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POST-MARKET CLINICAL FOLLOW-UP SURVEY OF THE ELECTRIC NASAL ASPIRATOR: A EVALUATION OF PERFORMANCE AND SAFETY

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Abstract: Background: Due to the inflammation, children with bronchiolitis suffer from hypoxia, difficulty feeding and respiratory distress. Most patients can be easily managed at home, but some require additional interventions such as supplemental oxygen, frequent nasal suctioning, intravenous (IV) fluids, and/or nasogastric tube feeds. Post-market clinical follow-up (PMCF) studies are essential for verifying the real-world safety and performance of the Electric nasal aspirator(model:BC026). The study was aimed at testing if cleaning the nasal cavities of children with recurrent wheezing using an electric nasal aspirator improves the upper and lower respiratory symptoms in routine clinical practice. Methods: A prospective, observational, single-center study was conducted at Guangzhou Xinshi Hospital, China. In this randomized controlled pilot study, we compared two separate nasal suction devices, namely the over counter device by the brand name of NoseFrida and the Electric nasal aspirator(model:BC026), in hospitalized children with bronchiolitis to assess equivalence of length of stay within a ± 5-h equivalence margin and to compare respiratory symptoms including sneezing, cough and so on. Additionally, parental satisfaction for the the electric nasal aspirator(model:BC026) was measured with a four question survey. A total of 100 cases (50 cases, 50 controls) completed the study. Parents of wheezing children (age 2-12 years) answered questionnaires and learned using a Manual nasal aspirator (50 cases) and using an electric nasal aspirator (model:BC026) (50 controls). Results: The electric nasal aspirator(model:BC026) demonstrated non-inferiority to the brand name of NoseFrida in performance and safety, supporting its continued use in diverse clinical applications. Serious Adverse Events: No device-related adverse events occurred. Customer Satisfaction: 90% of parents/ caregivers agreed this nose suction device is easy to use, 94% agreed I am comfortable using this nose suction device, 94% agreed this nose suction device is effective to clear my children's nose, 86% agreed that I am satisfied with this nose suction device.
Keywords: Nasal aspiration; Post-market clinical follow-up; Safety; Performance; Therapy; Satisfaction

1 INTRODUCTION

Bronchiolitis is the most common cause of lower respiratory tract infection in the first year of life, and respiratory syncytial virus (RSV) is the most common causative pathogen (60–85% of cases)[1]. RSV is an inflammation of the lower respiratory tract, specifically targeting the small airways and leading to necrosis and sloughing of the airway lining cells, edema, increased mucous production and bronchospasm[2]. The American Academy of Pediatrics (AAP) practice guidelines on bronchiolitis do not support routine deep suctioning of the posterior pharynx or larynx [3-5] due to complications related to deep suctioning such as irritation, swelling and bleeding. The AAP does support suctioning of the nares to provide temporary relief of nasal congestion.

The Electric nasal aspirator, developed by Shenzhen Kingboom Technology Co., Ltd, is a medical device. The Electric nasal aspirator is intended for intermittent removal of nasal secretions and mucus from children (aged 2-12 years old). This device is used in a home environment.

This PMCF study aimed to validate its real-world performance and safety per EU MDR 2017/745 and MEDDEV 2.7/1 Rev.4[6-8].

2 METHODS

2.1 Study Design

The design of this study was a randomized controlled trial (RCT) pilot study. The target population for the study was patients from the age of 2 to 12 years of age with bronchiolitis requiring admission for respiratory distress, and/or the need for frequent suctioning.

Additional data collected included the following: patient demographics including (gender and age), length of stay, respiratory symptoms, and frequency of suctioning to understand baseline characteristics of this population and compare these variables in the study arms.

2.2 Eligibility Criteria

Patients who met all the following criteria including principal diagnosis of bronchiolitis, age 2-12 years with signs and

symptoms of bronchiolitis and clinical respiratory score (CRS) of less than or equal to 4, admitted to the Emergency Department Observation Unit(EDOU) or acute care unit were enrolled in the study. The CRS score was used to determine the severity of respiratory distress and consists of the child's mental status, oxygen saturation, color, auscultations findings, accessory respiratory muscle use and respiratory rate[8].

Exclusions for participation included patients with bronchiolitis and with a prior history of prematurity, patients <2 years or ＞12 years of age, CRS >4, underlying chronic illness, oro-facial or cardiac abnormalities.

2.3 Devices

In this study, we compared an Electric nasal aspirator (Figure 1)
developed in China to a nasal aspirator by the brand name of NoseFrida (Figure 2).
The Electric nasal aspirator was equipped with three types of suction nozzles, tips for choose the Suction Nozzle:
All three types of suction nozzles for the Electric nasal aspirator are effective in removing nasal secretions. Choose based on the location/state of nasal mucus for more convenient suction:
Flat Nozzle: More convenient for removing deep-seated nasal mucus.
Angle Nozzle: More convenient for removing mucus adhering to the nasal wall.
Gourd Nozzle: More convenient for removing mucus that blocks the nostril opening.
Pumping instructions
1) Hold the child in an upright position (Figure 1).
2) Insert the clean, dry Suction nozzle into the child's nostril, make sure the collection chamber is below the nostril (Figure 1)
3) Press the power button for 3s to turn on the device, and the suction starts. Short press (1s) the power button can pause/start suction.
4) Press the flow level button step by step to adjust the air flow level.
-- There are 3 levels can be adjusted, the default level is level 1.
-- Level 1: 1.5~2.7L/min; level 2: 2.8~3.7L/min; level 3: 3.8~5L/min;
5) Turn off the device
Press the power button for 3s to turn off the device.

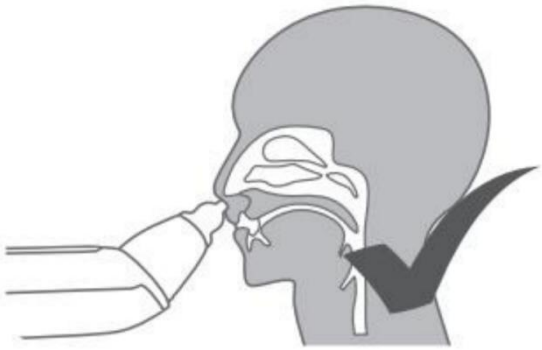

Figure 1 Electric Nasal Aspirator

Figure 2 NoseFrida

2.4 Settings and Locations

We conducted a non-blinded parallel group randomized controlled trial at an urban tertiary-care freestanding pediatric hospital with an annual emergency department (ED) census of about 100,000 visits.

2.5 Outcomes

The goals of this study were: to assess parents and caregivers of children using electric nasal aspirators regarding the device's ease of use, comfort during use, effectiveness in clearing nasal secretions, and overall satisfaction with the device.

2.6 Statistical Analysis

The Two One-sided Tests (TOST) procedure was used to test for equivalence of the two devices' length of stay within the ±5-h equivalence margin.

Age of patient and frequency of both superficial and deep suctioning were compared between the two devices using the Wilcoxon rank sum test. Gender, the proportion of patients presenting with various types of respiratory symptoms(such as sneezing) between groups using Fisher's exact test. Two factor analysis of variance was used to compare devices' length of stay after controlling for whether or not the patient was from the EDOU. For patients randomized to the the electric nasal aspirator arm, Likert scale responses to questions about parental satisfaction with the the electric nasal aspirator were summarized using frequencies and percentages. The research team did not assess satisfaction in the NoseFrida group as this device is only used by the RN or RT. All data analysis was performed using SAS version 9.4 . A 5% significance level was used for all hypothesis tests.

3 RESULTS

According to table 1, analysis demonstrated strong consistency between the electric nasal aspirator And NoseFrida, with no statistically significant differences (P > 0.05).
The manual nasal aspirators with oral suction rely on manually controllable suction power. They are gentle and flexible, allowing you to adjust the strength in real time based on your children’s condition, making them suitable for the delicate nasal cavities of children. When used with saline solution to soften nasal crusts, they can thoroughly suck out nasal discharge and clear blocked noses. They offer excellent cost performance and can be used anytime without worries about battery life.
Electric nasal aspirators deliver stable, constant negative pressure with consistent suction that never fluctuates. Their one-touch operation frees up your hands, saving time and effort. They work more efficiently on thick nasal mucus and stubborn nasal crusts, resulting in less crying and resistance from children.
In summary, when operated properly, both types of nasal aspirators can precisely clean nasal cavities and relieve nasal congestion with identical parenting effects. Manual aspirators excel in flexibility and portability, while electric ones stand out for convenience and high efficiency. You may choose either according to your personal childcare routine.

Table 1 Patient Characteristics and Outcomes

Characteristic	NoseFrida (n =50)	Electric nasal aspirator (n =50)	p-value
Male Gender[1]	27 (54)	32 (64)	0.416
Female Gender[1]	23 (46)	18 (36)	0.416
Age (years)[2]	4 (2–12)	5.5 (2-12)	0.536
Fever[1]	25 (50)	27(54)	0.841
Work of breathing[1]	44(88)	43(86)	0.684
Sneezing[1]	27 (54)	37 (74)	1.000
Wheezing[1]	25 (50)	35 (70)	0.066
Congestion[1]	44(88)	47 (94)	0.487
Runny nose[1]	32 (64)	40 (80)	0.118
Cough[1]	48 (96)	48 (96)	1.000
Number of dep suctions[2]	4 (0–8)	2 (0–6)	0.527
Deep suctioning[1]	36 (71)	35 (70)	1.000
Length of stay (hours)[2]	26.24 (17.62–40.47)	25.15 (19.72–45.44)	0.951

[1]Frequency (percent), Fisher's exact test p-value.
[2]Median (interquartile range), Wilcoxon rank sum test p-value.

Parents were generally satisfied with the electric nasal aspirator(Table 2). When “agree” and “strongly agree” responses were combined, 90% of parents/ caregivers agreed this nose suction device is easy to use, 94% agreed I am comfortable using this nose suction device, 94% agreed this nose suction device is effective to clear my children's nose, 86% agreed that I am satisfied with this nose suction device.

Table 2 Parental Satisfaction with the Electric Nasal Aspirator

Attribute	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Easy to use	-	-	5	16	29
Comfortable using	-	-	3	23	24
Effective	-	-	3	24	23
Satisfied	-	-	7	19	24

4 CONCLUSION

The study is the first suggesting that aspiration of the nasal secretions with an electric device improves respiratory symptoms in wheezing children in China. The study also shows a wide acceptance and efficacy of a nasal aspirator for children (ages 2 to 12).
Clinical Implications: The study supports the Electric nasal aspirator(model:BC026) adoption for routine treatment use while meeting all EU MDR post-market surveillance requirements. Healthcare facilities can consider this electric nasal aspirator as a good option for the general application.

5 STUDY LIMITATIONS AND FUTURE DIRECTIONS

This study was limited by the small sample size. In the future, larger sample size randomized clinical trials or PMCF activities will be needed to prove the ease of use, comfort of use, effectiveness of nasal secretion clearance, and satisfaction with the device of the nasal aspirator.
Results from this pilot study can provide estimates to compute sample size requirements for such future research.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

INFORMED CONSENT STATEMENT

Patient consent was waived due to the retrospective nature of the study and the use of anonymized data.

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