

# International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion

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## Summary

**Background** Two types of treatment are being used for patients with ruptured intracranial aneurysms: endovascular detachable-coil treatment or craniotomy and clipping. We undertook a randomised, multicentre trial to compare these treatments in patients who were suitable for either treatment because the relative safety and efficacy of these approaches had not been established. Here we present clinical outcomes 1 year after treatment.

**Methods** 2143 patients with ruptured intracranial aneurysms, who were admitted to 42 neurosurgical centres, mainly in the UK and Europe, took part in the trial. They were randomly assigned to neurosurgical clipping (n=1070) or endovascular coiling (n=1073). The primary outcome was death or dependence at 1 year (defined by a modified Rankin scale of 3–6). Secondary outcomes included rebleeding from the treated aneurysm and risk of seizures. Long-term follow up continues. Analysis was in accordance with the randomised treatment.

**Findings** We report the 1-year outcomes for 1063 of 1073 patients allocated to endovascular treatment, and 1055 of 1070 patients allocated to neurosurgical treatment. 250 (23·5%) of 1063 patients allocated to endovascular treatment were dead or dependent at 1 year, compared with 326 (30·9%) of 1055 patients allocated to neurosurgery, an absolute risk reduction of 7·4% (95% CI 3·6–11·2, p=0·0001). The early survival advantage was maintained for up to 7 years and was significant (log rank p=0·03). The risk of epilepsy was substantially lower in patients allocated to endovascular treatment, but the risk of late rebleeding was higher.

**Interpretation** In patients with ruptured intracranial aneurysms suitable for both treatments, endovascular coiling is more likely to result in independent survival at 1 year than neurosurgical clipping; the survival benefit continues for at least 7 years. The risk of late rebleeding is low, but is more common after endovascular coiling than after neurosurgical clipping.

## Introduction

The International Subarachnoid Aneurysm Trial (ISAT), a randomised trial comparing neurosurgical clipping with endovascular coiling in patients with ruptured intracranial aneurysms, closed recruitment after an interim analysis showed a benefit of endovascular treatment on the primary outcome: death or dependency at 1 year. Our first report\* of the interim results used the outcome data available at the time of that analysis. These data were incomplete because 1-year follow-up was available for only 1594 of the 2143 patients enrolled. However, the difference between the two treatments was significant: endovascular coiling was associated with an absolute reduction in the risk of death or dependence at 1 year of 6·9% (a relative risk reduction of 22·6%, p<0·001) compared with neurosurgical clipping.<sup>1</sup> The 1-year data are now complete and we report here the primary outcome at 1 year for all patients combined and subdivided by the prespecified subgroups.<sup>1</sup> We also report results for secondary outcomes: epilepsy,

rebleeding from the treated aneurysm, deaths during medium-term follow-up (with survival curves to 7 years), and the findings on follow-up angiography. Patients were eligible for enrolment into ISAT if the responsible neurosurgeon and neuroradiologist were uncertain about the best treatment. If there was insufficient uncertainty, the patient could not be randomised.<sup>1</sup>

## Methods

### Patients

The trial protocol and methods, including the randomisation and minimisation criteria, recruiting centres, patient demographics and aneurysm characteristics, have already been published.<sup>1,2</sup> Eligible patients had subarachnoid haemorrhage due to intracranial aneurysm, suitable for either endovascular or neurosurgical treatment. These subgroups were pre-specified: World Federation of Neurosurgical Societies (WFNS) grade at randomisation, age groups by decade (<40, 40–49, 50–59, 60–69, ≥70 years), amount of

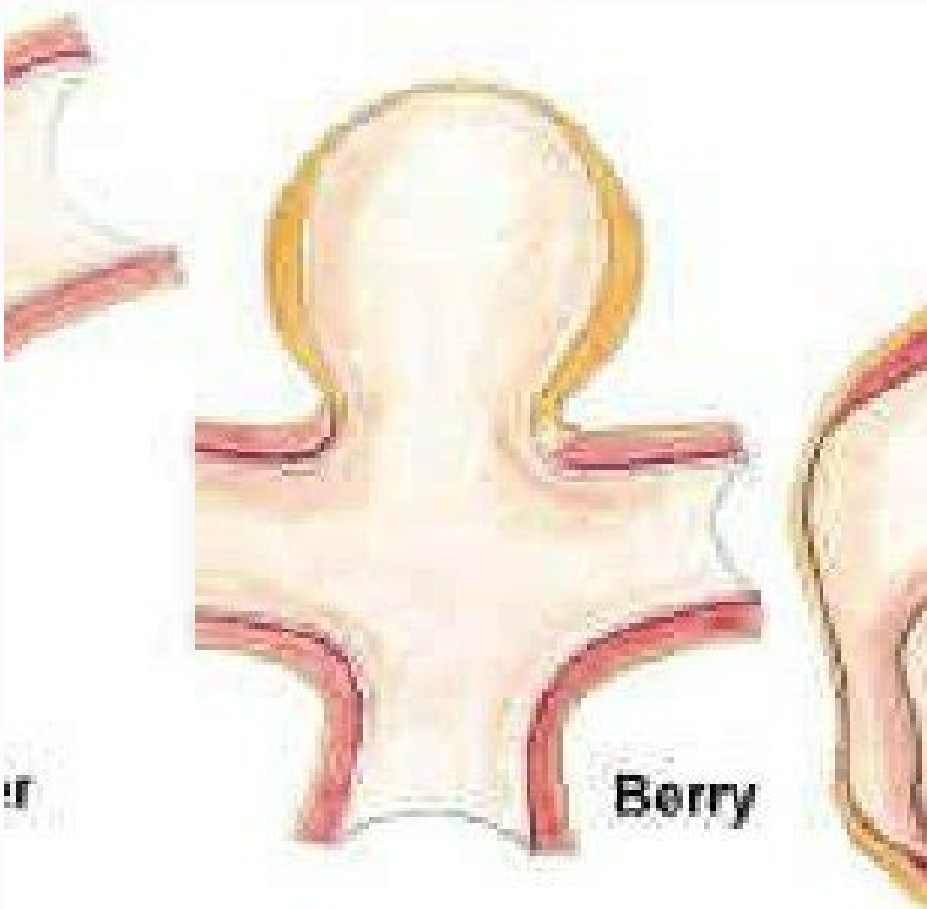
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## Level of headaches after surgical aneurysm clipping decreases significantly faster compared to endovascular coiled patients

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## Abstract

In incidental aneurysms, endovascular treatment can lead to post-procedural headaches. We studied the difference of surgical clipping vs. endovascular coiling in patients with ruptured aneurysms. Sixty-seven patients with aneurysmal subarachnoid haemorrhage were treated in our department from September 1<sup>st</sup> 2015 - September 1<sup>st</sup> 2016. 43 Patients were included in the study and the rest was excluded because of late recovery or high-grade subarachnoid bleedings. Twenty-two were surgical treated and twenty-one were interventionally treated. We compared the post-procedural headaches at the time points of 24 h, 21 days, and 3 months after treatment using the visual analog scale (VAS) for pain. After surgical clipping the headache score decreased for 8.8 points in the VAS, whereas the endovascular treated population showed a decrease of headaches of 3.3 points. This difference was highly statistical significant and remained significant even after 3 weeks where the pain score for the surgically treated patients was 0.68 and for the endovascular treated 1.8. After 3 months the pain was less than 1 for both groups with surgically treated patients scoring 0.1 and endovascular treated patients 0.9 (not significant). Clipping is relieving the headaches of patients with aneurysm rupture faster and more effective than endovascular coiling. This effect stays significant for at least 3 weeks and plays a crucial role in stress relief during the acute and subacute ICU care of such patients.

## Introduction

There is still controversy about occurrence of post-procedural headaches and

coil-embolization of intracranial non-ruptured aneurysms. There are studies indicating a relief of headache after coil-embolization<sup>1</sup> and others showing an increase of headache after the procedure, at least for a short time.<sup>2</sup> However, there are no studies evaluating the severity of headaches of endovascular vs surgical treatment in ruptured aneurysms. In the present study we aimed to compare the incidence of post-procedural headaches as assessed by the visual analog scale (VAS) after surgical clipping or interventionally coiling in patients with aneurysmal subarachnoid haemorrhage (sSAH) of WFNS grades I–3.

## Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

## Materials and Methods

### Study design

For the retrospective study there was no approval needed as given by the Physicians Chamber of Nordrhein.

### Participants

Inclusion criteria of our present retrospective analysis were: (i) patients with aneurysmal subarachnoid haemorrhage suffering from WFNS grade I–3; (ii) evaluation of the patient at maximum 12 hours after aneurysm occlusion; (iii) full orientation regarding time and situation; (iv) reliable answering to questions without any aphasic disturbances. (v) treatment between September 1<sup>st</sup> 2015 and September 1<sup>st</sup> 2016. Patients with non-aneurysmal or high-grade SAH, comatose, confused or aphasic patients were excluded.

### Standard treatment

After confirmation of an aneurysmal SAH by native computed tomography and CT-angiography, patients were admitted to the neuro intensive care unit (NICU) and treated according to the AHA- and institutional guidelines.<sup>3</sup> All patients with a GCS < 12 received an external ventricular drainage (EVD) but most of these patients had a WFNS score of ≥ 3 and where excluded from the study. Digital subtraction angiography was performed for aneurysm visualization and confirmation. Aneurysm was

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Key words: Headache; aneurysm; subarachnoid haemorrhage; surgical clipping; endovascular coiling

Conflicts of interest: the authors declare no potential conflict of interest.

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repaired either by microsurgical or endovascular technique within 24 hours after admission. After the procedure, patients in both groups were treated in the same manner, were transferred to the ICU and – if possible – were extubated. Prophylactic treatment with diltiazem L-type calcium channel antagonists was started and all patients underwent serial perfusion computed tomography (PCT) during their stay on the NICU.

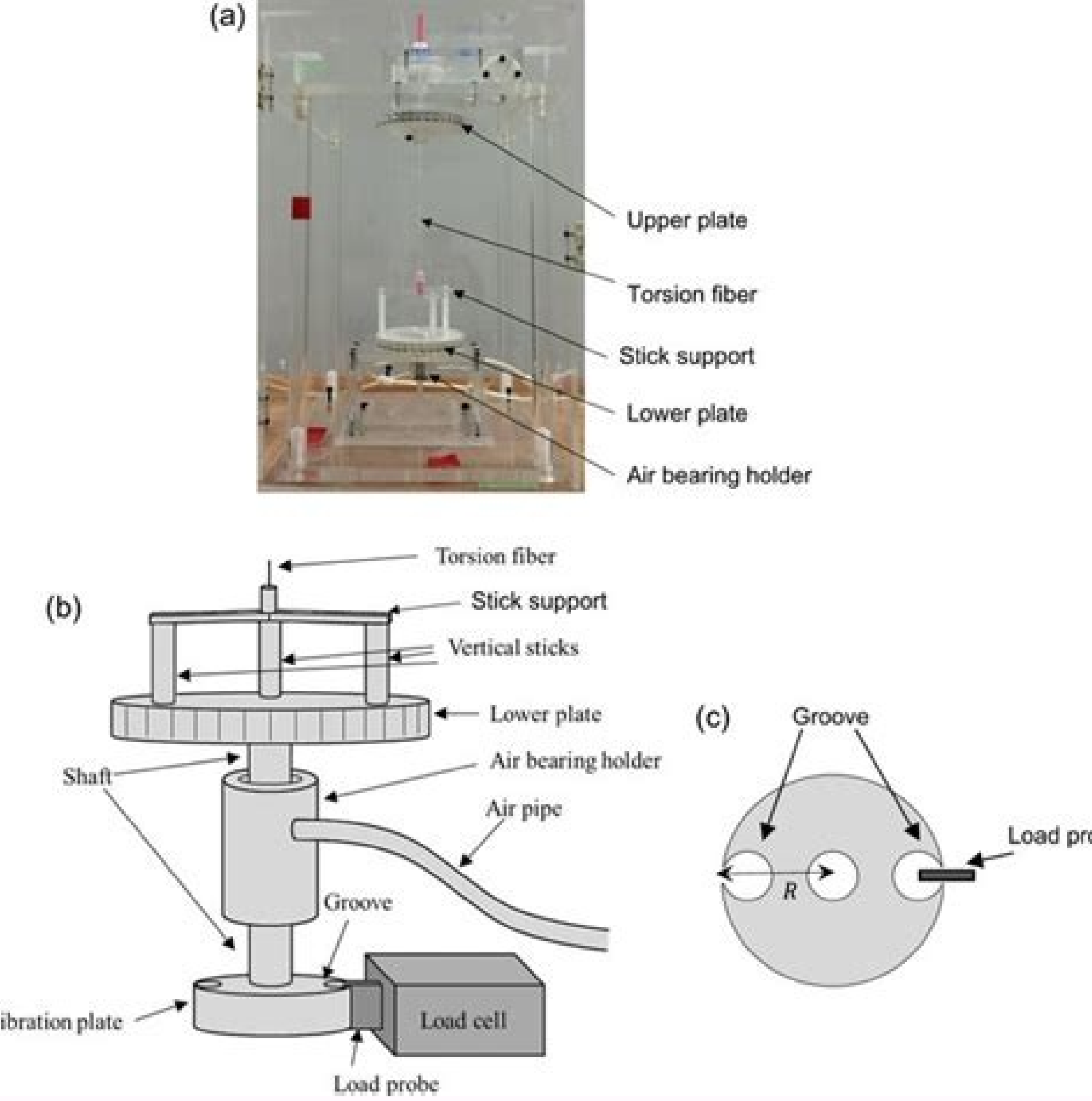
Standardized pain medication was paracetamol (30 mg), metamizole (30 mg) and – only if required – piritramid (3 mg i.v.).

### Variables

Headache was assessed by the visual analog scale (VAS; no pain: 0, to maximal pain: 10), which was the main study parameter. The pain scores were recorded for the initial headache at aneurysm rupture, 24 h (N=43), 21 days (N=43), 3 months (N=19) and 6 months (N=3) after surgery. For the 24 h time point patients were asked 3 times a day in fixed time points and the mean VAS score was calculated in order to minimize any immediate effect of analgesics which could have possibly given to the patient at the time point of assessment of the VAS. At the same time, dosage and specific analgesia was recorded. Other parameters were age, gender, aneurysm location, vasospasm, ischemia.

Cerebral vasospasms were defined as transcranial Doppler mean velocity of MCA > 120 cm/sec, a Lindegaard Index of >4.5 or clinical deterioration.





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Our product range includes more than 200 aneurysm clips of different shape, model and application. All clips are available in phynox or titanium and can be supplied sterile and non-sterile. Each clip will be delivered in a individual package, which shows the most important information like size, closing force, model, LOT number and manufacturing date on the first view. A individual LOT number will be laser marked on every clip in order to ensure the traceability of all production data for 30 years. The shaft of our special clip applying forceps is made from memory steel and can be bent very flexible in almost every position. This makes even the most complicated accesses possible. Due to the heat during the washing and sterilisation process, the shaft will become straight again and goes back to its initial shape. Products Aneurysm Clips neurological clip evoClip evoClip - sterile, effective, easy to attach The evoClip scalp haemostatic clips are designed for being attached to the scalp flap, in order to stop the bleeding during a craniotomy. Our evoClips are available in two different variations: ... Clipping is a surgery performed to treat an aneurysm — a balloon-like bulge of an artery wall. As an aneurysm grows it can become so thin that it leaks or ruptures, releasing blood into the spaces around the brain. A neurosurgeon opens the skull (craniotomy) and places a tiny clip across the neck of the aneurysm to stop or prevent it from bleeding. What is aneurysm clipping? The goal of surgical clipping is to isolate an aneurysm from the normal circulation without blocking off any small perforating arteries nearby. Under general anesthesia, an opening is made in the skull, called a craniotomy. The brain is gently retracted to locate the aneurysm. A small clip is placed across the base, or neck, of the aneurysm to block the normal blood flow from entering. The clip works like a tiny coil-spring clothespin, in which the blades of the clip remain tightly closed until pressure is applied to open the blades. Clips are made of titanium and remain on the artery permanently. Figure 1. Most aneurysms resemble a balloon, with a narrow neck at its origin and a large expanding dome. During surgery, a clip is placed across the neck of the aneurysm to prevent blood from entering. Aneurysms vary in their size and shape. Saccular aneurysms have a neck at their origin on the main artery and a dome that can expand and grow like a balloon (Fig. 1). These are the easiest to place a clip across. Some aneurysms have a wide neck or are fusiform in shape having no definable neck. These are more difficult to place a clip across. Since aneurysms have various neck configurations, clips are made in a variety of shapes, sizes, and lengths (Fig. 2). Figure 2. Aneurysm clips come in a variety of sizes and curves. A clip applicator opens the blades of the aneurysm clip. Who is a candidate? The choice of aneurysm treatment (observation, surgical clipping or bypass, or endovascular coiling) must be weighed against the risk of rupture and the overall health of the patient. Because clipping involves the use of anesthesia and surgically entering the skull, patients with other health conditions or who are in poor health may be treated with observation or coiling. Clipping may be an effective treatment for the following: Ruptured aneurysms burst open and release blood into the space between the brain and skull, called a subarachnoid hemorrhage (SAH). The risk of repeated bleeding is 22% within the first 14 days after the first bleed. So, timing of surgery is important - usually within 72 hours of the first bleed. Unruptured aneurysms may not cause symptoms and are typically detected during routine testing for another condition. The risk of aneurysm rupture is about 1% per year but may be higher or lower depending on the size and location of the aneurysm. However, when rupture occurs, the risk of death is 40%, and the risk of disability is 80%. The surgical decision The treatment decision for observation, surgical clipping or bypass, or endovascular coiling or flow diversion largely depends on the aneurysm's size, location, and neck geometry. The less invasive nature of coiling is likely to be favored in patients who are older, are in poor health, have serious medical conditions, or have aneurysms in certain locations. In patients younger than 40 years of age, the difference in the safety between coiling versus clipping is small. Therefore, the better long-term protection from bleeding may give patients with clipped aneurysms an advantage in life expectancy. Comparing the long-term results of coiling versus clipping of aneurysms is an area of ongoing study. Clipping has proven its long-term effectiveness over several decades. Coiling is a relatively new technique (since 1990s) and its long-term protection against rebleeding is not known. The International Subarachnoid Aneurysm Trial (ISAT) explored this topic over a period of years (1994-2007) [1,2]. But because the study was limited to ruptured aneurysms and included a very select group of patients, its results cannot be applied to all aneurysm patients. Therefore, the best treatment option remains highly individualized. Discuss with your doctor the technique most appropriate for your specific case. Who performs the procedure? Surgical clipping is performed by a neurosurgeon. Many neurosurgeons have specialized training in cerebrovascular surgery. Ask your surgeon about their training, especially if your case is complex. What happens before surgery? Preparation before surgery differs if you are brought to the emergency room with a ruptured aneurysm or if you are considering clipping for an unruptured aneurysm. A ruptured aneurysm is life threatening - you may be taken immediately to the operating room after the doctors have located the aneurysm and your blood pressure is stabilized. To decrease blood pressure doctors may use medication, hyperventilation on a breathing machine, or sedation. An arterial pressure line may be inserted into your arm to monitor blood pressure. Visits with your loved one may be restricted in order to create a calm environment with little stimulation. If you have an unruptured aneurysm, you will fill out paper work and sign consent forms so that your surgeon knows your medical history (i.e., allergies, medicines, anesthesia reactions, previous surgeries). Presurgical tests (e.g., blood test, electrocardiogram, chest X-ray) may need to be done several days before surgery. Consult your primary care physician about stopping certain medications and ensure you are cleared for surgery. Stop taking all non-steroidal anti-inflammatory medicines (ibuprofen, naproxen, etc.) and blood thinners (Coumadin, aspirin, Plavix, etc.) 7 days before surgery. Stop using nicotine and drinking alcohol 1 week before and 2 weeks after surgery to avoid bleeding and healing problems. You may be asked to wash your skin and hair with Hibiclens (CHG) or Dial soap before surgery. It kills bacteria and reduces surgical site infections. (Avoid getting CHG in eyes, ears, nose or genital areas.) Don't eat or drink after midnight before surgery (unless the hospital tells you otherwise). You may take permitted medicines with a small sip of water. Patients are admitted to the hospital the morning of surgery. An anesthesiologist will talk with you to explain the effects of anesthesia and its risks. What happens during surgery? There are six steps to the procedure. The operation generally takes 3-5 hours or longer if a complex craniotomy is planned. Step 1: prepare the patient You will lie on the operating table and be given general anesthesia. After you are asleep, your head is placed in a three-pin skull fixation device, which attaches to the table and holds your head in position during surgery. Next, the incision area of the scalp is prepped. Skin incisions are usually made behind the hairline. A hair sparing technique is used, where only a 1/4-inch wide area along the proposed incision is shaved. Sometimes the entire incision area may be shaved. A lumbar drain may be inserted in your lower back to remove cerebrospinal fluid (CSF) and allow the brain to relax during surgery. A brain-relaxing drug (mannitol) may be given. Step 2: perform a craniotomy Depending on the location of your aneurysm, a bone flap, or craniotomy, will be made in your skull. There are many types of craniotomies. Ask your surgeon to describe exactly where the skin incision will be made and the bone to be removed. Figure 3. A craniotomy is made in the skull over the area where the aneurysm is located. The bone flap is lifted and temporarily removed. After your scalp is prepped, the surgeon will make a skin incision to expose the skull. The skin and muscles are lifted off the bone and folded back. Next, small burr holes are made in the skull with a drill. The burr holes allow entrance of a special saw called a craniotome. Similar to using a jigsaw, the surgeon cuts an outline of a bone window (Fig. 3). The cut bone flap is lifted and removed to expose the protective covering of the brain, called the dura mater. The bone flap is safely set aside and will be replaced at the end of the procedure. Step 3: expose the aneurysm The dura is opened to expose the brain. Retractors may be used to gently open a corridor between the brain and skull. Working under an operating microscope, the surgeon carefully locates the artery and follows it to the aneurysm. Before placing the clip, the surgeon obtains control of the blood flow in and out of the aneurysm. Handling of the aneurysm, especially the dome, can cause rupture. Should rupture occur during surgery, a temporary clip can be placed across the parent artery to stop the bleeding. Depending on the aneurysm size and location, vascular control may be obtained at the carotid artery in the neck through a separate incision. Step 4: insert the clip The aneurysm neck is prepared for clipping. Often the aneurysm is held tight by connective tissue and must be freed and isolated from other structures. Small arteries called perforators must be noted so they are not included in the clip. The clip is held open with a tweaser-like applicator and placed across the aneurysm neck. Once released, the jaws of the clip close pinching off the aneurysm from the parent artery (Fig. 4). Multiple clips may be used. The clip is made of titanium and remains on the artery permanently. Figure 4. A titanium clip is placed across the neck of an aneurysm preventing blood from entering. Without blood flow, the aneurysm will eventually shrink. The clip is made of titanium and remains on the artery permanently. Step 5: check the clip The surgeon inspects the clip to make sure it is not narrowing the parent artery or has other arteries in its jaws. The dome of the aneurysm is punctured with a needle to make sure blood is no longer filling it. Intraoperative angiography may be performed to confirm blood flow through the parent artery. Step 6: close the craniotomy The dura is closed with sutures. The bone flap is replaced and is secured to the skull with titanium plates and screws. The muscles and skin are sutured back together. A soft adhesive dressing will be placed over the incision. What happens after surgery? After surgery you'll be taken to the recovery room, where vital signs are monitored as you awake from anesthesia. Then you'll be transferred to the intensive care unit (ICU) for observation and monitoring. Pain medication will be given as needed. You may experience nausea and headache after surgery. Medication can control these symptoms. Ruptured aneurysm patients stay in the NSICU for 14 to 21 days and are monitored for signs of vasospasm, which is a narrowing (spasm) of an artery that may occur 3-14 days following a SAH. Signs of vasospasm include arm or leg weakness, confusion, sleepiness, or restlessness (see SAH). After 24 to 48 hours, unruptured aneurysm patients are usually transferred to a regular room. Monitoring will continue as you increase your activity level. In a few days you'll be released from the hospital and given discharge instructions. Be sure to have someone at home to help you for the first 24 to 48 hours. Follow the surgeon's home care instructions for 2 weeks after surgery or until your follow-up appointment. In general, you can expect: Restrictions Don't lift anything heavier than 5 pounds. No strenuous activity including yard work, housework, and sex. Don't drink alcohol. It thins the blood and increases the risk of bleeding. Also, don't mix alcohol with pain medicines. Don't smoke or use nicotine products: vape, dip, or chew. It may delay healing. Don't drive, return to work, or fly air travel until your surgeon says it's OK. Incision Care You may shower the day after surgery and wash your hair with mild baby shampoo. Gently wash the incision area with soap and water every day. Don't scrub or let the water beat hard on your incision. Pat dry. If Dermabond skin glue covers your incision, don't rub or pick at the glue. Don't submerge or soak the incision in a bath, pool or tub. Don't apply lotion/ointment on the incision, including hair styling products. You may hear strange noises (popping, crackling, ringing) inside your head. This is normal healing as air and fluid reabsorb. Don't color your hair for 6 weeks. If you cut your hair, use caution near the incision. Medications Headaches are common after surgery. You may take acetaminophen (Tylenol). Take pain medicines as directed by your surgeon. Reduce the amount and frequency as your pain subsides. If you don't need the pain medicine, don't take it. Narcotics can cause constipation. Drink lots of water and eat high-fiber foods. Stool softeners and laxatives can help move the bowels. Colace, Senokot, Dulcolax and Miralax are over-the-counter options. Anti-seizure medicine may be prescribed. Some patients develop side effects such as drowsiness, balance problems, or rashes. Call the office if any of these occur. Don't take anti-inflammatory pain relievers (Advil, Aleve), blood thinners, or supplements without surgeon's approval. Activity Get up and walk 5-10 minutes every 3-4 hours. Gradually increase walking as you are able. Swelling and bruising of the eye or face may occur. It will take several weeks to go away. Sleep with your head elevated and apply ice 3-4 times per day for 15-20 minutes to help reduce pain and swelling. When to Call Your Doctor Fever over 101.5° (unrelieved by Tylenol). Signs of incision infection, such as spreading redness, separation, or colored drainage. Increased drowsiness, weakness of arms / legs, increased headaches, vomiting, or severe neck pain that prevents lowering your chin to chest. New or worsening vision, speech or confusion. Swelling at the incision with leaking of clear fluid from your ear or nose. Swelling and tenderness in the calf of one leg. Seizure Call 911 if you have: trouble breathing (blood clot in lung), facial droop, slurred speech, arm weakness, confusion (signs of a stroke), a sudden severe headache, popping or snapping sensation in the head, nausea and vomiting, or a stiff neck (signs of an aneurysm rupture). What are the risks? No surgery is without risk. General complications related to brain surgery include infection, allergic reactions to anesthesia, stroke, seizure, and swelling of the brain. Complications specifically related to aneurysm clipping include vasospasm, stroke, seizure, bleeding, and an imperfectly placed clip, which may not completely block off the aneurysm or blocks a normal artery unintentionally. Several studies have suggested that memory loss and cognitive disability is more common after craniotomy for aneurysm clipping than after endovascular coiling, especially in patients over 50. What are the results? Aneurysms that are completely clipped have an extremely low risk of regrowth. However, if the aneurysm has been partially clipped, patients need to have periodic angiograms to make sure the aneurysm is not growing. Ask your neurosurgeon about the need for radiologic follow-up. Recovery Aneurysm patients may suffer short-term and/or long-term deficits as a result of a rupture or treatment. Some of these deficits may disappear over time with healing and therapy. For ruptured aneurysms, the recovery process may take months or years to understand the deficits you incurred and regain function. Today most aneurysm clips are made of titanium and are not detected by security gates. However, it is very important to know if your clip is MRI compatible before undergoing an MRI scan. You must check your clip lot number with the manufacturer. The clip lot number is obtainable from the operative notes at the hospital where you underwent surgery. Sources & links If you have more questions, please contact Mayfield Brain & Spine at 800-325-7787 or 513-221-1100. Sources Molyneux A, et al. International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion. Lancet 366(9488):809-17, 2005. Links Brain Aneurysm Foundation, BAFound.org The Aneurysm and AVM Foundation, TAAOnline.org Glossary aneurysm: a bulge or weakening of an artery wall. aneurysm clip: a coil-spring device used to treat aneurysms. angiogram: a type of X-ray that takes pictures of blood vessels with the help of contrast dye injected via a catheter. coiling: a procedure to insert platinum coils into an aneurysm; performed during an angiogram. craniotomy: surgical opening in the skull. dura mater: a tough, fibrous, protective covering of the brain. embolization: inserting material, coil or glue, into an aneurysm so blood can no longer flow through it. subarachnoid hemorrhage: bleeding in the space surrounding the brain; may cause a stroke. titanium: a strong, low-density, highly corrosion-resistant metal alloy. vasospasm: abnormal narrowing or constriction of arteries due to irritation by blood in the subarachnoid space. updated > 1.2021 reviewed by > Andrew Ringer, MD and Ryan Tackla, MD, Mayfield Clinic We comply with the HONCode standard for trustworthy health information: verify here.



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