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ORIGINAL ARTICLE

Effectiveness of using the Mask with Innovative Nutrition Adaptor of Non-Invasive Mechanical Ventilation Machine for Patients with COVID-19

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ABSTRACT

Background: Oral feeding of COVID-19 patients receiving NIMV is not possible due to the drastic demand for oxygenation. Removal of the mask for feeding is not possible.The presence of the innovative nutritional adaptor in the non-invasive ventilation mask(NA-NIMV) enables eating mixed foods and liquids through the mouth without the need to remove the mask, contrary to what happens in the standard hospital mask(SH-NIMV) where the mask is removed for feeding or using parenteral nutrition, and the use of the NA-NIMV does not cause air leakage during its use and thus maintains the level of oxygen saturation, respiratory rate, and heart rate. The objective of this study was designed to determine the effect of the mask with the innovative nutritional adaptor of NIVM (NA-NIMV) on the nutritional status of patients with COVID-19 in the ICU concerning air leakage, oxygen saturation (SPO2), respiratory rate (RR), and pulse rate (PR).

Design: A crossover randomised controlled trial (RCT) design was used to accomplish the aforementioned goals.

Methods: A randomised sample of 24 patients with Covid-19 who were hospitalized in the ICU in two public hospitals, in Baghdad city. we include adult patients infected with COVID-19 who required NIV with (SH-NIMV) and (NA-NIMV), the intervention was: every patient received two interventions, apply (SH-NIMV) for 24hrs and received (NA-NIVM)for 24hrs. The outcomes of the endeavour were the amount of nutrition provided Calculated according to ESPEN guidelines, air leakage, SPO2, RR, and PR during each intervention.

Results: A significant statistical difference between calories provided during apply (SH-NIMV) (Average Required calories= 1917, Mean Difference=1644.417* , Average Provided=272 = 14% from total calories need) and NA-NIVM(Average Required calories= 1917, Mean Difference=110.583* Average Provided=1806 = 94% from total calories need), a proteins (SH-NIMV) (Average Required proteins = 82.82917g Mean Difference=66.075*g , Average Provided=17g = 20% from total proteins need) and NA-NIVM(Average Required proteins = 66.075*g, Mean Difference=4.188*, Average Provided=79 = 95% from total proteins need), the mean differences between SH-NIMV and NA-NIMV in SPO2 Sig. (2-tailed = .0001), RR Sig. (2-tailed = .0001), air leakage Sig. (2-tailed = .0001), RR Sig. (2-tailed = .0001), PR Sig. (2-tailed = .001).Conclusion: Large amounts of calories and proteins while maintaining the absence of air leakage, SPO2, RR, and PR when using the NA-NIMV contrarily when using the SH-NIMV.

Recommendation: manufacture a mask with a nutritional adaptor (NA-NIMV) according to the researchers' design. Recourse to the NA-NIMV in the ICU for patients undergoing NIMV.

Trail Registration: Clinical Trial Registry https://www.irct.ir/ reference number (IRCT20211022052840N1).

Keywords: Mask, innovative Nutrition Adaptor, Non-Invasive Mechanical Ventilation Machine, COVID-19.

INTRODUCTION

Since the onset of the COVID-19 pandemic in the year 2020, health care providers encountered a major challenge in disease progression, associated with nutritional therapy. Consequently, Since the beginning of the pandemic, there have been strategies in the nutritional therapy guidelines for patients in the ICU, However, the erratic disease processes combined with the drastic demand for oxygenation created a barrier limiting the conveyance of nutrition to patients, especially those who subject to non-invasive mechanical ventilation (NIMV) because of the difficulty of mask removal [(1)].The medical staff fears the removal of the NIMV mask and cannot use a nasogastric tube (NG tube) that causes air leakage [(2)]. and gastric dilatation that may affect the diaphragmatic function and may have an effect on NIV outcome, patients who end up after a period of 25 days or more without oral feedings or nutritional support may develop malnutrition and muscle mass wasting and in some cases develop starvation, these effects are common among hospitalized patients with COVID-19 in ICU on NIMV [(3)(4)]. High flow nasal cannula is unattainable during nutrition delivery since the hypoxemic patient breathes by mouth and also it would cause air leakage [(5)]. When the patient is unable to tolerate detachment from Noninvasive positive pressure ventilation (NPPV) to take oral feeding; fluid volume deficit occurs thus the staff member recourse to the use of the 0.9% saline as a substitute to the gastrointestinal loss or rather perform routine maintenance that leads to an overload of sodium and chloride in the body [(6)]. Increased use of 0.9% saline as a replacement might lead to bowel edema and gastrointestinal failure [(7)]. patients who are admitted to the hospital due to COVID-19 usually receive non-invasive pressure supported ventilation (BIPAP or CPAP) in the intensive respiratory unit to treat respiratory failure which is generated from both hypercapnic (elevated carbon dioxide (CO2) levels in the blood)and hypoxemic (decrease levels of oxygen in the blood) and also to improve oxgenation and reduce WOB. That is installed with a hood or full-face mask, without the use of an endotracheal or tracheostomy tube. The oral intake of food and fluid is impossible because removing the mask leads to an instantaneous decrease in oxygen saturation [(8)(9)].

METHODS

Study design, sample, and setting: The study creates a crossover randomized controlled trial (RCT) was used, which is a sort of RCT in which two or more interventions are evaluated. All participants receive all interventions in this design, but the order in which they receive them is randomized. Crossover RCTs can aid in determining if digital products or services meet their objectives. It was conducted on 24 patients with Covid-19 who were hospitalized at ICU in Baghdad Medical City, Al-Shifa Specialized Center for Crises from 25 January 2022 to 15 March 2022

Procedure: Nutritional requirements were appraised based on the recommendations of the ESPEN guide [(10)]).

Energy Requirements: In a patient with COVID-19 who is on mechanical ventilation in the ICU, 70% of the daily caloric requirement is given and then progressively increases to reach 80-100% after the 3 days.

Protein requirements: In critically ill patients it takes 1.3 g/kg/day, and about 70% of the daily requirement for protein is given, which progressively increases to meet the need after 3 days.

Data collection: post hoc the review of medical records, data were collected, and interviews with the relatives of the patients infected with COVID-19 who had NIMV applied in respiratory isolation wards have taken place as well as collecting samples from (25

January 2022 to 15 March 2022), and the participant's consent was obtained through their approval to participate in the study. The research tool is composed of two parts; the first part includes socio-demographic characteristics such as age, gender, medical history, weight, food allergy, and appetite. , in addition to, medical parameters research variables such as spo2, HR, RR, and air leakage. The second part consists of the proteins and calories calculated according to their ESPEN guideline

Outcome measure: The patient's aptitude to receive food orally through the innovative nutritional adaptor, as the daily requirement was fully provided by a calculated approach harmonious to the recommendations of the ESPEN guide without the influence of variables (spo2, HR, RR, and air leakage).

Blending: Single-blind: the participants in the study do not know which group they have been allocated to, intervention or control.

Trail Registration: The study was registered for Clinical Trial Register at https://www.irct.ir/ reference number (IRCT20211022052840N1). Date of enrolment: 2021-11-05.

Limitations of the Study

1. No funding.
2. The scarceness of dietitians in the ICU.
3. Deficiency of nutritional guidelines in the ICU.

Adaptor Design: An innovative nutritional adaptor is the groundwork of this study. It is made of polymer material, its length is 31 mm, its width is 19 mm, and its diameter is 8 mm. It is occupying the lower part of the mask from the right side of the patient, and it has an aperture that opens and closes when needed. The adaptor enables the feeding tube to enter the patient's mouth and is attached to the outer part that represents the food source (such as a feeding syringe or any feeding container). The nutritional adaptor was designed to comply with the available potentials, and the researcher has room for further improvement if support is available.

Study algorithm

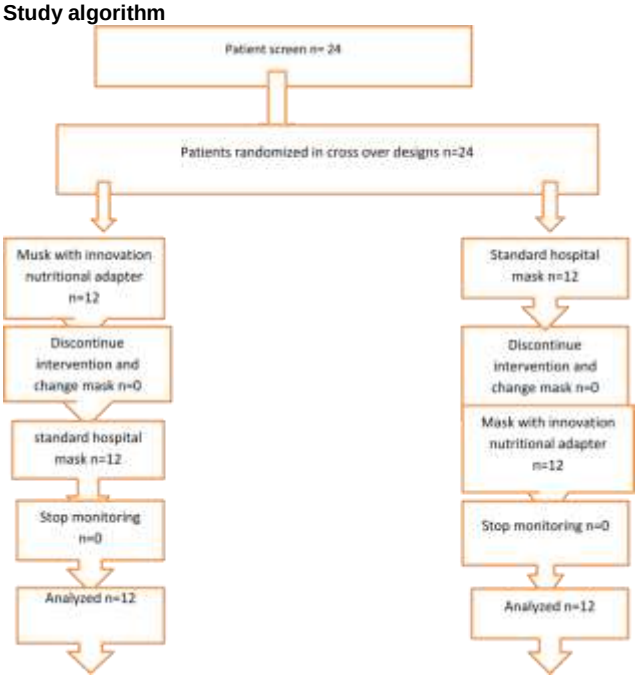

Figure. A

Figure. B

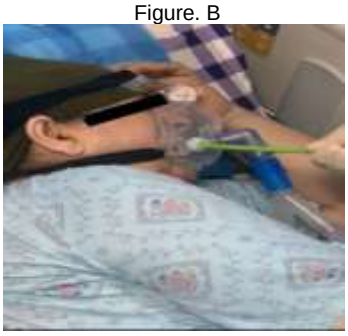

Figure. C

Figure. C.2

Figure: Nutritional Use of Adaptor during MNIV: A. Application of adaptor on MNIV. **B**. Inserting the feeding tube through the adaptor. **C**. The patient is fed by an adaptor.

Table 1: The Demographics and medical history characteristics:

Gender	Frequency	Percent
Male	13	54.2
Female	11	45.8
Total	24	100.0
Age	Frequency	Percent
28 – 35	2	8.3
36 – 43	3	12.5
44 – 51	2	8.3
52 – 59	2	8.3
60 – 67	8	33.3
68 and Older	7	29.2
Total	24	100.0
Weight	Frequency	Percent
58 – 64	3	12.5
65 – 71	4	16.7
72 – 78	4	16.7
79 – 85	8	33.3
86 – 92	5	20.8
Total	24	100.0

The underlined numbers in table1 (A), represent the highest percentages of the selected variables. Which, more than half (54.2%) of the study sample were males. More than a quarter (33.3%) of the study sample were classified as elderly individuals within the age range of (60 – 67) years.

Table 2. A: descriptive statistics SPO2 between measures on standard hospital mask (SPO_2 1) and measure on the mask with innovative nutritional adaptor (SPO_2 2).

SPO_2	Paired Differences					T	df	Sig. (2-tailed)	Cohen's d or (Effect Size)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
				Lower	Upper				
SPO_2 1 SPO_2 2	-37.875-	11.426	2.332	-42.700-	-33.050-	-16.239-	23	.0001	-3.31 Very Large
effect sizes= small (d = 0.2), medium (d = 0.5), and large (d = 0.8) (Romano et al 2006).									

The underlined numbers in (table2) all the statistical equations that were applied showed that there are significant SPO2 differences between the measure on a standard hospital mask (SPO_2 1) and the measure on the mask with an innovative nutritional adaptor (SPO_2 2), the mean differences very large (-37.875-), Sig. (2-tailed) very high (.0001) and Cohen's d (Effect Size) very large (-3.31).

Table3.A: Difference in respiratory rate between measure on standard hospital mask (RR1) and measure on the mask with innovative nutritional adaptor (RR2)

Respiratory Rate	Paired Differences					T	df	Sig. (2-tailed)	Effect Size
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
				Lower	Upper				
RR1 - RR2	12.292	4.877	.995	10.232	14.351	12.348	23	.0001	2.52 Very Large
effect sizes= small (d = 0.2), medium (d = 0.5), and large (d = 0.8)									

The statistical analysis showed that there are significant (RR) differences between the measure on standard hospital mask(RR1) and measure on the mask with innovative nutritional (RR2), the mean differences large (12.292), Sig. (2-tailed) very high (.0001) and Cohen's d (Effect Size) very large (2.52).

Table 4. A: Difference in pulse rate between measure on standard hospital mask (pulse R1) and measure on the mask with innovative nutritional adaptor (pulse R2)

Pulse Rate	Paired Differences					T	df	Sig. (2-tailed)	Effect Size
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
				Lower	Upper				
Pulse R1 - Pulse R2	7.500	9.441	1.927	3.513	11.487	3.892	23	.001	0.79
effect sizes= small (d = 0.2), medium (d = 0.5), and large (d = 0.8)									

The statistical analysis showed that there are significant (Pulse Rate) differences between the measure on standard hospital mask and measure on the mask with innovative nutritional, the mean differences large (7.500), Sig. (2-tailed) high (.001) and Cohen's d (Effect Size) large (0.79).

Table 5. A: Difference in air leakage measured on standard hospital mask (Air L 1) and measure on the mask with innovative nutritional adaptor (Air L2)

Air Leakage	Paired Differences					T	Df	Sig. (2-tailed)	Effect Size
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
				Lower	Upper				
Air L 1 - Air L2	89.333	2.057	.420	88.465	90.202	212.742	23	.0001	43.42
effect sizes= small (d = 0.2), medium (d = 0.5), and large (d = 0.8)									

The underlined numbers in (table 5) all the statistical equations that were applied showed that there are significant air leakage differences between the measure on a standard hospital mask (Air L 1) and the measure on the mask with an innovative nutritional adaptor (Air L2), the mean differences large =(89.333), very high Sig. (2-tailed)=(.0001) and Cohen's d very large (Effect Size)=(43.42).

Table 6. Calories are provided to patients by measuring on a standard hospital mask and measuring on the mask with an innovative nutritional adaptor.

Calories	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	Provided calories	
					Average Provided	%
Average Required calories (1917 Calories)	Measure (standard hospital mask)	1644.417*	70.147	.000	272	14%
	Measure (mask with innovative nutritional adaptor).	110.583*	20.119	.000	1806	94%

In the underlined numbers in (table 6), there is a high mean difference = (1644.417*) between total body requirements from calories (1917 Calories) and delivery during applying a stander hospital mask, which is equal (272 calories) = (14%) from total body requirements. and low mean difference =(110.583*) between total body requirements from calories (1917 Calories) and delivery during applying the mask with the innovative nutritional adaptor, which is equal to (1806 calories) = (94%) from total body requirements.

Table 7. Protein is provided to patients between measure on a standard hospital mask and measure on the mask with an innovative nutritional adaptor.

Protein	(J) factor1	Mean Difference (I-J)	Std. Error	Sig.[b]	Provided Protein	
					Average Provided	%
Average Required Protein (82.82917 grams)	Measure (standard hospital mask)	66.075*	3.231	.000	17	20%
	Measure (mask with innovative nutritional adaptor).	4.188*	.663	.000	79	95%

In the underlined numbers in (table 7), there is high a mean difference = (66.075*) between total body requirements from proteins (82.82917 grams) and proteins delivered during applying a stander hospital mask, which is equal to (17g) = (20%) from total body requirements. and low mean difference = (4.188*) between total body requirements from proteins (82.82917 grams) and proteins delivered during applying the mask with the innovative nutritional adaptor, which is equal to (79 g) = (95%) from total body requirements.

DISCUSSION

Section1: Socio-demographics characteristics: This section is concerned with presenting the results of descriptive tables as they play an important role in clarifying and describing the basic variables. The findings in the table (1) showed that more than a quarter (33.3%) of the study sample was classified as elderly individuals within the age range of (60 – 67) years. The results of the study were astonishing, in light of the fact that the vulnerable age group is not consistent with this finding. The literature shows a

higher risk of mechanical ventilation starting from 50-59 years of age [11].

Table (1), shows that more than half of the study participants were male. These findings are endorsed by a study that detected that the male gender may be more affected by COVID-19 when compared with the female gender [12]).

Table (1), shows that more than half of the study participants were overweight. These findings are rather supported by another study that found that overweight individuals might be more affected by COVID-19 when compared with individuals within the normal weight range [11].

Section 2: Medical history and assessment variables: In table 1, more than one-third of the study sample had no medical history at the time of data collection. However, the majority proportion of the study sample was those with a history of illness and chronic diseases. The result is not astonishing. People with underlying chronic disease have a higher likelihood of COVID-19 infection, with the addition of a higher chance of dying from the viral infection, according to a study of COVID-19 patients[13].

The highest percentage of the study samples had a normal appetite at the time of data collection. The result is surprising considering the frequently altered appetite in COVID-19 patients in the ICU [3].

In table 2 the results show that all patients who applied the SH-NIMV mask suffered from very low Spo2 during the removal of the mask for the sake of eating or drinking. Furthermore, all patients who apply the NA-NIMV do not suffer from a decrease in the level of Spo2 during eating or drinking via a nutritional adaptor. Whereas, the mean Difference in Spo2 level between measures acquired during feeding through the nutritional adapter and feeding through a SH-NIMV mask (-37.875-) and The correlation (Cohen's d or Effect Size) was very large (-3.31) of arterial oxygen saturation of patient who uses the adaptor for eating. These findings are supported by a study that found that most patients with COVID-19 applied NIMV associated with decreased arterial oxygen saturation during removing the mask for eating or drinking [13].

This indicates that the use of the innovative NA-NIMV mask does not cause a desaturation because it does not disturb the effectiveness of the mechanical ventilation function.

In table 3 regarding the Respiratory Rate (RR), the results showed that all patients who applied the SH-NIMV suffered an increase in respiratory rate after removing the mask for eating or drinking. Besides, all patients who apply the mask with the NA-NIMV do not suffer from an increase in the level of respiratory rate during eating or drinking via a nutritional adaptor. Whereas, the mean Difference in (RR) level between measured during feeding through the innovative nutritional adapter and feeding through a SH-NIMV mask (12.292) and The correlation (Cohen's d or Effect size) was very large (2.52) respiratory rate of a patient who uses the adaptor for eating. These findings are supported by a study that found that most patients with COVID-19 applied NIMV associated with increased RR during the removal of the mask for eating or drinking[2].

In table 4 regarding the Pulse Rate, the results showed that the majority of patients who applied the SH- NIMV suffered from an increase in pulse rate during removing the mask for eating or drinking. And that all patients who applied the NA-NIMV did not experience any changes in regard to pulse rate during eating or drinking via the innovative nutritional adaptor. Whereas, the mean Difference in pulse rate level between measured during feeding through the nutritional adapter and feeding through a SH-NIMV mask (7.500) and The correlation (Cohen's d or Effect size) was large (0.79) pulse rate of patients who use an innovative adaptor for eating or drinking. These findings are supported by a study that found that most patients with COVID-19 applied NIMV associated with increased pulse rate during removing the mask for eating or drinking[2].

In table 5 the results showed that for the ruling number of patients who applied the SH-NIMV mask, the mechanical ventilation malfunctioned when the mask was discontinued and removed for feeding, and the air leakage level did not exceed 10% for the patients who applied the mask of NA-NIMV. Whereas, the mean difference in air leakage level between the measurement taken during feeding through the nutritional adapter and feeding through a SH-NIMV (89.333), mean air leakage on a SH-NIMV mask (100.00), mean air leakage on the NA-NIMV mask (10.67) and The correlation (Cohen's d or Effect size) was very large (43.42) air leakage of a patient who uses adaptor for eating. These findings are supported by a study that found that most patients with COVID-19 applied NIMV associated with air leakage during removal of the mask for eating or drinking[6][2].

And this air leakage is not from the innovative nutritional adaptor, but rather from the area where the mask is attached to the face, meaning that the adapter does not cause air leakage during use, except for a few seconds when opening and closing the adaptor earlier to the insertion of the tube that will control passageway and prevent air leakage.

Section 3: calories and proteins provided: In table 6 the results of the study showed that patients infected with COVID-19 and who applied a NIMV mask suffered from a severe insufficiency of oral feeding, on the contrary when patients who applied the NA-NIMV, they take their food according to their nutritional needs which is calculated based on their weight, Whereas, the mean difference between the daily caloric requirement (1917 Calories) and the average provided (272 calories) is high (1644.417*) during the application of the SH-NIMV mask as this constitutes (14%) of the total body requirement/day. These results were not unforeseen, because the mask cannot be removed for the purpose of feeding, as this will lead to failure of the device and, thus malnutrition [3][14][15]. And the mean difference between the daily caloric requirement (1917 Calories) and the average provided (1806 calories) is low (110.583*) during the application of a NA-NIMV mask as this constitutes (94%) of the total body requirement/per day.

Whereas, in table 7 the mean difference between the daily proteins requirement (82.82917 grams) and the average provided (17g) is high (66.075*) during the application of the SH-NIMV mask as this constitutes (20%) of the total body requirement/day. These results were not surprising, because the mask cannot be removed for the purpose of feeding, as this will lead to the collapse of the device, which leads to malnutrition [16]. And the mean difference between the daily proteins requirement (82.82917 grams) and the average provided (79g) is low (4.188*) during the application of a NA-NIMV mask as this constitutes (95%) of the total body requirement/day.

Through the results that proceeded in the first and second section, the researcher finds the opportunity to clarify and reflect on the fact that the NA-NIMV mask can maintain the nutritional level in sufficient quantities without affecting the body's variables (SPO2, RR, HR, and air leakage) during feeding and thus does not need nutritional support or parenteral nutrition.

Section 4: Associations between the mask with nutritional adaptor and the covered variables: Table 8, 9,10,11,12 shows that there is no statistically significant deference between gender and assessment variables, SPO2 (mean= -0.238, P=0. 864), RR (mean= 2.231, P=0. .316), Pulse Rate (mean= -3.049-, P=0.706), calories (mean= -201.594-, P=0.247), proteins (mean= -8.2140-, P=0.245) during use of the NA-NIMV mask. It also displays in table (13), no statistically significant correlation between types of age and assessment variables SPO2(r=0.190, p=0.375), RR(r= - 0.126 - , p=0.558), Pulse Rate (r= 0.143, p=0.504), calories (r= 0.243, p=0.252), and proteins (r= 0.209, p=0.328) during use the NA-NIMV mask.

Thus the researcher notices and regards the NA-NIMV mask as suitable for both gender and all ages.

In table 14 shows that there is a no statistically significant deference between patients' weight and assessment variables, SPO2(r= - 0.085- , p=0.693), RR(r= - 0. 131 - , p=0.543), Pulse Rate (m r= - 0.138 -, p=0.520), proteins (r= 0.396 , p=0.056) and

there is a statistically relationship (low) between patients' weight and calories =(r= 0.421 , p=0.040) during use the NA-NIMV mask.

This shows the researcher that the NA-NIMV mask is suitable for all weights.

In table 15 shows that there is a no statistically significant deference between patients' chronic diseases and assessment variables, SPO2(r=0.253, p=0.232), RR(r= - 0.008 - , p=0.972), Pulse Rate (r= 0.063, p=0.769), calories (r= 0.208, p=0.329) and proteins (r= 0.164, p=0.443) during use the NA-NIMV mask.

This shows the researcher that the NA-NIMV mask is suitable for chronic disease.

In table 16 shows that there is a no statistically significant deference between patients' appetite and assessment variables, SPO2(r= -0.193-, p=0.367), RR(r= 0.062, p=0.774), Pulse Rate (r= 0.262, p=0.216), calories (r= -0.165- , p=0.440) and proteins (r= -0.143 -, p=0.505) during use the NA-NIMV mask.

This shows the researcher that the NA-NIMV mask is not affected by the patient's appetite.

CONCLUSIONS

Based upon the study's main findings, the null hypothesis was rejected, considering the fact that a statistically significant difference was authenticated between using a NA-NIMV mask and the SH-NIMV mask. Other significant conclusions are as follows:

1. Intensive COVID-19 affected all ages, especially the elderly age, group.
2. The results of the research showed that all of the study samples who applied the SH-NIMV mask suffered from severe hypoxia while feeding. On the other hand, when they applied the NA-NIMV mask, the SPO2 level did not change amidst feeding through the adaptor.
3. The results of the research showed that all the study samples had an increase in the respiratory rate during the application of the SH-NIMV mask for feeding, while there was no alteration when using the mask with the NA-NIMV mask.
4. The results of the research showed that the majority of the study sample had an increase in the respiratory rate during the application of the SH-NIMV mask for feeding, while there was no change when using the NA-NIMV mask.
5. The results of the research showed that discontinuing the SH-NIMV mask for feeding causes the failure of the mechanical ventilation due to high air leakage, while when using the nutritional adaptor there is no air leakage.
6. The results of the research showed that the patients who applied the SH-NIMV mask suffered from severe oral intake insufficiency, while most of the daily requirement was provided when using the innovative adaptor
7. The results of the research showed that the NA-NIMV mask is suitable for both genders and all ages.
8. According to the results of the research, it was shown that the NA-NIMV mask is suitable for all weights, and its use is not affected by chronic diseases, nor is it related to appetite.

Recommendations:

In light of the outcomes and conclusions of this study; the researcher's recommendations are as follows :

1. Manufacture of a mask with a nutritional adaptor according to the researcher's design.
2. Have recourse to the innovative Nutrition adaptor Mask in the ICU for patients undergoing NIMV.

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