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Full Length Research Paper

Noninvasive ventilation in relapse of acute respiratory failure outside ICU

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The transfer of patients to the ICU from the general ward could be a frequent issue of major concern in many hospitals around the world. We accessed the effectiveness of NIMV protocol outside ICU in sub-group of patients with relapse of acute respiratory failure and we also determined the factors associated with ICU transfer. This work is a prospective observational study. A total of 525 patients were treated of acute respiratory failure during this period of three years study. Of this, 353 (67.2%) were managed with standard therapy and 46 (8.7%) were presented with relapse and required NIMV outside ICU. The most frequent diagnoses were: COPD 22 (47.8%), CAP 13 (28.3%), CHF 5 (10.9%), asthma 4 (8.7), and diffuse interstitial pulmonary disease 2 (4.3%). Levels of IPAP were 13.5 ± 2.1 and EPAP 6.1 ± 0.8. Respiratory acidosis, the most recent finding, was (82.6%); transfer to the ICU, 5 (10.9%), and need for endotracheal intubation, 3 (6.5%). 2 (4.3%) patients in the study died and 44 (95.7%) patients were alive. The variables associated with transfer to the ICU were: IPAP level (p = 0.005), EPAP level (p = 0.03), antibiotic regimen changes (p = 0.01), and elevated HR (p = 0.04) and acid-base disorders (p = 0, 10). Cumulative survival at 13 months was 86% and in 36 months it was 73% by the Kaplan-Meier method. We identified a sub-group of patients who can benefit from the early application of NIMV protocol outside ICU after the relapse of acute respiratory failure. However, a multi-centre study that involves a greater number of patients with these characteristic could be required

Key words: Noninvasive mechanical ventilation, inspiratory positive airway pressure, emergency room, relapses, transfers UCI, failure.

INTRODUCTION

Non-invasive mechanical ventilation (NIMV) has been shown to be an effective treatment for acute respiratory failure (Brochard, 1995; Masip, 2005; Confalonieri, 1999; Antonelli, 2000; Hilbert, 2001). Most of the research on NIMV has been conducted in Intensive Care Unit (ICU) setting (Lightowler et al., 2003). Nevertheless, several studies found conclusive information about the role of NIMV outside ICU. Plant et al. (2000), found difference in mortality (20%) in the standard treatment and 10% in the NIMV group ($p < 0.05$), and they also showed that, in a subgroup of patients with arterial pH < 7.30, mortality results were higher than that of the ICU.

Further studies have shown benefits from the early introduction of NIMV therapy in patients with arterial pH < 7.35 (7, 8) (Plant, 2000; Keenan, 2003). However, Keenan et al. found poor outcomes with this approach during early hospitalization period (Keenan et al., 2005).

Several studies using NIMV outside ICU had heterogeneous population that included patients with normal pH, compensated and uncompensated hypercapnic and some were hypoxemic (Bardi et al., 2000; Barbé et al., 1996).

In most studies, emergency room patients with acute respiratory failure who are NIMV candidates are either stabilized (Briones et al., 2008), and then transferred to the general ward or treated in ICU. Indeed most studies that

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use NIMV outside ICU do so because of lack of space in the ICU (Bardi et al., 2000; Barbé et al., 1996; Carlucci et al., 2003). However, the great majority of patients that come to emergency with acute respiratory failure are stabilized with standard treatment. Nevertheless, a sub group of patients could appear relapse of the acute respiratory failure. Our hypothesis is that in this subgroup of patients NIMV protocol can be applied early avoiding the transfer of patients to ICU.

Our objectives are:

(1.) Primary: To evaluate if our NIMV protocol is effective in this group of patients. We consider transfering to the ICU (for monitoring, constant NIMV or endotracheal intubation), as indicator of failure.
(2.) Secondary: To determine the factors associated with failure in this subgroup of patients.

MATERIALS AND METHODS

Patients

We included all patients that were admitted to Military Hospital in Guayaquil, Ecuador, between December 1st, 2004 and January 1st, 2007. Consent was obtained from the patients or their relatives if they were unable to do so. This study was approved by the Ethics Committees from "University of San Francisco de Quito" in Cumbaya, and Military Hospital in Guayaquil - Ecuador.

Selection criteria

We selected patients who presented with signs of acute res-piratory failure at the emergency room (RR >25 (breath for minute), those who use accessory muscles, bronchospasm), and those who have been partially stabilized (RR < 25 rpm, PaCO2 < 45 - 50 mmHg with normal arterial pH) with a standard treatment protocol (those who have been given supplemental oxygen, bronchodilator therapy with albuterol plus ipatropium bromide, intravenous treat-ment and corticosteroids, and were subsequently transferred to the general ward; and who later on deteriorate during early hospitalization period, fulfilling therefore inclusion criteria for NIMV treatment protocol (RR > 25 rpm, pH < 7.35 and PaCO2 > 45 mmHg)).

To avoid the possible influence of nosocomial pneumonia (Masterton et al., 2007) in relapse of acute respiratory failure, we considered only patients during the first 48 h of hospital stay

During hospitalization, changes of antibiotic regimen were based on isolation of a specific pathogen on cultures, antibiotic susceptibility pattern and presence of indicators of clinical deterioration defined as new pulmonary infiltrate in chest X-ray (CRX). White cell count (x109/L) (WCC) increased to >50% from baseline, persistent fever, and increased heart rate was >20% from baseline)

Basal acid-base status was recorded prior to the initiation of NIMV protocol (Kellium, 2007) by means of Arterial Blood Gases measurement.

Standard hospitalization therapy

All patients received supplemental Oxygen (< 3 liters for minutes to avoid oxygen-induced hypercapnic), Bronchodilator therapy (200 mcg Albuterol/36 mcg + Ipatropium Bromide every 2 - 4 h) with a metered-dose inhaler with a spacer, Corticosteroid (100 mg Hydrocortisone IV every 6 h), and antibiotics at the discretion of the staff pulmonologist (Ampicillin/Sulbactam or Piperacillin/Clavulanate plus a Fluoroquinolone).

NIMV protocol

We use a BIPAP S (Duet System with Autotrack, manufactured by Respironics Murrysville Inc., Pennsylvania, USA), and a VPAP S/T A manufactured by RESMED.

The spontaneous IPAP and EPAP levels were initially set to 12 cm H2O and 6 cm H2O respectively.

Two types of interface devices were used: the Respironics Comfort Full Mask (manufactured by Respironics Murrysville Inc., Pennsylvania, USA), and the Mirage Full Face series II or Ultra Mirage series III (manufactured by Resmed).

NIMV therapy was given first on an initial non - interrupted 6 h period that was strictly monitored by a Respiratory Technician, an NIMV - Trained Medical Resident, or by the Attending Physician; and after that NIMV therapy was given in an alternating form of 3 h duration, following the tolerance of the patient and monitored by a Respiratory Technician or the head nurse. Weaning was initiated after correct stabilization of clinical parameters. We pursued this protocol as long as the patient's tolerability allows it.

Exclusion criteria for NIMV

Patients were excluded if they presented hemodynamic instability, excessive airway secretions, if they appear uncooperative or agitated, unable to use the interface device, or if they have had recent upper airway surgery, or received NIMV with a "do not resuscitate" order.

NIMV withdrawal

Clinical stability was defined as: 1.) RR <25 rpm, 2.) HR < 100 bpm, and 3.) a compensated arterial pH with SaO_2 (%) > 90% at room air or with low flow oxygen (< 3 L for minutes)

Measurements

Arterial blood gases measurements were done before admission to general ward and before initiation and during NIMV therapy. Mask's complications such as excessive discomfort, nasal ulcer, gastric distention, and claustrophobia were also recorded.

Outcomes

The primary outcome was effectiveness of NIMV Protocol, defined as necessity of transference to UCI for appropriate monitoring.

Secondary outcomes were: hospitalization days, percentage of patients needing endotracheal intubation, and death.

Statistical analysis

All data were expressed as means ± standard deviations for continual variables, and percentages for nominal ones. Each variable was analyzed independently to look for any association with the event defined as failure (transfer to ICU). The t-test for independent samples was used for data with a normal Gaussian distribution and similar variance (determined via variance homogenity test or Levene's test).

A non-parametric test (chi square and Fisher's exact test) was

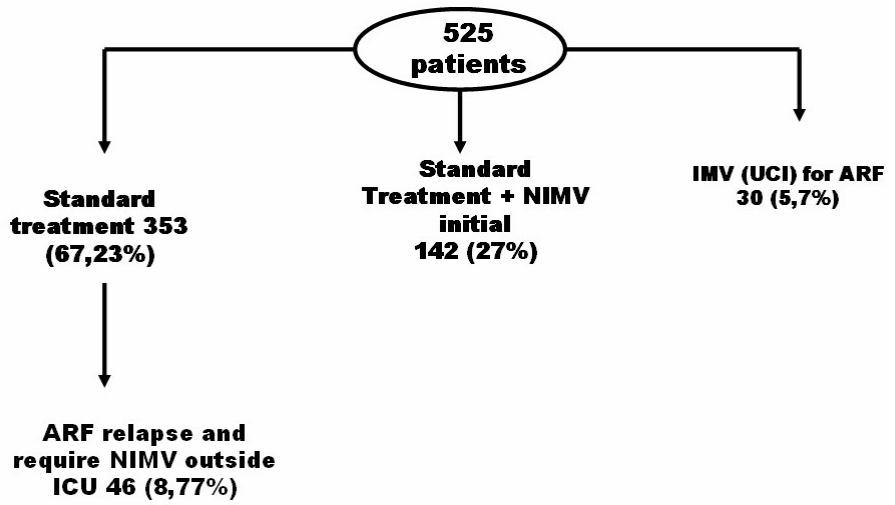

Figure 1. Shows patients taken care in emergency room with acute respiratory failure.

used for data with non-normal distribution and for nominal variables. A p-value of < 0.05 was considered statistically significant. Independent variables that had a p-value of < 0.15 on the univariate analysis was considered in the multiple logistic regression analysis.

Follow up

All patients were evaluated for outpatient survival rate within a 36 month period of home follow-up. The Kaplan-Meier method (Kaplan and Meier, 1958) was used to determine survival rate outside the hospital.

RESULTS

A total of 525 patients were treated for acute respiratory failure. During this period 353 (67.2%) were managed with standard therapy of whom 46 (8.7%), had relapse of acute respiratory failure and required NIMV outside ICU (Figure 1).

The mean age was 72.8 ± 14.1 years, 26 (56.5%) were men and 20 (43.5%) were women.

Previous NIMV events were 0.09 ± 0.2 events. Mean time from admission to NIMV treatment initiation was 1.5 ± 0.5 d. The number of previous admissions in the last three years was 0.8 ± 0.9.

The most frequent diagnoses were: 1.) Chronic obstructive pulmonary disease (COPD) 22 (47.8%), 2.) Community acquired pneumonia (CAP) 13 (28.3%), 3.) Congestive heart failure 5 (10.9%), 4.) Asthma 4 (8.7%), 5.) Diffuse interstitial pulmonary disease 2 (4.3%). Mean levels of IPAP were 13.5 ± 2.1 and for EPAP 6.1 ± 0.8. The frequency of acid-base disorders were: 1). Acute respiratory acidosis 26 (56.5%), 2.). Chronic uncompensated respiratory acidosis 12 (26.1%), 3.) Compensated metabolic acidosis 3 (6.5%), 4.) Metabolic acidosis with Uncompensated respiratory alkalosis 1 (2.2%) and 5.) Compensated metabolic alkalosis 1 (2.2%).

Patient's CRX showed compromise of 1 quadrant in 12 (26.1%), 2 quadrants in 17 (37%), 3 quadrants in 3 (6.5%), and no compromise was observed in 14 (30.4%).

Patients' conditions requiring NIMV were: 1.) Hypercapnic with raised respiratory effort 36 (78.3%), 2.) respiratory effort 8 (17.4%), and 3.) Hypercapnic 2 (4.3%). Changes in antibiotic regimen were made in 6 patients (13%) and no change was made in 40 (87%).

Mean NIMV therapy duration was 4.7 ± 1.9 d. Mean hospitalization length was 6.3 ± 1.9 d. 43 (93.5%) patients remained in the general ward, while the final events 5 (10.9%) patients were transferred to the ICU. Endotracheal intubation was required in 3 patients (6.5%) while 43 patients (93.5%) did not. Two (4.3%) patients in the study died, leaving 44 (95.7%) patients alive (Table 1).

The arterial blood gas sequence and RR of the patients' acute respiratory failure in were in the emergency room for 12, 24 h and at the beginning of NIMV (Table 2).

The variables associated with transfer to the ICU in the univariate analysis were (Tables 3 and 4): IPAP level (p = 0.005), EPAP level (p = 0.03), Antibiotic Regimen Changes (p = 0.01), and elevated HR (p = 0.04) and acid-base disorders (p = 0, 10).

The multiple logistic regression analysis resulted in an OR of 5.9 (0.2 - 163.3, 95% CI) appropriate antibiotic regimen and or of 1.64 (0.9 - 2.8, 95% CI) for IPAP levels. Cumulative survival at 13 months was 86%. Survival rate at 36 months was 73% as calculated by the Kaplan-Meier method (Figure 2).

DISCUSSION

This study shows a clear benefit with early implementation of the NIMV protocol in this subgroup of patients (8.7%) who presented acute respiratory failure relapse

Table 1. Shows the characteristics of the study population.

Characteristic of study population	Mean (Range)
Age (years)	72.8 ± 14.1 (40 - 97)
Sex (Men/Women; %)	26 (56.5)/20 (43.5)
Previous NIMV events	0.09 ± 0.2 (0 - 1)
Time from admissions to beginning of NIMV (days))	1.5 ± 0.5 (1 - 2)
Previous admissions in the last 3 years	0.8 ± 0.9 (0 - 3)
Diagnoses	
COPD (%)	22 (47.8)
Community acquired pneumonia(%)	13 (28.3)
Congestive heart failure(%)	5 (10.9)
Bronquial Asthma(%)	4 (8.7)
Difusse interstitial pulmonary disease	2 (4.3)
Equipment used (%)	
BIPAP S DUET LX SYSTEM. (RESPIRONICS) WITH AUTOTRAK	43 (93.5)
VPAP ST -A (RESMED)	3 (6.5)
Ventilator mode	
BIPAP S	45 (97.8)
CPAP	1 (2.2)
Levels EPAP (cmH_20)	6.15 ± 0.84 (5 - 10)
Levels IPAP (cmH_20)	13.5 ± 2.15 (11 - 18)
Acid base disorders (%)	
Acute respiratory acidosis	26 (56.5)
Chronic uncompensated respiratory acidosis	12 (26.1)
Compensated metabolic acidosis	3 (6.5)
Metabolic acidosis plus uncompensated respiratory alkalosis	3 (6.5)
Metabolic acidosis plus uncompensated respiratory acidosis	1 (2.2)
Compensated metabolic alkalosis	1 (2.2)
Status requiring NIMV (%)	
Hypercapnia plus respiratory effort	36 (78.3)
Respiratory effort	8 (17.4)
Hypercapnia	2 (4.3)
Changes in antibiotic regimen (%)	
No	40 (87)
Yes	6 (13)
Chest X-ray (%)	
Normal	14 (30.4)
1 quadrant	12 (26.1)
2 quadrant	17 (37)
3 quadrant	3 (6.5)
Days NIMV	4.78 ± 1.93. Range (2 - 10)
Days Hospitalization	6.39 ± 1.9. Range (3 - 12)
Final outcomes	
Transfer to the UCI (%)	
No	41 (89.1)
Yes	5 (10.9)
Endotraqueal intubation (%)	
No	43 (93.5)
Yes	3 (6.5)
Mortality (%)	
No	44 (95.)
Yes	2 (4.3)

Data are presented as numbers and percentages unless otherwise specified.
NIMV, No invasive mechanical ventilation; IPAP, inspiratory positive airway pressure; EPAP; Expiratory positive.

Tables 2. Diagnosis, characteristics of 46 consecutive patients receiving NIMV outside the intensive care unit.

Diagnoses	Ph (emergency)	Ph (12 h)	Ph (24 h)	Ph (NIMV)	PCO_2 (emergency)	PCO_2 (12 h)	PCO_2 (24 h)	PCO_2 (NIMV)
COPD	7.34 ± 0.03	7.38 ± 0.03	7.38 ± 0.03	7.32 ± 0.08	47 ± 11.4	46.7 ± 11.4	46.9 ± 1	52.4 ± 13.7
Community acquired pneumonia	7.34 ± 0.01	7.34 ± 0.02	7.38 ± 0.03	7.29 ± 0.06	54.9 ± 5.6	54.5 ± 9.4	55.1 ± 8.3	66.2 ± 16.4
Congestive Heart Failure	7.34 ± 0.01	7.39 ± 0.02	7.37 ± 0.02	7.30 ± 0.02	40.8 ± 13.3	41.8 ± 9.4	44.8 ± 12.3	43.7 ± 15.7
Bronquial Asthma	7.33 ± 0.01	7.40 ± 0.03	7.39 ± 0.03	7.34 ± 0.04	52 ± 2.4	51.2 ± 3.9	51 ± 2.7	58.8 ± 4.9
Difusse Interstitial Pulmonary Disease	7.34 ± 0.01	7.40 ± 0.01	7.37 ± 0.01	7.32 ± 0.01	53.7 ± 4.2	51.7 ± 4.2	53.3 ± 0.5	58.7 ± 4.2
All	7.34 ± 0.02	7.38 ± 0.03	7.37 ± 0.03	7.30 ± 0.07	49.3 ± 10.4	49 ± 10.6	49.7 ± 9.8	56.2 ± 15.4

Tables 2. Contd.

Diagnoses	HCO_3 (emergency)	HCO_3 (12 h)	HCO_3 (24 h)	HCO_3 (NIMV)	PaO_2 (emergency)	PaO_2 (12 h)	PaO_2 (24 h)	PaO_2 (NIMV)
COPD	28.2 ± 7.5	25.1± 4.3	25.3 ± 3.7	27.2 ± 6.6	56.1 ± 8.5	74.8 ± 6.9	77.9 ± 12	79.8 ± 8.5
Community acquired pneumonia	33 ± 6.1	27.4 ± 3.8	29.1 ± 6.5	35.1 ± 9.4	60.9 ± 11.8	74.1 ± 7.6	80.5 ± 9.1	60.9 ± 11.8
Congestive heart failure	27 ± 9.9	22.4 ± 3.2	22.5 ± 3.8	21.7 ± 7.1	55 ± 3.6	72.6 ± 7.3	80.2 ± 4.7	55 ± 3.6
Bronquial asthma	32.4 ± 5.3	25.6 ± 1.3	27 ± 3.8	31.5 ± 5.1	55 ± 5.6	77.7 ± 4.5	82.5 ± 3.7	55 ± 5.6
Difusse interstitial pulmonary disease	37.7 ± 4.2	25.1 ± 0.4	25.3 ± 0.5	29.9 ± 2.1	71 ± 16.9	82.5 ± 6.3	90.5 ± 3.5	71 ± 16.9
All	30.3 ± 7.5	25.6 ± 4	26.3 ± 5.0	29.4 ± 8.3	57.9 ± 9.7	75.0 ± 7	79.9 ± 10	80.4 ± 16.1

Tables 2. Contd.

Diagnoses	SaO_2% (emergency)	SaO_2% (12 h)	SaO_2% (24 h)	RR (emergency)	RR (12 h)	RR (24 h)	RR (NIMV)
COPD	83.8 ± 10.1	92 ±1 .9	94.7 ± 3.9	31.3 ± 3.1	23.3 ± 2.6	21 ± 1.7	29.7 ± 3.8
Community acquired pneumonia	83.2 ± 10.4	89.8 ± 9.4	91.8 ± 6.5	30.2 ± 3.4	23.3 ± 3	20 ± 1.5	28.1 ± 3.3
Congestive heart failure	85.2 ± 5.7	91.4 ± 1.9	94.2 ± 1.3	31.6 ± 3.36	23.4 ± 1.3	22 ± 14	28.5 ± 0.8
Bronquial asthma	87.2 ± 4.9	93 ± 2.1	94.7 ± 2.6	30.5 ± 3	21.7 ± 2	20.5 ± 1.9	29.7 ± 4.3
Difusse interstitial pulmonary disease	89.5 ± 3.5	92 ± 2.8	94.5 ± 0.7	32 ± 5.6	23 ± 1.4	23 ± 1.4	33 ± 9.9
All	84.4 ± 9.2	91.4 ± 5.2	93.9 ± 6.1	31.0 ± 3.2	23.2 ± 2.6	21.1 ± 1.7	29.3 ± 3.8

Data are presented as numbers and percentages unless otherwise specified.
pH, arterial blood; PaCO2 partial pressure of arterial carbon dioxide (mm Hg); HCO3 bicarbonate sodium concentration (mosm/L). PaO_2 partial pressure of arterial oxygen (mm Hg); SO_2%, percentage of oxygen saturation; RR, respiratory rate.

Table 3. Shows the variables associated with transfer to the ICU in the univariate analysis.

	Success (means ± SD)	Failure (Transfer to the UCI) (means ± SD)	Valor p
Previous admissions in the last 3 years	41 (0.88 ± 1)	5 (0.8 ± 0.8)	P = 0,86
Previous NIMV events	41 (0.1 ± 0.3)	5	P = 0,91
Age (years)	72.7± 14.7	73.8 ± 8.7	P = 0,87
Time from admissions to beginning of NIMV (dyas)	1.5 ± 0.5	1.4 ± 0.5	P = 0,75
DAYS NIMV	4.7 ± 1.9	4.8 ± 1.7	P = 0,98
Days hospitalization	6.4 ± 1.9	6.2 ± 1.9	P = 0,81
Ph	7.31 ± 0.06	7.29 ± 0.14	P = 0,29
$PaCO_2$	55.4 ± 13.4	62.9 ± 28.5	P = 0,31
HCO_3	29.1 ± 8.6	31.2 ± 5.6	P = 0,50
PaO_2	81.2 ± 14.4	73.8 ± 28	P = 0,20
SaO_2 (%)	93.3 ± 5.8	89.5 ± 8.2	P = 0,19
RR (rpm)	29.2 ± 3.9	29.9 ± 2.3	P = 0,57
Levels IPAP cmH_20)	13.2 ± 1.8	15.4 ± 3.5	P = 0,005*
Levels EPAP (cmH_2O)	6.2 ± 0.8	5.8 ± 0.4	P = 0,03*
HR (bpm)	91.5 ± 11.8	103.5 ± 22.3	p = 0,04*

Data are presented as numbers and percentages unless otherwise specified.
NIMV, No invasive mechanical ventilation; IPAP, inspiratory positive airway presure; EPAP; expiratory positive ; airway presure; HR, heart rate; $PaCO_2$ partial pressure of arterial carbon dioxide (mm Hg); pH, arterial blood; PaO_2 partial pressure of arterial oxygen (mm Hg); RR, respiratory rate; SaO_2 arterial oxygen saturation (%). RR, Respiratory rate
*P < 0.01 = statistically significant.
*P < 0.05 = statistically significant.

outside ICU. With this therapy, 41 (89.1%) patients were managed and did not require ICU transfer. Of the 5 (10.9%) patients which had to be transferred to the ICU, 2 (4.3%) subsequently died.

In our study we identified a sub-group of patients, who after an initial improvement with standard treatment, they make relapse of the acute respiratory failure of the 353 (67.2%) patients with standard therapy alone 46 (8.7%) required NIMV outside ICU. Although our patients were hypercapnic (PCO_2 49.7 ± 9.8 and 7.38 ± 0.03 at 24 h) in the emergency room, it does not constitute an indication for the beginning of NIMV. Keenan et al. (2005) demonstrated that the use of NIMV in patients with hypercapnic and a compensated pH of 7.40, is poorly tolerated. In Keenan's study, 2 (7.4%) out of 27 patients with standard treatment failed. In our institution, the decision of where to initiate the NIMV protocol, either in the emergency room, the ICU or the general ward, relies solely on the staff pneumonologist- ICU.

This is because our group has reached the sufficient expertise in applying the NIMV protocol. It has been well demonstrated that a unit skills in NIMV are greatly improved only after a completion of a "learning curve" (Carlucci et al., 2003).

Paus-Jenssen et al. (2004) studied 75 subjects treated with NIMV. The results showed that 1/4 (41%) of NIMV therapies were started outside ICU. Nevertheless, they did not specify the use of a standardized NIMV protocol. An 18% of patients received NIMV because of shortness of breath.

Viñay Maheshwari et al. (2006) showed that 82% of NIMV therapies were started in the general ward and that in 75% of patients, NIMV could be maintained with favorable response. Also, the use of a NIMV protocol was associated with a better outcome (56% vs. 43.5%). Cabrini et al. (2009) showed that under the supervision of a Medical Emergency Team, the NIMV could be applied in a wide variety of settings, outside the ICU.

A 56.5% of our patients had acute respiratory acidosis as the primary arterial blood gases disorder. These data are consistent with Farha et

Table 4. Shows the variables associated with transfer to the ICU in the univariate analysis.

Diagnoses	Patients (Total)	Success (Total and %)	Failure (Transfer to the UCI) Total and (%)	Valor p
COPD	22	19 (41.6)	3 (6.2)	P = 0.8505
CAP	13	11 (23.9)	2 (2.3)	
CHF	5	5 (10.8)	0	
Asthma	4	4 (8.6)	0	
Difusse interstitial pulmonary disease	2	2 (2.3)	0	
				P = 0.36
CRX				
Normal	14	12 (26)	2 (4.34)	
1 quadrant	12	12 (26)	0	
2 quadrant	17	15 (32.6)	2 (2.3)	
3 quadrant	3	2 (2.3)	1 (2.1)	
				P = 0.1034
Acid base disorders				
Metabolic acidosis plus uncompensated respiratory acidosis	1	1 (2.1)	0	
Metabolic acidosis plus uncompensated respiratory alkalosis	3	3 (6.2)	0	
Compensated metabolic acidosis	3	3 (6.2)	0	
Acute respiratory acidosis	26	23 (50)	3 (6.2)	
Chronic uncompensated respiratory acidosis	12	11 (23.9)	1 (2.1)	
Compensated metabolic alkalosis	1	0	1 (2.17)	
				P = 0.8746
Status requiring NIMV				
Hypercapnic plus respiratory effort	36	32 (69.5)	4 (8.6)	
Hypercapnic	2	2 (2.3)	0	
Respiratory effort	8	7 (15.2)	1 (2.1)	
				P = 0.2037
Ventilator mode				
BIPAP S	45	40 (86.9)	5 (10.8)	
CPAP	1	1 (2.1)	0	
				P = 0.51
Equipment use				
BIPAP DUET LX (WITH AUTOTRAK). respironics	44	39 (84.78)	5 (10.8)	
VPAP II ST- A (RESMED)	2	2 (4.2)	o	
				p = 0.01*
Changes in antibiotic regimen				
No	41	38 (82.6)	3 (6.2)	
Yes	5	2 (4.34)	3 (6.2)	

Data are presented as numbers and percentages unless otherwise specified. COPD, chronic obstructive pulmonary disease; CAP, Community acquired pneumonia; CHF, congestive heart failure. Bipap S: Bilevel positive airway pressure mode spontaneous; CPAP: Continuous positive airway pressure; CRX = CHEST X-RA. *P < 0.01 = statistically significant. *P < 0.05 = statistically significant.

al. (2006) findings, which reported 58.82% of cases with primary respiratory acidosis.

In this study we showed that the patients with COPD, the values of PCO2 were high, in spite of the partial normalization of pH, PaO2, Sato 2%, RR in the first 24 h. Of equal way our patients with CAP showed high values of PCO2.

Some authors Confalonieri et al. (1999) and Wysocki et al. (1995) have demonstrated that NIMV in CAP can be useful under certain conditions, especially in hypercapnic patients. Nevertheless, other studies have demonstrated that patients with pure hypoxemic respiratory failure have lower response rates (Delclaux et al., 2000; Antonelli et al., 1998). Even though, improvement is seen due to mechanical development (interface devices, equipment and techniques) (Ferrer et al., 2003; Rocco et al., 2004), there is not sufficient evidence to recommend NIMV in patients with pure hypoxic respiratory failure, decompensated metabolic acidosis with hypoxemia or severe shock (Rocker et al., 1999; Rana et al., 2006).

Our study showed that the increasing level of IPAP is a factor associated with a failure. Patients with IPAP levels of ≥ 18 cm H_20 had higher probabilities of being transferred to the ICU. Even if changes in IPAP level are

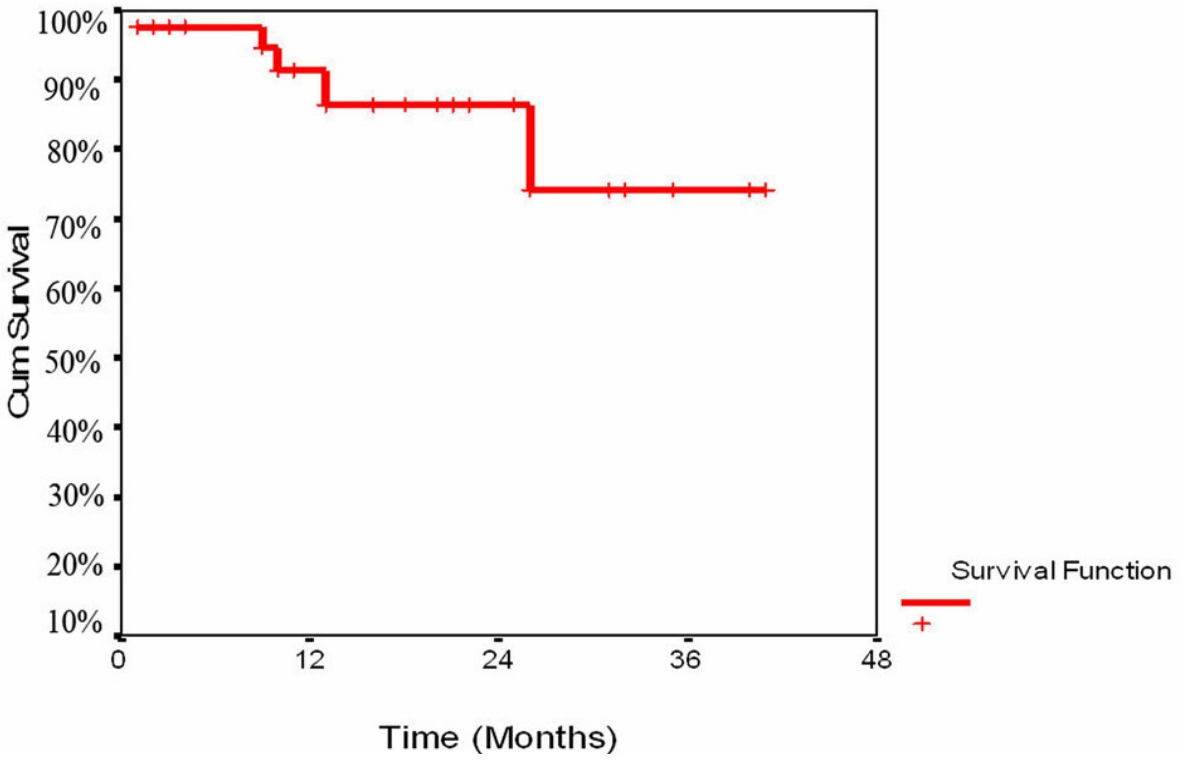

Figure 2. Shows Cumulative survival at 13 months was 86% and in 36 months it was 73% by the Kaplan-Meier method.

related to those on $PaCO_2$, this single variable is not a predictor of outcome (López-Campos et al., 2006). IPAP levels are linked to the RR, exhaled minute volume, $PaCO_2$ levels, bronchospasm persistency and patient comfort levels. Another factor associated with a failure was the HR. Patients who had tachyarrhythmias should be managed and controlled with continued monitoring in the ICU.

We also found that basic acid disturbance was a factor associated with transference to UCI, metabolic acidosis, shock and hypoxaemia has high probability of failure to the NIMV, and therefore it must be always made in the UCI.

In the multivariate analysis we found that the appropriateness of antibiotic use and IPAP pressure levels were factors associated with the transfer of the patient to the ICU. However, our model will be unstable, evidenced by estimated OR by its extremely wide CI (Peduzzi et al., 1996). As a result, multi-centre study that involves a greater number of patients with these characteristic could be required.

Limitations in our study are:

(1.) It is a monocentric, observational study that can not represent the actual NIMV management in other hospitalization areas.

(2.) Due to a small sample size, we did not consider the relationship that may have subsisted between baseline co-morbidities or diseases (diabetes mellitus, cancer, hypothyroidism), and antibiotic therapy failure and/or mortality.

(3.) Since NIMV is a standard treatment for uncompensated hypercapnic respiratory failure, a control group was not included.

On the other hand, in this study the NIMV protocol applied to certain patients showed advantages over others outside ICU, because of:

(1.) Availability of beads in the ICU was not an issue.

(2.) Patients were included to NIMV protocol only after they have had experienced-respiratory failure posterior to partial stabilization with a standard treatment. Therefore, we tried to minimize the superimposed effect of conventional BIPAP therapy in respiratory insufficiency.

(3.) Finally, the relapse of acute respiratory insufficiency outside ICU constitutes a fact that there is need to have account of sub-groups of patients with respiratory pathologies in which the early intervention with NIMV would be indicated.

Based on these results, we consider that an NIMV protocol (administered by a well trained group of health care providers and physicians) applied early outside UCI in patients with worsened respiratory failure, after the application of a standard treatment, could be used success-

fully, avoiding transference of the patients to ICU.

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