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Best Practices to Prevent Complications in Non-Invasive Ventilation

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Abstract

Objective: Non-invasive ventilation (NIV) refers to the delivery of positive pressure ventilation without using invasive methods. To develop a best practices protocol to standardise nursing interventions for preventing complications associated with the interface and air pressure/flow and to optimise NIV.

Methods: A non-probability snowball, convenience or intentional study was carried out using the Delphi technique. Online questionnaires in two rounds were applied to 24 nurses who were experts in the field under study, selected according to previously defined criteria.

Results: The expert panel reached a consensus on 67 nursing interventions to prevent two types of NIV complications: those associated with the interface (facial pain or discomfort, noise, skin lesions on the nasal bridge and face, carbon dioxide rebreathing, claustrophobia, and patient-ventilator asynchrony) and those associated with air pressure/flow (air leaks; nasal and oral dryness/congestion, conjunctivitis; aerophagia and abdominal distension).

Conclusion: A validated protocol for patients undergoing NIV can support decision-making, provide a set of evidence-based interventions and promote the quality and standardisation of nursing care practices to improve the effectiveness and, consequently, the success of NIV.

Keywords Non-invasive ventilation · nursing care · prevention

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INTRODUCTION

Non-invasive ventilation (NIV) is the administration of positive pressure ventilatory support without the use of invasive methods, with proven benefits in the treatment of various clinical conditions associated with respiratory failure (1,2). It is applied via the upper airways with an external interface, thus avoiding the use of an invasive artificial airway such as an endotracheal tube or tracheostomy (3). It allows alveolar ventilation to be increased using masks (oronasal, nasal, full-face, helmet/Helmet® or mouthpiece) that act as a patient-ventilator interface (4).

As it is a technique that does not require invasive methods in the airway, it has become critical due to its therapeutic safety and the efficacy demonstrated in daily practice. However, the effectiveness of NIV can be associated with possible complications that require preventive attention from nursing teams.

Lazovic et al. (5) reported good tolerance rates in people undergoing NIV, but emphasised that the treatment is not without complications, which are mostly considered tolerable. Other authors have noted that some of the main complications of NIV include pneumothorax, NIV-related pneumonia, gastric insufflation, agitation and encephalopathy, with haemodynamic, respiratory and neurological effects that can lead to cardiorespiratory arrest (6).

Its effectiveness and success depend on the knowledge and technical competence of the nursing team, which requires trained and qualified professionals capable of preventing, monitoring and treating the potential complications associated with the procedure in critically ill patients.

This study aimed to answer the following research question: 'Which nursing interventions prevent complications related to the interface and air pressure/flow in patients undergoing non-invasive ventilation?'.

The main aim of this study was to develop a protocol of good practice for standardising nursing interventions to prevent these complications.

MATERIALS AND METHOD

This study used the Delphi methodology, also known as the Delphi study or the Delphi technique. This technique consists of a resource that aims to obtain the opinions of experts, who use their knowledge, developed research, experience, logical reasoning skills, and exchange of information to reach a consensus on the questionnaires proposed in the panels within the area under study.

Its fundamental attributes include anonymity, statistical representation of the distribution of results, and feedback from group responses, together with two essential principles that support the development of the technique: flexibility and the contributions that experts bring to the group (7).

It is a methodological strategy for qualitative and quantitative research designed to build a consensus of opinions among a group of experts. It is carried out in successive rounds with the aim of evaluating a particular problem or intervention proposal when there is no consensus due to a lack of scientific evidence or the presence of contradictory information (8).

According to Valdés and Marín (9), performing a Delphi study involves completing a series of successive tasks and actions, the rigorous execution of which affects the quality of the results:

1. Preparatory phase-which includes selecting the experts, drafting, and choosing the means of disseminating the questionnaire to be submitted to the experts.
2. Consultation phase-carrying out the rounds, statistical processing of the data and feedback of the results to the experts, and the retrieval of the experts who did not respond.
3. Consensus phase: building consensus among the group and drawing up the final report.

The selection of experts is a pivotal element of the ***preparatory phase*** as it significantly influences the success of the Delphi panel, directly affecting the quality of the results. An expert or specialist is an individual with a high level of knowledge and skill, extensive experience on a specific topic or a specialist in their area of knowledge and identified as such by their peers (10,11).

To find experts who met the inclusion criteria, a nationwide search was conducted for articles published by nurses in the field of NIV, nurses who are trainers in accredited bodies and/or postgraduate courses in the area under study. The Portuguese Association of Medical-Surgical Nurses was consulted to assist in identifying nurses with training/interest in NIV. Subsequently, the "snowball" technique was used, where experts who agreed to take part in the study indicated other experts who met the criteria for inclusion in the study.

Therefore, the experts were selected using a non-probability, snowball, convenience, or intentional sampling technique.

The following criteria were used:

- Be a nurse and have advanced training (in postgraduate, post-specialisation, master's or training courses) in NIV;

- Provide direct nursing care to patients undergoing NIV;
- Have at least five years of professional experience in NIV;
- Come from different institutions/units/locations;
- Agree to participate in the study.

The exclusion criteria were nurses who were not directly involved in patient care and who had less than five years of professional experience.

Initially, 30 expert nurses were identified for the panel, but four declined to take part in the study and one was the coordinator of an inpatient unit, so they were excluded from the group. This resulted in a panel of 25 expert nurses.

The first-round questionnaire was based on a literature review carried out by the authors to identify the evidence available on NIV: the potential complications associated with the interface and air pressure/flow, the nursing practices used to prevent them, and the identification of current protocols that identify the steps necessary for safe and effective implementation of the technique. Then, the questionnaire was subjected to a pre-test involving two independent experts, whose profiles were similar to those of the panel members, to evaluate, test, and validate it. According to the suggestions of these experts, minor changes were made to two items that were rephrased.

According to Valdés and Marín (9), preparing and administering the questionnaire is part of the ***preparatory phase***. The Google Forms® online platform was used to send the link to each expert, monitor the evolution of the results, and show the statistical representation of the responses. According to Gomes (10), the use of online questionnaires has proved to be a useful and effective tool in research, facilitating not only their construction and dissemination but also reducing response times and the time spent summarising each Delphi round.

The questionnaire began with a brief introduction, which included the aim of the study, the reasons for the topic selected, and a description of the methodology adopted, always ensuring data anonymity and confidentiality. In the first round, the questionnaire consisted of three parts:

- The first part aimed at characterising the experts and included the following items: age range, gender, education level, professional category, length of professional experience, NIV training, and NIV experience;
- The second part addressed the intervention domain: A - Nursing interventions to prevent complications associated with the interface (facial pain or discomfort, noise, skin lesions on the nasal bridge and face, carbon dioxide rebreathing, claustrophobia, and patient-ventilator asynchrony);
- The third part addressed the intervention domain: B - Nursing interventions to prevent complications associated with air pressure/flow (air leaks; nasal and oral dryness/congestion, conjunctivitis; aerophagia and abdominal distension).

In these last two parts, closed-ended answers were used on a 3-point Likert scale, allowing experts to indicate their level of agreement from 1 to 3, where 1 means "I disagree", 2 "I agree" and 3 "I totally agree", eliminating the neutral option, which has no relevance to the study.

Thus, in this consultation phase, the experts were asked to indicate their level of agreement or disagreement with each nursing intervention presented. If they wanted to include the intervention analysed, they could indicate their level of agreement by choosing "Agree" or "Totally Agree". The experts could also give their opinion or suggest other interventions not included in the list provided in the two fields for short/open-ended answers entitled "Opinion" and "Suggestion of another intervention" at the end of each intervention group. However, it was established that each new intervention proposed would only be subject to a second round if it was related to the study's objective (12).

The Delphi technique is a valuable tool for achieving consensus in modern health research. Consensus guidelines can be very valuable in providing "best practice" evidence-based care for a specific clinical problem (13).

Although the consensus criteria can be defined by the researchers, we also considered the work carried out by Malta (14) and Passos et al. (12) when using this same technique to define the criteria and consensus levels for classifying the results of the Delphi rounds. A minimum consensus criterion of 75% agreement in the positive answers given by the experts was defined for this study (Table 1).

Table 1. Consensus Criteria

Consensus
• At least 75% of experts answer positively, i.e. the experts believe that the interventions proposed in the questionnaires were valid and/or appropriate for the topic under study. • Positive responses are those resulting from the sum of the percentages of scores 2 and 3 on a 3-point Likert scale (scores from 1 to 3). • In the second round, at least 75% of the experts believed that the new intervention was valid on a score of 3 "totally agree".
No consensus
• Less than 75% of the experts answered positively to the interventions proposed in the questionnaires.

Table 2. Levels of Consensus

Consensus	Definition
Perfect Consensus	Positive agreement = 100% in "totally agree"
High Consensus	Positive agreement with "totally agree" ≥ 85%
Moderate Consensus	Positive agreement with "totally agree" ≥ 75%
Low Consensus	Positive agreement with "totally agree" < 75%

To make the results more objective, the type of consensus was classified into four levels based on the inclusion criteria. These levels were defined as: perfect, high, moderate, and low for each intervention, with the score of 3 indicating complete agreement whenever the conditions shown in the (Table 2) below were met. Note that interventions with a low level of consensus will be restructured to achieve a higher level of consensus in the next round. However, the intervention will be excluded if it maintains a low level of consensus in the second round or if less than 75% of the experts consider the new intervention to be valid in score 3 "Totally Agree".

After being selected, the participants were formally invited by email to voluntarily participate in the study and were assured of their anonymity, secrecy, and confidentiality.

Taking into account the electronic data collection, the research team was committed to ensure the confidentiality of the results and prevent their use by third parties. The anonymity of the participants was maintained to prevent any harm, thus complying with all ethical standards and legal requirements.

Organising and classifying the data obtained from the questionnaire, based on the criteria and levels of consensus established, made it possible to systematise the experts' assessment and understand whether consensus had been reached. The data were processed using the Excel program, version 19. For statistical processing, descriptive statistics were used, namely absolute (N) and relative (%) frequencies, measures of central tendency, such as the mean ($\overline{x}$), median (Md) and measures of dispersion, such as the standard deviation (s), with the results presented in tabular form, with the respective description. As such, qualitative and quantitative strategies were used to collect and analyse the data.

RESULTS

This study started by sending the link (via Google Forms) to the experts' email addresses, giving them access to the data collection tool from March 7 to 21, 2022. In the first round, 24 of the 25 expert nurses who agreed to participate in the study responded, which corresponds to a response rate of 96%. Table 3 shows the socio-professional characteristics of the panel of experts.

Table 3. Socio-Professional Characteristics of The Panel of Experts (R1)

Socio-professional characteristics	N	%
Age range (years)		
26-36	9	37.5
37-47	12	50
48-58	2	8.3
59-69	1	4.2
$\overline{x}$= 40; Md = 39.5; sd = 8.4		
Gender		
Female	18	75
Male	6	25
Education level		
Bachelor's degree	10	41.7
Master's degree	13	54.2
Doctoral degree	1	4.2
A professional category		
Nurse	1	4.2
Nurse specialist	23	95.8
Length of professional experience (years)		
5-10	3	12.5
11-16	8	33.3
17-21	6	25
22-26	4	16.7
27-31	2	8.3
32-36	0	0
37-41	1	4.2
$\overline{x}$ = 18; Md = 17.7; sd = 7.4		
Department		
IMU/ICU	9	37.5
Pneumology	3	12.5
Medicine	1	4.2
COVID Inpatient Unit	4	16.7
Emergency	6	25
Medical specialties	1	4.2
NIV training		
Yes	24	100
No	0	0
Where did you receive your training?		
Specialisation	6	25
Master's degree	4	16.7
Training courses	10	41.7
Post-graduation	4	16.7
NIV experience for at least five years		
Yes	24	100
No	0	0

Note: $\overline{x}$ - mean; Md – median; sd – standard deviation; IMU – Intensive Medicine Unit; ICU – Intensive Care Unit

The second round brought together a consensus of experts on nursing interventions for preventing NIV complications, which were presented in two distinct domains:

A-Associated with the interface (facial pain or discomfort, noise, skin lesions on the nasal bridge and face, carbon dioxide rebreathing, claustrophobia, and patient-ventilator asynchrony);

B-Associated with air pressure/flow (air leaks, nasal and oral dryness/congestion, conjunctivitis, aerophagia, and abdominal distension).

A consensus was reached on 47 of the 62 nursing interventions initially proposed during the first round.

The remaining 15 interventions were revised according to the experts' feedback to be subjected to a new analysis/round. Twelve new nursing interventions were also developed.

In the first round, the following nursing interventions had a low level of consensus and gave rise to the greatest disparity of opinions: leaving dental prostheses in place in conscious patients who are able to protect the airway, facilitating patient-interface adaptation; changing the interface (oronasal/full-face mask or helmet/Helmet®); and implementing comfort measures through prudent sedation, analgesics, and anxiolytics.

After analysing the experts' opinions/suggestions, three new interventions were submitted to the second round: regular skin cleansing and moisturising; selection of the appropriate interface (size, physiognomy, degree of tolerance, and patient comfort); and monitoring of synchrony and signs of possible therapy failure. As such, 27 nursing interventions were submitted to the second round, and consensus was reached for 20 of them.

Two new interventions emerged from the experts' feedback, namely assessing nutritional status and performing facial trichotomy on male patients, which were submitted to the experts for agreement in the second round. The participants validated the first, while only 41.7% totally agreed with the second, showing a low level of consensus for this new intervention. The experts agreed that facial trichotomy should be avoided due to the risk of cuts, and beard trimming should be chosen when necessary.

The experts also recommended the inclusion of important aspects related to verifying the material's condition, operability, and compatibility with the ventilator, considering that the material is often sterilised and can be damaged. As such, two new interventions emerged: "confirming in advance the operability of the circuit/mask and its compatibility with the ventilator" and "adapting the exhalation valve and the leak points of the interface to the type of patient", both of which obtained a high level of consensus in the second round.

Based on the suggestions made, two questions were reformulated: the use of interfaces that are easy to remove in the event of vomiting and the need for patients to know how to put on and take off the interface, promoting their adherence and cooperation in therapy.

At the end of the two Delphi rounds, the nursing interventions that obtained consensus from the experts were compiled and systematised, resulting in a total of 67 interventions, and subsequently incorporated into the nursing protocol (Appendix I).

DISCUSSION

The use of the Delphi technique proved to be crucial for achieving the aim of this research. In this study, there was no loss of experts between rounds; all the participants remained active throughout the process. This aspect contradicts Chalmers and Armour (13) and Scarparo et al. (15), who state that an abstention rate of 20% to 30% is to be expected in the second round.

Two rounds were carried out and were enough to achieve a satisfactory degree of consensus among the experts, avoiding their fatigue and conformism, as mentioned by Wright and Giovinazzo (16) and Scapolo and Miles (17). Consensus was achieved with at least 75% agreement in the experts' answers (18).

The selection of experts seemed appropriate for the objectives of this study, given the qualifications and level of specialisation of the nurses in the Delphi panel. The nurses had an average of 18 years of professional experience in the area under study. Most of them were nurse specialists (95.8%; *n*=23), 54.2% (*n*=13) had a master's degree, 4.2% (*n*=1) had a doctoral degree, and the remaining 41.7% (*n*=10) had a bachelor's degree, showing that the group consisted of qualified nurses who possessed the knowledge, skills, and abilities, as well as the human, technical, and scientific training required to provide specialised nursing care in more complex settings, such as in caring for critically ill patients under NIV (19).

Cunha (20) also points out that expert nurses stand out for their specialised knowledge and professional experience.

With regard to specific training in NIV, the results show that all expert nurses (100%) have specific training in this area, most of which was acquired in training courses (41.7%; *n*=10), during their specialisation (25%; *n*=6), and in postgraduate and master's degrees (16.7%; *n*=4).

Table 4. Levels of Agreement Between The Experts For Each Intervention in Axes A and B in the First Round.

A - Nursing interventions to prevent complications associated with the interface					
Complications	**1-Pain or discomfort in the face**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	1.1- Assess the level of consciousness	C-5	–20,8	100	Moderate
		CT-19	–79,2		
	1.2- Assess skin integrity and the existence of facial deformities	C-2	–8,3	100	High
		CT-22	–91,7		
	1.3- Explain the procedure and its advantages, promoting patient and co-operation with the therapy whenever possible	C-2	–8,3	100	High
		CT-22	–91,7		
	1.4- Select the mask made of soft, flexible, lightweight and transparent material	C-1	–4,2	100	High
		CT-23	–95,8		
	1.5- Maintain the use of dental prostheses in patients who are conscious and able to protect the airway, facilitating the patient/ interface adaptation	NC-5	–20,8	79,2	Low
		C-3	–12,5		
		CT-16	–66,7		
	1.6- Position the patient with the head elevated in Fowler's or semi-Fowler's position, respecting their degree of tolerance (optimising ventilation and avoiding obstruction of the upper airway)	NC-1	–4,2	95,9	Moderate
		C-4	–16,7		
		CT-19	–79,2		
	1.7- Promote progressive lifting appropriate to the patient's clinical situation, degree of comfort and tolerance	NC-1	–4,2	95,9	High
		C-2	–8,3		
		CT-21	–87,5		
	1.8- Continually reassess and readjust the tension exerted by the harness straps (2-finger rule)	C-3	–12,5	100	High
		CT-21	–87,5		
	1.9- Reposition the interface regularly (every 2 to 4 hours)	NC-1	–4,2	95,8	Moderate
		C-5	–20,8		
		CT-18	–75		
	1.10- Switch the type of interface (oronasal/full- face mask or Helmet helmet) for periods	NC-3	–12,5	87,5	Low
		C-9	–37,5		
		CT-12	–50		
	1.11- Monitor pain, respiratory rate and SPO2	C-1	–4,2	100	High
		CT-23	–95,8		
	1.12- Promote comfort measures through prudent sedation, analgesics and anxiolytics	NC-1	–4,2	95,8	Low
		C-6	–25		
		CT-17	–70,8		
Complications	**2– Noise**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	2.1- Checking ventilator parameters and alarms	C-3	(12; 5)	100	High
		CT-21	–87,5		
	2.2- Change the interface if necessary	C - 3	(12; 5)	100	High
		CT-21	–87,5		
	2.3- Use earplugs and/or other insulated material	NC-2	–8,3	91,7	Low
		C-10	–41,7		
		CT-12	–50		
Complications	**3– Skin lesions of the nasal bridge and face**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	3.1 - Assessing the level of consciousness	C-5	–20,8	100	Moderate
		CT - 19	–79,2		
	3.2 - Assess and monitor skin integrity before and during NIV use	CT-24	–100	100	Perfect
	3.3 - Selecting the right mask size	CT-24	–100	100	Perfect
		C - 1	–4,2	100	High

	3.4 - Select a mask made of soft, flexible, light and transparent material	CT - 23	–95,8		
	3.5 - Apply and adjust the appropriate contact pressure	CT-24	–100	100	Perfect
	3.6 - Use the harness with good adaptability, appropriate and adjusted tension (2-finger rule)	C - 1 CT - 23	–4,2 –95,8	100	High
	3.7- Change or interchange the interface whenever necessary	C - 3 CT - 21	(12; 5) –87,5	100	High
	3.8 - Reposition and/or take regular breaks from the mask if the patient's clinical condition allows it	CT-24	–100	100	Perfect
	3.9 - Regularly sanitise and moisturise your skin	CT-24	–100	100	Perfect
	3.10- Apply protective material: hydrocolloid afterbeds or adhesive polyurethane foams	NC-2 C - 4 CT - 18	–8,3 –16,7 –75	91,7	Moderate
Complications	**4– Carbon dioxide rebreathing**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	4.1- Changing the interface (smaller devices)	NC-1 C-10 CT-13	–4,2 –41,7 –54,2	95,9	Low
	4.2- Always check that the is an exhalation valve in the circuit or on the mask	CT-24	–100	100	Perfect
Complications	**5- Claustrophobia**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	5.1- Explain the procedure and its advantages in order to reassure the patient	CT-24	–100	100	Perfect
	5.2- Selecting the right interface (size, physiognomy, degree of tolerance and patient comfort)	C-1 CT-23	–4,2 –95,8	100	High
	5.3– Select a mask made soft, flexible, light and transparent material	C-2 CT-22	–8,3 –91,7	100	High
	5.4- Choose interfaces with quick and easy removal mechanisms	C-5 CT-19	–20,8 –79,2	100	Moderate
	5.5- Ask the patient to co-operate in the application	C-6 CT-18	–25 –75	100	Moderate
	5.6- Apply gradually (starting with the front support of the mask) and only then fix in place	C-2 CT-22	–8,3 –91,7	100	High
	5.7– Consider cautious sedation and anxiolytics if necessary	C- 11 CT-13	–45,8 –54,2	100	Low
Complications	**6– Patient-ventilator asynchrony**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	6.1- Prepare all the necessary equipment in advance: ventilator, antibacterial filters, circuit, exhalation valve (if not incorporated into the circuit or mask), mask and headgear	NC-1 C-2 CT-21	–4,2 –8,3 –87,5	95,8	High
	6.2– Test the ventilator, check the prescribed parameters and alarms	CT-24	–100	100	Perfect
	6.3- Explain the procedure, advantages and possible complications, promoting the patient's compliance and co-operation whenever possible	C-2 CT-22	–8,3 –91,7	100	High
	6.4- Establish an empathetic and therapeutic relationship, encouraging the patient to express: doubts, signs of difficulty breathing, pain, leaks or the need to eliminate secretions	C-2 CT-22	–8,3 –91,7	100	High
	6.5- Select the right interface (size, physiognomy, degree of tolerance and patient comfort)	C-1 CT-23	–4,2 –95,8	100	High
	6.6– Switch on the ventilator previously connected to the oxygen ramp	NC-1 C-1	–4,2 –4,2	95,9	High

		CT-22	–91,7		
	6.7- Apply the mask gradually, encouraging the patient to collaborate in putting it on and wait a few seconds before fastening it	C-1	–4,2	100	High
		CT-23	–95,8		
	6.8- Start by applying it to the front support and then attach it, starting with the top strips and then the bottom strips	NC-2	–8,3	91,7	High
		C-1	–4,2		
		CT-21	–87,5		
	6.9- Reposition the mask, minimising possible leaks	NC-1	–4,2	95,9	High
		C-1	–4,2		
		CT-22	–91,7		
	6.10- Continuously monitor and the patient (level of consciousness, pain, comfort, electrocardiographic tracing, heart rate, blood pressure, peripheral oxygen saturation, respiratory rate, chest wall movement and use of accessory muscles)	C-1	–4,2	100	High
		CT-23	–95,8		
	6.11- Consider cautious sedation and anxiolytics if necessary	C-7	–29,2	100	Low
		CT-17	–70,8		
B - Nursing interventions to prevent complications associated with air pressure/flow					
Complications	**7– Air leaks**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	7.1 - Select the right interface (size, physiognomy, degree of tolerance and patient comfort)	C-1	–4,2	100	High
		CT-23	–95,8		
	7.2- Use the harness with good adaptability, appropriate and adjusted tension (2-finger rule)	C-1	–4,2	100	High
		CT-23	–95,8		
	7.3- Keep dental prostheses as long as the airway is protected, and the patient is conscious	NC-2	–8,3	91,7	Low
		C-6	–25		
		CT-16	–66,7		
	7.4- Check for possible leaks by reaching around the mask with your hands and checking the percentage of leakage at the ventilator (up to 30-40l/m is acceptable at high pressures)	C-1	–4,2	100	High
		CT-23	–95,8		
	7.5- Change the interface if necessary	C-1	–4,2	100	High
		CT-23	–95,8		
Complications	**8– Nasal and oral dryness/congestion, conjunctivitis**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	8.1- Select the right interface (size, physiognomy, degree of tolerance and patient comfort)	CT-24	–100	100	Perfect
	8.2- Minimising possible leaks	C-2	–8,3	100	High
		CT-22	–91,7		
	8.3- Provide and encourage good oral hydration	C-2	–8,3	100	High
		CT-22	–91,7		
	8.4- Promote oral hygiene (several times a day)	CT-24	–100	100	Perfect
	8.5-Eye moisturization with saline solution or artificial tears	C-2	–8,3	100	High
		CT-22	–91,7		
	8.6- Hydration or nasal hygiene with saline solution or nasal gel	C-5	–20,8	100	Moderate
		CT-19	–79,2		
	8.7- Humidification and heating of ventilated gases	C-6	–25	100	Moderate
		CT-18	–75		
Complications	**9– Aerophagia and abdominal distension**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	9.1- Encourage ventilator patient synchronisation	C-1	–4,2	100	High
		CT-23	–95,8		
	9.2- Encourage mobilization and elimination of secretions through effective coughing	NC-1	–4,2	95,9	High
		C-1	–4,2		

		CT-22	–91,7		
	9.3- Monitor the occurrence of vomiting	C-3	–12,5	100	High
		CT-21	–87,5		
	9.4- Instruct patients to remove mask in case of vomiting or choking suffocation	NC-1	–4,2	95,8	Moderate
		C-4	–16,7		
		CT-19	–79,2		
	9.5- Place SNG if necessary	NC-1	–4,2	95,8	Moderate
		C-5	–20,8		
		CT-18	–75		

key: NC - Don't agree; C - Agree; CT - Totally Agree Positive inclusion agreement - (sum of C and TC ≥ 75%)

Table 5. Levels of Agreement for The Interventions Altered According to The Experts' Suggestions, in Axes A and B, in The Second and Final Round

A - Nursing interventions to prevent complications associated with the interface					
Complications	**1– Pain or discomfort in the face**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	1.1- Manage the use of dentures in patients who are conscious and able to protect the airway	C-5	–20,8	100	Moderate
		CT-19	–79,2		
	1.2- Reposition and/or take regular breaks from the mask (if the patient's clinical condition allows)	C 3	–12,5	100	High
		CT-21	–87,5		
	1.3- Change or intersperse the interface, whenever possible, allowing the support points to be rotation	C-3	–12,5	100	High
		CT-21	–87,5		
	1.4- Regularly sanitise and moisturise the skin	C-3	–12,5	100	High
		CT-21	–87,5		
	1.5- Select the right interface (size, physiognomy, degree of tolerance and patient comfort)	C-1	–4,2	100	High
		CT-23	–95,8		
	1.6- Position the patient correctly, respecting their comfort and degree of tolerance	C-2	–8,3	100	High
		CT-22	–91,7		
	1.7- Promote comfort measures by optimising the prescribed analgesic therapy	C-3	–12,5	100	High
		CT-21	–87,5		
	1.8- Monitor ventilatory synchrony and signs of possible therapy failure	C-3	–12,5	100	High
		CT-21	–87,5		
Complications	**2– Noise**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	2.1 - Consider the use of hearing protectors (if tolerated by the patient and not interfere with their ability to communicate)	NC-3	–12,5	87,5	Low
		C-12	–50		
		CT-9	–37,5		
	2.2 - Promote non-pharmacological strategies to reduce anxiety (when present) and induce sleep	C-7	–29,2	100	Low
		CT-17	–70,8		
Complications	**3– Skin lesions of the nasal bridge and face**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	3.1- Assess the patient's nutritional status	C-5	–20,8	100	Moderate
		CT-19	–79,2		
	3.2- Perform facial trichotomy in male patients if possible	NC-5	–20,8	79,2	Low
		C-9	–37,5		
		CT-10	–41,7		
	3.3- Consider the use of skin protection: extra-thin hydrocolloid dressings or adhesive polyurethane foams (daily surveillance)	NC-2	–8,3	91,7	Moderate
		C-3	–12,5		
		CT-19	–79,2		
Complications	**4– Carbon dioxide Rebreathing**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
		C-2	–8,3	100	High

Nursing Interventions	4.1- Confirm in advance the operability of the circuit/mask used and its compatibility with the ventilator	CT-22	–91,7		
	4.2- Adapt the exhalation valve as well as the leakage points of the interface, to the patient's typology	C-2 CT-22	–8,3 –91,7	100	High
	4.3- Change or intercalate the interface according to each patient's therapeutic goal	C-3 CT-21	–12,5 (87,5))	100	High
Complications	**5– Claustrophobia**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	5.1- Teach the patient how to put on and take off the mask, promoting their adherence and co-operation in therapy whenever possible	NC-2 C-3 CT-19	–8,3 –12,5 –79,2	91,7	Moderate
	5.2- Consider using interfaces with easy-to-remove mechanisms in situations where there is a risk of vomiting, choking or bronchorrhoea	C-3 CT-21	–12,5 –87,5	100	High
	5.3- Promote comfort measures by optimising the prescribed anxiolytic therapy in contexts of continuous monitoring and surveillance	C-5 CT-19	–20,8 –79,2	100	Moderate
Complications	**6– Patient-ventilator asynchrony**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	6.1- Consider humidifying the technique for bronchorrhoeal patients (increases comfort and the ability to eliminate secretions)	C-17 CT-7	–70,8 –29,2	100	Low
	6.2- Encourage effective coughing to mobilise and eliminate secretions/bronchial hygiene	NC-1 C-2 CT-21	–4,2 –8,3 –87,5	95,8	High
	6.3- Aspirate secretions whenever necessary	C-3 CT-21	–12,5 –87,5	100	High
	6.4- Promote comfort measures by optimising the anxiolytic therapy prescribed in a context of continuous monitoring and surveillance	C-5 CT- 19	–20,8 –79,2	100	Moderate
B - Nursing interventions to prevent complications associated with air pressure/flow					
Complications	**7– Air leaks**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	7.1- Manage the use of dentures in patients who are conscious and able to protect the airway	NC-1 C-8 CT-15	–4,2 –33,3 –62,5	95,8	Low
	7.2- Position the patient correctly, respecting their comfort and degree of tolerance	C-3 CT-21	–12,5 –87,5	100	High
Complications	**8– Nasal and oral dryness/congestion, conjunctivitis**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	8.1- Consider humidifying the technique and heating ventilated gases in prolonged therapy	C-8 CT-16	–33,3 –66,7	100	Low
Complications	**9– Aerophagia and abdominal distension**	**Expert responses N (%)**		**Concordance (%)**	**Level of consensus**
Nursing Interventions	9.1- Consider the temporary placement of small-caliber siliconized NGS in situations of: dysphagia, reinforcement of hydration and/or feeding and relief of gastric distension	NC-1 C-10 CT-13	–4,2 –41,7 –54,2	95,9	Low

key: NC - Don't agree; C – Agree; CT - Totally Agree Positive concordance of inclusion – (sum of C and CT ≥ 75%)

All of them had been caring for NIV patients for at least 5 years. Rodrigues et al. (18) also established the minimum criterion of five years of experience and work in the field of study. It is clear that the development of expertise among nurses is a dynamic and continuous process, which requires extensive experience in practical contexts and implies continuous personal investment through training to ensure that specific knowledge of the area is kept up to date (20).

With regard to the professional background, the panel of experts included professionals from different areas of clinical practice with diverse experiences, as indicated by Marques and Freitas (8). Scarparo et al. (15) also pointed out that diverse experiences are fundamental to building consensus on the subject.

The results obtained in this study allow concluding that the main nursing interventions to prevent complications include: preparation of the material and confirmation of its operational status for performing NIV; assessment of the state of consciousness; explanation of the technique, obtaining the patient's cooperation and their correct adaptation to the technique; appropriate selection of the interface and its correct application and adjustment, as well as rotation and alternation of the support points; minimisation of possible leaks; vigilance and continuous monitoring of skin integrity, as well as protection of pressure points; rigorous hydration and hygiene of the mucous membranes and the patient; vigilance and continuous monitoring of the patient as a whole (hemodynamic stability, adaptation and identification of risk situations); correct patient positioning and, not least, the care to be taken in the presence of secretions.

Finally, it is important to reflect on the positive aspects and limitations of this study.

The positive aspects include the fact that the panel of experts consisted of nurses who work in different geographical areas and care settings, allowing for a more diverse experience in NIV. This study is expected to encourage the development of up-to-date knowledge on this subject, as well as to raise nurses' awareness of the importance of implementing standards of practice, protocols, and manuals, guided by effectiveness, improvement, and safety in the care of NIV patients. Also noteworthy was the large number of participants in the panel of experts in both rounds (n=24), with no abstentions. This study also provided new insights into NIV, contributing to the refinement and improvement of practices through more efficient, safer, and better quality care, as well as the advancement of knowledge about the research methodology used.

CONCLUSION

Non-invasive ventilation has many indications across acute and chronic respiratory failure. When used appropriately, it has numerous physiological and clinical benefits, including improved gas exchange, improved respiratory muscle function, and improvements in breathlessness, quality of life, and survival (21).

Surveillance of the person subjected to NIV, namely their adaptation and prevention of associated complications, are extremely important for their safety and success (22).

Within the multidisciplinary team, nurses play a key role in caring for patients undergoing NIV therapy. They are required to have experience, knowledge, skills, and technical competence based on evidence and guidelines in order to standardise and systematise nursing interventions at the highest level of quality. Thus, the results obtained allowed identifying a set of autonomous nursing interventions to prevent complications associated with the interface and air pressure/flow, which allow for the optimisation and, consequently, the success of NIV.

It also made it possible to draw up a support tool or guide for more differentiated and standardise nursing care practices, as recommended by the Joint Commission International (23) and Sales et al. (24), who demonstrated that the design and use of protocols and/or guidelines, as quality and safety measures, are essential for health professionals to provide standardise and evidence-based care.

The protocol presented here, when applied in units where nurses have the opportunity to care for people who need non-invasive ventilation, provides greater knowledge and autonomy in decision-making, guaranteeing safe, quality practice for both the person being cared for and the professional. As a result, nurses have the opportunity to raise the profile of their work in this area.

Ethics Committee Approval	This study was approved by the ethics committee of Health Sciences Research Unit: Nursing (UICISA:E) (P820_11_2021).
Informed Consent	Written consent was obtained from the participants.
Peer Review	Externally peer-reviewed.
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Appendix

Final protocol of the nursing interventions approved by consensus

Best Practices Protocol

Prevention of Complications Associated with the Interface and the Air Pressure/flow in Non-invasive Ventilation

Objectives

- Prevent complications ;
- Standardise nursing interventions ;
- Optimise non-invasive ventilation (NIV) ;
- Promote safe, effective, and quality care.

Responsibility

- Nurses

I. Description

Non-invasive ventilation (NIV) is defined as continuous or intermittent positive pressure ventilatory support applied via the upper airways using an external interface without the use of an artificial airway, such as an endotracheal tube, laryngeal mask, or tracheostomy. It is the first-line ventilatory support recommended for critically ill patients with acute respiratory failure (ARF) of various origins, particularly those with exacerbations of chronic obstructive pulmonary disease (COPD) and acute pulmonary oedema (APE). Its main advantages are to prevent the side effects and complications associated with invasive mechanical ventilation (IMV) and to reduce the intubation rate, length of stay, associated costs, and hospital mortality.

II. Objectives of the NIV

- Improve pulmonary compliance;
- Recruit atelectatic alveoli;
- Increase gas exchange and alveolar ventilation;
- Improve the ventilation/perfusion ratio;
- Decrease the work of breathing;
- Improved cardiac function.

III. Indications of NIV

- Exacerbation of COPD;
- Cardiogenic APE;
- Immunosuppressed patients with pulmonary infiltrates and hypoxia;
- ARF or acute-on-chronic respiratory failure;
- Post-extubation and postoperative ARF;
- ARF in palliative patients with a do-not-resuscitate order;
- Patients with chest wall deformities/neuromuscular diseases;
- Patients with obesity hypoventilation syndrome.

IV. Criteria to initiate NIV

- Diagnosis of the potentially reversible condition;
- Moderate to severe dyspnoea of increased intensity;
- Tachypnoea (Respiratory Rate (RR) > 25 breaths per minute (c/m) in patients with an obstructive pattern and RR > 30 c/m in patients with a restrictive pattern);
- Paradoxical breathing with accessory muscle use;
- Blood gas changes: hypercapnia [partial pressure of carbon dioxide ($PaCO_2$) > 45 mmHg) and/or respiratory acidosis (pH < 7.35);
- Ratio of partial pressure arterial oxygen (PaO_2) and fraction of inspired oxygen (FiO_2) < 200 mm Hg (PaO_2/FiO_2< 200 mmHg).

* Under these conditions, NIV should be started as early as possible.

V. Contraindications

Relative contraindications	*Absolute contraindications**
• Confusion and psychomotor agitation with poor patient cooperation; • Impaired consciousness; • Glasgow coma scale score < 10; • Uncontrolled arrhythmia; • Inability to protect the airways; • Hypersecretion and inability to eliminate secretions; • Risk of pulmonary aspiration of the gastric contents; • Undrained pneumothorax; • Upper gastrointestinal bleeding or vomiting; • Multiple organ failure.	• Confirmed or imminent cardiopulmonary arrest; • Severe hemodynamic instability; • Refractory hypotension; • Total obstruction of the upper airway; • Inability to fix the interface, namely due to surgery, facial trauma, or facial deformity. * These situations are less common and are a reason for early endotracheal intubation and timely IMV.

VI. Predictors of failure

- Inadequate ventilator settings;
- Interface intolerance;
- Excessive air leakage;
- Patient-ventilator asynchrony;
- Poor tolerance of NIV;
- Underlying neurological disease;
- HACOR score <5;

- AND, after 1 h of NIV, agitation, no reduction in RR and $PaCO_2$, signs of respiratory fatigue, and no improvement in pH and oxygenation (PaO_2 /FiO_2).

VII. **Predictors of success**

- Absence of pneumonia;
- Less severe initial clinical situation;
- Improved neurological status;
- Small amounts of secretions;
- Younger age;
- Good ability to cooperate;
- Good patient-ventilator synchrony;
- Good adaptation to the interface/no significant leaks;
- Clinical improvement in gas exchange in the first 2 h assessed by reduction in RR (< 30 cycles/minute);
- Improvement in pH (between 7.10-7.35);
- Improvement in oxygenation (PaO_2/FiO_2 > 146 mmHg) after 1 h of hypoxemic RI and reduction in hypercapnia ($PaCO_2$ approximately 45-92 mmHg).

VIII. **Monitoring**

- *Parameters:* Heart Rate, RR (patient effort), SPO_2 (to adjust FiO_2), pH, and $PaCO_2$ (to assess efficacy). *Frequency:*
- Every 15 minutes in the first hour;
- Every 30 minutes in the 1-4 hour period;
- Hourly in the 4-12 hour period.
- *Arterial blood gases*:
- Taken at 0 h when initiating NIV;
- At 1 h, 4 h and 8 h after initiating NIV;
- 1 h after any change in FiO_2 or ventilatory parameters
- *Electrocardiography*:
- Continuous for all patients;
- Requires greater vigilance in patients with tachycardia, dysrhythmia, or known cardiomyopathy.
- *Capnography*:
- End-tidal carbon dioxide ($ETCO_2$) measurements should be a common practice;
- The reduction in $ETCO_2$ should reflect an improvement in ventilation-perfusion and consequent clinical improvement.
- *Continuous vigilance*:
- Patient-ventilator synchrony;
- Patient comfort, pain, interface tolerance, and level of consciousness;
- Work of breathing and chest wall movement;
- Leaks and skin integrity.

* Patients who have difficulty responding to therapy or are at high risk of failure should be subjected to more frequent assessments.

IX. **Criteria for discontinuing NIV**

- Interface intolerance;
- Patient-ventilator asynchrony;
- No improvement in gas exchange and/or dyspnoea after 2 h of NIV;
- Myocardial ischaemia or ventricular arrhythmia;
- Progressive worsening of pH, $PaCO_2$ or PaO_2 despite NIV;
- Progressive signs of fatigue during NIV (respiratory exhaustion);
- Inability to protect the airways;
- Copious secretions;
- Inability to maintain SpO_2 > 85-88%;
- Persistent hemodynamic or electrocardiographic instability;
- Agitation or intolerance to NIV with progressive respiratory failure;
- Inability to improve the state of consciousness after 30 min of NIV in hypoxemic and agitated patients;
- Cardiorespiratory arrest.

X. **Complications**

Related to the interface	*Related to the air pressure and flow*
• Facial pain or discomfort; • Noise; • Skin lesions on the nasal bridge and face caused by the pressure exerted by the mask; • CO_2 rebreathing; • Feeling of claustrophobia; • Patient-ventilator asynchrony.	• Air leaks; • Nasal and oral dryness/ congestion and conjunctivitis; • Aerophagia and abdominal distension.

XI. **Nursing interventions**

A–Nursing interventions to prevent interface-related complications

1–Facial pain or discomfort

- Assess the level of consciousness
- Assess skin integrity and the existence of facial deformities
- Explain the procedure and its advantages, promoting patient cooperation and compliance with the therapy whenever possible
- Select a mask made of soft, flexible, lightweight, and transparent material

- Select the correct interface (size, physiognomy, degree of patient tolerance and comfort)
- Regularly clean and hydrate the skin
- Change or interchange the interface whenever possible, allowing the support points to rotate
- Continual reassess and readjust the strap tension (2-finger rule)
- Reposition and/or take regular breaks from the mask (if the patient's clinical condition allows)
- Manage the use of dentures in patients who are conscious and able to protect the airway
- Position the patient correctly, respecting their comfort and degree of tolerance
- Promote progressive lifting appropriate to the patient's clinical situation, degree of comfort and tolerance
- Monitor pain, RR, and SPO_2
- Promote comfort measures by optimising the prescribed analgesic therapy
- Monitor ventilatory synchrony and signs of possible therapy failure.

2–Noise

- Check the ventilator parameters and alarms
- Change the interface if necessary

3–Skin lesions of the nasal bridge and face

- Assess the level of consciousness
- Assess the patient's nutritional status
- Assess and monitor skin integrity before and during NIV
- Select the appropriate mask size
- Select a mask made of soft, flexible, lightweight, and transparent material
- Apply and adjust the appropriate contact pressure
- Use straps with good fitting and adjusted tension (2-finger rule)
- Change or interchange the interface whenever necessary
- Reposition and/or take regular breaks from the mask (if the patient's clinical condition allows)
- Regularly cleanse and hydrate the skin
- Consider the use of skin protection: extra-thin hydrocolloid dressings or adhesive polyurethane foams (daily monitoring)

4–Carbon dioxide rebreathing

- Ensure in advance that the circuit/mask is operational and compatible with the ventilator
- Always confirm the presence of an exhalation valve in the circuit or mask
- Adapt the exhalation valve and the interface leak points to each patient
- Change or alternate the interface according to each patient's therapeutic goal

5–Claustrophobia

- Explain the procedure and its advantages to reassure the patient
- Teach the patient how to put on and take off the mask, promoting their cooperation and adherence to therapy whenever possible
- Select a mask made of soft, flexible, lightweight, and transparent material
- Select the appropriate interface (size, physiognomy, degree of tolerance and patient comfort)
- Apply the mask gradually, starting with the front support, and then proceeding to fix it in place
- Consider using interfaces with easy-to-remove mechanisms in situations where there is a risk of vomiting, choking, or bronchorrhea.
- Promote comfort measures by optimising the anxiolytic therapy prescribed in the context of continuous monitoring and surveillance

6 – Patient-ventilator asynchrony

- Prepare all the necessary equipment in advance: ventilator, antibacterial filters, circuit, exhalation valve (if not incorporated into the circuit or mask), mask, and straps
- Test the ventilator and check the prescribed parameters and alarms
- Explain the procedure, advantages, and possible complications, promoting patient compliance and cooperation whenever possible
- Establish an empathetic and therapeutic relationship, encouraging the patient to express doubts, signs of difficulty breathing, pain, leaks, or the need to eliminate secretions
- Select the appropriate interface (size, physiognomy, degree of patient tolerance and comfort)
- Turn on the ventilator previously connected to the oxygen ramp
- Apply the mask gradually, encouraging the patient to cooperate in putting it on and waiting a few seconds before securing it

- Apply the mask starting from the front support and then proceeding to fix it, first the upper straps and then the lower ones
- Reposition the mask, minimising possible leaks
- Continuously monitor the patient (level of consciousness, pain, comfort, electrocardiographic tracing, HR, BP, SPO2, RR, chest wall movement, and use of accessory muscles).
- Encourage effective coughing to mobilise and eliminate secretions/bronchial hygiene
- Aspirate secretions whenever necessary
- Promote comfort measures by optimising the anxiolytic therapy prescribed in the context of continuous monitoring and surveillance

B-Nursing interventions to prevent complications associated with air pressure/flow

7–Air leaks

- Select the appropriate interface (size, physiognomy, degree of patient tolerance and comfort)
- Use straps with good fitting and adjusted tension (2-finger rule)
- Check for possible leaks by reaching around the mask with your hands and checking the percentage of leakage at the ventilator (up to 30-40l/m is acceptable at high pressures)
- Position the patient correctly, respecting their comfort and degree of tolerance
- Change the interface if necessary

8–Nasal and oral dryness/congestion and conjunctivitis

- Select the correct interface (size, shape, degree of patient tolerance and comfort)
- Minimise leakage (ideally <25l/m)
- Provide and encourage good oral hydration
- Promote oral hygiene (several times a day)
- Moisture the eyes with saline solution or artificial tears
- Clean and moisten the nose with saline solution or nasal gel

9–Aerophagia and abdominal distension

- Promote patient-ventilator synchrony
- Encourage mobilisation and elimination of secretions through effective coughing
- Monitor the occurrence of vomiting
- Instruct the patient to remove the mask in case of vomiting or choking sensation.