



Original Article

Associated factors of facial pressure ulcers in patients under non-invasive ventilation during hospital stay in an intermediate care facilities of a Portuguese hospitalCarlos Filipe dos Santos Quitério^{1*}, Isabel Cordeiro¹, Mariana Pereira²¹ Setúbal Hospital Center, Setúbal, Portugal² School of Health, Polytechnic Institute of Setúbal, Setúbal, Portugal

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ABSTRACT

Background & Aim: Non-invasive ventilation is a procedure that reduces respiratory stress and improves gas exchange, using a patient-ventilator interface; however, it presents consequences such as the development of facial pressure ulcers. We aim to identify the factors associated with facial pressure ulcers in Intermediate Care Facilities patients submitted to non-invasive ventilation.

Methods & Materials: A cross-sectional descriptive and analytic study was performed in an intermediate care facilities, of a Portuguese hospital, from August to October of 2018, the study population consisted of patients hospitalized in this unit, who underwent to non-invasive ventilation. Data were collected through an observational form developed to obtain the information of the entire period of hospitalization of the patient. The software used to analyze the data was IBM SPSS Statistics for Windows, Version 23.0. For the descriptive analysis, absolute and relative frequencies also means and standard deviations were computed. Also, to describe the association between the variables, The point biserial correlation coefficient (rpb) were calculated. For data analysis, a significance level of .05 (α) was used.

Results: 14.6% of the individuals developed PU, all in the nasal pyramid. NIV was used for 6.07 ± 3.91 days, and PU developed between the 3rd and the 20th day. It was observed that the presence of PU had a significant positive correlation with the GCS score (rpb=0.390, p=0.012) and a significant negative correlation with the duration of NIV (rpb=-0.438, p=0.004). Dependency level, PU risk, and nutritional risk did not correlate with the development of PU.

Conclusion: The pressure ulcers associated with non-invasive ventilation appear to be more frequently developed on the nasal pyramid and between the 3rd and the 20th day. Moreover, the level of consciousness and the time of administration of non-invasive ventilation are associated with the development of pressure ulcers.

Introduction

Non-invasive ventilation (NIV) is a ventilatory procedure that can reduce respiratory effort, respiratory rate, improving gas exchange, and comfort management. In this procedure, a mask is used as a patient-ventilator interface and artificial airway and sedation are not needed (1). In this context, this procedure represents an option in several types of respiratory insufficiency and maybe a resource in cases of acute obstructive pulmonary disease and acute pulmonary edema (2). For the last two

decades, the use of NIV has almost triple (3). This technique is currently applied in intensive care units, emergency departments, and at home (4). There are situations in which NIV is considered an alternative to endotracheal intubation since it has the same physiological benefits and has advantages when compared with other ventilation procedures (5). Furthermore, NIV does not exhibit the same complications from endotracheal intubation (e.g., respiratory infection risk linked to a mechanical ventilator) (6), and also allows greater autonomy for the patient, since it enables activities such as communication and feeding, reducing the occurrence of long-term adverse outcomes (1).

However, despite the tolerance of individuals in the use of NIV, its side effects

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and complications cannot be disregarded (6), e.g., pain, discomfort, skin changes, psycho-emotional changes, increased time of hospitalization time and consequently the associated costs (6,7). Furthermore, the most common adverse effects are those related to the interface, such as pain, erythema (20 to 34%), and injury on the nasal skin (2 to 50%) (6). Other studies, such as BaHammam et al. (8), report that the main problems associated with NIV interfaces are nasal erythema or ulceration (5-30%), air leakage, nasal congestion, oral dryness and eye irritation. Also, according to Diez et al. (1), the proportion of nasal injuries ranges between 5 and 20%.

These injuries usually appear at the contact points of the interface with the skin (7), hence considered pressure ulcers (PU). Additionally, a PU is a wound in the underlying skin and/or tissue, usually on a bone prominence resulted from pressure or a combination of pressure with shear. They are classified into four categories: Category I (nonblanchable erythema), Category II (partial skin thickness loss), Category III (total skin thickness loss) and Category IV (total thickness tissue loss) (9). Regarding skin injuries associated with NIV, it is relevant to describe pressure ulcers related to medical devices (URMD). These do not represent a new PU category and should be classified according to the level of tissue loss through the National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel (9).

The term PU will be used instead of URMD because the objective is to study the facial PU associated with the NIV and not all the URMD. As a literature review of 62 clinical trials shows, the proportion of skin damage ranges between 2% and 50% and increases to 100% after 48 hours (7). Some authors (10), consider that these changes in the proportions could be explained by the fact that most of the studies contained data regarding the proportion of all complications, associated with NIV, rather than only the skin damage.

Thus, a facial injury affects the patient level of comfort, leading to the suspension

of the NIV and to the increase of leakages, which are associated with a higher risk of treatment lack of success in patients with acute respiratory failure (7). Furthermore, these injuries may contribute to a lengthy hospital stay, increased venous thrombo-embolic risk, infections, and psychological and emotional damage (11).

Therefore, it is essential to develop strategies to reduce their incidence (7), where create these strategies will be necessary to increase the knowledge of the associated factors related to the facial PU development in patients who undergo NIV. Consequently, we aimed to identify the factors associated with facial PU in the Intermediate Care Facilities (IMCF) patients submitted to NIV.

Methods

This cross-sectional descriptive and analytic study was performed and data were collected through an observational form after the medical release of the patient, developed to obtain the information of the entire period of hospitalization of the patient at the IMCF retrieved through the clinical process.

For the present study, all the necessary authorizations were asked to the Administration Council of the Hospital, the consent to obtain the data was asked to the Data Protection Committee, and the Ethical Commission and the Research and Development Office has approved the study (institutional authorization number 07/19).

The study population consisted of patients hospitalized in the period between August and October of 2018 in an IMCF, of a Portuguese Hospital, who underwent NIV at the IMCF. Individuals who presented facial PUs at the time of admission to the IMCF, individuals submitted to NIV through tracheostomy, and individuals under 18 years were excluded. So, the convenience sample was composed of 41 individuals, after 2 were excluded because they presented facial PUs at the time of the admission and 1 because the NIV was administered through the tracheostomy.

To calculate the total size of this sample, G* Power version 3.1.9.2 software was used. Thus, observing the proportion of pressure ulcers presented in a 2% randomized controlled trials review (1), using a significance level of 0.05 and a power of 95%, we obtained a required total of 31 individuals (n).

To maintain the participants' anonymity, the data gathering from the medical records was performed by the IMCF nursing staff, and the data analysis was carried out by the researchers. The form used was composed by i) sociodemographic variables, such as gender, age and diagnostic; ii) variables related to mobility: level of dependency—assessed by the Barthel index (13), pressure ulcer risk—evaluated by the Braden scale (14), consciousness evaluation – analyzed by the Glasgow Coma Scale (GCS) (15); iii) health-related variables: reasons for hospitalization and nutritional risk—through the Nutritional Risk Screening 2002 (NRS 2002) (16) and iv) variables related to NIV. Barthel's index assesses the level of patient dependency to perform the basic activities of daily living. This scale ranges from 0 to 100, meaning, a score of 0-20: total dependency; 21-60: severe dependency; 61-90: moderate dependency; 91-99: slight dependency; and 100: independence (17).

Moreover, in the context of the risk assessment of PUs development the Braden scale (has an internal consistency, calculated by the Cronbach's alpha, of 0,250) can be used. This scale has six dimensions: sensory perception, moisture, activity, mobility, nutrition, friction and shear forces. The dimensions are weighted from 1 to 4, except the last one which is weighted from 1 to 3. Any individual with a score of 16 or below (14) is considered in high risk of PU development.

Concerning consciousness evaluation, it can be assessed by the GCS (has an internal consistency, calculated by the Cronbach's alpha, of 0,832). This scale is divided into eye-opening, verbal response, and best motor response. The ocular opening score varies from 1 to 4, the verbal response varies from 1 to 5 and the best motor response

varies from 1 to 6 (15). The score range from 3 to 8 corresponds to a severe decreasing of consciousness, from 9 to 12 moderate decreasing and from 13 to 15 a slight decreasing or unchanged consciousness (15).

In this study, we considered relevant to access the level of conscience because, according to Raurell-Torredà et al. (10), NIV is associated with a decreased level of consciousness due to sedatives and painkillers. Also, an unconscious individual cannot express discomfort. Regarding malnourishment assessment, the NRS-2002 is designed to detect malnutrition or the risk of developing malnutrition. Two components are scored, undernutrition and disease severity, with a score ranging from 0 to 6. With a total score of 3 or higher, the patient is classified as nutritionally at-risk (16). If the individual age is above 70 years old, it must be added a point to the final score.

Data analysis was performed using IBM SPSS Statistics for Windows, Version 23.0. For the descriptive analysis, absolute (n) and relative (%) frequencies also means and standard deviations were computed for qualitative and quantitative variables, respectively. Also, to describe the association between the presence of PU and the level of dependency (Barthel index), the risk of PU (Braden scale), nutritional risk (NSR 2002) and consciousness (GCS), point-biserial correlation coefficients (rpb) were calculated, given the categorical nature of the PU variable (0 - yes; 1 - no) and the quantitative (ordinal) nature of the remaining variables. For data analysis, a significance level of .05 (α) was used.

Results

In the Table 1, it could be observed the sample demographics where male sex represented 63.4% of the sample, with an average age of 78 ± 9.72 years old. Also, acute respiratory failure and respiratory infection were the main reasons for hospitalization (24.4% and 22.0%, respectively).

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Of the 41 individuals, 6 (14.6%) developed PU, and all injuries were in the nasal pyramid between the 3rd and the 20th day. At Table 2, it can be observed that most of the participants had a total dependency level (40.5%) and 51.4% of them presented nutritional risk, where 66.7% of the PU developed in patients with severe dependence and 83.3% of the PUs developed in individuals with higher nutritional risk.

The risk of PU development and the state of consciousness can be observed in Table 2. From 41 participants, 95.1% were at high risk for PU development, 92.7% presented

changes slightly, or did not present any changes in the consciousness level.

NIV was used for 6.07±3.91 days (a minimum of 1 day and a maximum of 20 days), and PU developed. After performed the point-biserial correlation coefficient (Table 3), it was observed that the presence of PU had a significant positive correlation with the GCS score ($r_{pb}=0.390$, $p=0.012$) and a significant negative correlation with the duration of NIV ($r_{pb}=-0.438$, $p=0.004$). On the other hand, the dependency level (Barthel Index), PU risk (Braden scale), and nutritional risk (NRS 2002) did not correlate with the development of PU.

Table 1. Sample characterisation (n=41)

Variables	N (%)	
Sex	Male	26 (63,4)
	Female	15 (36,6)
Age	48-73 years	9 (22,0)
	74-83 years	19 (46,3)
	84-93 years	13 (31,7)
Admission diagnostic	Acute respiratory failure	10 (24,4)
	Respiratory infection	9 (22,0)
	Lung edema	6 (14,6)
	Heart failure	6 (14,6)
	Respiratory acidosis	4 (9,8)
	Chronic obstructive pulmonary disease	2 (4,9)
	Traumatic brain injury	1 (2,4)
	Hypovolemic shock	1 (2,4)
	Pleural effusion	1 (2,4)
	Heatstroke	1 (2,4)

Table 2. Description of the level of dependency (Barthel index), nutritional risk (NRS 2002), PU risk (Braden scale), state of consciousness (GCS), and NIV average use

Variable	N (%)	
Level of dependency (n=37)	Total dependency	15 (40,5)
	Severe dependency	14 (37,8)
	Moderate dependency	6 (16,2)
	Light dependency	2 (5,4)
Nutritional risk (n=37)	No malnutrition risk	18 (48,6)
	Malnutrition risk	19 (51,4)
PU risk (n=41)	High risk	39 (95,1)
	Normal risk	2 (4,9)
State of consciousness (n=41)	Severe alteration	2 (4,9)
	Moderate alteration	1 (2,4)
	Slight alteration	38 (92,7)
NIV average use (n=41)	1-2 days	5 (12,2)
	3-6 days	22 (53,7)
	7-20 days	14 (34,1)

Table 3. Point-biserial correlation between pressure ulcer development with individuals characteristics

	Presence of PU
GCS score	0,39; p=0,012
Duration of NIV	-0,438; p=0,004
Dependency level	0,292; p= 0,079
PU risk	0,254; p=0,109
NRS 2002 score	-0,149; p= 0,372

PU: Pressure Ulcer; GCS: Glasgow Coma Scale; NIV: Non-invasive Ventilation; NRS: Nutritional Risk Screening

Discussion

With this study, we aim to identify the factors associated with facial PU in IMCF patients submitted to NIV, so a retrospective study was developed. The findings show that all PU developed in the nasal pyramid. In other studies, such as the one of Gregoretti et al. (18) and Black et al. (19), these wounds usually occur in the nasal pyramid, since there is less subcutaneous tissue in this area. Also, Barros, Talaia, Drummond, and Natal-Jorge (20) reported that the proportion of PU occurrence was higher in the nasal pyramid, and the variation of soft tissue depth had a direct influence on the amount of pressure applied.

Regarding the dependency level of participants, it was observed that most of the ones included in the present study were severely dependent or dependent; however, these values did not show any association with the development of PU. Although 66.7% of PU developed in severely dependent individuals. Hence, in the study of Tarazona Santabalbina (21), the average value of the Barthel index score was lower in patients with PU when compared with subjects without PU (33% vs. 45%, $p < .001$), so individuals with PU had a higher level of dependency when compared to individuals without PU. Therefore, according to Iizaka, Okuwa, Sugama and Sanada (22), factors such as immobility in bed and chair (high levels of dependency) were associated with PU occurrence.

In this study, about half of the individuals presented a malnutritional risk; however, this risk was not associated with the occurrence of PU. These results could be

explained due to the information about the nutritional risk that was assessed and registered in the clinical process at the patient's admission at the care facility, not predicting the evolution of the individual's health.

In this context, Tarazona Santabalbina (21) reported that patients with PU had a higher risk of malnutrition when compared to individuals without PU (23.4% vs. 15.5%). Also, Weng (23) reported that 53.3% of subjects had malnutrition or inadequate nutrition in a sample of subjects submitted to NIV, which agrees with the results of the present study. It should be noted that malnutrition, besides increasing the risk of pressure ulcers, impairs their treatment. It is also worth mentioning that in the study by Iizaka et al. (22) there were more malnourished individuals in the PU group comparing to those in the non-PU group.

In the current study, 39 individuals (95.1%) presented a high risk of PU, on the other hand, Martins et al. (24) found that 60.0% of the participants in their study had a high risk for PU (measured by the Braden scale). The differences between the results may be explained by the conditions/typology of individuals included in the studies and by how the Braden scale is applied in the different hospitals. According to Choi & Kim (25), although the higher frequency of nurses' responses is consistent with expert opinion, the large variation in responses may influence the consistency and reliability of the risk assessment of PU by the Braden scale.

The values obtained in the Braden scale, in this study, did not present a correlation

with the occurrence of PU. According to Black et al. (19), although there are common risk factors in the development of PU and URMD, there is no statistical relationship between the two groups about the Braden scale evaluation, for this reason, traditional tools may not be adequate to assess the risk of URMD.

After computing the point-biserial correlation coefficient, it was observed that the presence of PU presents a significant positive correlation with the score obtained in the GCS, a relation corroborated by Dyer (26), which affirms that PUs are associated with factors such as nutritional compromise and limited ability to signal discomfort. Also, Ham, Schoonhoven, Schuurmans and Leenen (27) attest this result, because in their study on the development of PU in vertebro-medullary lesion victims, they demonstrated that the development of PU was associated with lower GCS scores (OR 1.21; $p < .001$), and by Dhandapani, Dhandapani, Agarwal, and Mahapatra (28) who, comparing subjects with GCS of 4 to 6 with individuals with GCS of 7 to 8 obtained values of development of PU of 27% and 10%, respectively, showing that a low score in the GCS had a significant association with the development of PU.

Regarding the state of consciousness, it was verified that 92.7% of individuals presented slight alterations or did not present any alteration of the level of consciousness. Similar results were observed by Martins et al. (24), in their study about patients who underwent NIV in an IMCF, reporting a proportion of 96.7% of individuals who presented a GCS score of 11 to 15.

In the present study, the occurrence of PU occurred between the 3rd and 20th days. Martins et al. study (24) obtained similar values since the meantime to development of PU was 3.3 days, which led the authors to conclude that after 3 days of NIV, the risk of PU increases. Also, Schallom et al. (29) noticed that the development of PU varied between 1.25h and 74h with an average of 28.4h with an oronasal mask.

It should also be noted that more prolonged use of the NIV interface increases

contact pressure in the nasal area leading to facial injury (4). There was also a significant negative correlation with the duration of NIV use and the appearance of PU. Other studies attest to this result since in the study by Yamaguti et al. (30) the mean number of NIV applications maintained for more than two hours was higher in individuals with facial lesions (mean: 7.1 SD: 13.3) that in individuals without facial lesion (mean: 4.4 SD: 7.5, $p = 0.03$), Carron et al. (7) also presented an incidence of facial lesion, after 2h of NIV, from 5 to 50 %, increasing dramatically after significant days of NIV. Furthermore, Gregoretti et al. (18) demonstrated that the development of PU increased by 20% between 24h and 48h, suggesting that a period of NIV greater than 24h is associated with a higher risk of PU.

The main limitations of the present study are the delimitation of the geographical area of the sample, the fact that the characteristics of the individuals' skin have not been evaluated (such as sweating rate or skin temperature) and the Braden Scale does not present the possibility of predicting the risk of URMD, as described by Black et al. (19). Also, in this study, the mask was fixed to the patient's face with the same type of headgear, but by different nurses, so the amount of pressure exerted in the face could be different. Still, other limitations are the fact that it was not possible to identify the development time of PU in hours, it was not possible to verify the possible use of protective dressings nor the time of pause in the NIV and, finally, it was not possible to study the relationship of intermittent NIV and continuous NIV in the development of PU. The impact of these limitations may be diminished in future works by applying a method of data collection that involves not only the information in the process but a direct observation of the individual. It would also be essential to collect information in other units of the country, in order to diversify the sample.

Thus, future studies should consider the limitations described above, evaluating other scales of risk assessment of PU with their development of PU in the face, and

evaluating other types of interface. Also, it would be essential to study the relationship between the development of PU with other variables (personal factors - intrinsic to individuals, environmental factors and institutional factors - management policies and maintenance of devices).

Since the highest percentage of PU associated with NIV appear in the nasal pyramid, a more significant effort should be focussed on the protection of this zone, either by applying protective dressings or moisturizing products or by promoting a greater vigilance. This surveillance should also be closer in individuals with decreased consciousness or who cannot demonstrate discomfort and in individuals who undergo NIV for more extended periods. Thus, the nurse role should be the promotion of practices that respect human rights and the professional responsibilities and to manage the care so that the appropriate care is given to individuals with a higher risk of development of facial PU.

Conclusion

With the accomplishment of this research we concluded that the facial PU associated with the NIV interface develops more frequently in the nasal pyramid and that, although individuals submitted to NIV in an IMCF have a high degree of dependence, this dependence may not influence the development of facial PU, however, PU developed in 66.7% of the patients with severe dependence. It was also understood that about half of these individuals present nutritional risk; though, this risk was not related to the development of PU on the face. Similarly, the score of the Braden Scale is not related to the appearance of PU, but the great majority of the individuals presented a high risk of developing a PU. Also, we observed that the time of NIV use may influence the development of facial PU.

Finally, the level of consciousness were associated with the development of PU. However, in this study, the proportion of individuals that presented considerable

changes in the level of consciousness was low.

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Conflict of interest

The authors declare that no competing interests exist.

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