Investigation of factors influencing procedural parameters in atrial fibrillation ablation

PhD thesis

by

Kristóf-Ferenc Jánosi, MD

Pécs, 2024

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University of Pécs, Medical School, Heart Institute

Supervisor: Péter Kupó, MD, PhD

Head of Doctoral School: Lajos Bogár MD, PhD, DSc

Program leader: István Szokodi, MD, PhD, DSc

Pécs

2024

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LIST OF ABBREVIATIONS

AAD: anti-arrhythmic drug

ACL: advanced catheter location

AF: atrial fibrillation

CA: catheter ablation

CAD: coronary artery disease

CCB: calcium channel blocker

CF: contact force

CKD: chronic kidney disease

CV: cardiovascular

DOAC: direct oral anticoagulant

EAMS: electroanatomic mapping system

ECG: electrocardiogram

ESC: European Society of Cardiology

HF: heart failure

HFrEF: heart failure with reduced ejection fraction

ICE: intracardiac echocardiography

IQR: interquartile ratio

LA: left atrium

LIPV: left inferior pulmonary vein

LSPV: left superior pulmonary vein

LV: left ventricular

MI: myocardial infarction

MMC: multipolar mapping catheter

QoL: quality of life

PAD: peripheral artery disease

PFA: pulsed field ablation

PSVT: paroxysmal supraventricular tachycardia

PV: pulmonary vein

PVI: pulmonary vein isolation

RF: radiofrequency

RIPV: right inferior pulmonary vein

RPSV: right superior pulmonary vein

SCD: sudden cardiac death

SD: standard deviation

SS: steerable sheath

TIA: transient ischemic attack

VKA: vitamin K antagonist

Cardiac electrophysiology has emerged as a pivotal field in understanding the complex electrical activities governing heart rhythms. Among various cardiac arrhythmias, atrial fibrillation (AF) stands as the most prevalent, affecting millions globally and posing significant morbidity and mortality risks. AF is characterized by rapid and irregular atrial contractions, leading to inefficient blood flow, potential thromboembolic events, and heart failure. The multifactorial etiology of AF includes genetic predispositions, structural heart diseases, and lifestyle factors, complicating its management and necessitating advanced therapeutic approaches.

Catheter ablation (CA) has revolutionized the treatment landscape for AF. 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. By isolating these triggers, CA aims to restore and maintain normal sinus rhythm, thus alleviating symptoms and reducing AF recurrence. Despite its effectiveness, CA is not without challenges and limitations.

This dissertation delves into the nuances of cardiac electrophysiology with a focus on CA for AF. It explores the classification of AF, evaluates current ablation strategies, and investigates novel approaches to enhance procedural outcomes. By addressing these aspects, this research aims to contribute to the optimization of CA therapy, ultimately improving procedural outcomes of AF ablations and advancing the field of cardiac electrophysiology.

1. INTRODUCTION

1.1. Atrial Fibrillation

1.1.1. Definition

AF is a disorganized, chaotic and rapid atrial electrical activation resulting in an ineffective atrial contraction [1]. The diagnosis of clinical AF is confirmed on electrocardiogram (ECG) showing irregular R-R intervals, no discernible P waves, and irregular atrial activation. The consensus on minimum duration for the diagnosis is 10 seconds on a standard 12-lead ECG recording or ≥ 30 seconds on single-lead or multiple-lead ECG tracing [1].

1.1.2. Epidemiology, Morbidity and Mortality

AF is known as the most common sustained cardiac arrhythmia in adults with an estimated global prevalence of over 59 million persons [2]. 1 in 3 older individuals is estimated to develop AF [1,3]. Due to the aging population, it is expected that the prevalence of AF will double over the following few decades [1].

AF is associated with up to a two-fold increased risk of all-cause mortality [4]. For non-fatal adverse events, patients with AF are associated with and increased risk of heart failure (HF), risk of stroke, ischaemic heart disease, risk of sudden cardiac death (SCD), chronic kidney disease (CKD), peripheral artery disease (PAD), and vascular dementia [5–8] . The most important comorbidities and risk factors include increasing age, hypertension, diabetes mellitus, HF, coronary artery disease, CKD, obesity, and obstructive sleep apnoea, therefore, risk stratification, primary and secondary prevention, and developing effective treatment strategy for AF are crucial [1,9–12] .

1.1.3. Classification

The classification of AF according to the recently published European Society of Cardiology (ESC) Guidelines for the management of AF is based mainly on presentation and arrhythmia duration:

- first diagnosed, with an episode of AF never diagnosed before in a patient
- paroxysmal, in which the duration of AF is less than 7 days, either by a spontaneous termination or due to intervention
- persistent, with a duration beyond 7 days, including episodes terminated by cardioversion (drugs or electrical cardioversion) after ≥7 days
- long-standing persistent AF, that is continuous beyond 12 months
- permanent, in which by the common consensus of the patient and the physician no further attempts are made to restore or maintain sinus rhythm. [1]

1.1.4. Treatment

The management of AF requires a complex, multidisciplinary and holistic approach that is patient-centred, meaning that patients with AF are active participants in a shared decision-making process, rather than passive recipients of health services. Therefore, the management of AF is guided by the "AF-CARE" pathway developed by the ESC [1]. The systematic, time-orientated AF-CARE approach is based on four pillars, focusing on searching and treating comorbidities ("C"), avoidance of stroke and thromboembolism ("A"), reducing symptoms and morbidity with rate and rhythm control ("R"), and dynamic evaluation ("E") and re-evaluation of AF and its related comorbidities [1].

1.1.4.1. Comorbidity and risk factor management

The first pillar of the management pathway represents the identification and management of the comorbidities, such as hypertension, HF, DM, obesity, sleep apnea, physical inactivity, excessive alcohol consumption. These factors significantly influence the risk of developing AF and the likelihood of arrhythmia recurrence. Early detection and treatment of comorbidities play a crucial role not only in symptom relief and rhythm control but also in reducing the risk of stroke and, consequently, mortality [1].

1.1.4.2. Avoid stroke and thromboembolism

AF increases the risk of stroke due to various thromboembolic factors. Optimal management for stroke prevention requires an individualized risk assessment. Although newer risk stratification scores, such as ATRIA [13–15] or GARFIELD-AF [16,17] have become available, the CHA_2DS_2-VA score is still the most validated score for this purpose, summarizing key stroke risk factors such as congestive HF, hypertension, age, diabetes mellitus, previous stroke, vascular disease [18] .

For patients with AF who have a low risk (CHA_2DS_2-VA score of 0), stroke prevention therapy is generally not necessary, except in specific situations such as for patients with hypertrophic cardiomyopathy or cardiac amyloidosis, whom oral anticoagulation is recommended regardless of the CHA_2DS_2-VA score. Anticoagulation should be considered for patients with CHA_2DS_2-VA score of 1 as part of shared decision-making. Anticoagulation is recommended for those with high stroke risk (CHA_2DS_2-VA score of 2 or more) [1,19] . Direct oral anticoagulants (DOACs) are recommended for patients without a history of mechanical heart valve, rheumatic mitral stenosis over vitamin K antagonists (VKA) [20–27] . DOAC therapy may also be considered for patients with high estimated stroke risk and subclinical AF, where the asymptomatic AF episodes were detected by either implanted cardiac electronic devices or wearable AF monitoring devices [1,28].

1.1.4.3. Reduce symptoms by rate and rhythm control

1.1.4.3.1. Rate control

The primary objectives for rate control in patients with both new onset and persistently ongoing AF with a rapid ventricular response are to manage symptoms and reduce the risk of developing left ventricular (LV) systolic dysfunction. In an acute setting, rate control is indicated as adjunct therapy for rhythm control. For long-term rate control, nondihydropyridine calcium channel blockers (CCB) and beta blockers are effective, additionally, digoxin can also be beneficial for patients who have limited tolerance to other medications or as an additional therapy for those with a ventricular rate that is difficult to control [1,19] .

In patients with AF and a persistently rapid ventricular response refractory to rate-control medications, AV nodal ablation and pacemaker implantation can be useful to improve symptoms and QoL, and in selected HF patients, AV node ablation may also improve LV systolic function [29–33] . Biventricular pacing or conduction system pacing may be beneficial as a treatment option to prevent pacing-induced ventricular dyssynchrony and consequent HF [34–36].

1.1.4.3.2. Rhythm control

Rhythm control encompasses therapeutic attempts to restore and maintain sinus rhythm, including electrical cardioversion (ECV), the use of antiarrhythmic drugs (AAD), and CA, all conducted under appropriate anticoagulation and rate control [1,37,38]. The primary indication for rhythm control therapy is the reduction of symptoms associated with AF and improve QoL. Data have consistently demonstrated the importance of monitoring patients for increased AF burden once AF has been identified. Rhythm-control therapies are more likely to be successful when implemented early, as AF burden begins to increase [39–42] .

ECV is a more rapid and effective way of restoring sinus rhythm compared to AADs, and it is the treatment of choice in acute rhythm control for patients with hemodynamically

unstable AF [43]. It can also be performed in patients with AF after an unsuccessful pharmacological cardioversion [44] .

Whenever ECV is contraindicated or not desired by the patients, wait-and-see approach can be adopted, waiting for a spontaneous conversion to sinus rhythm, or alternatively AADs can be used for acute cardioversion in hemodynamically stable patients [43], but they are primarily used for long-term maintenance of sinus rhythm, especially in patients who prefer drug therapy over CA. AADs are mainly Class IA (quinidine, disopyramide), Class IC (flecainide, propafenone), and Class III (amiodarone, dronedarone, sotalol, dofetilide) agents. The choice of AAD depends on several factors, including the presence of structural heart disease or a history of prior MI [37,45–51] .

CA is established as a safe and effective therapy for long-term rhythm control in patients with AF, and it has been shown superiority over AADs for the maintenance of sinus rhythm and improvement of the QoL [52–57] . CA can also be chosen as a first-line therapeutic option within shared decision-making, especially in patients with paroxysmal AF [1,56–58].

1.1.4.4. Evaluation and dynamic reassessment

Risk profiles and treatment strategies vary from one patient to another, therefore each patient requires individualized, dynamic evaluation and re-evaluation to ensure optimal AF management. Regular re-evaluation of the patient's status can have an impact on therapeutic decisions and an individualized, patient-centred shared decision-making approach that better addresses the patient's needs can improve well-being and treatment adherence [1].

1.2. Catheter ablation of atrial fibrillation

1.2.1. Indications

In patients with symptomatic AF (both paroxysmal and persistent) after failure of AADs or drug intolerance, CA is recommended to reduce the risk of AF recurrencies and

improve symptoms, making it a useful option for those desiring continued rhythm control [19,39,45,53,59–61].

Considering the patient's choice as part of shared decision-making, CA as a first-line therapy can be a useful and suitable option for improving symptoms and reducing the progression of AF to persistent AF in patients with symptomatic paroxysmal AF and in selected patients with persistent AF [1,19,56–58,62].

Patients with heart failure with reduced ejection fraction (HFrEF) may derive even greater benefits from CA, as it is recommended to improve functional status, LV function, and cardiovascular outcomes [1,63,64].

In cases when AF-mediated tachycardiomyopathy is suspected, CA is recommended to restore LV function [1,65,66].

1.2.2. Techniques and technologies

The primary aim of CA for AF is to create an electrical isolation of the pulmonary veins (PV), eliminating the arrhythmogenic triggers often originating from the PVs. Pulmonary vein isolation (PVI) is considered the cornerstone of the procedure [1,67]. Numerous methods are available for achieving complete isolation of the PVs, using either a single-shot technique or point-by-point technique (Figure 1).

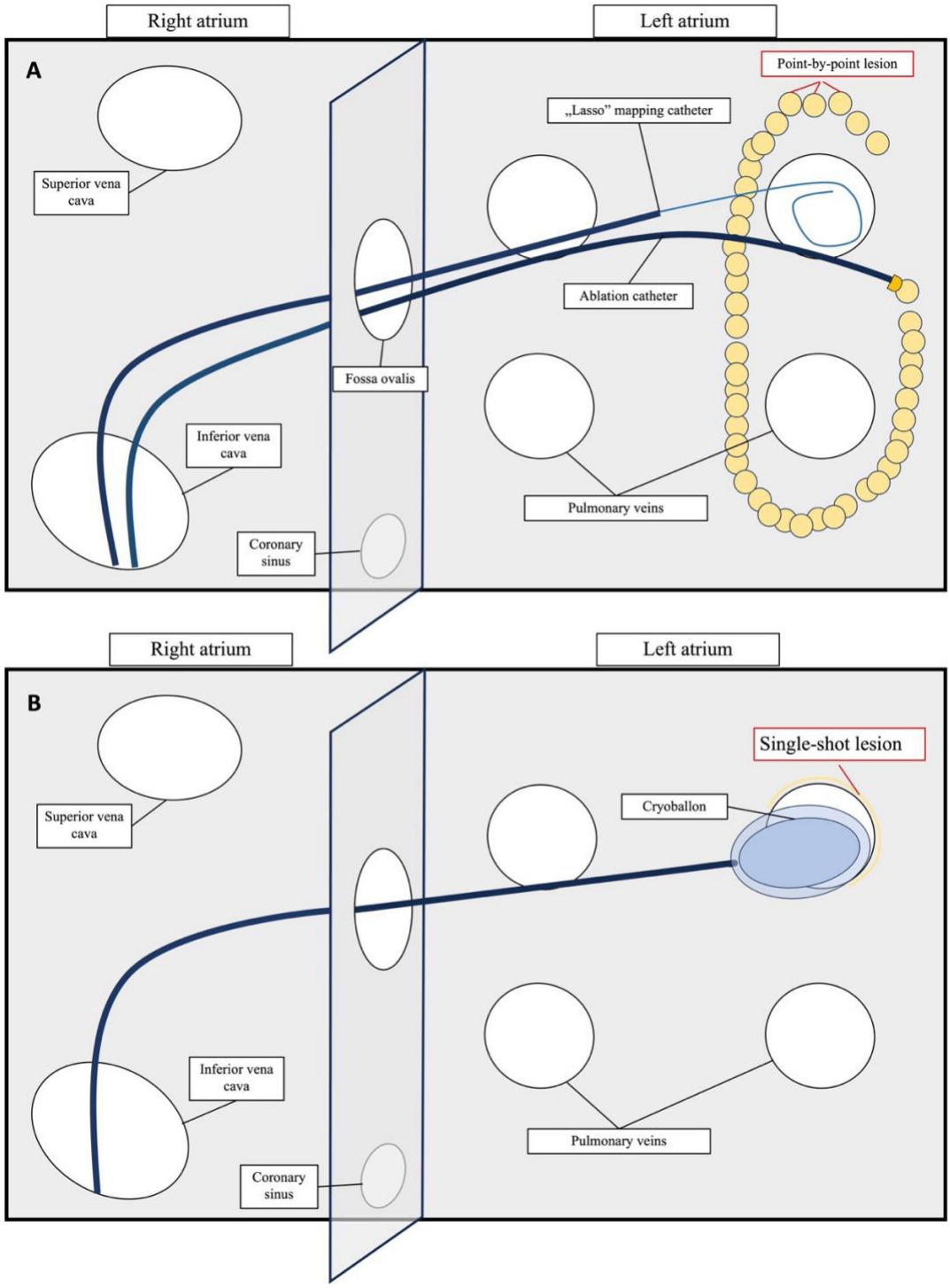

Figure 1. Schematic representation of the main differences between point-by-point and cryoballoon PVI. *In Panel A point-by-point lesions created by the catheter are illustrated as a series of dots or short lines around the pulmonary vein ostia. These lesions form a continuous circumferential line (circle) around each vein to electrically isolate it from the rest of the atrium. Panel B represents the single-shot PVI method using a cryoballoon catheter, where the catheter is positioned at the ostium of the pulmonary vein. When inflated, the balloon is intended to completely seal the opening of the vein.*

1.2.2.1. Point-by-point ablation technique

The incidence of single-shot AF ablations employing pulsefield ablation (PFA) methods are increasing [68,69], with other available options include single-shot cryoenergy and radiofrequency (RF) techniques [67,70], however, the prevailing method worldwide continues to be point-by-point RF ablation [70]. This workflow aims to achieve PVI with point-by-point application, resulting in a contiguous ablation line around the antrum of the PVs. The introduction of irrigated catheters with contact force (CF) sensing has positively impacted the procedural outcomes of the point-by-point approach [71–73]. Further technological advancements, such as ablation index (AI) [74] , force time integral (FTI) [75] , lesion size index (LSI) [76] , the introduction of CLOSE protocol [77] has resulted in improved outcomes with higher first-pass isolation rates and 1 year success rates [78–80].

Although point-by-point PVI is conventionally performed using RF thermal energy, new systems and catheters are starting to emarge, using PFA as their primary non-thermal energy source such as the TRUEPULSE™ System (Biosense Webster, CA, USA) [81] or CENTAURI™ System (Galvanize Therapeutics, CA, USA) [82]. Hybrid energy delivery catheters with PFA/RF source are also getting increased attention, like the Affera Sphere-9™ lattice-tip catheter (Affera, Inc, Watertown, MA) [83] or the OMNYPULSE™ Catheter (Biosense Webster, CA, USA) [84].

In case of point-by-point PVIs, mapping catheters are often employed in addition to the ablation catheters. These catheters have multiple electrodes for increased mapping speed and high-quality electrogram signal acquisition. Multipolar mapping catheters (MMCs) are extensively used during PVIs, 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 a pivotal role in significantly reducing both mapping and fluoroscopy time [85–88]. Furthermore, their

utility extends to facilitating the achievement of zero-fluoroscopy approach during PVI procedures [89] . Several MMCs with varying shapes, sizes, and electrode configurations are available for use in clinical practice (Figure 2).

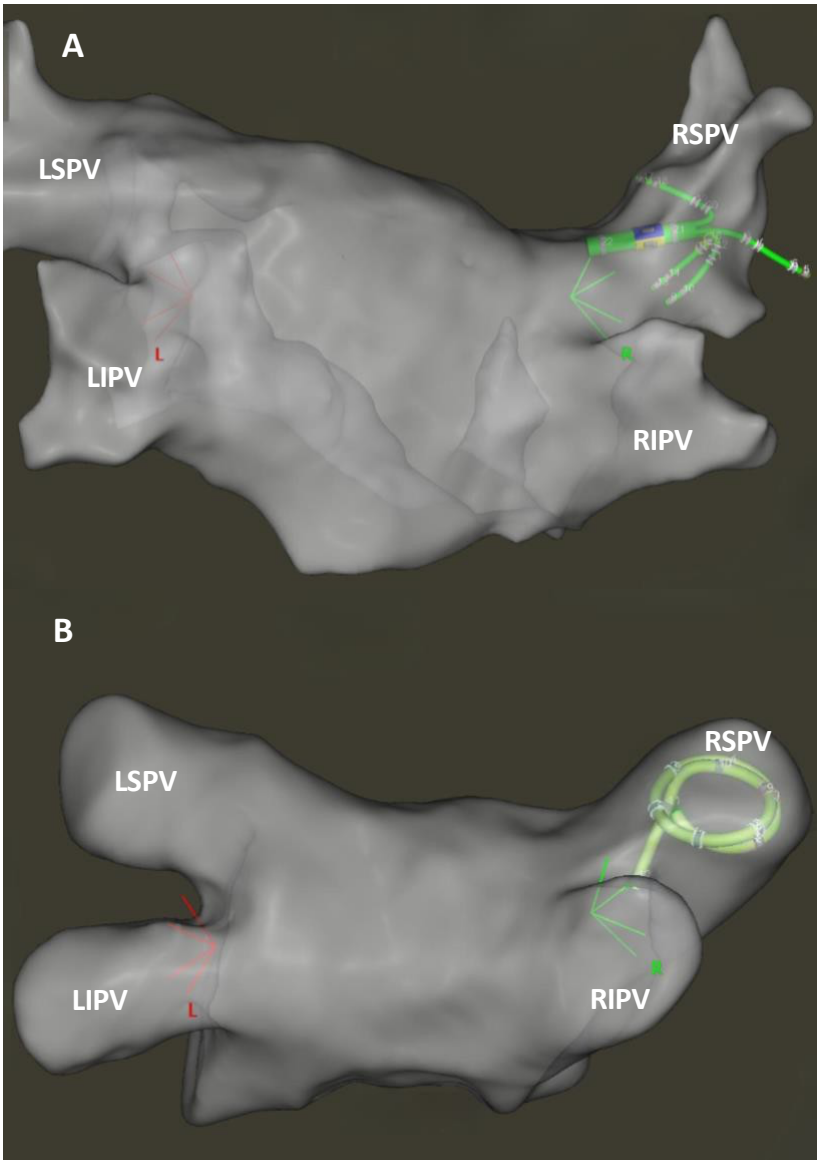

Figure 2. *Anatomical map of the left atrium in a posteroanterior view, generated using the CARTO 3 electroanatomic mapping system. The map was created with the five-spline-shaped PentaRay™ NAV catheter (A) and the circular-shaped LASSO™ NAV multipolar mapping catheter (B). Both the LASSO™ and PentaRay™ catheters are positioned in the right superior pulmonary vein. Abbreviations: LIPV - left inferior pulmonary vein, LSPV - left superior pulmonary vein, RIPV - right inferior pulmonary vein, RSPV - right superior pulmonary vein*

1.2.2.2. Single-shot ablation technique

Single-shot ablation catheters are able to isolate the PV with one or some circumferential ablation. These catheters were developed as an alternative approach to the conventional point-by-point RF ablation catheters but with the elimination of potential gaps between lesions, extensive LA mapping time, slower learning curve and lower complication rates caused by the damage of the adjacent esophagus [90]. The first single-shot approach to PVI was the Pulmonary Vein Catheter (PVAC), a multi-electrode circular RF ablation catheter which was ulteriorly withdrawn from the clinical practice because of an observed higher rate of silent cerebral infarcts [91]. Another single-shot technique is cryoablation balloon therapy, introduced over a decade later to point-by-point RF catheters. This technique relies on a nitrogen balloon, which inserted into the ostium of the PVs, allows a one-shot delivery, resulting in the creation of well-demarcated homogeneous lesion [92]. Other single-shot ablation systems employing laser and ultrasound energy have been explored, but none have gained significant attention as a PVI strategy, however a novel technique became emerged, the PFA which is a non-thermal energy form for PVI [93]. High electrical fields are applied to cardiac tissue, leading to nanopores and subsequently cell death. PFA carries a cardiac tissue-specific effect compared with conventional thermal energies, sparing, for example, nerves, as well as esophageal tissue [94,95].

1.2.3. Electroanatomic mapping systems

When performing PVI, navigation of the catheters require precision. To facilitate mapping and catheter manipulation, the procedure is often facilitated by electroanatomic mapping systems (EAMS). These systems help to visualize the three-dimensional (3D) location of the catheters, and the chamber of interest, without the use of fluoroscopy. One of the most well-known magnetic field–based EAMS is the CARTO™ system (Biosense Webster Inc., Irvine, CA, USA). CARTO™ consists of a magnetic field emitter, a magnetic field generator

locator pad placed beneath the operating table, an external reference patch fixed on the patient and location sensors inside the tip of the catheter (Figure 3). By collecting electrical and spatial data from various endocardial locations, the 3D geometry of the mapped chamber is reconstructed in real time. This data is then analysed to evaluate the arrhythmia mechanism and determine the optimal site for ablation [96–98].

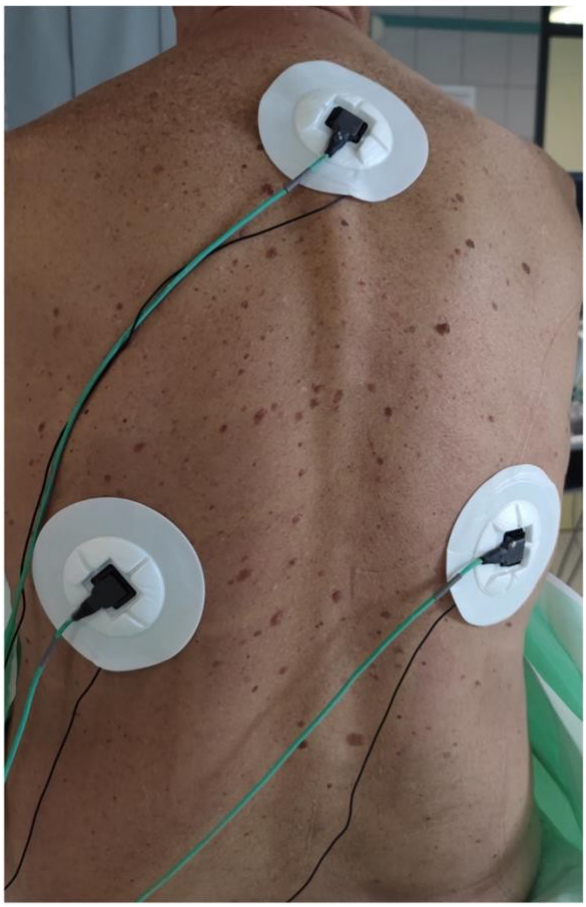

Figure 3. *External back patches fixed on the patients back used for EAMS.*

1.2.4. Steerable sheaths

In a PVI procedure, access to the heart is gained by introducing catheters through the femoral vein. This is followed by a puncture of the oval fossa (transseptal puncture) and the subsequent positioning of the catheters at the openings of the PVs. Catheters are introduced in

the LA through transseptal sheaths (either with a steerable or a fixed mechanism), which are an active component of the procedure and have a significant role in the outcomes (Figure 4).

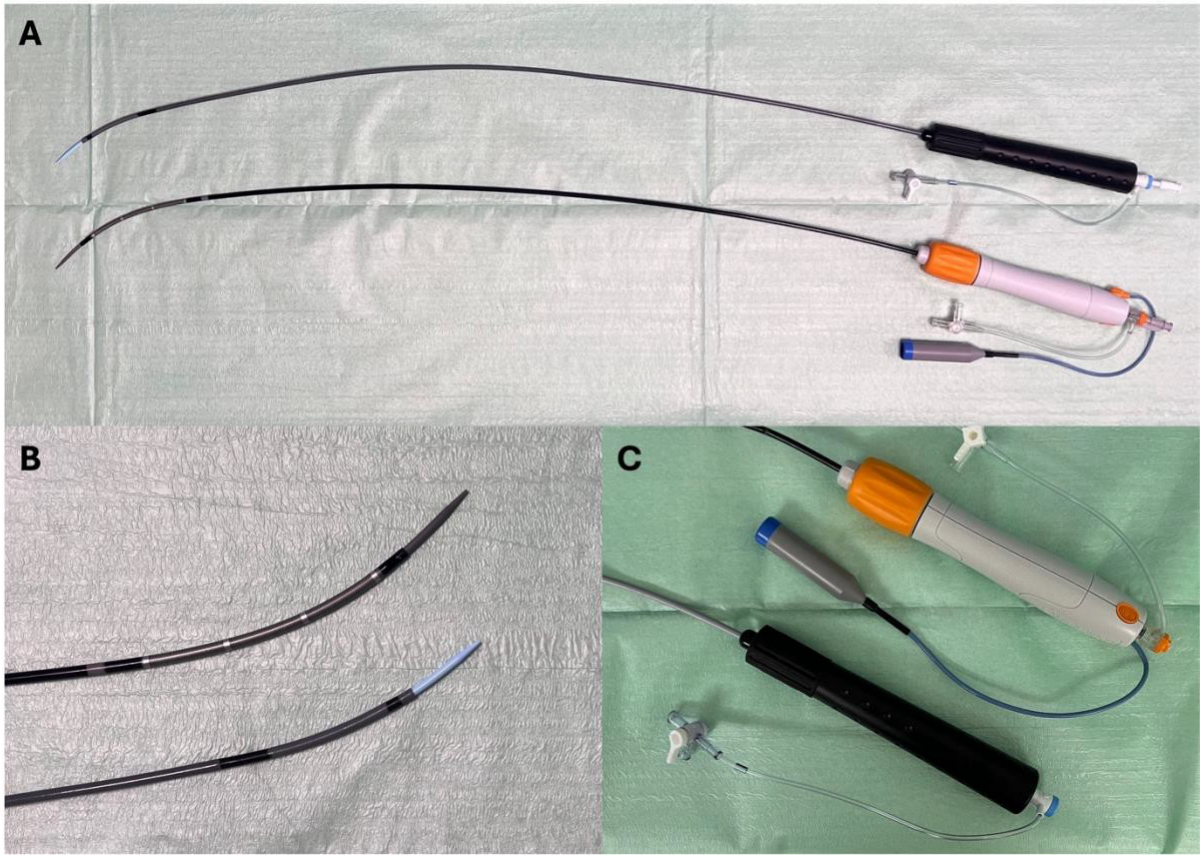

Figure 4. *Two of the several steerable sheaths available in the clinical practice. On Panel A the Agilis™ (NxT, St. Jude Medical, St. Paul, MN, USA) steerable sheath with a black handle and VIZIGO™ (Biosense Webster Inc., Irvine, CA) steerable sheath with orange and gray handle. VIZIGO™ is a visualizable in the CARTO™ EAMS due to the four distal electrodes (Panel B, upper sheath). Panel C shows an extra pigtail on the contralateral part of the irrigation port to connect with the EAMS.*

For long-term PVI durability, the continuity and transmurality of the formed lesions are crucial [99]. This can be achieved through a stable catheter–tissue contact and stability. Sheaths play a major role in maintaining this contact and stability during mapping and ablation, especially compared to an ablation catheter that does not use a sheath [100]. Several manufacturers

produce sheaths with different lengths, diameter, and either steerable mechanism or fixed curvature.

A new type of steerable sheath (VIZIGO™, Biosense Webster Inc., Irvine, CA) has been available for clinical treatment in 2018, which can be visualized by CARTO™ EAMS (Figure 5).

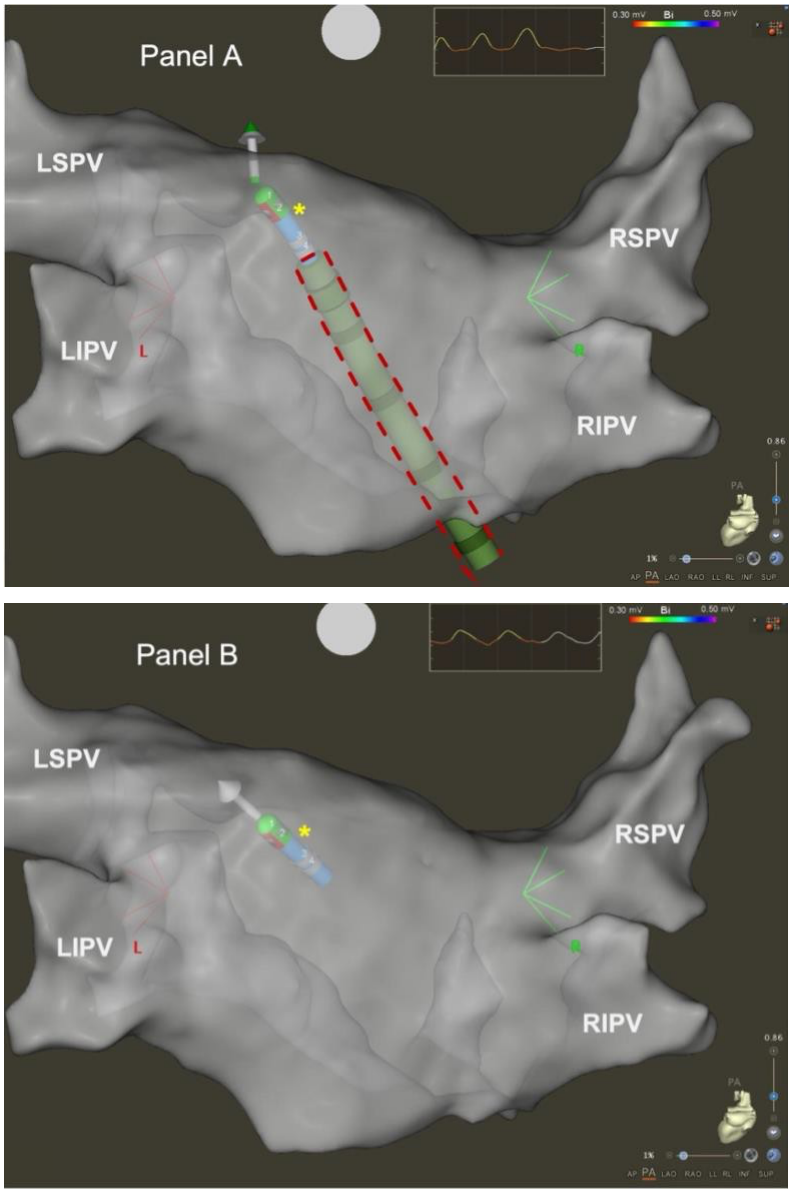

Figure 5. *3D electroanatomic map of LA in posteroanterior view visualized by CARTO™ 3 EAMS. (A) Using the VIZIGO™ visualizable steerable sheath (red dashed line), it is easier to understand spatial relationship between the ablation catheter (yellow asterisk) and the sheath. (B) Using standard steerable sheath, only the ablation catheter is visualized by the CARTO™ 3.*

2. AIMS

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

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

3.1.1. Study population

In our prospective single-center study, 100 consecutive patients undergoing a PVI procedure for paroxysmal or persistent AF at our clinical centre were randomized into two groups: one using the visualizable sheath (VIZIGO™) and the other using the standard, non-visualizable sheath (Agilis™ NxT, St. Jude Medical, St. Paul, MN, USA). We excluded patients who had previously undergone a PVI procedure, those who required additional ablations beyond PVI (including cavotricuspid isthmus ablation), and patients under 18 years of age. All procedures were performed by the same expert electrophysiologist. The study protocol adheres to the Declaration of Helsinki and was approved by the regional ethics committee. All patients provided written informed consent before participating in the study.

3.1.2. Study protocol

For the procedures, midazolam ± fentanyl was administered to achieve conscious sedation. After local anesthesia and vascular ultrasound-guided femoral venous puncture, a decapolar steerable catheter (Dynamic Deca, Bard Electrophysiology, Lowell, MA, USA) was positioned in the coronary sinus (CS). Following intracardiac echocardiography (ICE)-guided double transseptal puncture, a multipolar, steerable, circular mapping catheter (LASSO™ NAV, Biosense Webster Inc., Diamond Bar, CA, USA) was introduced into the left atrium via an SL0 sheath (Abbott Laboratories, Chicago, IL, USA). Additionally, a contact force (CF)-sensing radiofrequency (RF) ablation catheter (Thermocool SmartTouch ST™ NAV, Biosense

Webster Inc., Diamond Bar, CA, USA) was positioned in the left atrium through either visualizable or standard SSs. For visualizable sheaths, we used the VIZIGO™ bi-directional guiding sheath, which can be visualized on the CARTO™ system utilizing advanced catheter location technology. A fast anatomical map of the left atrium was created with the LASSO™ NAV catheter, supported by the CARTO™ EAMS. Ablation was performed with 35 W of power on the posterior wall of the left atrium, while the catheter was set to power-controlled mode with a maximum power of 45 W and a maximum temperature of 43°C elsewhere.

During RF ablations, the CARTO VISITAG™ Module was used, with a maximum location stability range of 2.5 mm and a minimum stability time of 4 seconds. The Visitag Surpoint (ablation index) targets were 350 for the posterior wall and 450 for the anterior wall, with a target interlesion distance below 5 mm. Real-time monitoring of contact force and impedance was maintained during the point-by-point ablation technique, with CF held between 5 and 15 g during ablation.

To blind the operator to the presence or absence of first-pass isolation, the LASSO catheter was positioned in the PV contralateral to the ablation catheter. Intravenous unfractionated heparin was administered immediately after the first transseptal puncture, and an activated clotting time of >300 seconds was maintained for the duration of the procedure. The procedural endpoint was considered achieved once all PVs were isolated.

Procedure time was recorded from the first femoral vein puncture until catheter removal. Left atrial time was measured from the end of the transseptal puncture until the withdrawal of the sheaths from the left atrium. Fluoroscopy time and radiation dose were automatically recorded by the fluoroscopy system. The total number of RF applications, the sum of delivered RF energy (expressed in joules), and the total ablation time (expressed in seconds) were calculated and stored by the EP recording system (CardioLab, GE Healthcare, Chicago, IL, USA).

The occurrence of major complications (e.g., cardiac tamponade, stroke, phrenic nerve paralysis, or atrioesophageal fistula) was monitored throughout the entire hospitalization period of the patients.

3.1.3. Statistical analysis

The distribution pattern of the data was evaluated using the Kolmogorov–Smirnov tests. All tests were performed two-tailed with a significance level set to $p < 0.05$. Continuous data were presented as the mean ± SD or median (interquartile range, IQR), as appropriate while categorical variables are presented as absolute numbers and percentages. For comparisons, chi-square test and Mann–Whitney U test were used as appropriate. Statistical analyses were 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

3.2.1. Study Patients

In our prospective, observational trial, 70 consecutive patients undergoing PVI procedures for paroxysmal AF between November of 2022 and July of 2023 were enrolled. Exclusion criteria encompassed (a) prior PVI procedures; (b) supplementary ablations extending beyond PVI, including both left and right atrial ablations; and (c) individuals below 18 years of age. We categorized the enrolled patients into two groups according to the type of MMC catheter employed during the ablation. The initial 35 patients, between November of 2022 and March of 2023, underwent PVI procedures with LASSO™ NAV guidance (Lasso group). Subsequently, in cases 36–70, between April of 2023 and July of 2023, the PentaRay™ NAV catheter was utilized for electroanatomic mapping due to the unavailability (i.e., backorder on the part of the manufacturer) of LASSO™ NAV catheters (PentaRay group).

All procedures were conducted by the same expert electrophysiologist. The trial protocol adhered to the principles of the Declaration of Helsinki. Written informed consent for participation was obtained from all patients.

3.2.2. Study Protocol

During the procedures, conscious sedation was induced using fentanyl ± midazolam after 12 h continuous fasting. Following local anaesthesia, a decapolar steerable catheter (Dynamic Deca) was placed in the coronary sinus after vascular ultrasound-guided femoral venous puncture. Then, a single transseptal puncture guided by ICE was performed via SL0. From a distinct femoral venous puncture, the steerable 8.5-Fr-long sheath (VIZIGO™) was directed to the superior vein cava, gently retracted, and secured against the intra-atrial septum.

Subsequently, with the sheath's guidewire penetrating the left atrium under fluoroscopic and/or ICE guidance, the VIZIGO™ was advanced over the initial transseptal puncture alongside the SL0 sheath. This sliding technique resulted in an SL0 and a VIZIGO™ sheath in the left atrium. Then, a MMC (either LASSO™ NAV or PentaRay™ NAV) was introduced into the left atrium via SL0. Additionally, a CF-sensing radiofrequency (RF) ablation catheter (Thermocool SmartTouch™ ST NAV, Biosense Webster Inc., Diamond Bar, CA, USA) was positioned in the left atrium through a VIZIGO steerable sheath. A fast anatomical mapping of the left atrium was conducted with the MMC catheter, supported by the CARTO™ 3 EAMS. No other mapping points were collected and analysed other than an anatomical map. The ablation catheter operated in a power-controlled mode with a maximum power of 45 W for the anterior and 40 W for the posterior wall, employing a maximum temperature of 43 °C.

During RF ablations, the CARTO VISITAG™ Module was employed with a minimum stability time of 4 s and a maximum location stability range of 2.5 mm. The Visitag Surpoint (ablation index) was utilized with targets set at 350 for the posterior wall and 450 for the anterior wall. The target interlesion distance was maintained below 5 mm. The point-by-point ablation technique was applied, with real-time monitoring of CF and impedance. CF was maintained between 5 and 15 g during the ablation process.

To blind the operator from the presence or absence of first-pass isolation during ablations, the MMC catheter was positioned in the contralateral PVs. Intravenous unfractionated heparin was administered immediately after the femoral vein punctures, and an activated clotting time of >300 s was sustained throughout the entire procedure. The procedural endpoint of the ablation was considered achieved when all PVs were isolated.

3.2.3. Procedural Outcomes

The primary endpoint of this study was the procedure time, defined as the duration from the initial femoral vein puncture to the removal of the catheters. Additionally, various time

intervals were compared, including the duration between femoral vein puncture and the beginning of mapping, mapping time, time between the first and last RF applications, validation time, and left atrial dwelling time. The first pass success rate, the number of RF applications, and the total RF time were also calculated. Mapping time was measured from the conclusion of the transseptal puncture until the initiation of the first RF ablation. Left atrial dwelling time was determined from the conclusion of the transseptal puncture until the withdrawal of sheaths from the left atrium.

Fluoroscopy time and radiation dose were automatically recorded by the fluoroscopy system. The RF generator (SMARTABLATE™ System, Biosense Webster Inc., Diamond Bar, CA, USA) documented the total number of RF applications and the overall ablation time.

The occurrence of major complications, such as vascular complications, pericardial effusion, cardiac tamponade, stroke, or atrio-esophageal fistula, was systematically assessed throughout the entire hospitalization and the periprocedural period.

3.2.4. Statistical Analysis

The data underwent analysis based on their conformity to normal distribution through the application of the Kolmogorov–Smirnov goodness-of-fit test. Continuous data were expressed using either the mean ± standard deviation (SD) or median (interquartile range, IQR), as deemed suitable. Categorical variables were represented by absolute numbers and corresponding percentages. Comparative assessments employed the chi-square test, t-test, and Mann–Whitney U test, as applicable. A significance threshold of $p < 0.05$ was employed for all statistical evaluations. The statistical analyses were executed using SPSS 28 software (SPSS, Inc., Chicago, IL, USA).

4. RESULTS

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

100 patients were randomized into two groups: the visualizable SS group (n = 50) and the non-visualizable SS group (n = 50). There were no significant differences in baseline characteristics between the groups (male sex: 70% vs. 80%, p=0.25; age: 58.2 ± 13.1 vs. 56.0 ± 17.4 years, p=0.74; Table 1).

	Visualizable steerable sheath group (n=50)	**Non-visualizable steerable sheath group (n=50)**	**P-value**
Age, years	56.0 ± 17.4	58.2 ± 13.1	n.s.
Male (%)	40 (80.0)	35 (70.0)	n.s.
Paroxysmal AF (%)	37 (74.0)	39 (78.0)	n.s.
Persistent AF (%)	13 (26.0)	11 (22.0)	n.s.
Hypertension (%)	39 (78.0)	35 (70.0)	n.s.
Diabetes mellitus (%)	7 (14.0)	10 (20.0)	n.s.
Prior stroke / TIA (%)	1 (2.0)	2 (4.0)	n.s.
Heart failure (%)	2 (4.0)	1 (2.0)	n.s.
Chronic kidney disease (%)	3 (6.0)	4 (8.0)	n.s.
Left atrial diameter, mm	52 ± 10.6	55.0 ± 12.2	n.s.

Table 1. *Clinical characteristics of the study population. Abbreviations: AF - atrial fibrillation, TIA - transient ischemic attack, n.s. – non-significant*

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 ± 35.2 minutes vs. 99.5 ± 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 ± 89 sec. vs. 193 ± 44 sec.; p=0.79) or total fluoroscopy dose (9.12 ± 1.98 mGy vs. 9.97 ± 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. The results are summarized in Table 2.

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

Table 2. *Procedural parameters in the study population. N.A. - not applicable; n.s. - non-significant.*

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 ± 52 s vs. 244 ± 84 s, p=0.02). Data shown in Table 3.

	Visualizable steerable sheath group(n=13)	Non-visualizable steerable sheath group(n=11)	P-value
Total procedure time (min)	100 ± 19.0	103 ± 21.5	0.36
Left atrial procedure time (min)	54.8 (44.3; 59.0)	66.9 (50.0; 73.7)	0.23
Total fluoroscopy time (s)	182 ± 52	2443 ± 84	0.02
Total fluoroscopy dose (mGy)	14.4 ± 11.2	17.6 ± 12.4	0.43
Left atrial fluoroscopy time (s)	0 (0; 0)	25 (6; 77)	<0.001
Left atrial fluoroscopy dose (mGy)	0 (0; 0)	1,13 (0.16; 1.74)	0.02
Number of fluoroless procedure after transseptal puncture (%)	11 (84.6)	2 (18.2)	<0.01
Number of acute success (%)	50 (100)	50 (100)	1
Number of radiofrequency ablations (n)	68 (55; 78)	79 (73; 86)	0.04
Total ablation time (s)	951 (829; 1095)	1265 (1085; 1441)	0.04
First pass isolation (%)	92%	82%	0.44
Major complications (n)	0	0	N.A.

Table 3. *Procedural parameters in persistent AF cases. N.A. - not applicable.*

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). Baseline characteristics were compared between the two groups, with no significant differences in male sex distribution (Lasso: 80% vs. PentaRay: 74%; p = 0.57) or age (68.6 [58.7; 71.5] vs. 66.5 [50.6; 73.5]; p = 0.36), as shown in Table 4.

	Group Lasso (n = 35)	**Group PentaRay (n = 35)**	**P-value**
Age, years	28 (80)	26 (74)	0.57
Male (%)	68.6 (58.7; 71.5)	66.5 (50.6; 73.5)	0.88
Hypertension (%)	28 (80)	28 (80)	1.0
Heart failure (%)	5 (14.3)	6 (17.1)	0.74
Coronary artery disease (%)	5 (14.3)	8 (22.9)	0.36
Diabetes mellitus (%)	8 (22.9)	7 (20.0)	0.77
Chronic kidney disease (%)	6 (17.1)	7 (20.0)	0.76
Prior stroke / TIA (%)	1 (2.9)	5 (14.3)	0.09
Left atrial diameter, mm	54.5 ± 8.1	52.9 ± 7.8	0.18

Table 4. *Baseline characteristics. Abbreviation: TIA - transient ischemic attack.*

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 ± 17.7 min. vs. 75.7 ± 14.8 min.; p=0.13). The time from femoral vein puncture to the initiation of mapping was also comparable (31.2 ± 7 min. vs. 28.9 ± 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 ± 71 sec. vs. 143 ± 56 sec.; p=0.14) and dose (6.7 ± 4 mGy vs. 7.4 ± 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-signifficant. The results are detailed in Table 5.

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

Table 5. *Procedural data and outcome. Abbreviation: N.A. - not applicable.*

5. DISCUSSION

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

CA for AF is the most frequently performed ablation procedure worldwide. The integration of novel technologies in procedural workflows can help to achieve significant reductions in fluoroscopy exposure and procedural times for PVI. During these procedures, transseptal sheaths are routinely used to reduce procedural time and improve acute and long-term success rate. SSs can improve the contact and stability of the ablation catheter, thus have been shown superior compared to fixed sheaths [101]. This is also supported by a recent meta-analysis about steerable vs. non-steerable sheaths, SSs being superior in terms of reducing AF recurrencies and acute PV reconnections, however there were no significant differences regarding to procedure time or fluoroscopy time [102].

The novel type Vizigo™ SS, unlike the standard steerable sheaths, can be visualized in CARTO™ navigation system with the help of electrodes and the magnetic sensors of the ablation catheter. The visualisation of the sheath aids in understanding spatial relationship between the ablation catheter and the sheath during catheter manipulation.

Results from a recent retrospective study by Fitzpatrick et al. showed several similarities with our results, with a significant reduction of radiation exposure with the Vizigo™ sheath, compared to a non-visualizable steerable sheath, although they did not find any differences between the RF application times, and mapping time was longer with the visualizable sheath, however this did not affect the overall procedure time [99].

A recently published observational study by Rajendra et al. compared low-fluoroscopy PVI approach performed by Vizigo™ sheaths vs. no transseptal sheaths and found no difference regarding to the outcomes of clinical effectiveness, however Vizigo™ sheath helped to improve

catheter stability, to reduce ablation time and more procedures could be performed without applying fluoroscopy [100].

In an observational study published by Guo et al., Vizigo™ sheath was compared to fixed sheath in patients who underwent PVI procedures, found that the visualized SS for CA not only reduced radiation exposure but also significantly improved contact force and initial PVI rate. Total procedural time was shorter with the use of Vizigo™ SS, however left atrial procedural time did not differ between the groups [103].

Our results showed that use of Vizigo™ reduced left atrial procedural time, left atrial 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 due to the improved catheter stability, however we did not collect data about contact force values. 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 steerable sheaths visualized by 3D EAMS facilitates the fluoroless PVI by effectively reducing fluoroscopy exposures when compared with conventional, non-visualizable steerable sheaths [98].

During an AF ablation procedure, the average patient fluoroscopy dose approximates 15 mSv, which increases the absolute lifetime risk of fatal cancer for an adult by 0.075% [104]. Besides, annual radiation exposure of interventional cardiologists and electrophysiologists may even reach an effective dose of 5 mSv yearly [105]. Although this risk can be reduced by applying various forms of radiation protection and the “as low as reasonably achievable” (ALARA) principle, it remains still of great importance. Furthermore, the wearing lead aprons is associated with a higher rate of work-related musculoskeletal pain [106–108].

The use of EAMS with ICE can efficiently help in reducing the radiation exposure without compromising the safety and efficacy of the ablation procedures. With the constantly evolving technology in 3D EAMS, they offer a reliable alternative to fluoroscopy, and fluoroless procedures have become available [109]. Initially, the zero-fluoroscopy approach was mainly used in CA for paroxysmal supraventricular tachycardias (PSVT) [89]. This may be explained by transseptal puncture necessary for PVI, which conventionally is performed with fluoroscopic guidance, but with the implementation of ICE and EAMS the necessity of fluoroscopy for the transseptal puncture can be bypassed and zero fluoroscopy can be achieved also for PVI, as a recent meta-analysis showed by our research group [110]. It has been shown, that PVI can be executed safely and effectively with the zero fluoroscopic approach with significant reduction in procedure time and radiation exposure, without compromising the acute and long-term success rates or complication rates. This is also supported by a previous meta-analysis performed by Huang et al., comparing conventional fluoroscopy vs. low/zero-fluoroscopy PVI procedures, resulting in similar clinical efficacy and safety by the adoption of alternative imaging modalities such as 3D EAM systems, force-sensing ablation catheters and ICE. Moreover, low/zero-fluoroscopy approach was associated with shorter procedure time besides reduced fluoroscopy time and exposure [111].

Our results should be interpreted with the careful consideration of the following limitations. Firstly, this was a randomized, single-centre, single-operator study with a limited number of patients enrolled, which may limit its generalizability. Secondly, data about contact force parameters were not available. Finally, our study does not provide data on whether the long-term results are influenced by the type of SS. Multicentre trials are required to assess and to improve clinical outcomes with visualizable SSs.

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

In our prospective, single-center, observational trial comparing the LASSO™ NAV and PentaRay™ MMCs, we observed no significant differences in mapping, ablation, or fluoroscopy parameters among patients undergoing PVI for paroxysmal AF.

PVI is widely regarded as the gold-standard approach in CA for AF. Although various ablation techniques can achieve electrical isolation of the PVs, point-by-point RF ablation remains the most commonly utilized method [70]. These procedures are guided by an EAMS, which offers detailed visualization of left atrial anatomy and precise localization of RF lesions [112] . 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.

The initial utilization of MMCs in PVI guided by EAMS was reported in 2008, employing the PentaRay™ NAV catheter with the EnSite EAMS. [113]. Subsequent studies demonstrated the superiority of MMCs in PVI procedures compared to point-by-point contact mapping with the ablation catheter alone. [86,114,115] . This advantage stems from the impact of interelectrode spacing and electrode size on mapping resolution and efficiency. Smaller electrodes with closer interelectrode spacing enhance mapping resolution and significantly reduce mapping time.

Bun et al. reported faster mapping times and an increased number of mapping points in LA tachycardia ablation using the PentaRay™ NAV catheter compared to traditional ablation catheter approaches [115]. Similarly, a study involving 30 patients with scar-related atrial arrhythmias found that mapping with the PentaRay™ NAV MMC provided superior resolution in scarred regions compared to 3.5 mm electrode-tip linear ablation catheters [86] . Additionally, the use of the LASSO™ NAV MMC proved advantageous over point-by-point mapping in patients undergoing repeat AF ablation procedures, particularly for detailed left atrial scar mapping [114] .

In addition to contact-based multipolar mapping catheters (MMCs) such as the LASSO™ NAV and PentaRay™ catheters, non-contact mapping technologies have also been introduced

into clinical practice. These advancements offer alternative approaches for electroanatomical mapping in ablation procedures.

Knecht et al. compared bipolar voltage electrograms recorded using the ORION™ catheter, the LASSO™ NAV catheter, and a focal ablation catheter in patients undergoing redo PVI for AF recurrence. Their findings revealed significant differences in voltage measurements among the devices. Specifically, both the ORION™ and LASSO™ NAV catheters demonstrated lower bipolar voltage amplitudes in low-voltage areas (LVAs) compared to the focal ablation catheter. This suggests that lower voltage cut-off thresholds should be considered when identifying LVAs using these mapping technologies [116].

The innovative Octaray™ multipolar MMC by Biosense Webster Inc., featuring a 48-electrode, eight-spline design, has demonstrated enhanced mapping efficiency. Studies in animal models have shown that the Octaray™ catheter provides increased mapping speed and a higher number of acquired electrograms compared to the PentaRay™ NAV catheter. Additionally, it exhibited superior accuracy in identifying intact ablation lines, highlighting its potential to improve procedural outcomes in mapping-guided ablation techniques [117] .

MMCs play a critical role in the identification of atrial scar, facilitating detailed electroanatomical mapping and characterization of LVAs. However, the utility of targeting LVAs as part of a substrate-based ablation strategy beyond PVI remains a subject of debate. Conflicting evidence exists regarding the efficacy and clinical outcomes of this approach, underscoring the need for further research to clarify its role in arrhythmia management.[118–124] .

In the ERASE-AF multicenter randomized clinical trial, Huo et al. demonstrated that PVI combined with substrate modification was more effective than PVI alone in reducing arrhythmia recurrences in patients with persistent AF. These findings support the potential benefits of incorporating substrate-based strategies into ablation protocols for this patient population [118].

Conversely, the CAPLA randomized clinical trial, which included 338 patients undergoing CA for persistent AF, found that additional ablation beyond PVI did not significantly enhance

freedom from AF at the 12-month follow-up. These results suggest that the benefits of substrate modification may vary depending on patient characteristics or procedural factors, highlighting the need for further investigation to refine ablation strategies for persistent AF [122] .

Furthermore, a systematic review and meta-analysis conducted by Jia et al., which included 14 studies, revealed that targeting scarred atrial tissue during ablation was associated with a higher recurrence rate of AF and did not lead to improved outcomes compared to PVI alone. These findings underscore the ongoing controversy regarding the efficacy of substrate-based ablation strategies in improving long-term outcomes for patients with AF. [124] .

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.

Several limitations of this study should be acknowledged. First, the trial was conducted at a single center, which may limit the generalizability of the findings to broader patient populations with diverse demographic and clinical characteristics. Second, the relatively small sample size of 70 patients may reduce the statistical power to detect subtle differences between the two groups. Larger studies would be needed to enhance the reliability of these findings and allow for a more precise comparison between the two catheter types. Third, all procedures were performed by a single expert electrophysiologist, which introduces the possibility of operator-specific effects on the outcomes. This limitation suggests that the results may not be universally applicable, as variations in operator skill and experience could impact the reproducibility of these findings in other clinical settings. Additionally, the group of patients treated with the PentaRay™ NAV catheter underwent procedures later than those treated with the LASSO™ NAV catheter,

introducing the potential for bias related to increasing operator experience over time. Finally, the study was not randomized, raising the possibility of selection bias and making it challenging to fully account for confounding variables that might influence the outcomes. A randomized design would have strengthened the validity of the conclusions by minimizing these sources of bias.

6. NOVEL FINDINGS

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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8. PUBLICATION LIST

8.1. 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**

8.2. 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**

Debreceni D, Janosi K-F, Vamos M, Komocsi A, Simor T, Kupo P: Zero and Minimal Fluoroscopic Approaches During Ablation of Supraventricular Tachycardias: A Systematic Review and Meta-Analysis

Frontiers in Cardiovascular Medicine (2022): 856145 **IF=3.6 Q1**

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
Cardiologia Hungarica (2022); 254-256

Janosi K-F, Debreceni D, Simor T, Kupo P: Diagnosztikus elektrofiziológiai vizsgálatok indikációi az ESC 2022. Évi kamrai tachycardiák ellátására és a hirtelen szívhalál megelőzésére vonatkozó irányelvei alapján
Cardiologia Hungarica (2023); 212-217

Debreceni D, Janosi K-F, Bocz B, Turcsán M, Simor T, Kupo P: Bal pitvari fülcsethrombus 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.
Scientific Reports (2024); 16332 **IF= 3.8 Q1D1**

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**

8.3. 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**

Kupó Péter, Jánosi Kristóf-Ferenc, Debreceni Dorottya, Jánosa Benedek, Simor Tamás: Vizualizálható vs. standard hajlítható sheatek alkalmazása pulmonális vénaizoláció során: Randomizált egycentrumos vizsgálat. A Magyar Kardiológusok Társasága 2022. évi Tudományos Kongresszusa, Balatonfüred, 04-07. May 2022.
Cardiologia Hungarica (2022); Suppl. C; C86

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Jánosi Kristóf-Ferenc, Jánosa B, Bocz Botond, Simor Tamás, Debreceni Dorottya, Kupó Péter: Vizualizálható vs. nem-vizualizálható hajlítható sheath-ek pulmonális vénaizolációban: randomizált vizsgálat. Magyar Kardiológusok Társasága, XIV. Magyar Aritmia és Pacemaker Kongresszus. Szeged, 28-30. May 2023.
Cardiologia Hungarica (2023); Suppl. B; B7

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.
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Jánosi Kristóf-Ferenc, Bocz Botond, Debreceni Dorottya, Keserű Márk, Torma Dalma, Kupó Péter: Multipoláris térképező katéterek összehasonlító vizsgálata pulmonális vénaizolációban. A Magyar Kardiológusok Társasága 2024. évi Tudományos Kongresszusa, Balatonfüred, 08-11. May 2024.
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8.4. NON-TOPIC RELATED ABSTRACTS PUBLISHED IN SCIENTIFIC JOURNALS

D Dorottya, K Janosi, G Vilmanyi, T Simor, P Kupo: Comparison of conventionally performed and electroanatomic mapping system guided catheter ablation for AV nodal reentrant tachycardia-prospective single-centre study.
Europace (2021); 22 (Abstract supplement); 304 **IF= 5.486 Q1**

Debreceni Dorottya, Jánosi Kristóf, Simor Tamás, Kupó Péter: Zero-fluorószkópiás stratégia összehasonlítása paroxysmalis supraventricularis tachycardiák katéterablációja során – metaanalízis. XIII. Aritmia és Pacemaker Kongresszus. Eger, 23-25 September 2021.
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Debreceni Dorottya, Simor Tamás, Kutasi Bence, Jánosi Kristóf, Kupó Péter: Konvencionálisan végzett, valamint zero- fluoroszkópos katéterablációk összehasonlítása AVNRT-k esetén: prospektív, single-center vizsgálat. XIII. Aritmia és Pacemaker Kongresszus. Eger, 23-25 September 2021.
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K Janosi, D Debreceni, M Turcsan, T Simor, P Kupo: Comparison of intracardiac echocardiography-guided versus conventionally performed cavotricuspidal isthmus ablation in patients with atrial flutter.
Europace (2022); 24 (Abstract supplement); 53 **IF= 6.1 Q1**

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8.5. ORAL AND POSTER PRESENTATIONS

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Cumulative impact factor of topic related articles: 6.6

Cumulative impact factor: 33.493

Cumulative impact factor including citable abstracts: 90.679

9. ACKNOWLEDGMENTS

I want to express my appreciation and gratitude to my mentor, Dr. Péter Kupó, for his guidance and support throughout my journey. Without his contributions, expert advice, and encouragement, my thesis would not have been possible. The insights and perspectives he provided throughout the entire mentorship were not only profound but also transformative, pushing me to think critically and innovatively, helping me overcome complex challenges, and significantly improving the quality of my work. His support has made a lasting impact on my academic and personal growth.

I would like to express my thankfulness to Prof. Dr. Attila Cziráki, chair of our institute for the opportunities he has provided me.

My appreciation also extends to my colleague, Dr. Dorottya Debreceni, for her positive and supportive attitude and belief in my abilities, which have been a source of great motivation and confidence.

Last but not least, I am grateful for my colleagues from the entire electrophysiology department, and for the medical students who became part of our daily work routine and scientific research, as working alongside them has been both a professional pleasure and a personally enriching experience.

frontiers | Frontiers in Cardiovascular Medicine

TYPE Clinical Trial
PUBLISHED 16 November 2022
DOI 10.3389/fcvm.2022.1033755

OPEN ACCESS

EDITED BY
Julia W. Erath,
University Hospital Frankfurt, Germany

REVIEWED BY
Ting-Chun Huang,
National Cheng Kung University Hospital, Taiwan
Alexander Benz,
Johannes Gutenberg University Mainz, Germany

*CORRESPONDENCE
Peter Kupo
peter.kupo@gmail.com

SPECIALTY SECTION
This article was submitted to Cardiac Rhythmology, a section of the journal Frontiers in Cardiovascular Medicine

RECEIVED 31 August 2022
ACCEPTED 31 October 2022
PUBLISHED 16 November 2022

CITATION
Janosi K, Debreceni D, Janosa B, Bocz B, Simor T and Kupo P (2022) Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: Randomized, single-centre trial.
Front. Cardiovasc. Med. 9:1033755.
doi: 10.3389/fcvm.2022.1033755

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

Kristof Janosi, Dorottya Debreceni, Benedek Janosa, Botond Bocz, Tamas Simor and Peter Kupo*

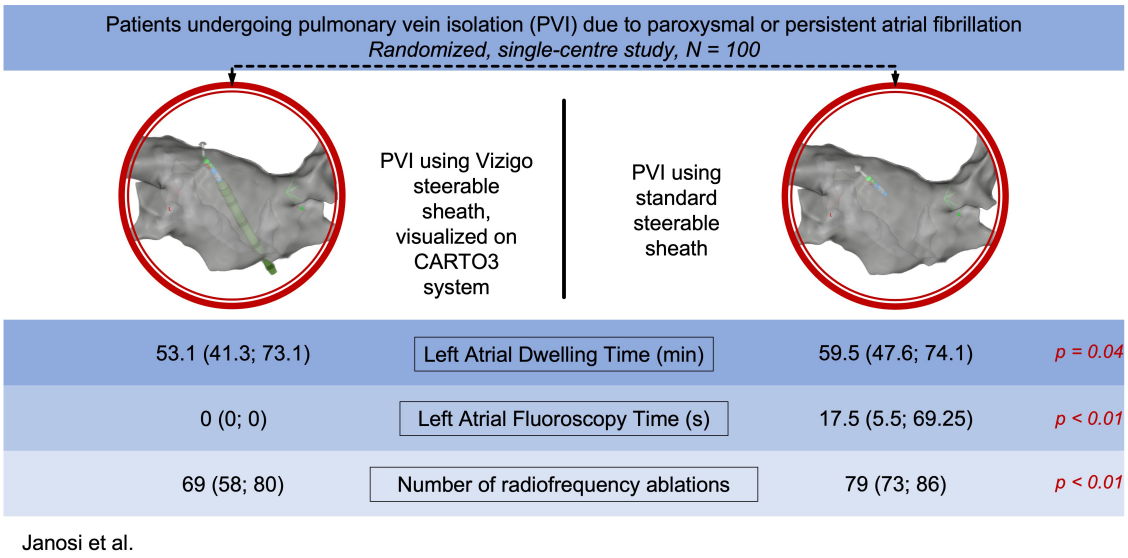
Heart Institute, Medical School, University of Pécs, Pécs, Hungary

Introduction: Steerable sheaths (SSs) are frequently used to improve catheter contact during pulmonary vein isolation (PVI) procedures. A new type of visualizable (by electroanatomical mapping system) SS has become available in clinical treatment.

Purpose: We aimed to compare procedural data of visualizable vs. non-visualizable steerable sheath assisted PVI procedures in patients with atrial fibrillation (AF).

Methods: In this single-centre randomized study, we enrolled a total of 100 consecutive patients who underwent PVI due to AF.

Results: A total of 100 patients were randomized into 2 groups (visualizable SS group: 50; non-visualizable SS group: 50). Acute ablation success was 100% and the rate of the first pass isolation were similar (92% vs. 89%; $p = 0.88$). Using visualizable SS, left atrial (LA) procedure time (53.1 [41.3; 73.1] min vs. 59.5 [47.6; 74.1] min.; $p = 0.04$), LA fluoroscopy time (0 [0; 0] s vs. 17.5 [5.5; 69.25] s; $p < 0.01$) and LA fluoroscopy dose (0 [0; 0.27] mGy vs. 0.74 [0.16; 2.34] mGy; $p < 0.01$) was significantly less, however, there was no difference in the total procedural time (90 ± 35.2 min vs. 99.5 ± 31.8 min; $p = 0.13$), total fluoroscopy time (184 ± 89 s vs. 193 ± 44 s; $p = 0.79$), and total fluoroscopy dose (9.12 ± 1.98 mGy vs. 9.97 ± 2.27 mGy; $p = 0.76$). Compared to standard, non-visualizable SS group, the number of radiofrequency ablations was fewer (69 [58; 80] vs. 79 [73; 86]; $p < 0.01$) as well as total ablation time was



GRAPHICAL ABSTRACT

Using visualizable or non-visualizable steerable sheaths for pulmonary vein isolation.

reduced (1049 sec. [853; 1175] vs. 1265 sec. [1085; 1441]; $p < 0.01$) in the visualizable SS cohort. No major complications occurred in either group.

Conclusion: Compared to the standard, non-visualizable SS, visualizable 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.

KEYWORDS

atrial fibrillation, pulmonary vein isolation (PVI), catheter ablation, visualizable steerable sheath, electroanatomical mapping system

Introduction

Atrial fibrillation (AF) is the most common arrhythmia, with a prevalence between 2 and 4% in adults (1). According to the most recent guidelines published by the European Society of Cardiology (ESC), in the management of AF, the primary indication for rhythm control strategy is to reduce AF-related symptoms and improve quality of life (2). Catheter ablation (CA) for AF is superior to antiarrhythmic drugs (AAD) for the maintenance of sinus rhythm (3–8).

The cornerstone of the AF ablation procedures is the complete electrical isolation of the pulmonary veins (2). To achieve pulmonary vein isolation (PVI) steerable sheaths (SS) are frequently used, which enables the operator to improve the contact and stability of the ablation catheter, which are crucial for effective lesion formation in the left atrial myocardium during point-by-point radiofrequency (RF) ablation (9–11).

Advance in technology can help to optimize procedural workflow and reduce radiation exposure for AF ablation procedures. A new type of SS (VIZIGO, Biosense Webster Inc., Irvine, CA) has become available in clinical treatment, which can be visualized by CARTO electroanatomical mapping system (Biosense Webster Inc., Irvine, CA, USA; **Figure 1**). VIZIGO can be visualized on the CARTO3 System based on advanced catheter location (ACL) technology. The sheath itself has an 8.5 French inner lumen, and it is bi-directional, allowing a 180 degrees deflection in both directions.

In our prospective randomized trial, we aimed to compare the procedural outcomes of patients undergoing PVI procedures performed by either visualizable or standard, non-visualizable SSs.

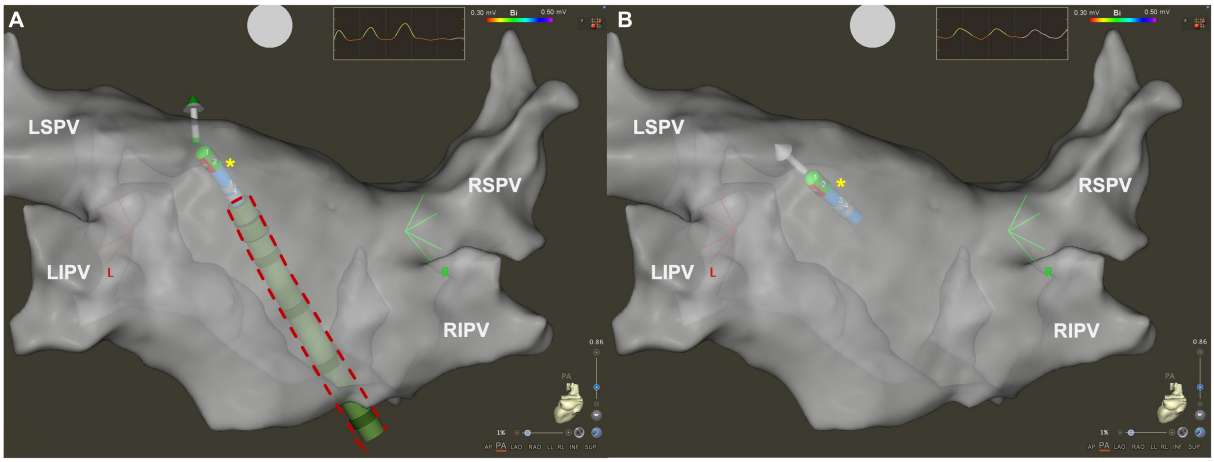


FIGURE 1
Three dimensional electroanatomical map of left atrium in posteroanterior view visualized by CARTO3 system. **(A)** Using visualizable steerable sheath (red dashed line), it is easier to understand spatial relationship between the ablation catheter (yellow asterisk) and the sheath. **(B)** Using standard steerable sheath, only the ablation catheter is visualized by the CARTO3 system. LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein.

Methods

Study patients

In our prospective singe-centre trial, 100 consecutive patients undergoing PVI procedure for paroxysmal or persistent AF were randomized into visualizable (VIZIGO, Biosense Webster Inc., Irvine, CA) or standard, non-visualizable (Agilis^{TM} NxT, St. Jude Medical, St. Paul, MN, USA) SS groups.

Exclusion criteria were (a) previously performed PVI procedure; (b) additional ablations beyond PVI (including any left or right atrial ablations); and (c) age under 18 years.

All procedures were accomplished by the same expert electrophysiologist. The protocol of the trial is in accordance with the Declaration of Helsinki and the study protocol was approved by the regional ethics committee. All patients provided written informed consent for the study protocol.

Study protocol

During the procedures, fentanyl ± midazolam was used to achieve a conscious sedation. After local anesthesia, following vascular ultrasound guided femoral venous puncture one decapolar steerable catheter (Dynamic Deca, Bard Electrophysiology, Lowell, MA, USA) was positioned in the coronary sinus (CS). After intracardiac echocardiography (ICE)-guided double transseptal puncture a multipolar, steerable, circular mapping catheter (Lasso NAV, Biosense Webster Inc., Diamond Bar, CA, USA) was inserted in the left atrium *via* SL0. Besides, a contact force (CF)–sensing ablation radiofrequency (RF) ablation catheter (Navistar Thermocool SmartTouch ST NAV, Biosense Webster Inc., Diamond Bar, CA, USA) was positioned into the left atrium through either visualizable or standard, non-visualizable SSs. A fast anatomical map of the left atrium was performed with the Lasso NAV catheter supported by CARTO electroanatomical mapping system (Biosense Webster Inc., Diamond Bar, CA, USA). Ablation catheter was set in a power-controlled mode with a maximum power of 45 W for anterior and 35 W for posterior wall using a maximum temperature of 43°C.

During RF ablations, CARTO VISITAG^{TM} Module was used with minimum stability time of 4 s and maximum location stability range of 2.5 mm. Visitag Surpoint (i.e., ablation index) was applied with targets of 350 at the posterior wall and 450 at the anterior wall. Target interlesion distance was <5 mm. Point-by-point ablation technique was used, contact force (CF) and impedance was monitored in real time. CF was held between 5 and 15 g during ablation.

During the ablations, to blind the operator to the presence or absence of first-pass isolation, Lasso catheter was positioned in the contralateral pulmonary veins. Intravenous unfractionated heparin was administered immediately after the first transseptal puncture, and an activated clotting time of >300 s was held for the whole duration of the procedure. The procedural endpoint of the ablation was obtained if all PVs were isolated. Based on our institutional protocol, only PV isolation was performed even in persistent AF cases.

Procedure time was defined as the time from the first femoral vein puncture until the removal of the catheters. Left atrial time was measured from the end of the TS until the withdrawal of the sheaths from the left atrium. Fluoroscopy time and radiation dose were automatically measured by the fluoroscopy system. Total number of the RF applications and total ablation time were recorded by the EP recording system (CardioLab, GE Healthcare).

The occurrence of major complications (i.e., vascular complications, pericardial effusion, cardiac tamponade, stroke, or atrio-esophageal fistula) were systematically evaluated during the whole hospitalization.

Statistical analysis

Data were analyzed according to their normal distribution on the Kolmogorov–Smirnov goodness-of-fit test. Continuous data were presented as the mean ± SD or median (interquartile range, IQR), as appropriate while categorical variables are presented as absolute numbers and percentages. For comparisons, chi-square test, *t*-test, and Mann–Whitney U test were applied as appropriate. A p-value < 0.05 was considered statistically significant in all analyses. Statistical analyses were performed using SPSS 24 software (SPSS, Inc., Chicago, IL, USA).

Results

A total of 100 patients were randomized into visualizable or non-visualizable SS groups. No intra- or postprocedural patient exclusion was applied. We did not find any significant difference in the baseline characteristics of the study population between the groups (male sex: 80% vs. 70%, $p = 0.25$; age: 56.0 ± 17.4 vs. 58.2 ± 13.1 years, $p = 0.74$, Table 1).

In all 100 cases PVs were isolated, thus procedural endpoint was achieved, and acute procedural success was 100%. The rate of the first pass isolation were similar (92% vs. 89%; $p = 0.88$). Total procedural time did not differ between visualizable vs. non-visualizable SS groups (90 ± 35.2 min. vs. 99.5 ± 31.8 min.; $p = 0.97$). Using visualizable SS, 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] s vs. 17.5 [5.5; 69.25] s; $p < 0.01$) and left atrial fluoroscopy dose (0 [0; 0.27] mGy vs. 0.74 [0.16; 2.34] mGy; $p < 0.01$) was significantly less, however, there was no difference in total fluoroscopy time (184 ± 89 s vs. 193 ± 44 s; $p = 0.79$), and total fluoroscopy dose (9.12 ± 1.98 mGy vs. 9.97 ± 2.27 mGy; $p = 0.76$). More procedures were performed fluoroless following the transseptal puncture in the visualizable SS group (88.0% vs. 16.0%, $p < 0.001$).

Compared to non-visualizable SS, the number of radiofrequency ablations was fewer (69 [58; 80] vs. 79 [73; 86]; $p < 0.01$) as well as total ablation time was reduced (1049 s. [853; 1175] vs. 1265 s. [1085; 1441]; $p < 0.01$) in the visualizable SS cohort. No major complications occurred in either group. We summarized our results in Table 2.

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

TABLE 1 Clinical characteristics of the study population.

	Visualizable steerable sheath group ($n = 50$)	Non-visualizable steerable sheath group ($n = 50$)
Age, years	56.0 ± 17.4	58.2 ± 13.1
Male (%)	40 (80.0)	35 (70.0)
Paroxysmal AF (%)	37 (74.0)	39 (78.0)
Persistent AF (%)	13 (26.0)	11 (22.0)
Hypertension (%)	39 (78.0)	35 (70.0)
Diabetes mellitus (%)	7 (14.0)	10 (20.0)
Prior stroke/TIA (%)	1 (2.0)	2 (4.0)
Heart failure (%)	2 (4.0)	1 (2.0)
Chronic kidney disease (%)	3 (6.0)	4 (8.0)
Left atrial diameter, mm	52.0 ± 10.6	55.0 ± 12.2

AF, atrial fibrillation; TIA, transient ischemic attack.

TABLE 2 Procedural parameters in the study population.

	Visualizable steerable sheath group ($n = 50$)	Non-visualizable steerable sheath group ($n = 50$)	*P-value*
Total procedure time (min)	90 ± 35.2	99.5 ± 31.8	0.97
Left atrial procedure time (min)	53.1 (41.3; 73.1)	59.5 (47.6; 74.1)	0.04
Total fluoroscopy time (s)	184 ± 89	193 ± 44	0.79
Total fluoroscopy dose (mGy)	9.12 ± 1.98	9.97 ± 2.27	0.76
Left atrial fluoroscopy time (s)	0 (0; 0)	17.5 (5.5; 69.25)	<0.01
Left atrial fluoroscopy dose (mGy)	0 (0; 0.27)	0.74 (0.16; 2.34)	<0.01
Fluoroless procedure after transseptal puncture	44 (88.0)	8 (16.0)	<0.001
Acute ablation success (%)	50 (100)	50 (100)	1
Number of radiofrequency ablations	69 (58; 80)	79 (73; 86)	<0.01
Total ablation time (s)	1049 (853; 1175)	1265 (1085; 1441)	<0.01
First pass isolation (%)	92%	89%	0.88
Major complications (n)	0	0	N.A.

n.s., non-significant; N.A., not available.

TABLE 3 Procedural parameters in persistent atrial fibrillation cases.

	Visualizable steerable sheath group (n = 13)	Non-visualizable steerable sheath group (n = 11)	*P-value*
Total procedure time (min)	100 ± 19.0	103 ± 21.5	0.36
Left atrial procedure time (min)	54.8 (44.3; 59.0)	66.9 (50.0; 73.7)	0.23
Total fluoroscopy time (s)	182 ± 52	244 ± 84	0.02
Total fluoroscopy dose (mGy)	14.4 ± 11.2	17.6 ± 12.4	0.43
Left atrial fluoroscopy time (s)	0 (0; 0)	25 (6; 77)	<0.001
Left atrial fluoroscopy dose (mGy)	0 (0; 0)	1.13 (0.16; 1.74)	0.02
Fluoroless procedure after transseptal puncture	11 (84.6)	2 (18.2)	<0.01
Acute ablation success (%)	50 (100)	50 (100)	1
Number of radiofrequency ablations	68 (55; 78)	79 (73; 86)	0.04
Total ablation time (s)	951 (829; 1095)	1265 (1085; 1441)	0.04
First pass isolation (%)	92%	82%	0.44
Major complications (n)	0	0	N.A.

N.A., not available.

visualizable SS group (182 ± 52 s vs. 244 ± 84 s, $p = 0.02$). Data shown in **Table 3**.

Discussion

Catheter ablation for AF is the most frequently performed ablation procedure worldwide. The integration of novel technologies in procedural workflows can help to achieve significant reductions in fluoroscopy exposure and procedural times for PVI. During these procedures, transseptal sheaths are routinely used to reduce procedural time and improve acute and long-term success rate. SSs can improve the contact and stability of the ablation catheter, thus were found superior compared to fixed sheaths (12).

The novel type SS, unlike the standard SS, can be visualized in CARTO3 navigation system with the help of electrodes and the magnetic sensors of the ablation catheter. The visualization of the sheath helps to determine the spatial relationship between the ablation catheter and the sheath during catheter manipulation. However, to date, limited scientific data (only from observation studies) are available evaluating the effect of using visualizable SS for AF ablation procedures.

In an observational study performed by Guo et al. visualizable SS was compared to fixed sheath in patients who underwent PVI procedures for paroxysmal AF, found that the novel type SS for CA reduced radiation exposure, moreover, it significantly improved CF and initial PVI rate. Total procedural time was shorter with the use of visualizable SS, however, left atrial procedural time did not differ between the groups (13).

A recently published observational study by Rajendra et al. compared PVI procedures performed by visualizable SS sheaths vs. a cohort, where no transseptal sheaths were used. They found no difference in clinical effectiveness, however, visualizable SS helped to improve catheter stability and to reduce ablation time, besides, more procedures could be performed without applying fluoroscopy (14).

In our single-centre randomized trial we found that use of visualizable SS reduced left atrial procedural time, left atrial 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 due to the improved catheter stability, however, we did not collect data about contact force values. Importantly, using visualizable 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. Moreover, the use of visualizable SS reduced total fluoroscopy time in persistent AF cases compared to non-visualizable SS group.

During an AF ablation procedure, the average patient fluoroscopy dose approximates 15 mSv, which increases the absolute lifetime risk of fatal cancer for an adult by 0.075% (15). Besides, annual radiation exposure of interventional cardiologists and electrophysiologists may even reach an effective dose of 5 mSv yearly (16). Although this risk can be reduced by applying various forms of radiation protection and the "as low as reasonably achievable" (ALARA) principle, it remains still of great importance. Furthermore, the wearing of lead aprons is associated with a higher rate of work-related musculoskeletal pain (17–19).

The use of EAM systems besides ICE can efficiently help in reducing the radiation exposure without compromising the safety and efficacy of the ablation procedures. With the implementation of visualizable VIZIGO sheath, the fluoroscopy exposure can be reduced effectively, thus it can support to achieve zero- or minimal fluoroscopic AF ablations.

Based on the results of the meta-analysis performed by Huang et al., comparing conventional fluoroscopy vs. low/zero-fluoroscopy PVI procedures, similar clinical efficacy and safety can be reached by the adoption of alternative imaging modalities such as 3D EAM systems, force-sensing ablation catheters and ICE. Moreover, low/zero-fluoroscopy approach was associated with shorter procedure time besides reduced fluoroscopy time and exposure (20). Visualizable SS was not used in either involved studies, however, considering the available scientific data, application of these types of SSs could help in the feasibility of the low/zero-fluoroscopy approach and improve procedural outcomes of PVI procedures.

Limitations

Our results should be interpreted with the careful consideration of the following limitations. Firstly, this was a randomized, single-centre, single-operator study with a limited number of patients enrolled, which may limit its generalizability. Secondly, data about contact force parameters were not available. Finally, our study does not provide data on whether the long-term results are influenced by the type of SS. Multicentre trials are required to assess and to improve clinical outcomes with visualizable SSs.

Conclusion

Compared to the standard, non-visualizable SS, visualizable 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.

Data availability statement

The datasets presented in this article are not readily available because of Hungarian legal regulations. Requests to access the datasets should be directed to PK, peter.kupo@gmail.com.

Ethics statement

The studies involving human participants were reviewed and approved by the Regional Ethics Committee of University of Pécs. The patients/participants provided their written informed consent to participate in this study.

Author contributions

KJ, PK, and TS contributed to the concept and design of the study. PK performed the statistical analysis. KJ, PK, and DD wrote the different sections of the manuscript. DD, BB, and BJ contributed to the data collection and making of the figure and tables. All authors contributed to the manuscript revision, read, and approved the submitted version.

Funding

PK was supported by the ÚNKP-22-4 New National Excellence Program of the Ministry for Culture and Innovation from the source of the National Research, Development and Innovation Fund.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Journal of
Clinical Medicine

MDPI

Article

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

Kristof-Ferenc Janosi, Dorottya Debreceni, Botond Bocz, Dalma Torma, Mark Keseru, Tamas Simor and Peter Kupo *

Heart Institute, Medical School, University of Pecs, 7624 Pecs, Hungary; y0v7wy@tr.pte.hu (M.K.)
* Correspondence: kupo.peter@pte.hu

Abstract: (1) Background: During pulmonary vein isolation (PVI) for atrial fibrillation (AF), multipolar mapping catheters (MMC) are often used. We aimed to compare the procedural outcomes of two MMCs, specifically a circular-shaped and a five-spline-shaped MMC. (2) Methods: We enrolled 70 consecutive patients in our prospective, observational trial undergoing PVI procedures for paroxysmal AF. The initial 35 patients underwent PVI procedures with circular-shaped MMC guidance (Lasso Group), and the procedures for the latter 35 cases were performed using five-spline-shaped MMC (PentaRay Group). (3) Results: No significant differences were identified between the two groups in total procedure time (80.2 ± 17.7 min vs. 75.7 ± 14.8 min, $p = 0.13$), time from femoral vein puncture to the initiation of the mapping (31.2 ± 7 min vs. 28.9 ± 6.8, $p = 0.80$), mapping time (8 (6; 13) min vs. 9 (6.5; 10.5) min, $p = 0.73$), duration between the first and last ablation (32 (30; 36) min vs. 33 (26; 40) min, $p = 0.52$), validation time (3 (2; 4) min vs. 3 (1; 5) min, $p = 0.46$), first pass success rates (89% vs. 91%, $p = 0.71$), left atrial dwelling time (46 (37; 53) min vs. 45 (36.5; 53) min, $p = 0.56$), fluoroscopy data (time: 150 ± 71 s vs. 143 ± 56 s, $p = 0.14$; dose: 6.7 ± 4 mGy vs. 7.4 ± 4.4 mGy, $p = 0.90$), total ablation time (1187 (1063; 1534) s vs. 1150.5 (1053; 1393.5) s, $p = 0.49$), the number of 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, $p = 0.35$). (4) Conclusions: This study finds comparable procedural outcomes bet-ween circular-shaped and five-spline-shaped MMCs for PVI in paroxysmal AF, supporting their interchangeability in clinical practice for anatomical mapping.

Keywords: atrial fibrillation; pulmonary vein isolation; multipolar mapping catheter; catheterablation

Citation: 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. *J. Clin. Med.* **2024**, *13*, 1029. https://doi.org/10.3390/jcm13041029

Academic Editors: Vidal Essebag, Ahmed AlTurki and Christian Sohns

Received: 28 December 2023
Revised: 27 January 2024
Accepted: 9 February 2024
Published: 11 February 2024

1. Introduction

Atrial fibrillation (AF) is known as the most common cardiac arrhythmia, affecting over 40 million people worldwide [1]. As per the recent guidelines from the European Society of Cardiology (ESC) on managing AF, the main purpose of opting for a rhythm control strategy is to ease AF-related symptoms and improve overall quality of life [1]. Catheter ablation for AF is deemed more effective than antiarrhythmic drugs (AAD) in sustaining sinus rhythm [2–4]. During catheter ablation treatment for AF, electrical isolation of the pulmonary veins (PV) is considered as the cornerstone of the procedure [1,5].

Multiple techniques exist for pulmonary vein isolation (PVI). The prevalence of AF ablations utilizing pulsed field ablation (PFA) techniques is on the rise [6,7], with available options including single-shot cryoenergy and radiofrequency (RF) devices [5,8]. Nevertheless, the globally predominant approach remains point-by-point radiofrequency (RF) ablation [8].

The guidance for point-by-point PVI procedures is facilitated by electroanatomical mapping systems (EAMS). After transseptal puncture, obtaining an electroanatomical map of the left atrium becomes pivotal for the ablation process.

MMCs are extensively employed in these procedures, offering supplementary insights into left atrium geometry creation, voltage mapping, complex fractionated atrial electrograms, validation of isolated pulmonary veins, and identification of reconnected or atrial fibrotic regions. Notably, they play a pivotal role in reducing both mapping and fluoroscopy time significantly [9–12]. Furthermore, their utility extends to facilitating the achievement of zero-fluoroscopy approach during PVI procedures [13].

Several multipolar mapping catheters are available in the clinical practice with different shapes, sizes, and electrode conformation, and most of them are widely used in cases of redo PVIs, left atrial focal tachycardias, and in macro-reentrant tachycardias; however, there is a lack of data referring the utilization of the PentaRay^{TM} NAV in de novo PVIs. In this prospective study, our objective was to assess and compare the procedural outcomes of two frequently employed mapping catheters integrated into the CARTO 3 EAMS (Biosense Webster Inc., Irvine, CA, USA) for PVI procedures. Specifically, we examined the PentaRay^{TM} NAV multielectrode catheter (Biosense Webster Inc., Irvine, CA, USA), characterized by five soft, radiating spines, and the circular-shaped LASSO^{TM} NAV catheter (Biosense Webster Inc., Irvine, CA, USA) which are equipped with 20 electrodes each (Figure 1).

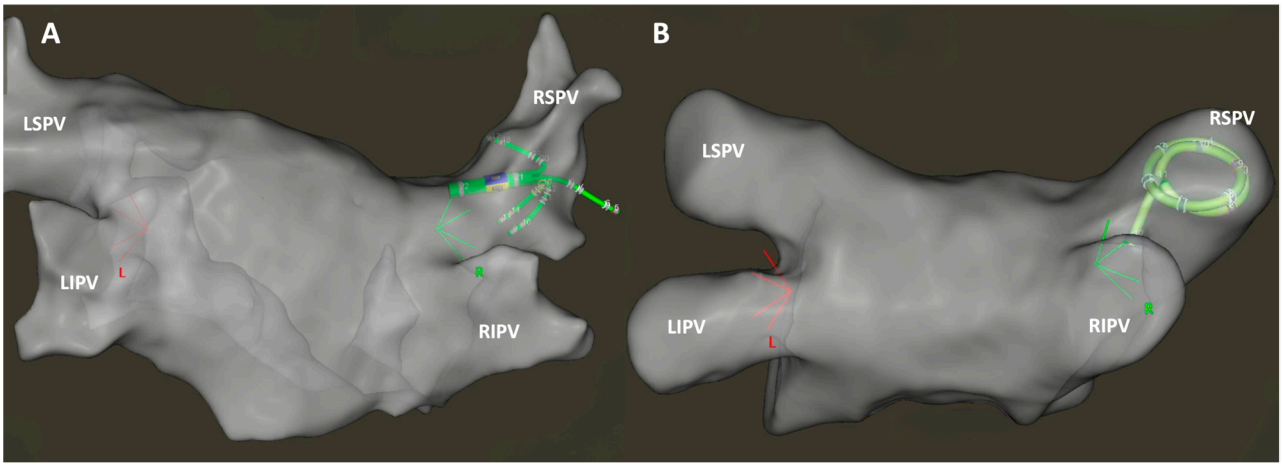

Figure 1. Anatomical map of the left atrium in a posteroanterior view, generated using the CARTO 3 electroanatomical mapping system. The map was created with the five-spline-shaped PentaRay^{TM} NAV catheter (**A**) and the circular-shaped LASSO^{TM} NAV multipolar mapping catheter (**B**). Both the LASSO and PentaRay catheters are positioned in the right superior pulmonary vein. Abbreviations: LIPV—left inferior pulmonary vein; LSPI—left superior pulmonary vein; RIPV—right inferior pulmonary vein; RSPV—right superior pulmonary vein.

2. Materials and Methods

2.1. Study Patients

In our prospective, observational trial, 70 consecutive patients undergoing PVI procedures for paroxysmal AF between November 2022 and July 2023 were enrolled. No sample size calculation was performed. Exclusion criteria encompassed (a) prior PVI procedures; (b) supplementary ablations extending beyond PVI, including both left and right atrial ablations; and (c) individuals below 18 years of age. We categorized the enrolled patients into two groups according to the type of MMC catheter employed during the ablation. The initial 35 patients, between November 2022 and March 2023, underwent PVI procedures with LASSO^{TM} NAV guidance (Lasso group). Subsequently, in cases 36–70, between April 2023 and July 2023, the PentaRay^{TM} NAV catheter was utilized for electroanatomical mapping due to the unavailability (i.e., backorder on the part of the manufacturer) of LASSO^{TM} NAV catheters (PentaRay group).

All procedures were conducted by the same expert electrophysiologist. The trial protocol adhered to the principles of the Declaration of Helsinki. The study protocol

received approval from the Regional Ethics Committee (Approval No.: 9409/2022; Date: 18 November 2022). Written informed consent for participation was obtained from all patients.

2.2. Study Protocol

During the procedures, conscious sedation was induced using fentanyl ± midazolam after 12 h continuous fasting. Following local anesthesia, a decapolar steerable catheter (Dynamic Deca, Bard Electrophysiology, Lowell, MA, USA) was placed in the coronary sinus after vascular ultrasound-guided femoral venous puncture. Then, a single transseptal puncture guided by intracardiac echocardiography (ICE) was performed via SL0 (Abbott Laboratories, Chicago, IL, USA). From a distinct femoral venous puncture, the steerable 8.5-Fr-long sheath (VIZIGO, Biosense Webster Inc., Irvine, CA, USA) was directed to the superior vein cava, gently retracted, and secured against the intra-atrial septum. Subsequently, with the sheath's guidewire penetrating the left atrium under fluoroscopic and/or ICE guidance, the VIZIGO was advanced over the initial transseptal puncture alongside the SL0 sheath. This sliding technique resulted in an SL0 and a VIZIGO sheath in the left atrium. Then, a MMC (either LASSO™ NAV or PentaRay™ NAV) was introduced into the left atrium via SL0. Additionally, a contact force (CF)-sensing radiofrequency (RF) ablation catheter (Navistar Thermocool SmartTouch ST NAV, Biosense Webster Inc., Diamond Bar, CA, USA) was positioned in the left atrium through a VIZIGO steerable sheath. A fast anatomical mapping of the left atrium was conducted with the MMC catheter, supported by the CARTO3 EAMS. No other mapping points were collected and analyzed other than an anatomical map. The ablation catheter operated in a power-controlled mode with a maximum power of 45 W for the anterior and 40 W for the posterior wall, employing a maximum temperature of 43 °C.

During RF ablations, the CARTO VISITAG™ Module was employed with a minimum stability time of 4 s and a maximum location stability range of 2.5 mm. The Visitag Surpoint (ablation index) was utilized with targets set at 350 for the posterior wall and 450 for the anterior wall. The target interlesion distance was maintained below 5 mm. The point-by-point ablation technique was applied, with real-time monitoring of CF and impedance. CF was maintained between 5 and 15 g during the ablation process.

To blind the operator from the presence or absence of first-pass isolation during ablations, the MMC catheter was positioned in the contralateral PVs. Intravenous unfractionated heparin was administered immediately after the femoral vein punctures, and an activated clotting time of >300 s was sustained throughout the entire procedure. The procedural endpoint of the ablation was considered achieved when all PVs were isolated.

2.3. Procedural Outcomes

The primary endpoint of this study was the procedure time, defined as the duration from the initial femoral vein puncture to the removal of the catheters. Additionally, various time intervals were compared, including the duration between femoral vein puncture and the beginning of mapping, mapping time, time between the first and last RF applications, validation time, and left atrial dwelling time. The first pass success rate, the number of RF applications, and the total RF time were also calculated. Mapping time was measured from the conclusion of the transseptal puncture until the initiation of the first RF ablation. Left atrial dwelling time was determined from the conclusion of the transseptal puncture until the withdrawal of sheaths from the left atrium.

Fluoroscopy time and radiation dose were automatically recorded by the fluoroscopy system. The RF generator (SMARTABLATE System, Biosense Webster Inc., Diamond Bar, CA, USA) documented the total number of RF applications and the overall ablation time.

The occurrence of major complications, such as vascular complications, pericardial effusion, cardiac tamponade, stroke, or atrio-esophageal fistula, was systematically assessed throughout the entire hospitalization and the periprocedural period.

2.4. Statistical Analysis

The data underwent analysis based on their conformity to normal distribution through the application of the Kolmogorov–Smirnov goodness-of-fit test. Continuous data were expressed using either the mean ± standard deviation (SD) or median (interquartile range, IQR), as deemed suitable. Categorical variables were represented by absolute numbers and corresponding percentages. Comparative assessments employed the chi-square test, *t*-test, and Mann–Whitney U test, as applicable. A significance threshold of $p < 0.05$ was employed for all statistical evaluations. The statistical analyses were executed using SPSS 28 software (SPSS, Inc., Chicago, IL, USA).

3. Results

Seventy patients were prospectively included. For the initial 35 patients, mapping and validation were conducted using a LASSO™ NAV catheter (Group Lasso), whereas for patients 36–70, a PentaRay™ NAV catheter was employed (Group PentaRay). No statistically significant differences were observed in the baseline characteristics of the study population between the two groups, including male sex distribution (Lasso: 80% vs. PentaRay: 74%, $p = 0.57$) and age (68.6 (58.7; 71.5) vs. 66.5 (50.6; 73.5), $p = 0.36$), as detailed in Table 1.

Table 1. Baseline characteristics. Abbreviation: TIA—transient ischemic attack.

	Group Lasso (*n* = 35)	Group PentaRay (*n* = 35)	*p* Value
Male, *n* (%)	28 (80)	26 (74)	0.57
Age, y	68.6 (58.7; 71.5)	66.5 (50.6; 73.5)	0.88
Hypertension, *n* (%)	28 (80)	28 (80)	1.0
Heart failure, *n* (%)	5 (14.3)	6 (17.1)	0.74
Coronary artery disease, *n* (%)	5 (14.3)	8 (22.9)	0.36
Diabetes mellitus, *n* (%)	8 (22.9)	7 (20.0)	0.77
Chronic kidney disease, *n* (%)	6 (17.1)	7 (20.0)	0.76
Prior stroke/TIA, *n* (%)	1 (2.9)	5 (14.3)	0.09
Left atrial diameter, mm	54.5 ± 8.1	52.9 ± 7.8	0.18

No significant differences were identified between the two groups in various procedural time metrics. Specifically, there were no differences in total procedure time (Group Lasso: 80.2 ± 17.7 min vs. Group PentaRay: 75.7 ± 14.8 min, $p = 0.13$). In addition, the time from the femoral vein puncture to the initiation of the mapping (31.2 ± 7 min vs. 28.9 ± 6.8, $p = 0.80$) was similar between the groups. Likewise, comparable findings were observed for 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 the time required for validation (3 (2; 4) min vs. 3 (1; 5) min, $p = 0.46$). First pass success rates were also equal regardless the type of MCC used (89% vs. 91%, $p = 0.71$).

Regarding the left atrial dwelling time (46 (37; 53) min vs. 45 (36.5; 53) min, $p = 0.56$) and fluoroscopy data (time: 150 ± 71 s vs. 143 ± 56 s, $p = 0.14$; dose: 6.7 ± 4 mGy vs. 7.4 ± 4.4 mGy, $p = 0.90$), no significant differences were identified between the two groups. Additionally, the total ablation time (1187 (1063; 1534) s vs. 1150.5 (1053; 1393.5) s, $p = 0.49$), the 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, $p = 0.35$) did not reveal any significant differences between the two groups. Results are summarized in Table 2.

Table 2. Procedural data and outcome. Abbreviation: NA—not applicable.

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

4. Discussion

In our prospective, single-centre, observational trial comparing LASSO™ NAV and PentaRay™ MMCs, we identified no discernible differences in mapping, ablation, or fluoroscopy data among patients undergoing PVI for paroxysmal AF.

PVI is considered the gold standard technique in AF catheter ablation. While various ablation techniques can potentially achieve electrical isolation of the PVs, point-by-point RF PVI remains the most frequently employed method [8].

These procedures are guided by an EAMS, providing insights into both the left atrial anatomy and the localization of RF lesions [14]. In the context of point-by-point PVI procedures, a pivotal aspect involves generating the anatomical map of the left atrium, facilitated by either MMCs or the ablation catheter.

The initial experiences utilizing an MMC in PVI guided by EAMS were published in 2008, employing the PentaRay™ NAV catheter with the EnSite EAM system [15]. Subsequently, the use of MMCs demonstrated superiority in PVI procedures compared to point-by-point contact mapping with the ablation catheter alone [10,16,17]. These advantages arise from the influence of interelectrode spacing and electrode size on mapping time and resolution. Smaller electrodes with closer interelectrode spacing can enhance mapping resolution and expedite mapping time. Bun et al. observed a quicker mapping time and the acquisition of more mapping points in left atrial tachycardia ablation with the PentaRay™ NAV catheter compared to the conventional approach using the ablation catheter alone [17]. Moreover, in a study involving 30 patients with scar-related atrial arrhythmias, mapping with the PentaRay™ NAV MMC improved mapping resolution in the scarred area compared to 3.5 mm electrode-tip linear ablation catheters [10]. Correspondingly, using the LASSO™ NAV MMC proved beneficial compared to point-by-point mapping in patients undergoing repeat AF ablation procedures, particularly in left atrial scar mapping [16].

The novel 48-electrode, eight-spline design Octaray ™ MMC (Biosense Webster Inc., Diamond Bar, CA, USA) has been shown to have an increased mapping speed and number of electrograms acquired, and was more accurate in identifying intact ablation lines compared to the PentaRay™ NAV catheter in animal models [18].

The role of MMCs in the identification of atrial scar remains crucial; however, results in targeting low-voltage areas for a substrate-based ablation strategy beyond PVI are controversial [19–25]. In an ERASE-AF multi-center randomized clinical trial, Huo et al. found that PVI along with substrate modification was superior to PVI only in arrhythmia recurrences for the treatment of patients with persistent AF [19]; however, in a CAPLA randomized clinical trial including 338 patients undergoing catheter ablation for persistent AF, additional ablations beyond PVI did not significantly improve freedom from AF at a 12-month follow-up [23]. Furthermore, a systematic review and meta-analysis by Jia et al. including fourteen studies showed that patients in whom scarred atrial tissue was targeted had an even higher AF recurrence rate and did not have improved outcomes compared to PVI only [25].

In contrast to the LASSO™ NAV catheter, the five-spline design of the PentaRay™ NAV can be helpful in acquiring geometry in case of smaller pulmonary veins, which may be difficult to enter with the circular design of the LASSO™ NAV. Furthermore, the splines of the PentaRay™ NAV can visualize when the catheter is pressed against the wall of the atrium, helping avoid overestimation of the anatomy and acquiring a more accurate anatomical mapping. However, despite these advantages for the PentaRay™ NAV catheter, it did not influence the procedural outcomes of PVI in our study.

5. Study Limitations

There are several limitations that need to be acknowledged. The trial was conducted at a single center, potentially limiting the generalizability of the findings to broader patient populations with varying demographic and clinical characteristics. The sample size of 70 patients might limit the statistical power, especially for detecting subtle differences between the two groups. Larger sample sizes would enhance the reliability of the findings and enable a more precise assessment of the comparability between the two catheter types. All procedures were performed by a single expert electrophysiologist, introducing the possibility of operator-specific influences on the outcomes. The results may not be universally applicable, and variations in operator skill and experience could impact the reproducibility of the findings in different clinical settings. The second group of patients, in which the PentaRay™ NAV catheter was employed, were treated later than the LASSO™ NAV group; therefore, it is not possible to rule out the potential for bias in terms of the operator's experience. Finally, this study is not randomized, which could carry the potential for selection bias and difficulties in controlling confounding variables that might influence the outcomes.

6. Conclusions

In this prospective observational trial 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.

Author Contributions: Conceptualization, P.K. and K.-F.J.; methodology, P.K.; software, P.K.; validation, K.-F.J., T.S. and D.D.; formal analysis, P.K.; investigation, P.K., K.-F.J. and D.D.; resources, M.K., D.T. and B.B.; data curation, M.K., B.B. and D.T.; writing—original draft preparation, K.-F.J.; writing—review and editing, P.K. and D.D.; visualization, K.-F.J.; supervision, T.S. and P.K.; project administration, P.K. and K.-F.J.; funding acquisition, P.K. All authors have read and agreed to the published version of the manuscript.

Funding: PK was supported by the ÚNKP-22-4 New National Excellence Program of the Ministry for Culture and Innovation from the source of the National Research, Development and Innovation Fund (ÚNKP-23-4-II-PTE-2156).

Institutional Review Board Statement: The trial protocol adhered to the principles of the Declaration of Helsinki. The study protocol received approval from the Regional Ethics Committee (Approval No.: 9409/2022; Date: 18 November 2022).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to Hungarian legal regulations.

Acknowledgments: We extend our appreciation to Zoltan Bagoly for his indispensable aid in technical assistance and the extraction of data.

Conflicts of Interest: The authors declare no conflicts of interest.

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