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Optimizing Comfort Through Vocal Amplification During Non-Invasive Ventilation in the Acute Settings: A Proof-of-Concept (POC) Study

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1. Abstract

1.1. Introduction: Refusal of Non-Invasive Ventilation (NIV) in acute respiratory failure is associated with a worse prognosis. This study aimed to evaluate the impact of improving the subject's verbal communication on comfort and frustration levels during NIV sessions.

1.2. Methods: Setting and design: Single-center, prospective, cross-over, randomized, double blind study. Population: NIV-naïve subjects with an indication for NIV. Interventions: subjects received two sessions of NIV using different masks: a regular masks (RM) and a mask with vocal amplification (MVA). Subjects were randomized as to the order of the sessions. A washout period separated the two sessions. Comfort of speech (COS), frustration (F) and global comfort (GC) were assessed at the end of each session using a visual analog scale (VAS) by a blinded investigator.

1.3. Results: 18 subjects were randomized, with 1 drop out after the first session. COS, F, and GC were significantly improved with the use of MVA compared to RM. No significant differences in clinical and blood gas parameters were observed between the RM and MVA sessions.

1.4. Conclusions: Improving the subject's ability to communicate during NIV sessions using MVA in an acute setting is perceived more comfortable and less frustrating. Larger trials are necessary in order to determine the impact of MVAs on NIV failure, subject adherence, and clinical outcomes.

2. Introduction

Non-Invasive Ventilation (NIV) is strongly recommended in cardiogenic pulmonary edema [1, 2] as well as in hypercapnic COPD exacerbations [1, 3, 4]. NIV effectively reduces the risk of mortality and the need for endotracheal intubation compared to usual medical care [2, 3, 5]. NIV intolerance or misuse is responsible for poor clinical outcomes and increased healthcare cost. Previous negative experiences with the therapy and comfort issues were actually established as predictors of poor NIV adherence [6]. Multifactorial interventions targeting subject motivation, skills and cognitive-emotional aspects effectively improved therapeutic adherence in COPD subjects [7].

Strapping a mask over the subject's face can be very frightening to a breathless subject in acute respiratory failure, particularly in NIV-naïve and claustrophobic subjects [8, 9]. A careful explanation of what will happen and why NIV is used as well as a description of the sensation the subject is likely to experience can help facilitate the treatment. In fact, mask intolerance was reported in 14% of subjects receiving CPAP [10] and was associated with early discontinuation of non-invasive pressure support ventilation [11]. Mask-related complications such as claustrophobia and subject agitation frequently impose the use of sedatives in order to prevent NIV failure and consequently endotracheal intubation [12].

The effect of masks and invasive breathing tubes implicated in the majority of ventilation methods on mechanical ventilation failure could lie in their restriction of subjects' ability to communicate. Loss

of speech was actually reported as a major form of physical distress and bodily restriction in mechanical ventilation [13]. Ventilation-induced distress could be attributed to high levels of subject frustration due to the inability to communicate their needs to caregivers and family [14].

However, the relationship between communication and subject variables such as comfort are poorly examined in the literature. Thus, this proof-of-concept study aims to investigate the influence of vocal amplification, and consequently, communication improvement, on the comfort and frustration of NIV-naïve subjects in acute respiratory failure requiring NIV.

3. Methods

3.1. Study design

We designed a prospective, cross-over, single center, randomized, double-blind study. NIV sessions were conducted in the intensive care unit and regular in subject ward of the Hotel-Dieu de France university hospital in Lebanon in accordance with the amended Declaration of Helsinki.

Written informed subject consent was obtained from all subjects. The study was approved by the ethics committee at Hotel-Dieu de France university hospital (CEHDF 976) and was promoted by the "conseil de la recherche" at Saint Joseph University in Lebanon.

All subjects were ventilated using a facial mask. During interventional sessions, the voice of ventilated subjects was amplified through the adjunction of a contact microphone to the external surface of the mask. A wireless Bluetooth receiver was connected to an amplifier. Integrated noise suppression allowed the amplification of intelligible subject speech through the improvement of the signal/noise ratio.

Using the same mask during both consecutive sessions, the amplification was either activated during Masks with Vocal Amplification (MVA) sessions or inactivated during Regular Masks (RM) sessions. Subjects were randomized in two groups as to the order of the sessions. NIV sessions were conducted for 120 minutes using a bilevel positive airway pressure (BiPAP) or CPAP at the physician's discretion, separated by a 120-minute washout period (Figure 1). Ventilation parameters were set by the treating physician and were kept identical during the two sessions. Standardized speech was employed in order to stimulate speech. Five minutes after the start of each session, subjects were asked to cite the days of the week and count to ten. Oxygen was administered as needed by treating physician using nasal cannula or oronasal mask during the washout period.

Clinical parameters were collected at the beginning of each session for all subjects. To that end, Respiratory Rate (RR), Cardiac Rate (CR), modified Borg Dyspnea Scale (BDS), Richmond Agitation-Sedation Scale (RASS), as well as systolic and diastolic blood pressures were recorded.

In order to minimize bias, registered nurses blinded to the type of the session questioned the subject after each session as to the Comfort of Speech (COS), Global Comfort (GC) and Frustration (F) using a Visual Analog Scale (VAS) for each parameter. Subjects were also asked to attribute the discomfort to different elements (bronchial secretions, the NIV mask, the positive pressure, global communication loss and air leaks) using a 3-point Likert scale.

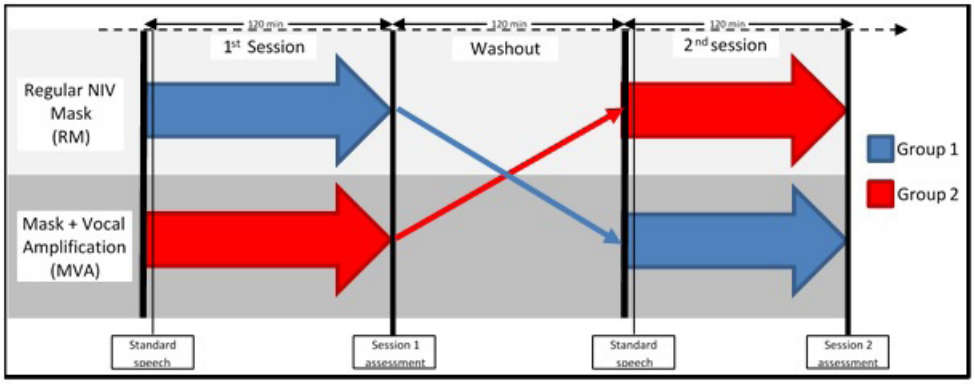

Figure 1: Study design

3.2 Outcomes

The primary objective was to evaluate the impact of using MVA as compared to RM on the COS in subjects requiring NIV in an acute context. To that end, the researchers employed a visual analog scale with 10/10 representing maximal comfort.

The secondary objectives were the evaluation of GC as well as frustration depending on mask type, and the potential impact of vocal amplification on air leaks, partial carbon dioxide pressure (paCO2) drop, blood pressure, heart rate, and respiratory rate.

3.3 Subject Population

We included hospitalized, NIV-naïve adults for whom the treating physician had prescribed non-invasive ventilation in an acute context. NIV-naïve was defined as having never been on CPAP or NIV or having a lifetime NIV usage of less than 2 months, with no NIV usage in the 6 months preceding enrollment in the study.

We excluded subjects with NIV contraindication, severe acidosis (pH<7.15), hemodynamic instability (defined as requiring the equivalent of 0.1 μg/kg/min of norepinephrine), a Glasgow coma scale of <14, lack of cooperation, and/or incapability of spontaneous

verbalization, as well as subjects requiring sedation during the NIV sessions.

3.4 Blinding

The present study was a double blinded investigation during which both subjects and evaluators of subject comfort variables were blinded regarding group assignments. As such, the registered nurse in charge of collecting the VAS results was not aware whether a RM or MVA was used in the NIV session. However, subject medical care was ensured independently of the researchers by hospital ward personnel such as treating physicians, nurses, and respiratory therapists. As a result, hospital ward personnel were not blinded to group assignments seeing as they arranged the experiment setup.

3.5 Assessments

3.5.1 Subject comfort: Subject Comfort of Speech (COS), Global Comfort (GC) and Frustration (F) were evaluated at the end of each session. A nurse blinded to group assignments completed the evaluation by asking subjects to rate their COS (eg 10: maximal confort of speech), GC (eg 10: maximal confort) and F (negative eg 10: maximal frustration) according to a visual analog scale (VAS). Subjects were also asked to evaluate the discomfort attributable to different elements (bronchial secretions, the NIV mask, the positive pressure, global communication loss, and air leaks) according to a numerical scale representing light, moderate and severe discomfort.

3.5.2 Clinical data: Clinical parameters were collected at the beginning of each session for all subjects. To that end, Respiratory Rate (RR), Cardiac Rate (CR), modified Borg Dyspnea Scale (BDS), Richmond Agitation-Sedation Scale (RASS), as well as systolic and diastolic blood pressures were measured by a non-blinded resident or internal researcher. Subject follow up during the NIV sessions was also undertaken in order to monitor session duration, time elapsed before eventual drop out, and time elapsed before intubation, in addition to other factors.

Arterial Blood Gas (ABG) was similarly measured at the beginning as well as the end of each NIV session. Measured blood parameters included pH, partial pressure of carbon dioxide (PaCO2) and partial pressure of oxygen (PaO2).

3.6 Statistical Analysis

Data analysis was completed using SPSS v.23.0. A p-value less 0.05 was taken to indicate statistical significance. Independent sample t-test and Mann-Whitney U test were employed for the analysis of normally and abnormally distributed continuous variables, respectively. Moreover, chi-square or a Fisher exact tests were used when appropriate for the analysis of categorical variables.

4. Results

Two hundred and six new subjects were admitted to the pulmonary department between October 2016 and January 2017 and were assessed for eligibility. Of the 20 eligible subjects, 2 were converted to mechanical ventilation prior to randomization while 1 subject dropped-out following the first session. Seventeen subjects were randomized into two groups as indicated in the flowchart (Figure 2).

Acute COPD exacerbation was the most common indication for NIV in both groups, followed by endotracheal intubation and acute pulmonary edema (Table 1). Reported subject comorbidities included hypertension, diabetes and dyslipidemia, with variable rates in study groups. None of the subjects had been sedated in the 48 hours preceding NIV. Of the 17 included subjects, previous exposure to NIV was noted in 2 subjects. No baseline difference was seen in clinical or blood gas parameters between the 2 subject groups (Table 2).

VAS scores of COS, GC and frustration were significantly higher in intervention sessions as compared to RM sessions. In fact, COS was 7.076±2.964 on MVA vs. 5.152±3.180 on RM (p=0.013). Frustration was lower with a VAS of 7.127±3.247 on MVA, as compared to RM sessions 5.538±3.276 (p=0.005). GC was improved with use of vocal amplification with a VAS of 6.834±2.206 and 5.655±2.302 in MVA and RM sessions, respectively (p=0.007) (Table 3).

The various contributing factors to the discomfort during NIV were also explored. Moreover, subject-reported discomfort levels indicated no significant difference between the MVA and RM groups in regard to bronchial secretions, air leaks, positive pressure, and the NIV mask itself.

Clinical parameters, such as respiratory rate, modified Borg dyspnea scale, Richmond agitation sedation scale, and Glasgow coma scale did not exhibit statistical significance between VMA and RM sessions. Cross-tabulation revealed a significant (p <0.001) association between smoking and higher COS levels as well as lower frustration (p <0.001). Moreover, males exhibited significantly less frustration than women (p 0.03).

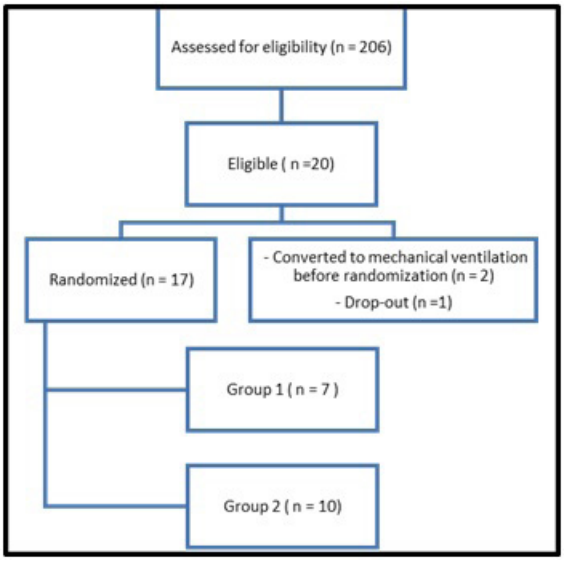

Figure 2: Flowchart of the study.

Table 1: Demographic and clinical characteristics of subjects in each study group.

Parameter	Group 1 (RM-MVA)	Group 2 (MVA-RM)	Total subject population
Subject number (n)	7	10	17
Median Age (years)	63	74	70
gender (n)			
Male	4 (57.14%)	4 (40%)	8 (47.06%)
Female	3 (42.86%)	6 (60%)	9 (52.94%)
BMI (kg/cm^2)	25.71	28.99	28.23
Smoking (n)			
Yes	4 (57.14%)	6 (60%)	10 (58.82%)
No	3 (42.86%)	4 (40%)	7 (41.18%)
Comorbidities (n)			
Hypertension	2 (28.57%)	4 (40%)	6 (35.30%)
Diabetes	2 (28.57%)	2 (20%)	4 (23.53%)
Dyslipidemia	1 (14.29%)	2 (20%)	3 (17.65%)
NIV-indicating diagnosis: (n)			
Acute COPD exacerbation	4 (57.14%)	5 (50%)	9 (52.94%)
Acute pulmonary edema	1 (14.29%)	4 (40%)	5 (29.41%)
Endotracheal intubation	2 (28.57%)	0 (0%)	2 (11.76%)
Hypercapnic respiratory failure associated with a chest-wall disease	0 (0%)	1 (10%)	1 (5.89%)
Sedation in previous 48h (n)			
Yes	0 (0 %)	0 (0 %)	0 (0%)
No	7 (100%)	10 (100%)	17 (100%)
Previous exposure to PPNIV (n)			
Yes	2 (28.57%)	0 (0%)	0 (0%)
No	5 (71.43%)	10 (100%)	17 (100%)

Table 2: Clinical and blood gas parameters before and after ventilatory sessions.

Parameter	MVA (n=17)	RM (n=17)	P value
Pre-NIV session blood pressure (mmHg)			
Systolic	130.820±17.529	129.760±19.276	0.501
Diastolic	71.880±11.895	67.530±12.011	**<0.05**
Pre-NIV session respiratory rate (breaths/min)	22.94±5.129	23.760±4.423	0.241
Pre-NIV session cardiac rate (beats/min)	81.650±7.648	80.880±8.396	0.678
Pre-NIV session modified Borg Dyspnea Scale	1.529±1.096	1.588±1.162	0.683
Richmond agitation sedation scale	0.290±0.686	0.240±0.752	0.332
Air leak (%)	13.530±16.535	16.290±17.207	0.406
Blood gas			
pH			
Pre-NIV session pH	7.382±0.055	7.383±0.050	0.961
Post-NIV session pH	7.419±0.039	7.4159±0.052	0.742
$PaCO_2$ (mmHg)			
Pre-NIV session	54.650±7.786	55.53±11.598	0.723
Post-NIV session	46.530±6.115	48.650±10.712	0.341
PaO_2 (mmHg)			
Pre-NIV session	70.59±11.012	65.840±22.732	0.28
Post-NIV session PaO_2	86.530±20.100	83.88±16.963	0.584
HCO3 (mEq/L)			
Pre-NIV session	31.365±5.120	29.070±4.943	0.442
Post-NIV session	30.500±3.952	31.218±4.810	0.667
hemoglobin O_2 saturation (%)			
Pre-NIV session	91.965±4.512	92.600±4.204	0.667
Post-NIV session	95.118±2.056	94.424±2.694	0.256

MVA: mask with vocal amplification, RM: Regular NIV mask

Table 3: variation of COS (comfort of speech), F (frustration), and GC (general comfort) VAS between sessions of ventilation completed through MVA (mask with vocal amplification), and RM (regular NIV mask).

	MVA		RM		P value
COS VAS	7.076±2.964	5.552; 8.600	5.152±3.180	3.517; 6.788	0.013
F VAS	7.127±3.247	5.457; 8.797	5.538±3.276	3.853; 7.220	0.005
GC VAS	6.834±2.206	5.699; 7.968	5.655±2.302	4.472; 6.839	0.007

5. Discussion

The alteration of communication experienced during mechanical ventilation had previously been associated with feelings of helplessness, decreased subject satisfaction, and increased frustration (15). The inability to speak therefore constitutes a notable source of physical distress imposed by ventilation therapy [13], leading to psychological distress, and anxiety [16]. The application of different ventilation interfaces such as mouth piece ventilation was found to pose less speech restrictions on subjects and thereby improve NIV acceptance and compliance [17]. New oxygen supply techniques, such a nasal high flow, do not impede speech, and were actually found to increase subject comfort and tolerance when compared to face masks [18]. The results of the present study reflect the importance of communication in subject comfort outcome measures. The sessions using RM and MVA only differed in the activation of the vocal amplification, which attributes speech restoration as the probable cause of the observed improvement in comfort and reduction in frustration levels.

The use of vocal amplification had no significant effect on clinical and blood parameters. The impact of MVA could be restricted to subject comfort outcomes without any spill-over on clinical parameters. However, previous studies have shown the significant effect of different ventilation interfaces on clinical outcome measures such as mortality and oxygenation levels [20]. Further investigation using a larger subject sample is thus necessary in order to establish the clinical implications, if any, of vocal amplification in NIV.

The employment of a VAS for the assessment of comfort outcomes probably affected the accuracy of study results. However, with the absence of a validated scale for the evaluation of the comfort and frustration of a ventilated subject in extant literature, we used VAS, which had been used in various NIV [18, 21] and high-flow nasal cannula studies [19].

5.1. Limitations

As with any research, the present study was not without limitations. Firstly, including medical personnel in the double-blinding process was not feasible due to the practical impossibility of establishing the experimental setup without knowledge of subject group. Secondly, our study was a proof-of-concept study with a small sample size. Large-scale, multi-centered research would therefore be necessary for the elucidation of generalizable results reflecting the impact of vocal amplification on the clinical efficacy of NIV as well as subject acceptance and adherence to therapy.

6. Conclusions

The presence of vocal amplification during NIV significantly improved subject comfort of speech, global comfort as well as frustration levels, compared to the use of regular ventilation masks. No significant difference was observed in clinical and blood parameters with the use of a MVA.

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