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National Horizon Scanning Unit

Horizon scanning prioritising summary

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**Niobe[®] magnetic navigation guidance
system for percutaneous coronary
interventions in patients with cardiac
arrhythmias.**

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Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This *Horizon scanning prioritising summary* was prepared by Adriana Parrella and Linda Mundy from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.

PRIORITISING SUMMARY

REGISTER ID: 000146

NAME OF TECHNOLOGY: NIOBE®

PURPOSE AND TARGET GROUP: MAGNETIC NAVIGATION GUIDANCE SYSTEM FOR PERCUTANEOUS CORONARY INTERVENTIONS IN PATIENTS WITH CARDIAC ARRHYTHMIAS

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" 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 type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

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

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		
Germany	✓		

IMPACT SUMMARY:

Stereotaxis Inc. has recently received Food and Drug Administration approval for the Niobe® magnetic guidance system for use in patients requiring percutaneous coronary interventions. It is currently not available in Australia

BACKGROUND

An arrhythmia is an abnormal rhythm of the heart, which occurs as a result of the disruption of the electrical signals responsible for the normal pumping of the heart muscle. Arrhythmias result in disturbances of the heart's contractile patterns, either pumping too fast, too slow or irregularly, causing the heart to pump less effectively and resulting in inadequate blood flow to the body.

An atrial arrhythmia is an abnormal rhythm that develops in the upper chambers (atria) of the heart. Atrial fibrillation occurs when the atria contract in a rapid and irregular fashion, interfering with the ability of the atria to empty blood into the ventricles that pump blood to the body. Atrial fibrillation may lead to heart failure and may increase the risk of blood clot formation which, in turn may lead to an increased risk of stroke (Beers and Berkow 1999).

Electrophysiologic cardiac mapping studies are invasive tests in which a small electrode catheter is inserted through the groin or neck of the patient into the heart. Cardiac mapping

may be performed to locate cardiac arrhythmias and directly measure the electrical activity from various regions in the heart. The physician stimulates the atria or ventricles of the heart electrically to determine response. These studies are performed for both diagnostic and therapeutic purposes. Determining the exact location of an arrhythmia is a pre-requisite for understanding the pathophysiological mechanisms that underlie the arrhythmia and allows for the evaluation of the effect of drugs, as well as facilitating surgical catheter-ablation procedures.

Manually controlled catheters and guidewires used in conventional electrophysiologic studies of patients with cardiac arrhythmias may have inherent functional limitations. It has been suggested that manual control of the distal tip becomes increasingly difficult as blood vessels become smaller and less accessible (Ernst et al 2003 and Faddis et al, 2003).

The Niobe[®] Magnetic Navigation System is an interventional workstation for the navigation of catheters or guidewires through tissue to designated target sites in the right and left cardiac and coronary vasculature. The system uses computer-controlled permanent magnets for orienting the tip of the magnetically adapted interventional device. The Niobe[®] allows for continuous, 360°, omni-directional control, irrespective of the number of turns or the distance the distal tip must travel to reach its target (Stereotaxis 2005).

The Niobe[®] is intended for use in patients to treat cardiac arrhythmias such as atrial fibrillation. It may also be of use in patients with difficult lesions, where it is difficult to manually place guidewires or catheters.

The system employs an arrangement of magnets that create a 360° magnetic field around the patient to orient or steer the tip of a magnetic device in the desired direction. Magnets are placed at the tip of the catheters and guide wires, which are inserted into the arteries. The opposing magnetic field immediately surrounding the patient on the catheterisation table is used to align the catheter's magnet. The physician then uses the device to pinpoint the affected area and guide the catheter to the location. This new way of "steering" catheters differs from the more traditional method of manually twisting, turning and pushing the catheter through the arteries. In addition, the Niobe[®] can be operated via remote control, thereby reducing physician exposure to radiation.

CLINICAL NEED AND BURDEN OF DISEASE

In 2002-3 there were a total of 36,657 hospital separations for principal diagnosis (I48) of atrial fibrillation and flutter, and a total of 7,043 separations for principal diagnosis (I49) of other cardiac arrhythmias (AIHW 2005).

DIFFUSION

The Niobe[®] device may receive wide acceptance from interventional radiologists as it overcomes limitations of manual navigation. The manufacturer claims that the device is more flexible and also results in reduced radiation exposure for health professionals (Stereotaxis 2005). The Niobe[®] is currently unavailable in Australia.

COMPARATORS

For cardiac mapping, standard electrophysiological studies are performed where the operator manually navigates the catheter towards the heart under fluoroscopic guidance.

There are several different options for the treatment of symptomatic arrhythmias depending on the type of arrhythmia, the severity of symptoms experienced, and the presence of other conditions such as diabetes, kidney failure or heart failure. Treatments may include lifestyle modification and medication or cardioversion, when a small electrical shock is delivered to

the heart through the chest to stop certain very fast arrhythmias such as atrial fibrillation, supraventricular tachycardia, or sinus tachycardia. Surgical treatment for arrhythmias is usually performed when all other treatment options have failed. One such treatment is surgical ablation. This is a major surgical procedure, requiring general anaesthesia where the chest is opened exposing the heart, the site of the arrhythmia located and the arrhythmia is eliminated by either radiofrequency ablation or cryoablation. Other surgical therapies for the treatment of atrial fibrillation include the implantation of a pacemaker or an implantable converter defibrillator.

EFFECTIVENESS AND SAFETY ISSUES

Faddis et al (2003) evaluated the safety and effectiveness of the Niobe[®] (level IV intervention evidence) for intracardiac navigation, recording and pacing. The primary endpoint was the successful navigation and recording of ten specific target points within the right atrium (RA) and right ventricle (RV) in 20 patients. The secondary endpoint was the measurement of stimulation thresholds with the magnetic catheter within the RA and RV. The safety of the Niobe[®] was assessed by echocardiographic evaluation immediately before and after catheter navigation, in addition to assessing patient recovery from the procedure 7 to 10 days later in a telephone interview. Navigation success was assessed both fluoroscopically and electrophysiologically. After enrolling 20 patients, the trial was expanded to include navigation to left atrial and ventricular sites and the ablation of supraventricular tachycardia (SVT): this study reports on the first seven of these patients.

Catheter navigation was successful in 213 of 215 attempted sites. In a subset of five patients, intracardiac electrograms and stimulation thresholds recorded at the high RA and RV apex with both the Niobe[®] catheter and a standard ablation catheter resulted in no significant difference between the two with respect to electrogram amplitudes and stimulation thresholds. Ablation of arrhythmias with the Niobe[®] was performed successfully in the seven patients with SVT with no complications. In relation to safety, echocardiograms performed after magnetic navigation showed that there were no cardiac structural abnormalities caused by the procedure. No adverse events occurred at the time of procedure or were reported during the follow-up phone interview (Faddis et al, 2003).

In a study of 42 patients (level IV intervention evidence) with atrioventricular nodal re-entrant tachycardia (AVNRT), the Niobe[®] was used to perform magnetic catheter ablation (Ernst et al 2004). In this study each patient initially received a standard electrophysiological study to identify and confirm the underlying tachycardia before magnetic mapping and ablation with the Niobe[®] was performed. All 42 patients underwent successful remote-controlled mapping and catheter ablation with the Niobe[®]. Slow pathway modulation (n=27) or ablation (n=15) was performed with a mean number of 7.2 ± 4.7 radiofrequency current applications. Repeated control stimulation failed to induce AVNRT in all patients. No complications occurred during the follow up period of 112 ± 48 days.

COST IMPACT

No information regarding the cost of the device or the cost of cardiac mapping and ablation procedures with the Niobe[®], compared to conventional cardiac electrophysiological studies was available at the time of writing this summary (despite several attempts to contact the manufacturer).

The current Medicare Benefits Schedule (MBS) fees for cardiac electrophysiological studies (item numbers 38209 and 38212) are \$700.00 and \$1,164 respectively. There were a total of 4,513 procedures performed between July 2003 and June 2000, resulting in a total \$2,953,116 Medicare contribution (Health Insurance Commission 2005). The MBS fees for arrhythmia ablation for item numbers 38287, 38290 and 38293 are \$1,780, \$2,267 and \$2,433 respectively. Medicare contributed a total of \$3,190,288 for the 2,255 procedures performed

for these item numbers between July 2003 and June 2004 (Health Insurance Commission 2005).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

There is a lack of good quality studies comparing the performance of the Niobe[®] with standard cardiac mapping and ablation devices.

HEALTHPACT ACTION:

To be advised.

LIST OF STUDIES INCLUDED

Total number of studies
Level IV intervention evidence 2

SOURCES OF FURTHER INFORMATION:

AIHW 2005 'Principal Diagnosis 0203. Interactive national hospital morbidity database' [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/cognos/cgi-in/ppdscgi.exe?DC=Q&E=/AHS/principaldiagnosis0203> [Accessed 2nd March, 2005].

Beers, M.H., Berkwow, R. (1999) The Merck Manual of Diagnosis and Therapy. Merck Research Laboratories.

Ernst, S., Ouyang, F. et al (2004a). 'Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation', *Circulation*, 109 (12), 1472-1475.

Ernst, S., Ouyang, F. et al (2004b). 'Modulation of the slow pathway in the presence of a persistent left superior caval vein using the novel magnetic navigation system Niobe', *Europace*, 6 (1), 10-14.

Faddis, M. N., Blume, W. et al (2002). 'Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation', *Circulation*, 106 (23), 2980-2985.

Faddis, M. N., Chen, J. et al (2003). 'Magnetic guidance system for cardiac electrophysiology: a prospective trial of safety and efficacy in humans', *J Am Coll Cardiol*, 42 (11), 1952-1958.

Faddis, M. N. & Lindsay, B. D. (2003). 'Magnetic catheter manipulation', *Coron Artery Dis*, 14 (1), 25-27.

Health Insurance Commission (2005) *HIC - Professional - Statistics - Medicare Benefits Schedule (MBS) Item* [Internet] Available from: http://www.hic.gov.au/statistics/dyn_mbs/forms/mbs_tab4.shtml [Accessed 23rd March, 2005].

SEARCH CRITERIA TO BE USED:

Catheter Ablation/ instrumentation
Fluoroscopy
Heart Catheterization/ instrumentation

Radiography, Interventional