

# Investigation of factors influencing the procedural parameters of atrial fibrillation ablation

PhD thesis

*by*

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# 1. INTRODUCTION

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Atrial fibrillation (AF) is known as the most common sustained cardiac arrhythmia in adults characterized by a disorganized, chaotic and rapid atrial electrical activation resulted in an ineffective atrial contraction. It is associated with and increased risk of stroke, myocardial infarction (MI), risk of sudden cardiac death (SCD), heart failure (HF), chronic kidney disease (CKD), peripheral artery disease (PAD), and cognitive impairment or dementia. Based on the presentation and duration, AF can be categorized into first diagnosed, paroxysmal, persistent, long-standing persistent and permanent AF. The treatment of AF requires a complex, patient-centred, holistic and multidisciplinary approach. The main focuses of the AF management are searching and treating comorbidities, avoidance of stroke and thromboembolism, reducing symptoms and morbidity with rate and rhythm control, and dynamic evaluation and re-evaluation of AF and its related comorbidities.

As part of the rhythm control strategy, aiming to restore and maintain sinus rhythm, catheter ablation (CA) plays a significant role in thus alleviating symptoms and reducing AF recurrence. This minimally invasive procedure involves the targeted delivery of energy to ablate aberrant electrical pathways within the atria, particularly around the pulmonary veins, which are often the source of ectopic electrical triggers. Pulmonary vein isolation (PVI) is considered as the cornerstone of the procedure. Several methods are available for achieving complete isolation of the PVs, either with a single-shot technique or point-by-point technique.

Despite the new technologies involving pulsefield ablation (PFA) and other single-shot devices, point-by-point technique remains the prevailing method for PVI. Using radiofrequency (RF) thermal energy, this workflow aims to achieve PVI with point-by-point application, resulting in a contiguous ablation line around the antrum of the PVs.

With the single-shot technique ablation catheters are able to isolate the PV with one or some circumferential ablation. The first single-shot approach to PVI was the Pulmonary Vein Catheter (PVAC), using RF energy was withdrawn from the clinical practice, and the cryoablation became the most popular choice when it came to single-shot PVI. The mechanism of the cryoablation catheter relies on a nitrogen balloon, which inserted into the ostium of the PVs, allowing a one-shot delivery to isolate the PVs. Recently, the PFA became available, which is a non-thermal energy form, with a cardiac tissue-specific effect compared with conventional thermal energies for PVI.

Point-by-point PVI is often combined with three-dimensional (3D) electroanatomic mapping systems (EAMS) to visualize the catheters, and their relations with the anatomical structures in the chamber of interest, without the use of fluoroscopy. Moreover, they provide important data arrhythmia mechanism and help in the determination the optimal site for ablation. One of the most well-known EAMS is the CARTO™ system (Biosense Webster Inc., Irvine, CA, USA), which is a magnetic field-based EAMS.

To facilitate the process of PVI, multipolar mapping catheters (MMC) are often employed, providing additional insights into left atrium (LA) geometry creation, voltage mapping, complex fractionated atrial electrograms, validation of isolated PVs, and identification of reconnected or atrial fibrotic regions. These catheters also play an important role in reducing both mapping and fluoroscopy time significantly.

Transseptal sheaths are also pivotal part of the procedure, as they enhance the stability between the tip of the catheter and the tissue, thus contributing to a durable, contiguous and transmural RF lesion. There are several sheaths available, but a new type of steerable sheath (VIZIGO™, Biosense Webster Inc., Irvine, CA) has become available in clinical treatment in 2018 which can be visualized by CARTO™ EAMS.

## 2. AIMS

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The main aims of our studies were the following:

- to examine the impact of visualizable steerable sheaths (SS) on the procedural outcomes in patients undergoing EAMS-guided, point-by-point RF PVI procedures compared to standard, non-visualizable SSs.
- to assess and compare the procedural outcomes of two most frequently used mapping catheters for CARTO™ EAMS-guided PVI procedures. Specifically, we examined the PentaRay™ NAV multielectrode catheter (Biosense Webster Inc., Irvine, CA, USA), characterized by five soft, radiating spines, and the circular-shaped LASSO™ NAV catheter (Biosense Webster Inc., Irvine, CA, USA) which are equipped with 20 electrodes each.

### 3. METHODS

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#### 3.1. Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: randomized, single-centre trial.

In our single-center, prospective study, we included 100 consecutive patients who underwent PVI at our clinic due to paroxysmal or persistent AF. Patients with prior PVI in patient history, additional ablations beyond PVI, or patients under 18 years were excluded from the study. Patients were randomized into two groups: in the first group, the visualizable steerable sheath (VIZIGO™) was used, while in the second group, a standard non-visualizable sheath (Agilis™ NxT, St. Jude Medical, St. Paul, MN, USA) was utilized. All procedures were performed by the same experienced electrophysiologist.

During the PVI, local anaesthesia was used, followed by ultrasound-guided femoral vein puncture, then a decapolar catheter was placed in the coronary sinus (CS). Subsequently, using intracardiac ultrasound (ICE), a double transseptal puncture was performed. A multipolar mapping catheter (LASSO™ NAV) was advanced into the left atrium via an SL0 sheath (Abbott Laboratories, Chicago, IL, USA), along with a radiofrequency (RF) ablation catheter (Thermocool SmartTouch ST™ NAV, Biosense Webster Inc., Diamond Bar, CA, USA) inserted through either the visualizable or standard sheath. For visualizable sheaths, the bidirectional VIZIGO™ sheath, which can be visualized in the CARTO™ system, was employed. Ablations were performed at a power setting of 35 W on the posterior wall of the left atrium and 45 W on other areas, with a maximum temperature of 43°C. RF ablations were guided by an ablation index (target value 350 for the posterior wall and 450 for the anterior wall, with lesion spacing of less than 5 mm).

Procedure duration was measured from the first femoral vein puncture to catheter removal. Left atrial time was defined as the period from the end of the transseptal puncture to the withdrawal of the sheaths from the left atrium. Fluoroscopy time and radiation dose were automatically recorded by the fluoroscopic system. The total number of RF applications, the amount of RF energy delivered (in joules), and the total ablation time (in seconds) were calculated and stored by the electrophysiological system used in our lab (CardioLab, GE Healthcare, Chicago, IL, USA). Data analysis was performed using SPSS 24 software (SPSS, Inc., Chicago, IL, USA).

### 3.2. The Influence of Different Multipolar Mapping Catheter Types on Procedural Outcomes in Patients Undergoing Pulmonary Vein Isolation for Atrial Fibrillation

In our prospective, observational study, we included 70 consecutive patients who underwent PVI due to paroxysmal AF between November 2022 and July 2023. Exclusion criteria were as follows: (A) patients who had previously undergone PVI, (B) patients requiring additional ablations beyond PVI, and (C) patients under the age of 18. The included patients were divided into two groups based on the type of multipolar catheter used during the ablation.

For the first 35 patients, between November 2022 and March 2023, PVI was performed using the LASSO NAV™ catheter (Lasso group). Subsequently, for cases 36-70, from April 2023 to July 2023, the PentaRay™ NAV catheter was used for electroanatomical mapping due to the unavailability of LASSO™ NAV catheters in the market (PentaRay group). All procedures were performed by the same experienced electrophysiologist.

After vascular ultrasound-guided femoral vein puncture in local anesthesia, a decapolar catheter (Dynamic Deca) was placed in the coronary sinus. Transseptal puncture was then performed using the sliding technique under intracardiac echocardiography (ICE) guidance, with SL0 and VIZIGO™ sheaths advanced into the left atrium. Subsequently, a multipolar mapping catheter (either LASSO NAV™ or PentaRay™ NAV) was introduced into the left atrium via the SL0 sheath. Additionally, a contact force (CF)-sensing RF ablation catheter (Thermocool SmartTouch™ ST NAV) was positioned in the left atrium through the VIZIGO™ sheath. Left atrial anatomical mapping was performed using the multipolar mapping catheter and the CARTO 3™ electroanatomical mapping system (EAMS). The ablation catheter operated in power-controlled mode, applying a maximum power of 45 W on the anterior wall and 40 W on the posterior wall, with a maximum temperature of 43°C. RF applications were guided by the Ablation Index, targeting values of 350 for the posterior wall and 450 for the anterior wall. The endpoint of the ablation was achieving PVI.

The primary endpoint of the study was the total procedure time, measured from femoral vein puncture to catheter removal. Additionally, we compared various time intervals, including the duration from femoral vein puncture to the start of mapping, mapping time, the time between the first and last RF application, validation time, and total left atrial dwell time. We also recorded the first-pass isolation rate, the number of RF applications, and the total RF ablation time.

Mapping time was defined as the interval from the completion of transseptal puncture to the start of the first RF ablation. Left atrial dwell time was defined as the interval from the completion of transseptal puncture to the withdrawal of the sheaths from the left atrium. Fluoroscopy time and radiation dose were automatically recorded by the fluoroscopic system. Statistical analysis of the data was performed using SPSS version 24 software.

## 4. RESULTS

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### 4.1. Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: randomized, single-centre trial.

PVs were successfully isolated in all 100 cases, achieving a 100% acute procedural success rate. The rate of first-pass isolation (92% vs. 89%;  $p=0.88$ ) and the total procedural time showed no significant difference between the visualizable SS and non-visualizable SS groups ( $90 \pm 35.2$  minutes vs.  $99.5 \pm 31.8$  minutes;  $p=0.97$ ).

When using the Vizigo sheath, the visualizable SS group demonstrated significantly reduced left atrial procedure time (53.1 [41.3; 73.1] min. vs. 59.5 [47.6; 74.1] min.;  $p=0.04$ ), left atrial fluoroscopy time (0 [0; 0] sec. vs. 17.5 [5.5; 69.25] sec.;  $p<0.01$ ), and left atrial fluoroscopy dose (0 [0; 0.27] mGy vs. 0.74 [0.16; 2.34] mGy;  $p<0.01$ ). However, no differences were observed in total fluoroscopy time ( $184 \pm 89$  sec. vs.  $193 \pm 44$  sec.;  $p=0.79$ ) or total fluoroscopy dose ( $9.12 \pm 1.98$  mGy vs.  $9.97 \pm 2.27$  mGy;  $p=0.76$ ). Notably, a higher proportion of procedures were performed without fluoroscopy after transseptal puncture in the visualizable SS group (88.0% vs. 16.0%;  $p<0.001$ ).

The visualizable SS group also required fewer radiofrequency ablations (69 [58; 80] vs. 79 [73; 86];  $p<0.01$ ) and had shorter total ablation time (1049 [853; 1175] sec. vs. 1265 [1085; 1441] sec.;  $p<0.01$ ). No major complications occurred in either group.

We performed statistical analysis separately for persistent AF cases. Results showed similar data as the overall cohort, however, there was no difference between the groups in the left atrial procedure time (54.8 [44.3; 59.0] min. vs. 66.9 [50.0; 73.7] min.,  $p=0.23$ ) and the total fluoroscopy time was reduced in the visualizable SS group ( $182 \pm 52$  s vs.  $244 \pm 84$  s,  $p=0.02$ ). The main findings are summarized in Table 1.



	<b>Visualizable steerable sheath group (n=50)</b>	<b>Non-visualizable steerable sheath group (n=50)</b>	<b>P-value</b>
<b>Total procedure time (min)</b>	90 ± 35.2	99.5 ± 31.8	n.s.
<b>Left atrial procedure time (min)</b>	53.1 (41.3; 73.1)	59.5 (47.6; 74.1)	0.04
<b>Total fluoroscopy time (s)</b>	184 ± 89	193 ± 44	n.s.
<b>Total fluoroscopy dose (mGy)</b>	9.12 ± 1.98	9.97 ± 2.27	n.s.
<b>Left atrial fluoroscopy time (s)</b>	0 (0; 0)	17.5 (5.5; 69.25)	<0.01
<b>Left atrial fluoroscopy dose (mGy)</b>	0 (0; 0.27)	0.74 (0.16; 2.34)	<0.01
<b>Number of fluoroles procedure after transseptal puncture (%)</b>	44 (88.0)	8 (16.0)	<0.001
<b>Number of acute success (%)</b>	50 (100)	50 (100)	n.s.
<b>Number of radiofrequency ablations (n)</b>	69 (58; 80)	79 (73; 86)	<0.01
<b>Total ablation time (s)</b>	1049 (853; 1175)	1265 (1085; 1441)	<0.01
<b>First pass isolation (%)</b>	92%	89%	n.s.
<b>Major complications (n)</b>	0	0	N.A.

**Table 1.** Procedural parameters in the study population. N.A. - not applicable; n.s. - non-significant.

#### 4.2. The Influence of Different Multipolar Mapping Catheter Types on Procedural Outcomes in Patients Undergoing Pulmonary Vein Isolation for Atrial Fibrillation

Seventy patients were prospectively enrolled in the study. The first 35 patients underwent mapping and validation using a LASSO™ NAV catheter (Group Lasso), while the subsequent 35 patients (patients 36–70) were made using a PentaRay™ NAV catheter (Group PentaRay). No significant differences were observed between the two groups across various procedural time metrics. Total procedure time was similar between Group Lasso and Group PentaRay ( $80.2 \pm 17.7$  min. vs.  $75.7 \pm 14.8$  min.;  $p=0.13$ ). The time from femoral vein puncture to the initiation of mapping was also comparable ( $31.2 \pm 7$  min. vs.  $28.9 \pm 6.8$  min.;  $p=0.80$ ). Mapping time (8 [6; 13] min. vs. 9 [6.5; 10.5] min.;  $p=0.73$ ), the duration between the first and last ablation (32 [30; 36] min. vs. 33 [26; 40] min.;  $p=0.52$ ), and validation time (3 [2; 4] min. vs. 3 [1; 5] min.;  $p=0.46$ ) were likewise similar. First-pass success rates were equivalent between the groups (89% vs. 91%;  $p=0.71$ ).

Additionally, left atrial dwelling time (46 [37; 53] min. vs. 45 [36.5; 53] min.;  $p=0.56$ ) and fluoroscopy parameters, including fluoroscopy time ( $150 \pm 71$  sec. vs.  $143 \pm 56$  sec.;  $p=0.14$ ) and dose ( $6.7 \pm 4$  mGy vs.  $7.4 \pm 4.4$  mGy;  $p=0.90$ ), showed no significant differences. The total ablation time (1187 [1063; 1534] sec. vs. 1150.5 [1053; 1393.5] sec.;  $p=0.49$ ), number of RF ablations (78 [73; 93] vs. 83 [71.3; 92.8];  $p=0.60$ ), and total ablation energy (52,300 [47,265; 66,804] J vs. 49,666 [46,395; 56,502] J;  $p=0.35$ ) were also non-significant. The results are detailed in Table 2.

	<b>Group Lasso (n = 35)</b>	<b>Group PentaRay (n = 35)</b>	<b>P-value</b>
<b>Procedure time (min)</b>	80.2 ± 17.7	75.7 ± 14.8	0.13
<b>Time from access to start of mapping (min)</b>	31.2 ± 7.0	28.9 ± 6.8	0.80
<b>Mapping time (min)</b>	8 (6; 13)	9 (6.5; 10.5)	0.73
<b>Time between first and last ablation (min)</b>	32 (30; 36)	33 (26; 40)	0.52
<b>Validation time (min)</b>	3 (2; 4)	3 (1; 5)	0.46
<b>First pass rate (%)</b>	89%	91%	0.71
<b>Left atrial dwelling time (min)</b>	46 (37; 53)	45 (36.5; 53)	0.56
<b>Total ablation time (s)</b>	1187 (1063; 1534)	1150.5 (1053; 1393)	0.49
<b>Number of ablations (n)</b>	78 (73; 93)	83 (71.3; 92.8)	0.60
<b>Total ablation energy (J)</b>	52,300 (47,265; 66,804)	49,666 (46,395; 56,502)	0.35
<b>Fluoroscopy time (s)</b>	150 ± 71	143 ± 56	0.14
<b>Fluoroscopy dose (mGy)</b>	6.7 ± 4.0	7.4 ± 4.4	0.90
<b>Complications (n)</b>	0	0	N.A.

**Table 2.** Procedural data and outcome. Abbreviation: N.A. - not applicable.

5.

## DISCUSSION

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### 5.1. Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: randomized, single-centre trial.

The integration of novel technologies in procedural workflows can help to achieve significant reductions in fluoroscopy exposure and procedural times for PVI. SSs can improve the stability of the ablation catheter, thus have been shown superior compared to fixed sheaths. Our results showed that use of Vizigo™ SS reduced LA procedural time, LA fluoroscopy time, total ablation time and number of RF applications, while effectiveness and safety was equal compared to the standard, non-visualizable SS. These results could be explained by the improved catheter stability.

Importantly, using Vizigo™ SS in 44 out of 50 cases, we performed the procedure fluoroless following the transseptal puncture, which also proved to be more common compared to the standard, non-visualizable SS group. The recently published expert consensus statement on catheter and surgical ablation of AF also supports our results and perspective, that the introduction of SSs visualized by 3D EAMS facilitates the fluoroless PVI by effectively reducing fluoroscopy exposures when compared with conventional, non-visualizable SSs.

### 5.2. The Influence of Different Multipolar Mapping Catheter Types on Procedural Outcomes in Patients Undergoing Pulmonary Vein Isolation for Atrial Fibrillation

PVI is considered the gold standard technique in AF CA. In point-by-point PVI procedures, a critical step is the creation of an accurate anatomical map of the LA, which is achieved using either MMCs or the ablation catheter.

Unlike the circular design of the LASSO™ NAV catheter, the five-spline design of the PentaRay™ NAV catheter offers advantages in specific scenarios, such as acquiring geometry in smaller PVs, where the circular catheter may face challenges in navigation. Additionally, the splines of the PentaRay™ NAV catheter allow for better visualization when the catheter is pressed against the atrial wall, minimizing the risk of overestimating the anatomy and enabling more precise anatomical mapping. Despite these benefits, our study

found that the use of the PentaRay™ NAV catheter did not significantly impact the procedural outcomes of PVI.

## 6. NOVEL FINDINGS

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Based on the results of the cited experiments and studies, our major novel findings can be summarized as follows:

- Compared to the standard, non-visualizable SSs, the visualizable Vizigo™ SS significantly reduces the left atrial procedure time, RF delivery and fluoroscopy exposure without compromising its safety or effectiveness in patients undergoing PVI procedures for AF.
- SS visualized by EAMS have shown significant total fluoroscopy time reduction and no differences in left atrial procedure time in PVI procedures for persistent AF.
- Based on our results, comparing circular-shaped LASSO™ NAV and five-spline-shaped PentaRay™ NAV catheters for PVI in paroxysmal AF, no statistically significant differences were detected in procedural times, first-pass success rates, or safety outcomes. These findings indicate comparable efficacy and safety profiles of the two catheter types, supporting their interchangeability in clinical practice for anatomical mapping during PVI procedures.

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## 7. PUBLICATION LIST

### 7.1. TOPIC-RELATED SCIENTIFIC ARTICLES

Janosi K-F, Debreceni D, Janosa B, Bocz B, Simor T, Kupo P: Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: Randomized, single-centre trial

**Frontiers in Cardiovascular Medicine** (2022); 1033755 **IF=3.6 Q1**

Janosi K-F, Debreceni D, Bocz B, Torma D, Keseru M, Simor T, Kupo P: The Influence of Different Multipolar Mapping Catheter Types on Procedural Outcomes in Patients Undergoing Pulmonary Vein Isolation for Atrial Fibrillation

**Journal of Clinical Medicine** (2024); 13041029 **IF= 3.0 Q1**

### 7.2. NON-TOPIC RELATED SCIENTIFIC ARTICLES

Vancsa S, Hegyi PJ, Zadori N, Szako L, Vorhendi N, Ocskay K, Foldi M, Dembrovszky F, Domotor ZR, Janosi K-F, Rakonczay Z Jr, Hartmann P, Horvath T, Eross B, Kiss S, Szakacs Z, Nemeth D, Hegyi P, Par G: Pre-existing Liver Diseases and On-Admission Liver-Related Laboratory Tests in COVID-19: A Prognostic Accuracy Meta-Analysis With Systematic Review

**Frontiers in Medicine** (2020); 572115 **IF= 5.093 Q1**

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Kupo P, Janosi K-F, Debreceni D, Simor T, Pap R, Saghy L: Vaszkuláris ultrahangvezérelt vena femoralis punkciók szív-elektrofiziológiai beavatkozások során

**Cardiologia Hungarica** (2022); 204-207

Janosi K-F, Debreceni D, Simor T, Kupo P: AV-nodális reentry tachycardia, mint a pitvarfibrilláció potenciális triggere

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**Cardiologia Hungarica** (2023); 212-217

Debreceni D, Janosi K-F, Bocz B, Turcsán M, Simor T, Kupo P: Bal pitvari fülcséthrombus kimutatása intrakardiális echokardiográfiával  
**Cardiologia Hungarica** (2023); 259-261

Debreceni D, Janosi K-F, Bocz B, Turcsán M, Lukacs R, Simor T, Bor A, Vamos M, Komocsi A, Kupo P: Zero fluoroscopy catheter ablation for atrial fibrillation: a systematic review and meta-analysis  
**Frontiers in Cardiovascular Medicine** (2023); 1178783 **IF=2.8 Q2**

Bocz B, Debreceni D, Janosi K-F, Turcsan M, Simor T, Kupo P: Electroanatomical Mapping System-Guided vs. Intracardiac Echocardiography-Guided Slow Pathway Ablation: A Randomized, Single-Center Trial  
**Journal of Clinical Medicine** (2023); 5577 **IF=3.0 Q1**

Marton Turcsan, Kristof-Ferenc Janosi, Dorottya Debreceni, Daniel Toth, Botond Bocz, Tamas Simor, Peter Kupo: Intracardiac Echocardiography Guidance Improves Procedural Outcomes in Patients Undergoing Cavotricuspidal Isthmus Ablation for Typical Atrial Flutter  
**Journal of Clinical Medicine** (2023); 6277 **IF=3.0 Q1**

Dorottya Debreceni, Kristof-Ferenc Janosi, Marton Turcsan, Daniel Toth, Botond Bocz, Tamas Simor, Peter Kupo: Feasibility and safety of cavotricuspid isthmus ablation using exclusive intracardiac echocardiography guidance: a proof-of-concept, observational trial.  
**Frontiers in Cardiovascular Medicine** (2023); 1244137 **IF=2.8 Q2**

Dalma Torma, Kristof-Ferenc Janosi, Dorottya Debreceni, Botond Bocz, Mark Keseru, Tamas Simor, Peter Kupo: Initial experience with zero-fluoroscopy pulmonary vein isolation in patients with atrial fibrillation: single-center observational trial.  
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Dorottya Debreceni, Maja Mandel, Kristof-Ferenc Janosi, Botond Bocz, Dalma Torma, Tamas Simor, Peter Kupo: Comparison of Conventionally Performed and Intracardiac Echocardiography Guided Catheter Ablation of Atrioventricular Node in Patients with Permanent Atrial Fibrillation-A Retrospective Single-Center Study.  
**Frontiers in Cardiovascular Medicine** (2024); 13154565 **IF= 2.8 Q1**

### 7.3. TOPIC-RELATED ABSTRACTS PUBLISHED IN SCIENTIFIC JOURNALS

K Janosi, D Debreceni, B Janosa, T Simor, P Kupo: Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: randomized, single-center trial.  
**Europace** (2022); 24 (Abstract supplement) 53 **IF= 6.1 Q1**

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Jánosi Kristóf-Ferenc, Bocz Botond, Debreceni Dorottya, Simor Tamás, Kupó Péter: Multipoláris térképező katéterek összehasonlító vizsgálata pulmonális vénaizolációban. XIV. Magyar Aritmia és Pacemaker Kongresszus. Szeged, 28-30. September 2023.

**Cardiologia Hungarica** (2023); Suppl. B; B8

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K. Janosi, D Debreceni, M Turcsan, T Simor, P Kupo: Comparison of intracardiac  
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**Cumulative impact factor of topic related articles: 6.6**

**Cumulative impact factor: 33.493**

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