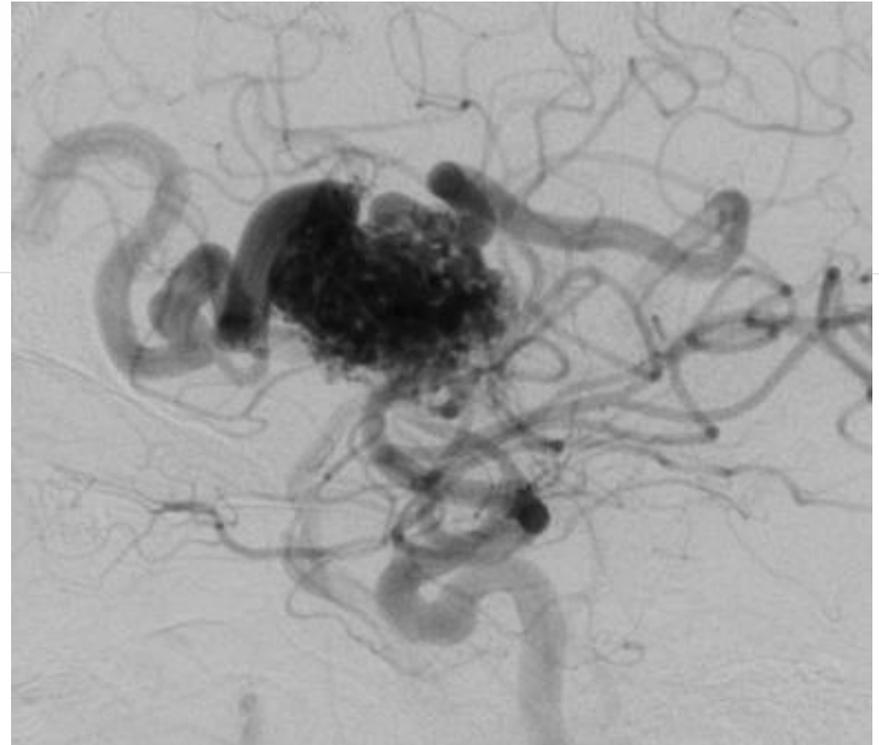
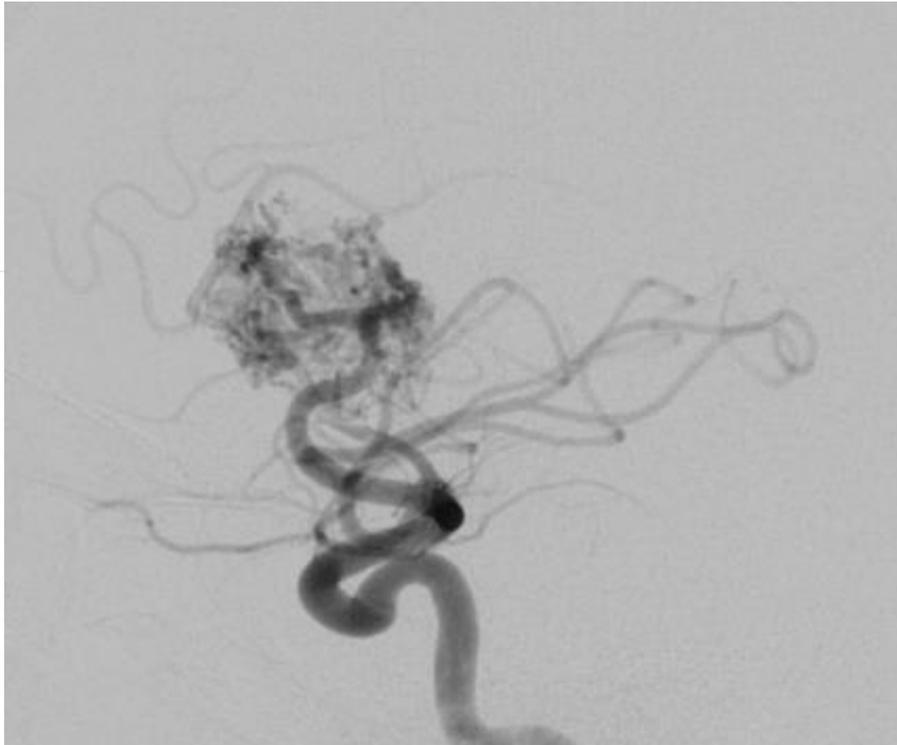




NG •







Options

- Surgery



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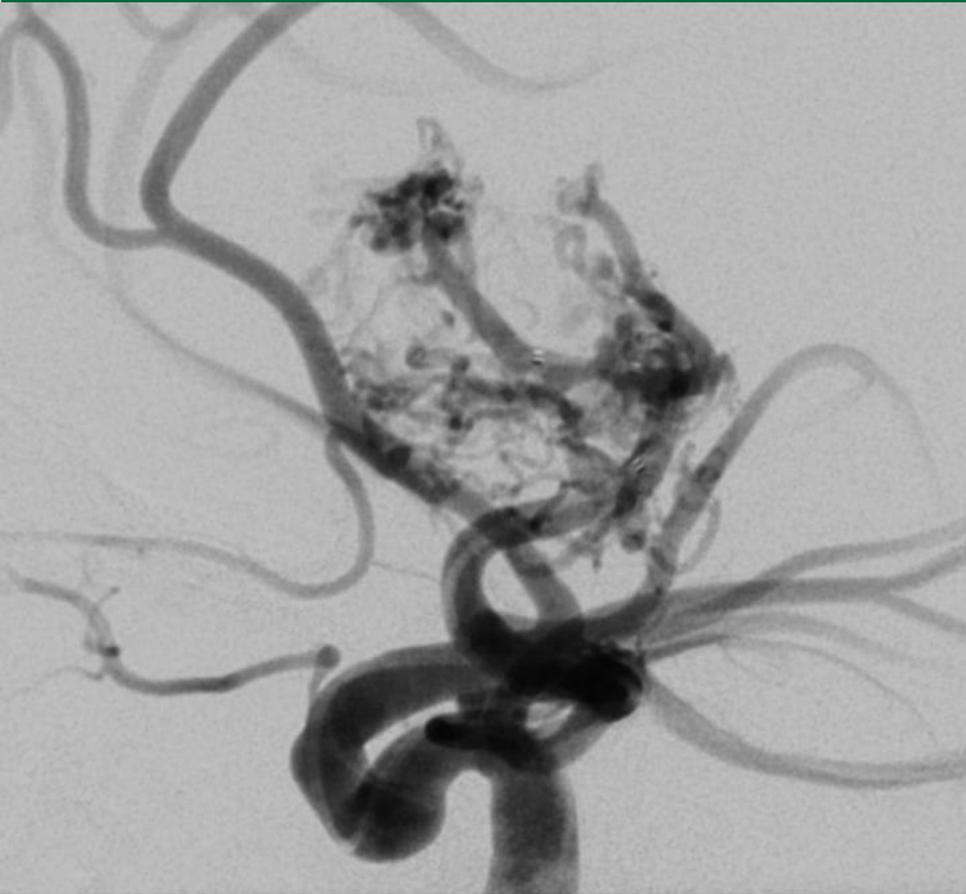
RUSH MEDICAL COLLEGE • COLLEGE OF NURSING • COLLEGE OF HEALTH SCIENCES • THE GRADUATE COLLEGE

- Embolization

- Radiosurgery

- Features unique to case:

- Deep nidus, eloquent location, superficial drainage, 2-3cm nidus, unruptured, 36 year old man.



Guide catheter run

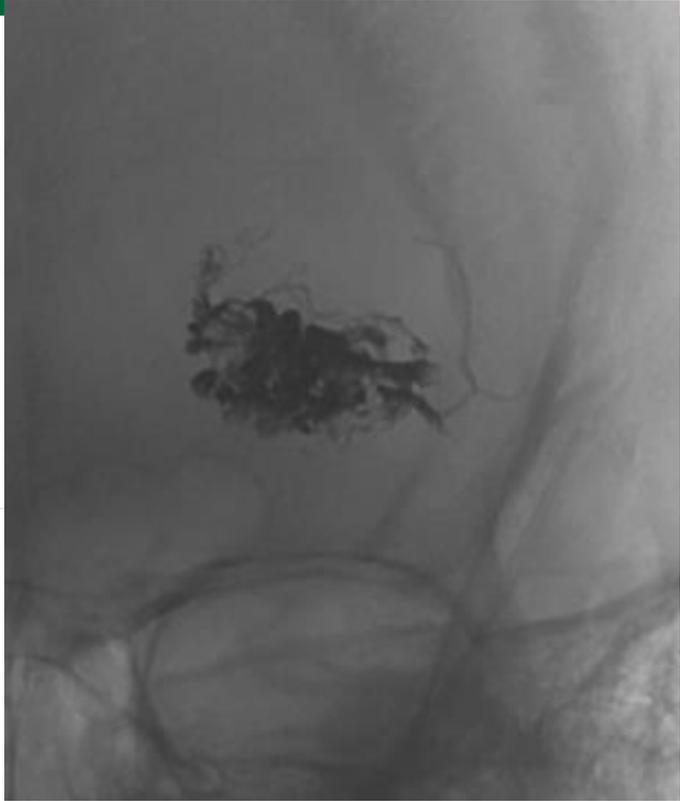


Microcatheter run

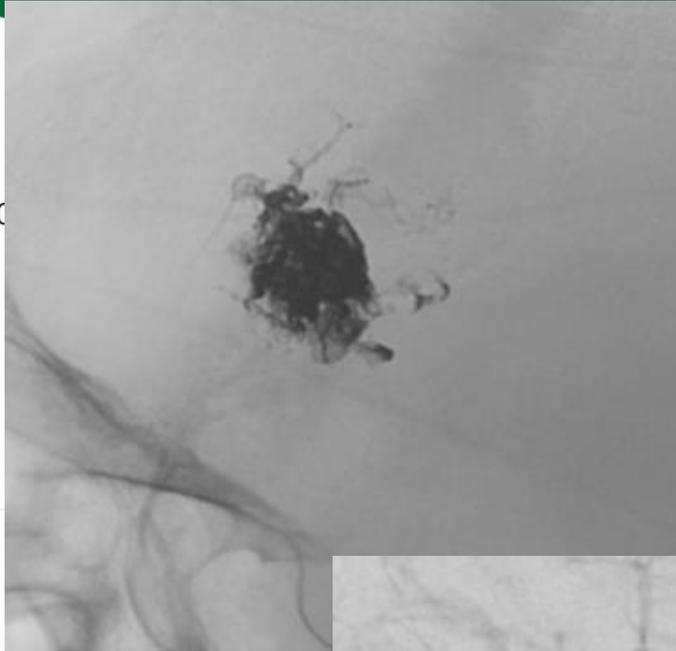
Fairly tortuous but large feeder which helped.
More important than where the distal tip is placed, where
distal balloon marker is.

Stage 1 embolization in January 2016

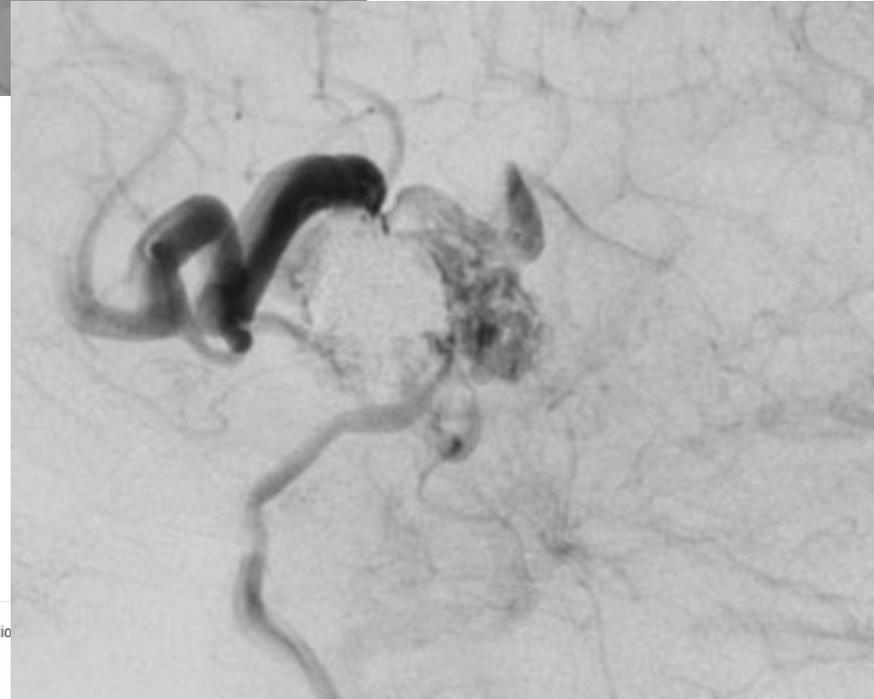
40% occlusion



AP cast
view



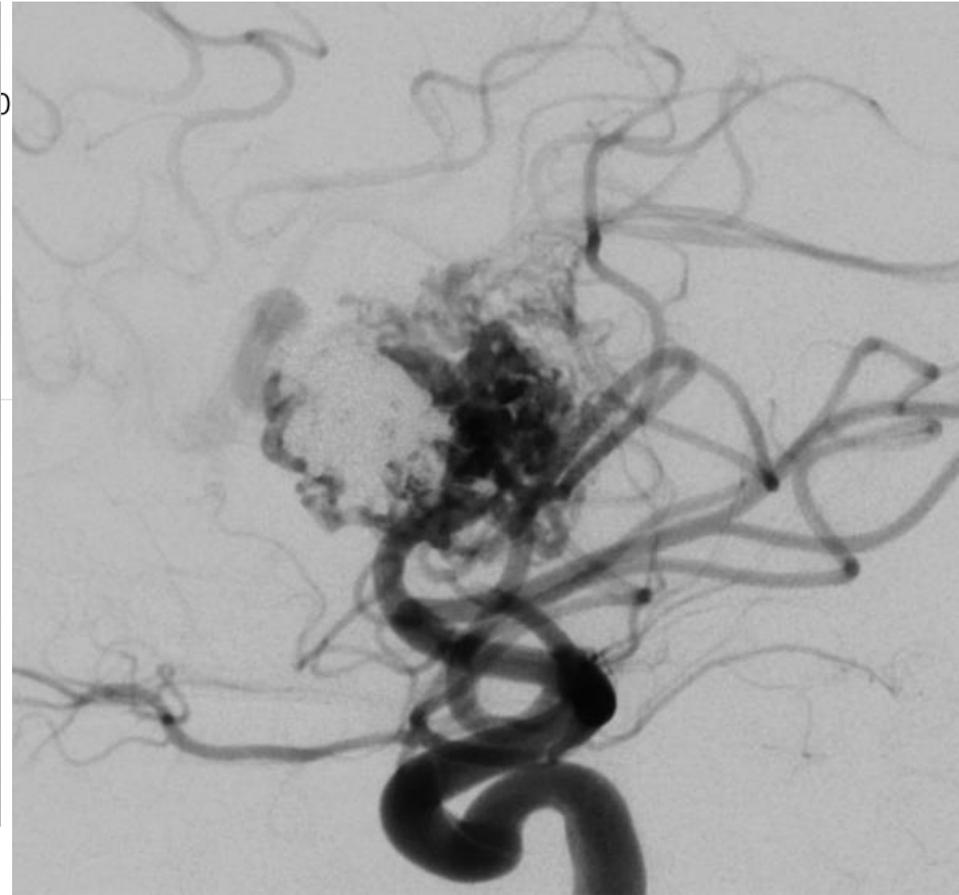
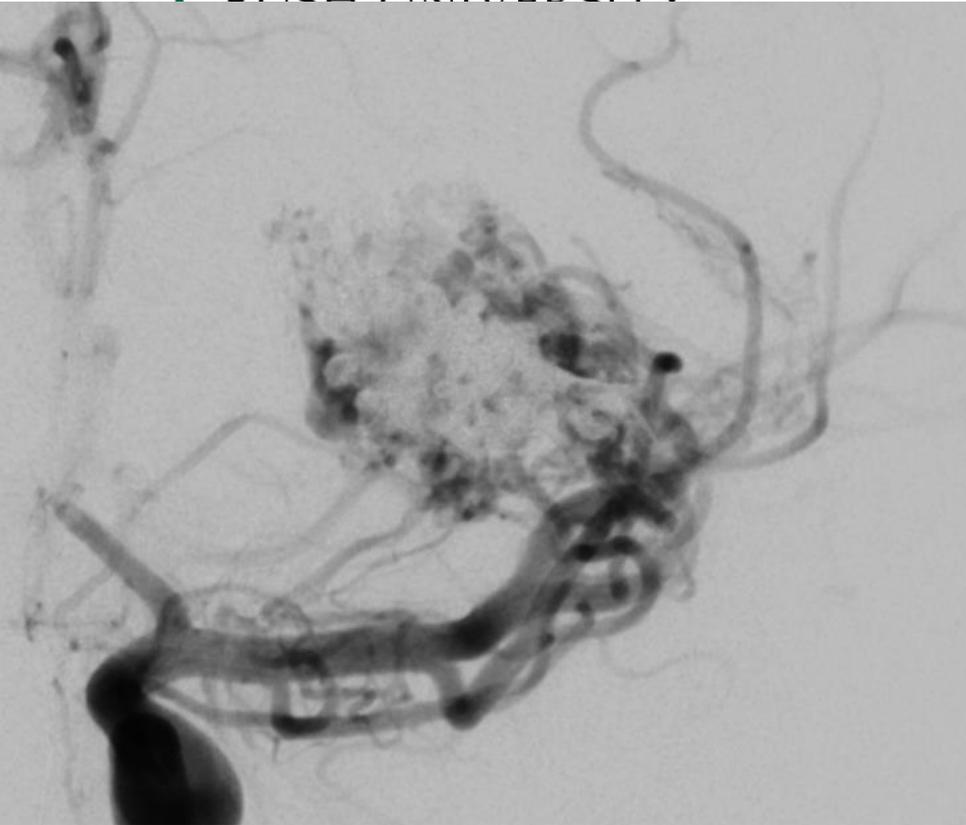
Lateral
cast and
DSA view

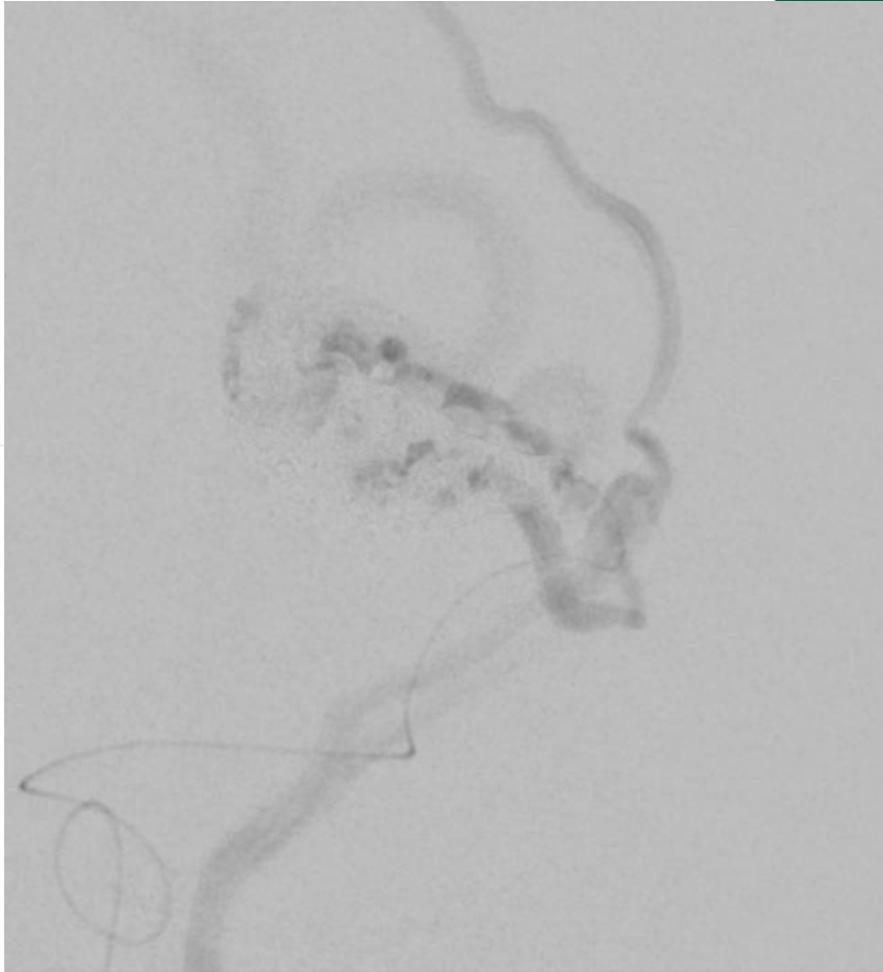


Stage 2 embolization in April 2016

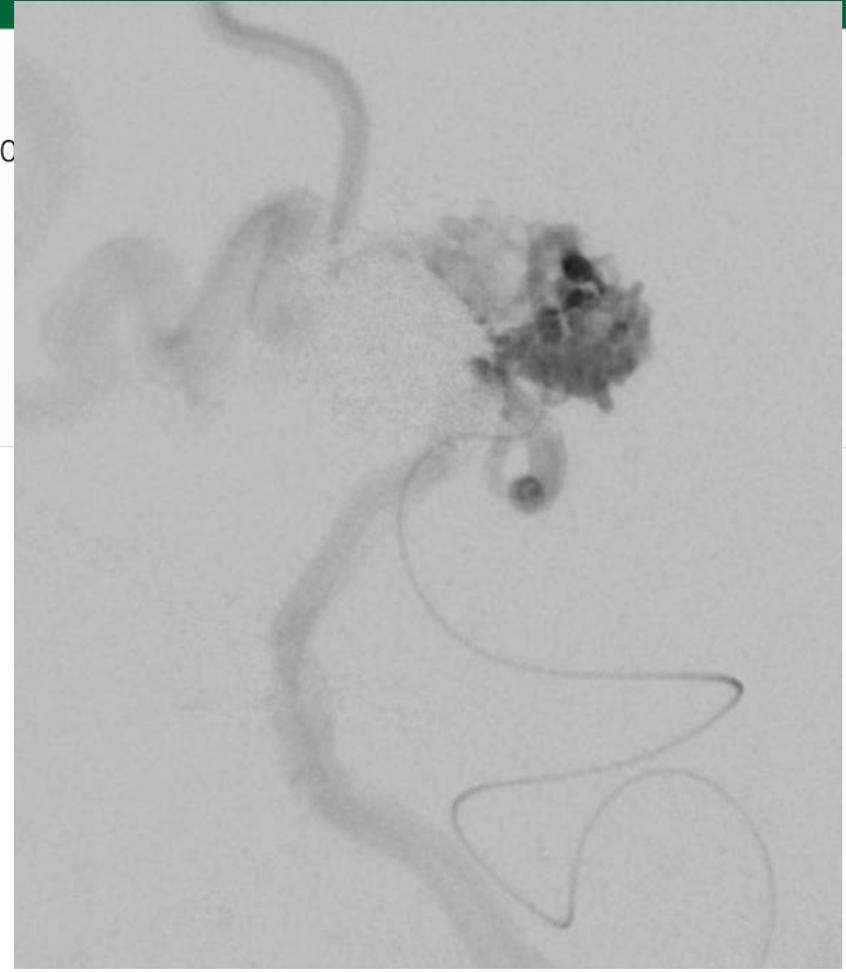
Preintervention runs

 DULUTH UNIVERSITY

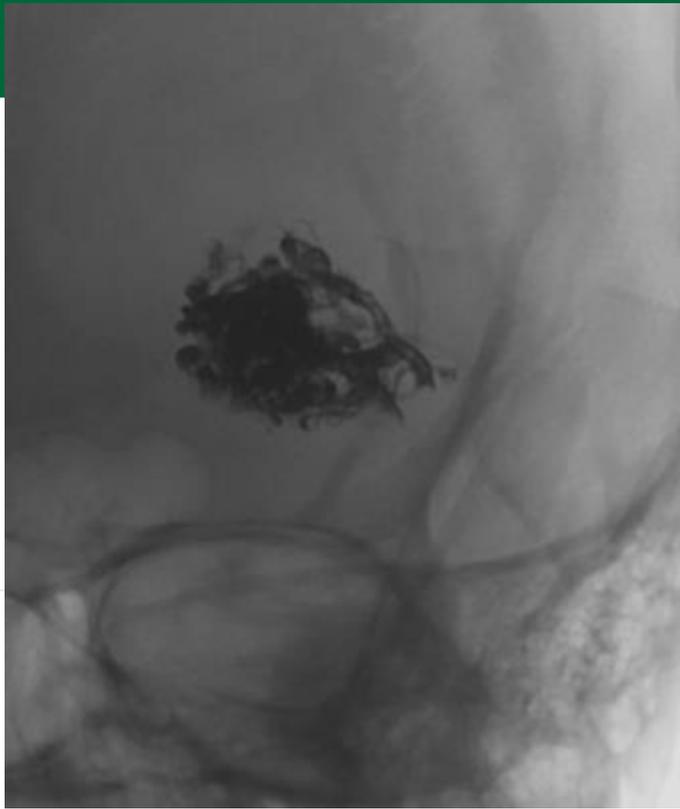




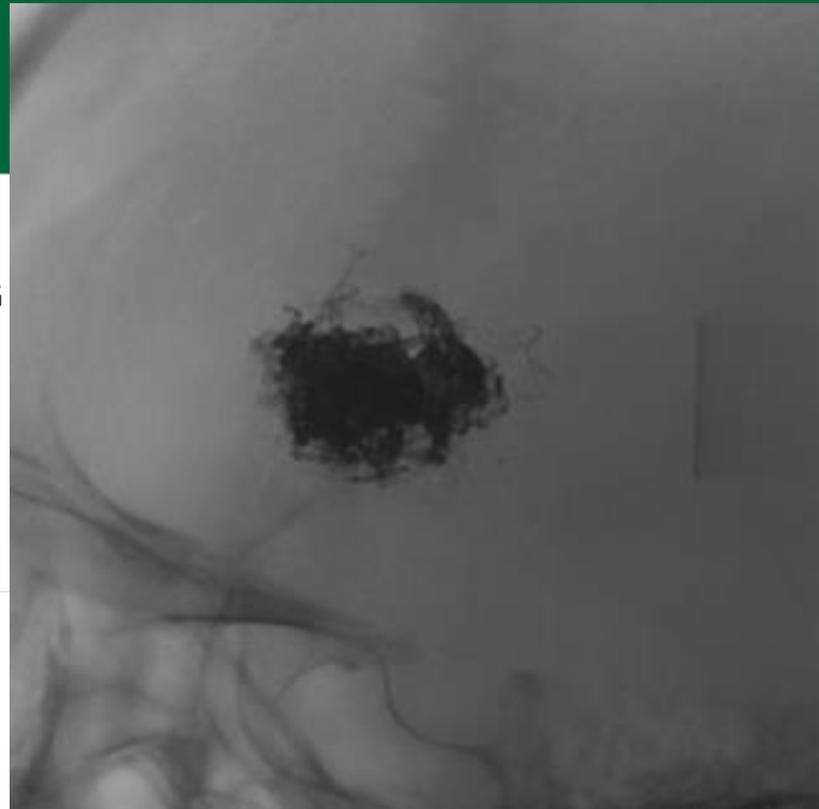
AP microcatheter injection
injection



Lateral microcatheter



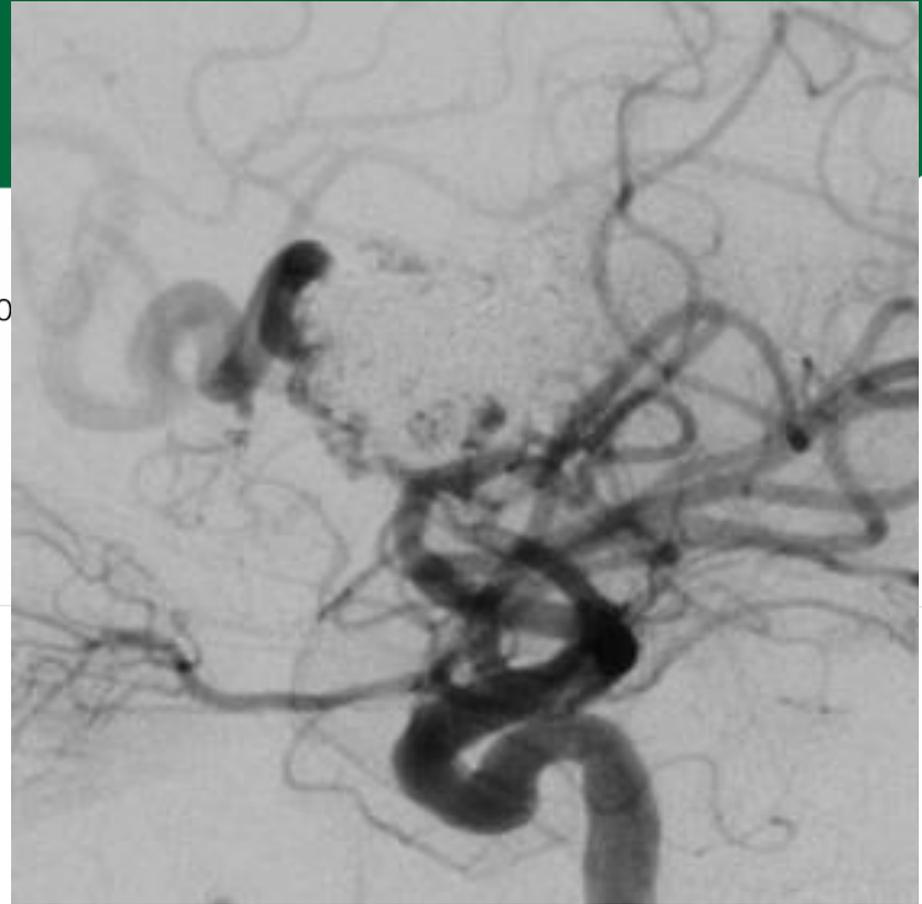
AP cast view



Lateral cast view



• CO

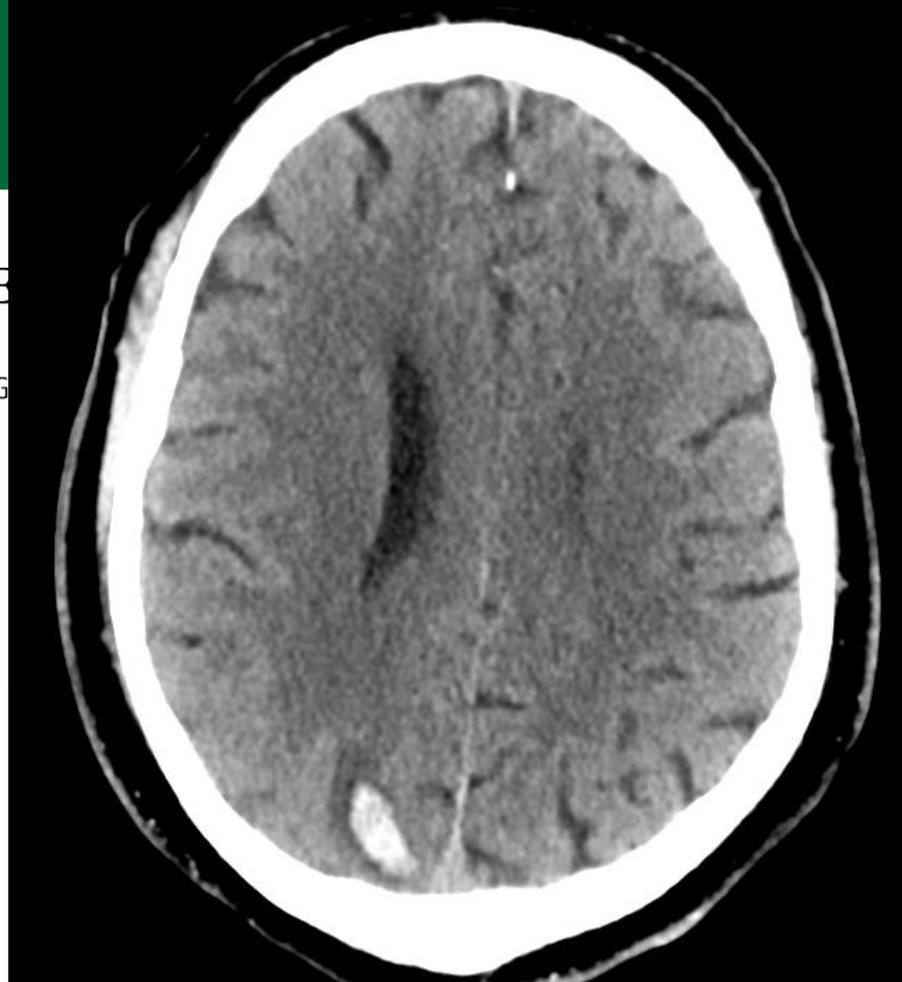


Final control runs showing about 10% residual—going for radiosurgery in October 2016

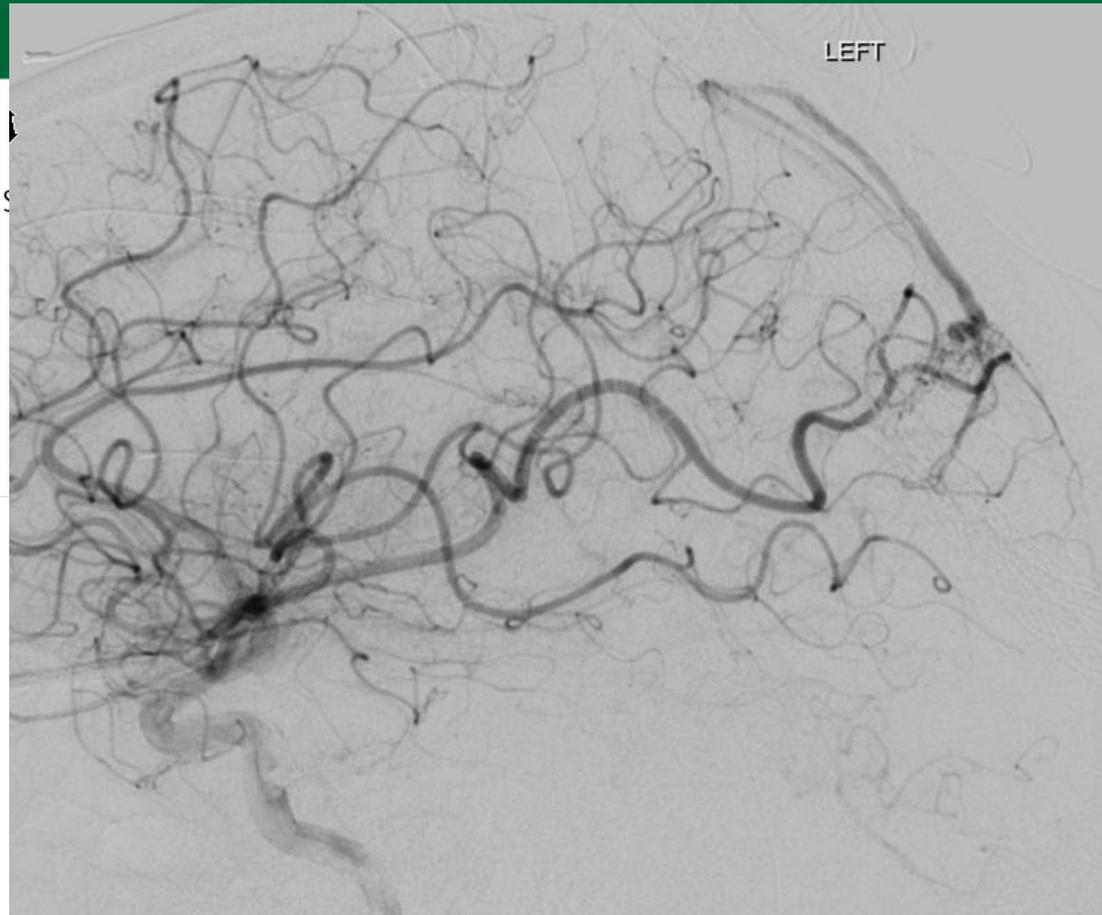
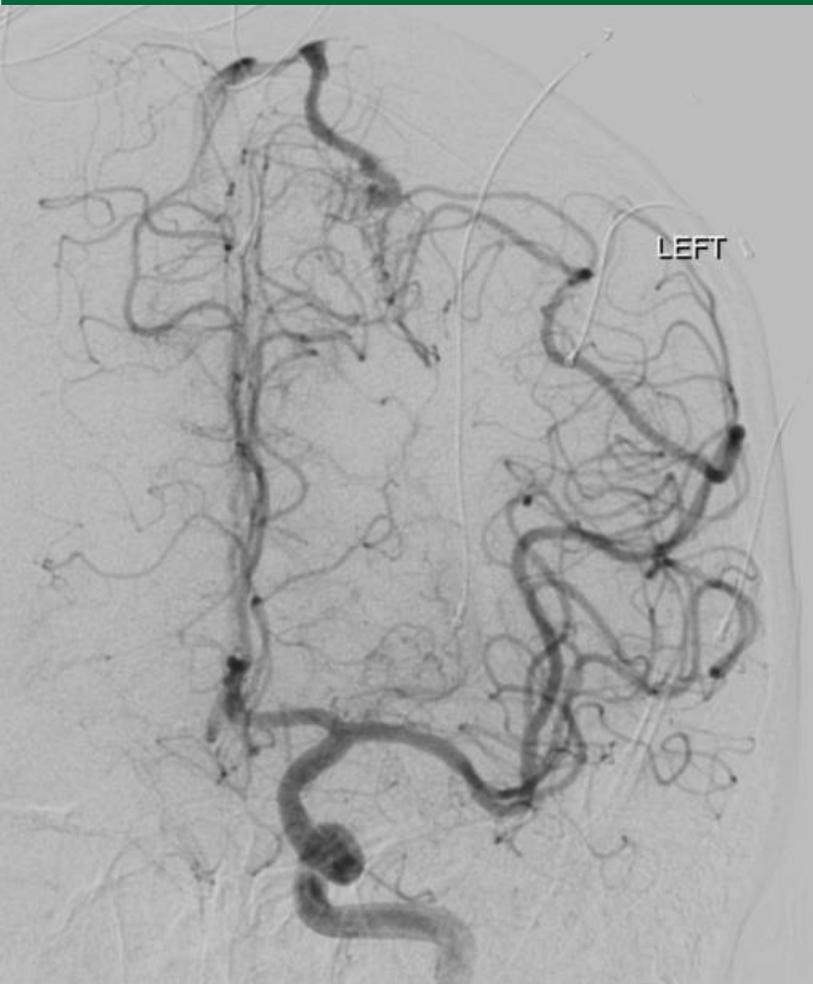
NIHSS=0



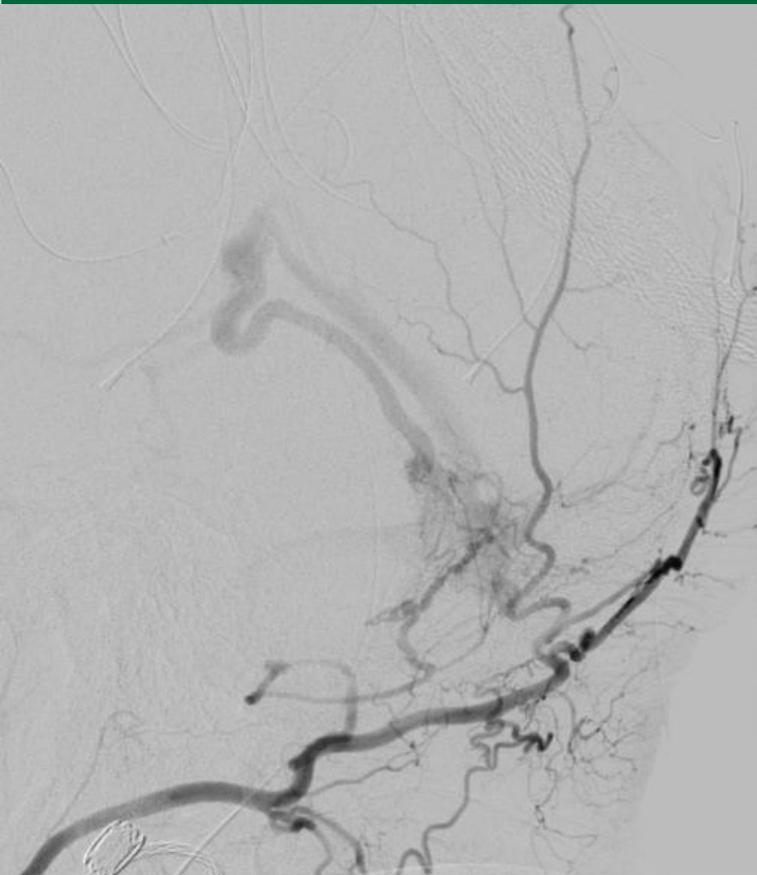
Rush is a not-for-profit health care, education and research enterprise comprising Rush University Medical Center, Rush University, Rush Oak Park Hospital and Rush Health.



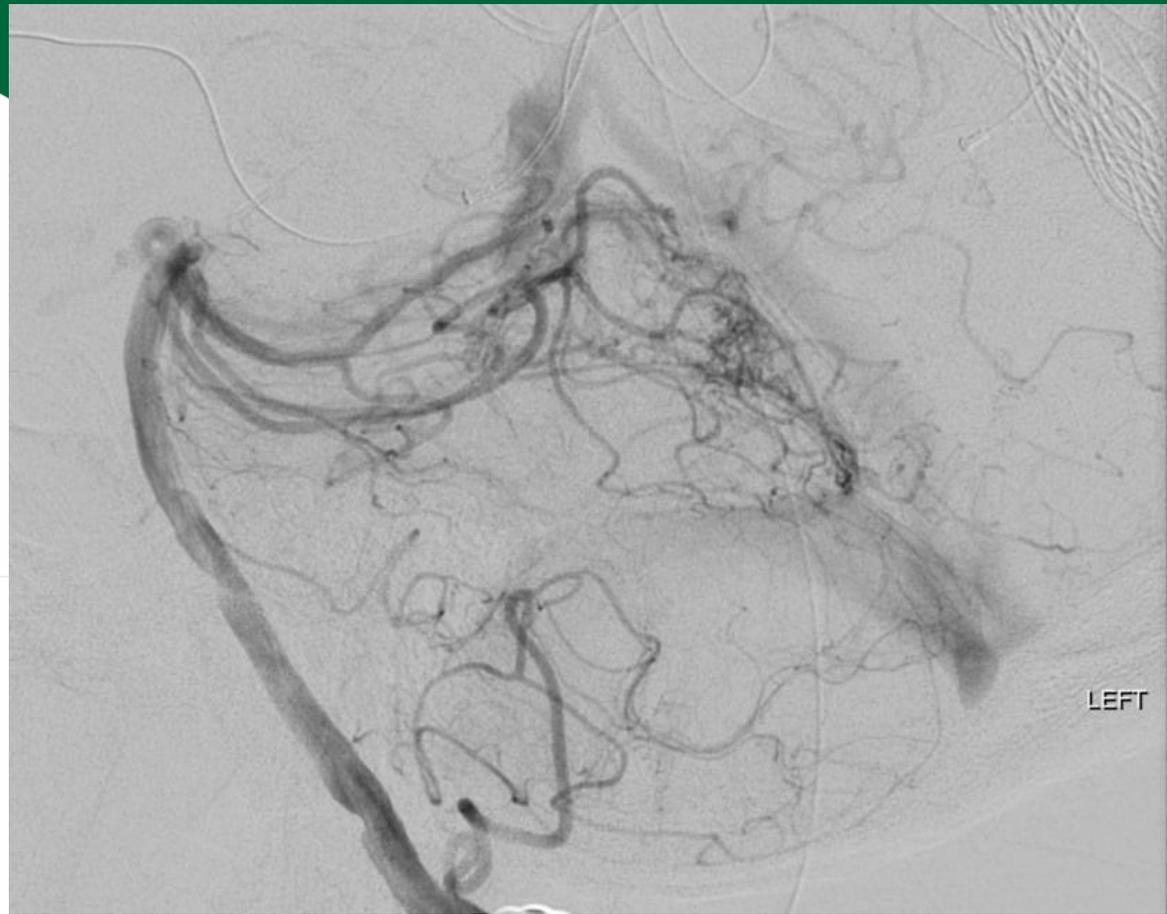
67 year old man with severe headache



<1cm left parietal convexity AVM with venous aneurysm
Contralateral to hematoma



Left ECA lateral view
view



Posterior circulation lateral
view

Resection of left parietal convexity AVM

Followup angiography showed now very small left parietal convexity AVM in vicinity of initial hematoma.

This was also r



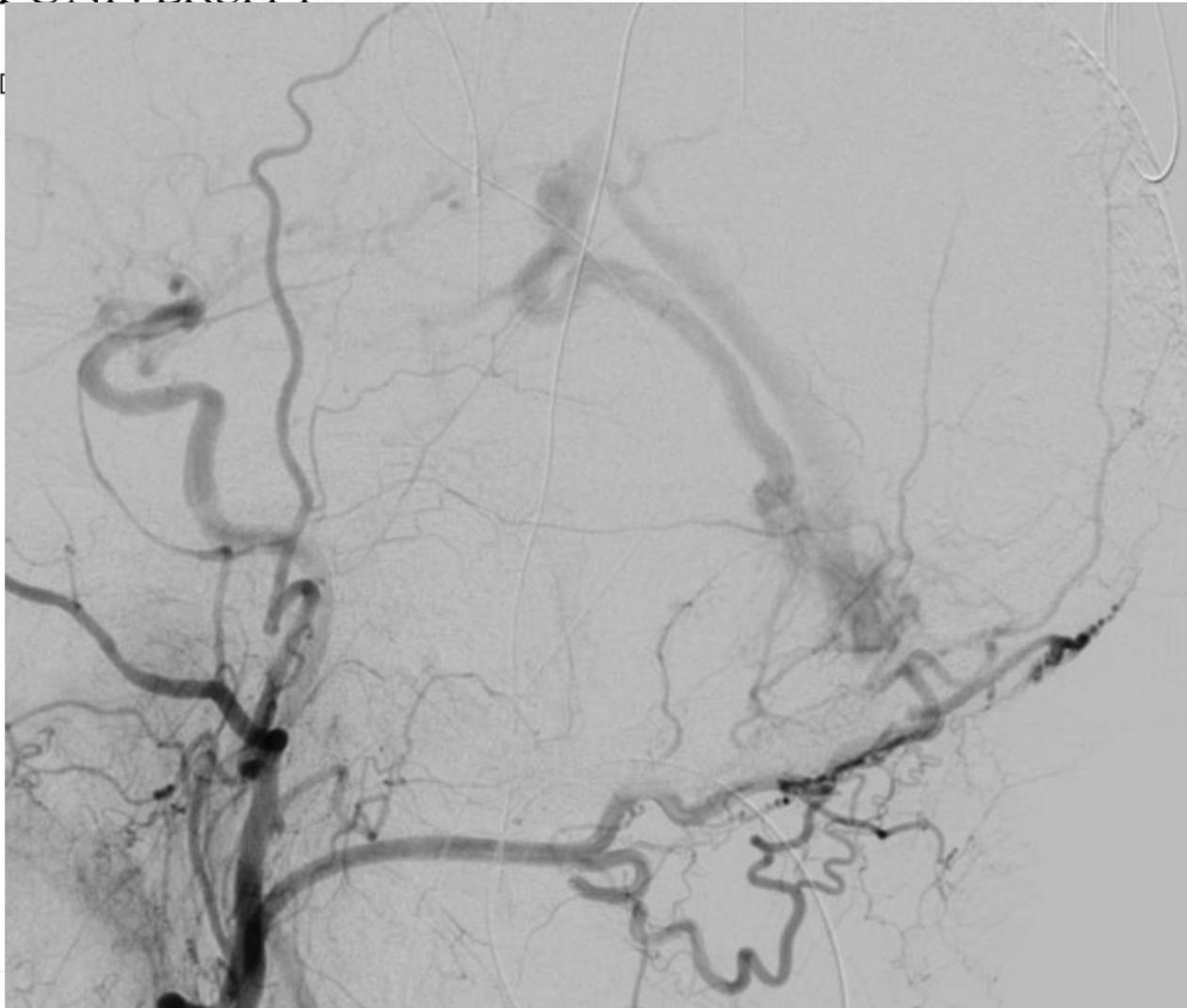
THE GRADUATE COLLEGE

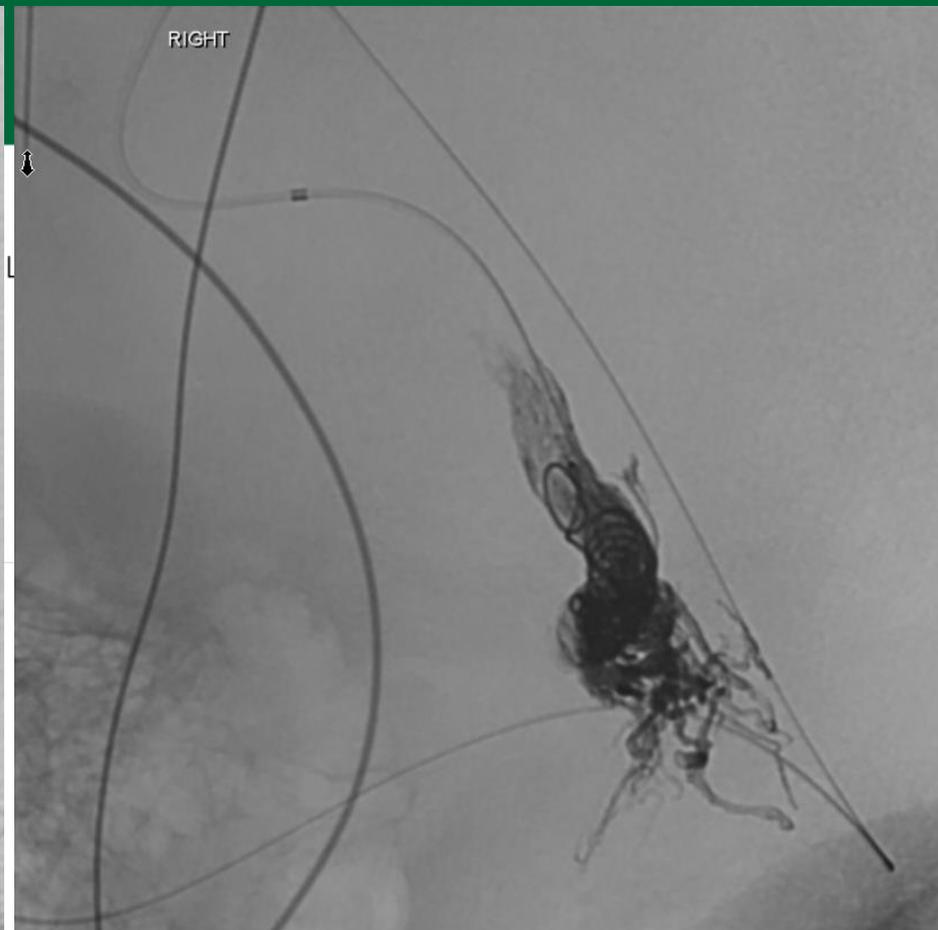
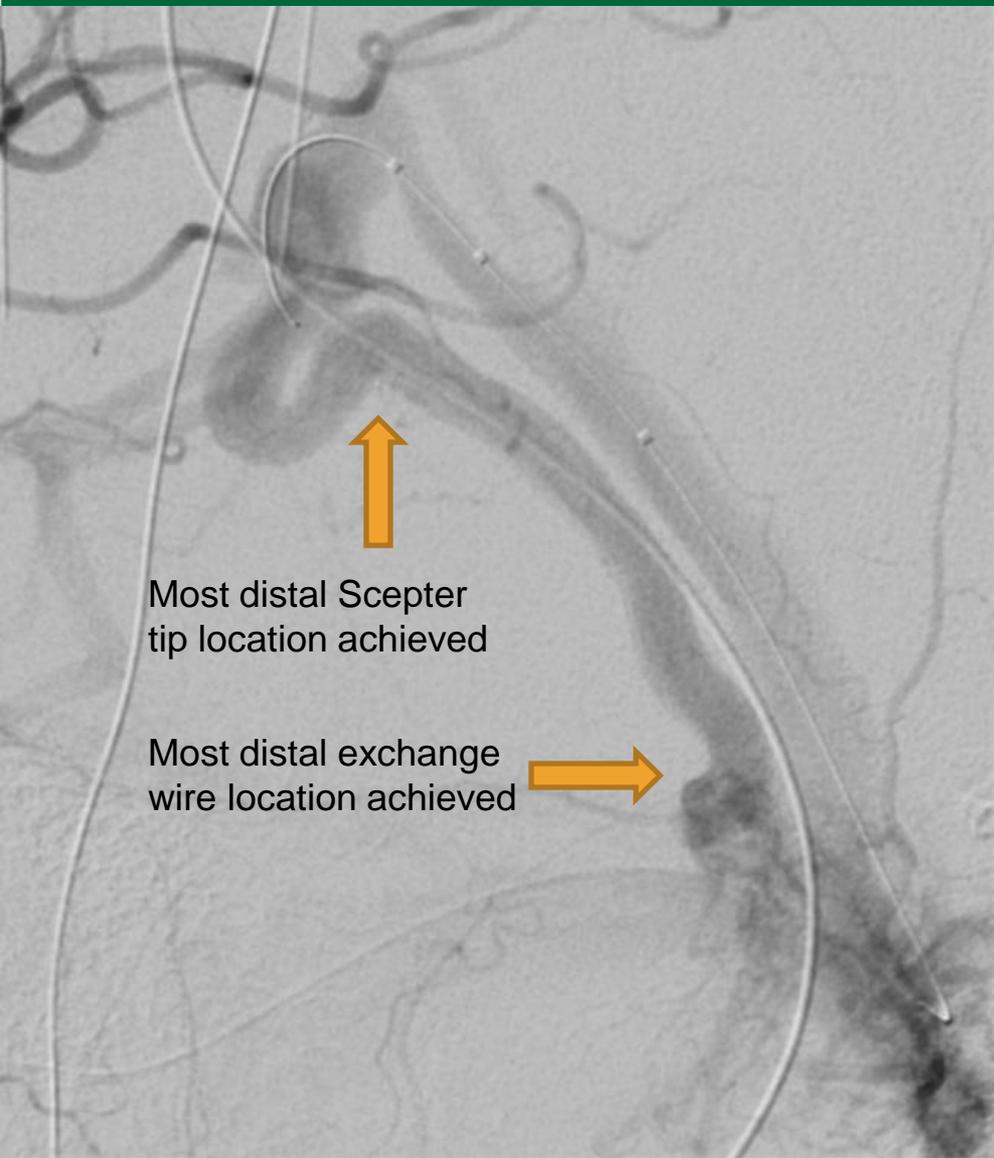
Two months later, plan for transvenous embolization of infratentorial fistula

 RUSH UNIVERSITY

RUSH MED

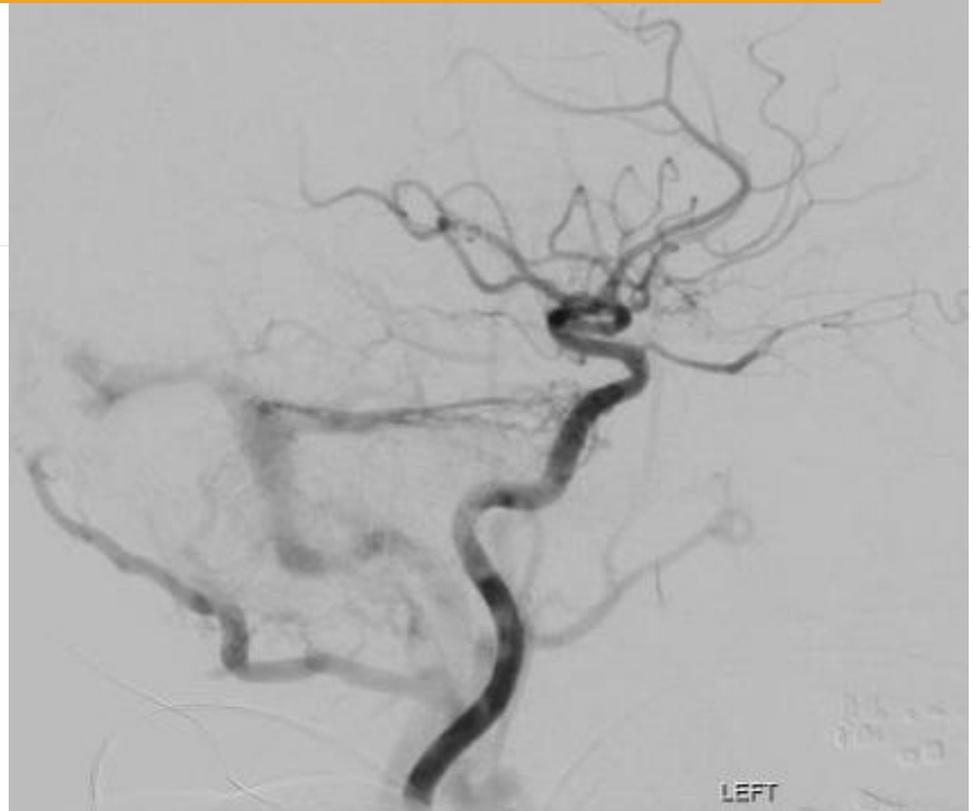
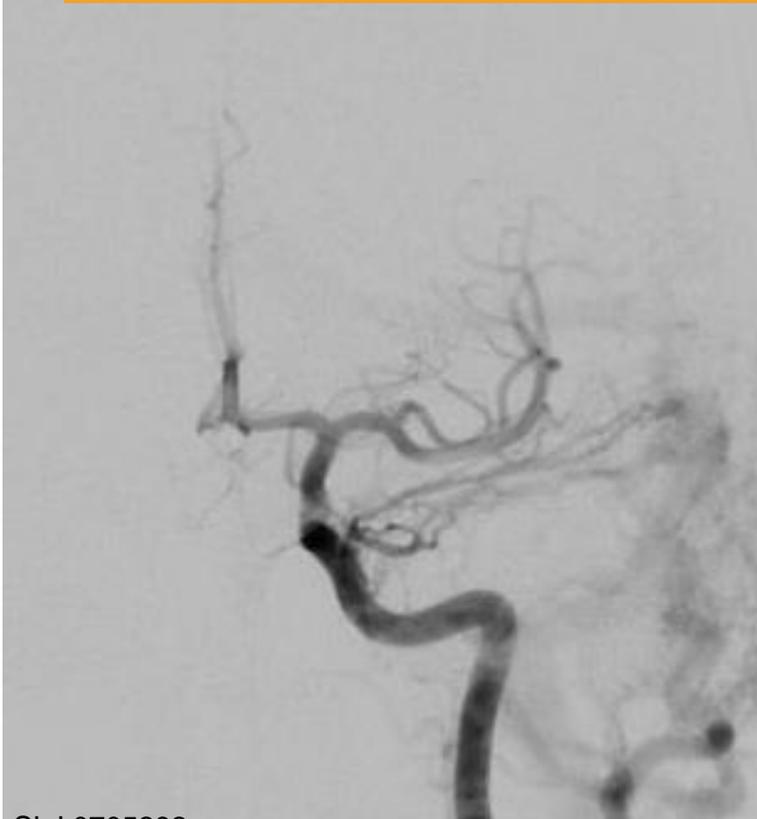
COLLEGE



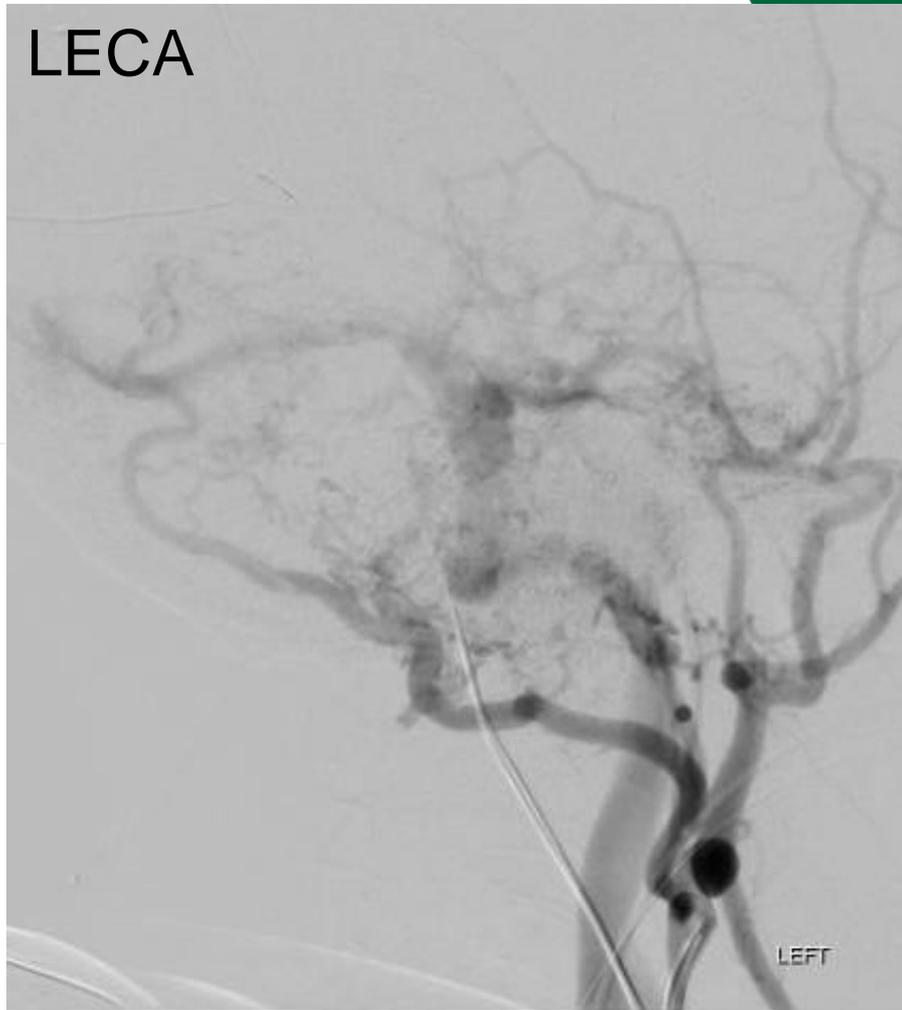


1. Unable to navigate Scepter around superior vermian vein bend even with exchange wire down to

43 year old with pulsatile tinnitus of left ear.
Initially intermittent, now is constant.

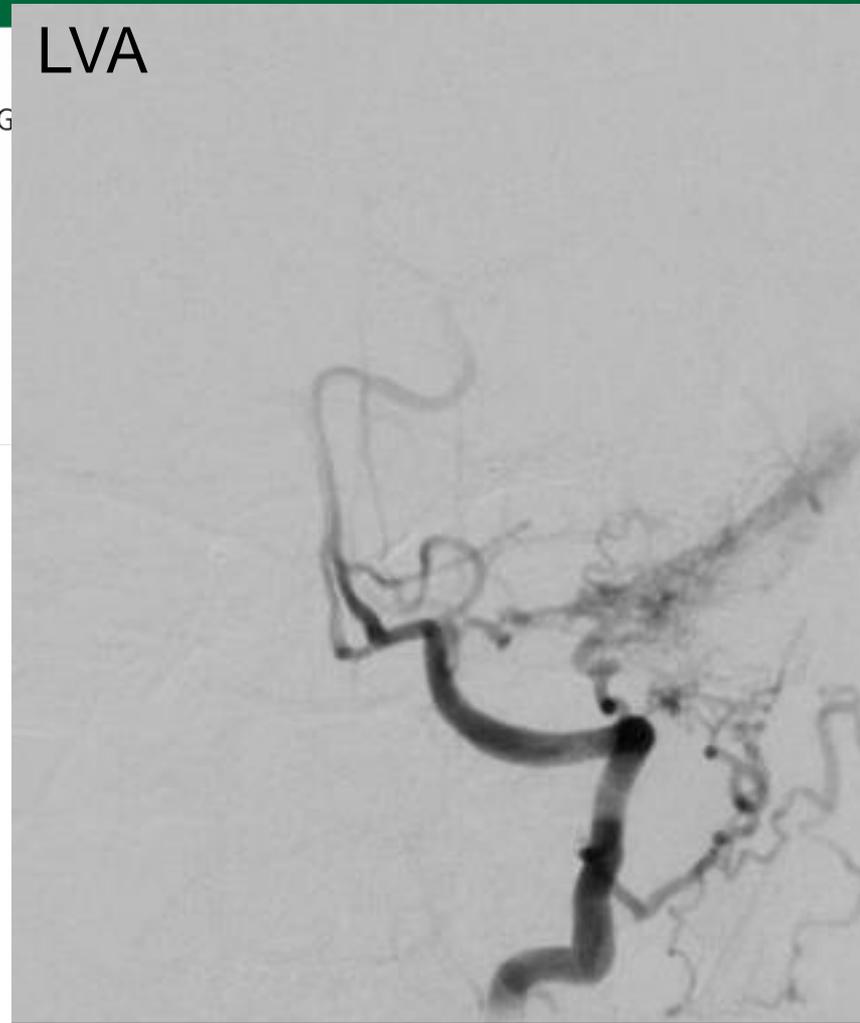


LECA

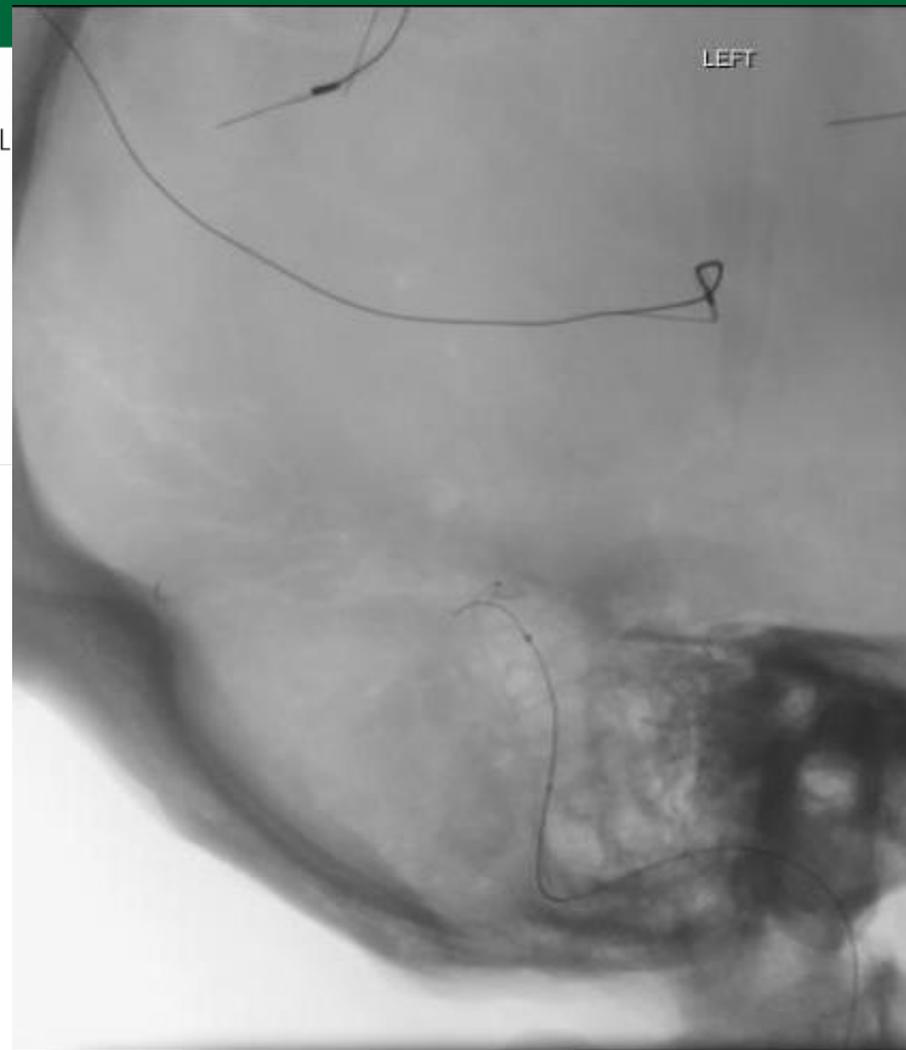
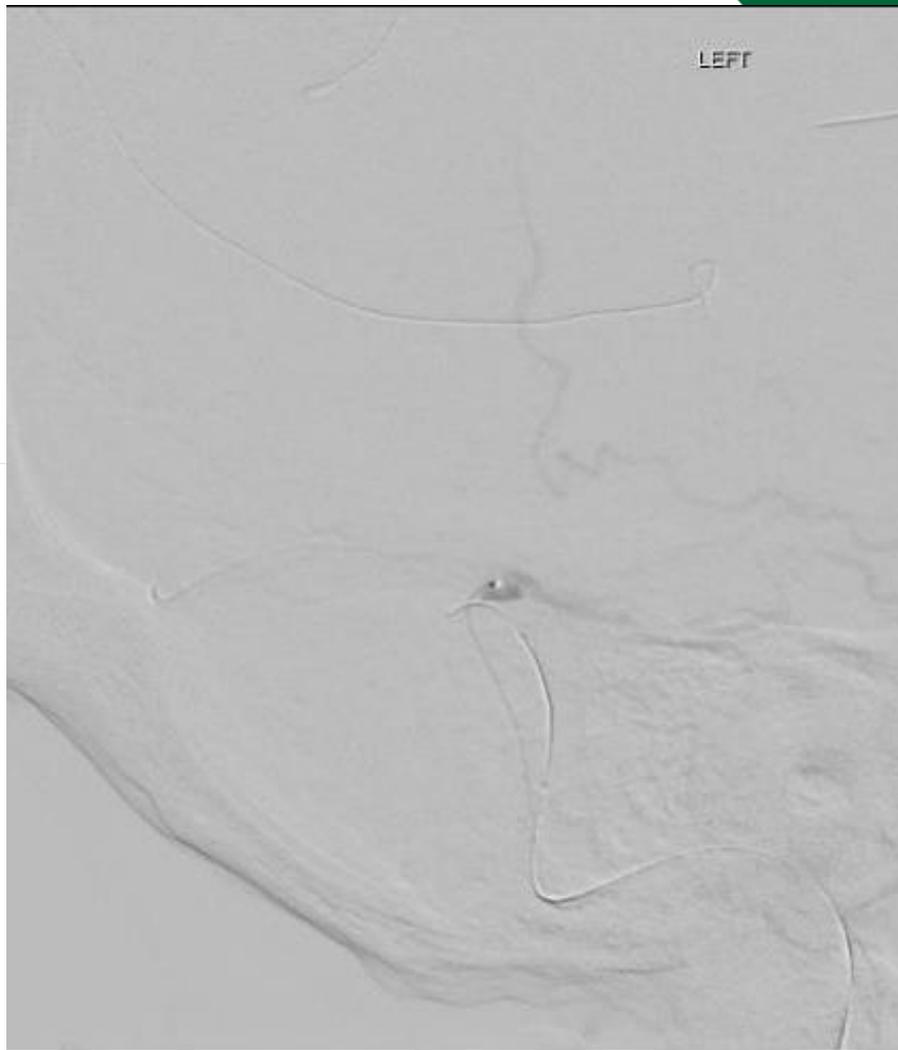


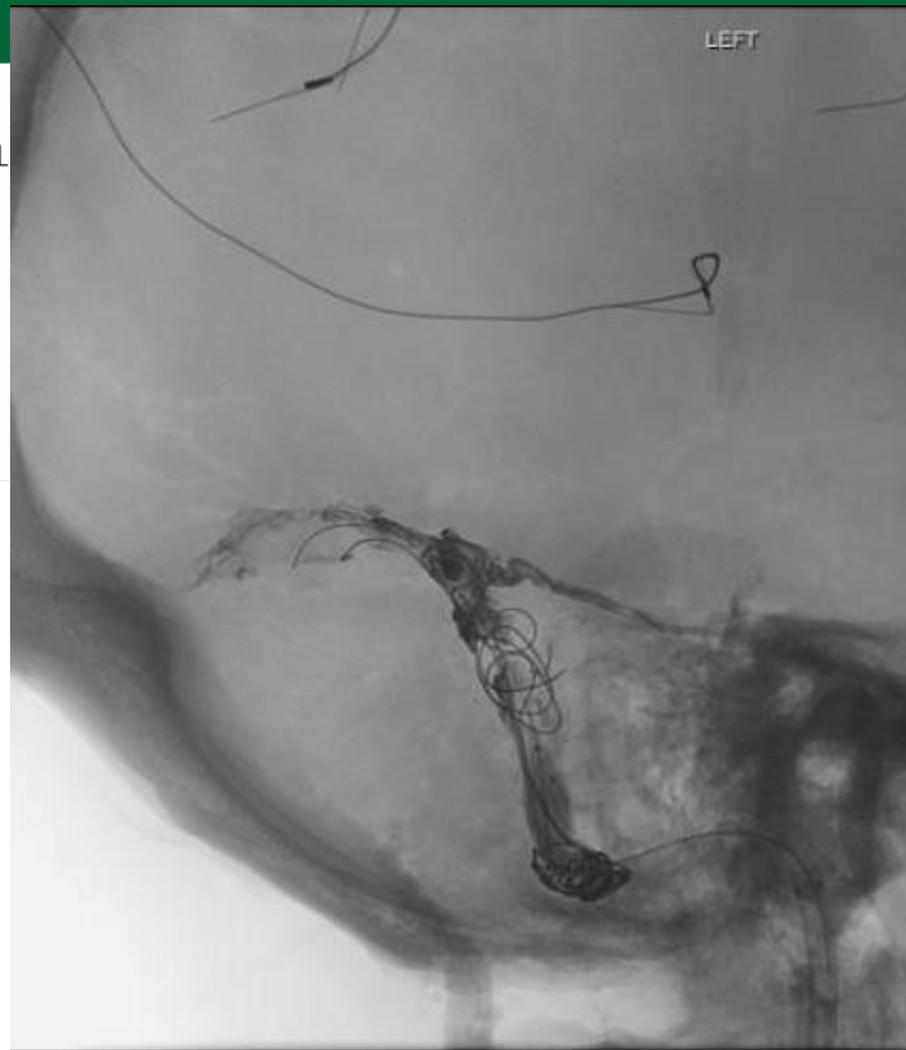
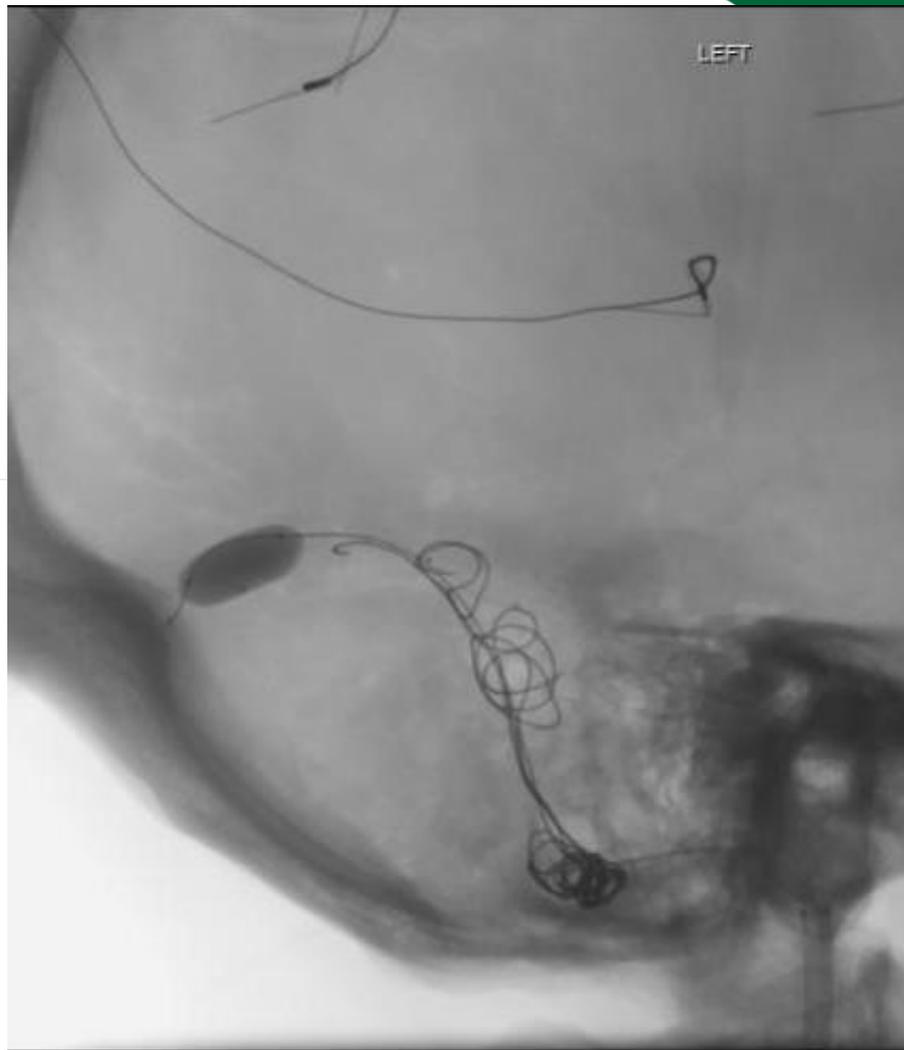
COLLEG

LVA

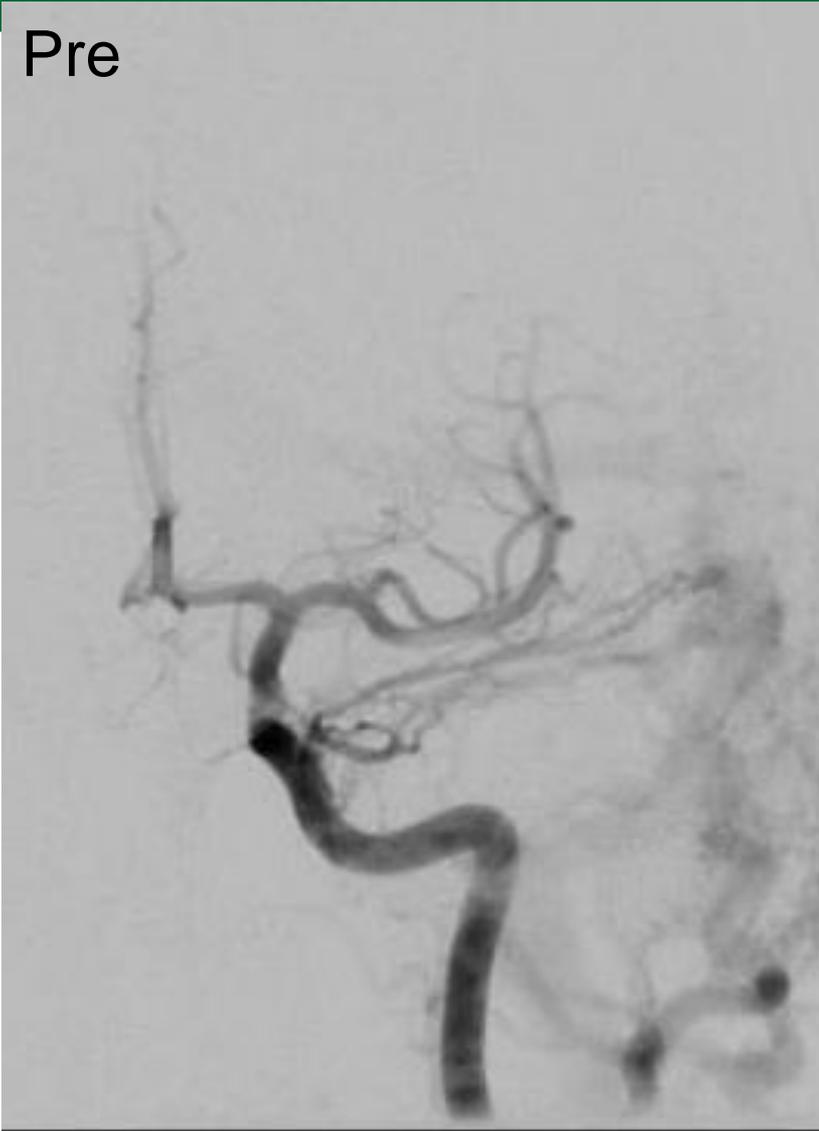


Venous approach: Balloon + 2 Micros

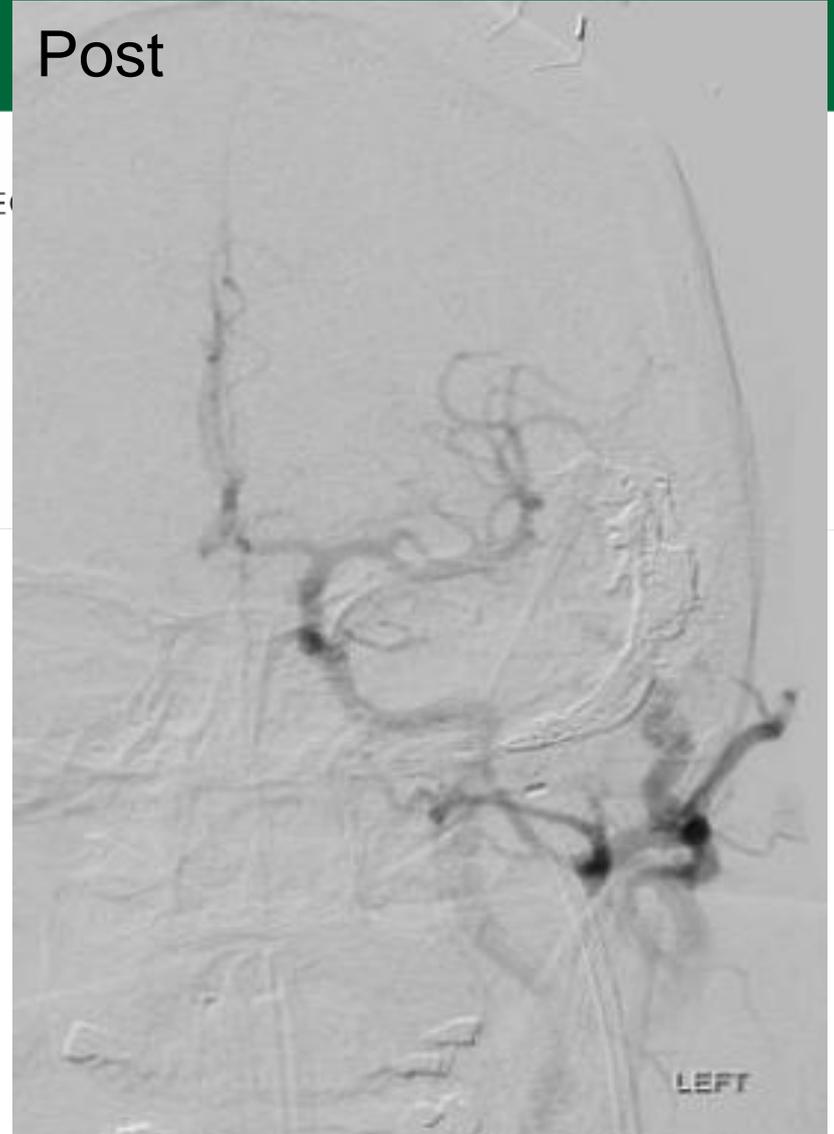




Pre

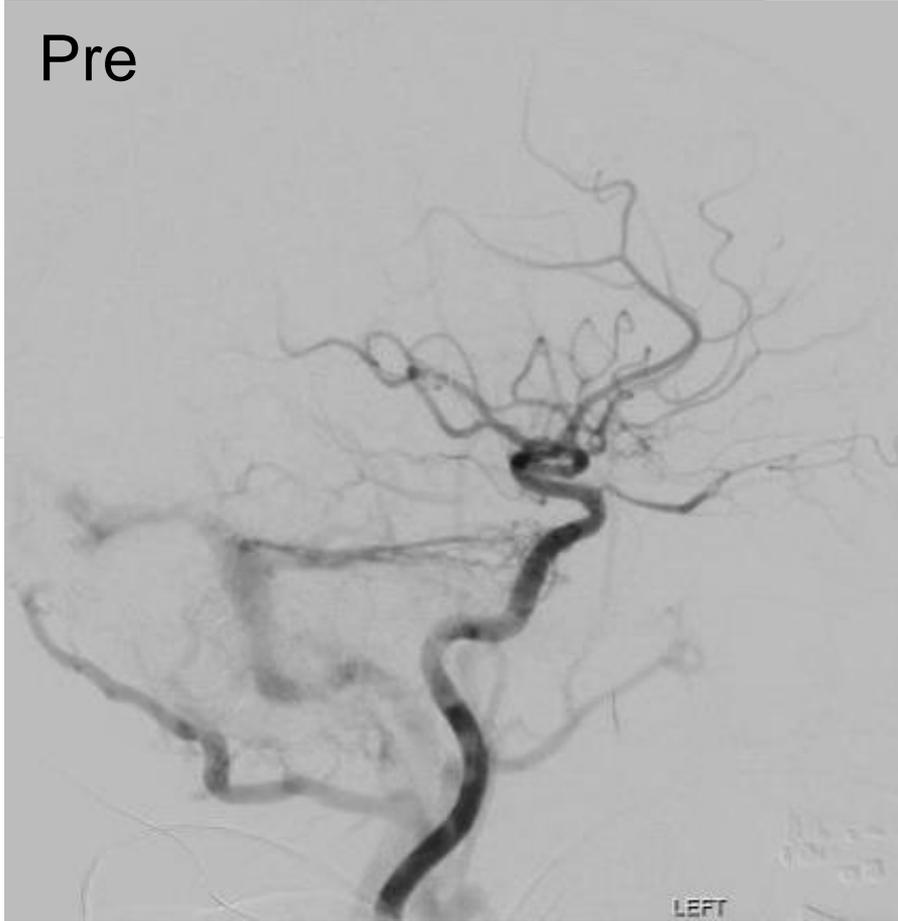


Post



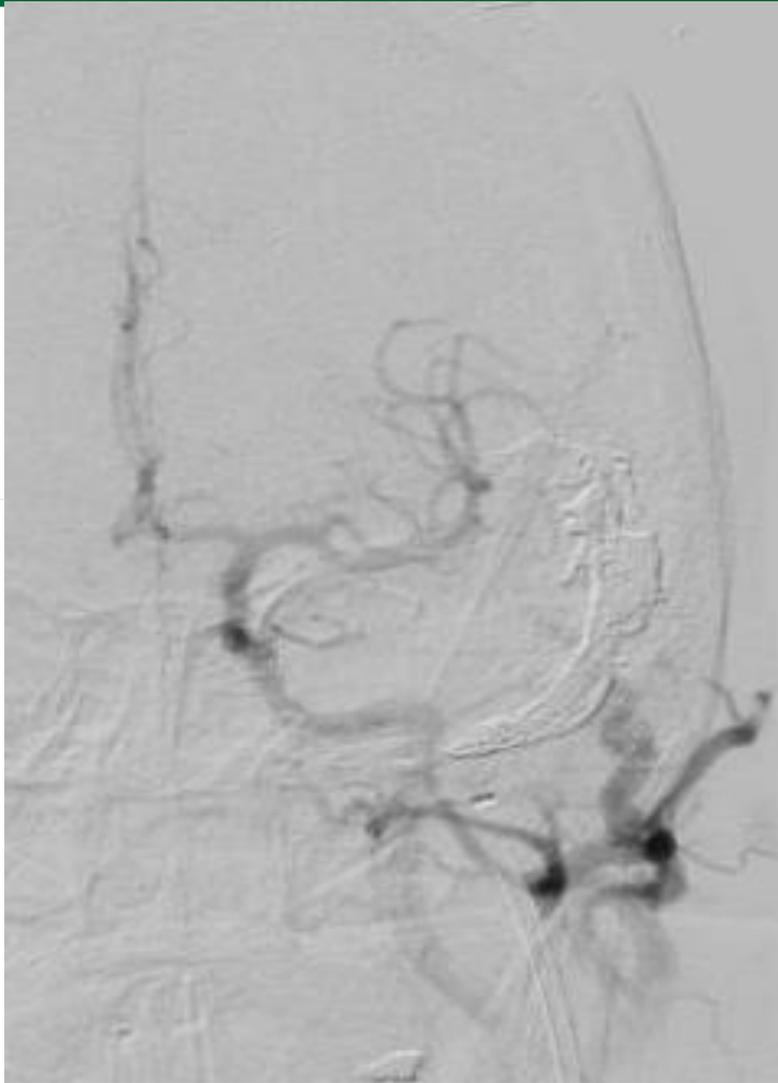
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Pre



Post

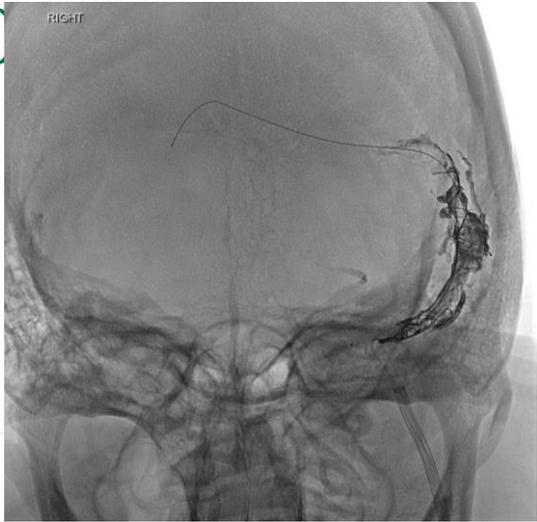




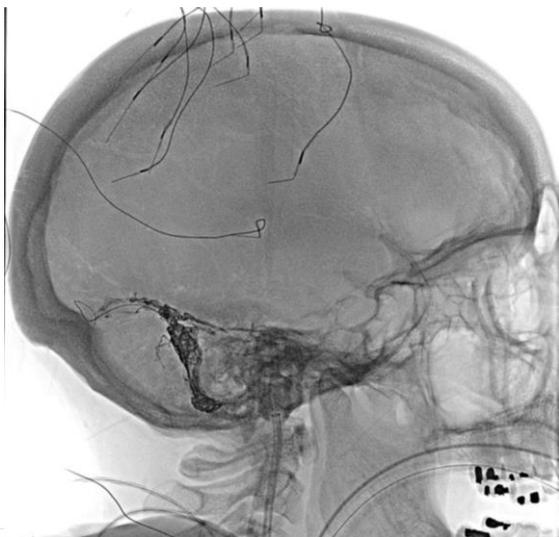
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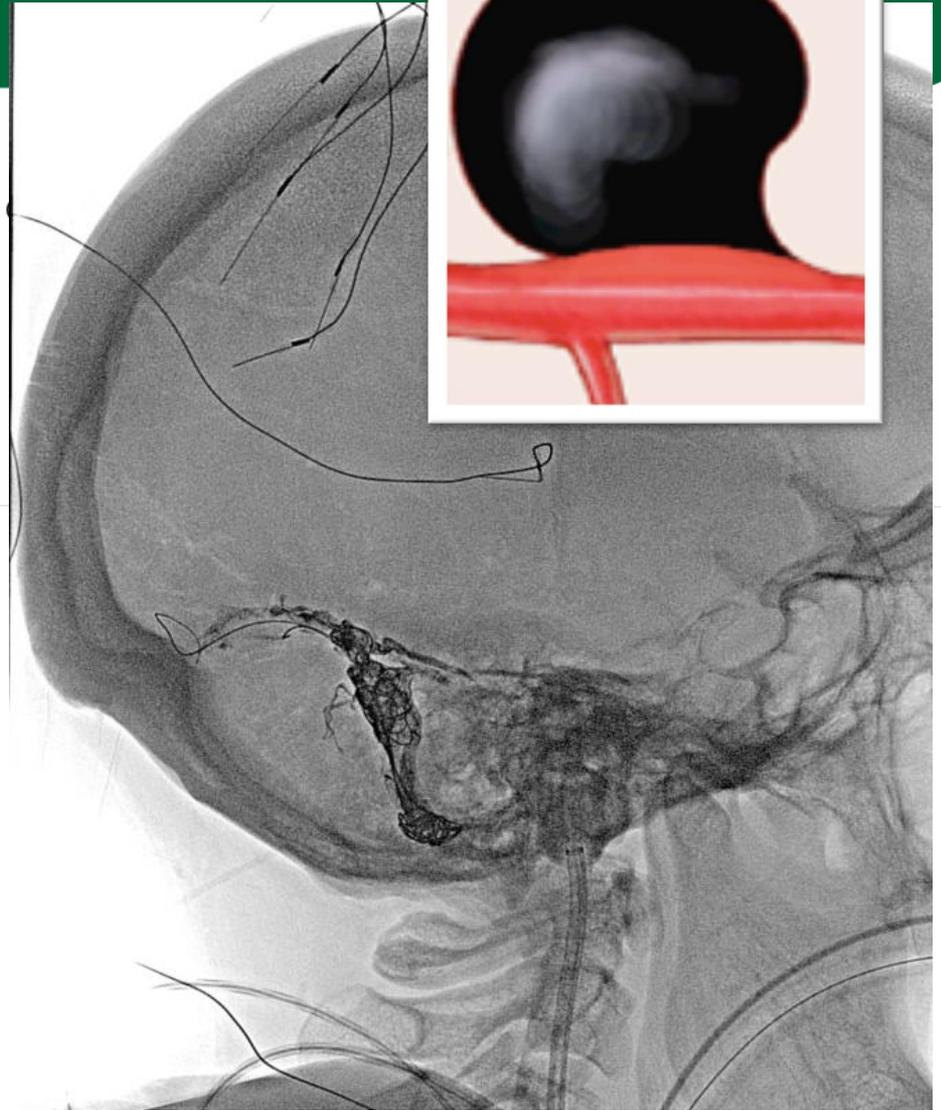


Sinus reconstruction with balloon and onyx



OF NURSING





Cerebral Vasospasm



Cerebral Vasospasm



- Clinically significant vasospasm occurs in up to 30% of patients with SAH
- When medical therapy (e.g. triple H) fails, endovascular treatments are initiated
 - IA infusions (e.g. verapamil)
 - Transluminal balloon angioplasty

Angioplasty for Cerebral Vasospasm



- Balloon angioplasty for vasospasm following SAH first described by Zubkov in 1984, using flow-directed latex balloon
- Typically restricted to larger (> 2 mm) intracranial vessels (e.g. ICA, M1, A1, basilar, P1)
- Small sized HyperForm balloons have been successful in accessing A2, M3, P2 segments

Angioplasty for Cerebral Vasospasm

THE IMPACT OF BALLOON ANGIOPLASTY ON THE EVOLUTION OF VASOSPASM-RELATED INFARCTION AFTER ANEURYSMAL SUBARACHNOID HEMORRHAGE

- 57 vessel segments treated with angioplasty compared to 61 vessel segments not treated

	Angioplasty	No angioplasty
Infarction	4 (7%)	23 (38%)

- Complications occurred in 3 patients (5%)
 - 2 MCA occlusions (1 with permanent morbidity)
 - 1 ICA dissections

Angioplasty for Cerebral Vasospasm



- 16% reduction in in-hospital mortality

TABLE 3. Institutional Predictors of In-Hospital Death in Multivariable Analysis*

	RR	95% CI	P
Ruptured aneurysms			
Treatment volume (per 10 cases per year)	0.99	0.96–1.03	0.75
Angioplasty for vasospasm (used vs not)	0.84	0.71–0.98	0.03
Portion endovascular-treated cases (per 10%)	0.91	0.86–0.96	0.001

- Hoh & Ogilvy studied 530 patients and found 62% clinical improvement after angioplasty

Complications of Angioplasty



- Most serious complication is arterial rupture
 - Rates reported as 1-4%
 - Most commonly a result oversizing the balloon
- Thromboembolism
- Branch occlusion
 - Severe spasm with limited distal runoff may make balloon placement more difficult
- Dissection

- Accounts for 8-10% of ischemic events
 - Symptomatic ICAD associated with a 10-50% annual risk of recurrent stroke
- Endovascular procedures are considered when medical therapy fails
 - Stenting
 - Transluminal balloon angioplasty
- Intracranial angioplasty inherently more dangerous than extracranial
 - Intracranial vasculature fragility
 - Fewer media and muscular layers

ORIGINAL ARTICLE

Comparison of Warfarin and Aspirin for Symptomatic Intracranial Arterial Stenosis

Marc I. Chimowitz, M.B., Ch.B., Michael J. Lynn, M.S., Harriet Howlett-Smith, R.N., Barney J. Stern, M.D., Vicki S. Hertzberg, Ph.D., Michael R. Frankel, M.D., Steven R. Levine, M.D., Seemant Chaturvedi, M.D., Scott E. Kasner, M.D., Curtis G. Benesch, M.D., Cathy A. Sila, M.D., Tudor G. Jovin, M.D., and Jose G. Romano, M.D., for the Warfarin–Aspirin Symptomatic Intracranial Disease Trial Investigators*

ABSTRACT

CONCLUSIONS
Warfarin was associated with significantly higher rates of adverse events and provided no benefit over aspirin in this trial. Aspirin should be used in preference to warfarin for patients with intracranial arterial stenosis.

ORIGINAL ARTICLE

Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis

Marc I. Chimowitz, M.B., Ch.B., Michael J. Lynn, M.S., Colin P. Derdeyn, M.D., Tanya N. Turan, M.D., David Fiorella, M.D., Ph.D., Bethany F. Lane, R.N., L. Scott Janis, Ph.D., Helmi L. Lutsep, M.D., Stanley L. Barnwell, M.D., Ph.D., Michael F. Waters, M.D., Ph.D., Brian L. Hoh, M.D., J. Maurice Hourihane, M.D., Elad I. Levy, M.D., Andrei V. Alexandrov, M.D., Mark R. Harrigan, M.D., David Chiu, M.D., Richard P. Klucznik, M.D., Joni M. Clark, M.D., Cameron G. McDougall, M.D., Mark D. Johnson, M.D., G. Lee Pride, Jr., M.D., Michel T. Torbey, M.D., M.P.H., Osama O. Zaidat, M.D., Zoran Rumboldt, M.D., and Harry J. Cloft, M.D., Ph.D., for the SAMMPRIS Trial Investigators*

CONCLUSIONS
In patients with intracranial arterial stenosis, aggressive medical management was superior to PTAS with the use of the Wingspan stent system, both because the risk of early stroke after PTAS was high and because the risk of stroke with aggressive medical therapy alone was lower than expected. (Funded by the National Institute of Neurological Disorders and Stroke and others; SAMMPRIS ClinicalTrials.gov number, NCT00576693.)

Negative results of SAMMPRIS and WASID have renewed interest in angioplasty for the treatment of ICAD

Balloon Angioplasty for Intracranial Atherosclerotic Disease Periprocedural Risks and Short-Term Outcomes in a Multicenter Study

Thanh N. Nguyen, MD; Osama O. Zaidat, MD; Rishi Gupta, MD; Raul G. Nogueira, MD;
Nauman Tariq, MD; Junaid S. Kalia, MD; Alexander M. Norbash, MD; Adnan I. Qureshi, MD

- 74 patients with symptomatic ICAD 50-99%
- Balloons = Gateway or Maverick

Pre-treatment stenosis	79%
Post treatment stenosis	34%
Morbidity	4 (5%)
30-day stroke rate	4 (5%)
Retreatment rate	2 (2.8%)

- Identification of 36 studies
 - 1027 patients undergoing angioplasty alone
 - 1291 patients undergoing angioplasty + stenting

	Angioplasty	Stenting
Mean pre-treatment stenosis	85%	82%
Mean post-treatment stenosis	30%	10%
Technical success*	79%	95%
30 day stroke and/or death	9 (8.9%)	104 (8.1%)
1 year stroke and/or death*	125 (17.1%)	123 (11.2%)
Restenosis rate	115 (14.2%)	119 (11.1%)

*statistically significant

Submaximal angioplasty for symptomatic intracranial atherosclerosis: a prospective Phase I study

Travis M. Dumont, MD,¹⁻³ Ashish Sonig, MD, MS, MCh,^{2,3} Maxim Mokin, MD, PhD,²⁻⁴
 Jorge L. Eller, MD,^{2,3,5} Grant C. Sorkin, MD,^{2,3} Kenneth V. Snyder, MD, PhD,^{2,3,6,7}
 L. Nelson Hopkins, MD,^{2,3,6,8,9} Elad I. Levy, MD, MBA,^{2,3,6,8} and Adnan H. Siddiqui, MD, PhD^{2,3,6,8,9}

- Studies evaluating angioplasty and/or stenting for ICAD have been modeled after coronary trials with the goal of anatomic normalization
 - This may come at the expense of a higher rate of iatrogenic injury

$$Q = \frac{\pi Pr^4}{8\eta l}$$

Normalization of anatomy may not be necessary

Submaximal Angioplasty

Submaximal angioplasty for symptomatic intracranial atherosclerosis: a prospective Phase I study

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Mean pre-treatment stenosis	80%
Mean post-treatment stenosis	54%
30 day stroke rate	0 (0%)
1 year stroke rate	1 (5.5%)
Mortality	0 (0%)
Hemorrhage	0 (0%)

Extracranial Vascular Disease

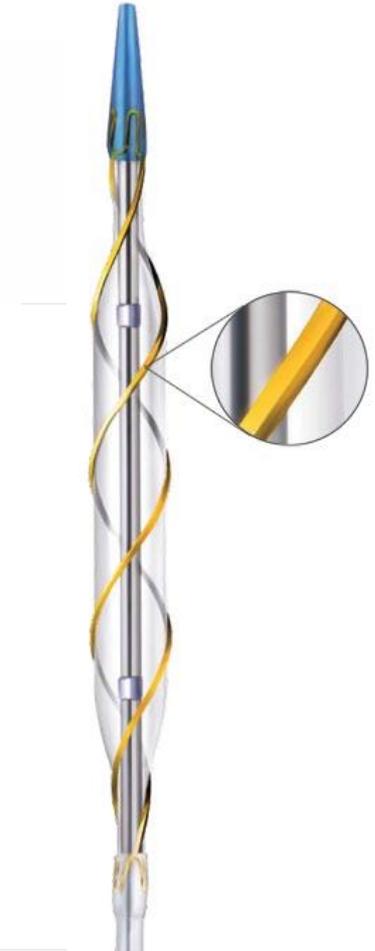


- Due to the high risk of embolization with angioplasty alone, it has fallen out of favor
- However, angioplasty with stenting (with distal embolic protection) is routinely utilized
 - Addresses stent waist
 - With stent deployment (wall apposition)

Cutting balloon angioplasty



- Derived from use in coronary literature demonstrating larger initial treatment effect and lower restenosis
- Micro- blades/ridges longitudinally oriented on non-compliant balloon
- Slices neointimal tissue → extrusion of fragmented intimal tissue through stent by balloon



Cutting balloon angioplasty



- May be used to treat re-stenosis after carotid stenting

<i>Patient no.</i>	<i>Initial CAS indications</i>	<i>Presenting ISR symptoms</i>	<i>Treatment</i>	<i>ISR % before treatment</i>	<i>ISR % after treatment</i>	<i>Outcome</i>
1	Post-CEA stenosis	Asymptomatic	PTA (5.5-mm balloon)	80	20	Restenosis (80%) at 6 mo treated with CB-PTA
2	Cardiac morbidity	Asymptomatic	CB-PTA (6-mm balloon)	90	20	Died of MI at 14 mo
3	Neck irradiation	Asymptomatic	CB-PTA (5.5-mm balloon) and CAS (8-mm diameter)	80	10	No restenosis at 8 mo of follow-up
4	Post-CEA stenosis	TIA	CB-PTA (5-mm balloon)	98	30	No restenosis at 3 mo of follow-up
5	Cardiac morbidity	Asymptomatic	PTA (5-mm balloon) and CAS (8-mm diameter)	90	20	No restenosis at 12 mo of follow-up
6	Post-CEA stenosis	Asymptomatic	CB-PTA (5.5-mm balloon)	90	5	No restenosis at 8 mo of follow-up
7	Post-CEA stenosis	Asymptomatic	CB-PTA (6-mm balloon)	85	10	Restenosis (80%) at 8 mo, treated with CB-PTA

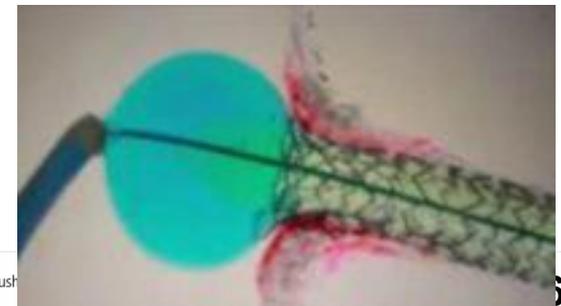
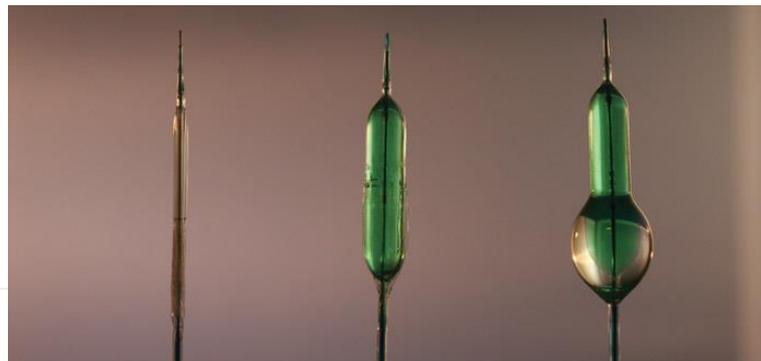
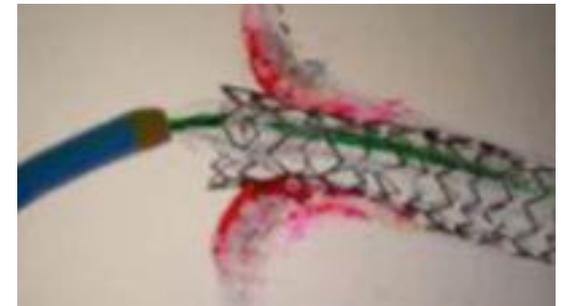
Not just for extracranial carotid stenosis!

ORIGINAL RESEARCH

Experience with vertebral artery origin stenting and ostium dilatation: results of treatment and clinical outcomes

Leonardo Rangel-Castilla,^{1,2} Sirin Gandhi,^{1,2} Stephan A Munich,^{1,2} Marshall C Cress,^{1,2} Ashish Sonig,^{1,2} Chandan Krishna,^{1,2} L Nelson Hopkins,^{1,2,3,4,5} Kenneth V Snyder,^{1,2,3,4} Elad I Levy,^{1,2,3,4} Adnan H Siddiqui^{1,2,3,4,5}

- Traditional stenting of VA ostial stenosis is technically challenging
 - Requires part of the stent to overhang within lumen of the subclavian artery to prevent foreshortening and completely cover plaque
- Ostial Flash System
 - Traditional non-compliant balloon with stent
 - Second compliant balloon at proximal end



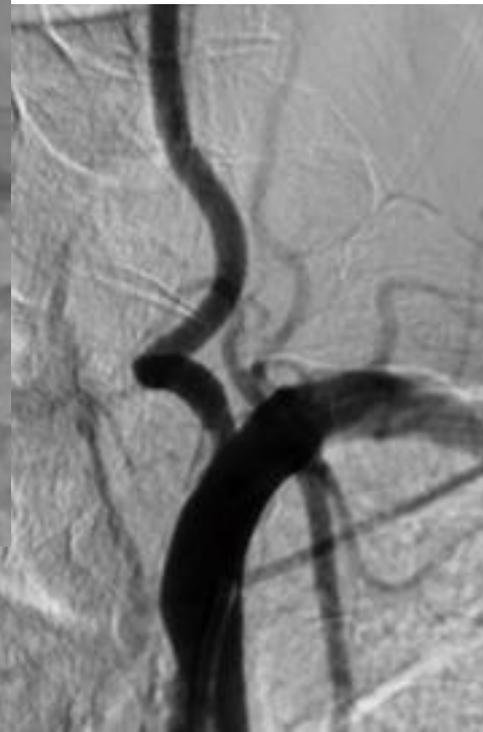
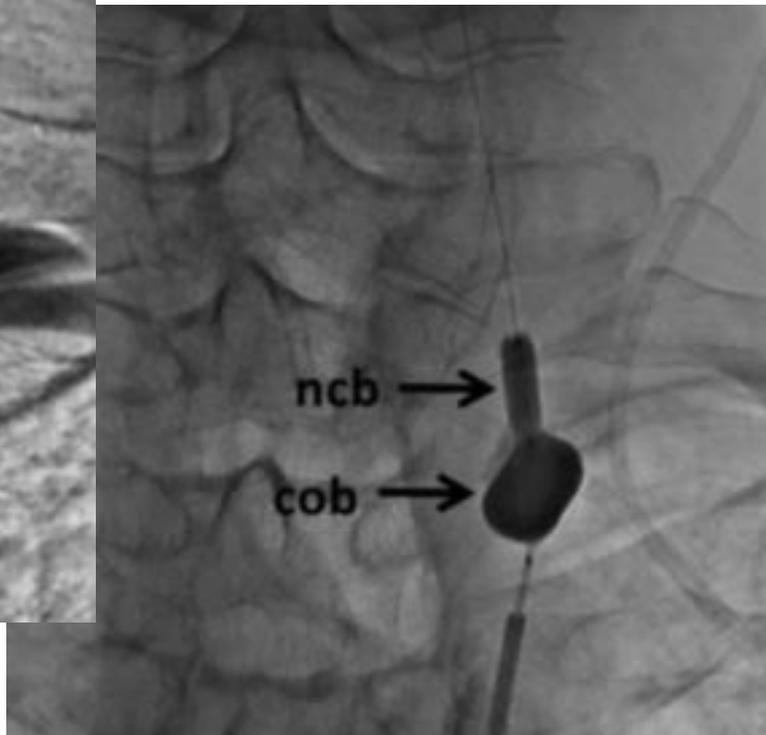
comprising Rush

Not just for extracranial carotid stenosis!

ORIGINAL RESEARCH

Experience with vertebral artery origin stenting and ostium dilatation: results of treatment and clinical outcomes

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- During revascularization procedures, balloon guide catheters may be used for proximal protection
- Benefits of balloon guide catheters:
 - Proximal protection
 - Protection prior to crossing the lesion
 - May reduce risk of embolization of mobile thrombus
 - Improved clinical outcome

Balloon Guide Catheter Improves Revascularization and Clinical Outcomes With the Solitaire Device
Analysis of the North American Solitaire Acute Stroke Registry

	Balloon guide	Non-balloon Guide
N	149	189
Mean procedure time*	120 min	161 min
Median # of passes	1	2
TICI 3 or 2b	113 (76%)	133 (71%)
Discharge NIHSS*	6	11
mRS \leq 2 at 3 months*	65 (51.6%)	62 (35.8%)

*statistically significant

- Use of balloon guide catheters was an independent predictor of good clinical outcome at 3 months

Comparison of a Balloon Guide Catheter and a Non-Balloon Guide Catheter for Mechanical Thrombectomy¹

- 183 consecutive patients with ICA terminus or MCA occlusions revascularized with stent retriever
 - No statistically significant difference in baseline characteristics

	Balloon guide	Non-balloon Guide
N	102	81
Mean procedure time	25.6 min	54.8 min
Median # of passes	1	2
TICI 3 or 2b	96 (94.1%)	61 (75.3%)

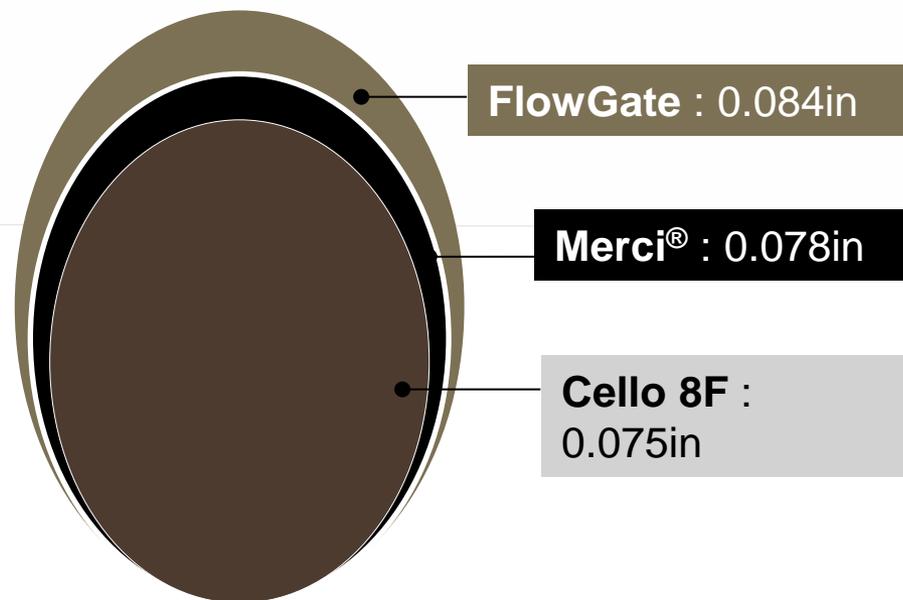
- No statistically significant difference in rate of procedure-related complications

Balloon Guide Catheter Comparison



RUSH MEDICAL COLLEGE • COLLEGE OF NURSING • COLLEGE OF HEALTH SCIENCES • THE GRADUATE COLLEGE

- **Largest 8F BGC lumen for clot capture and Trevo system compatibility**
- **Optimized combination of trackability and support**
- **Proximal flow control correlates with better procedural, angiographic and clinical outcomes**



Clinical Data



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The Importance of Flow Control

SWIFT Prime

- Sub-analysis of the Solitaire arm
- Stent retriever with a BGC (n=48) vs.

UMASS

- In Vitro
- Favorable results to BGC arm
- Merci® BGC, Merci Retriever, Trevo® Pro Retriever, Solitaire

NASA

- Sub-study of the use of Solitaire with BGC (n=149) vs. non- BGC (n=189)
- Merci® BGC

STAR

- Solitaire registry
- Mandatory use of BGC

TRACK

- Trevo Retriever must be the FIRST retrieval device used in the case, Any age, Any time of onset, All

Velasco et al

- Multicenter retrospective study
- Stent retriever with a BGC (n=102) at one center vs. non-

1 Effectiveness of Mechanical Endovascular Thrombectomy in a Model System of Cerebrovascular Occlusion. Chueh, Ju-Yu, et al. Stroke 44(5) May 2013

2 Reduction of Distal Emboli With Proximal Flow Control During Mechanical Thrombectomy. Chueh, Ju-Yu, et al. Stroke 44(5) May 2013

3 Analysis of the NASA registry, T Nguyen et al. J Neurointervent Surg 2013(5) A2-A3 2013.

4 V Pereira et al, J NeuroIntervent Surg 2015;7(Suppl 1):A1-114

5 Osama O Zaidat, TRACK, SVIN 2014

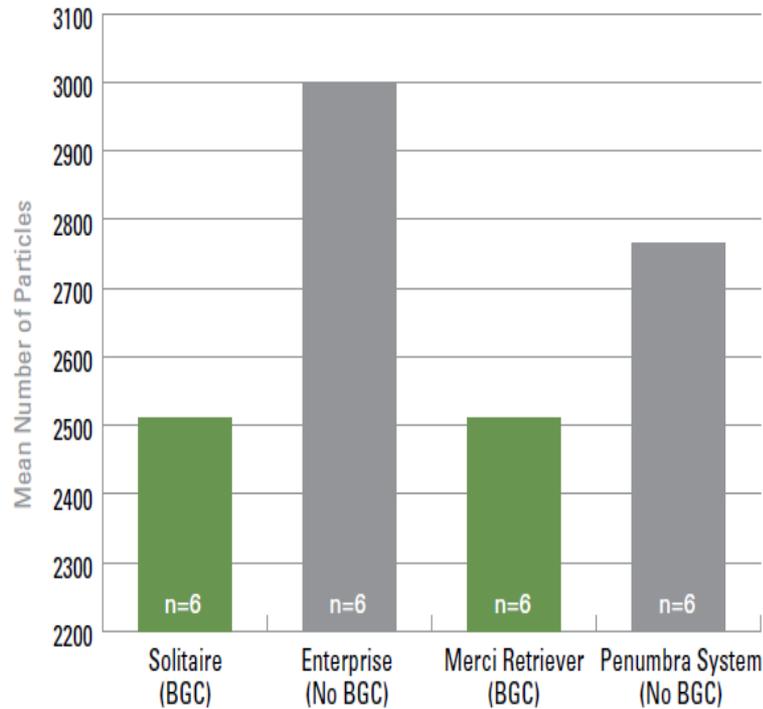
6 Aglaé Velasco et al Radiology 2016



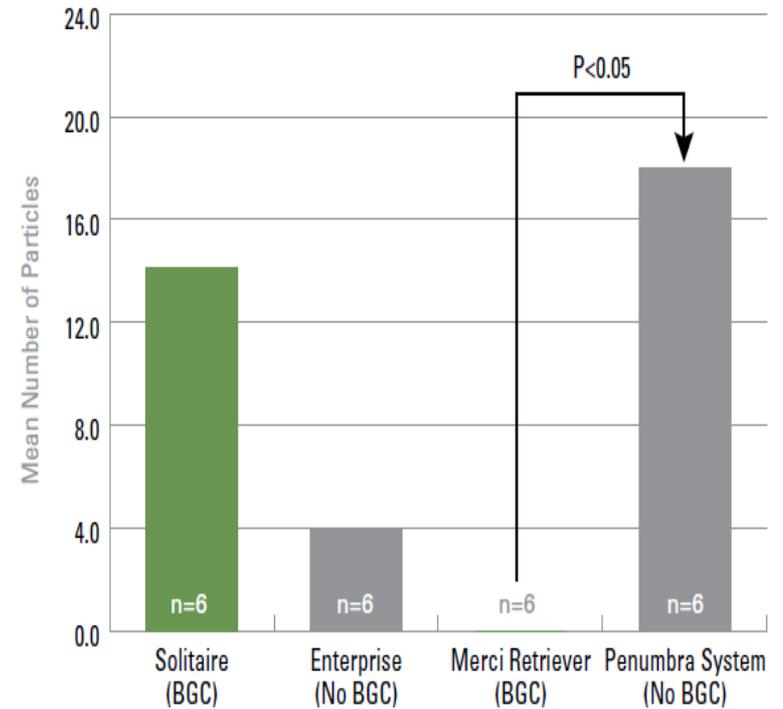
Fewer emboli with balloon guides



Small Distal Emboli (<400µm)



Large Distal Emboli (>2000µm)



Effectiveness of Mechanical Endovascular Thrombectomy in a Model System of Cerebrovascular Occlusion

J.Y. Chueh, A.K. Wakhloo, M.J. Gounis AJNR 33 Nov 2012

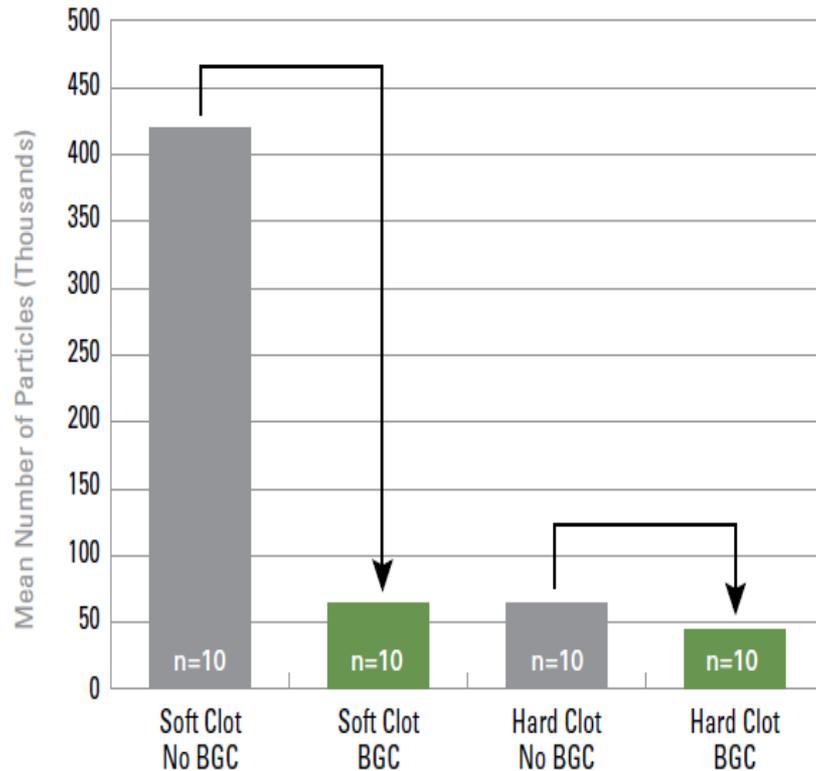


Rush is a not-for-profit health care, education and research enterprise comprising Rush University Medical Center, Rush University, Rush Oak Park Hospital and Rush Health.

Benefits with all clot types

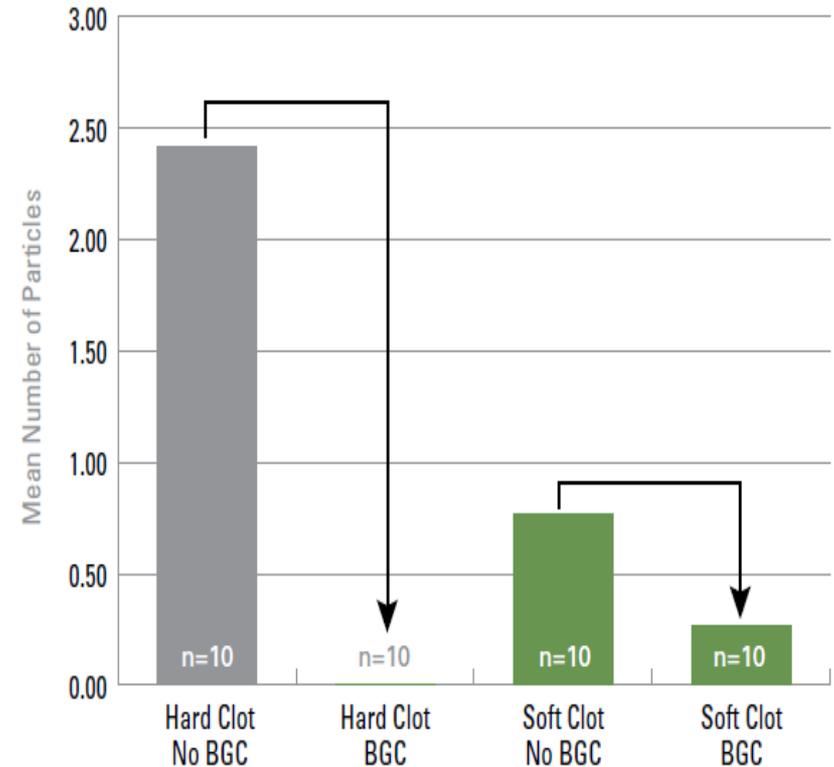
Small Distal Emboli (<200 μ m)

Proximal flow arrest decreased small distal emboli in soft clot



Large Distal Emboli (>1mm)

Proximal flow arrest decreased large distal emboli across soft clot types

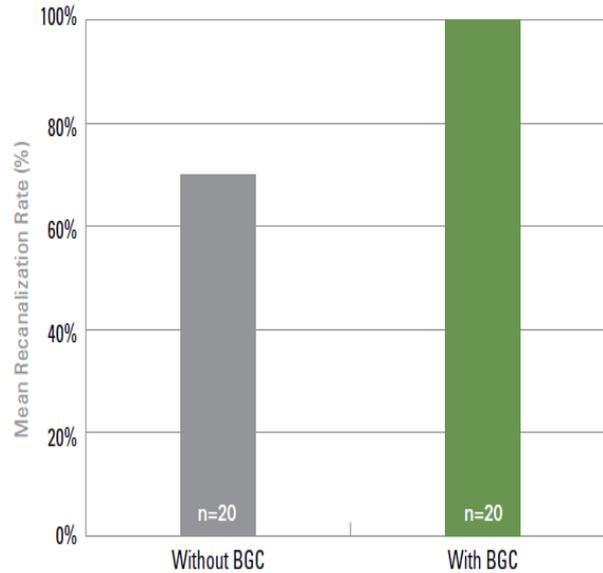


Efficacy and Safety of Balloon Guide Catheter Proximal Flow Control for Mechanical Thrombectomy in a Model System of Cerebrovascular Occlusion.

J.Y. Chueh and M.J. Gounis

More from the UMASS study

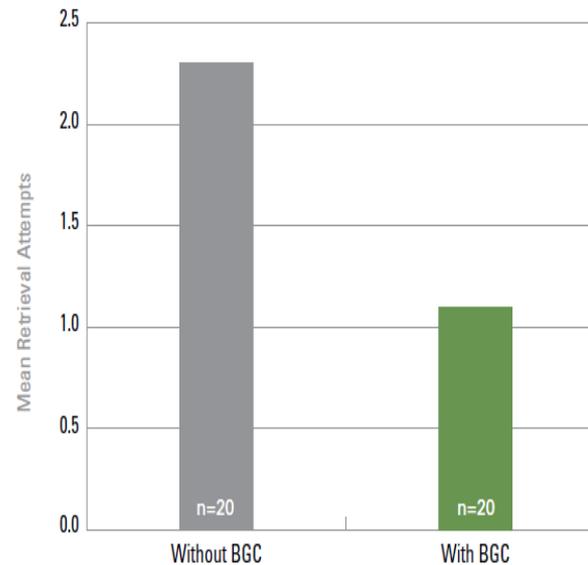
Improved recanalization rate



43% higher recanalization with the BGC

ILLEGE

Fewer retrieval attempts



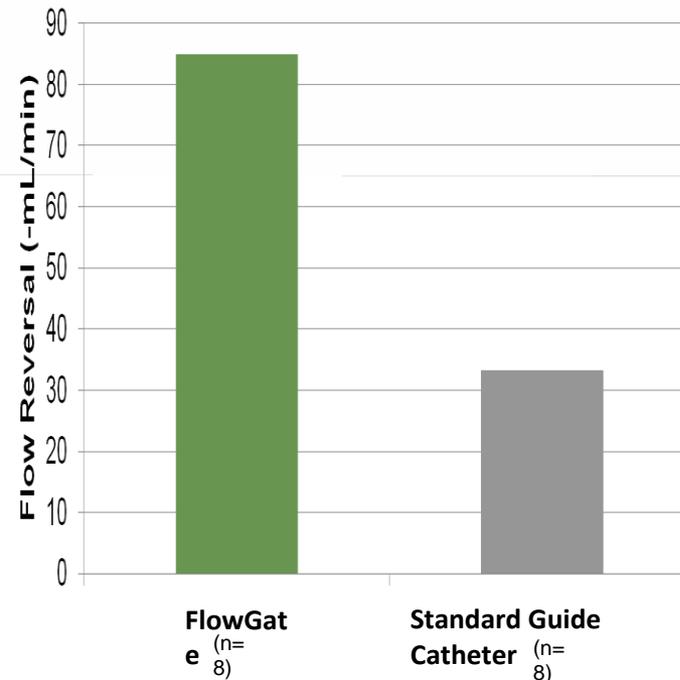
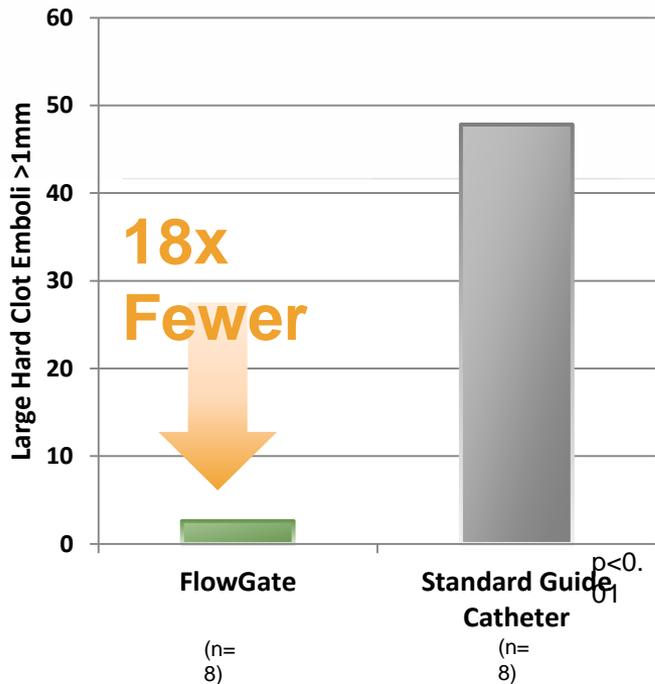
Half as many retrieval attempts with the BGC

Studies Supportive of Flow Control



Fewer Distal Emboli

3x Flow Reversal

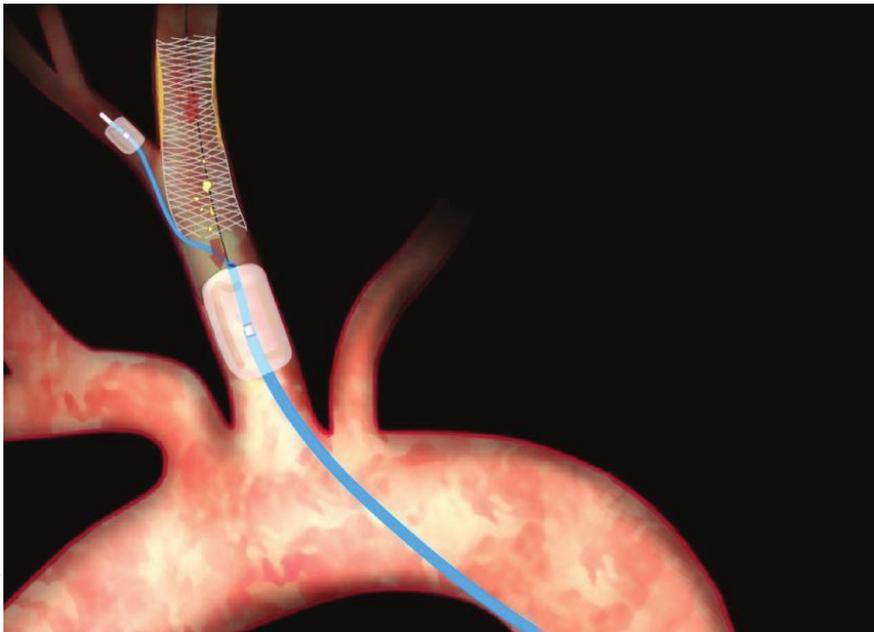


Reduction of Distal Emboli With Proximal Flow Control During Mechanical Thrombectomy. Chueh, Ju-Yu, et al. Stroke 44(5) May 2013



Bench test results may not necessarily be indicative of clinical performance

- Utilization of balloons in ECA and CCA during carotid stenting
 - Complete flow cessation
 - Ability to aspirate for temporary flow reversal



Always use protection!



- For revascularization procedures, protection is obligatory
- If distal embolic protection is not feasible, proximal protection with balloon-guide catheters is a efficacious alternative.