

# FEASIBILITY, SAFETY AND COST EFFECTIVENESS OF SAME-DAY DISCHARGE FOR CATHETER ABLATION REQUIRING A TRANSSEPTAL PUNCTURE: A FRENCH SINGLE HIGH-VOLUME CENTER EXPERIENCE

## SAME-DAY DISCHARGE FOR LEFT-SIDED CATHETER ABLATION

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### ABSTRACT

**Background:** The number of catheter ablations requiring a transseptal puncture is increasing. These procedures have a significant complication rate that decreased over recent years. As a result, we have developed a same-day discharge protocol and this study investigates the safety and efficacy of this protocol.

**Methods:** This single center study evaluated the complication rate following the index procedure for patients undergoing left-sided accessory pathway, atrial fibrillation (AF) or left sided premature ventricular contraction (PVC) ablation using a transseptal puncture with a same-day discharge protocol. In addition, the cost-effectiveness of the protocol was evaluated.

**Results:** From November 2015 to March 2020, 2654 ablations in the left cardiac cavities requiring a transseptal puncture were performed. Among them, 121 (4.6%) patients followed the same-day discharge protocol. Strict inclusion criteria (mainly low comorbidities) were applied for patients undergoing AF ablation. We used a single catheter approach to perform AF and PVC ablation. After 10 days and a specific follow-up, we observed 1 cardiac tamponade (0.8%) and 3 arrhythmia recurrences (2.5%). There were no deaths, local vascular complications or stroke. The night stay cost of 900€ could be saved for the same-day strategy compared to conventional care but the global balance was still negative at -917€ for the hospital.

**Conclusion:** A same-day discharge protocol for patients undergoing left sided catheter ablation requiring a transseptal puncture is feasible and safe. However, this strategy is not cost-effective in France despite a single catheter approach for AF ablation highlighting the need for improved reimbursements.

**Key words:** catheter ablation, transseptal puncture, same-day discharge

## INTRODUCTION

Catheter ablation (CA) has gained increased popularity in treating cardiac arrhythmias (1). Some CA procedures including left sided accessory pathway ablation, left premature ventricular contractions (PVCs) ablation or atrial fibrillation (AF) ablation, require access to the left cardiac cavities that can be achieved via an atrial transseptal puncture. Notably, the number of AF ablation procedures performed worldwide has increased significantly over recent years and, the transseptal puncture required to perform these procedures can be associated with serious complications such as tamponade, stroke or vascular complications (2).

Over the last decade, left sided CA techniques have improved significantly, resulting in a decrease in procedural-related complications. This has been achieved in part due to improved monitoring of the transseptal puncture, technology advancements such as more accurate 3D mapping systems and the use of contact force ablation catheters. This has resulted in electrophysiological procedures becoming safer and with reduced procedure times.

More recently same-day discharge strategies to perform left sided CA procedures have been proposed with an acceptable efficacy and safety profile.

In addition, to utilizing a same day discharge protocol we further simplified many of these procedures having developed a single catheter approach to perform AF (3), PVCs and cavo-tricuspid isthmus (CTI) ablation (4).

The aim of this study is to evaluate the same-day discharge protocol in our center in terms of safety and cost effectiveness.

## METHODS

### Patient selection and ablation procedure

One hundred and twenty-one patients listed for left sided CA were prospectively included in this single center study from November 2015 to March 2020. Patients were recruited at the Institut Mutualiste Montsouris, Paris. From November 2015 patients undergoing left sided accessory pathway ablation or PVC ablation were included and from July 2019 AF ablation patients were enrolled. Due to the potential comorbidities amongst the AF ablation cohort, the same-day discharge protocol was restricted with the following inclusion criteria: non-valvular paroxysmal lone AF with EHRA guidelines ablation indication; planned intervention: pulmonary vein isolation (PVI), +/- CTI line for patients with documented right common flutter; age > 18 years and < 75 years. Exclusion criteria were: left ventricular ejection fraction (LVEF) < 50% ; body mass index (BMI) > 35 kg/m<sup>2</sup> ; CHA<sub>2</sub>DS<sub>2</sub>-VASC score > 3 ; lack of consent capacity ; associated antiplatelet therapy ; severe chronic respiratory failure ; home located more than 45 minutes drive away from the hospital ; patient alone at home the night after the procedure. This study complied with the declaration of Helsinki and was approved by our institutional ethics review board. Baseline patient characteristics, periprocedural data and follow-up data were obtained from patient medical records. Intra-procedural complications were adjudicated by 2 physicians (Dr Sebag and Dr Mignot). Importantly, the first operator for all ablation procedures was a senior physician.

### Ablation procedure and follow-up

Informed consent was obtained for all patients and the procedure was scheduled after 4 to 6 hours of fasting. All same day discharge protocol procedures were scheduled to start at 08:00 AM and performed under general anesthesia or deep sedation using intravenous propofol administered by a nurse specialist.

For the femoral vein puncture, the use of the ultrasonography was left at the discretion of the operator. For left sided accessory pathway ablations, the use of a 3D mapping system was left at the discretion of the operator. However, all left PVCs and AF ablation procedures were performed using the CARTO 3 system (Biosense Webster, Irvine, CA, USA).

Transseptal puncture was systematically performed with transoesophageal echocardiography (TEE) guidance. Following transseptal access, a single bolus of 100 UI/kg body weight of heparin was administered with

repeated doses if required to maintain an ACT >300s. For AF ablation procedures, oral anticoagulation (OAC) was continued without interruption.

A 3.5 mm externally irrigated-tip ablation catheter using contact force (SmartTouch SF Thermocool; Biosense Webster) was used for all mapping and ablation. Importantly, for AF and CTI ablation, a single catheter approach was used systematically according to the CLOSE protocol (5, 6). Briefly, a circle around the pulmonary veins (PVs) was performed with the Carto 3 System® (Biosense Webster, Irvine, CA, USA). Ablation was delivered point-by-point during sinus rhythm to form a contiguous circle enclosing the PVs. For CTI ablation, the same protocol was used. Real-time automated display of RF applications (Visitag®, Biosense Webster Inc.) was used with predefined settings of catheter stability (3 mm for 8 s) and minimum CF (30% of time >4 gr). Radiofrequency (RF) was delivered until an ablation index (AI) of  $\geq 350$  was achieved at the posterior left atrial wall/roof or  $\geq 430$  at the anterior left atrial wall and CTI. Once the target AI was reached, the RF application was terminated, and the catheter was moved to the adjacent spot. In case of instability resulting in an RF tag not reaching the target AI, a new RF application reaching the AI target was applied. The maximal authorized distance between two lesion points was  $\leq 6$  mm. To assess PV entrance block, pacing was performed from the distal dipole of the ablation catheter at 4 equidistant antral sites with CF  $\geq 10$ g. The pacing output of 10mA at 2ms was reduced to 5mA at locations adjacent to structures such as the LA appendage or superior vena cava, in order to avoid far-field capture. The antrum was designated as disconnected in the absence of LA capture at all pacing sites (based on the P wave of the surface ECG). For CTI ablation, bidirectional block was confirmed when the PR interval difference measured during atrial pacing between the lateral and the septal side of the ablation line was greater than 70 ms (4). For left PVC ablation, the single catheter approach was also used and for left sided accessory pathway ablation an additional decapolar catheter was positioned within the coronary sinus, Xtrem, (Microport, Le Plessis Robinson, France).

RF energy was delivered with power up to 25-30 W using irrigation rates of 7 mL/min (0.9% saline via Cool Flow, Biosense-Webster) or more to achieve the desired power delivery. Temperature was limited to 45°C.

Post-procedure, all catheters and sheaths were removed and manual groin compression was applied until complete vascular haemostasis was achieved. A femoral compression pad was subsequently applied for 24 hours. This pad was removed at home by a nurse the day after the procedure.

Patients were allowed to stand up 4 hours post-procedure and underwent a systematic nursing evaluation including heart rate, blood pressure and ECG for 6 hours. Post-procedural transthoracic echocardiography (TTE) was performed if patients presented with symptoms such as dyspnoea or chest pain. All patients were contacted by telephone the day following the procedure to assess for any complications (palpitations, shortness of breath, chest pain, bleeding, cough). All patients were screened for the following complications: femoral vascular complication, stroke or tamponade, or any clinical visit or rehospitalization within the 10 days following the index procedure.

Early arrhythmia recurrences were managed in the community with a loading dose of antiarrhythmic drugs (AAD) (amiodarone or flecainide).

### **Cost analysis**

In France, the ablation procedure performed in a medical institution does incur a reimbursement from the state to the hospital. The amount of this reimbursement depends on the severity and the comorbidities of the patient and the type of intervention. This amount is intended to cover the materials and the medical and paramedical personnel cost, pertaining to the ablation. We calculated, according to the cost of the left sided procedures and the mean reimbursement of the procedure, the cost of the same-day discharge left sided ablation and compared it to the cost of the same procedure performed in patients adding one or two nights stay in the cardiology unit (standard of care), to evaluate the cost saving of the same-day discharge protocol and the global balance of these procedures.

### **Statistics**

Descriptive results are displayed as mean $\pm$ SEM or median (interquartile range) for continuous variables, according to the normality of the distributions. Categorical variables are described as numbers (percentage).

## **RESULTS**

### **Baseline Characteristics**

Within the study period, a total of 3923 ablations were performed of which 2654 were in the left cardiac cavities requiring a transseptal puncture. As shown in Table 1, 121 patients (4.6%), were included in the day case discharge protocol with a mean age of  $42 \pm 16$  years. All patients had one ablation within our analysis. The main ablation indications were left sided accessory pathway (83 patients, 69%) followed by AF ablation in 33 patients (27%), left atrial tachycardia in 2 (%) patients and left PVC ablation in 3 (%) patients. The drug therapies at baseline are presented in Table 1. Importantly, all patients listed for AF ablation received oral anticoagulation (OAC) for a minimum of 2 months prior to the procedure as recommended in current guidelines (1). In 2019, we performed 648 AF ablation procedures, of whom 18 patients (3%) underwent the same-day discharge protocol. The mean ablation procedure duration and fluoroscopy times were relatively short at 86 min and 4.2 min, respectively.

### Procedure complications

In this study, all complications and reasons for consultation or rehospitalization within 10 days post-procedure were recorded (Table 2 and 3). One patient undergoing left PVC ablation suffered an acute tamponade, necessitating surgical drainage during the procedure. Two patients had early arrhythmia recurrences treated successfully with AAD. No other complications were noted. Post-discharge, 1 patient consulted for arrhythmia recurrence after a left sided accessory pathway ablation and was managed with AAD. One patient consulted for chest pain attributed to a post-RF pericarditis without pericardial effusion confirmed with TTE and was treated successfully with non-steroid anti-inflammatory medication. Finally, 2 patients were consulted for anxiety as no organic disease was observed after clinical examination, ECG and TTE and the patients were reassured prior to home discharge. No patients were re-hospitalized within the 10 days following the same-day discharge protocol.

### Cost-analysis

We evaluated the global cost of the EP procedure for patients treated with the same-day discharge protocol. As shown in Table 4, the amount of the reimbursement from the state to the hospital in France is identical whether the patient is admitted overnight post-procedure or not. This amount is 5875 euros per patient. The cost of the ablation catheter and 3D mapping patches are fixed at 4078 euros. For patients admitted to the hospital post-procedure the mean cost of the admission is 900 euros (1 or 2 nights stay). Finally, the global cost of the paramedical and medical personnel necessary for the procedure and in-hospital stay is estimated at 2714 euros. The total cost for the same-day discharge strategy is 6792 euros compared to the conventional overnight care of 7692 euros. Finally, the balance is negative for both strategies, -917 euros for the same-day discharge protocol and -1817 euros for the conventional overnight care.

## DISCUSSION

The main findings of this study are: 1) The same-day discharge protocol is feasible and safe for patients undergoing left sided ablation requiring a transseptal puncture; 2) Even when using a single catheter ablation approach, these procedures have a negative cost balance in France.

Over the past years, CA has importantly increased in popularity particularly due to the clinical benefits reported with AF ablation. Electrophysiologists have been well versed in performing transseptal punctures for left sided accessory pathway ablation with complications rates falling. However, the procedures requiring transseptal puncture can be associated with potential serious complications including stroke, pericardial effusion, tamponade and local vascular complications such as hematoma or fistula (2, 7). Numerous tools have been developed to reduce the risk of these complications: ultrasonography for femoral vascular access, improvements in 3D mapping systems with the benefits of contact force data, the monitoring of the transseptal puncture with echocardiography and the management of anticoagulation during the ablation. This has resulted in the rates of these complications drastically decreasing over the last few years.

In parallel, the same-day discharge protocol has been proposed for numerous procedures in interventional cardiology and electrophysiology. Initially, these procedures were mainly right sided ablations. Indeed Marijon et al (8) evaluated the feasibility and the safety of the same-day discharge protocol in 1270 patients undergoing right sided ablations including common flutter, AVNRT or AV node ablation. After one month follow-up, no death occurred and the readmission rate was low at 0.79%. However, recently the same-day discharge protocol was also applied for patients undergoing transseptal puncture and particularly AF ablation. Theodoreson et al (9) reported the outcomes of 897 patients undergoing 921 ablations, of which, 119 had transseptal puncture, almost exclusively for left sided accessory pathway ablation. They found a 3.4% rate of total complications, 0.8% of tamponade and 1.7% of femoral bleeding. Few other studies have evaluated more specifically the prognosis of patients with same-day discharge protocol during AF ablation, which has become the most frequent ablation

procedure performed in everyday practice. This procedure potentially comes with a greater risk of complications due to the potential comorbidities associated with AF patients and due to the management of OAC peri-procedure. Nowadays, most electrophysiological centers are performing AF ablation with uninterrupted or minimally interrupted OAC. The safety of this strategy has been established by numerous studies (10, 11). Notably, the strategy of uninterrupted OAC during AF ablation is systematic for our patients.

Due to these potential complications, we reserved the same-day discharge protocol for very low risk thrombotic and hemorrhagic patients and excluded most of them (97%). With these restrictions, our complication rates were very low with a 0.8% tamponade, 0% death, stroke or femoral vascular complications. In addition, most of the clinic consultations following our procedures were due to arrhythmia recurrences that were managed with AAD therapy. Interestingly, 2 patients in our study experienced significant anxiety leading to medical consultation. This highlights the importance that for the same day discharge protocol patients require sufficient explanations and reassurances of the potential complications and advice regarding warning signs that should trigger immediate consultation. It is also reassuring within our practice to have this systematic telephone contact with these patients within the days following the procedure.

Other studies have evaluated the application of the same-day discharge protocol for a wider population of patients undergoing AF ablation. Bartoletti et al (12) evaluated 169 AF ablation discharges the same-day of the procedure from 2014 to 2017. Their complication rate was slightly higher than in our study with 0.7% transient right phrenic nerve palsy, 3.5% minor complications and 2.1% rehospitalization. In our study, no patients were rehospitalized after the ablation procedure. This discrepancy could be due to the single catheter approach which we applied in our study and with the systematic use of a 3D mapping system combined with our more restrictive indication for AF ablation. Finally, Deyell et al (13) recently published a larger study evaluating AF ablation patients with the same-day discharge protocol. In this study, 2418 patients underwent AF ablation from 2010 to 2014. Of note, 79% of AF ablation procedures were performed with the same-day discharge protocol, including more patients with higher comorbidities compared to our more selected population. The readmission rate was relatively high at 7.7%. We propose that each center should decide which AF patients could be candidates for the same-day discharge protocol highlighting that if practitioners select patients with more established AF substrate and comorbidities one may observe a higher complication rate with more hospital readmissions.

In France, the procedure reimbursement from the state to the hospital is dependent on the type of intervention, the comorbidities of the patient and potential post-procedural complications. Indeed, if the patient has numerous comorbidities or develops complications post-procedure, the reimbursement significantly increases. However, this reimbursement for the same-day strategy protocol or patients with fewer comorbidities is identical for left-sided ablations requiring a transseptal puncture. Furthermore, using a single catheter ablation approach, as in our center, for almost all AF or PVC ablations and a saving night stay cost of 900 euros, the balance is still negative for hospitals in France. However, these interventions are still performed and established within our health care system, in accordance with our administration. This is likely justified by the fact that the negative balance observed with left-sided catheter ablation is counterbalanced by other EP procedures that have a high positive balance, such as pacemaker implantation or simple ablations such as atrio-nodal or right common flutter ablation. This also highlights that the expected development of the same-day discharge protocol for these procedures in the future should be associated with a reimbursement increase in France that is still under debate.

Our study has several limitations including the single center evaluation. No control group with a standard of care was included to compare the complication rate. Our follow-up was short (10 days) and we are currently increasing our number of patients treated with the same-day discharge protocol with a longer follow-up duration. Finally, the same-day discharge is a major priority for the French government and we are expecting a reevaluation of this reimbursement in the near future to further develop this strategy.

## CONCLUSION

Same-day discharge protocol after left-sided ablation with transseptal puncture is feasible and safe in a high-volume ablation center. However, this strategy is not cost-effective in France even when using a single catheter approach for AF ablation.

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Table 1: Patient's baseline characteristics

<b>Patient characteristics</b>	All patients n=121
<b>Age, years</b>	42±16
<b>Male gender, n (%)</b>	79(65)
<b>Risk factors, n (%)</b> Hypertension Diabetes mellitus Dyslipidemia	12 (10) 0 (0) 3 (2)
<b>Cardiovascular history, n (%)</b> Coronary artery disease Other cardiomyopathy	1 (0.8) 2 (1.6)
<b>Type of ablation</b> Left sided accessory pathway n (%) AF ablation n (%) Left AT/flutter n (%) Left PVCsn (%)	83 (69) 33 (27) 2(2) 3 (2)
<b>Drugs at baselinen (%)</b> Flecainide Betablockers Sotalol Amiodarone Calcic Inhibitors VKA NOAC Aspirine	35 (29) 28 (23) 5 (4) 4 (3) 6 (5) 0 (0) 33 (27) 5 (4)
<b>Procedural data</b>  Procedure time (min) Fluoroscopy time (min) Fluoroscopy dose (cGy/cm <sup>2</sup> )	  86±32 4.18±4.76 2.41±4.17

**Table 2: Complications following the procedure (within 10 days following the procedure)**

	All patients n=121	Index Procedure
Tamponade n, (%)	1 (0.8)	Left PVCs
Femoral Hematoma n, (%)	0	
Acute Stroke n, (%)	0	
Arrhythmia recurrences n, (%)	2 (1.6)	2 Left sided accessory pathways

**Table 3. Causes of early consultation or rehospitalisation**

	All patients n=121	Index procedure
Arrhythmia recurrences	1 (0.8)	Left sided accessory pathway
Femoral Hematoma n, (%)	0	
Acute Stroke n, (%)	0	
Chest pain n, (%)	1 (0.8)	Left sided accessory pathway
Anxiety n, (%)	2 (1.6)	2 left sided accessory pathways

**Table 4. Cost analysis of the same-day discharge vs. conventional care**

	Same-day discharge	Conventional care
<b>Mean reimbursement to the hospital (euros)</b>	5875	5875
<b>Procedural cost: Smart Touch catheter ablation + patch cost (euros)</b>	4078	4078
<b>Mean night stay cost (euros)</b>	0	900
<b>Global cost of the paramedical and medical personal (euros)</b>	2714	2714
<b>Total cost (euros)</b>	6792	7692
<b>Balance</b>	<b>-917</b>	<b>-1817</b>



