Assessment of the substrate for atrial fibrillation using tissue velocity imaging of the fibrillating wall

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Primary Objective: to show that TVI of the atrial wall during ongoing AF may be used to predict long-term progression to (or recurrence of) persistent AF in patients with paroxysmal and persistent AF undergoing rhythm control.Secondary Objective(s...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON36728

Source
ToetsingOnline

Brief title
Assessment of the substrate for AF using TVI of the fibrillating wall

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: antiarrhythmic agents, atrial fibrillation, cardioversion, echocardiography

Outcome measures

Primary outcome

Primary endpoint:

persistent AF during one year follow-up.

Secondary outcome

(a) conversion to sinus rhythm

(b) serial AFCL-TVI and AFV-TVI assessments completed

(c) development of persistent AF on amiodarone

(d) development of persistent AF or major adverse cardiovascular or

cerebrovascular events during 3-5 years follow-up.

Study description

Background summary

Atrial fibrillation (AF) may provoke palpitations, dyspnea, chest pain, fatigue and syncope, all of which may be relieved by rhythm control. Unfortunately, AF recurrence is frequent with over 50-70% of patients again in AF within one year after initial treatment. In addition, rhythm control may not prevent progression to persistent AF in 8.6-15% of paroxysmal AF patients. Identifying patients who will respond to rhythm control is worthwhile since it will prevent unnecessary use of antiarrhythmic drugs, electrical and pharmacological cardioversions and ablations. Predictors of recurrence or progression include advanced age, long AF duration, type of underlying heart disease, transient ischemic attack or stroke, chronic obstructive pulmonary disease, hypertension and large left atrial size. These predictors are not used in a systematic fashion in clinical practice because they lack predictive accuracy, conceivably due to the fact that they only relate indirectly to atrial remodelling. It may be conjectured that parameters derived directly from the atrial wall are better predictors.
The atrial refractory period (ARP) is an important parameter of electrical

remodelling and it may predict the response to rhythm control. The shorter the ARP, the worse arrhythmia outcome, i.e. the higher the risk of progression to persistent AF. To predict the response to treatment, ideally one needs to assess the patient before the treatment is given, i.e. during ongoing AF. One way to do this is to assess the AF cycle length (AFCL) during ongoing AF, because it represents the ARP. However this measurement is complex and invasive since it involves the use of catheters which is patient unfriendly and not without risk .
Current echocardiographic techniques include the option of tissue velocity imaging (TVI) enabling detailed assessment of the atrial walls. Using this new technique we recently validated a so-called echoelectrocardiographic method to assess AFCL using tissue velocity imaging (AFCL-TVI) of the fibrillating atrial myocardium. We demonstrated that AFCL-TVI matches accurately with the invasively measured electrophysiological AFCL.[9], and thus also reflects the ARP. Considering the above, it is reasonable to assume that the AFCL-TVI may be used to assess atrial electrical remodelling and hence also arrhythmia prognosis.
Apart from electrical remodelling (i.e. shortening of ARP) also structural remodelling causes recurrences of AF. The latter is characterised by fibrosis and loss of contractility of the atrial wall. Clinically, structural remodelling is assessed only indirectly by measuring atrial size and transmitral and left atrial appendage flow velocities.
Nowadays, direct information on atrial contractility may be obtained by imaging the atrial fibrillatory wall motion velocity using TVI (AFV-TVI). Using atrial TVI we have recently shown that advanced electrical and structural remodelling in patients with AF is characterized by short AFCL-TVI and low AFV-TVI. Conceivably this direct information on atrial contractility reflecting structural remodelling may provide a firmer basis for predicting arrhythmia outcome after AF treatment compared to conventional echocardiographic and clinical parameters. However, at present it is unknown whether atrial TVI focusing on electrical and structural remodelling may be used to predict arrhythmia prognosis in patients with paroxysmal and persistent AF (primary objective). In addition, atrial TVI may provide information about the clinical and electropharmacological response to pharmacological conversion, both during intravenous and oral administration of the anti-arrhythmic drug (secondary objectives). Clinically, it is of utmost importance to identify patients who will not respond to pharmacological rhythm control to avoid unnecessary adverse drug effects.

Study objective

Primary Objective:
to show that TVI of the atrial wall during ongoing AF may be used to predict long-term progression to (or recurrence of) persistent AF in patients with paroxysmal and persistent AF undergoing rhythm control.

Secondary Objective(s):

(a) in paroxysmal AF patients to show that acute pharmacological cardioversion may be predicted by atrial TVI before drug treatment
(b) in patients with persistent AF undergoing amiodarone loading, to show that TVI can reveal electropharmacological and contractility effects of amiodarone
(c) in patients with persistent AF undergoing amiodarone loading, to show that time-dependent changes in atrial TVI parameters can be used to predict long-term outcome on amiodarone

Study design

This is a multicentre exploratory study to assess the value of echocardiographic tissue velocity imaging (TVI) in predicting short and long term arrhythmia outcome in patients with AF undergoing rhythm control treatment. After obtaining informed consent, patients will undergo complete trans-thoracic echocardiography while still in AF, including recording of the novel atrial TVI parameters. All baseline characteristics and echocardiographic measurements will be noted in a case record form. These include demographic characteristics, medical history, use of anti-arrhythmic drugs, previous rhythm control, data on electrocardiogram and echocardiogram. After the baseline echocardiogram, pharmacological or electrical cardioversion will be performed. After the cardioversion, patients will be followed in the outpatient clinic at 1 month and at regular intervals thereafter, for a minimum of 1 year. During follow-up the rhythm as well as major adverse cardiovascular and cerebrovascular events will be recorded. If AF is continuously present for > 48 hours (Holter) the primary endpoint will be reached. In patients with paroxysmal AF undergoing pharmacological cardioversion using flecainide or ibutilide, the rhythm will be continuously monitored for at least 1-4 hours after ending the intravenous treatment. The time point of conversion to sustained (>1 minute) sinus rhythm will be noted. If conversion to sinus rhythm occurs within 60 minutes after start of the infusion, one of the secondary endpoints (2a) will be reached. In patients with persistent AF undergoing amiodarone loading, serial follow-up echocardiograms will be taken at weekly intervals after start of loading and on the day of the electrical cardioversion (secondary endpoint 2b). After cardioversion all patients will be followed as mentioned above and recurrence of persistent AF while treated with amiodarone will be noted (secondary endpoint 2c). See figure with study flow chart and numbered objectives.

Study burden and risks

Patients with paroxysmal AF only receive one echocardiography before treatment. Patients do not have to come for an extra visit. In patients with persistent AF undergoing amiodarone loading, serial follow-up echocardiograms will be taken at weekly intervals after start of loading and on the day of the electrical cardioversion. There is no risk of undergoing an echocardiography. In some patients , if the heart rate is too high carotid sinus massage will be

performed or patients will receive a low dose of betablocker (metoprolol) or verapamil. In this way, a heart rate < 80 beats per minute can be achieved to obtain optimal echocardiographic images. Carotid sinus massage or intravenous administration of metoprolol or verapamil are frequently used in patients with supraventricular rhythm disorders. Infusion of these agents in patients with high heart rate may have beneficial effects by lowering heart rate. If applied following clinical rules, infusion of these rate slowing drugs is not related with significant side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with acute paroxysmal AF referred for pharmacological cardioversion or patients with

persistent AF referred for electrical cardioversion.

Exclusion criteria

- <18 years, permanent AF
- patients with a clinical contra-indication for flecainide, ibutilide or amiodarone (including pregnancy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2011
Enrollment:	229
Type:	Actual

Ethics review

Approved WMO Date:	11-05-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34913.068.11