Non-invasive mechanical ventilation vs. oxygen mask following successful weaning from invasive mechanical ventilation in a pediatric tertiary center

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AUTHOR CONTRIBUTIONS

MMA, KS, and MAF designed the study, followed the patients. MKT and AMA analyzed the data and drafted the manuscript. All authors were involved in the critical analysis of the final version of the manuscript. All authors approved the manuscript as submitted and agree to be accountable for all aspects of the work.

Abstract
Objective: This study aimed to evaluate outcome measures in pediatric patients who underwent non-invasive mechanical ventilation (NIMV), as compared to conventional oxygen mask recipients, following successful invasive mechanical ventilation (IMV).
Methods: This randomized observational trial included 110 pediatric patients with respiratory failure and connected to IMV. Patients were randomly categorized into two groups of equal numbers (n=55). Group (I) included oxygen mask recipients, while group (II) included patients who underwent NIMV. The outcome measures were assessed in both groups.
Results: The differences between groups as regards age, sex, causes of connection, and duration of IMV were not significant; however, the mean length of stay at the PICU post disconnection of IMV, was significantly shorter for group II compared to group I (2.55 ± 1.42 vs. 4.76 ± 2.01 days, $p<0.01$). The number of patients with the normal respiratory rate (RR) was higher in group II as compared to group I ($p<0.05$ at 3, 12, and 48 hours). Group II had significantly fewer patients requiring reconnection to the ventilator than group I patients (4 cases vs. 12 cases, $p=0.03$).
Conclusion: NIMV was superior to conventional oxygen delivery by facemask; NIMV significantly decreased the duration of hospital stay and the risk of patient's reconnection to IMV. Moreover, NIMV led to a significant improvement in RR post successful IMV weaning.
KEYWORDS: Non-invasive mechanical ventilation, Oxygen Mask, Weaning, children

"What this paper adds"

Section 1: What is already known on this subject:
Non-invasive ventilation (NIMV) is a promising therapeutic option in the PICU; it is a critical ventilatory support after successful IMV weaning. There are few studies on the use of NIV in pediatrics. Thus, the purpose of our study was to assess the frequencies of acute respiratory failure, reintubation, length of stay in PICU, in patients who received non-invasive mechanical ventilation rather than the routine oxygen face mask following successful weaning.

Section 2: What this study adds

Non-invasive ventilation was superior to conventional oxygen delivery by facemask; NIMV significantly decreased the duration of hospital stay and the risk of patient's reconnection to IMV. Moreover, NIMV led to a significant improvement in RR post successful IMV weaning. So NIMV is recommended in pediatric patients following successful weaning.

1. Introduction

Mechanical ventilation (MV) is crucial in the pediatric intensive care unit (PICU). It was estimated that about 30-64% of pediatric patients requiring MV and hospitalized in PICU [1]. Weaning should begin once the patient can breathe spontaneously. The disconnection process includes two situations: weaning "progressive decline in ventilation" and extubation "removal of the endotracheal tube" [2]. Although invasive ventilation is effective, it has some complications such as upper airway pathology, respiratory muscle weakness, ventilator-associated pneumonia, and sinusitis [3].

Non-invasive ventilation (NIV) is mechanical ventilation (MV) administration without using an endotracheal tube or tracheostomy. It was first used in adults by the end of the 1980s and is increasingly used in PICUs. NIV is a way of assisting a patient's breathing that utilizes positive pressure ventilation through an oronasal, nasal, or complete face mask at the patient-ventilator interface. Additionally, NIV protects the patient's capacity to speak and cough and has been proven to decrease intubation-related problems, including ventilator-associated pneumonia [4].

For many reasons, achieving effective ventilatory support without intubation and its complications is relevant in pediatric patients. Like invasive ventilation, NIV can alleviate respiratory distress, increase tidal volume, promote gas exchange, and rest the respiratory muscles [3]. Additionally, NIV is frequently utilized in lieu of invasive ventilation in clinically stable patients but have developed acute hypercapnic respiratory failure [5]. Moreover, it has been reported that NIV is an effective and safe mode of support for pediatric patients with acute respiratory distress syndrome and respiratory failure; it has been shown to reduce the need for intubation and ventilation, shorten the length of stay in PICU, and improve patient comfort [6].

There are few studies on the use of NIV in pediatrics. NIV is a promising therapeutic option in the PICU; it is a critical ventilatory support alternative [7]. Thus, the purpose of our study was to assess the frequencies of acute respiratory failure, reintubation, length of stay in PICU, in patients who

received non-invasive mechanical ventilation rather than the routine oxygen face mask following successful weaning.

2. Patients and methods

2.1.Ethical considerations:

The ethical committee approved the study protocol and all procedures of the Department of Pediatrics, Faculty of Medicine, Assiut University. Written informed consent for mechanical ventilation was obtained from the parents or guardians of the cases as a routine in our PICU.

2.2.Patients

This randomized observational study was carried out at the PICU of Assiut university children's hospital from January 2017 till December 2019. The study was conducted on 110 child patients (aged one month to 18 years) who presented with respiratory failure and connected to invasive mechanical ventilation. Patients were randomly divided into two equal groups (n=55 each); group (I) included patients who received oxygen by mask, and group (II) included patients who received Non-invasive mechanical ventilation after successful weaning from MV. Our study included all the patients aged from one month up to the age of 18 years admitted to the PICU and connected to invasive mechanical ventilation for more than 24 hrs and underwent a successful weaning process. We excluded all patients who were ineligible for NIV (patients with maxillofacial trauma, gastrointestinal obstruction, and severe irreversible organ failure), patients with chronic diseases as congenital heart disease, chronic pulmonary diseases, chronic neurological conditions (as myopathy, neuropathy, and cerebral palsy).

2.3.Methods

All participants were subjected to complete history taking and clinical examination, including vital data, oxygen saturation, skin color, and mental status at the time of extubation and followed up at 1, 3, 6, 12, 24, 48 hours. Total days before disconnection of ventilation and days of PICU stay after

disconnection from ventilation were recorded. The routine investigations were done, including complete blood count, blood Na, K, Ca, serum creatinine, liver enzymes, albumin, CRP, and arterial blood gases. The primary outcome was to measure the risk of respiratory failure in patients who used Non-invasive ventilation and causes of the connection between groups were recorded. The secondary outcome was to measure the length of hospital stay in patients who used Non-invasive ventilation and monitor any complications due to its use.

2.4.Statistical analysis

SPSS version 20 was used to analyze the data. The mean and standard deviation were used to express quantitative data (SD). The frequency and percentage of qualitative data were reported. The Chi-Square test was used to compare groups based on qualitative data, whereas the independent sample T-test or Mann–Whitney U test was used to compare groups based on quantitative data. Significant value was defined as a probability less than 0.05.

3. Results:

Table (1) shows no significant differences between groups regarding age, sex, and the total days before disconnection of ventilation. However, the mean PICU stay after disconnection of ventilation was significantly shorter in NIMV group compared to oxygen mask group (2.55 ± 1.42 vs. 4.76 ± 2.01 days, $p<0.01$). Regarding O2 saturation, no significant differences were found between groups at different follow-up intervals except at 48 hrs, where NIMV group had a significantly higher number of patients with normal values. The number of cases with normal RR was higher in NIMV group compared to oxygen mask group ($p<0.05$ at 3hrs, 12 hrs, and 48 hrs), and the improvement in RR was noticed in NIMV group just after 1 hour and continued at all follow-up intervals compared to the immediate value. In contrast, the improvement was started at 24 hrs in oxygen mask group. There was an improvement in heart rate in NIMV compared to oxygen mask group ($p=0.03$ at 12 hrs.). In addition, there were no significant differences between the two groups regarding body

temperature, skin color, blood pressure, and mental status at all follow-up intervals (Table 1). There was no significant difference between groups regarding causes of connection (Table 2). The number of cases who needed reconnection to ventilator was higher in O2 mask group compared to NIMV group (p=0.03). Table 3 shows the frequency and causes of reconnection to mechanical ventilation in studied groups. No significant differences were found between groups regarding all laboratory data and blood gases.

4. Discussion:

While MV increases survival in pediatric patients, it also has the potential to cause complications such as lung injury, ventilator-associated pneumonia, and right ventricle dysfunction [2].

Non-invasive ventilation is an alternative to intubation that allows for the provision of MV in the treatment of acute respiratory failure in infants and children and aids in the rapid restoration of diaphragmatic function. [8].

The present study included 110 pediatric patients who presented with respiratory failure and connected to invasive mechanical ventilation. These patients were randomly divided into two equal groups. Group (I) received oxygen by mask, and group (II) received Non-invasive mechanical ventilation. After successful weaning, we compared the vital data, reintubation, and length of PICU stay among both groups. Data about NIV use after successful weaning in pediatrics in our locality are scarce. In this study, both groups were almost homogenized with no significant differences between the baseline characteristics and mechanical ventilation causes to ensure accurate results from comparisons between studied procedures.

The present results revealed that the mean PICU stay period after disconnection from ventilation was significantly shorter in NIMV group compared to oxygen mask group. Our results agreed with those of El-Naggar et al. [9]. They examined the effect of NIV on the outcome of extubated chronic hypercapnic patients in the respiratory intensive care unit and compared it to standard oxygen

therapy. They found that ICU stay after extubation was significantly shorter in NIV group patients than in conventional oxygen therapy group (1.6 ± 0.49 vs. 6.13±1.79 days P<0.01). Other reports showed that the length of ICU stay after extubation in patients receiving NIV was statistically shorter than that of patients receiving conventional oxygen [10, 11]. In contrast, others reported a non-significant difference [12].

In this study, no significant differences were found between groups regarding O2 saturation at different follow-up intervals except at 48 hrs., where NIMV group had a significantly higher number of normal values. Similar findings were reported by Adıyeke et al. [13] reported similar findings, who found that the number of patients who developed respiratory failure in the NIV group was significantly lower than the venturi face mask group. "Using NIV decreased respiratory failure ratio after extubation by 64%". Also, NIV decreased reintubation and mortality rate by 8%. In addition, Ornico et al. [12] reported similar findings, adding that the relative risk analysis indicated that the use of NIV immediately following extubation was beneficial, and the use of NIV to avoid reintubation was approximately eight times more frequent in patients with acute respiratory failure when compared to the oxygen mask.

An earlier study [14] reported that 85% of patients in the NIV group were discharged from the ICU, compared to 52% in the conventional oxygen therapy group, and 15% of patients in both groups had respiratory failure following extubation.

Additionally, Ferrer et al. [15] reported that the use of NIV significantly decreased the incidence of respiratory failure following extubation and the rate of ICU mortality. Respiratory muscle dysfunction is a significant disease that contributes to the development of respiratory failure in patients, and NIV assistance has been shown to improve respiratory muscles in patients with acute and chronic heart failure [16]. Another possibility is that there were direct increases in transmural

pulmonary arterial occlusion pressure during T-piece application, which might have been prevented by employing intrathoracic pressure to lower the heart's preload and afterload.

Moreover, Hussein et al. [17] reported that NIPPV administered immediately after extubation lowered reintubation, mortality, ICU stay, and the rate of development of several therapy-related sequelae in patients with hypercapnic respiratory insufficiency. Additionally, Nava and Hill [18] reported that early extubation with immediate application of NIV has a beneficial effect on critical outcomes, such as the incidence of ventilator-associated pneumonia, the length of ICU and hospital stay, and the total duration of mechanical ventilation, in addition to reducing patient mortality. Additionally, a recent Cochrane database comprehensive review found that using NIV to treat acute hypercapnic respiratory failure in patients with COPD decreased mortality by 46% and the requirement for reintubation by 65% [19]. NIV has been shown to be beneficial in reducing the time required for MV weaning in stable patients recovering from an episode of acute respiratory failure who had previously failed a conventional weaning trial. Additionally, NIV has been shown to reduce mortality and pneumonia rates without increasing the risk of weaning failure, primarily in patients with chronic obstructive pulmonary disease [20]. NIV is a feasible and safe method of ventilatory aid in the treatment of mild acute respiratory failure [21]. Additionally, NIV was utilized as the predominant mode of ventilation in children with a low respiratory tract infection, in patients with acute or chronic respiratory insufficiency, or to avoid reintubation.

Regarding our study, the NIMV group had a significantly lower number of cases needing reconnection to ventilator than the oxygen mask group (4 cases vs. 12 cases, $p=0.03$). There was no significant difference between both groups regarding causes of connection, and chest causes were the leading causes in both. Similar findings were observed by Adıyeke et al. [13] and Vargas et al. [22]. Recently, Pavone et al. (2020). [23] studied the characteristics and the outcomes of long-term MV in pediatrics, and they found that children suffered mainly from neuromuscular complications

(30.6%), upper airway (24.8%), and central nervous system diseases (22.7%). Esteban et al. [24] found that the main cause of reintubation in their trial was a lack of improvement in signs of muscle fatigue in 45% of patients of both groups, followed by persistent hypoxia in 16 and 29% of both groups, respectively. In a previous meta-analysis evaluating the role of NIV in post-extubation respiratory failure (included 13 RCTs), Krishna et al. [25] observed that prophylactic NIV significantly reduced the rate of reintubation and mortality in patients. Bandyopadhyay et al. [26] found positive effects of NIV during decannulation in a group of chosen pediatric patients with severe upper airway obstruction, as well as in the treatment of respiratory failure following decannulation. Non-invasive ventilation has been used for a variety of reasons during MV withdrawal, including advancing extubation in patients who have had difficult or prolonged weaning, preventing the development of post-extubation respiratory failure, and avoiding reintubation in patients who have developed post-extubation respiratory failure [27]. Our work and previous research indicate that NIV is a valuable and safe modality of support for children with acute respiratory distress syndrome and respiratory failure since it may reduce the need for intubation and ventilation, shorten intensive care days, and improve patient comfort [6]. This study is not without limits. Among these, patient enrollment in each group could have contributed to selection bias.

5. Conclusion

Using NIMV significantly decreased the length of hospital stay and the risk of invasive ventilation reconnection frequency. Also, respiratory failure was lower when NIMV was used after extubation, even if the patient is regarded as "successfully weaned." NIMV helps patients with severe lung pathology to be weaned from invasive ventilation, and it can help many patients with multiple organ failure in the early termination of invasive ventilation. So NIMV is to be recommended in such patients to avoid unexpected ventilator failure.

Declarations

Conflict of Interest

The authors declare no competing interests.

Ethics Approval

All protocols and investigations of our study followed the regulations of the research ethics committee of Assiut University.

Consent to Participate

All caregivers of all participants have given their informed written consent.

Consent for Publication

Not applicable.

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Tables

Table (1): Baseline clinical characteristics and follow up between groups.

Variable		Group (I) Oxygen Mask (n=55)	Group (II) NIMV (n=55)	*P*. Value
Age (year)		8.01 ± 3.02	7.34 ± 2.38	0.20
Gender	**Male**	27 (49.1%)	30 (54.5%)	0.57
	Female	28 (50.9%)	25 (45.5%)	
Total days consumed before disconnection of ventilation		3.57 ± 1.54	3.39 ± 1.68	0.56
Total days of PICU stay after disconnection of ventilation		4.76 ± 2.01	2.55 ± 1.42	**< 0.01***
Oxygen saturation	**Immediate**	46 (83.6%)	45 (81.8%)	0.80
	1 h	46 (83.6%)	48 (87.3%)	0.59
	3 hrs.	47 (85.5%)	51 (92.7%)	0.22
	6 hrs.	48 (87.3%)	51 (92.7%)	0.34
	12 hrs.	49 (89.1%)	52 (94.5%)	0.30
	24 hrs.	50 (90.1%)	53 (96.4%)	0.24
	48 hrs.	51 (92.7%)	55 (100.0%)	**0.04***
Respiratory rate	**Immediate**	42 (76.4%)	43 (78.2%)	0.82
	1 h	44 (80.0%)	50 (90.1%)	0.10
	3 hrs.	45 (81.8%)	52 (94.5%)	**0.04***
	6 hrs.	47 (85.5%)	52 (94.5%)	0.11
	12 hrs.	48 (87.3%)	54 (98.2%)	**0.04***
	24 hrs.	50 (90.1%)	54 (98.2%)	0.09
	48 hrs.	50 (90.1%)	55 (100.0%)	**0.02***
Heart rate	**Immediate**	39 (70.1%)	38 (69.1%)	0.84
	1 h	41 (74.5%)	44 (80.0%)	0.49
	3 hrs.	44 (80.0%)	48 (87.3%)	0.30
	6 hrs.	47 (85.5%)	50 (90.1%)	0.38
	12 hrs.	48 (87.3%)	54 (98.2%)	**0.03***
	24 hrs.	52 (94.5%)	55 (100.0%)	0.07
	48 hrs.	55 (100.0%)	55 (100.0%)	1.0
Blood pressure	**Immediate**	51 (92.7%)	52 (94.5%)	0.70
	1 h	52 (94.5%)	54 (98.2%)	0.31
	3 hrs.	53 (96.4%)	54 (98.2%)	0.56
	6 hrs.	55 (100.0%)	55 (100.0%)	1.0
	12 hrs.	55 (100.0%)	55 (100.0%)	1.0
	24 hrs.	55 (100.0%)	55 (100.0%)	1.0
	48 hrs.	55 (100.0%)	55 (100.0%)	1.0
Mental status	**Immediate**	51 (92.7%)	52 (94.5%)	0.70
	1 h	53 (96.4%)	54 (98.2%)	0.56
	3 hrs.	55 (100.0%)	55 (100.0%)	1.0
	6 hrs.	55 (100.0%)	55 (100.0%)	1.0
	12 hrs.	55 (100.0%)	55 (100.0%)	1.0
	24 hrs.	55 (100.0%)	55 (100.0%)	1.0
	48 hrs.	55 (100.0%)	55 (100.0%)	1.0

Chi-square test was used to compare between groups. * Significant

Table (2): Causes of connection to mechanical ventilation in studied groups.

Causes of connection		Group (I) Oxygen Mask (n=55)	Group (II) NIMV (n=55)	*P*. Value
Chest causes	**Pneumonia**	11 (20.0%)	14 (25.5%)	0.52
	Bronchiolitis	10 (18.2%)	7 (12.7%)	
CNS causes		9 (16.4%)	11 (20.0%)	
Multisystem affection		10 (18.2%)	9 (16.4%)	
Poisoning & toxicity		8 (14.5%)	7 (12.7%)	
Gastroenterology		7 (12.7%)	7 (12.7%)	

Chi-square test was used to compare between groups.

Table (3): Frequency and causes of reconnection to mechanical ventilation in studied groups.

Variable		Group (I) Oxygen Mask (n=55)	Group (II) NIMV (n=55)	*P*. Value
Cases needed reconnection		12 (21.8%)	4 (7.3%)	**0.03***
Causes	**Respiratory**	6 (50.0%)	2 (50.0%)	0.19
	Neurologic	4 (33.3%)	1 (25.0%)	
	Multisystem affection	2 (16.7%)	1 (25.0%)	

Chi-square test was used to compare between groups. *Significant