Minimal fluoroscopy approach for right-sided supraventricular tachycardia ablation with a novel ablation technology: Insights from the multicenter CHARISMA clinical registry

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Minimal fluoroscopy approach for right-sided supraventricular tachycardia ablation with a novel ablation technology: insights from the multicenter CHARISMA clinical registry

Short Title: Minimal fluoroscopy approach in current clinical practice

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Abstract

Background: No data exist on the ability of the novel Rhythmia 3-D mapping system to minimize fluoroscopy exposure during transcatheter ablation of arrhythmias.We report data on feasibility and safety of a minimal fluoroscopic approach using this system in supraventricular tachycardia (SVT) procedures.

Methods: Consecutive patients were enrolled in the CHARISMA registry at 12 centers. All right-sided procedures performed with the Rhythmia mapping system were analyzed. The acquired electroanatomic information was used to reconstruct 3-D cardiac geometry; fluoroscopic confirmation was used whenever deemed necessary.

Results: 325 patients (mean age=56±17years, 57% male) were included: 152 AVNRT, 116 AFL, 41 and 16 right-sided accessory pathway and AT, respectively. Overall, 27481 seconds of fluoroscopy were used (84.6±224sec per procedure, equivalent effective dose=1.1±3.7mSv per patient). 192 procedures (59.1%) were completed without the use of fluoroscopy (zero fluoroscopy, ZF). At multivariate analysis the presence of a fellow in training (OR=0.15, 95%CI:0.05 to 0.46; p=0.0008), radiofrequency application (0.99, 0.99 to 1.00; p=0.0002) and mapping times (0.99, 0.99 to 1.00; p=0.042) were independently associated to ZF approach. Acute procedural success was achieved in 97.8% of the cases (98.4 vs 97% in the ZF vs non-ZF group, p=0.4503). During a mean of 290.7±169.6days follow-up, no major adverse events were reported, and recurrence of the primary arrhythmia was 2.5% (2.1 vs 3% in the ZF vs non-ZF group, p=0.7206).

Conclusions: The Rhythmia mapping system permits transcatheter ablation of right-sided SVT with minimal fluoroscopy exposure. Even more, in most cases, the system enables a ZF approach, without affecting safety and efficacy.

Clinical Trial Registration: Catheter Ablation of Arrhythmias with a High-Density Mapping System in Real-World Practice (CHARISMA). URL: http://clinicaltrials.gov/ Identifier: NCT03793998.

Keywords: Low fluoro, Rhythmia mapping system, Fluoroscopy reduction, Catheter Ablation, Supraventricular tachycardia

Abbreviations: 3-D, three-dimensional; SVT, supraventricular tachycardia; ZF, zero fluoroscopy; EPS, electrophysiology studies; CS, coronary sinus; RF, radiofrequency; KAP, (kerma)-area product; ED, effective dose;

AVNRT, Atrio-Ventricular Nodal Reentrant Tachycardia; AVRT, Atrio-ventricular reciprocating tachycardia; AT, atrial tachycardia; AFL, atrial flutter; AF, atrial fibrillation; CI, confidence interval.

Introduction

Whereas radiation exposure related to natural sources is relatively minimal, medicine-related exposure is a major source and may induce harm both following acute exposition and during long-term follow-up [1] by increasing the lifetime risk of malignancies and fatal cancer, skin injuries, cognitive impairment or genetic defects [2-6]. Electrophysiological studies (EPS) and ablation procedures are traditionally performed under fluoroscopic guidance and, therefore, expose both physicians and patients to a relevant amount of radiation. To date, three-dimensional (3-D) mapping systems permit electroanatomic heart chamber reconstruction and provide accurate tracking of catheters, possibly allowing reduction of the need of fluoroscopic guidance [7, 8]. In fact, the rapid development of new electroanatomic mapping technologies is leading to significant reductions of fluoroscopy exposure, from the lowest "reasonably achievable" to more often "zero fluoroscopy" approaches [9-11]. Despite large retrospective and prospective series [12-18] reporting on safety and efficacy for several commonly used 3-D mapping systems, only anecdotal data [19] exists on the ability, in this respect, of the novel Rhythmia™ mapping system (Boston Scientific, Marlborough, MA, USA). Aim of this study is to report data on feasibility and safety of a minimal fluoroscopic approach using the Rhythmia™ mapping system for right-sided supraventricular tachycardia (SVT) transcatheter ablation procedures in a routine clinical setting.

Methods

Patient population and study design

Consecutive patients referred for arrhythmia ablation were enrolled in the Catheter Ablation of Arrhythmias with High Density Mapping System in the Real World Practice (CHARISMA) study at 12 Italian high volume centers from January 2019 to January 2020. The CHARISMA study (ClinicalTrials.gov Identifier: NCT03793998) is a prospective, single-arm, multicenter cohort study designed to describe Italian clinical practice on transcatheter ablation of different arrhythmias. The study complies with the Declaration of Helsinki, the locally appointed ethics committee approved the research protocol, and informed consent was obtained from all patients. For the purpose of the present analysis all 325 consecutive right-sided SVT procedures performed with the Rhythmia™ mapping system were analyzed. Right-sided ablation performed within left atrial flutter or atrial fibrillation (AF) ablation procedures were excluded, as all EPS where no arrhythmia was induced. Patients were followed-up at the same hospital, from the time of the index procedure to the last available follow-up visit.

Mapping and Ablation procedure

The procedures were performed under standard clinical practice guidelines [12]. All procedures were performed under local anesthesia with mild to moderate sedation in accordance to centers' protocol.

Rhythmia™ set up for minimal fluoroscopy has previously been described [19]. Briefly, the patient is prepared with standard ECG electrodes placement and the Rhythmia™ HDx back patch. For internal system reference, an external indifferent electrode is used. This electrode is chosen as impedance reference for the field map. Diagnostic and ablation catheters are inserted into the heart through the femoral veins in biplane views, to visualize the path of the catheters. During this step, system optimization and respiratory compensation are performed. According to center's preference a quadripolar catheter is introduced via the femoral vein and positioned in the right ventricular apex, or on the His bundle. Differently, the His bundle is anatomically tagged during geometry reconstruction. A steerable decapolar electrode is then placed in the coronary sinus (CS) via the femoral vein. A 3-D geometry of the heart chambers of interest is reconstructed and standard EPS performed. The study design provided open choice in terms of the use of mapping catheters; the use of a point by point vs multipolar mapping catheter was at center's discretion Ablation, when appropriate, was performed connecting the IntellaNav™ MiFi XP, IntellaNav™ ST, or the IntellaNav™ MiFi OI catheters (Boston Scientific, Marlborough, MA, USA) to the Rhythmia™ mapping system (Figure 1). Fluoroscopy was used whenever deemed necessary, according to operator's preference.

Definitions

The following parameters were recorded for each procedure [15] : total anatomical mapping time (the time required to reconstruct the geometry of the heart chambers of interest); number of radiofrequency (RF) applications, total ablation time (the cumulative time of energy delivery) and total fluoroscopy time (the cumulative duration of fluoroscopy used during the entire procedure). In accordance with previous literature, radiation dose was recorded using the air kinetic energy released per unit mass (kerma)-area product (KAP, defined elsewhere as dose area product) [20]. The effective dose (ED) was calculated using the conventional formula, where ED (mSv)=KAP (Gy·cm2)×0.2 (mSv/Gy·cm2) [21]. Zero fluoroscopy (ZF) was defined as termination of the entire procedure without the use of fluoroscopy.

Procedural success was defined as non-inducibility of the clinical arrhythmia. Major complications were defined as complications that exposed the patient to significant risks or that required an intervention, procedure, or hospitalization for the management and treatment of the patient. A minor complication was defined as an adverse event that did not require an intervention and that could be managed on an outpatient basis.

Follow-up

Complications and follow-up data were reported on the registry case report form and collected during follow-up, during which clinical evaluation and 12-lead ECG were performed. In cases of palpitations a 24-h Holter ECG monitoring was recommended.

Recurrence was defined as relapse of the arrhythmia targeted at index procedure demonstrated by ECG, remote monitoring, or typical patient's symptoms, independently from the need for repeat catheter ablation.

Statistical analysis

Descriptive statistics is reported as means±SD for normally distributed continuous variables, or medians with 25th to 75th percentiles in the case of skewed distribution. Normality of distribution was tested with the non-parametric Kolmogorov–Smirnov test. Differences between mean data were compared with a t-test for Gaussian variables, and the F-test was used to check the hypothesis of equality of variance. The Mann-Whitney non-parametric test was used to compare non-Gaussian variables. Differences in proportions were compared by applying χ^2 analysis or Fisher's exact test, as appropriate. A logistic regression model was fitted to assess the ability of a series of covariates to predict radiation exposure. Factors reporting a p value <0.05 on univariate analysis were entered into the model. A p value <0.05 was considered significant for all tests. All statistical analyses were performed with STATISTICA software, version 7.1 (StatSoft, Inc., Tulsa, OK).

Results

Study population

A total of 325 consecutive patients referred for right-sided SVT ablation were enrolled: 116 (35.7%) atrial flutters (AFL), 152 (46.8%) atrio-ventricular nodal reentrant tachycardias (AVNRT), 41 (12.6%) atrio-ventricular reentrant tachycardias (AVRT) and 16 (4.9%) atrial tachycardias (ATs). The mean patient age was 56±17 years, mean body mass index was 25.4±5 kg/m^2 and patients were mostly males (n=186, 57.2%). Forty-nine (15.1%) patients had an underlying structural heart disease, 40 (12.3%) history of AF. Most of the cases were de novo procedures (n=300, 92.3%). Detailed description of the study population is reported in Table 1a.

Procedural features and fluoroscopic use

During the study, 27481 seconds of fluoroscopy were used (84.6±224 seconds per procedure), reaching an ED equivalent of 1.1±3.7 mSv per patient. The mean mapping time was 12.2±7 min. The mean number of RF applications to achieve arrhythmia termination and non-inducibility was 9.4±9 (mean delivery time = 6.7±6 minutes). Detailed procedural data are summarized in Table 1b.

One hundred ninety-two procedures (59.1%) were completed without the use of fluoroscopy; the remaining 133 procedures (39.9%) required 206.6±313.4 seconds of fluoroscopy, a mean equivalent ED of 2.8±5.4 mSv. Fluoroscopic exposure was greater than 1 minute in 90 cases (27.7%), and in a minority (n=25, 7.7%), longer than 5 minutes (Figure 2).

Fluoroscopy time and dose varied within the various types of procedures (Figure 3 A to C). A ZF approach was more commonly achieved in AVNRT (111 out 152, 73%) compared to other procedures (81 out 173, 47%, p<0.0001). In addition, the presence of a fellow in training (4 out of 27, 15% with a fellow in training vs 188 out 298, 63%

without, p<0.0001) related to a lower percentage of ZF procedures.

Factors associated to the radiation exposure

At multivariate logistic analysis adjusted for baseline confounders (Table 2), presence of a fellow in training (OR=0.1489, 95%CI: 0.0487 to 0.4555; p=0.0008), total RF applications (OR=0.9986, 95%CI: 0.9978 to 0.9993; p=0.0002) and mapping time (OR=0.9994, 95%CI: 0.9988 to 1.0000; p=0.042) resulted independently associated to the achievement of a ZF approach. RF applications (OR=1.0014, 95%CI: 1.0007 to 1.0022; p=0.0001), and inversely, female gender (OR=0.538, 95%CI: 0.2947 to 0.9822; p=0.0435) significantly related to a fluoroscopic exposure above the median ED value (1.2 mSv; Table 3).

Acute outcome and follow-up

Acute procedural success was achieved in 318 (97.8%) cases (Figure 4) (98.4 vs 97% in the ZF vs non-ZF group, p=0.4503). At 290.7±169.6 days follow-up, no procedure-related major adverse events were reported (Table 4). Overall, recurrence rate of the primary arrhythmia during follow-up was 2.5% (n=8) (2.1 vs 3% in the ZF vs non-ZF group, p=0.7206): 4 (3%) in patients treated for AFL, 3 (2%) for AVNRT and 1 (2%) for AVRT (Figure 4). Fourteen cases (4.3%) suffered a relapse not related to the index arrhythmia, mostly AF (n=9, 2.8%) (Table 4).

Discussion

In this single-arm prospective study, we investigated radiation exposure during transcatheter mapping and ablation of right-sided SVTs with the use of a novel 3-D mapping system. The use of the investigated technology permitted, without affecting safety and effectiveness, not to use fluoroscopy in about 60% of the cases, and, overall, to expose the patients to low dosages. Factors inversely related to achievement of a ZF approach were presence of a fellow in training, total RF applications and mapping time.

EPS and ablation procedures unfortunately expose both physicians and patients to a large amount of radiation [1-6], resulting in a non-negligible risk of biological damage [22]. However, there is no magnitude of exposure that may be considered completely safe [23]. In the attempt to optimize radiological hazard management, driven by the European Council's Regulation update (Euratom 2013/59), several cardiological societies have issued guidelines and recommendations [22, 24, 25]. Overall, the principles of exposure optimization and justification emerge as guiding, recommending to expose the patient and medical staff to a dose as low as that reasonably achievable (the ALARA principle). Over the past decades the rapid development of new electroanatomic mapping technologies is leading to significant reductions of fluoroscopy exposure, from the lowest "reasonably achievable" to more often "zero fluoroscopy" approaches [1, 26] In fact, large retrospective and prospective series have reported on safety and efficacy of several commonly used 3-D mapping systems for a wide range of arrhythmias [12-18]. Data on the Rhythmia, a novel 3-D mapping system, instead, are scarse, based on a limited (n=20), single center experience [19]. The present analysis on a large, multicenter population documents feasibility of a minimal fluoroscopy routine approach with the Rhythmia mapping system for right-sided SVTs. Similarly to what achieved by other technologies [13-16], ZF was achieved in a high number of procedures and overall radiation exposure was extremely low in all procedures. Within recorded parameters, RF applications and mapping time emerged as inversely associated to the achievement of a ZF approach. This correlation may surely be interpreted as an indirect sign of wider or more complex arrhythmia substrate, most likely requiring the need of additional "confirmatory" fluoroscopy checks of catheter placement and stability. It is also well known that, in interventional cardiology, fluoroscopy use decreases with operator experience [27]. In the majority of cases the Orion catheter was not used and atrial chambers were mapped through point-by-point approach only. Anyhow, when used, it did not relate to an increase in fluoroscopy exposure. It is therefore not surprising that the presence of a fellow increases the fluoroscopy exposure and this can be due to various factors (like catheter position check, learning objective during training), however it calls for the need of including specific radiation awareness education in the early training stages of the fellows [28]. Female gender was found to be inversely related to fluoroscopy use. This data can plausibly be attribuited to subtle attention to radiaton especially in young (fertile) age. The most relevant finding, however, is that the minimal fluoroscopy exposure permitted by the Rhythmia 3-D system mapping did not affect safety of the procedures. In fact, no periprocedural complication was reported in-hospital and at follow-up end. In addition, success rates achieved, the recurrence of the index arrhythmia over follow-up was 2.5%, appear extremely satisfactory and in line with previous literature. As shown with different technologies [13-16], the positive outcomes hereby described, suggest the use of the system may also be applicable to more complex ablation procedures such as ablation of AF, atypical flutters, or ventricular tachycardia. [9; 29-31] . Even the manuscript was not designed to demonstrate superiority over other mapping system a potential benefit that must be noted is the completely magnetic navigation which allows high accuracy either in mapping and ablation phases.

Limitations

The results of the present study should be interpreted in the light of several limitations. Firstly, not being a randomized controlled study, direct comparisons with other technologies cannot be made. In addition, the study was not intended to compare safety and efficacy in different arrhythmia types. Moreover, patient population is represented by predominantly healthy patients, without rare anatomical variations and/or underlying structural heart disease; present findings may not apply to a more diseased population. Finally, even though RF application and mapping times emerged as inversely associated to the achievement of a ZF approach there was no mention of fluoroscopy use stratified for phases of the procedure.

Conclusion

The Rhythmia 3-D mapping system permits transcatheter ablation of right-sided SVTs with minimal fluoroscopy exposure. Even more, in most cases, the system enables a zero fluoroscopy approach, without affecting safety and efficacy.

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Table legends

Table 1a. Baseline characteristics of the study population.

Parameter	n=325
Age (years)	56 ± 16.6
Gender male, n (%)	186 (57.2)
BMI (kg/m^2)	25.4 ± 4.6
Indication for transcatheter ablation, n (%):	
- AFL	116 (35.7)
- AVNRT	152 (46.8)
- AVRT	41 (12.6)
- AT	16 (4.9)
Procedure type, n (%):	
- De novo	300 (92.3)
- Repeat	25 (7.7)
History of AF, n (%)	40 (12.3)
LVEF (%)	57.7 ± 6.5
Structural heart disease, n (%)	49 (15.1)
Valvular disease, n (%)	14 (4.3)
History of Heart Failure, n (%)	12 (3.7)
CKD, n (%)	7 (2.2)
Hypertension, n (%)	74 (22.8)
COPD, n (%)	8 (2.5)
History of major bleedings, n (%)	2 (0.6)
Antiarrhythmic administration, n (%)	66 (20.3)
Antiplatelet therapy, n (%)	32 (9.8)
Anticoagulation therapy, n (%)	95 (29.2)

AF=Atrial fibrillation; AFL=Atrial flutter; AT=Atrial tachycardia; AVNRT=Atrio-Ventricular Nodal Reentrant Tachycardia; AVRT=Atrioventricular reciprocating tachycardia; BMI=Body mass index; CKD=Chronic Kidney disease; COPD=Chronic obstructive pulmonary disease; LVEF=Left ventricular ejection fraction.

Table 1b. Procedural details of the 325 procedures analysed.

Parameter	n=325
Achievement of ZF, n (%)	192 (59)
Fluoroscopy time (sec):	
- overall	84.6 ± 224.4
- in non-ZF procedures	206.6 ± 313.4
RF applications, n	9.4 ± 8.6
RF duration time (sec)	403.2 ± 351.7
Procedure duration (sec)	4404.2 ± 1706.7
Mapping time (sec)	734.4 ± 420.5
Right atrium mapping volume (cc)	99.4 ± 53.9
Mean Power (W)	50.1 ± 19.3
Effective dose (mSv):	
- overall	1.1 ± 3.7
- in non-ZF procedures	2.8 ± 5.4

RF=radiofrequency; ZF=zero fluoroscopy approach.

Table 2. Univariate and multivariate factors associated to zero fluoroscopy achievement.

Variable	OR	95% CI	*p*	OR	95% CI	*p*
Femoral access guided by echography	1.4353	0.6711 to 3.0697	0.3515			
AVNRT*	3.075	1.9289 to 4.9021	<0.0001			
AVRT	0.6939	0.3597 to 1.3383	0.2755			
BMI	0.9725	0.9206 to 1.0275	0.3206			
COPD	0.6862	0.1685 to 2.7935	0.599			
CAD	0.6125	0.2294 to 1.6353	0.3278			
Structural heart disease	0.6799	0.3695 to 1.2512	0.215			
Patient's age	0.9983	0.9851 to 1.0118	0.8078			
Operator's age	0.9829	0.9562 to 1.0103	0.2191			
AFL*	0.3784	0.2372 to 0.6037	<0.0001			
Hypertension	0.7137	0.4234 to 1.2030	0.2055			
LVEF	1.0099	0.9715 to 1.0498	0.6187			
Valvular disease	0.2617	0.0803 to 0.8531	0.0262	0.4679	0.1258 to 1.7402	0.2571
Operator's experience in EP procedures	1	0.9998 to 1.0003	0.7264			
Number of RF applications	0.9272	0.8998 to 0.9555	<0.0001			
Fellow in training during the procedure	0.1018	0.0343 to 0.3019	<0.0001	0.1489	0.0487 to 0.4555	0.0008
Female gender	1.8757	1.1874 to 2.9632	0.007	1.456	0.8890 to 2.3845	0.1356
History of AF	0.657	0.3383 to 1.2758	0.2147			
AT	0.8852	0.3213 to 2.4390	0.8136			
RF application time*	0.9983	0.9975 to 0.9990	<0.0001	0.9986	0.9978 to 0.9993	0.0002
Mapping time	0.9995	0.9989 to 1.0000	0.0451	0.9994	0.9988 to 1.0000	0.042
Type of procedure (redo vs de novo)	0.8723	0.3832 to 1.9858	0.7448			
Mapped volume	0.9966	0.9920 to 1.0011	0.1397			

AF=Atrial fibrillation; AFL=Atrial flutter; AT=Atrial tachycardia; AVNRT=Atrio-Ventricular Nodal Reentrant Tachycardia; AVRT=Atrioventricular reciprocating tachycardia; BMI=Body mass index; CAD=Coronary artery disease; COPD=Chronic obstructive pulmonary disease; EP=Electrophysiology procedure; LVEF=Left ventricular ejection fraction; RF=Radiofrequency.

*AVNRT, AFL and Number of RF applications were not entered into the multivariate model, owing to their correlation with RF application time.

Table 3. Univariate and multivariate factors associated to high-dose exposure (above median value of the population = 1.2 mSv)

Variable	OR	95% CI	*p*	OR	95% CI	*p*
Femoral access guided by echography	0.3635	0.1074 to 1.2302	0.1037			
AVNRT*	0.3498	0.1931 to 0.6336	0.0005			
AVRT	0.9446	0.4142 to 2.1545	0.8923			
BMI	1.0295	0.9649 to 1.0985	0.3793			
COPD	2.419	0.5631 to 10.3926	0.2349			
CAD	1.242	0.3898 to 3.9574	0.714			
Structural heart disease	1.5194	0.7535 to 3.0639	0.2424			
Patient's age	1.008	0.9913 to 1.0251	0.3501			
Operator's age	1.0216	0.9878 to 1.0564	0.213			
AFL*	2.4811	1.4312 to 4.3011	0.0012			
Hypertension	1.2295	0.6580 to 2.2973	0.5171			
LVEF	0.9872	0.9430 to 1.0334	0.5816			
Valvular disease	1.6065	0.4875 to 5.2935	0.4359			
Operator's experience in EP procedures	0.9998	0.9995 to 1.0001	0.1217			
Number of RF applications*	1.0649	1.0342 to 1.0966	<0.0001			
Fellow in training during the procedure	1.7423	0.7267 to 4.1772	0.2133			
Female gender	0.4683	0.2606 to 0.8415	0.0112	0.538	0.2947 to 0.9822	0.0435
History of AF	1.8333	0.8762 to 3.8361	0.1076			
AT	1.848	0.6191 to 5.5164	0.2711			
RF application time	1.0015	1.0008 to 1.0022	<0.0001	1.0014	1.0007 to 1.0022	0.0001
Mapping time	1.0003	0.9997 to 1.0009	0.3565			
Type of procedure (redo vs de novo)	1.2632	0.4834 to 3.3005	0.6336			
Mapped volume	1.0016	0.9963 to 1.0069	0.5593			

AF=Atrial fibrillation; AFL=Atrial flutter; AT=Atrial tachycardia; AVNRT=Atrio-Ventricular Nodal Reentrant Tachycardia; AVRT=Atrioventricular reciprocating tachycardia; BMI=Body mass index; CAD=Coronary artery disease; COPD=Chronic obstructive pulmonary disease; EP=Electrophysiology procedure; LVEF=Left ventricular ejection fraction; RF=Radiofrequency.

*AVNRT, AFL and Number of RF applications were not entered into the multivariate model, owing to their correlation with RFC application time.

Table 4. Acute and end of follow-up procedural outcome.

Parameter	**n=325**
Acute success, n (%)	318 (97.8)
Recurrence of the primary arrhythmia during follow-up, n (%)	8 (2.5)
Occurrence of other arrhythmias (beyond primary arrhythmia), n (%)	14 (4.3)
Major adverse events related to the procedures, n (%)	0 (0.0%)
Follow-up duration (days)	290.7 ± 169.6

Figures

Figure 1. Procedural workflow of the minimal fluoroscopy approach by Rhythmia™ mapping system (adapted from Cauti et al. [20]).

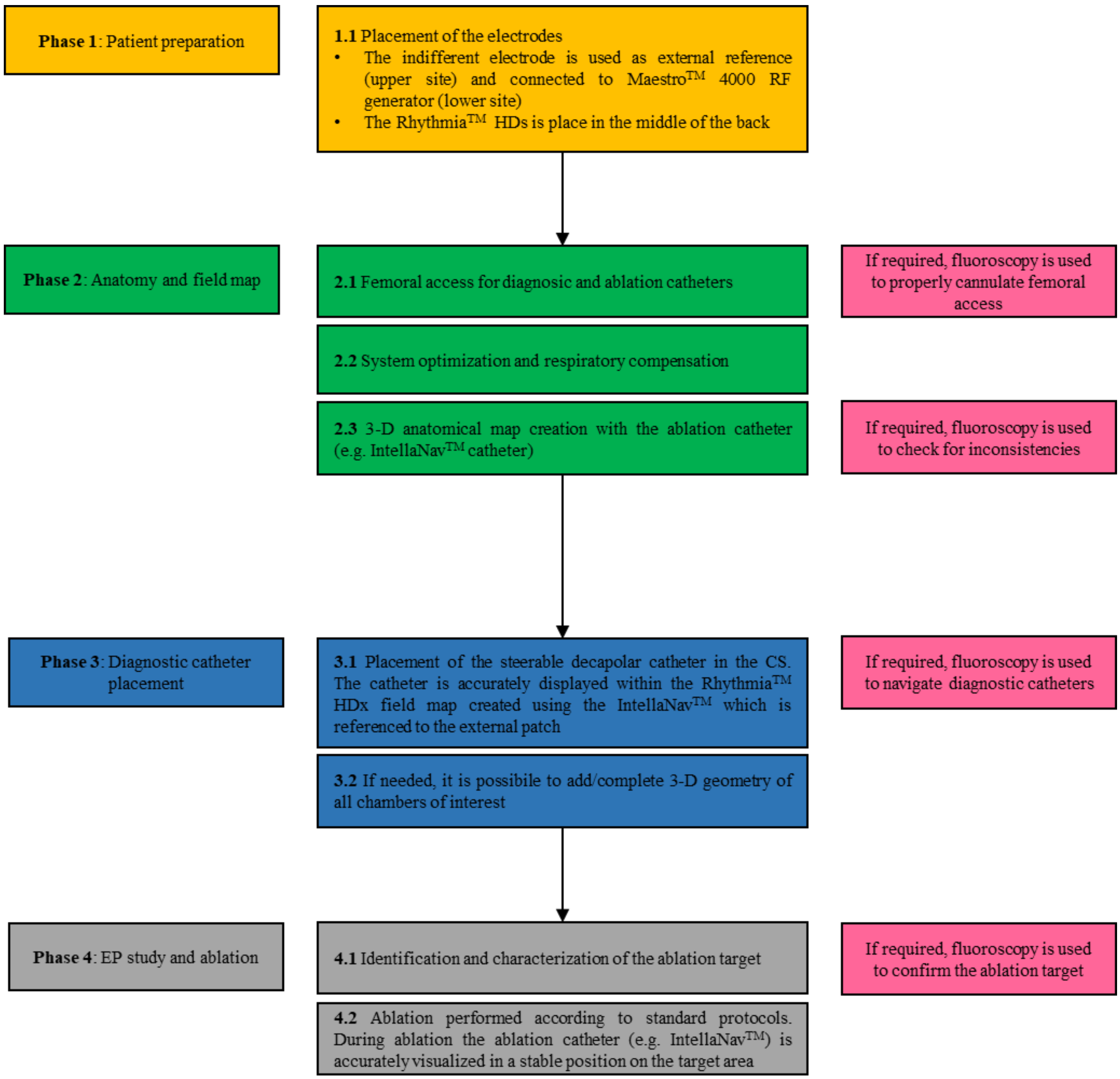

Figure 2. Procedure stratification for radiation exposure time (ZF=no fluoroscopy use).

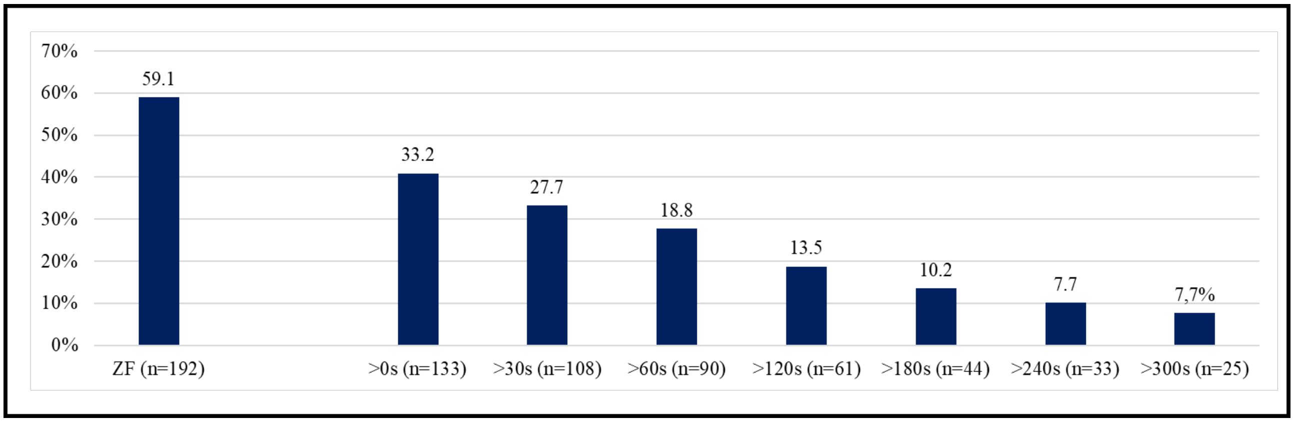

Figure 3, A to C.

A: Achievement of a zero fluoroscopic approach according to procedure type; **B:** Fluoroscopy, RF and Mapping times according to procedure type; **C:** Mean effective dose according to procedure type, in the entire population and exposed patients (excluding ZF procedures).

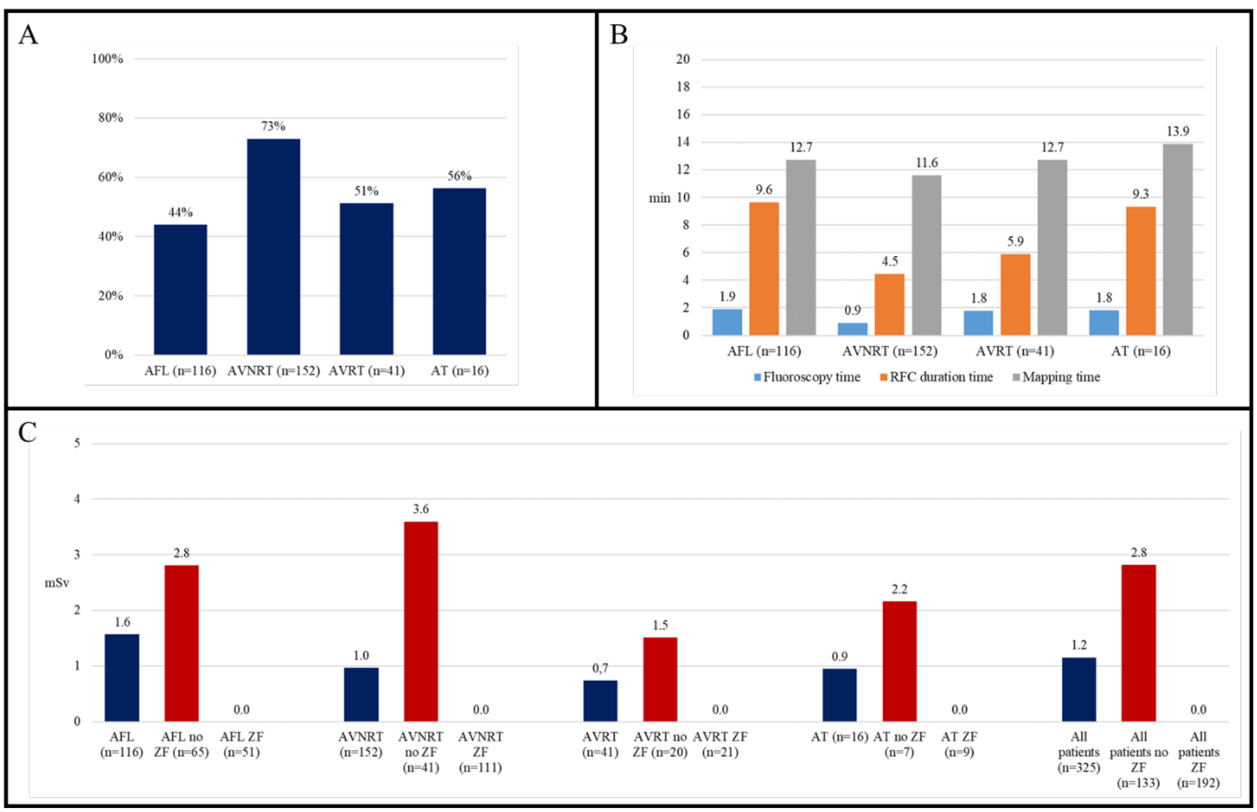

Figure 4. Acute success and long-term recurrence rate according to index arrhythmia