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## Gasometric parameters after tracheal aspiration in patients with septic shock: a clinical trial

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### ABSTRACT

**Hypothesis:** There is no hypoxemia after tracheal aspiration when there is no optimization of O<sub>2</sub> pre-aspiration. **Aim:** To verify, through the assessment of arterial gasometry, if there is a significant difference in the values of SaO<sub>2</sub>, PaO<sub>2</sub> and P/F in patients on ventilatory assistance and septic shock when FiO<sub>2</sub> is not kept to 100% after tracheal aspiration. **Method:** a randomized clinical trial-type crossover, with two interventions, one arm, double-blind, phase III. A convenience sample of 27 patients is used by calculation for discrete variables of finite populations. Inclusion criteria: septic shock due to local infection, mechanical ventilation for more than 12 hours, optimal FiO<sub>2</sub> <95%, PEEP <24 mmHg. For the statistical analysis we will use the student's t-test with a significance level of 5% supported by software R version 2.5.1.

**Keywords:** Anoxia; Suction; Clinical Trial; Nursing; Intensive Care Units

## **PROBLEM SITUATION AND ITS SIGNIFICANCE**

Randomized clinical trials have shown that the supply of 100% oxygen, before and after tracheal aspiration, in stable patients undergoing a ventilator weaning process, shows no significant differences in gasometric parameters and clinical results, a behavior which has not been tested in septic patients. Although tracheal aspiration is essential in caring for such patients, it has been done the same way since its creation in 1936<sup>(1)</sup>. This technique aims to maintain airway patency, prevent infection, promote gas exchange, improve arterial oxygenation and improve lung function in patients who are intubated or tracheostomized with decreased level of consciousness, and have a diminished cough reflex. When there is an accumulation of secretions in the respiratory tract, the nurse must act to remove and/or facilitate the removal of this secretion<sup>(2)</sup>.

## **RESEARCH QUESTION**

Are there significant differences in gasometrical rates and in SpO<sub>2</sub> in critically ill patients, when hyper oxygenation with FiO<sub>2</sub> is not kept to 100% before tracheal aspiration, using as a parameter, the baseline physiological data?

## **HYPOTHESIS**

There is no hypoxemia, comparing PaO<sub>2</sub>, SaO<sub>2</sub>, P/F and SpO<sub>2</sub> after tracheal aspiration when the hyper oxygenation to 100% is not used before tracheal aspiration in critically ill septic patients.

## **AIM**

To verify if there is a significant difference in the data with regard to SaO<sub>2</sub>, PO<sub>2</sub>, P/F and SpO<sub>2</sub> in septic critically ill patients on mechanical ventilation, when the hyper oxygenation is not kept to 100% before tracheal aspiration. This is demonstrated by comparing before and after aspiration gasometry data, according to baseline physiological data.

## **PRIMARY OUTCOME**

The tracheal aspiration without using the FiO<sub>2</sub>, for less than 15 seconds, and reconnection with mechanical ventilation between the aspiration is found to be as effective as the optimization of oxygen before the aspiration as a means of preventing hypoxemia.

## **METHOD**

Randomized clinical trial of crossover, one arm, double-blind, phase III. The data will be compared to two or more treatments or interventions in which subjects or patients, after completing a stage of treatment, will undergo other therapeutic interventions<sup>(3)</sup>.

There will be a baseline for patient selection and pre-aspiration gasometry, named ideal gasometry. Randomization will be in groups of four patients, selected from a sequence of random numbers generated by the spreadsheet Microsoft Office Excel 2010 owned by Microsoft Corporation<sup>®</sup>. Group A will undergo aspiration FiO<sub>2</sub> to 100% and group B will undergo aspiration without an increase in the FiO<sub>2</sub> baseline. At the end of the experiment will be test a new gasometry test and then we will exchange groups. Tracheal aspiration is performed through an open system with catheter No. 14 using an aseptic technique. A Quartz Time<sup>®</sup> stopwatch will be used for timing.

Eligibility criteria: 18 years of age minimum, suffering from septic shock with a focus of local infection, mechanical ventilation for more than 12 hours, ideal FiO<sub>2</sub> <95%; PEEP <24 mm / Hg. Surgical patients with Chronic Obstructive Pulmonary Disease Gold IV, patients receiving only palliative care, postpartum women and thrombocytopenic patients will be excluded.

The convenience sample of 21 patients was estimated by calculation for discrete variables of finite populations at a significance level of 0.05 and confidence interval of 95%.

The *wasout* time will be determined by auscultation to confirm the presence of tracheal secretions.

For the analysis of the tests an in vitro diagnostic cartridge, single use, disposable, with analyzers for human whole blood, will be used at the bedside.

The follow-up time is estimated at six months - August 2012 to February 2013 aiming to reach the *n* sample.

## **DATA ANALYSIS**

Student t-test for comparison of two-tailed paired samples adopting an  $\alpha = 0.05$  using the software R version 2.5.1 will be used.

## **ETHICAL ASPECTS**

The project was submitted to the Ethics Committee of the Federal University of Rio de Janeiro according to Resolution 196/96 of the National Health Council, approved with the number CAAE 04432812.0.0000.5257 and Protocol 061-12. Primary Registers of UTN WHO: U1111-1132-8681 in the Brazilian clinical trial registry project N°. REQ: 796.

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