# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

# INTERVENTIONAL PROCEDURES PROGRAMME

## Interventional procedure overview of Coil embolisation of ruptured intracranial aneurysms

**Introduction**
This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

**Procedure name**
Coil embolisation of intracranial aneurysms

**SERNIP procedure number**
038

**Specialty societies**
British Society of Interventional Radiology
Society of British Neurological Surgeons

**Indication(s)**
Intracranial aneurysm.

Intracranial aneurysms are small balloon-like dilated portions of blood vessels that may occasionally rupture, causing haemorrhage, stroke or death. Usually, the cause is unknown but people with genetic causes of weak blood vessels are more likely to develop aneurysms.

Rupture of intracranial aneurysms (subarachnoid haemorrhage) has a poor prognosis. About 30% of people die within 24 hours and a further 25-30% more die within four weeks (Source: protocol of the International Subarachnoid Aneurysm trial http://users.ox.ac.uk/~isat/isat_protocol.pdf).

Most western countries have an annual incidence of subarachnoid haemorrhage of between 6 and 12 cases per 100,000 people.[1]

**Current treatment and alternatives**
The traditional treatment for ruptured or unruptured intracranial aneurysm involves open surgery to clip the abnormal blood vessels inside the skull.

## Summary of procedure

The coil technique involves approaching the aneurysm from inside the diseased blood vessel, avoiding the need to open the skull (an endovascular technique). This is claimed to be less invasive and risky. The technique is only suitable for people with aneurysms, in which the entrance to the dilated part of the blood vessel (the aneurysm neck) is relatively narrow.

A thin tube, containing the coil on a guidewire, is inserted into a large artery, usually in the groin, and passed up into the skull under radiological guidance. The coil is placed inside the aneurysm and detached from the guidewire. Multiple coils may be placed into the aneurysm through the same tube until the aneurysm is filled with coils, which cause clotting and stop blood from entering the aneurysm.

The coil technique is mainly carried out on ruptured aneurysms but may also be used to treat unruptured aneurysms.

# Literature review

## Appraisal criteria

We included studies of coil technique in the treatment of intracranial aneurysms.

## List of studies found

We found one systematic review (described in table).[2] It found 37 studies.

We found two randomised controlled trials.[3,4]

We found seven non-randomised controlled studies and 19 case series including 100 or more people. The table describes the two largest non-randomised studies[5] and the largest case series.[6]

The annex gives the references to the smaller non-randomised controlled studies and the case series including 100 people or more.

## Summary of key efficacy and safety findings (1)

| Authors, location, date, patients | Key efficacy findings | Key safety findings | Key reliability and validity issues |
|---|---|---|---|
| Brilstra[2]<br>Systematic review<br>Search dates 1990 to 1997<br><br>37 studies; study designs not described<br><br>Studies included 1256 patients (mean age 51) with ruptured or unruptured intracranial aneurysms receiving treatment with controlled detachable coils;1136 received Guglielmi coils | Aneurysm radiographic >90% occlusion: 654 people | • aneurysm perforations: 30<br>• ischaemic complications: 107<br>• procedure related death: 6 | Search strategy described<br><br>Study design and quality not described |
| International Subarachnoid Aneurysm Trial Collaborative Group[3]<br><br>Randomised controlled trial<br>1997 onwards<br><br>2143 people with ruptured intracranial aneurysms<br>• 1073 Guglielmi coil; median age: 52 (range 18-87)<br>• 1070 surgical clipping; median age: 52 (range 18-84)<br><br>Inclusion criteria:<br>• proven subarachnoid haemorrhage preceding 28 days<br>• demonstrated intracranial aneurysm<br>• uncertainty as to which treatment better<br><br>Follow up 12 months | No symptoms:<br>• coil: 26%<br>• clipping: 19%<br><br>Significant restriction of lifestyle:<br>• coil: 10%<br>• clipping: 13%<br><br>Fully dependent:<br>• coil: 3%<br>• clipping: 3%<br><br>Dead<br>• coil: 8%<br>• clipping: 10%<br><br>Relative risk of death at 12 months with coil v clipping: 0.77, 95% confidence interval 0.66 to 0.91 | | Randomisation appropriate<br><br>Characteristics of groups similar<br><br>Blinding of outcomes assessment not described<br><br>Outcomes appropriate<br><br>Follow-up length is appropriate – longer follow up planned<br><br>Follow up complete for 98% of the patients randomised up to Feb 2001 |

## Summary of key efficacy and safety findings (2)

| Authors, location, date, patients | Key efficacy findings | Key safety findings | Key reliability and validity issues |
|---|---|---|---|
| Vanninen[4]<br>Randomised controlled trial<br>Kuopio, Finland<br>1995 to 1997<br><br>111 with ruptured aneurysm<br>• 52 Guglielmi coil mean age 49<br>• 57 clipping, mean age 50<br><br>Exclusion criteria:<br>• age >75<br>• bleeding >3 days<br>• large haematoma<br>• mass effect causing neurological deficit<br>• previous surgery for aneurysm<br>• neck of aneurysm wider than fundus<br>• fusiform aneurysm<br>• neck and its relationship to the parent vessel not distinguishable<br>• aneurysm diameter <2mm<br><br>Follow up 3 months | Good/moderate recovery:<br>• coil: 42 people<br>• clipping: 45 people<br>'not significant'<br><br>Severe disability/vegetative state:<br>• coil: 4 people<br>• clipping: 6 people<br>'not significant'<br><br>Death<br>• coil: 6 people<br>• clipping: 6 people<br>'not significant' | Surgery required in coil group: 8 people<br>• perforation: 3 people<br>• intracranial haematoma: 1 person<br>• rebleeding: 1 person<br><br>Stroke: 2 people<br><br>Transient ischaemic attack: 1 person<br><br>Coil migration: 1 person | Rrandomisation method not described<br><br>Baseline characteristics of the two groups comparable<br><br>No blinding described<br><br>Outcomes appropriate<br><br>Small; may lack power<br><br>Follow up short; longer follow up planned |
| Richling[5]<br>Non-randomised controlled study<br>Vienna & Salzburg, Austria<br>Published 2000<br><br>470 with ruptured aneurysms<br>• 173 coil<br>• 297 clipping<br><br>Treated according to aneurysm shape<br><br>Exclusion criteria:<br>• multiple or unruptured aneurysms<br><br>Mean follow-up 44 months (range: 3-79) | Asymptomatic or minimal functional deficit (by site of aneurysm):<br><br>Posterior communicating artery:<br>• coil: 19/31 (61%)<br>• clipping: 26/40 (65%)<br>Anterior communicating artery:<br>• coil: 29/45 (64%)<br>• clipping: 86/120 (72%)<br>Middle cerebral artery:<br>• coil: 14/18 (78%)<br>• clipping: 45/73 (62%) | None provided | Treatment decided by neurosurgeons<br><br>Outcomes appropriate<br><br>Follow up fairly long |

## Summary of key efficacy and safety findings (3)

| Authors, location, date, patients | Key efficacy findings | Key safety findings | Key reliability and validity issues |
|---|---|---|---|
| Leber[6]<br>Retrospective comparison of case series<br>Graz, Austria<br>1992 to 1995<br><br>248 people with ruptured or unruptured aneurysms<br>• 106 (134 aneurysms) coil, mean age 54<br>• 142 (162 aneurysms) clipping, mean age 49<br><br>Mean follow-up<br>• coil: 2.6 years<br>• clipping: 1 year | Death:<br>Unruptured (61 people)<br>• coil: 5%<br>• clipping: 6%<br>'not significant'<br><br>Rupture (187 people)<br>• coil: overall figures not provided<br>• clipping: overall figures not provided<br>'not significant' | Complications not described in detail<br><br>Coil:<br>• 2 fatal ruptures during procedure | Not clear how people were selected for treatment groups<br><br>Follow up different for different group |
| Vinuela[7]<br>Case series<br>Los Angeles & Houston, USA<br>1990 to 1995<br><br>403 with ruptured intracranial aneurysms, unclippable or considered poor operative risk, mean age 58<br><br>Variable follow up 6 to 36 months | Neurological outcomes:<br>• improved or unchanged: 342/403 (85%)<br>• deterioration: 36/403 (9%)<br>• death: 25/403 (6%) | Complications:<br>• perforations: 11/403 (3%)<br>• cerebral embolisations: 10/403 (2%)<br>• parent artery occlusions: 12/403 (3%)<br>• coil migration: 2/403 (0.5%)<br>• arterial vasospasm: 2/403 (0.5%) | Uncontrolled case series<br><br>Variable length of follow-up |

**Validity and generalisability of the studies**
The studies were carried out in settings applicable to the UK.

We found one large high quality randomised controlled trial.[3] The other randomised controlled trial may have lacked power to show clinically important differences between people who had a coil inserted and people who had neurosurgical clipping.

Both randomised controlled trials included only people with ruptured aneurysms.[3,4]

The retrospective comparison of case series was the only study to have included people with unruptured aneurysms.[6]

The case series provided useful information on the risk of complications.[7]

**Bazian comments**
None.

**Specialist advisor's opinion / advisors' opinions**
*Specialist advice was sought from the British Society of Interventional Radiology and the Society of British Neurological Sugeons.*

- Procedural death (1-3%) and stroke (5-8%) are the main adverse effects
- There is uncertainty about long term durability of coils and long term rebleeding from a treated aneurysm
- Training in coil insertion important

**Issues for consideration by IPAC**
None other than those discussed above.

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## Annex: References to studies not described in the table

| Reference | Number of study participants |
|---|---|
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