

MANAGEMENT OF SLEEP APNEA PATIENTS BY A CLINICAL NURSE (SUPERNURSE)

PROTOCOL SYNOPSIS

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1. BACKGROUND

Obstructive sleep apnea is the most common of sleep-related disorders and references for the evaluation of this disease often exceeds the sleep clinic's evaluation capacity thus creating important delays in patients' care. In the past two years, the Institut Universitaire de Cardiologie et de Pneumologie de Québec-Université Laval (IUCPQ-UL)'s Department of Respiriology has reorganized the clinical activities of its sleep clinic and incorporated the completion of a nocturnal ambulatory investigation before the patients being seen at the sleep clinic. These improvements to the system not only have increased the number of patients seen by the respirologist but also increased the number of time slots available for new patients' consultations. This strategy was victim of its own success as the number of patients evaluated at the sleep clinic increased from 1239 patients per year in 2012-2013 to 2255 patients in 2014-2015. While the number of patients assessed had peaked, the number of references for new patient consultations continues to grow up, with a mean of 83 new references weekly. Our center currently provides between 40 and 55 time slots weekly for patient evaluation by a respirologist, thus creating an excess of requests from 28 to 43 patients per months. Therefore, other strategies must be implemented to preserve accessibility and quality of patients care.

The variety of symptoms presented by patients with sleep-disordered breathing and the complexity, variety and limited access of investigation modalities have led to concentration of investigation and treatment of sleep-related disorders to specialized physicians, mainly composed of respirologists. Two randomized clinical trials (RCT) have demonstrated that these steps can be efficiently performed by properly trained nurses. A recent RCT compared two models of management in the sleep clinic, one with supervision and management by a trained sleep clinic nurse compared to a traditional physician-directed clinical care. Overall the study included 195 patients who were unrepentant snorers with an Epworth Sleepiness Scale (ESS) score greater than 8/24 and an oxygen desaturation index (ODI) (2%) greater than 27 events per hour as determined by home oximetry testing. The prescription of automatic continuous positive pressure (CPAP) treatment or CPAP titration, the interpretation of results and the follow-up were assured independently either by the nurse or the physician. Follow-up at 3 months did not find any difference between the two groups in terms of correction of daytime sleepiness, as measured by the Epworth Sleepiness Scale and by objective measurement by wakefulness test, improvement of quality of life and treatment follow-up.¹ Another RCT evaluated 155 patients randomized to receive primary care management (primary care physician and a community-based nurse trained for the

management of obstructive sleep apnea) or management in a specialized sleep center. Patients enrolled had a high probability of sleep apnea based on symptoms, an ESS greater than 8/24 and ODI (3%) greater than 15 events per hour. Follow up at six months showed no difference between the two groups in terms of improvement in daytime sleepiness measured by the ESS scale, improvement in quality of life and differences in treatment adherence.²

Considering the increasing number of references for evaluation of new patients with clinical suspicion of sleep apnea and the lack of additional resources available from the IUCPQ-UL respirologists, other strategies must be implemented to preserve quality of care. Therefore, this project aims to assess the feasibility and effectiveness of creating a multidisciplinary team at the sleep clinic, allowing a clinical nurse to receive and evaluate selected patients for their first consultation.

2. METHODS

2.1 Study Design Overview

This study is a randomized open label non-inferiority study. The research protocol was approved by the IUCPQ-UL research ethics committee. Patients are to provide written informed consent upon inclusion in the study.

2.2 Settings and Participants

The patients will be selected for inclusion based on information available to the investigators or pulmonologist of the sleep clinic from data from the cardio-respiratory recording reports completed for patients who are to be seen for an initial, non-urgent, outpatient visit to the sleep clinic. The reports are available every morning at the sleep laboratory.

The list of eligible patients will be scheduled by the sleep clinic secretary on the time slots available for consultation. Patients meeting all of the following criteria will be eligible:

- Body mass index (BMI) $\leq 35 \text{ kg/m}^2$;
- Apnea-hypopnea index (AHI) ≥ 20 events per hour according to the report of the cardio-respiratory home recording;
- Central apnea index ≤ 5 events per hour;
- Percentage of recording time spent below 90 % saturation $\leq 15\%$.

Exclusion criteria :

- Patient needing an urgent sleep clinic evaluation
- Patients who had a polysomnographic study required before being seen at the

sleep clinic

- Patients not meeting the aforementioned inclusion criteria

2.3 Randomization

The randomly patient assignment will be in a 1:1 ratio to receive either the evaluation from the nurse or the chest physician. A senior statistician with no clinical involvement in the trial conducted a randomisation list of 200 patients using SAS software v9.4 to generate random numbers. The randomisation allocation was stratified by block of twenty patients to assume an equal number of patients in each group if the study ended much earlier than expected with less patients. After the nurse will have obtained the patient's consent, the nurse will use the list for the patient allocation strategy.

2.4 Interventions

Multidisciplinary group

Patients randomized in the multidisciplinary group will receive their first sleep clinic evaluation with a specifically trained clinical nurse. For the past five years, a clinical nurse has been attached to the IUCPQ-UL sleep clinic. Her training enables her to complete the follow-up of patients treated with CPAP with a special attention to observance issue, identification and advices regarding any side effects patients may report. Before initiating consultation with patients as needed in this study, a specific training will be performed. Reference documents on diagnostic and therapeutic options will be selected by the respirologist in charge of the sleep clinic and given to the clinical nurse for instructions. She will also have a period of observation in the Ear Nose and Throat clinic and in the sleep laboratory for basic training regarding the completion and scoring of cardio-respiratory recordings by our sleep laboratory technicians. The clinical nurse will then complete her training assisting at the consultations of the respirologist at the sleep clinic's. The minimal duration of this observation period will be 1 month but could be extended if the nurse, the sleep clinic's physician or the principal investigator deemed it necessary.

After completion of the different steps of the training program, the clinical nurse will initially evaluate 2 patients per clinic and progressively increase to 5 patients per clinic. After complete evaluation of the patient, including questionnaire, physical and ENT examination, cardio-respiratory recording analysis and therapeutic discussion with the patient, the patient case will be discussed with the sleep clinic's appointed respirologist to determine the final treatment plan and/or the need for complementary investigations if required. Follow-up will be ensured by the clinical nurse with discussion with the physician if necessary.

Physician directed care group

Patient randomized in the physician directed care group will receive their first sleep clinic evaluation with a respirologist trained in sleep-disordered breathing disorders' evaluation and treatment. The physician will direct the questionnaire and physical examination, perform analysis of the cardio-respiratory recording and determine the treatment plan or additional complementary investigations, if necessary. Follow-up will be ensured by the clinical nurse of the sleep clinic.

2.5 Study outcomes and follow-up

Primary outcome: to assess the non-inferiority of a nurse-based compared with physician-based evaluation in the sleep clinic on:

1- Improvement in symptoms based on the Epworth Sleepiness Scale (ESS) which ranged from 0 to 24 points. Higher values are associated with increased sleepiness.

2- Quality of life as assessed by the Quebec quality of life questionnaire which is a questionnaire developed to assess health-related quality of life in patient with obstructive sleep apnea.³ It has 32 items scored on a 7 points Likert scale, providing a quality of life score for five different domains (with 4 to 7 items per domain):

- 1- Hypersomnolence;
- 2- Diurnal symptoms ;
- 3- Nocturnal symptoms;
- 4- Emotions;
- 5- Social interactions.

The lower the score, the higher the impact on the affected domain. Minimal clinically important difference differs for each domain. Lacasse et al. defined this value as such : hypersomnolence, 1.8; diurnal symptoms, 2.0; nocturnal symptoms, 1.5; emotions, 1.1; social interactions, 2.5.^{REF3}

These outcomes will be assessed at a three and six months' time frame.

Secondary objectives: to assess the non-inferiority of nurse-based compared with physician-based evaluation in the sleep clinic on treatment adherence. Outcome assessment will differ according to the treatment option chosen:

- 1- Positive pressure treatment (number of hours used/night according to CPAP report)
- 2- Mandibular advancement device (patient's usage report)
- 3- Surgical treatment
- 4- Weight loss treatment (changes in weight)
- 5- Positional therapy (proportion of time spent supine at baseline and at control cardio-respiratory recording)
- 6- Observation

2.6 Data extraction

ACL will be responsible of data extraction through the digital patient files. Baseline demographic and anthropometric data, randomization group, baseline cardiorespiratory polygraphy, initial ESS and Quebec Quality of life questionnaire and retained treatment option will be extracted. Change in ESS and Quality of life as well as follow-up cardiorespiratory polygraphy examination will be reported at three and six months of follow-up. Any change in anthropometric data will also be

evaluated.

2.7 Statistical analysis

Statistical analysis for primary and secondary clinical end points will compare changes in scores at 3 months and six months between groups, using ANOVA. The lower limit of the two-sided 95% confidence intervals will be used to determine noninferiority. We anticipated an equal drop out rate (10 %) in the two study arms. All analyses were conducted in an intention-to-treat manner.

2.7.1 Sample size

It was a priori determined, based on the reduction of ESS, that a sample size of 100 patients per group (200 patients total) was required for a power of 90%, assuming for a non-inferiority margin of 2.0 and a standard deviation of ESS changes of 2.0. The one-sided significance level (alpha) of the test was set at 0.025.

2.8 Study timeline

February 2018- June 2018	Patient enrollment
September 2018	Primary completion
December 2018	Study completion

3. FUNDING

The clinical nurse will work part-time on this project over an anticipated period of one year. Taking into account her hourly salary including social security contributions, the budget for this project is 31 860 \$. These fees will be covered by the Sleep Apnea Research and Teaching Fund of the IUCPQ_UL Fondation & Alphonse L'Espérance Funds.

4.REFERENCES

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