The Use of Innovative Technologies to Guide Cardiac Procedures

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Abstract

The advantages of intracardiac echocardiography (ICE) include shorter procedure times, reduced radiation exposure and the elimination of the need for general anesthesia. It is also effective in the safe performance of transseptal punctures. These have led to its increasing use in electrophysiology (EP) procedures. The use of ICE provides unrestricted access to the cardiac anatomy and guides interventional cardiac procedures by providing high-quality images of intracardiac structures and devices. As well as their use as imaging in catheter ablation of atrial fibrillation and other arrhythmias, ICE ultrasound catheters may be used in cardiac valve repair and the closure of atrial septal defects (ASDs).

Integration of ICE catheters with electroanatomical mapping systems that construct three dimensional (3D) images have further increased the application of the technique. The use of magnetic navigation systems (MNS) have conferred further advantages including reduced exposure to fluoroscopy and increased operator comfort. This article presents four clinical cases and reviews clinical studies of these techniques.

Keywords

Electroanatomical mapping system, electrophysiology, intracardiac echocardiography, magnetic navigation systems

Interventional cardiology has seen great advances in the past decade. Electrophysiology (EP) has resulted in an enhanced understanding of the anatomy of the heart which has led to improved catheter ablation procedures. As cardiac surgeries and electrophysiology (EP) studies are becoming less invasive, high quality imaging is essential for clinicians to accurately diagnose and avoid complications as well as to guide increasingly complex procedures.

In the past, transesophageal echocardiography (TEE) was often used for closure of atrial septal defects (ASD) and patent foramen ovales (PFO) and had some application as an imaging technique in EP. However, the risk and discomfort associated with general anesthesia and endotracheal intubation during extended monitoring led to intracardiac echocardiography (ICE) replacing it as a method of visualization. Transvenous ICE was first described over 20 years ago. The initial limitations of poor tissue penetration and difficult manipulation with mechanical intracardiac catheters have been overcome with the development of low-frequency transducers and multi-directional steerable devices. These ICE catheters can be inserted under local anesthesia and have other advantages over TEE, including clearer imaging, shorter procedure times, and reduced radiation doses to the patient.

Currently available ICE catheters include the ACUSON AcuNav™ ultrasound catheter (Biosense Webster) and the SoundStar™ 3D catheter (Biosense Webster).

Recently, ICE catheters have been integrated with electroanatomical mapping systems which construct three dimensional (3D) images (CartosoundTM, Biosense Webster, Diamond Bar, CA, US). These systems are equipped with an ICE probe with a location sensor tracked by the mapping system, which can map endocardial contours of the left atrium (LA) and PVs while the catheter is still in the right atrium (RA). The integrated system can visualize the interatrial septum during transseptal puncture and monitor the catheter’s position and stability. It can also detect complications, such as catheter-related thrombus formation and pericardial effusion, and identify PV stenosis. The Soundstar catheter in conjunction with the Cartosound system has been used to identify scar tissue and facilitate catheter ablation in ventricular tachycardia (VT).

The NIÖBE™ magnetic navigation system (MNS, Stereotaxis, St Louis, MO, US) employs a soft ablation catheter that is manipulated by two external magnetic fields situated on either side of the patient. The catheter tip aligns with the magnetic vector produced by the system, allowing the operator to navigate the catheter to the desired site, minimizing physical stress and radiation exposure for the physician. The MNS is used in conjunction with the Cartosound electroanatomical mapping system which tracks the location of the catheter in real-time and shares this information with the MNS. After the magnetic vector is selected, the catheter can be advanced or retracted by increments of 1 mm along the chosen vector. When the catheter has been placed in the cardiac chamber, the cardiodrive automatic advance allows remote manipulation from a control room utilizing joystick, keyboard, or mouse control of the catheter and also remote control of the fluoroscopy.

The first application of ICE was as an imaging modality in the closure of ASDs, which has been found to be safe and effective with promising
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Figure 1: A 37-year-old Female Previously had a Heart Surgical Closure of an Atrial Septal Defect

The image of a 37-year-old female patient’s heart showing the tip of the intracardiac echocardiography (ICE) catheter (top arrow) and the way the anatomy had been reconstructed in addition to the tricuspid valve (bottom arrow). The different colors illustrate the activation map and the mechanism of the atrial flutter.

long-term results. The technique may also be used in valve replacement and repair. The need for ICE guidance of interventions for anatomical device placement for closure of ASDs has been largely superseded by extremely aggressive approaches to EP ablation therapy for treatment of cardiac arrhythmias to assist transseptal puncture and localize catheters in proximity to anatomical landmarks including the cavopulmonary isthmus, AV nodal region and the upper and lower left pulmonary veins after entry into the left atrium. Direct imaging of these sites allows the accurate guidance of the ablative procedure and shortens the fluoroscopy time. ICE also permits continuous monitoring for radiofrequency (RF) energy delivery during ablation, hemodynamic performance of the myocardium, and pericardial space monitoring. ICE is now well established in guidance of transseptal catheterization. The use of ICE catheters also facilitates the visualization of other specific regions, such as the crista terminalis, the Eustachian ridge, the tricuspid annulus and the coronary sinus ostium that cannot be adequately visualized at fluoroscopy. More importantly, ICE catheters allow for safe transseptal puncture. With the application of this device, complex EP procedures become easier and safer to perform. Realtime anatomy can be obtained with ICE thereby providing cardiologists with a more thorough understanding of the mechanism of arrhythmias. This underlies the success of this technology in the EP lab. In particular, when working on a system remotely and without direct contact with the patient, a realtime anatomy of the heart helps physicians navigate the map and accurately position the working tip.

Another major use of ICE in EP is in catheter ablation of atrial fibrillation (AF). The prevalence of AF is increasing, and curative procedure for AF remains a major goal in clinical CE. Ablation studies to isolate the pulmonary vein (PV) have become the treatment of choice for patients with AF. The procedure is associated with good success rates and long-term effectiveness. However, it remains technically challenging, results are difficult to replicate, and success is dependent on operator expertise. ICE imaging facilitates the ablation of AF by enabling direct visualization of the PVs, the location of the atrial-venal junction and the location of the ablation catheter tip within the PV antrum. The technique is also employed in other complex arrhythmia ablations. Identification of areas prone to arrhythmogenicity facilitates ventricular fibrillation (VF) catheter ablation. Furthermore, direct monitoring of complications by ICE potentially increases the safety of VF ablations. Single-use ICE catheters are expensive, but a study of their application in paroxysmal atrial fibrillation suggested that the avoidance of general anesthesia might result in overall cost savings.

These novel technologies provide physicians with realtime mapping of the heart and constant information regarding the location of their working tip thereby allowing for safer, simpler, and more effective cardiac interventions in the EP laboratory. Exposure of patients and staff to X-rays and fluoroscopy is also reduced. This article will use four case studies to illustrate the successful clinical application of ICE catheters in a selection of patients and procedures as well as review studies that demonstrate the efficacy and safety of these new techniques.

Case Studies

The following case reports of four patients demonstrate the use of these technologies in effectively performing a variety of EP procedures in a clinical setting.

Case 1—Atypical Right-sided Atrial Flutter
A 37-year-old female had previously had a heart surgical closure of an ASD. For one year, she had symptomatic atrial flutter with a 3:1 conduction. The use of the MNS and 3D reconstruction identified a wave mechanism which includes the tricuspid valve and the scar of the ASD closure patch. The arrhythmia was corrected by creating a line of block with the right-sided isthmus connected to the patch, which was then connected to the venacava superior. Using the ICE catheter, it was possible to create a 3D anatomy of the RA and LA as can be seen in Figure 1. The image is projected with the Mapping 3D carto system which is effective in identifying the mechanism of the arrhythmia (early [red] meets late [blue] area). Figure 1 shows that the mechanism is not only around the tricuspid valve but also the septal part of the RA or scar.

Case 2—Ventricular Tachycardia
A 17-year-old female presented with high frequent symptomatic long-lasting VT. No structural heart disease was detected. Reconstruction of the left ventricle was performed using AcuNav ICE together with 3D reconstruction using the Cartosound system. Following trans-septal puncture, a fascicular origin of the VT in the left septum was identified; successful ablation was completed through guidance with MNS. No recurrence was reported in a three-month follow-up. Total X-ray exposure to the patient was limited to only 2.1 minutes for the entire procedure.

Case 3—Atrial Fibrillation Ablation
A 46-year-old female presented with paroxysmal high symptomatic atrial fibrillation despite antiarrhythmic therapy. Attempted PV isolation was complicated by pericardial effusion. Four weeks later, ICE and MNS was used to guide approach with trans-septal puncture and reconstruct the left atrium. The PV isolation was subsequently completed safely and successfully. At six months after the procedure, the patient had stable sinus rhythm.
Case 4—Ebstein Anomaly
A 72-year-old female presented with a challenging heart anatomy due to an ‘Ebstein’ anomaly; for three years, she experienced atrial arrhythmias. She had been taking amiodarone for two years and two months ago required external KV. During the EP study, the complex anatomy of the Ebstein heart was reconstructed with ICE-catheter. A focal atrial arrhythmia was identified as the clinical documented arrhythmia with a cycle length of nearly 340 ms. After rebuilding an activation map with Carto 3, a successful ablation with termination and not re-inducibility was performed via MNS.

Clinical Studies
Numerous clinical studies have demonstrated that the use of AcuNav ICE catheters, the Cartosound electroanatomical mapping systems and the Stereotaxis MNS allow shorter procedure times and minimize radiation risk in cardiac ablation procedures without compromising efficacy. Early studies employing ICE catheters in AF ablations imaged the LA indirectly from the RA,25,26 which may result in suboptimal LA visualization. However, a subsequent study found that direct LA imaging with placement of the ICE catheter in the LA is feasible and results in improved visualization and image integration.27 In a randomized controlled trial (n=60), PV antrum isolation (PVAI) using ICE guidance was found to result in a reduced incidence of atrial tachyarrhythmias off antiarrhythmic medication compared to circumferential PV ablation (CPVA).28 A prospective comparison (n=95) of ICE and TEE in patients with AF undergoing right heart catheterization who underwent LA and interatrial septal (IAS) demonstrated that the two techniques had equivalent efficacy.29 In a study of patients (n=315) undergoing PV isolation for treatment of AF, the use of the AcuNav catheter was more effective than angiography-guided circular mapping. In addition, monitoring of energy delivery using ICE further improved long-term success and was associated with a decreased risk of embolic complications.30

In a recent study, patients (n=60) were randomized to AF ablation with Cartosound electroanatomical mapping integrated with either preprocedural magnetic resonance imaging (MRI), ICE, or a combination of the two. Total procedural time and total ablation time were similar between groups. A higher fluoroscopy time was found in the MRI group (24 versus 11 and 14 minutes with ICE and ICE/MRI, respectively; p<0.005) as well as a longer time spent in the LA (109 versus 78 and 75 minutes with ICE and ICE/MRI respectively, p=0.03) in comparison to ICE integration. At a mean follow-up of nine months, there were no significant differences in AF recurrences among the groups.31 It has recently been reported that combined epicardial and endocardial mapping and ablation is a feasible and reasonably efficacious option for monomorphic VT (MMVT) in patients with hypertrophic cardiomyopathy (HCM) if refractory to aggressive trials of antiarrhythmic drugs and anti-tachycardia pacing.32

Considerable published data supports the use of MNSs in cardiac ablation. A study comparing MNS with manual ablation techniques for various arrhythmias in 58 pediatric patients found significant decreases in the procedure and fluoroscopy times (139 minutes versus 204 minutes and 13 minutes versus 31 minutes, respectively; p=0.01 and p=0.04).33

The largest body of clinical trial data for ablation of supraventricular tachycardia (SVT) utilizing MNS involves ablation of atrioventricular nodal
Electrophysiology

Figure 4: 3D Reconstruction of the Complex Anatomy (Ebstein) of the Right and Left Atriums of a 72-year-old Female Patient

Activation projection of the atrial arrhythmia was created using the cartosystem. Red dots represent the ablation points with termination and elimination of the arrhythmia.

reentrant tachycardia (AVNRT). The first randomized trial was the Helios Electrophysiology Ablation Remote Treatment (HEART) trial which randomized patients to ablation with MNS or manual navigation. Total fluoroscopy time was reduced by a median 17.8 minutes in the MNS group compared with manual navigation (p<0.05). The acute success rates did not differ between groups. The number of lesions delivered was less for magnetic navigation (6 versus 10, p<0.05). Total procedure time and complication rates were similar between the groups. A review of seven published studies of MNS for ablation of AVNRT involving a total of 221 patients found combined acute and intermediate success rates of 95 and 93%, respectively. When these data were compared to manual navigation, fluoroscopy time (10.6 versus 15.0 minutes, p=0.043) and total patient radiation exposure were significantly lower in the MNS group. However, total procedure time (113.5 versus 77.2 minutes, p<0.0001) and RF application duration (17.1 versus 7.5 minutes, p<0.0001) were significantly longer in the MNS 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).

Ablation utilizing MNS is well suited for VT as it enables fine movements of the catheter for precise activation and pace mapping while minimizing damage to thin-walled outflow regions, valvular structures, and coronary ostia. A recent study (n=610) found that the use of MNS improves safety without compromising efficiency of ablations. MNS was more effective than manual ablation for VT with acute success rates of 93 versus 72% in those treated by manual techniques (p<0.05). A systematic review of 11 published studies of MNS in the ablation of VT found success rates ranging from 71 to 80% in patients with ischemic cardiomyopathy, 50–100% in patients with non-ischemic cardiomyopathy populations and 86–100% in patients with structurally normal hearts. In a recent analysis of ablation data of 113 consecutive patients with VT treated with catheter ablation, the rate of acute success was 82% in those treated by MNS versus 66% treated by manual techniques (p=0.046). The overall procedural time (177 versus 232 minutes, p=0.01) and mean patient fluoroscopy time (27 versus 56 minutes, p<0.001) were significantly lower using MNS. After 20 months follow-up, VT recurred in 23.7% of the MNS group versus 44.4% in the manually treated group (p=0.047).

The use of RMS also offers advantages in complex anatomic situations. A study of the Stereotaxis MNS in combination with the Cartosound system in patients (n=36) with arrhythmias associated with complex congenital heart disease (CHD) had a success rate for CHD complexity of type I, II, and III of 50, 88, and 89%, respectively. No major complications related to the procedures occurred. Of the patients, 67% remained free of recurrence during a mean follow-up of 26 ± 4 months. Recurrence developed in 0%, 16%, and 45% of patients with CHD type I, II, and III, respectively.

In summary, the use of integrated ICE catheters, electroanatomical mapping systems and MNS have been studied across the whole range of cardiac arrhythmias and have shown improved outcomes compared to manual techniques in a number of clinical situations, particularly ablation of SVTs. Although the integrated systems have not yet demonstrated superiority over manual techniques in the ablation of AF and atrial flutter, any novel technology has a learning curve and early results will need to be compared to data available as the number of reported cases continues to grow.
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Future Developments

A recent review concluded that new technologies are still necessary to improve MNS ablation for AF.10 Furthermore, identifying the ideal candidate for this technique remains a significant challenge. A recent study has found that circumferential PV antral scarring predicts ablation success in mild LA fibrosis, while posterior wall and septal scaring is needed for moderate fibrosis.11

Although MNS has been demonstrated to be safe and effective for ablation of atrial arrhythmias, optimal outcomes often require frequent manual manipulation of a circular mapping catheter. The Vdrive robotic system (‘Vdrive’) allows remote navigation of circular mapping catheters, and when integrated with MNS enables a fully remote procedure. A prospective, multi-centre, non-randomized consecutive case series (n=94) found that the procedure is feasible and safe in the ablation of atrial arrhythmias.12 Finally, the 3D technology will likely be included in the ICE catheter in the future thereby improving upon current two dimensional techniques and providing a better anatomy and image of the heart. The remote procedure will also become easier as physicians will be able to see the online and movement of the catheter within the heart in 3D.

Summary and Conclusion

The clinical study data and case presentations have demonstrated the effectiveness of new technologies in EP. The AcuNav ultrasound catheter gives real-time visualization of the surrounding structural anatomy and provides additional anatomic information during EP procedures. Stereotaxis™ MNS navigation system further contributes to the accuracy of the images produced. The use of these systems has been applied to the entire spectrum of cardiac arrhythmias. Together, these innovations allow clinicians to obtain realtime, high-resolution images of the heart, making complex procedures more manageable with fewer complications.

As the demand for catheter ablation for arrhythmias such as AF rises and the number of centers performing these ablations increases, the demand for systems which reduce the level of expertise required and improve the safety of the procedure will also increase.

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