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

Dr. Chiara 11630 Mega chiara.mega@tiscalinet.it MD ¹, Dr. Lara 11631 Pisani larapisani81@gmail.com MD ¹, Dr. Paolo 11636 Navalesi paolo.navalesi@gmail.com MD ², Dr. Andrea 11637 Bellone andreabellone@libero.it MD ³, Dr. Raffaele 11638 Scala raffaele_scala@hotmail.com MD ⁴, Dr. Vanessa 11640 Repetto vanessa.repetto@gmail.com MD ², Dr. Corrado 11641 Zenesini c.zenesini@ausl.bo.it ⁵, Dr. Luca 11642 Fasano luca.fasano@aosp.bo.it MD ¹, Dr. Manuela 15012 Del Forno manuela.delfo@gmail.com MD ¹ and Dr. Stefano 15013 Nava stefanava@gmail.com MD ¹. ¹ Respiratory and Critical Care, Sant’Orsola Malpighi Hospital, Bologna, Italy; ² Medicina Traslazionale, Università Piemonte Orientale, Novara, Italy; ³ Emergency Department, A.O Sant’Anna, Como, Italy; ⁴ Respiratory Unit, San Donato Hospital, Arezzo, Italy and ⁵ Dipartimento Sanità Pubblica, AUSL Bologna, Area Epidemiologia, Bologna, Italy.

**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.