Pressure support ventilation and NAVA during noninvasive ventilation in acute respiratory failure: a pilot study

Published: 05-04-2011
Last updated: 27-04-2024

The aims of the current study are:1. Demonstrate that during noninvasive ventilation a patient with acute respiratory failure is in better synchrony with the ventilator during NAVA compared to PSV mode.2. Demonstrate that the Servo-i ventilator is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36788

Source
ToetsingOnline

Brief title
PSV and NAVA during noninvasive ventilation

Condition

- Musculoskeletal and connective tissue disorders NEC
- Respiratory disorders NEC

Synonym
acute respiratory failure, Dyspnea

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Maquet,The NAVA

catheter and software are an unrestruicted gift from Maquet;Sweden.

Intervention

Keyword: COPD, Noninvasive ventilation, Patient-ventilator synchrony

Outcome measures

Primary outcome

* Patient - ventilator asynchrony index

Secondary outcome

* Dyspnea score (VAS)

* Arterial carbondioxe and oxygen tension after each change in protocol (0, 30,

60, 90, 125, 155 and 185 minutes)

* Oxygenation index

* Airleak during NIV

* Ventilator efficiency (airway pressure / diaphragm electrical activity)

Study description

Background summary

Noninvasive machanial ventilation (NIV) is an established intervention for selected patients with acute respiratory failure. NIV reduces work of breathing and improves oxygenation by recruitment of alveoli and optimizing ventilation - perfusion matching. The application of NIV prevents endotracheal intubation in a number of patients. Established reasons for NIV include acute exacerbation of chronic obstructive airway disease, acute heart failure and in selected cases

pneumonia and exacerbation of asthma.
Unfortunately in many patients NIV fails and subsequent endotracheal intubation is necessary. Important reasons for failed NIV include patiënt - ventilator asynchrony and major airleak between the patients face and the interface. Neurally adjusted ventilatory assist (NAVA) is a relatively new ventilatory mode. NAVA is characterized by ventilator activation based on changes in electrical activity of the inspiratory muscles (diaphragm). Instead in the conventional ventilatory modes (i.e. pressure support ventilation) the ventilator is triggered by negative pressure generated by the inspiratory muscles. An important delay occurs between activation of the inspiratory muscles and the detection of the negative pressure in the ventilator (up to 400 ms), resulting in elevated work of breathing and patient discomfort. In NAVA electrical activity of the diaphragm is continuously monitored with a dedicated nasogastric tubes. Elevated electrical activity of the diaphragm is interpreted by the ventilator as the beginning of an inspiration. The delay between patient inspiration and ventilator inspiration is very shot (microseconds), resulting in better patient - ventilator synchrony. Moreover, in pressure support ventilation inspiratory efforts may not be sensed by the ventilator (wasted efforts) due to intrinsic PEEP or respiratory muscle weakness. As electrical activity of the diaphragm is a much more sensitive measure for inspiratory effort, wasted efforts are very uncommon during NAVA. Indeed, recent studies in invasive ventilated patients have shown that NAVA improves patient - ventilator interaction compared to pressure support ventilation.

Patient discomfort during noninvasive ventilation does not only result from asynchrony with the ventilator but also from airleak between the patients face and the interface. Many different interfaces are available. In the current study we will test which of the most common interfaces is the best match with NAVA.

Study objective

The aims of the current study are:
1. Demonstrate that during noninvasive ventilation a patient with acute respiratory failure is in better synchrony with the ventilator during NAVA compared to PSV mode.
2. Demonstrate that the Servo-i ventilator is suitable for noninvasive ventlation in both the PSV and NAVA mode.
3. Provide insight in patient preference for type of interface (nose vs full face) during NAVA ventilation.

Study design

Pilot study
Prospectieve cross-over design

Intervention

Noninvasive ventilation with two different ventilators (BiPAP Vision and Servo-i), two ventilator modalities (pressure support ventilation and NAVA) and two different interfaces (nose and full face mask).

Study burden and risks

1. Nasogastric tube
For this study patients need a dedicated nasogastric feeding tube that is suitable for NAVA ventilation (12 or 16 french NAVA catheter). This catheter is commercially available (Maquet, Solna Sweden) and is currently used in clinical care worldwide, including our own ICU. initially a 16 Frnech catheter is used, as this will be most suitable for later clinical purposes, inclusing feeding. Although the 12 french cathter can be used for nasogastric feeding, more frequent obstrction of the catheter occurs in our experience. If a patient included in this study does not have a nasogastric tube yet, this dedicated catheter will be inserted. As all mechanically ventilated patients in our ICU need a nasogastric feeding tube, this will not impose additional discomfort or risk for the patient. If the patient already has a nasogastric feeding tube (but not the dedicated NAVA catheter), this tube needs to be replaced by the NAVA catheter. The insertion of a 12 french nasogastric tube is associated with temporal mild discomfort. The insertion of a nasogastric tube is a routine procedure in ICU patients, and will be performed by an experienced critical care nurse. Adequate position of the nasogastric tube will be verified according to the clinical protocols for this procedure. If high-risk patients are excluded as in the current study (see exclusion criteria) the risk of complications is minimal.
Again it should be stressed that all mechanically ventilated patients need a nasogastric tube, independent of this study.

2. Blood withdrawal
Blood will be withdrawn via an indwelling arterial catheter. This catheter is available in all mechanically ventilated patients for routine clinical care. During the study approximately 7.0 ml of blood will be withdrawn within a time frame of 190 minutes. This low volume does not impose an additional risk for adult patients.

3. Switching between ventilators and interfaces.
A. Interface
During the study patients will be ventilated with two different interfaces. Therefore, after 90 minutes the patient will be disconnected from the ventilator to change the interface. The change in interface will take less than 30 seconds. This brief period of disconnection from the ventilator will not impose additional risks, as patients with very severe respiratory failure (not able to maintain adequate oxygenation when disconnected from the ventilator for

2 minutes) will not be included in this study as sated in the exclusion criteria. The disconnection from the ventilator in order to change the interface does not take more than 30 seconds. It should be noted that during routine clinical care patients are disconnected from the ventilator a couple of times per day for mouth care and sometimes feeding.
B. Ventilator
As two different ventilators are tested in this study, the patient needs to be disconnected from the ventilator twice. This disconnection will take less than 30 seconds and as outlined above will not impose an additional risk for the patients.

It should be noticed that with the design of the study we have specifically taken into account patient comfort. Although from a research perspective it might have been better if we had randomized both the order of the ventilator mode, the type of ventilator and the interface. However, this could have resulted in much more ventilator disconnections (5). Although not a high risk for the patients, it may result in additional discomfort, especially in patients with acute respiratory failure. With the current study design the patients are disconnected from the ventilator three times within a time frame of ± 3 hours.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Acute respiratory failure requiring noninvasive ventilatory support in ICU.
* COPD (past medical history)
* Able to adequately oxygenate and ventilate without support for ± 5 minutes (necessary for changing the interface).
* Age > 18 years
* Mentally competent

Exclusion criteria

* Severe hypoxemic failure (Pa,o2 < 8.0 kPa with nonrebreathing mask) at time of inclusion
* Planned endotracheal intubation
* Hemodynamic instability requiring high dose vasopressors (>0.5 ug/kg/min)
* Contraindication for insertion of nasogastric tube (recent esophageal, facial or cranial trauma or surgery. espohageal varices, recent (< 4 weeks) upper gastrointestinal bleeding)
* Severe agitation
* Myopathy before ICU admission (including Steinert disease, Duchenne muscular dystrophy)
* Severely decreased consciousness (GCS < 11)
* Tracheostomy
* Inability to obtain informed consent.
* Nasogastric tube in situ

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2011
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Insertion of dedicated nasogastric feeding tube ("NAVA catheter")
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-04-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33351.091.11