Fundació La Marató de TV3
21st SYMPOSIUM
Heart diseases

EFFECTS OF CPAP TREATMENT IN DE NOVO APPEARANCE OF AF IN PATIENTS WITH NON-SERIOUS OSAS

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1. Summary of the project

Goals

The first goal of the study is to analyse the difference in the incidence of de novo AF in patients with high risk of AF and affected by OSAS who are treated with CPAP compared with those not treated with CPAP. Another goal is to study the incidence of de novo AF in these patients according to the degree of OSAS. A further goal is the study of the predictor factors, both clinical and analytical, of appearance of de novo AF in these patients, placing special emphasis on the role of the microRNA.

These are patients who a priori have a high risk of appearance of AF (defined in this study by a risk >30% for a period of 3 years in the PACE risk calculator, in the annexe, or by the presence of history of typical flutter previously treated invasively).

The last goal is to study the predictor factors of evolution to de novo AF in patients with ablation of typical flutter and to perfect the PACE risk calculator by means of the invasive follow-up (insertable Holter) of all the patients.

Design and plan of work

This is a single-centre, prospective, randomised study, which will include patients affected by moderate and serious OSAS (more than 15 apnoeas-hypopnoeas per hour) and with high risk of AF. As well as the study group there will be a control group, without PSG because of low suspicion of OSAS or with PSG but with a non-significant degree of OSAS (AHI <15). The members of this group will undergo an initial visit in which they will be told about the study and its goals, the inclusion and exclusion criteria will be assessed and the informed consent will be signed. Then, the injectable subcutaneous Holter will be inserted via the day hospital (except in the patients of the pacemaker (PM) group), and the extraction for analysis will be made, which will be centrifuged, aliquoted and frozen. After that, the patients with significant OSAS will be randomised in one of the intervention groups: with CPAP treatment (group 1) or without treatment (group 2), with parallel follow-up of the patients of the control group (group 3).

PM subgroup

The study will include a maximum of 10% of patients from the pacemaker data base. These patients will have to meet all the inclusion criteria, and must not present any of the of exclusion criteria. They will also have one particular characteristic: because they have pacemakers it will not be necessary to insert a Holter as the pacemaker is equally capable of diagnosing de novo AF.

The arrhythmias unit will monitor all the patients with telemetric controls (ECG data which it will send weekly to the implanted device transtelephonically) with the aim of making the diagnosis of AF as sensitive and early as possible. Also, cardiology will make an annual check in the dispensary of arrhythmias during a minimum follow-up period of 2 years, and pneumology will check the CPAP settings after 1, 3, 6 and, 12 months and annually thereafter. The intention analysis of the data will be by intention to treat.

The subjects to be studied will be volunteers, and to participate in the study they must meet the inclusion criteria set out below according to the group they belong to. For the intervention group patients the inclusion criteria are:

-They must be affected by moderate or serious OSAS (apnoea-hypopnoea index greater than 15 per hour) and must be asymptomatic.
-They must present high risk of AF (risk >30% in the following 3 years according to the PACE risk calculator or previous ablation of the flutter).

For the control group patients the inclusion criteria are:

-They must be affected without suspicion of OSAS, with mild OSAS or with normal PSG (apnoea-hypopnoea index less than 15 per hour).
-They must present high risk of AF (risk >30% in the following 3 years according to the PACE risk calculator or previous ablation of the flutter).

The exclusion criteria are:

-Patients with known AF.
-Patients under 45 years (limitation due to the age ranges treated in the previous

studies, which define the predictor factors of AF).
-Indication of CPAP by severe symptomatic OSAS.
-Serious illness that makes expected survival less than 2 years.
-Impossibility of understanding the protocol to do the necessary controls.

The sample size necessary to detect as sadistically significant a difference of 30% in the appearance of AF over the 2-year follow.-up between the two groups is of 35 patients per group (expected incidence: 40% in group 1 and 10% in group 2), and assuming a statistical power of 80%, an alpha error of 0.05 and a maximum loss during follow-up of 10%.

The study foresaw an approximate inclusion period of 12 months and a duration of 3 yearns (minimum follow-up of 2 years), but it was extended due to the difficulty of recruiting patients during the first part of the study.

Survival curves will be made to compare the incidence of de novo AF (principal endpoint, defined as at least one occurrence of AF of at least 2 minutes duration) in the two treatment groups and in the control group. Survival curves and Cox regression analysis curves will also be used to establish which are the clinical and analytical predictor factors connected with the evolution of the appearance of AF.