REVISTA CHILENA DE PEDIATRÍA
Sociedad Chilena de Pediatría
www.scielo.cl

Rev Chil Pediatr. 2017;88(3):354-359
DOI: 10.4067/S0370-41062017000300007

ORIGINAL ARTICLE

Face protective patches do not reduce facial pressure ulcers in a simulated model of non-invasive ventilation

Uso de parches protectores faciales no reduce la presión facial en un modelo simulado de ventilación mecánica no invasiva

Hugo Riquelme M.[a,c], David Wood V.[a,c], Santiago Martínez F.[a,c], Fernando Carmona M.[c], Axel Peña V.[c], Adriana Wegner A.[b]

[a]Intensivist Physical Therapist and Respiratory Therapist, Pediatric Intensive Care Unit, Complejo Asistencial Dr. Sótero del Río, Santiago, Chile
[b]Pediatric Intensivist, Pediatric Intensive Care Unit, Complejo Asistencial Dr. Sótero del Río, Santiago, Chile
[c]School of Physical Therapy Finis Terrae University, Santiago, Chile

Received: 28-6-2016; Accepted: 19-11-2016

Abstract

Background: Non-invasive mechanical ventilation (NIMV) frequently involves the development of pressure ulcer (PU) secondary to face-masks. Its prevention considers the empirical use of protective patches between skin and mask, in order to reduce the pressure exerted by face-masks. **Objectives:** To evaluate the effect of protective patches on the pressure exerted by face-masks, and its impact on ventilatory parameters. **Method**: A simulated model of BiPAP using total face mask on a training phantom with a physiological airway model (ALS PRO+) in supine position was used. The pressure on the front, chin and cheek was measured using 3 types of patches commonly used versus a control group, using pressure sensors (Interlinks Electronics(R)). The values obtained with the model of mask-protective patches in the programmed variables (peak inspiratory flow (PIF), expired tidal volume (Vte) and inspiratory positive pressure (IPAP)) were evaluated with a Trilogy 100 ventilator, Respironics(R). The programming and recording of the variables were carried out in 8 opportunities in each group by independent operators. **Results:** Any decrease in facial pressure with the protective patches used was observed, compared to the control group. Moltopren(R) increased facial pressure at all support points ($p < 0.001$), increased leakage, decreased PIF, Vte and IPAP ($p < 0.001$). Hydrocolloid patches increased facial pressure only in the left cheek, increased leakage and decreased PIF. Polyurethane patches did not produce changes in facial pressure or ventilatory variables. **Conclusion:** The use of Moltopren(R), hydrocolloid and transparent polyurethane protective patches did not contribute to the decrease on facial pressure. A deleterious effect of Moltopren and hydrocolloid patches was observed on the administration of ventilatory variables, concluding that the non-use of the protective patches allowed a better administration of the programmed parameters.

Keywords:
Noninvasive ventilation;
interface;
facial pressure ulcer;
protective patches

Correspondence:
Hugo Riquelme M.
hugo.riquelme.m@gmail.com

Introduction

The success of non-invasive mechanical ventilation (NIMV) depends, among other things, on an adequate interface or mask, as this directly influences the tolerance and comfort of the patient to the system, patient-ventilator synchrony and correct delivery of the ventilatory parameters[1,2]. The correct selection of the mask, associated to its adequate positioning, achieves in most cases an accurate delivery of the programmed parameters and a decrease of complications associated to the NIMV interface[3,4].

A common complication of NIMV is facial pressure ulcers (PU), which affects up to 50%[5,6]. In normal clinical practice, masks used in NIMV are tightly fitted to the face of the patient to achieve a tight seal, which is capable of reducing leakage and thereby ensuring the delivery of pressures, fraction of inspired oxygen (FiO_2) and programmed trigger sensitivity and cycling. This control of leakage through the fixation of the mask can cause points of overpressure, mainly in areas where there is little subcutaneous tissue (chin, cheekbones, forehead and nasal bridge), which predisposes to the generation of PU[6-9]. Additionally, in the pediatric population, there are particular risk factors for developing PU, such as the presence of immature skin[10], a poor variety of masks, and a difficult adaptation to the facial anatomy of each child, which in many cases requires an excessive adjustment to the face to achieve the proper seal[11]. In the case of PU, the constant and/or elevated pressure that is exerted by the NIMV mask could generate tissue ischemia. They would only have two hours of pressure of 35 mmHg or 47.6 cmH_2O on the skin to produce occlusion of the microcirculation and generate regional tissue ischemia[12-14]. In addition to generating aesthetic problems and impairing the patient's quality of life, hospitalization costs increase, with potential medical and legal implications for health professionals[15].

Currently, measures to prevent PU consider the use of suitable masks, with strong evidence for the use of the total face mask model, as well as periodical revision of the skin and the placement of facial patches between the skin and the mask in risky areas[10,16-18]. The protective patches are intended to create a physical barrier between the mask and the skin, in order to theoretically attenuate the pressure exerted on the skin, in an effect that we could call "meniscus effect", given the functional similarity achieved by the cartilaginous (meniscus) joint in the knee[19]. The meniscus biomechanically express properties that allow it to adapt to withstand the forces exerted on them, acquiring a crucial role in the absorption of the impact, support and transmission of load towards the underlying bone[20]. The interaction between sustained pressure and tissue tolerance to pressure is essential prior to necrosis, as the external pressure in the blood vessels causes an increase in irrigation through the activation of self-regulation mechanisms[21]. This meniscus effect would be achieved through 3 mechanisms: 1) Achieve congruence of the surface system (mask-skin); 2) Increase the area of contact between surfaces, and 3) Distribute the force between the mask and the skin[20]. Despite this theoretical benefit and the massive use of these patches, there is no evidence to sustain its use.

Our objective was to evaluate the effect of the protective patches on the pressure exerted by the face mask, and its impact on the delivery of the ventilatory parameters.

Equipment and Methods

We used a simulation model consisting of a manikin with a physiological airway (ALS PRO+), which was connected to a non-invasive mechanical ventilator model Trilogy 100, Respironics (R), through a total face mask (PerforMax size S, Respironics (R)). The mask was fixed with a headgear; model Softcap, Respironics(R). Between the face of the simulation manikin and the mask were placed protective patches of 2 cms of surface and simultaneously pressure sensors in 4 key points: forehead (facial pressure on forehead = FPF), chin (facial pressure on chin = FPC), right cheek (facial pressure on right cheek = FPRC) and left cheek (facial pressure on left cheek = FPLC). Facial pressure was measured with pressure sensors model FSR 402 round, Interlinks Electronics(R) with 0.5 cms of sensitive diameter, attached to an Arduino UNO-R3 card, a 640 distribution x 200 power distribution protoboard and an alphanumeric display of 16x2 (MCI00154) according to the connection diagram recommended by the manufacturer of the sensor (Interlinks Electronics(R))[22]. In this way a mask-patch-sensor-surface interface of the manikin was created for the experimental groups, unlike the control group whose interface did not use protective patches.

The simulation manikin was placed in supine position with a head height of 13.5 cm above the support surface. The frontal sensor was located in the midline at 2.5 cm above the eyebrows, the chin sensor was in the midline at 2 cm under the lower lip and finally the right and left sensors were 3 cm anterior to the external auditory canal (figure 1).

The fixation force of the mask was determined by clinical criteria of "*congruence of the mask with the surface of the face that allows a slight play of the mask with the least possible leakage*". Once the clamping force was determined, it was standardized for all measurements (constant clamping force) by 24 cms in length for the

two upper straps and 20 cms for the two lower straps of the headgear.

During the measurements all parameters of the mechanical ventilator were maintained constant: mode Timed, IPAP 14 cmH_2O, EPAP 8 cmH_2O, backup respiratory rate of 12/min, inspiratory time of 0.85 sec, FiO_2 of 21%.

The study groups were divided according to the type of patch used: group with patch of Moltopren, group with waterproof hydrocolloid dressing (Duoderm(R) Convatec) and group with transparent polyurethane dressing (Tegaderm(R) IV, 3M).

A study group was measured per day in a randomly defined order, with 8 daily measurements being performed for each group. This number of measurements was determined by performing a previous reliability study, averaging a number of facial pressure measurements where it did not score significant differences with respect to the previous averages (< 0.5 cmH_2O).

The interface mask-patch-sensor-surface of the manikin was applied by an operator other than the one who made the measurements, both unrelated to the investigation. Each measurement was obtained after 1 minute, after having fixed the mask with the headgear and at the moment of delivering the IPAP. For the next measurement, the interface (mask, patch, sensor) was disconnected, the sensor was repositioned by inserting a new protective patch at each support point and the mask was reattached. This sequence was applied for each of the following measurements, using a total of 32 protective patches per group. For the control group the same sequence was used. The critical pressure was defined as that greater than 47.6 cmH_2O[12].

In addition, the level of leakage of the mask (leakage), peak inspiratory flow (PIF), expired tidal volume (Vte) and inspiratory positive airway pressure (IPAP) were evaluated through a pneumotachograph incorporated into the Trilogy 100 ventilator. Continuous variables were represented by mean ± standard deviation. A normality analysis was performed with the ShapiroWilk test. The variables FPF, FPRC, leakage and PIF variables had a normal distribution using the one-way ANOVA test for repeated measures. For the variables without normal distribution (FPC, FPLC, IPAP, Vte) the Friedman test was used. Dunnett's post-test (one-way ANOVA for repeated measures) and Dunn's posttest (Friedman's test) were used for the variables with statistically significant differences. The analyses were performed with a confidence level of 95% with a maximum error of 5%, considering an alpha error lower than 0.05. Data analysis was performed using the Graphpad Prism(R) computer statistical program.

Results

The Moltopren patch generated facial overpressure at all support points of (FPF 198 ± 58 cmH_2O, FPC 244 ± 31 cmH_2O, FPLC 76 ± 20 cmH_2O and FPRC 78 ± 20 cmH_2O) with respect to the control group (FPF = 26 ± 9.2 cmH_2O, PFC = 44 ± 10 cmH_2O, PFLC = 26 ± 5.8 cmH_2O and FPRC = 34 ± 12 cmH_2O), exceeding critical pressure at all support points. In addition, it increased leakage, decreased Vte, PIF, and IPAP. The hydrocolloid patch generated facial pressure only in the left cheek (FPLC of 36 ± 4.6 cmH_2O) with respect to the control group. It also increased leakage and decreased PIF, but to a lesser extent with respect to Moltopren. The transparent polyurethane patch did not change the pressure with respect to the control group, and had

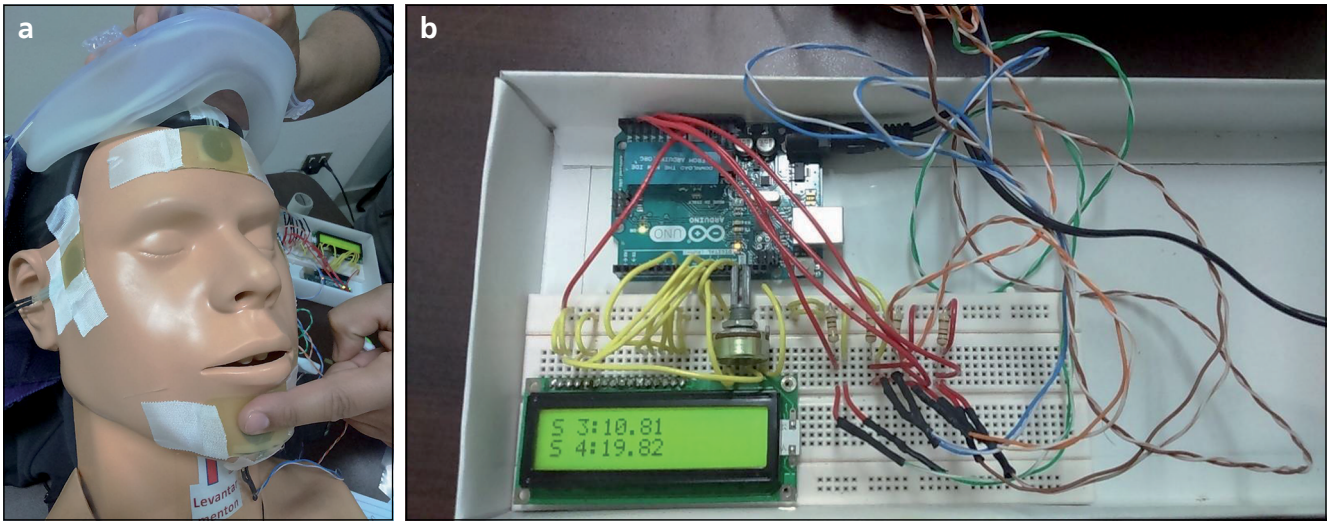

Figura 1. a) Simulation manikin with sensors and patches. **b)** Pressure monitor.

no effect on the ventilatory parameters administered (Table 1).

In the control group the pressure was at all points of support under critical pressure.

Discussion

The results of our simulated model of BiPAP NIMV evidenced an inability of the protective patches to reduce facial pressure, and even the Moltopren and hydrocolloid patches generated overpressure. The use of the mask without any patches did not generate immediate overpressure using a usual clamping force.

According to what was observed in this study, three scenarios would be generated with the use of protective patches: 1) A high leakage that does not allow to maintain the IPAP in the desired parameters, favoring the fall of the PIF and the decrease of Vte; 2) The compensation of a moderate leak manages to keep the IPAP, but at the expense of a fall of the PIF and the Vte, and 3) A decrease in the leak keeps the IPAP, increasing the PIF and Vte.

Scenario 1 (Moltopren) and 2 (hydrocolloid) would require a greater fixation force of the mask to achieve adequate adaptation and seal that favors a good patient-ventilator synchrony (trigger and cycling) and a correct delivery of ventilatory parameters. This increased fixation force, however, would result in increased pressure on the surface of the skin, conditioning the genesis of facial PU. Because of these two scenarios, the use of protective patches not only increases the risk of facial PU, but also impairs the effectiveness of NIMV.

Scenario 3 (polyurethane), although it does not generate meniscus effect, does not require increasing the fixation force to achieve a suitable adaptation and seal of the interface, so that it does not generate overpressure in the patient's skin nor worsen the effectiveness of the ventilator.

Consequently, if a suitable mask is being used, it may not be necessary to use protective patches, unless only its lubricating, moisturizing and / or antifriction properties are sought. In this way, the preventive strategy of the facial PUs would only involve the use of suitable masks, fixed to an optimal pressure and the periodic revision of the skin. For this reason, the arrangement of an apparatus for measuring the fixation pressure level of the mask, such as the one used in this study, would allow for the future application of a therapeutic approach, based on the mechanical equation, that describes the pressure as directly proportional to the fixation force of the mask and inversely proportional to the area of contact of the mask with the skin (P = F/A), resulting in a rational preventive measure of facial PU in those users of NIMV. There is no doubt

Table 1. Effect of protective patches on the pressure exerted by the facial mask and its impact on ventilatory parameters programmed in simulated model of non-invasive mechanical ventilation

		Control	Moltopren patch	Hydrocolloid patch	Polyurethane patch
FPF	cmH_2O	26 ± 9.2	198 ± 58*	55 ± 13	37 ± 6.6
	CV	35.40%	29.56%	23.01%	18.17%
FPC	cmH_2O	44 ± 10	244 ± 31*	57 ± 13	41 ± 8.1
	CV	23.08%	12.53%	22.01%	19.81%
FPLC	cmH_2O	26 ± 5.8	76 ± 20*	36 ± 4.6*	28 ± 4.7
	CV	22.33%	26.47%	12.66%	16.72%
FPRC	cmH_2O	34 ± 12	78 ± 20*	44 ± 12	31 ± 8
	CV	37.28%	25.08%	27.43%	25.75%
Leakage	L/min	46 ± 1.5	171 ± 6.3*	67 ± 2.6*	40 ± 1.9
	CV	3.25%	3.66%	3.87%	4.80%
Vte	mL	45 ± 1.2	13 ± 5.5*	27 ± 1.4	48 ± 0.99
	CV	2.76%	43.11%	5.05%	2.06%
PIF	L/min	19 ± 0.23	2.6 ± 0.61*	15 ± 0.98*	20 ± 0.19
	CV	1.19%	23.74%	6.36%	0.95%
IPAP	cmH_2O	14 ± 0.046	11 ± 0.52*	14 ± 0.074	14 ± 0.092
	CV	0.33%	4.90%	0.53%	0.66%

FPF= facial pressure on forehead; FPC= facial pressure on chin; FPLC= facial pressure on left cheek; FPRC= facial pressure on right cheek; Vte= expired tidal volume; PIF= peak inspiratory flow; IPAP= inspiratory positive airway pressure; CV= Coefficient of variation. Values expressed as mean ± standard deviation. *P < 0.05 with respect to control.

that the development of induced skin ulcers depends on the magnitude of the pressure, individual factors and the time of continued use of the mask, so that continuous monitoring would also seem even more desirable in this context[8,13,14,19,21,23-29].

The limitations of this study include the use of patches only at critical points and not the entire face, the use of only 3 types of protective patches and one type of mask. The limitations inherent to the use of a simulated model are also added: absence of skin and / or mechanical properties similar to this, absence of movement in the simulation manikin, which makes mask fixation and seal difficult, as well as variability in respiratory volumes and flows. Two variables not considered in this study and of vital importance in future investigations are the exposure time between protective patches-mask and the temperature inside the mask. Both two variables could influence the physical-molecular properties of force distribution and congruence of a patch. Despite the limitations described, we believe it is relevant to question the empirical use of the commonly used protective patches in the prevention of facial PU secondary to the adjustment of the NIMV mask.

Conclusion

The use of protective patches of Moltopren, hydrocolloid and transparent polyurethane did not contribute to the decrease of the facial pressure in a simulated model of NIMV. A deleterious effect of the Moltopren and hydrocolloid patches on the administration of ventilatory variables was observed, concluding that the non-use of the protective patches allowed a better administration of the programmed parameters.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors state that any conflict of interest exists regards the present study.

References

1. Meduri GU. Noninvasive positive pressure ventilation in patients with acute respiratory failure. Clin Chest Med 1996;17:513-53.
2. Mehta S, Hill NS. Noninvasive ventilation. Am J Respir Crit Care Med 2001;163:540-7.
3. Schönhofer B, Sortor-Leger S. Equipment needs for noninvasive mechanical ventilation. Eur Respir J 2002;20:1029-36.
4. Meduri GU, Spencer SE. Noninvasive mechanical ventilation in the acute setting. Technical aspects, monitoring and choice of interface. Eur Respir Mon 2001; 16:106-24.
5. Carron M, Freo U, BaHammam AS, et al. Complications of non-invasive ventilation techniques: a comprehensive qualitative review of randomized trials. Br J Anaesth 2013;110:896-914.
6. Maruccia M, Ruggieri M, Onesti MG. Facial skin breakdown in patients with non-invasive ventilation devices: report of two cases and indications for treatment and prevention. Int Wound J 2015;12(4):451-5.
7. Artacho R, García de la Cruz JI, Panadero JA, et al. Ventilación mecánica no invasiva. Utilidad clínica en urgencias y emergencias. Emergencias 2000;12: 328-36.
8. Baumgarten M, Margolis DJ, Localio AR, et al. Pressure ulcers among elderly patients early in the hospital stay. J Gerontol 2006;61:749-54.
9. Tleyjeh I, Berlowitz D, Baddour LM. Infectious complications of pressure ulcers. UpToDate 2012.
10. Schindler CA, Mikhailov TA, Fischer K, et al. Skin integrity in critically ill and injured children. Am J Crit Care 2007; 16:568-74.
11. Visscher MO, White CC, Jones JM, et al. Face masks for noninvasive ventilation: fit, excess skin hydration, and pressure ulcers. Respir Care 2015;60(11):1536-47.
12. Ahmad Z, Venus M, Kisku W, et al. A case series of skin necrosis following use of non invasive ventilation pressure masks. Int Wound J 2013;10(1):87-90.
13. Berlowitz B. Epidemiology, pathogenesis and risk assessment of pressure ulcers. In UpToDate (accedido el 12 de noviembre de 2014).
14. Bhattacharya S, Mishra RK. Pressure ulcers: Current understanding and newer modalities of treatment. Indian J Plast Surg. 2015;48:4-16.
15. Sociedad Iberolatinoamericana de úlceras y heridas. Declaración Río de Janeiro sobre la prevención de úlceras por presión como derecho universal. Octubre 2011. (serie en internet) (citado 17 octubre 2016) (aprox. 1p) Disponible en: URL: http://silauhe.org/img/Declaracion%20de%20Rio%20-%20Espanol.pdf
16. Schallom M, Cracchiolo L, Falker A, et al. Pressure ulcer incidence in patients wearing nasal-oral *versus* full-face noninvasive ventilation masks. Am J Crit Care 2015;24:349-56.
17. Yamaguti WP, Moderno EV, Yamashita SY, et al. Treatment-related risk factors for development of skin breakdown in

subjects with acute respiratory failure undergoing noninvasive ventilation or CPAP. Respir Care 2014;59:1530-6.
18. Brill AK. How to avoid interface problems in acute noninvasive ventilation. Breathe 2014;10:230-42.
19. Weng MH. The effect of protective treatment in reducing pressure ulcers for non-invasive ventilation patients. Intensive Crit Care Nurs 2008;24: 295-9.
20. Makris EA, Hadidi P, Athanasiou KA. The knee meniscus: structure-function, pathophysiology, current repair techniques, and prospects for regeneration. Biomaterials 2011;32: 7411-31.
21. Munckton K, Ho KM, Dobb GJ, et al. The pressure effects of facemasks during noninvasive ventilation: a volunteer study. Anaesthesia 2007;62:1126-31.
22. Force sensing resistor integration guide and evaluation parts catalog. Interlink electronics; 1-25 (serie en internet) (citado el 17 de octubre de 2016) (aprox. 26pp) Disponible en: URL: https://www.sparkfun.com/datasheets/Sensors/Pressure/fsrguide.pdf
23. National pressure ulcer advisory panel, european pressure ulcer advisory panel and pan pacific pressure injury alliance. Prevention and treatment of pressure ulcers: Quick reference guide. Emily Haesler (Ed.); 2014. (serie en internet) (citado el 17 de octubre de 2016) (aprox. 75 pp) Disponible en: URL: http://www.npuap.org/wp-content/uploads/2014/08/Updated-10-16-14-Quick-Reference-Guide-DIGITAL-NPUAP-EPUAP-PPPIA-16Oct2014.pdf
24. Gregoretti C, Confalonieri M, Navalesi P, et al. Evaluation of patient skin breakdown and comfort with a new face mask for non-invasive ventilation: a multi-center study. Int Care Med 2002; 28(3):278-84.
25. Yong SC, Chen SJ, Boo NY. Incidence of nasal trauma associated with nasal prong *versus* nasal mask during continuous positive airway pressure treatment in very low birthweight infants: a randomised control study. Arch Dis Child Fetal Neonatal Ed 2005;90:480-83.
26. Pender LR, Frazier SJ. The relationship between dermal pressure ulcers, oxygenation and perfusion in mechanically ventilated patients. Intensive Crit Care Nurs 2005;21:29-38.
27. Terekeci H, Kucukardali Y, Top C, et al. Risk assessment study of the pressure ulcers in intensive care unit patients. Eur J Intern Med 2009;20:394-7.
28. Dellweg D, Hochrainer D, Klauke M, et al. Determinants of skin contact pressure formation during non-invasive ventilation. J Biomech 2010;43:652-7.
29. Newnam KM, McGrath JM, Estes T, et al. An integrative review of skin breakdown in the preterm infant associated with nasal continuous positive airway pressure. J Obstet Gynecol Neonatal Nurs 2013;42: 508-16.