Risk factors of non-invasive positive pressure ventilation therapy mask-related pressure ulcers

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Original Article

Risk factors of non-invasive positive pressure ventilation therapy mask-related pressure ulcers

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Abstract

Recently, the occurrence of medical device-related pressure ulcers (MDRPUs) caused by the tight application of face masks during non-invasive positive pressure ventilation (NPPV) treatment for serious respiratory disorders has attracted attention. Such ulcers can be life threatening because they make it difficult to continue NPPV, compounding the criticality of the respiratory disorder. However, as the masks cannot be removed, the factors involved in the development of such ulcers and the indices of their prevention have not been elucidated.

To determine the factors involved in the development of pressure ulcers caused by tightly applied NPPV masks, we examined the skin condition of patients in the area covered by the mask and examined the causes based on the relationships between morphological characteristics of the face and external and internal factors.

The study population consisted of 31 and 20 patients with and without pressure ulcers, respectively, representing a cumulative incidence rate of 60.8%. The most common site of pressure ulcers was the nasal bridge. Examining the depths of these ulcers showed that 28 patients had persistent blanchable erythemas, and three had ulcers that extended to the dermis, which were not seen at sites other than the nasal bridge. With regard to ulcer morphology, distinctive irregular shapes were seen with particular frequency on the nasal bridge. The variable for which a significant difference was seen was unsuitable mask size, and the number of patients fitted with masks of unsuitable size was higher among patients with ulcers ($p=0.021$). In addition, of the 13 patients for whom the mask size was unsuitable, seven had irregularly shaped ulcers, and all seven of these had mask shear.

The results discussed above suggested that pressure and/or shear caused by application of an NPPV mask of unsuitable size was associated with the development of pressure ulcers. NPPV is performed for patients in critical condition, and for whom whole-body management is of the highest priority. However, the findings presented here suggest that after 24 hours, when the patient's condition has stabilized, selecting a suitable mask size can prevent pressure ulcers and that measures should be taken to reduce pressure and shear.

KEY WORDS

medical device-related pressure ulcer (MDRPU), non-invasive positive pressure ventilation (NPPV), risk factor, mask size, wound shape

Background

Pressure ulcers are defined as localized injury to skin and/or underlying tissue usually over a bony prominence because of pressure or a combination of pressure and shear force. Critically ill patients have been identified to be at risk of pressure ulcers because of prolonged immobility.

Recently, diversification and advancements in medical care have enabled individuals to continue receiving treatment during their activities of daily living while wearing various medical devices. This has resulted in

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medical device related pressure ulcers (MDRPU), which have become an issue worldwide.

In Japan, the incidence of pressure ulcers was 1.37%, of which 35% was due to MDRPUs[1]. The prevalence rates of MDRPU were 1.3%[2] to 3.1%[3] in adults in critical wards, and it was reported that this corresponds to 34.5% of all pressure ulcers[2]. In critically ill patients, daily used medical devices that place patients at risk include oxygen delivery devices, endotracheal devices, feeding tubes, urinary catheters, and monitoring devices.

When patients are treated using non-invasive positive pressure ventilation (NPPV), placing a mask on the face may cause pressure ulcers and aggravate the critical situation, i.e., respiratory disturbance, by making it technically difficult to continue this treatment. For common pressure ulcers, it is possible to alleviate pressure by positioning the patient to avoid contact with the mattress; however, this is not feasible in the case of MDRPUs. The crucial difference is that the medical device is important for patient survival and cannot be simply removed from the body. In addition, an ulcer that develops on the face may cause immense physical and mental stress to the patient. Previous studies reported that the incidence of NPPV mask (N mask)-related pressure ulcers was 20% to 34%[4].Nomura et al[5] and Tanaka et al[6] reported incidence rates of 23% and 41.7%, respectively, from the hospital records. To prevent N mask-related pressure ulcers, Weng[7] conducted a quasi-experimental study regarding the efficacy of wound dressing. In this study, the development of pressure ulcers was examined in 90 NPPV patients who were divided into adhesive dressing group and control group. Accordingly, it was reported that pressure ulcers were common in the control group, with a significant difference observed between the two groups, but the incidence was high in the adhesive dressing group. In other words, the incidence rate of N mask-related pressure ulcers was not decreased by dressings.

To the best of our knowledge, no previous studies have focused on N mask-related pressure ulcers by directly examining the patient's skin at the contact site of the mask with respect to the development of pressure ulcers. Therefore, risk factors have not been elucidated.

Purpose of the study

The purpose of this prospective study was to clarify the risk factors for N mask-related pressure ulcers.

Methods

1. Study design

We conducted a prospective, longitudinal observational study.

2. Participants

Patients who were admitted to the medical institution and underwent NPPV were included.

1) Inclusion and exclusion criteria

(1) Inclusion criteria

Patients aged≥20 years were included if 24 h had passed since the initiation of NPPV, and/or those who had a history of NPPV and 24 h had passed since their admission were included.

(2) Exclusion criteria

Patients were excluded if permission was not obtained from the attending physician and if their general physical condition was very poor.

2) Setting

Surveys were conducted at two medical institutions in Ishikawa Prefecture (Hospital A: 838 beds; hospital B: 314 beds), and at one medical institution in Hyogo Prefecture (Hospital C: 690 beds). The locations included the intensive care unit (ICU), emergency ward, and general ward.

3) Survey period: January 2014 to March 2015

3. Determination of N mask-related pressure ulcers

The patient's skin was assessed three times a week immediately after the N mask was removed by a staff nurse. The skin regions in contact with the N mask was directly observed, and skin changes were recorded by a researcher, who was a Wound, Ostomy and Continence Nurse (WOCN) certified nurse. All N mask-related pressure ulcers were classified according to DESIGN-R[8] depth score.

4. Data collection

1) The skin regions in contact with the N mask were assessed by a researcher using a qualitative morphological method[9]. When permission was obtained, pressure ulcers were assessed by the transparent disk method[10], and photos were obtained. The skin regions in contact with the N mask was observed in detail from the photos, and a sketch of the overall aspect of the face was drawn, including the state of the skin at the contact site of the mask. Information obtained by visual examination and

palpation was verbalized and noted in a summary. In addition to the assessment at the time of skin observation, the sketches were observed for skin changes, specifically describing the site, form, and depth. The day when the N mask-related pressure ulcers developed was confirmed, and observations were performed until the ulcers healed. There was a case report regarding N mask-related pressure ulcers developing at multiple sites[11-12]. We analyzed the most frequently developed pressure ulcer and seriously site.

2) Potential risk factors for N mask-related pressure ulcers

Risk factors that may contribute to the development of N mask-related pressure ulcers include stress from external forces, shear force, and internal factors. The most important parameter is the interface pressure at the contact site of the N mask. However in critical patients, it is actually difficult to ensure safety and measure interface pressure because obtaining such measurements would require interruption of treatment. Therefore, on the basis of a previous study by Munckton et al[13], we examined factors other than interface pressure.

Potential risk factors were examined according to the literature reviewed.

Factors associated with external force include morphological characteristics of the face and external factors. There are considerable individual differences with regards to the morphology of the face. External factors include shape, flexibility, and fixation state of the mask, whereas care factors include skin care. It appeared that internal factors associated with tissue durability include the patient's physical condition, such as circulatory disturbance or hypoxemia.

(1) Morphological characteristics of the face:

Length, nose angle, and presence or absence of dentures were examined.

Measurement of the face length was carefully performed based on the photographs of patients facing the camera. The longitudinal distance from the root of the nose up to the inferior border of the lower lip was measured using Image J® software. The angle of the forehead and nose was carefully measured by the same Image® J analysis software based on the photographs of patients in the side view. Each measurement was obtained three times using Image J, and the mean value was calculated.

During NPPV, patients were requested to remove their dentures, if any, because they change the shape of the cheeks. We examined the presence or absence of dentures.

(2) External factors:

Nasogastric tube, mask fixation belt strength, air leak, mask size suitability, NPPV duration, ventilation mode, pressure setting, shear of mask, facial cleaning frequency, wound dressing usage, skin moisture, oral intake, and sitting position were examined. The strength of mask fixation belt was measured by inserting the right forefinger of the researcher up to the middle phalanx between the skin and center of the folded back mask fixation belt. If the index finger could be moved effortlessly, mask tightness was considered to be "suitable", whereas if the finger could not be moved, it was considered to be "tight." Suitability of mask size was determined by comparing the vertical length of the mask and the length of the patient's face. The upper part adhered to the root of nose, which is a flat was the site and fixation of the full face mask to cover the mouth and nose. The inferior part adhered to and fixated the inferior border of the lower lip. There was a 1–2 cm wide flap on the portion of the N mask that adhered to the skin. To effectively prevent air leak and ensure ventilation, this flap strongly adhered to the skin during inspiration, and loosened during exhalation. In other words, widths of this adherent flap would be necessary. Therefore, we aimed to evaluate a method of measuring mask size conformity. If the length of the face was within a range of 0.5 times the vertical length of the mask ± the width of the flap at the contact site of mask, the mask size was considered suitable; if the length of the face was outside this range, it was considered unsuitable (Figure 1). Skin moisture was evaluated by palpation at the contact site of the mask. Shear refers to the shifting of the mask from its original position and then returning it to the original position. N mask shear was subjectively evaluated by the patients. For patients who could not provide their own evaluation, the researcher evaluated and obtained information from the attending nurse. Information regarding air leaks, ventilation mode, pressure setting, and skin moisture was directly collected during face observation. Information regarding the frequency of facial cleaning, use of wound dressings, oral intake, and sitting position were obtained from the nurse's records.

(3) Internal factors

The basic attributes obtained from the medical records

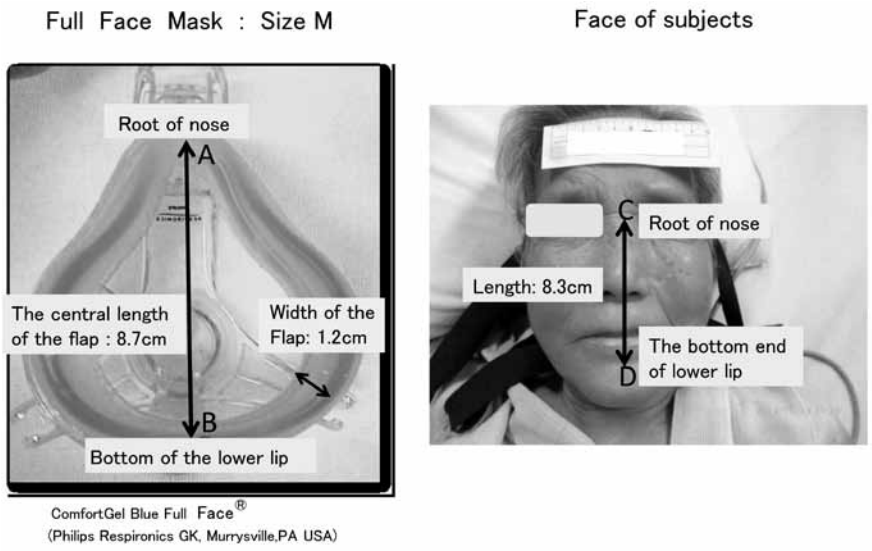

Figure1. Method of the evaluation of the mask size suitability
A.B: We did the length of the mask with the top of the mask and the central length of each lower flap.
C.D: The length of the face of the patients assumed it a root of nose part and the length of the bottom end of lower lip.
We assumed the thing in the length of the mask ± the width of the flap × 0.5 the mask size was considered suitable. It was assumed that it was unsuitable anything other than it. In the figure, a conformity range of the length of the mask is, 8.7㎝ ± 1.2㎝× 0.5 = 8.1 9.3 ㎝ .The length of the face of the patients is 8.3cm and is size suitable.

were age, gender, underlying disease, and body mass index (BMI). Internal factors obtained medical records were blood pressure, pulse, temperature, respiratory rate, and presence or absence of edema around the orbit. The Glasgow Coma Scale[14] (GCS) for the evaluation of the level of consciousness, and the Acute Physiology and Chronic Health Evaluation II[15] (APACHE II) and Sequential Organ Failure Assessment[16] (SOFA) for the evaluation of severity were also obtained from medical records. The laboratory data obtained were Hct, Hb, WBC, RBC, Plt, PaO_2, $PaCO_2$, HCO3−, pH, SpO_2 Na, K, Cr, Alb, Bil, and Glu. The presence or absence of diabetes and the use of steroids and catecholamines were likewise recorded.

5. Study procedure

1) The purpose and content of the study were explained, verbally and in writing, to the patients who were requested to participate in the study and a written consent was obtained.

2) The patient's safety was given utmost priority during the observation of facial pressure ulcers that required mask removal. Observations were scheduled to coincide with the daily care provided by the nurses, and the N masks were never removed for the sole purposes of this study.

3) During initial observation, basic attributes, including age, gender, disease, and BMI, were collected.

4) Information on the study parameters was collected on the day of observation.

5) The study endpoint was the discontinuance of NPPV. When pressure ulcers developed, observation was performed until the ulcer healed in order to verify the depth.

6. Analysis

1) The incidence density, according to the number of individuals per day, and cumulative incidence were calculated using the formulae mentioned below: Incidence density (individuals per day) = the number of patients with N mask-related pressure ulcers/the number of days for follow-up observation. Cumulative incidence (%) = the number of patients with N mask-related pressure ulcers/ the number of follow-up patients × 100

2) For the state of pressure ulcers, such as the shape and depth of each site from the sketches drawn, descriptive statistics was performed.

3) Risk factors for the development of N mask-related pressure ulcers were identified by comparing variables between the two groups of patients: patients who did not develop N mask-related pressure ulcers (non-development group) and patients who developed N mask-related pressure ulcers (development group).

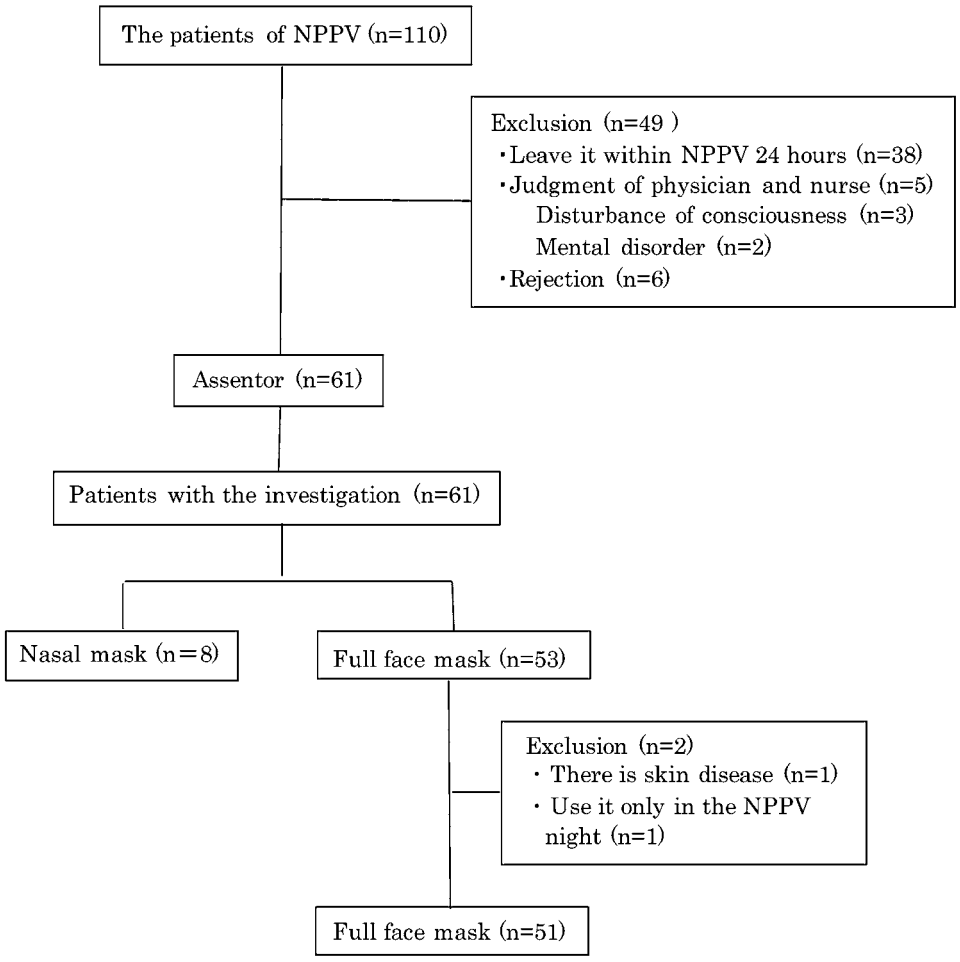

Figure 2. Flow of the participants through the study

Data on external and internal factors used in the comparisons included data obtained on enrollment and data obtained on the day prior to development of ulcers in the non-development and development group, respectively. Furthermore, data obtained on the day preceding the enrollment were only used in the event of development prior to enrollment.

Statistical analyses were performed using SPSS for Windows, version 22. Tests performed were the Chi-square test, Fisher's exact test, Student's t-test, and Mann–Whitney U-test. Parameters that showed a significant difference were included in the multivariate analyses. In descriptive statistics, the interval scale for normal distribution was shown as mean (±SD), or else values were shown as median (range).

7. Ethical consideration

This study was conducted with the approval of the ethics committees of Kanazawa University School of Medicine (No. 482) and other institutions when available. In particular, this study was conducted with utmost consideration of the danger posed to the life of the patient.

Results

1. Characteristics of the subjects

Of the 110 patients who underwent NPPV during the study period, 61 patients passed the inclusion criteria. The type of mask used included nasal mask in eight patients and full-face mask in 53 patients. The nasal and full-face masks differed in shape and applied pressure at different sites of the face; moreover, the duration of pressure for the nasal mask differed because it was only applied at night. We included only patients who used full-face mask. Among 53 patients who used full-face mask, one who had an underlying skin disease and one who only used the

Table 1. Patient demographic

n=51

Gender		Male 28	Female 23
Age(mean(SD))		76.1 (±10.2)	
Underlying disease	Respiratory disease	27 (53.0)	
	Cardiovascular disease	15 (29.5)	
	Internal secretion metabolic disorders	3 (5.9)	
	Digestive system disease	2 (3.9)	
	Blood immune disorders	2 (3.9)	
	Cranial nerve disease	1 (1.9)	
	Neuromuscular system disease	1 (1.9)	
BMI(mean(SD))		21.1 (±4.9)	n=44

Note.Value were Number(%).

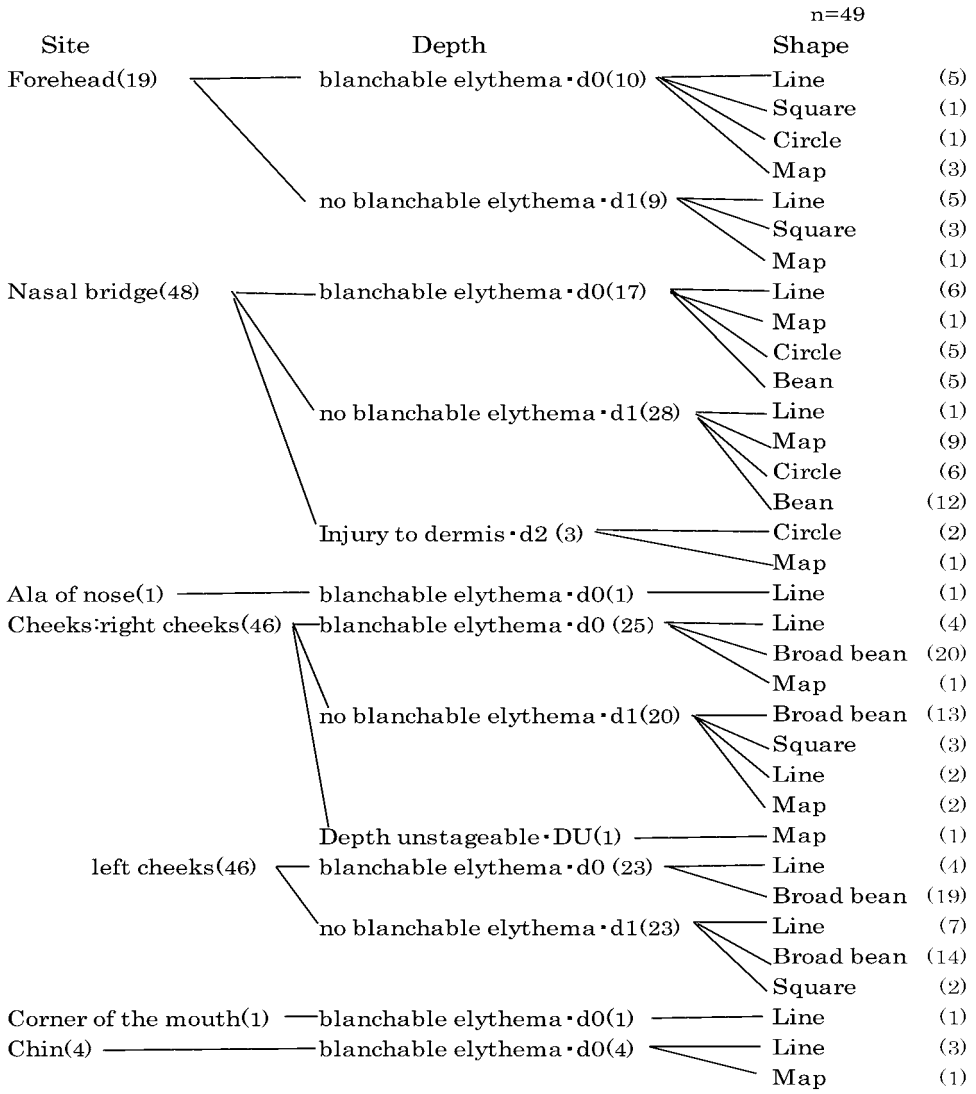

Figure 3. Change in the skin at the site of NPPV mask contact.
Changes in the skin were classified by site, ulcer depth, and ulcer shape. Sites was the forehead, nasal bridge, ala of the nose, cheeks, corner of the mouth, and chin. Depths were blanchable erythema d0, no blanchable erythema d1. Injury to the dermis d2. Depth unstageable DU.The shape included a line, a circle, the bean that form was regulated well.Also, there was the indeterminate form that the form that we could not name it was not regulated well.

mask at night were excluded. A total of 51 patients were analyzed (Figure 2)

There were 28 male and 23 female patients with a mean age of 76.1 (±10.2) years. The underlying conditions included respiratory disease in 27 patients (53.0%), followed by cardiovascular disease in 15 patients (29.5%). The mean BMI was 21.1 (±4.9) (Table 1).

2. The skin regions in contact with N mask

1) Incidence

A total of 31 patients developed pressure ulcers, with an observation follow-up period of 203 days and an incidence of 15.27 people per day. The cumulative incidence during the overall study period was 60.78 %.

2) The actual situation of the pressure ulcer

Skin changes at the contact site of the N mask were observed in 49 patients (96.1%), whereas two patients (3.9%) did not show any change. Skin changes in one patient were found at one or multiple sites; one site in two patients, two sites in one patient, three sites in 26 patients, four sites in 18 patients, and five sites in two patients. There were six sites with skin changes, the most common of which was the nasal bridge (n=48; 98%) followed by the left and right cheeks (n=46; 94%) and the forehead (n=19; 38.8%). With regards to the invasion depth, d1 or no blanching erythema was most commonly observed on the nasal bridge in 28 patients (57.1%) followed by the right cheek in 20 patients (40.8%) and the left cheek in 23 patients (46.9%). Furthermore, d2 damage to the dermis was observed in three patients (6.1%), all of which were on the nasal bridge. Unclear invasion depth was observed on the left cheek in one patient (2.0%). The shapes included a line, circle, and bean form, which was well-regulated. We mapped irregular forms, which were not well-regulated. Regular shapes were observed at all sites. Irregular shapes were observed on the forehead in four patients (8.2%), nasal bridge in 11 patients (22.4%), right cheek in four patients (8.2%), and chin in one patient (2.0%) (Figure 3).

Accordingly, the nasal bridge was the most common site with highly severe skin changes. The nasal bridge was deemed to be the site that was most easily prone to pressure ulcers from the N mask. In the present study, we focused our analyses on the nasal bridge.

In patients who wore an N mask, a pressure ulcer developed after 24 h in 12 patients (38.7%), after three days in 13 (41.9%), after five days in three (9.6%), after seven days in two (6.5%), and on the 15th day in one (3.2%).

3. Characteristics of the non-development and development group

The 20 patients in the non-development group and 31 patients in the development group had a median age of 78 years, respectively. There were 11 male and nine female patients in the non-development group, whereas there were 17 male and 14 female patients in the development group. There was no significant difference observed between the two groups in terms of age and gender. Respiratory and cardiovascular diseases accounted for

Table 2. Comparisons within groups of patient demographics n=51

	Pressure ulcer non-development n=20	Pressure ulcer development n=31	p value
Age (median(range))[a] Years	78 (52-89)	78 (43-89)	0.779
Gender[b]			
Male	11(55.0)	17(54.8)	0.991
Female	9(45.0)	14(45.2)	
Underlying disease			
Respiratory disease[b]	11(55.0)	16(51.6)	0.813
Cardiovascular disease[b]	5(25.0)	10(32.3)	0.579
Internal secretion metabolic disorder[b]	1(5.0)	2(6.5)	0.830
Digestive system disease[c]	1(5.0)	1(3.2)	0.635
Blood immune disorders[c]	1(5.0)	1(3.2)	0.635
Cranial nerve disease[c]	1(5.0)	0	0.392
Neuromuscular system disease[c]	0	1(3.2)	0.608
BMI (mean(SD))[d]	21.5(±3.61) n=16	20.9 (±5.58) n=28	0.710

Note.Value were Number(%). a) Mann-Whitney. b) chi-square test. c) Fisher's exac. d) t-test

80% of the underlying diseases in both groups. There was no significant difference in BMI. (Table 2).

4. Risk factors for N mask-related pressure ulcers

1) Morphological characteristics of the face

The mean length of the face was 9.9 (± 0.72) cm in the non-development group, and 9.6 (± 0.95) cm in the development group with no significant difference observed (p=0.307) between the two groups. The forehead and nose angle had a median of 140.3° (range,137.7° –149.1°) in the non-development group, and 140.9° (range,137.2° –147.1°) in the development group, with no significant difference observed (p=0.655) between the two groups. Dentures were worn by 13 patients in the non-development group and 25 patients in the development group, with no significant difference observed (p=0.211).

2) External factor

A significant difference was observed between the two groups in terms of suitable mask size. Mask size was unsuitable in two patients from the non-development group and in 13 patients from the development group. Unsuitable N mask size was used for more patients in the development group than in the non-development group (p=0.021) (Table 3).

In the development group, N mask was undersized in three patients and oversized in 10 patients. The shear and shape of pressure ulcer varied among the 13 patients with unsuitable N mask; one patient had a regular shaped ulcer, whereas two patients had irregular shaped ulcers. Furthermore, among the 10 patients with oversized N masks, five had regular-shaped ulcers and five had irregular-shaped ulcers. All seven patients with irregular N mask shapes (oversized and undersized N masks) exhibited N mask shear (Figure 4).

3) Internal factor

There was no significant difference observed for any internal factor between the two groups (Table 4).

Discussion

Previous studies on N mask-related pressure ulcers have only focused on healthy adults[17], and most studies on patients were case studies[18-20] because masks could not be removed. Therefore, the risk factors were only speculative, and although prevention is important, the circumstances have not been ascertained. In the present study, we directly observed the contact site of the N mask and examined the factors associated with pressure ulcers to elucidate the status and risk factors for N mask-related pressure ulcers.

1. Incidence

In the present study, the cumulative incidence was high at 60.78%. Only one individual researcher with clinical experience as a WOCN performed the skin observations and patient assessments to ensure consistency and decrease bias. The validity of pressure ulcer assessment was guaranteed by continuing the observations and performing further observations after two and four days even if the erythema had dissipated. This was done to continuously confirm the shift to normal pigmentation and to ensure that evaluation of the development of pressure ulcers was thorough and not overlooked. An irreversible ischemia developed because of external force is the initial stage of pressure ulcer development. At this stage, we should assess the factors for the development of pressure ulcers and consequently prevent exacerbation. The high incidence of N mask-related pressure ulcers in our study once again suggested that these ulcers are a major problem.

2. N mask-related pressure ulcers

N mask-related pressure ulcers most commonly developed on the nasal bridge, and we found that in terms of severity, the nasal bridge showed the most persistent erythema and skin damage, which were not observed in other areas. Dyer [21] indicated that MDRPUs were caused by the hardness of the device, limited choice of devices, placement at a site with less body fat, and the skin. The nasal bridge has less subcutaneous fatty tissue and has a very irreversible surface area. A hard mask attached at this site can easily cause pressure ulcers. Phillips et al[22] reported that compared with other races, the soft tissue of the entire face is thin in Japanese people; this may explain why the nose was particularly affected in our study population. Furthermore, Ninomiya et al[23] attached a nasal mask to a finite element model that they created based on cross-sectional images of the head, and found that stress was applied according to finite element analysis. They reported that soft tissue thickness was approximately 26 mm on the cheeks, compared with 6.67 mm on the nasal root; and that contact pressure was the greatest on the forehead followed by the nasal root. However, the facial model that they created was based on the cross sectional body images of Westerners. In several instances, when a mask optimized for Westerners was

Table 3. Comparisons within groups of external factors n=51

	Pressure ulcer non- development n=20	Pressure ulcer development n=31	p value
Nasogastric tube[a]			
presence	13(65.0)	14(45.2)	0.166
absence	7(35.0)	17(54.8)	
Mask is fixed[b]			
Upper belt ;suitable tighten[a]			
presence	11(55.0)	13(42.0)	0.361
absence	9(45.0)	18(58.0)	
Tighten stiff [a]			
presence	9(45.0)	18(58.0)	0.361
absence	11(55.0)	13(42.0)	
There is a bilateral difference[b]			
presence	1(5.0)	1(3.2)	0.635
absence	19(95.0)	30(96.8)	
Lower belt ;suitable tighten[a]			
presence	13(65.0)	14(45.2)	0.166
absence	7(35.0)	17(54.8)	
Tighten stiff [a]			
presence	7(35.0)	16(51.6)	0.244
absence	13(65.0)	15(48.4)	
There is a bilateral difference[b]			
presence	1(5.0)	1(3.2)	0.635
absence	19(95.0)	30(96.8)	
Air leak[a]			
presence	4(20.0)	25(80.6)	0.345
absence	16(80.0)	6(19.4)	
Mask size suitability[a]			
suitable	15(75.0)	16(51.6)	0.021
unsuitable	2(10.0) n=17	13(42) n=29	
NPPV continuation days(median(range))[c]	48(24-130)	67(24-360)	0.218
Ventilation mode			
S/T[a]	8(40.0)	13(41.9)	0.891
CPAP[a]	12(60.0)	10(32.3)	0.510
Others[2]	0	8(25.8)	0.120
Pressure S/T (cmH_2O)(Mean(SD))[d]	6.8(±4.13) n=8	8.7(±4.04) n=14	0.290
PressureCPAP (cmH_2O)(Mean(SD))[d]	6.8(±4.13) n=8	7.5(±1.43) n=10	0.598
Shear of mask[a]			
presence	9(45.0)	20(64.5)	0.169
absence	11(55.0)	11(35.5)	
Frequency of the cleanliness of the face[b]			
once/day	3(15.0)	8(25.8)	0.300
more than twice/day	16(80.0) n=19	22(71) n=30	
Cleanliness of the mask[b]			
wipe mask	20(100.0)	30(96.8)	0.608
wash mask	0	1(3.2)	
Use of wound dressing[a]			
presence	14(70.0)	23(74.2)	0.685
absence	6(30.0)	8(25.8)	
Skin moisture[a]			
presence	6(30.0)	9(31.0)	0.938
absence	14(70.0)	20(69.0) n=29	
Oral in take[a]			
presence	8(40.0)	18(58.0)	0.208
absence	12(60.0)	13(42.0)	
Activity(Sitting positions)[a]			
presence	12(60.0)	20(64.5)	0.745
absence	8(40.0)	11(35.5)	

Note.Value were Number(%). a) chi-square test. b) Fisher's exact-test. C) Mann-Whitney. d) t-test

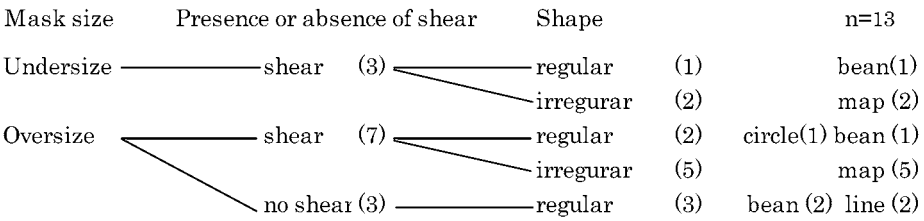

Figure 4. Presence, shape of mask size unsuitable and the shear

adapted to Japanese people, who have an underdeveloped nasal root, the upper strap needed to be tightly fastened to prevent leakage; this tends to considerably increase the pressure on the forehead and nasal root. The nose has a shape that protrudes much more than other parts of the face and differs among individuals, whereas a mask has a constant shape and may be difficult to fit everyone. It is believed that when the face moves, it should be difficult for the mask to move along with the skin on the nose.

The N masks that are currently used in Japan are manufactured overseas, and it is believed that most of these masks do not fit Japanese faces. In the future, masks should be improved in terms of shape and material flexibility. Cooper et al [24] suggested that masks should not be fixed very tightly to avoid strong pressure on the nasal protrusion; however, at present, there is no evidence to support this. In the present study, the tightness of mask fixation did not significantly affect the development of pressure ulcers. Moreover, fixation is determined at the discretion of the practitioner because there is currently no standard recommendation. In the future, fixation should be standardized for critical patients.

3. Risk factors for N mask-related pressure ulcers

In the present study that compared the non-development and development groups, a significant difference was observed in terms of suitability of N mask size. Unsuitable N mask size can result in pressure ulcers because the shape of the N mask frame does not follow the facial contours, thus, pressure cannot be equally dispersed. Nasal bridge protrusion varies considerably among patients. An unfitted mask can slip and move. It is assumed that because the nose has only thin subcutaneous tissue, mask shear can easily cause the epidermis and dermis to exfoliate; this can further displace the epidermis, resulting in an irregularly shaped mask fixation.

Based on the results of our study and previous studies, the causes of pressure ulcers can be identified from the shape. Nanjo et al[25] confirmed that the unique "leaf-type" pressure ulcer developed in ICU patients after events, such as myocardial ischemia and infection. They found that with peripheral circulatory disturbances and physical restrictions, when nurses frequently changed the position of the patient, skin changes occurred in the sacral region, resulting in "leaf-type" pressure ulcers. Fujimoto et al[26] reported that pressure ulcers on the buttocks in wheelchair-bound elderly individuals were regular in shape and were associated with pressure, whereas irregularly shaped ulcers were associated with shear force. By observing the shape of the pressure ulcer we can obtain indices to predict orientation of the external force. As in the present study, all irregularly shaped ulcers were associated with shear or damage to the N mask; thus, the presence or absence of N mask shear affected the ulcer shape.

To prevent the development of N mask-related pressure ulcers, a suitable-sized mask should be chosen for the face, and in the event of an emergency, we recommend assessing the suitable size of the N mask 24 h after application. Furthermore, it was suggested that correspondence should be provided upon the assessment of whether pressure or shear force was generated based on the shape of the ulcer.

Limitation

In identifying risk factors for pressure ulcers, the measurement of interface pressure is an indispensable parameter. Due to the fact that investigation was conducted with the utmost priority of safety for critical patients, contact pressure at the site of N mask adhesion could not be measured. Munckton et al[13] measured contact pressure at three sites, including the nose and both cheeks, in healthy adults when NPPV was administered. They found that upon applying continuous positive airway pressure (CPAP) at 5 cmH_2O, pressure was 67.8 mmHg

Table 4. Comparisons within groups of internal factors n=51

	Pressure ulcer non- development n=20	Pressure ulcer development n=31	p value
Physical state(Mean(SD))			
Blood pressure			
Contraction phase(mmHg)[a]	128(±22.52)	121(±20.76)	0.211
Diastolic phase(mmHg)[a]	65(±11.83)	64(±13.79)	0.786
Pulse(/min)[a]	91(±14.24)	92(±23.3)	0.964
Temperature(℃)[a]	37.0(±0.55)	37.1(±0.90)	0.388
Respiratory rate(/min)[a]	26(±8.72)	26(±8.74)	0.931
Blood test(Mean(SD))			
Hct(%)[a]	32.3(±8.11) n=19	32.9(±5.65) n=23	0.672
Hb(g/dl)[b]	9.7(±2.84) n=19	10.6(±2.41) n=23	0.770
WBC(×10^3/μL)[a]	10.4(±4.90) n=19	10.0(±3.91) n=23	0.573
RBC(×10^4/μL)[a]	345.6(±73.3) n=19	356.0(±57.94) n=23	0.536
Plt(×10^3/μL)[b]	143(±58.68) n=19	151(±64.64) n=23	0.742
Blood gases data(Mean(SD))			
PaO_2 Torr(mmHg)[a]	65.9(±27.17) n=19	67.9(±29.80) n=22	0.929
$PaCO_2$ Torr(mmHg)[b]	41.5(±13.27) n=19	47.5(±13.25) n=22	0.690
HCO3-(mEq/L)[a]	27.9(±6.70) n=19	28.9(±6.59) n=22	0.748
pH[a]	7.44(±0.05) n=19	7.40(±0.086) n=22	0.141
SPO_2(%)[a]	94.6(±0.347)	94.7(±2.40)	0.810
Biochemical examination of blood(Mean(SD))			
Na(mEq/L)[b]	142(±83) n=19	140(±5.03) n=23	0.568
K(mEq/L)[a]	3.9(±0.49) n=19	4.1(±4.10) n=23	0.257
Cr(mg/dl)[b]	1.1(0.47) n=19	1.1(±0.731) n=23	0.810
Alb(g/dL)[b]	2.6(±0.54) n=19	2.9(±0.54) n=23	0.710
Bil(mg/dL)[b]	1.3(±1.06) n=19	1.2(±1.29) n=23	0.594
Glu(mg/dL)[b]	169.6(±53.7) n=19	180.5(±82.5) n=23	1.000
State of consciousness(Mean(SD))			
GCS[b]	13.8(±2.24)	14.0(±2.03)	0.548
Evaluation of the severity(Mean(SD))			
APACHEⅡ[b]	19.3(±5.06)	19.4(±5.00) n=28	0.592
SOFA[a]	6.3(±2.5) n=19	5.8(±2.59) n=20	0.492
Edema around the orbit(n(%))[c]			
presence	17(85.0)	24(77.4)	0.387
absence	3(15.0)	7(22.6)	
Diabetes(n(%))[d]			
presence	11(55.0)	11(35.5)	0.169
absence	9(45.0)	20(64.5)	
Use of drug(n(%))			
Use of steroid(oral)[c]			
presence	5(25.0)	5(16.1)	0.501
absence	15(75.0)	26(83.9)	
Use of steroid(injection)[c]			
presence	6(30.0)	6(19.4)	0.293
absence	14(70.0)	25(80.6)	
Use of catecholamine[c]			
presence	3(15.0)	6(19.4)	0.613
absence	17(85.0)	25(80.6)	

Note.Value were Number(%). a) t-test. b) Mann-Whitney. c) Fisher's exact-test. d) chi-square test.

for the nose, 15.7 mmHg for the left cheek, and 16.3 mmHg for the right cheek, with a significant difference in pressure between the nose and both cheeks. It was inferred that contact pressure was higher on the nose. Also, as the present study targeted Japanese individuals, the validity of our results cannot be generalized to include Westerners who tend to have different facial contours. Moreover, the researcher directly visited the medical institutions to conduct cutaneous observations and assessments; this may have altered the perception of the staff regarding pressure ulcers. It is possible that this resulted in the Hawthorne effect and influenced the development of N mask-related pressure ulcers.

Conclusion

We prospectively observed 51 patients to examine the state and risk factors for N mask-related pressure ulcer and obtained the following findings.

1. The incidence was 15.27 people per day and the cumulative incidence was 60.78%.

2. The nasal bridge was the most common site with highly severe and irregularly-shaped skin changes.

3. Unsuitable mask size was determined as the cause of N mask-related pressure ulcers.

Accordingly, it was suggested that to prevent N mask-related pressure ulcers, nursing intervention should include selecting an suitable mask size 24 h after the condition of critical patients has eased and determining whether there is pressure or shear force based on the shape of the ulcer.

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非侵襲的陽圧換気療法のマスクによる圧迫創傷の発生要因の抽出

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要　　旨

近年、注目されている医療関連機器圧迫創傷の中でも重篤な呼吸障害に対してマスクを顔に密着させて呼吸管理を行う非侵襲的陽圧換気療法（NPPV = noninvasive positive pressure ventilation）は、マスクによる圧迫創傷が発生すると、患者は呼吸困難という危機的状況に加えてNPPVの継続が難しくなることから生命をも脅かされる。しかし、これまでマスクが外せないという理由で発生要因および予防の指標は明らかにされなかった。

今回、NPPVのマスクによる圧迫創傷の発生要因を抽出することを目的に、患者のマスク密着部の皮膚の状態を観察するとともに顔の形態的特徴、外的要因、内的要因の関係から原因を検討した。

対象は51名であり圧迫創傷非発生20名、発生31名、累積発生率は60.8％であった。発生部位は鼻背が最も多く、深達度も持続発赤28名、また他の部位ではみられない真皮までの損傷が3名あった。形状でも特徴的な不定形が特に鼻背に多くみられた。調査項目で有意差があったものはマスクサイズ不適合であり、創傷発生した人はサイズ不適合のマスクを装着している人が多かった（$p = 0.021$）。また、マスクサイズ不適合の人13名のうち形状は不定形が7名であり、全員マスクのずれを伴っていた。

以上より、NPPVマスクの圧迫創傷の発生要因は、マスクサイズ不適合による圧力とずれが関連していることが考えられた。NPPV導入時はクリティカルな状態であり全身管理が最優先されるが、患者の状態が落ちついた24時間以後には適切なマスクサイズを選択することが圧迫創傷の予防に繋がるとともに、圧力やずれ力に対する対策が必要であることが示唆された。