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Effect of Left atrial Volume and Pulmonary Vein Anatomy on Outcome of nMARQ™ Catheter Ablation of Paroxysmal Atrial Fibrillation

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ABSTRACT

Purpose. Left atrial volume (LA) and pulmonary vein (PV) anatomy may potentially relate to technical challenges in achieving stable and effective catheter position in case of atrial fibrillation (AF) ablation by means of “one shot” catheters. The aim of this study was to investigate whether LA volume and PV anatomy, evaluated by computed tomography (CT) or magnetic resonance (MR) prior to ablation, predict acute and mid-term outcome of AF ablation by nMARQ^{TM}.

Methods*.* We included 75 patients (mean age 58 ± 11y ears, 67% male) with symptomatic paroxysmal AF. All patients underwent CT/MR scanning prior to catheter ablation to evaluate LA volume and PV anatomy. All patients underwent PV isolation by nMARQ^{TM}, an open-irrigated mapping and radiofrequency (RF) decapolar ablation catheter. Ablation was guided by electroanatomic mapping allowing RF energy delivery in the antral region of PVs from 10 irrigated electrodes simultaneously.

Results. Mean LA volume was 75±40 ml. A normal anatomy (4 PVs) was documented in 40 (53%) patients, an abnormal anatomy (common truncus or accessory PVs) in 35 patients. Mean procedural and fluoroscopy times were 94 ± 55 minutes and 8 ± 5 minutes, respectively, without significant differences among patients with normal or abnormal anatomy (92±45 min vs 95±64 min, p=0.85 and 6±3 min vs 8±4 min, p=0.65, respectively). Mean ablation time was 14±3 min, 99% of the targeted veins were isolated with a mean of 23±5 RF pulses per patient. After a mean follow-up of 17±8 months, 23(31%) patients had an atrial arrhythmia recurrence. Neither LA volume nor PV anatomy were predictors of outcome.

Conclusions. LA volume and PV anatomy did not effect procedural data and outcome in patients who underwent PV isolation by an open-irrigated mapping and RF decapolar ablation catheter.

Key words: Atrial fibrillation; Catheter ablation; Multielectrode ablation catheter; Anatomy; Safety; Mid-term outcome

1 INTRODUCTION

Catheter ablation (CA) has become an established option for the management of drug refractory atrial fibrillation (AF) [1,2]. Although several ablation approaches have been developed, the HRS/EHRA/ECAS Expert Consensus [3] recommends the complete electrical isolation of all pulmonary veins (PVs) as the goal of every ablation procedure. Two major limitations of CA of AF are the high rate of recurrences, during short- and long-term follow-up, mainly due to electrical reconnection of the PVs, and the great variability of effectiveness reported among several centers and operators.

One shot-based technologies have been developed in the attempt to deliver ablative energy in a more continuous pattern avoiding conduction gaps in cardiac tissue isolation. Another potential advantage over the point-to-point approach is the decreased impact of the operator skills on the ablation outcome allowing a more standardized and reproducible approach.

Several one-shot catheters have been developed, including balloon-based technology and multielectrode ablation catheters [4-7]. At present, there is no data analyzing the influence of PV anatomy on the clinical efficacy of the irrigated multielectrodes ablation catheter (nMARQ ^{TM}) for PV isolation in patients with AF.

The aim of this study was to investigate whether left atrium (LA) volume and PV anatomy, evaluated by computed tomography (CT) or magnetic resonance (MR) prior to ablation, will predict acute and mid-term outcome after AF ablation using the nMARQ ^{TM} ablation catheter.

2 METHODS

2.1 Patients selection. This multicenter registry enrolled patients in 4 Italian centers (see the Appendix). Patients aged between 18 and 90 years with documented symptomatic paroxysmal episodes refractory to drug therapy (Class I or III drugs). Exclusion criteria

were: (1) persistent and long-standing persistent AF, defined as AF being the sole rhythm for >12 months before the enrolment; (2) previous CA of AF; (3) New York Heart Association functional class > II; (4) unstable angina or acute myocardial infarction within three months; (5) need for or prior cardiac surgery within six months; (6) contraindication to treatment with oral anticoagulants or bleeding diathesis; and (7) severe chronic renal or hepatic impairment.

This study was approved by the institutional review committees, and all patients signed informed consents. The principle outlined in latest update of the Declaration of Helsinki were followed.

2.2 CT and MR protocol and analysis of LA anatomy. All patients underwent CT or MR left atriogram within 24 hours of AF ablation. For CT scan a 64-slice scanner was used and iodinated intravenous contrast was administered. Contrast-enhanced MR of the LA was performed by intravenous administration of Gadobutrol.

Left atriograms acquired were reconstructed with 3-dimensional(3D) segmentation software using CARTO3 (Biosense Webster, DiamondBar,CA). The number and distribution of PVs were recorded for each patient, including the left and right superior PV, the left and right inferior PV, and the presence of PV variations, for example a common left or right trunk, and left- or right-sided accessory PVs [8](Figure 1). A common trunk was defined as a superior and inferior PV that join proximal to the LA resulting in a single atrio pulmonary venous junction. An accessory PV has its own independent atrio pulmonary venous junction separate from the superior and inferior PVs and is named for the pulmonary lobe or segment that it drains.

To evaluate the effect of the PV anatomy on the outcome of radiofrequency (RF) catheter ablation, the left- and right-sided anatomy was additionally classified as normal or atypical. Atypical anatomy was defined as the presence of a common trunk or an additional PV [9].

LA volume was calculated using the biplane dimension-length formula: LA volume= 4/3 π (anteroposterior diameter/2) x (longitudinal diameter/2) x (transversal diameter/2).

2.3 Ablation procedure. The mapping and ablation protocol has been reported in details elsewhere [10]. Operators involved in this study had previous experience in the use of nMARQ ™ ablation catheter in a 3-month period prior to study commencement. Briefly, the nMARQ™ is a steerable 8.4 F ablation and mapping 10-pole irrigated RF catheter with a novel irrigation design. Platinum electrodes are 3 mm long, with a spacing of 4 mm. Each of the electrodes retains a thermocouple and holes for irrigation. Each 3-mm electrode is individually irrigated via 10 irrigation holes using a constant flush of 4 mL/min during mapping and 60 mL/min flushing rate during ablation. By a steering mechanism placed at the handle, the catheter can be deflected unidirectionally. The 10 electrodes are arranged in a nearly circular array and the diameter may be changed in between 35mm down to 20 mm. RF ablations were preset at 30-60 seconds duration in temperature-controlled mode and energy delivery can be individually arranged over each combination of the 10 electrodes in unipolar mode (maximum 25 W and 45 ◦C) or bipolar mode over 2 adjacent electrodes (maximum 15W and 45 ◦C). The nMARQ™ catheter was visualized in the CARTO3 system (Biosense Webster Inc, Diamond Bar,CA) and ablation was directed towards the antrum of each PV sequentially (Figure 2). Before ablation, the left atrial anatomy was acquired using the nMARQ™ catheter or with the decapolar catheter previously placed in the coronary sinus (DecaNav, Biosense Webster Inc, Diamond Bar,CA). Maps were acquired during AF or coronary sinus pacing using respiratory gating. Further information on wall contact was gained from an impedance based technology built into the EAMS (Tissue Connect, Biosense Webster Inc, Diamond Bar,CA). Ablations were performed usually via all 10 electrodes and increase in temperature, drop in local impedance, and energy delivery were continuously monitored using the novel nMARQ™

Multi-Channel RF System ablation generator (Biosense Webster Inc, Diamond Bar,CA) capable of synchronously applying energy to all 10 nMARQ^{TM} electrodes.

All ablations in our patient group were performed in unipolar mode. After ablation the catheter was slightly rotated to ablate in potential gap regions only if electrograms were still identified. Electrodes were only deselected for ablation if no electrogram was visible on adjacent bipolar readings or in case of overlaps. In our patient cohort ablations were performed in a range between 20 and 25W over all applicable electrodes. Pacing for phrenic nerve capture was usually performed during right PVs isolation. Esophageal temperature monitoring was not routinely performed. However, power was limited to 15-20W in case of electrodes in contact with the posterior wall. Before ablation, electrograms templates were captured for each PV and after PV isolation abatement of electrograms and PV potentials were checked. In addition, PV high-output pacing (10 V, 2.0 milliseconds) was performed to identify PV exit block if the nMARQ^{TM} was managed into the PV. Early PV reconnection was tested 30 minutes after PV isolation, or by means of adenosine infusion, for each PV.

2.4 Postablation management and follow-up. Oral anticoagulation was not discontinued for the procedure and thereafter administered for at least 3 months (indefinitely in patients with a CHA2DS2-VASC score ≥ 2). Antiarrhythmic drugs were usually discontinued ≥5 half-lives prior to ablation, except for amiodarone (discontinued the day before ablation) and patients were usually discharged without antiarrhythmic drugs. After discharge patients were followed with a clinical visit and a 12-lead electrocardiogram scheduled at 1, 3, 6, and 12 months, and after every 6 months. In addition, a 24-hour Holter monitoring was obtained at 3, 6, and 12 months, and after every 12 months. Moreover, patients were instructed to obtain an ECG in the event of palpitations.

Ablation was deemed successful in the absence of symptomatic or asymptomatic atrial tachyarrhythmias lasting more than 30 seconds identified on surface ECG or on Holter monitoring, off antiarrhythmic drug therapy. As early relapse of atrial tachyarrhythmias within the first 3 months after RF ablation may be a transient phenomenon, this transition period was excluded from the final analysis [11].

2.5 Statistical analysis. Normally distributed continuous variables were expressed as mean (±SD) and compared by unpaired Student's t test. Skewed variables were expressed as median (25-75 quartiles) and compared by the rank sum test. Normality was assessed by the Shapiro-Wilk test. Categorical variables were presented as counts and percentages, and compared by Chi square test (Pearson, Yates or Fisher's exact test as appropriate). A Kaplan-Meier curve was plotted for the time to first atrial arrhythmia recurrence following initial ablation procedure. The probabilities of freedom from atrial arrhythmia recurrence at each 3-month follow-up time point post-blanking are presented. Differences between the curves were tested for significance by means of the log-rank statistics. A p value <0.05 was considered statistically significant. Analysis was performed by means of SPSS (version 11.0, SPSS Inc., Chicago, Illinois, USA).

3 RESULTS

3.1 Study population. The clinical characteristics of the study population are shown in Table I. Forty (53 %) patients exhibited a normal drainage pattern with separate ostia for the upper and lower PVs, an abnormal anatomy was documented in 35 (47%) patients: a left common trunk was seen in 32 (43 %) patients; a right common trunk was seen in one (1 %) patient, and two (3 %) patients had a right accessory PV. Mean LA volume was 75±40 ml.

3.2 Procedural data. Mean procedural and fluoroscopy times were 94 ± 55 minutes and 8 ± 5 minutes, respectively, without significant differences among patients with normal and

abnormal anatomy (92±45 min vs 95±64 min, p=0.85 and 6±3 min vs 8±4 min, p=0.65, respectively) (Figure 3). Mean ablation time was 14±3 min, 99% of the targeted veins were isolated with a mean of 23±5 RF pulses per patient. In only one (2.2%) patient a single point ablation strategy was required to achieve PV isolation. Intraprocedural early PV reconnection occurred in 64/269 (24%) PVs and all PVs were effectively re-isolated.

3.3 Follow-up data. During the blanking period 9/75 (12%) patients had an atrial arrhythmia recurrence. Among them 2 were atrial tachycardia or atrial flutter and the remaining AF episodes. Recurrences observed during the blanking period did not predict later event. After a mean follow-up of 17±8 months, 23(31%) patients had a recurrence (Figure 4 and 5). Neither LA volume nor PV anatomy were predictors of outcome. (Table II). Overall 5/23 (22%) patients with atrial arrhythmia relapse underwent a second ablation procedure.

3.4 Complications. No stroke/TIA, pericardial effusion or cardiac tamponade, phrenic injury, and acute PV stenosis were observed. One groin hematoma was reported, conservatively treated.

4 DISCUSSION

The main findings of this study are as follows: 1) atypical PV anatomy is documented in almost half of patients with paroxysmal AF undergoing AF catheter ablation; 2) PV anatomy does not impact the efficiency (procedural time, fluoroscopy time and ablation time) of PV isolation by means of an open-irrigated mapping and RF decapolar ablation catheter; 3) PV anatomy did not impact the mid-term freedom from atrial arrhythmias.

Typical PV anatomy, with four distinct PV ostia, is present in approximately 20% to 60% of subjects [8,12-16]. Our findings confirm these data: almost half of patients presented an abnormal PV anatomy with the left common trunk being the most common PV anomaly. Understanding these variations can be useful for the application of ablation lesions around

or antral to the PV ostia. This seems of particular importance when PV isolation is performed with a one-shot tool. These tools have been developed to overcome some limitations of standard the ablation approach, as long procedure and fluoroscopy times, moreover point-by-point ablation outcome is highly impacted by center volume and operator experience. However due to the remarkable PV anatomical variety the use of a presized circular multipolar ablation catheter may present some limitations. In our cohort we were able to achieve PV isolation in nearly all patients, regardless of the PV/left atrium anatomy, that did not impact the procedural time, fluoroscopy time or ablation time. Neither the mid-term atrial arrhythmia freedom was impacted by the presence of an abnormal PV anatomy or enlarged LA.

The results of this study therefore support the fact that the nMARQ^{TM} catheter is sufficiently flexible to be effective in almost all left atrial anatomies and PV configurations. In fact, if abnormal PV anatomy is known to little influence the ablation outcome in case of the point-by-point approach [17,18], more conflicting data have been reported with other "one-shot" technologies.

Tsyganof et al [19] evaluated the correlation between PV anatomy and acute and long-term success of PV isolation with two balloon-based ablation catheter techniques (cryoballoon catheter and the visually guided laser ablation catheter). They found that, in the cryo group, a larger left inferior PV size was associated with worse long-term outcome, and in the laser group, a larger left superior PV size and a more oval RIPV were associated with worse acute success. Metzner et al [20] looked at PV shape and PV drainage in their study of 51 patients treated with laser balloon for PVI. They found no correlation between anatomy and clinical outcome. Schmidt et al [21] investigated the role of PV ostial anatomy during cryoballoon PV occlusion and consequent AF recurrence rate. Patients with AF recurrence had "more oval" left-sided PVs compared to patients free from AF recurrence (LSPV 0.40±0.2 vs. 0.33±0.2; p=0.04 and LIPV 0.41±0.3 vs.

0.32±0.2;p=0.03), whereas no significant association was found for right sided PVs. They concluded that the ostial PV anatomy seems to have an important impact on clinical outcome and should be considered when planning and performing cryoballoon AF ablation procedures. Similarly Kubala et al. [22] compared outcomes of cryoballoon ablation in AF patients with respect to the PV anatomy. The analysis found a better AF-free survival in patients with a “normal” PV anatomy. Abnormal anatomy was defined as the presence of a left common os which was found in 25% of 118 included patients. Sorgente et al. [23] reported an inverse association between the degree of PV occlusion during ablation and the ovality of the left-sided PV ostia. They concluded that despite the fact that operating maneuvers may overcome some discordance of ostium orientation and catheter shape, circumferential adhesion of the cryoballoon may be limited in cases where the PV ostium is oval.

For balloon technologies, therefore, PV anatomy would seem to be a potential limitation, compromising the principle “one size fits all” [24]. With the nMARQ^{TM} catheter, otherwise, we were able to manipulate the catheter, which diameter may be changed from 35mm to 20 mm , allowing a better fit to the PV anatomy and shape, without limiting the “one size fits all” principle. Although requiring future randomized trials, it is therefore plausible that, as with the point-by-point conventional RF ablation, with the multielectrode nMARQ^{TM} catheter ablation, the operator may handle the ablation catheter in a flexible way to adjust to any actual PV anatomy. It is plausible that balloon based ablations are more dependent on the left atrial and PV ostial anatomy compared to RF ablations. However, this needs to be addressed in future randomized trials comparing both RF and balloon technology ablation.

We do not know if all patients undergoing PV isolation by means of “one-shot” tools need a pre-ablation left atrium imaging. To date no randomized study has ruled out this point, and even without the use of pre-procedural imaging high acute and long-term success rate

using the cryoballoon therapy was reported. In the meantime, although with the nMARQ^{TM} catheter we demonstrated no impact of PV anatomy on acute and mid-term outcome, pre-ablation imaging however allowed a reduction in the fluoroscopy time [10] and, in case of MR, holds the potential to reduce esophageus-related complications by directly localizing its anatomical relationships with the LA and guiding selective ablation power reductions [25].

4.1 Limitations. Our data are collected from limited number of patients and this could be a limitation of the study, however other studies (20,23), also evaluating the impact of PV anatomy on AF ablation feasibility and outcome, enrolled a lower number of patients.

We analyzed only few anatomical criteria (common truncus and accessory PV) and, perhaps, other anatomical findings, like PV ostrium dimension and PV bifurcation, might influence procedural data and mid-term success rate.

Esophageal temperature monitoring was not routinely performed. Larger series, enrolling thousands of patients, are required to assess if our strategy, to reduce the power to 15-20 W in case of electrodes in contact with the posterior wall, is effective in preventing atrio-esophageal fistula.

In our series LA volume did not impact the mid-term outcome after RF catheter ablation. This might be explained by our choice to enroll only patients with paroxysmal AF that usually have a less severely enlarged LA volume. The findings of our study may be different for patients with persistent or permanent AF. In these patients several studies [9,26] demonstrated that LA volume is an independent predictor of AF recurrence after catheter ablation, whereas PV anatomy did not have any effect on the outcome.

Length of mean follow-up was slightly more than one year. LA anatomy impact on long-term success rate is therefore not yet available.

Finally, we assess arrhythmias recurrences by means of scheduled visit, ECG, and Holter monitoring, or visit and ECG performed in the event of palpitations. However, we cannot

exclude the possibility that brief or asymptomatic atrial arrhythmias relapses could have been undetected during the follow-up.

4.2 Conclusions. LA volume and PV anatomy did not affect procedural data and outcome in patients who underwent PV isolation by an open-irrigated mapping and RF decapolar ablation catheter.

Appendix

Participating centers:

Clinica Mediterranea, Napoli (Giuseppe Stabile, Assunta Iuliano, Alfonso Panella); Policlinico Casilino, Roma (Leonardo Calò, Gildo De Ruvo, Luigi Sciarra); Azienda Ospedaliero Universitaria Pisana, Pisa (Ezio Soldati, Maria Grazia Bongiorni); Dipartimento di Scienze Mediche, Università di Torino (Matteo Anselmino, Federico Ferraris, Fiorenzo Gaita).

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Figure legend.

Figure 1. Classification of PV anatomy. *(A)* Separate ostia of left-sided and right-sided PVs. *(B)* Common trunk of left-sided PVs (defined as joint part of superior and inferior PVs of >5 mm, before entering left atrium). *(C)* Additional right-sided PV (defined as supranumerary vein directly entering left atrium).

Figure 2. Postero-anterior view of CT left atrium reconstruction with nMARQ catheter positioned at the antrum of the right inferior pulmonary vein (red dots: radiofrequency ablation points).

Figure 3. Mean Procedural and Fluoroscopic time in all cases, normal and abnormal anatomy.

Figure 4. Kaplan–Meier estimation of the time to atrial arrhythmia recurrence after the blanking period in patients with normal (N) and abnormal (A) anatomy.

Figure 5. Kaplan–Meier estimation of the time to atrial arrhythmia recurrence after the blanking period in patients with left atrial volume belove vs those above the mean LA volume value (75 ml).

Table I. Clinical characteristics of study population

Mean age (years)	58±11 (24-75)
Male sex	67%
Left atrium diameter (mm)	42±6 (33-58)
Left atrium volume (ml)	75±40 (46-165)
Left ventricle ejection fraction (%)	58±13 (45-70)
Previous stroke/TIA	5%
Heart disease Hypertensive Ischemic Valvular Restrictive	55% 49% 13% 3% 1%
Diabetes	5%

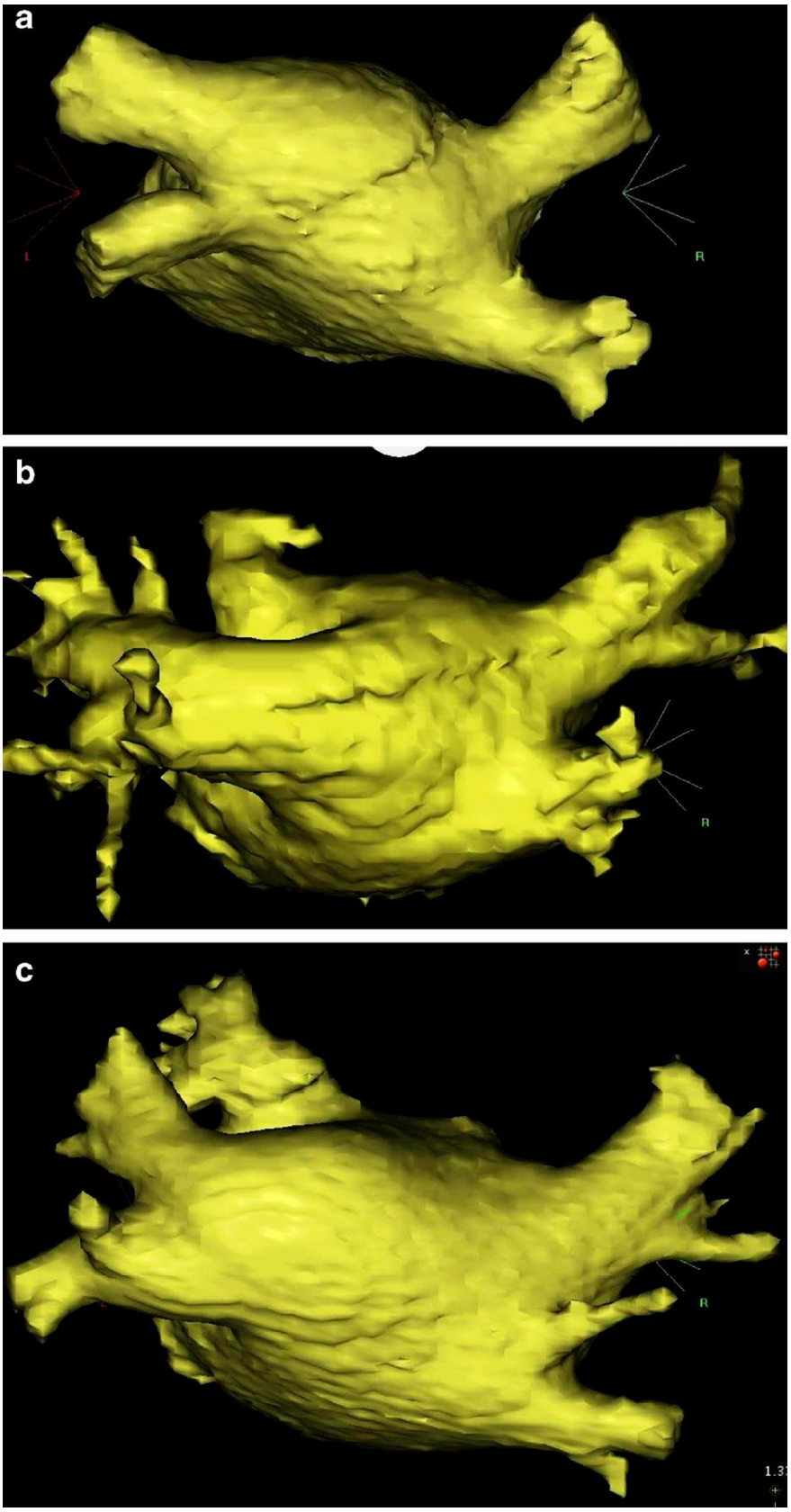
TIA= transient ischemic attack

Table II. Clinical characteristics of patients with and without atrial arrhythmias recurrence.

	No recurrence	Recurrence	p
Mean age (yrs)	59±10 (24-75)	56±13 (31-74)	0.25
Male	67%	68%	0.86
Left atrium diameter (mm)	43±6 (35-55)	40±6 (33-58)	0.27
Left atrium volume (ml)	78±42 (48-131)	63±39 (46-165)	0.12
Previous stroke/TIA	4%	6%	0.8
Heart disease	52%	56%	0.78
Diabetes	9%	4%	0.4

TIA= transient ischemic attack

Figure 1.



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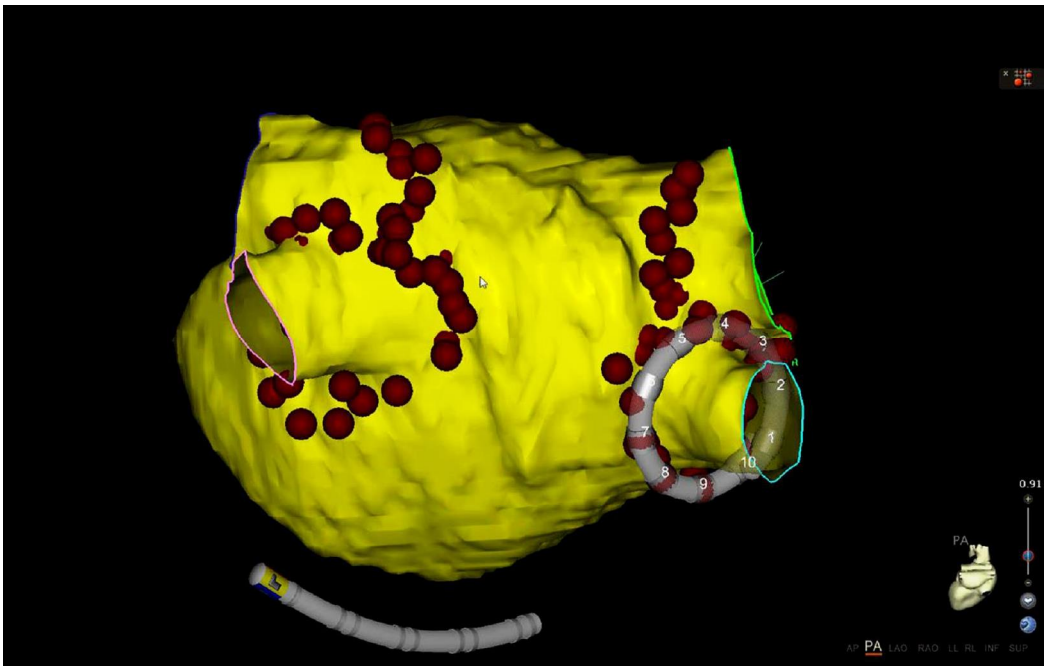

Figure 3.

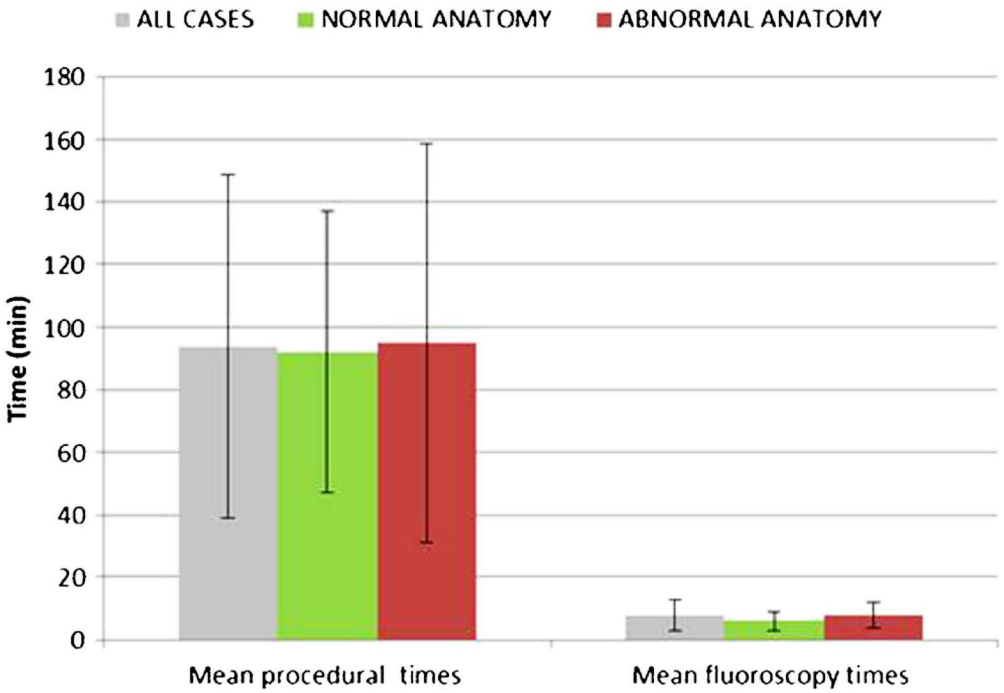

Figure 4.

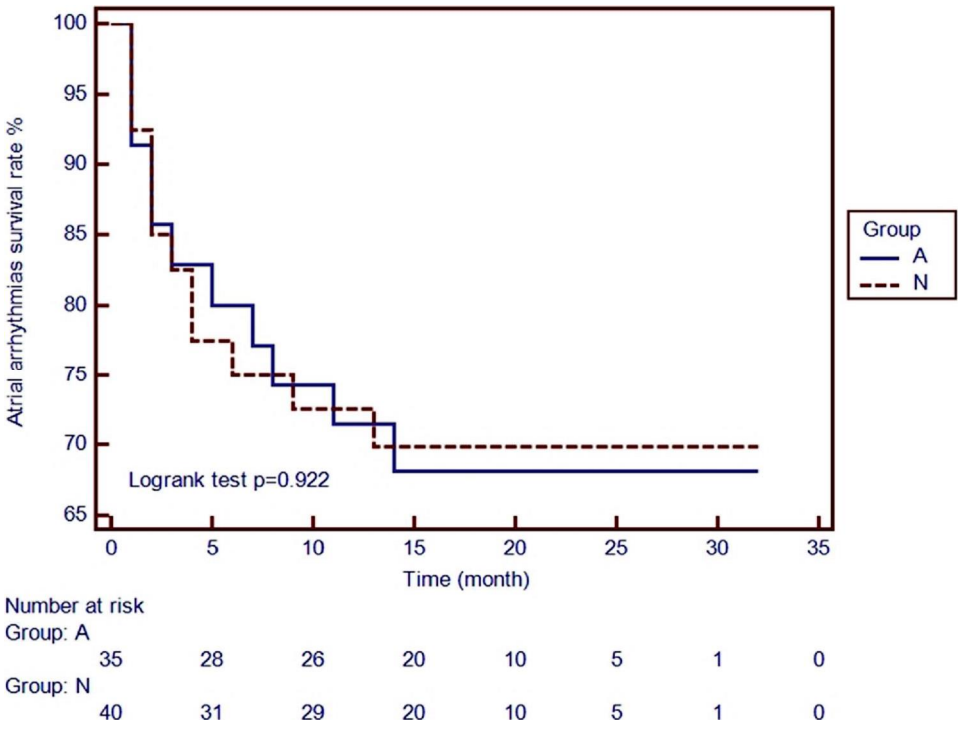

Figure 5.