Ventilation After the Hospital

What is Home Non-Invasive Ventilation?

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Learning Objectives

- At the conclusion of this presentation, the attendee will be able to:
- Distinguish between home Bi-Level devices and home non-invasive ventilators (NIV)
- Identify patient populations who could benefit from domiciliary NIV
- Understand the basic functions of a non-invasive ventilator in post-hospital care
- Be able to explain the process by which targeted tidal volume is delivered in the home
- Discuss scenarios when auto-EPAP may be beneficial

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Definition of Terms

During the course of this presentation, we will be discussing different means of providing positive pressure ventilation via non-invasive interfaces in the home.

There are several devices that can accomplish this basic goal. They are:

CPAP- Continuous Positive Airway Pressure. This is the most basic form of positive pressure therapy. Positive pressure is constantly applied to the patient's airway, but there is no driving pressure to aid in ventilation.

Bi-Level- Bi-Level therapy is a positive pressure therapy providing two levels of pressure: IPAP and EPAP. The difference between these levels is the pressure support, or driving pressure, which assists a patient in ventilation.

NIV- A therapy incorporating two levels of pressure set in ranges to target a tidal volume and overcome airway obstruction. The pressure support assists in ventilation and allows the machine to target a tidal volume by fluctuating based on patient feedback.

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Qualifying for Therapy

When considering how to treat respiratory patients most immediately, it is important to note the process of qualifying a patient for respiratory equipment in the home:

Bi-Level devices require:

In-facility sleep study to rule out OSA if charted

Arterial blood gases (ABGs) determining that $PaCO_2$ level is high in spite of current treatment

Overnight pulse-oximetry

NIV devices require:

Testing to show that the patient suffers from a chronic respiratory condition (PFT, ABG, recurrent admissions)

Notes that support diagnosis

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NIV vs. Home Bi-Level

Aside from qualifying, there are a number of important differentiations between home Bi-Level (billing code E0470,) and home NIV (billing code E0466.) These include:

- NIV includes user selectable alarms
- NIV devices include backup battery for added security and mobility
- NIV devices typically include targeted tidal volume, automatic backup rate and automated EPAP
- Frontline Bi-Level devices deliver pressure-based therapy; NIV devices deliver volume assured pressure support (VAPS)

For the duration of this presentation, we will be discussing home NIV (E0466) devices

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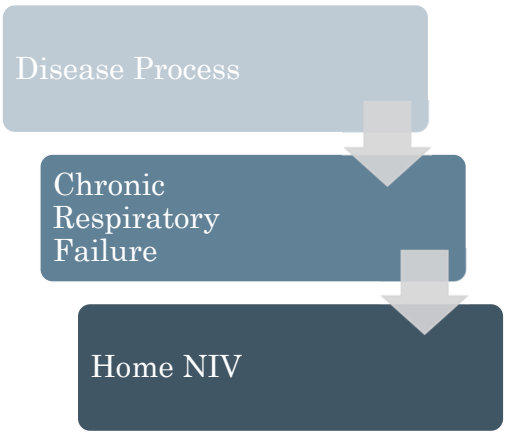
NIV in the Home

- Patients with Chronic Respiratory Failure (CRF) consequent to several chronic respiratory diseases are often treated with NIV in the home.
- Other diagnoses that may benefit from NIV treatment include neuromuscular disease, restrictive thoracic disorders, and obesity hypoventilation syndrome.



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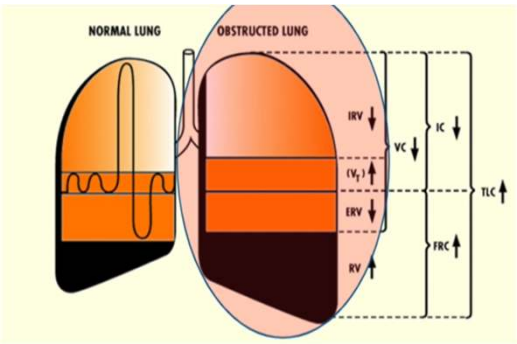
Obstructive Lung Diseases

Patients with obstructive lung disease make up the majority of the domiciliary NIV population. These patients are typically managed with high intensity NIV and a goal of decreasing CO_2 in hypercapnic patients.[1] Chronic obstructive diseases that may lead to respiratory failure include:

- COPD/Emphysema
- Bronchiectasis
- Chronic Bronchitis

These patients typically present with increased lung compliance, decreased elastance, and air trapping caused by tissue damage, ineffective secretion clearance, or a combination of both.



1) T. Kohnlein et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. Lancet Respiratory Medicine. Sept 2(9); 2014.

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Neuromuscular Disease

Patients with neuromuscular disease make up a significant portion of the NIV patient population in the home. Neuromuscular patients typically exhibit preserved anatomy and lung function, but the inability to effectively ventilate. This is caused by respiratory muscle weakness or loss of muscle tone. Ventilation via mask, mouthpiece, or both has proven to be beneficial to these patients.[1] Neuromuscular patients include:

- Amyotrophic Lateral Sclerosis (ALS)
- Gullian-Barre Syndrome
- Myasthenia Gravis
- Muscular Dystrophy
- Patients with impaired diaphragmatic function

1) J. Dorst et al. Non-invasive Ventilation in Amoytrophic Lateral Sclerosis. Therapeutic Advances in Neurological Disorders; (12) 2019.

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Restrictive Thoracic Disease

Restrictive Thoracic Disease includes patients suffering from a number of disease processes or anatomical restrictions to airflow. Due to unique anatomical challenges, these patients are often treated with NIV. These patients may suffer from:

- Scoliosis
- Kyphoscoliosis
- Fibrotic changes to lung tissue (IPF, Post-COVID)
- Obesity Hypoventilation Syndrome

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NIV at Home

In each patient population discussed, non-invasive ventilation can be used to offset the patients work of breathing, support the respiratory muscles, and decrease arterial CO_2. Goals of therapy in the home are typically not normocapnia, but improved quality of life, decreased hospital admissions and improved mortality.[1]

Over the next several slides, we'll review the unique settings on home ventilators, and how they may help improve patient outcomes in the home.

1) W. Frazier et al. Early Initiation of non-invasive ventilation at home improves survival and reduces healthcare costs in COPD patients with chronic hypercapnic respiratory failure: A retrospective cohort study. Respiratory Medicine. Aug-Sept 2022.

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Improving Patient Outcomes

In a recent retrospective study using the Medicare patient database, COPD patients with chronic respiratory failure who were started on NIV after diagnosis were less likely to be admitted to the hospital, had lower associated healthcare costs, and showed lower all-cause mortality.[1]

Another recent study showed marked improvement in quality of life scores, with an emphasis on improved sleep and decreased anxiety after home mechanical ventilation initiation, although both invasive and non-invasive patients were included in the study.[2]

1) W. Frazier et al. Early Initiation of non-invasive ventilation at home improves survival and reduces healthcare costs in COPD patients with chronic hypercapnic respiratory failure: A retrospective cohort study. Respiratory Medicine. Aug-Sept 2022.
2) L. Valko, et al. Home mechanical ventilation: quality of life patterns after six months of treatment. BMC Pulmonary Medicine. 20 (221); 2020.

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Overview of Mechanisms of Action

Home-based NIV therapy combines several automated features on most devices. These include:

- Targeted Tidal Volume, allowed by variable Pressure Support
- Auto-backup Rate, in an attempt to increase patient-ventilator synchrony
- Auto-EPAP, to overcome upper airway obstructions
- The ability to set multiple prescriptions (sick/well, rest/exertion, mask/mouthpiece, etc)

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Mechanisms of Action: Targeted Tidal Volume

One of the defining features of NIV in the home is the ability to estimate exhaled tidal volume and automatically adjust pressure support to target a set return. This allows the practitioner to consistently ventilate patients over time, regardless of anatomy, patient position or disease state.

With a Bi-level device, delivered tidal volume will vary based on compliance and resistance of the patient's lungs.

While this is also true with NIV, a range of pressure support levels and a means of adjustment allow the ventilator to respond to changes in tidal volume automatically.

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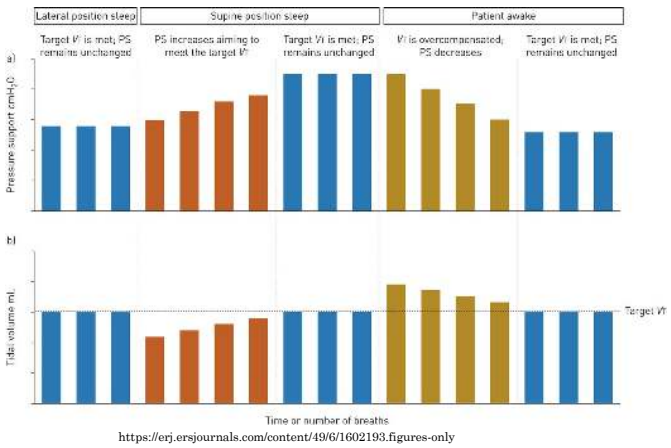
Targeted Tidal Volume

- The targeted tidal volume feature allows the clinician to set pressure support minimum and maximum.
- Clinicians also typically define the rate of change, or how fast the ventilator will allow the pressure support to adjust.
- Once these parameters are set, the ventilator works on a feedback loop, measuring estimated exhaled tidal volume.



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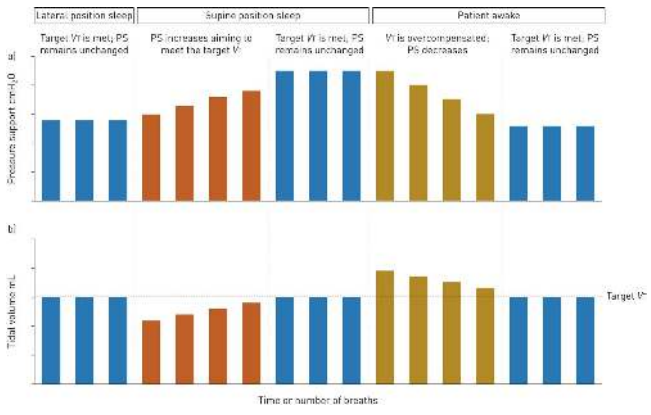
Targeted Tidal Volume (Cont.)

- If the Vte < Target Vt, the pressure support is automatically increased within the predefined range to increase volume delivery
- If Vte=Target Vt, no change occurs
- If Vte > Target Vt, pressure support is decreased toward PS Min.



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Mechanisms of Action: Backup Rate

Most home ventilators incorporate an auto backup rate into patient treatment options.

Backup rates can be set to either fixed or auto on most devices.

Auto backup rates are algorithmically controlled and vary based on ventilator manufacturer. However, the basic function of an auto-rate is to learn the patients breathing pattern over a period of time and set a safety threshold below the patient's learned baseline. If the respiratory rate decelerates below this threshold, the auto rate will deliver breaths to a patient until they begin to spontaneously breath again.

Once spontaneous ventilation continues, the algorithm resets.

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Backup Rate (Cont.)

A fixed backup rate is also an option on home ventilators. This allows the ventilator to continue to function in a VAPS mode while also assuring a minimum minute ventilation. The other functions of VAPS mode (targeted tidal volume, auto-EPAP, etc) still function normally.

Backup rates are another key difference between home NIV devices and home Bi-Level devices. When qualifying a patient for a Bi-Level, guidelines dictate that a device without a backup rate (S) be tried and failed prior to prescription of a device that includes a rate (S/T.)[1] When prescribing ventilation, this requirement is removed.

1) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33800

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Mechanisms of Action: Auto EPAP

Home ventilators often include the ability to set EPAP in ranges, similar to the pressure support ranges that allow us to target tidal volumes.

Many chronic respiratory patients also suffer from obstructive sleep apnea, although literature is inconclusive as to a defined percentage. Studies suggest a wide range of between ~11-65%.

In patients with known or suspected OSA in addition to chronic respiratory failure, auto-EPAP is used to overcome upper airway obstruction and assure ventilation reaches the terminal lung zones.

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Auto EPAP (Cont.)

The ability to set EPAP in ranges allows the ventilator to detect upper airway obstructions and respond by increasing the EPAP level to overcome the issue.

The algorithms controlling this function vary by ventilator manufacturer. Some ventilators have a flow-based feedback loop, while other products use micropulses to determine the reactivity of the airway.

One ventilator manufacturer studied their algorithm, proving it non-inferior to manual EPAP titration during overnight studies.[1]

1) J. Orr et al. Automatic EPAP Intelligent Volume-Assured Pressure Support is Effective in Patients with Chronic Respiratory Failure: A Randomized Trial. Respirology. April 2019.

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Multiple Prescriptions

Another potential benefit of home NIV devices is the ability to set multiple prescriptions based on patient's individual needs.

Most home ventilators can accommodate at least 2 prescriptions, and some can accommodate 4 to 5.

These varying prescriptions can be used to treat patients at baseline, during exacerbation, after exertion, etc.

Some examples of multiple prescriptions include:

- Mask ventilation via VAPS at night, on-demand mouthpiece ventilation during day for ALS patient.
- Mask ventilation one value at night, higher value during day or with exertion
- Mask ventilation via VAPS at night, High Flow Oxygen Therapy during the day for COPD

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Reportable Data

As technology continues to improve, access to data is increasing as well. Most home ventilators offer cloud-based reporting of usage and statistics, either via stick-to-cloud transmission or direct modem access.

This allows providers and prescribers access to in-depth patient data including average volumes, pressures, machine settings, compliance data, etc.

Because NIV devices are considered life-support devices, settings cannot be changed remotely. However, most modems upload patient information one to two times daily, so data is routinely reviewable, if necessary.

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Alarms and battery

A final potential benefit of home ventilators is the ability to set physiological alarms and operate on backup battery power.

Alarms on most home ventilators are similar to what is available on acute care ventilators including volume, pressure, minute ventilation, respiratory rate, etc.

Backup batteries typically consist of some combination of internal lithium-ion batteries and detachable external batteries. Battery life on non-invasive ventilators range from 4 hours to upwards of 18 hours, depending on how batteries are connected to devices.

This offers options for mobility and safety in the event of sustained power outages.

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Conclusion

Home non-invasive ventilators are a relatively new product class that are designed to provide complex clinical therapy in patient's homes.

Home NIV devices are distinct in qualification, features and billing code from home Bi-Level devices.

NIV provides algorithmically controlled ventilation including targeted tidal volume, auto-backup rate and auto-EPAP.

NIV has been shown to improve mortality, decrease hospitalizations and improve quality of life when used in appropriate patient populations.

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Thank you

At this time, I'd be happy to answer any specific questions related to home respiratory therapy, NIV, and how it can be utilized in the home to help improve patient outcomes.

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