Helmet CPAP for Infants and Pediatric Patients with Acute Respiratory Distress

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Principal Investigator: Patrick T. Wilson, MD

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Background

Study Purpose and Rationale:

Continuous positive airway pressure (CPAP) has become standard of care in pediatric patients with acute lung infections such as bronchiolitis and pneumonia. CPAP is currently delivered with several different patient interfaces: facemask, nasal mask and nasal prongs. In order for CPAP to be most effective there should be very little leak between the patient and the interface. This can be challenging in young pediatric patients as they are often not as compliant as adults with maintaining their interfaces in place. Leaks with the use of traditional CPAP interfaces may decrease effective delivered pressures also increase the risk of aerosolization of viral particles. Thus, an ideal interface would be one that forms a complete seal and is well tolerated. The use of a helmet interface to deliver CPAP could offer an effective alternative to traditional nasal or facemask CPAP interfaces and more consistently provide the prescribed pressure and decrease the chance of aerosolizing viral particles. Thus, we propose a pilot study to determine tolerability of helmet CPAP in children one month to five years of age with acute respiratory distress admitted to the pediatric ICU (PICU).A prior randomized controlled trial in the United States demonstrated helmet CPAP significantly decreases the intubation rate (18.2% versus 61.5%) compared to face mask CPAP in 83 adults with acute respiratory distress syndrome (ARDS). 1 The rate of adverse events were similar with three interface-related skin ulcers in each group: 6.8% in the helmet group had neck ulcers and 7.6% in the face mask group had nose ulcers. By achieving a complete seal with the use of a helmet CPAP, constant pressures can be delivered to the patient compared to air leaks often seen with traditional interfaces such as a full facemask or nasal mask. In a multicenter randomized controlled trial in Italy, 30 infants (children under one year of age) with respiratory syncytial virus (RSV) acute respiratory failure were randomized to receive CPAP by helmet (n = 17) or facial mask (n = 13).2 Helmet CPAP had a lower treatment failure rate due to intolerance (17% vs 54%, P = .009) and fewer infants required sedation (35% vs 100%, P = .023). There was no difference in the rate of invasive mechanical ventilation and no major adverse events were observed. Another pediatric study in Spain enrolled infants less than three months of age admitted to the PICU with bronchiolitis.3 Sixteen patients were randomized to receive CPAP via a helmet or nasal prongs for the first hour then crossed over to the other group for another hour (helmet then nasal prongs or nasal prongs then helmet. Modified Wood's Clinical Asthma Score (M-WCAS) was measured at 30 minute intervals and failure was defined as the need for further respiratory support. CPAP significantly reduced respiratory distress in both groups and the failure rate was similar in both groups demonstrating CPAP delivered by nasal prongs and CPAP delivered by helmet are similar in terms of efficacy in young infants with acute bronchiolitis. Prior clinical trials have demonstrated efficacy in adults with acute respiratory distress syndrome, superior tolerance and improved respiratory scores compared to nasal/facial CPAP in infants, and no major safety concerns were identified with the use of helmet CPAP. We propose a prospective pilot study to (1) determine if infants and pediatric patients requiring CPAP in the PICU will tolerate helmet CPAP for at least four hours and (2) measure changes in the respiratory rate, oxygen saturation, heart rate and blood pressure over four hours. If helmet CPAP is found to be well tolerated in this small cohort, we will move forward with a larger study.

Study Design:

Prospective, non-randomized, single arm, interventional study.

Inclusion Criteria:

1 month to 5 years of age (inclusive) admitted to the PICU with community acquired pneumonia or bronchiolitis, having been stable on nasal or facemask CPAP for at least two hours, and parental informed consent.

Exclusion Criteria:

Age less than 1 month or greater than 5 years, positive for COVID19, need for invasive mechanical ventilation or higher levels of non-invasive ventilation such as bi-level positive airway pressure (BPAP), unresponsiveness (GCS 8 or less), hypotension as defined as a systolic blood pressure less than 5th percentile for age, existing head or neck trauma, known or suspected air leak syndrome (pneumothorax, pneumomediastinum, sub-cutaneous emphysema), known or suspected increased cranial pressure, non-English speaking parent.

Methods:

Convenience sampling will be used to enroll 30 patients admitted to the Pediatric Intensive Care Unit (PICU) already receiving CPAP through a facemask or nasal prongs or mask for at least two hours. All patients will be transitioned to the Vyatil nonpowered oxygen tent system (Rochester, NY) by trained respiratory therapists per the manufacturer's instructions: patient's neck circumference will be measured with a soft tape measure to ensure appropriate sizing. The helmet will be connected to at least 30 liters per minute of high flow medical air with an oxygen blender. The expiratory limb will be attached to the PEEP valve (initially set at 5 centimeters of water pressure) connected to a HEPA filter to prevent any viral particles from being released into the environment. A disposable manometer will be used to measure the pressure within the helmet. Once the flow to the helmet interface is on, the helmet will be sealed and secured with the system's arm straps.

Vital signs will be recorded hourly per standard PICU care (respiratory rate, pulse oximetry, pulse, blood pressure) along with transcutaneous carbon dioxide (CO_2). The presence of adverse events (aspiration pneumonia, skin breakdown, hypotension, eye irritation, gastric distension, other) will be recorded prospectively along with total time on helmet CPAP, reason for discontinuation (patient improved, escalation of respiratory support/death, or patient not tolerating), and clinical outcome (discharged home, transferred out of PICU, intubated or death). Laboratory data (Respiratory viral panel, blood gas, complete blood count, C-reactive protein) and chest radiograph results will be recorded if obtained by the treating healthcare provider.

Primary Outcome Measure: Percentage of patients that tolerate helmet CPAP for at least four hours. Tolerance is defined as the successful application and maintenance of helmet CPAP without any unplanned, prolonged (>5 minutes) removals or disruptions. We hypothesize that at least 80% of the patients will tolerate the helmet CPAP interface for four hours.

Secondary Measures: Change in vital signs (respiratory rate, oxygen saturation, hear rate, and systolic blood pressure) over four hours. We hypothesize that vital signs will improve or remain stable throughout the application of helmet CPAP as compared to pre-helmet CPAP.

Statistical Plans:

We will present median values of vital signs longitudinally, median duration of helmet CPAP in hours, and reasons for discontinuation along with clinical outcomes and laboratory testing and imaging if available.

Study Procedures:

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Potential Risks:

Skin irritation around the neck, too much air pressure to the lungs causing discomfort and lowering blood pressure are potential risk of using helmet CPAP. There is a small risk of breach of confidentiality.

Potential Benefits:

Helmet CPAP may provide a better seal thus delivering CPAP more effectively leading to improved respiratory status. Helmet CPAP may be more comfortable than face mask, nasal mask or nasal prong CPAP.

Alternatives:

The alternative is not to participate and continue receiving CPAP through a facemask, nasal mask or nasal prongs.

Data Security & Monitoring:

The PI is an experienced pediatric critical care physician who will review all adverse and unanticipated events.

References

1. Patel BK, Wolfe KS, Pohlman AS, Hall JB, Kress JP. Effect of Noninvasive Ventilation Delivered by Helmet vs Face Mask on the Rate of Endotracheal Intubation in Patients With Acute Respiratory Distress Syndrome: A Randomized Clinical Trial. JAMA. 2016 Jun 14;315(22):2435-41. doi: 10.1001/jama.2016.6338. PMID: 27179847

2. Chidini G, Piastra M, Marchesi T, De Luca D, Napolitano L, Salvo I, Wolfler A, Pelosi P, Damasco M, Conti G, Calderini E. Continuous positive airway pressure with helmet versus mask in infants with bronchiolitis: an RCT. Pediatrics. 2015 Apr;135(4):e868-75. doi: 10.1542/peds.2014-1142. Epub 2015 Mar 16. PMID: 25780074.

3. Mayordomo-Colunga J, Rey C, Medina A, Martínez-Camblor P, Vivanco-Allende A, Concha A. Helmet Versus Nasal-Prong CPAP in Infants With Acute Bronchiolitis. Respir Care. 2018 Apr;63(4):455-463. doi: 10.4187/respcare.05840. Epub 2018 Jan 30. PMID: 29382794.