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ATE score diagnostic accuracy for predicting the absence of intra-atrial thrombi before atrial fibrillation ablation

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ABSTRACT

Background

In a preliminary study in patients hospitalized for catheter ablation of atrial fibrillation (AF), the Atrial Thrombus Exclusion (ATE) score (stroke, hypertension, heart failure, d-dimers > 270 ng/ml) was developed to rule out the diagnosis of intra-atrial thrombus, with a negative predictive value (NPV) of 100%, and to avoid performing transesophageal echography (TEE).

Objectives

The present study was designed to prospectively confirm the NPV of the ATE score in an independent population.

Methods

Consecutive patients hospitalized for catheter ablation of AF or left atrial tachycardia (LAT) were prospectively enrolled in a multicenter study. D-dimer levels were measured within 48 hours before ablation. A zero ATE score was considered predictive of no thrombus. TEE was routinely performed at the beginning or just before the ablation procedure. The primary endpoint was the presence of atrial thrombus diagnosed by TEE.

Results

The analysis includes 3,072 patients (53.3% paroxysmal AF, 36.7% persistent AF and 10% LAT). A thrombus was detected in 29 patients (0.94% [95%CI 0.63-1.35]), all on appropriate anticoagulant therapy. A zero ATE score was observed in 818 patients (26.6%), and the sensitivity, specificity, PPV and NPV were 93.1, 26.8, 1.2 and 99.8%, respectively. Follow-up of the two false-negative patients revealed the persistence of chronic organized thrombi.

Conclusions

In patients hospitalized for catheter ablation of AF or LAT, the ATE score identifies a population at very low risk for atrial thrombus. In consultation with the patient, the cardiologist may consider not performing a preoperative TEE in case of zero ATE score.

KEY WORDS

Atrial fibrillation

Catheter ablation

Thrombosis

Diagnostic Techniques, Cardiovascular

Risk factors

ATE score

CONDENSED ABSTRACT

The ATE score (stroke, hypertension, heart failure, D-dimers>270ng/ml) was developed to exclude the diagnosis of intra-atrial thrombus in patients hospitalized for atrial fibrillation catheter ablation. In the EXTRALUCID-dCs prospective multicenter study, transesophageal echography detected 29 atrial thrombi in 3,072 patients (incidence rate 0.94% [95%CI 0.63-1.35]). Considering a zero ATE score as a negative result, the negative predictive value was 99.8%. The two false-negative patients revealed the persistence of chronic organized thrombi. A zero ATE score identifies a population at very low risk for atrial thrombus, and in consultation with the patient, the cardiologist may consider not performing a preoperative TEE.

ABBREVIATIONS LIST

AF	Atrial fibrillation
ATE	Atrial Thrombus Exclusion
AUC	Area under the curve
INR	International normalized ratio
OAC	Oral anticoagulant
ROC	Receiver operating characteristic
TEE	Transesophageal echocardiography
VKA	Vitamin K antagonists

INTRODUCTION

Atrial fibrillation (AF) is the most common heart rhythm disorder and is associated with increased mortality and morbidity, particularly through its thromboembolic complications. CHADS₂ and CHA₂DS₂VASc scores assess the risk of ischemic stroke in a person with nonvalvular AF, i.e. assess the need for anticoagulant therapy.

Invasive treatment of atrial fibrillation by catheter ablation is indicated in symptomatic and recurrent AF forms. Catheter ablation of atrial fibrillation is one of the most complex procedures in electrophysiology. Thromboembolic events are possible procedure-related complications and are responsible for cerebral embolism. Their incidence rate is approximately 1% (1). The embolic risk is limited by performing imaging tests to rule out the presence of a left atrial thrombus. The standard reference is the transesophageal echocardiography (TEE), which is an unpleasant examination. Recommendations for preoperative TEE have evolved over the years. The most recent recommendations on atrial fibrillation ablation indicate that it has not been possible to reach a consensus on the indication for TEE in patients on well-controlled anticoagulant therapy (2).

The Atrial Thrombus Exclusion (ATE) score, which combines thromboembolic risk factors (heart failure, hypertension, history of stroke) and D-dimer level, has been described for the prediction of intra-atrial thrombus in the EXTRALUCID-d study (3), which included 2,494 patients hospitalized for atrial fibrillation ablation (4). The primary outcome was the number of intra-atrial thrombi diagnosed by transesophageal echocardiography. The absence of heart failure, hypertension, history of stroke, and a D-dimer < 270 ng/ml, i.e. an ATE score of zero, was found to have a 100% negative predictive value for the diagnosis of intra-atrial thrombus. The objective of the present study is to confirm the accuracy of the ATE score in an independent population.

METHODS

Study design

This diagnostic accuracy study was conducted prospectively in 15 electrophysiology centers in France and Switzerland.

Participants

Consecutive patients hospitalized for catheter ablation of AF (paroxysmal or persistent) or left atrial tachycardia were enrolled between September 2018 and November 2020 in electrophysiology centers that routinely performed TEE for thrombus screening in the left atrium before catheter ablation. Exclusion criteria were contraindication to TEE, TEE made in another center than the center of ablation, pregnant woman, parturient mother and nursing mother, patient living in an institution on court or authority order, severely altered psychological health, minor, under guardianship, person unable to give their consent, and refusal to participate in the study.

Ethics

The study complied with the Declaration of Helsinki. It was approved by the institutional review board (18.003, CPP Sud Méditerranée V). Physicians provided appropriate information about the study to patients who gave written consent before inclusion.

The study was registered in the clinicaltrials.gov database (NCT03455673).

Test methods

ATE score

Plasma D-dimer level was systematically measured within 48 hours before catheter ablation. STA-Liatest D-Di Plus (Stago, Asnières sur Seine, France) was the only test used according to the protocol.

Hypertension, heart failure and history of stroke were defined during clinical examination.

The ATE score was automatically calculated from the clinical history of the patients and the D-dimer level in the electronic case report form.

Transesophageal echocardiography

TEE was performed according to the guidelines of the European Association of Cardiovascular Imaging within 48 hours before the ablation procedure. The detection of a hyperechoic mass revealed an intra-atrial thrombus. Because the aim of the study was to propose an alternative method to TEE to exclude an atrial thrombus, the other findings that resulted from the TEE were not collected (sludge, left appendage velocity). Operators were blinded to the results of the D-dimer levels and the ATE score results were not available to the assessors of the reference standard.

The presence of left atrial thrombus was a contraindication to catheter ablation. The ablation procedure and patient monitoring were performed according to local practices.

Analysis

The index test was the ATE score. A zero score was a negative result, while a score above zero was a positive result. The reference test was the TEE. The negative condition was the absence of thrombus, and the positive condition was the presence of thrombus. Sensitivity, specificity, positive predictive value, negative predictive value, and 95% confidence intervals were calculated for the ATE score, CHADS₂ score, and CHADS₂VASc score. As the relevance of the female sex data is controversial in the CHA₂DS₂VASc score, a further

analysis was carried out ignoring this data (modified CHA₂DS₂VASc). The Receiver operating Characteristic curves were built for the ATE score.

Given the low rate of atrial thrombi (about 2 % of patients eligible to atrial fibrillation ablation (3)), this study required a high number of participants in order to allow reliable estimation of diagnostic performance. To detect a 0.5 % deviation between two negative predictive values (binomial test), 2,000 patients were required for a power of 70 %; 2,400 patients for a power of 80 %; and 3,000 patients for a power of 90%. Due to the high enrolment capacities of this multicenter study and its simplicity for the centers involved, it was chosen to focus on the power of the study and to retain a sample size of 3,000 patients.

RESULTS

Description of the population

Of the 3,099 eligible patients with available ATE score, twenty-seven were not included in the final analysis because TEE was not performed (Figure 1). The study population included 2,209 men (72%) and 863 women (28%), with a median age of 66 years (Table 1). They had paroxysmal AF (53.3%), persistent AF (36.7%), and left atrial tachycardia (10.0%).

Hypertension, diabetes mellitus, heart failure, and history of stroke were reported in 42.1%, 11.4%, 14.9%, and 5.7%, respectively. The mean CHADS₂ and CHA₂DS₂VASc scores were 0.9 ± 0.9 and 1.8 ± 1.4 , respectively (5).

Rate of thrombus

TEE performed before or at the beginning of the procedure detected an atrial thrombus in 29 patients (incidence rate 0.94% [95% CI 0.63-1.35]). All 29 patients with atrial thrombus were on appropriate anticoagulant therapy (8 patients on vitamin K antagonists and 21 patients on direct oral anticoagulation therapy). The incidence rate of thrombus was different according to the initial atrial rhythm disorder (left atrial tachycardia 2.3%, paroxysmal atrial fibrillation 0.3%, and persistent atrial fibrillation 1.5%; $p < 0.001$).

ATE Score

Diagnostic accuracy

The ROC curve showed the diagnostic ability of the five-level ATE score to classify patients with or without intra-atrial thrombus (Figure 2). The area under the curve (AUC) was 0.74 (95% CI 0.64-0.83). The best balance between positive and negative predictive value was achieved with a cut-off of one. However, the optimal cut-off for obtaining the highest negative predictive value was a zero ATE score.

When considering a zero ATE score as a negative result, the negative predictive value was 99.8% (95%CI 99.1-99.9) (Table 2). Among patients with a zero ATE score, two thrombi were observed on TEE, i.e. 0.24%.

Clinical description of false negative

A 70-year-old woman with an artificial biological mitral valve, had left atrial tachycardia, complete left bundle-branch block, left ventricular ejection fraction measured at 45%, New York Heart Association (NYHA) class-2 exertional dyspnea, but no described episodes of congestive heart failure. She was treated with warfarin with an international normalized ratio (INR) in the therapeutic range. TEE showed a left appendage thrombus confirmed by CT scan. The D-dimer level was less than 270 ng/ml. The ablation was cancelled. Three cardiac scans performed over the next year showed persistent thrombus.

A 60-year-old man had a history of mechanical aortic valve replacement with maze procedure in 2012 and a complementary radiofrequency procedure for persistent AF in 2013. He was hospitalized for catheter ablation of atypical atrial flutter. He was treated with warfarin with an INR within the therapeutic range. The D-dimers level was less than 270 ng/ml. TEE showed a minimally mobile thrombus in the left appendage. Injected cardiac CT confirmed the presence of a chronic calcified thrombus on two occasions 9 months apart despite a target INR of 3 to 4.

CHADS₂ and CHA₂DS₂VASC score

The performances of the CHA₂DS₂VASc score with or without sex, and the CHADS₂ score, in predicting patient's risk of atrial thrombus were also studied. The area under corresponding receiver operating characteristic curves were respectively 0.73, 0.73 and 0.78. A binary analysis considered a zero score as a negative result, and a score above zero as a positive

result. The number of false negatives were 3, 3 and 4 for the CHA₂DS₂VASc score with or without the sex data and the CHADS₂, respectively. Sensitivities, specificities, and predictive values are presented in Table 2.

DISCUSSION

Incidence rate of thrombi

The incidence rate of thrombus observed in this study was 0.94%. In a preliminary study, we found an incidence of 1.92% (3). The increase in the prescription of direct oral anticoagulants may be responsible for this decrease in incidence. Nevertheless, the data in the literature remain unclear. In a population of 2,494 patients, we found no significant difference in the incidence rate of thrombus between patients treated with vitamin K antagonists (VKA) (2.5%) and patients treated with direct oral anticoagulant (OAC) (1.6%). Göldi *et al.* reported a similar rate of thrombus under VKA (0.5%) and OAC (0.56%) in a series of 1753 TEE performed before pulmonary vein isolation (6). Whereas Schaeffer *et al.* found, in a population of 1,286 patients hospitalized for external electrical cardioversion, a thrombus incidence rate of 2.5% in patients on OAC and 5.3% in patients on VKA ($p < 0.05$) (7). The results of these studies are probably affected by biases related to the lack of randomization of anticoagulant treatments and the absence of information on the INR in the therapeutic zone in patients treated with VKA, and on compliance to OAC therapy.

We also found a higher incidence of thrombus in the non-paroxysmal arrhythmia population and particularly in atrial tachycardia. Many studies have described a much higher incidence of thrombus in persistent atrial fibrillation than in paroxysmal fibrillation (8–13). Of these, two found that non-paroxysmal AF was an independent factor related to the presence of an atrial thrombus (12,13). In the present study and the previous one, the rate of paroxysmal AF was exactly the same (53%). Consequently, this cannot explain the low incidence of thrombus.

ATE score performance

This study was designed to confirm the negative predictive value of the ATE score. This score, including clinical thromboembolic risk factors (hypertension, history of stroke, heart

failure) and a biological parameter used in current practice (D-dimer level greater than 270 ng/ml), was derived from a prospective multicenter study of 2,494 patients hospitalized for ablation of atrial fibrillation or left atrial tachycardia (3). In this five-level score, the cut-off was defined to exclude the risk of thrombus and the highest negative predictive value was preferred to avoid the risk of a false negative. From a clinical point of view, the risk of a patient having a thrombus and a negative result must be as low as possible. An ATE score of zero was therefore considered a negative result, and a score greater than zero a positive result. The negative predictive value of the ATE score was found to be 100%, in a population with a TEE-diagnosed thrombus incidence rate of 1.92% (95%CI 1.42-2.54). In the present study analyzing 3,072 patients, the sensitivity and specificity were 93.1% (95%CI 76.7-99.0) and 26.8% (95%CI 25.2-28.4), respectively. As would be expected, the negative predictive was high with a value of 99.8% (95%CI 99.1- 99.9). Interestingly, the follow-up of both false-negative patients revealed the presence of chronic atrial thrombi on successive examinations. The increased in D-dimer levels reflects the levels of product degradation of fibrin plug in its initial phase of development. The presence of chronic thrombus with fibrous organization despite well-conducted anticoagulant therapy at the time of D-dimer level measurement could explain the low level of fibrin degradation products in these patients. It should be noted that both patients had a history of prosthetic valve replacement, which may suggest a limitation to the use of the ATE score in this population. Appropriate use of the ATE score would apply to patients hospitalized for catheter ablation of AF or left atrial tachycardia without valvular AF or mechanical valve prosthesis (Central illustration). Finally, given the risk of underestimating the diagnosis of heart failure in patients with few symptoms, it is advisable to use the ATE score with caution when the left ventricular ejection fraction is reduced.

Relevance of the D-dimer assay

The value of D-dimer measurement to exclude the presence of an intra-atrial thrombus has already been demonstrated by several studies, including a recent meta-analysis (14). The cut-off value chosen to optimize sensitivity and specificity was 390 ng/ml. In clinical conditions of programmed ablation of atrial fibrillation, it is desirable to rule out the presence of atrial thrombus before the procedure. Low cut-off values should be used to optimize the negative predictive value.

CHADS₂ AND CHA₂DS₂VASC score performance

Several single-center studies have examined the value of the CHADS₂ score in excluding the diagnosis of intracardiac thrombus with conflicting results (8,9,12). Our study was not designed to draw conclusions about the CHADS₂ and CHA₂DS₂VAsc scores, but their diagnostic performance was also of interest for selecting a low-risk population.

Study limitations

The threshold chosen in the ATE score for D-dimer values was 270 ng/ml. The variability of the measurements for this cut-off value is 14% according to STAGO, the manufacturer of the STA-Liatest D-Di Plus reagent used in the present study. This variability in measurements is a limitation to the interpretation of results for patients with low D-dimer values.

The low incidence of thrombus affects the power of the study and limits the significance of its conclusions.

Conclusion

The EXTRALUCID-d Cs study showed a 99.8% negative predictive value of the ATE score to exclude the diagnosis of intra trial thrombus. In patients hospitalized for catheter ablation of atrial fibrillation or left atrial tachycardia, the ATE score identifies a population at very low

risk for atrial thrombus. In consultation with the patient, the cardiologist may consider not performing a preoperative TEE in case of zero ATE score.

PERSPECTIVES

Clinical competencies in medical knowledge and in patient care and procedural skills

The ATE score is a simple score, combining common clinical data and a routinely used blood bioassay, developed to rule out the diagnosis of intra-atrial thrombus before catheter ablation of atrial fibrillation or left atrial tachycardia. Its interest is to identify a population at very low risk of atrial thrombus and to avoid performing a TEE, thus reducing the costs of care and simplifying hospitalizations. False negatives are very rare and seem to correspond to old and organized thrombi. Although their ability to embolize is not well known, it can be assumed that it is weaker than that of cruoric thrombus.

Translational outlook

The ATE score apply to patients hospitalized for catheter ablation of AF or left atrial tachycardia without valvular AF or mechanical valve prosthesis. It is calculated according to thromboembolic risk factors (heart failure = 1, hypertension = 1, history of stoke = 1) and D-dimer level ($> 270\text{ng/ml} = 1$). Particular attention should be paid to heart failure, which should be considered a risk factor if there is left ventricular dysfunction.

Given its excellent negative predictive value in this population, a zero ATE score is in favor of avoiding preoperative TEE. Nevertheless, some physicians may still perform peroperative TEE or an intracardiac echocardiography to guide the transeptal puncture.

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FIGURE TITLES AND LEGENDS

Figure 1. Flow diagram

Description of the number of patients from screening to patients retained in the analysis.

Patients analyzed were classified according to an Atrial Thrombus Exclusion (ATE) score of zero or greater. Transesophageal echocardiography (TEE) was the reference method used for thrombus diagnosis. A zero ATE score was observed in 818 patients and thrombus was detected in 29 patients. The observed thrombus incidence rate of 0.94% is lower than previously described, which may be due to the increased prescription of direct oral anticoagulants. With a negative predictive value of 99.8%, the ATE score identified a population at very low risk for atrial thrombus.

Figure 2. ROC curve

Receiver operating characteristic (ROC) curve showing the diagnostic capacity of the five-level ATE score to classify patients with or without intra-atrial thrombus. The area under the curve (AUC) was 0.74, which is close to what was observed in the first study describing the development of the ATE score.

Central illustration. Decision algorithm for thrombus diagnosis before catheter ablation

In patients hospitalized for catheter ablation of AF or left atrial tachycardia without valvular AF or mechanical valve replacement, the ATE score is calculated. When it is greater than zero, a TEE or other test is needed to exclude the presence of a thrombus before ablation. A zero ATE score, indicating a very low risk of atrial thrombus, is an argument for avoiding preoperative TEE, in consultation with the patient.

ATE: Atrial Thrombus Exclusion; TEE: Transesophageal echocardiography

TABLES

Table 1. Baseline characteristics

EXTRALUCID-d CS population study	
(n = 3,072)	
Demographics	
Female	863 (28.1)
Age (years)	66 (58 – 71)
Medical history	
Heart failure	459 (14.9)
Stroke or transient ischemic attack	175 (5.7)
Hypertension	1292 (42.1)
Diabetes mellitus	350 (11.4)
Vascular disease	376 (12.2)
CHA ₂ DS ₂ VASc score	2 (1–3)
CHADS ₂ score	1 (0–1)
Diagnosis	
Left atrial tachycardia	308 (10.0)
Paroxysmal fibrillation	1638 (53.3)
Persistent fibrillation	1126 (36.7)
D-Dimer level	270 (270–370)

Values are count and percentage or median and interquartile range.

Table 2. Sensitivities, specificities, positive predictive values, and negative predictive values of the ATE score, CHA₂DS₂VASc score with or without sex, and the CHADS₂ score, in predicting the presence of thrombus

	Modified			
	ATE	CHA₂DS₂VASc	CHA₂DS₂VASc	CHADS₂
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Sensitivity	93.1 (76.7-99.0)	89.7 (72.6-97.8)	90.0 (72.6-97.8)	86.5 (68.3-96.1)
Specificity	26.8 (25.2-28.4)	19.9 (18.4-21.3)	25.0 (23.5- 26.6)	42.2 (40.4-44)
PPV	1.2 (0.8-1.7)	1.0 (0.7-1.5)	1.1 (0.7-1.7)	1.4 (0.9-2.1)
NPV	99.8 (99.1-99.9)	99.6 (98.6-99.9)	99.6 (98.9-99.9)	99.7 (99.2-99.9)

PPV: Positive predictive value; NPV: Negative predictive value

Figures

Central figure

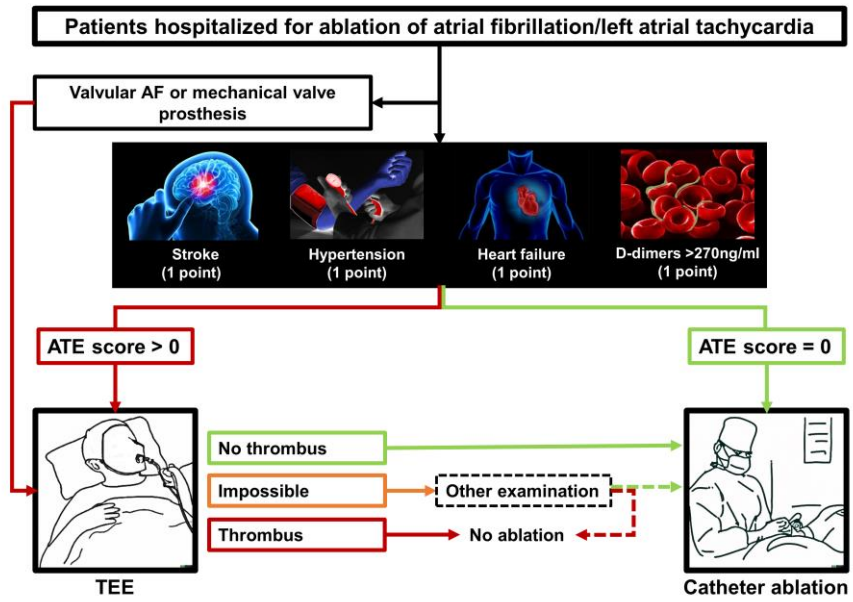


Figure 1

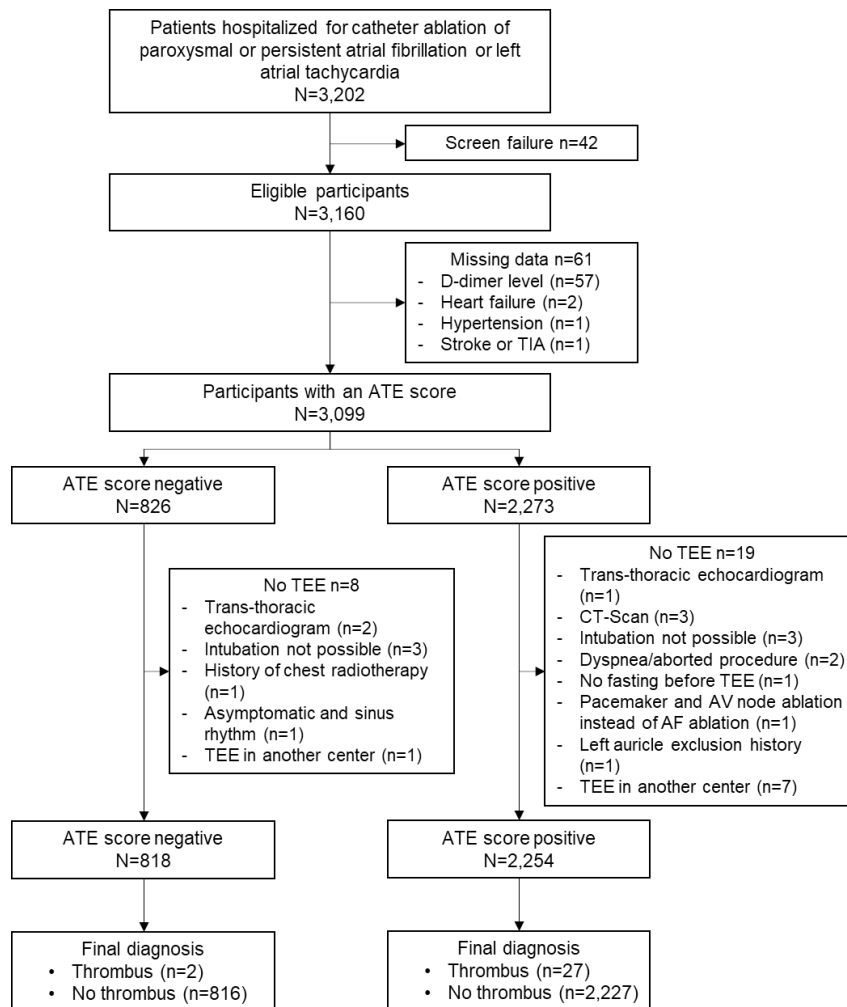


Figure 2

