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## **Radiation exposure reduction during atrial fibrillation ablation in real-life population using fluoroscopy and 3D mapping system integration**

**Authors:** Krzysztof Myrda, Piotr Buchta, Jan Głowacki, Adam Józef Wojtaszczyk, Mateusz Witek, Mariusz Gąsior

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## **Radiation exposure reduction during atrial fibrillation ablation in real-life population using fluoroscopy and 3D mapping system integration**

Redukcja ekspozycji na promieniowanie podczas ablacji migotania przedsionków z wykorzystaniem systemu elektroanatomicznego 3D zintegrowanego z fluoroskopią w codziennej praktyce klinicznej.

Krzysztof Myrda<sup>1</sup>, Piotr Buchta<sup>1</sup>, Jan Głowacki<sup>2,3</sup>, Adam Wojtaszczyk<sup>1</sup>, Mateusz Witek<sup>1</sup>,  
Mariusz Gąsior<sup>1</sup>

<sup>1</sup>3rd Department of Cardiology, SMDZ in Zabrze, Medical University of Silesia, Katowice, Silesian Centre for Heart Disease in Zabrze, Poland

<sup>2</sup>Laboratory of Imaging Diagnostics, Silesian Center for Heart Diseases in Zabrze, School of Medicine with the Division of Dentistry in Zabrze, Poland

<sup>3</sup>Chair and Institute of Medical Radiology and Radiodiagnostics in Zabrze, Medical University of Silesia in Katowice, Poland

**Address for correspondence:** dr n. med. Krzysztof Myrda, 3rd Chair and Clinical

Department of Cardiology, Silesian Center for Heart Diseases, ul. M. Curii-Skłodowskiej 9

41-800 Zabrze, e mail: k\_myrda@interia.pl

**Abstract**

**Introduction:** Fluoroscopy integration with three dimensional (3D) electroanatomical mapping system may allow dose reduction while invasive electrophysiological procedures. In this retrospective study we present real-population experience with integrated model.

**Material and methods:** 96 patients with paroxysmal AF after radiofrequency (RF) pulmonary vein isolation (PVI) have been analyzed. In 48 patients, 3D mapping system integrated with fluoroscopy (Carto 3 UniVu) has been used. Clinical and peri-procedural data, inclusive, fluoroscopy time and dose, in-hospital complications and efficacy rate at 6 months have been compared.

**Results:** Patients treated with classic 3D mapping system were significantly older ( $p = 0.036$ ). Both fluoroscopy mean time ( $11.6 \pm 4.3$  vs.  $6.7 \pm 2.9$  minutes,  $p < 0.05$ ) and a median of the fluoroscopy dose ( $460.0$  [IQR:  $288.0$ ;  $785.5$ ] vs.  $271.0$  [IQR:  $145.0$ ;  $535.0$ ] mGy,  $p < 0.05$ ) have been significantly reduced by using Carto3 UniVu. Total procedure time was comparable between groups. Periprocedural complications and recurrence of clinical arrhythmia rate in 6-month follow-up were comparable.

**Conclusions:** Utilization of novel 3D mapping systems with classic fluoroscopy integration support the radiation time and the dose reduction during AF ablation procedure, without any adverse impact on the total procedure time neither complication or success rate. This real-life population results corresponds with previously presented prospective studies.

**Key words:** atrial fibrillation; fluoroscopy; radiofrequency catheter ablation; radiation protection; medical imaging

## **Streszczenie**

**Wstęp:** Integracja obrazu fluoroskopowego z systemem obrazowania elektroanatomicznego 3D może zmniejszać ekspozycję na promieniowanie jonizujące podczas zabiegów elektrofizjologicznych. W tym retrospektywnym badaniu prezentujemy wyniki stosowania

zintegrowanego systemu elektroanatomicznego u pacjentów poddawanych ablacji migotania przedsionków w codziennej praktyce.

**Materiał i metody:** Przeanalizowano 96 pacjentów z napadowym migotaniem przedsionków poddanych zabiegowi izolacji żył płucnych prądem o częstotliwości radiowej. U 48 z nich wykorzystano system elektroanatomiczny 3D zintegrowany z fluoroskopią (Carto 3 UniVu). U pozostałych zastosowano klasyczny system elektroanatomiczny 3D (Carto 3). Analizie poddano dane kliniczne a także około zabiegowe, szczególnie dawkę i czas skopi, a także częstość powikłań i nawrotu arytmii w okresie 6 miesięcy.

**Wyniki:** Pacjenci leczeni z użyciem klasycznego systemu 3D byli istotnie starsi ( $p = 0,036$ ). We wszystkich przypadkach uzyskano całkowitą izolację żył płucnych. Zarówno średni czas skopi ( $11,6 \pm 4,3$  vs.  $6,7 \pm 2,9$  minut,  $p < 0,05$ ) jak i mediana dawki ( $460,0$  [IQR:  $288,0$ ;  $785,5$ ] vs.  $271,0$  [IQR:  $145,0$ ;  $535,0$ ] mGy,  $p < 0,05$ ) były istotnie mniejsze u pacjentów w grupie Carto3 UniVu. Całkowity czas zabiegu był w obydwu grupach porównywalny. Częstość powikłań około zabiegowych oraz nawrotu klinicznej arytmii była porównywalna w obydwu grupach.

**Wnioski:** Wykorzystanie nowego systemu elektroanatomicznego 3D zintegrowanego z klasyczną fluoroskopią pozwala na zmniejszenie ekspozycji na promieniowanie jonizujące podczas zabiegów ablacji migotania przedsionków nie wpływając jednocześnie negatywnie na czas zabiegu, ryzyko komplikacji czy skuteczność. Dane te, uzyskane w toku codziennej praktyki, korespondują z wcześniejszymi dowodami uzyskanymi z badań klinicznych.

**Słowa kluczowe:** migotanie przedsionków, ablacja przezskórna, obrazowanie diagnostyczne, ochrona radiologiczna

## **Introduction**

The ablation of atrial fibrillation (AF) with the usage of the radiofrequency energy (RF) is a well-established and widely performed procedure in electrophysiology (EP) laboratories [1]. However, high radiation doses during a single procedure, a repetitive exposure of the electrophysiology lab personnel as well as possible genetic consequences [2] gave rise to the persistent search for the new ways of radiation exposure reduction.

Implementation of electroanatomical systems in a daily clinical practice has significantly reduced the applied doses in a single procedure [1,3,4]. The current studies focusing on the complex left atrial ablation undermine the necessity of X-ray radiation in such procedures [5]. Therefore, the further investigation to optimize the navigation and to reduce the radiation exposure are needed. One of the possible ways is the integration of classical fluoroscopy and the 3D model created with electroanatomical system [6,7].

This work is aimed to demonstrate the clinical experience in radiofrequency ablation of atrial fibrillation using the integrated module in real-life population.

## **Material and methods:**

### *Study objectives*

To show the possible improvement in efficacy, safety and fluoroscopy time reduction during AF ablation with integrated mapping module (Carto 3 UniVu™), the clinical, peri-procedure data, in-hospital complications and efficacy at 6th month after the ablation with classic 3D mapping system have been compared.

### *Technology description*

UniVu™ is the Carto 3 module, that allows integrating entirely the classic fluoroscopy image with electroanatomical maps (EAM). In order to obtain an integrated image, two additional components are needed: a registration plate — mounted on the location pad — and the software component. A complete localizing calibration during each consecutive procedure —

'registration' — is achieved through the capture of the disc marker located on the Registration plate. After the "registration", prerecorded single x-ray images, fluoroscopy video loops or left atrium (LA) angiographies could be transferred to mapping system and combined with EAM. Such approach allows to project the catheters on those images in real-time and repeated utilization of fluoroscopy is not necessary. Two different views can be used simultaneously. Other technical details of this module have previously been described [6,7].

### *Population*

The population study consists of 96 patients with the symptomatic, documented, drug-resistant paroxysmal AF, who have undergone pulmonary vein isolation between May 2014 and May 2015. The patients were included into analysis, if were > 18 years old. The exclusion criteria were: prior AF ablations, significant enlargement of left atrium in transthoracic echocardiography (TTE) — defined as LA > 55mm in TTE long axis view — or the need for LA substrate modification with the additional ablations lines.

### *Pre-ablation procedure*

Prior to the admission the computer tomography (CT) for 3D cardiac imaging was performed. On admission to hospital all patients underwent clinical examination, laboratory check and transesophageal echocardiography (TEE) for the recognition of the intra-cardiac thrombi. If thrombus was found, the patient was not qualified to the procedure, and the ablation was postponed. Medication with vitamin K antagonists (VKA) and novel anticoagulant drugs (NOAC) was interrupted one day prior admission and withdraw during hospitalization. In patient with INR < 2,0 or in patients on NOAC, the additional low molecular weight heparin (LMWH) was administered.

Anti-arrhythmic medication was continued during the hospital stay and modified if needed.

### *Catheter Ablation Procedure*

All procedures were performed by two experienced operators (more than 5 years of experience in EP studies and AF ablations). The procedures were performed, after written informed consent, under general anesthesia using sevoflurane and/or Propofol with boluses of midazolam and fentanyl. During the whole procedure time the patients stayed under anesthetist control. For invasive blood pressure monitoring, routinely radial approach was used. The intraesophageal temperature feedback during the ablation was achieved by the usage of a temperature probe (SensiTherm, St Jude Medical). After veins punctures, decapolar steerable coronary sinus catheter and quadric-polar non-steerable right ventricular apex catheter were placed under fluoroscopy guidance. A single transseptal puncture (TSP) was performed directly with the use of steerable sheath — Agilis, St Jude Medical, St Paul, MN). After TSP, heparin was administrated and added to achieve ACT level of 300-350 seconds. In the case of AF ablation with UniVu™ Module after positioning of the diagnostic catheters and fluoroscopy guided TSP, localizations reference for UniVu™ Module were registered. Thereafter, routinely right anterior oblique (RAO), left anterior oblique (LAO) and posterior-anterior (PA) cine loops were captured (Figure 1). The electroanatomical map of LA was created and merged with reconstructed CT scans. In patients ablated with UniVu™ Module obtained additional fluoroscopy information (cine loops) were used to facilitate the CT - merging. For LA mapping and ablation, pre-recorded cine loops were used predominantly. The level of temperature probe in the esophagus in reference to ablation catheter was controlled using fluoroscopy. All mapping and RF ablation were performed with the same ablations catheter: F or D-Type, irrigated tip, Thermocool® SmartTouch™ Catheter (Biosence Webster, Inc., Diamond Bar, CA) which allowed for the measurements of catheter contact force. For ablation, a maximum power of 35 Watts, upper temperature limit of 43°C and flow rate of 30ml/min were set. Maximal power delivered at posterior wall and near

esophagus was reduced and adapted according to the intraesophageal temperature. To avoid the atrio-esophageal fistula, intraesophageal temperature was limited to 41°C [8]. In all cases, the circumferential ablation around the pulmonary veins (PV) was performed. The acute success of the procedure was defined as the bidirectional conduction block for PV isolations lesions after 20 minutes from the last application proven by both: pacing along ablation line with mapping catheter (MAP), thereafter with a multipolar spiral mapping catheter (Lasso® eco NAV catheter, Biosense Webster) introduced via Agillis after MAP removal. After ablation and removal of the Agilis sheath from LA, protamine was administered to the reverse heparin. If the activated clot time was lower than 200 seconds, the femoral sheaths were removed. LMWH was continued 6 hours after the procedure — after exclusion of groin complications and pericardial effusion in TTE. We recommend continuing previous anticoagulation therapy after the procedure.

Between May and November 2014 only the Carto 3 electroanatomical mapping system was used (Carto 3 group). UniVu™ Module was not available. Thereafter, during consecutive 6 months, we performed AF ablations only with Carto UniVu™ support (UniVu group).

#### *Analyzed parameters*

Demographics data and body mass measurements were collected on the day of admission. For the calculation of the stroke risk and bleeding risk, CHA<sub>2</sub>DS<sub>2</sub>-VASc score and HASBLED score were used. LA diameter was measured in a TTE parasternal long-axis view and the LA area was measured in an apical four-chamber view. The total procedure time was measured from the first femoral puncture to the removal of all sheaths. All patients have been controlled and undergone 7-days Holter electrocardiogram monitoring in our outpatient clinic after 3 and 6 months form hospital discharge.



### *Statistical analysis*

Continuous parameters with normal distribution were presented as an arithmetic mean  $\pm$  standard deviation, while qualitative parameters were presented as percentages. The parameters the distribution of which was found to be different than normal were presented as a median with an interquartile range (IQR). The differences regarding clinical and periprocedural parameters were compared with t-Student,  $\lambda^2$  test or U-Mann Whitney respectively. Statistical significance was considered by  $p \leq 0.05$  bilateral. All analyses were conducted using Statistica 10.0.

## **Results**

### *Study population, efficacy and safety endpoints*

We analyzed 96 patients with paroxysmal atrial fibrillation, who have undergone PV isolation with 3D electroanatomical mapping system. We included 48 consecutive patients both in Carto 3 group and UniVu group. Patients treated with the support of UniVu<sup>TM</sup> Module were younger ( $p = 0.036$ ). No further statistical differences in demographic and echocardiographic data were observed (Table I). Furthermore, neither total procedure time ( $140 \pm 27$  vs.  $149 \pm 24$  minutes,  $p = ns$ ) nor the acute success rate (100% vs. 100%,  $p = 1.0$ ) were significantly different. The rate of complications and in-hospital AF episodes after the ablation were comparable in both groups. During the hospital stay there were noted complications such as: two haematomas and one femoral bleeding that needed blood transfusion. After 6 months follow-up 78.2% of the patients of the whole study population were free from arrhythmia. There were no statistically significant differences between two compared groups. (Table II).

### *Fluoroscopy*

In the UniVu group, a significant reduction in the mean total fluoroscopy time ( $11.6 \pm 4.3$  vs.  $6.7 \pm 2.9$  minutes,  $p < 0.05$ ) was observed. The decrease corresponded to a reduction of the median total fluoroscopy dose ( $460.0$  [IQR:  $288.0$ ;  $785.5$ ] vs.  $271.0$  [IQR:  $145.0$ ;  $535.0$ ] mGy,  $p < 0.05$ ). The results of the radiation exposure are presented in the Table II.

### *Learning curve*

Out of 48 patients ablated with an integrated module, a radiation exposure data of the first 10 patients and the next 38 patients were compared. The growing operators' work experience with the integrated module allowed a significant reduction in the total fluoroscopy time ( $8.3 \pm 3.0$  vs.  $6.3 \pm 2.8$  minutes,  $p = 0,044$ ).

### **Discussion**

In our study we found that the usage of an integrated model of classic fluoroscopy and 3D mapping system is a feasible and effective technology for the interventional AF ablation. The usage of it shows the same acute success rate in the same procedure time with a lower use of the total fluoroscopic time and dose. These results correspond with data obtained from prospective studies [6,7].

The usage of 3D mapping systems as a clinical routine in an interventional electrophysiology was correlated with the reduction of the total fluoroscopy time and dose. Estner et al. in a prospective randomized study demonstrated a significant reduction in the total fluoroscopy exposure time ( $p < 0.01$ ) and dose ( $p = 0.03$ ) in patients who underwent catheter ablation for drug refractory AF using 3D system [9]. The same group from Italy [10] compared clinical data of patients with atrial fibrillation who had undergone circumferential PV isolation with use of 3D Carto 3 or Carto XP system. The acute success rate was the same in both groups. In the same time of the procedure duration ( $157 \pm 67$  vs.  $159 \pm 65$  minutes,  $p$

= 0.8), the use of Carto 3 system was associated with the reduction in fluoroscopy time ( $15.9 \pm 12.3$  vs.  $26.0 \pm 15.1$  minutes,  $p < 0.001$ ). The reduction of fluoroscopy time in Carto 3 group was greater in patients with paroxysmal AF ( $14.2 \pm 12.7$  vs.  $26.3 \pm 15.2$  minutes,  $p < 0.001$ ).

Our results are comparable with data from prospective studies analyzing results of utilization Carto 3 with UniVu™ Module during AF ablation [6,7,11]. The use of fluoroscopy integrated with EAM was studied in the group of 295 patients with a wide spectrum of cardiac arrhythmias. Using the UniVu™ Module has significantly contributed to the reduction in the fluoroscopy time and dose without a prolongation in the total procedure time (median ablation procedure time 135 [IQR: 113; 170] minutes) (11). In AF group, using UniVu™ has reduced the radiation exposure by 60% of the time ( $p < 0.001$ ) and 49% of the dose ( $p < 0.001$ ). In the prospective, randomized study, 80 patients with paroxysmal AF will also have benefitted from the UniVu™ Module use. The implementation of the integrated fluoroscopy with 3D system resulted in 84% of fluoroscopy time reduction ( $1,75$  [IQR: 1,08; 1,37] vs.  $10,7$  [IQR: 8,8; 12,8],  $p < 0,001$ ) and 73% of fluoroscopy dose reduction during the AF ablation [12]. Similar results were published in the study by Akbulak et al. [7]. In observation of 60 patients with paroxysmal AF both were reduced: the dose ( $476.5 \pm 282.0$  vs.  $882.9 \pm 550.4$  cGycm<sup>2</sup>,  $p = 0.001$ ) and the radiation exposure time ( $7.4 \pm 2.6$  vs.  $11.9 \pm 2.1$  minutes,  $p = 0.0006$ ).

What draws the attention in a closer analysis of data is the comparable efficacy of the procedures 6 months after the experience in both groups (75.0% vs. 81.3%,  $p = ns$ ) and in the whole population (78.2 %). The results correlate with those published by the Akbular et al. after  $125.7 \pm 45.6$  days observation with the attested 81.7 % patients free from any AF episodes, similarly to the Huo et al. with  $5.9 \pm 1.3$  months observation and 76.3 % patients without AF(12).

## **Conclusions**

The AF catheter ablation using an integrated model of classic fluoroscopy and 3D mapping system is safe and has resulted in a significant reduction of fluoroscopy time and dose. The same success rate after a follow-up was achieved without a prolongation of the procedure time and an increase in the rate of complications. This real-life population results corresponds with previously presented prospective studies.

### **Study limitations**

The study we present is, a retrospective observational analysis from the single center. Secondly, only patients who suffered from paroxysmal AF were recruited in the present study. Moreover, compared group has not been homogenous. As mentioned previously patients from UniVu™ Module group were younger ( $p = 0.036$ ). Due to retrospective nature of this study a limited number of parameters was a subject to our analysis with the measurements of the entire dose and time of fluoroscopy, without any emphasis put to the state after TSP. One should also remember about that additional dose of radiation exposure during pre-procedural CT scan, not analyzed in our study. Lastly, since this study was designed to investigate whether a novel non-fluoroscopic imaging system reduces the procedure and fluoroscopy times of catheter ablation in real-life population, we limited data only to the mid-term clinical outcomes, without any information on long-term outcomes.

**All authors declare no conflict of interest**

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**Table 1.** Baseline characteristics

**Table 2.** Peri-procedural and outcome data depends on the used 3D mapping system.

**Figure 1.** Standard RAO 30 and PA position captured with integrated fluoroscopy.

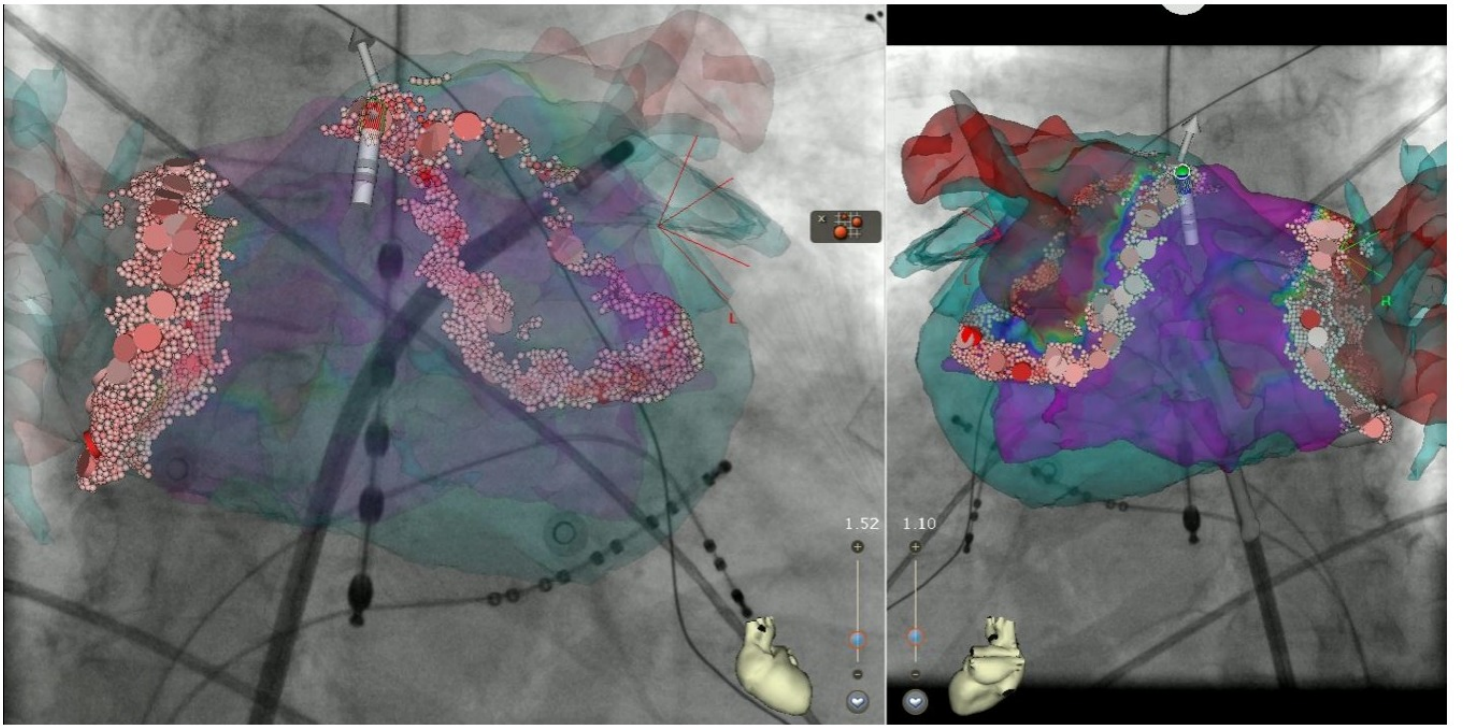




Table 1. Baseline characteristics.

	<b>All (n=96)</b>	<b>Carto 3 group (n=48)</b>	<b>UniVu group (n=48)</b>	<b>P</b>
<b>Demographics data</b>				
Age [years]	58 ± 10	60 ± 11	56 ± 9	<b>0.036</b>
Male [%]	63.5	66.7	60.4	0.53
Weight [kg]	79 ± 17	90 ± 14	89 ± 17	0.78
BMI [kg/m <sup>2</sup> ]	29.4 [25.7; 33.1]	29.2 [27.1; 31.6]	30.1 [25.3; 33.4]	0.73
Hypertension [%]	71.2	72.9	70.8	0.82
Diabetes [%]	25.0	18.8	31.3	0.16
CHA <sub>2</sub> DS <sub>2</sub> VASc	1.0 [1.0; 3.0]	2.0 [1.0; 3.0]	1.0 [1.0; 2.0]	0.13
HASBLED	1.0 [1.0; 1.0]	1.0 [0.0; 2.0]	1.0 [0.0; 1.0]	0.28
<b>Echocardiographic parameters</b>				
LVEF [%]	55 ± 7	55 ± 5	55 ± 8	0.98
LA diameter [mm]	42.0 ± 4.5	42.2 ± 4.6	41.0 ± 4.6	0.21
LA diameter ≥ 40mm [%]	64.6	70.8	58.3	0.25
LA area [cm <sup>2</sup> ]	21 ± 4.8	21.6 ± 3.3	20.9 ± 5.6	0.64

Table 2. Periprocedural and outcome data depends on the used 3D mapping system.

	<b>All (n=96)</b>	<b>Carto 3 group (n=48)</b>	<b>UniVu group (n=48)</b>	<b>P</b>
<b>Periprocedural data</b>				
Total procedure time [min]	144 ± 26	140 ± 27	149 ± 24	0.07
Total fluoroscopy dose [mGy]	345.5 [221.3; 682.3]	460.0 [288.0; 785.5]	271.0 [145.0; 535.0]	<b>0.001</b>
Total fluoroscopy time [min]	9.2 ± 4.4	11.6 ± 4.3	6.7 ± 2.9	<b>&lt;0.001</b>
Total RF applications time [seconds]	3092 ± 1131	3161 ± 1212	3010 ± 1037	0.54
<b>Efficacy and safety endpoints</b>				
Periprocedural efficacy [%]	100.0	100.0	100.0	1.0
AF recurrence during hospital stay [%]	8.3	10.4	6.3	0.16
In-hospital complications [%]	3.1	4.2	2.1	0.14
6-months efficacy [%]	78.2	75.0	81.3	0.31