NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Coil embolisation of 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 dilated blood vessels within the skull. Sometimes they are present from birth, or they may develop as a result of by damage to the wall of the blood vessels by high blood pressure or fatty deposits. People with genetic causes of weak blood vessels are more likely to develop aneurysms. Often the cause is unknown.

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 <u>http://users.ox.ac.uk/~isat/isat_protocol.pdf</u>).

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

Summary of procedure

Traditional treatment for ruptured or unruptured intracranial aneurysm involves open surgery to clip the abnormal blood vessels inside the skull. 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 X ray control. The coil is placed inside the aneurysm and detached from the guidewire. Multiple coils can be placed the aneurysm through the same tube until the aneurysm is densely packed.

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 studies⁵ 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	Aneurysm radiographic >90% occlusion:	aneurysm perforations: 30	Search strategy described
Systematic review	654 people	 ischaemic complications: 107 	
Search dates 1990 to 1997		• procedure related death: 6	Study design and quality not described
37 studies; study designs not described			
Studies included 1256 patients (mean			
age 51) with ruptured or unruptured			
intracranial aneurysms receiving			
treatment with controlled detachable			
coils;1136 received Guglielmi coils			
International Subarachnoid Aneurysm	No symptoms:		Randomisation appropriate
Trial Collaborative Group ³	• coil: 26%		
	clipping: 19%		Characteristics of groups similar
Randomised controlled trial 1997 onwards			Dlinding of outcomes accomment not
1997 Onwards	Significant restriction of lifestyle:		Blinding of outcomes assessment not described
2143 people with ruptured intracranial	• coil: 10%		described
aneurysms	clipping: 13%		Outcomes appropriate
1073 Guglielmi coil; median age: 52	Fully dependent:		
(range 18-87)	coil: 3%		Follow-up length is appropriate – longer
 1070 surgical clipping; median age: 	 clipping: 3% 		follow up planned
52 (range 18-84)			
	Dead		Follow up complete for 98% of the
Inclusion criteria:	• coil: 8%		patients randomised up to Feb 2001
 proven subarachnoid haemorrhage 	 clipping: 10% 		
preceding 28 days			
 demonstrated intracranial aneurysm 	Relative risk of death at 12 months with		
 uncertainty as to which treatment 	coil v clipping: 0.77, 95% confidence		
better	interval 0.66 to 0.91		
Follow up 12 months			

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	Good/moderate recovery:	Surgery required in coil group: 8 people	Rrandomisation method not described
Randomised controlled trial	coil: 42 people	 perforation: 3 people 	
Kuopio, Finland	clipping: 45 people	 intracranial haematoma: 1 person 	Baseline characteristics of the two
1995 to 1997	'not significant'	 rebleeding: 1 person 	groups comparable
111 with ruptured aneurysm52 Guglielmi coil mean age 49	Severe disability/vegetative state: • coil: 4 people	Stroke: 2 people	No blinding described
 57 clipping, mean age 50 	 clipping: 6 people 'not significant' 	Transient ischaemic attack: 1 person	Outcomes appropriate
Exclusion criteria:	not significant	Coil migration: 1 person	Small; may lack power
 age >75 	Death		
 bleeding >3 days 	coil: 6 people		Follow up short; longer follow up planned
 large haematoma 	clipping: 6 people		
 mass effect causing neurological deficit 	'not significant'		
 previous surgery for aneurysm 			
 neck of aneurysm wider than fundus 			
 fusiform aneurysm 			
 neck and its relationship to the 			
parent vessel not distinguishable			
 aneurysm diameter <2mm 			
Follow up 3 months			
Richling ⁵	Asymptomatic or minimal functional	None provided	Treatment decided by neurosurgeons
Non-randomised controlled study	deficit (by site of aneurysm):		
Vienna & Salzburg, Austria			Outcomes appropriate
Published 2000	Posterior communicating artery:		
170 with must used as a unions	• coil: 19/31 (61%)		Follow up fairly long
470 with ruptured aneurysms173 coil	• clipping: 26/40 (65%)		
	Anterior communicating artery:		
297 clipping	• coil: 29/45 (64%)		
Treated according to aneurysm shape	• clipping: 86/120 (72%) Middle cerebral artery:		
	• coil: 14/18 (78%)		
Exclusion criteria:	 clipping: 45/73 (62%) 		
 multiple or unruptured aneurysms 			
Mean follow-up 44 months (range: 3-79)			

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

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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