The Level of Comfort among Patients Treated with Helmet Non-Invasive Ventilation (NIV) Therapy

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ABSTRACT

Introduction

Studies suggested that helmet noninvasive ventilation (NIV) therapy is more tolerated with better clinical outcomes than the other interfaces in treating Acute Respiratory Failure (ARF) patients. However, helmet NIV intolerance and failure are the typical responses reported. Since the helmet NIV is new in Malaysia, therefore this study was proposed to provide an overview of the comfort level of ARF patients who have been treated using helmet NIV. Thus, the aim of this study was to investigate the comfort level of the patient treated with helmet NIV therapy.

Methods

This study was using a quantitative, descriptive design. Sixty-seven (67) ARF patients completed helmet NIV therapy were purposively selected from the Emergency Department in one of the Northern Malaysia public hospitals. After at least 15 minutes post therapy and confirmed hemodynamically stable, patients were asked to score their comfort level on a 0-100 mm visual analog scale (VAS), where 0 is the most comfortable and 100 is the most uncomfortable.

Results

Evaluation by VAS scores were completed by 43 male and 24 female ARF patients, with the mean age of 65.03 (SD 12.43). The general comfort level was moderate, with the mean score of 24.17, SD 20.53.

Conclusion

The study provides an overview and insight on the level of comfort of the patient, who has been treated with helmet NIV. This knowledge can provide a basis for the development of therapy improvement.

Keywords

Acute Respiratory Failure; Comfort Level; Helmet NIV

BACKGROUND

Comfort is a core component in patient-centered care (PCC); a contemporary strategy introduced by the Institute of Medicine (IoM) to heighten the health care quality (1). This strategy emphasized the active and meaningful involvement of the patient in care provision, to ensure the service provided optimally fulfils their needs (1,2). This strategy is parallel to the World Health Organization (WHO) framework on integrated people-centered health services in ensuring the coordinated, individualized, safe, effective, efficient, affordable and high-quality health care system are accessible to everyone (3). Malaysia in its latest Eleventh National Plans is also sharing the same strategy (4); integrating comfort as an ultimate goal of healthcare provision. Undeniably, the practice of comfort care or PCC leads to positive consequences; such as an increase in patient satisfaction, increase in treatment adherence and better health outcome (5).

The rapid progression of ventilation support is an example of quality care improvement. Congruous with the PCC concept, the numbers of comparative studies between noninvasive ventilation (NIV) interfaces are escalating in inquiring the most effective and superior interface (6) in managing patient with Acute Respiratory Failure (ARF). Helmet NIV (refer Figure 1.2) turns out to be one of the preferred latest NIV interfaces, considering to abundance of positive outcomes: improve oxygenation (7–9), reduce work of breathing (10), more comfort and better tolerance (8,11–13), lower incidence of delirium and sedative requirement (14), ease oral and enteral intake (15) and reduce the risk for endotracheal intubation (7,16,17), which collectively reduce mortality rate (7,17,18), and reduce length of hospital stay(18). All of these indirectly contribute to cost-effective ARF management (19).

Figure 0: Helmet NIV

Despite the superiority of helmet NIV over the other interfaces, treatment intolerance is a typical response demonstrated by helmet NIV therapy recipients. Based on one comprehensive qualitative review of randomized trials (6) on common NIV interfaces including helmet NIV, there were 30-50 % of NIV intolerance incidences occurred, with 12-33% were NIV failure due to discomfort despite the best effort demonstrated by the skilled caregivers. This is further weighted through the

empirical evidences of comfort detractors of helmet NIV: such as patient-ventilator asynchrony (20,21), interface-related complications (6,22), claustrophobia (6,8,23,24), noise (8,11,13), humidity and temperature issues (13,23,25) which indirectly germinate the feeling of fear and anxiety (26) among patients and contribute to the incident of NIV intolerance and failure as aforementioned figures.

In the local context, the application of helmet NIV in managing ARF patients in Malaysia is still in the infancy stage, as it was just introduced in 2013. As far as the researcher's knowledge, only three government hospitals have been integrated helmet NIV as their ARF treatment modality. However, only one hospital (the research setting) bents it as a gold standard in ARF management. Looking at the positive impacts of helmet NIV, this ingenious effort of introducing helmet NIV in patient's care is parallel to the call of PCC. However, given to the downsides of helmet NIV on the aspect of physical, psychological, social and environmental, the cautious plans and actions should be exercised. According to PCC concept, comfort is a significant need that crucial to catalyze a positive experience that able to empower the patients. Furthermore, comfort which is also can be implied as treatment outcome, is valuable information in reflecting the overall level of care (27). In relation to this, there is an obvious requirement for a study focusing on the comfort level of patients on helmet NIV therapy. Thus, this study was conducted to investigate the level of comfort of ARF patients treated with helmet NIV.

METHOD

This study is a quantitative descriptive study. The study was conducted at Emergency Department of Hospital Raja Permaisuri Bainun, Ipoh, Malaysia. Permission granted from concerned authorities for conducting research. In this study, the target population was patients treated with helmet NIV, specifically helmet NIV with Continuous Positive Airway Pressure (CPAP) mode. The total of 67 samples was selected by using non-probability purposive sampling. The inclusion and exclusion criteria were followed to ensure the homogeneity of the sample chosen.
The inclusion criteria of this study are any ARF patients, who;

1. were over 18 years old of age,
2. require helmet CPAP therapy,
3. were hemodynamically stable after helmet CPAP therapy, as confirmed by the doctor,
4. were able to provide informed consent, and
5. were able to understand and speak English or Malay language.

The exclusion criteria of this study are any ARF patients, who were;

1. received other than helmet CPAP (helmet with Bilevel Positive Airway Pressure (BiPAP) mode, other NIV interfaces, advanced airway adjunct, intubation)

2. unable to hear, and
3. with learning disabilities.

The data collection began after the completion of helmet CPAP therapy. To be precise, the data were taken after at least of 15 minutes post therapy and confirmed to be hemodynamically stable as comfirmed by the in charge doctor. A comfort score was obtained from the patients using the Visual Analogue Score (VAS), without any undue influence. Before that, the VAS scale was shown to patients and the explanation on how to rate it was given. The patients were then asked to place a mark (|) on the horizontal line of the VAS score chart corresponding to their perception of their comfort level after been treated with helmet CPAP. There is four cut-off of the scale, as shown in Table 1. Data were analysed using descriptive analysis of statistical software Statistical Package for the Social Sciences (SPSS), version 21.

Table 1: Cut-off of VAS

Level Of Comfort	**Scoring**
Most Comfortable	0-4 mm
Moderate level of Comfort	5-44 mm
Mild level of Comfort	45-74 mm
Not Comfortable At All	75-100 mm

RESULT

The sample consists of 67 participants, with the mean age of 65.03, with standard deviation (SD) 12.43. There were 64.2 % male and 35.8% female. Malay contributed the larger percentage of participants, followed by Indian, Chinese and Other with the rate of 41.8%, 32.8%, 23.9% and 1.5% respectively. As for the diagnosis, more than half of patients treated with helmet CPAP were Acute Pulmonary Oedema (APO) patients (52.2%), while the remaining were non-APO patients (47.8%). Table 2 summarizes the participants' profile of this study. Those who were non-APO, were commonly diagnosed either as Chronic Lung Diseases; such as bronchiectasis or Acute Exacerbation Chronic Obstructive Airway Disease (AECOAD), Acute Coronary Syndrome (ACS), Congestive Cardiac Failure (CCF), Community-Acquired Pneumonia (CAP), Fluid Overload or End Stage Renal Failure (ESRF), or combination of aforementioned diagnoses that forces the usage of helmet CPAP.

Table 2: The profile of participants (*N*=67)

Variable	**Frequency**	**(%)**
Age, mean (SD)	65.03	12.43

Gender:		
Male	43	64.2
Female	24	35.8
Race:		
Malay	28	41.8
Chinese	16	23.9
Indian	22	32.8
Other	1	1.5
Diagnosis:		
APO	35	52.2
Non-APO	32	47.8

The VAS Score of Perceived Comfort of Patient with Helmet Ventilation Therapy

The general comfort level of participants after completion of helmet ventilation therapy was considered as moderate, as indicated by the mean score of 24.17, SD 20.53. When the detailed analysis was performed on participants' level according to the type of diagnosis: APO versus non-APO, the individual mean score specifies similar pattern with the value of 20.57, SD 18.30 and 28.13, SD 22.35 respectively. The large SD value reflects that the comfort scores were distributed out over a broader range of values. It can be observed through the comfort score frequency in each comfort level; as 22.40 % participants rated their comfort level as most comfortable; within the range of 0- 4 mm. Majority of the participant (62.70%) ranked as moderately comfort in any range of 5- 44 mm, 10.40 % rated between 45-74 mm which indicate the mild level of comfort and few (4.50%) rated as totally discomfort: within the range of 75-100 mm, which indirectly affects the score distribution. Table 3 and 4 provide the details.

Table 3: Mean of comfort score based on VAS

Variable	**Mean of VAS Score**
Comfort score[a], mean (SD)	24.17 (20.53)

a Mean based on the re-coded score.

Table 4: General comfort level based on diagnosis

Level of Comfort Based on VAS Score	**Diagnosis**	
	APO	**Non-APO**
Comfort score, mean (SD)	20.57 (18.30)	28.13 (22.35)

Comfort level		
Most comfortable (%)	8 (11.90)	7 (10.4)
Moderate level of comfort (%)	24 (35.80)	18 (26.90)
Mild level of comfort (%)	2 (3)	5 (7.50)
Not comfortable at all (%)	1 (1.50)	2 (3)

DISCUSSION

In this study, we found that most of the ARF patients who were undergoing helmet NIV therapy experienced a moderate level of comfort. However, this is not a surprising finding as numerous earlier studies found the almost similar result. One study conducted on a healthy individual found noise, temperature and ear pressure as factors that contribute to discomfort state (13), whereas another study, agreed the comfort is relatively correlated to humidification and temperature inside the helmet NIV (25). Apart of it, other studies specified further contributing factors such as patient-ventilator asynchrony (21), interface-related skin ulcer (22) and claustrophobia (8). As presented in table 3 and 4, the mean of comfort value is profoundly influenced by the uneven distribution of the comfort score rated by the participants. This result indicates that each perceived the comfort experience with helmet NIV differently. One descriptive phenomenological study on patients' experience on helmet NIV, proved that each responded differently; ranging from reluctantly to willingly accepting the therapy, although the participants managed to complete the treatment (23). The study result also is congruent with the findings of one thematic synthesis (26) which attributed the experience of being on the NIV as unexpected and stressful. Having said so, further study to understand the overall perception and experience of patients on helmet NIV is required. The survey which concerns specific factors that impede the comfort state during helmet NIV therapy is also needed. Thus the focused corrective action can be done, consistent with the PCC concept.

LIMITATION

The main limitation of this study was recruiting challenges. This study was conducted only in one center, and sample was taken purposively among ARF patients, who were receiving helmet CPAP. Though this sampling is reasonable to ensure representativeness of the population but the generalizability of the finding may be limited. Hence, the results of this research cannot necessarily be generalized beyond the population studied. As to confirm the generalizability of the research's finding to other settings, replication of this research is required. Future research may want to employ probability sampling method and examine the proposed framework across different context, particularly different sample and helmet mode (BiPAP)

CONCLUSION

This research was an attempt to investigate the level of comfort of ARF patients, who were receiving helmet NIV therapy. The proposed research framework has enabled the generation of required findings on comfort value of the therapy given, which also can be reflected as treatment outcome. Having knowledge on these facts will assist in the provision of health care as per PCC standard and the goal set by the government.

Declaration

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Ethics approval and consent to participate
Medical Research Ethics Committee of Universiti Teknologi Mara (UiTM), Selangor, National Medical Research and Committee (MREC) of Ministry of Health (MOH), Malaysia and Director of Hospital Raja Permaisuri Bainun (HRPB), Ipoh and Head of Emergency Department of HRPB, Ipoh. Both verbal and written expressed consent were taken from patient prior the data collection process.

Consent for publication
Medical Research Ethics Committee of Universiti Teknologi Mara (UiTM), Selangor, National Medical Research and Committee (MREC) of Ministry of Health (MOH), Malaysia

Availability of data and materials
Model of helmet NIV consented the use of his picture.

Competing interests

The authors have no conflict of interest to declare.

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