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A new tool for screening severe sleep apnea syndrome

Submission date
19/03/2019

Recruitment status
No longer recruiting

Registration date
22/03/2019

Overall study status
Completed

Last Edited
22/03/2019

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aim
Obstructive sleep apnea syndrome (OSAS) affects nearly one billion people worldwide. Specific screening tools are not available to identify OSAS in nocturnal polyuria (NP) populations. To develop a screening tool for detecting severe OSAS in patients presenting with NP.

Who can participate?
Men aged over 18 years who have nocturia due to nocturnal polyuria

What does the study involve?
This is a retrospective review of patients diagnosed with nocturia due to nocturnal polyuria and screened for obstructive sleep apnea syndrome between 2016 and 2018. The researchers gathered data about the collection of data, the characteristic of patients and their follow up. This is done to develop a screening tool for detecting severe OSAS in patients presenting with nocturnal polyuria.

What are the possible benefits and risks of participating?
There are no benefits or risks for participating.

Where is the study run from?
Clinique Pasteur, Toulouse

When is the study starting and how long is it expected to run for?
January 2016 to December 2018.

Who is funding the study?
The Clinique Pasteur

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2212434

Study information

Scientific Title
A tool for severe obstructive sleep apnea syndrome screening in patients with unexplained nocturnal polyuria

Study objectives
Obstructive sleep apnea syndrome (OSAS) affects nearly one billion people worldwide. Specific screening tools are not available to identify OSAS in nocturnal polyuria (NP) populations. Our aim was to develop a screening tool for detecting severe OSAS using a large single-institutional dataset of patients referred for nocturnal polyuria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/01/2016, Commission nationale de l'informatique et des libertés (CNIL, 3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07, France; +33(0)153732222), ref: 2212434

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied
Nocturia

Interventions
Medical records of patients diagnosed with nocturia due to nocturnal polyuria and screened for obstructive sleep apnea syndrome (OSAS) with a sleep study (overnight polygraphy)
Patients diagnosed with severe OSAS were compared to a group of patients without OSAS or diagnosed with mild to moderate OSAS. Clinical predictive factors associated with severe OSAS were identified via logistic regression. A score combining the main predictors was created and evaluated.

Intervention Type
Other

Primary outcome(s)
To design and validate a new “score” (the Clinique Pasteur score) to detect severe OSAS in patients with unexplained nocturnal polyuria.

Key secondary outcome(s))
To validate this “score” (internal validation)

Development of the score
Step 1: logistic regression model
The first step in constructing the score was to perform a multivariate logistic regression analysis. All variables associated with severe OSAS according to a p value <0.2 in the logistic regression were selected. For continuous variables, the log-linearity assumption had to be fulfilled to ensure the validity of the model. If this assumption was not fulfilled, the continuous variable was categorized. The continuous variables included in the final model were age and BMI, and the assumption of log-linearity was not fulfilled. The thresholds chosen for the categorization of BMI were 25 kg/m2 and 30 kg/m2 according to anthropometric definition (normal/overweight /obese). The threshold for age (70 years) was much more arbitrary and was choose for sample size and powerful of the prediction reasons. The results of the model are expressed by means of odd-ratio together with their 95% confidence intervals computed by Wald’s methods.
The performance was assessed by the rate of prediction error, the receiver operating characteristic (ROC) curve and a graphical illustration of the specificity/sensitivity of the model. The area under this curve (AUC) and its 95% confidence interval computed by bootstrap procedure (2000 replicates) indicated the predictive performances of the model.
The internal validity of the model was investigated by splitting the database into two cohorts: a learning cohort (65% of the sample size) to create the model and a validation cohort (35% of the sample size) to assess. Individuals were randomly assigned to one of the cohorts. The predictive performance was assessed by the rate of prediction error and ROC curves.
Step 2: construction of the score
As the variables involved in the model were discrete, it was possible to construct a simplified score by choosing intergern proportional values to rounded values of the logistic regression coefficients. This simplified score was constructed by using the connection between the values of the score and the predicted probabilities for a patient presenting with unexplained NP to have a severe OSAS. The choice of the cut-off score was made according to the plot of PPV and NPV as a function of the threshold.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Diagnosed with a nocturia due to nocturnal polyuria
2. Screened for sleep apnea syndrome with overnight polygraphy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients presenting with the following potential causes of nocturnal polyuria:
1.1 Diabetes insipidus
1.2 Uncontrolled diabetes mellitus (defined by a serum glucose level > 200 mg/dL)
1.3 Severe renal impairment (defined by a glomerular filtration rate of <30 ml/min)
1.4 Hart failure
1.5 Oedematous state

Date of first enrolment
21/01/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
France

Study participating centre
Clinique Pasteur
45 avenue de Lombez
Toulouse
France
31300

Sponsor information

Organisation
Clinique Pasteur

ROR
https://ror.org/03er61e50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinique Pasteur

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date