Medtronic

Engineering the extraordinary

Treatment choices for brain aneurysms

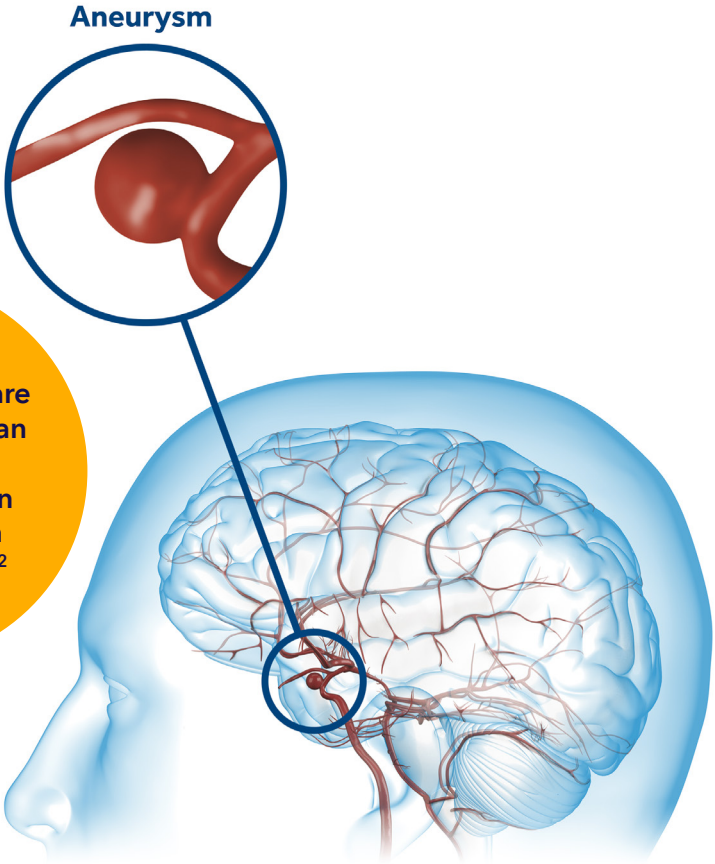
Medtronic offers several products to treat aneurysms. Talk to your doctor about your treatment options.

What is a brain aneurysm?

A cerebral or brain aneurysm is a bulge or ballooning in an artery in the brain caused by weakness in the blood vessel wall.

Untreated brain aneurysms may have risk of rupture (burst), resulting in what's called hemorrhagic or cerebral stroke. Every year, approximately 24,000 in Europe*,[1] have ruptured aneurysms.

Brain aneurysms are slightly more common in women than men, especially those who are in their late 40s to mid-50s. However, an aneurysm may occur at any age.[2]



Brain aneurysms are more common than you may think. An estimated 1 in 50 people has a brain aneurysm.[2]

*In a population without comorbidity, a mean age of 50 years, and a 50:50 gender split. United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019, Online Edition. Rev. 1.

Ruptured brain aneurysm symptoms

Symptoms* of ruptured aneurysm include, but are not limited to:[3]

When an aneurysm ruptures, one always experiences a sudden and extremely severe headache (e.g., the worst headache of one's life) and may also develop:

- Nausea/vomiting
- Stiff neck
- Blurred or double vision
- Sensitivity to light
- Seizure
- Drooping eyelid
- A dilated pupil
- Pain above and behind the eyes
- Loss of consciousness (this may happen briefly or may be prolonged)
- Confusion
- Weakness and/or numbness

* Talk to your doctor about your symptoms

Types of brain aneurysms

The types of brain aneurysms can be classified by both size and shape.[4]

Aneurysm size classifications	
Small	< 7 mm in diameter
Medium	7-12 mm in diameter
Large	13-24 mm in diameter
Giant	> 25 mm in diameter

Shape classifications

Saccular aneurysm

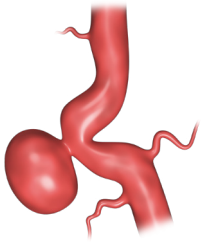
Also known as "berry" aneurysms due to their round, sac-like shape, saccular aneurysms are the most common type, accounting for 80-90% of cases.[2]

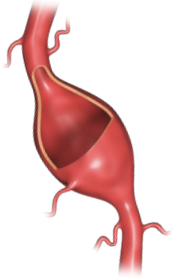
Fusiform aneurysm

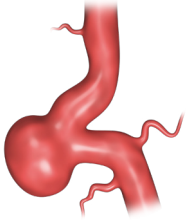
This aneurysm resembles an engorged blood vessel and can extend several centimeters in length. Fusiform aneurysms rarely rupture.[2]

Wide-necked aneurysm

A saccular aneurysm with a neck 4 millimeters wide, or twice as wide as the aneurysm is tall, is known as a wide-necked aneurysm.[5-6]

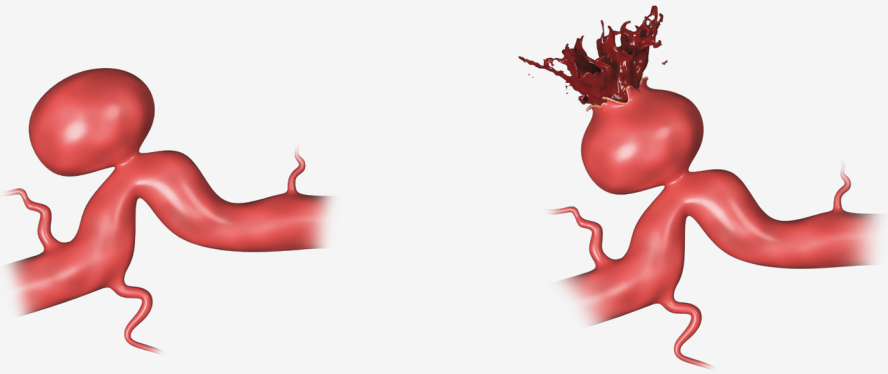






Ruptured brain aneurysm

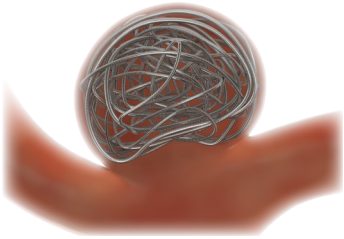
- As the bulge grows, the artery becomes thinner and weaker. It can become so thin that the blood pressure within can cause it to leak or burst open[4]
- As blood spreads and clots, it irritates the lining of the brain and damages brain cells[4]
- Ruptured brain aneurysms are fatal in about 50% of cases. Of those who survive, about 66% suffer some permanent neurological deficit[7]
    - Most deaths occur within two weeks after the stroke, with 10% occurring before the patient receives medical attention and 25% within 24 hours after the event[8]
    - Ruptured aneurysms have their highest rate of rebleeding on Day 1, and at least 50% will rebleed during the 6 months after the first hemorrhage (bleed)[9]



Treatment choices: endovascular

Coiling

- Endovascular coiling is usually carried out under general anesthetic. The procedure involves inserting a thin tube called a catheter into an artery in your leg or groin
- The tube is guided through the network of blood vessels, up into your head and finally into the aneurysm
- Tiny platinum coils are then passed through the tube into the aneurysm
- Once the aneurysm is full of coils, blood cannot enter it - the aneurysm is sealed off from the main artery, which may prevent it from growing or rupturing[10]



Scan here to experience coiling in an aneurysm![11]

The Axium™ Detachable Coil Family offers implant designs for a variety of coiling procedures in both ruptured and unruptured aneurysms.

Flow diversion

- Aneurysm flow diversion is a minimally invasive treatment in which a device known as a neurovascular stent placed in the parent blood vessel of a brain aneurysm may divert blood flow away from the aneurysm
- Over time, blood flow into the aneurysm may slow down, eventually ceasing to enter the aneurysm altogether
- As the body's natural healing process works with the flow diversion device, the blood vessel may heal, and the aneurysm may shrink[12-15]

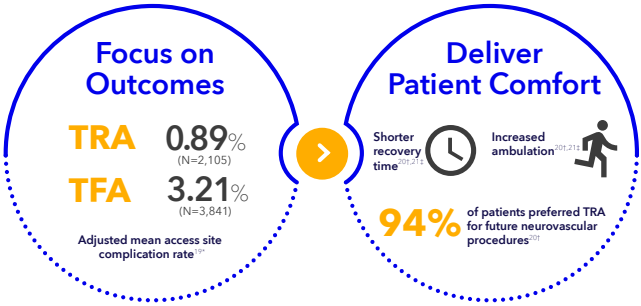
Flow diversion with the Pipeline™ device*

- The Pipeline™ embolization device is designed to divert blood flow away from brain aneurysms in certain segments of the internal carotid artery (ICA)
- The device features a braided cylindrical mesh tube that is implanted across the base or neck of the aneurysm
- The device decreases blood flow to the aneurysm, reconstructing the diseased section of the parent vessel[16]
- This may result in the aneurysm shrinking in size or resolving over time

Shield Technology™ builds on the clinically proven Pipeline™ Flex and Pipeline™ Vantage embolization devices.[13,14,16]

Radial access

- Transradial access (TRA) via the radial artery with the wrist as entry point is an alternative to traditional transfemoral access (TFA) via the groin for catheter-based procedures.



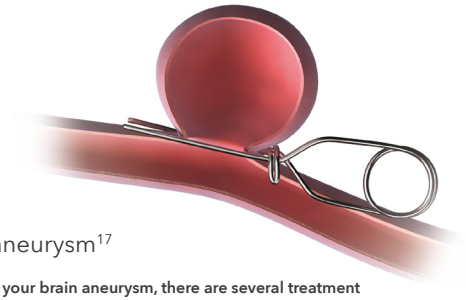
- TRA is associated with a lower incidence rate of access site complications versus TFA[10]
- TRA is associated with increased patient satisfaction and preference versus TFA[17,18]

* Comprehensive report based on 32 studies. † Patients who underwent both TRA and TFA procedures (N=66). TRA 95% CI: 0.31% to 1.47%. TFA 95% CI: 1.88% to 4.55%.
‡ Patients surveyed on discomfort and pain (N=80). Patients preference for TRA vs TFA (N=58).

Treatment choices: Surgical

Clipping

- Surgical procedure requiring an opening of the skull or a craniotomy
- Placement of a clip on the neck of the aneurysm to prevent blood flow into the aneurysm[17]



If you have talked to your doctor and are considering treatment for your brain aneurysm, there are several treatment options your doctor may discuss with you, including the risks and benefits. Not every person will receive the same results.

Risk factors for an aneurysm to rupture

Size

The largest aneurysms are the ones most likely to rupture in a person who previously did not show symptoms.[22]

Location

Aneurysms located on the posterior communicating arteries (PCoA) and possibly those on the anterior communicating artery (ACoA) have a higher risk of rupturing.[22]

Smoking

Although smoking increases the risk of rupture, smoking is not a trigger factor for aneurysmal rupture. Smoking weakens the wall, making unruptured aneurysms more vulnerable to trigger factors and thus rupture.[23]

Hypertension

High blood pressure damages and weakens arteries, making them more likely to form and to rupture. Hypertension was a significant risk factor for rupture of aneurysms 7 mm or smaller, with odds for rupture of 2.58.[24]

Growth

Aneurysm growth was associated with a rupture rate of 3.1% per year compared with 0.1% per year for nongrowing aneurysms.[25]

Family history

Patients with familial aneurysms had 17 times higher risk of rupture than nonfamilial aneurysms.[26]

Ethnicity

Within unruptured aneurysms, Finnish patients exhibit a 3.6x increased risk and Japanese patients exhibit a 2.8x increased risk.[27]

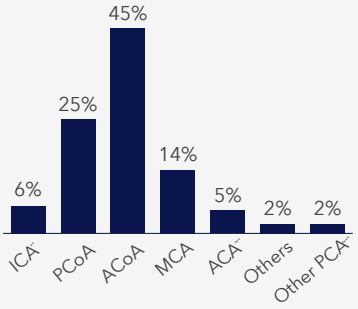
Women

The risk of rupture for women is 1.6 times higher than the risk for men.[28]

Distribution of patients with ruptured aneurysms

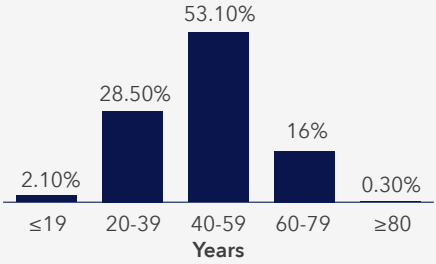
Location*

The most common sites for ruptured aneurysms (in order) were: Anterior Communicating Artery (ACoA), Posterior Communicating Artery (PCoA), Middle Cerebral Artery (MCA).[29]



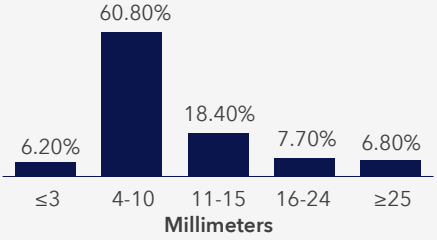
Age

The average age of patients with ruptured aneurysms was 46 years.[30]



Size

The mean size of all ruptured aneurysms is 10.8 mm.[29]



* Talk to a physician for full descriptions of your aneurysm location.
** Internal carotid artery
*** Anterior choroidal artery
**** Other posterial cerebral artery

The unruptured intracranial aneurysm treatment score (UIATS)[10]

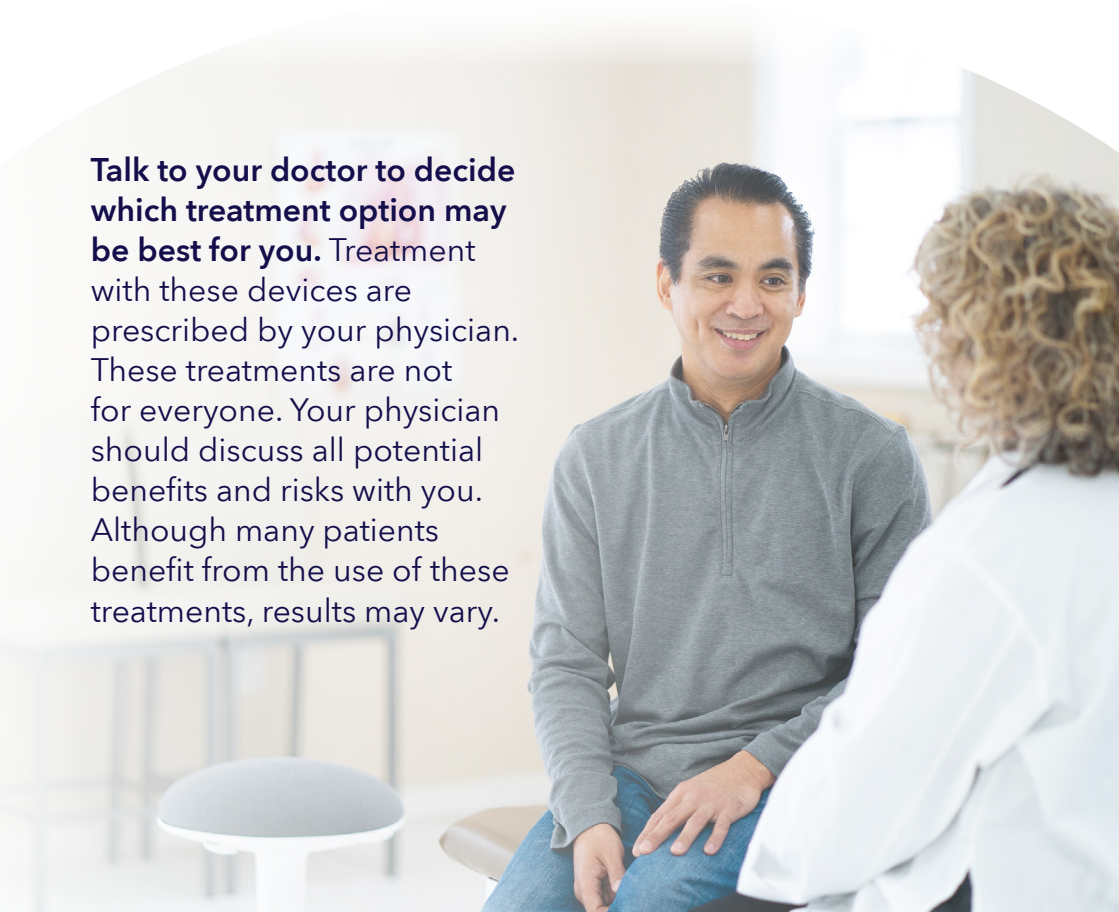
Patient	Age (single)	< 40 years	4		
		40-60 years	3		
		61-70 years	2		
		71-80 years	1	○	
		> 80 years	0		
	Risk factor incidence (multiple)	Previous SAH from a different aneurysm	4		
		Famillial intracranial aneurysms or SAH	3		
		Japanese, Finnish, Inuit ethnicity	2		
		Current cigarette smoking	3		
		Hypertension (systolic BP > 140mm Hg)	2		
		Autosomal-polycystic kidney disease	2		
		Current drug abuse (cocaine, amphetamine)	2	○	
		Current alcohol abuse	1		
	Clinical symptoms related to UIA (multiple)	Cranial nerve deficit	4		
		Clinical or radiological mass effect	4		
		Thromboembolic events from the aneurysm	3	○	
		Epilepsy	1		
	Other (multiple)	Reduced quality of life due to rupture	2	○	
		Aneurysm multiplicity	1		
	Life expectancy due to chronic and/or malignant diseases (single)	< 5 years	4		
		5-10 years	3		○
		> 10 years	1		
	Comorbid disease (multiple)	Neurocognitive disorder	3		
		Coagulopathies, thrombophilic diseases	2		○
		Psychiatric disorder	2		
Aneurysm	Maximum diameter (single)	≤3.9mm	0		
		4.0-6.9mm	1		
		7.0-12.9mm	2		
		13.0-24.9mm	3	○	
		≥25mm	4		
	Morphology (multiple)	Irregularity or lobulation	3	○	
		Size ratio > 3 or aspect ratio > 1.6	1		
	Location (single)	BasA bifurcation	5		
		Vertebral/basilar artery	4	○	
		AcomA or PcomA	2		
	Other (multiple)	Aneurysm growth on serial imaging	4		
		Aneurysm de novo formation on serial imaging	3	○	
		Contralateral stenoocclusive vessel disease	1		

Treatment	Age-related risk (single)	< 40 years	0	
		41-60 years	1	
		61-70 years	3	
		71-80 years	4	
		> 80 years	5	
	Aneurysm size-related risk (single)	< 6.0mm	0	
		6.0-10.0mm	1	
		10.1-20.0mm	3	
		> 20mm	5	
	Aneurysm complexity-related risk	High	3	
		Low	0	
	Intervention-related risk	Constant*		5

Favors UIA repair

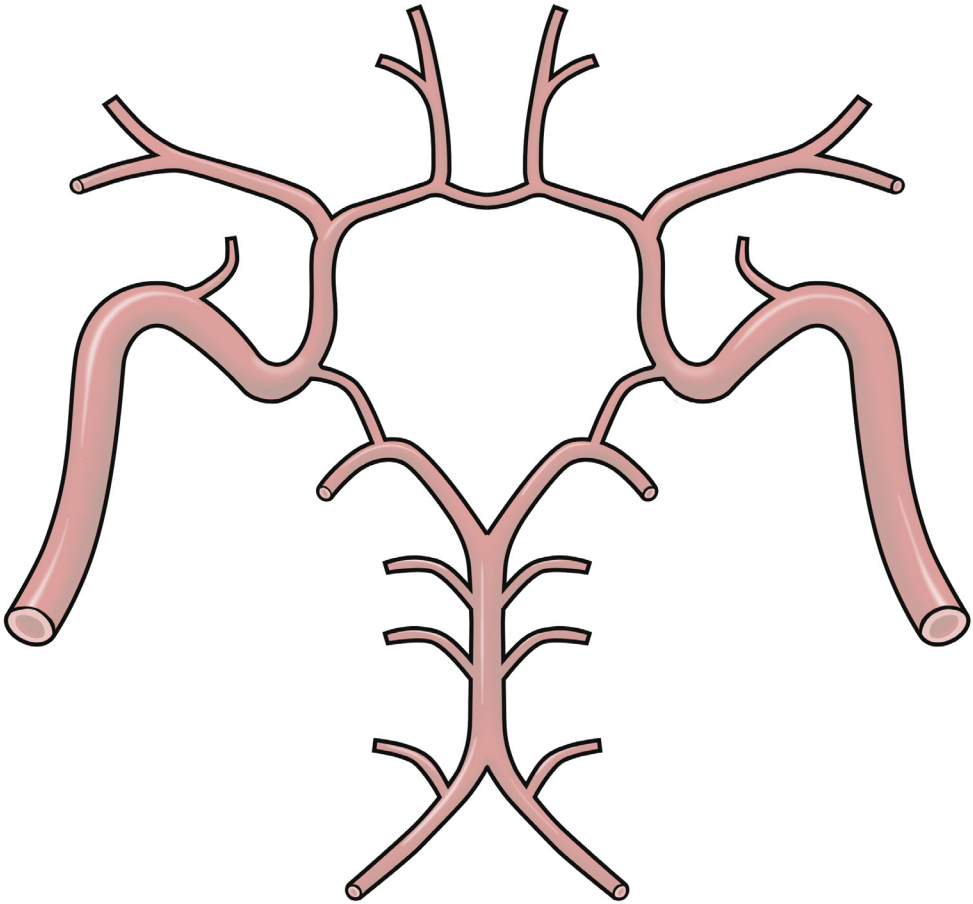
Favors UIA conservative management

Talk to your doctor to decide which treatment option may be best for you. Treatment with these devices are prescribed by your physician. These treatments are not for everyone. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of these treatments, results may vary.



Physician to patient scratch pad

Pre and post coil case discussion



References

1. United Nations, Department of Economic and Social Affairs, Population Division (2019). World Population Prospects 2019, Online Edition. Rev. 1.
2. Neurologic disorders (Chapter 3). In: Professional Guide to Diseases, 9th edn. Lippincott Williams & Wilkins, 2009.
3. https://www.mayoclinic.org/diseases-conditions/brain-aneurysm/symptoms-causes/syc-20361483. Accessed on 2022-08-16.
4. https://mayfieldclinic.com/pe-aneurrupt.htm. Accessed on 2022-08-16.
5. Statistics and Facts. BRAIN ANEURYSM FOUNDATION Website https://bafound.org/about-brain-aneurysms/brain-aneurysm-basics/brain-aneurysm-statistics-and-facts. Accessed on 2022-08-16.
6. Becske, T. et al. Long-term clinical and Angiographic outcomes following Pipeline Embolization Device treatment of complex internal carotid artery aneurysms: Five-year results of the Pipeline for uncoilable or failed aneurysms trial. www.neurosurgery-online.com. Volume 80. January 2017. Accessed on 2022-08-16.
7. Vallée JN, Pierot L, Bonafé A, et al. Endovascular treatment of intracranial wide-necked aneurysms using three-dimensional coils: Predictors of immediate anatomic and clinical results. *Am J Neuroradiol*. 2004;25(2): 298–306.
8. Jose I. et al. Aneurysmal Subarachnoid Hemorrhage. *N Engl J Med* 2006;354:387-96.
9. Jane JA. et al. The natural history of aneurysms and arteriovenous malformations. J Neurosurg. 1985;62(3):321-3.
10. Etminan N, Brown RD Jr, Beseoglu K, et al. The unruptured intracranial aneurysm treatment score: a multidisciplinary consensus. *Neurology*. 2015;85(10):881-889.
11. https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html#soft. Accessed on 2022-08-16.
12. Cerebral Aneurysms Fact Sheet, NINOS, Publication date May 2018. *NIH* Publication No. 18-NS-5506.
13. Pipeline™ Flex Embolization Device IFU.
14. Szikora I, Marosfoi M, Salomváry B, Berentei Z, Gubucz I. Resolution of mass effect and compression symptoms following endoluminal flow diversion for the treatment of intracranial aneurysms. *AJNR Am J Neuroradiol* 2013;34:935-9.
15. PREMIER Clinical Study Report Medtronic FD3563 Rev B.
16. Kallmes, DF et al. International Retrospective Study of the Pipeline Embolization Device: A Multicenter Aneurysm Treatment Study, AJNR Published online, Oct 29, 2014.
17. https://bafound.org/treatment. Accessed on 2022-08-16.
18. https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/axium.html#soft. Accessed on 2022-08-16.
19. Internal Medtronic Clinical Study Report D00358316: Safety and Performance of Radial Versus Femoral Access in Neurointervention.
20. Khanna, O., et al. Radial Artery Catheterization for Neuroendovascular Procedures. Stroke, 2019. 50(9): 2587-2590.

21. Snelling, BM., etal. Transradial cerebral angiography: techniques and outcomes. J Neurointerv Surg. 2018 Sep;10(9): 874-881.
22. Cerebral Aneurysms Fact Sheet. NIH Website https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Cerebral-Aneurysms-Fact-Sheet#6. Accessed on 2022-08-16.
23. Vlak MH, Rinkel GJ, Greebe P, Algra A. Risk of rupture of an intracranial aneurysm based on patient characteristics: A case-control study. *Stroke* 2013; 44: 1256-9.
24. Nahed BV, DiLuna ML, Morgan T, et al. Hypertension, age and location predict rupture of small intracranial aneurysms. *Neurosurgery*. 2005;57: 676–683.
25. W. Brinjikji, et al. Risk Factors for Growth of Intracranial Aneurysms: A Systematic Review and Meta-Analysis. *American Journal of Neuroradiology*. April 2016, 37 (4) 615-620.
26. Broderick JP, Brown RD, Jr., Sauerbeck L, Hornung R, Huston J, III, Woo D, et al. Greater rupture risk for familial as compared to sporadic unruptured intracranial aneurysms. *Stroke* 2009; 40: 1952-7.
27. Greving JP, Wermer MJ, Brown RD, Jr., Morita A, Juvela S, Yonekura M, et al. Development of the phases score for prediction of risk of rupture of intracranial aneurysms: A pooled analysis of six prospective cohort studies. *Lancet Neurol* 2014; 13: 59-66.
28. J. P. Mohr, Philip A. Wolf, Michael A. Moskowitz, Marc R Mayberg, Rudiger Von Kummer. Stroke E-Book: Pathophysiology, Diagnosis, and Management. 2011; 589-590.
29. A. Molyneux, et al International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomized trial *Lancet*, 360 (2002), pp. 1267-1274.
30. Weir B, et al. Sizes of ruptured and unruptured aneurysms in relation to their sites and the ages of patients. *J Neurosurg* 96:64–70, 2002.

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Discuss indications, contraindications, warnings, precautions, adverse events and any further information with your health care professional.

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