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Comparing ventilation strategies for patients with de novo hypoxemic respiratory failure

Submission date
19/05/2019

Recruitment status
No longer recruiting

Registration date
11/07/2019

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Noninvasive mechanical ventilation (NIMV) is an effective treatment for insufficiency with acute respiratory failure of various etiologies. When NIMV is initiated in patients with acute respiratory failure, ventilatory parameters (variations of blood gases, tidal volumes, volume min. and in some cases, flow and pressure monitoring from the mask to the ventilatory circuit) are classically determined during the clinical evaluation. The conventional way of NIMV in this approach has been based on the elevations of the support pressure levels programmed by the operator. Different ventilatory modes have been used, such as spontaneous, spontaneous/time (S/T), PCV, PAV and NAVA; these last two with better adaptation of patient to the ventilator and better clinical results.

The ventilatory strategy BiPAP S/T–AVAPS allows the use of a fixed preprogrammed tidal volume, which is kept constant by virtue of the inspiratory pressure variations. The fan estimates the volume delivered and adjusts its parameters to ensure a predetermined destination volume. The initial information on the use of this new ventilatory strategy with BiPAP S/T plus AVAPS was focused on patients with chronic respiratory affectation, obstructive sleep apnea or patients with alveolar hypoventilation. However, this technique began to be used in patients with acute hypercapnic respiratory failure. In 2013, Briones-Claudett et al. observed a rapid recovery of the sensorium, as measured by the Glasgow coma scale in patients with infectious exacerbation of chronic obstructive pulmonary disease (COPD) subjected to BiPAP S/T–AVAPS (Briones-Claudett, 2013b). Subsequently, other authors have observed similar results when used in patients with COPD (Cao Z, 2016), (Çiftci F, 2017), exacerbated (Thanthitaweewat V, 2018).

We recently evaluated this mode in patients with "novo" hypoxemic respiratory failure and observed that it provides a better proximity to protective ventilation in a select group of subjects with mild to moderate hypoxemic respiratory insufficiency and spontaneous breathing to control the tidal volume exhaled and inspired pressures (Briones-Claudett KH, 2018d).
The main objective of this study is to compare the results of the use of gu
aranteed volume support pressure (AVAPS) versus high nasal flow in patients with mild to moderate "de novo" hypoxemic respiratory failure.

We designed this study to compare the use of ventilatory strategy BiPAP S/T vs BiPAP S/T–AVAPS in mild to moderate hypoxemic respiratory failure by a case-control study.

Who can participate?
It is a retro - prospective, control case study (control - mached) in which all patients were admitted during the period between January 2010 — December 2013. The patients chosen for the study will be those who present with de novo hypoxemic respiratory failure ranging from mild (PaO2 / FiO2: 200-300mmHg) to moderate (PaO2 / FiO2: 100-200mmHg), mild to moderate with PaO2 / FIO2 less than or equal to 300.

What does the study involve?
Comparisons were made between the 2 groups BiPAP S/T or BiPAP S/T AVAPS, patients were divided according to de novo hypoxemic respiratory failure in mild to moderate.

The use of those technique that offers the alternative of avoiding endotracheal intubation with fewer days of hospital stay and fewer complications.

What are the possible benefits and risks of participating?
The main benefits are related to the use of non-invasive ventilation such as the use of additional medication (sedation) and a tube in the mouth that predisposes to major infections. On the other hand, this technique diminishes the work of the respiratory muscles giving rest the same in comparison with the conventional treatment (use of 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?
The study was approved by the Department of Teaching and Research of the Santa María Clinic and Hospital Militar with registration number Santa Mara: approval March 8, 2013 serial: 2013 (3), these 2 hospitals participated in this study. Fifty-six patients were recruited for this study 29 from the BiPAP S/T plus AVAPS group and 29 from the control group (BiPAP S/T alone). The person responsible for the decision to participate in the study will be the patient or his surrogate in case he / she cannot make the decision. The study is carried out based on CONSORT regulations.

When is the study starting and how long is it expected to run for?
January 2013 to January 2016.

Who is funding the study?
Universidad San Francisco de Quito

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
8/03/2013 serial: 2013 (3),

Study information

Scientific Title
Noninvasive mechanical ventilation with guaranteed support pressure with medium volume (AVAPS) vs BiPAP S/T in Novo hypoxemic respiratory failure

Acronym
N/A

Study objectives
(H0) Null hypothesis—The use of the ventilatory strategy with BiPAP S/T–AVAPS does not offer better results than the noninvasive ventilatory strategy with only BiPAP S/T in patients with mild to moderate de novo hypoxemic respiratory failure.
(H1) Alternative hypothesis—The use of the ventilatory strategy with BiPAP S/T–AVAPS offers better results than the noninvasive ventilatory strategy with only BiPAP S/T in patients with mild to moderate de novo hypoxemic respiratory failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/03/2013, the Department of Teaching and Research of the Santa María Clinic and Hospital Militar (Lorenzo de Garaycoa 3209 y Argentina; 2404650-2401767; 0992248556001), ref: 0I/12/2013.

Study design
Two centre, bservational, case-control study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied

"de novo" hypoxemic respiratory failure

Interventions

PAIRING
Patients with BiPAP S/T were paired with those of BiPAP AVAPS, according to age, within 5 points, their arterial pH 2 points APACHE II 5 points and PaO2 / FiO2 10 points and pCO2 of 5 points.

INTERVENTION
Patients assigned to the intervention group will be those who receive NIMV with Guaranteed Volume Support Pressure (AVAPS) during 12 hours a day for at least 24 hours.

VENTILATORY STRATEGY IN AVAPS MODE
Ventilation parameters were initially programmed in the BiPAP S/T mode with AVAPS with maximum inspiratory positive pressure (IPAP) programmed in the device of 14-26 cm H2O and a minimum programmed IPAP of 8 cm H2O with a positive expiratory pressure (EPAP) of 6 to 8 cm H2O.

The programmed tidal volume was 6 to 8 ml/kg of ideal body weight with the following formula: 55.5 ± 2.3 (height in inches - 60) for men and 45.5 ± 2.3 (height in inches - 60) for women. The respiratory rate was 14 to 20 breaths/min; the rise time was 300 to 400 ms; The inspiratory time was 0.8 to 1.2 s. Inspired fraction of oxygen was programmed to maintain a SaO2 above 90%. The maximum IPAP, exhaled tidal volume (Vtexh), Vmin and leaks were controlled through the fan software. The synchronization of BiPAP with AVAPS and Autotrak (Respironics Inc., Murrysville, Pennsylvania, USA) was used along with a series of Mirage IV (Resmed) facial masks.

VENTILATORY PARAMETERS OF THE CONTROL GROUP. BiPAP S/T
Ventilatory parameters were initially programmed in S/T mode. IPAP was programmed at 12 -20 cm H2O according to the doctor's assessment, EPAP was programmed at 6 cm H2O. The respiratory rate was set at 15 breaths/min, rise time set at 300 to 400 ms, and inspiratory time was 0.6 to 1.2s. The IPAP was progressively increased in 2 cm increments of H2O according to the prescriptions of the attending physician. O2 supplements were added through an O2 adapter close to the mask, with the aim of maintaining SaO2 above 90%. Exhaled current volume (EVT), Vmin and leaks were controlled through the fan software. We use BiPAP Synchrony with AVAPS and Autotrak (Respironics Inc., Murrysville, Pennsylvania, USA) and a series of Mirage IV (Resmed) masks. and the Confourt Series II mask (Respironics).

Intervention Type

Other

Primary outcome(s)

1. Superiority of the ventilatory strategy with BiPAP S/T–AVAPS compared to the noninvasive ventilatory strategy with BiPAP S/T is measured using the percentage of success or failure for each strategy.
2. Mortality.

Key secondary outcome(s))

1. Percentage of patients that undergo intubation.
2. Days of hospital stay.
3. Days of mechanical ventilation using the ventilatory strategy with BiPAP S/T–AVAPS vs noninvasive ventilatory strategy with BiPAP S/T.

Completion date
10/06/2016

Eligibility

Key inclusion criteria
1. Age, 18 years or older.
2. Showed signs of acute respiratory failure in the emergency room (RR,> 25 breaths per minute, use of accessory muscles) for "de novo" hypoxemic respiratory failure (not produced by acute exacerbations of COPD, disease chronic pulmonary, or congestive heart failure), with PaO2 / FIO2 from mild to moderate according to the thresholds defined by the Berlin criteria for ARDS (9,10).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Facial deformity.
2.Obstruction in the upper airway by surgery or trauma.
3. Alterations in the central nervous system.
5. Hypercapnia encephalopathy.
6. Cardiogenic pulmonary edema, pneumothorax, pulmonary embolism thrombus, hemoptysis or shock septic.
7. Urgent intubation due to cardiorespiratory arrest and hemodynamic instability with systolic pressure less than 80 mmHg.
8. Demonstrated hemodynamic instability.
9. Demonstrated excess respiratory secretions.
10. Did not cooperate or were agitated.
11. Could not use the interface device.
12. Had recently undergone upper airway surgery.
13. Had received NIV with "Do not resuscitate" orders.

Date of first enrolment
01/03/2013

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Ecuador

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Sponsor information

Organisation
Universidad San Francisco de Quito

ROR
https://ror.org/01r2c3v86

Funder(s)

Funder type
University/education

Funder Name
Universidad San Francisco de Quito

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/08/2022	16/08/2022	Yes	No
Participant information sheet		09/07/2019	16/07/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes