ATRIAL FIBRILLATION

RESEARCH ARTICLE

SANS FLUORO (SAY No Series to FLUOROScopy): A First-Year Experience

JASMINE PERCELL, BS1, ERIN SHARPE, APRN2 and ROBERT PERCELL, MD2

1Creighton University, Cardiac Center, Omaha, NE
2Bryan Heart Institute, Electrophysiology Section, Lincoln, NE

ABSTRACT. This was a retrospective, single-center, single-operator study examining the safety, feasibility, and short-term efficacy of treating patients with predominantly persistent atrial fibrillation (AF) undergoing pulmonary vein isolation (PVI) with or without cavo-tricuspid isthmus (CTI) ablation by a first-year electrophysiologist (EP) with and without fluoroscopy. The study included 72 consecutive patients undergoing PVI for symptomatic drug refractory paroxysmal (30%) and persistent (70%) AF from August 1, 2015 to August 1, 2016. Fifty-two patients who underwent traditional PVI (30 with radiofrequency (RF) and 22 with cryoablation) with fluoroscopy were compared to 20 patients who underwent RF PVI without fluoroscopy. RF PVI utilized the CARTO® 3-D mapping system (Biosense Webster Inc, Diamond Bar, CA) with a contact force-sensing catheter. All transseptal access was achieved with intracardiac ultrasound (ICE). More patients in the NO fluoroscopy group had coronary artery disease (CAD), but there were no significant differences for other clinical variables. Overall, procedure time was less in the NO fluoroscopy group despite similar ablation times. There was no significant difference in complication rates including vascular complications, tamponade, stroke, and death. Maintenance of sinus rhythm was the same in both groups (70% in the Fluoro group and 68% in the NO Fluoro group). AF ablation with PVI in predominantly persistent patients using RF with NO fluoroscopy in a new operator is feasible and safe with similar short-term efficacy with 3-D electroanatomic mapping in conjunction with contact force-sensing catheters.

KEYWORDS. Atrial fibrillation, catheter ablation, pulmonary vein isolation, radiation, zero fluoroscopy.

Introduction

The majority of electrophysiologists (EPs) who perform pulmonary vein isolation (PVI) procedures for patients who have symptomatic atrial fibrillation (AF) rely heavily on fluoroscopy despite having multiple visualization modalities at their disposal, including 3-D mapping techniques, intracardiac ultrasound (ICE), and remote magnetic navigation systems. Fluoroscopy was considered a “necessary evil.”1 As an EP fellow, it was not uncommon to have 60 to 90 minutes of fluoroscopy time. Frequent complications of radiation exposure include both deterministic and stochastic (dose-related and dose-independent, respectively) effects including local erythema, cataracts, skin desquamation, leukopenia, organ atrophy, birth defects, and multiple organ and bone cancers.2,3 Additionally, there is the whole issue of wearing lead protection, which leads to a whole host of orthopedic problems.4,5 The lifetime age- and sex-averaged risk for a fatal malignancy resulting from RF ablation (RFA) requiring 60 minutes of fluoroscopy reportedly ranges from 0.03% to 0.23%.6,7 The policy most EPs are familiar with to minimize X-ray exposure during interventional procedures is known as ALARA (as low as...
Materials and Methods

All patients underwent PVI with general anesthesia. RF ablation (RFA) patients received the following catheters from femoral access: CS (Inquiry®, St. Jude Medical, St. Paul, MN), ICE (8 Fr SOUNDSTAR®, Biosense Webster Inc, Diamond Bar, CA) and transseptal puncture with a long guide catheter (Preface®, Biosense Webster Inc) and a HEARTSPAN (Biosense Webster Inc) transseptal needle. Right and left atrial mapping was performed with a multi-electrode (PentaRay®, Biosense Webster Inc) or a circular mapping catheter (Lasso®, Biosense Webster Inc). PVI was performed with an irrigated contact force-sensing catheter (THERMOCOOL SMARTTOUCH®, Biosense Webster Inc).

NO FLUORO patients: specifically, after access with an 8 Fr and a 7 Fr sheath on the right and a 9 Fr sheath on the left, the ablation catheter was advanced to the right atrium (RA), and a fast anatomical map (FAM) was created with careful attention shown to the superior vena cava (SVC) and the takeoff of the CS (Figure 1A). This allowed placement of the CS catheter without fluoroscopy (Figure 1B). Following this, the ICE catheter was advanced into the RA, and the esophageal stethoscope was visualized. Then, the short 8 Fr sheath was exchanged for the long guiding catheter. The guide was advanced to the SVC over the ablation catheter, which was easily seen on CARTO® (Biosense Webster Inc), confirmed by loss of atrial electrograms, and noted by the two dark bands and “SH”, which denotes that the catheter is in the sheath (Figure 1C). Following this, the dilator was advanced over the wire and snapped into place. Finally, the transseptal needle was advnace to the distal portion of the dilator, and LA access was achieved solely using ICE after clearly visualizing “tenting” (Figure 1D). If no tenting was seen after pull down, the procedure was repeated. LA access was confirmed by saline bubbles and the presence of the sheath in the mid LA (Figure 1E). LA FAM was performed using the mapping only catheter, and no additional points were taken (Figure 1F). The mapping catheter was removed, and the ablation catheter was placed into the LA. The ablation catheter was zeroed, and PVI was performed with a minimum force of 5 g, 50% stability at 2 mm for 20 s on the posterior wall and 30 s elsewhere using a “dragging” technique.

Esophageal temperature was monitored for rises >0.5°C. After PVI, veins were tested for entrance and exit block. In some cases, adenosine was administered to evaluate reconnection. Additional ablation lesions were delivered as necessary until complete isolation of all veins was confirmed.

In RF patients in the fluoroscopy group, no RA FAM was performed, and all catheter and wire placements were visualized with fluoroscopy. Otherwise, there were no differences from the above technique.

In patients who underwent PVI using cryoablation, the same procedure as the FLUORO RF patients was utilized for transseptal puncture. The main difference was that after puncturing, the cryoballoon sheath was exchanged over a wire in the left superior pulmonary vein. Then the Arctic Front Advance® Cardiac Cryoablation Catheter (Medtronic Inc, Minneapolis, MN) second-generation cryoballoon was used for ablation with two freezes per vein at 240 followed by 180 s in the standard previously described method. A multipolar catheter (Octopolar, Biosense Webster Inc) was used to monitor phrenic nerve activity. A circular mapping catheter was used to confirm isolation. Additional freeze was performed if the vein was not isolated. All veins were isolated with the cryotechnique, and no additional lesions were performed with RF. Patients were cardioverted prior to confirming isolation if still in AF. In 25 patients with a diagnosis of typical flutter, a cavotricuspid isthmus (CTI) ablation was performed. Complete isthmus blockade was achieved without any complications in all patients. Heparin was administered with a target activated clotting time (ACT) of 350 s and administered after ICE revealed no thrombus in the LA appendage. All catheters and sheaths were removed after the ACT was less than 180 s.

All clinical variables were taken from the patient’s electronic medical records. Total procedure time was taken directly from the anesthesia record, which included time in
the room until time out. All statistical analysis was performed using SPSS version 21.0 (SPSS Inc, Chicago, IL). For comparison of numerical values, Student’s t tests were used. Categorical variables were compared using chi-square tests. A p value < 0.05 was considered statistically significant (two-sided). Patients were divided into two groups: NO Fluoro and Fluoro. All patients receiving cryoablation were placed into the fluoroscopy group.

**Results**

There were no significant differences between the two groups with regard to the clinical variables listed except that more patients in the Fluoro group had coronary artery disease than in the NO Fluoro group (p < 0.01) (Table 1). More patients required CTI lines and cardioversions after PVI in the NO Fluoro group. Procedure time, fluoroscopy time and exposure were all significantly less in the NO Fluoro group. More patients in the NO Fluoro group required CTI lines and cardioversions postprocedure. There was no difference in the ablation time; however, the overall procedure time was shorter in the NO Fluoro group and notably this included the cryo patients. The fluoroscopy time and radiation exposure were significantly less in the NO Fluoro group. Moreover, length of

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**Figure 1: NO FLUORO technique.** A: RA FAM map with CS in green and the tricuspid valve cut away. B: RA FAM with CS catheter and His marked in yellow as well as the ablation catheter. C: Sheath placement in the SVC noted by 2 dark bands and the SH. D: Tenting of the intra-atrial septum on ICE. E: Placement of the sheath into the left atrium with confirmation of bubbles in the left atrium. F: LA FAM with PENTARAY multi electrode catheter in the right inferior pulmonary vein of the left atrium. Note the white highlighted numbers (tissue proximity indicator) that denote tissue contact. FAM: fast anatomical map; ICE: intracardiac ultrasound; LA left atrium; RA: right atrium; SH: sheath; SVC: superior vena cava.
stay was not significantly different between the groups. No vascular complications were noted. All patients are still alive, and there were no strokes (Table 2). Total procedure times decreased over the course of the series (Figure 2). There was no statically significant difference in the 2-week or 3-month efficacy as measured by in-office ECG and 3-month Holter, respectively. At 3 months, 70% of patients in the Fluoro group and 68% in the NO Fluoro group were in sinus rhythm (Table 3).

The single patient who developed tamponade in the NO Fluoro group had a pericardial drain placed and was discharged 2 days later. This patient developed hypotension during RF ablation near the ostium of the left inferior pulmonary vein as it was difficult to advance the ablation catheter out of the sheath. The total of 0.1 min of fluoroscopy came from confirming that the wire was in the proper position prior to drain placement.

### Discussion

The pertinent results of this series demonstrate that zero radiation ablation of complex arrhythmias, namely PVI with or without CTI, is quite feasible, safe and may be achieved in a short period after EP training with similar efficacy. Despite multiple small series and a randomized trial, fluoroscopy-less ablation has not been widely adopted. Learning to perform high-quality ICE at an early stage is critical to decreasing radiation exposure. All pulmonary veins were identified using only ICE in every patient. The single patient in whom the right inferior pulmonary vein could not be seen received a postprocedure CT that revealed that the vein was previously ligated during a partial pneumonectomy for lung cancer.

There are many limitations of this series. The most obvious limitation is that this is a single-center, single-operator study. The operator could be seen as an outlier, but that conclusion would be dubious and unlikely. As expected, the fluoroscopy time and exposure were miniscule in the NO Fluoro group as that was entirely from the one patient with tamponade. However, the amount of radiation exposure could have been reduced by adjusting the fluoroscopy settings including reducing the frame rate to $r \leq 3/s$, reducing the energy per frame, and optimizing collimation. However, these adjustments do not reduce the exposure to zero and still require that the physician and staff wear lead aprons.

The majority (58/72) of these patients were on novel oral anticoagulants (NOACs) with no increase in adverse events or complications. The single patient in the NO Fluoro group who developed tamponade was also on a novel agent. One patient in the NO Fluoro group on a
novel agent had a lupus anticoagulant that caused a delay in pulling the sheath as it interacted with the commonly used measures of coagulation including ACT, partial thromboplastin time, and prothrombin time. Yet still there was no difference in hospital stay or vascular complication. As a greater number of patients have been placed on NOACs and more studies have been performed, more recently trained EPs are comfortable performing PVIs with them on board.

The definition of procedure time was “real world” in that it measured the time the patient came into the room until the time they left. Therefore, these times may be longer than previously reported. The overall procedure time was shorter in the NO Fluoro group, which is a direct contradiction to most studies in which cryo appears to be less time consuming. This may be secondary to the fact that a single transseptal puncture was performed in all cases, and only two patients required roof lines. Additionally, previous studies have suggested that fluoroscopy-less PVIs may be more time consuming, though this was not validated in the single randomized trial. In this series, RA and LA FAM were obtained quickly, and no additional points were taken, thereby saving time. The only additional FAM was performed with the ablation catheter if the anatomy was unclear (usually the superior ridge area). Finally, some of the difference in the procedure times between the groups may reflect the “learning curve” that occurs as an operator becomes more experienced, as indicated by the observation that the total procedure time decreased in all groups over time.

There was no difference in the short-term efficacy of Fluoro versus NO Fluoro patients despite the fact that the majority of patients (70%) were persistent. Also, only two patients received additional LA roof lines, which supports the conclusion of the STAR-AF trial that PVI is the central tenet of AF ablation, even in persistent patients. To completely study this issue, this series would require a larger sample size with more operators and longer follow-up, as well as randomization. The next step would be a randomized controlled study, but this may be difficult to achieve as knowledge of a study may make an operator less likely to “step on the pedal.” Commitment to eliminating fluoroscopy should be the goal of all EPs during most if not all ablations. Since the writing of this study, all ablations are now performed without fluoroscopy with the exception of atrioventricular node ablations. This mostly simple procedure may not be cost-effective to perform without fluoroscopy. In this series, no patients received a preprocedural CT or transesophageal echocardiogram, which reduced cost. As a newly trained EP, I think this paper offers a unique perspective on recent technologies (ICE, 3-D Electro-Anatomic Mapping, and contact force-sensing catheters) and a technique that could make fluoroscopy much less utilized and eventually obsolete.

**Conclusion**

In the SANS-FLUORO series, RF AF ablation without fluoroscopy in predominantly persistent patients was
feasible and safe with similar short-term efficacy by a newly trained operator using 3-D electroanatomic mapping in conjunction with contact force-sensing catheters.

REFERENCES