



**TITLE:** The Use of Remote Magnetic Navigation in Catheter Ablation of Atrial Arrhythmias

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**PUBLISHER:** California Technology Assessment Forum

**DATE OF PUBLICATION:** February 8, 2012

**PLACE OF PUBLICATION:** San Francisco, CA



## THE USE OF REMOTE MAGNETIC NAVIGATION IN CARDIAC ABLATION OF ATRIAL ARRHYTHMIAS

### *A Technology Assessment*

#### **INTRODUCTION**

The California Technology Assessment Forum (CTAF) was asked to assess the evidence for the use of remote magnetic navigation during catheter ablation of atrial arrhythmias. Catheter ablation using radiofrequency energy has become standard therapy for the treatment of patients with symptomatic supraventricular tachycardia and is increasingly being used to treat atrial fibrillation. The procedures may last for hours with repeated use of fluoroscopy to help guide the placement of catheters in the heart. Remote magnetic navigation was developed to improve the precision and flexibility of catheter movement to increase the efficacy of ablation while lowering the risk of unintended damage to the heart and reducing radiation exposure to both patients and healthcare providers.

#### **BACKGROUND**

##### Catheter ablation of atrial arrhythmias

In the past, surgery was sometimes performed to treat arrhythmias such as atrioventricular nodal reentrant tachycardia (AVNRT), atrioventricular reentrant tachycardia (AVRT), atrial tachycardia (AT), atrial flutter (AFlut) and atrial fibrillation (AFib).<sup>1-5</sup> The key insight that allowed for surgical treatment of these arrhythmias was that they have a focal site of origin in the heart. The surgeon destroyed the tissue at that critical site in order to prevent recurrence of the arrhythmia.

In the early 1980's, catheter ablation was introduced as a less invasive approach to produce the same effect.<sup>6,7</sup> Catheter ablation is performed in the electrophysiology laboratory. Multiple percutaneous catheters are positioned in the heart, most commonly using the femoral vein for access. The catheters are used for electrical pacing and recording at multiple sites within the heart in order to map the electrical pathway responsible for the arrhythmia. The initial catheter technique used direct current energy to cause tissue damage, but this approach rapidly fell out of favor because it required general anesthesia and had a high incidence of significant complications including death.<sup>8</sup> Radiofrequency (RF) energy produces a more controlled heating of tissue and has become the standard technique for the past two decades.

Temperatures above approximately 50° C are sufficient to cause irreversible damage to tissue in the heart.<sup>9,10</sup> However, temperatures above 90°C can cause clotting and tissue char that can cause embolic strokes or pulmonary emboli.<sup>9,11</sup> The radiofrequency power is adjusted to maintain temperatures near 65° C<sup>9,12,13</sup> and more recent catheter designs include cooling devices<sup>14</sup> or saline irrigation<sup>15,16</sup> to avoid the risks associated with overheating. The lesions produced by typical radiofrequency catheters are about 7 mm in diameter and penetrate about 3 mm into the myocardium. This is sufficient to block electrical conduction through that small region of the heart. Multiple lesions are commonly needed to eradicate the arrhythmia.

As noted above, a wide variety of arrhythmias can be treated with catheter ablation. The most common are the so-called supraventricular arrhythmias: AVRT, AVNRT, and AT. In AVRT, there is an accessory pathway allowing electrical conduction between the atria and ventricles through tissue other than the usual atrioventricular (AV) node. The arrhythmia is caused by a circuit loop with electrical conduction down one pathway from the atria to the ventricles and back up through the other pathway. Using sophisticated mapping techniques, electrophysiologists can identify the location of the accessory pathway and use radiofrequency energy to destroy tissue along the accessory pathway, thus preventing a looping circuit from being established. The pathophysiology of AVNRT is similar, except that there is both a slow and a fast pathway within the AV node itself. Thus, the reentrant circuit is within the AV node. The slow pathway is usually ablated in AVNRT because of greater long term success rate and a lower risk of causing complete AV nodal block. In atrial tachycardia, there is often a single focus of tissue that is the source of the electrical impulse causing the arrhythmia. By ablating that tissue, the arrhythmia can be cured.

Catheter ablation can also treat two other common atrial arrhythmias: atrial flutter and atrial fibrillation. In typical atrial flutter, there is a reentrant circuit within the right atrium that is amenable to treatment by destroying tissue along the pathway of the circuit. Atrial fibrillation is more difficult to treat because there are usually multiple regions of the heart that can trigger the arrhythmia. However, in most cases they are localized near the pulmonary veins. By creating a ring of ablated tissue encircling the pulmonary veins (pulmonary vein isolation), electrical signals from this area can be isolated and atrial fibrillation can be prevented from recurring.

The majority of these arrhythmias present with episodic symptoms caused by a rapid heart rate. The most common symptoms include palpitations, shortness of breath, fatigue, lightheadedness and chest pressure. Less commonly, the patient may present with syncope or sudden death. Catheter ablation using radiofrequency energy is now considered as the initial therapy for most patients who are symptomatic from

these arrhythmias.

The harms of catheter ablation are relatively uncommon, but can be serious including strokes, heart attacks, heart block requiring a pacemaker, and emergency heart surgery. One early summary of 1,205 patients with accessory pathways who were treated with RF ablation at multiple institutions reported that the most common serious complication was perforation of the heart causing non-fatal tamponade (0.5%).<sup>17</sup> The other relatively common complications included atrioventricular block (0.5%), femoral artery complications (0.5%), coronary artery spasm (0.2%), coronary artery thrombosis (0.1%), transient ischemic attack (0.1%), and bacteremia (0.1%).<sup>17</sup> The frequency of complications varies by the complexity of the ablation procedure being performed. A recent case series of 1,676 consecutive catheter ablations at a single site reported that the major complication rate ranged from 0.8% for the treatment of supraventricular tachycardias to 5.2% for atrial fibrillation.<sup>18</sup>

The other, more subtle harm associated with catheter ablation is radiation exposure. Fluoroscopy is used to guide the catheters into the heart and to help position them within the heart. Depending on the procedure, the fluoroscopy time can range from 20 minutes to over an hour.<sup>19-22</sup> This can cause radiation damage to the skin<sup>23-25</sup>, but more importantly it can increase the risk for future cancers.<sup>19,26</sup> Studies have estimated that 50 to 60 minutes of fluoroscopy will cause one or two excess deaths from cancer per 1000 treated individuals.<sup>19,26</sup>

### Remote Magnetic Navigation

Electrophysiologists require extensive training and great skill to be able to precisely position the catheters within the heart through manual manipulation of catheter sheaths inserted through the femoral vein. Remote magnetic navigation was developed to facilitate the positioning of catheters within the heart. The system uses two computer-controlled external magnets to create and adjust an external magnetic field (0.08 Tesla) in order to guide the magnetic tip of the catheter used for ablation. The catheter is advanced or retracted from a remote workstation using a computer console that controls both the magnets and a motor-driven catheter at the bedside. The catheter tip is more flexible than a traditional ablation catheter and it moves parallel to the lines of the magnetic field established by the external magnet. By adjusting the external magnetic field, the operator can direct the catheter to the desired location within the heart. Because of the strong magnetic field, the device must be used in a specially built electrophysiology laboratory with

equipment designed specifically for magnetic guidance.

Potential benefits of remote magnetic navigation include more precise control of the catheter facilitating more rapid and accurate guidance of the catheter to the desired location in the heart. This may reduce the time that the patient is exposed to radiation during fluoroscopy as well as the total time of the procedure. In addition, once initial fluoroscopic images are obtained, they can be viewed on the remote console throughout the procedure to guide navigation without additional fluoroscopy. The risk for cardiac puncture and tamponade may be lower because the catheter tip is much softer than that of a traditional catheter. Because the device is controlled remotely, the operator no longer is exposed to radiation from bedside fluoroscopy during much of the procedure. Thus the operator no longer has to wear a lead apron for long periods of time while performing catheter ablation, reducing operator fatigue in addition to their lifetime exposure to ionizing radiation.

## TECHNOLOGY ASSESSMENT (TA)

**TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.**

The NIOBE Remote Magnetic Navigation system first received FDA 510(k) approval in January 2003. It is categorized as a Class 2 device under the product code DXX. NIOBE is integrated with Siemens' and Phillips' digital x-ray fluoroscopic imaging systems and Biosense Webster's three dimensional catheter location sensing technology and ablation catheter technology. The list of FDA 510(k) approvals is shown below.

	Date of approval	FDA approval type and number
Stereotaxis Niobe Magnetic Navigation System	January 2003	510(k): K021555
Navigant Workstation with Niobe Magnetic Navigation System	May 2006 October 2006	510 (k): K051760 510 (k): K060967
Biosense Webster Navistar/Celsius ThermoCool Diagnostic/Ablation Deflectable Tip Catheters*	November 2004	PMA: P030031
*There have been many supplemental approvals for the integration of the Biosense Webster products with Niobe.		

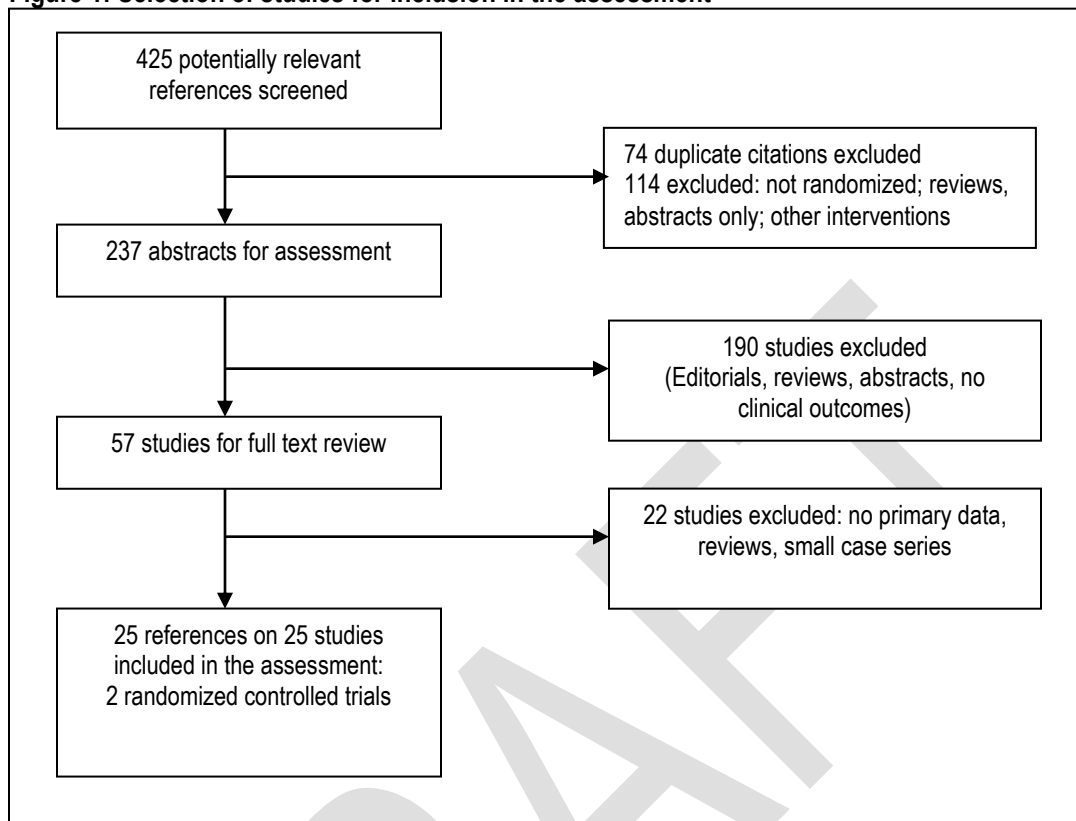
**TA Criterion 1 is met.**

**TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

The procedure time and complication risk during catheter ablation vary dramatically by the type of arrhythmia. This assessment will focus on atrial arrhythmias because they were initially the primary type of arrhythmia treated with catheter ablation and because a recent systematic review of remote magnetic navigation for catheter ablation of ventricular tachycardias concluded that additional comparative and randomized trials were needed.<sup>27</sup> The Medline database, Embase, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words “remote navigation” OR “remote magnetic navigation” OR “Niobe” OR “Stereotaxis.” The search was performed for the period from 1945 through December 2011. The detailed search criteria are shown in the Appendix. The bibliographies of systematic reviews and key articles were manually searched for additional references. References were also solicited from the manufacturers and local experts. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full. We excluded studies of ventricular arrhythmias.<sup>28-38</sup>

The search identified 425 potentially relevant studies (Figure 1). After elimination of duplicate and non-relevant references including reviews and animal studies the search identified 25 articles describing seven case series<sup>39-45</sup>, 16 comparative studies<sup>46-61</sup> and two small randomized trials.<sup>62,63</sup> An additional 11 early case series were excluded because they were too small to provide reliable estimates for the outcomes of interest.<sup>64-74</sup>

**Figure 1: Selection of studies for inclusion in the assessment**



**Level of Evidence: 2, 3, 4 and 5.**

**TA Criterion 2 is met.**

**TA Criterion 3: The technology must improve net health outcomes.**

The most important outcome for catheter ablation is long-term freedom from recurrence of the arrhythmia. Patients need to be followed for a relatively long time to be sure that they are free from the arrhythmia. Randomized trials that demonstrated the value of catheter ablation for the treatment of atrial fibrillation followed patients for a minimum of nine to twelve months<sup>75,76</sup> and one ongoing trial comparing different techniques for catheter ablation plan to follow more than 240 patients for twelve months in order to have adequate power to demonstrate the equivalence of the two techniques.<sup>77</sup>

Other important outcomes are primarily safety outcomes: freedom from adverse events such as cardiac

tamponade, permanent heart block, myocardial infarction (MI), stroke, major vascular complications, radiation exposure, and death.

### Case series

The seven case series of catheter ablation for atrial arrhythmias were all small: there were only a total of 338 patients described in these series.<sup>39-45</sup> The characteristics of the studies are described in Table 1. Most reported on the results from a single type of atrial arrhythmia, but the largest case series described results of treating six different arrhythmias including ventricular tachycardia.<sup>43</sup>

The outcomes and adverse events are summarized in Table 2. The acute procedural success rate for AVRT and AVNRT was generally high (81% to 100%), but in the initial study of atrial fibrillation, the acute success rate was only 8% and more than half recurred during 11 months of follow-up.<sup>41</sup> In a second case series reporting the results of catheter ablation of atrial fibrillation using remote magnetic navigation, the acute success rate was much higher (70%), though the long-term durability of these results was not reported.<sup>45</sup> The improvement in results likely represents the availability of newer catheters and electrical mapping equipment that can be used with magnetic navigation.

There are two notable findings from these case series. First, the complication rate was low. Five of the case series reported no significant complications<sup>39-42,44</sup> and there were a total of five complications in the other two series.<sup>43,45</sup> As expected, the complication rate for the treatment of atrial fibrillation was greater than that of the other arrhythmias.<sup>45</sup> Second, in the three studies that reported operator exposure to fluoroscopy, the operator exposure was much shorter than the total fluoroscopy time. This is one of the benefits of remote navigation, though it does not have direct impact on patient outcomes.

**Table 1:** Characteristics of the published studies of remote magnetic navigation for atrial arrhythmia ablation

Study	Arrhythmia	Group	N	Follow-up (months)	Location
<b>Case series</b>					
Ernst 2004	AVNRT	RMN	42	3.7	Hamburg, Germany
Chun 2007	AVRT	RMN	59	12	Hamburg, Germany
Di Biase 2007	AFib	RMN	45	11	Cleveland, Ohio
Thornton 2007	AVRT	RMN	20	3	Rotterdam, Netherlands
Latcu 2009	AVNRT, AVRT, AFib, AFlut, AT, VT	RMN	84	NR	Monaco
Xu 2009	AVNRT, AVRT	RMN	32	6	Hong Kong, China
Chun 2010	AFib	RMN	56	18	Hamburg, Germany
<b>Comparative studies</b>					
Kerzner 2006	AVNRT	RMN MAN	28 28	3	St. Louis, Missouri
Pappone 2006	AFib	RMN MAN	40 28	NR	Milan, Italy
Thornton 2006	AVNRT	RMN MAN	20 17	3	Rotterdam, Netherlands
Arya 2008	AFlut	RMN MAN	26 40	NR	Leipzig, Germany
Katsiyannis 2008	AFib	RMN MAN	20 20		Minneapolis, Minnesota
Kim 2008	AFib, AFlut, AT, AVNRT, AVRT, RVOT	RMN MAN	127 594	NR	San Francisco, California
Moreno 2009	AVNRT	RMN MAN	18 18	6	Madrid, Spain
Huo 2010	AFlut	RMN MAN	26 25	6	Leipzig, Germany
Miyazaki 2010	AFib	RMN MAN	30 44	12	Bordeaux, France
Ricard 2010	AVNRT	RMN MAN	26 11	16	Monaco
Sorgente 2010	AFib	RMN MAN	35 26	13	Brussels, Belgium
Anne 2011	AFlut	RMN RMNi MAN	17 14 8	NR	Rotterdam, Netherlands
Arya 2011	AFib	RMN MAN	70 286	6	Leipzig, Germany



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<b>Study</b>	<b>Arrhythmia</b>	<b>Group</b>	<b>N</b>	<b>Follow-up (months)</b>	<b>Location</b>
Bauernfeind 2011	AFib, AFlut, AT, AVNRT, VT	RMN MAN	292 318	15	Rotterdam, Netherlands
Luthje 2011	AFib	RMN MAN	107 54	12	Gottingen, Germany
Solheim 2011	AFib	RMN RMNi MAN	26 23 65	12	Bergen, Norway
<b>Randomized trials</b>					
Wood 2008	AVNRT, AVRT, AV junction ablation	RMN MAN	56 15	3	Multicenter, USA
Vollmann 2009	AFlut	RMN MAN	45 45	6	Gottingen, Germany

**Table 2:** Procedural and 30 day benefits and harms of transcatheter aortic valve implantation

Study	Arrhythmia	Group	N	Procedural success, %	Recurrence, %	Procedure time, minutes	Fluoro time, minutes	Operator fluoro time, minutes	Complications, n
<b>Case series</b>									
Ernst 2004	AVNRT	RMN	42	100	0	145	8.9	3.4	None
Chun 2007	AVRT,	RMN	59	81	0	190	10.6	NR	None
Dibiase 2007	AFib	RMN	45	8	55	NR	NR	NR	None
Thornton 2007	AVRT	RMN	20	65	0	162	31	9	None
Latcu 2009	AVNRT, AVRT, AFib, AFlut, AT, VT	RMN	84	81	NR	169	14	1.5	2: 1 hematoma, 1 pericardial effusion
Xu 2009	AVNRT, AVRT	RMN	32	94	0	129	7.4	NR	None
Chun 2010	AFib	RMN	56	70	NR	315	19	13	3: 1 MI, 1 TIA, 1 PV stenosis
<b>Comparative studies</b>									
Kerzner 2006	AVNRT	RMN	28	100	0	204	16.9	NR	2: AV block; IVC thrombus 3: 2 AFib; 1 AT
		MAN	28	100	0	204	16.0		
Pappone 2006	AFib	RMN	40	100		152.5	32.3	NR	None None
		MAN	28	100		110	30.3		
Thornton 2006	AVNRT	RMN	20	90	0	163	12	NR	None None
		MAN	17	100	NR	159	18		
Arya 2008	AFlut	RMN	26	92	NR	53	7.5	NR	None None
		MAN	40	100		45	14.3		
Katsiyannis 2008	AFib	RMN	20	100	20	209	19.5	NR	None None
		MAN	20	100	25	279	58.6		
Kim 2008	AFib, AFlut, AT, AVNRT, AVRT, RVOT	RMN	127	NR	NR	332	51	NR	None 2 tamponade
		MAN	594			243	51		
Moreno 2009	AVNRT	RMN	18	100	0	169	18	NR	None None
		MAN	18	100	6	141	19		
Huo 2010	AFlut	RMN	26	96	8	53	7.5	NR	None None
		MAN	25	100	8	45	14.3		
Miyazaki 2010	AFib	RMN	30	100	31	263	63	NR	2 hematoma 3: 1 tamponade; 2 hematoma
		MAN	44	100	38	165	45		
Ricard 2010	AVNRT	RMN	26	100	4	129	12	NR	1 prolonged PR interval None
		MAN	11	100	0	84	7		
Sorgente 2010	AFib	RMN	35	100	33	178	59.1	NR	1: pseudoaneurysm 4: 2 pseudoaneurysms; 1AV fistula; 1 pericardial effusion
		MAN	26	100	34	195	66.7		
Anne 2011	AFlut	RMN	17	59	NR	148	23	NR	None 1 pseudoaneurysm None
		RMNi	14	64		143	22		
		MAN	8	83		106	20		



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Study	Arrhythmia	Group	N	Procedural success, %	Recurrence, %	Procedure time, minutes	Fluoro time, minutes	Operator fluoro time, minutes	Complications, n
Arya 2011	AFib	RMN	70	88	42	223	13.7	NR	1 femoral vascular complication 11: 7 pericardial effusions; 1 each phrenic nerve injury, PV stenosis, brachial plexus injury, femoral vascular complication
		MAN	286	99	34	166	34.5		
Bauernfeind 2011	AFib, AFlut, AT, AVNRT, VT	RMN	292	92	14	168	30	NR	1 AV block 10: 1 AV block; 9 pericardial effusion or tamponade
		MAN	318	94	11	159	35		
Luthje 2011	AFib	RMN	107	90	46	226	12	NR	5: 2 tamponade; 2 hematoma; 1TIA 1: aspiration pneumonia
		MAN	54	87	44	166	37		
Solheim 2011	AFib	RMN	26	NR	46	324	54.5	NR	None None None
		RMNi	23		39	340	53.7		
		MAN	65		40	215	46.1		
Randomized trials									
Wood 2008	AVNRT, AVRT, AV junction ablation	RMN	56	91	5	151	17.8	NR	3: 2 repeat ablation; 1 PE 1 chest pain
		MAN	15	87	13	151	27.1		
Vollmann 2009	AFlut	RMN	45	84	27	114	10.6	NR	None 1: local hemorrhage
		MAN	45	91	11	77	15.0		

**Table 3:** Evidence for a learning curve

Study	Group	N	Procedural success, %	Procedure time, minutes	Fluoroscopy time, minutes	Operator fluoroscopy time, minutes
<b>Case series</b>						
Thornton 2007	First	10	50	180	33.7	10.2
	Last	10	80	137	24.4	7.6
Xu 2009	First	14	100	139	8.0	NR
	Last	13	100	112	3.2	
<b>Comparative studies</b>						
Pappone 2006	First	12	100	192	34.5	NR
	Last	28	100	148	30.3	
Thornton 2006	All	20	90	Significant decrease	NR	NR
Arya 2008	First	10	NR	80	11.0	NR
	Last	15		45	7.2	
Kim 2008	First	75	NR	Significant decrease 0.67 minutes per case (from 393 to 342 minutes)	Significant decrease 0.58 minutes per case (from 82 to 38 minutes)	NR
Luthje 2011	First	27	NR	Not significant	~15	NR
	Last	27			~9	

### Comparative studies

The search identified sixteen studies that compared the outcomes for 945 patients treated using remote magnetic navigation to 1582 controls.<sup>46-61</sup> The majority were single site studies that used historical controls from their local experience to evaluate the impact of remote magnetic navigation. Only a handful of the studies carefully matched the characteristics of patients treated with manual navigation to those of the patients treated with remote magnetic navigation. None of the studies used more sophisticated statistical techniques, such as instrumental variables or propensity scores to account for differences between the two groups of patients. The vast majority of the studies had fewer than 50 patients in each group, so that sophisticated modeling was not feasible.

It is remarkable that seven of the first eleven studies reported 100% success rates for both the manual and magnetic navigation groups.<sup>46,47,50,52,54-56</sup> Only one of the studies reported a nominally higher success rate with remote magnetic navigation and the difference was not significant.<sup>60</sup> The recurrence rates were also low, except for studies of atrial fibrillation, which is more difficult to treat with catheter ablation than other atrial arrhythmias.

The average total procedure time varied from 45 minutes to 340 minutes, depending on the arrhythmia, but was consistently longer for remote magnetic navigation. Fluoroscopy time, on the other hand, was consistently shorter for remote magnetic navigation. None of the studies reported operator fluoroscopy time.

The overall complication rate was remarkably low: less than two percent in both the remote and manual navigation groups. Pericardial effusions and tamponade tended to occur less often in the remote navigation group, but the numbers were so small in each study that the differences were not significant.

### Learning curve

Seven of the observational studies provided data on changes in outcomes with increasing experience with remote magnetic navigation.<sup>42,44,47-49,51,60</sup> Five studies compared the outcomes for their first 10 to 27 patients treated using remote magnetic navigation to those of later patients in the study (Table 3).<sup>42,44,47,49,60</sup> All reported significant decreases in both total procedure time and fluoroscopy time with greater experience. Two other studies performed linear regression to evaluate the effect over all procedures in their studies.<sup>48,51</sup> The largest study reported that both the procedure time and fluoroscopy continued to decrease even after 75 cases.<sup>51</sup> In that study, the total procedure time for the ablation of atrial fibrillation decreased by an average of 51 minutes and the fluoroscopy time decreased by 44 minutes. Across all studies, there was

clearly a significant learning curve to the use of remote magnetic navigation that may require more than 75 cases to achieve optimal efficiency.

### Summary of observational studies

Several things are clear from the observational data. First, as expected, the operator exposure to radiation from fluoroscopy is markedly reduced. This may translate into less occupational cancers among staff working in electrophysiology laboratories. Second, catheter ablation procedures are longer when magnetic navigation is used, although the extra time tends to decrease with increasing experience. Third, it is likely that the total time that patients are exposed to radiation from fluoroscopy is decreased, but the comparisons were not randomized, so the differences could be due to secular trends in the success rate of catheter ablation or to selection bias. In general the success rate was high, but no higher than that obtained with manual navigation. Similarly, the complication rates were low and appeared comparable to manual navigation. The individual studies were small, so the confidence intervals around each of the estimates of procedural success and complications were wide. In addition, the same concerns about secular trends in outcomes and selection bias increase the uncertainty about the reliability of these findings. Randomized trials are needed to demonstrate equivalence. Given expected differences in the success rate and complications based on the type of arrhythmia, randomized trials should either focus on one type of arrhythmia or stratify randomization by arrhythmia. Studies addressing similar questions in atrial fibrillation suggest that the trials should randomize 250 to 300 patients and follow them for at least one year.<sup>75-77</sup>

### Randomized clinical trials

#### *The Helios Electrophysiology Ablation Remote Treatment (HEART) trial*

The Helios Electrophysiology Ablation Remote Treatment (HEART) trial randomized patients with supraventricular tachycardia in a 3:1 ratio to ablation with remote magnetic navigation or manual navigation.<sup>62</sup> The study included patients at least 18 years of age who had a documented episode of SVT in the prior year and were scheduled for ablation of either AVNRT, an accessory pathway, or AV junctional ablation. The study excluded patients with any of the following: contraindications to magnetic resonance imaging; recent MI or cardiac procedure; intra-cardiac thrombus, or unstable angina. The primary outcome was total fluoroscopic time. Secondary outcomes included the acute success rate, the success rate at 90 days, total procedure time, and adverse events. Based on power calculations, the study was designed to randomize 256 patients. The study was stopped after 71 patients (28% of goal) when a magnetic catheter

became commercially available. Follow-up at three months was also low at only 65%. The randomization procedures, allocation concealment, and blinding were not described. In addition, one patient randomized to the remote magnetic navigation group was excluded because ablation was not attempted, a violation of the intention to treat principle. Thus, the overall quality of the trial was poor.

The study required physicians to perform a minimum of five and a maximum of twenty procedures using remote magnetic navigation before randomizing any patients. The study reported outcomes on the 73 patients treated during this skill-building phase in addition to the 56 patients randomized to magnetic navigation and 15 patients randomized to manual navigation. There were no statistically significant baseline differences between the remote magnetic navigation group and the manual navigation group, but some of the differences were large. For example, the average age in the remote navigation group was 53 years compared to 43 years in the manual navigation group ( $p=0.17$ ). Similarly, there were more men in the remote magnetic navigation group (41% versus 27%,  $p=0.49$ ) and all of the patients receiving AV junction ablation were in the remote magnetic navigation group (9% versus 0%,  $p=0.91$ ). In a larger trial, these differences would have been statistically significant.

Total fluoroscopy time, the primary outcome, was shorter in the remote magnetic navigation group (17.8 minutes versus 27.1 minutes,  $p<0.003$ ). The total procedure time was identical in the two groups (151 minutes). The acute success rates were similar for the two groups (91% versus 87%,  $p>0.05$ ). Among the 65% of patients who returned for the three month follow-up, the chronic success rates were also similar and favored the remote magnetic navigation group (95% versus 87%,  $p>0.05$ ). Finally, the major adverse event rates were also similar (5.4% versus 6.7%,  $p=1.0$ ). The adverse events in the remote magnetic navigation group were two repeat ablations for treatment failure within one week of the initial ablation and one pulmonary embolism. The adverse event in the manual navigation group was chest pain that resolved with antacid therapy. Given the small sample size, baseline differences between the two groups, and poor follow-up, it is impossible to make any firm conclusions about the acute or chronic success rate or the adverse event rate. The differences in fluoroscopy time are large enough, that they are likely to be real, though the differences in case mix (more AV junction ablations) and the lack of blinding could explain some of the difference in fluoroscopy time.

#### *Atrial Flutter Trial – Vollmann 2009*

The second trial randomized 90 patients with documented typical atrial flutter to catheter ablation with either remote magnetic navigation or manual navigation.<sup>63</sup> The study excluded patients with prior ablations and

those with a device at risk for magnetic interference (pacemaker, implantable cardioverter defibrillator). The primary endpoints were total fluoroscopy time and the duration of radiofrequency application duration. Secondary outcomes included total procedure time, patient radiation exposure, the acute success rate, long-term success through six months, and adverse events.

The study randomized 45 patients to each group. The two groups were reasonably similar in age (69 versus 68 years) and sex (80% versus 73% male), though there were fewer patients with coronary artery disease in the remote magnetic navigation group (40% versus 51%) and fewer taking statins (33% versus 47%). The study did not report p values for these baseline characteristics and did not comment on statistical significance.

Both fluoroscopy time (10.6 versus 15.0 minutes,  $p=0.043$ ) and total patient radiation exposure (3274 versus 4304 microGrey,  $p=0.032$ ) were significantly lower in the remote magnetic navigation group. Total procedure time (113.5 versus 77.2 minutes,  $p<0.0001$ ) and radiofrequency application duration (17.1 versus 7.5 minutes,  $p<0.0001$ ) were significantly longer in the remote magnetic navigation group. There were no significant differences in the acute procedural success rate (84% versus 91%,  $p=0.52$ ) or in the six-month success rate (73% versus 89%,  $p=0.063$ ), although there was a trend towards more recurrences in the remote magnetic navigation group (13% versus 2%,  $p=0.073$ ).

### *Summary*

The observational data demonstrated that operator exposure to radiation is decreased with remote magnetic navigation at the expense of longer total procedure time. The observational data also suggested that remote magnetic navigation reduced patient exposure to radiation. This finding was confirmed in the two randomized trials. However, both randomized trials were underpowered to demonstrate the equivalence of remote magnetic navigation to manual navigation for the two most important clinical outcomes: long-term freedom from arrhythmia recurrence and major complications. In the HEART trial, the acute success rate was higher by 4.2% in the remote navigation group, but the 95% confidence interval ranges from 15% worse to 23% better.<sup>62</sup> For the other randomized trial, the 95% confidence interval for the difference in success rates ranges from 20% worse to 6.8% better.<sup>63</sup> These confidence intervals contain absolute differences in success rates that would be clinically unacceptable. It is unfortunate that the HEART trial was of poor quality and was terminated early because the planned sample size should have been sufficient to confirm the equivalence of remote magnetic navigation to manual navigation within reasonably narrow confidence intervals.

**TA Criterion 3 is not met.**

**TA Criterion 4: The technology must be as beneficial as any established alternatives.**

Manual navigation is the established alternative to remote magnetic navigation. As noted above, remote navigation clearly reduces both operator and patient exposure to ionizing radiation from fluoroscopy. These are clear benefits compared to manual navigation. However, there is too much residual uncertainty about the magnitude of difference in the acute and long-term success rate. In the HEART trial, the acute success rate with remote magnetic navigation was higher, while in the other randomized trial it was lower. In both studies, the confidence intervals were wide. The situation was reversed for recurrence rates: in the HEART trial the recurrence rate was higher in the remote magnetic navigation group, while in the other randomized trial it was lower. Finally the confidence intervals surrounding the major complication rates were also wide. In the HEART trial, there was only a 1.2% difference in the complication rate and it favored remote navigation, but the confidence interval ranged from 13% worse to 15% better. Larger, better quality trials are needed to clearly demonstrate equivalence in clinical effectiveness and safety.

**TA Criterion 4 is not met.**

**TA Criterion 5: The improvement must be attainable outside of the investigational setting.**

Catheter ablation is a technically demanding procedure, whether performed with remote magnetic navigation or manually. There is also an important learning curve with magnetic navigation. Success rates appear to be relatively stable, but the total procedure time and fluoroscopy time decrease significantly with increased experience with magnetic navigation, even after the performance of 75 procedures. If inexperienced clinicians attempt to proceed too quickly, it is likely that the success rate suffers. If clear improvements are demonstrated, careful training and proctoring will be needed to ensure optimal results. However, to date, improvements have not been clearly demonstrated even in the investigational setting.

**TA Criterion 5 is not met.**

## CONCLUSION

Radiofrequency catheter ablation has been a great leap forward in the treatment of supraventricular arrhythmias. Patients can now be cured without the risks of open-heart surgery or the burden of lifelong daily medications. Long-term studies report that catheter ablation is a cost-effective therapy that improves patients' quality of life.<sup>78</sup> However the procedure is technically difficult and laborious. Multiple steerable catheters are advanced into the heart in order to map out the electrical pathway causing the patient's arrhythmia and then a catheter must be precisely positioned against the inside of the heart to deliver radiofrequency energy to permanently destroy tissue at the location needed to prevent abnormal electrical pathways from becoming established, while not damaging normal electrical pathways. This process requires repeated use of fluoroscopy to guide catheter placement and to avoid puncturing the heart.

Remote magnetic navigation was developed to allow more precise positioning of catheters within the heart. After the initial insertion of the catheters, they can be guided from a remote computer-controlled workstation so that the operator no longer needs to be at the patient's bedside while positioning the catheters. This decreases the operator's exposure to radiation during fluoroscopy and may reduce fatigue, because the operator does not need to wear a lead apron for hours at a time. The magnetic catheters are also much more flexible than traditional steerable catheters, which may decrease the risk for cardiac perforation and tamponade.

Early case series<sup>39-45</sup> reported that remote magnetic navigation could effectively treat many arrhythmias with few complications, although the first report on the treatment of atrial fibrillation<sup>41</sup> was disappointing. Later case series and comparative studies reported more favorable results for the treatment of atrial fibrillation.<sup>45,54,56,58,60</sup> The case series and comparative studies<sup>46-61</sup> documented large decreases in operator exposure to radiation and a low incidence of procedure-related adverse events and suggested that remote magnetic navigation reduced patient exposure to radiation. This was confirmed in the two randomized trials.<sup>62,63</sup> However, both randomized trials were underpowered to demonstrate the equivalence of remote magnetic navigation to manual navigation for successful treatment of the arrhythmia and complications. In order to demonstrate equivalence of remote magnetic navigation to manual navigation, larger clinical trials are needed. The studies to date suggest equivalence in outcomes, with reduced radiation exposure to patients and clinicians, but considerable uncertainty remains.



## **RECOMMENDATION**

It is recommended that use of remote magnetic navigation does not meet CTAF TA Criterion 1 through 5 for safety, effectiveness and improvement in net health outcomes when used for the treatment of atrial arrhythmias using radiofrequency energy catheter ablation.

**February 8, 2011**

This is the first review of this technology by the California Technology Assessment Forum.

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## **RECOMMENDATIONS OF OTHERS**

### **Blue Cross Blue Shield Association (BCBSA)**

No reports reviewing the technology were found at the BCBSA Technology Evaluation Center website.

### **Centers for Medicare and Medicaid Services (CMS)**

There is not a National Coverage Determination code specific to the use of this technology

### **Society of Interventional Radiology (SIR)**

SIR has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

### **The Society of Cardiac Angiography and Interventions (SCAI)**

SCAI has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

### **American College of Cardiology, CA Chapter (ACC)**

The California Chapter of the ACC has been invited to provide an opinion and to send a representative to participate at the meeting.

### **Society of Thoracic Surgeons (STR)**

SCAII has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

### **American Association for Thoracic Surgery (AATS)**

AATS has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

### **Advanced Medical Technology Association (ADVAMED)**

ADVAMED has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

### **Canadian Agency for Drugs and Technologies in Health (CADTH)**



No reports or guidelines were found on the NICE website.

**National Institute for Health and Clinical Excellence (NICE)**

No reports or guidelines were found on the NICE website.

**National Guidelines Clearing House**

No guidelines were found.

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## ABBREVIATIONS

CTAF	California Technology Assessment Forum
DARE	Database of Abstracts of Reviews of Effects
FDA:	US Food and Drug Administration
RCT	Randomized Controlled Trial
NS	Not significant
CI	Confidence Interval
NR	Not reported
NYHA	New York Heart Association
MI	Myocardial infarction
Tamp	Tamponade
CI	Confidence interval
HR	Hazard ratio
OR	Odds ratio
UK	United Kingdom
US	United States
AR	Aortic regurgitation
ACC	American College of Cardiology
AHA	American Heart Association
RMN	Remote magnetic navigation

RMNi	Remote magnetic navigation with an irrigated tip
MAN	Manual catheter navigation
AVNRT	Atrioventricular nodal re-entrant tachycardia
AVRT	Atrioventricular re-entrant tachycardia
AP	Accessory pathway
AFib	Atrial fibrillation
AFlut	Atrial flutter
AT	Atrial tachycardia
SVT	Supraventricular tachycardia
VT	Ventricular tachycardia
MI	Myocardial infarction
TIA	Transient ischemic attack
PV	Pulmonary vein
RF	Radiofrequency
AV	Atrioventricular
HEART	Helios Electrophysiology Ablation Remote Treatment trial

**APPENDIX: Search strategy**

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