General initiation protocol for long-term NIV

In order to ensure successful initiation of long-term non-invasive ventilation (NIV), ventilator settings have to be sufficient to maintain a patent upper airway and correct nocturnal hypoventilation. Settings need to be comfortable to ensure they are tolerated by the patient. Therefore, ventilator settings need to be individualized. One approach when noninvasive ventilation is started for the first time is to use low pressures to familiarize the patient with NIV, settings are progressively adjusted over the first few minutes to achieve efficacy and comfort.

Condition for NIV initiation:

Initiation should be ideally performed during the day in a quiet environment. Patients are educated about their disease, how and why NIV will help the progression to nighttime use, and benefits of the treatment.

Initiation should ideally occur with the patient sitting up in the bed or if this is not available sitting in a well-supported chair. Where possible start titration without entraining supplementary oxygen therapy. Monitor oxygenation saturation by pulse oximetry (SpO₂) should be performed.

NIV has the potential to cause dryness and also make secretions more tenacious. Therefore, heated humidifier may be useful in chronic obstructive pulmonary disease (COPD) patients and in patients with high usage. Caregivers will need to be trained in the use of NIV, the patient's clinical condition and physical abilities. They will also need to attend the initiation session for training.

Ventilation mode and settings:

The preferred ventilation mode for long-term NIV is pressure support (pressure support ventilation (PSV) or spontaneous timed (S/T)) with a backup respiratory rate. During sleep patients with chronic respiratory failure may have very weak inspiratory efforts and not able to trigger the ventilator. Setting a backup RR will ensure that there is no hypoventilation and subsequent arousals due to ineffective triggering.

Main settings:

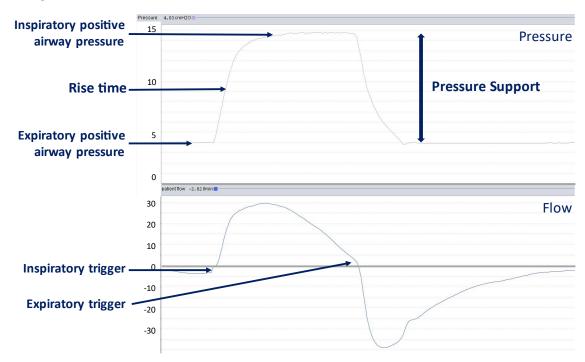


Figure 1: Main ventilator settings in pressure support mode.

IPAP: Inspiratory positive airway pressure is the pressure maintained in the interface during the ventilators inspiratory time. IPAP is the sum of EPAP and pressure support (PS). Home care ventilators require setting of EPAP and IPAP while ICU ventilators use positive end expiratory pressure (PEEP) and PS. Therefore, IPAP is the most important setting to correct nocturnal hypoventilation and daytime hypercapnia. The level of IPAP needed is determined by the level of ventilation needed to stabilize the blood gasses. An increase in IPAP (PS) will result in greater tidal volume (Vt) which will decrease the PaCO₂.

EPAP: Expiratory positive airway pressure is the pressure maintained in the interface during the ventilators expiratory time. Most of the time an EPAP of 4 cmH₂O is recommended to maintain a continuous flow-during expiration and prevent inhalation of CO₂. EPAP maintains the upper airway patency in patients at risk of upper airway obstruction such as obesity hypoventilation and overlap syndromes. In COPD, EPAP may counterbalance intrinsic PEEP (PEEPi) if present and decrease the effort required to trigger the ventilator to cycle into inspiration. EPAP may decrease the risk for the development of atelectasis and therefore improve oxygenation in addition to increasing FRC and pulmonary compliance.

Inspiratory trigger: Inspiratory trigger setting will set how difficult it is to trigger the ventilator to cycle into inspiration. The goal is to trigger the breath with minimal effort without auto triggering. When titrating NIV during the day, you need to factor in, that the patient's respiratory effort decreases during sleep and application of nocturnal NIV.

Rise time: Rise time is the time taken for the increase in pressure from EPAP to IPAP. A Short rise time is associated with high peak inspiratory flow, while increasing rise time decreases peak inspiratory flow. Rise time is often seen as a comfort setting and the goal is to mimic the patients' spontaneous inspiratory flow. Often a COPD patient often need a short rise time and a restrictive patient will be more comfortable with a longer rise time. Rise time is also part of patient's inspiratory cycle. A longer

the rise time results in a shorter time that the ventilator will be on the actual IPAP pressure, this can cause a decrease in tidal volume. The faster the respiratory rate the shorter rise time is needed.

Expiratory trigger: Expiratory trigger, also called cycling criteria determines the end of the ventilators inspiratory time. It is calculated as a percentage of the peak inspiratory flow. Expiratory trigger is a very important setting to optimize patient-ventilator synchronization and comfort. The optimal setting depends on the patient's respiratory mechanics with an early cycling setting for obstructive diseases which will give longer time for exhalation and prevent PEEPi and a late cycling setting for restrictive diseases which will prevent a premature end of breath and maintain a normalized inspiratory time (Ti). Most of the ventilators offer the option to set this parameter or use a pre-set trigger. The level of cycling will also have an effect on the Ti, an early cycle will result in a shorter Ti which will give a lower tidal volume. Conversely late cycling will result in a longer Ti and will potentially result in a higher tidal volume. Prolonging the cycling criteria is often more comfortable than prolonging the min inspiratory time (Timin).

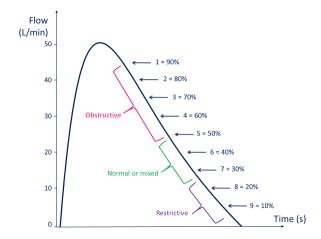


Figure 2: This figure shows the expiratory trigger. The mechanical breath ends at a set percentage of the peak inspiratory flow. On Breas ventilators the expiratory trigger is set from 1 (very early cycling) to 9 (late cycling). The optimal setting depends mainly on the respiratory mechanics.

Backup rate: Backup rate ensures that a breath will be delivered to the patient if the patient does not trigger a breath in a set time period. The backup rate should not interfere with the patients spontaneous breathing rate as this will cause discomfort and desynchrony. It is normal to have the backup rate set 2-4 breaths lower than the patient's spontaneous rate. The backup rate should be set high enough to maintain sufficient ventilation in case of an ineffective respiratory effort or apnea. Remember that the patient will breathe slower during sleep compared to awake.

If the goal is to off load the work of breathing then, the backup rate should be set slightly above patients' spontaneous rate so that the ventilator does most of the work.

<u>More</u>

Minimum inspiratory time: Minimum inspiratory time setting ensures a minimum time of IPAP. The advantage of this setting is if the expiratory trigger criteria is reached early the patient will have a short breath in. Having a minimum inspiratory time ensures that a breath in will be delivered for a set time.

It can be set to a short time for all patients except for those with a restrictive pathology where it is useful to prolong the Ti to increase the Vt. Often this is the second choice when the setting of a late cycling is not solving the issue of too short a breath in.

Maximum inspiratory time: Maximum inspiratory time ends the length of the breath in delivered by the ventilator incase the expiratory trigger is not triggered due to non-intentional leaks. For COPD patients a shorter Maximum inspiratory time to secure a long enough exhalation time to prevent PEEPi is beneficial.

Back up inspiratory time: Back up inspiratory time determines the length of the non-patient triggered ventilator-initiated breaths. This should be set accordingly to the patient's spontaneous rate and desired I:E ratio in case of an ineffective inspiratory effort or apnea. Having a fixed Ti on back up breaths ensures a normalized Ti and stable Vt despite lack of patient effort during an event.

Target volume: Target volume can be used in combination with any pressure ventilation mode. It will not active when you choose the use Pressure Support only. Target volume is not usually used as a first choice during NIV initiation. Target volume could be used for patients where the pulmonary compliance may change during the night or over time, such as COPD, OHS, chest wall restrictions and NMD patients or maybe an option when conventional modes of ventilation are not controlling arterial blood gas tensions.

Ramp time: Ramp is a progressive increase in the first few minutes of ventilation, of EPAP and IPAP when the patient starts a new NIV session. Ramp is not used during NIV initiation and should not be confused with "rise time" (see the previous explanation). Ramp can be useful for patient requiring high treatment pressure where it give the patient some time to acclimatize to the high pressure. In patients with severe respiratory insufficiency, it is not advisable to use this feature as it will not provide the desired level of PS.

Adult Patient Proposed Initiation protocol:

Ventilator initial settings:

 $IPAP = 10-15 \text{ cmH}_2O$

EPAP = 4 cmH₂O. In patient at risk of upper airway obstruction, initial EPAP is 7 cmH₂O.

Rise time = 2

Insp. trigger = 2

Exp. trigger = 5

Min Insp. Time = 0.4 s

Max Insp. Time= 2.0 s

Backup Rate = 10 bpm

Backup Insp. Time = 1.0 s

Target volume = Off

Ramp = Off

Gestures and words:

- 1. Explain the procedure to the patient
- 2. Test the ventilator and ensure the correct circuit is attached
- 3. Set the ventilator with initial settings
- 4. Select interface carefully. A nasal mask for patients who are able to breathe through their nose and can keep their mouth shut and an oral nasal mask for those with nasal obstruction.
- 5. Place the mask on patient's face and check the seal, in order that there are no non-intentional leaks around the mask. Connect the circuit.
- 6. Start the ventilator
- 7. Make sure the patient is able to trigger the breath and feels "air coming in" in the interface each time he/she has an inspiratory effort.
- 8. Ask the patient to wait for the ventilator to make sure there is no auto triggering. Explain that the patient is controlling the ventilator respiratory rate.
- 9. If patient does not get enough air, IPAP can be increased by 2 cmH₂O at this point
- 10. When the patient is comfortable, ask him/her to hold the interface
- 11. Put the interface strap and adapt it carefully to prevent non-intentional leaks without overtightening.

Ventilator setting adjustments:

A. Main settings:

IPAP is increased by 2 cmH₂O every 2- 5 min up to the maximum tolerated by the patient or before if the patient requests it. The minimal pressure support to achieve benefit in term of gas exchange is 8 cmH₂O.

EPAP is increased by 1 cmH2O in COPD and obstructive diseases if the patient struggling to trigger the ventilator. Increasing EPAP should reduce the use of accessory muscles. The goal is to set EPAP slightly below the PEEPi, which is very difficult to assess in real life. In patients with upper airway obstruction during sleep, EPAP is increased by 1 cmH₂O and the effect on upper airway obstruction is reevaluated the next night. When EPAP is increased, it is important to increase IPAP at the same time and with the same amount in order to keep the same pressure support.

Inspiratory trigger sensitivity is decreased by one if auto triggering occurs, i.e. inspiratory trigger setting is increased from 2 to 3.

Rise time is prolonged by one if patient is uncomfortable due to flow being too strong at the beginning of the breath in.

Expiratory trigger sensitivity is adjusted to optimize patient ventilator synchronization and comfort.

Most of the setting adjustments are done during the first 10-15 min of the first NIV session.

B. Other settings:

Minimum inspiratory time is set 0.2 - 0.4 s below the actual inspiratory time, if you are unsure start at 1.0 seconds.

Maximum inspiratory time is set 0.2 s above the actual inspiratory time if you are unsure start at 2.0 seconds.

Backup rate is set 2-4 breaths below the actual respiratory breath or around 12-15 breaths per-minute.

Back up inspiratory time is set at the actual inspiratory time.

Monitoring:

During NIV initiation, the most informative monitoring results are from your clinical examination. The Clinician needs to assess the inspiratory effort of the patient. This is done by looking at the use of the accessory muscles and the patient ventilator synchronization. In case of poor synchronization or patient discomfort, some simple question can help to adjust ventilator settings:

- "Is it difficult to get the air in?" This identifies if there is an inspiratory trigger delay and ineffective efforts.
 - → Increasing the sensitivity of the inspiratory trigger and/or increasing EPAP in case of PEEPi
- "Do you feel that the breaths are coming too fast for you? "This identifies auto triggering. →
 Decrease the sensitivity of the inspiratory trigger
- "Do you want more air?" Identifies low pressure support and/or long rise time.
 - → Increase the IPAP and/or shorten the rise time
- "is the breath in too deep?" Identifies high pressure support and / or flow overshoot.
 - → Decrease the IPAP and / or the Rise time
- "Is the breath too short?" This identifies early cycling.
 - → Prolong the Expiratory trigger setting and if needed prolong also the maximum inspiratory time
- "Is the breath too long?" This identifies late cycling.
 - → Increase the sensitivity of the Expiratory trigger

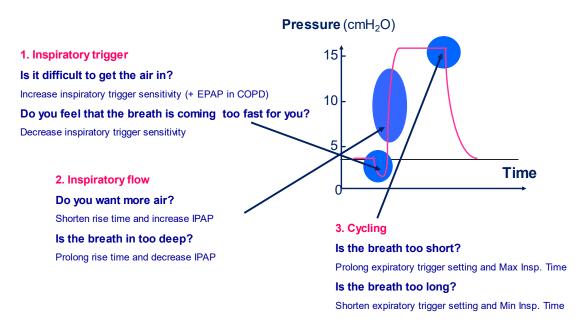


Figure 3: Usual questions to individualize ventilator settings during NIV initiation.

Leaks can be detected clinically or by the patient. The ventilator provides monitoring of the estimated total average leakages over the breath cycle. Total average leakage is the sum of intentional (normal leaks of the mask) and non-intentional leaks (abnormal leaks due to a poor fitting mask or, mouth leak, etc.). Therefore, any increase in total leak during the night is due to non-intentional leak. An increase of more than 10L/min over the intentional leak is considered significant.

Tidal volume and minute volume shall be looked upon with care as under some circumstances they may be overestimated by the presence of large non-intentional leaks.

Pressure and flow waveforms on the ventilator screen are useful to assess patient-ventilator asynchrony when clinical observation is insufficient.

Continuous monitoring of heart rate, blood pressure, and transcutaneous capnography are not mandatory because these variables are not expected to change rapidly during and after NIV initiation.

Duration of NIV sessions:

The first NIV session is often short, one to two hours. The goal is to familiarize the patient and find the optimal ventilator settings. Where possible let the patient try it in their normal sleeping position once they are comfortable as further optimization of the settings maybe required. The patient should use NIV at home in the evening with the support of a caregiver or family members to position the interface if required. Some patients are able to fall asleep the first day with NIV. Some are too uncomfortable to fall asleep. In this situation, NIV is stopped rapidly and a repeat session is performed the next day to adjust ventilator settings. The second day, patients uses NIV in the morning and afternoon as acclimatizing sessions and tries again at night. NIV initiation is considered successful when the patient is able to use the NIV equipment on his own and can sleep the full night with NIV. At this point, analyzing data recorded overnight by the ventilator is useful to assess non-intentional leaks, upper airway obstruction, and patient-ventilator synchronization. Further ventilator settings adjustments may then be required. Then, efficacy of the treatment is assessed by morning arterial blood gas measurement, or a nocturnal oximetry or transcutaneous capnography. In some patients, a polygraphy is needed to characterize upper airway obstructions. Using the effort belts connected to the ventilator can mimic such a polygraphy.

Success of NIV:

Success of NIV is an optimal balance between clinical efficacy and patient's tolerance of NIV. Clinical efficacy, defined as the is the improvement of nocturnal hypoventilation symptoms without a decrease in quality of life which can be measured by dedicated questionnaires. Efficacy is also demonstrated by improvement of gas exchange during daytime ($PaCO_2 \le 45 \text{ mm Hg for all diseases}$ and $\le 48 \text{ mm Hg or}$ a decrease of 20% for COPD) and an improvement in respiratory events during the night, both upper airway obstructions (AHI < 10 events/h) and nocturnal hypoventilation (assessed by nocturnal oximetry or transcutaneous capnography).

Patient's tolerance is good if patient use NIV at least 5 hours per night, with short latency to fall asleep (≤ 30 min), the absence of discomfort due to the NIV, less than 3 awakenings during the night, and the feeling of improved quality of sleep.