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Severity of sleep apnoea in chronic obstructive pulmonary disease patients who require non-invasive mechanical ventilation with pressure support guaranteed with average volume

Submission date
05/10/2019

Recruitment status
No longer recruiting

Registration date
14/01/2020

Overall study status
Completed

Last Edited
14/01/2020

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea (OSA) is a condition characterized by increased upper airway resistance associated with an intermittent decrease or absence of inspiratory airflow, often causing arousals during sleep. Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. This study was designed to determine the coexistence and clinical evolution of OSA in patients hospitalized with acute respiratory failure due to COPD exacerbation receiving NIV with pressure support guaranteed with average volume (AVAPS).

Who can participate?
Patients with sleep apnoea exacerbated by COPD who require non-invasive mechanical ventilation in the intensive care unit

What does the study involve?
Patients will provide a number of measurements that assess their respiratory capability.

What are the possible benefits and risks of participating?
The main benefits are related to the experiences of the group of patients who responded to the AVAPS ventilation strategy. The polygraph study provided additional information that would allow us to establish strategies aimed at one towards the correction of that associated condition. On the other hand, this technique diminished the work of the respiratory muscles, giving rest the same in comparison to the conventional treatment (use of the mask of oxygen). The risks are related to the facial complications that could arise from the use of the mask and the airway pressure.

Where is the study run from?
Hospital Clinica Santa Maria Intensive Care Unit, Ecuador

When is the study starting and how long is it expected to run for?
August 2013 to August 2014

Who is funding the study?
School of Medicine, Universidad San Francisco de Quito, Ecuador

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18-2-2013; serial: 2013 (2)

Study information

Scientific Title
Apnoea-hypopnoea index in COPD exacerbation and AVAPS

Study objectives
H0: The apnoea-hypopnoea index in patients hospitalized with COPD exacerbation receiving non-invasive mechanical ventilation (NIV) with pressure support guaranteed with average volume (AVAPS) in the Intensive Care Unit is frequent
H1: The apnoea-hypopnoea index in patients hospitalized with COPD exacerbation receiving NIV with pressure support guaranteed with average volume (AVAPS) in the Intensive Care Unit is not frequent

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2013, Teaching and Research Committee of the Santa Maria Clinic (Lorenzo de Garaycoa 3209 y Argentina, Guayaquil, GUAYAS, 090314, Argentina; +593 995527059; dra. maricabrera_21@hotmail.com), ref: 2013 (2)

Study design
Single-center prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep apnoea, COPD

Interventions
Protocol of noninvasive mechanical ventilation for the treatment of acute respiratory failure:
When the patient had been diagnosed with ARF in the emergency department, a senior physician was consulted for assessment and management, who decided to take the patients to the ICU, start NIV, and adjust its parameters. Accordingly, the patients were observed and evaluated by respiratory therapists, resident doctors, and nurses trained in NIV.

NIV with Pressure Support Guaranteed with Average Volume (AVAPS)
Patients could be placed in the modes that were spontaneous/timed with AVAPS with maximum inspiratory positive pressure (IPAP) programmed in the 20 cm H2O device and a minimum programmed IPAP of 12 cm H2O with positive expiratory pressure (EPAP) of 6 to 8 cm H2O. The programmed tidal volume was 8 mL/kg of the ideal body weight using the following formula: 55.5 ± 2.3 (height in inches – 60) for men and 45.5 ± 2.3 (height in inches – 60) for women. Moreover, the respiratory rate was 12–14 breaths/min; the rise time was 300 to 400 ms; the inspiratory time was 0.8 to 1.2 s. Subsequently, the O2 supplements were added through an O2 adapter close to the mask to keep the SaO2 above 90%. The maximum IPAP, exhaled tidal volume (EVT), Vmin, and leakages were controlled through the ventilator software. The BiPAP synchrony with AVAPS and Autotrak (Respironics Inc., Murrysville, Pennsylvania, USA) was used along with a series of Mirage IV (Resmed) face masks.
In addition to ventilatory support, both groups received bronchodilators, intravenous corticosteroids, and antibiotic therapy consisting of beta-lactam in combination with a fluoroquinolone.

Measurements:
ABG was measured at the baseline of NIV use. Further, any complications related to the interphase (mask) were documented, and the mask use and tolerability related to excessive discomfort, nasal ulcer, gastric distension, and claustrophobia were evaluated as well. The following parameters were also collected: Vt, IPAP, Vt exh, Vmin, leakage, RR, and positive end-inspiratory pressure.
The data were measured as follows: age, sex, arterial blood gases at the beginning of the NIV protocol (pH, pCo2, HCO3, base excess), SaO2, HR, RR, systolic blood pressure (SBP), diastolic blood pressure (DBP), and radiological alterations including (described as alterations in 1, 2, 3, an 4 quadrants) intercurrent disease, body mass index, and neck circumference. The Epworth sleepiness scale and Mallampati score were applied in this study.
The ABGs were made before and during treatment with NIV; the ventilatory parameters used were: mode (spontaneous, spontaneous/time, AVAPS), positive inspiratory pressure (IPAP), and positive expiratory pressure (EPAP). Further, the type of mask used was: mirage series IV. All the patients were evaluated by respiratory therapists under the strict supervision of trained NIV physicians.
Discontinuance Therapy with NIV
The process of weaning off the NIV was initiated when clinical stability was achieved, which was

defined as: RR less than 24 breaths/min and improvement of (SaO2 > 92%), with a percentage of inspired FiO2 below 35%. Once the patient remained stable, the NIV was withdrawn.

NIV Withdrawal:
Clinical stability was defined as: 1) RR <25 rpm; 2) HR < 90 bpm; 3) compensated arterial pH with SaO2 (%) > 90% in ambient air or with low flow oxygen (< 3 L per minute).

Follow-up and Measurements During Hospitalization:
Pre and post-bronchodilator spirometry, using 400 mcg of salbutamol inhaled by MDI along with nightly sleep apnea monitoring, was obtained from patients before hospital discharge.
We used a spirometer with a turbine transducer DATOSPIR 70 (SILBELMET W-10) SIBEL S.A. Barcelona, Spain, and Polygraphy equipment (Apnea Link. Resmed) for these measurements.

Intervention Type
Procedure/Surgery

Primary outcome measure
Severity of sleep apnea measured using the apnoea-hypopnoea index during stay in the emergency department

Secondary outcome measures
1. Days of hospital stay in the emergency department
2. NIV rates during stay in the emergency department
3. Intubation rates during stay in the emergency department

Overall study start date
03/01/2013

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Age: 18 and older
2. Admitted to the intensive care unit of Santa Maria Clinic
3. Patients with ventilatory failure secondary to hypercapnia (PaCO2 > 45 mmHg, pH 7.35 or less)
4. Patients with inadequate oxygenation (PaO2 < 60 mmHg) breathing ambient air (SaO2 < 92%); e) severe dyspnea (RR > 25 breaths per minute) and use of accessory muscles during hospitalization

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Hemodynamic instability
2. Noncooperative or agitated
3. Unable to use the interface device
4. Had recent surgery of the upper airway tract
5. Used NIV with a do-not-resuscitate (DNR) order
6. Received some type of sedation during the period of study

Date of first enrolment
01/07/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
Ecuador

Study participating centre
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Sponsor type
University/education

Funder(s)

Funder type
University/education

Funder Name
School of Medicine, Universidad San Francisco de Quito

Results and Publications

Publication and dissemination plan
2018–2020: Presentations for publication.
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request