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How Much Can Systematic Use of 3D Mapping Systems Reduce X-ray Exposure During Catheter Ablation in a Standard EP Lab?

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ABSTRACT

Background: 3D non-fluoroscopic mapping systems have been proposed as a useful tool for catheter ablation for many arrhythmias.
Objectives: The present study aimed to evaluate the effect of a methodical use of 3D mapping systems on the amount of X-ray exposure during catheter ablation.
Patients and Methods: Our study was conducted on 495 consecutive patients who underwent catheter ablation from January 2007 to December 2011. Since October 2008, all ablation procedures in our EP Lab have been performed using a mapping system. In this study, we compared fluoroscopy time, total X- ray exposure, and duration of each procedure. The data from Atrial Fibrillation (AF) ablations and Supra-Ventricular Tachycardia (SVT) ablations were also analyzed using unpaired non-parametric Mann-Whitney test (MW-test). Besides, Chi-square test (χ^2-test) was used to evaluate the impact of mapping system development on X-ray exposure.
Results: The overall median fluoroscopy time decreased significantly by 78% in 5 years, falling from 29.2 min (95% Confidence Interval (CI) [24.3 - 37.8]) in 2007 to 6.3 min (95% CI [5.3 - 9.7]) in 2011 (MW-test, P < 0.001). Additionally, the median total X-ray exposure decreased from 58.18 $Gy^{*}cm^{2}$ (95% CI [41.73 - 71.35]) in 2007 to 14.48 $Gy^{*}cm^{2}$ (95% CI [9.61 - 18.26]) in 2011 (MW-test, P < 0.001). There was also a slight reduction in the duration of the procedures, 79% of which were acutely successful.
Conclusions: The systematic use of a mapping system markedly reduced fluoroscopy time and total X-ray exposure during catheter ablation. Although improvement in technology and growth in operators' experience play a central role in radiation exposure reduction, our study showed that only daily use of mapping systems maximized the possibility of reducing exposure.

►*Implication for health policy/practice/research/medical education:*
In our opinion, this study presents the first systematic use of a mapping system for all catheter ablation procedures in a small EP Lab with consecutive unselected patients in the context of real-life experience of this Lab. If our results are corroborated by other researches (multi-center randomized studies), this should form the basis for a new approach to electrophysiological procedures and in fact an ethical imperative to always incorporate the use of a mapping system for treatment of cardiac arrhythmias.

1. Background

Radiofrequency Catheter Ablation (CA) is currently considered to be the first-line therapy for curing many cardiac arrhythmias (1, 2), but this treatment may require extended X-ray exposure (3). Nowadays, the relationship between X-ray exposure time and an increased risk of developing cancer has been well-established (4). In the recent years, 3D Non-fluoroscopic Mapping Systems (NMSs) have been proposed as a useful tool for CA of many arrhythmias and their use has allowed us to understand and

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ablate complex arrhythmias. Additionally, studies published in the literature have demonstrated that NMSs can confer the extra benefit of significantly reducing radiation exposure (5-9). However, complete elimination or "near-zero" use of X-ray fluoroscopy during electrophysiological procedures may be achieved only after adequate experience and training (10).

2. Objectives

We hypothesized that extensive use of NMSs could yield an overall greater reduction in radiation exposure during CA as opposed to its use only in selected cases. In this paper, we give an account of a change in our working method, which resulted in a shift from a more sporadic use of NMSs to a systematic and intensive use of them in procedures. Our five-year experience is reported here with a focus on the resulting reduction in radiation exposure. This study aims to evaluate the feasibility, efficacy, safety, and effect of extended use of NMSs for CA in our EP Lab focusing on the amount of X-ray exposure.

3. Patients and Methods

3.1. Study Population

This non-randomized study was conducted on consecutive patients who underwent CA procedures from January 2007 to December 2011. The catchment area of the EP Lab of our hospital has 350,000 people and approximately 150 CA procedures are performed per year. Herein, we report the data of all the CA procedures performed each year underlining that some of the procedures in 2007 and 2008 were performed using only fluoroscopy, whereas all the procedures in 2009, 2010, and 2011 were performed using an NMS. Thus, this paper presents a study that was carried out from 2008 to 2011 and includes a comparison to the data collected previously (2007 - 2008). During the study, written informed consents were obtained from all the involved patients. It should be emphasize that the data of each year (2008 to 2011) were compared to the data from 2007 when the CA procedures in our EP Lab were mainly performed with fluoroscopy. Yet, a year-by-year comparison was also made. A sub-analysis for Atrial Fibrillation (AF) CA and Supra-Ventricular Tachycardia (SVT) CA was included, as well.

3.2. Electrophysiological Procedure, Evolution, and Philosophy of Our Lab

We started in 2001 using a single NMS (CARTO, Biosense-Webster, Diamond Bar, CA, USA Unix Version) for treatment of complex arrhythmias (atrial fibrillation, atypical atrial flutter, atrial tachycardia, and ventricular tachycardia). In 2007, the new CARTO XP Version allowed us to integrate CT/MRI images of the cardiac chambers with the electroanatomic maps. As a result, images of the Left Atrium (LA) were integrated during AF ablation or during atypical atrial flutter ablation procedures. In the following year (2008), we started to use a second NMS (EnSite NavXTM St. Jude Medical, St Paul, MN, USA) for SVT CA (AVNRT, AVRT, atrial tachycardia, and atrial flutter). Since October 2008, in agreement with our administration, all CA procedures, except for His-bundle ablation procedures, have been performed using one or other of these two NMSs. It should also be specified that since the beginning even before the study period, all AF and VT CA procedures have been performed using the CARTO system in our EP lab. In contrast, SVT CA procedures were performed using fluoroscopy in the period from January 2007 to October 2008 after which, our team changed strategy and decided to perform all SVT CA procedures using the EnSite system. This use of an NMS for SVT CA procedures has continued from that time to the present in our EP Lab. Our use of a specific mapping system for a specific type of ablation procedure, as described above, was for no other reasons than our prior experience and confidence with the particular NMS. New updated hardware and software versions of these NMSs were used over the last two years (CARTO3 and EnSite Velocity from 2010). Fluoroscopy was performed using a Toshiba Radiographic/Fluoroscopic Unit (Infinix-I Series CAS, Toshiba Medical System Corporation, Japan). We always utilized the same number of catheters during the procedures without any variation in the protocol, irrespective of whether fluoroscopy or an NMS was used. This was the case throughout the whole period of the study. For SVT CA procedures, we used four diagnostic catheters and the ablation catheter: three quadripolar catheters through the right femoral vein in the right atrium, right ventricle, and His bundle, a decapolar catheter through the right jugular vein in the coronary sinus, and the ablation catheter through the right femoral vein. Besides, we used the Ensite system to navigate the femoral vein using a skin patch as a positional reference. The geometry reconstruction and anatomy chamber acquisition was performed as well described in the paper by Casella et al. (11). For AF CA procedures, we used three diagnostic catheters and the ablation catheter: a duo-decapolar catheter through the right jugular vein in the coronary sinus, a quadripolar catheter through the right femoral vein positioned in the right ventricle, the circular mapping catheter through the right femoral vein positioned in the left atrium, and the ablation catheter through the right femoral vein in the left atrium. For VT CA procedures, we used two diagnostic catheters and the ablation catheter: a decapolar catheter through the right jugular vein in the coronary sinus, a quadripolar catheter through the right femoral vein positioned in the right ventricle, and the ablation catheter through the right femoral vein in the left or right ventricle.

3.3. Procedure and Fluoroscopy Data

This study aimed to compared fluoroscopy time, total X-ray exposure, and duration of each CA procedure. Fluoroscopy time was defined as the cumulative duration of fluoroscopy during the entire procedure, whereas radiation dose was defined as the calculated dose to the patient recorded by the Dose Area Product (DAP) meter. Finally, procedure time was measured as the interval between the initial recording of intracardiac signals and the final ECG recording before the end of the procedure.

3.4. Procedural Success, Complications, and Follow-up

The definition of acute and chronic procedural success for this study was, in each case, based on the specific type of tachycardia in question as is commonly the international criteria (1, 2). In particular, for SVT CA procedures in our EP Lab, success was judged as the absence of arrhythmia after the procedure and absence of recurrences in the following 2-3-month period. For AF CA procedures, success was estimated as the absence of AF recurrences in a 12-month period following the procedure. Besides, the endpoint for AF CA procedures was the circumferential ablation of the ostia of the pulmonary veins observing a bidirectional block of the atrium-vein conduction using a circular mapping catheter. All the patients underwent a 24-hour monitoring telemetry and a post-procedural echocardiogram to exclude pericardial effusion or other acute complications. We also recorded any other complications that might have occurred during the procedure or during the same hospital stay. A follow-up outpatient visit was also scheduled for all the CA patients between 2 and 3 months after the procedure (or when the need arose) and at 6 and 12 months after the procedure only for AF CA patients.

3.4. Statistical Analysis

Kolmogorov-Smirnov test was performed on the continuous variables to examine the normal distribution of the data. Unpaired non-parametric Mann-Whitney test (MW-test) was used to compare all the continuous variables, whereas Chi-square (χ^2 test) was used for outcome data. All the statistical analyses were performed using R software, version 2.15 (The R Foundation for Statistical Computing). $P < 0.05$ was considered as statistically significant.

4. Results

4.1. Total Population

Our study included 570 procedures performed on 495 patients (495 pts, 289 males and 206 females) who underwent CA from January 2007 to December 2011. The clinical characteristics of this population have been summarized in Table 1. Accordingly, distribution of arrhythmias was about 40% SVT and up to 35% AF, which changed over years. For each of the various kinds of arrhythmias, there was a difference over the years. This difference was not statistically significant in the case of SVT procedures, whereas there was a more notable change over time for VT procedures (from 0.9% in 2007 to 11.5% in 2011) and AF procedures (from 31.8% in 2007 to 40.2% in 2011).

The change in fluoroscopy time over time (2007 - 2011) has been shown in Figure 1. As the Figure depicts, the median fluoroscopy time of the overall CA procedures decreased by 78%, from 29.2 min (95% CI [24.3 - 37.8]) to 6.3 min (95% CI [5.3 - 9.7]) (MW-test, $P < 0.001$). There was also a complementary reduction of the total X-ray exposure (Figure 1) from 58.18 Gy*cm ^{2} (95% CI [41.73 - 71.35]) in 2007 to 14.48 Gy*cm ^{2} (95% CI [9.61 - 18.26]) in 2011 (MW-test, $P < 0.001$) and the reduction came about without prolonging the total procedure time (median value of 150 min in 2007 and 134.5 min in 2011, MW-test, $P > 0.05$). The difference in the decrease of fluoroscopy use was also significant while comparison of each year to its previous year, excluding the comparison between 2011 and 2010. However, no statistically significant difference was observed in the rate of reduction of fluoroscopy use between the two operators notwithstanding the fact that one of them was in the training period (MW-test, $P > 0.05$).

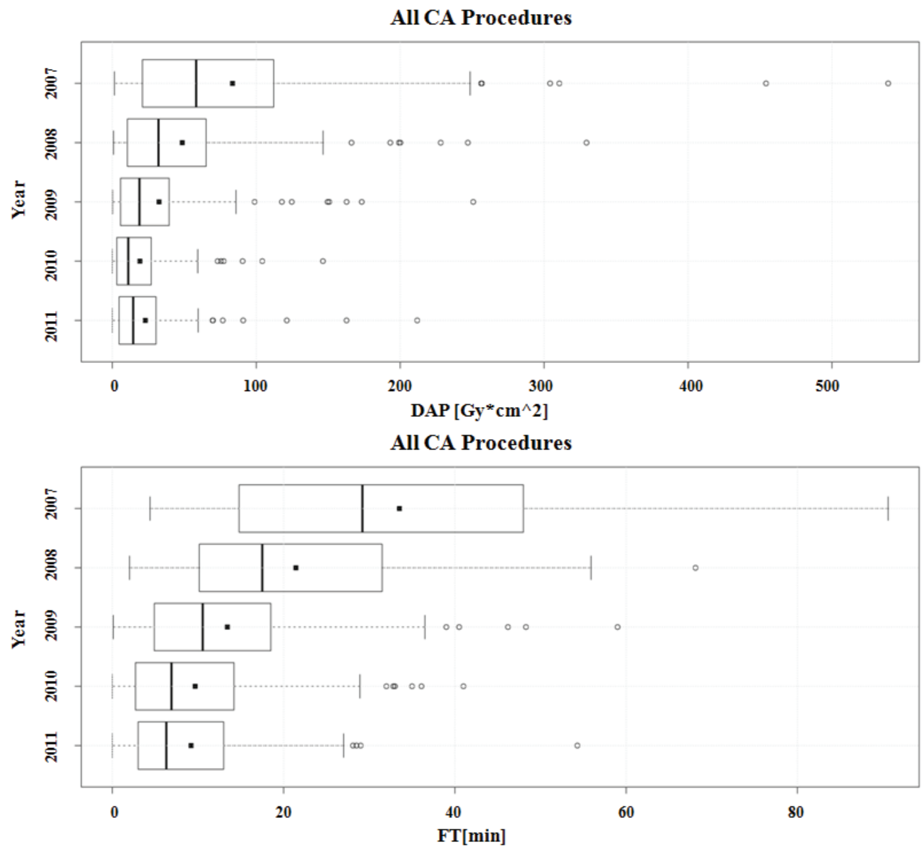
The estimated effective radiation dose to the patients reduced from 8.7 mSv to 2.2 mSv. Furthermore, 44% and 34% of the CA procedures were performed using only fluoroscopy in 2007 and 2008, respectively. On the other hand, 56% and 66% of the CA procedures were performed using only an NMS in 2007 and 2008, respectively. During 2009, 2010, and 2011, no CA procedures were carried out using only fluoroscopy.

Table 1. The Clinical Characteristics of the Study Population

		Total		2007	2008	2009	2010	2011
	#		%	#	#	#	#	#
Procedures	570			110	119	102	117	122
Age	Mean	54.9		53.9	53.3	57.2	54.7	56.5
	Standard deviation	16.2		16.2	16.8	14.4	16.7	16.22
Sex	F	227	39.8	39	55	44	44	45
	M	343	60.2	71	64	58	73	77
Heart disease	None	263	46.1	57	55	36	59	56
	Hypertensive	134	23.5	23	27	28	25	31
	Valvular	50	8.8	8	15	12	5	10
	Ischemic	42	7.4	10	6	8	11	7
	Dilated cardiomyopathy	35	6.1	6	5	4	8	12
	Other	46	8	6	11	14	9	6
LVEF	< 35%	22	3.9	6	1	5	5	5
	> 55%	446	78.3	89	85	78	97	97
	35 - 45%	29	5.1	5	5	4	7	8
	45 - 55%	73	12.8	10	28	15	8	12
Arrhythmia	AF	180	31.6	35	29	28	39	49
	SVT	228	40.0	49	54	46	46	33
	AFL/AT	124	21.7	25	32	23	18	26
	VT	38	6.7	1	4	5	14	14

Abbreviations: F, female; M, male; LVEF, Left ventricular ejection fraction; AF, Atrial fibrillation; SVT, Supra-ventricular tachycardia; AFL, Atrial flutter; AT, Atrial tachycardia; VT, Ventricular tachycardia

Figure 1. The Box and Whisker Plots Show the Reduction of Fluoroscopy Time and Total X-ray Exposure in All CA Procedures in Our EP Lab from 2007 to 2011.



The data for fluoroscopy time are expressed in minutes (min) and the data for total X-ray exposure have been presented as Dose Area Product (DAP) (Gy-cm^2). The difference between the first and the last year is statistically significant (P < 0.0001). FT, Fluoroscopy time; DAP, Dose area product.

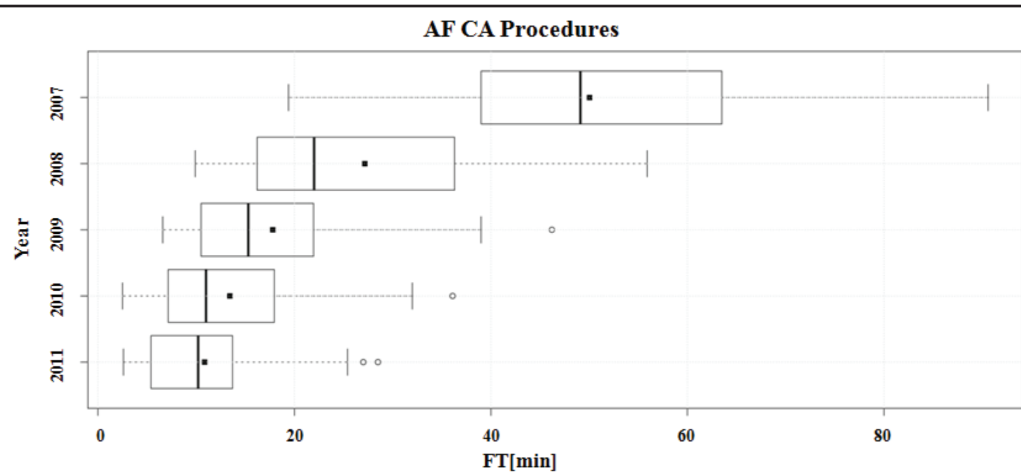
4.2. Atrial Fibrillation CA Procedures

During the study period, 180 AF CA procedures (152 patients) were performed and all of them were treated using a single NMS (CARTO). From 2007 to 2011, there was a 79% reduction in fluoroscopy time, from 49.1 min (95%CI [41.9 - 55.8]) to 10.2 min (95% CI [6.1 - 11.9]) (MW-test, P < 0.001) (Figure 2) and an 84% reduction in total X-ray exposure, from 137.62 Gy*cm^2 (95%CI [74.78 - 170.63]) to 22.59 Gy*cm^2 (95%CI [16.80 - 29.52]) (MW-test, P < 0.001). Over that period, different versions of the CARTO mapping system were used for the procedures (CARTO XP, CARTO 3), permitting a further reduction in fluoroscopy time and X-ray exposure as shown in Figure 3. In addition, the median value of the procedure time fell from 240 min to 170 min (MW-test, P < 0.05).

4.3. Supraventricular Tachycardia CA Procedures

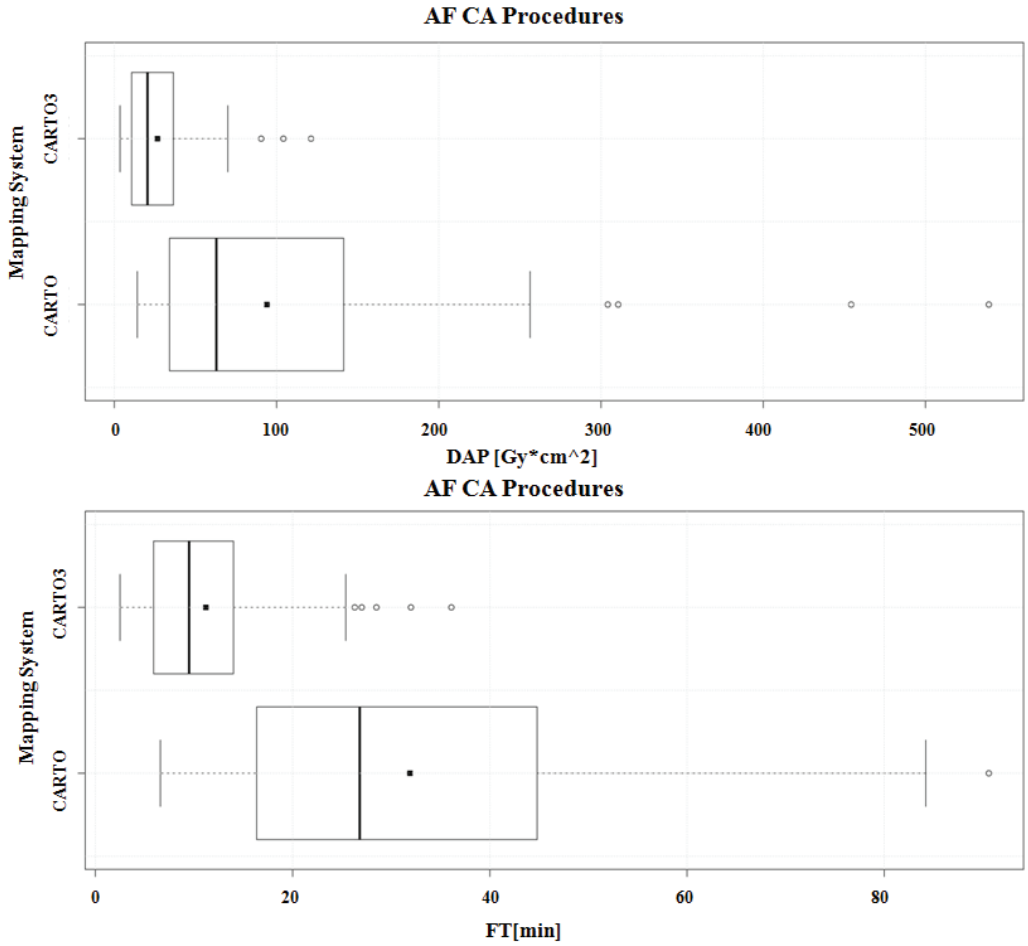
Through the study period, 228 SVT CA procedures (219 pts) were performed. Fluoroscopy time was reduced by 82% from 16.6 min (95%CI [13.0 - 20.3]) to 2.9 min (95% CI

Figure 2. The Box and Whisker Plot Depicts the Fluoroscopy Time Reduction during AF CA Procedures from 2007 to 2011.



The data for fluoroscopy time have been expressed in minutes (min). The difference between the first and the last year is statistically significant (P < 0.0001). FT, Fluoroscopy time

Figure 3. The Box and Whisker Plots Show the Reduction of Fluoroscopy Time and Total X-ray Exposure in AF CA Procedures Performed Using CARTO XP and CARTO 3 over the Study Period.



The data for fluoroscopy time have been expressed in minutes (min). The data for total X-ray exposure have been presented as Dose Area Product (DAP) (Gy-cm ^{2}). The difference is statistically significant (P < 0.05). FT, Fluoroscopy time; DAP, Dose area product.

[2.3 - 3.6]) (MW-test, P < 0.001). Besides, there was zero X-ray exposure for 8% of the population. Comparison of the data of CA procedures performed using the mapping system (EnSite) revealed that using the EnSite NavX version instead of the EnSite Velocity version caused the fluoroscopy time to decrease from 7.3 to 2.6 min (Figure 4).

4.4. Complications

The post-procedural echocardiogram was normal in almost all the patients after CA procedures. However, we had 5 cases of pericarditis after AF CA and 1 case of transseptal puncture complicated by pericardial effusion, which stopped the procedure. Furthermore, we had 11 cases of post-procedural femoral haematoma in the patients under anticoagulation therapy that were also after AF CA procedures. It must be stated, however, that the nature of these complications was not any different from the types of complications our group encountered in the years of work in our EP Lab before the study.

4.5. Follow-up

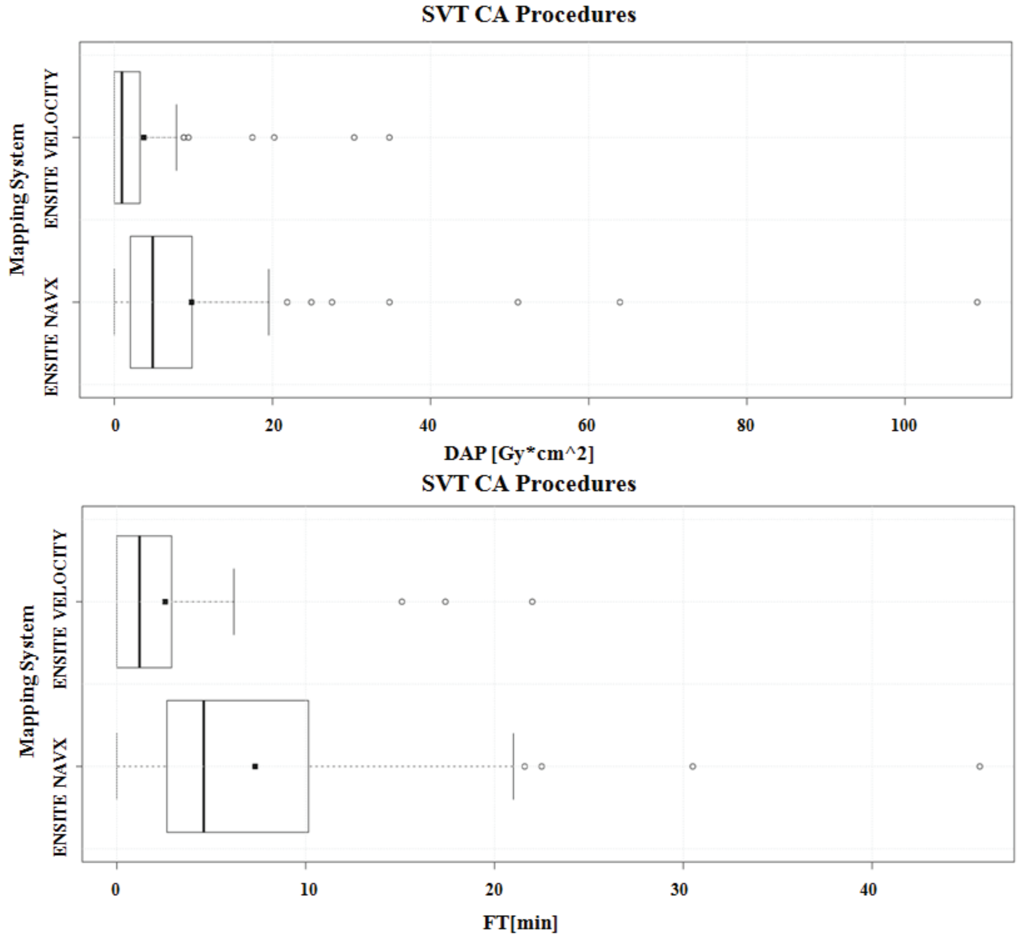
The immediate success rate was 79.1% for all the CA procedures performed from October 2008. However, the acute procedural success was 92% for all the SVT CA procedures and 71% for the AF CA procedures. During the follow-up period (2 - 6 years), the success rate of the AF CA procedures decreased to 57%. It must be stated that these success rate figures were essentially not different from our EP Lab success rates in the period from January 2007 to October 2008 (91% for SVT CA and 53% for AF CA).

5. Discussion

Mapping systems were originally created and designed as tools in procedures dealing with complex arrhythmias. Although mapping systems are extremely useful in treatment of these complex conditions, in the last ten years, some studies demonstrated that they could also be applied to CA of simple arrhythmias (11). The use of mapping systems in these cases does not compromise the treatment or make it less effective in comparison to traditional CA and in some instances, the procedure can even become simpler and quicker (9, 12-14). At this point in time, a multi-center, randomized, controlled trial is ongoing to test the safety, efficacy, and cost-effectiveness of treating supra-ventricular tachyarrhythmias with the use of an NMS in comparison to fluoroscopy (15).

An added aspect and indeed an advantage of the use of a mapping system is a significant reduction in fluoroscopy exposure for both patients and operators (16). Within the cardiological community, invasive procedures traditionally involved the use of X-ray, but now with new mapping systems, a reduction in fluoroscopy is possible and has

Figure 4. The Box and Whisker Plots Show the Reduction of Fluoroscopy Time and Total X-ray Exposure Comparing SVT CA Procedures Performed Using Different EnSite Software Versions (EnSite NavX and EnSite Velocity).



The data for fluoroscopy time have been presented in minutes (min). The data for total X-ray exposure have been presented as Dose Area Product (DAP) (Gy-cm^2). The difference is statistically significant ($P < 0.05$). FT, Fluoroscopy time; DAP, Dose area product.

come to be seen not just as an added advantage, but as an important step in the direction of a "zero-fluoroscopy" ethos (17-19). In accordance with the ALARA policy (radiation doses "As Low As Reasonably Achievable") (20) and with the support of our administration, we decided to systematically implement the use of a mapping system in all CA procedures starting from October 2008. Our results showed the feasibility, efficacy, and safety of using an NMS as the main imaging modality to guide ablation of a wide range of tachyarrhythmias in all type of patients.

This study demonstrated that the extended use of an NMS dramatically reduced radiation exposure in an unselected population of patients who underwent CA procedures for all types of tachyarrhythmias. The reduction in radiation exposure was approximately 80% and did not incur any prolongation of the procedure time.

The fall in fluoroscopy was more dramatic in the first years of our study and has become more gradual, but still present, in the recent years. In our opinion, the reason for the decrease in general seems to be a complex interaction among several factors. First of all, the increase in the use of an NMS for procedures simply reduced fluoroscopy time. Indeed, the initial decrease in radiation exposure was mainly due to the fact that from January 2007 to October 2008, just below half of the CA procedures were performed using fluoroscopy as the only imaging modality and this was followed by a change in the systematic use of NMSs in our EP Lab. A second factor is that developments and improvements in NMS software give the operator the opportunity to use less fluoroscopy to check catheter movements. This consideration is mainly supported by the data coming from the AF CA procedures; after the image integration of the LA, the possibility to visualize the circular mapping catheter with CARTO 3 (Figure 3) permitted a further reduction in fluoroscopy compared to the use of CARTO XP version. Similarly, implementation of the new software version of EnSite Velocity which improved the stability of the catheter imaging led to a reduction in fluoroscopy use (Figure 4). However, technological improvements alone cannot explain the progressive and continuous decrease in X-ray use observed in our study. An important point to make is that over the period from 2007 to 2011, systematic use of NMSs became the norm of our working day and not the exception.

Finally, it should be stated that during those years, the working relationship of the members of our team and the understanding between them developed and strengthened to give a high degree of confidence and expertise in the use of NMSs, which surely had an influence on the reduction of fluoroscopy.

The systematic use of an NMS dramatically reduced fluoroscopy time and total X-ray exposure compared to

CA procedures performed using fluoroscopy as the main guiding tool. All this came about without prolonging the procedure time and even reduced it in some cases. In our experience, this reduction was mainly related to the day-to-day use of NMSs, which provided an environment for the growth of the EP team's competence and confidence. We also think that the amount of X-ray exposure reduction reported in our "real-life" study makes a strong argument for the daily use of NMSs for CA procedures and justifies the increased cost. We must consider that there is an ethical imperative to protect the patients' and operators' health and if these data are confirmed by other randomized multicenter studies, there will be no more reason to cure cardiac arrhythmias without using an NMS.

5.1. Limitations

This study had at least three limitations. First, it was not a randomized multicenter study. Second, the cost/benefit effects of this extended use of NMSs were not assessed. Finally, we did not analyze the effect of the reduction in fluoroscopy on the specific risks of radiation exposure to patients and medical professionals.

We also have to consider that the second operator was in his training period during the study and this might have contributed to a reduction in fluoroscopy exposure only due to an improved expertise in the use of NMSs.

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Authors' Contribution

Maurizio Del Greco: Design of the study, drafting of the article, data analysis, critical revision of the article, approval of the article; Massimiliano Marini: Design of the study, drafting of the article, data analysis, critical revision of the article, data Collection; Ravanelli Daniele: Drafting of the article, data analysis, critical revision of the article, statistics, data collection; Alessio Coser: Drafting of the article, data analysis, critical revision of the article, statistics, data collection; Fabrizio Guarracini: Drafting of the article, data analysis, critical revision of the article; Aldo Valentini: Drafting of the article, data analysis, critical revision of the article; Stefano Indiani: Drafting of the article, data analysis, critical revision of the article; Roberto Bonmassari: Drafting of the article, data analysis, critical revision of the article.

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