Official Title of the study:

Assessment of Outcome and Tolerability of High Velocity Nasal Insufflation and Continuous Positive Airway Pressure in Children with Acute Respiratory Distress

Unique Protocol Id

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What is already known on this subject?
What does this study add?

Acute respiratory distress is medical emergency in children and infants, approximately 15- 20% of affected children require respiratory support and intensive care due to a rapid emergency of respiratory distress, it's a major cause of death in children under 5 years.

The study will discuss which is better Nasal Continuous Positive Airway Pressure or High Velocity Nasal Insufflation in treatment of children with acute respiratory distress that require oxygen therapy in PICU.

1. Introduction/ Review

Acute respiratory distress is medical emergency in children and infants ***(Friedman and Nitu, 2018)***.

Approximately 15–20% of affected children require respiratory support and intensive care due to respiratory distress ***(Meissner et al., 2016).***

Acute Respiratory distress is a major cause of death in children under 5 years and approximately one million children die annually due to respiratory failure worldwide ***(Walker et al., 2013).***

The World Health Organization and the American Academy of Pediatrics (AAP) both recommend oxygen supplementation at an arterial pulse oximetry (SpO2) lower than 90% because oxygen supply in children with acute lower respiratory tract infection is associated with reduced mortality ***(Duke et al., 2008).***

Different modalities for oxygen supplementation in children exist,the standard flow oxygen therapy (through a standard nasal cannula) provides oxygen without need for humidification when the oxygen flow is either low (i.e., 1–2 L/min) or the room air has high humidity ***(Ralston et al., 2014).***

On the other hand, high flow rates usually require humidification due to the drying effect of non-humidified cold oxygen on nasal secretions and the respiratory mucosa ***(Franklin et al., 2018).***

Non-invasive ventilation is widely used in the respiratory management of severe cases of respiratory distress, high-flow nasal cannula (HFNC) oxygen therapy delivers warm and humidified oxygen at a higher flow than the normal inspiratory flow ***(Lee et al., 2013).***

The nasal continuous positive airway pressure is another management modality that combines supplemental oxygen with a positive end-expiratory pressure, it has been shown to reduce the ventilation need duration and the overall hospitalization length in children with respiratory distress ***(Essouri et al., 2014).***

Both CPAP and High Velocity Nasal Insufflation are high flow systems and are

capable of generating PEEP ***(Pedersen and Vahlkvist, 2017).***

High Velocity Nasal Insufflation is considered to be a less invasive procedure than CPAP, better tolerated and comparatively easy to perform ***(Yoder et al., 2013).***

This probably makes High Velocity Nasal Insufflation a preferred procedure of choice in young children. One of the important differences between these two procedures is that CPAP employs an integrated pressure release valvular system, whereas in High Velocity Nasal Insufflation,the release of pressure is via the leak at the nares prong interface and through the mouth ***(Pedersen and Vahlkvist, 2017).***

The lack of the ability to regulate the pressure delivered to the airways in High Velocity Nasal Insufflation may run the risk of delivering high pressures at high flow rates if the leak is compromised ***(Sivieri et al., 2013).***

High Velocity Nasal Insufflation is thought to work through increasing the oxygen fraction in the alveoli by washout of the nasopharyngeal dead space, reducing the inspiratory resistance, improvement of airway conductance and by providing an end-distending pressure to the lungs ***(Dysart et al., 2019).***

On similar lines, CPAP decreases the inspiratory resistance, reduces atelectasis, reduces alveolar resistance, increases surface area of alveoli, and enhances ventilation and perfusion (V/Q) matching through PEEP ***(Gupta and Donn, 2016).***

A retrospective record-based study to compare CPAP with High Velocity Nasal Insufflation among infants with respiratory distress found no significant difference in length of hospital stay, respiratory rate, PaCO2, FiO2, or duration of oxygen supply ***(Metge et al., 2014).***

2.Aim/Objectives

To study outcome & tolerability of High Velocity Nasal Insufflation and Continuous Positive Air way Pressure in children with acute respiratory distress assessed by chest ultrasound in PICU.

3. Methodology:
Patients and Methods/ Subjects and Methods/ Material and Methods

– **Type of Study Design**: Cohort Study Design.

– **Proposed Study Design**: Prospective Interventional Study.

– **Study setting**: PICU, Children's Hospital, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

– **Study duration**: Two years starting from December 2022 to December 2024.

– **Study population**: Children aged 1 month - 5 years.

– **Sampling method**: Randomized sample.

– **Sample size**: 80 patients will be divided into 2 groups.

Group A: Patients on high velocity nasal insufflation .

Group B: Patients on nasal continuous positive airway pressure.

Inclusion criteria (for groups A and B)

- Patients aged from 1 month to 5 years, hospitalized in PICU with acute respiratory distress failed on low flow nasal oxygen and need non invasive respiratory support .

Exclusion criteria: Any chronic diseases & comorbidites including

- Cardiac diseases.
- Neuromuscular diseases.
- Chronic lung diseases.
- Recurrent wheezing.
- History of cardio-respiratory arrest.

– **Study procedures**:

The patients will be divided into two groups A and B, randomization will be done as follow: group A contains the patients with odd numbers and group B contains patients with even numbers and both groups will undergo the following:

1- Detailed medical history through patients and/or their legal guardian as well as data retrieved from patients' medical files compiled during admission and used for patient follow up post discharge, with emphasis on:

a- Demographic data: age, gender, age at disease onset and consanguinity.

b- History of the present illness with emphasis on systems affected in chronological order, with focus on respiratory affection e.g. Fever, cough, Shortness of breath, cyanosis.

2- General physical examination and respiratory examination for any residual findings at the time of the study, and retrieving data of examination findings from the medical files.

3- Results of Laboratory tests done for patients during and after hospital admission including CBC, blood gases, inflammatory markers including CRP, ESR, blood cultures and sputum cultures and viral respiratory panel.

4- Imaging results: chest ultrasound at day 0 then daily assessment by lung ultrasound score. Appendix 1

5- Assessment of pain by flacc pain rating scale. Appendix 2

– Ethical Considerations: This study will be conducted after approval of the Research Ethics Committee of Ain Shams University hospitals and an informed consent will be obtained from the parents or caregiver of each participant.

– **Statistical analysis:** Numerical data will be summarized using mean and standard deviations or medians and inter quartile ranges. Qualitative data will be presented as count and percentage, p-value <0.005 will be considered significant.

– **Statistical package:** Statistical analysis will be performed with statistical package for social science (SPSS) version 27.

4. References

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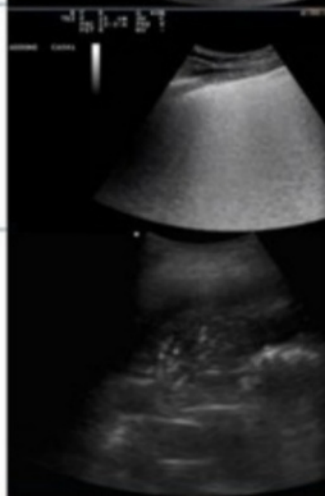
Appendix 1

Ultrasound Sign	Score	
Presence of lung sliding with A lines or fewer than two isolated B lines	0	
Multiple, well-defined B lines	1	
Multiple coalescent B lines “white lung”	2	
Lung consolidation, presence of a tissue-like pattern	3	

Lung ultrasound score ***(Bouhamed et al., 2015)***

Appendix 2

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
	0	1	2
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
	0	1	2
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
	0	1	2
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaints	Crying steadily, screams or sobs, frequent complaints
	0	1	2
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to". Distractable	Difficult to console or comfort

Flacc pain rating score ***(Voepel-Lewis et al., 1997)***