

European Respiratory Society Annual Congress 2012

Abstract Number: 1694

Publication Number: P2025

Abstract Group: 2.2. Noninvasive Ventilatory Support

Keyword 1: Acute respiratory failure **Keyword 2:** COPD - exacerbations **Keyword 3:** Critically ill patients

Title: Noninvasive ventilation (NIV) for acute hypercapnic respiratory failure (AHRF): Is the helmet an effective interface? A pilot RCT

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Body: To date the helmet is rarely used in AHRF, despite in hypoxic respiratory failure, it is employed as a “rotating” strategy when the facial mask is poorly tolerated. In a multicenter RCT, we compared the clinical efficacy of a new helmet designed to specifically improve the performance in COPD vs a full face mask during an episode of AHRF. 17 COPDs with AHRF were randomly assigned to receive NIV either with full face mask (GroupA,n=9pH=7,26±0.07PaCO₂=73.7±10.8mmHg,PaO₂/FiO₂=97.3±53.7) or the helmet (GroupB,n=8pH=7.24±0.05PaCO₂=83.3±14.2mmHg,PaO₂/FiO₂=100.6±41).In the former group the ventilator settings were decided according to the usual practice (i.e. the maximal inspiratory pressure tolerated and CPAP=4cmH₂O),while in latter group according to published data(Crit Care Med 2009; 37:1921). ABGs were evaluated at admission,1 and 6 hour and then everyday until discharge. Vital parameters, discomfort scale, dyspnea score and adverse events were recorded. Baseline characteristics did not differ significantly between the two groups. 2 and 1 patients for groupA and B respectively required intubation. NIV improved gas exchange vs baseline (p< 0.05) both with mask and helmet (pHA=7,34±0.08PaCO₂A=59.7±12.3mmHg, and pHB=7,30±0.06PaCO₂B=70.4±13.8mmHg, at 1h; and pHA=7,39±0.07,PaCO₂A=55.2±11.2mmHg, pHB=7,39±0.04,PaCO₂B=58.0±6.0mmHg, at 6 h). No differences in vital signs, patients' comfort and dyspnea score were observed between the two groups. In conclusion in this pilot RCT we have shown that the helmet may be a valid alternative to the “classical” full face mask during an episode of AHRF, making the former interface possible alternative for “rotating” strategy.