An epidemiological study to evaluate the use of vitamin K antagonists and new oral anticoagulants among non-valvular atrial fibrillation patients in Turkey- AFTER*-2 study design

Türkiye'de nonvalvüler atriyum fibrilasyonlu hastalarda vitamin K antagonisti ve yeni oral antikoagülan kullanımı uygulamalarını değerlendirmek için epidemiyolojik çalışma - AFTER*-2 çalışması dizaynı

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ABSTRACT

Objectives: Atrial fibrillation (AF) is one of the most common causes of preventable ischemic stroke and is related to increased cardiovascular morbidity and mortality. There is a lack of data in Turkey on the use of new oral anticoagulants (NOACs), and time in therapeutic INR range (TTR) in vitamin K antagonist users and AF management modality. In this multi-center trial, we aimed to analyze, follow and evaluate the epidemiological data in non-valvular AF patients.

Study design: Four thousand one hundred consecutive adult patients from 42 centers with at least one AF attack identified on electrocardiography will be included in the study. Patients with rheumatic mitral valve stenosis and prosthetic valve disease will be excluded from the study. At the end of one year, the patients will be evaluated in terms of major cardiac end points (death, transient ischemic attack, stroke, systemic thromboembolism, major bleeding and hospitalization).

Results: First results are expected in June 2015. Data about major cardiovascular end-points will be available in January 2016.

Conclusion: The rates and kind of oral anticoagulant use, TTR in vitamin K antagonist users and main management modality applied in non-valvular AF patients will be determined by AFTER-2 study. In addition, the rate of major adverse events (MACEs) and the independent predictors of these MACEs will be detected (AFTER-2 Study ClinicalTrials.gov number, NCT02354456.).

ÖZET

Amaç: Atriyum fibrilasyonu (AF) önlenebilir iskemik inmenin en sık nedenlerinden biri olup artmış kardiyovasküler morbidite ve mortaliteyle ilişkilidir. Ülkemizde yeni oral antikoagülan kullanım sıklığı, vitamin K antagonisti kullanan hastalarda Uluslararası Düzeltme Oranı'nın (INR) etkin düzeyde kalma oranı ve AF tedavi yönetimi ile ilgili büyük bir çalışma mevcut değildir. Bu çok merkezli çalışmada amacımız nonvalvüler AF hastalarında epidemiyolojik verilerin analizi, takibi ve değerlendirilmesidir.

Çalışma planı: Kırk iki merkezden elektrokardiyografisinde en az bir defa AF atağı tespit edilmiş ardışık 4100 erişkin hasta çalışmaya alınacaktır. Romatizmal mitral darlığı ve protez kapak hastalığı olan AF hastaları çalışmaya alınmayacaktır. Hastalar birinci yılın sonunda majör kardiyak sonlanım noktaları (ölüm, geçici iskemik atak, inme, sistemik tromboembolizm, majör kanama ve hastane yatışı) açısından değerlendirilecektir.

Bulgular: İlk sonuçlar Haziran 2015 yılında bekleniyor. Majör kardiyak sonlanım noktaları açısından veriler Ocak 2016'da elde edilecektir.

Sonuç: AFTER-2 çalışması ile ülkemizdeki non-valvüler AF hastalarının oral antikoagülan tedavi kullanım sıklığı ve çeşidi, varfarin alan hastalarda etkin INR düzeylerinde kalma oranı ve benimsenen tedavi yönetimi belirlenecektir. Ayrıca, ülkemizde AF'li hastalarda majör istenmeyen olay sıklığı ve bu olayların bağımsız belirteçleri de ortaya çıkarılacaktır (AFTER-2 Study ClinicalTrials.gov number, NCT02354456).

*AFTER: Atrial Fibrillation in Turkey: Epidemiologic Registry.

Received: January 24, 2015 *Accepted:* February 16, 2015

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a prevalence of 1-2% in the general population.[1] It is the most common cause of preventable stroke, and strongly associated with increased cardiovascular morbidity and mortality.

Abbreviations:

AF	*Atrial fibrillation*
AFTER	*Atrial Fibrillation in Turkey: Epidemiologic Registry*
INR	*International normalized ratio*
TTR	*Time in therapeutic INR range*

The prevalence of AF in Turkey is 1.25%, and its overall morbidity is 6.8/100 person-year according to the national TEKHARF study.[2] The first multi-center trial in AF patients in our country, Atrial Fibrillation in Turkey: Epidemiologic Registry (AFTER) Study, showed that 40% of non-valvular AF patients were on warfarin therapy, with an effective international normalized ratio (INR) rate of 37%, and that the most frequent cause of warfarin underuse was physician neglect.[3] However, the use of new oral anticoagulants, time in therapeutic INR range (TTR) in warfarin users and the main management modality (rhythm or rate control) in AF patients have not been studied in Turkey. In this multi-center trial, we aimed to evaluate the extent of effective anticoagulant use based on a 2012 focused update of the European Society of Cardiology Guidelines for the management of AF, and the epidemiological characteristics of non-valvular AF patients with the use of new oral anticoagulants in clinical practice in addition to the increased awareness provided by the AFTER study.

PATIENTS AND METHODS

Study design, sample size

The AFTER-2 study is planned as a prospective, observational and multi-center study with a 1-year patient follow-up. In the anticipation of a total of 86 deaths and 352 events with a death rate of 2.1 and approximately 10.7 combined events per 100 person/year will be necessary for the multivariate logistic regression analysis intended to find out the independent predictors of the major adverse events. A total of 4100 patients will be included in the study, reflecting the population of the twelve regions of Turkey according to the Nomenclature of Territorial Units for Statistics.

Sample representation

The sample size representing the population of all twelve regions was calculated. Under the leadership of Dicle University Cardiology Department, 42 centers were enrolled in the study after interview and the provision of information on the number of patients they will admit according to the population density of the region. The sample sizes of the regions included in the study are shown in Figure 1. The names of the coordinators and researchers are shown in Table 1.

Trial algorithm

Figure 2 depicts the main steps of the study protocol. “All consecutive adult non-valvular AF patients applying to the cardiology clinics with at least one attack of AF identified on electrocardiography, and

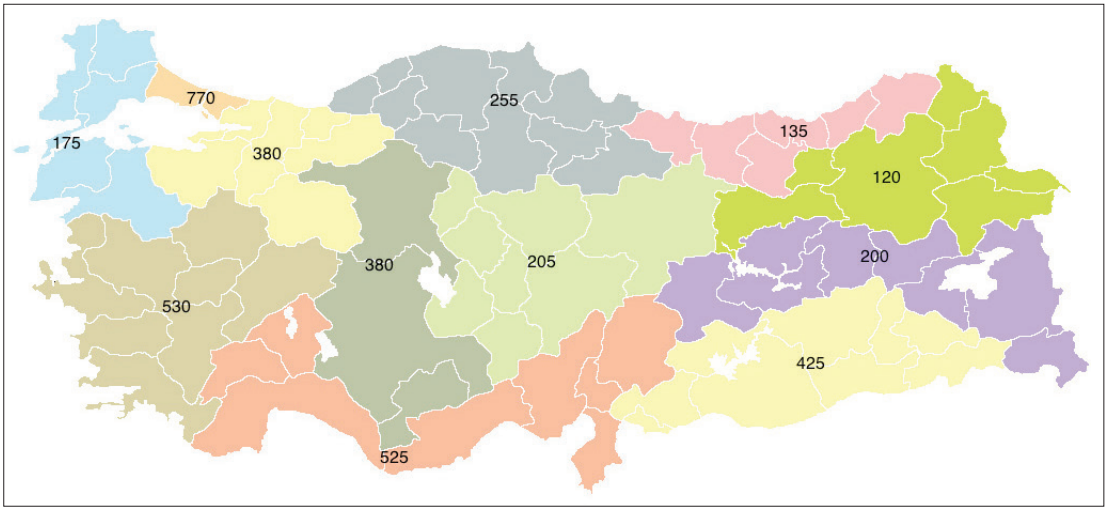

Figure 1. Distribution of the study population according to the Nomenclature of Territorial Units for Statistics.

Table 1. The names of the participating researchers and centers with patient number in AFTER-2 study

Name, Surname	City	Center	Patient number
Faruk Ertaş	Diyarbakır	Dicle University Hospital (Coordinating center)	100
Hasan Kaya	Diyarbakır	Dicle University Hospital (Coordinating center)	
Abdulkadir Yıldız	Diyarbakır	Dicle University Hospital (Coordinating center)	
İbrahim İlhan	Mardin	Mardin State Hospital	110
Vedat Davutoğlu	Gaziantep	Gaziantep University Hospital	135
M. Emre Erkuş	Şanlıurfa	Harran University Hospital	80
Hakkı Şimşek	Van	Yüzüncüyıl University Hospital	110
Yavuzer Koza	Erzurum	Atatürk University Hospital	60
Mehmet Ali Kobat	Elazığ	Fırat University Hospital	90
Tayyar Gökdeniz	Kars	Kafkas University Hospital	60
Ziyaeddin Aktop	Zonguldak	Bülent Ecevit University Hospital	55
Pelin Karaca Özer	Kastamonu	Kastamonu State Hospital	50
Halit Zengin	Samsun	19 Mayıs University Hospital	80
Yusuf Karavelioğlu	Çorum	Hitit University Hospital	70
Abdulkadir Kiriş	Trabzon	Karadeniz Technique University Hospital	135
Murathan Küçük	Antalya	Akdeniz University Hospital	110
D. Yıldıray Şahin	Adana-1	Numune Training and Research Hospital	105
Ç. Emre Çağlayan	Adana-2	Çukurova University Hospital	100
Nihat Şen	Hatay	Mustafa Kemal University Hospital	100
Mine Durukan	Mersin	Mersin State Hospital	110
Hasan Güngör	Aydın	Adnan Menderes University Hospital	100
Ebru Özpelit	İzmir-1	Dokuz Eylül University Hospital	110
Murat Eren	İzmir-2	Bozyaka Training and Research Hospital	110
Fatih M. Uçar	Denizli	Denizli State Hospital	110
Ferhat Özyurtlu	Manisa	Grand Medical Hospital	100
Ahmet Temiz	Çanakkale	18 Mart University Hospital	90
Gökay Taylan	Edirne	Trakya University Hospital	85
Erkan Ayhan	Bursa-1	Medical Park Hospital	100
Fahriye Vatansever	Bursa-2	Yüksek İhtisas Training and Research Hospital	100
Anıl Avcı	İstanbul-1	Koşuyolu Training and Research Hospital	130
Mehmet Gül	İstanbul-2	Mehmet Akif Ersoy Training and Research Hospital	120
Gökhan Ertaş	İstanbul-3	Siyami Ersek Training and Research Hospital	120
Serkan Bulur	İstanbul-4	Medeniyet University Hospital	110
Ahmet Yıldız	İstanbul-5	Cardiology Institute	110
Nuray Kahraman Ay	İstanbul-6	Bezmialem University Hospital	110
Mahmut Gündüz	İstanbul-7	Fatih University Hospital	70
Bülent Vatan	Sakarya	Sakarya University Hospital	100
İbrahim Dönmez	Bolu	İzzet Baysal University Hospital	80
Habibe Kafes	Ankara-1	Yüksek İhtisas Training and Research Hospital	130
Lale Dinç	Ankara-2	Dışkapı Training and Research Hospital	130
Abdullah Tuncez	Konya	Selçuk University Hospital	70
Hüseyin Katlandur	Konya	Mevlana University Hospital	50
Bekir Çalapkorur	Kayseri	Erciyes University Hospital	125
Selami Söylemez	Kırıkkale	Kırıkkale University Hospital	80

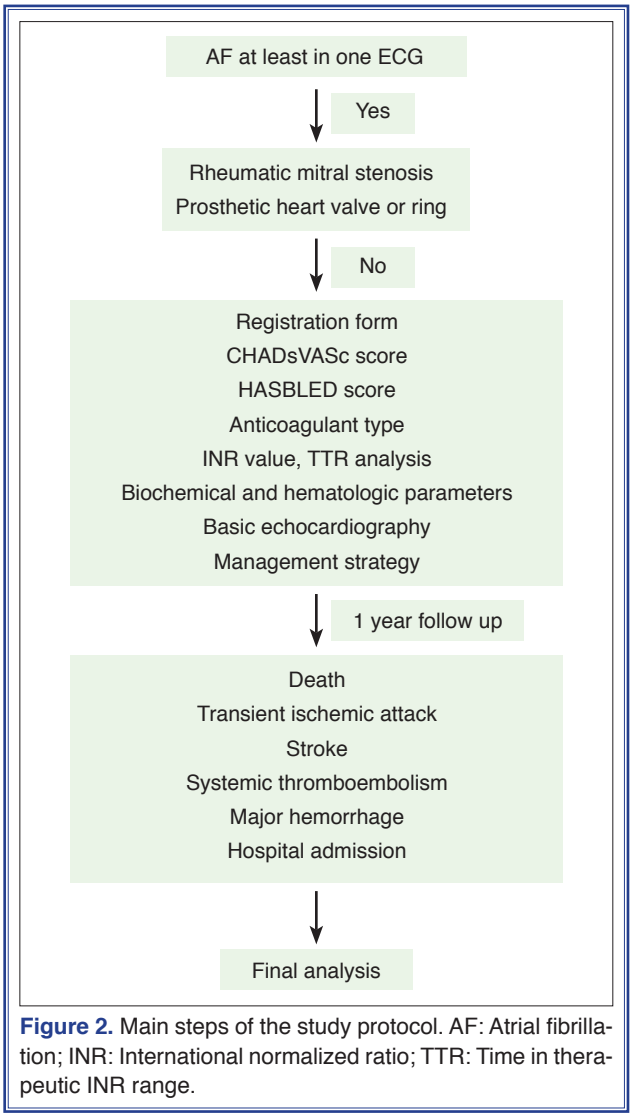

Figure 2. Main steps of the study protocol. AF: Atrial fibrillation; INR: International normalized ratio; TTR: Time in therapeutic INR range.

without rheumatic mitral valve stenosis or prosthetic valve disease" will be included in the study. Patients who refuse to be a participant or to sign the consent form will be excluded from the study. After signing a consent form, the standard registration form generated in accordance with the guidelines will be filled out for each patient (Suppl. 1).[4]

Ethical considerations

The study was approved by local Ethics Committee (The Ethics Committee of Dicle University; date and number: 26/12/2014-47). Every patient will sign a consent form.

Trial outcomes

Primary outcomes of the study are death, transient ischemic attack, stroke, systemic thromboembolism, major hemorrhage and hospital admission. In addition, management strategy and medications used will be assessed. Patient inclusion in the study will start in January 2015, and the date of achievement of the targeted number of patients will be the end date.

Definitions and measurements

The patients will be assessed in terms of basic demographic data and medical treatments. A cardiologist will perform the patient evaluation and the data obtained will be recorded in a patient registration form prepared for the study. Stroke risk will be assessed by CHA_2DS_2-VASc score and bleeding risk by the HAS-BLED score.[5,6] An echocardiographic examination of all patients will be performed to determine the diameters and ejection fraction of the left heart. Routine total blood count parameters, INR values, biochemical profile of the patients will be performed in each center's own laboratory. Assuming that changes between consecutive INR measurements (at least 6) are linear over time, the percent of time in therapeutic INR range will be calculated according to the Roosendaal method.[7] Target TTR level will be accepted as >60%, as the guidelines recommend.

According to International Society on Thrombosis and Hemostasis criteria, major bleeding is defined as that causing a fall in hemoglobin level of at least 2 g per deciliter, leading to transfusion of two or more units of whole blood or red cell, symptomatic bleeding in a critical area or organ, (such as intracranial, intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome) and/or fatal.[8]

Statistical analysis

Data will be analyzed with the Statistical Package for the Social Sciences (SPSS) software version 13.0 for Windows (SPSS Inc, Chicago, IL). The Kolmogorov-Smirnov test will be used to verify the normality of distribution of continuous variables. Continuous variables will be defined as mean ± standard deviation if data show normal distribution; and as median (interquartile range) if data show abnormal distribution. Categorical variables will be given as percentages. The Student t test or the Mann-Whitney U test will be used in comparison between two groups, and one- sided variance analysis (ANOVA) will be used in the comparison of >2 groups for continuous variables.

Abnormally distributed parameters will be compared using the Mann-Whitney U test and the Kruskal-Wallis test between two groups and >2 groups respectively. The Chi-square test will be used for the comparison of qualitative data. The Pearson or Spearmen test will be used in the correlation of variables. A multivariate logistic regression analysis will be used for determination of independent predictors of the primary endpoints, and Kaplan's graphics and Cox hazard proportional analysis will be used for survival analysis at the end of the study. Statistical significance will be defined as $p<0.05$.

DISCUSSION

Our previous multi-center AFTER study showed that fewer than half of the anticoagulation indicated non-valvular AF patients were using warfarin therapy, with almost one-third having an effective INR level. In addition, one-fifth of low-risk patients were using warfarin although it was not indicated according to the guidelines.[3]

With respect to the guideline recommendations, detailed characteristics of the patients with non-valvular AF, the rates and kind of oral anticoagulant use, the effect of increased awareness and NOACs on anticoagulant use rate, TTR in warfarin-using patients and the bleeding risks of the patients will be determined in this study. At the end of the study, we will question the patients in terms of major adverse events and analyze the independent predictors of these events. In addition to making a contribution to the literature, the data will then be channeled into clinical practice.

Conflict-of-interest issues regarding the authorship or article: None declared

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Key words: Anticoagulant agent; atrial fibrillation/epidemiology; drug utilization; electrocardiography; international normalized ratio; warfarin.

Anahtar sözcükler: Antikoagülan ilaç; atriyum fibrilasyonu/epidemiyoloji; ilaç kullanımı; elektrokardiyografi; uluslararası düzeltme oranı; varfarin.

Suppl. 1: AFTER-2 Study-Patient Registration Form

Protocol No		**Barcode**
Hospital		
Date		

Name-Surname				
Republic ID No			**Job**	
Tel 1			**Tel 2**	
Tel 3			**Tel 4**	
Age			**Gender**	
Weight			**Height**	
Blood Pressure	Syst:	Diast:	**Heart Rate**	

AF TYPE

☐	**First Diagnosed AF**	☐	**Paroxysmal**	☐	**Persistant**	☐	**Permanent**

(1) Every patient who presents with AF for the first time is considered a patient with first diagnosed AF, irrespective of the duration of the arrhythmia or the presence and severity of AF-related symptoms.
(2) **Paroxysmal AF** is self-terminating, usually within 48 h. Although AF paroxysms may continue for up to 7 days, the 48 hr time point is clinically important
(3) **Persistent AF** is present when an AF episode either lasts longer than 7 days or requires termination by cardioversion, either with drugs or by direct current cardioversion
(4) **Permanent AF** is considered when the presence of the arrhythmia is accepted by the patient (and physician). Thus, rhythm control interventions are, by definition, not pursued in patients with permanent AF. Should a rhythm control strategy be adopted, the arrhythmia is redesignated as 'longstanding persistent AF'.

EHRA SCORE

☐	**EHRA I**	**'No symptoms'**
☐	**EHRA II**	**'Mild symptoms'; normal daily activity not affected**
☐	**EHRA III**	**'Severe symptoms'; normal daily activity affected**
☐	**EHRA IV**	**'Disabling symptoms'; normal daily activity discontinued**

COMORBID SITUATIONS

☐	Coronary Artery Disease	☐	Deep Vein Thrombosis
☐	Ischemic Cardiomyopathy (CMP)	☐	Pulmonary Thromboemboli
☐	Dilated CMP	☐	Thyrotoxicosis
☐	Hypertrophic CMP	☐	Chronic Kidney Disease
☐	Chronic Obstructive Lung Disease	☐	Smoking

CHA_2DS_2VASc SCORE		Point	
C	Congestive Heart Failure/LV Dysfunction (EF<%40)	1	
H	Hypertension	1	
A	Age ≥75	2	
D	Diabetes Mellitus	1	
S	Stroke, TIA, Tromboemboli	2	
V	Vascular disease (MI, PAH, Aortic plaque)	1	
A	Age 65-74	1	
S	Sex Category	1	
		Total Point	

HASBLED SCORE		Point	
H	Hypertension	1	
A	Abnormal Kidney tests	1	
	Abnormal Liver tests	1	
S	Stroke	1	
B	Bleeding	1	
L	Labile INRs	1	
E	Elderly (>65)	1	
D	Drug	1	
	Alcohol	1	
		Total Point	

"Hypertension" is defined as systolic blood pressure >160 mmHg. No point is given to the controlled HT
"Abnormal kidney function" is defined as the presence of chronic dialysis or renal transplantation or serum creatinine ≥ 2.3mg/dl
"Abnormal liver function" is defined as chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin .2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase .3 x upper limit normal, etc.)
"Bleeding" refers to previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia, etc.
"Labile INRs" refers to unstable/high INRs or poor time in therapeutic range (e.g. <60%).
"Drugs/alcohol use" refers to concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse, etc.

HEMATOLOGICAL PARAMETERS
Hb (g/dl)
MPV
Htc (%)
RDW
PLT (x1000)
PDW
WBC (x1000)
Platecrit
Neutrophil (%)
Lymphocyte (%)
Monocyte (%)

BIOCHEMICAL PARAMETERS
Glucose
Urea
Creatinine
ALT
AST
GGT
Albumin
T.cholesterol
Trygliceride
LDL
HDL
Uric acid
Ind. Bilirubine
T. Bilirubine

LA volume = (0.85 x A1 x A2 / L

A1 = LA area apical 4-chamber (A-4C)

A2 = LA area apical 2-chamber (A-2C)

L = shorter LA length from mid plane of mitral anulus to superior LA from either A-4C or A-2C

ECHO PARAMETERS	
EF (%)	
LA diameter (mm)	
LA volume (mm^3)	
LA thrombus history	

CONSECUTIVE INR VALUES FOR TTR CALCULATION

Date (day/month/year)	INR	Mean daily warfarin dosage (mg)

NEW ORAL ANTICOAGULANT (NOAC) USE AND USAGE PERIOD (IF ANY)

☐ Pradaxa 110 mg	☐ Pradaxa 150 mg	Period (month):
☐ Xarelto 15 mg	☐ Xarelto 20 mg	Period (month):
☐ Eliquis 2.5 mg	☐ Eliquis 5 mg	Period (month):

ANTIAGGREGANT USE (IF ANY)

☐ ASA	☐ Prasugrel
☐ Clopidogrel	☐ Ticagrelor

RHTYHM DRUGS USE (IF ANY)

☐ B-blocker =	☐ Amiodarone
☐ Diltiazem	☐ Propofenon
☐ Verapamil	☐ Sotalol
☐ Digoxin	☐ Other

OTHER DRUGS (IF ANY)

☐ ACEI =	☐ Diuretics =
☐ ARB =	☐ Nitrate =
☐ Nifedipine	☐ Alfa-blocker =
☐ Digoxin	☐ PPI=
☐ Statin =	☐ Other

1. WHAT WAS THE REASON OF NOT TO USE ANTICOAGULANTS IN THE PATIENT?	
	High bleeding risk (HASBLED)
	Neuropsychiatric disorders (Demans, Alzheimer, Anxiety, Depression)
	Fall risk
	History of bleeding episodes
	Peptic ulcus disease
	Intracranial aneurysms
	Refusal of the patient
	Socioeconomic problems (where they live, the lack of follow-up opportunity, educational status)
	Physician neglect
	Physician choice due to teh advanced age of patient
	First diagnosed AF

2. ALTHOUGH NOACS ARE RECOMMENDED AS THE 1ST CHOICE BY THE GUIDELINES, WHY WERE THE PATIENTS NOT PRESCRIBED NOACS?	
	Distrust as they are new
	Because of the cost
	Contraindicated
	Physician choice
	Obligation of warfarin use before NOACs to be paid by social insurance system

3. IS THERE ANY SWITCH FROM NOACs TO WARFARIN OR VICE VERSA? WHY?	

4. WHAT IS THE MANAGEMENT STRATEGY APPLIED TO THE PATIENT?	
	Rate control
	Rhthym control (please answer the following questions)
	Medical cardioversion was previously applied. Current treatment?
	Electrical cardioversion was previously applied. Current treatment?
	AF ablation was previously applied. Current treatment?
	Rhyhym control was previously applied, recurrent AF was detected. Current treatment?
	LA appendage closure. Which method?