INPLASY PROTOCOL

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There is no conflict of interest.

Effect of bilevel continuous positive airway pressure for patients with type II respiratory failure due to acute exacerbation of COPD: A protocol for systematic review and meta-analysis

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Review question / Objective: **The purpose of this Meta analysis was to evaluate the effect of bi-level positive pressure ventilation intervention on acid-base balance, pulmonary function and other aspects in patients with AECOPD complicated with type 2 respiratory failure.**
Condition being studied: **1.COPD, referred to as COPD for short, is a respiratory disease characterized by persistent airflow limitation, and most of its airflow limitation is progressive. According to the Global burden of Disease study in 2010, (GBD) shows that there are 328 million COPD patients in the world, and the number of global COPD deaths is increasing year by year. COPD has become an important cause of disease and death in Chinese. Studies have shown that the standard prevalence rate of COPD in adults over 40 years old in China has reached 13.6%. 2.BIPAP intervention can avoid repeated breathing of exhaled gas, thus reduce the retention of carbon dioxide, correct the acid-base imbalance in patients, and prevent the deterioration of lung function.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 November 2020 and was last updated on 28 November 2020 (registration number INPLASY2020110003).

INTRODUCTION

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METHODS

Search strategy: This study will be included in the randomized controlled trial (RCT). Relevant literature searches are conducted in four Chinese literature databases, namely China knowledge Network, Wanfang Database, VIP Chinese Journal Database, China Biomedical Literature Service system (SinoMed) and five foreign literature databases, namely Pubmed, Cochrane, Springer, EBSCO and web of science, including all relevant randomized controlled studies before October 2020.

Participant or population: The subjects were adult patients with COPD, who met the clinical diagnostic guidelines of COPD and were in acute stage. Through blood gas analysis and related clinical diagnosis, it was found that the patients were complicated with respiratory failure (PH < 7.35and PaCO2 > 50mmHg), and the patients were conscious, without respiratory weakness and hemodynamic instability, and without multiple organ failure.

Intervention: The experimental group received bi-level positive airway pressure ventilation intervention, the adjustment mode was S/ T mode, and the inspiratory pressure (IPAP) was greater than expiratory pressure (EPAP), and the oxygen flow was adjusted according to the condition to ensure that the patient's SaO2 was more than 90%, and the daily duration was more than 5 hours.

Comparator: The control group will receive routine treatment, including bronchodilators, corticosteroids, antibiotic anti-inflammatory drugs, low flow oxygen therapy and respiratory stimulants if necessary.

Study designs to be included: (RCT), a randomized controlled trial published before October 2020, will be included.

Eligibility criteria: The included studies meet the requirements in terms of title, summary, study population, intervention measures, measurement methods and time, primary and secondary outcome indicators.

Information sources: 1. The selected electronic databases include China knowledge Network, Wanfang Database, VIP Chinese Journal Database, Chinese Biomedical Literature Service system (SinoMed), Pubmed, Cochrane, Springer, EBSCO, web of science. 2. If the full text of the included study cannot be found, the author will be contacted by email for help.

Main outcome(s): Main outcome measures: the results of blood gas analysis of the subjects, including PaO2 (partial pressure of oxygen), PaCO2 (partial pressure of carbon dioxide), PH, intubation rate, and the status of pulmonary function of the patients, including FEV1 and FEV1/FVC.

Additional outcome(s): Secondary outcome indicators: heart rate, respiratory rate, length of stay, incidence of complications, blood pressure, mortality.

Quality assessment / Risk of bias analysis: The Australian JBI evidence-based Health Care Centre (2016) will independently evaluate each of the 13 quality areas included in the literature on the RCT authentic evaluation tool. It includes random grouping, allocation concealment, baseline comparability, subject blind method, intervention blind method, evaluator blind method, full follow-up, comparison of other intervention measures, reliability of evaluation methods, comprehensive result analysis, the same

evaluation methods, the credibility of data analysis methods, and the reasonableness of research and design. The quality level of each study is divided into A, B, C and D grades from high to low. Any differences will be resolved through discussion and negotiation with the third researcher.

Strategy of data synthesis: 1. Assessment of reporting bias: funnel charts will be used to assess the potential for research bias and, if necessary, Egger test and Begger analysis will be used to assess reporting bias. two。 2. Heterogeneity evaluation: for the included studies, I2 statistics will be used to quantify statistical heterogeneity to evaluate the heterogeneity of the study. Grade of heterogeneity: I2: 0% muri 40%, heterogeneity is not important, I2: 30% muri 60%, moderate heterogeneity, I2: 50% muri 90%, high heterogeneity. 3. The measure of therapeutic effect: we use ReviewManager5.4 software for data analysis, and for continuous variables, we will calculate the average difference (MD) or the standard MD of 95% confidence interval. When I2 < 50%, choose the fixed effect model to calculate the MD, otherwise use the random effect model. For binary variables, we will calculate the risk ratio with 95% confidence interval (CI).

Subgroup analysis: If there is significant heterogeneity between the results, we will conduct a subgroup analysis: for example, grouping BIPAP inspiratory pressure (IPAP), grouping detection time points after intervention (< 1 day and > 1 day after intervention), and grouping intervention duration (intervention duration < 10h/ days and > 10h/ days).

Sensibility analysis: We will rule out the combined study one by one for sensitivity analysis to observe whether there is a significant change in the comprehensive results. If so, the removal study may affect the overall synthesis results, so we will re-evaluate and carefully decide whether or not to merge.

Country(ies) involved: China.

Keywords: Analysis of noninvasive positive pressure ventilation, COPD, respiratory failure and Meta.

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