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Safety of uninterrupted direct oral anticoagulant versus uninterrupted vitamin-K antagonist for ambulatory atrial flutter catheter ablation: a propensity score-matched cohort study

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Année 2018/2019

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DU GRADE DE DOCTEUR EN MÉDECINE

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Safety of uninterrupted direct oral anticoagulant versus uninterrupted vitamin-K antagonist for ambulatory atrial flutter catheter ablation: a propensity score-matched cohort study.

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Abréviations

APT = antiplatelet therapy;

BMI = body mass index;

CAF = common atrial flutter

CKD = chronic kidney disease;

DOA = direct oral anticoagulant;

INR = international normalized ratio;

IV = intravenous;

LMWH = low molecular weight heparin;

o.d. = once daily;

RF = radiofrequency;

t.d. = twice daily;

VKA = vitamin-K antagonist

Tableaux et figures

Table 1

<u>Demographics</u>		
Age, year-old		67 ± 11
Male gender, n (%)		784 (80)
BMI, kg/m ²		28 ± 7
Obesity, n (%)		234 (24)
<u>Thromboembolic and bleeding risks</u>		
CHA ₂ DS ₂ -VASc score		2.3 ± 1.4
HAS-BLED score		2.5 ± 1.1
CKD, n (%)		195 (20)
Antithrombotic therapy, n (%)	VKA	541 (55)
	DOA	410 (42)
	LMWH or IV Heparin	27 (3)
	None	3 (0.3)
Associated APT, n (%)		132 (14)
INR (for VKA patients)		2.5 ± 0.6
DOA type/dose (for DOA patients)	Apixaban 5mg t.d.	180 (44)
	Apixaban 2.5mg t.d.	9 (2.2)
	Rivaroxaban 20mg o.d.	135 (33)
	Rivaroxaban 15mg o.d.	11 (2.7)
	Dabigatran 150mg t.d.	70 (17)
	Dabigatran 110mg t.d.	5 (1.2)
<u>Procedural aspects</u>		
Sheaths ≥3, n (%)		300 (31)
Number of RF sessions, n (%)		10 ± 12

Procedure duration, minutes		72 ± 31
Procedural success, n (%)		865 (88)
Reason of procedural failure, n (%)	Conversion to atrial fibrillation or atypical flutter	54 (5.5)
	Unrelievable pain	22 (2.2)
	Failure to obtain complete isthmus block	15 (1.5)
	Unknown	25 (2.5)

Baseline characteristics of the study population (n=981).

Data are expressed as mean ± standard deviation and number (percentage).

Abbreviations: APT = antiplatelet therapy; BMI = body mass index; CKD = chronic kidney disease; DOA = direct oral anticoagulant; INR = international normalized ratio; IV = intravenous; LMWH = low molecular weight heparin; o.d. = once daily; RF = radiofrequency; t.d. = twice daily; VKA = vitamin-K antagonist.

Table 2

	Before matching			After matching		
	VKA (n=541)	DOA (n=410)	P-value	VKA (n= 410)	DOA (n = 410)	P-value
Age, year-old	67 ± 11	67 ± 11	0.586	67 ± 11	67 ± 11	0.845
Male gender, n (%)	445 (82)	315 (77)	0.047	326 (80)	315 (77)	0.398
Obesity, n (%)	104 (19)	122 (30)	<0.001	93 (23)	122 (30)	0.026
HAS-BLED score	2.6 ± 1.1	2.3 ± 1.1	<0.001	2.4 ± 1.2	2.3 ± 1.1	0.148
CHA ₂ DS ₂ -VASc score	2.5 ± 1.4	2.2 ± 1.5	0.008	2.3 ± 1.4	2.2 ± 1.5	0.154
CKD, n (%)	123 (23)	64 (16)	0.008	71 (17)	64 (16)	0.572
Associated APT, n(%)	87 (16)	38 (9,3)	0.003	49 (12)	38 (9,3)	0.257
Procedure duration, mn	75 ± 33	69 ± 29	0.016	72 ± 28	68 ± 28	0.063
Sheaths	2.33 ± 0.52	2.25 ± 0.45	0.014	2.29 ± 0.50	2.25 ± 0.45	0.240

Baseline characteristics of patients according to antithrombotic therapy (VKA or DOA), before and after propensity score-matching .

Data are expressed as mean ± standard deviation or number (percentage). Abbreviations: see **Table 1**.

	Total (n=820)	VKA (n=410)	DOA (n=410)	OR (95% CI)	P- value
<u>Complications (all-type)</u>	53 (6.5)	32 (7.8)	21 (5.1)	0.64 (0.36 – 1.13)	0.15
<u>Bleeding</u>	27 (3.3)	15 (3.7)	12 (2.9)	0.79 (0.37 – 1.72)	0.70
BARC 2	19 (2.3)	10 (2.4)	9 (2.2)	0.90 (0.36 – 2.23)	0.82
BARC 3a	2 (0.2)	1 (0.2)	1 (0.2)	1 (0.06 – 16.04)	1
BARC 3b	5 (0.6)	3 (0.7)	2 (0.5)	0.67 (0.11 – 4.00)	0.65
BARC 3c	1 (0.1)	1 (0.2)	0	1 (0.99 – 1.00)	0.32
BARC 5	0	0	0	-	-
<u>Non-bleeding complications</u>	26 (3.2)	17 (4.1)	9 (2.2)	0.53 (0.36 – 1.25)	0.40
Transient SND or AVB	11 (1.3)	7 (1.7)	4 (1.0)	0.57 (0.17 – 1.95)	0.36
Permanent SND or AVB requiring pacemaker	8 (1)	5 (1.2)	3 (0.7)	0.60 (0.14 – 2.52)	0.48
Congestive heart failure	5 (0.6)*	3 (0.7)	2 (0.5)	0.67 (0.11 – 4.00)	0.65
Symptomatic atrial fibrillation or flutter	3 (0.4)*	2 (0.5)	1 (0.2)	0.50 (0.05 – 5.52)	0.56

Table 3

Table 3: Safety outcomes at one-week.

*Same patient had both CHF and symptomatic AF.

Data are expressed as number (percentage). Abbreviations: see **text**.

Table 4

A		Bleeding		
<u>Model 1</u>	aOR	95% CI	P-value	
Male gender	0.271	0.135 – 0.545	< 0.001	
HAS-BLED score	1.865	1.372 – 2.536	< 0.001	
Associated APT	2.125	0.942 – 4.793	0.069	
Procedure duration ≥ 70 mn	3.017	1.351 – 6.739	0.007	

B		Bleeding		
<u>Model 2</u>	aOR	95% CI	P-value	
Male gender	0.315	0.158 – 0.627	0.001	
HAS-BLED Score	1.924	1.416 – 2.615	< 0.001	
Procedure year	0.881	0.763 – 1.019	0.087	
Procedure duration ≥ 70 mn	3.717	1.593 – 8.673	0.002	

C		Complication (all-type)		
<u>Model 1</u>	aOR	95% CI	P-value	
Male gender	0.349	0.196 – 0.619	< 0.001	
HAS-BLED Score	2.122	1.647 – 2.734	< 0.001	
Sheaths ≥ 3	1.743	0.969 – 3.136	0.064	
Procedure duration ≥ 70 mn	5.878	2.785 – 12.406	< 0.001	

D		Complication (all-type)		
<u>Model 2</u>	aOR	95% CI	P-value	
Male gender	0.378	0.210 – 0.679	0.001	
Obesity	1.724	0.948 – 3.135	0.074	

HAS-BLED Score	2.144	1.648 – 2.788	< 0.001
Procedure year	0.753	0.663 – 0.856	< 0.001
Procedure duration ≥ 70 mn	8.476	3.838 – 18.721	< 0.001

Table 4: Predictors of the safety endpoints using logistic regression multivariate analysis for the primary (**A:** model 1; **B:** model 2) and the secondary safety endpoint (**C:** model 1; **D:** model 2) in the study population (n=981).

Data are expressed as adjusted odds ratio and 95 % confidence interval. Abbreviations: see **Table 1**.

Figure 1

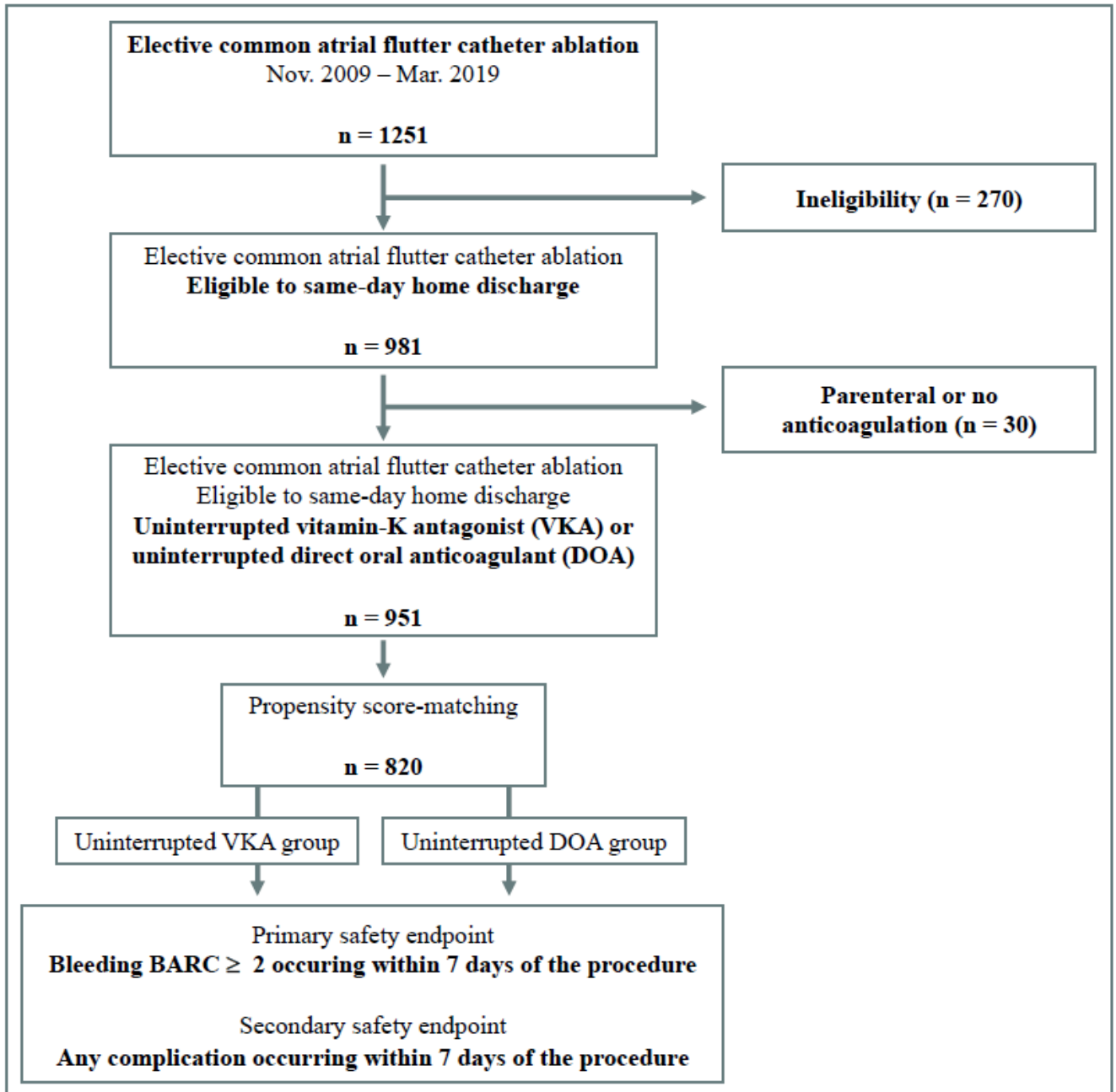


Figure 2

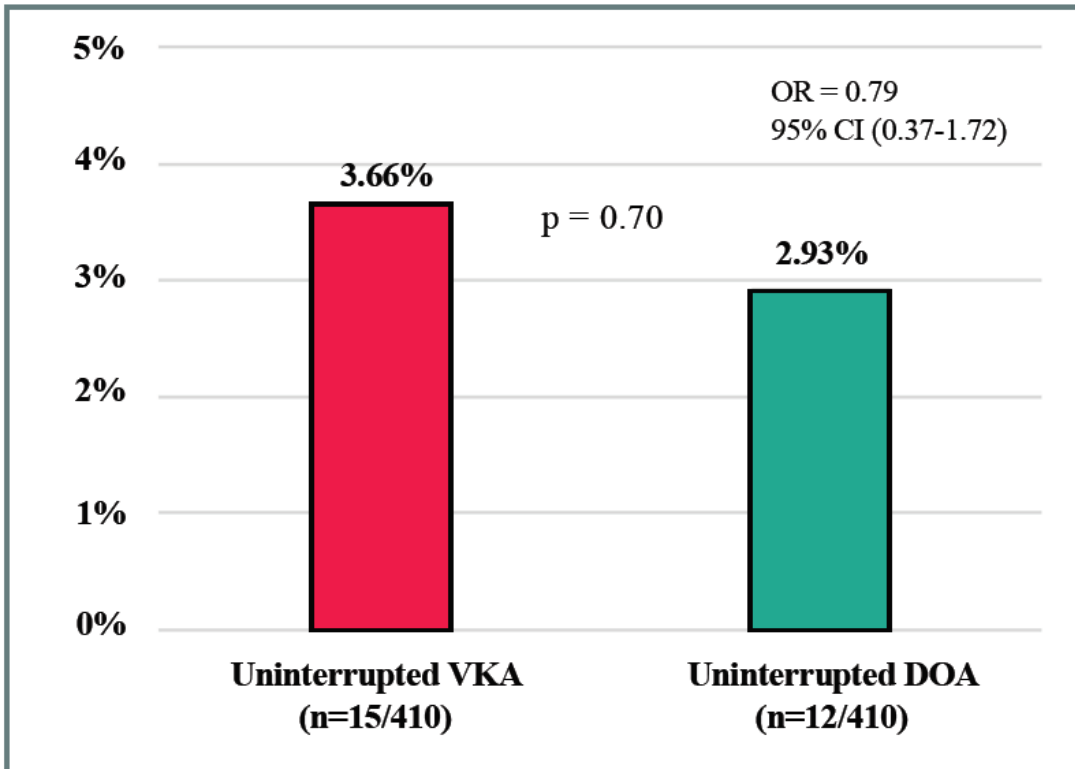


Figure 3

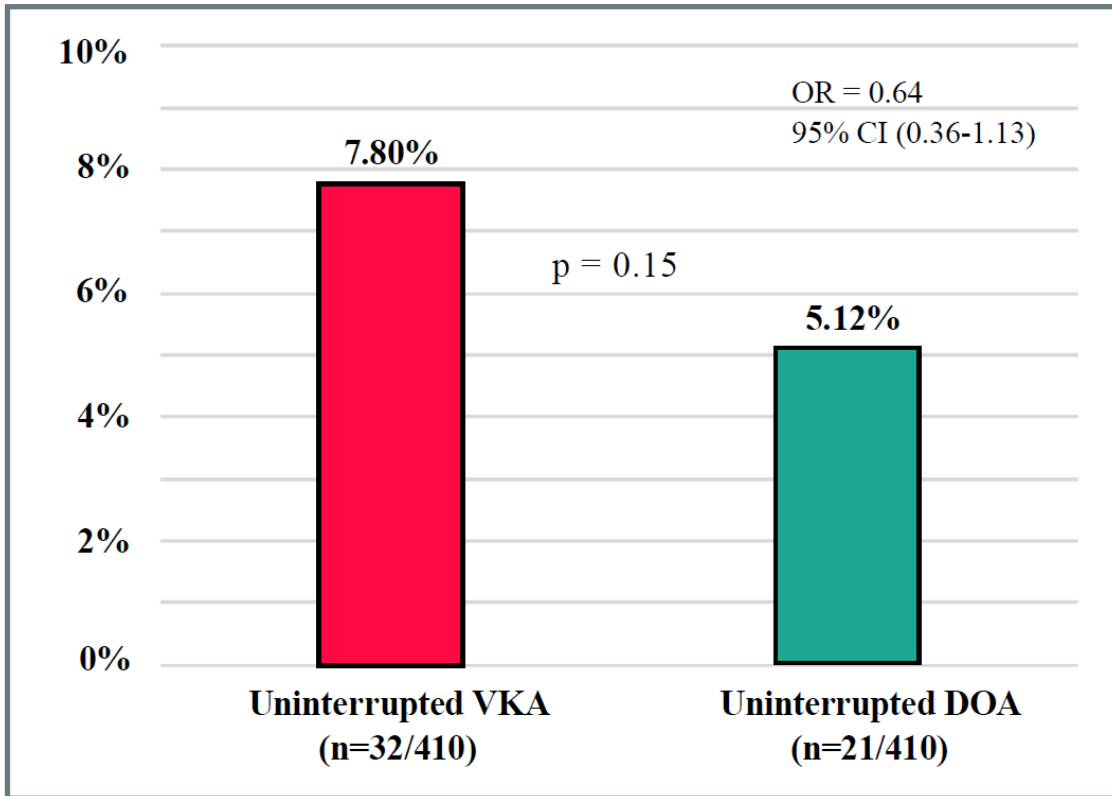
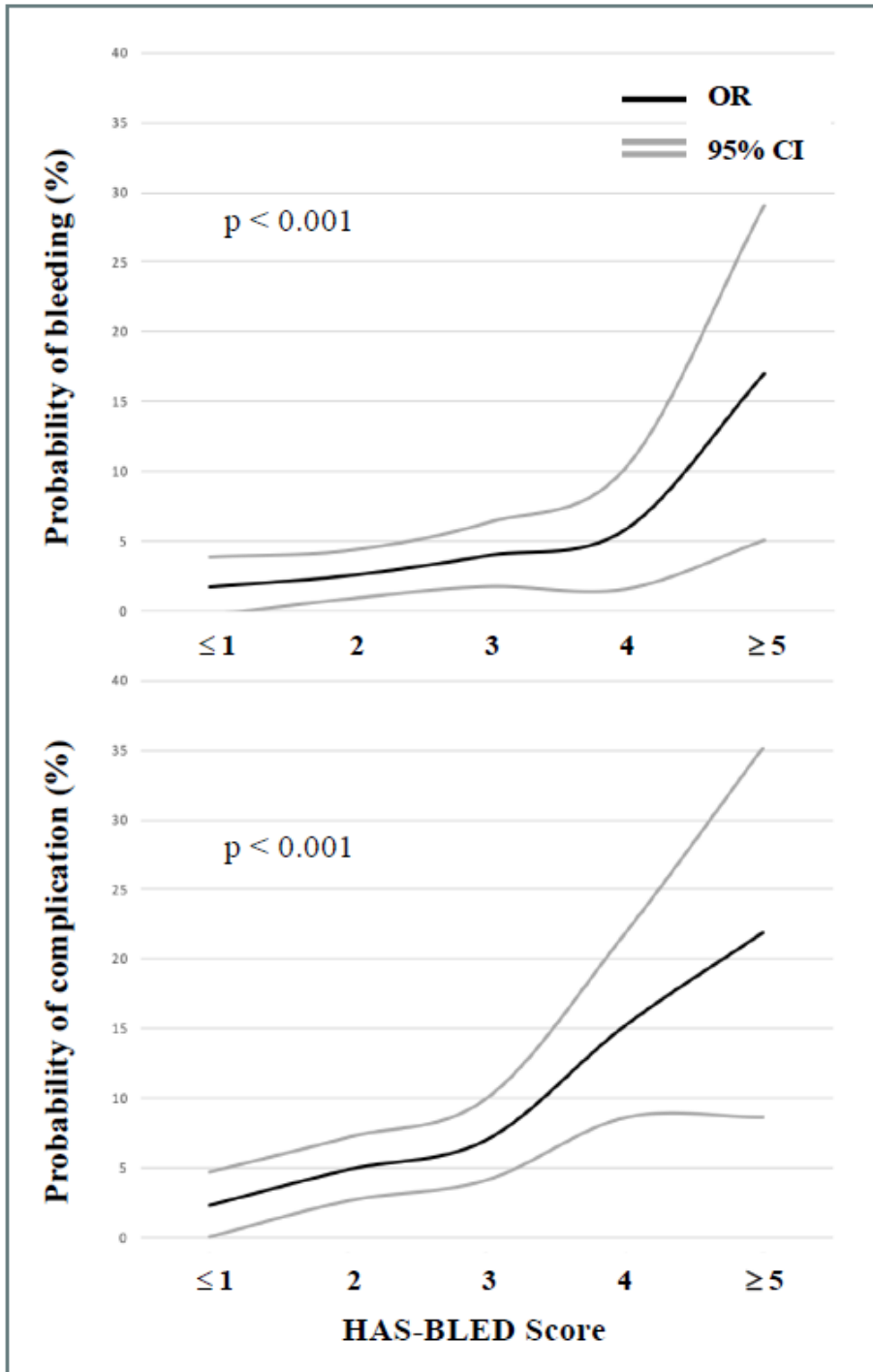


Figure 4



Sommaire

I.	INTRODUCTION.....	1
II.	METHODS.....	1
	a. Eligibility and inclusion.....	1
	b. Procedural aspects.....	2
	c. Follow-up and outcomes.....	3
	d. Statistical analysis.....	4
	e. Ethics.....	5
III.	RESULTS.....	5
	a. Baseline characteristics of patients undergoing ambulatory CAF catheter ablation.....	5
	b. Safety and feasibility of ambulatory CAF catheter ablation in patients with uninterrupted DOA.....	5
	c. Predictors of early complications after ambulatory CAF catheter ablation.....	6
IV.	DISCUSSION.....	6
	a. Safety of uninterrupted DOAs in ambulatory CAF catheter ablation.....	7
	b. Feasibility of ambulatory CAF catheter ablation.....	7
	c. Risk factors of complications after ambulatory CAF catheter ablation.....	8
	d. Limitations.....	9
V.	CONCLUSION.....	9

Introduction

Radiofrequency catheter ablation is the first-line therapy for symptomatic cavotricuspid isthmus-dependent (i.e. common) atrial flutter (CAF), and represents one of the most frequent procedures performed in invasive electrophysiology laboratories¹. Its high acute success rate is associated with a complication rate ranging from 2 to 5%, mostly bleeding events, favored by the necessity of periprocedural anticoagulation for thromboembolic prevention². The majority of tertiary medical centers practices CAF catheter ablation on an overnight stay-basis², although the advantages of same-day home discharge (i.e. ambulatory catheter ablation) are well described in the literature³⁻⁵. There is a predictable growth of rate of ambulatory catheter ablation procedures in the future because of the increased financial pressure from healthcare authorities^{5,6}. Direct oral anticoagulants (DOAs) have emerged as the preferred choices over VKAs for thromboembolic prevention due to a better efficacy-safety profile⁷. There is currently no data on the safety profile of uninterrupted DOA for ambulatory CAF catheter ablation, as most of the aforementioned studies only included patients with a vitamin-K antagonist (VKA) regimens^{4,5}.

Hence, we aimed to evaluate the safety of uninterrupted DOA regimen in ambulatory CAF catheter ablation, compared with uninterrupted VKA regimen. As secondary objectives, we aimed to evaluate feasibility of CAF catheter ablation in the modern era of DOA, and identify predictive factors of early postoperative complications (bleeding and total).

Methods

Eligibility and inclusion

Same-day home discharge has been a standard of care in our tertiary university center for every patient scheduled for radiofrequency catheter ablation for CAF for the last 10 years. We performed a retrospective analysis of our prospective protocol for ambulatory CAF catheter ablation, in order to evaluate feasibility, safety and cost-effectiveness of such practice. We report here the results of the safety and feasibility analysis. Between November 2009 and March 2019, 1251 patients \geq 18 year-old underwent elective CAF catheter ablation in our Regional University Hospital. Patients were not

eligible to ambulatory catheter ablation if procedure was scheduled too late to allow same-day discharge (i.e. after 1.00 the afternoon), or if CAF catheter ablation was associated to any other catheter ablation in the atria (e.g. atrial fibrillation, atypical atrial flutter, etc.).

Procedural aspects

All patients underwent a complete preoperative visit with the referring physician and/or the electrophysiologist, including clinical examination, twelve-lead electrocardiogram (ECG) and transthoracic echocardiography (TTE). Blood analysis was drawn at least 48-hours before the procedure, with hemostasis, platelet count, hemoglobin, electrolytes and creatinine. Individual bleeding and thromboembolic risks were integrated in HAS-BLED and CHA₂DS₂-VASc scores respectively. Obesity was defined as body mass index (BMI) $\geq 30\text{kg/m}^2$. Chronic kidney disease was defined as an estimated glomerular filtration rate (eGFR) $\leq 60\text{ml/mn/m}^2$ using CKD-EPI formula. All procedures were performed under either uninterrupted VKA (target INR 2 to 3) or uninterrupted DOA (apixaban, dabigatran or rivaroxaban, dose-adjusted if indicated) for at least three weeks before the procedure. In DOA patients, last dose was administered on the evening before or in the morning, depending on the scheduled time of the procedure. Preoperative transesophageal echography (TEE) was only performed in patients presenting with insufficient anticoagulation during the past three weeks, in order to rule-out intra-atrial thrombus. Patients were admitted in the ambulatory unit at 7.45 in the morning the day of the procedure, with a previous fasting time of at least 6 hours. All procedures were performed by a skilled senior electrophysiologist, eventually assisted by a junior and/or resident physician. Transfemoral venous access with two venous sheaths was performed under local anesthesia, potentialized by IV midazolam and morphine if necessary. Utilization of ultrasound guidance for venous puncture was at the discretion of the electrophysiologist. A quadri- or decapolar diagnostic catheter was placed within the coronary sinus through a 6Fr sheath, and eventually a halo duodecapolar catheter in the right atrium in order to confirm the isthmus complete block (through a second 6Fr sheath). Fluoroscopy-guided linear ablation between tricuspid annulus and inferior vena cava was performed using an 8-mm non-irrigated tip or a 4-mm irrigated tip catheter, at the discretion

of the electrophysiologist (settings at 60W-60°C or 40W-35°C respectively), through a single 8Fr or 8,5Fr sheath. Procedural success was defined as conversion to sinus rhythm during ablation (in patients presenting in flutter) associated with a bidirectional cavotricuspid isthmus block, persistent after at least 20 minutes after last radiofrequency application. Prolonged procedure duration was defined as superior to 70mn (mean procedure duration in the cohort). In case of conversion from CAF to atrial fibrillation or atypical atrial flutter procedure was aborted and re-scheduled under general anesthesia if necessary. No patient underwent electrical cardioversion because of the absence of anesthesiologist during procedure. After the procedure, catheters and sheaths were removed and manual compression was applied. A pressure bandage was applied during the next 6 hours after complete hemostasis and bed-resting was mandatory in declive position in the dedicated ambulatory unit. Patients were monitored by a trained nurse during 6 hours and, before discharge, assessed by the attending physician, including neurological and hemodynamic status, groin examination, 12-lead ECG and TTE in case of clinical suspicion of pericardial effusion. Patient were discharged from hospital at least 30 minutes after the pressure bandage was taken off and patient stood up without complication. In DOA patients, the next post-ablation dose was administered at least 6 hours following complete hemostasis. Patients were given both written and verbal instruction to contact if necessary the cardiology department in case of any alert sign (groin or limb pain, hematoma, neurological and cardiovascular symptoms, etc.). In case of suspected complication, patient was kept overnight and until resolution of the complication.

Follow-up and outcomes

All patients were contacted by phone at one-week by a clinical nurse for systematic complication screening. Primary safety endpoint was the occurrence of any early and clinically significant bleeding. Early bleeding was defined as occurring in a delay ranging from the beginning of the procedure (first attempt of vascular access) to the end of the first postoperative week, as the majority of complications occurs in the early postoperative time⁴. Clinically significant bleeding was defined as type 2 or greater bleeding according to the Bleeding Academic Research Consortium (BARC) classification⁸.

Secondary safety endpoint was the occurrence of any early and clinically significant complication in a delay ranging from the beginning of the procedure to the end of the first postoperative week, including : bleeding (BARC ≥ 2), transient sinus node dysfunction (SND) or atrioventricular block (AVB), persistent SND or AVB requiring pacemaker implantation, congestive heart failure or recurrent symptomatic atrial flutter or fibrillation. Effective same-day discharge was defined as a patient discharged from hospital, and without any of the primary or the secondary safety endpoint at the end of the first postoperative week.

Statistical analysis

Data are presented as mean \pm standard deviation and categorical variables are given as number of patients with the attribute (percentage). For continuous variables, a Student's *t* test or a Mann-Whitney U test, as appropriate, was performed for comparison between two groups. The Chi-square test was used for analysis of categorical variables. To limit the effect of potential selection bias, we performed a propensity score matching considering the confounding variables associated with the type of anticoagulation regimen in univariate analysis (age, gender, body mass index, HAS-BLED and CHA₂DS₂-VASc scores, chronic kidney disease, associated antiplatelet treatment, procedure duration and number of femoral venipunctures/sheaths for catheter ablation). Primary and secondary safety outcomes were then compared between VKA and DOA patients in the matched cohort. Odds ratio (OR) and 95% confidence intervals (95% CI) were calculated. Quality of the propensity score matching was evaluated using standardized differences before and after matching (**Figure S1**). Multivariate analysis for prediction of primary and secondary safety outcomes was performed using a stepwise logistic regression analysis. Since matching reduces the sample size and may limit external validity, we performed the analysis in the global population (n=981). We computed two models for both outcomes using or not the year of procedure (respectively model 1 and 2). Variables associated with outcomes with a $p < 0.20$ were included, but only variables with $p < 0.10$ were conserved in the final model. A $p < 0.05$ denoted statistical significance. Analyses and figures were conducted using

IBM SPSS Statistics for Macintosh (Version 23.0, IBM, Chicago, Illinois) and R (Version 3.1.1, R Foundation for Statistical Computing, Vienna, Austria) for propensity score-matching.

Ethics

Approval for this study was obtained from the Ethics Committee of Caen University Hospital and was in accordance with the declaration of Helsinki. The study protocol was compliant with the STROBE statement. All patients provided written informed consent before catheter ablation.

Results

Baseline characteristics of patients undergoing ambulatory CAF catheter ablation

Study flow chart is displayed in **Figure 1**. Nine hundred and eighty one patients were eligible to ambulatory CAF catheter ablation and therefore included in the study. Their baseline and procedural characteristics are detailed in **Table 1**. Sinus rhythm was obtained in 93% of patients at the end of the procedure (with or without complete and bidirectional isthmus block).

Safety and feasibility of ambulatory CAF catheter ablation in patients with uninterrupted DOA

Propensity score matching yielded 820 patients, 410 in each group. Patients receiving parenteral anticoagulation only (subcutaneous low molecular weight heparin or intravenous heparin; $n = 27$) or without any anticoagulant treatment ($n = 3$ patients) were excluded from the propensity score matching analysis. DOA and VKA patients had similar baseline characteristics (**Table 2**), except for a higher prevalence of obesity in the DOA group (30% versus 23%; $p = 0.03$).

Outcomes in the propensity matched-cohort are detailed in **Table 3**. Occurrence of the primary endpoint (defined as early and clinically significant bleeding) was 3.3% (27/810) at one-week, and occurrence of the secondary endpoint (defined as any early and clinically significant complication) was 6.5% (53/810) at one-week. Complications were immediate (i.e. before discharge) in 96% (51/53) of patients or during the first postoperative week (i.e. readmission after hospital discharge) in 3.7%

(2/53). Seventy percent (19/27) of bleeding events were classified as BARC 2; no fatal bleeding nor death occurred at the end of the first week. Pacemaker implantation rate was 1%. Mean lengths of hospital stay were 2.9 ± 6 and 3.5 ± 5 days for patients with bleeding and any complication respectively.

Considering anticoagulant regimen, occurrence of the primary safety endpoint was 2.9% (12/410) versus 3.7% (15/410) respectively for DOA and VKA patients (OR = 0.79; 95% CI 0.37 – 1.71; $p = 0.7$; **Figure 2**). Occurrence of the secondary safety endpoint was 5.1% (21/410) versus 7.8% (32/410) respectively for DOA and VKA patients (OR = 0.64; 95% CI 0.36 – 1.13; $p = 0.15$; **Figure 3**). Feasibility of same-day home discharge was comparable between DOA and VKA patients (effective same-day discharge 94.9% versus 92.2%; $p = 0.15$).

Predictors of early complications after ambulatory CAF catheter ablation

Table 4 summarizes the multivariate analysis for prediction of the primary and secondary safety endpoints in the study population ($n=981$). Female gender, high HAS-BLED score and prolonged procedure duration were independently associated with both safety endpoints, in both models. Year of the procedure was independently associated with the secondary safety endpoint, with a higher complication rate in the first years (driven by non-bleeding complications). Relationships between HAS-BLED score and probability of bleeding and complication at the end of the first postoperative week are illustrated in **Figure 4**.

Discussion

This propensity score matched-cohort analysis from a high-experienced tertiary center shows that uninterrupted DOA is a safe periprocedural anticoagulation regimen in patients undergoing ambulatory CAF catheter ablation, compared to uninterrupted VKA. We found a high effective same-day discharge rate in this setting. We also identified female gender, high HAS-BLED score and prolonged procedure duration as independent risk factors for adverse outcomes at the end of the first postoperative week.

Safety of uninterrupted DOAs in ambulatory CAF catheter ablation

The main finding of our study is that uninterrupted DOA regimen has a similar safety profile compared with uninterrupted VKA regimen in patients undergoing ambulatory CAF catheter ablation. DOA use in atrial arrhythmias at-risk of thromboembolic events has been increasing in the last years, because of a better long-term efficacy-safety profile compared with VKA⁹. In their recent and updated meta-analysis, Ha *et al.* found that continuous and minimally-interrupted DOA were safe periprocedural anticoagulation regimens in atrial fibrillation catheter ablation, with a lower risk of major bleeding compared with uninterrupted VKA⁷. Preliminary data from Amara *et al.* recently suggested that CAF catheter ablation could also be performed safely in patients taking continuous or minimally-interrupted DOA, but in a small cohort and in the non-ambulatory setting¹⁰. Still, a recent European survey found that DOA were interrupted before CAF ablation in 65% of patients¹¹. In the present study the bleeding rate is similar as previously reported in the non-ambulatory setting², supporting the safety of uninterrupted DOA for ambulatory CAF catheter ablation. One can note that despite propensity score matching, patients in the DOA group were more frequently obese than patients in the VKA group (30% versus 23%; $p = 0.03$). Obesity is a known risk factor for bleeding after catheter ablation¹² and, if this difference has a significant consequence, it would be in the way of an overestimation of bleeding risk in the DOA group. We therefore believe that it is not altering the main finding of the present study.

Feasibility of ambulatory CAF catheter ablation

This study shows that ambulatory CAF catheter ablation is feasible, even in patients with DOA, with a nearly 95% effective same-day discharge rate. Data concerning ambulatory catheter ablation are scarce in the current literature, and we describe here the largest cohort of ambulatory patients under a DOA regimen in the specific context of CAF catheter ablation. Previous studies on this topic included various types of electrophysiological procedures with different risk profiles, including CAF but also atrioventricular node, slow-pathway and accessory-pathway catheter ablations³⁻⁵. Moreover, none of

the aforementioned studies specifically accounted for the type of anticoagulation regimen. In this context, our work shows a an effective same-day discharge rate similar to previously reported (between 90 and 95%). However, one can note a higher procedural failure rate in our cohort compared with the recent European survey¹¹. Conversion from CAF to atrial fibrillation (or atypical atrial flutter) and unrelievable pain were responsible for nearly a half and a fifth of all procedural failures respectively. Because of the absence of anesthesiologist during the procedure, we weren't able to perform an electrical cardioversion in the first case, or to convert from local to general anesthesia in the second case. Therefore, our higher procedural failure rate might be the consequence of the lack anesthetic support rather than anticoagulant- or ambulatory-dependent.

Risk factors of complications after ambulatory CAF catheter ablation

There is currently no data in the literature concerning risks factors for complications after ambulatory CAF catheter ablation, and the present study gives some new insights for risk stratification of ambulatory patients. Similarly to non-ambulatory patients, we found that high HAS-BLED score was a risk factor for bleeding and non-bleeding complications¹³, as well as prolonged procedure duration¹⁴. There is accumulating evidence suggesting that women are at higher risk of developing complications after catheter ablation, and our findings are consistent with previous studies¹⁵⁻¹⁷. This association might reflect disparities in anatomical and electrophysiological substrate, response to medications/anticoagulants, referral for catheter ablation, etc. compared with men. Identification of such risk factors at the preoperative visit of patients eligible to ambulatory catheter ablation might help lowering the risk of postoperative adverse outcomes (e.g. by reducing procedure time when feasible or increasing the postoperative monitoring period to at-least an overnight stay).

Approximately two third of medical centers practice CAF ablation in an overnight stay-basis², although the advantages of same-day home discharge in terms of patient-reported outcomes, feasibility, safety, cost and resources consumption are well known^{4,5}. There are numerous incentives for the development of ambulatory catheter ablation, with a predictable growth of ambulatory practice

to every medical sector in the future⁶. It is likely that ambulatory catheter ablation will expand to atrial fibrillation management in selected patients someday, but caution as to be taken for now. Even though promising results were recently published by Opel *et al.*, numerous procedural aspects differ between CAF and atrial fibrillation catheter ablation¹⁸. A dedicated prospective study is therefore needed to evaluate the safety of such practice.

Limitations

Our study is an observational registry and not a randomized prospective trial. However, the propensity score analysis included risk factors associated with the anticoagulation regimen (individually or included in the HAS-BLED and CHA₂DS₂-VASc scores such hypertension, diabetes, chronic heart failure, left ventricular ejection fraction, etc.), in order to limit the impact of such bias. One can note that a prospective randomized design in this setting would be hardly justifiable, because of the preferred long-term safety profile of DOA over VKA^{7,9}. One can note that exhaustive anti-arrhythmic medication status (dose, duration and eventual interruption of treatment before procedure) was not collected for all patients, and it is known that the presence of such medication is a risk factor for intermittent and persistent conductive disorders¹³. We believe that it might not have impact on the primary safety endpoint of early and clinically significant bleeding, but caution as to be made concerning non-bleeding complications.

Conclusions

Uninterrupted DOA is a safe periprocedural anticoagulation regimen for ambulatory CAF catheter, in a high-volume center with a dedicated ambulatory unit, trained paramedical staff and clear patient information about alert signs. Effective same-day discharge is obtained in 95% of patients, and identification of high-risk patients at the preoperative visit might help in lowering the risk of postoperative adverse outcomes in this setting.

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Annexes

Table 1

Baseline characteristics of the study population (n=981).

Data are expressed as mean \pm standard deviation and number (percentage).

Abbreviations: APT = antiplatelet therapy; BMI = body mass index; CKD = chronic kidney disease; DOA = direct oral anticoagulant; INR = international normalized ratio; IV = intravenous; LMWH = low molecular weight heparin; o.d. = once daily; RF = radiofrequency; t.d. = twice daily; VKA = vitamin-K antagonist.

Table 2

Baseline characteristics of patients according to antithrombotic therapy (VKA or DOA), before and after propensity score-matching .

Data are expressed as mean \pm standard deviation or number (percentage). Abbreviations: see **Table 1**.

Table 3: Safety outcomes at one-week.

*Same patient had both CHF and symptomatic AF.

Data are expressed as number (percentage). Abbreviations: see **text**.

Table 4: Predictors of the safety endpoints using logistic regression multivariate analysis for the primary (**A:** model 1; **B:** model 2) and the secondary safety endpoint (**C:** model 1; **D:** model 2) in the study population (n=981).

Data are expressed as adjusted odds ratio and 95 % confidence interval. Abbreviations: see **Table 1**.

Figure 1: Study flow-chart.

Figure 2 (Representative Figure): No difference in early and clinically significant bleeding occurrence after ambulatory CAF catheter ablation in patient with DOA, compared with uninterrupted VKA. Abbreviations: see **Table 1**.

Figure 3: No difference in early and clinically significant complication occurrence after ambulatory CAF catheter ablation in patient with uninterrupted DOA compared with uninterrupted VKA. Abbreviations: see **Table 1**.

Figure 4: Association between outcomes and HAS-BLED score in the study population using ANOVA. Abbreviations: see **Table 1**.

« Par délibération de son Conseil en date du 10 Novembre 1972, l'Université n'entend donner aucune approbation ni improbation aux opinions émises dans les thèses ou mémoires. Ces opinions doivent être considérées comme propres à leurs auteurs ».

VU, le Président de Thèse

VU, le Doyen de la Faculté

VU et permis d'imprimer
en référence à la délibération
du Conseil d'Université
en date du 14 Décembre 1973

Pour le Président
de l'Université de CAEN et P.O

Le Doyen

ANNEE DE SOUTENANCE : 5 septembre 2019

NOM ET PRENOM DE L'AUTEUR : BITTAR Patrick

TITRE DE LA THESE : Sécurité des anticoagulants oraux directs ininterrompus par rapport aux anti-vitamine K ininterrompus dans l'ablation par radiofréquence des flutters atriaux communs en ambulatoire: étude de cohorte avec score de propension.

RESUME DE LA THESE EN FRANÇAIS :

Objectifs. La sortie effective à domicile le jour même après une ablation de flutter commun par radiofréquence est une pratique réalisable, sûre et rentable, mais il n'existe actuellement aucune donnée concernant les patients traités par un anticoagulant oral direct (AOD) ininterrompu. Nous avons évalué la sécurité et la faisabilité de l'ablation de flutter en ambulatoire chez des patients traités par AOD par rapport à un antagoniste de la vitamine K (AVK). **Méthodes et résultats.** Les patients devant subir une ablation isolée de flutter en ambulatoire dans notre centre universitaire entre 2009 et 2019 ont été inclus. Le score de propension pour le type d'anticoagulant a été calculé à partir de l'âge, du sexe, de l'indice de masse corporelle, des caractéristiques initiales et des facteurs de risque (inclus dans les scores HAS-BLED et CHA₂DS₂-VASc), de l'insuffisance rénale chronique, du traitement antiplaquettaire associé, de la durée de procédure et du nombre de ponction fémorale. L'appariement par score de propension a donné 820 patients (âgés de 67 ± 11 ans). L'ablation a été réalisée sous AVK ininterrompu (n = 410; INR = 2,5 ± 0,6) ou AOD ininterrompu (n = 410). La survenue du résultat principal de tolérance, définie comme tout saignement précoce et cliniquement significatif (BARC 2) à une semaine, était similaire chez les patients sous AOD et sous AVK (2,9 vs 3,7%; p = 0,70), ainsi que le taux de sortie effective le jour même (94,9% contre 92,2%; p = 0,15). Le sexe féminin, le score HAS-BLED élevé et la durée de procédure prolongée étaient des facteurs de risque de saignement à une semaine. **Conclusion.** Les AOD ininterrompus sont un traitement anticoagulant sans danger pour l'ablation du flutter en ambulatoire chez les patients sélectionnés, dans un habitué, avec une unité ambulatoire dédiée et une gestion standardisée de la procédure et du post-opératoire.

MOTS CLES : flutter atrial; ablation par cathéter; anticoagulant oral direct; soins ambulatoires; résultats.

TITRE DE LA THESE EN ANGLAIS : Safety of uninterrupted direct oral anticoagulant versus uninterrupted vitamin-K antagonist for ambulatory atrial flutter catheter ablation: a propensity score-matched cohort study.

RESUME DE LA THESE EN ANGLAIS :

Aims. Same-day home discharge after common atrial flutter (CAF) catheter ablation is a feasible, safe and cost-effective practice, but there is currently no data concerning patients treated by uninterrupted direct oral anticoagulant (DOA). We evaluated safety and feasibility of ambulatory CAF catheter ablation in patients treated by DOA compared with vitamin-K antagonist (VKA). **Methods and results.** Patients scheduled for isolated ambulatory CAF catheter ablation to our tertiary university center between 2009 and 2019 were included. Propensity score for anticoagulant type was calculated from age, gender, body mass index, baseline characteristics and risk factors (included in HAS-BLED and CHA₂DS₂-VASc scores), chronic kidney disease, associated antiplatelet treatment, procedure duration and number of femoral venipunctures. Propensity score matching yielded 820 patients (age 67 ± 11 years). Catheter ablation was performed under uninterrupted VKA (n=410; INR = 2.5 ± 0.6) or uninterrupted DOA (n=410). Occurrence of the primary safety outcome, defined as any early and clinically significant bleeding (BARC ≥ 2) at one-week, was similar between DOA and VKA patients (2.9 vs 3.7%; p = 0.70), as well as the rate of effective same-day discharge (94.9 vs 92.2%; p = 0.15). Female gender, high HAS-BLED score and prolonged procedure duration were risk factors for bleeding at one-week. **Conclusion.** Uninterrupted DOA regimen is safe for selected patients undergoing ambulatory CAF catheter ablation, in a high-volume center with a dedicated ambulatory unit and a standardized procedural and postoperative management.

KEY WORDS : atrial flutter; catheter ablation; direct oral anticoagulant; ambulatory care; outcomes.