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Noninvasive ventilation: open issues for nursing research

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Abstract. According to the current literature, Noninvasive Ventilation (NIV) is a well-recognized respiratory support technique for patients affected by Acute Respiratory Failure (ARF). As highlighted by recent meta-analysis, a tight adherence to protocols regarding patients' selection criteria, relative or absolute contraindications, plus highly skilled and experienced operators, can positively affect the NIV performance and mortality rates. Positive outcome from NIV respiratory support is dependent from: patient's clinical condition and education needs; confidence of the staff with NIV technology; choice and management of the most suitable interface available prevention of interface complications; nutritional assessment (artificial feeding if required) and conditioning of medical gas. Despite these issues, the air leakage represents the major threat during NIV support. Indeed, to obtain a positive outcome from this treatment, the 'NIV troubleshooting' management appears to be crucial. Common issues as air leakage, patient-ventilator asynchrony, interface related pressure ulcers, discomfort, and gastric distention should be promptly detected and solved. The analysis of these current issues reveals a lack of evidence based practice, resulting in bed-side clinical interventions based only on the expert consensus or local opinions. To improve this knowledge gap, more efforts are strongly recommended from medical and nursing research communities. Multicenter randomized controlled clinical trials are needed to achieve adequate knowledge to reach the best patient's outcome. Further information to identify new areas of nursing research on NIV, can be achieved from qualitative studies performed on patients and healthcare operators.

Key words: noninvasive ventilation, nursing research, outcome assessment (healthcare), qualitative research

Introduction

According to the current literature, Noninvasive Ventilation (NIV) is a well-recognized respiratory support technique for in and out of hospital patients affected by Acute Respiratory Failure (ARF) (1, 2).

In selected population of patients, early commence of NIV produces better positive effects. Beyond its well-known application in the chronic respiratory failure field as Obstructive Sleep Apnea, nowadays NIV is largely employed in the acute clinical settings to prevent complications related to endotracheal intubation, especially Ventilator Associated Pneumonia (VAP).

The use of Pressure Support Ventilation (PSV) during NIV represents a gold standard as respiratory support in patients affected by acute on Chronic Obstructive Pulmonary Disease (COPD), while Continuous Positive Pressure Ventilation (CPAP) plays the same role in Acute Cardiogenic Pulmonary Edema (ACPE) (3).

Despite high levels of evidence about its effectiveness are still lacking, NIV is more often used for clinical scenarios involving immunocompromised patients,

Acute Respiratory Distress Syndrome (ARDS), prevention of extubation failure after ARF, weaning from mechanical ventilation, acute asthma, cystic fibrosis, and during bronchoscopy procedures (3).

As highlighted by recent meta-analysis, a tight adherence to protocols regarding patient's selection criteria, the relative or absolute contraindications, plus highly skilled and experienced operators, can positively affect the NIV performance and mortality rate (4).

Skills and competences about NIV management are strictly related to a proper patient's recruitment process (identification of the entry criteria for a NIV trial), choice and setting of an appropriate mechanical ventilator according to the type of respiratory failure, and, nevertheless, the selection of the most suitable interface for the patients.

To obtain a positive outcome from this respiratory treatment, a crucial factor is the NIV troubleshooting performed by the staff. Common issues as air leakage throughout the interface, patient-ventilator asynchrony, interface related pressure ulcers, discomfort, and gastric distention, should be promptly detected and fixed.

The analysis of the abovementioned issues reveals a lack of evidence based practice, resulting in bed-side interventions based only on the expert consensus or local opinions. To minimize this knowledge gap, more efforts are strongly recommended from medical and nursing research communities. Multicenter randomized controlled clinical trials are needed to achieve the adequate knowledges to reach the best patient's outcome.

The aim of this paper is to offer an update about the "hot topics" of nursing research in NIV, that still need to be studied in deep. Moreover, the authors contribute with some critical thoughts about the current available knowledge from the published research on these issues.

Interface related pressure ulcers

One of the most common and reported complications of NIV is the rapid onset and development of pressure ulcers (PUs) on the body regions where the interface (usually the mask) is in contact with patient's skin. PUs development process occurs in most of the patients within 48 hours since the commence of treatment, and the nasal bridge represents the anatomical area interested by this complication since the very first hours of treatment (5).

Despite the shape and sizes, every type of NIV interface has its own pressure ulcer risk contact points.

Facial stage 1° PUs and nasal bridge pressure ulcers are the most common NIV-mask related PUs (respectively ranging from 20% to 34%, and from 2% to 50%) (5). These adverse events are usually determined by an excessive increase of the harnesses tightening to patients' head or face in the attempt to reduce the air leaks, plus the augmentation of the air cushions' volume, and inspiratory pressures' incrementation (5).

During the application of a NIV mask, the skin's contact pressure results higher in the expiration phase of the positive pressure ventilation (6). This effect is due to the decreased contact pressure of the mask, caused by the ventilator pressurization, that determines a lower seal in the contact points of the mask over the skin. During the expiration, instead, the force generated by the headgears exerts the highest pressure, since the target of the ventilator is to maintain the PEEP level inside the system.

Wearing an oro-nasal mask longer than 26 consecutive hours is an independent risk factor for the development of skin breakdown in patients with acute respiratory failure (7).

According to pre-clinical and clinical studies, pressure ulcers timing of development can be established in 4-6 hour under a sustained pressure load (8), and despite the fact that the threshold pressure of 32 mmHg for capillary flow closure is still questioning, a recent review indicates that tissue-interface pressures of 30-37 mmHg together with shear forces, can originate PUs (9).

Nevertheless, many different types of nasal-oral masks are available on the market. Nava et al., in their review about NIV interfaces, counted 13 different kind of nasal-oral masks (10). These elements should be considered as a variable in the risk management of interface related PUs.

Moreover, there is a plethora of risk factors for pressure sores development as Body Mass Index (BMI) (11), diabetes (12), oedema, infusion of ino-

trope/vasoactive medications (13), vascular disease, nutritional status, chronic skin condition, history of previous pressure damage, steroid therapy treatment, cytotoxic drugs (14). All these mentioned risk factors can ease the development of PUs, but no studies about the synergies of these factors, has been published yet.

The research about the employment of advanced wound dressing in the NIV mask related PUs, is currently limited, even if a lot of authors recommend the application of barriers between the face skin and the interface (5,15). Weng investigated the application of transparent versus hydrocolloid dressing on patients' skin to prevent mask related PUs, without finding any superiority of a kind of dressing over the others (16). Since the sample recruited was limited to 90 patients, the results of this study should be confirmed by a larger sample (and, possibly, multicentric) study.

The use of helmet can determine pain and discomfort under patients' armpits (17). Upper limbs oedema due to the armpit braces provoking venous and lymphatic stasis and deep venous thrombosis in the axillary vein was reported with an incidence less than 5% (5).

In this kind of interface, the application of 2.5 kilograms of weights on both the armpit braces, keeping the patients' arms free, seems to be effective in controlling the air-leaks during helmet-CPAP with PEEP levels of 10 cmH_2O, and preventing the complication related to the pressure exerted to the axillary region (17).

Taking in account these information, nursing research about interface related PUs should focus on some critical areas concerning the synergic action of the compresence of multiple risk factors, the effectiveness of advance wound dressing application in the prevention of PUs, and which type of product can be most adequate (foam, transparent dressing, or hydrocolloid). Moreover, the choice of a kind of mask over another should be investigated, as well as the implementation of standardized interfaces rotation protocols. Whereas, for helmet – CPAP, research should be focused on the replication on large sample scale of the application of the weights to armpit braces of the helmets, as introduced by Lucchini et al. in the helmet-bundle paper in 2010, since their strategy for PUs' prevention seems to be smart and safe (17).

Gas humidification

Gas humidification is a fundamental process that allows the airways mucociliary clearance to work efficiently, preventing the development of atelectasis, pneumonia and preserve the mucosa cells from the development of metaplasia (18).

Humidification during NIV remains controversial, especially due to the different types of ventilators and interfaces employed. Several clinicians assert that the use of turbine driven mechanical ventilators require less gas conditioning. The reason is the use of ambient air mixed with fresh oxygen.

Noninvasive ventilation, especially when implemented using specific ICU mechanical ventilator, is delivered with fresh and anhydrous medical gas, needing adequate conditioning to reach a minimum level of absolute humidity (AH) and a relative humidity (RH). Some groups of experts indicated that the gases delivered during NIV should contain an AH value of 10 mgH_2O/L) (19, 20).

Recent guidelines on gas humidification during mechanical ventilation, drafted by American Association of Respiratory Care, recommend the use of active humidification in NIV (21). The employment of heat and moisture exchange filters is not suggested, for the large rates of air-leaks that usually characterizes NIV, impeding the main part of expiratory flow to pass through the filter and determining an adequate conditioning of the gas during patient's inspiration (21).

Even if these guidelines recommend to keep the gas temperature according to the level of patients' tolerance, comfort, and the underlying lungs' conditions, there are no specific values to be followed during the implementation of active humidification during NIV (21).

One of the most uncomfortable effect related to active humidification in NIV is the so called "fog" effect, virtually present with all the types of NIV interfaces (mask, helmet), due to condensation inside the interface. Condensation phenomena may occur inside the interfaces when the gas is conditioned with higher temperatures in comparison with those detected inside the interface itself. During NIV without active humidification, the mean temperature inside the interfaces could vary from 28° to 29°C. So, if the active humidifi-

er's temperature is settled lower than 28°C, the formation of condensation can be avoided (22). Since active humidifiers operate in optimal conditions when the gases' temperature increases between the humidifier's chamber and the Y shape connector on the breathing circuit with a gradient of +2°, it can be assumed that the temperature of active humidification chamber should be settled from 24° to 26° (22). This temperature setting is currently impossible to implement with some of the newest humidification systems available, since they are engineered with automatic fixed set values. Therefore, only active humidifiers equipped with optional manual setting of the grades centigrade to be reached in the heating chamber, should be employed during NIV.

However, currently there are not large studies that have investigated and compared the adverse effects related to these active humidifiers' settings during NIV, in relation with all the kinds of available interfaces (helmet, oro-nasal mask, full face mask, and nasal mask). Overall, there is no published researches showing the efficacy of the aforementioned settings on the patient's respiratory system, the potential improvement of bronchial secretion clearance, and, eventually, the reduction of hospital acquired pneumonia incidence among patients undergoing to NIV support.

Enteral nutrition and nasogastric tube management

Vomit and consequent risk of inhalation is one of the most important concerns during NIV, even though aspiration pneumonia is reported as a rare complication (<5%), aerophagia is common, and gastric insufflation varies from 10% to 50% (5). Therefore, these aspects are crucial for the potential risks which patients may be frequently exposed (5).

There are some considerations to take in account. Patients undergoing to NIV support should be guaranteed with adequate pause periods from the ventilatory treatment. The time spent off from NIV should be used to provide adequate rest and comfort, suitable feeding and hydration, and to handle other adverse effects related to NIV, as airways dryness, nasal congestion, noise, and nose-sinus-ear pain. When the respiratory failure is severe and the patient becomes "NIV dependent" to provide adequate gas exchanges, the expected brakes from a NIV cycle to another can be very short, or lifted at all. Management of these scenarios is borderline, requiring the medical decision to intubate the patient and commence invasive mechanical ventilation. In this cases (or others medical conditions requiring artificial nutrition) the patient is not able to feed himself, therefore providing nutrients via enteral feeding, throughout a nasogastric (NG) tube is mandatory (unless there is a clear indication for parenteral nutrition). According to the literature, the insertion of a gastric tube still remains controversial (15). In fact, the first reason to insert an NG tube into patient's stomach is to evacuate it from the ingested air during NIV, preventing gastric distension, and the consequent risk of vomit and aspiration. Moreover, avoiding gastric distension improves diaphragmatic function, thoracic expansion and the gas exchanges during mechanical ventilation. The limit of inspiratory pressure that can be reached before overcoming the opening pressure of LES (lower esophageal sphincter) is 20-25 cmH_2O (23), but usually these values of pressure are not delivered during NIV.

The clinicians against the indiscriminate utilization of NG tube during NIV assert that the presence of a tube passing through the lower esophageal sphincter (LES) can determine an impairment of the LES function itself, increasing the risk of gastroesophageal reflux and consequent inhalation of gastric content (24). Moreover, NG tubes have a limited capability to remove the content of the stomach, especially for solid and semisolid materials (25).

Regarding the administration of enteral nutrition (EN) to patients during NIV, the scientific literature appears to be very limited. Kogo et al. in 2015 have published a retrospective study performed on 70 patients unable to feed themselves, treated with NIV (26). 70% of them received EN during NIV. This study did not show any difference in hospital mortality rate between the patients treated with NIV plus EN, in comparison with the group without EN, even if the first group recorded a higher rate of airways problems and a longer hospital length of stay (26). A subsequent, larger study performed by the same authors on 150 patients, has confirmed the previous results: higher rates of airway complications (total number of episodes of

vomiting, followed by desaturation, mucus plug, and aspiration pneumonia) in the EN-NIV group versus the no EN-NIV group (53% [32/60] vs 32% [15/47], p=0.03), and higher median of NIV duration (16 days, [IQR 7-43] vs 8 days [IQR 5-20], p=0.02), while no difference in hospital mortality was found between the 2 groups (27). Anyway, due to the several limitations of this study, the retrospective design and the unbalanced characteristics of the sample groups, the results showed should be confirmed in a prospective, larger and well-designed research (27).

At last, an important issue remains open: which is the optimal setting rate of administration for continuous EN during NIV? Is it better maintaining a lower nutrition regimen to limit the risk of gastric distension (for air ingestion) and prevent the risk of vomit/aspiration, or to guarantee a full rate NE administration to prevent patient's malnutrition plus its related adverse effects?

These two questions deserve adequate answers throughout well-designed and focused research studies, since the lack of specific literature. Furthermore, it's time to definitively explore the effectiveness of NG tube insertion to prevent gastric distension, through randomized controlled trials able to identify proper criteria for indications about the NG tube insertion, based on stratified risk categories of patients (e.g. patients with full cognitive state and well effective protective reflexes against drowsy state…).

Noise exposure during NIV

Noise exposure during NIV may be underestimated among the factors that influence patient well-being (28). Some authors reported that loud sounds can contribute to patient discomfort during NIV cycles. The noise exceeded the usual ICU background noise, potentially increasing patient discomfort and causing sleep disruption (29, 30). Cavaliere et al. in 2004 reported that the sound intensities registered during NIV cycles with different interfaces ranged between 60 and 110 dB (31). Interfaces affected the noise level associated with NIV significantly, while the difference related to the level of PSV (10 or 15 cmH_2O) did not reach statistical significance. During NIV with nasal or facial masks, the noise did not exceed 70 dB, while inside the helmet the noise exceed 110dB (31). However, the presence of HME filters on the inspiratory limb of a helmet-CPAP system was associated with the feeling of less noise inside the helmet (31). Lucchini et al., in 2010, investigated the dependence of the noise inside the helmet, according to the gas flow delivered (17). Authors concluded that, with a gas flow between 40 and 80 l/min, the use of an HME on the inspiratory limb of the helmet circuit allows the reduction of noise from 100 dB to 55 dB (17). In addition to the reduction of noise at source, Lucchini et al. suggest the use of earplugs in order to minimize the patient's discomfort during NIV support (17). The use of ear plugs is also supported by recent studies that investigate the field of interference to sleep in ventilated and not ventilated patients in ICUs (32, 33).

Nursing workloads

Since the first years of 2000s' the professional debate about the right setting (intensive care, high dependency unit, general wards, emergency department) where to deliver safely noninvasive ventilation has been intense and it goes on till nowadays (34). Anyway, the major emphasis given by the authors was about the need of adequate expertise to manage patients undergoing NIV, plus adequate advanced/specific skilled personnel available 24/7 (34). Even if the learning curve concept can explain the improvement of patients' outcome (35), and also, a speeding in the NIV performance of the operators, it's undeniable that the nursing workloads related to the implementation of NIV in the acute care settings is a variable depending from different factors. These factors are: patients' severity of illness, tolerance's level to the treatment, ventilators and interfaces employed, and the patient's individual needs of education about the management of the illness related effects and its treatment (anxiety, losing control sensation, panic, and irritation; 36).

Moreover, in the scientific literature there are no clear data about the nursing workload produced by NIV patients, mainly due to inadequate measuring tools employed in the studies, interferences from the research observers, and there's not clarity if the report-

ed achievement of patients' positive outcomes has been accomplished shifting the nursing time due to other patients (34).

Considering all these issues, the study of Lucchini et al. about the measurement of the Nursing Activities Score on a case mix of patients inside adult general intensive care units, acquires a special meaning, for the implementation of a widely accepted and validated scale able to evaluate the nursing workloads, even if, limited to the critical care setting (37). Lucchini et al. found that the NAS mean values for patients during NIV with pressure support ventilation (PSV) and oro-nasal or full-face mask was equal to 80.16% (SD±12.53 - range 65-126). The 3rd quartile of this group of patients had NAS values between 90% and 110%, that it means a nurse to patient ratio of 0.9 to 1.1. This type of measure indicates that 1/4 of observed patients on PSV delivered by mask requires one dedicated bedside nurse. If patients were treated with helmet CPAP, the measured mean NAS values were lower (69.7%±12.69; range 41-113), even if the 3rd quartile had about the same NAS values of the mask PSV group (37).

The results of this study performed on a low sample size, open the way to future nursing research and investigations, aimed to record objective nursing workloads measurement, overcoming some common beliefs about the simplicity of managing patients during NIV, as they requiring low levels of nursing care. Beyond the need of objective measurement of the nursing workload, some enhanced values to nursing care planning for these categories of patients can be derived from the results of qualitative studies, that can bring to nurses' attention some aspects and needs relevant for the patients' care that are not included in standardized quantitative scores (36). Moreover, qualitative research might offer some elements also from nurses' perspective and experience, that can lead to a better understanding of the real nursing workload lived during the caring to patients undergoing to NIV support. For example, in favor of this, Sorensen et al. revealed some key-points related to the practical wisdom necessary to manage this category of patients: achieving non-invasive adaptation, ensuring effective ventilation and responding attentively to patients' perceptions of NIV (38).

Conclusions

Noninvasive ventilation is currently a widespread respiratory treatment delivered in a lot of different clinical settings inside hospitals to counteract/counterbalance the effects of initial phases of ARF (for acute or chronic patients).

Reaching positive outcomes through this type of respiratory support can be obtained if an attentive and balanced management is provided, taking in account the critical aspects related to patients' clinical conditions, education requirements, operators' knowledge of the NIV technologies, choice and management of the most suitable interface available, prevention of interface complications, nutritional assessment and artificial feeding if required, adequate conditioning of delivered gas and optimization of the patient-ventilator interaction. Even if these aspects are fundamental, the major obstacle of the implementation of NIV is represented by the large air-leaks from the interfaces and the troubleshooting to manage them.

Almost all these issues show a gap of empirical derived knowledge, leaving the local opinions or the expert consensus to guide the clinical practice.

For these reasons a large effort is required from the medical, and overall, from the nursing scientific community. There's the need to perform large well-designed multicenter studies, to offer solid answers to the grey areas of clinical practice (interface related pressure ulcers, gas humidification, enteral nutrition, noise exposure), improving patients' outcomes through new evidence based knowledge.

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