1 Clinical Studies of a Purely 3D Navigation in Interventional Managements of Tachyarrhythmia

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Introduction

Catheter ablation has become the cornerstone treatment for tachyarrhythmias over the last 20 years [1]. Firmly established as first-line therapy for the treatment of right-sided arrhythmias (atrial flutter, atrial reentrant tachycardia, and atrioventricular nodal reentrant tachycardia), catheter ablation is moving toward becoming first-line therapy for complex arrhythmias such as atrial fibrillation and ventricular tachycardia [1, 2]. These complex ablations are often prolonged and require trans-septal puncture as well as use of several catheters from multiple access sites. A major downside to such complex procedures using conventional fluoroscopy is high exposure to radiation for both the patient and the electrophysiologist [3]. Radiation exposure poses significant risks to all those exposed in the electrophysiology lab. A typical procedure results in an estimated mean total radiation dose of 16.6 mSv (ranging from 6.6 to 59.2 mSv), equivalent to 830 chest X-rays, and is associated with a lifetime risk for a fatal malignancy estimated at 0.15% for female patients and 0.21% for male patients [3, 4].

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To counter these risks, there has been a movement toward non-fluoroscopic techniques allowing a zero or near-zero exposure [5]. These techniques have revolutionized our current practice of catheter ablation in the management of tachyarrhythmias [6]. These techniques include 3D mapping systems, remote magnetic navigation (RMN), contact force (CF) technology, and intracardiac echo (ICE). In addition to reducing radiation exposure, these techniques are thought to improve the accuracy of catheter ablation and allow the creation of an improved ablation lesion. Furthermore, these techniques reduce operator and staff fatigue due to the use of heavy-lead aprons when using fluoroscopy [7].

In this chapter, we review current technologies used for 3D navigation and their implementation and results in clinical practice as well as the state of utilization of these technologies in the targeting of different tachyarrhythmias.

Advanced 3D Electroanatomic Mapping Systems

There are variations in individual cardiac anatomy which warrant the use of a 3D electroanatomic mapping (EAM). Three-dimensional EAM systems, which were first introduced in 1997, have improved the understanding of cardiac chamber anatomy allowing precise catheter localization. EAM facilitates catheter ablation by keeping a

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catalog of activation time, voltage, and anatomic location at multiple points simultaneously and displaying them as readily understandable color-coded maps superimposed on the cardiac chamber geometry [8, 9]. Electroanatomic mapping systems can also display cardiac anatomy and sites of RF energy application with much more precision than fluoroscopic localization [9, 10]. Many arrhythmias have specific anatomic targets; electroanatomic mapping can greatly facilitate anatomic and scar-based ablation procedures [2, 11, 12]. Finally, by reducing the operator's need to use fluoroscopy to localize the mapping catheter, these systems have greatly reduced exposure to ionizing radiation [7].

Current 3D mapping systems used for electrophysiology catheter visualization include the following: CARTO (Biosense Webster Inc., Diamond Bar, CA), EnSite NavX and Mediguide technologies (Abbott, Abbott Park, IL), and Rhythmia (Boston Scientific, San Jose, CA) [9]. These EAM systems are able to integrate cardiac chamber anatomy acquired with the mapping catheter with an anatomical image that has been previously acquired with an imaging modality including fluoroscopy, MRI, or CT [13, 14]. This integrated imaging provides the electrophysiologist with an accurate rendering of cardiac anatomy to navigate catheters and perform ablation procedures [14].

One of the earliest studies using a mapping was performed by Gepstein and colleagues [15]. They used a non-fluoroscopic, catheter-based, endocardial mapping system and demonstrated highly reproducible and accurate results, both in vitro and in vivo. Gornick et al. also demonstrated the ability to place separate catheters at any site within the mapping chamber [16]. They also reported that the resolution of the 3D mapping system could be millimetric in size. The EAM systems facilitate the difficult interventional ablation procedure and can accurately navigate to a predefined site. It also shortens the fluoroscopic time and has a favorable spatial resolution [17]. In addition, after calculating and displaying the electrical activation sequence, the operator can visualize the activation sequence known as activation mapping and easily obtain the voltage information known as voltage mapping [9, 18]. Limitations of these systems include the need for patient immobility, accurate registration, and reference stability [18, 19].

Remote Magnetic Navigation

Remote magnetic navigation has been available as a tool for mapping and ablation since 2007. In that period of time, it has shown to be useful in most ablation procedures ranging from atrial flutter to ventricular tachycardia [20, 21]. 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 to guide the magnetic tip of the catheter [21]. A remote workstation, using a computer console that controls both the magnets and a motor-driven catheter, allows advancement or retraction of the catheter [20]. With a more flexible catheter tip, the catheter moves parallel to the lines of the magnetic field which are determined by the external magnet [21]. The operator can direct the catheter to the desired location within the cardiac chambers by adjusting the external magnetic field. RMN requires an electrophysiology laboratory with equipment designed specifically for magnetic guidance [22]. Potential benefits of remote magnetic navigation include more precise control of the catheter, facilitating more rapid and accurate guidance of the catheter, and significantly reduced radiation exposure [20, 22]. The softer and more flexible catheter tip theoretically reduces the risks of cardiac puncture and tamponade [21]. This lower risk comes with the possible disadvantage of smaller lesion volumes [12].

The efficacy and safety of RMN have been assessed in multiple studies especially in ablation of atrial fibrillation. In a cohort study of 356 patients, RMN did not decrease AF recurrence compared to manual navigation [23]. In addition, RMN was associated with a lower success rate of pulmonary vein isolation. However, the study showed lower procedural and fluoroscopic times as well as a trend toward a reduction in major complications [23]. In a systematic review and meta-analysis of seven studies, Proietti et al. did not demonstrate a reduction in AF recurrence or improved success of pulmonary vein isolation with RMN [24]. However, RMN was associated with a reduction in complications, procedural times, and fluoroscopic times [24]. Table 1.1 summarizes studies assessing the use of RMN in catheter ablation of AF.

More recently, RMN has been increasingly utilized for VT ablation. In a multicenter prospective observational study of 218 patients with structural heart disease, Di Biase et al. assessed the use of RMN compared to manual navigation in VT ablation in patients with ischemic cardiomyopathy [30]. In this study, RMN use was associated with a significant reduction in VT recurrence. In addition, another study showed a reduction in VT recurrence in patients with nonischemic cardio-

Table 1.1 Characteristics and results of studies assessing remote magnetic navigation in atrial fibrillation

Study first author (year)	Type of study	Population (number)	Results	Follow-up (months)
Arya (2011) [23]	Retrospective (single center)	70% Paroxysmal/30% persistent (356)	Similar freedom from AF at 6 months: 57.8% and 66.4% ($P = 0.196$). Longer procedure and ablation time with magnetic navigation 223 ± 44 min vs. 166 ± 52 min ($P < 0.0001$), and 75.4 ± 20.9 min vs. 53.2 ± 21.4 min ($P < 0.0001$).	6
Choi (2011) [25]	Retrospective (single center)	60% Persistent/40% paroxysmal (111)	Total procedure time was significantly longer (352 ± 50 min vs. 283 ± 75 min, $P < 0.0001$) and total fluoroscopy time was significantly shorter (99 ± 28 min vs. 238 ± 45 min, $P < 0.0001$) in the magnetic navigation group. Procedural success was similar in both groups (85% vs. 90%, $P = 0.08$).	3
Luthje (2011) [26]	Retrospective (single center)	67% Persistent/33% paroxysmal (161)	Procedural success and freedom from atrial fibrillation were similar in both groups (90% vs. 87%, $P = 0.6$, and 66% vs. 62%, $P = 0.8$). Magnetic navigation was associated with longer procedure duration (225.5 ± 54.6 min vs. 165.6 ± 52.4 min, $P < 0.0001$), longer ablation times (125.3 ± 46.5 min vs. 79.6 ± 28.5 min, $P < 0.0001$), and longer RF current application duration (50.4 ± 17.7 min vs. 43.9 ± 11.0 min, $P < 0.05$). However, fluoroscopy time was shorter (12, IQR = 9–17 min vs. 37, IQR = 29–44; $P < 0.0001$).	12
Miyazaki (2010) [27]	Retrospective (single center)	100% Paroxysmal (74)	Radiofrequency and procedure duration were higher in the magnetic navigation group (60 ± 27 min vs. 43 ± 16 min; $P = 0.0019$) and (246 ± 50 min vs. 153 ± 51 min; $P < 0.0001$). Freedom from atrial fibrillation was similar in both groups (69% vs. 62%, $P = 0.96$).	12
Solheim (2011) [28]	Retrospective (single center)	40% Persistent/60% paroxysmal (87)	Radiofrequency and procedure duration were higher in the magnetic navigation group (79 ± 19 min vs. 51 ± 25 min; $P < 0.001$) and (324 ± 74 min vs. 215 ± 61 min; $P < 0.001$).	4
Sorgente (2010) [29]	Retrospective (single center)	20% Persistent/80% paroxysmal (94)	Radiofrequency and procedure duration were higher in the magnetic navigation group (60 ± 27 min vs. 43 ± 16 min; $P = 0.0019$) and (246 ± 50 min vs. 153 ± 51 min; $P < 0.0001$). Freedom from atrial fibrillation was similar in both groups (66% vs. 67%, $P = 0.63$).	12

myopathy and scar-related VT [31]. Hendricks et al. also showed a significant reduction in VT recurrence with RMN in patients with idiopathic VT [32]. Turagem et al. performed a systematic review and meta-analysis of RMN versus manual navigation in VT ablation [30]. Compared to MAN, the use of RMN was associated with a 39% lower risk of VT recurrence (OR 0.61, 95% CI 0.44–0.85, $P = 0.003$). In patients with structural heart disease, there was a trend favoring lower VT recurrence with RMN versus MAN (OR 0.69, 95% CI 0.45–1.04, $P = 0.07$). In idiopathic VT, there was no significant difference between RMN and MAN (OR 0.58, 95% CI 0.31–1.1, $P = 0.1$) [30]. Studies assessing the use of RMN in VT ablation are summarized in Table 1.2. The ongoing MAGNETIC VT trial will assess if VT ablation using RMN results in superior outcomes compared to a manual approach in subjects with ischemic scar VT and low ejection fraction [37].

Ablation in patients with congenital heart disease is another avenue where RMN is important.

Table 1.2 Characteristics and results of studies assessing remote magnetic navigation in ventricular tachycardia

Study first author (year)	Type of study	Population (number)	Results	Follow-up (months)
Bauemfeind (2011) [33]	Prospective (single center)	Structural heart disease and idiopathic (83)	Magnetic navigation system was more successful for VTs (93% vs. 72%, $P < 0.05$). Less fluoroscopy was used in group MNS (30 ± 20 min vs. 35 ± 25 min, $P < 0.01$). There were no differences in procedure times and recurrence rates for the overall groups (168 ± 67 min vs. 159 ± 75 min, P = ns; 14% vs. 11%, P = ns; respectively).	15
Dinov (2012) [34]	Retrospective (single center)	Structural heart disease (102)	Acute success rate was similar in both groups (82% vs. 71%, $P = 0.246$). Remote magnetic navigation was associated with significantly shorter fluoroscopy time (13 ± 12 min vs. 32 ± 17 min, $P = 0.0001$) and ablation time (2337.59 ± 1248.22 s vs. 1589.95 ± 1047.42 s, $P = 0.049$), with similar total procedure time (157 ± 40 min vs. 148 ± 50 min, $P = 0.42$).	14
Akca (2012)	Prospective (single center)	Not available (28)	Overall recurrence rate and fluoroscopy time were significantly lower (25.0% vs. 41.4%, $P = 0.045$, and 22.8 ± 14.7 vs. 41.2 ± 10.9, $P = 0.011$) with magnetic navigation.	19
Szili-Torok (2012) [35]	Retrospective (single center)	Structural heart disease and idiopathic (113)	Higher acute success 82% vs. 66% ($P = 0.046$) and lower recurrence 24% vs. 44% ($P = 0.047$) with magnetic navigation. Overall procedural time (177 ± 79 min vs. 232 ± 99 min, $P < 0.01$) and mean patient fluoroscopy time (27 ± 19 min vs. 56 ± 32 min, $P < 0.001$) were all significantly lower using magnetic navigation.	20
Zhang (2013) [36]	Randomized (single center)	Idiopathic (30)	Procedural times were similar in both groups (131.8 ± 19.4 min and 115.1 ± 27.4; $P = 0.13$). Remote magnetic navigation was associated with 50.9% and 50.5% reduction in patients' fluoroscopic exposure and times, respectively, as well as 64% and 69% reductions in physician fluoroscopic exposure and times.	22
Hendricks (2015) [32]	Retrospective (single center)	Structural heart disease and idiopathic (198)	Procedural and ablation times were lower with magnetic navigation 150 (120–220) s vs. 190 (135–220) s and 400 (190–1065) s vs. 700 (300–1920) s. Higher acute success 88% vs. 71% ($P = 0.03$) and lower recurrence 42% vs. 57% ($P = 0.07$) with magnetic navigation.	25

Structural challenges such as the presence of baffles, conduits, patches, and shunts are better approached with RMN [38]. RMN provides several advantages in these complex congenital cases that may present with limited vascular access or difficult access to the target cardiac chambers due to previous surgical interventions [39].

Contact Force Technology

Tissue contact is critical to achieving lesion transmurality and success of radiofrequency ablation procedures. However, a delicate balance must be achieved. In power control ablation, the size and depth of ablation are directly related to the contact between the tip of the catheter and the myocardium [12]. The effectiveness of ablation may decrease if waste of resistive heating in the bloodstream occurs due to nonoptimal contact. Conversely, higher contact and excessive temperature rise may precipitate thrombus formation, steam pops, and myocardial perforation [40]. To overcome these issues, contact force-sensing catheters have been developed with the capability of monitoring in real time the degree of contact through a precision spring positioned on the tip and a sensor coil positioned on the shaft of the catheter [40].

Improving electrode-tissue contact maximizes the transfer of thermal energy to target tissue [41]. Increasing CF increases the proportion of the electrode surface in contact with the tissue. This reduces the electrode surface area that is exposed to the circulating blood pool, thus favoring greater current delivery to target tissue [40, 41]. Avitall et al. showed that increasing CF from 1 to 10 g led to greater deformation of the endocardium below the plane of the endocardial surface, which resulted in significantly greater lesion width and depth [42]. In a model, CF was demonstrated to wield as much influence on lesion size as RF power. When RF duration and power were kept constant, lesion depth, diameter, and volume increased proportionately with increasing CF. Importantly, lesion depth was greater with lower power (30 W) and moderate contact (40 g) than with higher powers (50 W) and lower contact (10 g) [42].

Contact quality is also critical. Spatiotemporal contact stability is predictive of lesion size [12]. Shah et al. showed that lesion volume was highest in constant contact, intermediate in variable contact, and lowest in intermittent contact [43]. Many factors affect spatiotemporal stability of contact: mean contact CF, cardiac and respiratory motion, catheter drift, and atrial arrhythmias [44]. The smaller lesion size that results from intermittent contact can be compensated for by increasing the duration of ablation.

Several studies have assessed the impact of contact force on procedural and clinical outcomes, mostly in catheter ablation of atrial fibrillation. Kerst et al. showed that contact force-guided and electroanatomic guided ablation is a feasible approach to achieve zero fluoroscopy. In a large retrospective study of 600 patients, contact force catheter ablation was associated with a decrease in atrial fibrillation recurrence and a decrease in total procedural time and ablation time as well as a significant reduction in fluoroscopic exposure. While there was a trend toward a lower complication rate including cardiac tamponade, this did not reach statistical significance [45]. In a meta-analysis of 11 studies including two randomized trials, Shurrab et al. showed similar findings [46]. The recurrence rate was lower with contact force (35.1% vs. 45.5%; OR 0.62, 95% CI 0.45–0.86, $P = 0.004$) as were procedural times (156 min vs. 173 min; standardized mean difference −0.85, 95% CI −1.48 to −0.21, $P = 0.009$) and fluoroscopic times (28 min vs. 36 min; standardized mean difference −0.94, 95% CI −1.66; −0.21, $P = 0.01$). There was a trend toward a decrease in major complications, but this did not reach statistical significance (1.3% vs. 1.9%; OR 0.71, 95% CI 0.29–1.73, $P = 0.45$) [46].

Intracardiac Echo

Intracardiac echocardiography (ICE) represents a major advancement in cardiac imaging and has become as indispensable part of electrophysiologic procedures [47]. ICE allows a real-time assessment of cardiac anatomy during interventional procedures and guides catheter manipulation in relation to the different anatomic structures [48]. A major advantage over transesophageal echocardiography is the ability to perform ICE by the primary operator [47].

Trans-septal puncture likely gives physicians the most pause when they consider a near-zero fluoroscopy approach. Many operators were trained using fluoroscopy to complete the critical steps of trans-septal puncture, which include placing the sheath and needle in the SVC, withdrawing the trans-septal apparatus into the level of the fossa ovalis, advancing and confirming the needle entry into the left atrium, and manipulating the dilator and sheath into the left atrium. For eliminating the need for fluoroscopy, ICE has become an indispensable tool for allowing safe trans-septal puncture. To place the guidewire and trans-septal sheath into the SVC, full visualization of the SVC right atrial junction is required. This view is obtained by positioning the ICE catheter in a neutral position in the mid-right atrium with appropriate clockwise or counterclockwise rotation to visualize the fossa ovalis and left atrium. From this position, posterior and rightward deflections are applied to fully view the SVC. Using this view, the guidewire, sheath, and trans-septal needle can be advanced into the SVC safely [49, 50].

With ICE, accurate 2D real-time and/or 3D imaging of the complex anatomy of LA and PVs is feasible [47]. Intracardiac ultrasound improves the efficacy of electrophysiological interventional procedures by exactly identifying anatomical structures and integrating this information with electrophysiological parameters and/or 3D reconstructions of CT/MRI data [51]. Early detection of periprocedural complications optimizes emergency management. Implementation of ICE in ablation procedures of AF results in reduction of fluoroscopy/procedure time, and potentially reduces complications and improves outcome [48].

Clinical Studies of Purely 3D Navigation

The abovementioned technologies have been utilized across the spectrum of ablation procedures performed in the electrophysiology lab. In a meta-analysis of ten studies in various cardiac arrhythmias that assessed the efficacy and safety of zero or near-zero fluoroscopic ablation, Yang et al. [52] found that zero or near-zero fluoroscopy ablation significantly showed reduced fluoroscopic time (standard mean difference [SMD] −1.62, 95% CI −2.20 to −1.05; $P < 0.00001$), ablation time (SMD −0.16, 95% CI −0.29 to −0.04; $P = 0.01$), and radiation dose (SMD −1.94, 95% CI −3.37 to −0.51; $P = 0.008$). This was done without any significant differences in acute or long-term success rates, complication rates, or recurrence rates [52]. Wannagat et al. showed that significant reductions in radiation exposures can be achieved in operators with varying degrees of experience (beginner, first-year fellow, second-year fellow, expert) without an increase in complications or procedure time [5]. Sadek and colleagues found that even complex ablations can be performed with zero fluoroscopy with a modest learning curve and no increase in procedural times [53]. Here, we review some of these studies in the context of the various arrhythmias. These studies are summarized in Table 1.3.

Atrial Flutter

Typical atrial flutter is an atrial arrhythmia in which catheter ablation is first-line therapy. The arrhythmia is maintained by a reentry mechanism in which the area between the tricuspid valve annulus and inferior vena cava forms a critical isthmus, known as the cavotricuspid isthmus, that is targeted for ablation [74]. Deutsch et al. demonstrated that complete elimination of fluoroscopy is feasible, safe, and effective during radiofrequency catheter ablation of atrial flutter [54]. The authors, in a study of 460 patients, compared techniques involving as low as reasonably achievable (ALARA) fluoroscopy and non-fluoroscopic techniques including electroanatomic mapping [54]. In another study, Schoene et al. used 3D mapping in 20 patients undergoing catheter ablation of the cavotricuspid isthmus and found no difference in freedom from recurrences, safety, and procedure duration while achieving a significant reduction

Table 1.3 Characteristics and results of studies reporting on purely 3D navigation

Study first author (year)	Type of study	Cardiac arrhythmia targeted (number)	Results	Follow-up (months)
Deutsch (2017) [54]	Prospective cohort study	Atrial flutter (460)	In the zero-fluoroscopy groups, the procedure time decreased (45.4 ± 17.6 and 47.2 ± 15.7 min vs. 52.6 ± 23.7 and 59.8 ± 24.0 min, $P < 0.01$) as compared to the as low as reasonably possible (ALARA) groups. In the zero-fluoroscopy groups, 91% and 98% of the procedures were performed with complete elimination of fluoroscopy and were associated with a significant reduction in fluoroscopy exposure (from 0.2 ± 1.1 and 0.3 ± 1.6 to 7.7 ± 6.0 min and 9.1 ± 7.2 min, $P < 0.001$) in the ALARA groups. No major complications were observed in either groups.	None
Schoene (2015) [55]	Randomized controlled trial	Atrial flutter (40)	Bidirectional isthmus block was achieved in all patients. Fluoroscopy time was significantly reduced in the zero-fluoroscopy group (0.3, IQR 0.2–0.5 min) when compared with the conventional group (5, IQR 4.2–11.5; $P < 0.001$). This resulted in a significant reduction in radiation dose in patients randomized to zero-fluoroscopy (17.4, IQR 11; 206.6 cGy cm) vs. the conventional group (418.4, IQR 277; 812.2 cGy cm; ($P < 0.001$). There were no significant differences in procedure duration between the zero-fluoroscopy group (49.5, IQR 37; 65 min) when compared with the conventional group (33.5, IQR 26.3; 55.5 min; $P = 0.053$). No adverse events were recorded. Freedom from atrial flutter at 6 months of follow-up was 19/20 (95%) in the zero-fluoroscopy and 18/20 (90%) in the conventional group, which was not statistically significant.	6
Alvarez (2011) [56]	Retrospective cohort study	Atrial flutter (80)	Success was obtained in 98.8% of the procedures; in 1 patient it was necessary to implant a pacemaker for sinus node dysfunction and 4 patients experienced minor complications. In 75 procedures (90.4%), fluoroscopy was not required.	None
Kopelman (2003) [57]	Randomized controlled trial	AVNRT (20)	Acute procedural success was 100% in both groups, with no complications. Although there were no differences in time taken for pre- and post-ablation electrophysiological evaluations, in the zero-fluoroscopy group, the ablation portion of the procedure showed a substantial reduction in duration (12.6 ± 6.8 min vs. 35.9 ± 18.3 min; $P < 0.001$) and fluoroscopic exposure (0.7 ± 0.5 min vs. 9.6 ± 5.0 min; $P < 0.001$) compared with the fluoroscopic group. This was reflected in reduced total procedure time (83.6 ± 23.6 min vs. 114 ± 19.3 min; $P = 0.008$) and total fluoroscopic exposure (4.2 ± 1.4 min vs. 15.9 ± 6.4 min; $P < 0.001$). Zero fluoroscopy was associated with a lower number (2.7 ± 1.6 vs. 5 ± 2.8; $P = 0.018$), duration (165.3 ± 181.6 s vs. 341 ± 177.7 s; $P = 0.013$), and total energy delivery (24.3 ± 3.1 W vs. 28.7 ± 4.5 W; $P = 0.042$) of radiofrequency applications. There were no acute or long-term complications or arrhythmia recurrence in either group	9
Luani (2018) [58]	Prospective cohort study	AVNRT/AVRT (25)	All EPS in the AVNRT subgroup could be accomplished without the need for fluoroscopy. Three patients (12%) required fluoroscopy during ablation. Mean EPS duration in the AVNRT subgroup was 99.8 ± 39.6 min, ICE-guided catheter placement 11.9 ± 5.8 min, time needed for diagnostic evaluation 27.1 ± 10.8 min, and cryo-application duration 26.3 ± 30.8 min.	None

(continued)

Table 1.3 (continued)

Study first author (year)	Type of study	Cardiac arrhythmia targeted (number)	Results	Follow-up (months)
Casella (2011) [59]	Retrospective cohort study	AVNRT/AVRT/ Atrial flutter (50)	In 38/50 cases (76%), a zero fluoroscopy approach was successfully attained. In the remaining 12/50 cases (24%), fluoroscopy use was limited to 122 ± 80 s, with a correspondingly low radiation exposure (dose area product 1.3 ± 1.1 mGy m). All procedures were acutely successful, with a procedural time of 113 ± 37 min, and without incurring in any major complication. Over a mean follow-up of 12 ± 3 months, there was one recurrence of AVRT and one of atrial flutter.	12
Clark (2008) [60]	Case series	AVRT (10)	All patients had acutely successful ablations, and none required the use of fluoroscopy. Mean procedure time was 4.4 h, with a range of 3.2–7.2 h. There were no complications. One patient (10%) had recurrence.	6
Scaglione (2015) [61]	Retrospective cohort study	AVRT (44)	Ablation without the use of fluoroscopy was successfully performed in every patient (33 with radiofrequency and 11 with cryoenergy). No complication occurred. There were seven recurrences (16%), of which three (43%) of them were successfully re-ablated without fluoroscopy.	16
Balli (2018) [62]	Retrospective cohort study	AVNRT/AVRT (109)	The mean procedure time was 109.8 ± 46 min, and the acute procedural success rate was 100%. Recurrence was noted in one patient (1%).	13
Bigelow (2014) [62]	Retrospective cohort study	AVNRT/AVRT (524)	Mean procedure time was 142 min (range 42–402 min). There were no complications. Twenty-five patients (5%) required the use of fluoroscopy, mostly as part of simultaneous diagnostic or interventional catheterization procedures. There was only one instance (0.2%) in which fluoroscopy was used when not anticipated at the start of the procedure.	None
Casella (2016) [63]	Randomized controlled trial	AVNRT/AVRT (262)	Zero fluoroscopy approach was associated with a significant reduction in patients' radiation dose (0 mSv, IQR 0–0.08 mSv vs. 8.87 mSv, IQR 3.67–22.01; $P < 0.00001$), total fluoroscopy time (0 s, IQR 0–12 s vs. 859 s, IQR 545–1346; $P < 0.00001$), and operator radiation dose (1.55 µS vs. 25.33 µS per procedure; $P < 0.001$).	12
Reddy (2010) [64]	Case series	Atrial fibrillation (20)	In all patients, single ($n = 18$) or dual ($n = 2$) transseptal access was successfully achieved. The left atrial-pulmonary vein anatomy was rendered using either a circular (14 patients) or a penta-array (6 patients) catheter in 22 ± 10 min; CT image integration was used in 11 patients. Using 49 ± 18 ablation lesions/patient, electrical isolation was achieved in 38/39 ipsilateral PV-isolating lesion sets (97%). The procedure time was 244 ± 75 min.	None
Razminia (2014) [65]	Case series	Atrial fibrillation (5)	A total of 20 pulmonary veins were identified and successfully isolated (100%) with the guidance of intracardiac echocardiography and three-dimensional electroanatomic mapping. No fluoroscopy was used for the procedures. There were no major procedural adverse events	None
Bulava (2015) [66]	Randomized controlled trial	Atrial fibrillation (80)	The total procedure duration and application time in both the zero-fluoroscopy and fluoroscopy groups were comparable (92.5 ± 22.9 min vs. 99.9 ± 15.9 min, $P = 0.11$, and 1785 ± 548 s vs. 1755 ± 450 s, $P = 0.79$, respectively). Zero fluoroscopic time was achieved in all patients in the zero-fluoroscopy group with the exception of one patient, where 8 s of fluoroscopy was needed to assess proper position of the guidewire in the femoral vein. No serious procedure-related complications were recorded and no differences in arrhythmia-free survival at 12 months were found between the groups.	12

Huo (2015) [67]	Randomized controlled trial	Atrial fibrillation (80)	Fluoroscopy time (10.42, IQR 8.45–12.46 min) vs. (1.45, IQR 1.05–2.22 min; $P < 0.001$) and radiation doses (2440, IQR 1593–3091 cGy cm) vs. 652 (IQR 326–1489 cGy cm; $P < 0.001$) in the zero-fluoroscopy group were significantly greater than those in the fluoroscopy group. The majority of reduction of radiation exposure was achieved after transseptal puncture, and near-zero fluoroscopic exposure procedure time did not differ significantly (1.39, IQR 1.18–2.10 h) vs. (1.37, IQR 1.17–1.50 h; $P = 0.362$). During follow-up, 61 patients (76.3%) had no recurrence of atrial arrhythmias. The recurrence rate between the 2 groups did not differ.	6
McCauley (2016) [68]	Case series	Atrial fibrillation (7)	Zero fluoroscopy procedure time was 183.9 ± 33.7 min versus 293.13 ± 129.9 min for conventional group controls ($P = 0.05$). Fluoroscopy time was 17.5 ± 14.1 min in zero-fluoroscopy patients versus 73.4 ± 50.3 min in controls ($P = 0.01$). AF recurrence in zero-fluoroscopy patients was 14% versus 25% in controls	12
Zhang (2017) [69]	Randomized controlled trial	Atrial fibrillation (342)	In group 1 (zero fluoroscopy), the average fluoroscopy time before LA reconstruction was similar to that in group 2 (conventional) (2.8 ± 0.4 min vs. 2.4 ± 0.6 min, $P = 0.75$). The average fluoroscopy time during ablation was significantly lower than that in group 2 (0 min vs. 7.6 ± 1.3 min, $P < 0.001$). The total X-ray exposure dose of the procedure in group 1 was significantly lower than that in group 2 (19.6 ± 9.4 mGy vs. 128.7 ± 62.5 mGy, respectively, $P < 0.001$). Kaplan-Meier analysis indicated that there were no statistical differences in the probability of freedom from atrial fibrillation recurrence at 12 months between group 1 and group 2 ($P = 0.152$). The success rate after a single ablation procedure and without drugs (Class I/III AAD) at 12 months was not significantly different between the 2 groups (67.6%, 95% confidence interval [CI]: 62–79.5% in group 1 and 68.9%, 95% CI: 63–80.7% in group 2, $P = 0.207$). Procedural related adverse events showed no significant different incidence between group 1 and group 2. A multivariate logistic regression analysis of risk factors was performed to evaluate the effectiveness outcome, which demonstrated that the percentage of contact force (within the investigator-selected work ranges) during therapy was significantly associated with positive outcomes (odds ratio: 3.68; 95% CI: 1.65–10.6, $P = 0.008$), whereas the LA dimension was negatively associated with effectiveness outcomes (odds ratio: 0.72; 95% CI: 0.52–0.84, $P = 0.016$).	12
Sommer (2018) [70]	Prospective cohort study	Atrial fibrillation (1000)	The median procedure time was 120 min, median fluoroscopy time was 0.90 min, and the median fluoroscopy dose was 345.1 cGy cm^2. Stratification of the first 750 patients (group 1) and the last 250 (group 2) cases showed significant improvement in the median procedure time (140–110 min) and reduction in the median fluoroscopy time (6–0.5 min) and the median dose (2263–151.9 cGy cm^2). The overall complication rate was 2.0%.	3
Cano (2016) [71]	Prospective cohort study	Ventricular tachycardia (41)	Median total fluoroscopy time and effective dose of 6.08 (1.51–12.36) min and 2.15 (0.58–8.22) mSv, respectively. Patients with ischemic VT had lower radiation exposure than patients with nonischemic VT (total fluoroscopy time, 2.53 [1.22–11.22] min versus 8.51 [5.55–17.34] min; $P = 0.016$). Epicardial access was associated with significantly higher levels of radiation exposure. Complications occurred in 4.9% patients, none of them being related to the use of the image integration tool. A near-zero fluoroscopy ablation could be performed in 14 of 44 procedures (32%), 43% of ischemic VT procedures, and 50% of procedures with endocardial access only.	None

(continued)

Table 1.3 (continued)

Study first author (year)	Type of study	Cardiac arrhythmia targeted (number)	Results	Follow-up (months)
Wang (2017) [72]	Prospective cohort study	Ventricular tachycardia (489)	The completely zero fluoroscopy approach was successful in 163 (100%) patients for electrophysiological study, and in 151 patients (94.4%) for arrhythmia ablation with 9 cases having to switch to the conventional approach due to the need for coronary angiography. There was no significant difference between the zero fluoroscopy approach and conventional approach in procedural success rate (84.1% vs. 85.4%, respectively), arrhythmia recurrence (1.9% vs. 2.2%), or severe complications (0.6% vs. 0.9%). The medical staffs using the zero fluoroscopy approach did not wear heavy protective apparels, and thus experienced significantly less fatigue compared with those using the conventional approach (2.1 ± 0.7 vs. 3.9 ± 1.6, $P < 0.05$).	
Akca (2012) [73]	Retrospective cohort study	Ventricular tachycardia (36)	In 31 patients, ablation was successful, with an endpoint of non-inducibility (86%). The success rate for congenital heart disease complexity of types I, II, and III was 50%, 88%, and 89%, respectively. The mean procedure and fluoroscopy time was 216 ± 101 and 40 ± 34 min, respectively. The number of radiofrequency applications was 42 ± 47. 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 congenital heart disease types I, II, and III, respectively	26

in radiation exposure [55]. Alvarez and colleagues reported the results of an observational study patients referred for atrial flutter ablation that utilized EnSite-NavX™ system to provide an almost zero fluoroscopy approach [56]. One or two diagnostic catheters and a cooled-tip ablation catheter were used in each procedure with the endpoint for success being bidirectional cavo-tricuspid isthmus block. Eighty-three ablation procedures were performed in 80 patients (82.5% men, 61 ± 10 years of age). Success was obtained in 98.8% of the procedures with the only major complication being the requirement of a pacemaker in one patient for sinus node dysfunction. In 90.4% of cases, fluoroscopy was not required, with visualization of the diagnostic catheters being the commonest reason for fluoroscopy use. Procedural time was similar to that seen using a conventional approach [56]. Macias et al. [75] showed that a zero fluoroscopy approach using the CARTO system yielded similar results to when using the EnSite-NavX with both systems leading to a high rate of procedural success and low rates of complications and recurrences. Both mapping systems allowed operators to avoid fluoroscopy in a very high percentage of cases, 90% [75].

AVNRT/AVRT

Atrioventricular-nodal reentry tachycardia (AVNRT) is a common supraventricular tachycardia and is also treated with catheter ablation as first-line therapy. Kopelman et al. were able to achieve a fourfold decrease in fluoroscopy duration using electroanatomic mapping and other non-fluoroscopic techniques [57]. Importantly, this did not compromise procedural efficacy and safety. Luani et al. demonstrated the safety and feasibility of using a zero fluoroscopy, ICE-guided approach to AVNRT ablation in 25 patients [58]. Similarly, Álvarez et al. [76] prospectively enrolled 100 patients with AVNRT who underwent catheter ablation by fluoroscopic versus non-fluoroscopic approaches. Procedural success was similar using the non-fluoroscopic approach (100%) and the fluoroscopic approach (96%) with no difference in complications, procedure, and ablation duration [76]. After an initial learning curve, catheter ablation of AVNRT can be performed in a similar timeframe using non-fluoroscopic technique [77]. Casella et al. [59] reported a case series of 50 patients who underwent electrophysiological testing and ablation for AVNRT and AVRT guided by electroanatomic mapping. In 78% of cases, acute procedural success was achieved with zero fluoroscopy while the remainder required only minimal fluoroscopy. In addition, there were no major complications and, over a 12-month period, only two cases of recurrence [59]. Clark et al. [60] reported a case series of ten patients with AVRT and accessory pathways mapped to the left side using the NavX system. All ten patients underwent successful ablation, and none required the use of fluoroscopy. Only one patient had a recurrence and there were no complications [60]. Scaglione et al. [61] also reported the results of a case series with 44 patients with accessory pathways, of which almost half were left sided and AVRT. In this case series, electroanatomic mapping was provided using the CARTO system, and ablation without the use of fluoroscopy was successfully performed in every patient without any complication [61]. Similar to the traditional approach with radiofrequency, Balli et al. [78] showed that AVRT can be successfully ablated using cryoablation and electroanatomic mapping without recurrence or complications. Bigelow et al. [62] reported their extensive 8-year experience, with 524 consecutive patients, in performing ablation of right-sided and left-sided supraventricular arrhythmias using a near-zero fluoroscopy approach with the EnSite system. There were no complications with procedure times as expected and no unanticipated use of fluoroscopy (except in one case) [62].

In a prospective, multicenter, randomized controlled trial that enrolled 262 patients with supraventricular arrhythmias who were randomized to a minimal fluoroscopy approach utilizing electroanatomic mapping compared to a conventional fluoroscopic approach, Casella and colleagues [63] found that a minimal fluoroscopy approach was associated with a significant reduction in patients' radiation dose (0 mSv, interquartile range 0–0.08 mSv vs. 8.87 mSv, interquartile range 3.67–22.01; $P < 0.00001$), total fluoroscopy time (0 s, interquartile range 0–12 s vs. 859 s, interquartile range 545–1346; $P < 0.00001$), and operator radiation dose (1.55 µS vs. 25.33 µS per procedure; $P < 0.001$). Stec et al. went one step further in implementing a zero-X-ray approach in which staff no longer used lead aprons. There were 188 patients (mean age, 45 ± 21 years; 55% women) included in the zero-X-ray approach who were then compared to 714 consecutive patients referred for a simplified approach using X-rays (age, 52 ± 18 years; 55% women). The procedure times (63 ± 26 min vs. 63 ± 29 min, $P > 0.05$), major complications (0% vs. 0%, $P > 0.05$), and acute (98% vs. 98%, $P > 0.05$) and long-term (93% vs. 94%, $P > 0.05$) success rates were similar between the two groups [63].

Atrial Fibrillation

Atrial fibrillation is the most common arrhythmia in older adults. Catheter ablation of atrial fibrillation is a relatively complex procedure. The full range of techniques are required to shift this procedure to a zero fluoroscopy approach. Reddy et al. [64] evaluated the feasibility and safety of pulmonary vein isolation with zero fluoroscopy use, using a combination of three-dimensional EAM and ICE. In this case series of 20 consecutive patients with paroxysmal atrial fibrillation, right-sided mapping required 5.5 ± 2.6 min. Trans-septal access was successfully achieved in all patients. Left-sided anatomy was visualized using either a circular (14 patients) or a penta-array (6 patients) catheter in 22 ± 10 min; CT image integration was used in 11 patients. Using 49 ± 18 ablation lesions, electrical isolation was achieved in 38 out of 39 ipsilateral PV-isolating lesion sets (97%). The procedure time was 244 ± 75 min. There were no complications [64]. Non-fluoroscopic atrial fibrillation ablation is also feasible using cryoballoon ablation [65].

Bulava and colleagues [66] performed a randomized trial of eight patients who randomized to fluoroscopic or non-fluoroscopic (using CARTO mapping and ICE) pulmonary vein isolation. The total procedure duration and radiofrequency application time in both groups were comparable (92.5 ± 22.9 min vs. 99.9 ± 15.9 min, $P = 0.11$, and 1785 ± 548 s vs. 1755 ± 450 s, $P = 0.79$, respectively). Zero fluoroscopic time was achieved in all patients in the non-fluoroscopic group apart from one patient, where 8 s of fluoroscopy was needed to assess proper position of the guidewire in the femoral vein. No serious procedure-related complications were recorded and no differences in arrhythmia-free survival at 12 months were found between the groups [66]. In a randomized trial of 80 patients, the use of 3D mapping in AF catheter ablation led to a significant reduction in fluoroscopy duration [67]. The use of CF catheters improves the quality of the ablation lesion [12] and imaging performed prior to the imaging such as magnetic resonance imaging may significantly improve ablation accuracy [79]. The main step limiting a zero fluoroscopy approach in AF ablation is the trans-septal puncture [51]. As mentioned, the mastering of ICE is essential for performing this step with little to no fluoroscopy. McCauley et al. showed that a zero fluoroscopy approach using EAM and ICE is safe and effective [68].

Zhang and colleagues [69] assessed the feasibility of zero fluoroscopy during reconstruction left atrium and atrial fibrillation ablation in 342 consecutive patients with paroxysmal atrial fibrillation. Patients were randomly divided into two groups after LA angiography: in the first group, reconstruction of the left atrium and isolation of the pulmonary veins were performed using EAM while the second group used both fluoroscopy and EAM. Total X-ray exposure dose of the procedure in first was significantly lower than that in latter group (19.6 ± 9.4 mGy vs. 128.7 ± 62.5 mGy, respectively, $P < 0.001$). There were no statistical differences in procedural success, the probability of freedom from atrial arrhythmia recurrence at 12 months, or complications between the two groups [69]. One of the largest experiences of zero-fluoroscopy atrial fibrillation ablation reported was performed by Sommer and colleagues [70]. In this prospective 1000 patient registry, the authors assessed the feasibility of zero-fluoroscopy ablation in terms of reduction in procedural and radiation time as well as safety aspects. The study showed that, in a cohort of 1000 patients (62.9 ± 11 years; 72% men; left ventricular ejection fraction 57%; and left atrial diameter 43.2 mm), the median procedure time was 120 min, median fluoroscopy time was 0.90 min, the median fluoroscopy dose was 345.1 cGy cm^2, and the overall complication rate was 2.0%. Stratification by operator experience (initial 75% of patients compared to last 25%) showed significant improvement in the median procedure time (from 140 to 110 min) and reduction in the median fluoroscopy time (from 6 to 0.5 min) and the median dose (from 2263 to 151.9 cGy cm^2) [70].

Ventricular Tachycardia

Catheter ablation of ventricular tachycardia is increasingly utilized. The VANISH trial has demonstrated the superiority of catheter ablation compared to escalation of anti-arrhythmic drug therapy in patients already receiving therapy [80]. In a subsequent trial, catheter ablation is currently being tested as first-line therapy for ventricular tachycardia (NCT02830360). Electroanatomic mapping has become a critical component of ventricular tachycardia ablation [51]. Cano et al. [71] compared radiation exposure in a case series of 41 patients with ventricular tachycardia (22 ischemic and 19 nonischemic) who underwent a catheter ablation using a minimal fluoroscopy approach; the authors compared the type of cardiomyopathy and the use of epicardial access. The use of the electroanatomical mapping system (CARTO) resulted in low levels of radiation exposure: median total fluoroscopy time and effective dose of 6.08 (1.51–12.36) min and 2.15 (0.58–8.22) mSv, respectively. Patients with ischemic cardiomyopathy had lower radiation exposure than patients with nonischemic ventricular tachycardia (total fluoroscopy time, 2.53 [1.22–11.22] min vs. 8.51 [5.55–17.34] min; $P = 0.016$). Epicardial access was associated with significantly higher levels of radiation exposure. A near-zero fluoroscopy ablation could be performed in 32% of cases [71]. Wang and colleagues [72] aimed to assess the safety and efficacy of a zero fluoroscopy approach, without the use of lead aprons, compared to a conventional approach for catheter ablation of idiopathic ventricular tachycardia in a prospective cohort study of seven centers. The zero fluoroscopy approach was successful in 163 (100%) patients for the electrophysiological study, and in 151 patients (94.4%) for ventricular tachycardia ablation with 9 patients having to switch to the conventional approach due to the need for coronary angiography. There was no significant difference between the two approaches in procedural success rate (84.1% vs. 85.4%), arrhythmia recurrence (1.9% vs. 2.2%), or major complications (0.6% vs. 0.9%) [72]. Several small studies have shown the feasibility and safety of a near-zero fluoroscopy approach to catheter ablation of ventricular tachycardia, including a study in complex congenital patients [73].

Conclusion

There has been considerable development and improvement in non-fluoroscopic techniques. 3D mapping, RMN, CF sensing, and ICE have all contributed to the safety and efficacy of purely 3D navigational procedures with zero or near-zero fluoroscopic exposure. Further studies are needed to assess the long-term outcomes of catheter ablation with purely 3D navigation.

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