

# Catheter Ablation Without Fluoroscopy: Current Techniques And Future Direction

Amee M. Bigelow, MD<sup>1</sup>, Grace Smith, MD<sup>2</sup>, John M. Clark, MD<sup>2</sup>

<sup>1</sup>Akron Children's Hospital, Department of Pediatrics, Akron OH. <sup>2</sup>Akron Children's Hospital, The Heart Center, Division of Pediatric Cardiology, Akron, OH.

## Abstract

**Background:** Catheter ablation is the treatment of choice for most forms of SVT. Traditionally, fluoroscopy has been the primary tool for visualizing catheter position. However, newer, 3-dimensional mapping technologies offer multiple options for minimizing fluoroscopy use. We review our 8 year experience of a zero-fluoroscopy approach using the Ensite system, and discuss our current techniques.

**Methods:** From January 2006 to October 2013, we performed 524 catheter ablation procedures with a zero-fluoroscopy approach. The Ensite system was used exclusively. Early in the study, NavX mode was employed. In the later time period, Velocity mode was used. The Ensite system allowed easy access to all right sided arrhythmias. For left sided arrhythmias, TEE was added to aid with transseptal puncture.

**Results:** Reviewing 524 consecutive procedures, mean age was 14 years (range 7 weeks to 65 years). Mean weight was 60.7 kg (range 3 to 174 kg). Mean procedure time was 142 minutes (range 42 – 402 minutes). There were no complications. Twenty-five patients required the use of fluoroscopy, mostly as part of simultaneous diagnostic or interventional cath procedures. There was only one instance in which fluoroscopy was used when not anticipated at the start of the procedure. With this data available, and seeing that fluoroscopy is rarely needed unexpectedly, we hypothesized that catheter ablation no longer requires a traditional cath lab. We present our early approach to ablation outside the catheterization lab.

**Conclusions:** Three dimensional mapping systems can eliminate fluoroscopy use in virtually all routine ablation procedures. As technology improves, ablation procedures will shift beyond the traditional cath lab.

## Introduction

Awareness of radiation exposure has changed significantly in recent years. In 1980, the most common source of radiation exposure for a US citizen was environmental. By 2006, that had been surpassed by medical radiation exposure. From 1980-2006, there was a 600% increase in medical radiation exposure.<sup>1</sup> Although medical imaging and procedures are diagnostically and therapeutically beneficial, there are long-term risks associated with such radiation exposure, which include dermatitis, cataracts, thyroid disease, and inducing malignant transformation.<sup>1-5</sup> According to most reports, children carry a 3 to 10-fold increased risk of malignancy compared to adults and have a longer life expectancy in which to express risk.<sup>5,6</sup> In addition to patients, these risks also accrue to medical personnel.<sup>5,7-10</sup>

## Key Words:

AtrialFibrillation, Stroke, Bleeding, Risk Assessment.

**Disclosures:**  
None.

**Corresponding Author:**  
John Clark, MD  
Heart Center, Division of Pediatric Cardiology  
Director, Arrhythmia Center  
Akron Children's Hospital  
One Perkins Square, Akron, OH 44308

Furthermore, breaks in double stranded DNA are generally considered the alterations responsible for the late effects of ionizing radiation, such as cancer.<sup>11</sup> In 2009, Beels et al. reported an elegant study, which prospectively looked at 49 children undergoing non-EP cardiac catheterizations. Peripheral blood lymphocytes were analyzed before and after the procedure and the number of DNA breaks in each cell were counted to assess how radiation contributes to DNA breaks.<sup>12</sup> They reported a significant number of DNA breaks at almost any dose of radiation, which was 4-fold greater than what had been predicted.<sup>12</sup> In recent years, the guiding principle has been to reduce radiation exposure to patients and medical personnel to "as low as reasonably achievable" (ALARA). This focus is especially important in the pediatric population.

As medical specialists began to focus attention on radiation reduction, the general public's awareness of medical imaging and procedural radiation risks has also grown. With this information before the public eye, the medical field is again challenged to minimize medical radiation. After mechanical barriers were developed for personnel, such as lead aprons, goggles, thyroid collars and shielding, occupational doses of radiation dramatically declined.<sup>5,13</sup> In EP studies, there have been technological advances to reduce radiation exposure, including better beam filtering, digital image enhancement,

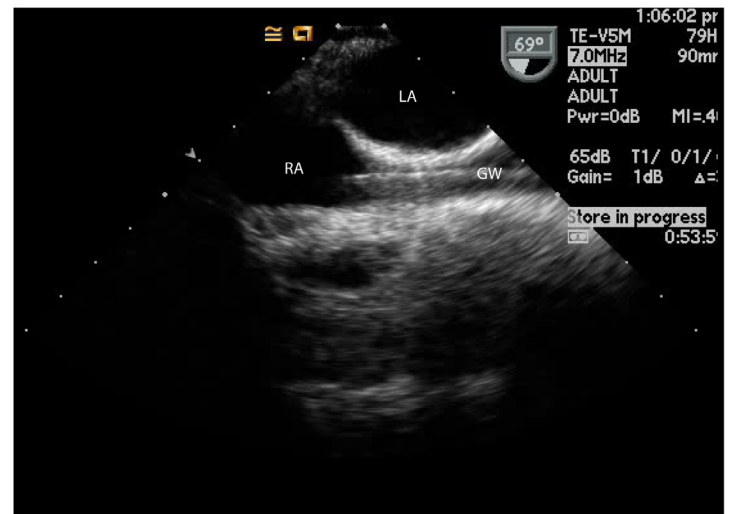
and fewer pulses/second. The most significant advance in radiation minimization, however, resulted from the development of three-dimensional mapping systems.

In 2002, shortly after 3-D mapping tools became available, a Journal of Cardiovascular Electrophysiology editorial questioned the value and feasibility of 3D mapping.<sup>14</sup> Since then, its utility has been demonstrated in multiple reports. In 2002, Drago reported the first experience of catheter ablation without use of fluoroscopy. However, technical limitations of 3-D mapping tools at that time constrained their use.<sup>15</sup> A 2006 report documented a series of adult patients in which fluoroscopy was minimized or eliminated.<sup>16</sup> A year later, the first series of catheter ablation without fluoroscopy in pediatrics were reported.<sup>17,18</sup>

In this article, we report our experience with more than 500 ablation procedures and discuss the direction we believe catheter ablation is headed in the future.

### Material & Methods

All but two procedures were performed under general anesthesia. The EnSite system (St. Jude Medical Inc., St. Paul, MN, USA) was used in NavX/Velocity mode. A 5F octapolar, steerable CRD2 catheter (St Jude Medical) was placed from the right femoral vein and advanced up the inferior vena cava (IVC) to the right atrium, and confirmed by the presence of atrial electrograms. For most procedures, an initial geometry is drawn consisting of SVC, IVC, right atrium, tricuspid valve and coronary sinus. The location of the His bundle is also marked. This process takes about 5 minutes at the start of the procedure. All EP catheters can then be maneuvered within this created geometry with real-time, continuous visualization (Figure 1). For all manifest accessory pathways, as well as AVNRT ablations, two catheters are utilized. The CRD2 catheter is positioned in the coronary sinus and the ablation catheter targets the substrate. For concealed accessory pathways a third catheter is positioned in the RV apex to allow for ventricular pacing during mapping and ablation. Standard atrial and ventricular protocols were then performed. This basic geometry is adequate to allow mapping of all right-sided arrhythmias. However, left-sided arrhythmias present a different set of obstacles. In most pediatric labs, ablating left sided arrhythmias involves performing a transseptal puncture. The transseptal sheath cannot be visualized on the Ensite system. Therefore, left-sided



**Figure 2:** Performing transseptal puncture by TEE with guide wire visualized in SVC

LA=Left atrium.RA=right Atrium.Gw=Guide Wire

substrates could not be reached using the 3D mapping system alone.

For left sided arrhythmias, we perform transseptal puncture utilizing TEE guidance. A guide wire is advanced up the SVC and visualized by TEE (Figure 2). The transseptal sheath is then advanced over the wire and the wire exchanged for the transseptal needle. The sheath is then positioned in the fossa ovalis. When the fossa is shown to be tenting into the left atrium with the correct orientation, (Figure 3) the needle is advanced. Saline contrast is used to confirm that the needle tip is in the left atrium and the sheath is advanced over the needle. The ablation catheter can then be positioned in the left atrium and geometry drawn, (Figure 4). It is possible to visualize the transseptal needle on the Ensite system. If an electrical coupling is established with the proximal end of the transseptal needle, the distal tip will show up on the 3D mapping system as a single point in space. However, it will only show up after the needle has exited the tip of the dilator. Because of this, there is no practical application of visualizing the transseptal needle on the 3D mapping system, and some other means of visualization must be utilized. With the combined tools of the Ensite system and TEE, fluoroscopy can be eliminated in nearly all routine EP procedures.

For right-sided arrhythmia substrates, patients were not anticoagulated. For left-sided targets patients were anticoagulated with heparin to achieve an activated clotting time of 250 seconds.

As this study is from a pediatric lab, there were no ablations of atrial fibrillation performed.

For all arrhythmia targets in the midseptal or anterosseptal location, cryoablation was performed. For all free-wall substrates, radiofrequency was the preferred energy source.

### Results

At our institution, from January 2006—to October 2013, we performed over 500 procedures with a minimal or no fluoroscopy approach. In 524 consecutive procedures, 499 of those were completed without the use of fluoroscopy. Age range was between 7 weeks and 65 years with a mean age of 14 + 7 years; and weight ranged from 3 to 174 kg with a mean weight of 60.7 + 23kg. Mean procedure time was 142 minutes with a range of 42 minutes to 402 minutes. No significant complications occurred. Fluoroscopy was used in 25 patients, most of whom were undergoing an interventional



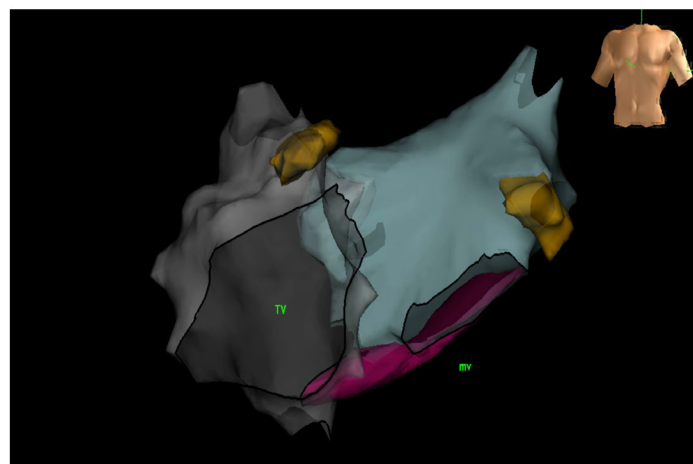
**Figure 1:** Typical,full right sided geometry as drawn by Ensite System

or diagnostic catheterization at the same time. However, in three patients, the ablation could not have been completed without the use of fluoroscopy. Of these, the first patient was a small 4-year old with a left-sided accessory pathway. The procedure was performed early in our experience with TEE and transseptal puncture. The TEE was technically difficult and adequate images necessary to perform the transseptal puncture could not be obtained, so fluoroscopy was used. The second case was a 14-year old patient with WPW and SVT in whom the procedure needed to be performed awake. She had a left sided pathway and TEE could not be performed with her awake, so fluoroscopy was used for transseptal puncture. The third patient was a 23-year old patient s/p mustard atrial switch procedure who had intraatrial re-entrant tachycardia. He also had a transvenous atrial pacemaker. The pacing lead cannot be visualized on NavX, so fluoroscopy was used to avoid entanglement or RF lesions on the pacing lead. In two of these three patients, fluoroscopy use was anticipated before the case started. Therefore, in 524 consecutive procedures, unplanned fluoroscopy was required only once.

### Discussion

This report summarizes our experience with a zero fluoroscopy method for both left and right-sided ablation procedures. Three-dimensional mapping without fluoroscopy provides a number of important benefits: 1) decreased radiation exposure, with its attendant risks; 2) staff comfort, and 3) easier access to ablation for certain populations, such as during pregnancy or radiation therapy.

The initial advantage of zero fluoroscopy results from the decreased radiation risk to patients and staff. We noted a significant reduction in radiation exposure after implementing a zero fluoroscopy approach, as reflected in radiation badge readings. (Figure 5). Nearly all radiation exposure seen on radiation badge readings now comes from device implants or background environmental radiation. With this zero fluoroscopy approach, lead vests and protective shields have been virtually eliminated. For more than five years we have not needed lead aprons in our lab. This not only makes the procedure more comfortable for the staff, but may also decrease the long-term likelihood of developing spinal orthopedic problems, which are well described.<sup>19</sup> A zero fluoroscopy approach also allows us to perform ablations on patients in whom radiation would otherwise be

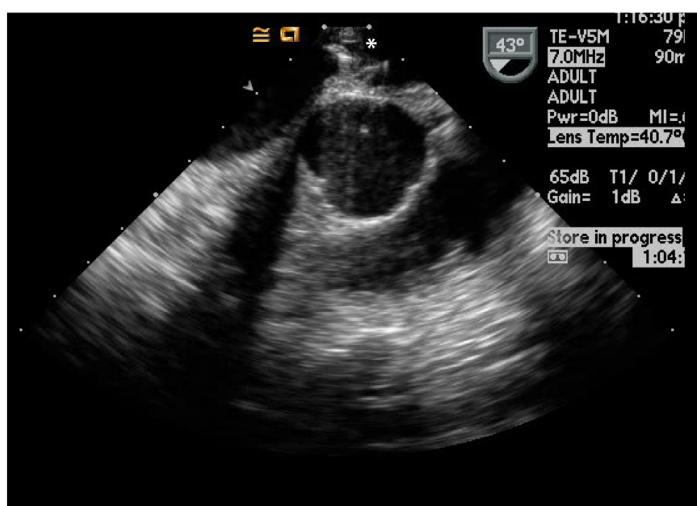


**Figure 4:** Right atrial(gray),left atrial(blue),and coronary sinus (magenta) geometries as drawn with Ensite System.

contraindicated.

Our institution, as well as others, has shown the feasibility of performing catheter ablation without radiation in the pregnant female.<sup>20-24</sup> In addition, we have had two staff members become pregnant and were able to continue their job in the EP lab throughout pregnancy, without the risk of an occupational hazard such as radiation. We have also had one referral for catheter ablation of SVT in a woman who had reached her maximum dose of radiation exposure due to radiation therapy for breast cancer. In this instance, the procedure was easily performed without additional radiation exposure to the patient. Although these isolated scenarios are uncommon, the capability to prevent radiation is tremendously beneficial to the patient's overall care.

Our institution uses the EnSite system exclusively. The alternative system most commonly used is CARTO (Biosense Webster, Diamond Bar, CA, USA). Each of these two systems functions in a unique manner. In the EnSite system, catheter electrodes are detected and displayed based on impedance measurements from three separate, orthogonal electrical fields. We find this system provides two important benefits: 1) it creates highly accurate geometry in minutes, and 2) any catheter can be visualized within the system. The system's drawbacks include a "drift" or "shift" in geometry resulting



**Figure 3:** Transseptal dilator seen "tenting" the fossa ovalis.

\*Dilator trip is aiming appropriately into left atrium, while avoiding aortic valve.

### Radiation Badge Readings

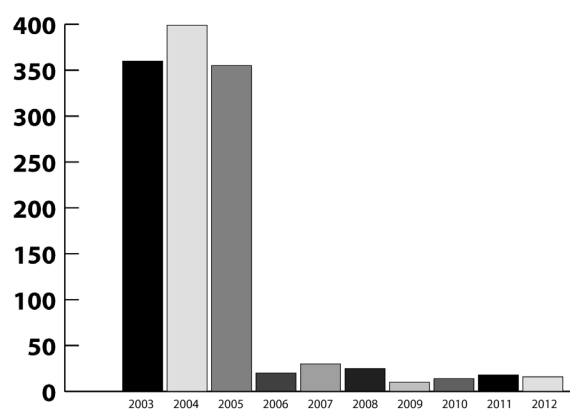


Image 5. Annual radiation badge readings from pre and post adoption of a minimal fluoroscopy technique.

**Figure 5:** Annual radiation badge readings from pre and post adoption of a minimal fluoroscopy technique.



**Table 1:** Characteristics of Patients Undergoing AF Ablation by Sex

Study	Left atrial diameter (mm)		LVEF (%)		Comorbidities (%)		
	Women	Men	Women	Men		Women	Men
Forleo, 2007	44.0±6.5	40.6±6.3*	57.4±3.4	57.0±7.5	HTN	52.1	30.7*
					Valvular disease	15.5	5.3*
					Stroke	8.5	8.7
					Structural heart disease	32.4	23.3
Patel, 2009	43±0.5	46±0.3*	56±8	49±5*	HTN	55.2	40*
					Diabetes type II	15	11*
					Stroke	3.8	1.6*
					CAD	11.3	7*
Zhang, 2013	45.9±0.5	45.5±5.7	59.6 ± 4.2	58.3± 6.2	HTN	42.5	40.1
					Rheumatic heart disease	19.2	1.4*
					Stroke	11.0	8.8
Takigawa, 2013	37.2±5.0	38.0±5.1	68.6 ± 6.2	65.6± 7.0*	HTN	46.5	43.1
					Valvular disease	7.0	4.4
					Stroke	7.7	7.5
					Structural heart disease	17.8	16.4

AF: atrial fibrillation; CAD: coronary artery disease; HTN: hypertension; LVEF: left ventricular ejection fraction. \*P < 0.05

from impedance changes as lung volumes or total body fluid volume changes. Shift could also occur from patient perspiration resulting from the administration of isoproterenol, as well as from changes in reference electrode contact. We find the optimal way to overcome this is to position a catheter in the coronary sinus, which provides a quite stable position to follow for evidence of shift or drift. Because of the confined size, shape and location of the coronary sinus, we can identify even small amounts of drift. Another helpful maneuver is to localize and mark the His bundle. If there is a question about catheter drift during the case, the His electrogram serves as a reasonable landmark for the geometry.

The CARTO system functions by measuring magnetic fields, rather than electrical impedances. Therefore, the CARTO system geometry is less prone to shift. It typically requires physical movement of the patient on the magnets to create any shift. This appears if the patient moves or simply coughs. Requirements for proprietary catheters and a significantly longer time to draw a reasonable geometry represent drawbacks of the CARTO system. Due to rapid improvements in both systems, the deficiencies of each are quickly disappearing.

In the early stages of our experience with minimal fluoroscopy catheter ablation, the most common reason for using fluoroscopy was with transseptal puncture. We chose transesophageal echocardiography (TEE) as our solution to the issue. This has proven effective, but other options include intracardiac echocardiography (ICE),<sup>25</sup> or intravascular ultrasound (IVUS).<sup>26</sup> The benefits of TEE include the capability to perform the study in any size patient as well as eliminating need for additional vascular access. In the pediatric population vascular access is often a limiting factor in the procedure. The downside of TEE is that an additional physician is needed to perform it, requiring orchestrating schedules to accommodate the transseptal puncture with TEE. By contrast, ICE and IVUS can be performed by the catheterizing physician, eliminating the need to coordinate the schedules of two physicians. This makes ICE and IVUS somewhat quicker to perform. The drawback, however, is that both require additional vascular access, which may be unavailable in small patients.

As previously stated, in more than 500 consecutive catheter ablations, unanticipated fluoroscopy was needed only once. As

technology and experience continues to evolve, permanently mounted fluoroscopic C arms will eventually become obsolete. We anticipate EP labs of the future will be completely portable. Convenience and flexibility will accrue when an ablation can be scheduled in any existing hospital operating room instead of exclusively in the cath lab, resulting in scheduling efficiencies. In addition, opening a portable EP lab will cost only a fraction of what is needed to construct a traditional catheterization lab.

Bringing the EP lab to some patients will also be safer than transporting the patient to the EP lab. This applies to the rare patient who presents in an incessant tachycardia with heart failure requiring ECMO support.<sup>27-28</sup> In that instance, it will be easier and safer to take the EP lab to the patient's bedside in the ICU, rather than attempting to transport the patient while on ECMO. Lastly, hospitals that adopt an early, aggressive approach to radiation reduction stand to see increased numbers of referrals and procedures due to today's level of public awareness and concern regarding radiation exposure.

Because of the above-mentioned factors, our hospital has adopted a protocol of performing catheter ablations outside of the traditional cath lab. Our first procedure was undertaken in October of 2013, on a 12-year-old male with AVNRT. Our decision tree is fairly simple: anyone who meets certain criteria can be scheduled for ablation in the OR instead of the EP lab. Exclusion criteria include children under the age of 5 years, complex congenital heart disease, a transvenous pacing device, or need for concomitant diagnostic or interventional cath. Schedules are verified to ensure availability of an echo physician in the event that TEE is necessary. Portable fluoroscopy is always readily available regardless of the room or location in which the procedure is being performed. This point must be emphasized. In the event that fluoroscopy is ever needed, it must always be immediately accessible. In addition, an echo machine is kept in the OR and turned on during the procedure. By adopting this approach, we are now routinely doing most of our ablations outside of the EP lab.

### Limitations

Zero-fluoroscopy ablation is still early in development, and ablation outside the cath lab is brand new. Therefore, all potential limitations are not yet known. A deliberate, planned, cautious approach is

**Table 2:** Outcomes of AF Ablation in Women

Study	Design (enrollment, N)	% Women	Age, years		% Paroxysmal AF		Success Rate, % (includes redo)		Complication Rate, %		Major Complication Type, %		
			Women	Men	Women	Men	Women	Men	Women	Men	Type	Women	Men
Forleo, 2007	Prospective, two center, cohort (221)	32.1	61.6 ± 8.3	56.9 ± 10.8*	56.3	61.3	83.1	82.7	5.6	4.7	Pericardial tamponade	2.8	1.3
											Thromboembolic	0	1.3
											Pericardial effusion	1.4	1.3
											PV stenosis	1.4	0.7
Patel, 2009	Retro-spective, multi-center (3265)	15.8	59 ± 13	56 ± 19*	46	55*	68.5	77.5*	5	2.4*	Hematomas	2.1	0.4
											PV stenosis	1.2	0.6
											Stroke	0.8	0.29
											Pericardial effusion	0.4	0.1*
											Pseudoaneurysms	0.6	0.9*
Zhang, 2013	Prospective, single center (220)	33.2	62.7 ± 10.6	61.1 ± 10.4	All persistent AF	35.6 (54.8)	57.1* (66.0)	8.2	3.4	Pericardial effusion	1.4	1.4	
										Pericardial tamponade	0	0.7	
										PV stenosis	0	0	
										Hematomas	6.8	0.7*	
										Pseudoaneurysms	8.2	3.4	
Takigawa, 2013	Prospective, single center (1124)	24	63.2 ± 9.1	60.0 ± 10.5*	All paroxysmal AF	56.4 (76.5)	59.3 (81.3*)	3.7	4.1	Tamponade/effusion	1.8	1.3	
										PV stenosis	0.3	0.1	
										Vascular injury	0.59	0.1	

n: number of patients enrolled. AF: atrial fibrillation; PV: pulmonary vein. \*P &lt; 0.05

necessary to define the learning curve and to delineate the potential pitfalls that have yet to be identified, as well as the tools necessary to advance the field.

### Conclusions:

In conclusion, catheter ablation can be routinely performed without fluoroscopy in the majority of procedures. By employing three-dimensional mapping and TEE, fluoroscopy is rarely required. The reduction and elimination of radiation has long-term benefits to both patients and staff. There are also significant cost-saving benefits to the hospital. As more demand is placed on industry to provide better tools for reducing radiation exposure, the technology will continue to evolve. Future EP labs are likely to be portable and institutions will not require a traditional catheterization lab.

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