ROLE OF NON INVASIVE POSITIVE PRESSURE VENTILATION AS A WEANING METHOD IN MECHANICALLY VENTILATED COPD PATIENTS

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ABSTRACT

Background: NIPPV appears to be a promising weaning modality for mechanically ventilated COPD patients and should be tried in resource-limited settings especially in developing countries. **Aim of the work:** to assess the role of NIPPV as a weaning method in mechanically ventilated COPD patients. **Patients and Methods:** Fifty six COPD patients (37) male and (19) female whom were mechanically ventilated due to acute on top of chronic respiratory failure and were candidates for weaning from mechanical ventilation according to RICU protocol**.** They were classified into 2 groups after being candidate for weaning: **Group (1): (28)** Patients were weaned using spontaneous breathing trial (SBT) ; 2 hours spontaneous breathing using t- tube trial . **Group (2) : (28)** Patients were weaned using NIPPV device. **Results:** there were statistically high significant differences between both the studied groups (24 hours after application of SBT or NIPPV group) for patients regarding PH and PCO2 (higher PH and lower PCO2 in NIPPV group). Also, there were statistically significant differences between both studied groups regarding days of ICU stay and days of hospital stay .The days of ICU and MV were shorter in NIPPPV in comparison to SBT group. **Conclusions:** the use of NIPPV immediately at readiness of weaning in COPD patients with hypercapnic respiratory faliure can decrease reintubation rate, mortality rate, duration of ICU stay and many complications especially VAP.

keywords : Weaning, COPD, Non Invasive Positive Pressure Ventilation

INTRODUCTION

Mechanical ventilation supports many patients for respiration and without this, they would die within hours to days due to acute hypoxemic and hypercapnic respiratory failure. Observational, physiological and case/control studies form a large body of evidence demonstrating that noninvasive ventilation (NIV) can be used in many situations to decrease a patient's dyspnea and work of breathing, improve gas exchange and ultimately avoid the need for endotracheal intubation (ETI) **[1].**

Weaning from invasive mechanical ventilation (MV) may be defined as the process of abrupt or gradual withdrawal of ventilator support, thereby shifting the work of breathing from machine to man. More than 40% of the time that a patient spends on MV is constituted by the weaning period, and around 20% of mechanically ventilated patients will fail their first attempt at weaning **[2].**

Achieving a careful balance between early versus delayed weaning is a must to minimize the risk of complications associated with either of the two. Premature discontinuation of MV may result in cardio-respiratory failure. Moreover, overloading and fatigue of respiratory muscles together with an inability to protect the airway leads to reintubation. The later by itself is associated with an increase in morbidity, mortality, duration of MV, and length of intensive care unit (ICU) and hospital stay **[3].**

On the other hand, if initiated late, weaning may be unsuccessful because of respiratory muscle weakness caused by deconditioning and disrupted breathing regulation. Further, prolonged MV, as often seen in COPD patients, is itself associated with complications like nosocomial pneumonia, cardiac morbidity, gastrointestinal bleeding, deep vein thrombosis and death. Thus, choosing the right time and right weaning strategy forms a crucial part of the management of such critically-ill patients and certainly affects their outcome **[4].**

NIPPV appears to be a promising weaning modality for mechanically ventilated COPD patients and should be tried in resource-limited settings especially in developing countries **[5].**

So the aim of this study is to assess the role of NIPPV as a weaning method in mechanically ventilated COPD patients.

Patients and Methods:

This Intervention prospective observational randomized controlled trial (RCT) study was carried out at respiratory intensive care unit (RICU), Chest Department, Zagazig University Hospitals during the period from April 2015 to March 2017. Ethics approval has been obtained from Medical Research Ethics Committee in April, 24th, 2015, Zagazig University.

Patients of the study :

Fifty six COPD patients (37) male and (19) female whom were mechanically ventilated due to acute on top of chronic respiratory failure and were candidates for weaning from mechanical ventilation according to RICU protocol **[6].**

- Patients were classified into 2 groups after being candidate for weaning:
  - **Group (1): (28)** Patients were weaned using spontaneous breathing trial (SBT) ; 2 hours spontaneous breathing using t- tube trial .
  - **Group (2) : (28)** Patients were weaned using NIPPV device

➢ **Inclusion Criteria:** COPD patients with ARF who recieved invasive MV and were ready for discontinuation of MV according to following criteria according to **Osler, (2014)[7]:** Checklist for identifying patients who can be considered for a trial of spontaneous breathing **[7] .**

Respiratory Criteria:

- PaO2 ≥ 60 mmHg on Fio2 ≤ 40- 50 % and PEEP ≤ 5 -8 cm H2O
- PaCO2 normal or baseline (except for permissive hypercapnia)
- Patient is able to initiate an inspiratory effort

Cardiovascular Criteria:

- No evidence of myocardial ischemia
- Heart rate ≤ 140 beats / minutes
- Blood pressure normal without vasopressors or with minimum vasopressor support (e.g., dopamine < 5µg/Kg/min)

Adequate mental status: Patient is arousable or Glasgow coma score ≥ 13

Absence of Correctible Comorbid Conditions:

- Patient is afebrile
- There are no significant electrolyte abnormalities

➢ **Exclusion criteria: (Burns et al .,2009)[8]**

Respiratory failure and patients with relative or absolute contra indication for NIPPV.

The studied patients were divided into two groups 28 patient in each group and the patients were assigned randomly to each group:

Group (1): They include Patients who fulfill weaning criteria and they were weaned using spontaneous breathing trial (SBT) ; 2 hours spontaneous breathing using t- tube trial .

Group (2) : They include Patients who fulfill weaning criteria and they were weaned using NIPPV device. Non-invasive ventilation was delivered continuously immediately after extubation using a ventilator specifically designed for NIPPV

(Servo ^{i} (Maquet – USA) ventilators were used) .

Methods:

All patients were subjected to the following :

Informed consent will be taken from all study participants' relatives.

All patients will be diagnosed as COPD according to GOLD (2014)[9].

Full medical history from the patient (if possible) or his relatives including smoking status, history of previous intubation and / or ventilatory support.

1. Full clinical examination: (general & local signs).
2. Plain chest and heart X – ray ;(antero-posterior view)
3. Ventilatory PFT (from previous admissions or after stabilization of the condition) using a computerized pulmonary function device and Expiratory flow volume curve was performed for all patients (ZAN 100).
4. Laboratory investigations:

a- ABG using blood gas analyzer (ABL-330-Radiometer Copenhagen system) in 2h,8h,24h,48h postweaning, to measure pao2 , paco2, sao2, HCO3.

b- Complete blood count (CBC).

c- Liver and kidney functions tests

d- Serum electrolytes (Na, K, Ca, Mg , Ph).

e- Thyroid function tests (Free T3, free T4 & TSH)

5. Electrocardiography for detection of weaning induced ischemic changes or arrhythmias.
6. Assessment for presence of other comorbidities.
7. **APACHE II Score "Acute Physiology and Chronic Health Evaluation II Score"(Knaus et al., 1985).[10]**
8. **Glasgow Coma Score (GCS) (Bastos et al.,1993)[11]**
9. **The Sequential Organ Failure Assessment (SOFA) Score. (Williams and Gannon, 2009).[12]**
10. **Mechanical Ventilation:**

- All patients were intubated orally using an ETT diameter of 7 or 7.5 .
- Patients were on Synchronized Intermittent Mandatory Ventilation with pressure support mode (SIMV+PS). (Servo **i** (Maquet – USA) ventilators were used)
- When patients fulfilled weaning criteria according to **(MacIntyre et al., 2001)[13],** patients were divided into the studied groups.

Table (a): Criteria used to determine the readiness for discontinuation (weaning).[13]

- **Adequate oxygenation**
  ($PaO_2 \geq 60$ mm Hg on $FIO_2 \leq 0.4$,PEEP ≤ 5–10 cm H_2O, $PaO_2/FIO_2 \geq 150–300$).
- **Stable cardiovascular system**
  (e.g. HR≤ 140,stable BP, no or minimal pressors)
- **Afebrile** (temperature < 38°C)
- **No significant respiratory acidosis**
- **Adequate hemoglobin (**e.g., HB ≥ 8–10 g/dL)
- **Adequate mentation**
  (e.g., arousable, GCS ≥13, no continuous sedative infusions)
- **Stable metabolic status (**e.g., acceptable electrolytes)
- **Subjective clinical assessments**
  -Resolution of disease acute phase
  -adequate cough
  -Cessation of sedative drugs.
  -Cessation of neuromuscular blocking drugs.

12. Spontaneous Breathing Trial (SBT) versus Non Invasive Positive Pressure Ventilation (NIPPV) as a method of weaning:

A. Spontaneous Breathing Trial (SBT): (group 1):

When patients fulfilled weaning criteria, SBT through T tube was done, in which only supplemental oxygen is supplied through a T-piece connected to an endotracheal tube. The initial few minutes of the SBT should be monitored closely before judgment is made to continue the SBT**.** Patient who showed no signs of distress with 2 hours SBT were followed by extubation. **[13].**

B- Noninvasive Positive Pressure Ventilation (group 2): All patients were ventilated using a ventilator specifically designed for NIPPV. Oronasal mask was applied to all patients. Inspiratory pressure support was initially set at 10 cmH_2O and then increased to the maximum tolerated with extrensic PEEP (2-6 cm H_2O). After the first 48 hrs, if patient is clinically stable, NIPPV was withdrawn.

13. Assessment of the following items

- Length of RICU and hospital stay.
- Duration of MV weaning.
- Occurrence of complications

➢ **End point of the study:**

- **Primary outcome:(as regard weaning success or faliure):**
  - success of weaning
  - failure of weaning and reintubation**.**
- **Secondary outcome:(as regard mortality):**
  - survival and successful discharge.
  - Death

Statistical Analysis:

Data were imported into Statistical Package for the Social Sciences (SPSS version 20.0) **(Statistical Package for the Social Sciences)** software for analysis. According to the type of data qualitative represent as number and percentage , quantitative continues group represent by mean ± SD , the following tests were used to test differences for significance;. difference and association of qualitative variable by Chi square test (X^2) . Differences between parametric quantitative independent groups by t test, paired by paired t . P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

Table (1) detected that there were no significant statistical differences between the studied groups regarding the demographic data of the studied cases **(p > 0.05).**

Table (2) showed that there were statistically significant differences between both studied groups regarding oxygen saturaton (p 0.017) as NIPPV group had higher oxygen saturation than that of SBT group otherwise there was statistically no significant differences between both the studied groups regarding other ABGs parameter **(p > 0.05)**.

Table (3) illustrated that there were statistically significant difference as regards GCS score 2h after weaning as it was higher in NIPPV group (**p 0.041**) but there were statistically no significant differences between two groups as regards APACHE II and SOFA scores (**p > 0.05**).

Table (4) showed statistically high significant differences between both the studied groups (24 hours after application of SBT or NIPPV group) for patients regarding PH and PCO2 (higher PH and lower PCO2 in NIPPV group) but there was statistically no significant differences between both studied groups (24 hours after application of SBT or NIPPV group)for patients regarding PO2 and oxygen saturation.

Table (5) showed statistically significant differences as regard GCS and SOFA score between SBT group and NIPPV group 24 H after weaning but there was statistically no significant differences as regard APACHE II score.

Table (6) detected that there were statistical significant differences between both the studied groups regarding success of weaning with higher rate in NIPPV group **(p 0.002**) but there was statistically no significant differences between the two groups as regaed survival in both groups.(**p > 0.05**)

Table (7) showed that there was no significant statistical differences between both studied groups regarding complications.

Table (8) showed that there were statistically significant differences between both studied groups regarding days of ICU stay and days of hospital stay .The days of ICU and MV were shorter in NIPPPV in comparison to SBT group but there was statistically no significant differences between the two groups as regards days of MV.

Table (1): Comparison between Socio-demographic characteristics in each studied group (n=56)

		Group				X^2	P
		SBT (28)		NIPPV (28)			
AGE		**Mean ± SD**		**Mean ± SD**			
		56.13 ± 4.7		**56.5 ± 3.6**			**0.745**
		NO.	**%**	**NO.**	**%**		
Sex	MALE	19	67.9	**18**	**64.3**	**0.08**	**0.77**
	FEMALE	**9**	**32.1**	**10**	**35.7**		
Smoking	MILD CIGGARETE SMOKER	**1**	**3.5**	**1**	**3.5**	**0.67**	**0.88**
	MODERATE CIGGARETE SMOKER	**5**	**17.9**	**6**	**21.4**		
	HEAVY CIGGARETE SMOKER	**12**	**42.9**	**10**	**35.7**		
	GOZA	**5**	**17.9**	**4**	**14.3**		
	EXSMOKER	**2**	**7.1**	**2**	**7.1**		
	NON SMOKER	**3**	**10.7**	**5**	**17.8**		
BMI	Obese	**8**	**7.1**	**7**	**25.0**	**0.28**	**0.86**
	Normal	**13**	**46.4**	**15**	**53.6**		
	Under WT	**7**	**25.0**	**6**	**21.4**		
Comorbidities	IHD	**2**	**7.1**	**2**	**7.1**	**1.7**	**0.82**
	HPN	**5**	**17.9**	**4**	**14.3**		
	CORPUMONALE	**4**	**14.3**	**5**	**17.9**		
	DM	**8**	**28.6**	**4**	**14.3**		
	CHRONIC RENAL DISEASE	**1**	**3.6**	**1**	**3.6**		
	CHRONIC LIVER DISEASE	**2**	**7.1**	**1**	**3.6**		
PREVIOUS NIPPV		**4**	**14.3**	**5**	**17.9**		
PREVIOUS MV		**2**	**7.1**	**2**	**7.1**		

Table (2): Arterial blood gases analysis of the studied groups 2H after weaning.

ABG parameters	Group I SBT (28)	Group II NIPPV (28)	Student t test	
	Mean ± SD	Mean ± SD	t	p
pH	7.34 ± 0.0571	7.35 ± **0.40**	1.054	0.29
PaO_2(mm Hg)	67.75 ± **9.8**	90.75 ± **5.30**	1.42	0.16
$PaCO_2$ (mm Hg)	57.2 ± **10.68**	55.32 ± 8.84	0.72	0.47
SaO_2 (%)	90.35 ± **5.1**	93.03 ± **2.76**	2.46	0.017

Table (3): Comparison between SBT and NIPPV groups 2 hours after weaning as regards APACHE II, GCS and SOFA scores.

Scoring systems	Group I SBT (28)	Group II NIPPV (28)	Student t test	
	Mean ± SD	Mean ± SD	t	P
APACHE II scores	22.35 ± **1.88**	22.11 ± **1.70**	0.519	0.60
GCS	**14.15 ± 1.64**	**14.55 ± 1.16**	**2.105**	**0.041**
SOFA score	3.93 ± **0.377**	4.00 ± **0.47**	0.63	0.53

Table (4): Arterial Blood Gases (ABG) analysis of the studied groups 24 hours after weaning.

ABG parameters	Group I SBT (28)	Group II NIPPV (28)	Student t test	
	Mean ± SD	Mean ± SD	t	p
pH	7.33 ± **0.063**	7.36 ± **0.044**	3.38	.001
PaO_2(mm Hg)	66.28 ± **10.01**	68.35 ± **7.53**	0.874	.038
$PaCO_2$ (mm Hg)	62.01± **8.87**	53.85 ± **9.38**	3.38	.001
SaO_2 (%)	89.82 ± **5.24**	90.35 ± **3.38**	0.435	0.665

Table(5): Comparison between SBT and NIPPV groups 24 hours after weaning as regard APACHE II, GCS and SOFA scores.

Scoring systems	Group I SBT (28) Mean ± SD	Group II NIPPV (28) Mean ± SD	Student t test t	P
APACHE II scores	21.1 ± **1.11**	21.31 ± **1.15**	0.821	0.415
GCS	14.107 ± **2.3**	14.501 ± **1.9**	2.104	0.047*
SOFA score	4.102 ± **0.377**	3.891 ± **0.47**	2.214	0.044*

Table (6): Comparison between SBT group and NIPPV group as regard outcome in the studied groups .

		Group				X^2	P
		SBT		NIPPV			
		No,	%	NO.	%		
SUCCESS	Success	**22**	**78.6%**	**26**	**92.9%**	.33	**0.002***
	Failure	**6**	**21.4%**	**2**	**7.1%**		
SURVIVAL	Died	**3**	**10.7%**	**1**	**3.6%**	**1.07**	**0.29**
	Survived	**25**	**89.3%**	**27**	**96.4%**		

Table(7): Comparison between SBT group and NIPPV group as regards complications in the studied groups .

		Group				X^2	P
		SBT		NIPPV			
		NO.	**%**	**NO.**	**%**		
Complication	arrhythmia	**3**	**10.7%**	**2**	**7.1%**	**9.9**	**0.076**
	Gas distention	**0**	**0.0%**	**4**	**14.3%**		
	Mask complication	**0**	**0.0%**	**4**	**14.3%**		
	VAP	**2**	**7.1%**	**1**	**3.6%**		
	stridor	**3**	**10.7%**	**1**	**3.6%**		

Table (8): Comparison between SBT group and NIPPV group as regards duration of Mechanical ventilation , ICU stay and hospital stay.

	SBT GROUP (28)	NIPPV GROUP (28)		
	Mean ± SD	**Mean ± SD**	t	P
DAYS_OF_MV	**3.57± 1 .13**	**3.04±.96**	**1.904**	**0.762**
DAYS_OF_ICU	**7.25 ± 1.94**	**6.07 ± 1.74**	**2.057**	**0.047***
DAYS_OF_HOSPITAL _STAY	**11.67 ± 2.99**	**10.071 ± 2.89**	**0.0772**	**0.002***

DISCUSSION

Weaning from mechanical ventilation is the process of liberating support and allowing the resumption of spontaneous breathing**[14].** Weaning from mechanical ventilation usually implies two separate but closely aspects of care, discontinuation of mechanical ventilation and removal of any artificial airway **[15].** Over 90% of critically ill patients require mechanical ventilation, and 40% of the time the patient is receiving mechanical ventilation is spent in the process of weaning from it **[16].**

Non-invasive ventilation provides an alternative method of supporting a patient's respiration by using positive pressure ventilation with either oronasal, nasal, or total face mask at the patient-ventilator interface. Non-invasive ventilation preserves the patient's ability to speak and cough and has been shown to reduce complications related to reintubation, especially ventilator associated pneumonia **[17].** Similar to invasive ventilation, non-invasive ventilation can reduce the frequency of breathing, augment tidal volume, improve gas exchange, and rest the muscles of respiration **[18].** Non-invasive ventilation has been widely investigated as an initial treatment to prevent intubation and intubation related complications and improve clinical outcomes in selected patients **[19].**

So, the present work aimed to evaluate the role of NIPPV as a weaning method in mechanically ventilated COPD patients and to show that NIPPV is an extremely valuable alternative weaning method in comparison to other traditional methods in mechanically ventilated COPD patients. It is generally much safer and has been shown to decrease resource utilization and to avoid the myriad of complications associated with other methods.

To accomplish this task, the study recruited 56 COPD patients with hypercapnic respiratory failure . They were randomized immediately after readiness of weaning to receive either spontaneous breathing trial (SBT) (28) or non invasive positive pressure ventilation (NIPPV) (n=28).

In the present study comparison between the SBT group and NIPPV group as regards age, sex, smoking and other associated comorbidities had shown statistically no significant differences between the two studied groups **(Table 1**) as they were cross matched.

The previous result is in harmony with the study of **Ferrer et al., (2009)[20]**, **Girault et al. (2011)[21] and Ornico et al., (2013)[22]** who found that general clinical characteristics and physiologic variables of patients (age, sex, cause of respiratory failure, other associated comorbidities and previous NIPPV) at entry to the study did not differ in SBT group and NIPPV group.

On the other hand there were high statistically significant differences between

the studied groups regarding oxygen saturation 2 hours after weaning and regarding PH and PCO2 24 hours after application of SBT or NIPPV with better parameters of NIPPV group **(Table 2 , 4)**.

Similarly ***Khilnani et al., (2011)[23]***, they found statistical no significance but better parameters of NIPPV group than conventional treatment group. Also, ***Ornico et al. (2013)[22]*** showed a higher PaO_2 and lower $PaCO_2$ in the NIPPV group compared with the OM group during the 24-hour period and also, ***El Solh et al. (2006)[24] .***

In this study comparing SBT group and NIPPV group 2 hours after weaning as regards APACHE II, GCS and SOFA scores , there was statistically no significant differences as regards APACHE II score and SOFA score but there was a astatistically significant difference as regards GCS with better parameter in NIPPV group **(Table 3).** After 24 hours of weaning there were statistically significant differences as regard SOFA score and GCS between SBT group and NIPPV group with better parameters in NIPPV group but there was statistically no significant differences as regard APACHE II score between SBT group and NIPPV group **(Table 5).**

In agreement with our results , **EL Solh et al., (2006)[24]** reported a a statistical no significant difference between SBT and NIPPV groups as regards APACHE II score. Also **Ferrer et al. (2009)[20]** found statistical non significant difference between SBT and NIPPV groups as regards APACHE II score. **Ornico et al., (2013)[22]** reported that there is no influence of SBT and NIPPV on APACHE II scores of their patients.

In this study as regards the comparison between failure of weaning and re intubation rates in the studied groups, it was found that higher frequency of failure of weaning and re intubation rates in patients treated with SBT (**21.4**%) when compared with patients treated with NIPPV (**7.1**%) **(Table 6).**

In agreement with this study, ***Hilbert et al.,(1998)[25]*** who found that the use of noninvasive ventilation significantly reduced the need for endotracheal intubationin the noninvasive ventilation group ($p<0.001$).Also ***Nava et al., (2005)[26]*** showed that the NIPPV group had a lower rate of reintubation .Also ***El Solh et al., (2006)[24]*** found that the institution of NIPPV post extubation resulted in 16% absolute reduction in the risk of respiratory failure compared with conventionally treated group (10% vs 26% $p=0.03$).

Regarding the comparison between mortality rates in the studied groups, the present study found higher rate of mortality in patients treated with SBT (**10.7%**) when compared with patients treated with NIPPV (**3.6%**) **(Table 6)** as the need of reintubation is associated with a higher risk of mortality.

Nava et al., (2005)[26] and El Solh et al., (2006)[24] found that hospital mortality was less in NIPPV than in conventional oxygen therapy group .In the study of ***Ferrer et al., (2009)[20],*** ICU mortality was 0% in NIPPV group and 18% in conventional oxygen therapy group ($p=0.003$). Hospital mortality was 4% in NIPPV group and 41% in conventional oxygen therapy group ($p=0.035$).

In this work, the comparison between SBT and NIPPV groups regarding duration of ICU and hospital stay they were astaistical significant difference between both groups with shorter duration in NIPPV group .**(Table 8)** .

In agreement with this study, ***Hilbert et al, (1998)[25] , El Solh et al., (2006)[24] and Girault et al., (2011)[21]*** found that ICU stay in NIPPV group was associated with less days than conventional oxygen therapy group and also hospital stay. In contrary to our results, the findings reported

by ***Ferrer et al., (2009)[20]*** and ***Khilnani et al., (2011)[23]*** who found that noninvasive ventilation and conventional oxygen therapy didn't contribute significantly to the length of ICU and hospital stays.

In respect to the reported complications, this study found a higher frequency of VAP, Arrhythmias, post extubation stridor in patients receiving SBT when compared with patients receiving NIPPV as repeated reintubations carry high risk for development of nosocomial pneumonia and many complications. On the other hand, patients receiving NIPPV group had higher frequency of gastric distention and mask related complications. **(Table 7)*EL Solh et al., (2006)[24]*** reported that higher frequency of hospital acquired pneumonia and blood steam infection in patients receiving conventional therapy (5% and 15% respectively) when compared with those receiving NIPPV (3%and 2% respectively).This was in agree with the results of ***Ferrer et al., (2009)[20]*** and ***Girault et al. (2011[21]),*** who reported that the most commonly reported complications were postextubation stridor, nosocomial pneumonia and atelectasis which were more in patients receiving conventional therapy when compared with those receiving NIPPV.

Finally the success of noninvasive ventilation could be dependent on the experience of the health care team using the technique ***(Esteban et al., 2004)[27]***.

The previous findings are in support for utilization of NIPPV after weaning in patients with hypercapnia especially in high risk patients and in patients with prolonged intubation to decrease rate of reintubation, decrease complications and improve survival rather than conventional oxygen therapy.

In conclusions, the use of NIPPV immediately at readiness of weaning in COPD patients with hypercapnic respiratory faliure can decrease reintubation rate, mortality rate, duration of ICU stay and many complications especially VAP. Improvement of blood gas parameters including ↑PH, ↓ $PaCO_2$ and ↑PaO_2 associated with the improvement of (GCS, APACHEII and SOFA scores) are more evident among NIPPV use and are considered good prognostic factors for success.

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