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Horizon Scanning Technology Prioritising Summary

Multielectrode Basket Catheter



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**

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College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID

S000112 (REFERRAL)

NAME OF TECHNOLOGY

MULTIELECTRODE BASKET CATHETER

PURPOSE AND TARGET GROUP

A THREE DIMENSIONAL DIAGNOSTIC DEVICE FOR THE TREATMENT OF ATRIAL FIBRILLATION

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

- Yes
 No
 Not applicable

INTERNATIONAL UTILISATION

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

IMPACT SUMMARY

The Constellation multielectrode basket catheter (MBC) (Boston Scientific, Boston, USA) is a diagnostic device which provides three dimensional (3D) mapping of abnormal electrical discharges within the atria of the heart in patients with atrial fibrillation. In addition, the MBC has a navigation function used to guide targeted ablation of tissue generating abnormal electrical discharge.

BACKGROUND

Atrial fibrillation (AF) is a common heart rhythm abnormality (arrhythmia) affecting the upper chambers of the heart (atria) (Rodgers et al 2008). Normal conduction of electrical discharge within the heart is highly synchronised and spreads from the sinus node in the

right atrium to the left atrium and down through the ventricles. This ensures that cardiac muscle contraction occurs in an organised manner. Abnormal electrical discharge within the heart results in disorganised and asynchronous muscle contraction, compromising heart function.

AF is characterised by irregular and rapid contraction of the muscles of the atria, which disrupts the pumping of blood into the circulatory system (Heart Foundation 2010; Rodgers et al 2008). AF may be symptomatic or asymptomatic and common symptoms include dizziness, chest pain, palpitations, irregular pulse and weakness (Heart Foundation 2010; Rogers et al 2008). AF may be categorised as either: paroxysmal, persistent or permanent (Rodgers et al 2008). Paroxysmal AF is characterised by recurrent episodes of AF which resolve spontaneously, but may progress if untreated. Persistent AF is characterised by recurrent episodes that do not resolve spontaneously. Permanent AF is long-standing AF for which cardioversion (electrical, surgical or pharmacological interventions intended to restore the AF to normal sinus rhythm) is either unsuccessful or not pursued.

The success of AF treatment depends upon the type and severity of the condition. Treatment comprises rate control or rhythm control strategies (Rodgers et al 2008). Rate control strategies attempt to control the heart rate without removing the underlying arrhythmia, and strategies include pharmacologic treatment or atrioventricular node ablation with insertion of a pacemaker (Rodgers et al 2008). Rhythm control strategies involve cardioversion through pharmacological, electrical or surgical means. Catheter ablation is a relatively new rhythm control strategy; involving the destruction of tissue which generates abnormal asynchronous electrical discharge, using cryoablation, laser, microwave, ultrasound or radiofrequency energies (Rodgers et al 2008). Common locations (foci) of abnormal electrical discharge include the left atrium, pulmonary veins and pulmonary vein-left atrial junction (PV-LA). Curative ablative therapy aims to not only destroy the tissue generating the abnormal electrical discharge, but also to isolate the tissue so that the surrounding region cannot propagate any further abnormal electrical discharge following the procedure. When foci are found in the pulmonary veins and subsequently destroyed the procedure is known as minimally invasive pulmonary isolation (or ablation) (Haissaaguerre et al 2000).

The most commonly cited safety issue of catheter ablation is the risk of pulmonary vein (PV) stenosis, which may occur as frequently as 40% of cases (Arentz et al 2003). Development of stenosis may depend on several factors such as the imaging technology, PV ablation methodology, and years of operator experience (Purerfellner 2005). In addition, more extensive or deeper ablations may lead to atrio-oesophageal fistula or cardiac perforation (Pappone and Santinelli 2006). Tamponade (accumulation of fluid in the pericardium), stroke and infection may also occur (Rodgers et al 2008).

Minimising the number of ablations performed and ensuring their accuracy may reduce these complications. Therefore accurate identification and mapping of the electrical conduction pathways from the left atrium into the PVs is important. Once these pathways

are identified, accurate targeted ablations may be performed in order to achieve PV isolation.

A recent innovation for mapping electrical pathways is the complex fractionated atrial electrogram. The procedural approach appears to differ between studies; however, generally it aims to identify atrial sites which exhibit multi-phasic and rapid activation (Lickfett et al, 2008). A more established option is the electroanatomical mapping technology. An electroanatomic mapping system uses impedance sensing between an externally applied electric field and the electrodes of an inserted catheter to construct 3D geometry and map focal arrhythmias in real time (Boston Scientific, 2010). Examples are the EnSite NAVX™ Navigation and Visualisation system (St Jude Medical Inc., Minneapolis, USA), the CARTO RMT Electroanatomical Navigation System (Biosense Webster Inc., California, USA), the QMS2™ (CathData Inc., Toronto, Canada), and the Astronomer (Boston Scientific, Boston, USA). A variety of catheter types can be used in conjunction with an electroanatomic mapping system:

1. *Circular or spiral catheters* (e.g. Livewire Spiral HPTM Catheter and Lasso 2515 Variable Circular Mapping Catheter)

These catheters can record circumferential PV potentials within the PV. The catheter is advanced into each PV, opened up (in the case of a spiral catheter with a variable diameter) and then retracted into the left atrium. Upon exiting the individual PV the reconstructed vein is displayed (Lickfett et al 2008). Circular or spiral catheters of a smaller diameter may not provide adequate tissue contact, thus preventing circumferential recording of PV potentials. Additionally, obtaining a stable position at the PV orifice is difficult due to the oblique nature of the antral-left atrium interface. Other sites where the spiral or circular catheters may encounter difficulties in reaching a stable insertion position are the anterior segments of the left PVs or septal segments of the right PVs (Poppone and Santinelli 2006).

2. *Bard HD Mesh Ablation Catheter*

The Mesh catheter represents an advance from spiral or circular catheters. The Mesh catheter can be advanced stepwise into the PV orifice, allowing better identification of the transition zone between left atrium and PV. However, the Mesh catheter can not be used to acquire left atrium geometry (Lickfett et al 2008).

The MBC is a new type of catheter for use with an electroanatomic mapping system. It provides a 3D reconstruction of the PV activation from the ostium to deep inside the PV (Aretz et al 2003). The MBC can identify the location of the PV ostium and of discharging foci in the PV during a single beat (Kumagai et al 2006).

The MBC can adapt to the size and anatomical form of most veins, thus providing exact ostium localisation (Aretz et al 2003). It can identify the transition zone at the PV-LA junction, and is particularly useful for 3D mapping of a left common PV trunk, when present. Due to the large size of common trunks, circular or spiral catheters generally either can not record PV potentials from the entire circumference simultaneously, or do not provide adequate tissue contact (Lickfett et al 2008). Unlike circular or spiral catheters, MBC provides a stable position at the PV orifice. Additionally, unlike the

MESH Mapper catheter, the MBC can be used to target PV antra potentials (i.e. the fusion of PV and left atrial potentials around PV ostia) (Pappone and Santinelli 2006).

Uniquely, the MBC incorporates a nonfluoroscopic, custom navigation system for guiding an ablation catheter (Astronomer, Boston Scientific, Boston, USA). The navigation system indicates which electrode of the MBC the ablation catheter is positioned at by sensing a weak current from the tip of the ablation catheter via the MBC electrode. This system enables an ablation catheter to accurately reach the target site indicated by the MBC, facilitating targeted ablation (Yamada et al 2005).

However, the MBC is not suitable for short veins as it will not sit in a stable position due to its larger diameter. In this circumstance a ring mapping catheter of a smaller diameter such as a Lasso 2515 Variable Circular Mapping Catheter (Biosense Webster Inc., California, USA) or Livewire Spiral HP™ Catheter (St Jude Medical, Inc., Minneapolis, USA) may be more appropriate.

CLINICAL NEED AND BURDEN OF DISEASE

AF is the most common arrhythmia, and its prevalence is higher in men than in women (Rodgers et al 2008). Its prevalence increases with age (from about 0.5% in people aged 50-59 years to 9% in people aged 80-89 years), with the overall prevalence of AF thought to be increasing due to an ageing general population (Rodgers et al 2008).

In 2007-08 there were 47,164 principle diagnoses of AF in the Australian public hospital system (Australian Institute of Health and Welfare 2010). The number of ablation procedures performed for the curative treatment of AF in the Australian private hospital system in 2008-09 was 1,549 (Medicare Benefits Schedule 2010).

DIFFUSION

The Constellation Full Contact Mapping Catheter (MBC) received Federal Drug Administration (FDA) 510(k) clearance on September 26 2000, and premarket approval on November 3 1999. On February 14 2005 the FDA sent Boston Scientific an enforcement notice to recall the device, as there was concern that the coating on the MBC's surface could generate debris, which could then move from the heart towards the brain, and result in ischaemic events (FDA 2005). No subsequent evidence could be located to suggest cessation of the recall or approval of any modifications.

COMPARATORS

When using electroanatomic mapping, three major cardiac mapping catheters are presently available in the international market. These are the **Lasso 2515 Variable Circular Mapping Catheter** (Biosense Webster Inc., California, USA); the **Livewire Spiral HP™ Catheter** (St Jude Medical, Inc., Minneapolis, USA); and the **Bard® HD Mesh Ablator Catheter** (CR Bard Inc., Massachusetts, USA). Product specifications are detailed in Table 1.

Table 1: Comparative cardiac mapping catheters

Product	Vein diameter	Number of electrodes	Function	3D mapping
Lasso 2515 Variable Circular	25 mm to 15	10 or 20	Mapping	Yes

Mapping Catheter (Biosense Webster Inc., California, USA)	mm			
Livewire Spiral HPTM Catheter (St Jude Medical, Inc., Minneapolis, USA)	NR	20	Mapping	Yes
Bard HD Mesh Ablation Catheter (CR Bard Inc., Massachusetts, USA)	25 mm to 30 mm	36	Mapping and ablation	Yes
Constellation® Full Contact Mapping Catheter (Boston Scientific, Boston, USA)	31 mm diameter	64	Mapping and navigation	Yes

Table data sources: Biosense Webster Inc., 2010; Bard Inc., 2008; St Jude Medical Inc., 2010

SAFETY AND EFFECTIVENESS ISSUES

Study description

Four clinical studies on the multielectrode basket catheter were identified and retrieved for inclusion in this summary. Two separate case series authored by Yamada et al (2005 and 2007) reported data on the same patient population. Yamada et al (2005) reports the primary results of the efficacy of the MBC as a diagnostic device and preliminary results of the overall minimally invasive pulmonary vein isolation (PVI) procedure. Yamada et al (2007) reports solely on the final overall safety and efficacy outcomes for PVI for the whole patient population studied.

Yamada et al (2005) reports on sixty five consecutive patients (58 men, age: 57 ± 12 years) with symptomatic paroxysmal AF refractory to 4 ± 1 class I or class III anti-arrhythmic drugs. The mean duration of paroxysmal AF previous to the procedure was 5 ± 4 years (range: 1 – 15 years). One patient had a history of myocardial infarction and five patients had emboli (blood clots). All anti-arrhythmic drugs were discontinued for at least five drug half-lives prior to the study. Prior to insertion of the MBC a transseptal procedure was performed with intracardiac echocardiography guidance in order to access the left atrium of the heart. All four pulmonary veins were visualised by selective angiography. Following insertion of the MBC the QMS2 Mapping system was used to construct a 3 dimensional colour map from the MBC recordings via an amplifier. Then for PVI the MBC was connected to a navigation system (Astronomer, Boston Scientific). RFA was delivered with a target temperature of 55 degrees Celsius and a maximum power output of 30 W for 30 to 45 seconds using a 4mm catheter. Follow-up was performed at 2 weeks, 1 month and then every month thereafter.

Yamada et al (2007) reports on 200 consecutive patients (155 men, 58 ± 11 years, range 29 – 80 years) with symptomatic paroxysmal ($n = 147$) or persistent ($n = 53$) AF refractory to 4 ± 1 class I or class III anti-arrhythmic drugs (not including amiodarone). The mean duration of AF prior to the procedure was 5 ± 4 years (range 1 – 15 years). Five patients had a history of ischemic heart disease. All anti-arrhythmic drugs were discontinued for at least five drug half-lives prior to the study. All patients underwent the electrophysiological study in a fasting state with intravenous sedation with pentazocine and propofol. A transseptal procedure was performed with intracardiac echocardiography

guidance in order to access the left atrium of the heart. The MBC was used to identify PVI targets and the MBC's navigation system (Astronomer, Boston Scientific) was then used to confirm the positioning of the ablation catheter. RFA was delivered at a target temperature of 55 degrees Celsius and maximum power output of 40W for 60 seconds with an 8mm catheter. Follow-up was performed at 2 weeks, one month, and every month thereafter.

Arentz et al (2003) reports on minimally invasive pulmonary vein isolation in 55 patients (40 male, 53 ± 11 years) with highly symptomatic drug-refractory (class I and III anti-arrhythmic drugs) paroxysmal or persistent AF. Patients with paroxysmal AF ($n = 37$) suffered more than 2 episodes per week and patients with persistent AF ($n = 18$) suffered greater than two episodes of AF after cardioversion lasting greater than 4 weeks. Patients had a history of AF lasting a mean of 6.4 ± 3.4 years and unsuccessful drug therapy for 3.6 ± 2.1 anti-arrhythmic drugs. Thirteen patients had evidence of structural heart disease (hypertensive heart disease $n=8$, left ventricular dysfunction $n=3$ and coronary artery disease $n= 2$). Seven patients were taking amiodarone at the time of the study. All anti-arrhythmic drugs except amiodarone were discontinued for >6 half lives before ablation. The MBC was inserted and its position in relation to the PV ostium was determined via angiography. During ectopic beats or initiation of AF, the activation was followed from the source of ectopy to its exit to the left atrium.

The Astronomer navigation system (Boston Scientific, Boston, USA) was used in conjunction with the MBC, to guide the ablation catheter. PVI was performed with a conventional 4mm tip ablation catheter at a maximum of 50 degrees Celsius and power of 30 W. Holter monitoring was performed for 48 hours in all patients and patients were discharged 3 days after the procedure if no complications occurred. Patients were scheduled for a follow-up examination 12 months after the procedure.

Kumagai et al (2006) reported the outcomes of 50 consecutive patients (35 men, 15 women, mean age 57 ± 11 years) with symptomatic drug refractory paroxysmal AF (PAF). PAF was defined as self-terminating within 7 days of onset and the mean duration of AF prior to ablation was 69 ± 65 months. Access to the right atrium was achieved via transseptal puncture and the MBC was then introduced. The proximal electrodes of the MBC were located at the PV-LA junction. The Astronomer navigation system (Boston Scientific) was also employed for MBC guided ablation. A 4mm ablation catheter was used to ablate the tissue at a target temperature of 50 degrees Celsius and a maximum output of 30 W for 30-60s at each ostial site.

Safety

Yamada et al (2005): At follow-up, asymptomatic PV narrowing between 25% and 50% occurred in 5 PVs in 5 cases (unclear whether patients or veins) and of $\leq 25\%$ in 9 PVs in 7 (unclear whether patients or veins). No PV stenosis of $\geq 50\%$ was reported. One patient developed a unilateral quadrantopsia after the procedure. No pericardial effusions were reported.

Yamada et al (2007): No PV stenosis or spontaneous LA flutter were observed. No other complications were reported.

Arentz et al (2003): One patient suffered pericardial tamponade which was caused by perforation of the left atrial appendage by the ablation catheter. The tamponade was drained percutaneously. Follow-up angiography at the end of the procedure detected no PV stenosis, although at 12 month follow-up there was 1 mild (approximately 30%) diameter reduction of a right upper PV and 1 severe (approximately 80%) ostial PV stenosis of a left upper PV, detected by MRA. Both patients were asymptomatic. There was no significant difference in mean PV diameter before (16.1 ± 2.8 mm) and 12 months after (15.5 ± 3.1 mm) ablation ($p=0.5$).

Kumagai et al (2006): One patient developed pericardial effusion which was drained percutaneously. As 12 month follow-up mild (<50%) PV stenosis was seen in 12% of patients and no PV stenosis >50% was detected by 3D CT.

Effectiveness

The studies reported upon a variety of effectiveness outcomes, which may be considered primary or secondary when considering the effectiveness of a diagnostic device. Primary effectiveness outcomes considered included successful mapping of AF foci, PVPs detected, and successful PVI. Secondary effectiveness outcomes considered included patient recovery, ablation time, and rate of recurrence.

a) Yamada et al (2005)

Primary outcomes:

Successful mapping: Mapping was successfully performed in 205 PVs including 8 left PVs with a common trunk. Mapping was not possible in 47 (right inferior) PVs due to anatomical constraints (small diameter or complex branching patterns).

PV potentials detected: A single segmental breakthrough was detected in 17 PVs and a single broad breakthrough was detected in 83 PVs. Multiple separate breakthroughs were detected in 16 PVs, where elimination of one breakthrough caused electrical disconnection. In 88 further PVs multiple separate breakthroughs were also detected; however, the PV musculature extending from the eliminated breakthrough had an electrical connection with the LA via another breakthrough. Due to this connection in these 88 PVs, PVP was not eliminated until the last breakthrough was eliminated. The extent of the breakthrough was larger in the superior PVs than in the left inferior PVs. In 75% of superior PVs, the extent of the breakthrough was larger than half of the circumference of the PV.

Non-PV potentials detected: No non-PV AF potentials were reported to have been identified.

PVI: Successful PVI was reported in all 204 PVs (100%) (One PV had no PVPs).

Secondary outcomes:

Procedure and fluoroscopy time: The mean total procedure time was 201 ± 82 minutes and the mean fluoroscopy time was 94 ± 36 minutes. The mean ablation time was not reported.

Ablative effectiveness: One RFA application was reported to be successful in 9 of 17 PVs with a single breakthrough (4 LSPVs, 1 RSPV, 3 LIPVs and 1 RIPV) (52.9%). In the remaining PVs the number of applications required was not reported.

Recurrence: Recovery of the electrical connection between the LA and the PVs was found in 43 (59%) out of 73 PVs isolated. Multiple procedures were performed in 23 patients with recurrent AF, and no AF foci were found in any of those patients on the LA side of the previous isolation lines or in non-isolated RIPVs during subsequent procedures.

Patient recovery: During 6±2 month follow-up after the last AF procedure, 51 (78%) patients were free of symptomatic AF without any anti-arrhythmic drugs (mean 1.3 procedures per patient). Seven (11%) patients were free of symptomatic AF with one anti-arrhythmic drug that had failed to control AF before the procedures. The remaining 7 (11%) patients still had recurrent AF.

b) Yamada et al (2007)

Primary outcomes:

Successful mapping: AF foci in 3 patients (two in the LA roof and 1 in the LA lateral wall) (1.5%) could not be located precisely by any mapping technique due to anatomic limitations and alternating multiple ectopic foci. Ablation of those foci was abandoned.

PV potentials detected: The number of PVPs detected was not reported.

Non-PV potentials detected: Spontaneous AF was induced after PVI in 45 patients and re-mapping was conducted. Non-PV AF foci were detected in the RA in 22 of these patients (14 of these in the SVC), in the LA in 18, and in both atria in 5. Five foci (4 in the PV antrum and 1 in the LA posterior wall) were speculated to be located epicardially. There were no significant relationships between the location of the non-PV AF foci and the PVI technique or type of AF. The incidence of non-PV AF foci was significantly greater in the persistent AF patients (36%) than in the paroxysmal AF patients (21%) ($p<0.05$).

PVI: PVI was reported to have been successfully performed in all 200 patients. Segmental ostial PVI was performed in 124 patients (paroxysmal n=94, persistent n=30) and circumferential PVI was performed in 76 patients (paroxysmal n=53, persistent n=23). Isolation of all 4 PVs was performed in 188/200 (94%) patients, while isolation of 3 PVs was performed in 12 (7 paroxysmal and 5 persistent AF) patients due to the right or left PVs having a common ostium in 8 patients and small right inferior PV in 4 patients.

Successful segmental ostial isolation of the SVC was successfully achieved in the 14 patients with AF foci in the SVC. Successful isolation of the remaining 31 non-PV AF patients was not reported.

Non-PV AF foci: Two AF foci in the coronary sinus ostium were eliminated by RFA guided by conventional mapping, although the reason for using this guidance was not supplied. One AF foci in the left atrial appendage was eliminated by RF catheter ablation guided by electroanatomic mapping. Aside from the 3 patients whose AF foci could not be located and in whom RFA was therefore abandoned, all remaining non-PV AF foci were eliminated by a mean of 2±1 RF applications with the guidance of an MBC. In five

of those foci (4 in the PV antrum and 1 in the LA posterior wall) (group 1), small far-field potentials preceding the near-field local potentials were recorded during the initiation of the AF from the MBC electrodes at the successful ablation site where a single large potential was recorded during sinus rhythm. There were no significant differences in the number of RFA applications between those 5 AF foci and the other non-PV foci (group 2). RFA was performed during sustained AF in all group 1 AF foci and in 15 of 21 (group 2) foci and during frequent atrial premature beats in the remaining 6. The AF terminated during the successful RFA in 4 of the group 1 AF foci (80%) and in 8 of the group 2 AF foci (38%). The duration of RFA required to eliminate the atrial premature beats or AF was significantly longer in the group 1 AF foci (46.0 ± 5.1 seconds) than in the group 2 AF foci (14.4 ± 3.5 seconds) ($p < 0.0001$).

In the remaining patients, sinus rhythm was restored by cardioversion after the RF applications and the elimination of the AF foci was confirmed by no spontaneous occurrence of AF or atrial premature beats originating from the same site.

Secondary outcomes:

Recurrence: AF recurred (without any anti-arrhythmic drugs) after the first RFA in 8 of 26 (31%) patients with non-PV AF foci who underwent successful segmental ostial PVI (5 paroxysmal 5 and 3 persistent) and in 5 of 19 (26%) patients with non-PV AF foci who underwent successful circumferential PVI (1 paroxysmal and 4 persistent). Recovery of an electrical connection was observed in more than one previously isolated PV in 7 patients, who then underwent a second RFA. In all 7 patients, successful electrical disconnection was achieved by the second procedure, and 5 patients (71.4%) were free of symptomatic AF without any anti-arrhythmic drugs.

Patient recovery: PV AF foci: A total of 124 patients underwent segmental ostial PVI. At mean 14 ± 5 months after the first procedure 78 of these patients (63%) (73% paroxysmal and 30% persistent) were free of any symptomatic AF without any anti-arrhythmic drugs. A total of 76 patients underwent circumferential PVI. At mean 14 ± 5 months after the first procedure 60 of these patients (79%) (85% paroxysmal and 65% persistent) were free of any symptomatic AF without any anti-arrhythmic drugs. A second procedure was performed in 41 of the remaining 62 patients with recurrent AF.

At mean 10 ± 3 months after the last procedure, 95 of the 124 patients who received segmental ostial PVI (77%) (82% paroxysmal and 60% persistent) were free of symptomatic AF without any anti-arrhythmic drugs. Also, 65 of the 76 patients who received circumferential PVI (85%) (paroxysmal 91% and 74% persistent) were free of symptomatic AF without any anti-arrhythmic drugs.

Patient recovery (non-PV AF foci): Recovery of patients with non-PV AF foci was not reported.

c) Arentz et al (2003)

Primary outcomes:

Mapping: Introduction of the MBC was successful in all right and left upper and all left inferior PVs, but only in 3 right inferior PVs. The 31mm MBC was used in 50 patients and the 38mm MBC in 5 patients; in 3 of the 5 for a common ostium of the left PVs. The 31 mm MBC had good contact (i.e. stable electrograms in all 32 bipoles of the MBC) and

stability (i.e. no dislocation during PV isolation) in PVs with a diameter between 12 and 26mm; and the 38mm MBC in PVs up to 32mm. In vessels smaller than 12mm, overlapping or bunching of the splines of the MBC resulted in artifacts on the electrograms. No interference between the ablation catheter and MBC was observed during mapping of the ostium.

PV potentials detected: 165 PVPs were detected.

Non-PV potentials detected: Three ostial foci, 2 left atrial foci, 2 right atrial foci, and 3 foci in the superior vena cava were identified. Seventeen patients received tricuspid annulus/inferior vena cava isthmus ablation, although the number of foci was not reported.

PVI: A total of 163 of 165 (98.7%) mapped PVs with activation in sinus rhythm were successfully isolated. Three ostial foci, 2 left atrial foci, 2 right atrial foci, and 3 foci in the superior vena cava were ablated. While 17 patients received tricuspid annulus/inferior vena cava isthmus ablation, the success of the procedure was not reported. Isolation was performed successfully during AF in nine patients; however, it is unclear how many patients in total were in AF during isolation.

Secondary outcomes:

Recurrence: A second ablation was required in 15 patients to treat symptomatic recurrence of AF (1.27 procedures per patient). Recurrence was due to recovery of conduction of a previously ablated PV (n=12), ostial foci (n=6), and left atrial foci (n=4).

Procedure and fluoroscopy time: The mean ablation time required to achieve complete isolation was 720±302 seconds per PV. The total fluoroscopy time was 40±17 minutes. On average, 2.5±1.2 distinct left atrium-to-PV connections were ablated per PV to achieve complete conduction block.

Secondary outcomes:

At one year follow-up 34 of 55 (62%) patients were free of AF without need for anti-arrhythmic drug treatment. An additional 14 patients (25%) had stable sinus rhythm with the aid of anti-arrhythmic drug treatment which was ineffective before RFA. The success rate was higher in patients with paroxysmal AF; 26 of 37 (70%) were free of AF without anti-arrhythmic drugs, whereas persistent AF patients experienced a drug free success rate of only 8 of 18 (44%) (p=0.06).

d) Kumagai et al (2006)

Primary outcomes:

Mapping: The total number of PVs mapped was not reported. The MBC was successfully introduced into all right and left superior and all left inferior PVs and in only 42 (of an unknown total) right inferior PVs.

PVI: PVI was successfully performed in 192 targeted PVs (mean 3.8 per patient).

PV potentials detected: PVPs were detected in a total of 192 PVs.

Non-PV potentials detected: No non-PV AF potentials were reported to have been identified.

Ablation: A total of 62 ablation procedures were performed in 50 patients. Segmental ablation was performed at the exit breakthrough points during distal PV pacing, and blocked electrical conduction from the PV to the LA. Bidirectional conduction block between the PV and LA resulted in PV-LA dissociation in all PVs.

Secondary outcomes:

Duration: The mean total ablation time and number of applications required to achieve complete isolation per PV was 11±6 minutes and 19±12 times for left superior PV, 8±4 minutes and 11±7 times for right superior PV, 6±4 minutes and 9±7 times for left inferior PV, and 6±5 minutes and 9±6 times for right inferior PV. A median of 5, 4, 3, and 2 splines were targeted in the left superior, right superior, left inferior; and right inferior PVs, respectively. The mean total duration of the procedure was 212±70 minutes and the mean total fluoroscopy time was 60±25 minutes.

Recurrence of AF: After the first ablation procedure AF recurred in 14 of the 50 patients (28%). A repeat ablation was performed 38±7 days after the initial procedure in 12 patients, and the recovery of PV-LA conduction was noted in 24 of the 48 PVs (50%). Of these 24 PVs, 5 (21%) had unidirectional block (recovery of exit block in 3, recovery of entrance block in 2).

Patient recovery: At 12 month follow-up after the most recent ablation, 44 patients (80%) were free of AF without the need for anti-arrhythmic drug treatment. An additional 6 patients (12%) were free of AF with the aid of anti-arrhythmic drug treatment, which had been ineffective before RFA.

COST IMPACT

No cost-utility analysis literature was available for the MBC. If the MBC is determined to be highly accurate, it may lead to cost savings by decreasing AF recurrence and therefore the need for reintervention.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieval material.

OTHER ISSUES

No other issues of relevance were identified for this device.

SUMMARY OF FINDINGS

Early peer reviewed evidence for the MBC indicates the diagnostic device is feasible, safe and effective. Current literature reports successful deployment of the MBC to all right and left upper and all left inferior PVs, but difficulty was encountered when attempting to access right inferior PVs in three of the included studies. One study also reported that access to the atrium was unavailable in 3 patients. One study reported that overlapping or bunching of the MBC's splines occurred when mapping vessels smaller than 12mm, which resulted in artifacts on the electrograms.

Two studies reported that non-PV AF foci were identified using the MBC. This is significant, as the literature indicates that the other major catheters on the market are unable to identify non-PV AF foci. No issues regarding the accuracy of the 3D images delivered by the MBC via a navigation system were reported in any studies. Overall, where reported, the studies included reported a high success rate (98.7% to 100%) for minimally invasive PVI guided by the MBC.

HEALTHPACT RECOMMENDATION

Based on the evidence available to date, it is recommended that the MBC be monitored for 12 months due to its ability to identify breakthroughs, confirm the elimination of breakthroughs and identify non-PV AF loci. Additional research is necessary as it is unclear if the attached navigational system with MBC translates into better patient outcomes.

NUMBER OF STUDIES INCLUDED

Total number of studies	4 (Two with patient overlap)
Level IV intervention evidence	4

REFERENCES

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SEARCH CRITERIA TO BE USED

Multielectrode basket catheter, multi-electrode basket catheter, atrial fibril*, atrial fibrillation.