RESCUE THERAPY BY SWITCHING TO TOTAL FACE MASK AFTER FAILURE OF FACE MASK-DELIVERED NONINVASIVE VENTILATION IN DO-NOT-INTUBATE PATIENTS IN ACUTE RESPIRATORY FAILURE

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Rescue Therapy by Switching to Total Face Mask After Failure of Face Mask-Delivered Noninvasive Ventilation in Do-Not-Intubate Patients in Acute Respiratory Failure*

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Critical Care Medicine



研究探討的問題為何?

Population

Patients with a do-not-intubate order and treated by noninvasive mechanical ventilation for acute respiratory failure.

Intervention

Standard face mask. [FM]

Comparison

Switching to total face mask. [TFM]

Facial pressure sore and Blood Gas Analysis.







Introduction

Noninvasive mechanical ventilation

- Noninvasive mechanical ventilation (NIV) is now considered as the cornerstone of the initial therapeutic management of patients admitted for acute on chronic respiratory failure.
- When appropriately indicated, NIV significantly reduces mortality
 mean
 hospital stay and intubation rate.
- NIV may relieve air hunger
 feeling of impending death and may be proposed as the treatment of last resort to these patients in spite of their poor prognosis.
- Despite careful precautions, painful facial pressure sores may rapidly occur when a facial mask (FM) is applied for long periods of time.
- The type of interface is widely recognized as a key point that can greatly influence the way the patient tolerates NIV.

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NIV-associated adverse events

- Skin breakdown
- Conjunctivitis
- Nausea
- □ Gastric distention
- Claustrophobia
- patient's discomfort





Design and Setting

Prospective observational study in an ICU and a respiratory step down unit over a 12-month study period.



Materials and Methods

- During a 12-month period, a prospective observational study was conducted in the Department of Emergency and Critical Care Medicine of <u>Schaffner Hospital</u> to evaluate all patients with a do-not-intubate order and treated by NIV for ARF.
- The local ethics committee approved the study and signed informed consent was obtained from all the patients or next of kin.
- In all cases, patients and their family should be informed that NIV is being used as a form of life support in this setting and should be given the option to refuse it.

Included criteria

- Clinical criteria defining ARF included :
 - --Tachypnoea(>24/min in obstructive, >30/min in restrictive).
 - --Signs of increased work of breathing.
 - --Accessory muscle use.
 - --Abdominal paradoxical motion.
 - --Blood gas criteria for entry included either pH< 7.35, PaCO2>45 mmHg, or PaO2/FIO2 ratio < 200.

Excluded criteria

- Respiratory or cardiac arrest.
- Multiple organ failure.
- Need for vasopressors.
- □ Fixed upper airway obstruction.
- Facial burns or trauma.
- Recent facial or upper airway surgery.
- Swallowing impairment
- □ Vomiting.
- Unresponsiveness.
- □ Agitation.
- Uncooperativeness.

Decision Making of Family

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- Patients were classified as do-not-intubate when their physical disability and their underlying debilitating conditions made them poor candidates for intubation.
- The patient's family was informed in a clear and loyal manner, and all efforts were provided to make them understand and adhere to the medical decision.
- When extubation was possible, NIV could be proposed to those patients or their families as a noninvasive form of life support to help them recover from ARF.

Failure of FM-NIV

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Failure of FM-NIV to reverse clinical signs of ARF was defined as :

No improvement or increase in the score for encephalopathy or in respiratory rate.

Failure of FM-NIV to improve pulmonary gas exchange was defined as no improvement or fall in pH or Pao2/Fio2.

□ No improvement or increase in Paco2.

Changing the interface

- Changing the interface during the first 12 hrs of NIV was considered as an "early switch".
- "Late switch" referred to switching from FM to total FM after the 12th hr.
- The decision to change the FM to a total FM was left up to the attending physician providing that it was motivated by any of the following:
 - 1) failure of FM-NIV to reverse clinical signs of ARF.
 - 2)failure of FM-NIV to improve pulmonary gas exchange.
 - 3)major discomfort or severe skin damage with the FM.

Characteristics of Total FM

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 - Total FM was comfortably placed on the patient's face with the bottom of the cushion sitting below the lower lip and above the chin, and the top of the cushion resting above the eyebrows in the middle of the front head.
 - The straps were adjusted to eliminate leaks without overtightening the headgear.



RESULTS



Figure 2. Flow chart showing the number of patients switched early(within the first 12 hrs), switched late (after the 12th hr), or never switched to total face mask (total FM).

FM-NIV = face mask-delivered noninvasive ventilation;

ARF = acute respiratory failure;

FM = facial mask;

DNI = donotintubate.

Parameters	Overall Population (n = 74)	Facial Mask Success (n = 38)	Facial Mask Failure (n = 36)	Р
Age (yr)	75 [64-80]	78 [67-80]	74 [62-79]	NS
Male, n (%)	52 (70.3%)	30 (79%)	22 (61%)	NS
Body mass index	27 [22-35]	27.8 [22-35.6]	27 [22-35]	NS
Albumin (g/L)	26.5 [23-29.7]	26.2 [23-29.4]	27 [23.2-29.8]	NS
Noninvasive ventilation indication, n (%)				
Initial hypercapnic ARF	49 (66.2%)	21 (55.3%)	28 (78%)	0.04
Initial hypoxemic ARF	8 (10.8%)	4 (10.5%)	4 (11%)	NS
Postextubation ARF	17 (23%)	13 (34%)	4 (11%)	0.02
Type of chronic lung disease, n (%)		1.14		
Obstructive	29 (39.2%)	16 (42%)	13 (36%)	NS
Restrictive	19 (25.7%)	6 (16%)	13 (36%)	0.04
Mixed	26 (35%)	16 (42%)	10 (28%)	NS
Chronic respiratory failure, n (%)	58 (78.4%)	30 (79%)	28 (78%)	NS
Cause of ARF, n (%)				
Exacerbation of chronic respiratory failure	30 (40.5%)	17 (44.7%)	13 (36%)	NS
Pneumonia	29 (39.2%)	11 (29%)	18 (50%)	NS
Cardiogenic pulmonary edema	15 (20.3%)	10 (26.3%)	5 (14%)	NS
Medical Research Council Dyspnea Score	5 [4.2-5]	5 [4-5]	5 [4.2-5]	NS
Knaus index C, n (%)	24 (32.4%)	15 (39.5%)	9 (25%)	NS
Knaus index D, n (%)	48 (64.9%)	23 (60.5%)	25 (69.4%)	NS
Charlson's Comorbidity Score	4 [3-5]	4 [3-5]	3 [2-5]	NS
Simplified Acute Physiologic Score 2	40 [35-49]	39 [35-47.5]	43 [34-53]	NS
Respiratory rate (breaths/min)	29±8	28±7	30±9	NS
Encephalopathy score	3 [2-4]	2 [2-3]	4 [3-4]	<0.000
Systolic arterial blood pressure (mm Hg)	132±19	130±19	135±20	NS
Arterial blood gases				
pH	728±0.12	73±0.12	726±0.12	NS
Paco _p (mm Hg)	70±25	63.5±19	77±29	0.02
Pao ₂ (mm Hg)	89±48	87±47	90±51	NS
Pao/Foy	217±79	229±89	204±65	NS
HCO, (mmol/L)	31.7±6.7	30.8±6.8	32.6±6.6	NS

TABLE 1. Patients Characteristics at Admission

Reasons for Changing the Mask

TABLE 2. Reasons for Changing the Interface From Facial Mask to Total Face Mask

Reasons	Total (<i>n</i> = 36)	Switched Early $(n = 21)$	Switched Late (n = 15)	P
Failure of FM-NIV to reverse hypercapnic ARF, n (%)	24 (66.7)	17 (81)	7 (46.7)	0.031
Skin breakdown or face mask intolerance, n (%)	11 (30.5)	3 (14.3)	8 (53.3)	0.001
Failure of FM-NIV to reverse hypoxemic ARF, n (%)	1 (2.8)	1 (4.8)	0 (0)	Noncal- culable

FM-NIV = facial mask-delivered noninvasive ventilation; ARF = acute respiratory failure.

Refractory Hypercapnia

- Two thirds of the patients were switched to total FM early.
- Changing the interface resulted in a significant result after 2 hrs of total FM-NIV (Fig.3):
 - --decrease in Paco2.
 - --increase in pH(7.24 \pm 0.1 vs. 7.32 \pm 0.09;p < 0.0001).
 - -- reduction of encephalopathy score
 - (3 [3-4] vs. 2 [2-3]; p < 0.0001).

A significant result after 2 hrs of total FM-NIV



Figure 3. Evolution of Paco₂ and pH during the first 48 hrs in 24 patients with hypercapnic respiratory failure refractory to facial mask (FM)-delivered noninvasive ventilation, and thus switched to total face mask (total FM). total FM H0 represents the time of switching from FM to total FM. *p < 0.01; **p < 0.0001, analysis of variance.



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TABLE 3. Comparison of Patients Switched Early to Total Face Mask With Those Switched Late Regarding Facial Pressure Sores and Length of NIV

Parameters	Switched Early to Tota Face Mask (n = 21)	I Switched Late to Tota Face Mask (n = 15)	l p
Pressure sore, n (%)	5 (24%)	13 (87%)	0.0002
Pressure sore score	0 [0-0]	1 [1-3]	<0.0001
Protective dressings, n (%)	2 (9.5)	8 (53.3)	0.007
Length of NIV during first 48 hrs (hrs)	44 [35-46]	34 [29-42]	0.05
Length of facial mask-delivered NIV during first 48 hrs (hrs)	2 [2-4]	20 [12-24]	< 0.0001
Length of NIV (days) ^a	8 [5-10]	8 [5-10]	0.9

NIV = noninvasive ventilation.

In critical care setting (in intensive care unit or in the step-down unit).

- Patients switched early to total FM were less likely to develop facial pressure sores, in spite of greater duration of NIV and less protective dressings use.
- The optimal cutoff value for the duration of FM NIV to predict facial pressure sores was
 11 hrs with a sensitivity of 84% (95% CI 69–93).
- 72% of the patients who required > 12 hrs of FM-NIV within the first 2 days developed facial pressure sores.

Comfort

The comfort score was higher with total FM

than with FM although it did not reach statistical.

significance(4 [3-5] vs. 2 [1-3]; p = 0.08, respectively).



DISCUSSION

- In the present study, the high rate of do-not-intubate patients surviving hospital discharge, although FM-NIV has already failed, suggests that changing the interface could have contributed to improved outcome.
- A beneficial effect of switching to total FM on Paco2 and pH could be demonstrated only in hypercapnic patients.
- This is the first study to investigate this new model of total FM, which has been used as a rescue therapy in a special clinical situation.
- Switching early to total FM can be useful when FM-NIV had already failed to reverse hypercaphic ARF.

Limitation

The present study has several potential limitations:

- □ It was a single-center study.
- Nonrandomized unblinded study design.
- Randomization would have been unethical regarding the donot-intubate status of our patients.
- In such a study dealing with interface strategy during NIV, masking of treatment assignment cannot be accomplished, leading to unavoidable detection bias.

Conclusion

- In patients in hypercapnic acute respiratory failure, for whom escalation to intubation is deemed inappropriate, switching to total face mask can be proposed as a last resort therapy when face mask-delivered noninvasive mechanical ventilation has already failed to reverse acute respiratory failure.
- This strategy is particularly adapted to provide prolonged periods of continuous noninvasive mechanical ventilation while preventing facial pressure sores.



Which is more appropriate?



Paul P.Glasziou, Chris Del Mar and Janet Salisbury (2003) Evidence-Based Practice Workbook . London : BMJ Publishing Group

- 世代研究:是一種觀察性研究方法(observational study),一群界定 清楚的人 (the cohort) 被追蹤一段時間
- 檢驗結果(outcome) 在不同次群組之間是否有差異,例如有(或沒有)暴露在某種介入之次群組,觀察其結果發生率
- 世代研究大多是前瞻性的,但也有少數是回溯性的







30http://www.casp-uk.net/#!casp-tools-checklists/c18f8

DISCUSSION

不急救(插管)病人,如何跟家屬說明長期使用 NIV 可能之合併症?

□ 早期觀察皮膚的變化,交替 FM 與 TFM 可能是 減少鼻部壓瘡的可行策略

- NIV 脫離及照護準則
- ■倫理議題
- ■教育訓練
- ■跨團隊照護



