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Effective reduction of fluoroscopy duration by using an advanced electroanatomic-mapping system and a standardized procedural protocol for ablation of atrial fibrillation: 'the unleaded study'

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Aims It is recommended to keep exposure to ionizing radiation as low as reasonably achievable. The aim of this study was to determine whether fluoroscopy-free mapping and ablation using a standardized procedural protocol is feasible in patients undergoing pulmonary vein isolation (PVI).

Methods and results Sixty consecutive patients were analysed: Thirty consecutive patients undergoing PVI using Carto3 were treated using a standardized procedural fluoroscopy protocol with X-ray being disabled after transseptal puncture (Group 1) and compared with a set of previous 30 consecutive patients undergoing PVI without a specific recommendation regarding the use of fluoroscopy (Group 2). The main outcome measures were the feasibility of fluoroscopy-free mapping and ablation, total fluoroscopy time, total dose area product (DAP), and procedure time. Sixty patients (age 60 ± 10 years, 73% male, ejection fraction 0.55 ± 0.09, left atrium 42 ± 8 mm) were included. In Group 1, total fluoroscopy time was 4.2 (2.6–5.6) min and mapping and ablation during PVI without using fluoroscopy was feasible in 29 of 30 patients (97%). In Group 2, total fluoroscopy time was 9.3 (6.4–13.9) min ($P < 0.001$). Total DAP was 13.2 (6.2–22.2) Gy*cm^2 in Group 1 compared with 17.5 (11.7–29.7) Gy*cm^2 in Group 2 ($P = 0.036$). Total procedure time did not differ between Groups 1 (133 ± 37 min) and 2 (134 ± 37 min, $P = 0.884$).

Conclusion Performing mapping and ablation guided by an electroanatomic-mapping system during PVI without using fluoroscopy after transseptal puncture using a standardized procedural protocol is feasible in almost all patients and is associated with markedly decreased total fluoroscopy duration and DAP.

Keywords Atrial fibrillation • Pulmonary vein isolation • Fluoroscopy • Radiation • Mapping systems

Introduction

Interventional treatment of cardiac arrhythmias using catheter ablation is commonly performed under fluoroscopic guidance resulting in exposure to ionizing radiation for patients and physicians.[1,2] Although data on late adverse effects of radiation in patients undergoing catheter ablation procedures requiring prolonged fluoroscopy times are missing, it is known that ionizing radiation has a small, but inherent risk of future neoplasms.[3] The U.S. Nuclear Regulatory Commission recommends making every reasonable effort to keep exposure to ionizing radiation as low as reasonably achievable (ALARA), a statement that is endorsed by the major societies of physicians working in an interventional laboratory.[4] Pulmonary vein (PV) isolation (PVI) has become the mainstay of interventional treatment in patients with atrial fibrillation.[5] The procedure was initially performed mainly under fluoroscopic guidance, and mean fluoroscopy times of >2 h were reported even by experienced centres for procedures performed between 2002 and 2006.[6] Various generations of electroanatomic-mapping (EAM) systems have increased the spatial

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What's new?

- Performing mapping and ablation without using fluoroscopy after transseptal puncture is feasible in the vast majority of patients undergoing atrial fibrillation ablation without additional technical equipment such as intracardiac or transesophageal echocardiography.
- Adopting a procedural protocol with the aim of avoiding fluoroscopy after transseptal puncture results in a marked decrease in fluoroscopy time, radiation dose, and effective dose compared with pulmonary vein isolation procedures using the same mapping system but no specific recommendation regarding fluoroscopy.
- Outcome and complication rates did not differ between the different approaches.

resolution of the available anatomical information and by that considerably decreased the radiation burden of the procedure.[7] To fully benefit from the technological improvement of the EAM systems, it is recommended that 'the operators need to develop procedural workflows to rely on non-fluoroscopic guidance as much as possible'.[8]

The aim of this study was to determine whether fluoroscopy-free mapping and ablation is feasible when using a standardized procedural protocol in patients undergoing PVI using radiofrequency energy and to compare this approach with procedures performed without a specific recommendation for the use of fluoroscopy.

Methods

This is a non-randomized comparison of 60 consecutive patients with paroxysmal or persistent AF undergoing PVI (without additional left atrial lesions). Thirty consecutive patients undergoing PVI were treated using a standardized procedural fluoroscopy protocol (Group 1) and compared with a set of previous 30 consecutive patients undergoing PVI before the standardized fluoroscopy protocol was implemented (Group 2). Exclusion criteria for the study were a history of any previous left atrial procedure (surgical or percutaneous) and documented left atrial tachycardia requiring additional ablation lines.

Transesophageal echocardiography to rule out left atrial thrombus was performed before the procedure. Oral anticoagulation was not interrupted for the procedure in patients on Vitamin-K antagonists or Rivaroxaban. In patients on Dabigatran, the dose the night before and the morning of the procedure was withheld. All patients gave written informed consent for participation in a prospective, observational registry.

Magnetic resonance imaging

Magnetic resonance imaging (MRI) was performed on a 1.5T scanner (MagnetomAvanto/Espree, Siemens, Germany) equipped with phased array body coils. A respiratory- and ECG-gated three-dimensional balanced steady-state free precession sequence was acquired in axial orientation covering the whole left atrium.

Electrophysiological procedure

Midazolam, Fentanyl, and Propofol were used to perform PVI under conscious sedation. Intravenous heparin was used to maintain an activated clotting time of 350 s. The sheaths were continuously flushed with heparinized saline. Intracardiac electrograms and surface electrograms were recorded and displayed at a speed of 100 mm/s. The endpoint was the elimination of all PV potentials on the variable 20-pole circumferential-mapping catheter. All procedures were performed in conjunction with a 3D EAM system (Carto3, Biosense Webster, Diamond Bar, CA, USA) and all patients underwent pre-procedural MRI for 3D reconstruction of the left atrium.

After obtaining vascular access via the right femoral vein, two long sheaths (SL1, 8.5F, St. Jude Medical, MN, USA) were placed in the superior vena cava over a J-tip guidewire. The irrigated tip ablation catheter (Navistar Thermocool/SF/SmartTouch, Biosense Webster) was placed in the coronary sinus to serve as a reference during transseptal puncture. Double transseptal puncture was performed in the usual fashion under radiologic guidance. No PV angiographies were performed.

Mapping and ablation protocol

In the fluoroscopy-free mapping and ablation group (Group 1), fluoroscopy was disabled and the operator took off the lead protection after double transseptal puncture. Fluoroscopy, however, was allowed to be turned back on at all times during the procedure and could be used at the operator's discretion at any time. No additional imaging technique (e.g. intracardiac or transesophageal echocardiography) was used. The workflow enabling fluoroscopy-free mapping and ablation is as follows.

The ablation catheter positioned in the coronary sinus during transseptal puncture was then pulled back to the right atrium while the fast anatomical-mapping (FAM) function of Carto3 was activated in order to acquire the anatomy of the coronary sinus (*Figure 1A*). The left atrial reconstruction of the pre-procedurally acquired MRI was provisionally positioned based on the previously acquired FAM map of the coronary sinus in order to have an approximation of the position of the PVs. The site of the transseptal access was marked with a 'sleeve' during advancing of the mapping catheter through the transseptal sheath. This tag helped to re-access the left atrium in case of inadvertent loss of the left atrial access during the procedure.

In the Carto3 system, the ring electrodes of the ablation catheter are shown in black as opposed to the standard grey if they are still within the sheath. Consequently, the end of the sheath is represented by the transition between the grey and the black visualization of the proximal electrodes of the mapping catheter (*Figure 1B*).

The ablation and circumferential-mapping catheter were then inserted into the left atrium with both catheters connected in order to visualize their entry into the left atrium (*Figure 1B*) in real-time and to observe the intracardiac electrograms, mainly in order to prevent inadvertent positioning of the circumferential-mapping catheter in the mitral valve apparatus.

The left atrium was mapped with the variable 20 pole circumferential-mapping catheter using the FAM feature and maximal resolution. The left atrial reconstruction from the MRI was used to define the anatomy of the PVs (*Figure 1C*). The circumferential-

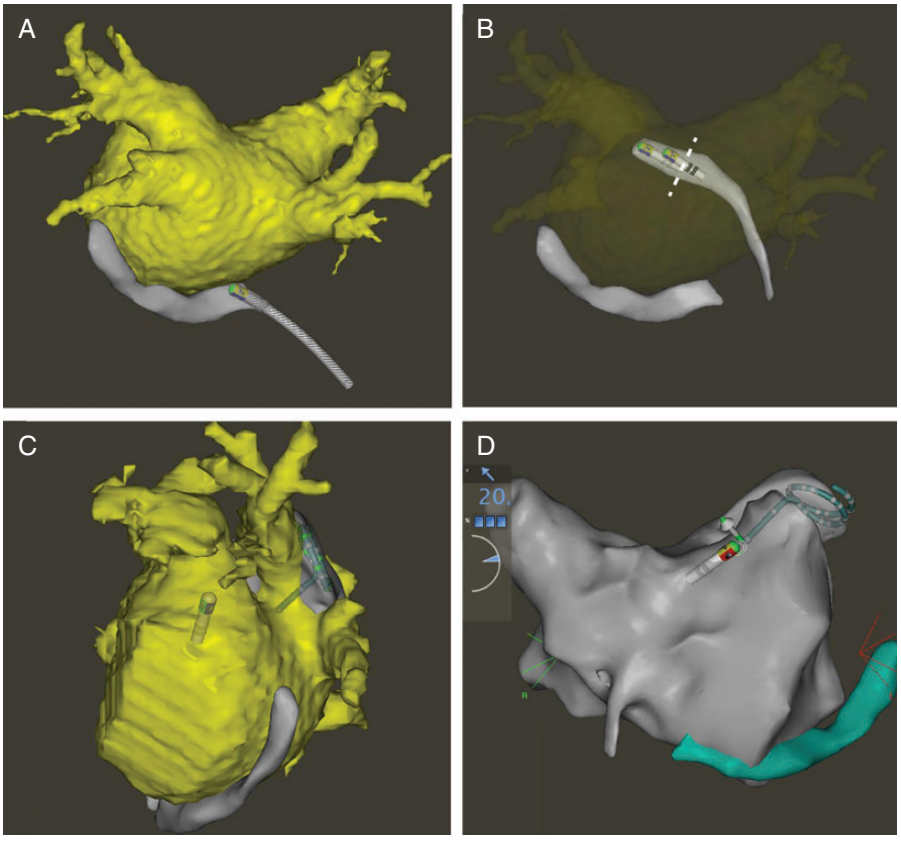

Figure 1 Images of the process and the features used for fluoroscopy-free mapping and ablation of the left atrium: (*A*) posterior view of the FAM of the coronary sinus (grey) with the manually registered anatomical reconstruction of the left atrium from MRI (yellow), (*B*) same posterior view as in (*A*) with the FAM of the transseptal puncture: the transition between the black and the grey visualization of the two proximal ring electrodes of the mapping catheter marks the exit of the catheter from the sheath and consequently the end of the sheath (dashed line). (*C*) Left lateral view of the left atrium with the Lasso catheter in the left superior pulmonary vein. (*D*) Contact force vector and the two-ring catheter projection as representation of the distance of the catheter tip from the closest FAM surface. The closer the catheter is to the surface, the smaller is the difference of the diameter of the two white rings projected on the grey surface.

mapping catheter was then advanced into the left superior and inferior, and then into the right superior and inferior PV. The remaining septal, posterior, superior, and antero-superior structures including the left atrial appendage were then mapped with the circumferential mapping catheter. The inferior left atrium (along the coronary sinus to the inferior septum) and the mitral annulus region were mapped with the ablation catheter using FAM in order to avoid mapping in close proximity to the mitral valve apparatus and to avoid inadvertent loss of left atrial access with the circumferential-mapping catheter. The previously acquired FAM map of the coronary sinus was used to predefine the inferior left atrium and mitral annulus region. Then, the ridge between the left atrial appendage and the left PVs was mapped in more detail using the mapping catheter.

After completing the left atrial map, PVI was achieved by performing circumferential antral ablation using radiofrequency energy with the power set to 25–30 W (maximum 40 W) and a maximum temperature of 50°C using continuous encircling lesions. Contact force information, where available, was used during ablation with a target force of 10 g and an upper limit of 40 g during the entire procedure (*Figure 1D*). The level of the catheter tip in relation to the tip of the sheath was determined by observation of the appearance of the proximal electrode pair of the ablation catheter (*Figure 1B*). The procedural endpoint of the ablation was the elimination of all PV potentials on the 20 pole circumferential-mapping catheter (entrance block). Pacing maneuvers were used to differentiate far field from PV potentials.

In Group 2 (standard use of Carto3 with no recommendation regarding fluoroscopy), transseptal punctures were performed as in Group 1 under radiologic guidance and fluoroscopy was used as deemed necessary by the operator during the mapping and ablation procedure. There was no specific workflow for mapping and ablation as described above. All analysed patients of the two groups were enrolled consecutively after at least 2 years of experience of the operators with the EAM system Carto3. All complications were classified according to the HRS/EHAR/ECAS expert consensus statement on AF ablation.[5]

Post-ablation management and follow-up

Transthoracic echocardiography was performed after the procedure to rule out pericardial effusion. The first dose of Dabigatran was given

four hours after achieving haemostasis and Vitamin K antagonists and Rivaroxaban were resumed the night of the procedure.[9] Oral anticoagulation was continued for at least 3 months. Follow-up consisted of outpatient clinic visits at 3 and 6 months and then every 6 months and included a detailed history, physical examination, 12-lead ECG, 24-h Holter monitoring and a 7-day Holter at 12 months. In addition, patients were seen in case of recurrent symptoms. Episodes of AF (>30 s) were counted as recurrences. Recurrence rates were analysed with a post-procedural blanking period of 3 months.

Main outcome measures

The primary endpoints of this study were the feasibility of fluoroscopy-free mapping and ablation (after transseptal puncture), total fluoroscopy time as a measure of the 'need' for fluoroscopy verification, total dose area product (DAP; defined as the sum of cine and fluoroscopic acquisition), effective dose (ED), and total procedure time in the fluoroscopy-free ablation (Group 1) compared with the control group undergoing PVI with the same EAM system but no specific recommendation regarding fluoroscopy (Group 2).

Secondary outcome measures were complications, the occurrence of radiation dermatitis, acute and 1-year single procedure success rates of PVI, and procedural details (time needed for mapping, time needed for ablation, and net RF time).

Statistical analysis

Continuous variables are presented as mean ± 1 standard deviation or as median and interquartile range (IQR) in case of skewed distribution. For continuous variables, comparisons were made using Student's *t*-test, or Mann–Whitney *U* test, as appropriate. Discrete variables were compared using the Fisher's exact test. A *P*-value of <0.05 was considered to indicate statistical significance. The statistical analyses were performed using the SPSS (version 22.0, SPSS Inc., Chicago, IL, USA) software package.

Results

Study population

A total of 60 patients undergoing PVI were included in the study. Patients had a mean age of 60 ± 10 years, and 44 (73%) were men. The majority of patients (72%) had standard PV anatomy with 4 PVs, 10 (17%) had a left common ostium, and 7 (11%) had a middle right PV. There were no differences in patient characteristics between the groups. Baseline characteristics of the patients are given in *Table 1*.

Table 1 Patient characteristics

	Group 1 fluoro-free (*n* = 30)	Group 2 standard (*n* = 30)	*P*-value
Age (years)	60 ± 10	59 ± 11	0.648
Weight (kg)	84 ± 16	84 ± 13	0.973
Height (cm)	175 ± 8	176 ± 9	0.543
BMI (kg/m^2)	28 ± 5	27 ± 3	0.633
Sex: Male	22 (73)	22 (73)	1.000
Duration of AF (months)	29 (7–99)	33 (12–56)	0.755
Left atrial size (mm)	43 ± 8	40 ± 7	0.231
Left ventricular ejection fraction (%)	58 (45–60)	57 (53–60)	0.811
No structural heart disease	24 (80)	23 (77)	1.000
HCVD	6 (20)	6 (20)	1.000
CAD	3 (10)	0 (0)	0.237

All values are given as *n* (%) for categorical and median (IQR) or mean ± standard deviation for continuous variables.
AF, atrial fibrillation; CAD, coronary artery disease; HCVD, hypertensive cardiovascular disease.

Table 2 Procedural data

	Group 1 fluoro-free (*n* = 30)	Group 2 standard (*n* = 30)	*P*-value
Fluoroscopy time (min)	4.2 (2.6–5.6)	9.3 (6.4–13.9)	<0.001
Total DAP (Gy × cm^2)	13.2 (6.2–22.2)	17.5 (11.7–29.7)	0.036
Effective dose (mSv)	2.65 (1.25–4.43)	3.49 (2.33–5.94)	0.036
Procedure time (min)	133 ± 37	134 ± 37	0.884
Mapping time (min)	18 ± 6	17 ± 10	0.951
Ablation time (min)	80 ± 26	86 ± 35	0.409
Net RF time (s)	1765 ± 719	2040 ± 861	0.185

All values are given as mean ± 1 standard deviation or median (IQR).
Conversion factor for ED (mSv) = DAP (Gy × cm^2) × 0.2 (mSv/Gy × cm^2).[8]
Mapping time: time from the beginning of the mapping of the left atrium to the start of the ablation. Ablation time: time from the start of the first ablation to the end of the procedure. Net RF time: duration of radiofrequency energy delivery.

Primary outcome measures

Performing the mapping and ablation procedure without using fluoroscopy after the transseptal puncture was feasible in 29 of 30 patients (97%). In one patient with a very small right inferior PV, 1.9 min of fluoroscopy was required to position the circumferential-mapping catheter in the right inferior PV for confirmation of PVI after ablation. Total fluoroscopy time was markedly shorter and total DAP and ED were significantly lower in the fluoroscopy-free group (Group 1) compared with the standard group (Group 2). Total procedure time did not differ significantly between the groups. A between group comparison including the time needed to acquire the map of the left atrium as described above, the time required to perform the ablation (ablation time), and the net duration of radiofrequency energy delivery (net RF time) in the groups is given in *Table 2*.

Secondary outcome measures

The procedural endpoint of PVI was reached in all patients. No complications occurred in the two groups. Acute radiation dermatitis occurred in none of the patients.

Success rates were similar between the two groups. In the fluoroscopy-free group (Group 1) and in the standard group (Group 2), respectively, 22 of 30 patients (73%) and 21 of 30 patients

(70%) did not have any recurrence of AF during a follow-up of 12 months ($P > 0.99$). A contact force-sensing catheter was used in 18 of the 30 patients (60%) in Group 1 and in 12 of 30 patients (40%) in Group 2 ($P = 0.196$). No statistical difference in procedural parameters, safety, and outcome between procedures performed with and without force-sensing catheters could be observed.

Discussion

Main findings

The main findings of this study are (i) Performing mapping and ablation during PVI without using fluoroscopy after transseptal puncture is feasible in 97% of patients undergoing AF ablation. This is the case without additional technical equipment such as intracardiac or transesophageal echocardiography. (ii) Adopting a procedural protocol with the aim of avoiding fluoroscopy after transseptal puncture by using routinely available features of a latest generation EAM system (Carto3) results in a marked decrease in fluoroscopy time, total DAP and ED compared with PVI procedures using the same mapping system but no specific recommendation regarding fluoroscopy. (iii) Mapping and ablation time and overall procedure duration was not longer when using the non-fluoroscopic approach compared to the standard approach. (iv) Outcome and complication rates did not differ between the groups.

Impact of novel technological developments

Electroanatomic-mapping systems[10] and other technological developments such as the MediGuide™ system (St. Jude Medical)[11] or remote magnetic navigation systems[12] have been introduced also with the intention to reduce radiation burden. In our study, fluoroscopy duration could be decreased to <5 min by the development and implementation of a standardized procedural workflow relying on non-fluoroscopic guidance as much as possible as recommended by Heidbuchel *et al.*[8] In our protocol, this included the precise description of the mapping workflow, the marking of the transseptal access site and the usage of additional features of the mapping system such as the electrode markings to determine sheath position and the two-ring catheter projection or the contact force information (*Figure 1D*). A contact force-sensing catheter was used overall in 50% of cases. Despite being considered useful, contact force information was not considered mandatory for a safe and successful procedure.

Reduction of radiation exposure

The main goal of adopting a protocol of fluoroscopy-free mapping and ablation is to reduce total DAP and ultimately to decrease the adverse effects of ionizing radiation to the human body. In that regard, total DAP and ultimately ED are the most important variables. However, it is valid to compare fluoroscopy duration as a measure of the 'need' for X-ray verification when analysing the impact of a new procedural protocol, especially because, in contrast, total DAP is dependent on a plethora of variables including the use of cine acquisitions, the type and configuration of the X-ray system used, operator training (collimation, less-irradiating angulations), and patient characteristics.[13,14]

Perisinakis *et al.* estimated the average excess of fatal cancers to be ~0.05% for patients undergoing ablation procedures with 60 min of fluoroscopy time.[3] However, although a significant reduction in DAP was achieved with our protocol, the question whether this has a measurable clinical impact with regard to the occurrence of cancer remains unknown. Acute adverse effects of radiation (acute radiation dermatitis) have been described after electrophysiologic procedures, but were not seen in any patient in this study.[15] There were no differences in success rates (freedom from AF during follow-up) between the groups, but this would not be expected since the procedural endpoint was the same in both groups.

Two previous studies have reported PVI without using any fluoroscopy.[16,17] Intracardiac ultrasound is routinely used in many institutions especially in the United States and was used in both previous studies to guide the procedure. In most European centres, however, intracardiac ultrasound is not used to guide PVI. It was the explicit aim of our study to perform mapping and ablation without fluoroscopy, but without using intracardiac (or transesopheageal) echocardiography in order not to increase the complexity of the procedure due to additional technology. The increased complexity is probably reflected in the longer procedure times of 3.5 and 4 h in the two previous studies.[16,17] In our study, procedure times were ~130–140 min and there was no difference between the fluoroscopy-free group and the standard group.

Potential benefits for the operator and staff

Reducing radiation exposure has a different implication when focusing on the operator and staff because exposure is long-term and lead aprons do not protect the whole body. Full-body protection has become available for physicians with the advent of radiation protection cabins. However, for the laboratory staff, no such physical protection is available. Apart from the potential reduction of malignancies and radiation cataracts, indirect consequences of radiation exposure are the relatively frequent orthopaedic problems associated with wearing protective apparel.[18,19] In our study, the operator and staff did not wear lead during mapping and ablation, but the effect on orthopaedic problems was not studied in this analysis.

Risks of fluoroscopy-free mapping and ablation

The circumferential-mapping catheter (Lasso Nav, Biosense Webster, Diamond Bar, CA, USA) is usually not visualized with the typical Lasso appearance upon entry into the left atrium. Therefore, it is of utmost importance to observe the intracardiac electrocardiograms to prevent the catheter from advancing into the left ventricle and ultimately to prevent entrapment in the mitral valve apparatus. By rotating the transseptal sheath posteriorly, observing the electrograms, the EAM information and by decreasing the radius of the adjustable circumferential-mapping catheter when exiting the sheath in the left atrium, avoiding the region of the mitral valve was possible in all cases without any inadvertent positioning or entrapment of the circumferential-mapping catheter in the mitral valve apparatus. Furthermore, the region of the mitral annulus was mapped using the ablation catheter.

Limitations

This is a non-randomized study performed at a single center. Definitive conclusions about the safety of the fluoroscopy-free approach cannot be drawn based on the results of this study because of the small sample size. Although no differences were seen in this study, it is conceivable that outcomes or complication rates differ between the two approaches when larger samples are studied. Finally, it has to be noted that the described protocol including a pre-procedural MRI may not be recommended in patients with pacemakers and ICDs.

Conclusion

Performing mapping and ablation guided by an EAM system without using fluoroscopy after transseptal puncture is feasible in the vast majority of patients undergoing PVI and is associated with markedly decreased total fluoroscopy duration and DAP. This approach may be important especially for younger patients with a higher life-time risk of radiation-induced neoplasms.

Conflict of interest: C.S. has served on the speakers' bureau of Biosense Webster; S.O. received an educational grant from Biosense Webster; M.K. has served on the speakers' bureau for Biosense Webster and is proctor for Medtronic.

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