



## Původní sdělení | Original research article

# The influence of the technology on the success of the treatment of paroxysmal atrial fibrillation – Single center experience

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## ABSTRACT

**Introduction:** Pulmonary vein isolation (PVI) is considered to be a cornerstone of invasive therapy of paroxysmal atrial fibrillation (PAF). However, numerous technologies appeared on the market during last 10 years and besides typical "point-by-point" ablation, other "single-burn" technologies or remote navigation emerged.

**Goal:** The aim of this article is to summarize single center experience with PVI using different technologies.

**Methods and results:** The study was conducted in partially retrospective and mainly prospective manner. Consecutive cohorts of patients with PAF were followed after their index procedure using four different systems (CARTO XP, pulmonary vein ablation catheter [PVAC], CARTO3 and Sensei robotic system). After 3-month blanking period, repeated 7-day Holters were carried out every three months following the index procedure, which consisted of catheter-based radiofrequency PVI. Documented episodes of AF lasting > 60 s on any of these 7-day Holters were considered a failure of treatment. Using of the PVAC technology was associated with the shortest procedure duration when compared to any other system ( $p < 0.0001$  for all) and significant shortening of fluoroscopic time when compared to CARTO XP ( $p < 0.0001$ ). Using of novel CARTO3 mapping system or robotic navigation led to significant decrease of procedural time when compared to older 3D mapping system CARTO XP ( $p < 0.0001$ ). Arrhythmia free survival at 12 months following the index procedure was 65.8%, 68.7%, 75% and 76.1% when using CARTO XP, PVAC, CARTO3 and robotic navigation, respectively. Using of either CARTO3 or robotic navigation system led to significant improvement of AF-free survival (log-rank  $p < 0.01$ ). One major vascular complication was recorded in the robotic group of patients while none in other groups. No minor or major late complications (beyond 30 days following the index procedure) were noted in any of the groups.

**Conclusions:** Novel technologies bring significantly better results in terms of arrhythmia recurrence and allow for shorter procedure duration and lower radiation burden both for patients and the operating physicians.

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## SOUHRN

**Úvod:** Izolace plicních žil je považována za klíčový moment v invazivní léčbě paroxysmální fibrilace síní (FS). Na trhu se v posledních letech objevila řada technologií a kromě klasického přístupu, kdy je ablační léze vytvářena „bod-po-bodu“, se objevila řada jiných technologií umožňujících cirkulární ablací jedním nebo několika páleními či dálkovou navigací.

**Cíle:** Cílem práce je shrnout zkušenosti jednoho centra s použitím různých technologií při izolaci plicních žil.

**Metody a výsledky:** Studie byla provedena částečně retrospektivně a částečně prospektivně. V jednotlivých kohortách byli sledováni konsektivní pacienti podstupující izolaci plicních žil pro paroxysmální FS za použití čtyř různých přístupů a systémů (CARTO XP, cirkulární ablační katetr PVAC, CARTO3 a robotický systém Sensei). Po tříměsíční zaslepené periodě byli pacienti vyšetřováni sériově po třech měsících pomocí sedmidenního holterovského monitorování s transtelefonním přenosem EKG. Za selhání léčby byla považována dokumentace jedné nebo více epizod FS s délkou trvání > 60 s při kterémkoliv z těchto vyšetření. Použití technologie cirkulárního multielektrodeového katetru PVAC bylo spojeno s nejkratší dobou trvání procedury ve srovnání s jakýmkoliv jiným systémem ( $p < 0,0001$ ) a se signifikantním zkrácením skiaskopického času ve srovnání se systémem CARTO XP ( $p < 0,0001$ ). Použití nové generace navigačního systému CARTO3 nebo použití robotické navigace (Sensei) vedlo k signifikantnímu zkrácení procedurálního času ve srovnání se starším systémem CARTO XP ( $p < 0,0001$ ). Stabilní SR bez recidivy FS byl po roce od provedení výkonu zaznamenán u 65,8 % pacientů při použití systému CARTO XP, u 68,7 % pacientů při použití katetru PVAC, u 75 % pacientů při použití systému CARTO3 a u 76,1 % pacientů při použití robotické technologie. Použití technologie CARTO3 nebo robotické navigace vedlo k signifikantně lepším výsledkům v potlačení recidiv FS (log-rank  $p < 0,01$ ) ve srovnání se starším systémem CARTO XP nebo s použitím katetru PVAC. Jedna významná vaskulární komplikace byla zaznamenána v roboticky ošetřené skupině pacientů. Jiné významné nebo malé komplikace po 30 dnech od výkonu nebyly v dlouhodobém sledování v žádné ze skupin pacientů zachyceny.

**Závěr:** Nové technologie přináší v léčbě paroxysmální FS významně lepší výsledky při zkrácení procedurálního času i skiaskopické zátěže pacienta a vyšetřujícího personálu.

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*Klíčová slova:*

Cirkulární multielektrodeový ablační katetr

Paroxysmální fibrilace síní

Radiofrekvenční energie s fázovým posunem

Robotická technologie

Srovnání technologií

3D mapovací systémy

## Introduction

Pulmonary vein isolation (PVI) is considered to be a cornerstone of invasive therapy of paroxysmal atrial fibrillation (PAF) [1,2]. However, numerous technologies emerged on the market during last 10 years and typical “point-by-point” ablation around the pulmonary vein (PV) ostia or antra was originally intended to be replaced by “single burn” technologies, which requires only one or a few radiofrequency (RF) or other energy applications to achieve pulmonary vein isolation, thus making the procedure more simple, shorter, safer and at the same time effective [3–6]. In parallel, 3D mapping systems evolved and recently, the electrophysiologists have gained the possibility of appropriate contact force measurement [7], a believed “last piece in the puzzle” tool to achieve durable electrical disconnection of the pulmonary veins, remote catheter navigation or real-time visualization of all catheters within the heart chamber. The precipitous testing of these new technologies, which can be thoroughly documented in the field of RF ablation for PAF during last few years [8], poses inherent risk of non-validated use, as one technology is rapidly replaced by the other with no proof of superiority and/or non-inferiority with all potential consequences.

The purpose of this article is to summarize experience of an expert single center with PVI using four different technologies. Rather than randomized comparison, we would like to provide consecutive cohort assessment in this analysis, with stress to the risks and benefits both for the patients and for the operators.

## Methods

### *Patients and procedure*

We partially retrospectively and mainly prospectively analyzed four groups of consecutive patients treated at our clinic between 2009 and 2011 who underwent catheter treatment for PAF with respect to the used technology and clinical results:

1. Patients treated with conventional “point-by-point” manual ablation using old generation 3D mapping system CARTO XP (Biosense Webster Inc., Diamond Bar, CA, USA) – group A.
2. Patients treated with conventional “point-by-point” manual ablation using the new generation 3D mapping system CARTO3 (Biosense Webster Inc., Diamond Bar, CA, USA) – group B.
3. Patients treated with decapolar circular ablation catheter (PVAC, Medtronic, USA) combined with a multi-channel, duty-cycled RF generator (GENius, Medtronic, USA) – group C.
4. Patients treated using robotic technology (Sensei X Robotic Catheter System, Hansen Medical, USA) and 3D mapping system NavX or later EnsiteVelocity (St. Jude Medical, USA) – group D.

AF was considered paroxysmal if patients had a history of recurrent, self-terminating episodes of arrhythmia spontaneously converted to normal SR or either electrically or pharmacologically cardioverted within 48 h if the symptoms were severe. Patients without structural heart disease were not required to test antiarrhythmic drugs prior to the procedure. Patients with persistent AF were

excluded from this study as well as patients with significant structural abnormalities (left atrial [LA] dimension  $\geq 50$  mm, left ventricular ejection fraction [LVEF]  $\leq 50\%$ , valvular insufficiency and/or stenosis  $\geq$  grade 3, hypertrophic cardiomyopathy with septal thickness  $\geq 20$  mm). Transoesophageal echocardiography was performed 1 day prior to procedure to exclude LA thrombus.

### CT imaging

Anatomy of the LA and PVs is known to be highly individual and variable. A 64-slice CT scan (Aquilion 64 TSX-101A, Toshiba) was performed on the day prior to the ablation procedure, with subsequent 3D reconstruction of the anatomy using the CARTO MERGE or CARTO3 (Biosense Webster Inc., Diamond Bar, CA, USA) software to ensure that all PVs were targeted for ablation.

### Ablation procedure

All procedures were done under conscious sedation using fentanyl or combination of fentanyl and diazepam. Heparin was given after accessing the LA in a loading dose of 100 IU/kg and continuous infusion with the target ACT between 280 and 330 s. Oral anticoagulation (coumadin) was restarted in all patients directly after the procedure, using low-molecular weight heparin for bridging until INR exceeded 2.0.

During procedures using CARTO XP or CARTO3 systems PV antra were targeted by contiguous focal lesions deployed at a distance  $> 5$  mm from the ostia of the PVs, creating a circumferential line around both ipsilateral veins (Fig. 1). Radiofrequency energy was applied using 3.5 mm irrigated tip NAVISTAR THERMOCOOL catheter (Biosense Webster Inc.) with temperature limitation of 45 °C and radiofrequency energy up to 35 W. Use of circular mapping catheter (LASSO, Biosense Webster Inc., Diamond Bar, CA, USA) to confirm absence of local PV potentials during sinus rhythm or pacing from the coronary

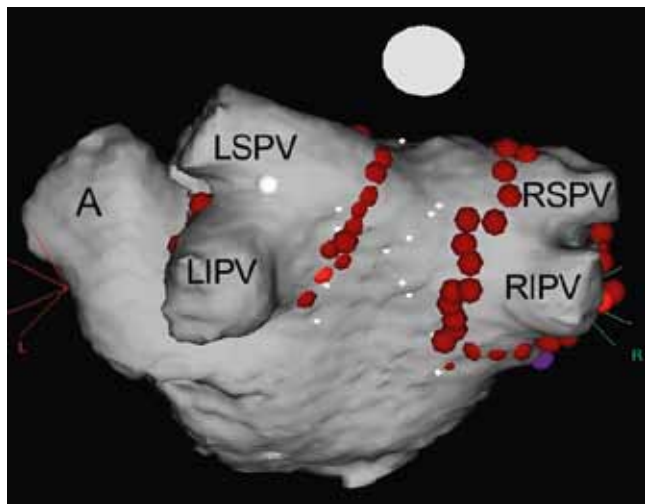


Fig. 1 – Example of pulmonary vein isolation by “point-by-point” technique under 3D electromagnetic guidance using CARTO system. A contiguous ablation line (red dots) is drawn around the ipsilateral pulmonary veins. Posteroanterior view. A – auricle; LIPV – left inferior pulmonary vein; LSPV – left superior pulmonary vein; RIPV – right inferior pulmonary vein; RSPV – right superior pulmonary vein.

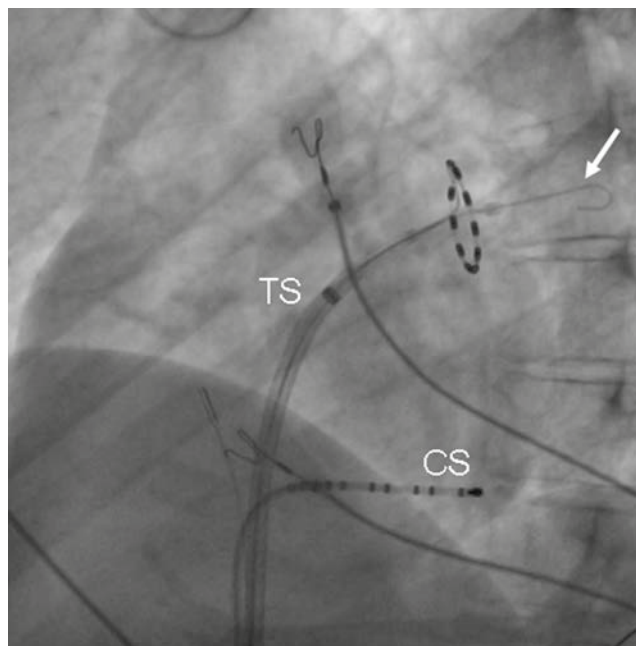


Fig. 2 – Example of the isolation of the left superior pulmonary vein using PVAC system. The catheter is introduced in the left atrium using over-the-wire technique, the J-shaped wire is parked in the left superior pulmonary vein (arrow) and the catheter is pushed against the venous antrum.

CS – catheter introduced in the coronary sinus; TS – 9F steerable transseptal sheath.

sinus and/or left atrial appendage, when appropriate, was mandatory in each procedure.

A detailed description of PVAC ablation procedure was described in details elsewhere [9]. In brief, after successful transseptal puncture the PVAC catheter was introduced to the LA via a 9F steerable transseptal sheath (Channel, BARD Electrophysiology, Lowell, MA, USA) (Fig. 2). The standard ablation setting was 4 : 1 bipolar to unipolar RF energy application during 60 s, with a power limit of 8 W and target temperature of 60 °C. Overlapping applications were performed until the local antral voltage abated (Fig. 3). PVI with entrance block was verified by mapping inside each vein using PVAC and finally at the



Fig. 3 – Example of the isolation of the left inferior pulmonary vein using PVAC system. (A) Before ablation, signals could be recorded from all five pairs of the circular ablation catheter. When RF application is started (RF on), signals are dumped by the noise from the RF generator and atrial ectopic beats are usually present. (B) After a 60 s application, no more signals are present and an ectopic, non-conducted pulmonary vein potential (arrow) is proof of an exit block and electrical isolation.



**Fig. 4 – Pulmonary vein isolation using Sensei robotic system and Ensite NavX navigation system.** The encircling of the left pulmonary veins was started at the roof of the left upper pulmonary vein antrum and continued down to left inferior pulmonary vein on the posterior wall of the left atrium (red dots). Fluoroscopic image, intracardiac echocardiography image and 3D map are integrated into one screen and contact force curve of the Artisan robotic catheter is instantaneously depicted in the left lower portion of the image (arrow).

end of the procedure using conventional circular mapping catheter (LASSO, Biosense Webster Inc., Diamond Bar, CA, USA) showing absence of local PV potentials during sinus rhythm or pacing from the coronary sinus and/or left atrial appendage, when appropriate.

The PVI in the Hansen group was made in a similar fashion as in the CARTO groups with following diffe-

rences: 1. Reconstruction of the LA was performed using Ensite NavX navigation system (St. Jude Medical, St. Paul, MN, USA). 2. Robotic steerable sheath Artisan (Hansen Medical, Inc., Mountain View, California, USA) was introduced in the LA after accessing the chamber with double transeptal puncture. 3. Radiofrequency energy was delivered by a 4-mm tip Celsius THERMOCOOL catheter (Biosense Webster Inc.) for up to 60 s on each spot with temperature limitation of 45 °C and radiofrequency energy up to 25–30 W. Contact force of the Artisan catheter was continuously monitored and kept within the range of 10–30 g (Fig. 4).

### Follow-up

Three-month blanking period to allow for tissue healing and lesion consolidation was planned and any recurrence of AF during this period was not considered failure of treatment. Patients were advised to continue their antiarrhythmic therapy that had proven to be previously ineffective, during this blanking period. After one month, the first 7-day Holter was performed, and if no arrhythmia recurrence was detected, discontinuation of all antiarrhythmic drugs was advised. Further 7-day Holters were performed every 3 months after the procedure until the 24<sup>th</sup> month following the index procedure. Documented episodes of AF lasting > 60 s on any of these three 7-day Holters were considered a failure of treatment. In addition, if patients felt palpitations and no arrhythmias were detected on the 7-day Holter, monitoring of the heart rhythm was done using a patient-activated, simple to use Holter device taking down a one minute ECG recording during symptoms. Patients remained on oral anticoagulation therapy with vitamin K antagonists with the target

**Table 1 – Baseline clinical characteristics of four groups of patients with PAF treated with different technologies.**

	Group A CARTO XP	Group B CARTO3	Group C PVAC	Group D Sensei
<b>N</b>	81	77	79	75
<b>Men</b>	48 (59.3%)	44 (57.1%)	53 (67.1%)	42 (56%)
<b>Women</b>	33 (40.7%)	33 (42.8%)	26 (32.9%)	33 (44%)
<b>Age (years)</b>	58 ± 9 (33–81)	58 ± 10 (30–78)	59 ± 10 (31–81)	61 ± 9 (35–79)
<b>Concomitant diseases</b>				
Hypertension	25 (30.9%)	24 (31.2%)	27 (34.2%)	17 (22.7%)
Diabetes	8 (9.9%)	4 (5.2%)	8 (10.1%)	5 (6.7%)
CAD	3 (3.7%)	3 (3.9%)	4 (5.1%)	2 (2.7%)
<b>Antiarrhythmic therapy</b>				
Propafenone	36 (44.4%)	43 (55.8%)	38 (48.1%)	45 (60%)
Sotalolol	18 (22.2%)	0 (0%)	22 (27.8%)	3 (4%)
Amiodarone	25 (30.9%)	28 (36.4%)	15 (19%)	27 (36%)
Flecainid	3 (3.7%)	1 (1.3%)	0 (0%)	0 (0%)
Dronedrone	0 (0%)	1 (1.3%)	0 (0%)	4 (5.3%)
None tested	9 (11.1%)	17 (22.1%)	14 (17.7%)	9 (12%)
<b>LAd (mm)</b>	41.5 ± 5.2 (28–48)	41.2 ± 5.2 (28–50)	41.1 ± 5.2 (28–49)	42.9 ± 5.5 (28–50)
<b>LVEF (%)</b>	69 ± 6 (55–78)	67 ± 6 (44–76)	69 ± 5 (60–80)	67 ± 8 (44–85)

CAD – coronary artery disease; LAd – left atrial diameter in parasternal long axis view; LVEF – left ventricular ejection fraction.



INR 2.5–3.0 throughout the whole study if the CHADS<sub>2</sub> (or later CHA<sub>2</sub>DS<sub>2</sub>-VASc) was  $\geq 2$ . In patients with lower CHADS<sub>2</sub> score the anticoagulation therapy was discontinued after 6 months following the index procedure if no arrhythmia was detected both at the 3<sup>rd</sup> and 6<sup>th</sup> month of the follow-up.

### Statistical analysis

Statistical analysis was performed using MedCalc software, ver. 12.3.0.0. Continuous variables are expressed as mean  $\pm$  standard deviation. Categorical variables are presented as absolute numbers and percentages. Comparisons between the two groups were made with a Fisher's exact test for categorical variables and a one-way ANOVA test for continuous variables. In cases of non-normal data distribution (Shapiro-Wilk test), a non-parametrical Kruskal-Wallis test was used, and for paired analysis a Mann-Whitney U-test complemented with Bonferroni correction was applied to limit a type I error at the level  $< 0.05$ . A  $p$  value  $< 0.05$  was considered statistically significant. The Kaplan-Meier method was used for the arrhythmia-free survival curve.

## Results

Number of patients in groups A, B, C and D and their baseline clinical characteristics are listed in Table 1. The patients in all four groups did not differ with respect to age, gender, concomitant diseases, antiarrhythmic therapy, that was proved to be ineffective prior to invasive procedure, and both left ventricular ejection fraction and left atrial diameter.

### Procedural outcome

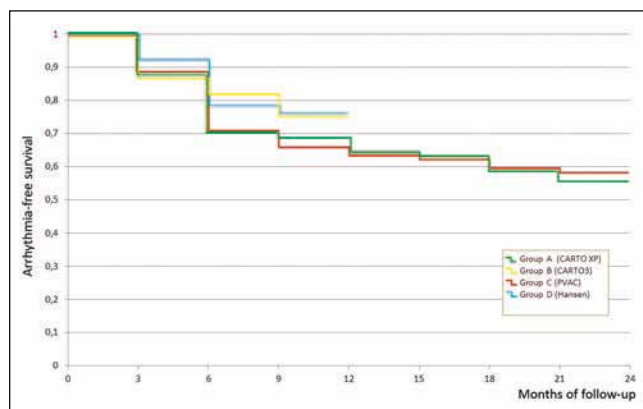
Procedural characteristics are shown in Table 2. Upgrading from CARTO XP (Group A) to any other technology (CARTO3, PVAC and Hansen, groups B, C and D, respectively), significantly shortened both total procedural time and X-ray time ( $p < 0.001$  for all). Moreover, using PVAC catheter for PVI was connected with significant shortening of procedural time when compared to any other technology ( $p < 0.001$  for all). There was no difference in procedural and fluoroscopic times detected between manual and robotic approach provided that manual approach was performed using CARTO3 electromagnetic

Table 2 – Procedural characteristics and early complications.

	Group A CARTO XP	Group B CARTO3	Group C PVAC	Group D Sensei
N	81	77	79	75
Total procedural time (min)	212 $\pm$ 46	134 $\pm$ 32 <sup>#,*</sup>	105 $\pm$ 30 <sup>*</sup>	141 $\pm$ 27 <sup>#</sup>
Fluoroscopic time (min)	26.4 $\pm$ 8.3	8.7 $\pm$ 4.5 <sup>*,†</sup>	15.1 $\pm$ 5.3	9.9 $\pm$ 3.4 <sup>†</sup>
RF application time (min)	49.7 $\pm$ 16.2	39.1 $\pm$ 11.8	20.0 $\pm$ 6.0	27.9 $\pm$ 9.3
% of veins acutely isolated	98.5% <sup>‡</sup>	100% <sup>‡</sup>	98% <sup>‡</sup>	99% <sup>‡</sup>
Days of hospitalization	5.2 $\pm$ 1.4 <sup>‡</sup>	5.1 $\pm$ 1.3 <sup>‡</sup>	4.5 $\pm$ 1.2 <sup>‡</sup>	5.6 $\pm$ 2.4 <sup>‡</sup>
<b>Major early complications</b>				
Tamponade	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Atrio-esophageal fistula	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Gastroparesis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Femoral vein injury requiring intervention	0 (0%)	0 (0%)	0 (0%)	1 (1.3%)
Phrenic nerve palsy	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Systemic infection/sepsis	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)
Stroke/TIA	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pulmonary vein stenosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Death	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Minor early complications</b>				
Pericardial effusion	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Large groin hematoma	1 (1.2%)	1 (1.3%)	1 (1.3%)	3 (4%)
AV fistula	2 (2.5%)	1 (1.3%)	0 (0%)	0 (0%)
Pseudoaneurysm	6 (7.4%)	0 (0%)	1 (1.3%)	1 (1.3%)
Venous thrombosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Local groin infection	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)

TIA – transitory ischemic attack. Large groin hematoma was defined as hematoma exceeding 100 cm<sup>2</sup> of discolored skin in groins.

<sup>‡</sup>  $p$  = NS between the groups; <sup>\*</sup>  $p < 0.0001$  for PVAC when compared to any other group; <sup>#</sup>  $p < 0.0001$  for CARTO3 or Sensei when compared to group A; <sup>†</sup>  $p = 0.06$  for CARTO3 when compared to group D; <sup>‡</sup>  $p$  = NS for CARTO3 when compared to group D; <sup>‡</sup>  $p < 0.0001$  for CARTO3 or Sensei when compared to groups A or C.



**Fig. 5 – Arrhythmia-free survival in four different groups of patients depending on technology used for pulmonary vein isolation (see the text for further details).**

mapping system, however, a trend towards shorter procedural time appeared using manual approach ( $p = 0.06$ ). Fluoroscopic time was significantly longer in CARTO XP group when compared to any other technology ( $p < 0.0001$  for all). Both CARTO3 and robotic group had shorter X-ray times than PVAC group ( $p < 0.0001$ ). Length of in-hospital stay did not differ between the groups.

Acute success of PV isolation was also comparable between all patient groups. Total RF time applied necessary to achieve all PVI was significantly longer in group A (CARTO XP) when compared to any other technology ( $p < 0.001$  for all).

In total 312 patients treated for PAF only one serious complication was noted. The complication was linked with the introduction of the robotic sheath (Artisan) in group D. Due to extreme tortuosity of the right iliac vein this vein was disrupted and continuous leakage of the blood to the pelvic interstitium was proved by injecting contrast agent to the femoral vein. Subsequently, the procedure had to be prematurely stopped and extravasation was solved by percutaneous implantation of a wall-graft in the torn area without any permanent sequelae. There was a higher cumulative incidence of minor local vascular complications (AV fistula, pseudoaneurysm, large hematoma, thrombosis and infection) in the CARTO XP group of patients when compared to other patient groups ( $p = 0.02$ ). All minor complications did not require any surgical intervention and were solved either by manual compression under sonographic guidance (AV fistulas, pseudoaneurysms) or by local and/or systemic antibiotic administration (groin infection).

### Clinical outcome

Arrhythmia free survival defined as absence of any supraventricular arrhythmia (both atrial tachycardia and fibrillation lasting  $> 60$  s) depending on used technology is illustrated in Fig. 5. Mean follow-up reached  $249 \pm 92$  days,  $618 \pm 100$  days,  $261 \pm 100$  days and  $631 \pm 122$  days in groups A, B, C and D, respectively. Patients in groups B and D (CARTO3 and robotic ablations) had shorter follow-up as these technologies were available later.

Arrhythmia free survival without antiarrhythmic drugs did not differ significantly between groups B and D

(i.e. CARTO3 and Sensei) at 12<sup>th</sup> month (75% vs. 76.1%,  $p = \text{NS}$ ). Arrhythmia free survival did not differ between groups A and C (i.e. CARTO XP and PVAC) either, both at 12<sup>th</sup> and 24<sup>th</sup> month of follow-up (68.7 % vs. 65.8%,  $p = \text{NS}$ , and 55.5 % vs. 58.2 %,  $p = \text{NS}$ , respectively). Both robotic and CARTO3 groups had significantly better arrhythmia-free survival than CARTO XP and PVAC groups (log-rank  $p < 0.01$  for all). No minor or major late complications (beyond 30 days following the index procedure) were noted in any of the groups.

### Discussion

The main result of our comparative study is that upgrading to novel technologies used during PVI can bring significant improvement in several aspects. *First*, the workflow of the electrophysiology lab can be accelerated by shortening total procedural time of AF ablation. Dramatic improvement was noted especially with an introduction of duty-cycled RF ablation with PVAC system. Entire duration of the procedure was almost halved. By simultaneously applying RF energy to virtually whole circumference of the PV antra it is possible to achieve complete electrical isolation just by a few one minute lasting burns. In our previous study we reported median of 6, 5, 4 and 4 burns needed for the disconnection of the left upper, left lower, right upper and right lower pulmonary vein, respectively [9], in line with other reports [5]. Also duration of PVI procedures using PVAC catheter in our center is in concordance with previous results described by other experienced centers using this technology [5,10,11].

Both CARTO3 mapping system and Sensei robotic technology also made ablation procedures much quicker, albeit not to such an extent as PVAC catheter.

*Second*, the fluoroscopic times during AF ablations are of a growing importance, especially in high-volume centers. Recent multicenter Italian study showed significant decrease in mean fluoroscopy time exposure comparing catheter treatment of AF using older CARTO XP system and new generation CARTO3, resulting in shortening of radiation exposure time almost to a half ( $26 \pm 15.1$  min to  $15.9 \pm 12.3$  min,  $p < 0.001$ ) [12]. We currently perform about 300 RF ablations for AF or complex supraventricular arrhythmias per year in our center (only two operating physicians). If a technology is able to save in average 17 min of X-ray time per procedure, as it was seen in our comparative study (CARTO3 vs. CARTO XP), the cumulative fluoroscopic time spared would reach hardly believable 85 h per year! Such a dramatic decline of radiation exposure is even pronounced during robotic ablations. While total X-ray time during Sensei cases is comparable to manual ablations using CARTO3, the absence of the operator in the operating theater during PV isolation itself leads to further reduction of X-ray exposure, as the operator is present in the lab only during catheter introduction, transseptal puncture and LA geometry creation (preparatory phase of the procedure). Our previous study showed that in such cases the mean X-ray exposure during robotic ablations of PAF can be reduced down to  $5.6 \pm 1.6$  min [13].

Other "single shot" devices have been recently tested for PV isolation in patients with PAF. In the cryoablation balloon study, however, the total procedural time increased to  $211 \pm 108$  min with excessive fluoroscopy times of  $52 \pm 36$  min [14]. Recent systematic review of published studies on cryoablation technology, which pooled results of 23 trials, proved average procedural time  $206 \pm 72$  min (range 108–371 min), with fluoroscopy time of  $46 \pm 13$  min (range 20.1–84.5 min) [15]. Thus, even the shortest X-ray time during cryoablation of PVs (about 20 min) is at least twice longer than mean time during "point-by-point" ablation using CARTO3 or robotic technology, and the procedure itself is prolonged by 60–70 min in average. Another technology, that was approved for PV isolation, but never got widely spread mainly due to technical reasons and low clinical success rate [16], was high-density mesh ablation/mapping catheter (Bard, Lowell, MA, USA). Steinwender et al. reported procedural times reaching  $187 \pm 36$  min and fluoroscopic times  $34 \pm 10$  minutes when using this high-density mesh ablation [3]. Thus, based on the published data and our results, the multipolar circular catheter PVAC seems to be the only technology for PV isolation that fulfils the expectations regarding shortening of an otherwise lengthy procedure, together with reducing radiation exposure.

Recently, several safety issues regarding silent cerebral microembolism (SCM) during RF ablation for AF have been raised [17,18]. Silent cerebral embolism is occlusion of a blood vessel in the brain due to an embolus that does not result in any acute clinical symptoms, i.e. it is "silent". During an AF ablation procedure, emboli may occur as a result of catheter manipulation, sheath materials, anticoagulation levels, air introduction during sheath/catheter introduction and/or as a result of the ablation process [19,20]. Recent studies showed that phased RF energy using PVAC system led to significant increase of SCM detected during diffusion weighted magnetic resonance imaging (DW-MRI) when compared to irrigated RF energy and cryoballoon (38.9% vs. 8.3% and 5.6%, respectively) [17]. However, SCM has also been observed following most of invasive cardiac procedures like cardiac valve replacement (47%), by-pass grafting (34%), coronary angiography (15%), carotid artery stenting (30%) and others [21]. Kruis et al. performed independent review of 22 cardiac surgery trials from the past 3 decades and showed that 66% of studies reviewed showed no associations between SCM and risk of cognitive decline, while 34% did [22]. The authors concluded that based on the review of published studies they could not confirm any association between microemboli and post-operative cognitive decline. Furthermore, there is no association between neurological symptoms and the presence of post procedural acute cerebral lesions in any of the published studies with AF ablation. Such a link would be difficult to find, as even with cardiac surgery procedures conducted over last 30 years, no association has been established between cerebral microemboli and post-operative cognitive decline.

All four groups in our study seemed to be comparable with respect to overall complication rate. There was no difference in occurrence of major adverse clinical events like tamponade, atrio-esophageal fistula, gastroparesis,

phrenic nerve palsy, embolic complications and death between the groups, as no such complication happened in our cohort of patients. We observed one serious complication during Artisan introduction, which was finally fixed by wall-stent implantation into the iliac vein without any permanent consequences. Therefore, we strongly advise a very careful introduction of the robotic sheath under continuous fluoroscopic control. The best technique may be to introduce cool-tip ablation catheter into the Artisan sheath as far as possible, bend it in the vasculature, keep the close loop of the ablation catheter so that the tip of catheter points always backwards and push it together with the Artisan forward while maneuvering with the ablation catheter handle until the right atrium is reached. The use of longer 14 F sheaths for Artisan introduction may be also beneficial, especially in obese patients.

Significantly higher incidence of local vascular complications in the CARTO XP group could be explained by our former practice to introduce a 4 F sheath in the left femoral artery for invasive blood pressure measurement. After several such complications we soon changed for radial artery cannulation (in fact in majority of group C patients and in almost all patients in groups B and D), which limited the incidence of AV fistulas and pseudoaneurysms close to 1%.

*Third*, clinically relevant observation made in our study was that novel technologies are capable of improving arrhythmia-free survival. We are awaiting long-term data from our hospital registries, but AF-free survival without antiarrhythmic drugs was improved by 10% in absolute number with novel technologies like robotic ablations or contemporary 3D mapping systems, at least at 12 months following the index procedure. Recent advantages in contact force measurement, a believed "last piece in the puzzle", which may be potent enough to ensure durable PV electrical disconnection by enabling to create transmural and continuous lesions, may increase clinical success rate.

## Conclusion

The use of novel ablation technologies during pulmonary vein isolation for paroxysmal atrial fibrillation significantly reduces total procedural and fluoroscopic times whilst achieving better clinical efficacy when compared to procedures supported by older generation of mapping systems. The safety profile of novel technologies seems to be comparable.

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## References

- [1] A.J. Camm, G.Y.H. Lip, R. De Caterina, et al., 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. An update of the 2010 ESC Guidelines for the management of atrial fibrillation. Developed with the special

- contribution of the European Heart Rhythm Association, *Europace* 14 (2012) 1385–1413.
- [2] H. Calkins, K.H. Kuck, R. Cappato, et al., 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design, *Europace* 14 (2012) 528–606.
  - [3] C. Steinwender, S. Honig, F. Leisch, et al., Acute results of pulmonary vein isolation in patients with paroxysmal atrial fibrillation using a single mesh catheter, *Journal of Cardiovascular Electrophysiology* 20 (2009) 147–152.
  - [4] S.R. Dukkipati, P. Neuzil, J. Kautzner, et al., The durability of pulmonary vein isolation using the visually guided laser balloon catheter: multicenter results of pulmonary vein remapping studies, *Heart Rhythm* 9 (2012) 919–925.
  - [5] L.V. Boersma, M.C. Wijffels, H. Oral, et al., Pulmonary vein isolation by duty-cycled bipolar and unipolar radiofrequency energy with a multielectrode ablation catheter, *Heart Rhythm* 5 (2008) 1635–1642.
  - [6] M. Kühne, S. Knecht, D. Altmann, et al., Validation of a novel spiral mapping catheter for real-time recordings from the pulmonary veins during cryoballoon ablation of atrial fibrillation, *Heart Rhythm* 2012, doi: 10.1016/j.hrthm.2012.10.009. [Epub ahead of print]
  - [7] M. Martinek, C. Lemes, E. Sigmund, et al., Clinical impact of a new open-irrigated radiofrequency catheter with direct force measurement on atrial fibrillation ablation, *Pacing and Clinical Electrophysiology* 35 (2012) 1312–1318.
  - [8] E.P. Gerstenfeld, New technologies for catheter ablation of atrial fibrillation, *Current Treatment Options in Cardiovascular Medicine* 13 (2011) 393–401.
  - [9] A. Bulava, J. Haniš, D. Sitek, et al., Catheter ablation for paroxysmal atrial fibrillation: a randomized comparison between multielectrode catheter and point-by-point ablation, *Pacing and Clinical Electrophysiology* 33 (2010) 1039–1046.
  - [10] S. Fredersdorf, S. Weber, C. Jilek, et al., Safe and rapid isolation of pulmonary veins using a novel circular ablation catheter and duty-cycled RF generator, *Journal of Cardiovascular Electrophysiology* 20 (2009) 1097–1101.
  - [11] M. Wiczorek, R. Hoeltgen, M. Brueck, et al., Pulmonary vein isolation by duty-cycled bipolar and unipolar antrum ablation using a novel multielectrode ablation catheter system: first clinical results, *Journal of Interventional Cardiac Electrophysiology* 27 (2010) 23–31.
  - [12] G. Stabile, M. Scaglione, M. del Greco, et al., Reduced fluoroscopy exposure during ablation of atrial fibrillation using a novel electroanatomical navigation system: a multicentre experience, *Europace* 14 (2012) 60–65.
  - [13] A. Bulava, J. Haniš, D. Sitek, et al., Randomized comparison of pulmonary vein isolation using robotic and manual approach – interim results and procedural characteristics of the ROMA study, *Europace* 14 (Suppl 1) (2012) i86.
  - [14] Y. Van Belle, P. Janse, M.J. Rivero-Ayerza, et al., Pulmonary vein isolation using an occluding cryoballoon for circumferential ablation: feasibility, complications, and short-term outcome, *European Heart Journal* 28 (2007) 2231–2237.
  - [15] J.G. Andrade, P. Khairy, P.G. Guerra, et al., Efficacy and safety of cryoballoon ablation for atrial fibrillation: a systematic review of published studies, *Heart Rhythm* 8 (2011) 1444–1451.
  - [16] L. Koch, K.G. Haeusler, J. Herm, et al., Mesh ablator vs. cryoballoon pulmonary vein ablation of symptomatic paroxysmal atrial fibrillation: results of the MACPAF study, *Europace* 14 (2012) 1441–1449.
  - [17] F. Gaita, J.F. Leclercq, B. Schumacher, et al., Incidence of silent cerebral thromboembolic lesions after atrial fibrillation ablation may change according to technology used: comparison of irrigated radiofrequency, multipolar nonirrigated catheter and cryoballoon, *Journal of Cardiovascular Electrophysiology* 22 (2011) 961–968.
  - [18] S.C. Herrera, T. Deneke, M. Hocini, et al., Incidence of asymptomatic intracranial embolic events after pulmonary vein isolation: comparison of different atrial fibrillation ablation technologies in a multicenter study, *Journal of the American College of Cardiology* 58 (2011) 681–688.
  - [19] L.D. Sauren, Y. Van Belle, L. De Roy, et al., Transcranial measurement of cerebral microembolic signals during endocardial pulmonary vein isolation: comparison of three different ablation techniques, *Journal of Cardiovascular Electrophysiology* 20 (2009) 1102–1107.
  - [20] D.S. Lee, P. Dorian, E. Downar, et al., Thrombogenicity of radiofrequency ablation procedures: what factors influence thrombin generation?, *Europace* 3 (2001) 195–200.
  - [21] M. Bendszus, G. Stoll, Silent cerebral ischaemia: hidden fingerprints of invasive medical procedures, *Lancet Neurology* 5 (2006) 364–372.
  - [22] R.W. Kuis, F.A. Vlasveld, D. Van Dijk, The (un)importance of cerebral microemboli, *Seminars in Cardiothoracic and Vascular Anesthesia* 14 (2010) 111–118.