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Horizon scanning technology prioritising summary

Cerecyte (bioactive) coils for the treatment of intracranial aneurysms

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PRIORITISING SUMMARY

REGISTER ID S000126

NAME OF TECHNOLOGY CERECYTE (BIOACTIVE) COILS

PURPOSE AND TARGET GROUP FOR USE IN NEUROSURGICAL PROCEDURES TO TREAT INTRACRANIAL ANEURYSMS (RUPTURED AND UNRUPTURED); THE BIOACTIVE COMPONENT WAS INTRODUCED WITH AN AIM TO REDUCE INCOMPLETE OCCLUSION AND RECANALISATION OF THE ANEURYSMS POST-PROCEDURE

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | | | |
|-------------------------------------|--------------------|--------------------------|--|
| <input type="checkbox"/> | Yet to emerge | <input type="checkbox"/> | Established |
| <input type="checkbox"/> | Experimental | <input type="checkbox"/> | Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> | Investigational | <input type="checkbox"/> | Should be taken out of use |
| <input checked="" type="checkbox"/> | Nearly established | | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | | |
|-------------------------------------|----------------|-------------|--------|
| <input checked="" type="checkbox"/> | Yes | ARTG number | 133001 |
| <input type="checkbox"/> | No | | |
| <input type="checkbox"/> | Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials underway or completed	Limited use	Widely diffused
Canada	✓	✓	
Germany	✓	✓	
Japan	✓	✓	
Turkey	✓	✓	
United Kingdom	✓	✓	
United States	✓	✓	

IMPACT SUMMARY

The Cerecyte[®] microcoil (Micrus Endovascular Corporation, San Jose, California) is a bare platinum coil with polyglycolic acid (PGA) running through its lumen. It is employed by neuroradiologists in minimally invasive endoscopic treatments for patients with intracerebral aneurysms (ruptured and unruptured). PGA was added to the traditional bare platinum coil to reduce incomplete aneurysm occlusion and recanalisation, complications that have been associated with the use of endovascular coils.

BACKGROUND

An aneurysm is an abnormal localised dilation of any vessel. Due to various histopathologic and haemodynamic factors, aneurysms generally occur in arteries supplying blood to the brain (Vega et al 2002). Intracranial aneurysms can be classified as saccular (developing from defects in the muscular layer of arteries), fusiform (developing from ectatic, tortuous cerebral arteries) or dissecting (resulting from cystic medial necrosis or a traumatic tear of an artery); the most common of these are saccular aneurysms (accounting for approximately 90% of all intracranial aneurysms) (Vega et al 2002). Patients with suspected or confirmed asymptomatic or symptomatic intracranial aneurysms have two options of invasive treatment: open craniotomy or endovascular treatment (Vega et al 2002).

Following publication of the International Subarachnoid Aneurysm Trial (ISAT), endovascular platinum coil treatment has become the therapy of choice for most patients with ruptured intracranial aneurysms (where vascular access and aneurysm morphology allow), and it has become a preferred treatment for those with unruptured aneurysms as well (Bendszus et al 2007; Butteriss et al 2008). Criteria that favor an endovascular approach can include: (1) older patient age (>50 years); (2) aneurysm size; (3) aneurysm location, i.e. posterior circulation; (4) aneurysm unruptured or, if ruptured, presence of vasospasm; (5) aneurysm poor grade; and (6) operator preference and/or availability (Linfante et al 2009).

Endovascular techniques have reduced length of hospital stay, hospital costs, and neurological complications and adverse outcomes (Veznedaroglu et al 2008). However, an ongoing concern is the long-term durability of endovascular treatment including whether the risk of rebleeding/bleeding can be lowered to that following surgical clipping (Bendszus et al 2007).

The frequency of angiographic aneurysm recurrence following coil occlusion is 17% to 33%, although the actual rebleed rate is low (Bendszus & Solymosi 2006). Ideally the recurrence rate can be decreased, although attempts to lower the recurrence rate must not be accompanied by increased complications. This challenge has been addressed via innovations in coil technology. New technologies include 3D coils, the liquid embolic agent Onyx, intravascular stents, increased packing density with the use of HydroCoils, radioactive coils, and bioactive modified coils such as Cerecyte (Geyik et al 2010).

The Cerecyte coil consists of a regular bare platinum coil with PGA running through the lumen of the primary platinum wind, which also provides stretch resistance when placing coils into the aneurysm (Bendszus & Solymosi 2006). PGA is a polymer shown to accelerate aneurysm fibrosis and neointima formation in animal studies, thus accelerating occlusion and preventing recanalisation of an aneurismal sac (Butteriss et al 2008). The PGA also maintains the soft properties of bare platinum systems, which minimises the risk of use and allows increased coil-packing density (Veznedaroglu et al 2008). It also results in a coil that has handling characteristics identical to bare platinum so there is no need to change operating practice or undergo a learning curve when changing from bare platinum coils (Butteriss et al 2008).



Figure 1: Micrus® Endovascular CERECYTE® Microcoil.

CLINICAL NEED AND BURDEN OF DISEASE

Intracranial aneurysms are fairly common and sufferers are often asymptomatic until the time of rupture. Subarachnoid haemorrhage associated with aneurismal rupture is potentially lethal, with an associated mortality rate as high as 50% (Vega et al 2002). In patients who survive initial haemorrhage many have permanent disability (Vega et al 2002). A systematic review of studies involving more than 56,000 patients reported that unruptured intracranial aneurysms occur in 3.6% to 6% of the general population (Rinkel et al 1998). Risk factors for the formation of aneurysms include a family history (with 8% to 9% of persons with two or more relatives who have had a subarachnoid haemorrhage or aneurysm likely to experience an intracranial aneurysm themselves), various inherited disorders, age greater than 50 years, female gender, current cigarette smoking and cocaine use (Vega et al 2002).

Endovascular embolisation of intracranial aneurysms with detachable coils is associated with lower morbidity and mortality rates compared with traditional microsurgical clipping; however, recanalisation of the aneurysm sac after coil embolisation occurs in 20% to 40% of patients (Linfante et al 2009).

DIFFUSION

Cerecyte coils were approved by the United States (US) Food and Drug Administration (FDA) in February 2004 with three subsequent modifications (FDA 2010). A letter to the manufacturer of Cerecyte coils (Micrus Endovascular Corporation) from the FDA in

2008 states that the Micrus Microcoil Delivery System is intended for endovascular embolisation of intracranial aneurysms, as well as other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae (FDA 2008). The letter also states the coils are intended for arterial and venous embolisations in the peripheral vasculature (FDA 2008). Cerecyte coils were also approved for use by Health Canada in 2001 (Health Canada 2010) and according to the Cerecyte Clinical Trial website have received European approval (Cerecyte Clinical Trial 2006).

Most recently, in February 2009, Cerecyte coils were approved for use in Australia (Australian Register of Therapeutic Goods number 133001) as a Class III device for endovascular embolisation of intracranial aneurysms (Therapeutic Goods Administration 2009).

COMPARATORS

Various coil technologies have been developed for the treatment of intracerebral aneurysms. The reference standard is bare platinum coils but manufacturers have introduced a variety of coil types specifically designed to promote ‘aneurysm healing’ following cerebral aneurysm coiling or to improve the durability and angiographic results of coiling including those integrating PGA or combined PGA/polylactic acid (PGLA), nylon/Dacron/PGLA fibres and hydrogel coating (White & Raymond 2009).

SAFETY AND EFFECTIVENESS ISSUES

Five studies were eligible for inclusion in this summary (Table 1). All were observational with three of the five including a comparison group in the analysis.

Table 1: Published Cerecyte coil studies

Study	Country	Study years	Cerecyte n= Control n=	Study type	Follow-up
Geyik et al, 2010	Turkey	NR	74; 80	Retrospective matched pair analysis of Cerecyte vs bare platinum coils	Mean 10.5 (range, 6-24) months
Linfante et al, 2009	US	2005-08	63; 65	Retrospective analysis of Cerecyte vs bare platinum coils	12 months
Butteriss et al, 2008	UK	2004-06	51	Single centre case series	6 months
Veznedaroglu et al, 2008	US	2004-06	81	Single centre case series	12 months
Bendszus et al 2007	Germany	NR	54; 55	Prospective case series vs historical controls with bare platinum coils	6 months

Study profiles

Geyik et al (2010) conducted a retrospective matched pair analysis, where outcomes for 74 patients with 80 aneurysms treated with Cerecyte coils were compared with database information for 80 patients with 80 aneurysms treated with bare platinum coils. Matching was based on aneurysm size, location, neck size, initial occlusion grade and clinical presentation (ruptured or unruptured) – risk factors that have the most significant impact

on recurrence rate. In both groups, sex distribution was about equal, mean age was 54 years (range, 18-68), most aneurysms were in the anterior communicating artery or the middle cerebral artery, and 55% of aneurysms had ruptured. Under general anaesthesia, patients had embolisation procedures that were technically similar regardless of coil type. Follow-up included angiography interpreted by blinded neurointerventionalists.

In the study by Linfante et al (2009), a database prospectively collected information on patients with ruptured or unruptured aneurysms who were treated with Cerecyte coils (n=63). These data were retrospectively compared with information on patients treated with bare platinum coils over the same time period (n=65). Patients received treatment under general anaesthesia and endovascular access was via a standard transfemoral approach. Aneurysms were coiled as densely as possible with Cerecyte and/or bare platinum coils according to operator judgment and coil availability. Aneurysm occlusion was estimated by two independent reviewers using the three-point Raymond classification system (Table 2). Age range was 25 to 87 years, 68% of patients were female, and 40% had ruptured aneurysms.

Butteriss et al (2008) reported a case series of 51 patients who were treated with Cerecyte coils for ruptured or unruptured intracerebral aneurysms. Most patients were female and most aneurysms had ruptured. Results were classified by the Raymond class (Table 2) and clinical follow-up was performed at six months.

Veznedaroglu et al (2008) reported a case series analysing results for 81 patients (89 aneurysms) who received Cerecyte coil treatment for ruptured (65%) or unruptured aneurysms over a 12-month period. Mean patient age was 50 years and 83% of aneurysms were located in the anterior circulation.

Finally, Bendszus et al (2007) conducted a prospective case series enrolling 54 patients (55 aneurysms) to receive Cerecyte coils. For analysis, patients were matched by aneurysm size and location to historical controls who had received bare platinum coils from 2002 to 2004. About half the patients were women and mean age was 50 years (standard deviation, 10 years). The same interventionalists treated all patients, surgical protocols were identical, and study analysts were blinded as to treatment.

Safety

The devices were generally deemed to be safe. Geyik et al (2010) did not report safety data. In Linfante et al (2009) there were two cases of intraoperative rupture in each group (with no long-lasting sequelae) plus one arterial dissection in the bare platinum group. Intraprocedural abciximab was required for clot-on-coil management in 15% of patients with Cerecyte versus 10% with bare platinum coils. Butteriss et al (2008) reported four patients (8%) with adverse events during the procedure including one aneurysm rupture and three minor thromboembolic events (6%) requiring saline flushing with no clinical sequelae. Veznedaroglu et al (2008) reported one thromboembolic event that led to a permanent neurological deficit. The earliest study, Bendszus et al (2007) reported that there was no procedure-related permanent morbidity or mortality.

Efficacy

In the study by Geyik et al (2010), initial treatment results were similar in both groups. However, at 6-month follow-up, results were superior in the Cerecyte group with Raymond Class I results (Table 2) achieved in 86% of patients versus 64% for bare platinum coils ($P=0.002$). Occlusion was also more durable in the Cerecyte group as seen on follow-up angiograms: among those with initial Raymond Class I results, 91% had stable occlusion versus 75% in the bare platinum group. Retreatment rates were 6% versus 13% in the Cerecyte and bare platinum groups, respectively.

Table 2: Raymond Classification Scheme (Source: Wong et al 2007)

Class	Description
I	Complete obliteration of aneurysm (no residual neck & no contrast within the aneurysm sac)
II	Residual neck (any remaining portion of the original defect in the arterial wall but without any contrast present within the aneurysm sac)
III	Residual aneurysm (any contrast present within the aneurysm sac)

Initial outcomes reported by Linfante et al (2009) were also similar between the groups with 49% of patients with Cerecyte achieving Raymond Class I versus 41% with bare platinum coils ($P=0.39$). Follow-up at 12 months (only 54% and 43% of patients were available, Cerecyte versus bare platinum) showed that recanalisation had occurred in 11% versus 23% of patients ($P=0.17$).

Butteriss et al (2008) reported complete occlusion in 71% of patients (36/51), near complete in 24% (12/51), and incomplete in 6% (3/51) initially. Six-month follow-up for 34 patients (68% of all patients) showed complete occlusion in 71% (24/34), near complete in 15% (5/34), and incomplete in 15% (5/34). With respect to stability at six months follow-up, 71% (24/34) of patients showed stable occlusion, 9% (3/34) improved, and 21% (7/34) worsened.

In the case series study by Veznedaroglu et al (2008), immediate postoperative angiographic occlusion was deemed complete (Raymond Class I; Table 2) in 45% (40/89) of aneurysms and partial with residual neck remnant (Class II) in 48% (43/89) of aneurysms, and incomplete (Class III) in 3% (3/89). Follow-up angiography at a mean of 11.4 months (median 8 months) identified recurrences requiring retreatment in six aneurysms (7%); five of these six were initially treated in the first month of Cerecyte coil use.

Bendszus et al (2007) also reported similar initial results between patients treated with bare and Cerecyte coils. At six-month follow-up, results were marginally superior for Cerecyte (Table 3).

Table 3: Six-month efficacy outcomes for Bendszus et al (2007)

Class	Cerecyte (n[%])	Bare coils (matched historical controls) (n[%])	<i>P</i> value
I	43 (78%)	34 (62%)	0.045
II	10 (18%)	14 (25%)	NR
III	2 (4%)	7 (13%)	NR
Retreatment	1 (2)	6 (11%)	0.056

COST IMPACT

No economic studies or cost information were identified in the included literature. A reference to cost occurs in a systemic review of coated-coil technologies, i.e. the authors state that many of these devices are sold at a substantial cost premium ‘despite the lack of grade 1 evidence for equivalent safety and improved efficacy compared with the proved bare platinum coil technology’ (White & Raymond 2009).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified in the included literature.

OTHER ISSUES

As noted above, available evidence is observational. However, the Cerecyte Coil Trial (CCT) is a prospective randomised controlled trial (RCT) comparing Cerecyte coils with bare platinum coils (Cerecyte Clinical Trial 2006). The trial’s primary objective is to determine if Cerecyte coils improve the proportion of patients with angiographic occlusion of intracranial aneurysms at six months by 50%, from a rate of 75% to 87.5%. Coordinated by Oxford University, the trial has enrolled 500 patients at 24 centres in six countries (Canada, Germany, Japan, Turkey, United Kingdom and US) since its launch in 2005. The last patient was enrolled late in 2009 and outcomes will be tracked up to 24 months. The study sponsor is Micrus Endovascular Corporation (recently purchased by Johnson & Johnson) and both arms of the trial employ devices made by this company. Preliminary results (six-month) were reported at a May 2010 conference, at which point the devices in both arms were performing well (freedom from disability: Cerecyte 95%, bare 99%; investigator-reported angiographic occlusion rate: Cerecyte 85%, bare 87%) which researchers found to be superior to the results reported in The International Subarachnoid Aneurysm Trial (ISAT) (Business Wire 2010).

An RCT sponsored by the University of Virginia (NCT01195128) is comparing treatment of patients with cerebral aneurysms using the Hydrogel coil (Microvention Inc., Tustin, California) in one study arm with treatment with the Cerecyte coil or a bare platinum coil in the other study arm (clinicaltrials.gov 2010). Planned enrolment at 11 US sites is about 1000 patients, follow-up will extend to 18 months and reporting is expected in 2012. Cost of treatment is included as a planned outcome. If the data are sufficient, post-hoc comparisons between results with Cerecyte versus bare platinum coils will be carried out although this is not the primary aim of the RCT (personal communication, Claire McKinley, University of Virginia, 4 October 2010).

With respect to study funding, one lead author (Dr. Martin Bendszus) has been a paid consultant and speaker for Micrus Endovascular, although the study report claims that Micrus ‘had no influence on the data collection, analysis, or writing of the manuscript’ (Bendszus et al 2007). Two study reports reported that the authors had no conflicts of interest (Butteriss et al 2008; Geyik et al 2010) and the remaining two reports included no financial disclosure information (Veznedaroglu et al 2008, Linfante et al 2009).

SUMMARY OF FINDINGS

From the limited literature available (five small observational studies), Cerecyte coils appear to be safe with occlusion/recanalisation rates that are as good or better than bare platinum coils (the traditional standard) for treatment of ruptured and unruptured intracerebral aneurysms. The technology was approved several years ago in a number of countries and appears to be in at least limited use. Cost data were not available in order to determine the financial impact of switching to Cerecyte (or its competitors) from bare platinum coils. At least one multicentre RCT will report within the next year or two, thus adding to the evidence base for this technology.

HEALTHPACT ASSESSMENT

The Cerecyte coil is seeing limited use in several countries based on small observational studies that have shown it to be safe and at least as effective as bare platinum coils for the treatment of ruptured or unruptured intracranial aneurysms. A large RCT of Cerecyte coils is currently underway at 24 centres in six countries. As results from the observational studies do not unequivocally establish its benefits over bare platinum coils, decision makers may wish to defer an opinion until the RCT results are available. Based on this it is recommended that the technology be monitored for 12 months.

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

HEALTHPACT ACTION

NUMBER OF STUDIES INCLUDED

Total number of studies	5
Level III-3 evidence	3
Level IV evidence	2

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

Cerecyte coil
Bioactive coil
Platinum coil AND polyglycolic acid
Intracranial aneurysm

HEALTH PACT DECISION

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

PRIORITY RATING

- High** **Medium** **Low**