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A comparative effectiveness study of continuous positive airway pressure-related skin breakdown when using different nasal interfaces in the extremely low birth weight neonate

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ABSTRACT

A three group prospective randomized experimental design was conducted to identify differences in frequency and severity of nasal injuries when comparing various interfaces used during continuous positive airway pressure (CPAP) and identified risk factors associated with injury. Seventy-eight neonates <1500 g were randomized into three groups: continuous nasal prongs; continuous nasal mask; or alternating mask/prongs. Repeated measures ANOVA with Bonferroni correction demonstrated that significantly less skin injury was detected in the rotation interface group when compared to both mask and prong groups. In the final stepwise regression model ($F = 11.51$; $R^2 = 0.221$; $p = 0.006$) significant predictors of skin injury included number of days on nasal CPAP ($p < 0.001$) and current mean post menstrual age ($p = 0.006$). Reduced nasal injury was demonstrated using rotating mask/prong nasal interfaces. Future best practices must include precise selection of device size, developmental and CPAP device positioning with focused skin assessment including rapid intervention for skin injury.

1. Introduction

The use of nasal continuous positive airway pressure (CPAP) is the standard for care of preterm infants with respiratory distress syndrome (RDS) (Davis, Morley, & Owen, 2009; Verder, 2007; Verder, Bohlin, Kamper, Lindwall, & Jonsson, 2009). Various nasal interfaces are currently available to provide neonatal CPAP yet few studies have compared the effectiveness of these devices to determine efficacy, tolerance and measure differences in the incidence and/or the severity of nasal skin breakdown—a well described side effect of this useful treatment (Ramanathan, 2010; Rego & Martinez, 2002; Yong, Chen, & Boo, 2005).

2. Background

Following an integrative review of 113 articles related to the use of nasal CPAP for preterm infants, only two randomized controlled trials (RCTs) included comparisons of nasal interfaces to determine the frequency of skin breakdown or nasal trauma (Rego & Martinez, 2002; Yong et al., 2005). Rego and Martinez evaluated the performance of two types of nasal prongs—Argyle™ and Hudson™—used to deliver nasal CPAP to preterm infants. Although both were found to be equally effective in the delivery of nasal CPAP, the Argyle™ prong was more difficult to maintain in the infant's nares and had a higher incidence of nasal hyperemia (first sign of skin breakdown) or erythma when compared to the Hudson™ prong. Yong et al. conducted an RCT to compare the incidence of nasal trauma associated with continuous nasal prongs or continuous nasal mask during nasal CPAP in neonates <1500 g. Although no significant differences were found in the incidence of nasal injury between the two interfaces (mask and prongs) there was a significant correlation between nasal trauma and length of therapy. Comparison studies examining prongs, mask or rotation of devices were not reported in the literature although this nursing care strategy was described to

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reduce pressure on nasal skin during the use of CPAP (McCoskey, 2008; Squires & Hyndman, 2009). Global recommendations in 46 of the 113 articles reviewed included frequent skin assessment, increased nursing care, and clinical expertise with clear agreement that nasal injury is a potential risk factor when using nasal interfaces during CPAP delivery in the preterm infant (Newnam et al., 2013).

Evidence based practice (EBP) supports clinical decision making based on scientific evidence with the clear aim of improving patient outcomes and reducing health care waste (Melnyk & Fineout-Overholt, 2011). Comparative effectiveness research (CER) has emerged as a research method to critically evaluate scientific evidence, identify major gaps in current evidence typically identified by systematic reviews, clinical guidelines developed by consensus review and other methods to aggregate clinical research and then compare this information with current patient care practices (Tricoci, Allen, Kramer, Califf, & Smith, 2009). Researchers are discovering that information that emerges from real world settings is a valuable aspect of evidence and should be considered to determine best clinical practices. CER findings support clinical decisions based on results from alternative study designs including non-experimental research (Prosser, 2012). The framework for this research used principals of CER, including the direct comparison of clinical interventions (i.e. nasal CPAP) whose efficacy was previously supported by empiric evidence and then design and execute a clinical research study to determine which clinical practices are statistically and clinically superior to others. EBP uses previous research findings to guide practice and does not compare practices through research methods. Specifically, the purpose of this study was to (1) identify differences in frequency and severity of nasal injuries when comparing nasal CPAP interfaces used to treat neonatal respiratory distress syndrome and (2) describe risk factors associated with nasal injury and skin breakdown during nasal CPAP.

3. Research design and methodology

A three group prospective randomized experimental study design was conducted in a 70 bed level III neonatal intensive care unit (NICU) in the southeastern United States. The study was approved by the Institutional Review Board (IRB), and parents provided informed consent for infant participation. A flow diagram describes the process of screening through completion of data collection following Consolidated Standards of Reporting Trials (CONSORT) guidelines (see Fig. 1). Each infant admitted to the NICU between April, 2012 and January, 2013 was screened for inclusion criteria. Inclusion criteria included preterm infants with birth weight (BW) 500 to 1500 g that required nasal CPAP treatment. Exclusion criteria included infants born with airway or physical anomalies that influenced their ability to extubate to nasal CPAP, infants not consented within 8 hours of nasal CPAP initiation, infants not treated with nasal CPAP or infants who had nasal skin breakdown at enrollment. An a priori sample size estimation was calculated using 80% power, $\alpha = 0.05$ with F tests as the statistical basis of the calculation using G*Power 3.0™. The calculated group size of 72 total subjects, 24 subjects in each of the three groups was deemed adequate to determine significant differences between groups.

3.1. Procedures

After informed consent was obtained and the patients were extubated to nasal CPAP they were randomized into one of the three groups, (1) continuous nasal prong, (2) continuous nasal mask, or (3) alternating mask/prongs every 4 hours. The specific timing of

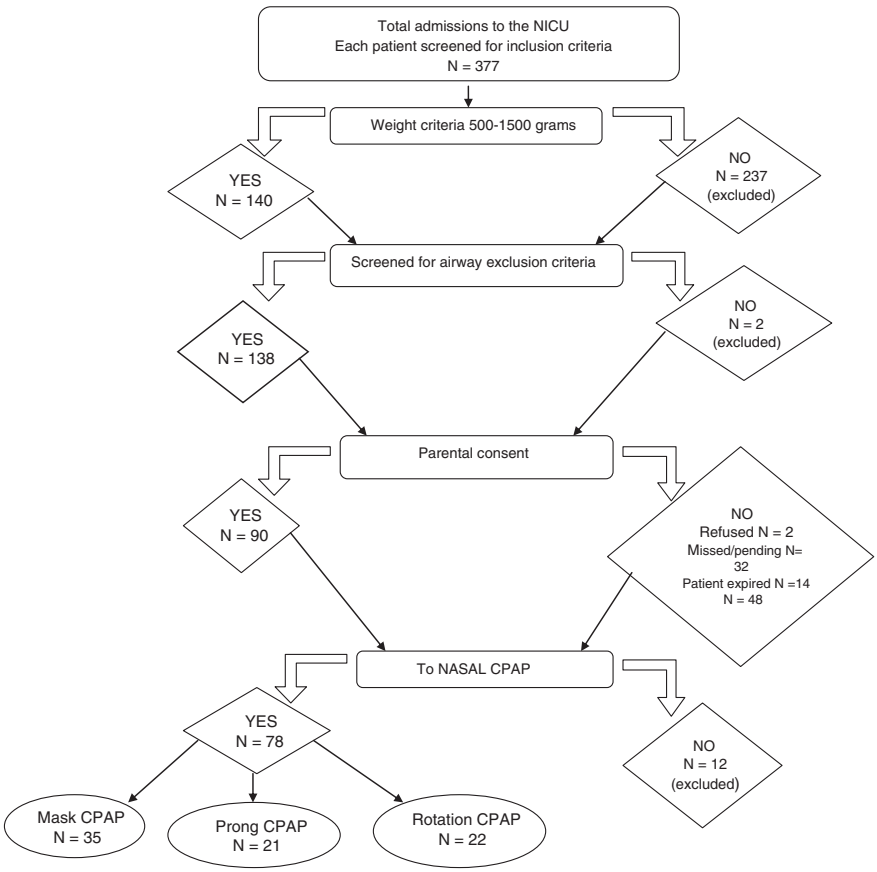

Fig. 1. Consort table for study screening and enrollment.