

New Breathing Masks Help Everyone Breathe Easier

To date, **NON-INVASIVE VENTILATION (NIV)** has not yet received the recognition that studies unanimously agree is its due. New critical care ventilators and more comfortable masks are contributing to its increased acceptance

IT'S A HORRIFYING prognosis: chronic obstructive pulmonary disease (COPD) will be the third most frequent cause of death worldwide by the year 2030. The World Health Organization (WHO) is forecasting the extraordinary increase in occurrences of this complex syndrome. This development makes it necessary to reassess the ventilation therapies used to date, as was recently done in Germany in the clinical practice guideline “Non-Invasive Mechanical Ventilation as Treatment of Acute Respiratory Failure” (edited by: Dt. Gesellschaft für Pneumologie und Beatmungsmedizin e.V.). The objective of the guide-

line is to extend and establish the use of NIV in cases where acute medical indications are present. This will be to the benefit of a large number of patients, as Prof. Ralf Kuhlen, Chief Physician at the Clinic for Intensive Medicine at the Helios Klinikum in the Buch district of Berlin, explains. Kuhlen was substantially responsible for the formulation of the clinical practice guideline on non-invasive ventilation (see interview, p. 15).

Support and replace

According to the guideline, in many cases invasive ventilation is still unavoidably necessary as a life-saving measure. It is, however, associated with the risk of nosocomial infections, in particular the risk of ventilator-associated pneumonia and the consequent higher mortality and increased costs. It entails the risk of infection, since the trachea functions like an “expressway for germs.” It also requires measures to provide sedation and eliminate pain, and its long-term application leads to atrophy of the musculature and the need for slow weaning off the ventilator.

If a patient’s breathing has been adversely affected by pathophysiological changes, it may have to be artificially maintained. This requires the mechanical supply of oxygen and air and the removal of CO₂. In many cases sedation is also required. Equipment that can mechanically take over the function of the inspiratory muscles has therefore been developed. Modern ventilators such as the Evita XL offer a wide range of ventilation modes for optimal adjustment to the specific clinical situation—whether the ventilation is invasive or non-invasive.

A respirator for non-invasive ventilation was available for use in hospitals as early as 1928 in the form of the “iron lung,” which reproduced the breathing process by means of a cyclic sequence of underpressure (inhalation) and overpressure (exhalation) on the thorax. Ventilation by means of a mask is a new technology which has developed since the 1980s.

Such techniques were initially utilized for chronic illnesses, but are increasingly being applied in acute cases as well. They were, however, initially unable to gain >

ABSTRACT Evidence-based non-invasive ventilation avoids the risks of nosocomial infections with the consequent increased mortality and substantially higher costs. The German Clinical Practice Guideline will increase the acceptance of NIV. Newly developed breathing masks are an important “accessory” for NIV, whose use is desirable for both medical and economic reasons.

ClassicStar®

- ▶ Disposable non-invasive ventilation mask with adjustable cushion for premium comfort with anatomical fit and optimal leakage control
- ▶ Adjustable forehead support for improved distribution of contact pressure on forehead and bridge of nose
- ▶ Improved stability and fixing due to six-point headgear
- ▶ Compatible with Dräger ventilators incorporating an NIV option: Evita series, Savina, and Carina

Movable forehead support and pad for greater stability

The air-filled mask cushion can be adjusted to the patient's facial contours for more comfort and a more effective seal

Optional fixation points on the mask frame enable the headgear to be fastened in the individually most comfortable and stable way possible

O₂ connection for oxygen bleed-in or pressure measurement

Access for nasogastric tube

The standard elbow can be rotated in 360° and adjusted vertically in order to provide increased flexibility

Mask ventilation complies with the most rigorous criteria for evidence-based medicine

> widespread acceptance due to technical reasons, including inadequate synchronization between the ventilator and the patient, which led to complications in this form of artificial ventilation.

Since then, the combination of improved masks and refined mechanical ventilation modes has continually expanded the area of application for mask ventilation, so that it is nowadays even being used in emergency care and neonatal intensive care units. Non-invasive ventilation (NIV) causes much less serious complications than invasive ventilation. This result was obtained in a number of studies with clear statistical significance in the area of intensive care, which showed a significantly lower mortality rate for ventilation using masks as compared to the figure for intubation (e.g. Brochard, Mancebo, and Wysocki et al.; 1995). Nonetheless, adds Kuhlen, the use of NIV in acute medicine “remains inadequate” despite a body of favorable evidence-based data.

Costs halved

Purposefully and correctly applied, NIV can “significantly” shorten the time taken to wean patients off a ventilator. In 2003, Ferrer et al. confirmed the generally shorter average duration of stays both in intensive care units and at hospitals in their randomized study “Non-invasive Ventilation during Persistent Weaning Failure” (*Am. J. Respir. Crit. Care Med.*, Vol. 168, No. 1, July 2003, 70-76).

According to a 2006 study by Schönhofer et al., an intubated ventilated pneumonia patient in Europe results in costs >

Breathe in and out, please



PHOTOGRAPHY: AP PHOTO

The lungs supply the body with oxygen and energy. A newborn baby inhales and exhales about 50 times per minute. Adults, on the other hand, fill and empty their lungs with approximately 0.5 liters of air only 12 to 16 times a minute. The inspiratory muscles have thus

exhaled more than a quarter of a million cubic meters of air by age 69—almost enough to inflate 23 of the first type of Zeppelin airship, the LZ-1, which was 128 meters in length.

The lung is a kind of fine-pored sponge with 30 million tiny sacs known as alveoli. In order to inhale (inspiration), the diaphragm contracts, creating a vacuum that sucks fresh air through the trachea and bronchi into the consecutive clusters of alveoli. From there, the air is transported into the arteries, which supply oxygen to the mitochondria (the so-called ATP factories), where it helps convert glucose into carbon dioxide (CO₂), water, and energy.

Annual CO₂ emissions equal to driving 888 km in a Porsche Cayenne

The CO₂ is then removed in reverse order, whereby veins carry the gas to the alveoli. When the lungs are passively exhaling (expiration), CO₂ and water are transported via the bronchia into the surrounding atmosphere. When a person is at rest, his or her “CO₂ footprint” is about 315 kilograms of CO₂ per year, which is equivalent to the amount produced by driving a Porsche Cayenne Turbo 888 kilometers.

The body makes use of various mechanisms to simplify respiration. What immediately comes to mind is the analogy of a lung with a spring. Primarily as a result of the diaphragm’s muscular force, the lung is expanded during inhalation and automatically deflates again during exhalation.

Another facilitator that is just as efficient but less noticeable is the substance that coats the alveoli and lowers the surface tension of water. Known as a surfactant, this substance stabilizes the differently sized alveoli and thus increases the expandability of the lung (compliance). The pressure difference during inhalation is reduced as a result, making the breathing process easier. A person whose respiratory system is obstructed will suffer either from oxygen deficiency (hypoxia) as the chief symptom, or else from increased CO₂ in the blood in the arteries (hypercarbia).

NovaStar®

- ▶ Reusable non-invasive ventilation mask
- ▶ Optimal fit thanks to individual adjustment to the contours of the face
- ▶ Extremely soft gel cushion for comfortable wear and an improved seal
- ▶ Adjustable forehead support for improved distribution of the contact pressure on the forehead and the bridge of the nose
- ▶ Compatible with Dräger ventilators incorporating an NIV option: Evita series, Savina, and Carina



Movable forehead support and bendable forehead pad for fitting to the curve of the forehead

Thumb wheel for adjusting the forehead support gradually

Customized fit due to the pliable ring embedded in the flexible clear shell

Silicone gel-filled cushion for improved comfort and seal

Standard elbow can be moved in 360° for increased flexibility

Magnetic clips for attaching the headgear enable rapid positioning and removal of the mask

NIV shortens the average length of stays and thus cuts case costs significantly

> of 25,000 euros, whereas non-invasive ventilation more than halves such costs to 10,300 euros. Further studies have revealed that, to date, the masks used have often been considered a limiting factor

for NIV.

On the one hand, masks must be comfortable to wear and may not cause lesions—i.e. skin irritations; on the other, they must not permit anything more than

minor leakage that can then be fully compensated for by the respirator. The new NIV ClassicStar and NovaStar full-face masks provide substantial improvements in these areas. Another focus is on mini-

Milestones: the road to patient-oriented ventilation

1771 Discovery of oxygen as a component of air: *Carl Wilhelm Scheele and later Joseph Priestley (1775)*

1775 Respiration serves to provide oxygen: *Antoine Lavoisier*

1858 Manual ventilation method: *Henry R. Silvester*

1876 Negative pressure ventilation—the Spirophore at the Paris World's Fair of 1878:

Eugène Woillez

1882 Inspiration is triggered by O₂ shortage, expiration by an excess of CO₂: *Julius Bernstein*



ILLUSTRATION: FROM PATENT SPECIFICATION

1883 First patent for a respirator apparatus (see illustration):

John Ketchum

1889 Lubeca® pressure regulator—supply of gases from bottles: *Heinrich Dräger*

1895 “Linde process”—filling bottles with gases such as oxygen: *Carl von Linde*

1903 “Biomotor”—portable devices for artificial respiration in a foot-driven cuirass:

Rudolf Eisenmenger

1904 Pressure difference method using a negative pressure chamber:

Ferdinand Sauerbruch

1906 Positive pressure machine (Brauer-Dräger®):

Ludolph Brauer

1907 Time-controlled alternating-pressure ventilation (Dräger Pulmotor®; prototype):

Heinrich Dräger

1908/09 Pressure-controlled alternating-pressure ventilation (dual-tube system) (Dräger Pulmotor®; series production):

Bernhard Dräger and

Hans Schröder

1928 Tank respirator, so-called “iron lung”—intermittent negative-pressure ventilation for the treatment of gas poisoning:

Philip Drinker and

Louis Agassiz Shaw

1937 Wooden Both respirator (Australia); produced by Morris Motors Ltd., UK (1938):

Edward Both

1940 Worldwide polio epidemics until the 1960s

1947 Production of the “iron lung” by the Deutsche Werft, Hamburg—the torpedo tube from a destroyer (pressure chamber), bellows from a field smithy (drive), part of a fishing cutter (gearbox):

Axel Dönhardt and

Reinhard Aschenbrenner

1947/49 Parallel development of the iron lung at Dräger (prototype)/Model E 52—series production (1952)

1952 “Bag ventilation”: manual ventilation by means of a to-and-fro system; 200 patients ventilated by 1,500 students in Copenhagen

1952 Control of the tidal volume and the respiratory rate (positive-pressure ventilation):

Engström Respirator®

1953 Ventilation via tracheotomy cannula or tube (Dräger Pulmotor principle): *Dräger Poliomat®*

1955 Controlled and assisted ventilation: time-controlled, constant volume—with humidification and warming of the breathing gas: *Dräger Spiromat®*

1965 Assisted ventilation: pressure-controlled, patient-triggered: *Dräger Assistor®*

1971 Volume-controlled ventilation with a feedback system: *SERVO® 900*

1982 Microprocessor-controlled ventilation and integrated ventilation monitoring: *Dräger EV-A*

1988 Introduction of patient-adapted ventilation: optimization of the spontaneous breathing support with BIPAP:

Dräger Evita® series

1995 Further development of patient-adapted ventilation—introduction of AutoFlow and then of PPS (1997) and NIV (2000):

Dräger Evita 4

2005 Reduction of ventilation time by automated weaning off the respirator using the knowledge-based SmartCare system

Dräger Evita XL

Heike Petermann



Prof. Ralf Kuhlen was substantially responsible for the formulation of the Clinical Practice Guideline on non-invasive ventilation.



mizing the dead space of the mask.

The NovaStar is the first full-face mask in hospital and institutional use to utilize an extremely soft gel-filled cushion, which provides an extremely good anatomical fit and combines a high level of both comfort and functionality. “We really like the gel cushion and the flexibility of the mask,” commented two physiotherapists after an exhaustive application test in a department of the Karolinska University Hospital in Solna, Sweden at the beginning of 2008. What’s more, the masks are “very easy” to use. In cases where artificial feeding is used, the nasogastric tube is covered by the gel cushion (NovaStar), or led to the patient via an opening (ClassicStar). Unlike conventional solutions, significant leakage and skin irritations can be avoided. Both masks cover the mouth and nose.

Accessories extend the range

A wide range of easy-to-fit accessories extends the range of applications. Components include both humidification filters and Barr-vent filters to protect against viral and bacterial infection. The masks with their respective filters and breathing circuits have, of course, been validated as complete systems. In total, the properties of current developments in mask technology contribute fundamentally to increasing the acceptance of NIV among both patients and care personal—and so promote the increased application of mask ventilation. **Imme Ubben**

Further information online:

-  Product information
 -  100 Years of Artificial Ventilation
- www.draeger.com/96/NIV

“NIV requires a different kind of patient management”

PROF. RALF KUHLEN (43) is Chief Physician at the Clinic for Intensive Medicine at the Helios Klinikum in the Buch district of Berlin.

Why was the Clinical Practice Guideline on non-invasive ventilation (NIV) developed?

Kuhlen: For some indications, especially in the area of hypercarbic forms of respiratory failure, NIV offers clear advantages in comparison with invasive ventilation. These advantages include fewer germs entering the respiratory system and consequently a lower incidence of nosocomial infections due to the non-use of a tube, and no need to sedate the patient. These advantages have not, however, been fully utilized in critical care medicine to date, so that one of the guideline’s objectives was to establish the recognition due to NIV for the area of acute medical care and to extend its application. But the guideline also warns against too great an extension of NIV in cases with unclear indications, such as severe forms of hypoxaemic gas exchange abnormalities.

What was previously the limiting factor preventing greater use of NIV?

Kuhlen: Many studies have shown the advantage of NIV, but this knowledge has not yet taken hold in day-to-day hospital practice. NIV also requires a different kind of patient management. Patients who are awake require more attention from medical and care personnel in the initial phase—that of adaptation of the NIV. However, this increased effort at the beginning is compensated for by the corresponding reduction in the care needed as treatment progresses. The total effort required by the two methods of treatment—invasive and non-invasive ventilation—is about equal. However, all studies of NIV in cases of hypercarbic respiratory insufficiency indicate that fewer patients require intubation and that the survival rate connected with the ventilation episode is better.

How do you see applications of NIV developing in the future?

Kuhlen: The demographic development in many industrialized countries will mean that we have to face an increase in the number of patients with advanced stages of chronic obstructive pulmonary diseases (COPD). Good data supports the observation that many patients in this group profit from NIV and also experience an improved quality of life when the process is used outside the hospital environment.

Where do you see a remaining need for improvement in mask ventilation?

Kuhlen: A couple of points occur to me as a specialist in this area. But the most important improvement as far as the patients are concerned will be the significantly increased consideration of NIV when adequate indications are present in the everyday hospital environment. The primary objectives of the Clinical Practice Guideline are to spread knowledge of the value of the procedure for these indications.