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Single Day Observational Experience at High Volume Ablation Programs: What is the Impact to Practicing Electrophysiologists?

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Abstract

Background: Significant improvements in catheter technology, electro-anatomic (EA) mapping and techniques to reduce fluoroscopy during radiofrequency ablation (RFA) of atrial fibrillation (AF) are on-going. However, few educational opportunities are available post fellowship for Electrophysiologists (EPs) to understand and integrate them into their practice, preventing widespread adoption. The impact of observational learning for adoption of new technologies and techniques in the field of cardiac electrophysiology has not been studied. We sought to report the impact of a visit to a high-volume center with experience in new technologies and fluoroscopy reduction to the clinical practice of EPs.

Methods: Between 8/2014 and 10/2017 a total of 150 EPs visited 3 hospitals that perform a high volume of AF RFAs. EPs observed a minimum of 4 RFAs, primarily AF. AF RFAs were performed without fluoroscopy, using Carto 3 Version 4 (Biosense Webster) and intracardiac Echocardiography. There was ample interaction and discussion between hosting and visiting EP.

Results: 73 EPs (48.6% of visitors) completed an electronic survey after the visit. The majority reported a significant reduction in fluoroscopy (>50%) and procedure (>20%) times. 68% adopted a rigorous workflow and reported an increase in their confidence level with intracardiac echo (79%), continuous mapping (52%) and the Visitag module (61%).

Conclusions: Observational experience can have an immense impact on the clinical practice of EPs. Further effort should be devoted to such programs and to study in a more systematic way their ultimate impact on patient care.

Introduction

As evidence of the safety and efficacy of atrial fibrillation (AF) radiofrequency ablation (RFA) has mounted, indications for catheter RFA for AF have expanded.[1] AF RFA is now the most common electrophysiologic procedure worldwide.[1] Catheter technology and electro-anatomic mapping (EAM) systems continue to evolve at a rapid pace posing a challenge for individual practitioners to incorporate these advances into routine practice. This is particularly true for AF RFA procedures.

The advent of contact force (CF) sensing catheters has improved AF RFA success rates,[2, 3] and improvements in EAM systems allow us to better understand the substrate and objectively evaluate some parameters of lesion sets delivered. The increased number of AF RFAs performed has also led to concerns about fluoroscopy exposure[4] and the health hazards of ionizing radiation to both patients and staff. The evolution of these new technologies has enabled physicians to develop techniques to perform catheter RFA for AF and other RFAs with zero-fluoroscopy.[5-7]

However, these advances in techniques and technologies have increased the complexity of our procedures. We now have a great deal more information available and must consider many more variables during AF RFA. Moreover, few educational opportunities are available post fellowship for practicing Electrophysiologists (EPs) to address the challenges of how to understand and incorporate new technologies and fluoroscopy reduction techniques safely, effectively and efficiently. This may become a barrier to widespread adoption of fluoroscopy reduction techniques and incorporation of new technologies for practicing EPs.

In other fields of medicine, similar paradigms have occurred as the technology and techniques evolved. In order to shorten the learning curve and improve adoption and widespread use training opportunities and pathways emerged.[8] The role of observational learning has been evaluated in different areas of surgical and procedural based medicine.[9] Its impact has also been evaluated in the

Key Words

Observational Learning, New Technologies, Fluoroscopy Reduction, Electroanatomic Mapping System, Catheter Ablation

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teaching of medical students[10] and for practicing physicians to learn new skills in the post training setting.[8]

To the best of our knowledge, the impact of observational learning for adoption of new technologies and techniques in the field of cardiac electrophysiology has not been studied. Our centers have received hundreds of visiting EPs and staff members to observe RFAs, with emphasis on AF, fluoroscopy reduction techniques and adoption of new technologies. Anecdotal reports from visitors following the visits were extraordinarily positive prompting our interest in scientifically examining these outcomes.

The purpose of this study is to assess the impact of a single day observational experience at high volume RFA center with experience in zero fluoroscopy techniques and advancements in EA and catheter technology into the RFA procedural practices of visiting EPs.

Methods

Between 8/2014 and 10/2017 a total of 150 EPs and their support staff members visited 3 hospitals that perform a high volume of AF RFAs annually. Visiting EPs were asked to submit their main goals for seeking to visit a high-volume center, academic affiliation and years post training prior to the visit.

The hosting EPs' main focus was:

1) Educate visiting EPs on the role of new technology in AF RFA, such as continuous mapping (Confidense™ Module in the Carto™ 3 System Version 4), automated catheter stability module (Carto Visitag™ Module (Visitag)), and the role of CF catheters;
2) Educate visiting EPs on fluoroscopy reduction techniques, particularly intracardiac echocardiography (ICE).

The structured visits consisted of a single day experience. Visiting EPs observed a minimum of 4 RFAs, mostly AF, all performed using Biosense Webster Carto 3 Version 4 EAM system. Visitors were provided observer status only, with no hands-on participation with cases at each site. The visiting EPs interacted with hosting EP before, during and after each procedure. Time for questions and answers was allotted. Hosting EPs provided step-by-step explanations of workflows used for fluoroscopy reduction and use of new technologies. All visiting EPs were given contact information for their hosts to follow up with any additional questions or concerns as they returned home to implement new strategies in their EP labs. The visits were funded by Biosense Webster.

The 150 EPs who attended were asked to complete an electronic survey a few months after the visit and up to 2 reminders were sent via email. 73 EPs completed the survey, with a 48.6% response rate. Host site visits were Grandview Medical Center (Birmingham, AL, 45 visits), Cottage Hospital (Santa Barbara, CA, 24 visits) and Greenville Memorial Hospital (Greenville, SC, 4 visits).

AF RFA Procedure

Although there was some variation in the AF RFA approach between each of the 3 centers, the procedures were similar in terms of technology used and zero-fluoroscopy techniques. While the visits were industry sponsored the EPs performed their standard workflow and equipment selection.

All procedures were performed using the Carto™ 3 Version 4 EAM system. Patients underwent RFA under general anesthesia. CF RFA catheters, either Smart touch or Smart Touch SF, were used for all procedures. After intra-venous access, the RFA catheter was inserted via the right femoral vein, guided by EAM until placed in the right

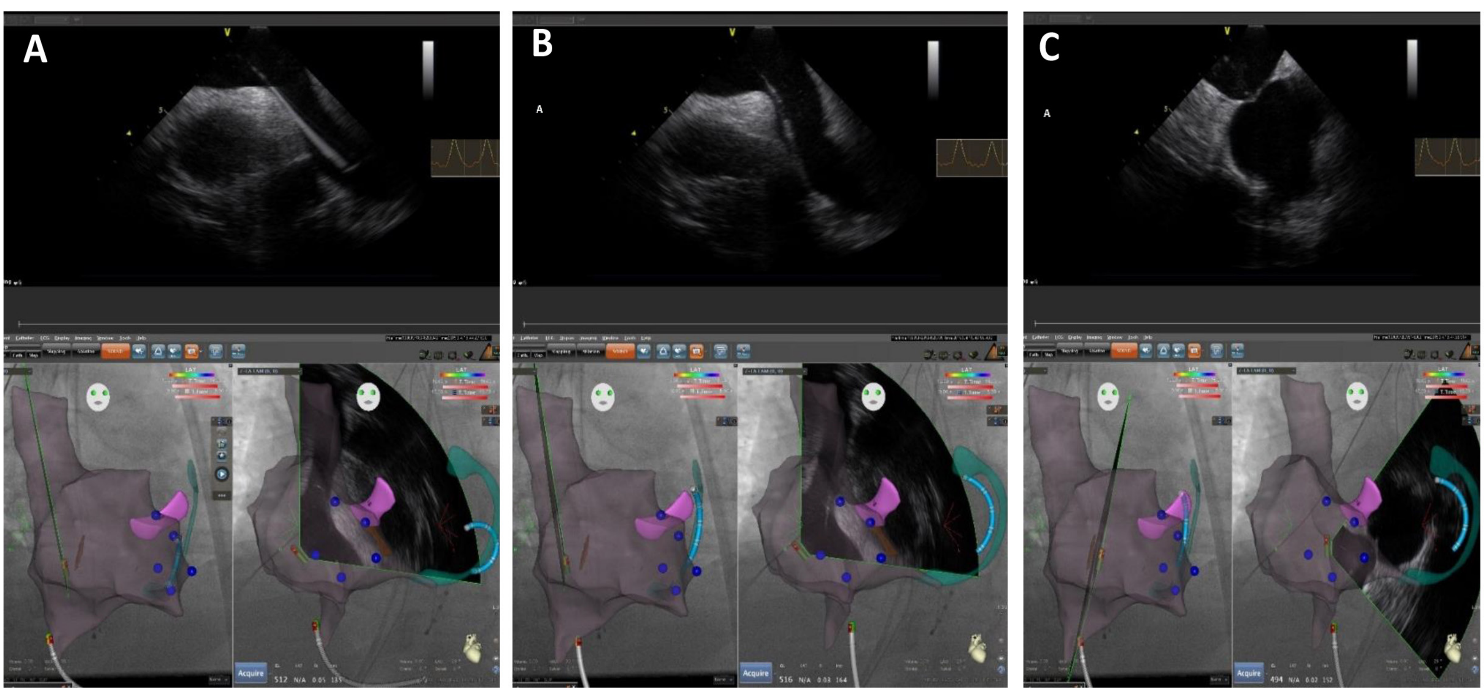

Figure 1: Stepwise approach used for transseptal access guided by intracardiac echocardiography (ICE). Images show ICE in the upper panel and corresponding electroanatomical map with reconstruction of the right atrium and the orientation of the ICE fan in the lower pannel. A) ICE shows J-tipped wire advanced into the superior vena cava. B) Transseptal apparatus positioned in the superior vena cava and high right atrium junction. C) Transseptal needle positioned at the fossa ovalis prior to access

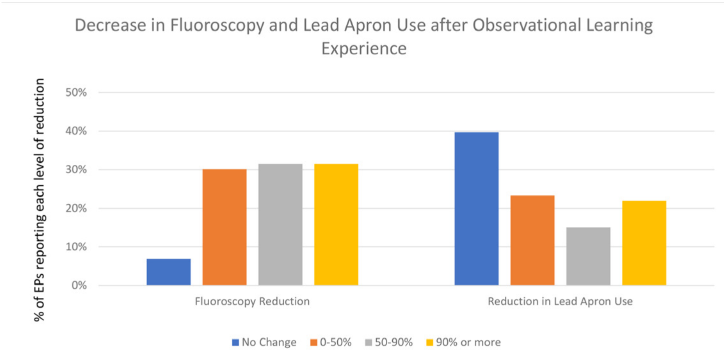

Figure 2: Decrease in Fluoroscopy and Lead Apron Use After Single Day Observational Experience

atrium (RA). A deflectable decapolar catheter was positioned into the coronary sinus, guided by either the EAM and/or ICE.

Intravenous heparin was administered before and after transseptal catheterization as necessary to achieve a target ACT of > 350 seconds. Either single or double transseptal catheterization was guided by ICE with no fluoroscopy (Figure 1) as previously described.[7]

The left atrium geometry and voltage was then acquired with fast anatomic mapping using a multipolar catheter (Lasso™ or Pentaray™), with use of continuous mapping. Wide area circumferential RFA around ipsilateral pulmonary veins (PVs) was performed in the standard fashion, guided by EAM system only. In patients with persistent AF, further RFA was at the discretion of the operators.

RFA was performed using 35-50 watts with a target, when safe, of 10-20 second lesions and 10-20 grams of force using a drag-burn approach. The distance of a drag to result in a reset of the timer and new lesion was set by the operator and Visitag filter. Lesion stability module (Visitag) was used for every procedure with the rationale of avoiding excessive and inaccurate marking of RF sites, and rather, marking sites where likely effective RF was applied based on adequate catheter time and contact force at any given ablation site. Simultaneous stress was placed on the concept that there may be an effective lesion and tissue damage despite lack of Visitag at a location due to filter settings. Thus, there was emphasis on the safe use of Visitag and integration of different filters. Specifically, we advocate that to maximize safety, Visitag use should not result in RF lesions that are inappropriately long or forceful simply to ensure a Visitag marker appears on the EAM.

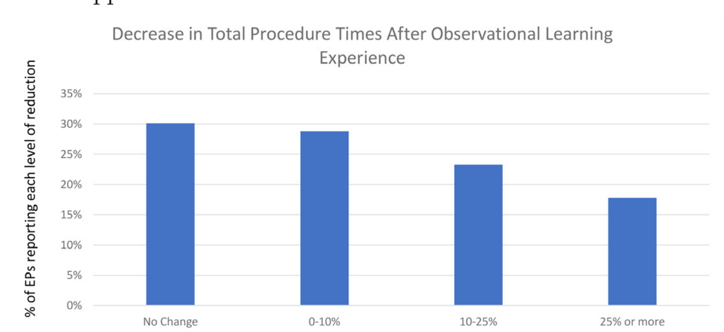

Figure 3: Decrease in Total Procedure Time After Single Day Observational Experience

Validation of PV isolation was performed using adenosine boluses, isoproterenol infusion at high doses for up to 20 mcg/min and pacing maneuvers, where appropriate. When necessary for additional validation, post RFA voltage mapping of the left atrial was performed.

Results

Of the 150 EPs attending the structured hosted visits, 73 (48.66%) completed an electronic survey in the months following the visit, after being given the opportunity to integrate the learning experience into their own RFA practice.

The mean age of the 73 EPs who completed the survey was 44 years (ranging from 36 to 65 years). On average, the EPs had completed fellowship training 10 years prior to the visit (range 2 to 30 years). And 20% were affiliated to an academic institution.

The most common reasons EPs cited for seeking to participate in the structured observational visits at the 3 high volume AF RFA centers were to: 1) reduce fluoroscopy and procedure times and to 2) understand and adopt new catheter and EAM system technologies. After the visit, 60% of EPs reported achieving a greater than 50% reduction in fluoroscopy with 30% reporting a 50-90% reduction. Greater than 20% reported a 10-25% decrease in procedure time with more than 15% reporting a greater than 25% reduction. Approximately 20% of attendees reported a 90% decrease in lead apron use and 15% estimated a decrease in lead apron use of 50-90% (Figures 2 and 3). The vast majority of visitors reported a significant improvement in their understanding and confidence with intracardiac ECHO (79%).

After the visit, there was a reported increase in the level of confidence with new technologies, such as continuous mapping (52%), automated Catheter Stability Module (Visitag) (61%) and CF sensing catheters (61.1%) (Figure 4). 68% of EPs adopted a rigorous workflow with more systematic use of RFA settings, such as power, time and force and the integration with new EAM and CF technologies. In particular, 61% reported an improvement in the understanding of Automated Catheter Stability Module (Visitag) and a 52% of Confidense Module.

Most visiting EPs reported an increase in overall confidence level with RFA of AF (67.1%) and that implementation of techniques and strategies learned had yielded improvement in short term RFA outcomes in terms of safety, efficacy and efficiency (43.8%, 41.1% and 67.1%, respectively).

Discussion

Main finding

We report that a structured, single day observational experience in a high-volume AF RFA center with significant experience with fluoroscopy reduction techniques and new technologies can have a positive impact on the clinical practice of visiting EPs, including significant reduction in fluoroscopy use, improved procedural workflow, and improved understanding of new technologies.

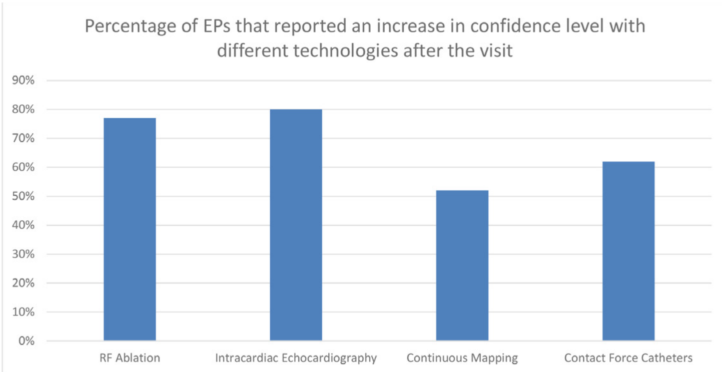

Figure 4: Increase in confidence level with different technologies after single day visit to high-volume Atrial Fibrillation Ablation Center.

Observational and Simulation based Learning

Across medicine, as techniques and technologies improve and progress, dissemination of these improvements remains challenging. In particular, the challenge is significant for proceduralists interested in incorporating new techniques and technologies into their daily practice safely and effectively.

The role of observational and simulation-based learning has been evaluated in different fields of medicine and different stages of the training process. [9-11]

Harris et all reported the effect on the acquisition of surgical skills on a robotic platform,[9] and Torricelli et al on laparoscopic surgical training.[8] In the field of endoscopy, Draganov reported that observation of experts performing endoscopic submucosal dissection not only shortened the learning curve and procedure times, but also decreased the number of unsuccessful procedures.[12]

It has also been shown that observational learning can be beneficial to improve medical skills' performance both when flawless and flawed demonstrations occurred, as long as learners were given confirmation when what they were observing was errorful.[13]

Observational learning can be particularly useful when there is a significant change in treatment paradigms, leading to a need to train a large number of physicians to give patients access to new treatment options. Minimally invasive surgery has been replacing the open standard technique in several procedures. However, the learning curve required to obtain laparoscopic expertise has been a barrier for its widespread use. Laparoscopic surgery training laboratories have emerged to aid surgeons to overcome this challenge, and it may include tutorials, simulators and operating room observation. These have shown to improve laparoscopic surgical skills and this short period of training is able to increase the laparoscopic practice of surgeons in their communities.8

In the field of EP, advances in EAM systems and catheters, along with the techniques required for zero fluoroscopy catheter RFA pose similar challenges and training needs of that seen in surgery when laparoscopic techniques were introduced. The fast evolution seen in techniques and technologies used specially for AF RFA can improve patient care, but may leave a large number of EP physicians with no formal training on such, therefore limiting its widespread use.

As practitioners at high-volume centers who have access to new technologies and actively invest our time in mastering their features, we are in a unique position to mentor EPs by providing practical, clinical-based opportunities to help them safely incorporate new technologies and techniques with demonstrated benefit and bring them to their communities as well.

Our study analyzed the impact of a single day observational visit to centers that have extensive experience with the newest technology described. Combined our procedural volume exceeds 5,000 RFAs without fluoroscopy. Feedback indicates that the impact of the visit was very positive, with reported reductions in fluoroscopy and procedural times, as well as better use of new technologies, and a significant increase in confidence level with RFA in general. The magnitude of the changes reported after a single visit was remarkable. We hypothesize that visitors were in essence pre-selected, as they were all motivated to make changes in their practice and procedural approach and needed primarily the tools and exposure to approaches that have been demonstrated to be safe and effective at the host institutions.

We hope that this effort will lead the way to the creation of structured post fellowship educational opportunities and centers of excellence for EPs that would like to learn and safely adopt the newest techniques in our field.

Zero-fluoroscopy RFA

The deleterious effect of ionizing radiation during RFA have been well established [4, 14-17]. The importance of minimizing radiation to ALARA (as low as reasonably achievable) has been promoted by the major scientific societies of physicians who work in the interventional X-ray laboratory environment [18]. There is no question that all efforts to safely reduce or avoid radiation are of value.

Although there is growing literature showing the safety of zero fluoroscopy AF RFA,[5-7] there are no training pathways available. Even though minimizing fluoroscopy has obvious benefit to patients, physicians and staff members, most EPs interested in adopting these techniques have been learning largely on their own. Many EPs however have simply avoided it or maintained their practice of fluoroscopy use. Even physicians who wish to reduce their reliance on fluoroscopy may not have guidance on how to accomplish this goal. As a result, there remains a significant and wide variation in fluoroscopy utilization across EP's.

To the best of our knowledge this is the first report of the impact that a visit to a center with experience in performing zero fluoroscopy RFAs has to practicing EPs. Although this survey has limitations and has not systematically analyzed procedural and fluoroscopy times before and after the visit, the magnitude of the self-reported fluoroscopy reduction was substantial.

Although zero fluoroscopy RFA has been shown to be safe in the hands of experienced operators, further studies need to look into the reproducibility of it. It is our opinion, however, that the observational experience can aid EPs in adopting it safely, by learning specific steps and techniques involved.

Catheter and EAM system technologies

New technologies for Radiofrequency AF ablation

Over the past decade we have seen several technological advances in the field of AF RFA. Improvements in EA mapping systems, such as continuous multielectrode mapping, have allowed us to obtain more information during AF RFA with short mapping times. CF sensing catheters have also been shown to be safe and effective, and now allow use to make better estimates of lesion delivered and ultimately achieve more durable lesions that can substantially improve procedural outcomes.[19]

The amount of information now available to physicians through these technological advances during AF RFA has increased significantly, nevertheless there exists no clear consensus and limiting supporting literature on how to use, apply and combine these new technologies to improve procedural outcomes

One of the main goals we had with each visitor was to show how we use CF catheters and Automated Lesion Annotation synergistically while having a strict and organized workflow. We believe that using strict parameters (such as power, force and lesion time) while programming Visitag to match one's procedural workflow may have significant benefits specially in terms of procedural efficacy and efficiency,[20] but more importantly safety (using parameters that would help prevent inappropriately long lesions as one waits for a tag).

After the visit, the majority of physicians reported the adoption of a structured workflow for AF RFA. Although we don't have information of the impact of such changes in their individual clinical practice at this point, our experience has been very positive at our own centers.[21]

Limitations

The main limitation of this study is the fact that the impact of the visit was assessed by a survey sent to each EP, and therefore subject to bias. The self-report nature of the survey precludes objectively analyzing the safety of adoption of these techniques, the extent to which changes were made and the true impact to clinical practice. Moreover, about half of the visiting doctors did not answer the survey, which may also introduce bias. Objective data evaluating the impact of training visits on fluoroscopy use, procedural efficiency, lead apron use, utilization of new technologies, and most importantly, clinical outcomes is needed and should be evaluated. We do have plans to complete an analysis of procedural data before and after each visit, however, which would allow to measure clinical endpoints. Further studies should also be performed to assess the durability of the practice changes made after the single visit.

Conclusion

There are few opportunities available for physicians to learn how to safely adopt new technologies and particularly how to minimize fluoroscopy. Our report shows that post fellowship educational opportunities (such as observational experience) can have an immense impact in the way EPs practice. Further effort should be devoted to the development and organization of such programs and to study in a more systematic way their ultimate impact on patient care.

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