

Effectiveness of Protective Cushions in Preventing NIV Face Mask - Associated Pressure Ulcers: A Prospective Study in Elderly Patients

Running Title: *Goel A: Protective Cushion for NIV Face Mask Associated Pressure Ulcer*

Dr. Amit Goel¹, Dr Shikha Jain², Dr. BR Shamanna³

¹DNB, PDCC, EDIC, Director and Head, Department of Critical Care Medicine, Yatharth Super Speciality Hospital, Saket, Greater Noida West - 201305, UP, India
Email: [amgoel3\[at\]gmail.com](mailto:amgoel3[at]gmail.com)

²MD, Associate Professor, Department of Physiology, NDMC &HRH, Malka Ganj, New Delhi - 110007, India
Email: [jshikha234\[at\]gmail.com](mailto:jshikha234[at]gmail.com)

³MD, DNB, PhD, Professor, School of Medical Sciences, University of Hyderabad, Gachibowli, Hyderabad - 500046, India
Email: [brsham\[at\]gmail.com](mailto:brsham[at]gmail.com)

Contribution Details -

AG, BS and SJ conceptualised, designed, defined the intellectual content of the study. AG did data acquisition. AG and SJ did literature search, data analysis, statistical analysis, manuscript preparation. AG, BS and SJ did manuscript editing and manuscript review.

Abstract: Introduction: Face mask is most applied interface while using Non - Invasive Mechanical Ventilation (NIV). NIV face mask associated pressure ulcers are widely reported. However clear preventive strategies for this issue are lacking. We aimed to evaluate the effect of protective cushion on NIV face mask associated pressure ulcers. Material & Methods: Total 64 elderly patients (32 in each arm - control and study) were taken in this prospective, randomised comparison study in a tertiary care ICU in North India, who were in respiratory failure and required NIV. Results: We reported significant delay in time of pressure ulcer formation in study group as compared to control group. There was 50% fewer pressure ulcer formation in study group; however it was not statistically significant. Conclusion: NIV mask associated pressure ulcer formation can be delayed and reduced with use of protective dressing.

Keywords: NIV, Pressure ulcers, Cushion, Foam dressing

1. Introduction

The use of non - invasive ventilation (NIV) devices has increased steadily in the last 2 decades to become the first line of therapy for various conditions leading to acute respiratory failure. (1, 2) Non - invasive ventilation refers to the delivery of regular positive pressure support to the patient through a mask, without invasive endotracheal intubation. (3)

Face mask, most used interface of NIV, needs to be applied on to the face with some pressure so that it seals well against the skin to prevent any air leak around it. However, too tightly applied a mask can lead to pressure changes over the area of contact and can lead to the formation of “pressure sores”.

Pressure sore can develop as quickly as few hours. It usually starts with change in the skin colour to dark red and may progress to blister to ulcer over a period if not intervened.

Most common site of pressure sore are nasal bridge, forehead, cheek area which comes under pressure contact of mask rim.

Pressure injuries have been described by the European Pressure Ulcer Advisory Panel (2014) as damage to the small area of skin or its underlying tissue, commonly over a bony prominence. Excessive pressure or pressure load in

combination with shear, leads to such damage. It has been classified into 4 types: Type I is the occurrence of non - blanching erythema; Type II is partial thickness skin loss; Type III is full - thickness skin loss; and Type IV is full - thickness tissue loss. (4) The reported facial skin pressure sore incidence rate is 5 - 50%. (5)

Development of facial pressure injuries related to the NIV interface is widely reported in the literature; however, limited data are available on the risk factors and prevention methods that reduce such complications. Two controlled trials compared the effect of different types of protective dressings on the development of facial pressure ulcers and reported a lower prevalence of facial pressure ulcers. (6, 7)

The aim of this study was to evaluate the effect of extra protective cushion applied to prevent NIV face mask associated pressure injuries in elder patients admitted to the tertiary care hospital in India.

Aims & Objectives

To evaluate the effect of extra protective cushion applied to prevent NIV face mask associated pressure injuries in elder patient admitted in ICU.

2. Material and Methods

The study was conducted in Department of Critical Care

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Medicine, at a tertiary healthcare centre in north India from December 2022 till March 2023. This was a Prospective, randomised comparison study and included 64 patients. The study population comprised of all elderly patients (age > 60 years) admitted in the ICU requiring NIV for respiratory failure. Two groups of equal number of patients (n=32) were made. Patients in control group received NIV with conventional face mask interface, while those in study group received NIV with face mask with extra cushion of soft silicon foam dressing applied at nasal bridge, face skin, forehead, and mask rim to decrease the pressure effect (figure 1 & 2). Conventional face mask used was UNIFIT™ Face Mask with silicon cushion from Zymes Bioscience India. Extra soft silicon foam will be from Mepilex® from MÖLNLYCKE Healthcare Sweden. Randomisation was done; all odd patients enrolled in control group while even number patient enrolled in study group.

Facial skin health and condition was checked daily every 6th hourly and any breach in the skin was notified till the patient stayed in the ICU or required NIV.

Statistical Methods

SPSS version 21.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for data management and statistical analysis. A Pearson correlation coefficient (r) was used to evaluate the relationship. Analyses is performed by the chi square test & independent sample t test. All tests will be two-tailed, with p < 0.05 defined as being significant.

3. Results

Total 64 patients were included with equal no (n=32) in each group. Demographic profile of patients in both the groups was not different, as shown in table - 1. The mean age in both the group was around 69 years (69.3±6.51 in control and 69 ±5.96 in study group). Equal gender distribution was observed in both the groups (male vs female - 56.2%: 43.8% in control and 59.4%: 40.6% in study group respectively).

12 (37.5%) patients in control group developed pressure ulcers after NIV application, however 6 (18.75%) patients in the study group developed pressure ulcer on NIV application (Table - 2). This was found to be approaching towards clinical significance (p=0.09). Out of 12 patients in control group who developed pressure ulcers, 58.33% were female while in study group 50 % were female, however it was not statistically significant (p=0.17). Three patients in control group and 1 patient in study group was requiring vasopressors while they developed pressure ulcer (p=0.14). Mean time of pressure sore occurrence since NIV mask application, was 31.42 (±15.68) hours in control group and 59.33 (±19.93) hours in study group. This was found to be statistically significant (p<0.001)

4. Discussion

NIV associated pressure ulcers have been documented and has been attributed primarily to the pressure exerted by the mask rim over the area of skin in contact. (8, 9) Other factors like - age, skin condition, nutrition etc. have also been shown in some study to affect development of pressure ulcers. (10) However in our study we could not find any

major impact of these factors on development of NIV induced pressure ulcers.

Our study revealed that application of a protective extra cushion at contact areas on face while applying NIV mask reduced pressure ulcer formation (Table - 2). However, there was an absolute risk reduction (ARR) by almost 50% but the results were not statistically significant (p=0.09). Study done by Weng et al had shown significant reduction in the pressure ulcer with protective dressing (p=0.0). ARR in their study was also 50% like in our study, however reported pressure ulcer with conventional method was 96.7% while in our case it was only 37.5%. Improved mask quality, better NIV application techniques, keen skin health observation may be some of the factors which can explain less ulcer development in our patients on conventional masks.

In both the group 4 patients required vasopressors. 75% patient in control group and 25% on study group on vasopressors developed pressure ulcers. There was 50% ARR of pressure ulcers in patients on vasopressors, however it was not statistically significant (p=0.14).

Use of protective dressing with NIV has also been shown to delay the onset of pressure ulcer formation. We found the time of occurrence of (first noticed) pressure ulcer since mask application, has been markedly prolonged with protective dressing by almost two times.

There were some limitations in our study 1) small number of participants could not yield effective result to have generalizability 2) subjective assessment of ulcer and skin colour especially dark skin may delay notification.

5. Conclusion

Improved mask materials and better NIV application understanding amongst physicians have decreased overall pressure ulcers. However extra cushion applied provides protection, better seal, and effective NIV results with overall reduced facial disfigurement due to pressure ulcers. Extra cushion is cost effective, and we recommend it should be used to preserve facial skin integrity while applying NIV to achieve excellent results.

Prior publications - Nil

Support - Nil

Conflicts of interest - Nil

Permission - Nil

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Figure 1



Figure 2

Table 1: General Characteristics

Sl no	Variable	Control (32)	Study (32)	p	
1	Age (Years)	69.3 (±6.51)	69 (±5.96)	0.26	
2	Gender	Male	56.2% (18)	59.4% (19)	0.37
		Female	43.8% (14)	40.6% (13)	
3	HR (per min)	81 (±12.7)	85 (±15.7)	0.12	
4	SBP (mmHg)	129 (±17.06)	128 (±16.61)	0.05	
5	DBP (mmHg)	59 (±7.46)	57 (±7.25)	0.27	
6	Hemoglobin (gm/dl)	12.06 (±1.16)	12.16 (±1.07)	0.18	
7	BLOOD SUGAR (mg/dl)	152.47 (±23)	158.19 (±21.6)	0.07	
8	Sr Albumin (gm/dl)	2.76 (±0.31)	2.82 (±0.35)	0.58	
9	APACHE - 2 SCORE	19 (±2.93)	18 (±2.58)	0.95	

Table 2: Comparison of frequency of pressure ulcer in two group -

S. no	Variable	Control (n - 32)	Study (n - 32)	P	
1	Pressure Sores (no.)	12 (37.5%)	6 (18.75%)	0.09	
2	Gender	Male	5 (41.67%)	3 (50%)	0.17
		Female	7 (58.33%)	3 (50%)	
3	Pressure Sore on vasopressors vs patients on vasopressors	3 (4) 75%	1 (4) 25%	0.14	
4	Duration of pressure sore occurrence since mask application (hours)	31.42 (±15.68)	59.33 (±19.93)	<0.001	

P<0.05 is significant.