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Non Fluoroscopic Approach in Atrial Fibrillation Ablation Procedures: The APRONLESS-AF Study

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Abstract

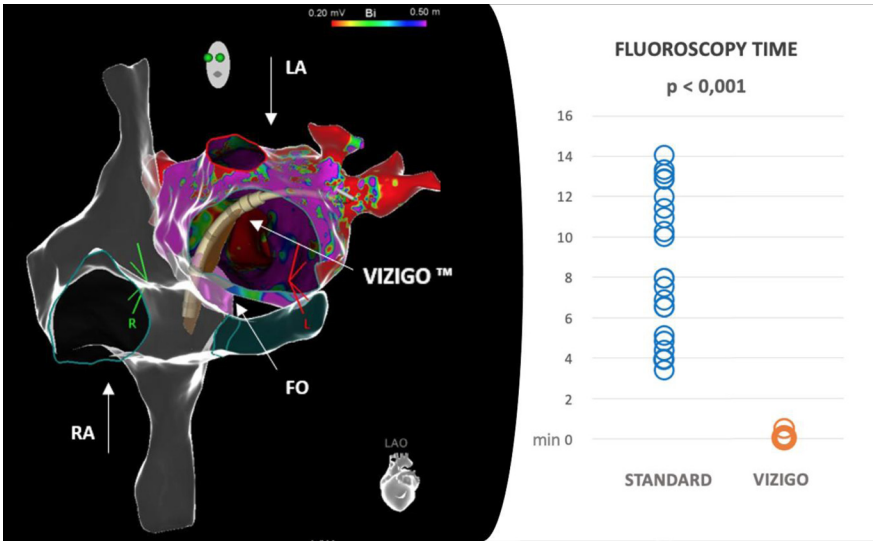
Background: Advanced 3D electroanatomic mapping (EAM) systems have revolutionized atrial fibrillation (AF) ablation by significantly reducing the use of fluoroscopy. In this study, we aimed to compare the initial experience of AF ablation procedures using the VIZIGO™ steerable sheath, which is visible on the 3D EAM, with the conventional approach involving a fixed sheath that is not visible on the 3D EAM.

Methods: A total of 50 consecutive patients undergoing AF ablation were enrolled in a prospective observational study. The patient population was divided in two groups: the first group consisted of 25 consecutive patients treated with a fixed sheath that is not visualized on the mapping system (standard group), and the second group consisted of 25 consecutive patients treated using the VIZIGO™ steerable sheath (VIZIGO group). Baseline characteristics of patients, procedural, fluoroscopy, and ablation time were included in the analysis. Primary endpoints were the evaluation of procedural and fluoroscopy time. Study protocol was approved by the local ethics committee and is registered on ClinicalTrials.gov (identifier: NCT05319769).

Results: No differences in baseline characteristics were present between the two groups. The median procedural and fluoroscopy time were 130 (IQR 117-181) minutes and 2.2 (IQR 0.0-8.1) minutes respectively. In the VIZIGO group, both procedural time and fluoroscopy time were significantly lower than in the standard group (118[IQR 100-120] vs. 180[IQR 132-202] minutes, p < 0.001, respectively and 0.0 [IQR 0.0-0.5] vs.8.1 [4.7-12.6] minutes, p < 0.001, respectively). At 12 months follow up, recurrences were significantly lower in the VIZIGO group compared to the group where a standard fixed sheath was used (8% vs. 32 %, p = 0.034).

Conclusions: Atrial fibrillation ablation with the use of steerable sheath visible on the 3DEAM system eliminates the need of fluoroscopy and reduces procedural time without compromising safety and efficacy.

Graphic Abstract



Introduction

Over the last three decades, catheter-based ablation of atrial fibrillation (AF) has made great advances in terms of efficacy and safety. Tools as advanced 3D electroanatomic mapping (EAM) systems have transformed a complete fluoroscopy-based procedure, recognized as the gold standard for a long time, into a minimal fluoroscopy procedure based on operator's expertise.[1] Furthermore, the use of steerable sheaths may improve the efficacy of the ablation procedure facilitating good contact and stability in challenging anatomical areas.[2] Thus far, steerable sheaths could not be visualized on 3D EAM systems and, consequently, their use required consistent use of fluoroscopy. Recently, the VIZIGO™ steerable sheath (8.5F Biosense Webster, Johnson & Johnson Medical S.p.a., CA) was launched. This steerable sheath can be visualized on the 3D CARTO® 3 mapping system (Biosense Webster, Johnson & Johnson Medical S.p.a., CA) allowing zero-fluoroscopy procedures.[3] In the present study (the APRONLESS study) we report our initial experience with the VIZIGO™ steerable sheath in atrial fibrillation (AF) ablation procedures and we compare it to the standard approach where a fixed sheath not visible on the mapping system is used to guide the ablation catheter.

Methods

Between June 1st, 2020, and June 1st, 2021, 50 consecutive patients undergoing AF ablation at Cardiological Center of S. Anna Hospital, University of Ferrara, Italy, were enrolled and data have been collected in a prospective registry. Inclusion criteria were AF ablation using the CARTO® 3 mapping system and pulmonary vein isolation following the CLOSE protocol.[4] Exclusion criteria were: 1) age <18 years, 2) ongoing pregnancy, 3) inability to give consent.

The patient population was divided in two groups: the first group consisted of 25 consecutive patients treated with a fixed sheath that is not visualized on the mapping system (standard group) and the second group consisted of 25 consecutive patients treated using the VIZIGO™ steerable sheath (VIZIGO group).

Baseline characteristics of patients, such as age, gender, co-morbidities, body mass index, and AF history were included in the analysis. The main parameters evaluated and compared between the two approaches are the procedure, fluoroscopy and ablation time, and the average contact force of the ablation catheter. All acute complications during in-hospital follow-up were recorded and analyzed. Long-term complications and recurrences of AF were also followed up during the clinic visits at three, six, and twelve months. Informed written consent was obtained prior to all procedures. Study protocol was approved by the local ethics committee (234/2022/Oss/AOUFe).

Key Words
atrial fibrillation; transcatheter ablation; fluoroscopy; electroanatomic mapping; arrythmia; visible steerable sheath

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All the procedures were performed by the same operator with an experience of more than 100 AF ablations done. Of note, the expert operator performed all previous AF ablations with non-steerable sheath.

The project is registered on ClinicalTrials.gov (identifier: NCT05319769) and all patients provided written informed consent for data storage and analysis.

AF ablation procedure

All the procedures were performed under general anesthesia with a laryngeal mask.[5] Percutaneous access through right and left femoral vein was obtained using the Seldinger technique for both study groups. In all the cases, intracardiac echocardiography (ICE) was performed using the sensor-based SOUNDSTAR® catheter (10 F, Biosense Webster, CA, USA).[6] The ICE catheter was advanced in the right atrium and oriented towards the septum, providing ultrasound images of the left atrium and the fossa ovalis. Moreover, using the CARTOSOUND® module (Biosense Webster, CA, USA), we obtained a fluoroless 3D map of the left atrium, which was later used as reference for the electro-anatomical mapping.

Standard group

Following ICE imaging of the left atrium and ultrasound map reconstruction, a single transseptal puncture was performed under fluoroscopic guidance using a non-steerable sheath (SL0; Abbott, St. Paul, MN) and a standard Brockenbrough needle 71 cm (Abbott, St. Paul, MN) through the following steps: 1) the sheath was placed in the superior vena cava (3 to 4 cm above the cavoatrial junction) over a guidewire. 2) the guidewire was removed and the transseptal needle with the stylet was gently inserted and advanced through the SL0 sheath avoiding to push the needle over the tip of the sheath. In this step, the needle and the sheath were held in the fingers between four and six o'clock. 3) the needle and the sheath were pulled back caudally under fluoroscopy in a left anterior view until the fossa ovalis (FO) is reached confirmed also by ICE. 4) From this location, the transseptal needle was exposed to perform the puncture. The correct puncture was confirmed by ICE visualizing bubbles flushing the transseptal needle 5) Both the transseptal sheath and the needle were advanced for 1-2 cm in the left atrium (LA). The sheath was then advanced over the needle, which was held firmly. 6) Finally, the needle and the dilator were kept steady, and the sheath was advanced over the dilator. The transseptal sheath was deaired and a 0.032-inch guidewire was advanced toward the left superior pulmonary vein under ICE guidance.[6] After successful transseptal puncture, the ThermoCool SmartTouch™ Surround Flow (STSF) catheter (Biosense Webster, CA, USA) was advanced through the SL0 sheath into the left atrium to perform fast anatomical mapping (FAM) with the CARTO® 3 mapping system, using the previously obtained CARTOSOUND map as guidance. Once the FAM was completed, circumferential pulmonary vein isolation (PVI) following the CLOSE protocol was performed using the ThermoCool SmartTouch™ SF catheter and the non-steerable sheath.[4]

VIZIGO group

In the group where the VIZIGO sheath was used, before advancing the ICE catheter, we reconstructed a bipolar map of

the right atrium with the STSF ablation catheter. We delineated the inferior and superior vena cava, the coronary sinus and we tagged in yellow the His potential. We carefully reconstructed the interatrial septum and, to define precisely the FO, we set the color range on the bipolar map to [0.25; 0.75] mV tagging in light blue all the fragmented and low voltage signals which are typical of the FO area. The FO location was further confirmed by ICE and, thanks to the CARTOSOUND® *module*, it was possible to mark the contours of the FO location and to visualize them on the FAM previously obtained, all without the use of fluoroscopy. Beside the FO, using ICE and the CARTOSOUND® *module*, it was possible to assess and to reconstruct the structures of the left atrium (left atrial appendage, pulmonary veins and esophagus), similar to the standard group. Next, a single transseptal puncture was performed using the VIZIGO™ sheath and a transseptal needle (standard Brockenbrough needle 98 cm from Abbott, St. Paul, MN). Since the sheath is visible on the Carto 3® EAM system, it was possible to place it in the superior vena cava (3 to 4 cm above the cavoatrial junction) without any use of fluoroscopy. At this point, the guidewire was removed and the transseptal needle with the stylet was gently inserted and advanced through the VIZIGO™ sheath, avoiding pushing the needle over the tip of the sheath. In this step, the needle and the sheath were held in the fingers between four and six o'clock. Next, the needle and the sheath were pulled back caudally visualizing the VIZIGO™ sheath until it reached the level of the coronary sinus ostium, and the tip of the dilator was placed in the FO. From this location, the VIZIGO™ sheath was pushed and placed on the FO under the guidance of the EAM system and confirmed by ICE imaging (**Figure 1**). When the sheath was in the right position, the transseptal needle was advanced to perform the puncture. Live tracking of the distal part of the needle on the mapping system was possible thanks to Alligator clip lead wires (FIAB Spa, Florence, Italy) connected to the proximal portion of the needle. After successful transseptal puncture, a 0.032-inch guidewire was placed in the left superior pulmonary vein following the steps 5 and 6 described in the previous section.[3] Next, the STSF ablation catheter was advanced through the VIZIGO™ sheath into the left atrium to perform fast anatomical mapping and PVI following the CLOSE protocol.[4]

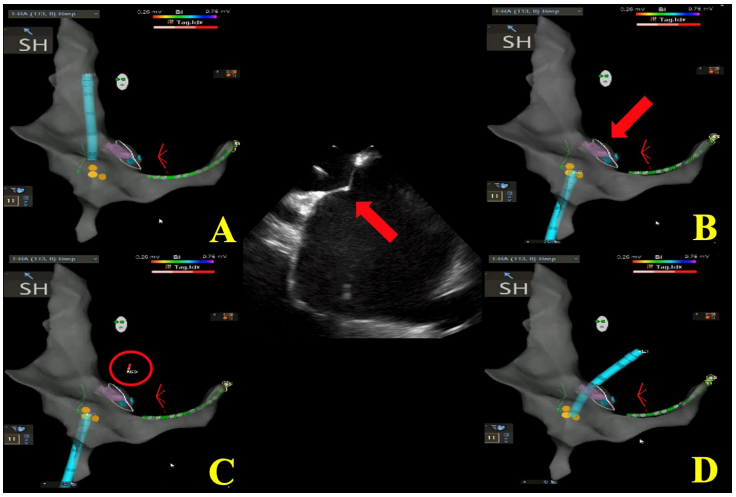

Figure 1: Sheath placed in the superior vena cava (Panel A). Catheter was advanced in the right atrium and pointed at the fossa ovalis (Panel B, fossa ovalis marked with the red arrow). Transseptal puncture was performed, and the needle is visible in the left atrium (Panel C, needle circled in red). VIZIGO™ sheath was pushed and placed on the fossa ovalis under the guidance of the EAM system and confirmed by intracardiac echography (ICE, Panel D). The central image represents the tenting of the needle on the fossa ovalis seen with ICE (marked with the red arrow).

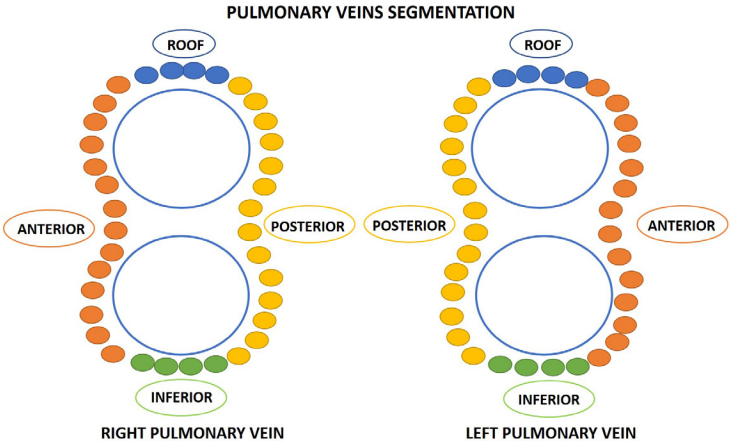

Figure 2: Pulmonary veins segmentation.

Pulmonary vein segmentation

To better evaluate the differences between lesions in the two groups, we divided the lesions' encircles of the pulmonary veins into four segments (**Figure 2**), for the left and right encircle respectively: roof, inferior, anterior, and posterior segment. The average force, the ablation time, and the ablation index value were recorded for each lesion.

Statistical analysis

Descriptive statistics are reported as means ± SD for normally distributed continuous variables, or medians with 25th to 75th percentiles interquartile range (IQR) in the case of skewed distribution. Normality of distribution was tested by means of the nonparametric Kolmogorov-Smirnov test. Categorical data are expressed as percentages. Statistical analyses were performed with SPSS Statistics version 25.0 (IBM Corporation).

Results

Baseline Characteristics

From June 2020 to June 2021, 50 consecutive patients were enrolled in the study protocol. The baseline characteristics of the study population are summarized in **Table 1**. No differences in baseline characteristics were present between the two groups.

Procedural data

The median procedural and fluoroscopy time were respectively 130 (IQR 117-181) minutes and 2.2 (IQR 0.0-8.1) minutes. In the VIZIGO group, both procedural time and fluoroscopy time were significantly lower than in the standard group (118 [IQR 100-120] vs. 180 [IQR 132-202] minutes, $p < 0.001$, respectively and 0.0 [IQR 0.0-0.5] vs. 8.1 [4.7-12.6] minutes, $p < 0.001$, respectively).

Table 1: Baseline Characteristics of the Patients.

	Total	VIZI group	No VIZI group	p-value
Characteristic	**N = 50**	**N = 25**	**N = 25**	
Sex - no. (%)				0.31
Male	39 (78%)	21 (84%)	18 (72%)	
Female	11 (22%)	4 (16%)	7 (28%)	
Median age (IQR) - yr	62 (56-67)	60 (54-64)	62 (58-69)	0.066
Median BMI (IQR) - kg/m^2	28 (25-32)	29 (25-31)	28 (23-32)	1.00
Medical History - no. (%)				
Hypertension	39 (78%)	20 (80%)	19 (76%)	0.73
Hypercolesterolemia	17 (34%)	7 (28%)	10 (40%)	0.37
Diabetes mellitus	5 (10%)	3 (12%)	2 (8%)	1.00
Active or previous smoking habit	23 (46%)	12 (48%)	11 (44%)	0.78
Coronary artery disease	6 (12%)	2 (8%)	4 (16%)	0.67
Previous PCI	6 (12%)	2 (8%)	4 (16%)	0.67
Heart failure	14 (28%)	7 (28%)	7 (28%)	1.00
Chronic obstructive pulmonary disease	1 (2%)	0 (0%)	1 (4%)	1.00
Previous CIED implantation	2 (4%)	0 (0%)	2 (8%)	0.49
Cronic kidney disease	3 (6%)	2 (8%)	1 (4%)	1.00
Previous ablation of atrial fibrillation - no. (%)	7 (14%)	3 (12%)	4 (16%)	1.00
Atrial fibrillation pattern - no. (%)				0.26
Persistent	24 (48%)	14 (56%)	10 (40%)	
Paroxysmal	26 (52%)	11 (44%)	15 (60%)	
Median CHA2DS2-VASc Score (IQR)	2 (1-3)	2 (1-2)	2 (1-3)	0.32
EHRA symptom scale - no. (%)			0.10	
I	4 (8%)	4 (16%)	0 (0%)	
II	30 (60%)	13 (52%)	17 (68%)	
III	16 (32%)	8 (32%)	8 (32%)	
Echocardiographic features				
Median ejection fraction (IQR) - %	60 (50-62)	60 (48-62)	60 (55-61)	0.91
Median indexed volume of left ventricle (IQR) - ml/m^2	62 (58-62)	62 (56-62)	62 (60-62)	0.57
Median indexed volume of left atrium (IQR) - ml/m^2	41 (39-43)	40 (38-42)	39 (37-41)	0.63
Severe mitral valve disease - no. (%)	1 (2%)	0 (0%)	1 (4%)	1.00
Severe aortic valve disease - no. (%)	1 (2%)	0 (0%)	1 (4%)	1.00
Medication at time of ablation - no. (%)				
Beta blockers	38 (76%)	21 (84%)	17 (68%)	0.19
Calcium antagonists	12 (24%)	7 (28%)	5 (20%)	0.51
Amiodarone	17 (34%)	9 (36%)	8 (32%)	0.77
Flecainide	10 (20%)	6 (24%)	4 (16%)	0.48
Propafenone	1 (2%)	1 (4%)	0 (0%)	1.00
DOAC	42 (84%)	21 (84%)	21 (84%)	1.00
Warfarin	7 (14%)	3 (12%)	4 (16%)	0.68
Mean serum hemoglobin (SD) - g/dl	13.9 (1.8)	13.4 (1.8)	14.4 (1.6)	0.053
Median serum creatinine (SD) - mg/dl	0.9 (0.8-1.1)	0.9 (0.8-1.0)	1.0 (0.8-1.1)	0.15
Mean glomerular filtration rate (SD) - ml/min/1.73 m^2	77.4 (14.8)	79.1 (11.3)	75.8 (17.7)	0.42
Rhythm at time of ablation				0.22
Sinus Rhythm	30 (60%)	14 (56%)	16 (64%)	
Atrial Fibrillation	18 (36%)	11 (44%)	7 (28%)	
Cavotricuspid isthmus atrial flutter	2 (4%)	0 (0%)	2 (8%)	
Median heart rate (IQR) - bpm	76 (22)	78 (25)	74 (20)	0.58
Mean PR (SD) - ms	169 (31)	161 (35)	177 (27)	0.18
Median QRS duration (IQR) - ms	98 (88-108)	96 (83-106)	102 (92-108)	0.32
Bundle branch block - no. (%)	3 (6%)	2 (8%)	1 (4%)	1.00

Specifically, procedural time was reduced by 32%, and fluoroscopy time was reduced by 94% (**Figure 3** and **Figure 4**).

Moreover, the overall average force was higher in the VIZIGO group compared to the standard group (12.23 ± 2.34 vs. 10.06 ± 0.76 g, p = 0.03) as shown in **Figure 5**. The comparison of the average force for the different segments of the pulmonary veins are presented in (**Figure 6**).

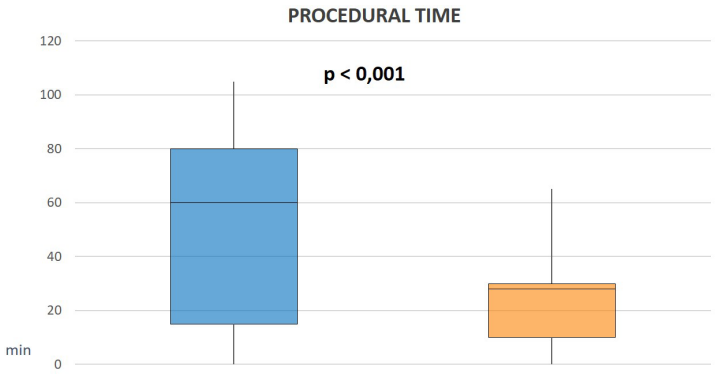

Figure 3: Procedural time in Standard and VIZIGO group.

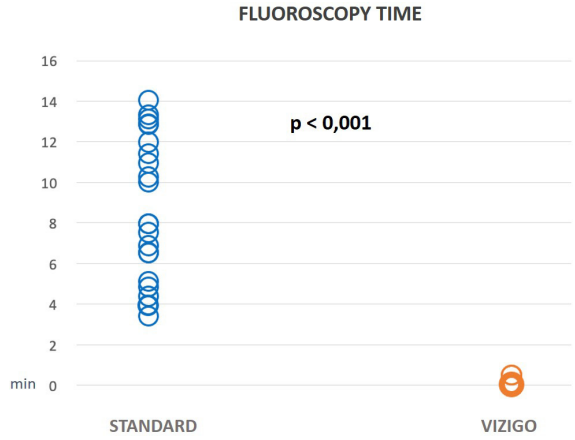

Figure 4: Fluoroscopy time in Standard and VIZIGO group.

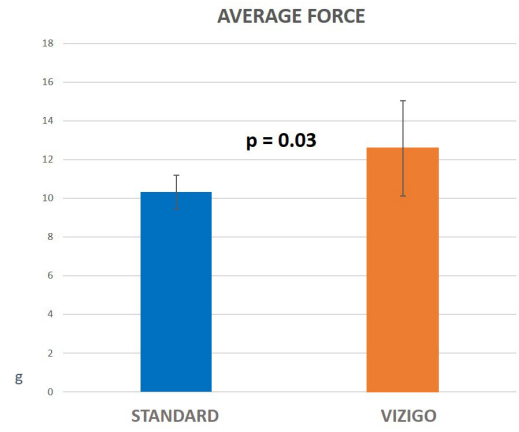

Figure 5: Average force in Standard and VIZIGO group.

When considering the ablation time, the overall average value was similar between the two groups (22.60 ± 3.02 in the VIZIGO group vs. 21.02 ± 4.18 min in the standard group, p = 0.57). However, when analyzing the different segments individually, the average ablation time on the roof and posterior sites (RPV and LPV) were significantly lower in the VIZIGO group than in the standard group (respectively 17.60 ± 0.58 vs. 20.15 ± 0.66 min, p = 0.01) (**Figure 7** and **Figure 8**).

Additionally, to evaluate the quality of the lesion, we considered the Ablation Index (AI) (Biosense Webster, Johnson & Johnson Medical S.p.a., CA), as described in the CLOSE protocol. Particularly, there was not a cutoff in timing to accept AI value because, when the catheter stability criterion is not satisfied during ablation, AI calculation is automatically stopped by the system. To recalculate the AI value at the same position, a new onset of RF energy is required. The redo AI in those points where the target was not reached was based on physician discretion after checking pulmonary vein isolation. The lesions that reached the target ablation index in the VIZIGO group were almost the totality of all the lesions as opposed to the standard group (98% vs. 85%).

Follow-up

During the study period, one patient died due to a non-cardiovascular reason. There was a strong trend towards lower recurrences of atrial fibrillation in the VIZIGO group at six months follow-up, but no statistically significant difference when compared to the standard group (8% vs. 28%, p = 0.066; **Table 2**). However, at 12 months follow up, recurrences were significantly lower in the VIZIGO group compared to the group where a standard fixed sheath was used (8% vs. 32%, p = 0.034; **Table 2**).

Discussion

The main findings of this study are that, compared to the procedures performed without the VIZIGO sheath, in the group where the VIZIGO™ sheath was used: 1) the use of fluoroscopy was near zero; 2) procedural time was significantly shorter; 3) average force was significantly higher; 4) recurrences

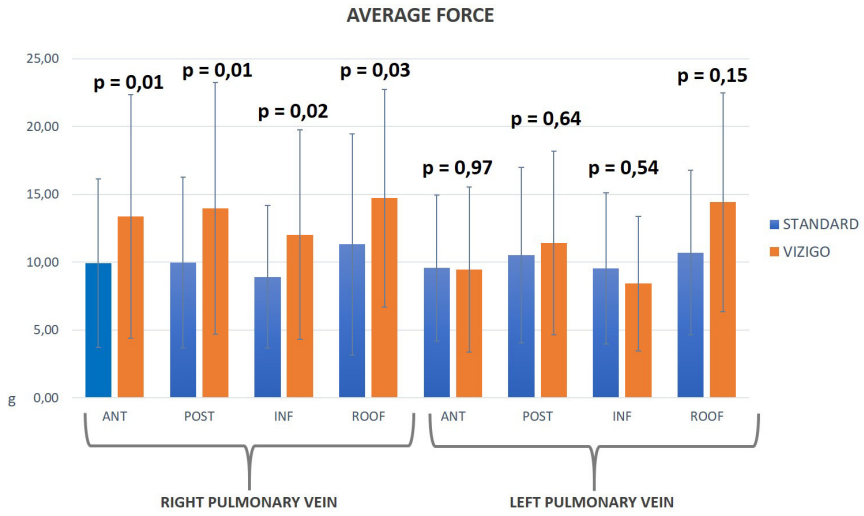

Figure 6: Average force in Standard and VIZIGO group considering lesions in the single ablation zones.

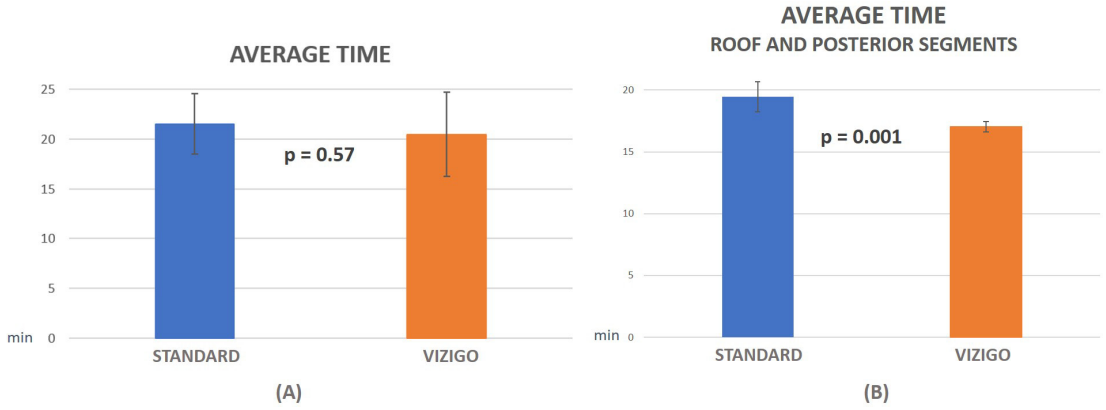

Figure 7: Average ablation time in Standard and VIZIGO group (Panel A), ablation time in roof and posterior segments (Panel B).

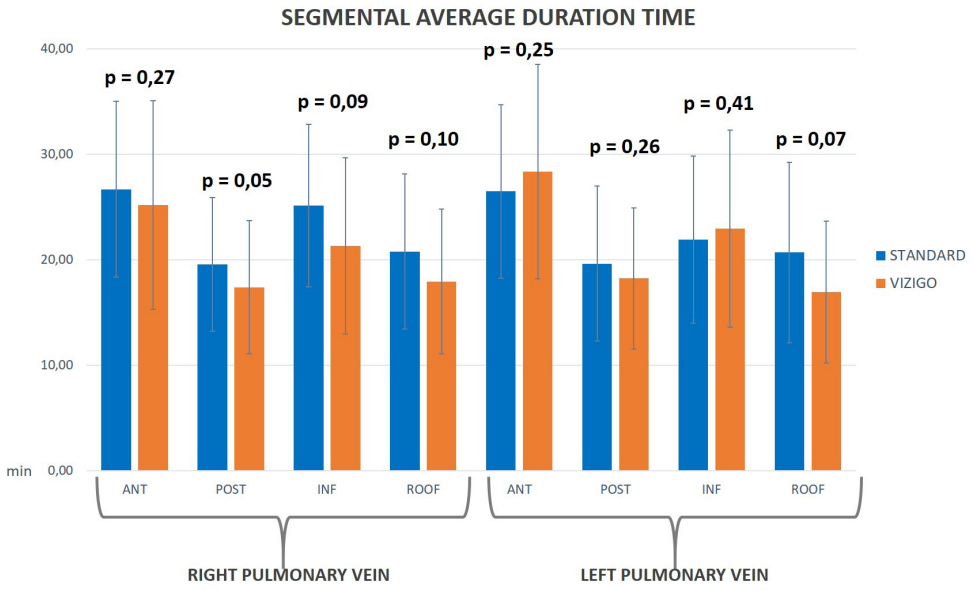

Figure 8: Average ablation time considering lesions in the single ablation zones.

Table 2: Characteristics of the patients at time of follow-up.

	Total	VIZI group	No VIZI group	p-value
	N = 50	N = 25	N = 25	
Recurrences during first 6 months - no (%)	9 (18%)	2 (8%)	7 (28%)	0.066
Recurrences during first 12 months - no (%)	10 (20%)	2 (8%)	8 (32%)	0.034
Death - no. (%)	1 (2%)	0 (0%)	1 (4%)	1.00
CIED implantation - no. (%)	4 (8%)	2 (8%)	2 (8%)	1.00
EHRA symptom scale at 6 month follow-up - no. (%)				0.11
I	43 (86%)	24 (96%)	19 (76%)	
II	5 (10%)	1 (4%)	4 (16%)	
III	2 (4%)	0 (0%)	2 (8%)	
Medication at 6 months of follow-up - no. (%)				
Beta blockers	33 (66%)	18 (72%)	15 (60%)	0.37
Calcium antagonists	13 (26%)	6 (24%)	7 (28%)	0.75
Amiodarone	26 (52%)	13 (52%)	13 (52%)	1.00
Flecainide	11 (22%)	6 (24%)	5 (20%)	0.73
DOAC	44 (88%)	22 (88%)	22 (88%)	1.00
Warfarin	5 (10%)	2 (8%)	3 (12%)	0.64
Echocardiographic features at 6 month follow-up				
Median ejection fraction (IQR) - %	60 (53-62)	60 (50-62)	60 (55-62)	0.95
Median indexed volume of left atrium (IQR) - ml/m^2	42 (42-42)	42 (42-42)	42 (42-42)	0.41
Median indexed volume of left ventricle (ml/m^2)	60 (56-60)	60 (54-60)	60 (58-60)	0.57

of atrial fibrillation at mid and long term follow up tended to be lower.

In the current study, to homogenize the procedure as much as possible, the only different variable between the groups was the use of VIZIGO™ sheath. In this way, we aimed to better understand the effect of introducing this tool in the procedure in terms of fluoroscopy time, procedural time, efficacy, and safety.

Fluoroscopy time

Data on zero-fluoroscopy atrioventricular nodal re-entrant tachycardia and flutter ablation have been available since several years;[6-9] AF ablation procedures are performed with low doses of fluoroscopy, while procedures with complete zero fluoroscopy are emerging.[3] To reduce the radiation exposure, recent publications reported the use of a transesophageal echocardiography during the transseptal puncture. However, the use of transesophageal echocardiography requires the presence of an experienced echocardiographer. A complete zero-fluoroscopy approach performed by an electrophysiologist is possible using ICE, but no standardized data are present.[10] Currently, although highly reduced thanks to the mapping systems, fluoroscopy is the main imaging modality during transseptal punctures.[11] All previous experiences with VIZIGO™ steerable sheath published in literature rely on the use of fluoroscopy. Radiation exposure was minimal but varied from three to nine minutes in the VIZIGO™ arm depending on the study.[12-15] A complete zero-fluoroscopy approach in AF procedures using ICE and the VIZIGO™ steerable sheath visible on the CARTO® 3 mapping system had never been described systematically nor compared to the standard approach. In the current study, almost all the procedures in the VIZIGO group were performed without fluoroscopy. Only in the first three procedures of this group, less than 30 seconds fluoroscopy imaging was used. These three procedures were the very early ablations that the operator performed with the VIZIGO™ steerable sheath, and fluoroscopy was mainly used to verify the position of the sheath reconstructed by the mapping system. The remaining procedures in the VIZIGO group were all performed without fluoroscopy.

In general, a procedure of AF ablation exposes patients to a dose up to 60 mSv and increases the absolute lifetime risk of fatal cancer in an adult by 0.08%.[1] Recent evidence shows that the median per year radiation exposure for interventional cardiologists is up to three

times higher when compared to a radiologist physician.[16] To be in line with ALARA principles, it is crucial to consider the spreading of AF ablation procedure, mainly due to the recent guidelines from the European society of cardiology[17] and the radiation exposure related to the transseptal puncture, to promote zero-fluoroscopy strategies.[18-20] The use of steerable sheaths has shown a reduction in total AF procedure time thanks to improved stability.[2]

However, the main limitation of these steerable sheaths has been for years the lack of visualization on 3D EAM systems resulting in a consistent use of fluoroscopy. Our data show the feasibility of complete zero-fluoroscopy AF ablation procedures, allowing the electrophysiologist to operate without wearing the apron lead (APRONLESS procedures).

Procedural time

The results of our study show that the use of the VIZIGO™ steerable sheath may lead to shorter procedure times, compared to the group where a fixed sheath is used. This reduced procedural time is explained both by the increased stability during ablation (particularly on the roof and the posterior wall of the left atrium) and by the ability to visualize the VIZIGO™ sheath on the CARTO® 3 mapping system, avoiding to continuously check its position with fluoroscopy. These results may help to further optimize ablation procedures through standardized workflows.

Efficacy and safety

In this study, all the ablation lesions were performed following the CLOSE protocol using the Ablation Index (AI) as a marker of lesion quality. The ablation index value integrates together three ablation parameters: power, contact force, and time. The lesions that have reached the target ablation index in the VIZIGO group were almost the totality of all the lesions performed (98%), whereas in the standard group only 85% of all the lesions performed reached the target ablation index value. This result demonstrates that using the VIZIGO™ sheath it is more likely that the ablation lesions will be more consistent and reproducible, resulting in increased efficiency.

The acute efficacy in the two groups appears to be comparable. As shown in Table 2, no differences at six months follow-up were recorded, but a strong trend towards lower recurrences in the VIZIGO group was reported. This trend becomes statistically significant at 12 months follow-up, with the patients treated using the VIZIGO™ sheath experiencing less recurrences. This could be explained by the higher number of lesions reaching the AI target value in the VIZIGO group. In the standard group, lesions with an ablation index value lower than the target value could lead to undertreatment, with more frequent pulmonary vein reconnection at follow-up.

The number of peri-procedural complications was low and comparable between the groups. No acute complications occurred during in-hospital, mid-term, or long-term follow-up in both groups. These results could suggest that conducting a completely fluoroless AF ablation procedure is feasible without compromising safety. Further studies are required to specifically study the safety and efficacy of this approach.

Learning curve

A final consideration is the learning curve in using VIZIGO™ steerable sheath. Considering that all the procedures were done by the same expert operator but used to perform AF ablation with non-steerable sheath, only three procedures were needed to optimize zero-fluoroscopy workflow while simultaneously reducing procedural timings without impact on safety and with a trend to improvement in efficacy.

Limitations

The present study has several limitations. First, this was a single-center center study done with a limited number of patients. Second, this was not a randomized controlled trial, and was not specifically designed to compare the safety and efficacy of the two different approaches. Therefore, a randomized controlled trial is necessary to further investigate these aspects. Third, the VIZIGO™ sheath was compared to a non-steerable sheath and not to another steerable sheath, because using a steerable sheath not visible on the 3D EAM system may increase the time of fluoroscopy as compared to a fixed sheath. However, further studies with a direct comparison between the VIZIGO™ sheath and a steerable sheath not visible on 3D EAM system are needed. Finally, using the VIZIGO™ sheath compared to a fixed sheath slightly increases the cost of the procedure but reduces fluoroscopy and procedure time, increasing efficacy. The real issue regarding the costs is the use of ICE but it is widely demonstrated that this tool significantly increases the safety.[6,21]

Conclusions

Atrial fibrillation ablation with the use of steerable sheath visible on the 3D EAM system eliminates fluoroscopy need and reduces procedural time without compromising safety and efficacy.

Conflict of Interests

No conflicts.

Ethical Approval

The study protocol was approved by the local ethics committee (234/2022/Oss/AOUFe)

Informed Consent

Informed written consent was obtained prior to all procedures.

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