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Original Article

A PROSPECTIVE ANALYSIS OF ADVERSE EVENTS ASSOCIATED WITH ENDOTRACHEAL TUBE USE IN PEDIATRIC PATIENTS AT A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Objective: To evaluate adverse events associated with endotracheal tube use in pediatric patients at a tertiary care teaching hospital.

Methods: This prospective observational study conducted over a three-month period was conducted in the Pediatric Intensive Care Unit. Pediatric patients requiring endotracheal intubation were enrolled according to predefined selection criteria. Each patient was monitored for up to 72 h (24, 48, and 72 h) following intubation. Information regarding medical device–associated adverse events (MDAEs) was systematically recorded. Causality assessment of reported events was performed using the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) causality assessment scale.

Results: A total of 68 patients were screened, with a mean age of 4.56±2.66 y. The overall incidence of endotracheal tube–related MDAEs was 11.7% (n=8). Among the reported adverse events, oropharyngeal injury was the most frequent (25%, n=2). Other observed events included tube blockage, aspiration, laryngeal trauma, laryngeal edema, vocal cord injury, and tube malposition (each 12.5%, n=1), presented concisely without redundancy.

Conclusion: Oropharyngeal injury was the most commonly observed adverse event associated with endotracheal tube use in pediatric patients. Early detection, careful monitoring, and systematic reporting of device-related adverse events are essential to improve patient safety. Further studies are required to explore potential risk factors, including the role of underlying clinical conditions.

Keywords: Medical device adverse event, Endotracheal tube, Pediatric patients, Oropharyngeal injury, Laryngeal edema

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INTRODUCTION

The World Health Organization (WHO) defines a medical device as any "instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes" [1]. Medical devices play a critical role in modern healthcare by supporting the diagnosis, prevention, monitoring, and treatment of diseases [2]. Globally, an estimated two million different types of medical devices are available in the market, classified into more than 7,000 generic device groups [3]. The demand for these devices continues to increase due to the growing burden of chronic and metabolic diseases such as stroke, obesity, diabetes, and cancer worldwide [4].

Among these, endotracheal tubes (ETTs) are one of the most frequently used Category B medical devices in hospital settings [5]. Endotracheal intubation followed by mechanical ventilation is a commonly performed and often lifesaving procedure in critically ill patients, particularly in intensive care units [6]. It ensures airway protection, adequate ventilation, and oxygenation in patients who are unable to maintain their airway independently [7, 8].

Despite their essential role in patient care, medical devices, like pharmaceuticals, are associated with potential risks and complications during their use [9]. Device-related adverse events may arise due to device malfunction, improper handling, or patient-related factors [10]. Several instances of device recalls have been reported globally due to manufacturing defects or safety concerns, highlighting the need for robust surveillance systems [11]. Medical device adverse events (MDAEs) may range from minor complications to serious, life-threatening events. A study by Porte *et al.* reported that approximately 2.8% of hospital admissions in Dutch hospitals were associated with medical device–related adverse events [12]. However, this estimate pertains to general hospital admissions and may not be directly comparable to critically ill pediatric patients requiring mechanical ventilation, who represent a higher-risk subgroup.

Therefore, continuous monitoring of medical devices throughout their lifecycle is essential to ensure their safety and effectiveness. This process is facilitated through a structured surveillance system that evaluates the risks and benefits associated with medical device usage. However, such monitoring mechanisms are currently well established only in a limited number of countries.

Materiovigilance refers to the systematic identification, collection, reporting, and analysis of adverse events associated with medical devices, with the objective of improving patient safety and preventing recurrence of such events. Although post-marketing surveillance systems for medical devices have been implemented in several countries, they are still less developed compared with pharmacovigilance systems for medicines. In India, the Materiovigilance Programme of India (MvPI) was launched on July 6, 2015, at the Indian Pharmacopoeia Commission to monitor adverse events related to medical devices, generate safety data, create awareness among stakeholders, and recommend regulatory interventions to improve patient safety [13, 14]. This program serves as a national framework for systematic reporting and analysis of MDAEs. At present, 293 Medical Device Adverse Event Monitoring Centres (MDMCs) have been established across the country, including eight centers in Gujarat [15].

Our institute has been functioning as a Medical Device Adverse Event Monitoring Centre since March 2021. However, reports of adverse events related to endotracheal tube use in pediatric patients remain limited, particularly in the context of real-world clinical practice in Indian tertiary care settings. Therefore, the present study aimed to evaluate adverse events associated with endotracheal tube use in pediatric patients at a tertiary care teaching hospital.

MATERIALS AND METHODS

This prospective, observational, single-center study was conducted in the Pediatric Intensive Care Unit (PICU) of Civil Hospital,

Ahmedabad from January 2024 to March 2024 (three-month study period). The study aimed to monitor and evaluate medical device–associated adverse events (MDAEs) related to the use of endotracheal tubes in pediatric patients requiring mechanical ventilation. Prior approval for conducting the study was obtained from the Institutional Ethics Committee of Civil Hospital, Ahmedabad (Approval No.: EC/Approval/II-117A/2024), as well as from the Head of the Department of Pediatrics. The study was carried out in accordance with ethical principles for biomedical research involving human participants. Written informed consent was obtained from the parents or legal guardians of all eligible pediatric patients before enrolment in the study.

Pediatric patients admitted to the PICU who required endotracheal intubation for mechanical ventilation were screened according to predefined eligibility criteria. Patients aged less than 12 y of either gender who underwent first-time endotracheal intubation in the PICU were included in the study. Patients older than 12 y of age, patients whose parents or guardians did not provide consent for participation, and those admitted to pediatric wards other than the PICU were excluded from the study.

Eligible patients were enrolled consecutively from the PICU during the study period. Each enrolled patient was prospectively followed for 72 h after endotracheal intubation, with assessments conducted at 24 h, 48 h, and 72 h. Relevant information including demographic characteristics, clinical diagnosis, and details of endotracheal tube insertion were recorded in a structured Case Report Form (CRF) by a trained research investigator to ensure consistency and reliability of data collection. Patients were closely monitored during the follow-up period for the occurrence of any medical device–associated adverse events related to the endotracheal tube. In cases where an adverse event occurred, detailed information regarding the nature of the event, duration, management, and clinical outcome was documented. Causality assessment of the reported adverse events was performed using the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) causality assessment scale [16].

The Medical Device Adverse Event (MDAE) reporting form used for documentation was obtained from the official website of the Indian Pharmacopoeia Commission and was used to systematically record details of device-related adverse events [15, 16]. No specific drugs, chemicals, or specialized instruments were evaluated in this study, as the focus was on clinical monitoring of a routinely used medical device. The primary objective of the study was to determine the incidence of adverse events associated with the use of endotracheal tubes in pediatric patients, while the secondary objective was to analyze factors associated with the occurrence of these adverse events. A sample size of all eligible patients during the study period (n=68) was included without prior sample size calculation due to the observational nature of the study.

The collected data were entered into a Microsoft Excel worksheet for analysis. Descriptive statistical methods were used to summarize the data. Continuous variables were expressed as mean±standard deviation (SD), while categorical variables were presented as frequencies and percentages.

RESULTS

A total of 68 pediatric patients admitted to the Pediatric Intensive Care Unit (PICU) of Civil Hospital, Ahmedabad and requiring endotracheal intubation for mechanical ventilation were enrolled in the study. The mean age of the enrolled patients was 4.56±2.66 y.

Among the 68 patients, 8 patients developed medical device–associated adverse events (MDAEs), yielding an overall incidence of 11.7% (n=8). The mean age of patients who developed MDAEs was 4.75±1.85 y, which was comparable to the overall study population. The male-to-female ratio was 1:1 (n=4 each) among patients who experienced adverse events.

The most frequently used endotracheal tube size in these patients was 4.0-4.5 mm.

The clinical diagnoses of pediatric patients who developed MDAEs are summarized in table 1. Among the 8 patients, protein-energy malnutrition (PEM) was observed in 4 patients (50%). Of these, 1 patient (25%) had Grade I PEM, 1 patient (25%) had Grade II PEM, and 2 patients (50%) had Grade III PEM.

Table 1: Clinical diagnoses of pediatric patients (n=8) who experienced endotracheal tube-associated adverse events

S. No.	Diagnosis
1	Septicemia with severe malnutrition
2	Tuberculous meningitis with obstructive jaundice and moderate anemia
3	Hepatic encephalopathy with upper motor neuron lesion and respiratory distress
4	Guillain-Barré syndrome with severe bronchopneumonia, bulbar palsy, and moderate anemia
5	Aspiration pneumonia with communicating hydrocephalus and moderate anemia
6	Severe bronchopneumonia with undernutrition and mild anemia
7	Polytrauma with flail chest, multiple joint fractures, and respiratory distress
8	Urinary tract infection with hepatic encephalopathy and respiratory distress

PEM = Protein Energy Malnutrition. This table illustrates the complex, multi-morbid conditions of the patients in whom adverse events were observed. For the specific adverse event each patient experienced, refer to fig. 1.

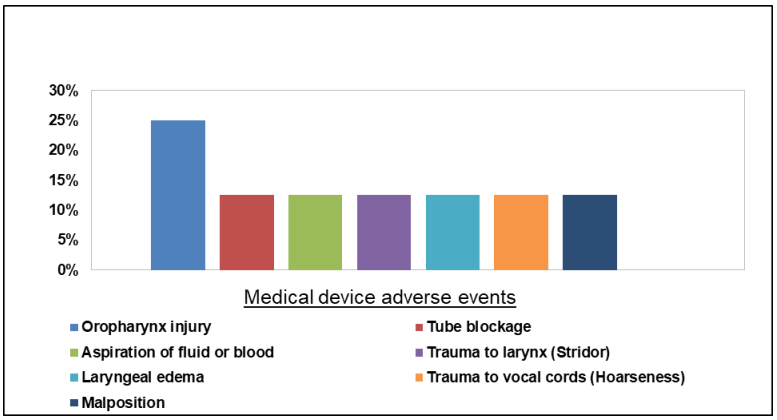

Fig. 1: Distribution of adverse events associated with endotracheal tube use (N=8 events) the total number of adverse events was eight. Oropharyngeal injury was the most frequently reported event, occurring in 25% (n=2) of cases. All other events were reported in 12.5% (n=1) of cases

The distribution of MDAEs observed in the study population is presented in fig. 1. The most common adverse event was oropharyngeal injury (25%, n=2). Other adverse events included tube blockage, aspiration, laryngeal trauma, laryngeal edema, vocal cord injury, and tube malposition (each 12.5%, n=1), presented concisely to avoid redundancy.

The mean duration of the adverse events and recovery time was 3.38±1.22 d.

Causality assessment of the reported MDAEs was performed using the World Health Organization–Uppsala Monitoring Centre (WHO-UMC) scale, as shown in fig. 2. Among the reported events, 4 (50%) were classified as probable and 4 (50%) as possible. None of the adverse events were categorized as certain, unlikely, or unassessable. Additionally, all reported MDAEs were non-serious in nature.

Causality was assessed using the WHO-Uppsala Monitoring Centre (UMC) system. 'Probable' indicates an event with a reasonable temporal relationship and a plausible response to de-challenge, and where other causes are unlikely. 'Possible' indicates an event with a reasonable temporal relationship but where other causes could also be responsible.

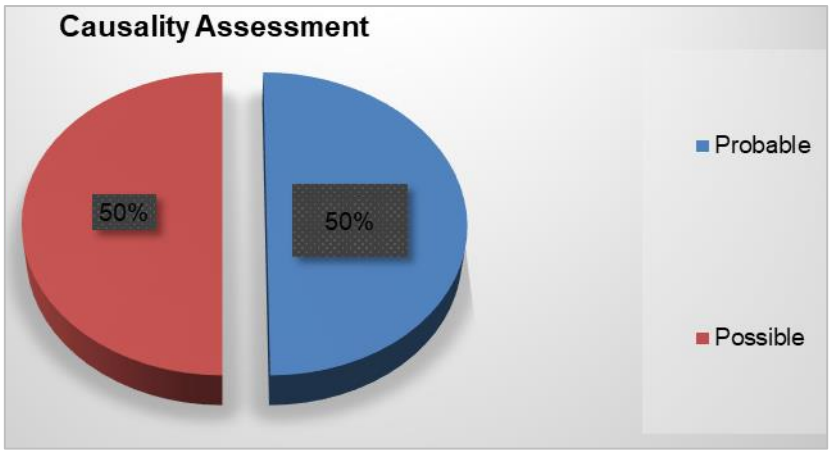

Fig. 2: Causality assessment of endotracheal tube-associated adverse events using the WHO-UMC Scale (N=8 events)

DISCUSSION

The present prospective observational study evaluated medical device–associated adverse events (MDAEs) related to endotracheal tube use in pediatric patients admitted to the Pediatric Intensive Care Unit of a tertiary care hospital. The incidence of MDAEs associated with endotracheal tubes in the present study was 11.7% (n=8), with a mean age of affected patients of 4.75±1.85 y. This finding is comparable to a study conducted at a tertiary care hospital in North India, which reported an incidence of approximately 15% MDAEs associated with medical devices in the pediatric age group [17]. The similarity in incidence rates indicates that adverse events related to medical devices remain a significant concern in critically ill pediatric patients and highlights the importance of systematic monitoring through materiovigilance programs.

In the present study, equal numbers of male and female patients experienced MDAEs related to endotracheal tube use. This observation differs from the findings of the study conducted by Saifuddin PK *et al.* [17], where male patients were found to outnumber female patients in the occurrence of medical device–associated adverse events. The difference observed in gender distribution may be attributed to variations in sample size, demographic characteristics of the study population, and the relatively small sample size and short study duration of the present study.

With respect to the pattern of adverse events, oropharyngeal injury (25%) was the most frequently observed MDAE, followed by tube blockage and other complications such as aspiration, laryngeal trauma, laryngeal edema, vocal cord injury, and malposition of the endotracheal tube. The predominance of oropharyngeal injury may be attributed to factors such as traumatic intubation, inappropriate tube size selection, repeated intubation attempts, patient movement, and increased mucosal fragility, particularly in critically ill or malnourished children. These findings are partially consistent with earlier studies. A four-year computerized database study reported accidental extubation and tube blockage as the most common adverse events associated with prolonged endotracheal intubation in children [18]. However, differences in study design, duration of intubation, and patient population (including prolonged ventilation in earlier studies) may explain variations in the pattern of adverse events. Similarly, a study conducted at a tertiary care teaching hospital in Eastern India reported haemorrhage during tracheostomy and tube blockage as the most frequently observed MDAEs [19]. These findings collectively suggest that airway trauma and tube-related complications are among the most common adverse events associated with airway management devices in pediatric patients.

In the present study, 50% of patients who developed MDAEs were found to have protein-energy malnutrition (PEM). Malnutrition may contribute to increased susceptibility to mucosal injury, impaired tissue integrity, and delayed healing, thereby predisposing patients to device-related complications. However, given the small sample size, this observation should be interpreted cautiously and considered as a potential area for further research rather than a definitive association.

Careful airway assessment and appropriate selection and handling of the endotracheal tube are essential to minimize device-related complications. Anaesthesiologists and intensivists should perform thorough airway examinations and adopt preventive strategies to reduce the risk of adverse events associated with intubation. In the present study, all reported MDAEs were non-serious in nature, indicating that early identification and timely management were effective in preventing severe complications. These findings are consistent with those reported by Saifuddin PK *et al.* [17], who observed that the majority (74%) of MDAEs related to medical devices were non-serious, while approximately 26% resulted in serious outcomes, including death.

Causality assessment using the WHO-UMC scale revealed that 50% of events were classified as “probable” and 50% as “possible.” A probable association indicates a reasonable temporal relationship with device use and a low likelihood of alternative explanations, whereas possible events may also be influenced by underlying disease conditions. This highlights the inherent challenge of attributing causality in critically ill pediatric patients with multiple comorbidities.

LIMITATIONS

The present study has certain limitations. The study was conducted over a short duration of three months, which limited the ability to assess long-term adverse events associated with endotracheal tube use. In particular, the follow-up period of 72 h may not capture delayed complications such as subglottic stenosis or late-onset airway injury, which can occur after prolonged intubation or following extubation. In addition, the study was performed at a single centre with a relatively small sample size, which may limit the generalizability of the findings. Furthermore, all potential risk factors contributing to the root cause of MDAEs, such as operator experience, intubation technique, duration of intubation, and device-specific characteristics, were not comprehensively evaluated. Despite these limitations, the study provides valuable preliminary data on MDAEs associated with endotracheal tubes in pediatric patients and, based on available literature, appears to be one of the first studies from this region to specifically report adverse events related to endotracheal tube use in pediatric patients.

CONCLUSION

Oropharyngeal injury was the most frequently observed adverse event associated with endotracheal tube use in pediatric patients in the present study. A proportion of patients who developed medical device–associated adverse events were also found to have protein-energy malnutrition; however, this observation requires further investigation to establish any definitive association. Early identification, prompt reporting, and systematic monitoring of adverse events related to endotracheal tubes are essential for effective management and prevention of device-related complications. Strengthening materiovigilance practices and enhancing awareness among healthcare professionals at all levels are crucial to ensure patient safety and to minimize adverse events associated with medical devices in clinical practice.

AI DISCLOSURE STATEMENT

The author used ChatGPT for language editing and improving clarity; all outputs were reviewed and the author takes full responsibility for the final content.

AUTHORS CONTRIBUTIONS

Dr. Maldev Rana (First Author) contributed to conceptualization, study design, data collection, data analysis, interpretation of results, and manuscript drafting; Dr. Megha H Shah (Second Author) provided supervision, methodological guidance, data validation, and critical revision of the manuscript for intellectual content; Dr. Sandip Jadav (Third Author) was involved in data analysis, interpretation of findings, and assistance in manuscript editing and literature review; and Dr. Chetna K Desai (Fourth Author) contributed to overall supervision, conceptual guidance, critical review of the manuscript, and final approval of the version to be published.

CONFLICT OF INTERESTS

Declared none

REFERENCES

1. Ravichandran R, Balakrishnan RP, Batcha JS, Ravi AL, Sam NC. Medical device: a complete overview. Int J Clin Trials. 2020;7(4):285-93. doi: 10.18203/2349-3259.ijct20204487.
2. Aswin Thacharodi, Prabhakar Singh, Ramu Meenatchi, ZH Tawfeeq Ahmed, Rejith RS Kumar, Neha V, Sanjana Kavish, Mohsin Maqbool, Saqib Hassan. Revolutionizing healthcare and medicine: the impact of modern technologies for a healthier future-a comprehensive review. Health Care Sci. 2024;3(5):329-49. doi: 10.1002/hcs2.115, PMID 39479277.
3. Huusko J, Kinnunen UM, Saranto K. Medical device regulation (MDR) in health technology enterprises: perspectives of managers and regulatory professionals. BMC Health Serv Res. 2023;23(1):310. doi: 10.1186/s12913-023-09316-8, PMID 36997978.
4. Jafleh EA, Alnaqbi FA, Almaeeni HA, Faqeeh S, Alzaabi MA, Al Zaman K. The role of wearable devices in chronic disease monitoring and patient care: a comprehensive review. Cureus. 2024;16(9):e68921. doi: 10.7759/cureus.68921, PMID 39381470.
5. Amrani G, Gefen A. Which endotracheal tube location minimises the device-related pressure ulcer risk: the centre or a corner of the mouth? Int Wound J. 2020;17(2):268-76. doi: 10.1111/iwj.13267, PMID 31724822.
6. Modi YC, Menia N, Jhawer A. Effect of bevel direction of the endotracheal tube on the proportion of cases developing epistaxis during nasotracheal intubation-a randomized controlled interventional study. Int J Curr Pharm Sci. 2024;16(4):124-8. doi: 10.22159/ijcpr.2024v16i4.5028.
7. Rampally S, Sowmya K, Bhargavi S, Pravalika R, Jaju S. Effects of lignocaine nebulization versus dexmedetomidine nebulization in blunting hemodynamic response in patients undergoing nasotracheal intubation in head and neck surgeries. Asian J Pharm Clin Res. 2026;19(2):196-200. doi: 10.22159/ajpcr.2026v19i2.57228.
8. Kasa S, Singh M, Rampally S, Sahithi Chowdary P, Sachidanand RS, Mantri A. Validation of a novel syringe-based monitor (AG CUFFILL) for measurement of endotracheal tube cuff pressure in adult patients. Indian J Clin Anaesth. 2025;12(4):710-4. doi: 10.18231/j.ijca.13430.1761639831.
9. Veeramani S, Murugesh SR, A MG, Palaksha S. Assessment of adverse events associated with medical devices among respiratory disorder patients at a tertiary care hospital. Indian J Med Res. 2025;161(6):672-8. doi: 10.25259/IJMR_1755_2024, PMID 40878347.
10. Amoore JN. A structured approach for investigating the causes of medical device adverse events. J Med Eng. 2014;2014:314138. doi: 10.1155/2014/314138, PMID 27006931.
11. Aaliya Parvin MJ, Sudheer Kumar T, Kamaraj R. A comprehensive analysis of class i medical device recalls: unveiling patterns causes and global impacts. Cureus. 2024;16(8):e67542. doi: 10.7759/cureus.67542, PMID 39310387.
12. Porte PJ, Smits M, Verweij LM, De Bruijne MC, Van Der Vleuten CP, Wagner C. The incidence and nature of adverse medical device events in Dutch hospitals: a retrospective patient record review study. J Patient Saf. 2021;17(8):e1719-25. doi: 10.1097/PTS.0000000000000620, PMID 32168269.
13. Meher BR. Materiovigilance: an Indian perspective. Perspect Clin Res. 2018;9(4):175-8. doi: 10.4103/picr.PICR_26_18, PMID 30319948.
14. Kumar Gupta SK. Medical device regulations: a current perspective. J Young Pharm. 2015;8(1):6-11. doi: 10.5530/jyp.2016.1.3.
15. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Ghaziabad: Indian Pharmacopoeia Commission; 2022. Available from: https://ipc.gov.in/. [Last accessed on 26 Aug 2025].
16. World Health Organization Uppsala Monitoring Centre. The use of the WHO-UMC system for standardized case causality assessment. Geneva: World Health Organization Uppsala Monitoring Centre; 2005. Available https://www.who-umc.org. [Last accessed on 26 Aug 2025].
17. Saifuddin PK, Prakash A, Samujh R, Gupta SK, Suri V, Kumar RM. Pattern of medical device adverse events in a tertiary care hospital in Northern India: an ambispective study. J Assoc Physicians India. 2024;72(6):62-8. doi: 10.59556/japi.72.0424, PMID 38881137.
18. Black AE, Hatch DJ, Nauth Misir N. Complications of nasotracheal intubation in neonates, infants and children: a review of 4 y experience in a Children's Hospital. Br J Anaesth. 1990;65(4):461-7. doi: 10.1093/bja/65.4.461, PMID 2248814.
19. Swain SK, Behera IC. Pediatric tracheostomy: a 10 y experience at a Tertiary Care Teaching Hospital in Eastern India. Indian J Health Sci Biomed Res (KLEU). 2022;15(3):224-9. doi: 10.4103/kleuhsj.kleuhsj_130_22.