TITLE:

Effectiveness of nasal suction in infants with bronchiolitis using a NoseFrida vs. bulb syringe: a prospective observational study

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Study Protocol

Title: Effectiveness of nasal suction in infants with bronchiolitis using a NoseFrida vs. bulb syringe: a prospective observational study

Abstract:

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Funding: The Fridababy company will supply 100 NoseFrida devices and replacement filters for use in this study. The trial design, implementation, analysis and any publication is entirely independent of the Fridababy company. The bulb syringe devices will be supplied by the Beaumont Emergency Center for those patients that will receive this device.

Background/rationale: Bronchiolitis is a common infectious process during infancy, with reported rates of up to 30% of infants affected each year [1]. The rates have been increasing in the United States and it is a common cause for hospital and PICU admission [1]. These infants also typically present with significant rhinorrhea and congestion, which poses an issue for young infants and neonates, as they are obligate nasal breathers [2]. With their increased work of breathing and the obstructing secretions, there is often, consequently, sleeping and feeding difficulties [3]. Clearing the nasal secretions and providing a patent airway is recommended to improve these symptoms [4]. One study on patients admitted to the hospital found that long intervals between suctioning led to increased length of stay [5], which may suggest that frequent suctioning is more beneficial. Despite much anecdotal experience with the NoseFrida devise there is no published data comparing it to the historic standard of care, the bulb syringe. We will complete an observational cohort study with patients receiving either a NoseFrida or a bulb syringe and asses which device provides better relief to infant with bronchiolitis under 18 months of age.

Study design: The study will be an observational prospective cohort study, with one group receiving a bulb syringe and one group receiving a NoseFrida device.

Study setting: The trial will be completed at a Beaumont Children's Emergency Center with recruitment beginning as soon as IRB approved..

Inclusion criteria:

- Infants 18 months of age or younger
- Evaluated in the Emergency Center at Beaumont, Royal Oak for 6 months.
- Diagnosis of bronchiolitis, or presenting symptoms that are consistent with this diagnosis:
    - Cough
    - Difficulty in breathing
    - Wheezing
    - Decreased oral intake
    - Fever
- Initial EC visit for the current illness

Exclusion criteria:

- Clinically ill, as defined by:
    - Requiring respiratory support (ex. O2 nasal canula, or HFNC)

    - Abnormal respiratory rate on most recent measurement, per PALS guidelines:
        - Infant- >53 breaths per minute
        - Toddler- >37 breaths per minute
- Any history of structural upper airway disease, including:
    - Cleft palate
    - Tracheomalacia/laryngomalacia
    - Subglottic stenosis
- Previously enrolled in the study

Intervention: Patients will be selected based on inclusion/exclusion criteria. The patient's caregiver will then be supplied with an information sheet that explains the study, and any follow-up questions will be answered. Those who verbally consent to participate will be enrolled in the study. They will then receive a device to suction their infant's nares as needed. The device supplied to each patient will be dependent on the week (we will rotate by supplying Nosefrida one week and bulb syringe the next week in order to attain similar size cohorts). Education will be given on how to use their respective suction device. Instructions on the home recoding form will be supplied to the caregiver for things to monitor while using the device: the average number of times the device is used per day, number of days after discharge until respiratory symptoms resolve, until the infant is eating/drinking well, until the infant is sleeping well, in addition to the number of provider visits during 7 days after discharge. The follOowing information will be recorded in Sharepoint: date o f presentation, MRN, age, sex, cohort group, number of older siblings, prior parental use of suction devices, caregiver's email address, and phone number. Starting on day 7 after the discharge from the Emergency Center and then again day 9, a survey will be sent via RedCap . If on day 11 the survey is not completed, a phone call will be made by the investigator to confirm email and then will resend if incorrect. If correct parent will be encouraged to complete the survey, (phone script attached).

Adherence assessment: A question on the Redcap survey will verify that the caregiver used only the intended method of suctioning for the infant in the 7 days post discharge from the Emergency Center.

Outcomes:

Primary outcomes

- Number of PCP/ER/urgent care visits for the same respiratory illness within 7 days following discharge
- Hospital admission for respiratory illness or dehydration within 7 days following discharge

Secondary outcomes

- Number of days (on a scale of days 1-7) after discharge until respiratory symptoms (tachypnea, retractions, increased WOB) return to pre-illness levels
- Number of days (on a scale of days 1-7) after discharge until eating/drinking returns to pre-illness levels

- Number of days (on a scale of days 1-7) after discharge until sleeping returns to pre-illness levels
- Parental satisfaction on a likert scale (1-strongly disagree, 2-disagree, 3-undecided, 4-agree, 5-strongly agree)
    - Does this product suction babies nose well?
    - Is this product easy to use?
    - Would you recommend this product to other parents?

Sample size: At the outset of our trial design, there was no data available in the literature regarding the use of NoseFrida as a suction device. For this reason, we are not able to calculate a formal sample size that would be needed to have a specified probability of detecting a difference with our data analysis. This study will be exploratory in nature. The sample size was arbitrarily chosen at 200 participants, 100 for each cohort.

References:

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3. National Collaborating Centre for Women's and Children's Health (UK). (2015, June). Supportive treatment. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK328408/.
4. Freeman, J. F., Weng, H.-Y. C., & Sandweiss, D. (2015, January). Outpatient management of home oxygen for bronchiolitis. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/25149905.
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