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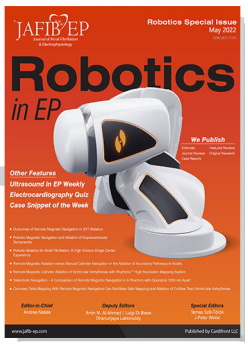

The Impact of Adoption of Fluoroless Robotic Navigation Ablation for Atrial Fibrillation on Procedural Time

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Abstract

Introduction: Exposure to ionizing radiation occurs during most EP procedures and is associated with increased risk of cancers and orthopedic complications associated with wearing heavy protective apparel. The use of fluoroless ablation technique has been gaining popularity over the past decade and has been shown to be safe and efficient although the data has been limited to the manual catheter ablation. Fluoroless robotic navigation (RMN) ablation procedure for atrial fibrillation has not been described previously and the impact of its adoption on procedural time and safety is unknown.

Material and Methods: The impact of adoption of fluoroless AF ablation was studied in this single-operator time-series analysis. A total of 58 consecutive patients undergoing RMN AF ablation were included in this study and different components of the procedural duration were assessed before and after the introduction of fluoroless technique. A meta-analysis of previously published procedural times using manual fluoroless technique was performed and used for comparison.

Results: Upon introduction of fluoroless RMN ablation, there was an increase in the access and mapping time of the procedure by 16.9±4.3 min (P<0.001). However, this increase was counteracted by a reduction in the ablation time and as a result the total procedure time was not significantly impacted (increase of 5.2±15.7 min, P=0.7). The total procedure time was comparable to previously published data on fluoroless manual AF ablation. No major intra-procedural complications occurred.

Conclusion: Zero fluoroscopy using Remote Magnetic Navigation is safe and efficient. The total procedural time is not significantly impacted after adoption of fluoroless technique.

Introduction

A significant number of patients and physicians are exposed to ionizing radiation. In 2014, close to 3.7 million cardiovascular procedures were performed on Medicare beneficiaries using ionizing radiation of which 250,000 were clinical electrophysiologic procedures.[1] Compared to early 1980s, in 2006, Americans were exposed to more than seven times as much ionizing radiation from medical procedures.[2] Although acute radiation toxicity is dose dependent and relatively rare, long-term stochastic radiation-induced damage to cellular DNA occurs frequently and may lead to increased risk of cancer in patients and staff. Stochastic effects are probabilistic in nature and do not require a definite dose threshold.[1] Furthermore, wearing the required heavy personal radiation protective apparel has been shown to be associated with multitudes of orthopedic injuries in operators and staff.[3] These deleterious effects are more pronounced with longer procedures such as atrial fibrillation ablation.

Over the past decade, the advent and wider availability of intracardiac echocardiography as well as increased accuracy of mapping technologies have allowed for EP ablation procedures to achieve significant reduction in radiation exposure without prolonging procedural time or increasing complication rates.[4] Despite increasing popularity of fluoroless technique for manual AF ablation, to date there has been no published data regarding procedural feasibility of Robotic Magnetic Navigation (RMN)-guided AF ablation and its safety and efficacy. The aim of this paper is to describe the fluoroless RMN-guided AF procedure and provide data regarding its safety and efficacy.

Key Words

Robotic Navigation; Ablation; Atrial Fibrillation; Fluoroless

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Material and Methods

1- Effect on procedural time

The data from 33 consecutive atrial fibrillation ablation procedures prior and 25 after adoption of fluoroless technique from a single operator were included in the study. RMN catheter navigation was performed using the Stereotaxis Niobe® Robotic Magnetic Navigation

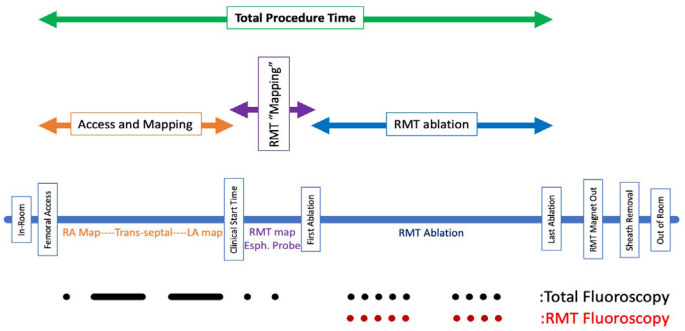

Figure 1: **Components of the total procedure time. Procedural began with access and mapping period which included all the steps from obtaining femoral access and trans-septal puncture to left atrial mapping using a multipolar catheter. RMN mapping included additional mapping with RMN catheter and insertion of esophageal probe. RMN ablation time encompasses the radiofrequency ablation component of the procedure.**

system.[5] The total procedure time was divided into 3 major components: access and mapping, RMN mapping, and RMN ablation (Figure 1) and were individually measured for each procedure. Access and mapping time included all the steps from obtaining femoral access and trans-septal puncture to left atrial mapping using a multipolar catheter. RMN mapping included additional mapping with RMN catheter and insertion of esophageal probe. Finally, RMN ablation time was defined as the interval between the application of the first and last RF lesion.

In order to provide a point of comparison and reference for the procedural time of the fluoroless RMN AF ablation, a meta-analysis of published studies of fluoroless ablation was performed.

Fluoroless atrial fibrillation ablation procedure technique has not been previously described and involves 6 steps as described below.

2- Fluoroless RMN ablation technique

Fluoroless RMN-guided AF ablation as was performed in this study has not previously been described and involves 6 major steps:

1- Pre-procedural preparation: The use of Foley catheter and invasive arterial blood pressure monitoring was limited and used infrequently only in patients who had significant cardiovascular risk. Deep sedation with propofol administration, monitored by nurse anesthetists and anesthesiologists was utilized for the majority of procedures. In rare cases, general anesthesia was deemed preferable by anesthesiologists often due to patients' body habitus or suboptimal respiratory status. After induction of anesthesia, an esophageal temperature probe was placed in mid-esophageal region adjacent to the left atrial posterior wall in order to monitor changes of temperature during ablation. A quadripolar diagnostic catheter was placed in the lumen of the temperature probe and connected to the mapping system to allow for visualization and adjustment of the probe throughout the procedure without fluoroscopy (Appendix-Figure 1). Fluoroscopic registration of the RMN catheter is required by some robotic navigation systems and was achieved using a standard x-ray image (Appendix-Figure 2).

2- Vascular access and placement of catheters: After patient was prepped and draped in sterile fashion the right femoral region was anesthetized and three venous accesses were obtained with ultrasound guidance. Heparin bolus and infusion was immediately started and titrated throughout the procedure to maintain an ACT of 350-400 seconds. Intracardiac Echo (ICE) catheter was advanced via a 9F short femoral sheath to the right atrium. Navigation of the ICE catheter without fluoroscopy requires careful tracking of the venous ultrasound contour and maneuvering (rotation and deflection) of the probe through venous branches (Video 1). A PENTARAY® catheter was subsequently advanced via the short 8F sheath to the right atrium if no resistance was felt. In rare situations, if there was difficulty in advancement of the mapping catheter, ICE probe was retracted from right atrium and used to guide maneuvering of the mapping catheter under direct visual ultrasound guidance (Video 1).

3- Right atrial mapping: With the aid of a multipolar catheter and under the guidance of ICE, a limited electroanatomic map of the right atrium including HIS bundle location, fossa ovalis, and coronary sinus (or CS ostium) was created (Video 2). A deflectable deca-polar catheter was advanced to the right atrium and placed in the previously mapped coronary sinus (Video 3). Mapping catheter was removed from the right atrium and a medium curve deflectable sheath was placed in the superior vena cava over a J wire and under ICE guidance.

4- Trans-septal access: ICE probe was deflected posteriorly and leftward to visualize superior vena cava and the deflectable sheath. A Brockenbrough™ (BK) curved needle was placed inside the deflectable catheter and advanced up to 1 inches from the proximal end of the sheath. Sheath and needle assembly were slowly pulled back under ultrasound guidance until tenting of the inter-atrial septum was visualized and BK needle was advanced completely. A SafeSept® Trans-septal Guidewire (135 cm, 0.014 inch) was used to cross the inter-atrial septum. The location of SafeSept® wire in the left upper or lower pulmonary vein was confirmed by ICE before advancing the sheath/needle assembly into the left atrium. Subsequently, dilator, needle and guide wire were removed and a multipolar mapping catheter (PENTARAY® NAV ECO) was advanced via the sheath to the left atrial cavity (Video 4).

5- Left atrial mapping: An electroanatomic map of the left atrium was created using either the multipolar mapping catheter or RMN ablation catheter. Location of each anatomic structure was confirmed with ICE image. After completion of mapping, multipolar catheter was replaced with RMN ablation catheter under ICE guidance. Deflectable sheath was retracted to the level of inter-atrial septum (Video 5).

6- Ablation: RMN irrigated ablation catheter was maneuvered around pulmonary vein ostia using Stereotaxis console. Ablation was performed while pacing at 15 mA, using 40-50 Watts of energy. Adequacy of tissue contact was confirmed by the following parameters: contact meter reading, ultrasound visualization, sharp EGM signal, and capture during pacing. If esophageal temperature increased by more than 1 degree centigrade, ablation was temporary halted to allow for tissue cooling to occur. Upon completion of pulmonary vein isolation, bidirectional block was confirmed using the multi-electrode mapping catheter (Video 5).

3- Statistical analysis

In order to compare the changes in procedural time before and after the introduction of fluoroless technique, an interrupted time series analysis was performed.[6] Since procedural time is affected by the operator experience and is expected to improve over time, the measurements are autocorrelated. Interrupted time series analysis controls for the auto-correlated changes and estimates the treatment effect over multiple periods.

Meta-analysis of published data on fluoroless atrial fibrillation ablation was conducted by searching PubMed, Embase, Web of Science, and Cochrane Database for articles describing procedural time in patients undergoing catheter ablation of AF using fluoroless technique from 2009-2020. The search was limited to randomized controlled trials, case–control studies, cohort studies, and case series. Citations were appraised by 2 independent reviewers (P.K., A.G.), with differences resolved by consensus. Selected publications were analyzed for the total procedure time. DerSimonian and Laird method was used for fitting the random effects model for pooled-parameter estimation. Meta-regression was performed to investigate the change in procedural time over time. Statistical analysis was performed using Stata software (Stata/IC 15.1 for Mac, StataCorp LLC), OpenMetaAnalyst, and R Programming Software (Version 1.2.1335).

Results

1- Effect of fluoroless atrial fibrillation ablation on procedural time

Of the 58 consecutive patients included in the study, fluoroscopy was used in the first 33 (age 66±12 years, 44% male) and fluoroless method in the last 25 (age 63±9, 51% male) ablations. Majority of ablations were performed in patients with paroxysmal atrial fibrillation (76.1%) and this ratio was not statistically different in pre- versus post-fluoroless groups (P=0.1).

In the pre-fluoroless group, 80% of fluoroscopy occurred during non-RMN portions of the ablation (non-RMN fluoroscopy time 6.3±2.8 min vs RMN fluoroscopy time 1.4±1.2 min) and the average fluoroscopy and procedure times were 7.7±3.7 and 130.5±32.2 minutes, respectively. Immediately after adoption of fluoroless technique, the access and mapping time of the procedure increased initially by 16.9±4.3 min (P<0.001) but demonstrated a trend towards reduction over the ensuing 25 procedures (a reduction of 0.25 minutes for each additional procedure, P=0.3) (Figure 2). This increase, however, was counterbalanced by a reduction in RMN ablation time of 17.2±12.8 minutes after fluoroless technique implementation (P=0.18). As a result, fluoroless technique did not result in a statistically significant increase in the total procedure time (5.2±15.7 min, P=0.7) (Figure 3).

In the fluoroless period of the study, there were rare occasions when brief fluoroscopy was used (in one case, a very brief fluoroscopy was needed to achieve trans-septal access and on few occasions, to locate and repositions esophageal probe resulting in an average fluoroscopy time of 8.4±23.4 seconds) mostly for the repositioning of the esophageal probe or guidance for trans-septal puncture fluoroless group. Complete PV isolation was achieved in all patients.

No acute major intra-procedural complications occurred during the study including pericardial effusion, vascular access complications or cerebrovascular accidents.

2- Historical trends in procedural duration of manual fluoroless AF ablation

Search of databases identified 15 papers from 2009 to 2019 that were included in the meta-analysis.[4, 7-20] The weighted average of procedure time for the fluoroless manual ablation was 155.5 minutes (95% CI, 133.9-177.2). No published data was available on fluoroless ablation using RMN. There was a trend towards reduction of procedural duration over time from 208 minutes in 2009 to 108.6 minutes in 2019 (Figure 4).

Discussion

Despite rising popularity and more than a decade experience with fluoroless manual ablation, no published data is available specifically regarding the methodology of RMN fluoroless ablation and the impact of its adoption on procedural time.

This paper for the first time outlines steps involved in fluoroless RMN atrial fibrillation ablation and many of the same fluoroless techniques can be used for other ablation procedures.

Adoption of fluoroless RMN-guided atrial fibrillation ablation results in an initial statistically insignificant prolongation of the total procedure time by 5 minutes (P=0.7). However, there is a trend towards gradual reduction of the access and mapping time with subsequent procedures.

Similar to other procedures in electrophysiology, novel technologies are often initially associated with longer procedural time and possibly higher complication rates. However, the current study confirms that adoption of fluoroless technique using RMN is not only safe but also does not significantly prolong procedure time. Previous studies have demonstrated RMN-guided ablation to be associated with superior safety and efficiency. Virk et al in their meta-analysis of 15 published trials confirmed that AF ablation performed using RMN is associated with reduced peri-procedural complications and fluoroscopy exposure although it was associated with slightly longer procedural duration compared to manual ablation.[21]

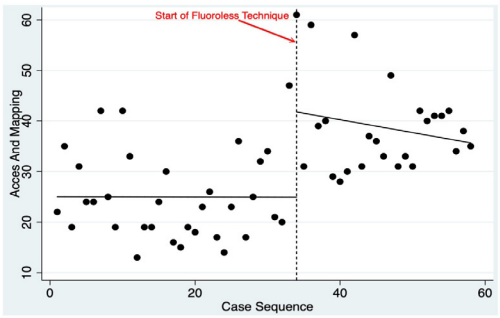

Figure 2: Adoption of fluoroless technique results in an initial increase in "Access and Mapping" portion of the procedure (16.9±4.3 min, P<0.001) with a trend in reduction in the ensuing procedures (-0.25 min per case, P=0.3).

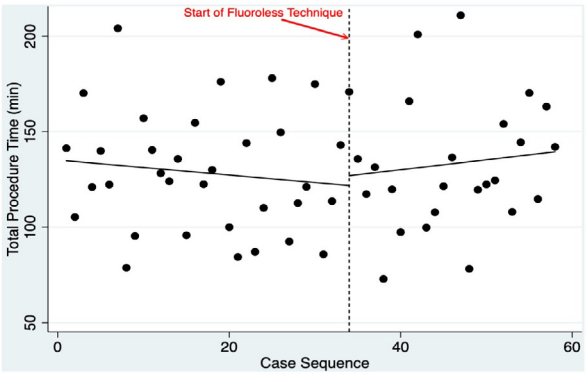

Figure 3: Adoption of fluoroless technique does not increase the total procedure time (5.2±15.7 min, P=0.7).

In order to provide a point of comparison, meta-analysis of published data on fluoroless manual AF ablation was performed. This clearly demonstrated that the total procedural time of fluoroless RMN-guided AF ablation (133.2 min) was indeed comparable to the reported published results for the fluoroless manual ablation (155.5 min).

This is a retrospective single-center, single-operator study which is one of its weaknesses. However, to address the issue of auto-correlation of data, which arises from this limitation, a time-series analysis was performed. Furthermore, the findings of this study favorably compares with other similar published studies of manual fluoroless AF ablation as demonstrated in the meta-analysis.

Due to the retrospective nature of the study, no follow-up data were available to compare the long-term clinical success in terms of freedom from recurrent atrial fibrillation in the fluoroless cohort compared to

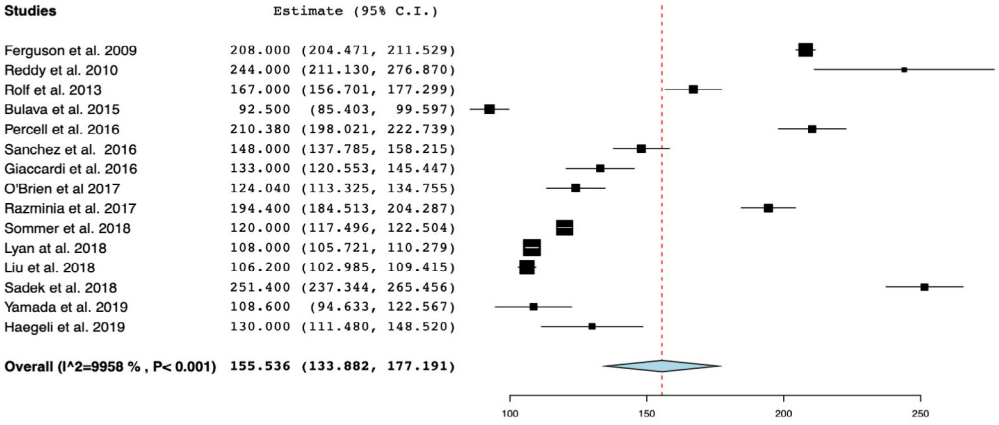

Figure 4: Adoption of fluoroless technique does not increase the total procedure time (5.2±15.7 min, P=0.7).

the standard RMN ablation. Nonetheless, procedural PV isolation was achieved in all patients, which likely portends similar long-term clinical outcomes in both groups.

The findings, however, remain to be validated by a larger multi-center, multi-operator trial that also includes long-term clinical outcomes.

Conclusion

Zero Fluoroscopy using Remote Magnetic Navigation is safe and efficient. Procedure times are not significantly affected by adoption of fluoroless technique.

Please Click below Links for Videos

Maneuvering of ICE to RA
Mapping RA 1
LA mapping and ablation
CS Positioning
Trans-septal access

Appendix - Content

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