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Title: Effects of long term home NIV on lung inflammation in stable COPD

Dr. Gregorino 11652 Paone rpaone1023@yahoo.com MD ¹, Dr. Vittoria 11653 Conti vittoria_conti@hotmail.com MD ^{2,3}, Dr. Corrado 11654 Mollica c.mollica@libero.it MD ⁴, Dr. Patrizio 11688 Palermo palermo.patrizio@gmail.com MD ¹, Dr. Ilio 11656 Cammarella ilio.cammarella@uniroma1.it MD ¹, Dr. Giuseppe 11658 Brunetti gbrunetti@scamilloforlanini.rm.it MD ⁴, Dr. Gianluca 11669 Monaco gmonaco@scamilloforlanini.rm.it MD ⁴, Dr. Gilda 11684 Giannunzio ggiannunzio@scamilloforlanini.rm.it MD ⁴, Dr. Giovanni 11655 Puglisi giovanni.puglisi@tiscali.it MD ⁴ and Dr. Giacomo 11689 Frati giacomo.frati@uniroma1.it MD ^{5,6}. ¹ Heart and Lung Institute, Sapienza University of Rome, S. Camillo-Forlanini Hospital, Rome, Italy ; ² Heart and Lung Institute, Respiratory Diseases Unit, School of Specialization of Respiratory Diseases, Sapienza University of Rome, Rome, Italy ; ³ Department of Respiratory Diseases, IRCCS San Raffaele - Pisana, Rome, Italy ; ⁴ Department of Respiratory Diseases, S. Camillo-Forlanini Hospital, Rome, Italy ; ⁵ Department of Medical Surgical Sciences and Biotechnology, Sapienza University, Latina, Italy and ⁶ Department of Angiocardioneurology, IRCCS "Neuromed", Pozzilli (IS), Italy .

Body: Background. COPD is the most frequent indication for home NIV. Despite this, while NIV role in COPD exacerbations is well established, its effectiveness in patients with stable disease is under debate. No studies have evaluated the lung inflammatory response during home NIV in stable COPD. Aims and objectives. We evaluated pulmonary inflammation during long-term home NIV in stable COPD. We also analyzed the hospitalization and mortality rate during a two years follow up period. Methods. A prospective observational study was conducted on a group of consecutive unselected patients treated with home NIV (n= 68) and on a control group of individuals undergoing long term oxygen-therapy (n=75). All participants underwent pulmonary function tests (PFTs), arterial blood gas analysis (ABG), and sputum samples collection for IL-6, TNF- α , IL-10 and Human Neutrophil Peptides (HNP) levels determination. Participants entered the follow up in which, at three months intervals, PFTs, ABG, hospital admission and survival rate were recorded. Results. Study and control group were similar in age, gender, PFTs and ABG parameters. Sputum levels of IL-6 (41.4 ± 27 vs 36.3 ± 17.6 pg/ml; p=0.4), TNF- α (68.4 ± 50.9 vs 59.7 ± 46.9 pg/ml; p=0.5), IL-10 (11.3 ± 10 vs 14.3 ± 10 pg/ml; p=0.3) and HNP (34.3 ± 5.9 vs 34.3 ± 3.7 μ g/ml; p=0.9) did not show significant differences between the two subsets of individuals. A significant reduction was observed in hospital admission in patients undergoing home NIV during the follow up ($3,42 \pm 3$ vs $1,3 \pm 1,6$; p=0,0001). Conclusions. Our study, confirms previous reports on the effect of NIV in reducing exacerbation numbers in COPD patients and shows that long-term home NIV may not affect lung inflammatory response.