



A PROSPECTIVE STUDY TO ASSESS THE EFFICACY AND SAFETY OF A NOVEL ANTERIOR NASAL FOREIGN BODY REMOVAL DEVICE IN A TERTIARY CARE CENTER IN INDIA

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ABSTRACT

This study aims to assess the efficacy and safety of an anterior nasal foreign body (NFB) removal device, Noxeno to remove NFBs from children. This study was a prospective, single-arm, interventional study conducted with IERB approval in a tertiary care centre. Result: The average age of the cohort was 4.1 years. Twenty-one of the patients were male (67.7%), and 10 were female (32.3%). The most common NFBs in this population was found to be peanuts, seen in 6 of the 31 cases (19.3% of cases). In 15 (48.3%) cases the NFB was extracted in the first attempt and in 10 (32.3%) it was successful in the second attempt (32.3%). In 6 (19.3%), more manoeuvring was needed, but the extraction was successful at the first point of care for all cases. Results indicate that Noxeno is safe and effective in the removal of anterior nasal foreign bodies subjected to patient selection and indications.

KEYWORDS

Foreign Bodies, Otolaryngology, Paediatrics

1.0 INTRODUCTION:

The estimated incidence of nasal foreign bodies (NFB) in India ranges from 25 to 30 million annually [1-3]. The frequency of foreign objects in the ear, the nose, and the throat are significantly higher in the pediatric population [4]. This increased risk is attributed to high levels of curiosity as the child passes through the developmental milestones and is especially common once pincer grip, has been achieved [5, 6]. This study deals explicitly with anterior nasal foreign bodies. Anatomically, nasal foreign body impaction is most common anterior to the middle turbinate, followed by the area below the inferior turbinate within the nose [7]. Commonly reported NFBs include food items, pebbles, button batteries, clay, small toys, erasers, and magnets [4]. The first point of contact in the Indian healthcare system is a general physician or a general paediatrician. An otolaryngologist referral is typically desired, but a specialist is seldom available in rural parts of the country, and the extraction is attempted nonetheless.

Nasal foreign bodies can lead to various complications like ulceration, congestion, epistaxis, swelling, tissue destruction, speech alteration, nasal discharge and halitosis [8]. General Physicians & Pediatricians, due to the lack of resources, use tools and techniques which fail to remove the NFB in approximately 70% of cases and lead to further injury [3]. Removal attempts may push the nasal foreign body, leading to respiratory distress. Nasal foreign body removal has been known to be associated with serious complications such as lodging in the bronchi and septal perforation [9]. In practice, the use of multiple techniques and attempts increase the risk of these complications primarily due to makeshift tools such as suction catheters, forceps, hooks, cerumen loops and lubricated balloon-tip catheter [10].

Noxeno is a novel device intended for the removal of anterior nasal foreign bodies. The objective of this study was to assess the safety and efficacy of Noxeno in the removal of anterior NFBs in a tertiary care centre in India.

2.0 MATERIALS AND METHODS

2.1 Ethical Considerations

This study was conducted for 12 months (February 2018 to February 2019). Since the patients were minors, informed consent was taken before every procedure from caregivers. IERB approval was received from the Research Committee at the Apollo Institute Medical Sciences and Research before the study on 12/1/2018. The IERB number is AIMSIRB/RC/2018/01/033

2.2 Study Design

The study was a prospective, single-arm interventional study. The objective of this study was to assess the safety and efficacy of Noxeno-an anterior nasal foreign body removal device, in a clinical setting at a Tertiary Care Centre.

2.3 Removal Device

Noxeno (Figure 1) consists of a Handle, Extractor and a Sterile Sheath. The pre-procedure protocol involves autoclaving the extractor followed by insertion of the sterile silicone sheath over it. The LED light is switched on for better visualisation and under vision is inserted inside the nasal orifice. Once the distal part of the extractor is confirmed to be beyond the foreign body, pressing the trigger bends the hinge to 90 degrees to permit extraction of the entire system along with the foreign body. Under direct visualisation, the nasal cavity is checked to ensure complete removal. The procedure is repeated if unsuccessful.



Figure 1: The Noxeno Device with Parts

2.4 Population

The study included pediatric patients (< 10 years of age) presenting in the Outpatient department or the Emergency Room with the presence of an anterior nasal foreign body. Complicated cases were defined as those cases with prior failed attempts at extraction outside the study setting, and patients with a high risk of posterior displacement of the nasal foreign body (not anterior FBs) were excluded.

2.5 Outcome Measures

The assessment parameters for the study outcome included the type of foreign body, success or failure of complete removal, number of attempts before a successful removal, and need for accessory tools. Information on patient demographics, removal success rate, technical issues and adverse events were also gathered as crucial parameters.

3.0 Results

In total, 31 patients were included in the study. The average age of the cohort was 4.1 years, 21 of the patients were male (67.7%), and 10

were female (32.3%). Although a wide range of nasal foreign body was observed, the most common nasal foreign body in this population was found to be peanuts, seen in 6 of the 31 cases (19.3% of cases).

There was a 100% point of care procedural success rate as all 31 cases attempted successfully removed the foreign bodies. Forceps were used in 7 cases to complete the extraction of the nasal foreign bodies. In 15 cases the nasal foreign bodies were extracted in the first pass (48.3%). In ten cases the extraction was successful in the second pass (32.3%). In 6 cases, more than two passes were needed (19.3%) were needed, but in all cases, the extraction was successful in the first encounter. 30 out of 31 cases took under 5 minutes to remove. There were no cases that required removal under general anaesthesia and no cases where a different department/physician had to assist in removal. 8 cases out of 31 necessitated the use of additional instruments to aid removal. Seven cases required forceps (22.5%) and one required suction due to the brittle nature of the foreign body (crayon) which had to be extracted piecemeal. In one case involving a tamarind seed, the skin peeled off the seed and thus required additional time and effort for its removal.

Minor adverse events were noted in 6 out of 31 cases (19.35%) [Table 1]. All diverse events were due to the sharp edges and surface of the foreign body itself. In all cases, the adverse events were minor and self-resolving, which required no further management. The device was not the cause of the adverse event, and no serious adverse event occurred.

Table 1: Adverse Event Summary

Adverse events	Incidence	Major/Minor	Cause	Device Failure/Use related
Bleeding	3	Minor	Sharp FB and severe impaction	None
Mucosal Injury	3	Minor	Lack of patient cooperation and sharp FB	None

4.0 DISCUSSION

Noxeno is one of the only dedicated anterior nasal foreign body removal devices for pediatric patients in India. Anterior nasal foreign body removal was successful in all 31 patients included in the study with no procedural severe adverse events noted. Accessory tools were necessary for extraction in some cases. These included forceps and suction, however, in these cases, it was to aid in the extraction along with Noxeno given the slippery nature of the nasal mucus surrounding the foreign body and, in one case, due to the brittle nature of a crayon necessitated piecemeal extraction.

In the field of Otorhinolaryngology, foreign bodies of the ear, nose, and throat account for approximately 11% of the cases seen in a clinical setting. [11] Children develop their pincer grip at about the age of nine months; in theory, this is necessary for most cases of NFB insertion. This development accounts for the majority of documented cases being in children aged 2-5 years [12]. A study by Scholes et al. suggested that emergency room practitioners, especially non-otolaryngologists, needed to be educated about nasal anatomy and removal methods for anterior nasal foreign bodies. The study included 102 patients. 35% required referral to the otolaryngology clinic, and 58.9% required operating room intervention. In 64.7% of cases, nasal foreign bodies extracted in the emergency room extraction, of which 45% of NFBs removed by an otolaryngology resident or attending physician [13]. There is a lack of data in India regarding the incidence and management of nasal foreign bodies. There is scant evidence regarding the optimal method of foreign body removal. The diverse nature of the clinical condition has meant that randomised controlled trials are cumbersome to conduct. Consequently, medical literature consists primarily of anecdotal case reports [14].

The limitations of the study include the relatively small sample size and with experienced users in a tertiary care setting. Given the high incidence of the condition, the development of a guideline for the standardisation of management since different practitioners using different approaches based on their experience [14].

5.0 CONCLUSIONS

This study proves that Noxeno is safe and effective in the removal of anterior nasal foreign bodies subject to patient selection and indications. Noxeno's hinge mechanism is indicated only for removal

of anterior nasal foreign bodies only. However, not all cases of ear, nose, and throat foreign bodies present in tertiary care centres. Thus, it is recommended that such a study be conducted outside of tertiary care centres to ensure suitability in all clinical settings. Additional mechanisms would help address a wider variety of foreign bodies better.

6.0 Acknowledgements and Conflict of Interest

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