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Atrial fibrillation in hypertensive patients

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Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia in humans and its prevalence is 1-2% of the general population worldwide. 1 It affects 6 million people in Europe, while it is expected that its incidence will increase up to 2.5-fold over the next 50 years. It is estimated that atrial fibrillation poses a high economic burden for the healthcare system, since it is responsible for up to one third of the hospitalizations for cardiac arrhythmias. Subjects, who have reached the age of 40, present a lifetime risk of 25% for developing atrial fibrillation and its incidence increases as the population ages2. Atrial fibrillation affects significantly morbidity and mortality (2-to 7-fold increased risk for stroke, 2-3 fold increased risk for dementia and 3-fold increased risk for heart failure), while it is responsible for approximately 20% of all strokes. Finally, undiagnosed or silent episodes of atrial fibrillation may be the main cause of cryptogenic strokes. 3-5

This study has the purpose to found new markers correlated with the presence of AF, markers that will probably explain the development of AF in the general population as well as to assess the use of anticoagulants and the % of patients on target INR goal. In addition, will be assessed the possible correlation of left atrial (LA) strain with arterial hypertension and with atrial fibrillation, the correlation of LA strain with AF incidence as well as the possible correlation of various drugs with LA strain. In addition will be assessed the possibility that reverse remodeling of left atrium or blood pressure control will affect also LA. The hypothesis is that the LA 2 D strain parameters may be significantly lower compared to the control subjects if the reservoir and/or contractile function of LA are impaired.

Methods

This is a multicenter, prospective, observational study that will enroll 400 patients with AF (80 AF patients per center), 350 patients with arterial hypertension (50 HTN patients per center) and 350 healthy subjects (50 controls per center). All patients will undergo to laboratory exams including thyroid, ECG, 24 hours holter monitoring, ABPM/ Office BP measurement, to an echocardiographic assessment that includes TDI, left atrium and left ventricle strain, pulse wave velocity, augmentation index and central aortic blood pressure. Patients and healthy subjects will be assessed at baseline and after 6 months of follow up.

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Main inclusion criteria

Patients with persistent or paroxysmal AF on sinus rhythm (1000 pts). Patients with hypertension and not other risk factors and diseases (300 pts). Control patients (300)

Main exclusion criteria

Patients with significant valvulopaties, with pacemaker, renal disease (GFR < 30 mL/min) as well as patients with major hematological, renal, hepatic, pulmonary, or cardiac disease, or any other clinically significant illness with poor health conditions, women on pregnancy, patients with secondary hypertension, clinically important abnormalities of baseline screening laboratory data and with thyroid disease.

Synthetic description of procedures and methods used to evaluate the effect of investigational treatment(s): clinical, laboratory, instrumental etc.

Enrollment

- 24-hour ambulatory BP monitoring (usual workday, measurements at 20 min intervals, validate oscillometric device SpaceLabs 90207 or 90217). This examination aims in the exclusion of overestimation of BP dew to the white coat hypertension and to avoid pointless treatment.
- Clinic BP (triplicate seated measurements after 5 min rest and with 30 sec between measurements using a standard mercury column, trough measurements for treatment titration and study completion).
- Blood for NT pro BNP, MR-proANP, VEGF, YKL-40, T lymphocytes
- Hct, Hb, WBC, P/L/M/E, MPV, P/L/M/E, PLT, K,Na, HbA1C,Glu, SGOT, SGPT, γGT, Urea, Creat, Uric acid, T.Chol, HDL-c,LDL-c, TGL, microalbumninuria, T3,T4,TSH,FT3, FT4,TPO.
- Measurement of Pulse Wave Velocity: Pulse wave velocity (PWVcf) will be measured at baseline. Patients will be rested in the supine position for 15 minutes; measurements will be taken after measurement of brachial blood pressure.
- Central blood pressure: Central aortic pressure can be derived noninvasively by examining the shape of the pulse wave at the wrist.
- Pulse pressure: Formally it is the systolic pressure minus the diastolic pressure.
- Assessment of a patient with echocardiography

Complete echocardiographycal assesment

Parameters to be measured
M mode examination
End diastolic Interventricular septum thickness cm
End diastolic Posterior wall thickness cm
End diastolic LV dimensions cm
End systolic Interventricular septum thickness cm
End systolic Posterior wall thickness cm
End systolic LV dimensions cm
Aortic root diameter cm
Atrial diameter cm
Right ventricular enddiastolic diameter cm
2D 2 chambers and 4 chambers examination
Atrial area (2 chambers)
Atrial area (4 chambers)
Vertical diameter (2 chambers)
Vertical diameter (4 chambers)
LV endsystolic area (4 chambers)
LV enddiastolic area (4 chambers)

Doppler examination

Mitral valve E Velocity cm/sec
Mitral valve A Velocity cm/sec
Mitral valve E wave deceleration msec
Systolic pulmonary artery pressure mmHg

Tissue doppler examination

Mitral valve peak early diastolic velocity Lateral Em
Mitral valve peak late diastolic velocity Lateral Am
Mitral valve peak systolic velocity Lateral Sm
Mitral valve peak early diastolic velocity Septal Em
Mitral valve peak late diastolic velocity Septal Am
Mitral valve peak systolic velocity Septal Sm
Left ventricle and left atrium strain.

At week 24

- Repeat the same measurements at baseline

SYNTHETIC FLOW-CHART OF THE STUDY

WEEK 0

PATIENT NUMBER _____ SCREENING VISIT_____-_____-201___
PATIENT NAME _____
DATE OF BIRTH ___-___-___
Sex:_____ Weight_____ Kg
Height_____cm BMI_____Kg/m2(Should BE<30 Kg/m^2
Waist:_____cm
Hip:_____cm

Valvulopaties	EXCLUDE IF YES
Pacemaker	EXCLUDE IF YES
Renal disease (GFR < 30 mL/min)	EXCLUDE IF YES
Major hematological, renal, hepatic, pulmonary, or cardiac disease, or any other clinically significant illness with poor health conditions	EXCLUDE IF YES
Women on pregnancy	EXCLUDE IF YES
Secondary hypertension	EXCLUDE IF YES
Clinically important abnormalities of baseline screening laboratory data	EXCLUDE IF YES
Thyroid disease	EXCLUDE IF YES

WEEK 0

SCREENING VISIT:_____-_____-201__

CLINIC BP (VISIT 1)
SEATED (after 5 min)

	BP (mmHg)	Pulse/min
1st	_____ / _____	_____
2nd	_____ / _____	
3rd	_____ / _____	

RESTING E.C.G. REPORT
E.C.G. WITHIN NORMAL LIMITS: YES NO

Comments_____
_____

LABORATORY DATA

Hct	Gluc	SGOT
Hb	Urea	SGPT
WBC	Creat	INR
P/L/M/E	Uric acid	γGT
PLT	K	TProt
HbA1C	Na	Alb
T.Chol	Urine Analysis: proteine	TBil
HDL-c LDL-c	TGL	MPV

MEDICATION

DRUG	DAILY DOSE	OTHER THAN DAILY	DATE STARTED

WEEK 0

1 HISTORY INCLUSION CRITERIA OK?	
2 BASELINE BLOODS OK ?	
3 ECG OK?	
4 CLINIC BP INCLUSION CRITERION OK ?	
5 AMBULATORY BP CRITERION OK?	

If all criteria satisfied, take bloods for:

- Blood for NT pro BNP, MR-proANP, VEGF, YKL-40, T lymphocytes
- Hct, Hb, WBC, P/L/M/E, MPV, P/L/M/E, PLT, K,Na, HbA1C,Glu, SGOT, SGPT, γGT, Urea, Creat, Uric acid, T.Chol, HDL-c,LDL-c, TGL, microalbumninuria, T3,T4,TSH,FT3, FT4,TPO.

Arrange measurements for: PWV, cBP and for: 24 hours holter monitoring and echocardiogram

24 HOUR AMBULATORY BP
Date started:__/__-201 time __:__ a.m
Date ended: __/__-201 time __:__ a.m

Satisfactory recording (Successful readings >70%)
NO → REPEAT 24H AMBULATORY BP MONITORING
YES

Sleeping Times Siesta: In bed:__-__ hrs Out of bed:__-__hrs

Nighttime sleep: In bed:__-__ hrs Out of bed:__-__hrs

Arrange next visit after 24 weeks

WEEK 24

CLINIC BP (VISIT 1)
SEATED (after 5 min)

	BP (mmHg)	Pulse/min
1st	_____ / _____	_____
2nd	_____ / _____	
3rd	_____ / _____	

RESTING E.C.G. REPORT
E.C.G. WITHIN NORMAL LIMITS: YES NO
Comments_____
_____

LABORATORY DATA

Hct	Gluc	SGOT
Hb	Urea	SGPT
WBC	Creat	INR
P/L/M/E	Uric acid	γGT
PLT	K	TProt
HbA1C	Na	Alb
T.Chol	Urine Analysis: proteine	TBil
HDL-c LDL-c	TGL	MPV

MEDICATION

DRUG	DAILY DOSE	OTHER THAN DAILY	DATE STARTED

Take bloods for:

- Blood for NT pro BNP, MR-proANP, VEGF, YKL-40, T lymphocytes
- Hct, Hb, WBC, P/L/M/E, MPV, P/L/M/E, PLT, K,Na, HbA1C,Glu, SGOT, SGPT, γGT, Urea, Creat, Uric acid, T.Chol, HDL-c,LDL-c, TGL, microalbumninuria, T3,T4,TSH,FT3, FT4,TPO.

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Date ended: __/__-201 time __:__ a.m

Satisfactory recording (Successful readings >70%)
NO → REPEAT 24H AMBULATORY BP MONITORING
YES

Sleeping Times Siesta: In bed:__-__ hrs Out of bed:__-__hrs

Nighttime sleep: In bed:__-__ hrs Out of bed:__-__hrs

Conflicts of interest/ source of funding

None.

Reference

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