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Suction-based airway clearance devices for foreign body airway obstruction: protocol for a systematic review

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Abstract. *Background and aim:* This paper outlines a protocol for a scoping review that will critically appraise the existing evidence base on the efficacy of airway clearance devices for foreign body airway obstruction. *Methods:* The search was conducted in the MEDLINE, CINAHL, the Cochrane Library, and Scopus databases. The quality, validity, and relevance of each study will be systematically evaluated using formal risk of bias/quality assessment tools, such as The Critical Appraisal and Data Extraction Tool. *Results:* The systematic review will identify and appraise all available studies on the efficacy of suction-based airway clearance devices for foreign body airway obstruction. The review will summarize the findings of the included studies and provide an overall assessment of the evidence on the devices' efficacy. *Conclusions*: The systematic review will inform best practices in airway management by providing a comprehensive evaluation of the current literature on the effectiveness of new devices for foreign body airway obstruction treatments. (www.actabiomedica.it)

Key words: foreign body airway obstruction, anti-choking, airway clearance devices, resuscitation, basic life support, systematic review protocol

Introduction

Airway obstruction refers to a condition where normal breathing is impeded due to various factors, both direct and indirect, disrupting the efficient exchange of gases with the surrounding environment. Prolonged obstruction leads to hypoxemia and hypoxia, resulting in oxygen deficiency in the blood and tissues, adversely affecting delicate organs such as the brain (1). Continual hypoxic conditions cause tissue dysfunction, leading to a sequence of events: loss of consciousness, irreversible brain damage, coma, and ultimately patient fatality. Even survival post-incident may result in severe cerebral hypoxia, leading to irreversible motor and/or sensory impairments due to nervous tissue necrosis. Despite being preventable, foreign body airway obstructions (FBAO) pose a significant global threat, contributing to injuries and fatalities. Annually, the United States reports over 5000 choking-related deaths, while England and Wales record approximately 400 fatalities attributed to this cause (2). In Japan, it stands as the leading cause of accidental death (3). Food ingestion accounts for the majority of airway obstructions, and mortality rates correlate with age (4). However, retrospective data on foreign body airway obstructions may underestimate their incidence. Notably, in one study, individuals aged over 74 years accounted for 56% of cases (5). The causes of choking involve three main factors: intrinsic or extrinsic airway obstructions, inadequate environmental oxygen concentration, and presence of chemicals disrupting normal respiration (6). Airway obstructions

can be partial or complete. Partial obstructions permit minimal air passage, allowing some ventilation and increasing the likelihood of expelling the foreign body through coughing. Thus, encouraging a conscious individual to cough aids in expelling the foreign body due to the higher pressures generated (6). Conversely, complete obstructions hinder air passage due to the foreign body, resulting in hypoxia, loss of consciousness, and cardiac arrest within minutes. Prompt treatment involves traditional techniques like the Heimlich maneuver, including back blows and abdominal thrusts (7). However, these techniques may fail in specific cases, complicating rescue efforts, especially with immobilized patients in wheelchairs, pregnant individuals, or those who are pathologically obese, highlighting the need to determine the most appropriate and effective technique (8). The most established airway clearance methods date back to 1975 when Dr. Heimlich introduced sub-diaphragmatic pressure as a means to expel obstructive objects. Prior to this, tracheotomy and, where feasible, bronchoscopy were commonly us (4). Recent years have seen the exploration and testing of alternative solutions in some regions, focusing on new airway clearance devices (ACDs) using portable aspiration and negative pressure within the airways (7). These devices come in non-invasive e.g., LifeVac© (LifeVac LLC, Nesconset, New York, NY, USA) and minimally invasive types e.g., DeChoker© (LLC, Wheat Ridge, CO, USA). The LifeVac is a non-invasive device resembling a plunger with a valve adhering to the patient's mouth, generating unidirectional suction to remove foreign bodies. Conversely, the DeChoker utilizes an oropharyngeal tube and a plunger-like mechanism to lower the tongue and create oropharyngeal communication. Equipped with a face mask, it employs negative pressure to expel foreign bodies (9). However, their effectiveness remains unproven, and the International Liaison Committee on Resuscitation (ILCOR) has refrained from specific recommendations due to the lack of evidence regarding safety, effectiveness, and user training for these devices. Currently, no study has directly compared these devices with standard airway clearance maneuvers (9). Nevertheless, in practice, DeChoker and LifeVac devices have proven reliable in resolving foreign body obstructions when traditional techniques failed, particularly in training scenarios, care facilities, and non-medical environments (10). While ACD device introduction holds promise in improving FBAO management, comprehensive clinical research is imperative to confirm their efficacy and safety. This protocol outlines the plan for an update of previous systematic reviews (8, 10).

Methods and analysis

Study design

This systematic review protocol presents the methods and procedures used to critically appraise the existing evidence base on the efficacy of negative-pressure, anti-choking devices in alleviating severe foreign body airway obstructions (FBAOs). The review assessed the strength of this evidence and identified any further research areas that warrant investigation before recommending widespread incorporation of these devices into resuscitation guidelines. The overarching goal of this review is to establish optimal standards in airway management practices**.** The PRISMA-P guidelines were followed for the protocol (11), while the PRISMA guidelines will be used for the review article (12).

Search methods

To ensure a comprehensive review, meticulously formulated search strings were crafted and deployed across various databases. These encompassed exhaustive exploration in esteemed databases like MEDLINE (via the PubMed interface), CINAHL (accessible through the Embase interface), the Cochrane Library, and Scopus. Furthermore, the search was delimited to publications released within the last five years - from January 1, 2019 - to encapsulate the most recent and relevant research findings in such field. The research will be conducted specifically from January 27th to January 2024 31st. We will use the PICO framework, which will allow us to select the studies to consider. Based on the relevance of our research question, this framework allows us to demarcate the study area (see Table 1.). In Box 1, the search string formulated for the MEDLINE database is displayed.

Table 1. Research Question Breakdown according to the PICO Model.

P (Problem)	I (Intervention)	C (Comparison)	O (Outcome)
• Foreign body airway obstruction • FBAO • Adult choking emergencies • Choking incidences • Choking victim • Life-threatening choking situation • Foreign body asphyxia • Aspiration	• Negative pressure devices for airway obstruction • LifeVac • Dechoker • Suction-based airway clearance devices • Anti-Choking Device • ACD	• Heimlich maneuver • Traditional airway clearance methods • Abdominal thrusts • Conventional methods	• Successful removal • Time to removal • Management of choking • Safety • Efficacy • Ease of application • Easy to use • Usability • Complications • Adverse events • Effective • Effectivenes • Appropriate • Pratical • Effective resuscitation • Benefits • Harms • Potential associated risks • Delayed resuscitation • First line treatment • Aspirate stomach content • Aspiration pneumonia post intervention • Chest infection • Trauma

Quality appraisal

The comprehensive assessment will employ validated risk of bias and quality assessment tools, notably the Crowe Critical Appraisal Tool (CCAT), facilitating a meticulous examination of the studies (13). These assessments will be independently conducted by two researchers. Any disparities in their evaluations will undergo rigorous discussions aiming for consensus. If discrepancies persist without resolution, a third impartial reviewer will be engaged to provide an objective assessment, thereby ensuring a conclusive resolution. The CCAT serves as a versatile instrument capable of assessing the methodological quality across a diverse array of research designs, including quasi-experimental, descriptive-exploratory-observational, qualitative, systematic review, and true experimental designs. With 22 items categorized into 8 distinct sections - Preliminaries, Introduction, Design, Sampling, Data Collection, Ethical Matters, Results, and Discussion - the CCAT provides a comprehensive framework for evaluation (14).

Data extraction and analysis

The study will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA) guideline (12). Data extraction and analysis will be conducted in a two-phase process. Initially, two authors will independently scrutinize the titles and abstracts of retrieved literature to identify potential articles for inclusion in the systematic review. Discrepancies in assessments will be resolved through discussion between the authors, with involvement from a third party in the event of unresolved matters. Subsequently, the same two authors will independently acquire full texts for selected articles and perform data abstraction using standardized forms. Any inconsistencies in the abstracted data will be addressed through discussion between the authors, with involvement from a third party if necessary. To ensure high standards of quality and reliability in the systematic review, we will implement a rigorous evaluation process. This process will thoroughly assess

Box 1. The search string formulated for MEDLINE database.

(successful removal OR time to removal OR management of choking OR safety OR efficacy OR ease of application OR easy to use OR usability OR complications OR adverse events OR effective OR effectivenes OR appropriate OR pratical OR effective resuscitation OR benefits OR harms OR potential associated risks OR delayed resuscitation OR first line treatment OR aspirate stomach content OR aspiration pneumonia OR post intervention OR chest infection OR trauma) AND (((((((Foreign body asphyxia) OR (life threatening choking situation)) OR (choking victim)) OR (choking incidences)) OR (choking emergencies)) OR ('Foreign body airway obstruction' OR (FBAO))) AND (((((Negative pressure devices for airway obstruction) OR (LifeVac)) OR (Dechoker)) OR (suction based airway clearance)) OR (Anti Choking Device))) Filters: **from 2019 - 2023**

the methodological robustness and relevance of each included study.

Inclusion criteria and exclusion criteria

The inclusion criteria for this systematic review encompass a broad range of pertinent studies while maintaining a clear focus on relevant content. Studies of any design published in peer-reviewed journals are eligible for consideration. The content of these studies is not restricted, allowing for a comprehensive analysis of various study types. Participants included in these studies should consist of humans aged over one year, along with mannequins or cadavers experiencing foreign body airway obstructions. The interventions encompass a spectrum of prevailing airway obstruction devices, such as negative-pressure devices, suction-based airway clearance devices, and Anti-Choking Devices. Additionally, the review will consider various scenarios serving as comparators or controls, including no action, the Heimlich maneuver, traditional airway clearance methods, and abdominal thrusts. This review aims to incorporate studies conducted across diverse clinical settings, embracing hospitals and community healthcare facilities worldwide. In contrast, exclusion criteria delineate parameters to maintain the focus and integrity of the review. Unpublished studies, including conference abstracts and trial protocols, will be excluded. Similarly, editorial pieces and opinion articles lacking primary data - as well as animal studies, experimental, or laboratory models - are outside the scope of this review. Additionally, studies exclusively focusing on infant populations below one-year-old (the unique anatomy and physiology of neonates and infants make them a distinct population with specific requirements) and those confined solely to animal research will be excluded from consideration. These criteria were carefully crafted to ensure the review's scope encompasses a comprehensive range of relevant studies while delineating boundaries to maintain precision and relevance in the analysis.

Data abstraction

The review adopts a systematic approach to extract relevant data, encompassing study design, participant demographics, and outcome measures from each included study. These studies are then categorized based on their respective levels of evidence, facilitating a comparative assessment of the strength and reliability of their findings.

Synthesis

The key findings from each study were meticulously presented in a synoptic tabular format to allow for a coherent and structured comparison. Subsequently, these findings were critically analyzed and discussed within the context of their respective evidence levels, fostering a comprehensive and informed synthesis of the cumulative evidence**.** No predetermined plans have been outlined for conducting subgroup analysis as part of this review. The focus remains on a comprehensive analysis encompassing diverse studies within the established scope and criteria. The findings of the studies were summarized in a narrative format, and the focus was on identifying patterns and themes in the data. The qualitative summary was also used to identify areas for further research. To assess the strength of evidence in the reviewed articles, it was employed the hierarchy of evidence proposed by Polit and Beck (15).

Conclusion

Our systematic review examined different airway obstruction devices to assess their effectiveness in

managing foreign body airway obstruction (FBAO) and choking emergencies. It maintains a stringent focus on diverse scenarios involving human subjects above infancy and simulated situations featuring mannequins or cadavers, excluding research centered on infants and animal studies. The extensive evaluation of airway obstruction devices, including negative pressure and suction-based devices, and the Anti-Choking Device, signifies a comprehensive approach. This thorough analysis not only aims to gauge their effectiveness but also their adaptability across varied clinical settings, spanning hospitals to community healthcare facilities worldwide. Such a comprehensive evaluation within diverse healthcare environments underscores the review's robustness and real-world relevance. The review's key outcomes encompass successful airway obstruction removal, time efficiency, and comprehensive choking emergency management, serving as critical benchmarks. Categorizing neurological outcomes based on validated criteria provides invaluable insights into the interventions' impact on neurological well-being. Beyond primary outcomes, the review encompasses usability metrics and potential adverse events associated with interventions, offering a comprehensive understanding of practical implications. Evaluation criteria include learning curves, user errors, task efficiency, and user satisfaction. Additionally, scrutinizing adverse events like aspiration pneumonia, chest infections, and trauma amplifies the depth of assessment, potentially influencing future guidelines. The holistic analysis of these diverse aspects enhances the review's significance in shaping comprehensive recommendations for addressing FBAO and choking emergencies in healthcare protocols.

Impact

What problem will the study address?

Foreign body airway obstructions pose grave risks, potentially resulting in fatalities and injuries, where traditional methods like the Heimlich maneuver may falter in specific cases. New Airway Clearance Devices offer less invasive approaches to clear airways, yet their effectiveness lacks robust clinical validation, leading to insufficient data for ILCOR to recommend them over standard techniques due to safety, effectiveness, and training concerns.

What will be the main findings?

The findings of our systematic review aim to offer evidence supporting the potential effectiveness of ACDs in clearing foreign body airway obstructions (FBAOs), especially when traditional methods like the Heimlich maneuver prove unsuccessful.

Where and on whom will the research have an impact?

Improved techniques or devices for clearing airway obstructions could significantly impact patient care, especially in scenarios where traditional methods might fail. If proven effective and safe through robust research, these devices could potentially save lives and reduce complications associated with FBAO, particularly among vulnerable populations like the elderly or those with physical limitations.

Study registration

This systematic review was registered with PROSPERO on 11 November 2023 (CRD42023477631).

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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