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LifeVac Comprehensive Research & General Recap

Retlif Force Test	Downward Compression
Retlif Force Test	Suction
Retlif Durability Test	Durability
The American Journal of Gastroenterology	Adult Simulation Study
The American College of Emergency Physicians	Adolescent Simulation Study
The American Journal of Emergency Medicine	Human Cadaver Study
The World Congress of Gastroenterology	Real Life Saves (2)
American Broncho-Esophagological Association	Summary Real Life Saves
International Journal of Clinical Skills	Peer Reviewed Medical Publication (10 Life Saves)
SEMES	Summary Real Life Saves
International Journal of Paediatric Otorhinolaryngology	Peer Review World Leading Physician Paediatric Airway Management
Journal of Clinical Gastroenterology	Submited
American Academy of Paediatrics Poster Presentation	Worldwide Real Lives Saved
Paediatrics & Therapeutics	Peer Reviewed Real World Data (21)
European Resuscitation Council (ERC)	Poster Tour – Device for The Resuscitation of the Choking Victim
Resuscitation Plus	Peer Reviewed – The Efficacy and Usability of Suction Based Airway Clearance Devices for FBAO vs Abdominal Thrusts
Frontiers	Peer Reviewed – Use of a Novel Portable Non-Powered Suction Device in Patients with Oropharyngeal Dysphagia During a Choking Emergency
International Journal of Environmental Research and Public Health	Peer Reviewed – Phase One of Global Evaluation of Suction Based Airway Clearance Devices in FBAO. A Retrospective Descriptive Analysis
Research Square	Anti-Choking Suction Devices for Foreign Body Airway Obstruction in Children. Would Parents and Kindergarten Teachers be Able to Use Them Without Training?
BMC Medical Education	Would Anti-Choking Devices be Correctly and Quickly Managed by Health Science Students? A Manikin Crossover Trial
Resuscitation Plus	Peer Reviewed - A 2-Year Prospective Evaluation of Airway Clearance Devices in Foreign Body Airway Obstructions
Journal of Pediatric Critical Care	The use of LifeVac, in the assistance of choking victims aged five and under: Results of a retrospective 10-year observational study
Resuscitation Plus	Knowledge and skills of pediatric residents in managing pediatric foreign body airway obstruction using novel airway clearance devices in Spain: A randomized simulation trial

LIFEVAC
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Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Our Ref: CA014885

MHRA

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Mr Eric Banagan
LifeVac Europe Limited
Carnanton
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16 June 2015

Dear Mr Eric Banagan,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19

Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of your company's details and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation, certifcation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices and Custom Made Active Implantable

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of the following chargable changes:

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARD).

Thank you for registering the following generic groups of devices:

Class I Devices:
Airway Devices/Monitoring Equipment And Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

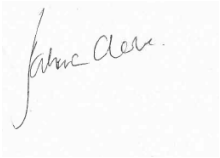
Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely



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Mr Eric Banagan
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Horswell Farm House
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Sent via email
20 June 2023

Dear Mr Banagan,

INC 8296 – Lifting of restrictions on LifeVac anti-choking device in the UK

I am writing to you in follow up to our letter issued on 17 June 2022, in which we shared the outcome of the MHRA's investigational review and outlined next steps, including an action plan that would progress LifeVac towards the lifting of restrictions that have applied since 30 August 2017 on the use of the LifeVac device in the UK.

This letter has been issued to confirm that these actions within the outlined plan have been satisfactorily completed by LifeVac Europe Ltd ("LifeVac"), and therefore as of the date of this letter the restrictions established in our 30 August 2017 letter may be lifted and the device freely marketed in the UK once again.

Yours sincerely,

Ms Suzanne Fuller

Head of Devices Compliance and Audit
Standards and Compliance
Healthcare Quality and Access, MHRA

REGISTRATION CERTIFICATE

this is to certify that the management system of

LifeVac Europe Limited

have been assessed by A CUBE TIC LIMITED and registered against the requirements of

BS EN ISO 13485:2016

scope of registration

Production, sales and distribution of the LifeVac device.

Unit 5 Torridge Business Park, Nadder Lane, South Molton, Devon, EX36 4HP, United Kingdom

Sites Registered		
23		23/17958
EAC		Certificate Number
1st June 2023	N/A	31st May 2026
Date Original Registration	Date Of Re-registration	Expiry Date
31st March 2026	12th June 2025	N/A
Next Re-Audit Due Date	Revision Date	Previous Expiry Date

Alfonso Pagliuca, President & Founder, A Cube TIC Limited

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Letter to the Editor

Counterfeit anti-choking suction devices: Prevalence and risks on online marketplaces

To the Editor,

Anti-choking suction devices represent an innovative first aid method designed to remove foreign body airway obstruction. Although they are not part of the current European Resuscitation Council guidelines,[1] they are used by many healthcare professionals and laypersons.[2–4] As with any medical devices, there appear to be many more affordable counterfeit and unbranded copies products on the market claiming to be anti-choking suction devices.[5] In June 2024, the United Kingdom's Office for Product Safety and Standards issued a recall for counterfeit anti-choking suction devices sold through online marketplaces. It is stated that they are lacking certification marks (for example European conformity = C€), details of the manufacturer, unique identifiers and serial numbers on the device. There is also a possibility that they will not work and could worsen the situation by pushing obstruction further down the airway, due to their poor design and quality.[6,7] The aim of this review is to investigate the prevalence of counterfeit and unbranded anti-choking suction devices on the most widely used online marketplaces.

We conducted a review using the keyword "anti-choking suction device" on the online marketplace AliExpress (AliExpress, China). The search was conducted in November 2023 and January 2025.

Fig. 1 – An example of a counterfeit anti-choking suction device without certification marks.

The shipping country was set to Slovenia. We investigated the number of products found, the number of products sold and their prices.

In November 2023, a total of 41 different anti-choking suction devices were identified, with an average price of €14.00 (SD ± 0.41) and over 3,324 units sold. By January 2025, the number of identified devices had increased to 59, with a higher average price of €16.27 (SD ± 26.66) and total sales exceeding 9,481 units. One of the counterfeit anti-choking suction devices was also purchased on AliExpress for €6.97. As shown in Fig. 1, the device lacked certification marks, manufacturer details, unique identifiers, and serial numbers.

The results highlighted a significant increase in the number of counterfeit anti-choking suction devices sold, despite being limited to one marketplace from China. Compared to certified anti-choking suction devices on the market, counterfeit versions are three to four times cheaper, especially considering that they are single-use devices. The question arises whether consumers knowingly purchase counterfeit anti-choking suction devices to save money or if they are unaware that these devices are uncertified. Experts, however, can recognize these counterfeits by their distinct appearance, absence of labels and identifiers, lack of a valve, and incomplete instruction manuals.[6,7] Beyond the questionable characteristics of anti-choking suction devices, concerns also arise regarding variations in their working principles and the suction they generate—both critical factors for effective functionality.

CRediT authorship contribution statement

Špela Metličar: Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nino Fijačko:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'Nino Fijačko is in ERC BLS Science and Education Committee. Špela Metličar declares no conflict of interest.'.

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Review

Do We Actually Help Choking Children? The Quality of Evidence on the Effectiveness and Safety of First Aid Rescue Manoeuvres: A Narrative Review

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Abstract: The management of foreign body airway obstruction has evolved over time from back blows and chest thrusts to abdominal thrusts. However, current guidelines worldwide are based on outdated data, with unclear evidence regarding the effectiveness and safety of these rescue manoeuvres. Concerns persist about the potential of these techniques to cause injury, especially in children; therefore, a critical revision to ensure optimal child safety is necessary. The literature on first aid for paediatric choking was identified through the searching of various databases. Studies were evaluated for their relevance, quality, and currency. The analysis examined guideline consistency with current evidenced-based medicine and identified research gaps. The analysis of the available data was supplemented by adult-based evidence due to the scarcity of paediatric-specific research. First aid guidelines and recommendations for paediatric choking are divergent and generally grounded in low-quality evidence derived primarily from case studies. Studies since 2015 have shown highly diverse methodologies and often lack details on the execution of individual techniques, body positioning or the specific characteristics of study groups, which are crucial when comparing the effectiveness and safety of rescue manoeuvres. Updating evidence-based scientific knowledge for future recommendations is crucial.

Keywords: first aid; paediatric; children; foreign body airway obstruction; choking; airway; back blows; chest thrusts; abdominal thrusts; Heimlich manoeuvre

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1. Introduction

1.1. Background

Children are particularly vulnerable to foreign body airway obstruction (FBAO) due to their unique anatomical features, including smaller airways and disproportionately larger tongues [1]. This not only increases the risk of blockage by small objects but also results in lower cough-generating forces, as explained by the Hagen–Poiseuille law, which further elevates the risk of complete airflow obstruction [2]. Additionally, during early development, children continuously explore their environment and learn about the world through senses such as touch and taste [2,3]. This exploratory behaviour often involves placing objects in their mouths, further increasing the risk of airway blockage. These factors contribute to FBAO being one of the leading causes of accidental deaths in children under the age of 16.

Bystander intervention in the form of first aid rescue manoeuvres is the primary method to treat severe FBAO, and clearing the obstruction before the arrival of emergency medical personnel is the strongest predictor of survival [1–5]. However, recent data suggest that up to half of these deaths occur with no action taken, indicating bystanders lack either proficiency or confidence using these manoeuvres, resulting in significant delays to proper care [1–7]. Untreated FBAO-induced hypoxia rarely occurs without serious neurological damage [8]. Individuals who experience prolonged airway obstruction are exposed to an increased risk of severe neurological impairment or brain death [4,5]. The choking person is also at risk of other life-threatening complications such as swelling and inflammation of the airway which occurs in 5% of cases after the delayed removal of a foreign body, even from a partial obstruction [1]. As complete blockage results in respiratory failure and cardiac arrest, the survival rate for paediatric out-of-hospital cardiac arrest due to FBAO remains very low [8,9].

1.2. The Past

Since the early days of first aid, managing a choking victim with a FBAO has conventionally involved the administration of back blows, also known as back slaps. Reports dating back to the 17th century describe attempts to aid choking individuals with "concussions to the body", which likely represent an early use of this rescue manoeuvre. Supposedly, back blows were used from time immemorial in conjunction with manual efforts to dislodge the object, inversion or succussion of the body, and percussion of the chest, a practice that also bears resemblance to modern chest thrusts [10,11]. While other manoeuvres faded over time due to ineffectiveness or safety concerns, back blows and chest thrusts persisted and were formally recommended as safe and effective by some of the earliest providers of resuscitation guidelines [10–12].

Uncertainty has arisen over time, however, and medical professionals have commenced debating on the relative benefits and risks of administering back blows and chest thrusts to a choking individual [10,12–15]. One vocal dissident to back blows and chest thrusts was Dr Henry J. Heimlich. Between 1974 and 1979, he cautioned against using back blows, which he referred to as "death blows", stating in his works that they could potentially result in a foreign object becoming lodged deeper into the airway, causing a hopeless blockage [16,17]. In 1987, he famously claimed that chest thrusts were "hazardous, even lethal" due to their functional similarity to chest compressions performed during cardiopulmonary resuscitation (CPR) and might lead to the same trauma, especially in children [11]. Dr Heimlich introduced abdominal thrusts, which were later named after him, as an alternative technique. By 1986, both the American Heart Association (AHA) and the American division of the International Federation of Red Cross and Red Crescent Societies (IFRC) had incorporated the abdominal thrusts into their guidelines, ceasing to recommend back blows and chest thrusts, which were either considered a "last, desperate effort" or discouraged altogether [10]. This shift was influenced by Dr Heimlich's promotion of abdominal thrusts, based on unsupported cases from lay press reports, as he sought to discredit AHA experts who still endorsed alternative techniques [10,18]. The Heimlich manoeuvre became a widely recognised and commonly recommended response for FBAO in both children and adults.

1.3. The Present

Nowadays, guidelines around the world indicate a lack of clarity among experts regarding the first aid management of paediatric FBAO. The International Liaison Committee on Resuscitation (ILCOR), a committee dedicated to promoting the implementation of evidence-informed first aid, continues to synthesise contemporary data on FBAO management. Despite this, committees such as the European Resuscitation Council (ERC), the American Heart Association (AHA), the Australian and New Zealand Committee on Resuscitation (ANZCOR), the Resuscitation Council of Asia (RCA), St John Ambulance (SJA), and similar organisations have discordant guidelines regarding recommended ma-

noeuvres. Abdominal thrusts continue to be a commonly advocated technique, although a significant number of organisations either completely reject them or include them in an algorithm that also consists of back blows and chest thrusts, which are once again gaining popularity [3,19–23]. These variations highlight the complexities in establishing uniformly accepted recommendations based on weak data. The inconsistencies are especially noticeable in the recommendations for treating children older than 1 year old who are conscious with an ineffective cough, as shown in Table 1.

Table 1. A comparison of the differences in recommended manoeuvres and their sequence for managing foreign body airway obstruction in children older than 1 year old, who are conscious with an ineffective cough [3,19–23].

Guidelines	Back Blows	Chest Thrusts	Abdominal Thrusts
ERC [1]	first	not recommended	second
AHA [2]	not recommended	not recommended	only
IFRC [3]	first	not recommended	second
MFMER [4]	first	not recommended	second
ANZCOR [5]	first	second	not recommended
JRC [6]	first or second (order does not matter)	first or second (order does not matter)	not recommended
KACPR [7]	only (if child < 8 yrs. old) first (if child ≥ 8 yrs. old)	not recommended	second (if child ≥ 8 yrs. old)
RCA [8]	not recommended	not recommended	only
RCSA [9]	second	not recommended	first
SJA [10]	first	second (Australia and New Zealand)	second
RCUK [11]	first	not recommended	second

[1] ERC—European Resuscitation Council, [2] AHA—American Heart Association, [3] IFRC—International Federation of Red Cross and Red Crescent Societies, [4] MFMER—Mayo Foundation for Medical Education and Research, [5] ANZCOR—Australian and New Zealand Committee on Resuscitation, [6] JRC—Japanese Resuscitation Council, [7] KACPR—Korean Association of Cardiopulmonary Resuscitation, [8] RCA—Resuscitation Council of Asia, [9] RCSA—Resuscitation Council of Southern Africa, [10] SJA—Saint John Ambulance, [11] RCUK—Resuscitation Council UK.

Despite efforts to standardise guidelines, some countries have multiple recommendations from national organisations. Canada is a unique case where five nationally recognised first aid and CPR training agencies have developed three distinctly different FBAO approaches, as shown in Table 2 [24–28]. To standardise first aid training, the Canadian Guidelines Consensus Task Force was formed in 2015, leading to the first publication of the Canadian Consensus Guidelines on First Aid and CPR in 2016 [29]. However, a literature search has shown no subsequent publications of these guidelines. As international organisations like the IFRC and ILCOR release new science and best practice recommendations, Canadian training agencies have returned to individually updating their training programmes, resulting in practice inconsistencies once again [28]. This scenario is not unique to Canada and reflects challenges shared by regions and countries without a dedicated, single resuscitation council [30].

Even in the presence of resuscitation councils, inconsistencies in recommendations versus practice can occur when additional authoritative bodies (e.g., government agencies managing workplace health and safety) develop their own standards which much be followed by companies and workers to adhere to local regulations. Although first aid and CPR programmes may have regional or nationally approved training curricula, these authoritative bodies may mandate standardised approaches within their jurisdictions. For instance, in the province of Ontario, Canada, five back blows are alternated with five abdominal

thrusts to receive programme accreditation [26]. This jurisdictional variation adds another layer of complexity and can lead to further discrepancies in training and practice within the same first aid and CPR training organisation. In the absence of resuscitation councils, health service organisations, medical colleges or licencing boards, and emergency medical services (e.g., ambulance services) must develop their own guidelines, recommendations, standards, or protocols to address these inconsistencies. This decentralised approach increases the risk of disparities in methods and practices. These challenges underscore the need for high-quality studies to inform recommendations for emergency procedure based on robust scientific evidence. Presently, the limited available evidence restricts ILCOR's ability to make strong treatment recommendations, resulting in significant disparity across various nations and councils as they must translate weak evidence into practice. Ongoing efforts to harmonise first aid and resuscitation practices globally must focus on improving the quality of the evidence base [31,32].

Table 2. A comparison of the algorithm differences in manoeuvres recommended by Canadian training agencies and their sequence for managing foreign body airway obstruction in children older than 1 year old, who are conscious with an ineffective cough [24,28].

Training Agencies	Back Blows	Chest Thrusts	Abdominal Thrusts
CRC [1]	Any combination of back blows, chest thrusts or abdominal thrusts		
CSP [2]	Any combination of back blows, chest thrusts or abdominal thrusts		
HSF [3]	not recommended	not recommended	only
RLSS [4]	Any combination of back blows, chest thrusts or abdominal thrusts		
SJA [5]	first	not recommended	second

[1] CRC—Canadian Red Cross, [2] CSP—Canadian Ski Patrol, [3] HSF—Canadian Heart and Stroke Foundation, [4] RLSS—Royal Life Saving Society Canada, [5] SJA—St. John Ambulance Canada.

1.4. The Future

The effectiveness of life-saving manoeuvres in the first aid management of paediatric FBAO has limited contemporary evidence. According to the ERC, "age-specific manoeuvres for FBAO have been part of resuscitation guidelines for more than 25 years" [3]. Yet, according to the ILCOR update on the issue, their recommendations are "weak" and based on evidence with a quality of "very low certainty" [33,34]. It is important to note that much of ILCOR's research is from several decades ago, with most of the referenced material originating from the previous century, which raises concerns about its current validity and relevance [3,33,34]. Therefore, it is accurate to state that there is a lack of knowledge about the effectiveness and safety of the recommended rescue manoeuvres, the balance of which is crucial when deciding which to recommend.

The issue of paediatric FBAO and the rescue manoeuvres for choking victims is alarming due to the high incidence of choking incidents, significant mortality risk and limited first aid provided in such cases [1,2,33]. The increased vulnerability of children to severe upper airway obstruction is compounded by the challenges in performing effective rescue manoeuvres. The disproportion between the size of an adult hand and a paediatric torso, as demonstrated later in the figures, highlights the risk of injury to a child's fragile body when forceful procedures are used. Yet, uncertainties remain regarding the evidence and reliance on outdated references, resulting in a lack of universal agreement on first aid recommendations and guidelines.

Consequently, to ensure the safety and well-being of children, an in-depth analysis is required to critically re-evaluate the life-saving manoeuvres recommended by the various global resuscitation guideline developers in the first aid management of paediatric FBAO. This analysis emphasises its most disputed and controversial section: treating children who are conscious and have an ineffective cough (otherwise known as a complete or severe obstruction). Therefore, we aim to conduct a narrative review of the recent literature,

assessing the effectiveness and safety of standard first aid rescue manoeuvres for children aged one year or older—back blows, chest thrusts, and abdominal thrusts—and identify the gaps in evidence and knowledge in order to outline the direction of future research.

2. Materials and Methods

2.1. Identification of Relevant Guidelines and Literature

After we carried out a search of the websites of resuscitation councils and organisations focused on first aid and resuscitation guidelines, in order to identify further literature, including those from ERC, AHA, IFRC, MFMER, ANZCOR, JRC, KACPR, RCA, RCSA, SJA, RCUK, CRC, CSP, HSF, RLSS, and SJA Canada, we identified studies describing the effectiveness and safety of paediatric FBAO manoeuvres. To conduct this review, we searched databases including PubMed (National Center for Biotechnology Information, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, USA), Google Scholar (Google LLC, 1600 Amphitheatre Parkway, Mountain View, CA 94043, USA) and CORE (The Open University, Walton Hall, Milton Keynes, MK7 6AA, United Kingdom) up until July 2024. We used a combination of keywords such as back blows, chest thrusts, abdominal thrusts, foreign body airway obstruction, choking, and foreign body aspiration. Articles were included based on specific criteria, namely relevance to first aid procedures for paediatric FBAO, methodological quality of the research, and recency of publication, with a focus on articles published from 2015. Finally, we included studies of adults for a more comprehensive analysis of the data, due to the limited quantity and quality of paediatric evidence. This process is represented in Figure 1 by a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

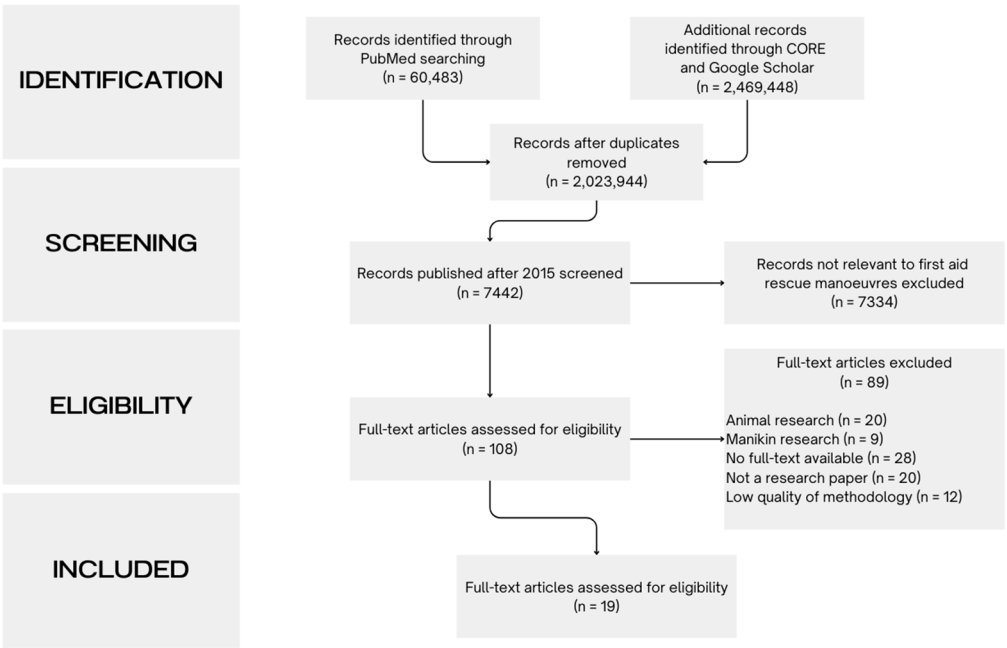

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

2.2. Analysis and Synthesis

One researcher reviewed all identified articles and guidelines to assess whether they met the inclusion criteria. After screening the abstracts, we conducted a full-text review to determine eligibility based on predefined factors such as relevance to the topic, study design, and quality of evidence. We extracted relevant data, including the effectiveness, safety, and application of various rescue manoeuvres, and compiled them into a narrative summary for each technique. We then compared the scientific evidence with guidelines and recommendations from different regions, highlighting the degree of alignment between

them. All researchers reviewed the findings together, discussing and identifying research gaps. We synthesised the literature to provide a comprehensive summary of rescue manoeuvres, noting any deficiencies, contradictions, or areas requiring further investigation.

3. Results and Discussion

3.1. Back Blows

Back blows are forceful slaps with the heel of the hand between the choking person's shoulder blades while leaning them over at the waist to face the ground, as presented in Figure 2. Back blows are widely believed to create a strong air vibration and increase the intrathoracic pressure in the airway, which helps to dislodge the obstruction [35]. Although this mechanism seems reasonable, it has not been clearly proven by any identified study.

Figure 2. The standard back blows method presented on a 16-month-old boy by his mother (the pacifier was used solely to soothe the child for the accurate demonstration of the rescue manoeuvre).

Back blows are recommended by the ERC, the ANZCOR, the IFRC, the Mayo Foundation for Medical Education and Research (MFMER), the Resuscitation Council UK (RCUK), the Japan Resuscitation Council (JRC) and the Korean Association of Cardiopulmonary Resuscitation (KACPR) as the initial, favoured manoeuvre [3,20,21,35–37]. These organisations, apart from the last two, recommend the "five by five" approach, alternating five back blows with the second manoeuvre, either five chest thrusts or five abdominal thrusts. Unique differences are only presented by the RCA, who do not specify the number of back blows' repetitions, and the Resuscitation Council of Southern Africa (RCSA), which recommends back blows as a secondary manoeuvre [21,22].

3.1.1. Effectiveness

Back blows' effectiveness has been found to vary across different studies and may not always be adequate to relieve FBAO in paediatric patients [34].

Dunne et al.'s study of 268 paediatric patients identified that back blows were associated with an improved likelihood of FBAO resolution and survival to hospital discharge, compared to abdominal thrusts and chest thrusts (adjusted odds ratio for FBAO relief of 0.39 and 0.92, respectively, compared to back blows). Furthermore, the researchers found that back blows did not result in any intervention-related injuries, unlike abdominal thrusts and chest thrusts [38].

In Norii et al.'s study, the success rate of back blows was estimated at 10.4%, which was half as effective as other interventions, i.e., suction and abdominal thrusts. In contrast, they also observed that patients with a favourable outcome were more likely to receive back blows as the initial intervention (23.2% vs. 11.0%). This indicates a relatively low success rate if they do not immediately relieve the object as the initial manoeuvre. However, their study included only two children: one under 10 years old and one aged between 10 and 19, within a total of 300 patients. It also only included individuals who presented to the emergency department; therefore, they were more likely to have a more complicated FBAO, and did not capture those who were treated on scene and discharged without transport. Most identified participants in this study were elderly individuals with pre-existing swallowing difficulties who needed a diet of semi-solid food and thickened fluids. The findings indicated that healthcare providers may have considered suction to be a more effective option than other manoeuvres. Therefore, the findings are not representative of the overall effectiveness of back blows in treating paediatric FBAO [39].

Igarashi et al. also conducted a FBAO study that demonstrated a higher success rate compared to Norii et al.'s study (27% vs. 10.4%, respectively). Again, however, patients had a median age of 80 years and there were no children included in this study. Patients who received back blows as the first intervention had significantly better neurological outcomes after the incident than those who received other manoeuvres. No statistical significance was observed for other actions. This study's sample size was very small. For back blows, there were only 22 identified individuals with 16 achieving a favourable neurological outcome compared to 6 with a poor neurological outcome [4].

Another study by Dunne et al. involving 124 patients who had airway clearance devices used as an FBAO manoeuvre demonstrated that back blows are widely utilised and commonly employed. This study included 55 paediatric cases. The study was not designed to assess the effectiveness of back blows; however, it is important to note that minimal adverse events were reported due to them [40].

Montana et al. described a case involving a 3-year-old girl who suffered from FBAO while consuming mozzarella cheese at school. Despite attempts by teachers to administer first aid with repeated back blows, and even the intervention of an experienced anaesthesiologist trying endotracheal intubation using a laryngoscope multiple times, they were unable to dislodge the obstruction. Postmortem examination revealed blockage at the aditus ad laringem (laryngeal inlet) [41]. It is likely that no bystander FBAO manoeuvre would have removed this obstruction.

3.1.2. Safety

The harm associated with back blows is considered minimal compared to other FBAO interventions [34]. The concerns about the lack of safety in administering back blows are based on case studies, but research articles investigating the effectiveness of back blows on larger populations demonstrate no adverse effects [4,37–39].

Ekim-Altun arrived at similar findings in their research as Dunne et al. [38]. Their investigation revealed that 31% of mothers administered back blows to children experiencing FBAO. Other actions taken included non-recommended interventions such as forcing the child to vomit and blind finger sweeping of the mouth. These results demonstrate that even untrained parents are familiar with the technique of back blows. Although they studied a group of 163 patients, mostly infants, they did not report any adverse effects, challenging claims about the potential risks associated with back blows [42].

Dr Heimlich's assertion that changed the world's attitude towards back blows stated that "back blows are ineffective for choking and can drive an object deeper into the airway" [17]. This has not been substantiated since the 1980s, when back blows were applied with other manoeuvres such as mouth-to-mouth ventilation and blind finger sweeping of the mouth. These other manoeuvres are far more likely to be responsible for this complication [3]. The study proving Dr Heimlich's thesis and comparing abdominal thrusts and back blows was conducted by Day–Crelin–DuBois in 1982 [43]. The researchers credited support

from "The Dysphagia Foundation Inc.", which later became "The Heimlich Institute", in their acknowledgments at the end of the paper [44]. This connection between Dr Henry J. Heimlich and the Yale scientists raises concerns about a possible conflict of interest. It appears appropriate to reformulate Dr Heimlich's thesis. The current data collectively suggest that, while any intervention carries some degree of risk, back blows remain one of the safer and more effective techniques for managing FBAO, particularly in paediatric cases [34,37–39,42].

The only recent study describing complications after administration of back blows, referenced by ILCOR, is the Guinane–Lee study. The research details a vascular injury in an older individual with risk factors for vascular diseases following FBAO first aid management involving chest thrusts and back blows, and they were unable to know which manoeuvre resulted in the injury. Further, the relevance of this case study to back blows, particularly in paediatrics, is limited [45].

3.2. Chest Thrusts

Chest thrusts squeeze the air out of the lungs by increasing intrathoracic pressure, performed by embracing the choking victim from behind and using a closed fist to press on the lower half of the sternum above the xiphoid process, as presented in Figure 3. A slight bend over the victim's waist toward the ground should be applied.

Figure 3. The standard chest thrusts method presented on a 16-month-old boy by his mother (the pacifier was used solely to soothe the child for the accurate demonstration of the rescue manoeuvre).

Most guidelines recommend using chest thrusts when abdominal thrusts are not feasible for the victim due to pregnancy or the individual's size [3,19,21]. Experts also recommend chest thrusts as a second manoeuvre to alternate with for infants. However, ANZCOR and the Australian and New Zealand divisions of SJA advocate an innovative approach and propose using chest thrusts as a secondary manoeuvre in older children, and JRC even allows the use of chest thrusts as an initial manoeuvre [20,21,46–49]. They claim it is safer with a lower potential of life-threatening complications compared to abdominal thrusts.

It is important to highlight some modifications that have been documented, or even recommended, which deviate from the standard chest thrust technique. ANZCOR guide-

lines recommend administering chest thrusts from the front, with the victim's back against a firm surface like a wall or a floor [20]. Additionally, the Australian and New Zealand divisions of SJA propose supporting one hand in the middle of the victim's back, between their scapulas, while placing the heel of the other hand on their lower sternum [46–48]. The reasoning behind this recommendation and which technique is superior remains unclear.

It continues to be an observable pattern, even within academic collective research, of incorrectly confusing chest thrusts with chest compressions and failing to specify the precise technique administered to the individual [4,5,38,40]. Chest compressions may have the potential to generate potentially greater force, as gravity assists the rescuer and the floor serves as a stable brace. Conversely, standard chest thrusts, performed while standing, may generate less force, as the rescuer's own body acts as the brace and gravity does not play a significant role. Not specifying which technique form was used when reporting on FBAO interventions can potentially lead to false conclusions about the effectiveness and safety of lifesaving manoeuvres.

3.2.1. Effectiveness

In 2010, ANZCOR determined that higher airway pressures could be generated by using chest thrusts rather than abdominal thrusts or back blows [20,44,45]. While the exact airway pressure values created by chest thrusts are currently unknown, standard chest compressions, used in CPR, can achieve pressure values of 40.8 $\pm$ 16.4 cmH_2O, which may provide an adequate or similar level of pressure for chest thrusts [50]. However, chest thrusts continue to be the least researched manoeuvre, advised by the fewest first aid experts.

Shim–Park documented a case involving a 12-month-old infant who required three sets of 5 chest thrusts and 5 back blows after swallowing a foreign object. These efforts proved ineffective and the patient deteriorated into respiratory failure and cardiac arrest. The foreign body was eventually pushed into a distal bronchus with an endotracheal tube and removed later with bronchoscopy after the return of spontaneous circulation. This case, however, describes a complex and challenging scenario of a foreign body located deep in the trachea [51].

Norii et al. conducted a study which documented 59 instances of chest thrusts being administered to adult patients with FBAO. However, no cases were found where the use of chest thrusts led to successful removal of the foreign object from the airway. The research specifically focused on elderly patients and its sample size of only two children may limit the generalizability of its findings on the effectiveness of chest thrusts in treating paediatric FBAO [39].

3.2.2. Safety

Chest thrusts have fewer case reports published where a traumatic injury occurs compared to abdominal thrusts. This may imply that chest thrusts could be a safer and potentially more effective intervention for the first aid management of paediatric FBAO, though the relative safety and efficacy of these techniques remains uncertain.

However, Dunne et al. reported that chest thrusts, also referred to as chest compressions in the study, showed the highest proportion of injuries. The study population encompassed both conscious and unconscious individuals, potentially diluting the results and complications of chest thrusts as an intervention [38].

It is worth mentioning the Guinane–Lee research again, which documented a single case of acute thoracic aortic dissection in an 85-year-old man with underlying conditions such as atherosclerosis, hypertension, hypercholesterolemia, and a history of significant smoking. The administration of other interventions to the patient and his vascular risk factor profile raises doubts about whether chest thrusts, back blows or choking itself is responsible [45].

3.3. Abdominal Thrusts

Abdominal thrusts, previously referred to as the Heimlich manoeuvre, are arguably the most frequently recommended manoeuvre in modern protocols for managing FBAO [3,19,21]. In this technique, a rescuer applies pressure to the bottom of the diaphragm from behind an individual bending forward to compress the lungs and dislodge an obstructing object from the airway by increasing intrathoracic pressure, as presented in Figure 4.

Figure 4. The standard abdominal thrusts method presented on a 16-month-old boy by his mother (the pacifier was used solely to soothe the child for accurate demonstration of the rescue manoeuvre).

The ERC, IFRC, MFMER, SJA, and RCUK suggest using this method as a secondary technique in combination with back blows [3,23,35–37,52–55]. The KACPR has a similar view but agrees on administering abdominal thrusts only to children older than 8 years old. The AHA, RCSA and most RCA members advise using it as an initial or sole approach [19,21]. It is widely agreed that this method should not be used on infants due to their fragility [34]. However, an increasing number of institutions now also advise against using abdominal thrusts in children over 1 year old for similar reasons. Consequently, ANZCOR, JRC, and the Australian and New Zealand divisions of SJA have opted to substitute chest thrusts for abdominal thrusts in children [20,21,46–49]. Abdominal thrusts are perhaps the most contentious manoeuvre of the three, with the most thorough examination and numerous modifications, with the most famous called the Heimlich manoeuvre.

It is essential to recognise that abdominal thrusts may not solely involve the Heimlich manoeuvre. Despite these terms being frequently interchangeable in scientific literature, the classical Heimlich manoeuvre involves placing the fist just below the ribcage and approximately two inches above the victim's navel with inward and upward thrusts [15,18]. However, this approach could be distressing for children. We found only one source that discusses the disparity between the two techniques [5]. There is a lack of studies demonstrating alternative techniques involving lower hand placement, flat hands, or interlocked fingers. Furthermore, several alternative methods have been reported to deviate or evolve from the standard abdominal thrust technique, including self-administering the manoeuvre manually and with the use of a chair, or performing the procedure while facing the victim [54].

3.3.1. Effectiveness

Langhelle et al. demonstrated in their study with adult cadavers that abdominal thrusts can produce an average peak airway pressure of approximately 26.4 ± 19.8 cm H_2O [50].

Norii et al. conducted a study involving a large group of patients with in-hospital FBAO. Abdominal thrusts were administered to 24 individuals, successfully removing the foreign body in 5 cases, resulting in a 20.8% success rate. It is crucial to emphasise that this was an assessment of abdominal thrusts as the initial response and primarily involved older patients with pre-existing swallowing issues who required semi-solid foods and thickened fluids [39].

3.3.2. Safety

Researchers found that the average peak stomach pressure during abdominal thrusts can reach 57 ± 17 cmH_2O, with potentially higher values in children [13]. This explains the effectiveness of the Heimlich manoeuvre and its potential to cause direct injury to abdominal organs or tissues, with gastric perforation being the primary concern [55,56].

Ebrahimi and Mirhaghi's review suggests that an adult can exert excessive force with an abdominal thrust, which may cause fatal internal injury in children. They documented 48 cases of severe complications following the Heimlich manoeuvre, a notable portion involved patients under 18 years old. Surgery successful treated the injury in 25% of cases with organ damage, while the remaining cases resulted in fatalities. The authors assert that life-threatening injuries related to the Heimlich manoeuvre indicate a need for a safer alternative procedure [57].

Koss et al. presented a case of cervical oesophageal perforation in a 16-year-old boy resulting from the Heimlich manoeuvre. The patient experienced symptoms and was eventually treated via a successful but difficult surgical repair. However, this injury is linked to a high mortality rate and requires coordinated, prompt care from multiple disciplines [58].

Wang et al. reported a story of a 52-year-old man who suffered from choking and loss of consciousness. After receiving abdominal thrusts from an inexperienced first aid provider, the obstruction was cleared, but he later experienced upper abdominal discomfort. An examination revealed gastrointestinal haemorrhage and severe damage to the anterior wall of the right ventricle, which proved fatal. The authors reviewed the literature on abdominal thrust complications and found 11 cases of gastric ruptures, 10 cases of aortic injuries, and 2 cases of pancreatic injuries, noting that these injuries also occur in younger individuals [55].

Basile et al. documented a situation where oesophageal rupture occurred resulting from the Heimlich manoeuvre. They indicated that abdominal thrusts could lead to traumatic injury of the gastrointestinal tract, pneumomediastinum, rib fracture, diaphragm rupture, acute thrombosis of an abdominal aortic aneurysm, and mesenteric laceration. Abdominal injuries were the most frequently observed complications, particularly oesophageal and gastric wall rupture. Moreover, they emphasised that abdominal thrusts are difficult to apply correctly and untrained individuals performing this manoeuvre may increase the likelihood of serious complications [59].

Pawlukiewicz et al. discussed a case involving a 56-year-old female patient admitted to the hospital with abrupt pain in her right foot following an episode of FBAO that was resolved using the Heimlich manoeuvre. An examination revealed distal arterial occlusion caused by cholesterol embolization syndrome, highlighting a previously unrecognised complication of this manoeuvre that can lead to substantial morbidity [60].

Herman et al. documented a case of an 85-year-old woman who experienced choking due to food ingestion. Medical personnel performed the Heimlich manoeuvre, successfully removing the obstruction but causing complications, including stomach herniation into the right lower chest. The patient required emergency surgery for hernia repair and subse-

quently faced challenges during her hospital stay, including peritonitis, fascial dehiscence, and necrotizing fasciitis, before being discharged home [61].

A comparable scenario was described by Truong et al. involving a patient with a substantial incarcerated hiatal hernia, necessitating surgical intervention for reduction and gastropexy. Despite initial improvement, the patient subsequently developed septic shock and severe malnutrition, resulting in an extended hospitalisation involving multiple surgeries and intubations. Similar cases exhibited unfavourable results, including mortality or additional surgeries to address various complications. Additionally, they referenced a case series detailing adverse outcomes associated with Heimlich manoeuvre complications: 13 out of 41 patients affected experienced fatalities, while another 17 required surgeries to repair different organs [62].

Lee et al. presented a case of a 67-year-old man without widespread medical conditions, who arrived at the emergency department with paralysis on his left side shortly after an emergency medical technician performed the Heimlich manoeuvre to clear a blocked airway caused by a piece of meat. The chest CT scan showed that he had a Stanford type A aortic dissection and an obstruction in the right innominate artery. An urgent surgical procedure was performed to repair the aorta using grafting, and he was discharged from the hospital without complications [63].

Tashtoush et al. reported a case involving an 84-year-old man who was taken to the emergency department after choking at a restaurant, followed by unsuccessful Heimlich manoeuvre attempts. Although a large piece of steak causing airway obstruction was successfully removed, the patient remained hypotensive and needed ongoing hemodynamic support. Subsequent laboratory tests conducted within 24 h of aspiration revealed a significant decrease in haemoglobin levels. A computed tomography scan of the abdomen and pelvis indicated a lacerated liver with a substantial subcapsular haematoma draining into the pelvis [64].

Bouayed et al. reported a case of a 45-year-old mentally disabled woman who experienced acute respiratory distress from choking on a large piece of chicken. After the Heimlich manoeuvre, she developed subcutaneous emphysema. CT scans showed a 3 cm bone fragment in the oesophagus and widespread emphysema. Endoscopy removed the bone, revealing a 3 mm tear. Despite initial treatment with antibiotics and a nasogastric tube, she developed fever and respiratory distress, leading to the emergency drainage of an abscess. Subsequent care included antibiotics and drainage, resulting in full recovery. The causation, however, remains unclear, as the incident was likely attributable to choking rather than the Heimlich manoeuvre, or at the very least, the specific cause remains uncertain [65].

3.4. Other Techniques

Although this review focuses on rescue manoeuvres used to relieve obstruction, it is important to acknowledge some alternative techniques that may be utilised in FBAO first aid cases or are not widely recognised by resuscitation councils.

Cough encouragement remains widely recommended in various guidelines and continues to be an important technique in first aid for conscious, choking children with an effective cough, which suggests a partial obstruction [3,19–23]. Despite its long-standing recognition, it has not been subjected to extensive recent research, which limits the availability of current data on its effectiveness and safety in paediatric patients. The belief is that coughing can manage the choking individual most effectively and safely because it does not require the application of an external force which risk secondary injuries as other FBAO interventions. However, there are several research gaps associated with its efficacy. In children, the lower respiratory strength due to their smaller thoracic musculature may be insufficient to generate the airway pressures needed to effectively clear the obstruction. Relying on cough encouragement in critical situations could delay more effective and relatively safe rescue manoeuvres, such as back blows, which could also be combined with the choking individual's own coughing efforts. Furthermore, it may be challenging for a

layperson to accurately assess the efficacy of the cough. Encouraging coughing may also create a false sense of security, further delaying necessary medical intervention. Additionally, young children may not comprehend instructions or may become uncooperative due to the distressing nature of the situation, making cough encouragement impractical. There is also a lack of evidence regarding the proper body position for the choking individual during coughing. Positioning the individual in a forward-leaning or knee-chest position may reduce the risk of inadvertently pushing the foreign object deeper, which could block the airway completely, and may improve the effectiveness of the procedure by utilising gravity to assist in clearing the obstruction. These considerations warrant further scientific investigation.

Blind finger sweep of the oropharynx is generally advised against by organisations such as the ERC, with some guidelines omitting the technique entirely from their recommendations [3,19–23]. It is rarely the focus of contemporary reports and lacks recent updates regarding its safety and effectiveness. Concerns include potentially fatal pharyngeal trauma, traumatic epiglottitis, or pushing the object further into the airway as well as its ineffectiveness in cases of obstruction localised in the trachea or larynx, as noted in studies conducted a decade or more ago [66–69]. A 2016 case study by Mori and Inoue describes a 1-year-old boy who began choking and coughing after swallowing a coin. The mother tried to remove it by performing a blind finger sweep but was unable to retrieve it. The child was taken to the hospital, where he showed mild gagging but no respiratory issues. X-rays revealed a nasopharyngeal foreign body, which was successfully removed under sedation by an otolaryngologist. The child was discharged without complications [70]. Similarly, Vunda and Vandertuin reported a case in which a 9-month-old girl developed respiratory distress after playing with a cufflink. Her mother attempted a blind finger sweep but failed to retrieve the object. At the emergency department, the child showed no respiratory distress, and an X-ray did not reveal the cufflink. However, additional imaging identified the cufflink lodged in the nasopharynx, and it was subsequently removed under general anaesthesia [71]. These two cases demonstrate instances where a rushed and unrecommended technique may have inadvertently pushed the foreign body from the oropharynx to the nasopharynx. It is important to emphasise that this may have led to a temporary restoration of respiratory function, but the outcome remained suboptimal. Given this weak scientific evidence, blind finger sweep might still have a potential to be appropriate in specific scenarios (e.g., as a method of last resort); further research could clarify its role in first aid for FBAO, particularly in paediatric cases.

Airway clearance devices, also referred to as anti-choking suction devices, provide a clear example of how the topic of FBAO should be actively investigated. They act as non-powered, negative pressure device that attempts to relieve a FBAO from above, instead of creating a force distal to the obstruction as in traditional FBAO manoeuvres. Due to their novelty, these devices have become a frequent subject of research, with studies focusing on their effectiveness, safety, and potential application [40,72–80]. The initial systematic review on the topic in 2020 found the available data on these devices were limited, and provided insufficient evidence to either support or discourage their use [76]. Since then, a number of subsequent studies have been published. Dunne et al. conducted two studies assessing the effectiveness and safety of the two widely recognised devices, LifeVac© (LifeVac LLC, Nesconset, New York, NY, USA) and Dechoker© (Dechoker LLC, Wheat Ridge, CO, USA). Data were collected from 371 patients, with a significant 58% of the studied population being children. In 361 cases, the airway clearance device was the final intervention before the successful resolution of FBAO symptoms. Its use was associated with only a few, generally mild, adverse events [40,72]. While the findings were promising, they should be interpreted cautiously due to study limitations, including self-reporting biases within the sample population and reliance on non-medical personnel for FBAO diagnosis. The study by Bhanderi and Hill found consistent results, with the Dechoker© reported to have successfully removed the obstruction in 26 out of 27 adult cases with few complications or adverse events reported [73]. Additionally, research by Cardalda-Serantes et al. and

Carballo-Fazanes et al. indicates that untrained health science students and paediatric residents were able to effectively learn and utilise airway clearance devices more effectively than the current FBAO algorithms [74,75]. To date, research largely relies on self-reported data and studies involving non-medical personnel. While this may raise concerns about the reliability and generalizability of these findings, these data are valuable given that FBAO incidents often occur in situations where only first aid measures are applied without professional intervention. An increasing number of sources suggest that airway clearance devices may have potential and could be considered in choking emergencies when standard protocols prove inadequate.

3.5. Take-Home Message

This review represents the most comprehensive evaluation of recent literature conducted to date. Table 3 was created to enhance the visualisation of reviewed scientific articles. It should be noted that the oldest article examined dates back to 2015, indicating that the reported data are current and up to date.

Table 3. Recent studies investigating the safety and efficacy of back blows, chest thrusts, and abdominal thrusts.

Author	Year	Type of Research	Reported Paediatric Case(s)	Rescue Manoeuvre(s) Studied
Shim-Park [51]	2024	case study	X	back blows and chest thrusts
Dunne et al. [38]	2024	observational cohort study	X	all three
Norii et al. [39]	2023	systematic review	X	all three
Ekim-Altun [42]	2023	retrospective review	X	back blows
Basile et al. [59]	2023	case study and literature review		abdominal thrusts
Igarashi et al. [4]	2022	multicentre retrospective observational study		all three
Dunne et al. [40]	2022	retrospective study	X	all three
Wang et al. [55]	2022	case study and literature review		abdominal thrusts
Pawlukiewicz et al. [60]	2021	case study		abdominal thrusts
Couper et al. [34]	2020	systematic review	X	all three
Montana et al. [41]	2020	case study and literature review	X	back blows and abdominal thrusts
Gutierrez-Strickland [56]	2020	case study		abdominal thrusts
Ebrahimi et al. [57]	2019	systematic review	X	abdominal thrusts
Lee et al. [63]	2019	case study		abdominal thrusts
Guinane-Lee [45]	2018	case study		back blows and chest thrusts
Koss et al. [58]	2018	case study	X	abdominal thrusts
Herman et al. [61]	2018	case study		abdominal thrusts
Truong et al. [62]	2017	case study		abdominal thrusts
Bouayed [65]	2015	case study		abdominal thrusts

As shown in the table above, despite rescue manoeuvres for severe FBAO in paediatric patients being widely recommended in various guidelines for decades as the best and only first aid treatment, there is a notable lack of valuable data and research on their effectiveness and safety. Only nine studies have reported paediatric cases, often involving small, non-representative samples.

4. Conclusions

Knowledge gathered from relevant research, analysis, and case studies on paediatric FBAO is scarce and insufficient, which explains why significantly differing guidelines are being created worldwide. Supplementing the data with adult FBAO cases, which are also limited, may lead to a subjective belief that back blows should be used as an initial manoeuvre due to their safety, followed by chest thrusts for generating high airway pressure with low reported complications. Abdominal thrusts were found to have the highest number of studies reporting the potential for trauma and may result in lower average peak airway pressure. However, this is likely due to the long-standing belief in the effectiveness of these rescue manoeuvres, which is often taken for granted, along with the recent focus on safety in research. This trend is especially apparent in abdominal thrusts. Future recommendations should focus on evaluating the optimal balance between safety and effectiveness.

5. Future Directions

We conclude that providing specific recommendations would be futile or even harmful without acquiring the necessary, currently non-existent, scientific evidence. FBAO is a common and significant concern, with over 75% of choking occurrence rate in children younger than 3 years [2,81]. Epidemiological data on children under 16 years old reveal thousands of documented fatalities every year, positioning FBAO as a leading cause of unintentional death [2]. It is widely recognised as one of the primary causes of death among paediatric populations and leads to an estimated annual 300 to 600 fatal incidents in developed countries each, with double the proportion occurring in undeveloped countries [81–83]. Despite increased awareness, the frequency of FBAO among children has consistently risen over an extended period [84].

It is shocking that so many children die each year due to choking, yet there is a worldwide shortage of data reports and research focusing on emergency interventions in FBAO, particularly in this specific demographic group, which demands special attention. This state of affairs is unacceptable. We propose a solution for data collection and flow, which is an original project for collecting high-quality data that can inform future recommendations and depicted in Figure 5.

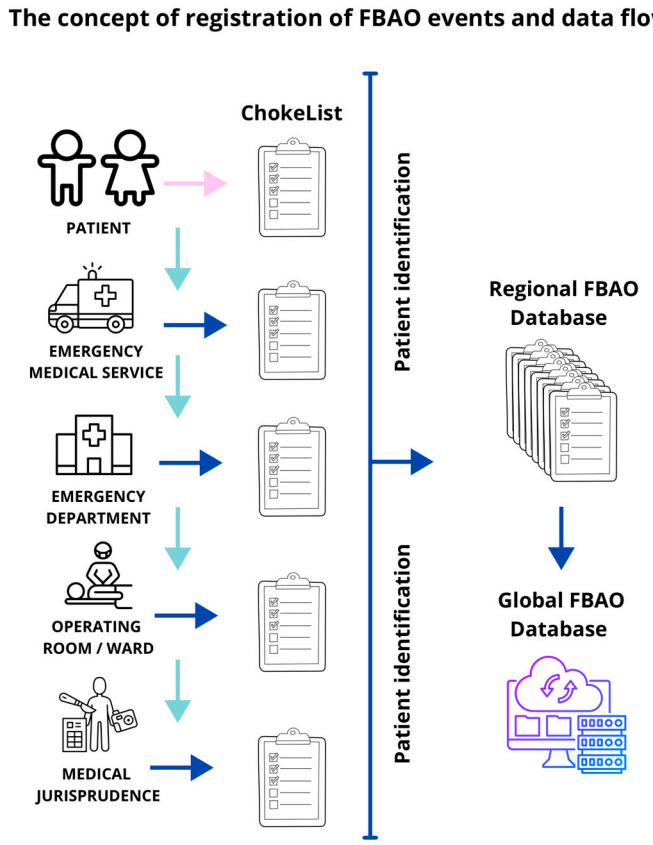

Figure 5. The original concept for data collection and flow for foreign body airway obstruction cases in children.

The FBAO Database functions by reporting cases documented by the healthcare provider, responsible for patients who experienced choking. Cases can be reported to the global or even local FBAO Database, whether in an ambulance or emergency department. Any patient with severe airway obstruction or who has received external force manoeuvres such as back blows, chest thrusts, and abdominal thrusts should be included. If the patient undergoes surgery as part of their treatment, or in a worst-case scenario, if choking results in fatality, it will be the operating doctor's or any care team member's responsibility to document and report the case.

The document responsible for reporting these cases to the FBAO Database is called a Chokelist. Our suggested Chokelist is presented in Figure 6 and comprises sections that are intended to present data and support EBM, based on the case studies examined in the review. The first part outlines the patient's details, such as age, sex, and medical history. The next section discusses the specific incident, symptoms, extent of obstruction, type of foreign object causing the blockage (e.g., food or toy), and first aid provided by bystanders. The third part focuses on the patient's medical care and their outcome, encompassing invasive rescue manoeuvres to alleviate ongoing obstruction and alternative treatments like surgical interventions and anaesthesia procedures. Finally, it concludes with an account of subsequent developments in the patient's condition and their final outcome.

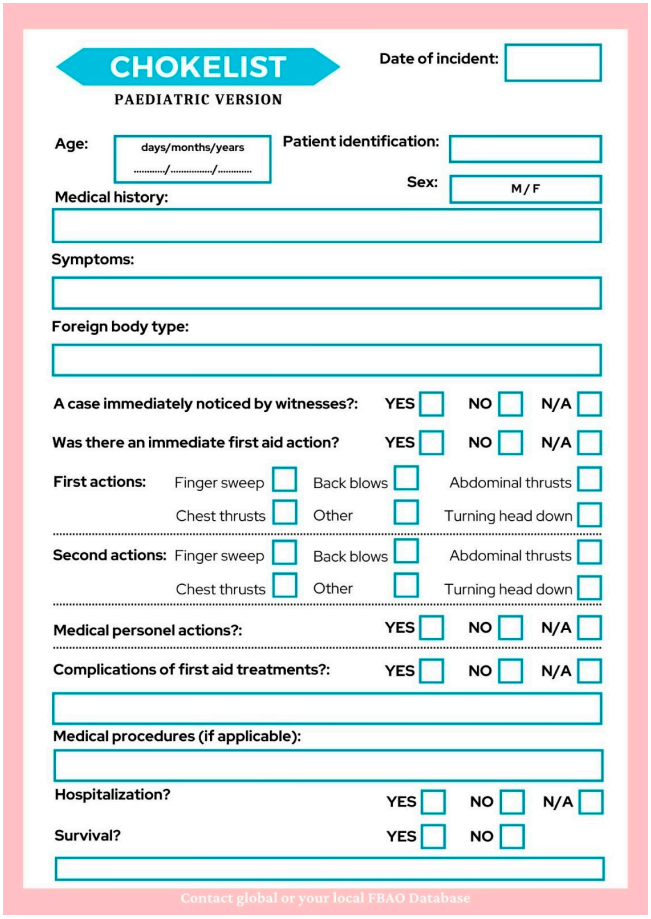

Figure 6. Paediatric Chokelist—original document responsible for reporting foreign body airway obstruction cases.

Our hope is that a standardised reporting tool will significantly increase available data and improve the understanding of paediatric FBAO, leading to the development of high-quality, evidence-based, dependable guidelines comprising effective and safe rescue manoeuvres.

Limitations

This study has limitations, including a small sample size due to the limited availability of material in the literature. The data were supplemented by adult research, which may not accurately reflect the specific challenges and nuances of paediatric foreign body airway obstruction. The collected data vary in quality and diverse characteristics, making it potentially non-generalizable to all healthcare settings. Most of the data comes from case studies and literature reviews, which also have limitations such as prejudice toward the discussed issue and a lack of generalizability. Additionally, being a narrative review, this

study is subject to some disadvantages, like potential bias from the authors of retrieved studies and article reviewers. In order to address the existing gaps in the data, which contribute to discordant recommendations, future research should periodically incorporate systematic reviews and meta-analyses, while also increasing the number of data-gathering studies. This effort would benefit from the structured use of our Chokelist and data collection flow concept to enhance consistency and comprehensiveness in reporting.

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Assessment of the LifeVac, an anti-choking device, on a human cadaver with complete airway obstruction

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Assessment of the LifeVac, an Anti-Choking Device, on a Human Cadaver with Complete Airway Obstruction

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We performed an independent study determine whether the anti-choking device LifeVac is capable of removing a food bolus from an obstructed airway when the potential for choking as a medical emergency exists.

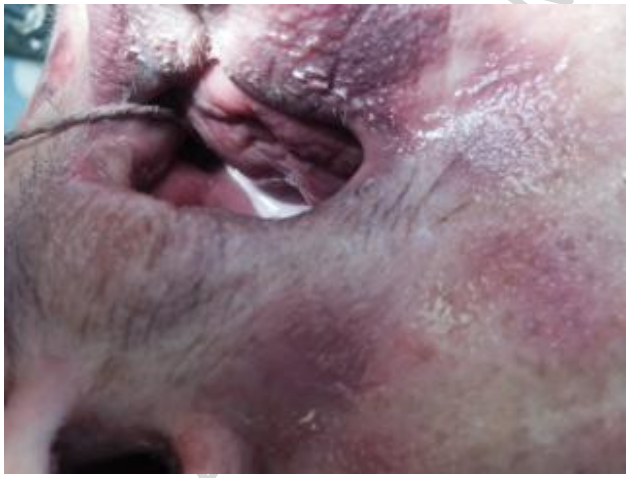
The LifeVac is a non-powered, single patient, portable suction apparatus (anti-choking device) developed for resuscitating choking victims when standard current choking protocol has been followed without success. The LifeVac is designed with a patented valve to prevent air from exiting through the mask. This patented valve is designed to prevent the strong pulse of air from pushing food or objects further downward, lodging the blockage deeper into the airway of the victim. A one-way suction stream is thus created to remove the lodged food or object. The negative pressure generated by the force of the suction is 3 times greater than the highest recorded choke pressure. The mean peak airway pressure with abdominal thrusts is 26.4 ± 19.8 cmH20 and with chest compressions, 40.8 ± 16.4 cmH20, respectively (P =0.005, 95% confidence interval for the mean difference 5.3-23.4 cmH20.) The LifeVac generates over 300 millimeters of mercury (mm Hg) of suction.

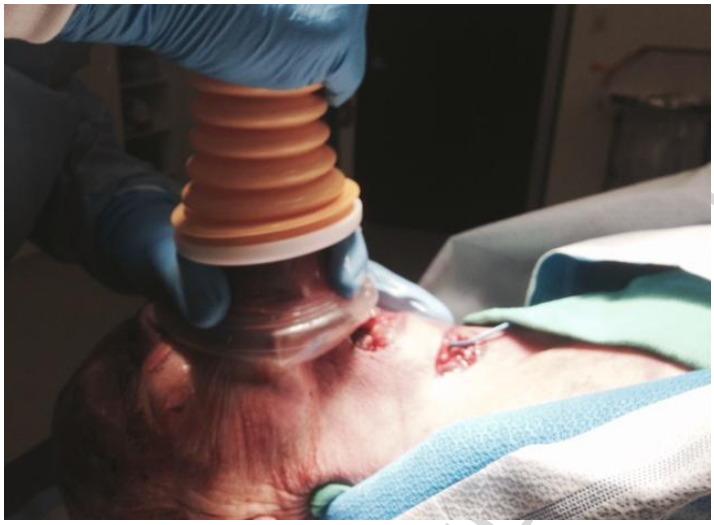
Each year, approximately 3,000–4,000 Americans die from choking. Children and the elderly present much higher risks for choking. At least one child dies from choking on food every five days in the U.S., and more than 10,000 children are taken to hospital emergency rooms each year for food-choking incidents. Semisolid foods are the major cause of a large number of asphyxiations, especially among the elderly.

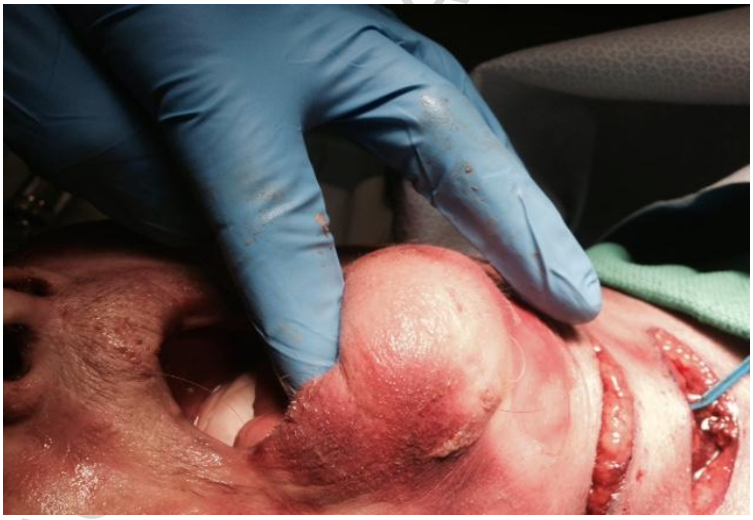
This study was conducted at Fusion Solutions, a cadaver based training center in New York. An unselected, recently diseased individual was employed in the study. The subject was a 71 year old, Caucasian female, 153 pounds, 65 inches with a Body Mass Index of 25. Medical history was remarkable for breast cancer.

The paramedic technician placed a simulated food bolus 7 to 10 centimeters into the subject's upper airway. The obstruction was visually and verbally confirmed prior to use of the LifeVac apparatus. Three simulated boli obstructions made of clay were used: a 2 cm (small), a 2 1/2 cm (medium) and a 3 cm (large) size. The simulated boli were attached to a string to maintain control during the study.

The paramedic technician placed an adult LifeVac mask on the cadaver following operating guidelines to remove the lodged bolus. The author observed and recorded the success rate. It was noted on one trial that 2 pulls were required with a tighter seal ensured following an initial failed trial. This achieved increased suction and ensured removal of the simulated bolus. The LifeVac removed the bolus successfully 49/50 trials on the first trial.







The American Red Cross' recent first-aid protocol de-emphasizes the use of the Heimlich for treating a conscious choking victim. The new protocol recommends calling 9-1-1, then giving the person several sharp blows to the back, right between the shoulder blades, with the heel of the hand. If this doesn't clear the obstructed airway, "abdominal thrusts" should be tried next, alternating with repeated back blows, until the person breathes freely or loses consciousness.

According to Langhelle et al, standard chest compressions are more effective than the Heimlich maneuver for treating complete airway obstruction by a foreign body.
The Heimlich maneuver on a frail individual who is in a wheelchair can be difficult to administer expediently. Complications include rib fractures, gastric or esophagus perforations, aortic valve cusp rupture, diaphragmatic herniation, jejunum perforation, hepatic rupture, mesenteric laceration. There has also been a new case of fatal hemoperitoneum due to hilar laceration of the spleen.

When treating a choking child, John Hopkins School of Medicine warns, " When applying the Heimlich maneuver, be careful not to use too much force so you don't damage the ribs or internal organs."

Choking is a medical emergency that warrants prompt, precise action by anyone available. This results of this study revealed that the LifeVac was able to clear a completely obstructed upper airway. Given the potentially life-or-death nature of given situations, the LifeVac is deemed to be a clinically effective alternative to current emergency protocol to save choking victims. Hence, the LifeVac can be utilized as a safe, simple and effective method to use in critical situations.

Speech Pathologists treat swallowing disorders. Dysphagia treatment consists of teaching compensatory strategies, aspiration precautions, appropriate diet and caregiver training to prevent risks for aspiration. The LifeVac is non invasive and can be used on anyone, both medical personnel and laypersons alike. Results of this study suggest that the LifeVac can be included as part of the guidelines used for basic life support management of choking victims.

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Successful Use of a Novel Device Called the Lifevac ton Resuscitate Choking Victims World-wide Results

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Abstract

Choking remains the fourth leading cause of accidental death worldwide. Despite major medical advances in other areas, there currently are no devices that exist to assist in the resuscitation of a choking victim when the standard abdominal thrusts and backblows fail. The Lifevac is a portable, non-powered suction device that was created for the resuscitation of a choking victim when standard protocol fails. It is noninvasive and simple to use, thus making it attractive for use

in choking emergencies. This article describes results of worldwide experience using the Lifevac in real life emergencies. Thus far the unit has been used successfully 100% of the time with limited to no side effects reported. The use of LifeVac has huge potential to save thousands of people from choking, including more susceptible populations such as children and the elderly. It can be used by EMS in the field, and the device could prove valuable in hospitals, nursing homes, day care centers, and other settings. Based on these encouraging results the Lifevac device should be considered as an option during a choking emergency when standard protocol fails.

Keywords

Choking, Resuscitation, Anti choking device, Lifevac

Introduction

Choking is a leading cause of accidental death throughout the world. According to the American Red Cross more than 3,000 people die each year in the United States alone as a result of choking [1], and according to Injury Facts 2016, choking is the fourth leading cause of unintentional death [1]. At highest risk of choking are the extremes of age: of the 4,864 people who died from choking in 2013, 2,751 were older than 75 [1]. In addition, choking is a leading cause of death among children, especially those under 4 years old [2]. Worldwide, a child dies every five days from choking on food. Choking is also a leading cause of brain injury in young children. When food or other small objects obstruct the airway, oxygen deprivation for just a few minutes may result in brain damage [3]. More than 17,000 children are treated in hospital emergency rooms for choking related injuries each year [4].

Unfortunately, despite these grim statistics, no advances have been made in the resuscitation of a choking victim since back blows were added to the American Red Cross ACLS protocol [5]. Recently however a new device called the Lifevac seems to show promise in assisting a choking victim when back blows or abdominal thrusts fail. To our knowledge, in the past no device had been shown to successfully resuscitate a choking victim. In a choking emergency, time is critical as it can take EMS more than six minutes to arrive on the scene. At this point brain damage is already occurring and after 8 to 10 min damage is irreversible [6]. Therefore a device that is inexpensive, easy to use and readily available would be advantageous in such an emergency. The Lifevac is a portable, nonpowered suction device that was developed for this reason. The device consists of a plunger with a one-way valve such that when the plunger is depressed air is forced out the sides and not into the victim and when the plunger is pulled back negative pressure is generated to suction out the obstructing object.

The Lifevac has been made available over the past several years worldwide. We herein report the successful use of Lifevac in ten cases that have been reported to date. Lifevac has previously been reported to be successful in removing a lodged object in both simulator [7] and cadaver [8] models. Lifevac is marketed in Europe with a class 1 CE mark, and the kit comes with contact information such that if the device is used feedback can be provided.

Case Report

Case No. 1-3: The incidents took place at an assisted living home in Wales. An 80 year-old female with dementia was eating lunch when suddenly she was noticed to be choking by the nursing home staff. Back slaps were attempted twice but with no result and the patient began losing consciousness. A nurse on duty then used the unit according to package directions and

with one application the food bolus was successfully removed from the patient's airway. The patient recovered without any adverse sequelae. One week later the same patient had a similar choking episode and once again the Lifevac was successfully used to resuscitate the patient.

In the same care home several months later, a 70 year-old male with Parkinson's was noted to be choking while eating. The Lifevac was used per instructions and the obstructing food was successfully suctioned to the mouth where the nurse could then finger sweep it out.

Case No. 4: Another case of a life saved using LifeVac occurred on September 7, 2015 in New Jersey. The patient, a female, was 31 years old and is wheelchair bound. The patient suffers from dysphagia, or difficulty swallowing, since a young age. She began to choke on her tuna sandwich while eating lunch. Her mother unsuccessfully patient supine, the Lifevac successfully removed the obstructing food.

Case No. 5: On April 23, 2017 in Idaho, Lifevac was used in a private home. The device was bought for children who have had choking episodes. On April 23, it was used on a guest to the home, a 60 year old female with no medical issues who choked on a piece of meat during dinner. Abdominal thrusts were attempted right away, but unsuccessfully. The patient was the placed supine on her back on the floor. The LifeVac was then applied and with one suction, the piece of meat was removed from the airway. No adverse effects were noted.

Case No. 6: On September 6, 2017 in Spain in a Parkinson center, there was yet another life saved using LifeVac. The patient was an 80-yearold male who choked on meat while eating. A nurse attended to the patient, giving 5 back blows followed by 5 abdominal compressions. When these were unsuccessful, she applied the LifeVac per operating instructions and with four applications the food was dislodged.

Case No. 7: On October 4, 2017, LifeVac was used in a New York assisted living facility. The patient was an elderly male in a wheelchair who choked while eating a sandwich. The attendants were unable to perform abdominal thrusts due to his wheelchair status and instead used the LifeVac right away, which cleared the full airway blockage and dislodged the food. Later, a medical exam was performed including x-rays, which showed no adverse effects.

Case No. 8: On October 31, 2017 in Greece, the patient was a 40-year-old female who choked on a piece of garlic. EMS was called and arrived two minutes later. The emergency personnel performed abdominal thrusts as well as back blows but they were unsuccessful. Four minutes later, an EMS rescuer used LifeVac and with 3 attempts, the garlic piece was removed. The patient's vital signs were all normal, and again no adverse events were reported. In addition the EMS team had a body camera and the entire resuscitation was captured on video.

Case No. 9: LifeVac was used on a 70 year old female with Huntingtons disease in a home care facility in the UK who choked on a sandwich during mealtime and become unconscious. The Lifevac was then used and required three pulls and the sandwich piece was successfully removed and was observed in the mask. The person operating the device was the 63 year old care manager. The patient briefly required CPR and was brought to the hospital where no adverse effects were reported and the patient was able to be returned to the home the next day.

Case No. 10: Lifevac was used successfully was in the United Kingdom where the patient was a 68-year-old male with Down's syndrome in a wheelchair who weighs 54 kg. The patient began choking on a piece of chocolate. A layperson saved the patient with 2 pumps of LifeVac and removed the obstruction successfully. Again no adverse events were reported.

Discussion

Choking emergencies constitute a common, potentially preventable cause of accidental death throughout the world. Despite medical advances, there are currently no devices that have been shown to successfully resuscitate a choking victim if abdominal thrusts and back blows fail. Lifevac has been previously reported to successfully remove an object from the airway in both a cadaver and a simulator model. Unfortunately it is extremely difficult to study this device in live humans and there is no animal model suitable for study. The Lifevac is a lightweight, portable, non-powered suction device **Figure 1** that is applied to the patient's face via a face mask, which comes with the unit in adult and pediatric sizes. A patent pending one-way valve on the plunger generates negative pressure. On downward thrust of the plunger, air is forced out the sides of the device and not into the victim (**Figure 2**). This avoids the possibility of pushing an obstructing object further into the airway. A negative pressure is then generated by pulling up on the plunger (**Figure 1**), thus removing the object. Since the device does not require placement of any part into the oropharynx there is no risk of pushing a lodged object further into the airway. Risks can include edema and bruising from the generated suction, but the benefit of saving a life clearly outweighs these small risks. It is interesting to note that the case reports were voluntary in their submission but represent populations at known risk for choking. There were no reports of the use of the device where it was unsuccessful. Based on the successful application of the LifeVac in real life situations described in this report, the Lifevac should be available for use in settings with high risk for choking such as nursing homes and day care centers, and possibly all public eating facilities. In addition it would be beneficial for EMS to carry for use in the field. Lifevac may be a viable option in a choking emergency when standard protocol fails.

Figure 1: The LifeVac Device.

Figure 1: The LifeVac Device.

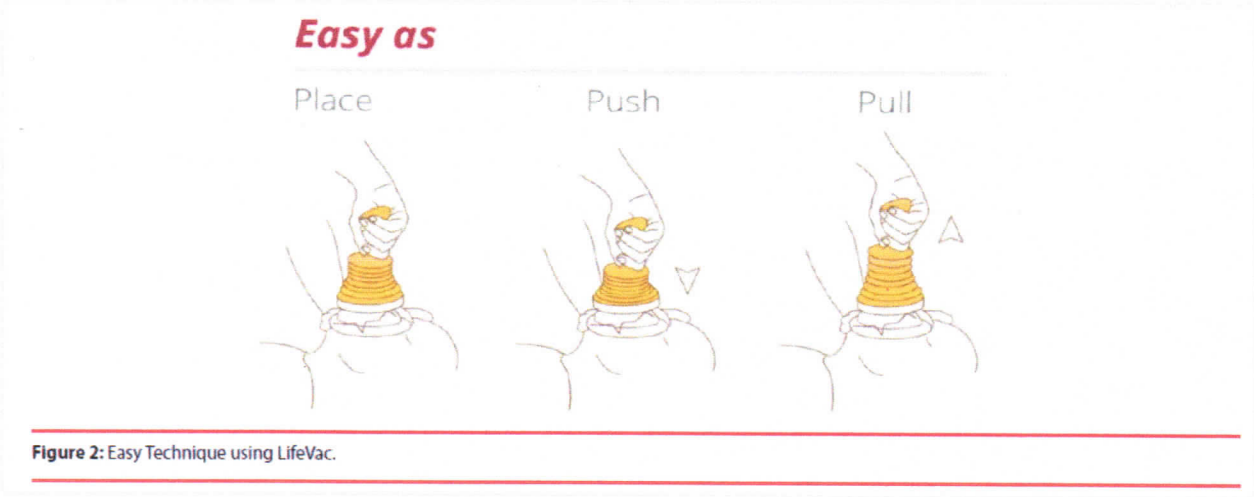

Figure 2: Easy Technique using LifeVac.

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Simulation and education

The efficacy and usability of suction-based airway clearance devices for foreign body airway obstruction: a manikin randomised crossover trial

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Abstract

Background: Newly-developed suction-based airway clearance devices potentially provide a novel way to improve outcome in patients with foreign body airway obstruction. We conducted a randomised controlled crossover manikin trial to compare the efficacy and usability of two of these devices with abdominal thrusts.

Methods: We randomised participants from a UK medical school to one of six groups which determined the order in which participants attempted the three techniques (abdominal thrusts; LifeVac, Nesconset, New York, USA; Dechoker, Concord North Carolina, USA). Randomisation was performed using an online randomisation system. Following brief training, participants sought to remove a foreign body airway obstruction from a manikin using the allocated technique. The primary outcome was successful removal of the foreign body. Usability was assessed in a questionnaire following the three simulations.

Results: We randomised and analysed data from 90 participants (58% male; 86% aged 18–29 years). Compared with abdominal thrusts, successful foreign body airway obstruction removal was achieved more frequently in manikins in the LifeVac group (odds ratio 47.32, 95% CI 5.75–389.40) but not in the Dechoker group (odds ratio 1.22, 95% CI 0.60–2.47). The usability of LifeVac and abdominal thrusts were generally evaluated more positively than the Dechoker.

Conclusion: In this manikin study, we found that, compared with abdominal thrusts, the success rate for foreign body airway obstruction removal was higher in the LifeVac group but not in the Dechoker group.

Keywords: Airway obstruction, Choking, Basic life support, Anti-choking device, Randomised controlled trial, Simulation

Introduction

Foreign body airway obstruction (FBAO) is an important cause of mortality and morbidity, particularly in the very young and old.[1–3] Each year, FBAO is responsible for almost 2,000 ambulance calls in London and approximately 250 UK deaths.[1,3]

Current treatment for FBAO is based on a step-wise approach, that incorporates techniques including coughing, back blows, abdominal thrusts, and chest thrusts/compressions.[4] Abdominal thrusts are reserved for severe cases of FBAO that are not relieved by back blows, due to associated risk of thoracic, vascular and gastro-oesophageal injury.[5] Evidence supporting specific interventions is limited, such that current treatment recommendations are based predominantly on case series and expert opinion.[5,6]

The risks associated with current treatments for FBAO have driven interest in alternative strategies for FBAO removal. In recent years, new suction-based airway clearance devices have been developed in

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which manual suction is applied via a face mask to relieve FBAO. A recent systematic review of these devices identified published data for only one device.[7] Available studies for this device were limited to manikin studies, cadaver studies, and clinical case series. Based on the limited data published to date, the International Liaison Committee on Resuscitation has decided that it would be premature to make a recommendation for or against the use of devices, and highlighted the urgent need for further research.[6]

To date, no study has compared these devices with standard care.[7] The efficacy and usability of new devices, in comparison with standard care, are important factors in determining whether a medical device should be adopted in practice. In view of the current absence of evidence in relation to this important issue, we identified the specific need for research in this area.

Methods

We conducted an open-label, randomised controlled crossover manikin trial to compare the efficacy and usability of two suction-based airway clearance devices (LifeVac, Nesconset, New York, USA; Dechoker, Concord, North Carolina, USA) with the abdominal thrust.

The LifeVac comprises a facemask attached to compressible bellows. To use the device, the mask is held over the choking patient's mouth and nose, and then the handle of the bellows is pressed downwards and sharply pulled upwards.[8] The Dechoker comprises a facemask attached to an oropharyngeal tube attached to a large cylinder with a plunger. To generate negative pressure, the plunger is pulled backwards sharply.[9] Both devices are promoted as being straightforward to use.[10,11]

The trial protocol was finalised before the start of the study. The study was reviewed and approved by the University of Warwick Biomedical & Scientific Research Ethics Committee (reference 108/18–19). Written informed consent was obtained from all participants. No changes were made to the trial protocol following commencement.

Setting and participants

The study was conducted in the Medical School at the University of Warwick. We included university staff and students that could communicate in English and who provided written informed consent to participate. We excluded individuals who had a physical disability that precluded use of the devices.

Randomisation

Following confirmation of eligibility and provision of written informed consent we randomised participants in an equal ratio to one of six groups that determined the order in which they completed the three interventions. Details of the groups and corresponding order are included in figure one and the electronic Supplement (Table S1). The randomisation sequence was developed using an online system using a fixed block size of six by a researcher that was not involved in participant recruitment.[12] For randomisation, we used an online randomisation system to maintain allocation concealment.[13] Following randomisation, participants were informed only of the intervention that they would be requested to complete next in the sequence.

Interventions and study process

The researcher showed the participant a short information video on how to deliver the first intervention. For the LifeVac and Dechoker, we extracted key information from manufacturer training videos freely available on the internet.[10,11] For abdominal thrusts, we extracted information from a video on foreign body airway obstruction developed by a UK first aid charity.[14] Participants were not given the opportunity to handle the device or practice any technique prior to the simulated scenario.

For the scenario, participants were informed that a 25-year old male was eating steak at a restaurant when they suddenly began to cough and pointing to their throat. Back slaps had been attempted, but these were ineffective. For the patient, we used a manikin (Choking Charlie, Laerdal Medical AS, Stavanger, Norway) with a simulated food bolus sited in the manikin's throat, as per manufacturer instructions. The participant was then to perform the allocated intervention. To ensure consistency across interventions, participants were permitted only to use the allocated intervention. Participants were given up to four-minutes to remove the obstruction.

After the first scenario, we adopted the same procedure for subsequent interventions. There was no break between attempting interventions. Following scenario three, participants completed a questionnaire on device usability. It was not possible to blind either the research participant or outcome assessor to treatment allocation.

Outcomes

The primary study outcome was successful removal of the foreign body airway obstruction within four-minutes. This was defined as the removal of the simulated food bolus from the manikin's mouth. The four-minute period was timed by a single researcher with a stopwatch.

The secondary efficacy outcome was time to FBAO removal. A single researcher present during the scenario measured the time in seconds from the start of the scenario to the point that the FBAO exited the manikin's mouth using a stopwatch. Secondary usability outcomes were captured in a survey completed at the end of the three scenarios. For each device, participants were asked to rank five statements on a scale of 1 (strongly disagree) to 10 (strongly agree). These statements were: I understood how to use the device; the device was easy to learn; the device was easy to use; I felt confident using this device; and I would feel confident using this device in a real-life emergency.

Sample size

We selected a sample size of 90 participants. In the absence of any preliminary data to provide insights in to expected effect size, our sample size was chosen based on the time frame available for data collection and the size of the pool of potential participants.

Statistical methods

We describe categorical data as number and frequency. We describe all continuous data as median and interquartile range to reflect the type of data collected. For our primary outcome (successful removal), we first assessed for a group, period or carryover effect, using a mixed-effects binary logistic regression model. In the absence of such effects, we used the same model framework to estimate the effect in

removing the foreign body airway obstruction for both LifeVac and Dechoker, compared with abdominal thrusts. Participants were included as a random-effect in the model. The analysis was not adjusted for any covariates.

For time to removal, we visualised data using a Kaplan-Meier survival curve. As indicated by the crossed curves, violation of the proportional hazards assumption precluded use of a cox proportional hazard model or ordinal regression. Weighted log-rank tests were not used as the crosses occurred at different time points. The proportional odds assumption was assessed by the test of parallel lines. As such, we categorised time to removal in to five groups based on time to removal (group 1: 0–59 seconds, group 2: 60–119 seconds, group 3: 120–179 seconds, group 4: 180–239 seconds, and group 5: not successfully removed). We then adopted the same modelling strategy described for our primary outcome to compare groupings (group one v all other groups; groups one/two v all other groups, etc).

For usability outcomes, we compared across all three groups using Friedman's test. In the event that the overall test was statistically significant ($p < 0.05$), we compared differences between pairs of groups (LifeVac v Abdominal thrusts; LifeVac v Dechoker; Dechoker v Abdominal thrusts) using the Wilcoxon signed-rank test.

The analyses were conducted on a per-protocol basis. We present model results as odds ratio and 95% confidence interval (CI) and reported p values for the non-parametric test results. All primary statistical tests were two-sided with a pre-specified significance level of 0.05. Pairwise comparisons of the usability outcomes were two-sided with a Bonferroni correction applied to account for multiple testing, such that pairwise level of significance was 0.017 (0.05 divided by three). We undertook analyses using SPSS (version 26.0, IBM Corp, Armonk, New York) and STATA (version 16.0, StataCorp, College Station, Texas).

Results

In October 2019, 93 individuals were screened for study participation, of which 92 participants were eligible, provided written informed consent and were randomised (Fig. 1). In two cases, participants did not complete all three tests correctly, such that they were not included in the analysis. Data from 90 individuals were available for analysis.

Most participants were male (n = 52, 58%), aged 18–29 (n = 77, 86%), and a medical student (n = 86, 96%) (Table 1). Most participants had previously attended a first aid course (n = 85, 94%). Few participants had previously seen a LifeVac or Dechoker device. Participant characteristics were similar across the study groups (Supplementary appendix Table S2).

For the primary outcome, the FBAO was successfully removed in 99% cases with LifeVac, 74% cases with Dechoker, and 71% cases with abdominal thrusts (Table 2). The odds of successful removal was significantly higher in the LifeVac group than abdominal thrusts (odds ratio 47.32, 95% CI 5.75–389.40), but was not significantly higher in the Dechoker group compared with abdominal thrusts (odds ratio 1.22, 95% CI 0.60–2.47).

For time to removal, Fig. 2 shows the timing of success across groups. The crossed curves indicate the violation of proportional hazards assumption. Removal in less than one-minute occurred in 82% cases using LifeVac, 44% cases using Dechoker and 67% using abdominal thrusts. After the first minute, the FBAO was successfully removed in 17% cases using LifeVac, 30% cases using Dechoker, and 4% cases using abdominal thrusts. Across group comparisons, Lifevac was consistently superior to abdominal thrusts. For Dechoker, comparison of group one (removal in less than one minute) with subsequent time periods showed Dechoker to be less efficacious than

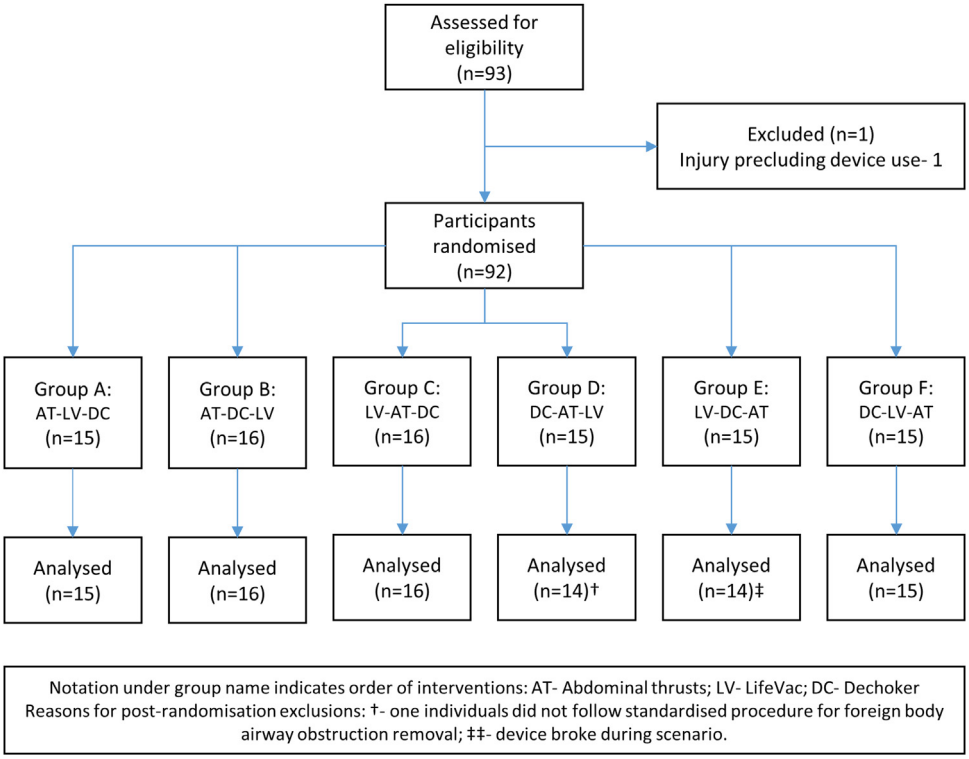

Fig. 1 – CONSORT participant flow diagram.

Table 1 – Participant characteristics.

	All (n = 90)
Age (years)-n(%)[a]	
18–29	77 (85.6%)
30–39	8 (8.9%)
40–49	2 (2.2%)
50–59	2 (2.2%)
Sex- male-n (%)[a]	52 (58.4%)
Role- n (%)	
Student-medical	86 (95.6%)
Student-other	0 (0%)
Staff	4 (4.4%)
Attended first aid course- Yes-n (%)	85 (94.4%)
Real-life experience of FBAO management-n (%)	
None	72 (80.0%)
Back slaps	15 (16.7%)
Back slaps/abdominal thrusts	3 (3.3%)
Previously seen Life-Vac-n (%)	6 (6.7%)
Previously seen Dechoker-n (%)	3 (3.3%)

[a] One participant declined to answer.

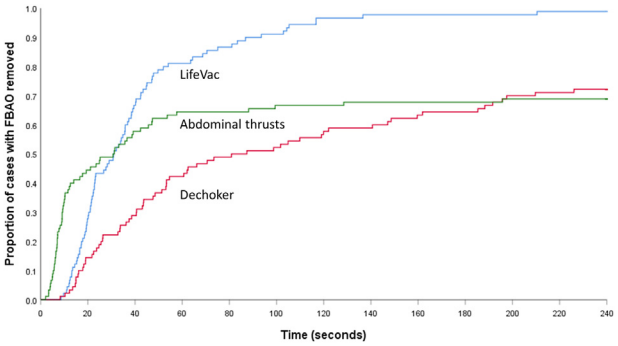

Fig. 2 – Time to removal of foreign body for study interventions.

abdominal thrusts (odds ratio 0.38, 95% CI 0.20 to 0.72). This effect was not observed in subsequent time point comparisons.

Participants reported that they understood how to use all three techniques (Table 3). For all other usability outcomes, we observed statistically significant differences across the three groups. The LifeVac consistently outperformed the Dechoker device, whilst comparisons between the other two groups (LifeVac v Abdominal thrusts; Dechoker v Abdominal thrusts) were mixed. Reported confidence using techniques in real-life was highest in the abdominal thrust group, although between group comparisons showed abdominal thrusts were not superior to the LifeVac.

Discussion

In this manikin randomised crossover trial of 90 participants, we identified that use of LifeVac resulted in both quicker FBAO removal and greater overall success. Dechoker was not superior to abdominal thrusts. Success rates in the LifeVac group were reflected across usability outcomes.

The successful removal of the FBAO without harm to the patient is the primary aim of all FBAO treatments. Following their first description in 1974 and despite early controversy, abdominal thrusts have become a core component of FBAO guidelines.[4,15,16] However, abdominal thrust success rates are challenging to determine as data are limited to case series. In our study, a population of predominantly medical students that had previously undertaken a first aid course achieved a success rate of 71%. The most robust clinical report of abdominal thrusts effectiveness reported a FBAO removal success rate of 79%, although this is likely an over-estimate due to selection bias and recall bias.[15] In contrast to suction-based airway clearance devices, a key advantage of abdominal thrusts is that they require no additional equipment to perform. Modifications have been described for use in patients that are unable to stand.[17]

For the two devices (LifeVac and Dechoker), published data on success rates are very limited.[7] A systematic review identified no published peer-reviewed studies of the Dechoker device.[7] In a manikin study of LifeVac, participants achieved a 94% success rate with one attempt and a 100% success rate with three attempts.[18] A cadaver study of LifeVac reported a 98% success rate on the first attempt, and a 100% success rate with two attempts.[19] The overall success rate for the LifeVac of 99% in our study is broadly consistent with these previous studies.

A key issue with these devices is that their use may distract the rescuer from other techniques, such as back slaps, abdominal thrusts and chest thrusts. The successful removal of an FBAO using devices

Table 2 – Study outcomes.

				Between group comparisons (odds ratio (95% confidence interval))	
	LifeVac	Dechoker	Abdominal thrust	LifeVac v abdominal thrusts	Dechoker v abdominal thrusts
FBAO removal success-n (%)	89 (98.9%)	67 (74.4%)	64 (71.1%)	47.32 (5.75–389.40)	1.22 (0.60–2.47)
Time to removal- n (%)					
Group 1: 0–59 seconds	74 (82.2%)	40 (44.4%)	60 (66.7%)	2.39[a] (1.17–4.88)	0.38[a] (0.20 – 0.72)
Group 2: 60–119 seconds	13 (14.4%)	14 (15.6%)	2 (2.2%)	13.53[b] (3.83–47.86)	0.67[b] (0.36–1.25)
Group 3: 120–179 seconds	1 (1.1%)	6 (6.7%)	1 (1.1%)	24.95[c] (5.17–120.50)	0.83[c] (0.42–1.65)
Group 4: 180–239 seconds	1 (1.1%)	7 (7.8%)	1 (1.1%)	47.32[d] (5.75–389.40)	1.22[d] (0.60–2.47)
Unsuccessful (Group five)	1 (1.1%)	23 (25.6%)	26 (28.9%)		

[a] Comparison of group 1 v groups 2–5.
[b] Comparison of groups 1–2 v groups 3–5.
[c] Comparison of groups 1–3 v groups 4–5.
[d] Comparison of groups 1–4 v group 5.

Table 3 – usability outcomes.

	LifeVac median (IQR)	Dechoker median (IQR)	Abdominal thrust median (IQR)	p-value[a]	P-value for comparison between groups[b]		
					LifeVac v Dechoker	LifeVac v abdominal thrusts	Dechoker v abdominal thrusts
Understand how to use technique	9.0 (7.0–10.0)	9.0 (7.0–10.0)	9.0 (8.0–10.0)	0.115	–	–	–
Technique easy to lean	9.0 (8.0–10.0)	8.0 (6.0–9.0)	9.0 (7.0–10.0)	<0.001	0.007	0.47	0.015
Technique easy to use	9.0 (6.0–10.0)	6.0 (4.0–8.3)	7.0 (5.0–9.0)	<0.001	<0.001	0.013	0.08
Confident using technique	8 (6.0–9.0)	6.0 (2.0–8.0)	7.5 (5.0–9.0)	<0.001	<0.001	0.50	<0.001
Confidence using technique in real-life emergency	7.0 (5.5–9.0)	5.0 (1.0–8.0)	8.0 (5.0–9.0)	<0.001	<0.001	0.84	<0.001

IQR, interquartile range.
[a] p-values based on 90 comparisons except confidence using technique in real-life emergency (89 comparisons).
[b] p-values based on 90 comparisons except confidence using technique in real-life emergency- LifeVac v Dechoker (89 comparisons); confidence using technique in real-life emergency-DeChoker v Abdominal thrusts (89 comparisons).

relies on the generation of sufficient negative pressure, which is dependent on achieving an effective facemask seal. Previous research highlights the challenge of achieving an adequate seal with a face mask, particularly when using a one-handed technique.[20–22] Our study recruited in a medical school such that most participants were medical students and may have a greater awareness of the importance and technique for generating an adequate seal than the general public.

The key difference between the Dechoker and LifeVac is that the DeChoker incorporates an oropharyngeal tube. Theoretically, the tube should focus the generated negative pressure to a specific location to facilitate FBAO removal. However, in our study, the LifeVac was superior to the Dechoker both in terms of overall success rates and time to removal. In the clinical setting, an important concern is that the insertion of the orophrangeal tube component of the Dechoker has parallels with a blind finger sweep, which are associated with harms such as soft tissue injury and the risk of inadvertent FBAO translocation making it more difficult to remove.[23–25]

Our study has a number of important limitations. Firstly, manikin studies provide an important way to test the efficacy of FBAO interventions using standardised processes. However, generalisability to the clinical setting is limited as it is not possible to recreate the fidelity of a time-critical clinical event. Secondly, our simulated obstruction was a small hard spherical object. Performance of different techniques will likely vary with obstructions of different consistencies and size. Thirdly, we recruited participants from a medical school which is reflected in the demographics of participants including the high proportion that had previously attended a first aid course. This may not be reflective of the general population. Fourthly, we were unable to blind either study participants or outcome assessors, which may have contributed to performance or detection bias.

Fifthly, the training for each intervention was relatively brief and did not allow participants the opportunity to practice. We used key components of manufacturer training information in our participant training videos. Based on this training, participants reported that they understood how to use study techniques. It is not known whether additional, more intense training may have influenced study results. Finally, we asked participants to continue using the same technique for the four-minute scenario. In contrast, clinical guidelines recommend alternating techniques if a specific technique does not quickly lead to successful FBAO removal.[4]

Conclusion

In this manikin study, we found evidence that individuals using the LifeVac were more successful in removing a simulated foreign body airway obstruction than individuals using abdominal thrusts. We did not find evidence of improved success by individuals using the Dechoker, compared with individuals using abdominal thrusts. Further research in the clinical setting is needed to understand the potential role of suction-based airway clearance devices in the management of FBAO.

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Conflict of interests

KC is an associate editor of Resuscitation Plus. The remaining authors have no conflicts of interest to declare.

CRediT authorship contribution statement

Emma Patterson: Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing. **Ho Tsun Tang:** Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing. **Chen Ji:** Formal analysis, Writing - review & editing, Supervision. **Gavin D. Perkins:** Conceptualization, Methodology, Formal analysis, Resources, Writing - review & editing, Supervision. **Keith Couper:** Conceptualization, Methodology, Formal

analysis, Resources, Writing - original draft, Writing - review & editing, Visualization, Supervision.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.resplu.2020.100067.

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Poster Tours (PT)

PT1

Patients assessment and triage in emergency room: From guidelines to daily practice

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The management of the flow in emergency room, gives the functioning as well as the criterion of efficiency and the functioning of the service. Who does what, with what tools and materials as well as according to what criteria, this is the problem of any emergency service. The criteria for the patients sorting in emergencies, the functions of the various parties involved and the procedures to be followed are variable in the different emergency departments and in different countries. Recommendations have been issued but not yet unanimously recognized and implemented.

A critical review of the different triage scales of emergency patients, with their advantages and disadvantages is discussed and solutions to different problems are proposed.

An ideal emergency service model is suggested, based on current recommendations and different practices.

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PT2

Device for the resuscitation of the choking victim

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Study objectives: Choking remains a leading cause of death in children and oldest. Currently there are no devices that assist in the resuscitation of a choking victim. Therefore we studied the device (Lifevac), a new apparatus that previously has been shown in a simulator model to successfully resuscitate an adult choking victim, in an adolescent simulator model.

Methods: The Laerdal choking adolescent simulator system was utilized and a hard candy (SOFT) piece was inserted into the airway. The Lifevac was then used per operating guidelines with the pediatric and adult mask attached to attempt to remove the lodged object and the outcome was recorded.

Results: The Lifevac successfully removed the obstructing SOFT in 496 out of 500 attempts in one attempt, in 498 out of 500 in two attempts, and all obstructions were removed in three attempts. The 97% confidence intervals for the point estimate of the probability that the device will remove the obstruction (calling the point estimate "S") shown for three scenarios depending on how you define success: success 1 attempt: 95%, success 2 attempts: 98%, success 3 attempts: 100%.

Conclusions: The Lifevac is an apparatus that can successfully remove a SOFT, which is a food that commonly leads to choking, lodged in an pediatric, adolescent and adult choking victim's airway in this simulator model. This apparatus deserves further study as there is potential to save lives if abdominal thrusts fail to resuscitate the choking victim

https://doi.org/10.1016/j.resuscitation.2020.08.069

PT3

Development of self-skill training and e-learning system for neonatal resuscitation

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Purpose of the study: The Japanese Society of Perinatal and Neonatal Medicine established the Neonatal Cardio-Pulmonary Resuscitation (NCPR) training course for perinatal medical staff in 2007. Since it is difficult to maintain and improve resuscitation skills and knowledge, we considered using a self-training system to learn in low-dose and high-frequency. We have developed a self-training system to keep their skills and knowledge of neonatal resuscitation.

Materials and methods: The chest-compression monitoring system records compression action digitally by attaching a film-spread pressure sensor to the chest of a newborn mannequin. The sensor measure compression tempo and depth, and trainee can see the results their skill displayed on the LCD monitor in real-time. This system transmits a set of pressure sensor records to PC simulta-

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Review Article

Resuscitation of Choking Victims in a Pediatric Population Using a Novel Portable Non-Powered Suction Device: Real-World Data

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ABSTRACT

Background: Foreign body aspiration remains a significant cause of pediatric morbidity and mortality. This study aimed to assess the use of a novel, portable, nonpowered suction device (The LifeVac; LifeVac LLC, New York, USA) in pediatric patients who experience a choking emergency, and for whom standard resuscitative protocols have failed.

Methods: This article provides a summary of self-reported instances of use in pediatric patients during real-world choking emergencies that occurred from January 2014 to July 2020.

Results: Over a 6-year period, a total of 21 pediatric patients recovered from a choking incident after using the device to remove the airway obstruction when standard resuscitative protocols failed. No long-term complications were reported.

Conclusion: These cases describe the successful use of the device in pediatric patients who experienced a choking emergency. This study is limited by a reliance on user-reported data; although no device failures have been reported to date, we cannot definitively declare that they have not occurred. Based on these findings, and the data collected from adult subjects, use of this device during choking emergencies should be studied further.

Keywords: Aspiration; Aerodigestive tract; Foreign body airway obstruction; Anti-choking apparatus; Suffocation risks; Pre-hospital

INTRODUCTION

The process of swallowing involves complex coordination of oropharyngeal skeletal muscles [1]. While a number of neurological and musculoskeletal conditions predispose patients to oropharyngeal dysphagia and increase choking risk, such as Down syndrome and cerebral palsy, children younger than 3 years old are merely at-risk due to an underdeveloped swallowing reflex [2]. The majority of choking-related incidents in children are associated with food, coins, or toys [3]. In pediatric patients 75% of foreign body aspiration occurs in patients under 3 years old, with the majority of these cases occurring during the third year of life [4]. Incidentally, male children are more likely to aspirate foreign bodies than female children [5]. Despite being a preventable condition, morbidity and mortality due to foreign body aspiration in pediatric patients remains a clinical concern. The primary cause of accidental infant mortality is due to the inhalation of foreign bodies; in children under 5 years old, it is the 4th leading cause of accidental death [6]. A child dies every 5 days in the United States by choking on food [7].

Since death due to choking can occur in under 5 minutes, rapid and effective intervention is necessary to increase chance of survival [8]. A maneuver that applies upward thrusts to the epigastrium to force an obstruction out of the airway was developed in 1974 to remove airway obstruction [9]. The current American Heart Association choking protocol for babies under 1 year of age suggests alternating 5 back blows and 5 chest compressions to remove the foreign body, with a progression to rescue breaths and chest compressions if the infant loses consciousness [10]. In children over 1 year old, alternating 5 back blows and 5 abdominal thrusts progressing to Cardio Pulmonary Resuscitation (CPR) if the child becomes unresponsive is also recommended [10]. However, what happens when these maneuvers do not remove the obstruction? Rescue breaths may force the foreign body further into the airway, and back blows and abdominal thrusts are not feasible in wheelchair-bound choking victims. Magill forceps have successfully removed foreign body airway obstructions, but since this is an invasive tool their use is limited to those with advanced medical training [11]. At present, a portable, non-invasive device that requires minimal training to assist a choking victim has not been readily available.

A simple-to-use, lightweight, portable, non-invasive, non-powered

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suction device for resuscitation of a choking victim has been developed (Figure 1). The device consists of a patented plunger attached to a one-way valve which, in turn, attaches to a standard face mask that covers the nose and mouth. The unit includes a pediatric face mask as well as an adult face mask. When the plunger is depressed, air is forced out the sides and not into the victim. Pulling back on the plunger applies suction, which removes the foreign body from the airway (Figure 2). In a laboratory setting the device generates an average of 333.16 mmHg of suction force when the plunger is pulled back [12]. Creating 3 times the force of a standard cough [13]. In a study conducted in healthy, conscious, nonobese men, the standard tactics used to resuscitate choking victims circumferential abdominal thrusts, the classic abdominal thrust-based maneuver, a self-administered abdominal thrust, and a self-administered chair thrust generated forces ranging from 22 cm H_20 to 138 cm H_20 (16.18 mmHg to 101.51 mmHg) [14]. This article summarizes user-reported implementation of this novel device to remove foreign body airway obstructions in pediatric choking victims around the world.

MATERIALS AND METHODS

Since its release in 2014 The LifeVac (LifeVac LLC, New York, United States [US]) has been distributed in countries around the world including the US, Greece, Australia, Israel, the United Kingdom, and Spain (LifeVac LLC data). Each unit comes with a feedback card that can be mailed to the company, or a feedback card that directs the user to a website form that encourages users to report back on their user experience, including any complications that are encountered (Figure 3) [15]. The website has instructions for use as well as a training video [16] LifeVac, LLC has documented reported uses of the device as part of an internal monitoring study. The results of self-reported resuscitation efforts using the device in pediatric patients are summarized and reviewed below. Preliminary pediatric data, coupled with adult data, were presented as a poster at The World Congress of Gastroenterology at The American College of Gastroenterology in October 2017 [17]. Data of use in

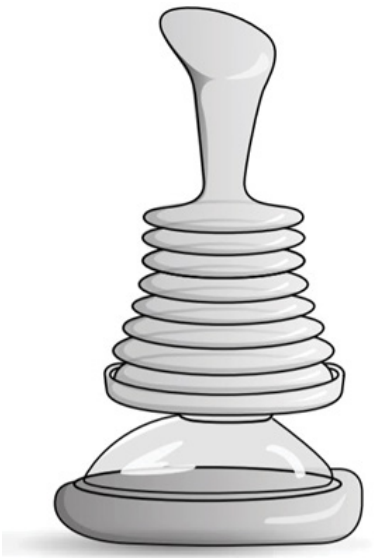

Figure 1: The device attached to a standard adult facemask.

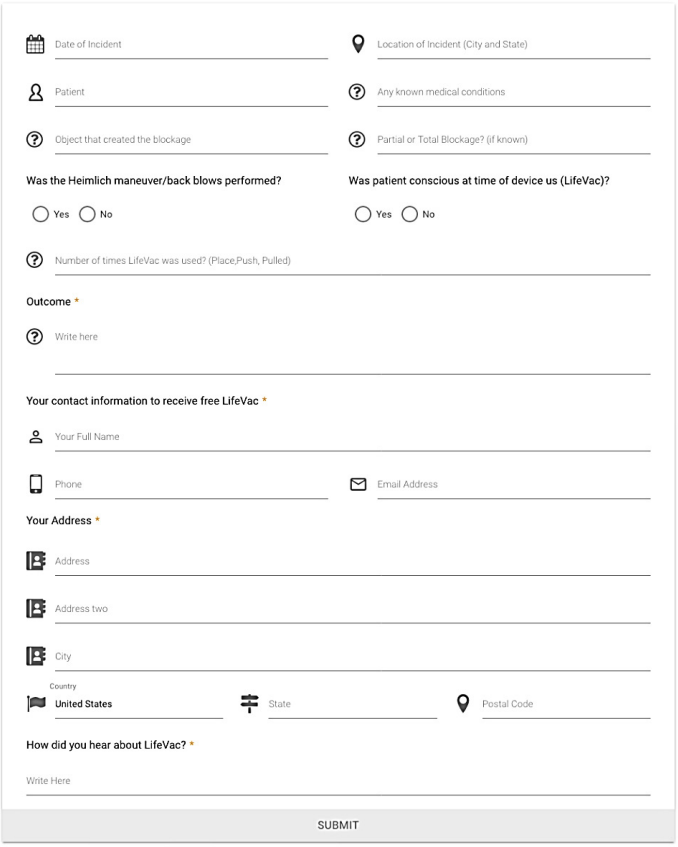

Figure 3: The online feedback form.

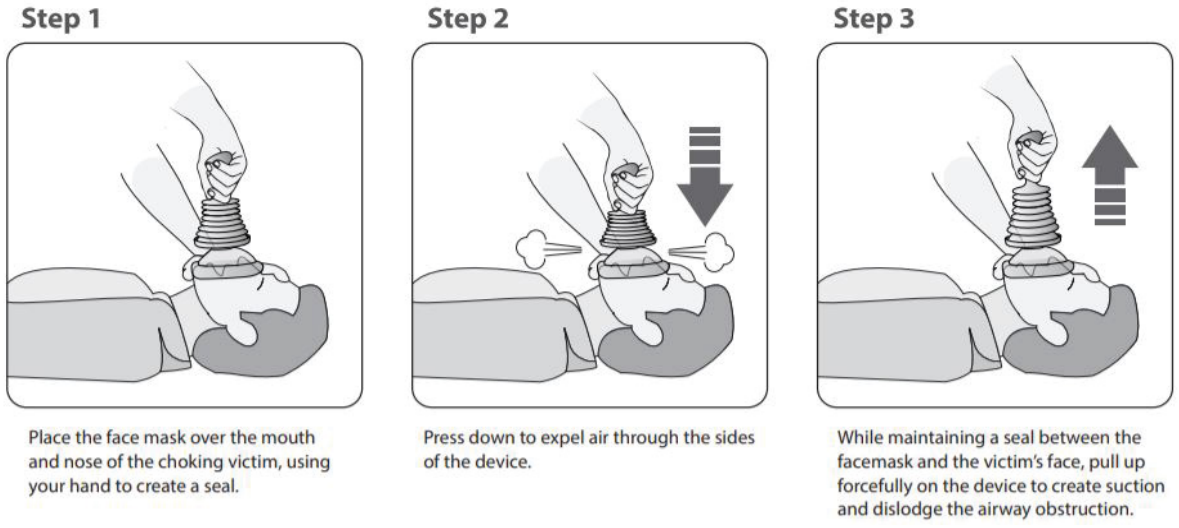

Figure 2: Instructions for use.

Table 1: Data summary for choking in pediatric population.

Age (y, m)	Sex †	Medical condition	Location of event	Person using device	Objects (s) removed	Number of attempts with device	BLS protocol attempted first	Conscious when device used?
3 y	M	Down syndrome	Airport	Security	Hot dog	1	Yes	No
1 y	M	None	Home	Parent	Chopped baby carrots	1	Yes	Yes
11 m	F	None	Home	Parent	Plastic wrapper	2	Yes	yes
5 y	M	None	Home	Parent	candy	2	Yes	Yes
6 y	M	None	Home	Parent	Coins	1	Yes	Yes
13 y	M	Dup15 syndrome	Home	Parent	Peanut butter and bread	1	Yes	Yes
6 y	M	None	Home	Parent	Cured ham	2	Yes	Yes
11 m	M	None	Home	Parent	Chopped tuna and pasta	2	Yes	yes
1 y	M	None	Home	Parent	Unknown††	2	Yes	Yes
3 y	M	None	Home	Parent	Cereal	1	Yes	Yes
11 m	F	none	Home	Parent	Orange slice	3	Yes	Yes
17 m	M	None	Home	Parent	Popcorn	2	Yes	Yes
Unknown	F	Unknown	Car	Parent	Mucus/phlegm/ vomitus	Unknown	Yes	Yes
17 m	F	Sotos syndrome	Home	Parent	Vomitus	1	Yes	yes
2.5 y	M	None	Home	Parent	Solid food	2	Yes	Yes
2.5 y	F	None	Home	Parent	Apple	1	Yes	Yes
7 y	F	Cerebral palsy, microcephaly	Home	Parent	Hamburger	2	Yes	Yes
3 y	F	None	Home	Parent (s)	Strawberry	1	Yes	Yes
1 y	F	None	Home	Parent	Leaf	3	Yes	Yes
4 y	F	None	Home	Parent	Sausage	2	Yes	Yes
4.5y	F	Asthma	Home	Parent	Whole grape	2	Yes	Yes

adult patients who were predisposed to oropharyngeal dysphagia will be reported separately.

RESULTS

Between January 2014 and 2020 there have been 22 reports submitted of use in pediatric subjects. We have included 21 of these cases in this report; although the 22nd case demonstrated a successful save using the device, the patient was 3 weeks of age and below the recommended minimal weight of 22 pounds [18]. Data from the 21 cases are summarized in Table 1. The subject's ages ranged from 11 months to 13 years old, with a mean age of 3.4 years. One patient's age was unreported but was described to be rescued in her car seat, so it is assumed that she is a pediatric case. In this dataset, 52.4% of patients were male. The majority of the subjects had no underlying medical conditions that predisposed them to oropharyngeal dysphagia, other than young age. However, patients with Down syndrome (n=1), duplication of chromosome 15 (n=1), cerebral palsy with microcephaly (n=1), and Sotos syndrome (n=1) were included in this summary. Reported foreign objects recovered included coins, popcorn, fruit, mucus, tuna, ham, peanut butter and bread, candy, plastic, hot dog, hamburger, strawberry, sausage, a leaf, a whole grape, and carrots. In 20 out of 21 cases, parents deployed the device; a security team member at an airport used it on the remaining patient. In each case the user(s) reported administering some form of Basic Life Support (BLS) protocol, which did not remove the obstructing object, before using the device. The foreign body was successfully removed by the device in all instances. The device was applied more than once in the majority of cases, resulting in at least 24 device implementations. In most cases (n=19) 1 or 2 deployments were successful in dislodging the foreign body. Three attempts were necessary to remove the obstructing object in 2 cases. No serious side effects were reported, and 20 patients returned to baseline health status without further medical intervention. Endoscopic surgery was required to remove 2 coins from 1 patient. The user-reported experiences with the device were all positive. One patient developed a contusion on her chin due to a vigorous placement of the facemask, but it resolved without intervention. To date there have been no reported device failures in pediatric patients. In one adult case that will be reported separately, the device successfully removed the obstruction but the patient succumbed to cardiac arrest.

DISCUSSION

Foreign body aspiration and asphyxia remains a serious clinical problem for the pediatric population, particularly in patients under 3 years of age [19-22]. Since brain damage can occur in minutes and death shortly thereafter, time is of the essence in a choking emergencies [23]. Early, pre-hospital intervention has been shown to improve outcomes in choking emergencies [24]. A retrospective study of 911 calls for choking emergencies in patients under 5 years old over a year-long period found that 59% of the emergencies were resolved by parents and caregivers prior to emergency medical services arrival [25]. Back blows and chest compressions with progression to CPR in the case of unconscious

infants, and back blows and abdominal thrusts for children with an advancement to CPR if the child is unresponsive are the current protocols [10]. Although these maneuvers have a high success rate, they can result in complications and are exceedingly difficult to employ on a wheelchair-bound patient [11,26]. If the standard choking protocols do not work, precious time is wasted waiting for emergency response teams. The average response time after a 911 call is placed ranges from about 7 to 14 minutes, making it unlikely that emergency responders could intervene before brain damage occurs in a choking victim [27]. It's estimated that over 12,000 children under 14 years old in the US visit emergency departments due to non-fatal choking incidents each year, and the majority of those patients are under 4 years of age [28]. The overall inhospital mortality rate for pediatric patients who suffered a choking incident is estimated at 2.5% [29]. The impetus of cardiac arrest in pediatric patients is commonly due to respiratory failure [30]. The neurological outlook after cardiac arrest for pediatric patients is generally unfavourable [31-33]. Besides the risk of death from asphyxia due to an immediate complete obstruction, a partial obstruction in the lower respiratory tract can lead to distal infection and inflammatory responses that progress to complete obstruction [5].

Most cases of foreign body aspirations occur due to food consumption in both adults and children [34,35]. There are certain foods that are of higher risk of being aspirated by children based on their size, shape, and pliability [36]. In a reported case series of pediatric patients who choked on whole grapes, a review of the 1 fatal case concluded that the patient may have survived if the grape were extracted with McGill forceps in the prehospital setting [37]. However, Magill forceps are an invasive tool that requires advanced medical training and can lead to complications. Although another portable device is currently being marketed, it has a tube that must be inserted into the patient's mouth and is therefore invasive [38]. The need for a non-invasive resuscitative aid that requires minimal training persists. This novel, portable, non-invasive suction device has been reported by users to be an effective tool during over 60 real-life choking emergencies in adults and children worldwide [39]. To date there have been no reports of significant adverse effects related to its use.

The results and interpretations from this study are limited, as it is a small, retrospective report of events that occurred and was not a prospective randomized study. However, designing a controlled, prospective study of the device in live patients presents an insurmountable ethical challenge. An animal model that suitably mimics human facial structure is also not available for testing. However, a study of the device that simulated choking in a human adult cadaver showed that the device successfully removed simulated food boli of varying sizes 49/50 times [40]. Similar efficacy was seen in a study of the device when used on an adult choking simulator manikin [41]. In the Laerdal choking adolescent simulator system a hot dog obstruction was successfully dislodged in 472/500 times in one attempt, in 497/500 in 2 attempts, and 500/500 times by 3 attempts [42]. LifeVac, LLC, is currently looking to partner with an independent research company to perform a prospective study on the device.

Since this current study relies on the proactive reporting of use and a retrospective recount of events, pertinent details about the patients' health status may not have been included in the submitted reports. Also, there may be an inherent bias to only report successful implementations of the device. However, an online survey of over 400 consumers reported that people were 21% more likely to leave a review after a negative experience with a product or business than a positive one [43]. While there have been no reports of failure of the device at this time we cannot definitively state that no device failure has occurred. Although a training module is available online, there is no way to reinforce that every user has reviewed it and understands how to properly implement the device in the event of a choking emergency. All of the reports to date in pediatric patients state that BLS protocols were attempted and unsuccessful before using the device. As this report relies on retrospective user-reported data, we have no way of knowing if these attempts were performed correctly in all instances and would have proven successful otherwise. However, given the promising real-world data of use on pediatric patients to date, the device deserves further exploration as an essential tool for use during choking emergencies.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Portable, non-powered, suction-generating device for management of life-threatening aerodigestive tract foreign bodies: Novel prototype and literature review

Poster presentation at: Combined Otolaryngology Spring Meetings (COSM), American Bronchoesophagological Association (ABEA), National Harbor, Maryland, USA

Pratik B.Patel Nina L.Shapiro
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Abstract

Objective

To present a novel approach for the emergent, pre-hospital management of life-threatening aerodigestive tract foreign body aspiration using a portable, non-powered, suction-generating device (PNSD), in the context of a literature review of emergent pre-hospital management of patients with foreign body airway obstruction.

Methods

The PubMed and MEDLINE databases were comprehensively screened using broad search terms. A literature review of pre-hospital management and resuscitative techniques of foreign body airway obstruction was performed. Further, independent measurements of PNSD pressure generation were obtained. Application of a PNSD in cadaveric and simulation models were reviewed. A comparative analysis between a PNSD and other resuscitative techniques was performed.

Results

Physiologic data from adult and pediatric human, non-human, and simulation studies show pressure generation ranging from 5.4 to 179 cm H_2O using well-established resuscitative maneuvers. Laboratory testing demonstrated that a protypic PNSD demonstrated peak airway pressures of 434.23 ± 12.35 cm H_2O. A simulation study of a PNSD demonstrated 94% reliability in retrieving airway foreign body, while a similar cadaveric study demonstrated 98% reliability, with both studies approaching 100% success rate after multiple attempts. Several case reports have also shown successful application of PNSD in the emergent management of airway foreign body in elderly and disabled patients.

Conclusion

PNSDs may play an important role in the emergent, non-operative, pre-hospital management of upper aerodigestive tract foreign body aspiration, particularly in settings and populations with high choking risk. Further characterization of effectiveness and safety in larger cadaveric or simulation studies mimicking physiologic conditions is indicated.

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Use of a Novel Portable Non-powered Suction Device in Patients With Oropharyngeal Dysphagia During a Choking Emergency

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Choking remains a leading cause of accidental death and morbidity worldwide. Currently, there is no device to assist in the resuscitation of a choking victim when standard maneuvers fail. A novel portable non-powered suction device (LifeVac; LifeVac LLC, Nesconset, NY) has been developed and may have potential use in patients with oropharyngeal dysphagia who are at increased risk of choking. The device is FDA registered and distributed worldwide. This case series provides a summary of self-reported data regarding the use of the suction device in adult patients with oropharyngeal dysphagia during real-world choking emergencies recorded between January 2014 and July 2020. Over a 6-year monitoring period the device has been reported to be successful in the resuscitation of 38 out of 39 patients with oropharyngeal dysphagia during choking emergencies. Although the obstruction was removed with the device from the 39th patient, resuscitation was not successful and he succumbed to his injuries. This portable, non-powered suction device may be useful in resuscitating patients with oropharyngeal dysphagia who are choking. The reported cases describe successful use of the device in real-world settings with minimal risk. Resuscitating patients with oropharyngeal dysphagia using this device may be a viable option when abdominal thrusts or back blows fail to resolve a choking emergency.

Keywords: choking, resuscitation, portable non-invasive non-powered suction device, dysphagia, oropharyngeal dysphagia, emergency, life saving

INTRODUCTION

The swallowing process is a complicated orchestration of skeletal muscles, requiring rapid coordination (1). Numerous neurologic and musculoskeletal conditions can lead to oropharyngeal dysphagia, including stroke, Parkinson's disease, amyotrophic lateral sclerosis, and myasthenia gravis, which increase the risk of choking (2). Medical conditions affecting skeletal muscle coordination and strength can also cause oropharyngeal dysphagia, including polymyositis, and very young (children or toddlers) or old age. Certain medications can also increase the risk of oropharyngeal dysphagia (3).

In the case of a choking emergency, defined as complete airway obstruction, time is of the essence, as brain damage will occur in 5 min and death will occur in several more minutes without oxygen (4). In the United States alone, 5,051 deaths from choking were reported in 2015 (5). In 1974, an abdominal thrust-based maneuver was developed to remove a bolus of food or other foreign bodies that become trapped in the back of the throat or trachea and obstruct the airway (6). The maneuver relies on forcing the obstruction out of the airway by applying upward thrusts to the epigastrium. The current American Heart Association choking protocol described back blows and abdominal thrusts for resuscitation of an adult choking victim, with a progression to chest thrusts if the abdominal thrusts are not effective (7). Current protocols suggest cardiopulmonary resuscitation (CPR) if abdominal thrusts do not provide a resolution to the choking incident which, without a patent airway, is likely to be futile as well as hazardous in that the object may be forced further into the airway by rescue breaths. In addition, maneuvers such as back blows and abdominal thrusts become almost impossible in individuals who are wheelchair bound, pregnant, or morbidly obese. While the use of Magill forceps has proven successful in choking cases refractory to abdominal thrusts, this is an invasive and more advanced skill that cannot be employed by an untrained caregiver (8). If a choking incident cannot be resolved by persons on-scene, emergency medical services (EMS) can be called to intervene. However, the average time for emergency responders to arrive on the scene of an emergency after a 911 call is placed is 7 min to as long as 14 min in the rural setting (9), making it unlikely that they will arrive before brain damage has occurred. Until recently a non-invasive device that could be used by both laypersons and medical professionals to assist in a choking emergency when standard maneuvers fail did not exist. A novel, non-powered suction device for resuscitation of a choking victim has been developed (LifeVac LLC, Nesconset, NY; **Figure 1**). The device is FDA registered and has been available since 2014. Over 80,000 units have been distributed worldwide, including to the United Kingdom, Greece, United States, Australia, Israel, and Spain (LifeVac LLC data). This simple-to-use, lightweight, portable, non-powered suction device includes a plunger with a patented one-way valve such that when the plunger is depressed, air is forced out the sides and not into the victim, and when the plunger is pulled back, suction is applied. The device attaches to a standard facemask, creating a seal over the nose, and mouth. Upon pulling up on the plunger, the object is removed from the airway (**Figure 1**). This case series summarizes user-reported implementations of the device in patients with oropharyngeal dysphagia during choking emergencies.

METHODS

Each device is supplied with either a feedback card that can be mailed to the company, or a card that directs the user to a website form such that if the unit is utilized the user can provide feedback regarding the event, including any complications encountered (10). The user can also request a free replacement of the device after deployment using this form, as it is a single use device. The use of the device is intuitive and when the use has been assessed in non-clinical lay people, the simplicity of its use has been confirmed. The device is shipped with both an online training video and explicit written directions as well as a practice mask so the user can practice upon receiving and become comfortable with its use (11). As part of an internal monitoring study, the manufacturer of the device has kept track of all reported uses of the device. Reports of use in patients with no underlying conditions causing oropharyngeal dysphagia were excluded. A subset of preliminary data was presented as a poster at The World Congress of Gastroenterology at the American College of Gastroenterology in October 2017, and reported as case studies (12, 13). Data that summarize the resuscitation of pediatric choking victims, as defined by an individual suffering from a complete airway obstruction, using this device was recently published (14).

RESULTS

Between January 2014 and July 2020 there were no reported failures of the device. A total of 42 reports of use on adult choking emergencies have been documented, 39 of which included patients with conditions predisposing them to oropharyngeal dysphagia, specifically advanced age (over 80 years old), cerebral palsy, dementia (including Alzheimer's disease), Down syndrome, Huntington's disease, multiple sclerosis, neurodegenerative disease, non-specific Parkinson's disease, severe intellectual disability, spina bifida, stroke, and traumatic brain injury. Further demographics are summarized and reviewed in **Table 1**. The majority of the patients resided in European countries ($n = 32$), with six in the United States of America, and one from Australia. Ten had no predisposing conditions besides advanced age, but the majority of the patients had a medical condition that predisposed them to oropharyngeal dysphagia. Ten of the patients were wheelchair-bound, making abdominal thrusts difficult. Another patient was described as "too frail for abdominal thrusts," while one patient had a percutaneous gastrostomy, making abdominal thrusts impossible.

In 38 patients the device resolved the choking incident and the patients survived. Although the device successfully removed the blockage from the 39th patient, as confirmed by paramedics who arrived on the scene, the patient was unable to be revived despite receiving 20 min of CPR. The device was used multiple times in several patients in order to resolve the choking incident, resulting in a total of at least 100 device implementations. In nine of the reported cases the first application of the device was successful in dislodging the foreign body from the airway and resulted in no adverse events. In the event of multiple applications, each patient returned to baseline health status without further incident, except for Patient 39, who was discussed above.

There were a few occasions where the device partially resolved the choking incident but further medical intervention was needed to fully remove the airway obstruction. In one patient, three attempts partially dislodged a piece of meat so that the patient could move air on his own and achieved

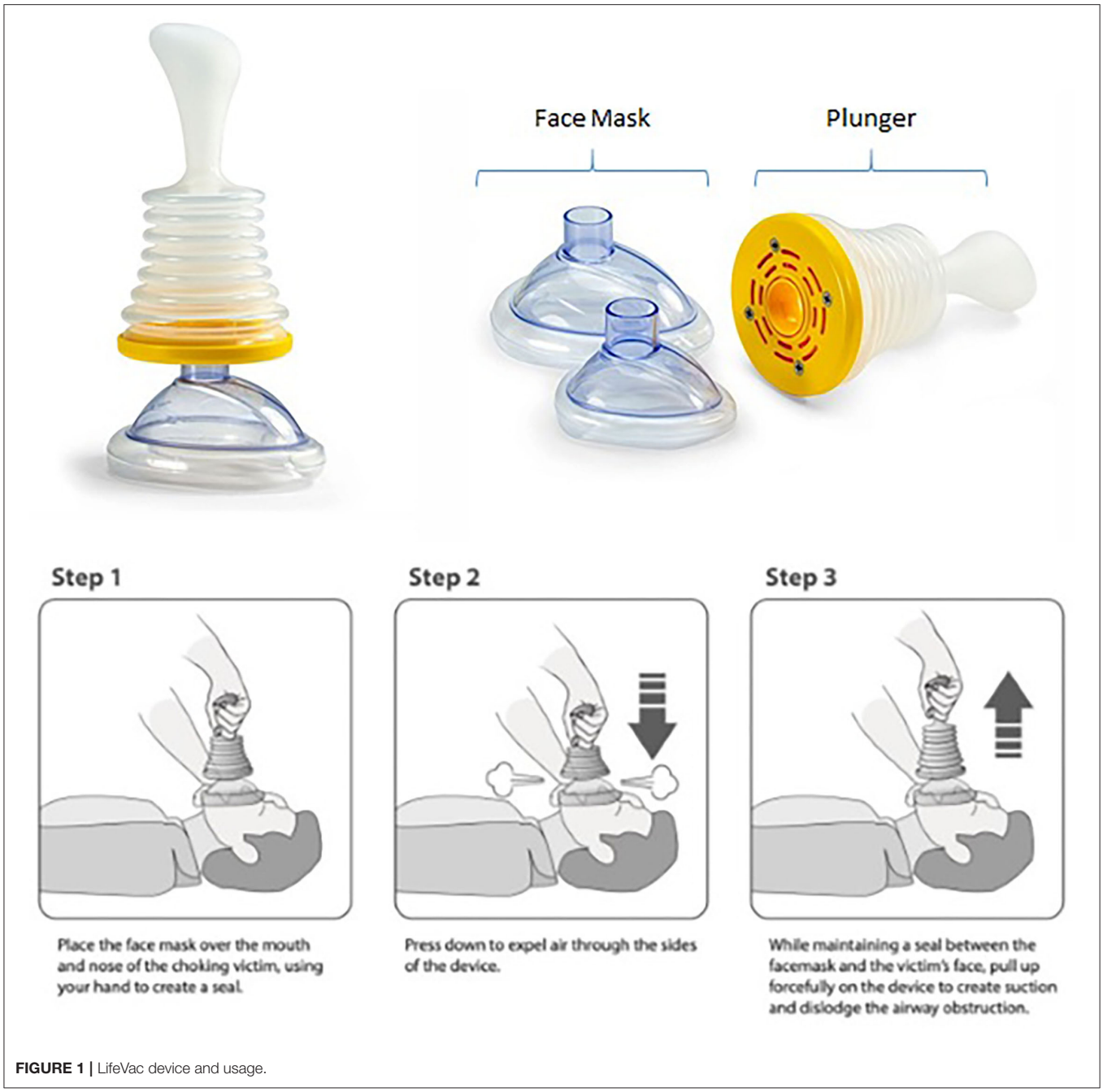

FIGURE 1 | LifeVac device and usage.

SpO_2 of 100% with supplemental oxygen, but EMS staff suspected that a partial airway obstruction persisted due to the presence of wheezing. After two additional applications by EMS staff, an emergency department physician successfully removed the partial airway obstruction by using the device three times in the hospital. In a patient with Alzheimer's disease who choked on a hamburger multiple device applications were required in both the pre-hospital and hospital setting to remove the boluses; all obstructions were fully removed in the emergency room. Two additional patients required the use of a powered suction device after the non-powered device partially removed their airway obstructions to fully resolve the issue.

The device was used successfully by a variety of individuals including EMS providers, an in-hospital physician, care home staff, and laypersons on conscious and unconscious choking victims. User reports were generally favorable in terms of their experiences employing the device during a choking emergency. Two users reported difficulty forming a seal with the face mask because the patients were diaphoretic. In the case of excessive sweatiness or other secretions present around the victim's mouth, users should take care to wipe the victim's face to help facilitate

TABLE 1 | Summary of 39 cases with risk factors for oropharyngeal dysphagia.

Characteristic	Value
Age range, years	28–98
Sex, *n*	
Male	18
Female	18
Not reported	3
Medical condition, *n*	
Advanced age	10
Cerebral palsy	5
Dementia (including Alzheimer's disease)	7
Down syndrome	2
Huntington's disease	2
Multiple sclerosis	2
Neurodegenerative disease, nonspecific	3
Parkinson's disease	3
Severe intellectual disability	1
Spina bifida	1
Stroke	2
Traumatic brain injury	1
Geographical location, *n*	
Europe	32
United States of America	6
Australia	1
Location of event, *n*	
Care home	33
Home/Car	2
Unknown	4
Person using device, *n*	
Nurse/other medical professional	34
Lay person	3
Unknown	2
No. of attempts, *n*	
1	10
2	8
3+	16
Unknown	5
Object removed, *n*	
Apple	1
Bread	4
Burger	1
Chicken	5
Chocolate	1
Coleslaw	1
French fries	1
Meat	3
Melon	1
Mushroom	1
Potato	3
Porridge	1
Rice	1
Saliva/Phlegm	5
Sandwich	1
Sausage	2
Tuna sandwich	1
Unknown	6
Patient consciousness, *n*	
Conscious	17
Unconscious	15
Unknown	7

(Continued)

a better seal. No serious adverse events were reported. One user remarked that the face mask left a contusion on the patient's nasal bridge, but since a further update was not received it's assumed the trauma resolved without further intervention.

DISCUSSION

In the event of a choking emergency current choking protocols suggest back blows and abdominal thrusts with a progression to chest compressions if abdominal thrusts do not dislodge the airway obstruction (7). While these protocols have been proven to be successful 86% of the time, they can result in complications (8, 15). Morbid obesity, pregnancy, and being wheelchair-bound can prevent the successful administration of standard anti-choking maneuvers. Additionally, when these maneuvers fail, one is left waiting for emergency personnel or continuing a protocol that has been unsuccessful thus far. Invasive procedures, such as a cricothyrotomy or the use of Magill forceps, require advanced medical training and can lead to complications. Therefore, there is an urgent need for an inexpensive, readily available, simple-to-use resuscitation aid for use during a choking emergency. A novel portable non-invasive suction device has been developed, which may have significant utility during a choking emergency.

The strengths of this study is the independent analysis of self-reported data regarding the experience with a novel portable non-invasive suction device. As all reported uses of the device in people with underlying oropharyngeal predisposing risks were included, there was no opportunity for bias in summarizing these outcomes. This device has been reported to be successful in more than 70 real-life choking emergencies worldwide (16). No significant adverse events have been reported thus far. While there may be concerns over esophageal or pulmonary injury from the force generated with this device, no barotrauma related injuries were reported to date.

The limitations of this study are that this was a small, retrospective report of events that occurred and was not a prospective randomized study. However, it is impossible to design an ethical controlled prospective randomized clinical trial of the device in live human subjects to demonstrate efficacy. No suitable animal model that simulates human facial structure is available for study. A study in a human cadaver found that the device successfully removed simulated food

boluses of varying sizes 49/50 times (17). The device has also demonstrated efficacy when used on a choking simulator mannequin (18). There have been no reports of failure of the device; although Patient 39 was not resuscitated, the device did successfully remove the obstruction, as confirmed by paramedics who assessed and treated the patient on-scene. However, since this current report relies on self-reported accounts of device use we cannot definitively state that no failures or complications have occurred, since it is not mandatory for users to report their experiences. While there is a training video available online (11), there is no way to determine whether the individuals completed any training prior to device utilization, and whether the device was used correctly in each event. However, given the promising real-world data reported thus far, the device deserves further consideration and study in patients with oropharyngeal dysphagia who are at increased risk of choking.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements. An IRB waiver was obtained on the basis of the above.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Anti-Choking Suction Devices for Foreign Body Airway Obstruction in Children. Would Parents and Kindergarten Teachers be Able to Use Them Without Training?

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Research Article

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Abstract

There is limited scientific evidence on the brand-new suction anti-choking devices as alternative or complementary tools for the treatment of foreign body airway obstruction (FBAO). However, they are already available in some public places. With the hypothesis that laypersons would not use them properly we have carried out the present simulation study.A randomized crossover trial study in a simulated FBAO scenario was conducted. Forty-two parents and eight kindergarten staff without knowledge about anti-choking devices voluntarily participated. Participants had to solve a simulated FBAO situation in three randomized scenarios: 1) Following the current choking international guidelines, 2) Using the LifeVac® device, and 3) Using DeCHOKER® device, according to the instructions provided by manufacturers. Data from 51 participants (54.9% female) were analyzed. Higher success rate was achieved with the LifeVac® and DeCHOKER® devices in comparison with the standard FBAO protocol (median [IQR]: 100.0% [83.0-100.0], 100.0% [75.0-100.0], and 50% [38.0-75.0] respectively; p=0.004). No significant differences were observed between both anti-choking devices (p=0.796). The procedure time was significantly shorter with the LifeVac® device (p<0.001).

Conclusion: Untrained laypeople, under simulated conditions, are able to properly handle LifeVac® and DeCHOKER® anti-choking devices according to the manufacturer's instructions in less than one minute. However, they have difficulties to perform the current recommended choking protocol. Further studies are needed to confirm whether the new devices could have a role in the FBAO management.

What Is Known

- Anti-chocking suction devices has recently emerged for the management of foreign body airway obstruction.

- Foreign body airway obstruction is relatively frequent in children.

- There is insufficient evidence for recommend or not recommend the use of anti-chocking suction devices.

What is new

- Laypeople were able to use anti-chocking suction devices under simulated condition.

- Participants had difficulties to carry out the recommended choking protocol even being provided with the instructions.

Introduction

Foreign body airway obstruction (FBAO) events are relatively common in children [1], particularly in preschool age because their behaviour predisposes to it [2]. FBAO situations represent a potentially life-

threating emergency that requires immediate recognition and intervention [3] since victims may quickly progress to unresponsiveness and death [4].

Bystanders often intuitively intervene in case of FBAO. In the case of children, most choking events happen at home or at school, where children spend most of their time [5]. Therefore, parents and/or teachers are more likely to be the first responders in such cases. Interventions required will differ depending on whether it is a mild or severe airway obstruction. Current guidelines recommend encouraging to cough while coughing is effective (mild airway obstruction) and afterwards the combination of back blows and abdominal trust ("Heimlich maneuver") [6] or chest thrust (in children under one year of age) (severe airway obstruction) [4,7].

However, despite FBAO being an important health problem, the evidence available to support these guidelines is weak [8–12]. This, in addition to the risk associated with abdominal thrusts in children (risk of thoracic, vascular, and gastroesophageal injury) [13], leads to a continuous search for a universally accepted and successful technique for FBAO removal.

Recent treatments proposed for the management of FBAO are anti-choking suction devices. Currently, two such devices are commercially available: LifeVac® [14] and DeCHOKER® [15]. Both are relatively simple and non-powered portable devices. They aim to generate a strong negative pressure in the oral airway that helps to relieve airway obstruction. By manufacturers' own choice, they recommend in the product leaflets and websites to apply them when the standard choking protocol fails.

These anti-choking devices are Class 1 registered by the Food and Drug Administration (FDA) for use in a choking emergency, simple registration for low-risk devices that are exempted from further FDA clearance or formal approval and have not passed through a submission and assessment process [8]. Nevertheless, they are widely available for anyone to use them in locations such as airports, hotels, or shopping centers [16]. A recent systematic review on the anti-choking suction devices showed that, given the limited scientific data and biased trials that have tested the use and effectiveness of these devices, there is insufficient evidence for or against their use [17]. Likewise, based on of the limited scientific literature on these devices, the International Liaison Committee on Resuscitation has revealed the need for further research to take a position supporting or opposing these devices [18].

Therefore, this study aimed to evaluate, in a simulated child choking scenario, the ability of parents and teachers (people with a high likelihood of involvement in an FBAO event) to perform the recommended actions for the management of FBAO and to compare it with the use of these two anti-chocking suction devices quickly and correctly.

Methods

Participants

Forty-two parents (84.3%) and eight kindergarten teachers (15.7%), (n=51; 54.9% female) without prior knowledge about suction devices took part voluntarily in this study. Written informed consent on the understanding that the data obtained would be anonymous and used only for research purposes was obtained from all participants. The study was conducted following the 2013 amended Declaration of Helsinki; the protocol was waived by the local Research Ethics Committee because it did not involve the use of participant's health data, the collection of biological samples, or intervention on participants.

Procedure

We conducted a randomized crossover trial in an in-situ (daycare center) simulated FBAO scenario. Participants (n=51) were asked to act in a simulated choking situation in three different scenarios: 1) performing the recommended protocol [Recommended protocol test]; 2) using LifeVac® device [LifeVac test]; and 3) using DeCHOKER® device [Dechoker test]. This resulted in 153 FBAO events (Figure 1). The tests' performance order was randomised.

In the "Recommended protocol" test participants were provided with instructions of the protocol for airway obstruction according to the international guidelines [4,7] displayed in a wall poster. Following these instructions, they were to respond initially on a simulated victim (a 21-year-old woman, heigh 1.53 m, weight 46.5 kg, member of the research team) who played a mild airway obstruction, which subsequently became severe, and finally, the victim simulated unresponsiveness, so that participants had to perform all the steps of the mentioned protocol.

Regarding LifeVac test and Dechoker test, the solving of the FBAO simulation was carried out with a junior manikin (Resusci Junior QCPR™; Laerdal) (Figure 1). In both tests, participants were given the anti-choking suction devices (LifeVac® or DeCHOKER®) with the manufacturer's leaflet instructions. Participants had not been previously trained and did not have the opportunity to handle or test the anti-choking suction devices before the tests.

Neither support nor advices were provided to participants during the tests, assuming that they were alone in the incident scenario. The execution of each of the steps (yes/no and correctly/incorrectly performed) according to the corresponding test was assessed by means of a specific checklist by a researcher. Another team member recorded the time taken to carry out the steps and the overall test time.

Instruments

Two anti-choking suction devices were used in the present study: LifeVac® and DeCHOKER®.
LifeVac® *LifeVac* (Nesconset, New York, USA) consists of a one-way valve and a plunger attached to a standard face mask (with three different sizes depending on the anthropometric profile of the victim: pediatric, child, and adult mask). To remove the foreign body from the airway, the mask is held over the choking victim's nose and mouth, and then, two repeated movements are required: push and pull handle. LifeVac® is not recommended for choking victims under 10 kg bodyweight.

DeCHOKER® (Concord, North Carolina, USA) is a single device composed of a mask attached to an oropharyngeal tube that needs to be positioned above the tongue, joined to a large cylinder with a plunger. To generate negative pressure, it is necessary to pull the plunger out with force. DeCHOKER® is also available in three different sizes (toddlers, children, and adults) according to the age of the victim, and it is recommended from one year onwards.

This study used for LifeVac test and Dechoker test the manikin Resusci Junior QCPR™ (Laerdal, Medical AS, Stavanger, Norway) which simulates a 6 year old child. For the LifeVac test the child size mask was used and for the Dechoker test the children device was used (participants did not have to select it, we gave them the right size).

Variables

Age, gender, weight and height of each participant were registered. In addition, they were asked about whether they had received previous training on choking (if yes, when it had happened); about whether they had witnessed a real FBAO situation (and when it had happened) and, whether they had acted or not. Moreover, they were also asked about their subjective perception of whether they feel they would be able to solve a FBAO situation (yes/no).

In all three tests, the performance of each step (yes/no) and, if done, the correct execution (yes/no) were recorded (Figure 1). To compare quantitatively the three tests, the variable *estimated success rate* was calculated taking into account whether or not the recommended steps were taken and whether or not they were performed correctly.

The estimated success rate for the "Recommended protocol" test comprised the following dichotomic items: 1) encouraging to cough; 2) giving back blows; 3) giving back blows correctly; 4) giving abdominal thrust; 5) giving abdominal thrust correctly; 6) continue to 5 back blows and 5 abdominal thrusts; 7) continue to 5 back blows and 5 abdominal thrusts correctly; and 8) Starting CPR for victim's unresponsiveness. The estimated success rate for the LifeVac test: 1) inserting the mask into the device, 2) place the mask covering nose and mouth of the victim correctly, 3) fixing the mask to the victim's airway, 4) push in handle, 5) pull handle, and 6) keeping the mask fixed to the victim's airway throughout the procedure. Lastly, the estimated success rate for Dechoker test: 1) place the mask covering nose and mouth of the victim correctly, 2) fixing the mask to the victim's airway, 3) pull the plunger out with force, and 4) keeping the mask fixed to the victim's airway throughout the procedure. Finally, the overall time of the tests and the partial times of each of the phases were recorded (Figure 1).

Statistical Analysis

Data were analysed with SPSS statistical software (IBM corp., v. 25.0 for Mac). Results are expressed as median (interquartile range) and absolute frequencies (relative frequencies) as appropriate. Non-parametric tests were used after checking the normality of variables using the Kolmogorov-Smirnov test. The non-parametric Friedman test for related samples was used for the comparison of the overall time

and estimated success rate between the 3 tests (Recommended protocol test, LifeVac test and Dechoker test) and the Wilcoxon signed-rank test for assessed paired differences. McNemar's test was used to compare categorical variables between LifeVac and Dechoker test. A significance level of $p<0.02$ (0.05/3) for the paired comparison analyses was considered and a significance level of $p<0.05$ for the rest.

Results

Anthropometric data and main characteristics of the 51 participants (54.9% female) are shown in Table 1. Nineteen (37.3%) (the eight kindergarten teachers and eleven parents) had received some prior training on how to handle a FBAO event according to recommended protocol. Of all participants, 11 (21.6%) referred to have witnessed a FBAO incident in the past but only 6 had intervened. Before the tests, participants were asked about their self-confidence for solving a FBAO scenario correctly. Twenty-eight (54.9%) answered that they would be able to intervene satisfactorily.

Table 2 shows data related to "Recommended protocol" test (overall sample and disaggregated by previous FBAO-training). Less than a half of the participants (45.1%) encouraged the victim to cough. This percentage was even lower in the case of untrained (31.3%) compared to trained participants (68.4%, $p = 0.010$). Giving back blows was performed by 76.5% of participants, with significant differences between those trained (100%) *vs* untrained (73.9%) ($p = 0.026$). The same was observed for abdominal thrusts, with a 94.1% of participants performing this step, and significant higher proportion of trained participants (52.6% trained *vs* 13.8% untrained) who have correctly performed it ($p = 0.004$). Thirty participants (58.8%) stated that they would start CPR when in the last part of the test the victim became unresponsive. Regarding the estimated success rate for the "Recommended protocol" test, overall participants obtained a median score of 50 (75% for those with previous training *vs* 38% for those without training, $p=0.003$).

The analysis of each step of the FBAO sequence treatment using LifeVac® and DeCHOKER® anti-choking suction devices is presented in Table 3. Most of the steps were performed correctly by the majority of participants without significant differences between both devices. The poorest performing step was keeping the mask fixed to the victim's airway throughout the procedure, with 43.1% failing to do so with the LifeVac device and 33.3% failing to do so with the DeChoker device.

The only variable with significant differences between LifeVac and Dechoker was the time spent performing the test where participants spent a median of 9 sec less to place the LifeVac® ($p < 0.001$) (Table 4). The estimated success rate was similar with both devices.

In terms of estimated success rate (Figure 2), a significantly higher rate was obtained with the two devices compared to the recommended protocol ($p < 0.001$). No significant differences were found between LifeVac® and DeCHOKER®.

Finally, significant differences were found when comparing the overall procedure time spent on each of the tests ($p < 0.001$) (Table 4). Participants spent significantly more time with the recommended protocol

and the DeCHOKER® device than with the LifeVac® device ($p < 0.001$). However, no differences in time were found between the DeCHOKER® and the recommended protocol.

Discussion

Our study is the first that aimed to assess, in a simulated scenario, the handling of new anti-choking devices (LifeVac® and DeCHOKER®) and to compare them with the recommended choking protocol by laypeople at risk of witnessing an FBAO: parents and kindergarten teachers. We observed that most participants achieved a higher success rate in managing FBAO using both anti-choking devices than with the currently recommended protocol. However, they often failed fitting and keeping the mask to the victim's airway. When devices were compared with each other, participants needed less time when using the LifeVac®, although in both cases, the mean total time was slightly shorter than one minute.

The main goal of the FBAO treatment is the removal of the obstruction as early as possible without injury to the victim, which means that bystanders are the target population to solve it [19,20]. Controversy about FBAO management is rooted on the limited evidence supporting these interventions, which are mainly based on case series and experts' opinion, and on the potential harms associated with these techniques [13]. This leads to a continuous search for a safe and effective alternative.

Previously published information and evidence on the new anti-choking devices are extremely limited and unconclusive. The recent systematic review by Dunne et al. [17] includes only five studies about the LifeVac® device, two of them on manikins [21, 22], one on a cadaver [23] and the others were case series [24,25] which report a high success rate for FBAO removal, in most cases in the first few attempts. However, these references are seriously biased (industrial involvement, measurement of outcomes, selection, and information bias, with hardly any information on the methodology used, imprecise results...) [17].

Up to now, only two new articles have been published since the above-mentioned review. In one study, the DeCHOKER® device was evaluated in 27 real choking victims, 26 of whom were successfully removed the obstruction with the device [26]. The other study, a manikin randomized crossover trial conducted with medical students, compared abdominal thrust, LifeVac®, and DeCHOKER® device and found a higher estimated success rate for FBAO removal with the LifeVac® device [19]. For these reasons, the need for further studies on this issue has been suggested [16,17].

The estimated success rate, calculated by taking into account the correct performance of all steps in each sequence, showed significantly better results for the anti-choking devices (without significant differences between them). In other words, participants found it easier to use the brand-new LifeVac® and DeCHOKER® devices as they did so with fewer errors than following the recommended protocol.

However, it has to be noted that, although instructions were provided for all three situations, we observed that participants followed the instructions more carefully in the case of the anti-choking devices perhaps because they were completely new tools to them. On the other hand, in the case of the recommended

standard protocol, they often acted instinctively or according to their prior knowledge without strictly paying attention and following the displayed instructions. This may explain why there were more errors while performing the recommended protocol sequence. In fact, only 5.9% of the participants performed all steps correctly compared to 51% with LifeVac® and 56.9% with DeCHOKER® devices.

One of the main problems blamed on these devices is that they can distract rescuers and cause a delay in the recommended techniques (such as back blows and abdominal thrust) [8,16,17,19]. However, in our study, participants spent less than one minute to apply the LifeVac® and DeCHOKER® devices to solve the FBAO simulation. Although our study did not assess the effective FBAO successful removal, the results agree with those of the study by Patterson et al. [19] who showed a higher number of successful FBAO removal in a shorter time with the LifeVac® device (82% in the first minute compared to 44% cases using DeCHOKER® and 67% using abdominal thrusts). Nevertheless, the three situations are not entirely comparable as the devices are theoretically recommended when the choking protocol fails [14,15].

When devices were compared with each other, both had similar success rates. Of the entire procedure, the most difficult step for the participants was the one related to fitting and keeping the mask to the victim's airway. This is a remarkable fact because although participants spent less time in the process with the LifeVac® device, they had more difficulties with the mask seal. In this line, the successful removal of a FBAO using devices depends on the generation of a strong negative pressure associated with an effective mask seal [19]. Previous studies using facemask also reported difficulty of use, especially for novices and above all with one-hand technique [27,28]. In this sense, further studies are needed to corroborate our preliminary results.

Regarding the management of a FBAO simulation acting according to recommended protocol, we have found that most participants (94.1%) gave abdominal thrusts and many also gave the back blows (76.5%). However, when it came to performing these steps correctly, we found that more participants who had received prior training did significantly better. As mentioned, the estimated success rate of executing the steps was lower than with the anti-choking devices. And, in turn, participants with prior training achieved a significantly higher rate. Although no previous studies on evaluating the effect of training on the choking recommended protocol have been found, our results might be related to other studies where different methods of training in BLS content, such as AED [29], and adult [30,31] and pediatric [32] CPR, improved performance outcomes.

Based on our results, we consider that the anti-choking devices are easy to use but a short training would be needed to reduce errors and take advantage of the devices' function. Further evidence on the efficacy of these devices is needed in order to be able to recommend their use as previously reported [17,18]. In agreement, the 2021 European Resuscitation Council Guidelines of Basic Life Support [33] maintain the prior recommendations for the management of a FBAO and insist that alternative techniques lack sufficient evidence for their introduction into the guidelines at this moment.

Limitations

Our study is not free of limitations. First, we conducted a simulation manikin study that involves two weaknesses: the manikin doesn't exactly reflect the characteristics of a real victim and participants might have different attitudes compared to a real FBAO scenario. Moreover, the manikin was a standard CPR model, not a specific one for FBAO. Although there are manikins for FBAO situations, they were not created for the evaluation of anti-choking devices effectiveness. Thus, no manikins exist that would allow reliable evaluation of the effectiveness of these devices. On the other hand, for the recommended protocol test we used a real person to simulate the FBAO instead of a manikin due to the particular characteristics of the manikin did not allow the technique to be executed correctly. Our sample was small and specific: parents and teachers in a kindergarten, which makes it necessary to interpret the results with caution and not to extrapolate them to the general population.

In addition, the success rate variable, calculated to compare quantitatively the three situations, has the limitation that in each test was calculated based on a different number of items (recommended protocol 8 items, LifeVac® 6 items, and DeCHOKER® 4 items).

Conclusions

Untrained laypeople, under simulated conditions and according to the manufacturer’s instructions, are able to handle LifeVac® and DeCHOKER® anti-choking devices in less than one minute. However, they have difficulties in applying the current recommended choking protocol. Further studies are needed to confirm whether the new devices could have a role in the FBAO management.

Abbreviations

FBAO: Foreign body airway obstruction

FDA: Food and Drug Administration

Declarations

Compliance with Ethical Standards

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Conflicts of interest/Competing interests: The authors declare that they have no conflict of interest.

Availability of data and material: The authors confirm that the main data supporting the findings of this study are available within the article. Additional data of this study are available from the corresponding author (CA-G) on request.

Code availability: N/A

Authors' contributions: AR-N conceived the idea. All authors designed the methodology. RB-F contacted with the kindergarten. AC-F, CA-G & ER-R collected the data. AC-F & CA-G performed the statistical analysis. AC-F wrote the first draft. CA-G carried out the first revision of the manuscript. All the authors reviewed the following versions of the manuscript and approved the final article.

Ethics approval: the protocol was waived by the local Research Ethics Committee because it did not involve the use of participant's health data, the collection of biological samples, or intervention on participants.

Consent to participate: Written informed consent to participate was obtained from all participants.

Consent for publication: Written informed consent to publish the data was obtained from all participants.

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Tables

Table 1. Characteristics of the participants.

Age $_{\text{in years}}$		40.0 (36.0 – 43.0)
Weight $_{\text{in kg}}$		70.0 (58.0 – 80.0)
Height $_{\text{in m}}$		1.7 (1.63 – 1.76)
Gender	Male	23 (45.1)
	Female	28 (54.9)
Training FBAO	Yes	19 (37.3)
	No	32 (62.7)
Years since training		5.0 (2.0 – 8.0)
Witnessed FBAO	Yes	11 (21.6)
	No	40 (78.4)
Years since witnessed FBAO		10.0 (8.0 – 17.5)
Intervened FBAO	Yes	6 (54.5)
	No	5 (45.5)
Feel to be able to solve the FBAO	Yes	28 (54.9)
	No	23 (45.1)

FBAO: Foreign Body Airway Obstruction

Continuous variables [median (interquartile range)]

Categorical variables [absolute frequency (relative frequency)]

Table 2. Descriptive analysis of the performance of the steps recommended for the treatment of the adult victim with FBAO.

			Overall (n=51)	Trained (n=19)	Untrained training (n=32)	χ^2 p-value
Encouraging to cough		Yes	23 (45.1)	13 (68.4)	10 (31.3)	6.653 0.010
		No	28 (54.9)	6 (31.6)	22 (68.6)	
Giving 5 back blows		Yes	39 (76.5)	16 (84.2)	23 (71.9)	1.008 0.315
		No	12 (23.5)	3 (15.8)	9 (28.1)	
Giving back blows correctly (n=39)		Yes	33 (84.6)	16 (100.0)	17 (73.9)	4.933 0.026
		No	6 (15.4)	0	6 (26.1)	
Giving back blows with an incorrect number (n=6)			6 (11.8)	0	6 (18.8)	1.800 0.180
Giving 5 abdominal thrusts		Yes	48 (94.1)	19 (100)	29 (90.6)	1.893 0.169
		No	3 (5.9)	0	3 (9.4)	
Giving abdominal thrusts correctly (n=48)		Yes	14 (29.2)	10 (52.6)	4 (13.8)	8.381 0.004
		No	34 (70.8)	9 (47.4)	25 (86.2)	
Giving abdominal thrusts with an incorrect number			20 (39.2)	6 (31.6)	14 (43.8)	1.218 0.270
Performance of the abdominal thrust (n=48)	Standing behind the victim and putting both arms round the upper part of the abdomen	Yes	47 (97.9)	19 (100)	28 (87.5)	2.577 0.108
		No	1 (2.1)	0	4 (12.5)	
	Leaning the victim forwards; clenching one hand and place it between the umbilicus and the ribcage	Yes	25 (52.1)	13 (68.4)	12 (37.5)	4.561 0.033
		No	23 (47.9)	6 (31.6)	20 (62.5)	
	Grasping both hands and pulling sharply inwards and upwards	Yes	45 (93.8)	18 (94.7)	27 (84.4)	1.233 0.267

	No	3 (6.3)	1 (5.3)	5 (15.6)	
Continue to 5 back blows and 5 abdominal thrusts	Yes	18 (35.3)	9 (47.4)	9 (28.1)	1.933 0.164
	No	33 (64.7)	10 (52.6)	23 (71.9)	
Continue to 5 back blows and 5 abdominal thrusts correctly (n=18)	Yes	12 (66.7)	7 (77.8)	5 (55.6)	1.000 0.317
	No	6 (33.3)	2 (22.2)	4 (44.4)	
Continue to abdominal thrust only		6 (11.8)	2 (10.5)	4 (12.5)	0.010 0.920
Starting CPR for victim's unresponsiveness	Yes	30 (58.8)	12 (63.2)	18 (56.3)	0.235 0.628
	No	21 (41.2)	7 (36.8)	14 (43.8)	
Performed all steps	Yes	8 (15.7)	5 (26.3)	3 (9.4)	2.687 0.108
	No	43 (84.3)	14 (73.7)	29 (90.6)	
Performed all steps correctly	Yes	3 (5.9)	2 (10.5)	1 (3.1)	1.180
	No	48 (94.1)	17 (89.5)	31 (96.9)	0.277
Estimated success rate (in %)	50.0 (38.0 – 75.0)		75.0 (50.0-88.0)	38.0 (25.0-63.0)	0.003†
Time until back blows (in seconds)	13.1 (10.7 – 15.3)		12.4 (10.7-14.2)	14.1 (10.2-15.8)	0.271†
Time until abdominal thrust (in seconds)	25.2 (19.1 – 32.9)		23.5 (16.2-26.4)	27.0 (20.8-34.2)	0.137†
Overall procedure time (in seconds)	48.3 (42.1 – 60.7)		48.6 (43.0-59.6)	47.4 (41.7-62.1)	0.778†
Overall time of participants who completed all steps (n=8) (in seconds)	55.1 (46.9 – 68.7)		60.7 (48.7-73.4)	46.8*	0.143†

FBAO: Foreign Body Airway Obstruction; CPR: cardiopulmonary resuscitation

* n=3 Unable to calculate interquartile range

Continuous variables [median (interquartile range)]

Categorical variables [absolute frequency (relative frequency)]

† Mann-Whitney U test

Table 3. Descriptive analysis of the performance of the treatment of the adult victim with FBAO with LifeVac® and DeCHOKER® device.

	LifeVac®		DeCHOKER®		p-valor
Inserting the mask into the device	Yes	46 (90.2)	–		–
	No	5 (9.8)			
Place the mask covering nose and mouth of the victim correctly	Yes	40 (78.4)	Yes	46 (90.2)	0.109†
	No	11 (21.6)	No	5 (9.8)	
Fixing the mask to the victim's airway	Yes	42 (82.4)	Yes	45 (88.2)	0.453†
	No	9 (17.6)	No	6 (11.8)	
Push in handle	Yes	50 (98.0)	–		–
	No	1 (2.0)			
Pull handle (LifeVac®) // Pull the plunger out with force (DeCHOKER®)	Yes	50 (98.0)	Yes	50 (98.0)	1.000†
	No	1 (2.0)	No	1 (2.0)	
Keeping the mask fixed to the victim's airway throughout the procedure	Yes	29 (56.9)	Yes	34 (66.7)	0.405†
	No	22 (43.1)	No	17 (33.3)	
Performed all steps correctly	Yes	26 (51.0)	Yes	29 (56.9)	0.678†
	No	25 (49.0)	No	22 (43.1)	
Estimated Success rate	100 (83.0 – 100.0)		100 (75.0 – 100.0)		0.796*

FBAO: Foreign Body Airway Obstruction

Continuous variables [median (interquartile range)]

Categorical variables [absolute frequency (relative frequency)]

* Wilcoxon test

† McNemar test

Table 4. Comparison of procedure time between recommended protocol, LifeVac® and DeCHOKER®.

	Recommended protocol	LifeVac®	DeCHOKER®	p-value	RP *vs* L	RP *vs* D	L *vs* D
Time until device fitting on the victim		31.9 (24.8 – 38.2)	39.6 (29.8 – 57.2)	< 0.001*			
Overall time	48.3 (42.1 – 60.7)	39.3 (31.4 – 44.4)	55.6 (38.9 – 71. 0)	< 0.001†	< 0.001*	0.115*	< 0.001*

L: LifeVac®; D: DeCHOKER®; RP: Recommended protocol

* Wilcoxon test

† Friedman test

Figures

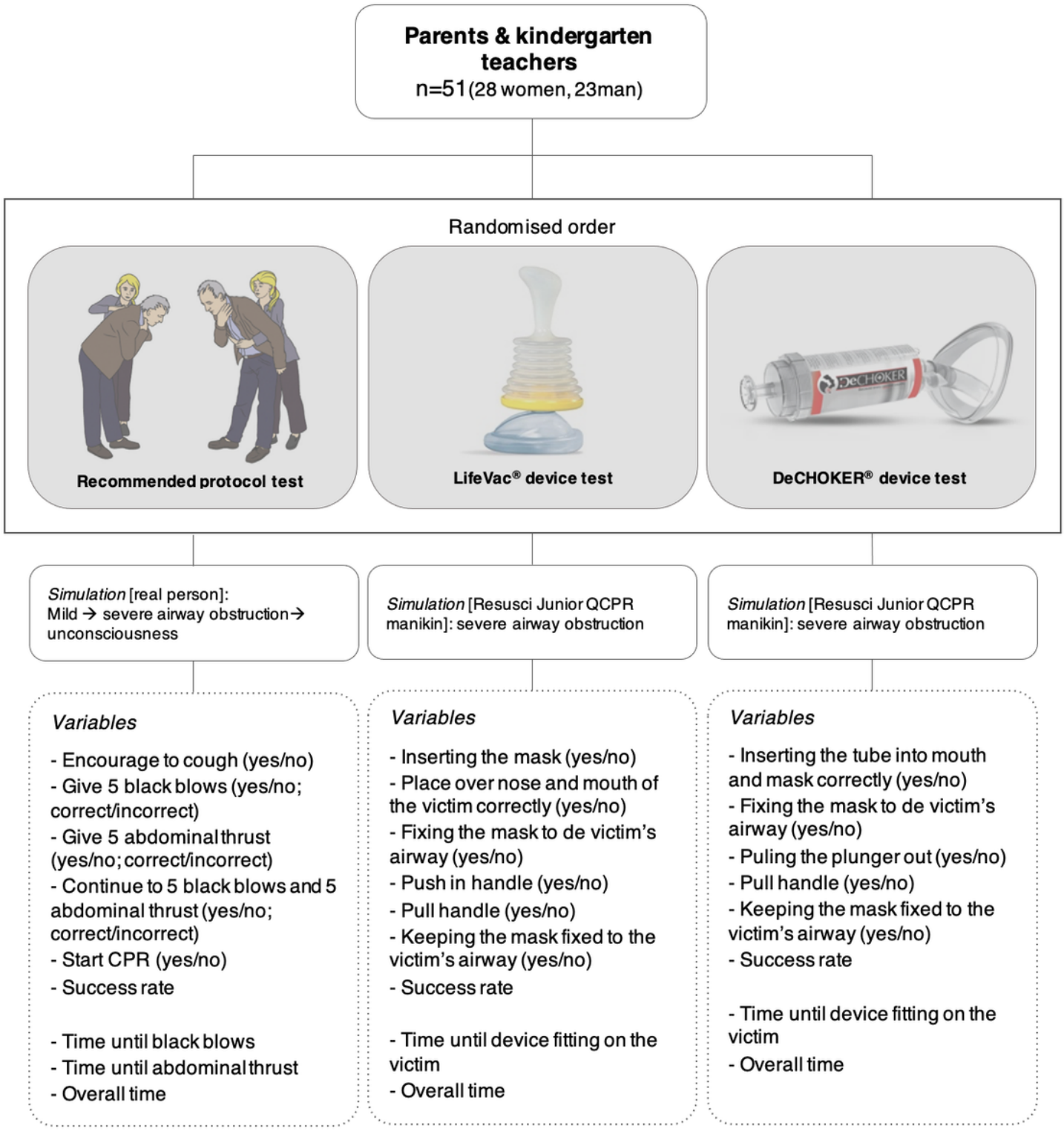

Figure 1

Flow chart of the design of the study.

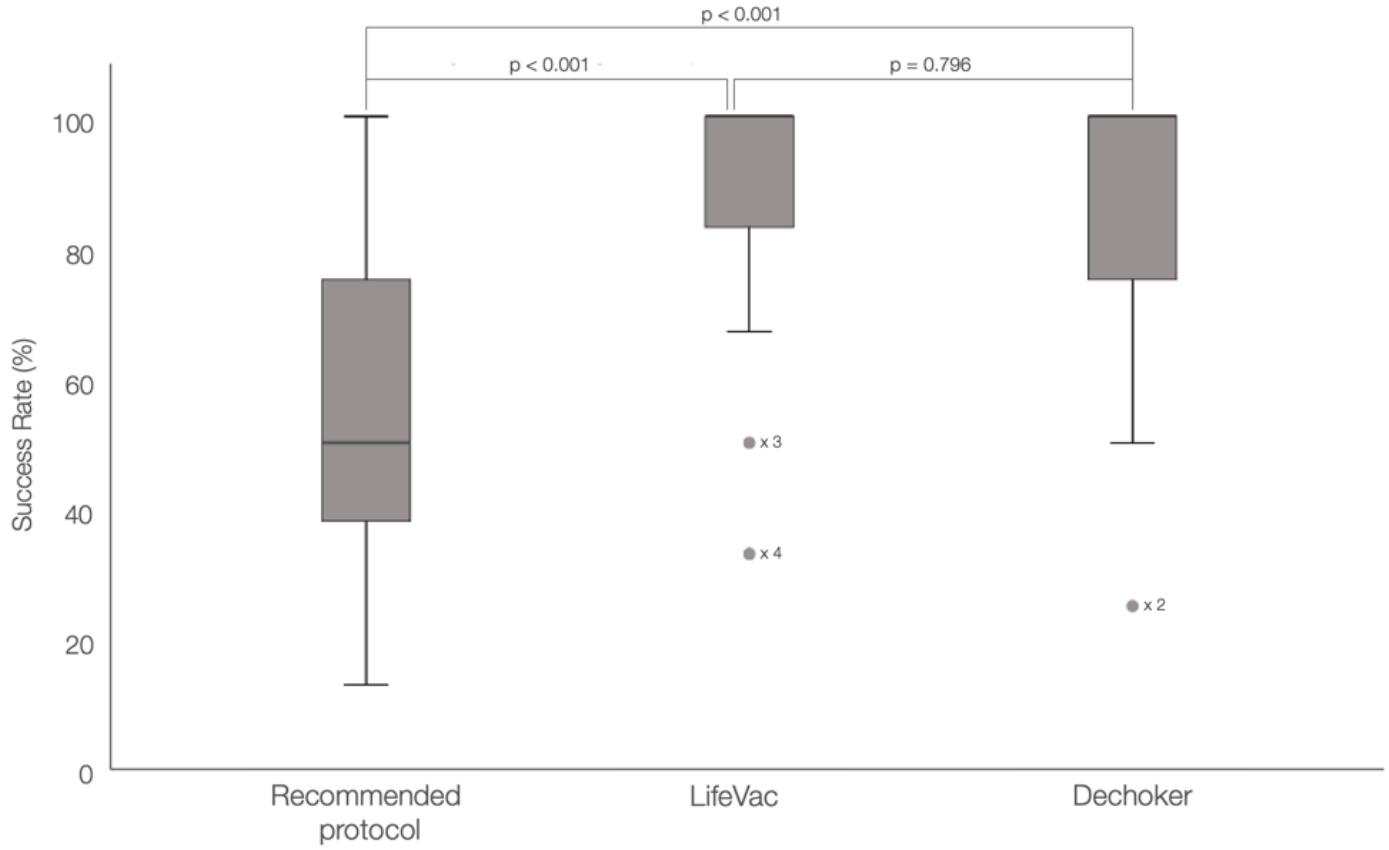

Figure 2

Comparison of estimated success rate between three tests. Grey dots symbolize outliers.

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Article

Phase One of a Global Evaluation of Suction-Based Airway Clearance Devices in Foreign Body Airway Obstructions: A Retrospective Descriptive Analysis

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Abstract: Background: Choking is a prevalent source of injury and mortality worldwide. Traditional choking interventions, including abdominal thrusts and back blows, have remained the standard of care for decades despite limited published data. Suction-based airway clearance devices (ACDs) are becoming increasingly popular and there is an urgent need to evaluate their role in choking intervention. The aim of this study was to describe the effectiveness (i.e., resolution of choking symptoms) and safety (i.e., adverse events) of identified airway clearance devices interventions to date. Methods: This retrospective descriptive analysis included any individual who self-identified to manufacturers as having used an ACD as a choking intervention prior to 1 July 2021. Records were included if they contained three clinical variables (patient's age, type of foreign body, and resolution of choking symptoms). Researchers performed data extraction using a standardized form which included patient, situational, and outcome variables. Results: The analysis included 124 non-invasive (LifeVac©) and 61 minimally invasive (Dechoker©) ACD interventions. Median patient age was 40 (LifeVac©, 2–80) and 73 (Dechoker©, 5–84) with extremes of age being most common [<5 years: LifeVac© 37.1%, Dechoker© 23.0%; 80+ years: 27.4%, 37.7%]. Food was the most frequent foreign body (LifeVac© 84.7%, Dechoker© 91.8%). Abdominal thrusts (LifeVac© 37.9%, Dechoker© 31.1%) and back blows (LifeVac© 39.5%, Dechoker© 41.0%) were often co-interventions. Resolution of choking symptoms occurred following use of the ACD in 123 (LifeVac©) and 60 (Dechoker©) cases. Three adverse events (1.6%) were reported: disconnection of bellows/mask during intervention (LifeVac©), a lip laceration (Dechoker©), and an avulsed tooth (Dechoker©). Conclusion: Initial available data has shown ACDs to be promising in the treatment of choking. However, limitations in data collection methods and quality exist. The second phase of this evaluation will be an industry independent, prospective assessment in order to improve data quality, and inform future choking intervention algorithms.

Keywords: foreign body airway obstruction; anti-choking; prehospital; basic life support; resuscitation

1. Introduction

Despite being preventable, foreign body airway obstructions (FBAO, choking) are a significant source of injury and mortality worldwide [1–5]. In the United States alone, over 5000 deaths from choking are reported annually [6]. Further, for each pediatric fatality due to choking, it is reported that 110 non-fatal events present to emergency departments, of which 10% result in-hospital admission [7]. Extrapolating to the entire lifespan, choking injuries result in a considerable burden on global healthcare systems and more importantly, preventable injury and loss of life.

Prehospital choking interventions have remained largely unchanged for several decades and consist of a combination of abdominal thrusts, back blows and chest compressions or thrusts [8–10]. However, the evidence for these techniques is almost entirely case series data and there is uncertainty over which intervention (if any) is superior [8].

Externally applied suction-based airway clearance devices (ACDs) have been introduced as a possible alternative when traditional techniques are unsuccessful [11,12]. Two types are currently marketed, those which are non-invasive (e.g., LifeVac©, LifeVac LLC, Nesconset, New York, NY, USA) and those which are minimally invasive (e.g., DeChoker©, LLC, Wheat Ridge, CO, USA) [11,12]. A third device is in the pre-market, fundraising phase [13]. Despite their increasing popularity, there is not yet sufficient data available in academic literature to fully assess their safety and effectiveness [8,9,14].

There is an urgent need for more data in this field as choking remains a significant cause of death and injury [1–5]. A new intervention for prehospital lay rescuers and emergency medical service (EMS) teams would be welcomed, provided it can be demonstrated to not cause harm and assist with choking relief. As the public gains awareness and the availability of ACDs increases, resuscitation councils who determine choking treatment guidelines must be able to clearly comment on their role [11,12].

This retrospective analysis is the first phase in a multi-method global evaluation of ACDs, which aims to fill this knowledge gap [15]. The objective of this study is to describe what situational and patient factors have been identified in cases where ACDs were used, as well as report on patient outcomes. These results will inform the next phase of this evaluation which will be the development of a prospective, industry independent database of ACD cases.

2. Methods

This is a retrospective study evaluating ACD interventions from 1 January 2016, to 30 June 2021, globally. The start date represents the earliest report of an ACD intervention to device manufacturers. A detailed description of the study development and methodology has been published previously [15]. A brief summary is presented below. The study was approved by the Human Research Ethics Committee (HREC) of the University of New South Wales (HC210242) on 25 May 2021.

3. Data Collection

Participants in the study include individuals who self-identified to device manufacturers as having used an ACD on someone choking between 1 January 2016, and 1 July 2021. A waiver of consent for the secondary use of a dataset was granted by the HREC. Device manufacturers have developed their own methods to allow customers who have used their ACD on a choking individual to report their experience and they agreed to provide all cases reported to them, regardless of outcome, for this initial evaluation. Due to the novelty of ACDs and relative rarity of interventions, investigation into a single health system was not feasible for this preliminary work and this represents the population of all cases reported to date.

Presently, two manufacturers are primarily responsible for the production of suction-based ACDs around the world. Each represents a different ACD type, and although they have a similar goal, the contrasting designs make it important to distinguish datasets. Non-invasive ACDs have no intraoral component, whereas minimally invasive do. These

both differ from invasive (or deep) suction devices (e.g., Laerdal© V-Vac®) which have no external facemask that anchors the device and therefore can extend deep into the airway [16]. Figure 1 displays both types of ACD devices.

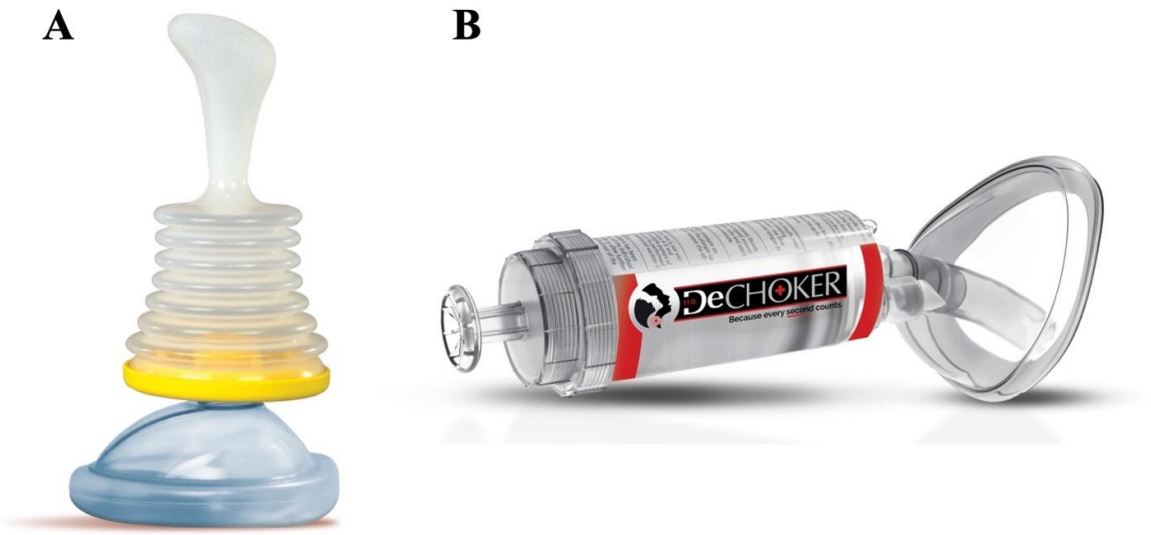

Figure 1. (**A**) LifeVac© airway clearance device (**B**) DeChoker© airway clearance device [images supplied by the respective manufacturers with permission to include].

3.1. Non-Invasive ACD

LifeVac LLC produces the LifeVac© ACD [11]. It consists of a facemask attached to compressible bellows and a one-way valve. The LifeVac database of ACD interventions relies primarily on their online reporting system (Supplementary File S1, Table S1) [17]. All purchasers are informed of this system in the shipping package, and it is promoted on their social media platforms. Once a user reports their experience, an administrator from one of their regional offices is notified and subsequently follows up with each user to confirm the details of the choking event and validate the report submission.

A standardized reporting form is used to record data from each clinical intervention (Supplementary File S1, Table S2). No intervention is recorded into the database until an administrator connects with the user. LifeVac LLC provided all their collected data (regardless of outcome) to the research team electronically from their compiled clinical evaluation reports.

3.2. Minimally Invasive ACD

DeChoker LLC produces the DeChoker© ACD [12]. It is designed with a face mask attached to a cylinder with a plunger. In the face mask is a 3-inch (7.6 cm) tube that is directed into the oropharynx to act as a tongue depressor. The tube also is the passageway for the negative pressure suction and has a diameter of 0.75-inch (1.9 cm).

The data obtained and how they are collected differs depending on geographic region. Outside of the United States of America (USA), most sales are directed towards care facilities via local distributors. Care facilities are encouraged to report any interventions regardless of outcome back to the distributors who then inform DeChoker LLC. In the USA, while some cases are also from care facilities, others are from individuals who self-identify directly to DeChoker either via an online reporting system or the device's social media platforms.

Regardless of region, once identified, a member of the DeChoker team attempts to follow up with users to confirm details and validate the database entry. No standardized reporting form is used consistently to record data by administrators. Dechoker LLC provided their data to the research team in several electronic documents consisting of

intervention reports from different global regions (namely North America and Europe) and social media posts.

3.3. Variables

Key demographical, clinical and safety data were categorized for analysis. Age was classified in six groups for analysis: under 1, 1 to 5, 6 to 18, 19 to 64, 65 to 80, and over age 80. Pre-existing medical conditions were classified into five groups: cardiovascular disease, respiratory disease, physical disability, neurocognitive disorder, and other.

Choking severity was classified into three categories: (a) partial (also known as incomplete or mild) is defined as when the patient can cough forcefully, cry, speak or still perform good air exchange; (b) complete (also known as severe) is defined as when the patient has a weak ineffective cough, unable to speak or cannot perform good air exchange (e.g., making only high pitch noise); and (c) unresponsive [18,19].

Choking location was grouped as: home, school/daycare, nursing home, or other. Type of foreign body was classified as: food, toy, or other. Non-ACD interventions were separated into abdominal thrusts (previously known as Heimlich maneuver), back blows, chest thrusts or compressions, finger sweep or none. ACD user profile categories were relative, healthcare worker, self, or other. An attempt with the ACD was defined as one plunge-release cycle.

All variables had a planned 'not recorded' option included as data completeness was anticipated to be variable due to the differences in intervention follow up and record keeping amongst manufacturers.

3.4. Outcomes

In the current study, both effectiveness and safety were described. Effectiveness was determined as cases where no further choking intervention was required (i.e., resolution of symptoms, yes/no) after use of the ACD, and survival (alive/dead) [20]. No further choking intervention being deemed needed by the rescuer was used as a surrogate marker of effectiveness as relief of obstruction could not be directly assessed. Safety was assessed by summarizing adverse events. Adverse events could be patient-related (e.g., injury to face from device use) or device-related (e.g., ACD broke when being applied).

3.5. Data Analysis

Two researchers (SO, KV) reviewed the raw clinical data and performed data extraction via a standardized form (Supplementary File S2). Subsequently, another researcher (CD) reviewed the extracted data and performed a secondary check of a random 20% of the entries for accuracy and consistency amongst the two extractors.

It was decided *a priori* that, for a record to be included in the final analysis, three clinical data points were required: the patient's age, a description of the foreign body material and commentary on the primary outcome. There were 140 LifeVac© interventions recorded, of which 124 (88.6%) were eligible for inclusion. There were 111 Dechoker© interventions recorded, of which 61 (55.0%) were eligible for inclusion. The one exception to this was for adverse events. For complete transparency, we decided to review all the cases included in the database (even those not meeting inclusion criteria) so that all potential adverse events were known.

Descriptive statistics were performed to summarize the data. Age and number of ACD attempts were reported as median and interquartile range (IQR). Categorical data were expressed as frequency distributions (*n* (%)).

4. Results

There have been 124 LifeVac© and 61 Dechoker© interventions (which met inclusion criteria for analysis) since 2016. Table 1 summarizes the characteristics of the person experiencing the FBAO.

Table 1. Characteristics of patients with a foreign body airway obstruction intervened by an airway clearance device.

		Non-Invasive ACD (LifeVac©) N = 124	Minimally Invasive ACD (DeChoker©) N = 61
Patient Gender (*n*, %)			
	M	56 (45.2)	24 (39.3)
	F	66 (53.2)	36 (59.0)
	Not recorded	2 (1.6)	1 (1.6)
Patient age (median, IQR)		40 (2–80)	73 (5–84)
Patient age groups (*n*, %)			
	0–1 years	19 (15.3)	5 (8.2)
	1–5 years	27 (21.8)	9 (14.8)
	6–18 years	9 (7.3)	8 (13.1)
	18–64 years	22 (17.7)	6 (9.8)
	65–80 years	13 (10.9)	10 (16.4)
	80+ years	34 (27.4)	23 (37.7)
Pre-existing medical conditions (*n*, %)			
	Cardiovascular disease	4 (3.2)	0 (0.0)
	Neurocognitive disorder	48 (38.7)	7 (11.5)
	Physical disability	32 (25.8)	2 (3.2)
	Respiratory disease	1 (0.8)	1 (1.6)
	Wheelchair use	18 (14.5)	2 (3.2)
	Other	16 (12.9)	1 (1.6)
	None	47 (37.9)	- *
	Not recorded	8 (6.5)	48 (78.7)
Known history of dysphagia or aspiration (*n*, %)			
	Yes	17 (13.7)	3 (4.8)
	Not recorded	107 (84.3)	58 (95.2)

ACD = airway clearance device. * Not able to be calculated as these data were not routinely collected and only identified if volunteered by report provided.

LifeVac© ACDs have a wide representation across the age span (median age, IQR = 40, range = 2–80 years) with about one-third of the interventions being younger than five years and another third aged 65 years and older. Pre-existing medical co-morbidities were common (59.6% having at least one), with neurocognitive disorders (38.7%) and physical disabilities (25.8%) being the most prevalent (Table 1). They were deployed for both partial (27.4%) and complete (41.9%) FBAO. For these ACDs, choking events were much more common at home (22.6%) or long-term care facilities (36.3%) compared to schools/daycares (0.8%).

Dechoker© ACDs were commonly used in a more elderly population (median age, IQR = 73, range = 5–84 years) with over half being 65 years and older. Medical comorbidities were documented infrequently (18.0%), though neurocognitive conditions were also the most prevalent (11.5%). Home (34.4%) and long-term care (39.3%) were the most common geographic locations, compared to schools (0.0%).

For both ACD types, females were more commonly treated (LifeVac©-53.2%; Dechoker©-59.0%) and a relatively small number of patients had a known history of dysphagia or aspiration (13.7%; and 4.8%). Similarly, food was the predominant foreign body for both ACD types (84.7%; and 91.8%). Besides food and toys, other foreign bodies included:

plastic, medication pills, saliva/mucus/phlegm, emesis, fluid, and coins. Table 2 further summarizes the FBAO details.

Table 2. Characteristics of the foreign body airway obstruction in patients intervened with an airway clearance device.

		Non-Invasive ACD LifeVac© (N = 124)	Minimally Invasive ACD Dechoker© (N = 61)
Severity of FBAO (*n*, %)			
	Partial	34 (27.4)	5 (8.2)
	Complete	52 (41.9)	8 (13.1)
	Unresponsive	24 (19.4)	11 (18.0)
	Not recorded	14 (11.3)	37 (60.7)
Geographical location of FBAO (*n*, %)			
	Home	28 (22.6)	21 (34.4)
	School/Daycare	1 (0.8)	0 (0.0)
	Long-term care facility/Nursing home	45 (36.3)	24 (39.3)
	Other	11 (8.9)	2 (3.3)
	Not recorded	39 (31.5)	14 (23.0)
Foreign body (*n*, %)			
	Food	105 (84.7)	56 (91.8)
	Toy	1 (0.8)	1 (1.6)
	Other	18 (14.5)	4 (6.6)

ACD = airway clearance device; FBAO = foreign body airway obstruction.

The pattern of non-ACD interventions were similar in both groups. Abdominal thrusts (LifeVac©-37.9% and Dechoker©-31.1%) and back blows (39.5% and 41.0%) were frequently utilized, while chest thrusts or compressions (3.2% and 3.3%) and finger sweeps (7.3% and 6.6%) were rarer. The median number of ACD attempts required before choking was considered resolved by the rescuer was two for both types. Table 3 presents data regarding the choking interventions and outcomes.

LifeVac© ACDs were the last intervention in 123 cases (of 124) and all patients subsequently survived. EMS was called in 42.7% of cases, and subsequent hospital admission occurred in 13.6%. There was one adverse outcome where an untrained individual attempted to use the device, but the bellows/mask disconnected prior to use due to incorrect assembly. The patient had a traditional technique subsequently applied and survived the event.

Dechoker© ACDs were the last intervention in 60 cases (of 61). All patients survived, except in one case where FBAO was relieved, but survival was not confirmed. EMS was called in 35.1% of cases, and subsequent hospitalization occurred in 2.8%. Two adverse events were reported. One where the user had difficulty inserting the tongue depressor into the panicked patient's mouth when they were conscious, and as a result, the patient had a cut on their lip from the device. The second was where a person's tooth was avulsed when the tongue depressor was inserted into the oropharynx.

Table 3. Intervention and outcome data for patients with a FBAO intervened by an airway clearance device.

		Non-Invasive ACD LifeVac© (N = 124)	Minimally Invasive ACD Dechoker© (N = 61)
Pre-ACD Intervention			
	Abdominal thrusts	47 (37.9)	19 (31.1)
	Back blows	49 (39.5)	25 (41.0)
	Chest thrusts or compressions	4 (3.2)	2 (3.3)
	Finger / mouth sweep	9 (7.3)	4 (6.6)
	Multiple interventions	25 (20.2)	15 (24.6)
	No intervention	11 (8.9)	10 (16.4)
	Not recorded	31 (25.0)	17 (27.9)
ACD User			
	Relative	42 (33.8)	22 (36.1)
	Healthcare worker	12 (9.7)	2 (3.3)
	Self	1 (0.8)	0 (0.0)
	Other	10 (8.1)	21 (34.4)
	Not recorded	59 (47.6)	16 (26.2)
Median number of ACD attempts to FBAO relief (IQR; range)		2 (1–3; 1–12)	2 (1–4; 1–12)
Effectiveness Outcomes			
	No Further Intervention Required Post-ACD	123	60
	Survival	123	59 *
Safety Outcomes			
	EMS called	33 (42.9) [1]	13 (35.1) [2]
	Hospital admission	9 (13.6) [3]	1 (2.8) [4]
	Adverse events reported	1 (1.1) [5]	2 (5.4) [2]

ACD = airway clearance device; FBAO = foreign body airway obstruction. Missing values: [1] $n = 77$; [2] $n = 37$; [3] $n = 66$; [4] $n = 36$; [5] $n = 94$. * One record did not confirm the survival status.

5. Discussion

Airway clearance devices appear to have the potential to help save lives. This study is the first of a multi-phase global evaluation of ACDs that aims to determine their effectiveness and clarify their role (if any) in future choking intervention algorithms [15]. Prior to this study, most published data were limited to mannequin studies, case reports with few entries, or only focused on a subset of the population [8,9,14,21,22]. This study included all ACD intervention data available, incorporating all ages from all regions of the world.

The initial data described are promising. LifeVac© and Dechoker© ACDs were the last intervention before resolution of choking symptoms in 123 and 60 cases, respectively. However, current data collection and quality processes require further research before definite conclusions are made.

Data collection via self-reporting is required presently as ACDs are not prevalent enough to investigate a particular health region for interventions. Self-reporting is known to predispose the results to exceptional (successful) cases [23–25]. This makes it inappropriate to conclude that the effectiveness of these devices is 99.2% (LifeVac©) and 98.4% (Dechoker©) as we have no way to determine the true denominator (i.e., total number of

times an ACD has been utilized in a FBAO). Further, self-reporting to manufacturers is much less likely to occur in cases where ACDs were used and did not work [23–25].

Data quality also limits interpretation of this data. The self-reported data are not supported by medical records and were not collected by trained medical professionals. This results in important details being omitted from the data. For example, 35 patients were reported as unresponsive during ACD use, but only 10 had EMS activated. Medical oversight would improve recognition of conflicting information, resulting in further questioning and clarity in our understanding of the situation.

Like all choking intervention research, confirmation of the severity of the obstruction is challenging because it relies on bystander interpretation of the patient's condition and symptoms. This data point is important however because traditional teaching recommends only encouraged forceful coughing for partial cases, due to the potential for harms or worsening the obstruction from interventions [18,19]. In our study, both LifeVac© (38.7%) and Dechoker© (68.9%) ACDs had a significant proportion of cases which were classified as a partial obstruction or unknown severity. It is possible that the cases with a partial obstruction may not have required any intervention to clear. In these situations, it is unclear if the ACDs truly prevented further deterioration or just appeared to have benefit due to early use in mild cases.

Despite the early application of ACDs in some cases, we fortunately found that reported adverse outcome rates were low and relatively benign for ACDs compared to those following other choking interventions such as abdominal thrusts or chest compressions (e.g., organ rupture and vascular injury) [8]. A recent cadaver evaluation, conducted without industry involvement, found injury to the tongue following use of the Dechoker© [26]. This was identified in our human study as well. No injury was found due to LifeVac in the cadaver evaluation [26]. Other studies have limited information on safety [8,9,14,21,22]. Unfortunately, self-reporting has been shown to have poor sensitivity for detecting adverse events [24,25], which is compounded in this study by limited patient follow up and the data quality concerns described previously. Any future evaluation of these devices requires specific questioning around potential adverse events from medical personnel to improve sensitivity.

The criticism of these data, however, needs to be interpreted in the context of what is available for other choking interventions. Current treatment recommendations for traditional interventions are based on only one cross-sectional study, and six case series published between 1979 and 2017 [8,9]. Figure 2 compares the number of published cases reporting relief of FBAO and adverse events for ACDs for traditional interventions. The two studies that contribute the largest amount of data also use a self-reporting methodology [27,28]. It is clear we need more investigation and better data for all choking interventions, not just ACDs.

The cases in the current study should not change current practice. However, they should encourage researchers and medical professionals to ask more questions and investigate further. LifeVac© and Dechoker© ACDs were used in 123 and 59 situations, respectively, where a bystander believed someone was choking and were the last intervention before the choking symptoms resolved. In 109 and 50 of these cases, other traditional interventions had been attempted prior but were not deemed by the rescuer to relieve the symptoms of choking. The potential of a novel layperson treatment for choking deserves attention, especially in the absence of high-quality data for other techniques.

To improve our present understanding, attention must be paid to data collection and quality. While a self-reporting methodology is inevitable presently, data that are prospectively collected, industry-distanced, with medical oversight and follow up, will shed more light on the role ACDs could play in the treatment of choking. One such study is ongoing, though multiple investigations are needed [15].

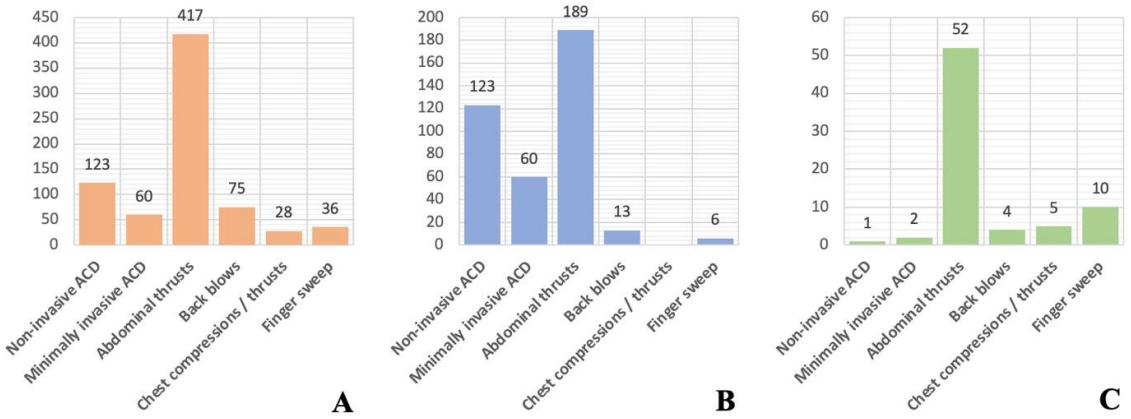

Figure 2. Reported counts in academic literature of effectiveness and safety outcomes for airway clearance devices and traditional FBAO interventions: (**A**) Relief of FBAO (**B**) Survival* (**C**) Adverse events [8,9]. * *Chest compressions/thrusts had survival with good neurological outcome reported, not survival.*

6. Conclusions

Non-invasive and minimally invasive ACDs are novel interventions with positive initial findings. Prospective evaluation, independent of manufacturers, that improves data quality will further determine the devices respective roles in the response of healthcare workers and layrescuers to a choking person.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19073846/s1, Table S1: LifeVac© online use reporting form data fields (16); Table S2: LifeVac© clinical evaluation report data fields; Supplementary File S2—Standardized reporting tool used by researchers for data extraction.

Author Contributions: Conceptualization, C.L.D., A.E.P., A.C.Q. and D.S.; methodology, C.L.D., A.E.P., A.C.Q. and D.S.; formal analysis, C.L.D., K.V. and S.O.; investigation, C.L.D., K.V. and S.O.; resources, A.E.P.; writing—original draft preparation, C.L.D., K.V. and S.O.; writing—review and editing, C.L.D., K.V., S.O., A.C.Q., D.S. and A.E.P.; supervision, C.L.D. and A.E.P. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Human Research Ethics Committee (HREC) of the University of New South Wales (HC210242 25 May 2021).

Informed Consent Statement: Consent was waived by the HREC as the data was the secondary use of an previously collected dataset.

Data Availability Statement: Restrictions apply to the availability of these data. Data were obtained from manufacturers and are available with the permission of the respective organizations.

Conflicts of Interest: The authors have no competing interest, financial or otherwise, to declare. Manufacturers of airway clearance devices agreed to participate in the study in three areas: identification and recruitment of participants, distributing the research survey as needed, and providing researchers access to their existing databases. Manufacturers were not involved in study design, nor do they have any financial involvement. Manufacturers will not have access to data (other than what they provide themselves), nor will they be permitted to view the results or manuscripts prior to publication.

Disclaimer: The views expressed in this article are that of the authors and are not an official position of the organizations we are affiliated with.

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Clinical paper

A 2-year prospective evaluation of airway clearance devices in foreign body airway obstructions

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Abstract

Aim: To collect, analyze and report the first prospective, industry-independent, data on airway clearance devices as novel foreign body airway obstruction interventions.

Methods: We recruited adult airway clearance device users between July 1, 2021 and June 30, 2023 using a centralized website and email follow-up. The data collection tool captured patient, responder, situation, and outcome variables. Multi-step respondent validation occurred using electronic and geolocation verification, a random selection follow-up process, and physician review of all submitted cases.

Results: We recruited 186 airway clearance device users (LifeVac©:157 [84.4%]; Dechoker©:29 [15.6%]). LifeVac© was the last intervention before foreign body airway obstruction relief in 151 of 157 cases. Of these, 150 survived to discharge. A basic life support intervention was used before LifeVac© in 119 cases, including the 6 cases where LifeVac© also failed. We identified two adverse events using LifeVac© (perioral bruising), while we could not ascertain whether another 7 were due to the foreign body or LifeVac© (3 = airway edema; 3 = oropharyngeal abrasions; 1 = esophageal perforation). Dechoker© was the last intervention before obstruction relief in 27 of 29 cases and all cases survived. A basic life support intervention was used before Dechoker© in 21 cases, including both where Dechoker© also failed. We identified one adverse event using Dechoker© (oropharyngeal abrasions).

Conclusion: Within these cases, airway clearance devices appear to be effective at relieving foreign body airway obstructions. However, this data should be considered preliminary and hypothesis generating due to several limitations. We urge the resuscitation community to proactively evaluate airway clearance devices to ensure the public remains updated with best practices.

Keywords: FBAO, Anti-choking, Prehospital, Basic life support, Resuscitation, ACD

Introduction

Foreign body airway obstructions (FBAO or choking) remain a preventable injury with high mortality and morbidity.[1–4] Longstanding techniques taught for relief of FBAO include some combination of abdominal thrusts, back blows, or chest compressions/thrusts, yet limited contemporary data on these basic life support (BLS) interventions exists. Despite being studied since the 1970s, a recent systematic review found only six case series and one cross-sectional study evaluating these techniques.[5,6]

Recently, novel choking interventions are being promoted. Airway clearance devices (ACDs) are non-powered suction-based devices being marketed by manufacturers as an alternative to traditional choking interventions. Two manufacturers are the main suppliers of ACDs. LifeVac© (LifeVac LLC, Nesconset, New York, NY, USA) produces a device consisting of a facemask with a one-way valve connected to compressible bellows which are entirely non-invasive.[7] In contrast, Dechoker© (Dechoker© LLC, Wheat Ridge, CO, USA) has an intraoral component (in addition to a cylindrical plunger) that acts as a tongue depressor.[8]

Several studies have previously reported on FBAO cases intervened by ACDs.[9–12] However, these have had significant limitations that have bias-introducing potential including data collection conducted by manufacturers, being retrospective in nature, having small sample sizes, or incomplete case data to accurately describe the

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effectiveness of the intervention in detail.[13] To address these research gaps, we conducted the first prospective study on ACD interventions for FBAO with systematically collected, analyzed, and reported data independent from manufacturers.

Methods

Study design

This prospective, observational, international study recruited participants between July 1, 2021, and June 30, 2023. A detailed study protocol was published *a priori* and is briefly discussed below.[14] Prior to study launch, both ACD companies (LifeVac© and Dechoker©) agreed to assist solely with identification and recruitment of participants, and had no role in study design, data analysis or reporting. The study was approved by the Human Research Ethics Committee of the University of New South Wales (HC210242) on May 25, 2021. Reporting of the study adhered to all relevant sections of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[15]

Eligibility criteria and participant recruitment

We recruited eligible individuals, aged 18 years or older, who used an ACD to attempt to dislodge a FBAO during the study period. The only exclusion criterion was an inability to read and write in English or Spanish due to availability of the data collection tool in those languages.

We set up a centralized website for recruitment where eligible individuals could access the data collection tool (https://www.acdresearch.org). Both ACD companies included information on their own websites and social media accounts which made potential participants aware of the study and provided links to our study's independent website. Finally, a one-time standardized email was sent by the research team to any eligible individuals that the ACD manufacturers were made aware of via their own tracking systems.

Data collection and validation

We administered the data collection tool using digital survey software (Qualtrics, Provo, UT). The tool was developed by the research team, and then administered to 10 individuals without healthcare or research experience, to optimize its format and comprehension (e.g., added in examples following medical terms such as: conscious [*still awake, eyes open*] or unconscious [*passed out, eye closed, not responding to you*]). The final data collection tool is available in Appendix 1.

We performed a three-step data validation process. First, all responses were verified electronically (via unique IP address) and using geolocation technology within Qualtrics. We removed any responses with duplicate IP addresses which did not contain the same identifying information. Further, if the same person or same IP address reported a second choking incident, we only included their first entry in the final analysis. Using the geolocation technology in Qualtrics, we also removed any entry where the location that the response was submitted from did not match the approximate region where the choking was reported to have occurred. Next, we only included entries in the analysis where participants agreed to be contacted for follow up questions and/or interviews. Finally, we contacted (electronically via e-mail or video conferencing) a randomly selected 25% of these individuals to confirm identities and details of the case. A medical doctor (CD) with experience in Emergency Medicine, reviewed all case submissions for medical clarity, and participants were contacted if further details were required.

Outcome variables and analysis

Our primary outcome of FBAO relief was defined as resolution of the choking symptoms and signs, requiring no further intervention. Secondary outcomes included whether emergency medical services (EMS) attended the scene, whether the choking person attended the hospital for evaluation, whether the choking person was hospitalized, and if they survived the event (and to discharge if hospitalized).

A complete list of our collected variables and associated values is available in Appendix 2.

We calculated descriptive statistics on each variable. Age and number of ACD attempts were reported as median and interquartile range (IQR). Categorical data were expressed as proportions (*n* (%)). We narratively described cases where the obstruction was not relieved with the ACD, or those with device malfunctions or patient-related adverse events. We used Likert-response questions to obtain feedback on the ACD users' experience.

Results

During the study period, there were 288 completed data collection tool responses (Fig. 1). Eight hundred and sixty-six ACD uses had been reported to manufacturers, and subsequently our research team, during the study period who were notified of the study. Of the submitted responses, we excluded due to declined follow up questions (n = 69, 24.0%), failed electronic verification (n = 20, 6.9%), reporting a second FBAO or duplicate response (n = 9, 3.1%), and four responses did not describe a choking incident treated with an ACD (n = 4, 1.4%). Of the remaining 186 responses, 157 (84.4%) cases used LifeVac© and 29 (15.6%) cases used Dechoker©.

LifeVac©

Tables 1–3 report on the choking person, responder, and outcome details.

LifeVac© was the last intervention before resolution of FBAO symptoms and signs in 151 (96.2%) cases and in about half of the cases (n = 82, 54.3%) the foreign body was dislodged entirely without needing a finger sweep or patient roll. All cases with complete follow up survived, although one case did not have complete follow up (due to limits of EMS information). Most LifeVac© responders attempted at least one BLS technique prior to using the ACD (n = 119, 75.8%), with back blows being the most common (n = 84, 70.6%).

Among the six unsuccessful cases, all had back blows performed before ACD use. In one case, the FBAO was resolved during transitioning between ACD use and preparing for another technique, and another FBAO resolved after subsequent back blows were applied (despite initial ones pre-ACD use). Three other responders were uncertain whether the ACD or a traditional technique resolved the FBAO as they were doing both in sequence. Finally, one FBAO was not resolved before arriving at the hospital.

Device malfunctions and patient-related adverse events

Three cases involved device malfunctions, all of which involved disconnection of the mask with the plunging unit making seal formation

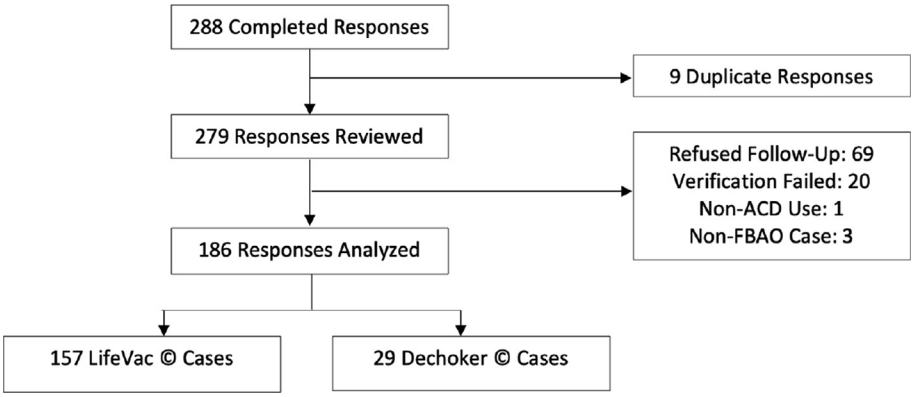

Fig. 1 – Flow of data collection tool responses.

Table 1 – Demographics of person with foreign body airway obstruction.

	LifeVac© N = 157 n (%)	Dechoker© N = 29 n (%)
Patient Gender		
M	88 (56.1)	18 (69.0)
F	69 (43.9)	9 (31.0)
Patient Age (median, IQR)	3 (1–32)	2 (0–36)
Patient Age Groups		
0–1 year	50 (31.8)	13 (44.8)
2–5 years	51 (32.5)	10 (34.5)
6–18 years	12 (7.6)	2 (6.9)
19–64 years	25 (15.9)	4 (13.8)
65+ years	19 (12.1)	0 (0)
Country		
England	1 (0.6)	0 (0)
New Zealand	1 (0.6)	0 (0)
United States of America	155 (98.7)	29 (100)
Medical Conditions: Cardiac[1]		
Present	13 (8.3)	0 (0)
Absent or Unsure	144 (91.7)	29 (100)
Medical Conditions: Respiratory[1]		
Present	14 (8.9)	1 (3.5)
Absent or Unsure	143 (91.1)	28 (96.5)
Medical Conditions: Neurologic[1]		
Present	35 (22.3)	3 (10.3)
Absent or Unsure	122 (77.7)	26 (89.7)
Medical Conditions: Other[1]		
Present	18 (11.5)	3 (10.3)
Absent or Unsure	139 (88.5)	26 (89.7)
History of Choking		
Present	43 (27.4)	9 (31.0)
Absent or Unsure	114 (72.6)	20 (69.0)
Foreign Body Airway Obstruction		
Emesis	3 (1.9)	1 (3.5)
Mucus	7 (4.4)	1 (3.5)
Object	29 (18.5)	6 (20.7)
Solid Food	112 (71.3)	21 (72.4)
Thickened Fluid	3 (1.9)	0 (0)
Unsure	3 (1.9)	0 (0)
Geographical Location		
Home	141 (89.2)	28 (96.5)
Long-term Care Facility	4 (2.5)	0 (0)
Public Space	11 (7.0)	1 (3.5)
School	2 (1.8)	0 (0)

IQR = Interquartile Range.

[1] **Appendix 3** includes a breakdown of specific medical condition frequency.

Table 2 – Demographics of responder who used the airway clearance device.

	LifeVac © N = 157 n (%)	Dechoker © N = 29 n (%)
Responder's Relationship to Choking Person		
Family or Friend	132 (84.1)	28 (96.5)
EMS or Fire First Responder	3 (1.9)	0 (0)
Nurse or Staff	6 (3.8)	0 (0)
Self	7 (4.5)	1 (3.5)
Unknown Bystander	9 (5.7)	0 (0)
Responder's Relevant Training		
Basic Life Support (BLS)	70 (44.6)	9 (31.0)
Nurse or Nurse Assistant	16 (10.2)	1 (3.5)
Paramedic or EMR	5 (3.2)	0 (0)
Physician	1 (0.64)	0 (0)
None	65 (41.4)	19 (65.5)
Airway Clearance Device Training		
Received In-person Training	14 (8.9)	3 (10.3)
Watched Online Training Video	104 (66.2)	13 (44.8)
Practiced On a Mannequin	24 (15.3)	5 (17.2)
Previously Used ACD	21 (13.4)	2 (6.9)

ACD = Airway Clearance Device; EMR = Emergency Medical Responder.

challenging. In all cases, the device was able to be reassembled and reused.

Respondents reported ten patient-related adverse events. We believe two cases of perioral irritation and bruising were likely to be caused by device application, whereas one case of subconjunctival hemorrhage was favoured to be related to the choking process. For the remaining seven events, we were unable to ascertain whether they were due to the FBAO or the device. These adverse events included: airway edema via inflammation (3 cases), intraoral abrasions/pain (3 cases), and esophageal perforation due to a plastic shard entrapped in mucosa. All airway edema cases resolved without intervention. The patient with an esophageal perforation also received back blows. This patient was temporarily admitted to the intensive care unit however has since been discharged from the hospital.

Dechoker©

Dechoker© was the last intervention before resolution of FBAO symptoms and signs in in 27 (93.1%) cases and did not require any additional maneuvers to remove the foreign body in 19 (70.4%) cases. Most users attempted at least one BLS technique prior to using the Dechoker© ($n = 21$, 72.4%), with back blows being the most common intervention ($n = 18$, 85.7%).

In both unsuccessful cases, the choking person ultimately resolved the FBAO while coughing. One of them did so in between device use and back blow alterations, and the other case after a single attempt of the ACD. Neither unsuccessful case was transported to hospital by EMS. One case had back blows and abdominal thrusts used before the ACD, while the other had just back blows.

Device malfunctions and patient-related adverse events

One device malfunction was reported, which involved the top of the pulley coming off and resulting in the air seal being lost. The responder was able to continue to use the device by covering the hole and maintaining a seal with their finger however it was one of the cases where the device did not remove the FBAO.

In one case, the choking person suffered abrasions to the oropharynx and gingiva because of the Dechoker© tube insertion.

ACD user experience feedback

Responses were similar among both devices (Fig. 2, Appendix 4). Almost all LifeVac© and Dechoker© respondents believed that ACDs were easy to use and should be a part of choking treatments. Three quarters of LifeVac© users reported if they had an intraoral component to their device, they would be more nervous to use the ACD and about 15% said this would make them not use it at all. Conversely, only one-quarter of Dechoker© users reported increased nervousness due to the intraoral component of the ACD.

Discussion

This study presents the first prospective evaluation of ACDs where data were collected, analyzed and reported independent of manufacturers. Within the reported cases, we find that LifeVac© and Dechoker© were effective at resolving FBAO with few, generally mild, adverse events. Further, most cases reported an unsuccessful BLS intervention prior to the ACD use.

The use of ACDs as an intervention for FBAO remains a controversial topic.[16,17] In fact, the rapid, widespread public interest and acceptance of ACDs with only case reports as supporting evidence has many parallels to the dissemination of the "Heimlich maneuver" (also known as abdominal thrusts) in the 1970s.[18,19] The data within our manuscript is like that presented by Redding in 1979 on traditional BLS interventions. Both describe a generous collection of cases, yet both are limited in their ability to make concrete conclusions (either statistical or theoretical) due to sampling bias from self-reporting recruitment strategies, and difficulties with precise outcome measurement (e.g., relief of obstruction). Despite these limitations, Redding's work remains the largest source of data on FBAO BLS interventions cited in present-day treatment recommendations.[6]

Table 3 – Airway clearance device use and outcome details.

	LifeVac © N = 157 n (%)	Dechoker © N = 29 n (%)
Initial FBAO Witnessed		
Witnessed	148 (94.3)	25 (86.2)
Unwitnessed	9 (5.7)	3 (10.3)
Unsure	0 (0)	1 (3.5)
Initial FBAO Severity		
Severe or Complete	108 (67.1)	18 (62.1)
Mild or Partial	41 (27.5)	11 (37.9)
Unsure	8 (5.4)	0 (0)
BLS Intervention Performed Before ACD	119 (75.8)	21 (72.4)
Abdominal Thrusts	39 (32.8)	4 (19.1)
Back Blows	84 (70.6)	18 (85.7)
Chest Compressions or Thrusts	9 (7.6)	2 (9.5)
Level of Consciousness When ACD Used		
Conscious	137 (87.3)	28 (96.6)
Unconscious	20 (12.7)	1 (3.5)
Number of ACD Attempts (median, IQR, range)	2 (1–2; 1–13)	2 (1–4; 1–15)
ACD Last Intervention Before Resolution of FBAO Symptoms / Signs (all cases)		
Yes	151 (96.2)	27 (93.1)
No or Uncertain	6 (3.8)	2 (6.9)
ACD Last Intervention Before Resolution of FBAO Symptoms / Signs (only severe cases)		
Yes	105 (97.2)	17 (94.4)
No or Uncertain	3 (2.8)	1 (0.6)
Foreign Body Removal		
ACD Removed Entirely	82 (54.3)	19 (70.4)
Required Finger Sweep or Rolling onto Side to Remove	51 (33.8)	8 (29.6)
Unsure	18 (11.9)	0 (0)
Other Outcome Indicators		
EMS Attended Scene	41 (26.1)	5 (17.2)
Sought In-hospital Evaluation	36 (22.9)	1 (3.5)
Admitted to Hospital	10 (6.4)	0 (0)
Admitted to Intensive Care Unit	3 (1.9)	0 (0)
Survived	150 (99.3)[1,2]	27 (100)[2]

ACD = Airway Clearance Device; BLS = Basic Life Support; EMS = Emergency Medical Services; FBAO = Foreign Body Airway Obstruction; IQR = Interquartile Range.

[1] One report from an EMS service did not have follow up information after admission to the intensive care unit.

[2] Proportion of cases which the ACD was the last intervention (LifeVac *n* = 151; Dechoker *n* = 27).

The difficulty identifying a study population is a prominent reason why data on traditional FBAO BLS interventions have not progressed significantly in decades. Our scientific basis for current recommendations includes abdominal thrusts (FBAO relief:417 case reports; survival:189 case reports; adverse events:52 case reports), and back blows (FBAO relief:75 case reports; survival:13 case reports; adverse events:4 case reports).[6] In comparison, LifeVac© ACD has 274 case reports of it being the final intervention before FBAO relief, with all patients with complete follow up subsequently surviving, and 9 reports of patient-related adverse events (including those analyzed in this study).[12]

The adverse events from ACDs published to date have been milder than those from abdominal thrusts, for example.[6] One notable exception from our study was the case of esophageal perforation where a plastic shard was entrapped in esophageal mucosa. The respondent mentioned that they were unsure what caused this injury as it could be due to the type of FBAO material, application of back blows or application of LifeVac©. Cases like this highlight why any new resuscitation intervention must be carefully assessed before use. As well, due to our inability to access health records for the patients assessed by medical providers in this study (25.1% of all cases), we need to strongly consider the likelihood of unaccounted adverse events given the reliance on layperson reporting.

Importantly, compared to other areas of evidence within resuscitation sciences, we are not concluding that the data quality for ACDs is sufficiently high, only that it is comparable to the present data for other FBAO interventions. There are additional reasons to pause however before considering a change of practice recommendations. Any benefit gained by introducing ACDs as standard interventions in resuscitation algorithms, must be balanced against potential barriers including implementation costs, equipment availability, and whether dispatchers would be able to instruct ACD use over the phone to providers.

There is also concern that laypeople will struggle with correct assembly of the devices and secure application of the face mask, resulting in a delay of other techniques.[5,16,17] Three mannequin studies have evaluated individuals' ability to use ACDs. Two mannequin studies assessed parents', educators', and healthcare learners' ability to correctly follow the steps provided by ACD manufacturers (written pamphlet) without other instruction.[20,21] Both studies found the

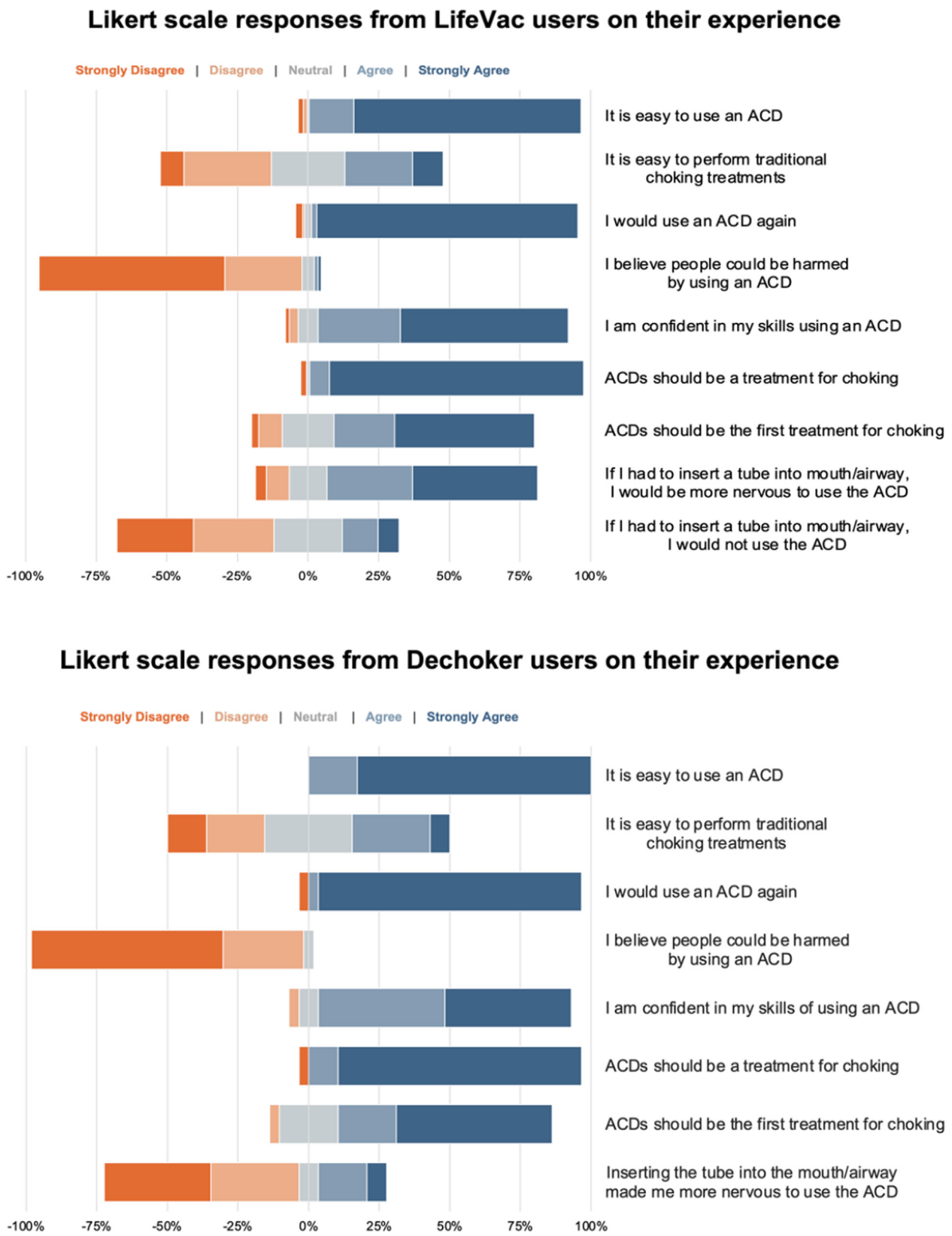

Fig. 2 – Comparison of Likert responses between LifeVac© (top) and Dechoker© (bottom) users describing their experience.

most common incomplete step was participants failing to keep the mask fixed to the face (performed correctly: LifeVac© 56.9–74.4%; Dechoker© 66.7–86.0%). LifeVac© was found to be more rapidly applied and executed then Dechoker© by 9–13.8 s.[20,21] When compared to applying current BLS interventions, both LifeVac© and Dechoker© had greater correct compliance rate than standard protocol (100% versus 50%), despite 72.1% of participants having prior training in FBAO BLS interventions.[21]

A third mannequin study evaluated efficacy of ACDs compared to abdominal thrusts. LifeVac© was found to be superior to abdominal thrusts at FBAO removal success (Odds Ratio [OR] 47.32 [95%CI 5.74–389.40]), whereas Dechoker© was not (OR 1.22 [95%CI 0.60–2.47]). Similar outcomes were also found when assessing rapidity of FBAO removal.[22] We were unable to find any studies assessing laypeople's ability to apply traditional FBAO BLS interventions correctly in the literature. Therefore, although widely adapted and taught, we remain uncertain of the effectiveness of these BLS interventions by laypeople.

FBAO intervention research has reached an impasse. On one side, our current FBAO BLS interventions have a weak scientific basis but have stood the test of time. On the other, a new intervention has now a similar body of evidence, but hesitation remains due to a shorter trial period and a number of barriers to widespread adoption that must be considered. With most case reports and simulation studies supportive of advancing ACD research further, traditional methods of research are unlikely to be helpful. As an example, querying health region databases will fail to capture enough (if any) events, as FBAOs are relatively infrequent, and ACDs as a FBAO intervention remain rarer to identify. We envision several ways forward.

First, further pre-clinical simulation research would be beneficial. This could include simulation trials, like Patterson's, investigating additional objectives such as comparing the effectiveness and usability of back blows versus ACDs, comparing different BLS interventions versus ACDs among untrained laypeople, comparing FBAO interventions in infant choking mannequins, and evaluating different instructional styles of ACDs (to see if the current model of watching an online video is sufficient for skill acquisition and retention).[21]

A next step for clinical data could be introducing ACDs into a highly controlled setting that sees a large volume of FBAOs and allow for detailed monitoring. This would allow initial ACD application by trained providers, with specific outcome and adverse event documentation, as well as comparison to other BLS interventions used in that setting.

Of note, we feel it is important to highlight that although both LifeVac© and Dechoker© fall under the umbrella term of ACD, they represent clinically different tools and should not be compared. The primary contrast is the tongue depressor attached to Dechoker© which is inserted intra-orally. Given Dechoker's© considerably fewer case reports in the literature, and industry-independent evidence suggesting inferior efficacy/usability, it is important guideline creators consider each device independently when making future recommendations.[9–13,22]

As clinicians and researchers, our concerns around safety and effectiveness are needed to protect our patients' interests, but we must also take a proactive approach to studying ACDs and guiding their introduction to the public, otherwise we will struggle to keep the public informed on best practices.

Limitations

There are several limitations relevant to our research including self-reporting sampling bias, reliance on layperson diagnosis of FBAO, and challenges attributing which intervention ultimately relieved the FBAO (where the last intervention is often only given credit). Self-reporting tends results towards exceptional outcomes (e.g., ACD cleared the FBAO or the patient had a severe adverse event such as death).[23] Cases where responders used an ACD and it did not clearly resolve the FBAO, responders may be less likely to seek out opportunities to submit an incident summary. This limitation highlights that our research does not have a denominator (i.e., total number of cases that a responder used an ACD worldwide). Therefore, we are unable to infer the proportion which ACDs are effective as we cannot account for the times when an ACD were used, and data were not collected. Further, in the cases where an ACD was used before a BLS intervention, we do not know if traditional intervention would have failed and negated the need for the ACD.

Although we employed multiple techniques to maximize validity (e.g., electronic and geographic verification, follow up with respondents, and physician review of all submissions), our study is still limited by lack of in-person medical assessment and documentation when the event occurred, similar to prior FBAO work.[18,23] Additionally, we did exclude 33.0% of all submitted cases, however, this was done based on pre-determined criteria which were selected to decrease other potential biases.

Conclusions

We report 157 LifeVac© and 29 Dechoker© airway clearance device uses, that were prospectively collected, validated, analyzed, and reported independent of industry. Within these reports, ACDs appeared to be effective at relieving FBAO with few adverse events, however, the results need to be interpreted within the context of their limitations. We urge resuscitation clinicians and researchers to be proactive in evaluating ACDs moving forward, to ensure the public remains informed and updated on best practices for FBAO management.

Disclaimer

The views expressed in this article are those of the authors and are not an official position of the organizations we are affiliated with.

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CRediT authorship contribution statement

Cody L Dunne: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing.

Kayla Viguers: Investigation, Formal analysis, Writing – review & editing. **Selena Osman:** Investigation, Formal analysis, Writing – review & editing. **Ana Catarina Queiroga:** Conceptualization, Methodology, Investigation, Writing – review & editing. **David Szpilman:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Amy E Peden:** Conceptualization, Methodology, Investigation, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors have no competing interests, financial or otherwise, to declare. The research team approached the manufacturers to seek their participation in this study. Manufacturers of airway clearance devices agreed to participate in the study in two areas: identification and recruitment of participants and distributing the research data collection tool as needed. Manufacturers were not involved in study design, nor do they have any financial involvement. Manufacturers do not have access to the collected data, nor have they been permitted to view the results or manuscripts prior to publication. Dr. Amy Peden is funded by a National Health and Medical Research Council (NHMRC) Emerging Leadership Fellowship (Grant ID: APP2009306) which supported open access publication. No funding was obtained for the conduct of the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resplu.2023.100496.

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Original Article

The use of LifeVac, a novel airway clearance device, in the assistance of choking victims aged five and under: Results of a retrospective 10-year observational study

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Abstract

Background: Choking is a leading cause of injury and death among children under the age of five. Despite notable advances in technology, regulations, and education, the prevalence of choking incidents and related fatalities persists as a global issue, demanding the implementation of improved assistance methods. This study aims to assess the efficacy of an innovative airway clearance device, LifeVac, in aiding children aged 5 and under in choking emergencies.

Subjects and Methods: LifeVac LLC maintained a comprehensive database of voluntary reports documenting the utilization of their device in choking emergencies over 10 years, collected through a dedicated website. Collected data included the age and sex of the choking victim, preexisting medical conditions, nature of the object causing airway obstruction, whether basic life support protocol was followed before employing the LifeVac, number of pulls required to dislodge the obstructing object, and adverse events.

Results: A total of 299 children were reported to have received assistance with the LifeVac device in choking emergencies. The age range of the assisted children varied from 3 days old to 5 years. One hundred and fifty-seven children were boys. There were 19 reports of preexisting conditions. The most common obstructing objects were plastic, mucus, candy, meat, and fruits. The number of pulls required to successfully dislodge the object ranged from 1 to 10. No failures were reported.

Conclusions: LifeVac should be considered a valuable complement to standard life support techniques in choking emergencies, particularly for at-risk groups such as children under the age of 5.

Keywords: Airway clearance device, children, choking, LifeVac

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INTRODUCTION

Choking is a leading cause of injury and death among children, particularly those under the age of five.[1] In the United States (US), an average of 140 choking-related deaths occur annually.[2] The act of choking occurs when an object or food item becomes lodged in the throat or windpipe, blocking airflow to the lungs.[3] Choking can be caused by small objects such as coins or food items, such as

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hot dogs or hard candies, and can result in life-threatening situations. Children are particularly vulnerable to choking, as they tend to put objects in their mouths and have smaller airways that can become easily obstructed.[4] Among young children, food has been identified as the most frequently reported cause of choking. Specifically, hard or round foods such as nuts, seeds, and popcorn are considered, particularly hazardous. In addition, small toys, coins, batteries, and small magnets also present choking hazards.

Choking incidents in children have a long history, spanning centuries. However, it is in recent decades that significant attention has been dedicated to addressing this issue and taking preventive measures. Through the 20th century, choking deaths in children were frequently attributed to small toys, candy, and food.[5] Recognizing the urgency, the US established the Consumer Product Safety Commission in 1972, aiming to regulate the safety of consumer products, including toys and other items that could potentially pose a choking hazard to children.[6] Since then, various regulations have been implemented to ensure that toys and similar products undergo choking hazard testing. Moreover, labeling and warning requirements have been mandated for items that pose a risk to young children.

In recent years, there has been a growing concern about the choking hazard associated with small, round, and cylindrical objects such as coins, batteries, and small magnets. This heightened awareness has prompted calls for additional regulations and enhanced education regarding the potential dangers these items pose to young children. To address this issue, informative platforms such as JTs Law[7] have been established, aiming to educate parents, caregivers, and others about the critical importance of supervising young children during mealtimes and play. These resources serve as reminders to keep small items out of reach of young children, emphasizing the significance of proactive measures in preventing choking incidents.

Overall, while choking deaths in children remain a serious problem, advances in technology, regulation, and education have helped to reduce the number of choking incidents and fatalities. Despite these advances, choking remains the leading cause of injury and death among children, especially those under the age of five. According to the World Health Organization, choking is a leading cause of death in children under the age of five, accounting for an estimated 3000 deaths per year globally.[8] Preventive measures such as constant supervision of young children, keeping small items out of reach, and preventing distractions during mealtime are important. In the event that a choking emergency does occur, there is very limited time (approximately 8 min) before brain injury or death occurs.[9] This makes it difficult to have trained personnel on the scene in time. Therefore, there exists a need to have an airway clearance device (ACD) available that is portable, easy to use, and lightweight for those at increased risk for choking.

Ten years ago, a novel ACD, LifeVac, was developed to assist choking victims [Figure 1a]. It consists of a plunger with a one-way valve such that when the plunger is depressed, air is forced out the sides and not into the victim. When the plunger is pulled back, suction is applied, thereby removing the obstructing object [Figure 1b]. It is attached to a detachable standard facemask (adult or pediatric) used for airway management. The device is lightweight, portable, and noninvasive. LifeVac is registered with the US Food and Drug Administration (FDA) for use in a choking emergency. LifeVac is also registered as a Class 1 device with the Medicines and Healthcare Products Regulatory Agency in the United Kingdom.

In this study, we describe real-world experience using LifeVac in choking emergencies in children aged five and under.

MATERIALS AND METHODS

The LifeVac device has been marketed worldwide for the past 10 years. From 2012 to 2022, LifeVac LLC, the creator company, maintained a comprehensive record of voluntary reports detailing the usage of LifeVac devices. These reports were collected through a dedicated website, as specified in the paperwork provided within the LifeVac Kit, which can be accessed online at: https://lifevac.net/lifevac-saved-a-life-report/. The purpose of this data collection strategy was to encourage individuals who used the device to share feedback regarding the outcomes, whether successful or unsuccessful, of using the LifeVac. The collected data included the age and sex of the choking victim, any preexisting medical conditions that could potentially contribute to choking incidents, the nature of the object causing airway obstruction, whether the standard basic life support (BLS) protocol was followed before employing of the LifeVac, the number of pulls required to dislodge the obstructing object, and any reported adverse events. Reports of use in patients above 5 years of age were excluded from the analysis.

Ethics statement

This study did not require ethical review and approval. Informed consent for participation was not required as there are no identifying factors related to the individuals

Figure 1: LifeVac device and use guidelines. (a) The device consists of a face mask, plunger, and one-way valve. Air comes out from the sides upon application of pressure. (b) LifeVac use guidelines: First, the face mask is placed on the choking victim (1). Second, the plunger is pushed, whereas air goes out the sides (2). Third, suction is applied to retrieve the choking object (3). Always monitor victim's conditions after each use. Images are courtesy of LifeVac LLC

involved. The study was cleared by an institutional review board (IRB) based on these factors (BRANY IRB File #23-12-439-1497).

RESULTS

Between 2012 and 2022, 299 children aged 5 and under were reported to have been assisted in a choking emergency by the LifeVac. The mean age of the victims was 1.65 years, ranging from 3 days old to 5 years. The age distribution of the children involved is as follows [Figure 2a]: 11 were between the ages of 0 and 6 months, 96 were between 6 months and 1 year, 37 were between 1 and 2 years, 79 were 2 years old, 40 were 3 years old, 23 were 4 years old, and 13 were 5 years old. Out of these incidents, there were 157 boys and 142 girls who were successfully assisted [Figure 2b].

Nineteen cases reported underlying medical conditions that were found to predispose individuals to choking. Among these cases, the following conditions were identified [illustrated in Figure 2c]: five patients had seizure disorders, four patients had autism, three patients had Down syndrome, and one patient each had a global delay, tracheoesophageal fistula, hydrocephalus and cerebral palsy, hypotonia, muscular dystrophy, and Cri-du-chat syndrome.

A comprehensive list of objects that led to airway obstruction is presented in Table 1. The range of objects varied from rocks to various types of foods. Among the cases examined, the most frequent cause of obstruction was plastic (from wrappers or toys), which occurred in 32 cases, followed by mucus in 31 cases, candy in 21 cases, chicken or meat in 19 cases, and strawberries in 18 cases [Figure 2d]. On average, it took approximately 1.7 attempts to successfully dislodge the obstructions, with the number of pulls required ranging from 1 to 10.

In several cases, the victims were subsequently taken to an emergency room for evaluation. Fortunately, there were no reports of adverse outcomes. It is noteworthy that none of the victims required hospital admission; instead, they were thoroughly evaluated and subsequently discharged. There were no reported instances of device failure.

DISCUSSION

Despite significant advances in medical care over the past 10 years, choking remains a significant cause of death and disability among children aged 5 and under. Several factors contribute to the prevalence of choking in children under the age of five: (1) Small airways: children in this age group have narrower airways compared to adults, making them susceptible to blockages from small objects, consequently heightening their risk of choking, (2) Curiosity and exploration: young children are naturally curious and often explore their environment by putting objects into their mouths, which increases the risk of choking on small items. (3) Poor chewing skills: children under the age of five are still developing their chewing abilities, which can make it difficult for them to fully break down food in their mouth, thereby increasing the risk of choking. (4) Inability to recognize danger: children in this age range may lack the ability to identify potential hazards and may not know how to respond if they experience choking. (5) Inadequate supervision: children under the age of five typically require close supervision due to their increased vulnerability to choking. Unfortunately, when they are not properly supervised, the risk of choking escalates.[10]

Constant supervision, education about choking hazards and proper emergency responses to children, and ensuring caregivers undergo mandatory choking assistance training can help prevent incidents and undesirable outcomes in children under five. However, when a choking incident does occur, even when the standard protocol is

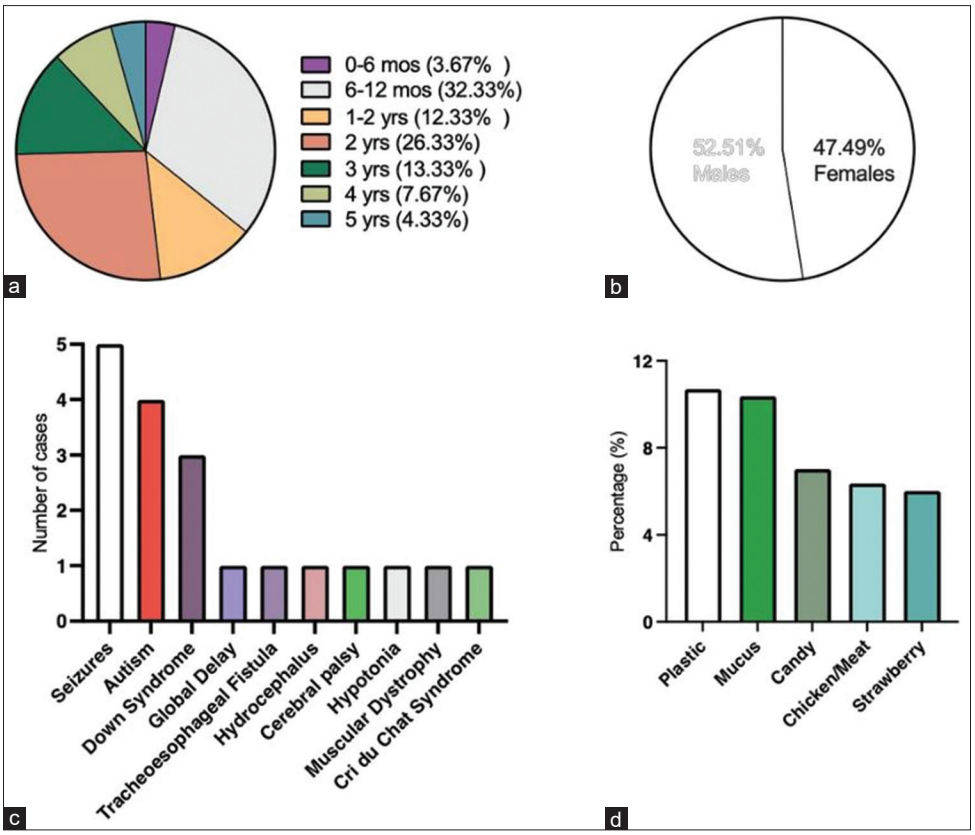

Figure 2: Characteristics of choking victims assisted by LifeVac and obstructing objects. (a) Age distribution of children assisted by LifeVac. (b) Sex distribution of children assisted by LifeVac in choking emergencies. (c) Preexisting conditions in choking victims. (d) Five most common obstructing objects in emergencies where LifeVac was used

followed (i.e., Heimlich maneuver), this fails around 26% of the time in the general population.[11] In addition, it takes several minutes to get first responders on the scene. Brain death can occur within a matter of minutes if the airway is completely obstructed, causing a lack of oxygen to the brain. In general, permanent brain damage can occur within 4–6 min of cardiac arrest caused by choking.[12] This highlights the importance of quickly and effectively addressing a choking emergency to restore airflow and prevent permanent brain damage or death.

To prevent choking incidents from becoming life-threatening, it is important to be trained in Cardiopulmonary resuscitation (CPR) and choking first aid and to know how to respond quickly and effectively in the event of a choking emergency. In addition, it would be beneficial to have an ACD readily available to assist a choking victim wherever food is served, in the event that standard protocol fails. A study by Dunne *et al.* reported LifeVac as an effective and safe ACD across a broad cohort of patients including ages 2–80 years.[13] The 10-year data discussed here on the success of the LifeVac focused on assisting pediatric choking victims demonstrates that lives can be saved by having such a device available in at-risk groups, and even in victims with underlying medical conditions. The device is simple to use, portable, lightweight, and small enough to keep in the kitchen or near the automated external defibrillator in school cafeterias. Having a noninvasive tool available, such as LifeVac, to use in this patient group would be a significant advancement.

An emerging problem is the rise of numerous knockoffs that, due to lack of regulation, do not adhere to the same quality standards as the original FDA-registered LifeVac device. Purchasing of such imitation devices is alarming as they could pose a risk to lives. Measures need to be taken to inform the public on how to verify the authenticity and regulatory compliance of these devices to make informed choices.

CONCLUSIONS

Although LifeVac is not intended to replace standard choking protocols (Heimlich maneuver, back blows, chest thrusts), the data presented here strongly support its utilization in choking emergencies, particularly among at-risk groups like children under the age of five. Incorporating LifeVac as an additional measure can

Table 1: Obstructing objects leading to choking

Obstructing object	Number of cases (%)
Plastic	32 (10.70)
Mucus	31 (10.37)
Candy	21 (7.02)
Chicken/meat	19 (6.35)
Strawberry	18 (6.02)
Grape	14 (4.68)
Unknown	12 (4.01)
Chips	12 (4.01)
Hot dog	9 (3.01)
Cereal	9 (3.01)
Apple	9 (3.01)
Cookie	9 (3.01)
Orange	8 (2.68)
Bread	7 (2.34)
Sausage	6 (2.01)
Banana	5 (1.67)
Sandwich	5 (1.67)
Coin	5 (1.67)
Pretzel	5 (1.67)
Potato	4 (1.34)
Pancake	4 (1.34)
Papaya	4 (1.34)
Carrots	4 (1.34)
Lettuce	4 (1.34)
Paper	4 (1.34)
Bacon	3 (1.00)
Popcorn	3 (1.00)
Watermelon	3 (1.00)
Pear	3 (1.00)
Ice Cube	2 (0.67
Stone	2 (0.67)
Broccoli	2 (0.67)
Meatball	2 (0.67)
Wood	2 (0.67)
Cracker	1 (0.67)
Tuna	1 (0.33)
Metal bolt	1 (0.33)
Corn	1 (0.33)
Velcro	1 (0.33)
Egg	1 (0.33)
Cheese	1 (0.33)
Ping pong ball	1 (0.33)
Gum	1 (0.33)
Raisins	1 (0.33)
Crayon	1 (0.33)
Lemon peel	1 (0.33)
Shrimp	1 (0.33)
Bean	1 (0.33)
Play-Doh	1 (0.33)
String	1 (0.33)
Olive	1 (0.33)

Total number of cases is 299

significantly contribute to preventing devastating outcomes in such situations.

Study limitations

The limitations of this study are that it is a voluntary retrospective analysis and not a double-blind, placebo-controlled prospective study. Conducting such a study in a choking emergency, where lives could be lost with a placebo method, is almost impossible.

It is important to acknowledge that the link provided for reporting the use of LifeVac directs users to a website specifically dedicated to reporting instances where LifeVac was successfully used to save a life. This inherent design of the reporting system may introduce a potential bias in the data, favoring reports of successful outcomes. In addition, due to the voluntary nature of the reporting, there could be missed cases where the failure occurred. However, it stands to reason that if there was a failure resulting in the loss of a life or a serious complication, it would be more likely to be reported than a success.

The weights of the victims were not reported, but the device is sold with a statement that it is not approved for use in victims <20 pounds. Nonetheless, in instances involving children aged 0–6 months, the device demonstrated a notable level of safety and effectiveness. Furthermore, the device is sold with instructions regarding standard BLS protocol that should be followed before considering the use of the LifeVac. It is only recommended to be used if standard protocol fails.

Data availability statement

Derived data from LifeVac LLC are available from the corresponding author upon request.

Author contribution statement

N.C: Conceptualization, methodology, data curation, writing of original manuscript. J.C.: Writing review and editing. G.R: Conceptualization, methodology, writing review and editing.

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Conflicts of interest

There are no conflicts of interest.

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Simulation and education

Knowledge and skills of pediatric residents in managing pediatric foreign body airway obstruction using novel airway clearance devices in Spain: A randomized simulation trial

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Abstract

Aim: Recent emergence of airway clearance devices (ACDs) as a treatment alternative for foreign body airway obstructions (FBAO) lacks substantial evidence on efficacy and safety. This study aimed to assess pediatric residents' knowledge and skills in managing a simulated pediatric choking scenario, adhering to recommended protocols, and using LifeVac© and DeCHOKER© ACDs.

Methods: Randomized controlled simulation trial, in which 60 pediatric residents from 3 different hospitals (median age 27 [25.0–29.9]; 76.7% female) were asked to solve an unannounced pediatric simulated choking scenario using three interventions to manage (randomized order): 1) following the recommended protocol of the European Resuscitation Council (encouraging to cough or combination of back blows and abdominal thrusts); 2) using LifeVac©; and 3) using DeCHOKER©. A Little Anne QCPR™ manikin (Laerdal Medical) was used. The variable compliance rate (%) was calculated according to the correct/incorrect execution of the steps constituting the proper actions for each test.

Results: Participants demonstrated a correct compliance rate only ranging between 50–75% in following the recommended protocol for managing partial FBAO progressing to severe. Despite unfamiliarity with the ACDs, pediatric residents achieved rates between 75% and 100%, with no significant difference noted between the two devices ($p = 0.173$). Both scenarios were successfully resolved in under a minute, with LifeVac© demonstrating a significantly shorter response time compared to DeCHOKER© (39.2 [30.4–49.1] vs. 45.1s [33.7–59.2], $p = 0.010$).

Conclusions: Only a minority of pediatric residents were able to adhere to the recommended FBAO protocol, whereas 70% of them were able to adequately use the ACDs. However, since a significant proportion could not, it seems that ACDs themselves do not address all issues.

Keywords: Choking emergency, FBAO, Basic Life Support, LifeVac, DeCHOKER, Training

Introduction

In the realm of emergency medical care, foreign body airway obstruction (FBAO; choking) remains a critical and potentially life-threatening challenge, representing the fourth leading cause of potentially preventable and treatable accidental death.[1,2] While FBAO can affect individuals of all ages, its prevalence is notably pronounced in young children and the elderly. The vulnerability peaks during mealtime, both out- and in-hospital setting.[3,4] In this sense, prompt recognition and quick and effective intervention is essential to ensure a positive patient outcome.[1]

In addressing FBAO, current recommendations from resuscitation councils are quite clear with step-by-step maneuvers to be performed according to the choking scenario and victim's age.[1,5,6] Despite these guidelines, the management of FBAO remains a complex undertaking, marked by weak level of evidence and controversy because of serious risk of bias and imprecision among studies.[7] This knowledge gap requires exploration into novel interventions to address this life-threatening event.

Airway clearance devices (ACDs) have emerged in recent years as non-powered suction-based devices: LifeVac© (LifeVac LLC, Nesconset, New York, NY, USA)[8] and DeCHOKER© (Dechoker

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LLC, Wheat Ridge, CO, USA),[9] which have been introduced on the market and are now available in public areas[10] These devices were designed to remove obstructing materials from the airways through the application of suction.[8,9] However, its role and effectiveness in case of FBAO it not clear. Previous mannequin studies,[11,12] cadaver studies[13] and studies in real choking victims[14–17] reported significant success in dislodging a foreign body. Nevertheless, recent studies indicate that ACDs may not be effective in relieving the obstruction caused by diverse types of foods and even cause harm.[18] Given the scarcity of substantial evidence surrounding them (due to industry involvement and reporting biases, small sample size or preliminary results)[15,19,20] and the controversial findings, international treatment recommendations in 2023 advise against them until new evidence is obtained.[7,21]

While there is limited research on the assessment of the correct use of suction-based ACDs in the general population[22] and among health science students,[23] to the best of our knowledge, there is no study with these devices in pediatric healthcare professionals, treating a population at risk of suffocation: the pediatric age group. We studied pediatric trainees because pediatricians not only as professionals but also to inform and, when necessary or requested, train families on how to manage home and public places accidents. Additionally, given the misinformation about ACDs in the media, pediatricians play a crucial role in ensuring families receive the accurate and reliable information. Thus, as residents are the future pediatricians, it is essential that they have direct knowledge of the recommended protocol, the specific devices, and their proper utilization when required. In this regard, the current study has assessed the knowledge and proficiency of pediatric residents in managing a pediatric choking simulated model, using the currently endorsed protocol[6] as well as LifeVac© and DeCHOKER© devices.

Materials and methods

Participants

Sixty pediatric residents engaged in their training at three hospitals in Spain—specifically, the University Clinical Hospital of Santiago de Compostela, Hospital Infantil Universitario Niño Jesús in Madrid, and the Central University Hospital of Asturias —were voluntarily enrolled and none of them dropped out during the study. The recruitment process of this convenience sample transpired at their respective workplaces over the duration of June to October 2023.

The Research Ethics Committee of Santiago-Lugo did not consider it necessary to review the research protocol since it is a simulation study. All study participants provided written informed consent, adhering to the ethical standards outlined by the Declaration of Helsinki. They willingly agreed to contribute their data for research purposes, with an assurance of complete anonymity.

Study design and procedure

In the present randomized controlled simulation trial residents encountered a simulated victim with a FBAO and had to solve the situation through three interventions: 1) adhering to the presently recommended protocol (Supplementary material); 2) using the LifeVac© device; 3) employing the DeCHOKER© device. The start of the three simulated scenarios was randomized for the participants using a random number sequence. The topic and methodology of the study were unannounced to all participants.

To solve the scenario using the recommended protocol pediatric residents should follow the guidelines.[1,5,6] They were informed that they were in a shopping center and were alerted to a 14-year-old child choking on a grape. They were the first responders and found the child coughing. Participants were instructed to address the situation by following the recommended protocol for managing a partial obstruction (encouraging coughing), which would escalate to a severe obstruction (requiring the combination of back blows and abdominal thrusts).[1,5,6]

In the remaining two scenarios involving the LifeVac© and DeCHOKER© devices, the case presentation differed in that, upon arriving at the FBAO emergency, someone had previously attempted the recommended maneuvers, and they had failed. Subsequently, the participant was provided with the suction-based ACD to attempt to resolve the situation. Each device was supplied in its original packaging and with the manufacturer's leaflet. In each scenario, the participants had to choose the correct size mask (LifeVac©) and the correct size device (DeCHOKER©).

To simulate a choking child scenario with ACDs, we employed a mannequin representing a 14-year-old (Little Anne QCPR™; Laerdal). Conversely, for the simulation adhering to the recommended protocol, we utilized a trained young adult victim with anatomical features closely mirroring those of a 14-year-old. In this instance, the participants were informed that they were dealing with a real person and that they had to exercise caution when carrying out the recommended protocol. No training was performed before each test, nor was any information provided to participants during the tests; letting them act as if they were alone in the FBAO scenario.

Two trained investigators were responsible for the assessment. One of them completed a checklist regarding the correct or incorrect performance of each recommended step in each test, while the other was responsible for measuring the partial (for each step) and total times.

Materials

The LifeVac© device is a non-powered, non-invasive ACD designed to dislodge foreign bodies from the airway through unidirectional suction phenomenon.[8] This device, consisting of a facemask with a one-way valve connected to a plunger, is FDA registered as a Class II medical device. Three interchangeable mask sizes are included: small pediatric (for children weighing more than approximately 10 kg between 1 and 4 years of age), large pediatric mask (children over 4 years of age) and adult mask.

The DeCHOKER© was developed as a device with a plunger system responsible for generating the negative pressure, also with unidirectional suction.[8] Unlike LifeVac©, it also features an oropharyngeal tube, acting as a tongue depressor, which makes it minimally invasive. DeCHOKER© is available in three different sizes: infants (1 to 3 years), children (3 to 12 years), and adults (12 years and older).

Little Anne QCPR™ (Laerdal; Stavanger, Norway) mannequin was used as a simulated FBAO victim when ACDs were employed to resolve the choking.

Measurements

Demographic information for participants, encompassing gender, age, year of residency, weight and height was recorded. Additional variables included their most recent training in FBAO, whether they had witnessed or addressed any choking incidents, and their familiarity with suction-based ACDs.

The primary study variables comprised the accurate execution of each step required for FBAO treatment using the recommended protocol, the LifeVac© device, and the DeCHOKER© device. Additionally, the time (in seconds) taken to resolve each scenario was measured. The variable correct compliance rate (%) was computed using the formula: (Σ steps correctly performed × 100)/number of steps assessed.

In this context, correct compliance rate for LifeVac© was calculated considering the following steps: 1) inserting the mask on the device's bellows, 2) correctly placing the mask to cover the victim's nose and mouth, 3) pushing in the handle/bellows, 4) pulling the handle upwards, and 5) ensuring the mask remains securely fixed to the victim's airway throughout the procedure.

DeCHOKER© correct compliance rate was determined by assessing the accurate or incorrect execution of the following sequence: 1) correctly placing the mask to cover the victim's nose and mouth, 2) pulling the plunger out, 3) forcefully pulling, and 4) ensuring the mask remains securely fixed to the victim's airway throughout the procedure.

The correct compliance rate for the current recommended protocol was computed by evaluating the precise or erroneous execution of the following sequence[1,5,6]: 1) encouraging coughing, 2) performing back blows, 3) accurately executing back blows, 4) performing abdominal thrusts, 5) accurately executing abdominal thrusts, 6) consistently applying 5 back blows × 5 abdominal thrusts, 7) accurately continuing 5 × 5, 8) indicating the initiation of CPR maneuvers in the event of unconsciousness.

Finally, following each test, participants were queried about a subjective variable—their choice between the two suction-based ACDs (LifeVac© and DeCHOKER©) and the reasons for their choice.

Data analysis

A descriptive analysis of the variables was performed. The researchers conducting the data analysis were blinded to which data belonged to each intervention. Categorical variables were reported as absolute and relative frequencies, while continuous variables were expressed as median (interquartile range) based on the non-parametric sample adjustment (Kolmogorov-Smirnov Test). The Chi-Square test was used to compare categorical variables. Furthermore, comparisons involving continuous variables between the LifeVac© and DeCHOKER© devices were conducted using the Wilcoxon signed-rank test. Analysis was performed using the SPSS statistical software (IBM corp., v. 25.0 for Mac), and for all analyses, a p-value of less than 0.05 was statistically significant.

Results

The characteristics of the 60 pediatric residents included in the study are detailed in Table 1. Over 70% of the participants had not undergone FBAO training for more than a year, and only one resident was acquainted with the related suction-based ACDs.

The outcomes concerning the scenario in which participants applied the steps of the currently recommended protocol for addressing FBAO are outlined in Table 2. It was noted that a majority of the steps were carried out by more than half of the sample, yet the percentage of correct execution varied significantly. In the case of back blows (performed by 60% of the sample), over 36% did them incorrectly due to a lack of knowledge regarding the correct number of blows. Similarly, while all participants performed abdominal thrusts, almost half did so incorrectly, as they were unaware of the exact number of thrusts. Regarding the execution of the abdominal thrusts, a substantial number of residents knew how to position themselves behind the victim and put both arms around de upper part of the abdomen (98.3%), place a closed fist between the umbilicus and the ribcage (86.7%), and grasp both hands and pull sharply inwards and upwards (95.0%).

Pediatric residents demonstrated the least recall for the step involving the continuation of 5 back blows and 5 abdominal thrusts while FBAO remained unresolved. Only half of the sample (30 participants) engaged in this step, and merely 16 (53.5%) executed it correctly. When considering the correct execution of all steps, only 13 (21.7%) of participants successfully achieved this. The median for the correct compliance rate stood at 62.5%, with the time taken until the initial clearance attempt being 47.6 s. No statistically significant differences were found between those who received training in the last year and those who received it over a year ago (Table 2).

Table 3 presents data on the utilization of LifeVac© and DeCHOKER© in the simulated FBAO scenario. No significant differences were observed between the two devices in the comparison of the correct execution of each step indicated by the manufacturers. The step prone to the highest error rate involved keeping the mask close-fitting to the victim's airway as more than 20% of participants struggled to maintain a sealed airway during the procedure with both devices. Moreover, considering incorrect device's use, 12 participants (20%) using DeCHOKER© applied insufficient force while pulling the plunger, and 9 (15%) using LifeVac©, disconnected the mask from the plunging unit.

Regarding the time taken with the devices until the first attempt at clearance (the moment when the case was stopped), all participants completed the process in less than one minute. This time was shorter with LifeVac© in comparison with DeCHOKER© (39.2s [30.4–49.1] vs 45.1s [33.7–52.2]; $p = 0.010$). No differences were observed in the correct compliance rate, as the median was 100% for both suction-based ACD.

When comparing participants' correct execution of all steps among the three different methods, about 70% of the residents achieved it using ACDs including the manufacture's instruction leaflet, while only 21.7% did so with the FBAO protocol (Tables 2, 3).

Concerning the subjective feedback following the use of the ADCs, 35 participants (58.3%) expressed a preference for the LifeVac© device, citing its simplicity (27, 45.7%) and intuitiveness (15, 25%). Conversely, those who identified more advantages with DeCHOKER© highlighted its pre-assembled design (10, 16%) and a perception of greater negative pressure generated, noted by 22 participants (36%).

Discussion

This study provides the first findings from the assessment of the use of ACDs in a simulated child choking scenario addressed by pediatric residents. Pediatricians in training showed a lack of awareness regarding the existence and functionality of ACDs, which would be a challenge in offering guidance or dissuasion regarding inquiries by some professionals with the duty to assist (e.g., policemen, lifeguards) and lay people. Nevertheless, participants have demonstrated proficiency in executing the skills required for using the LifeVac© and DeCHOKER© devices (when provided with manufac-

Table 1 – Characteristics of the participants.

Variables	Participants n = 60
Age (years)	27.0 (25.0–29.0)
Weight (kg)	60.0 (52.0–68.0)
Height (m)	1.65 (1.60–1.73)
Gender	
Male	14 (23.3)
Female	46 (76.7)
Year of residency	
1	13 (21.7)
2	16 (26.7)
3	14 (23.3)
4	17 (28.3)
Prior training in FBAO	
Less than 1 year	15 (25.0)
More than 1 year	44 (73.3)
None	1 (1.7)
Type of training	
CPR course	33 (55.0)
Hospital simulation	9 (15.0)
Medical Degree	18 (30.0)
Have you ever witnessed a real-life FBAO event?	
Yes	10 (16.7)
No	50 (83.3)
Have you intervened when the FBAO?	
Yes	4 (6.7)
No	56 (93.3)
Are you familiar with the suction-based airway clearance devices?	
Yes	1 (1.7)
No	59 (98.3)

Continuous variables are expressed with median (interquartile range).

Categorical variables are expressed with absolute frequency (relative frequency).

turers' instructions). On the other hand, curiously they faced more problems to implement the currently recommended FBAO protocol.

The objective of FBAO intervention is to alleviate obstruction without causing harm or injury to the victim. In this regard, finding the most effective, quick and suitable treatment remains a challenge.[7] The currently recommended protocol involves a combination of back blows, abdominal thrusts and/or chest thrusts/compressions) but relies on a low certainty evidence. Furthermore, potential risks of these techniques, such as abdominal bruising and rib injuries, emphasize the ongoing search for alternatives.[1,5] In addition, our study confirms that even health professionals fail when performing the FBAO guidelines.[1,5,7]

In our study, the pediatric residents demonstrated a correct compliance rate only ranging between 50–75% in adhering to the steps of the recommended protocol for a victim experiencing partial FBAO that progresses to severe FBAO. In this instance, the residents did not have explicit instructions or algorithms for resolving FBAO, neither for general nor in pediatric patients. We postulate that this may have resulted in lower success rates than those achieved with the ACDs. However, in a real-world setting, the pediatric residents would not have been provided with instructions to apply the recommended protocol. In this regard, it is worth mentioning that only around 22% of participants successfully executed all the steps of the recommended protocol. Moreover, when considering those who received their latest FBAO training within the past year, this figure only increases to 33%. This underscores the necessity for additional or more targeted training in Spain, suggesting not only the scheduling of refresher practice during pediatric residency every 3–6 months, but also emphasizing the need for a strict policy regarding training and refresher programs. Similar findings have emerged in previous studies involving health science students, where despite receiving specific training, fewer than 23% of participants (n = 31) executed the steps accurately.[23] Limited studies have assessed the proficiency in executing these techniques compared to those required for applying ACDs, but the findings appear to align with our results, suggesting that performing the maneuvers of the recommended protocol is more challenging.[23]

ACDs designed to suction fluids and even small objects have been put in the marketplace and are now available in multiple public areas like shopping centers and airports[10] without clear evidence of their safety and effectiveness and the consequent controversy.[8,14,19,24,25] Our results indicate that pediatric residents were not aware of the ACDs and did not know how to use them. Nevertheless, despite this initial unfamiliarity, the residents demonstrated competence in employing the ACDs with the use of the manufacturer's instruction leaflet. Prior previous studies involving parents, educators,[22] and healthcare learners,[23] also have shown that such devices should be easy to use in a real case without specific training and only following the manufacturers' leaflet.

However, ease of use should not be conflated with the efficacy of airway clearance. In this sense, the most common error observed in both our study (20% of participants) and previous research (ranging from 14% to 43%)[22,23] pertains to the challenge of achieving a proper seal between the facemask and the mannequin's face during the procedure. This is a critical step, as the absence of a close-fitting makes it difficult to generate negative pressure, leading to suction failure. Consequently, we emphasize the necessity for specific training in ACD implementation, with a particular focus on mastering this critical aspect. Research has shown that a brief training session, lasting between 15–30 min, can be sufficient for the effective utilization of these devices.[16]

A concern about the use of ACDs might by the delay in initiating the currently recommended maneuvers or even lead to the omission of them. In fact, studies by Bhanderi[16] and Dunne[15] observed that, despite stating that the devices should be used only after fail of properly performed recommended maneuvers, many first responders skipped steps or the entire protocol, opting to apply the devices immediately. This complicates the assessment of whether these situations could genuinely be resolved without the use of devices through the correct application of the protocol. In this sense, our results indicate that, in the simulated scenario, both devices could be used without significant delay, as all participants were able to use them in less than one minute, with some advantage for the LifeVac©, in agreement with previous simulation studies.[12,22,23]

The users' preference in our sample was in favor of LifeVac© over DeCHOKER© and was based on the ease of use and also on the feeling of risk of the big oropharyngeal tube of the DeCHOKER© device that appeared potentially dangerous. The presence of such intraoral component was also noted as a source of concern, leading to heightened nervousness among those surveyed, as documented by Dunne.[15]

Considering the observed ease of use in our study and the potential effectiveness in real-life scenarios[14–17] we suggest these devices should be assessed in clinical trials, at least as rescue resources

Table 2 – Descriptive analysis of participants' execution of recommended steps for treating a child victim with FBAO.

Variables	Overall (n = 60)	Training < 1 year (n = 15)	Training > 1 year (n = 44)	*v2* *p*-value
Encourage to cough				
Yes	55 (91.7)	15 (100)	39 (88.6)	1.198
No	5 (8.3)	–	5 (11.4)	$p = 0.371$
Give 5 back blows				
Yes	36 (60.0)	7 (46.7)	28 (63.6)	2.020
No	24 (40.0)	8 (53.3)	16 (37.4)	$p = 0.364$
Give black blows correctly	n = 36	n = 8	n = 28	
Yes	23 (63.9)	6 (75.0)	17 (60.7)	6.223
No	13 (36.1)	1 (12.0)	11 (39.3)	$p = 0.183$
Give 5 abdominal thrusts				
Yes	60 (100)	15 (100)	44 (100)	–
No	–	–	–	
Give abdominal thrusts correctly				
Yes	31 (51.7)	9 (60.0)	21 (47.7)	1.626
No	29 (48.3)	6 (40.0)	23 (52.3)	$p = 0.444$
Continue to 5 back blows and 5 abdominal thrusts				
Yes	30 (50.0)	7 (46.7)	23 (52.3)	1.158
No	30 (50.0)	8 (53.3)	21 (47.7)	$p = 0.561$
Continue to 5 back blows and 5 abdominal thrusts correctly	n = 30	n = 7	n = 23	
Yes	16 (53.3)	5 (71.4)	11 (47.8)	2.310
No	14 (46.7)	2 (28.6)	12 (52.2)	$p = 0.679$
Start BLS for unconscious victim				
Yes	55 (91.7)	14 (93.3)	41 (93.2)	11.187
No	5 (8.3)	1 (6.7)	3 (6.8)	$p = 0.004$
Start BLS for unconscious victim correctly	n = 55	n = 14	n = 41	
Yes	53 (96.4)	13 (92.8)	40 (97.6)	11.857
No	2 (3.6)	1 (7.2)	1 (2.4)	$p = 0.018$
Perform all the steps correctly				
Yes	13 (21.7)	5 (33.3)	8 (18.2)	1.794
No	47 (78.3)	10 (66.7)	36 (81.8)	$p = 0.408$
Correct compliance rate	62.5 (50.0–75.0)	50.0 (37.5–100.0)	62.5 (50.0–75.0)	0.836[b]
Time to back blows (sec)	14.5 (12.4–19.5)	13.0 (12.5–20.2)	14.5 (12.2–19.5)	0.712[b]
Time to abdominal thrust (sec)	21.5 (15.7–28.2)	19.5 (15.5–20.6)	24.3 (15.7–29.2)	**0.019**[b]
Total time (sec)	47.6 (43.2–57.6)	48.3 (43.9–53.2)	47.5 (42.5–59.4)	0.207[b]

Abbreviations: FBAO = Foreign Body Airway Obstruction; BLS = Basic Life Support; sec = seconds.

Continuous variables are expressed with median (interquartile range).

Categorical variables are expressed with absolute frequency (relative frequency).

p-values calculated by Chi-square test.

[b] Kruskal-Wallis test.

when FBAO recommended techniques (back blows and abdominal thrusts) fail or become unfeasible. In this context, earlier studies have highlighted the challenge of performing abdominal thrusts on individuals in wheelchairs or bedbound patients.[16] In such circumstances, ACDs could emerge as a viable alternative, given their adaptability in seated or reclined positions. Nevertheless, drawing substantial conclusions is constrained by the fact that most of these studies provided preliminary, limited data or industrial involved bias.[15,25] Furthermore, there are even studies conducted on cadavers that reveal difficulties and, in certain instances, ineffectiveness in clearing specific food items such as saltine crackers, whole grapes, and cashews using LifeVac© and DeCHOKER©.[18]

In addition, subsequent studies ought to investigate the negative pressures produced by both devices under varying forces and speed of traction, along with definition of the optimal pressure for effective and safe clearance of airway obstruction.[18]

Limitations

Our study has certain limitations. Firstly, the application of ACDs on a plastic mannequin may not precisely replicate the conditions in conscious humans experiencing severe FBAO, potentially leading to different results in a real-life scenario. Secondly, the efficacy of the devices in foreign body clearance was not assessed due to the non-specific nature of the mannequins used for FBAO, and the airway was not sealed. On the other hand, in the two scenarios involving ACDs, a mannequin was used for FBAO simulation whereas in the recommended protocol scenario a real trained victim was employed. This was necessitated by the inherent difficulty in effectively performing "encourage to cough", "back blows", and "abdominal thrust" on a dummy. Besides, the three scenarios were conducted consecutively without a wash-out period, under the assumption that they were distinct enough not to be influenced by this factor. Additionally, the order was randomized to minimize any potential learning bias. Participants

Table 3 – Descriptive analysis of the participants' performance with LifeVac© and DeCHOKER© devices during an adult victim FBAO.

Variables	LifeVac©	DeCHOKER©	*p*-value
Place the mask correctly covering the victim's nose and mouth			
Yes	56 (93.3)	54 (90.0)	0.301
No	4 (6.7)	6 (10.0)	
Push in handle			
Yes	59 (98.3)	–	–
No	1 (1.7)	–	
Pull handle (LifeVac©) // Pull the plunger out with force (DeCHOKER©)			
Yes	60 (100)	58 (96.7)	–
No	–	2 (3.3)	
Keep the mask fixed to the victim's airway throughout the procedure			
Yes	47 (78.3)	48 (80.0)	0.754
No	13 (21.7)	12 (20.0)	
Perform all the steps correctly			
Yes	42 (70.0)	44 (73.3)	0.445
No	18 (30.0)	16 (26.7)	
Correct compliance rate	100 (80.0–100)	100 (75.0–100)	0.173[a]
Time to device fitting on the victim	30.9 (25.8–39.2)	35.9 (27.8–47.2)	0.010[a]
Total time	39.2 (30.4–49.1)	45.1 (33.7–59.2)	0.010[a]

Continuous variables are expressed with median (interquartile range).
Categorical variables are expressed with absolute frequency (relative frequency).
p-values calculated by Chi-square test.
[a] *p*-values calculated by Wilcoxon test.

were asked not to share information with others to avoid risk of bias. Finally, our study lacks a formal sample size calculation.

Conclusions

In the case of simulated FBAO, pediatric residents faced challenges in applying the recommended protocol, as only a minority of them were able to complete all the steps correctly. In contrast, even though the ACDs were unfamiliar to almost all residents, about 70% were able to use these devices. However, a significant proportion could not, indicating that ACDs alone do not address all issues.

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CRediT authorship contribution statement

Aida Carballo-Fazanes: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation. **Verónica Izquierdo:** Writing – review & editing, Methodology, Investigation, Data curation. **Juan Mayordomo-Colunga:** Writing – review & editing, Project administration, Methodology, Investigation, Data curation. **José Luis Unzueta-Roch:** Writing – review & editing, Project administration, Methodology, Data curation. **Antonio Rodríguez-Núñez:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

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ORIGINAL ARTICLE

Comparative efficacy of LifeVac® and Heimlich maneuver in simulated airway obstruction

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Abdominal thrust;
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Abstract

Objectives: Foreign body airway obstruction is a significant cause of morbidity and mortality, especially in infants and young children. This study aims to compare the efficacy of the Heimlich maneuver and LifeVac® in a simulated environment.

Methods: A prospective experimental study was conducted using the Choking Charlie (Laerdal®) mannequin, which simulates the trunk from an adult male and is considered suitable for simulating choking events in young children. The study involved four operators: one Pediatric Advanced Life Support (PALS) instructor and professor of Trauma and Emergency Medicine, along with three members of the university's Pediatric Academic League, all previously trained in Basic Life Support (BLS). The primary outcome was the success rate of foreign body removal. Intracavitary pressures generated during the maneuvers were measured using a digital manometer.

Results: A total of 200 anti-choking maneuvers were performed, and both techniques successfully relieved airway obstruction in all cases. The LifeVac® device generated significantly lower intracavitary pressure differentials compared to the Heimlich maneuver ($p < 0.000$). Additionally, both techniques exhibited significant variability in applied pressure among different examiners ($p < 0.000$).

Conclusions: Both the Heimlich maneuver and LifeVac® are effective in relieving foreign body airway obstruction when performed by specialists in a simulated environment. Heimlich generated higher positive pressure gradients, while LifeVac® produced lower negative pressure gradients.

Abbreviations: BLS, basic life support; FB, foreign body; FBAO, foreign body airway obstruction.

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Introduction

Foreign body aspiration into the respiratory tract is associated with significant morbidity and mortality and is a major cause of accidental death worldwide.[1–4] Choking injuries are a major contributor to morbidity and mortality among young children and produce a substantial public health burden. Infants and children under three years old account for 75% of the victims in the pediatric population.[5] The impact on the pediatric population ranges from acute and temporary consequences to chronic manifestations and permanent sequelae.[6,7]

Foreign Body Airway Obstruction (FBAO) accompanied by asphyxia is considered a medical emergency, and rescue treatment may include abdominal thrusts (Heimlich maneuver), chest compressions, and back blows.[8,9] These maneuvers aim to increase subdiaphragmatic pressure, expelling the foreign body from the airway.[9] However, the evidence supporting these techniques is limited, and their use has been linked to various traumatic complications.[10,11]

Recently, anti-choking suction devices have emerged as a potential alternative for FBAO treatment. Unlike classical anti-choking maneuvers, which generate positive pressure in the airway, these devices displace the foreign body through negative pressure suction. LifeVac® is one such device that generates negative pressure to assist asphyxiated patients (Figure 1). According to the manufacturer, this device is portable, easy to operate, and does not require an external power source. Despite its biological plausibility, the literature on LifeVac®'s performance is sparse, with most studies involving experimental models or case reports and series.[2,12–15]

Experimental studies conducted with the LifeVac® device using mannequins and cadavers have shown promising results. Juliano et al. conducted an experiment on an adult human cadaver using clay to simulate a food bolus obstruction, achieving success in 98% of cases (one attempt) and 100% with an additional attempt.[14] Lih-Brody et al.[16,17] demonstrated LifeVac®'s efficacy at 94% (one attempt), 99% (two attempts), and 100% (three attempts) using different mannequin models.

There are limited real-life clinical studies on the device. Between 2014 and 2020, only 22 cases of LifeVac® use were reported, all of which successfully removed the foreign body within three attempts without side effects.[5] A prospective observational study of 157 LifeVac® cases from 2021 to 2023 reported nearly universal success but noted 10 adverse events potentially related to the device.[18] A systematic review indicated insufficient robust evidence to support or discourage the device's use.[9]

This study aims to evaluate the efficacy of disobstruction maneuvers (Heimlich and LifeVac®) in a simulated mannequin scenario and compare the intracavitary pressures generated by these techniques.

Methods

Study design

A prospective experimental study was conducted. Four researchers of different genders and age groups performed sequential disobstruction maneuvers for FBAO. The experiment was conducted on a mannequin in the realistic simulation laboratory of the Pontifical Catholic University of Rio Grande do Sul (PUCRS).

Participants

The group of operators included a Trauma and Emergency professor and three students from the University's Pediatric Academic League, all previously trained in Basic Life Support (BLS). Therefore, all operators were considered qualified and capable of performing the maneuvers. The study was approved by the local ethics committee (CAAE: 80,343,924.1.0000.5336).

Simulation model

The model used for the FBAO simulation was the Choking Charlie (Laerdal®) mannequin. It weighs 25 lb (11.3 kg) and measures 40.2 in (102.1 cm) in length and 21.2 in (53.8 cm) in width, simulating the trunk of an adult male. It is also considered suitable for simulating choking events in young children (3–4 years), despite having the characteristics of a larger trunk, because airway obstruction (or choking) has similar mechanics, regardless of size. According to the manufacturer, Choking Charlie's airway system is designed to simulate a realistic obstruction in adults and children. Pediatric training in the area of basic life support uses this mannequin for training in the Heimlich Maneuver from the age mentioned (3–4 years).

The model features anatomical landmarks, including the rib cage and navel, to enhance realism in hand positioning training. The mannequin's oral cavity is fixed in an open position and includes a tongue and dental arch. It is primarily made from high-strength plastics and silicone, providing durability and realism. The exterior has a texture that simulates human skin, offering a realistic feel during maneuvers. The internal components are made of plastic with varying degrees of rigidity to ensure that compression or manipulation actions simulate the behavior of a human body more accurately. The mannequin has an airway system structurally designed to mimic human anatomy, albeit in a simplified form for training purposes. The airway is not a rigid tube as found in other types of simulation mannequins. Instead, it is designed to simulate the human respiratory tract realistically, respecting anatomical proportions and allowing trainees to perform compression maneuvers and other first aid interventions with an appropriate tactile response. The head is adjustable, and the neck can be manipulated to alter the position of the airways, making the training more realistic.

The object used for simulating the foreign body (FB) was the accessory provided by the manufacturer (Bolus - Laerdal®). The bolus used as the FB has a spherical shape and, according to the producer, was designed to simulate food in the airway and weighs 0.88 lbs (0.4 kg). It is made of a compressible material and has an approximate diameter of 2 cm. According to the specifications provided by the company (Laerdal®), the object was designed to generate a complete airway obstruction. The Bolus is made from polyurethane foam, a lightweight, flexible material with a soft

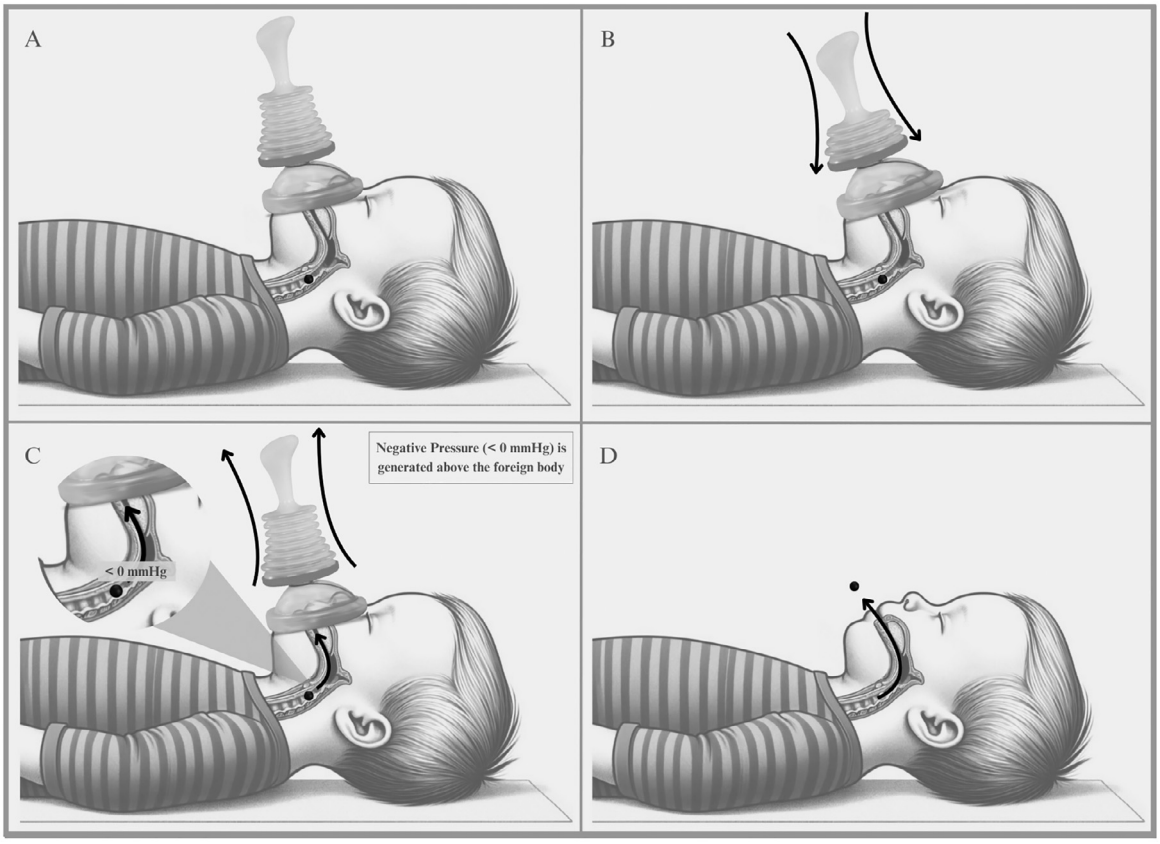

Figure 1 Sequential steps for airway obstruction relief using the LifeVac® device in a pediatric patient. Fig. 1 shows the sequence of using of the LifeVac® device to clear airway obstruction in a child. (A) Positioning the device over the child's mouth and nose, ensuring an airtight seal. (B) Pressing the plunger down to create positive pressure in the airways. (C) Quickly pulling the plunger up to generate negative pressure, dislodging the obstructive object. (D) Successful removal of the object from the airways, restoring the child's breathing ability.

texture but capable of providing the necessary resistance to simulate airway obstruction.

Procedure

Each operator performed both disobstruction maneuvers, i.e., using both the LifeVac® device and the Heimlich maneuver. The sequence of maneuvers (LifeVac® and Heimlich; or Heimlich and LifeVac®) was determined by a draw among the operators. Once the order was defined and the technique designated as "first" by the draw was initiated, the operator had to sequentially perform 25 disobstruction maneuvers. After completing this stage, the same operator had to sequentially perform another 25 disobstruction maneuvers with the technique designated as "second" by the draw. For the same operator, a 10-minute interval was allowed between the two stages.

In each new disobstruction maneuver, regardless of the technique used, the time was standardized. The same research team always prepared the mechanical obstruction in the model with the FB, which was manually positioned during each attempt to ensure total upper airway obstruction during the maneuvers. The FB was positioned past the first point of resistance, using the index finger and applying moderate pressure, creating a complete obstruction of the airway.

The estimated time between applying one maneuver and causing a new airway obstruction in the model was approximately 30 seconds. A 30-second pause was taken between each maneuver, totalling a cycle of approximately one minute between sequential maneuvers in each of the two stages.

Measurement of intracavitary pressure

To evaluate the negative and positive peak pressures generated during the maneuvers, a digital manometer (Homed MVD 300-U®)[19] was used, which recorded the peak pressure value obtained in real-time. The manometer has a silicone catheter that transmits the pressure from the point of interest to its sensor. Thus, during maneuvers performed with LifeVac®, the catheter's end should be positioned in the oral cavity above the FB to measure the negative peak pressure generated by the device (LifeVac®). During Heimlich maneuvers, on the other hand, the catheter should be positioned in the mannequin's larynx below the FB to measure the positive peak pressure generated by the Heimlich maneuver. The highest pressure value generated during each maneuver was recorded and transcribed to a standardized form.

Statistical analysis

Continuous variables were described by mean and standard deviation or median and interquartile range. In cases of sample asymmetry, the Kruskal-Wallis test was used. The Mann-Whitney U test was applied to compare distributions between the Heimlich maneuver and the LifeVac® device. To compare means between groups, one-way Analysis of Variance (ANOVA) with Bonferroni post-hoc was applied. Comparisons within groups were assessed by the Wilcoxon test. The significance level adopted was 5% ($p \leq 0.05$).

Results

Throughout the experiment, 200 anti-choking maneuvers were performed. Twenty-five sequential maneuvers for both disobstruction techniques by the four different operators. In all maneuvers, airway obstruction by the FB (Bolus®) was successfully relieved. During the Heimlich Maneuver, the peak positive pressure generated was recorded by the equipment's manometry function, generating a pressure gradient from the zero-pressure level. Similarly, in the LifeVac® maneuver, a pressure gradient was generated, but the peak pressure generated was negative, recorded by the equipment's vacuum measurement function. The measured values of peak pressures (both positive and negative), along with their standard deviations, are reported in the Supplementary Material.

Significant differences in the pressure gradients (△P) generated by the techniques, compared to the baseline (zero pressure), were observed across all four operators ($p < 0.001$). Specifically, the positive pressure gradients generated by the Heimlich Maneuver, which increase intra-abdominal and intrathoracic pressure, were higher than the negative pressure gradients produced by LifeVac®, which creates suction above the obstruction. The comparison between negative (LifeVac®) and positive (Heimlich) expulsive airway pressures is presented in Figure 2 in a single baseline normalization model to standardize the measurements.

When comparing the pressure gradients obtained by the four operators for both the Heimlich maneuver and LifeVac®, individual pressure differences were observed ($p < 0.000$). The average pressure gradient generated by the examiners applying the two different maneuvers was significantly different.

When comparing the intra-examiner pressure gradient by comparing the values obtained by the Heimlich Maneuver with those obtained using LifeVac®, individual behavior differences were found. Operators 1, 2, and 3 showed differences in the pressure gradients obtained between the two maneuvers ($p < 0.001$), while operator 4 did not show this difference ($p = 0.478$).

Discussion

In a simulated and controlled environment, with an adult with open mouth model, both the positive pressure-generating maneuver (Heimlich) and the negative pressure-generating maneuver (LifeVac®) were effective in disobstructing the mannequin's airway with a round object, which, according to the producer, was designed to simulate food in the airway. Thus, the previously described biological plausibility for using LifeVac® shows similar performance to the Heimlich maneuver in a controlled experimental environment. This finding is consistent with some reports and small case series, as well as a prospective observational study, that describe success in treating FBAO using the device.[18]

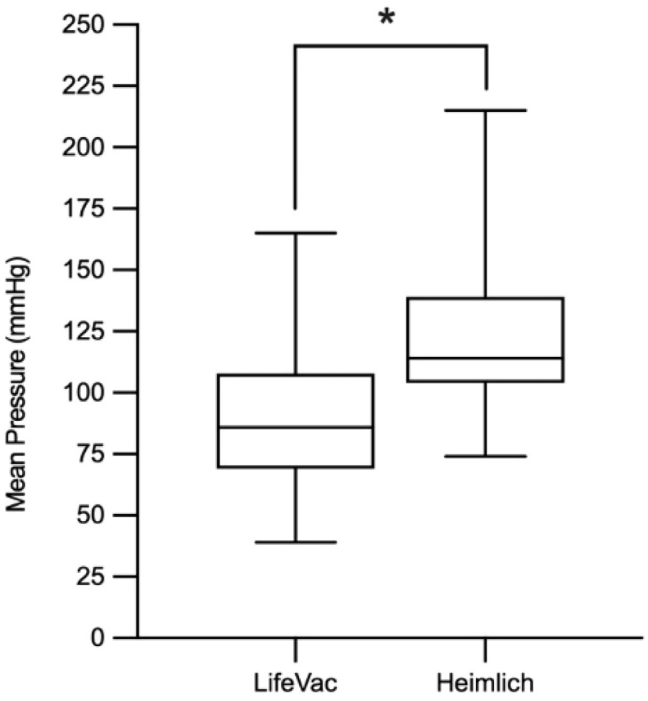

Figure 2 A Single-Baseline Comparison of Negative (LifeVac®) and Positive (Heimlich) Expulsive Airway Pressures. Fig. 2 presents **a** box plot illustrating the mean pressure (mmHg) generated by the LifeVac® device (negative pressure) and the Heimlich maneuver (positive pressure). The data are presented in a single baseline normalization model for standardization, with LifeVac® values not shown below the baseline, as both maneuvers produce a vector in the same direction, facilitating foreign body expulsion. Significant differences ($p < 0.001$, Mann-Whitney U test) between techniques are indicated by a (*).

This comparative finding between techniques is significant because, to our knowledge, no existing study, even in a simulated environment, has directly evaluated both techniques while incorporating the measurement of intracavitary pressures.[18] Our work aligns with the suggestion by Dunne CL and colleagues in a prospective case series, which proposed that pre-clinical studies in a simulated environment comparing disobstruction techniques are valuable. They argued that querying databases would not provide conclusive evidence for the use of these devices due to the rarity of such events and the challenges in their characterization.[18]

In the series by Dunne CL and colleagues, conducted over two years (July 2021—June 2023), the use of two different negative pressure-generating devices was evaluated in 186 adult patients: LifeVac® (n = 157/84.4%) and Dechoker® (n = 29/15.6%). LifeVac® was the last intervention before airway obstruction relief in 151 of 157 cases.[18] The

performance of the devices was similar, and operators agreed on the ease of applying the technique and the safety of these devices.[18]

In another study, McKinley MJ and colleagues described the use of the LifeVac device in adult patients from 2014 to 2020.[12] In their series, 39 patients had conditions that put them at risk for dysphagia. In 38 patients, the device resolved the choking incident, and the patients survived.[12] Although the device successfully removed the obstruction in the 39th patient, as confirmed by paramedics, the patient could not be resuscitated despite CPR maneuvers.[12]

Although the literature reports the ease of application of the device, our observations revealed differences in pressure gradients between techniques and among operators. While the device is generally easy to handle, its efficacy may vary among operators. Despite all maneuvers being effective in dislodging the obstruction, the pressure values generated varied significantly.

Cardalda-Serantes B. and colleagues outlined a study with 43 health science students to resolve FBAO in three simulated mannequin scenarios: 1) using LifeVac®, 2) using Dechoker®, and 3) following BLS protocol recommendations.[20] The technical compliance rates in the three scenarios and the time needed to complete each maneuver were evaluated.[20] All scenarios were adequately resolved with the employed techniques.[20] However, the time difference favoring the use of LifeVac® compared to other maneuvers stands out.[20] The adequacy rates for the technique at all stages were not different between devices.[20] They showed adequacy rates of 60% and 80%, respectively, considering the use of LifeVac® and Dechoker®.[20] This scenario indicates a percentage of operators who do not fully comply with all technical steps when using the devices.

Therefore, we can infer that variations in the final outcomes may arise due to differences in the execution of the techniques by different operators, even when considering the same intervention stage (Heimlich or LifeVac®). The reported ease of using the device may not translate into evaluative outcomes of technique and generated pressure gradient. We believe that regular and systematic training should contribute to better praxis and a consequent approximation of these technique-related outcomes.

As for the observed pressure gradient differences considering the use of LifeVac® compared to the Heimlich Maneuver, we were not surprised. The Heimlich Maneuver is known to be associated with a higher incidence of complications and traumatic events, including vascular, gastroesophageal, and thoracic injuries.[11–18,21] Severe complications such as pneumomediastinum, aortic valve rupture, diaphragmatic herniation, aortic dissection, gastric rupture, and splenic rupture have been reported.[11,21] Therefore, it is reasonable to expect that a technique generating higher pressure gradients would be associated with a higher occurrence of these complications, even though there may be other causes for these conditions, such as direct trauma during the maneuver.

Our study has some limitations. The primary limitation is the simulated and controlled nature of the experiment, which was conducted on mannequins. Although designed to replicate the human airway, the mannequin's system is simplified for training purposes. This does not fully replicate real-life conditions where the behavior of pressure gradients and the effectiveness of disobstruction techniques might vary. Additionally, the study involved only four operators, all of whom were highly trained and familiar with BLS, representing a small and specialized sample that may not be representative of the general population.

Despite the limitations, our study suggests that airway disobstruction in experimental models using negative pressure-generating anti-choking devices seems promising. However, for real-life scenarios, the results should still be interpreted with caution. Our findings indicate that the pressure gradients generated are lower than those from the Heimlich Maneuver and that there are variabilities in the intracavitary pressures generated by the technique among examiners. Additionally, although it is referred to as easy to apply in most related articles, our findings may suggest the need for greater training.

Both the Heimlich maneuver and LifeVac® are effective in relieving foreign body airway obstruction when performed by specialists in a simulated environment. The Heimlich maneuver generated higher positive pressure gradients, increasing intra-abdominal and intrathoracic pressure, while LifeVac® produced lower negative pressure gradients through suction above the obstruction. Moreover, our findings indicate that the device application may involve certain complexities.

Conflicts of interest

The authors declare no conflicts of interest.

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Supplementary materials

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(10) Anti-Choking Devices

Customer Name:	LifeVac LLC
Customer P.O.:	20160004
Date of Revised Report:	July 15, 2016
Test Report No.:	R-16001, Rev. A
Test Start Date:	July 8, 2016
Test Finish Date:	July 8, 2016
Test Technician:	J. Kingdon
Lead Env. Test Technician:	V. Rondon
Approved By:	M. Hull
Report Revision Prepared By:	G. Bradshaw
Government Source Inspection:	Not Applicable

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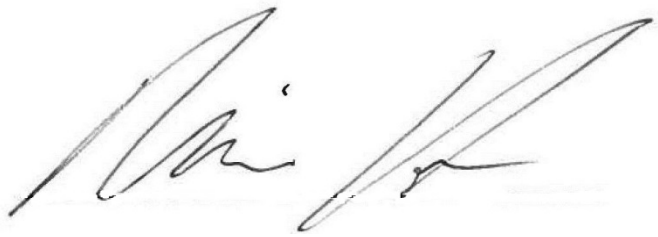
Certification and Signatures

We certify that this report is a true report of the results obtained from the tests of the equipment stated and relates only to the equipment tested. We further certify that the measurements shown in this report were made in accordance with the procedures indicated and vouch for the qualifications of all Retlif Testing Laboratories personnel taking them.

Victor Rondon
Lead Environmental Test Technician



Michael Hull
Environmental Laboratory Supervisor

Non-Warranty Provision
The testing services have been performed, findings obtained and reports prepared in accordance with generally accepted laboratory principles and practices. This warranty is in lieu of all others, either expressed or implied.

Non-Endorsement
This test report contains only findings and results arrived at after employing the specific test procedures and standards listed herein. It is not intended to constitute a recommendation, endorsement or certification of the product or material tested. This test report may not be used by the client to claim product endorsement by NVLAP, NIST or any agency of the U.S. Government.

Revision History

Revisions to this document are listed below; the latest revised document supersedes all previous issues of this document:

Revision	Date	Pages Affected
-	July 12, 2016	Original Release
A	July 15, 2016	Global Changes • Report Number: R-16001 to Revised Report R-16001, Rev. A 8 • Corrected the conversion from psi to mmHg on data sheet

Test Program Summary

Test Report Number:	R-16001, Rev. A
Customer:	LifeVac LLC
Address:	83 Rome Street
	Farmingdale, NY 11735
Manufacturer:	LifeVac LLC
Test Sample:	(10) Anti-Choking Devices

Test Environment
All testing was performed at the Retlif Testing Laboratories, Ronkonkoma, New York facility. Each test method was performed in the environment specified within the test standard.

Test Purpose
The purpose of this evaluation test program was to determine the output pressure of the (10) Anti-Choking Devices in accordance with the method requirements of Retlif Testing Laboratories Quote YE06296-6.

Test Specification
Retlif Testing Laboratories Quote: YE06296-6, Dated: July 1, 2016.

Mode of Operation
During the performance of all testing specified herein, the equipment under test (EUT) was operated as follows:

Mode 1:
- During the course of this test, the EUT was operated while verifying an output pressure

Acceptability Criteria
The following was considered EUT acceptability:

- No apparent visual damage noted
- Output pressure must be recorded for each EUT

Modifications
No modifications were made to the EUT during the course of this testing program in order to demonstrate compliance with the specified requirements.

Test Sequence and Results
Table 1 details the test method that was performed on the (10) Anti-Choking Devices and the test results obtained.

Table 1 - Test Sequence and Results

Testing Date	Test Method	Test Results
July 8, 2016	Pressure Verification	Complied[(1)]

[(1)]EUT complies with the Acceptability Criteria as described herein.

Pressure Verification
Test Data

TEST DATA SHEET

Test Method:	**Pressure Verification**		
Customer:	LifeVac LLC		
Job Number:	R-16001		
Test Sample:	(10) Anti-Choking Device		
Test Specification:	Retlif Testing Laboratories Quote: YE06296-6	**Para:**	N/A
Operating Mode:	Mode 1		
Technician:	J. Kingdon		
Date:	7/8/16		
Notes:			

Date	**Time**	**Test Log**
7/8/16	14:15	Began test. The pressure output from each EUT was measured as in the table below.

EUT	Trial 1 (PSI / mmHG)	Trial 2 (PSI / mmHG)	Trial 3 (PSI / mmHG)
1	0.001 / 0.0517	0.004 / 0.2068	0.002 / 0.0517
2	0.003 / 0.1551	0.006 / 0.3103	0.005 / 0.2586
3	0.002 / 0.0517	0.002 / 0.0517	0.003 / 0.1551
4	0.001 / 0.0517	0.004 / 0.2068	0.003 / 0.1551
5	0.001 / 0.0517	0.002 / 0.0517	0.001 / 0.0517
6	0.004 / 0.2068	0.002 / 0.0517	0.001 / 0.0517
7	0.001 / 0.0517	0.001 / 0.0517	0.002 / 0.0517
8	0.001 / 0.0517	0.001 / 0.0517	0.001 / 0.0517
9	0.001 / 0.0517	0.002 / 0.0517	0.002 / 0.0517
10	0.003 / 0.1551	0.001 / 0.0517	0.001 / 0.0517

	14:25	Test Complete.

Results:	There was no apparent damage noted as a result of this test. The EUT met the requirements of the Pressure Verification Test.

Test Photographs
Pressure Verification

Test Setup

Equipment List
Pressure Verification

EN	Manufacturer	Description	Range	Model No.	Cal Date	Due Date
886A	3D INSTRUMENTS	GAUGE, PRESSURE	0 - 30 Psi	65514-21B55	11/10/2015	11/30/2016

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Vacuum Verification Test Report

On

(10) Anti-Choking Devices

Customer Name:	LifeVac LLC
Customer P.O.:	Check Number: 1039
Date of Report:	January 15, 2016
Test Report No.:	R-15818
Test Start Date:	January 11, 2016
Test Finish Date:	January 11, 2015
Test Technician:	J. Schlee
Lead Env. Test Technician:	V. Rondon
Approved By:	M. Hull
Report Prepared By:	G. Bradshaw
Government Source Inspection:	Not Applicable

Test Program Summary

Test Report Number:	R-15818
Customer:	LifeVac LLC
Address:	83 Rome Street
	Farmingdale, NY 11735
Manufacturer:	LifeVac LLC
Test Sample:	(10) Anti-Choking Devices
Serial Number:	1 through 10

Test Environment
All testing was performed at the Retlif Testing Laboratories, Ronkonkoma, New York facility. Each test method was performed in the environment specified within the test standard.

Test Purpose
The purpose of this qualification test program was to determine if the (10) Anti-Choking Devices could withstand the anticipated environmental extremes in accordance with the method requirements of Retlif Testing Laboratories Quote YE1221501.

Test Specification
Retlif Testing Laboratories Quote: YE12215-1, Dated: December 23, 2015.

Mode of Operation
During the performance of all testing specified herein, the equipment under test (EUT) was operated as follows:

Mode 1:
- During the course of this test, the EUT was operated while verifying a minimum of 300mmHg

Acceptability Criteria
The following was considered EUT acceptability:

- No apparent visual damage noted
- The EUT must pull vacuum in excess of 300mmHg

Modifications
No modifications were made to the EUT during the course of this testing program in order to demonstrate compliance with the specified requirements.

TEST DATA SHEET

Test Method	**Vacuum Verification**	
Customer	LifeVac LLC	
Job Number	R-15818	
Test Sample	(10) Anti-Choking devices	
Part Number	N/A	
Model Number	N/A	
Serial Number	1 through 10	
Test Specification	Retlif Testing Laboratories Quote: YE12215-1	**Para: N/A**
Operating Mode	Mode 1	
Technician	J. Schlee	
Date	1/11/16	
Notes:	All Readings in mm/Hg.	

Date	Time	Test Log				
1/11/16	20:10	Began testing of EUT.				
		Unit	Reading 1	Reading 2	Reading 3	Result
		1	319.4	315.3	327.6	Pass
		2	327.9	330.2	329.1	Pass
		3	327.4	323.7	327.9	Pass
		4	325.9	336.1	331.5	Pass
		5	332.2	331.4	328.7	Pass
		6	343.1	332.0	346.5	Pass
		7	320.1	331.7	330.5	Pass
		8	332.4	348.7	341.6	Pass
		9	339.0	334.4	344.4	Pass
		10	349.7	344.8	341.6	Pass
	21:15	Testing completed.				

Results:	There was no apparent visual damage noted as a result of this test. The EUT performed properly during operation. The (10) Anti-Choking Devices met the requirements of the Vacuum Verification test.

Sheet 1 of 1

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Test Photographs
Vacuum Verification

Test Setup

Summary of Environmental Testing

Testing Lab: Retlif Testing Laboratories

795 Marconi Ave

Ronkonkoma, NY11779

Test dates: 6/22/15 thru 6/24/15

A total of 20 units, 10 new units and ten of the previous version (see notes at bottom) were tested in accordance with MIL-STD-810G for High Temperature (method 501.5), Low Temperature (method 502.5) and Temperature shock (method 503.5).

High temp was tested at 120 F. Exposure time was 5 hours (3 hours to stabilize and 2 to soak).

Low temp was tested at -10 F. Exposure time was 5 hours (3 hours to stabilize and 2 to soak).

The same temperatures were used as the extremes of the shock test. Test duration was 21 hours total (12 cold and 9 hot).

Testing among each batch of ten units (new and previous version) was broken down as follows:

- Unit 1 High Temp, Functional
- Unit 2 High Temp, Functional
- Unit 3 High Temp only
- Unit 4 High Temp only
- Unit 5 Low Temp, Functional
- Unit 6 Low Temp, Functional
- Unit 7 Low Temp only
- Unit 8 Low Temp only
- Unit 9 High Temp, Low Temp, Temp Shock
- Unit 10 High Temp, Low Temp, Temp Shock

Functional testing was performed on units 1, 2, 5, and 6 as soon as they were removed from test chamber. This consisted of plugging the center hole of the LifeVac unit and compressing the plunger and then pulling the plunger to confirm that suction was being generated and no leakage was occurring.

All four units passed this test.

Units 3, 4, 7, 8, 9, and 10 did not undergo functional test by Retlif but will be tested at LifeVac by pulling a blockage from the airway of a Laerdl Charlie simulator in order to demonstrate functionality after being exposed to temperature extremes.

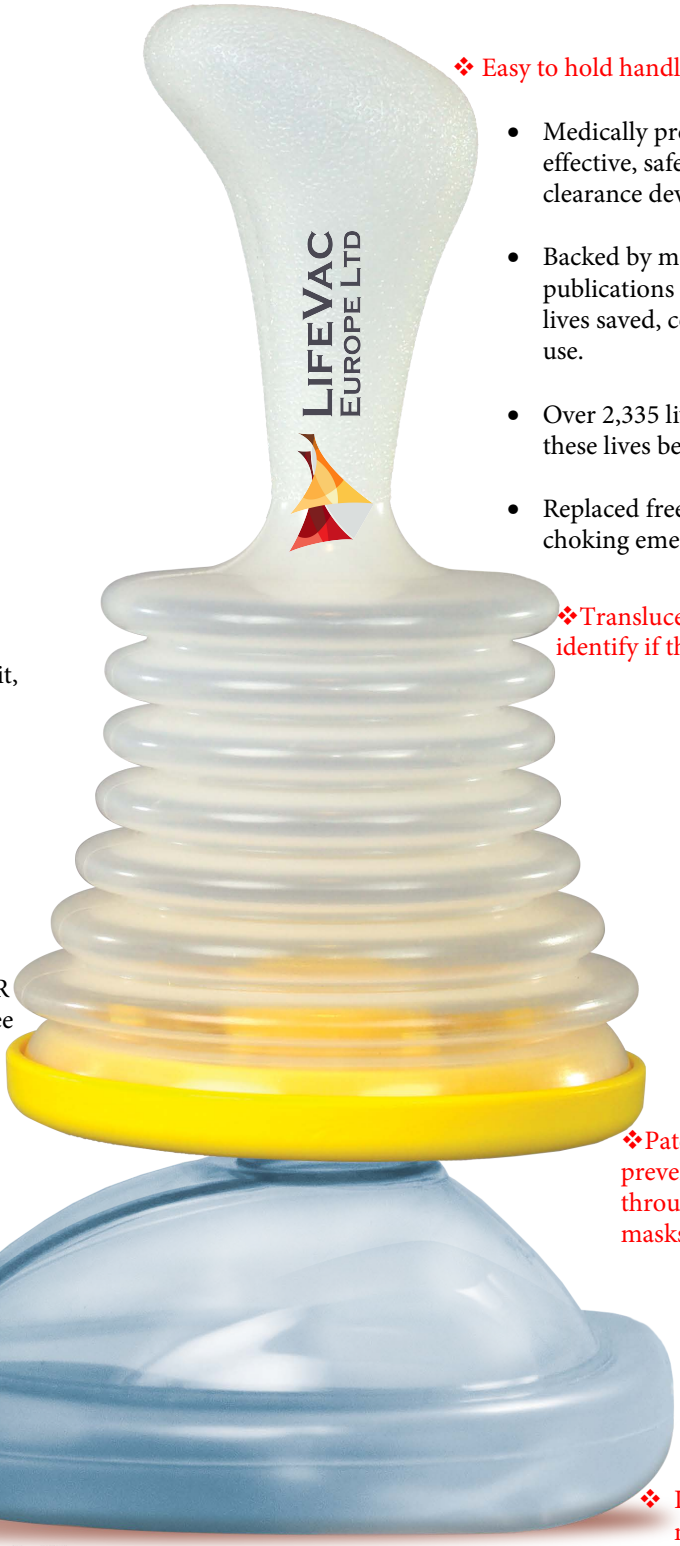
All units will also be examined by LifeVac for any evidence of the units physically coming apart as a result of the exposure to extreme temperatures. This will be done on Friday 6/26.

*** Old Units: 8 pin press fit construction with large O-ring, no O-ring on valve seat. New Units: 4 stainless screws and 4 pins, with large O-ring in a molded groove. Also a small O-ring in ball valve ***

Official test report from Retlif Testing Laboratories is available for view upon request

LifeVac Europe Ltd

- LifeVac is a patented non-invasive, portable airway clearance device.
- Interchangeable sized masks, clearly identified by colour coded indentifiers.
- No risk of pushing the tongue or obstruction back in a panic situation.
- Replaced free of charge when used in a choking emergency.
- Generates over 326mm Hg of suction, safely and effectively dislodging the obstruction.
- Can be used for full and partial obstructions.
- Saved thousands of lives around the world from choking to death.
- **Only** airway clearance device with independent medical testing, peer reviewed medical publications, peer reviewed abstracts proving safety, effectiveness and lives saved.
- Comes in four different variations, Standard LifeVac Kit, LifeVac Travel Kit, EMS LifeVac Kit and Wall mounted LifeVac Kit.
- LifeVac is FDA, MHRA, UKCA, TGA, HPFB, MOH, SAPHRA registered/ regulated as a class one medical device and CE marked.
- Can be applied if someone is standing, sitting or laying down. Can also be self applied in a choking emergency.
- Every kit comes with an easy to scan QR code which takes every end user to a free training video.



❖ Easy to hold handle for secure grip.

- Medically proven to be the worlds most effective, safest and easiest to use airway clearance device.
- Backed by multiple peer reviewed medical publications covering: Safety, effectiveness, lives saved, comparison studies and ease of use.
- Over 2,335 lives saved, with over 1,479 of these lives being children.
- Replaced free of charge if ever used in a choking emergency.

❖Translucent bellows, makes it easy to identify if the obstruction enters this area.

❖Patented one-way valve prevents any air being expelled through interchangeable sized masks.

Masks:

- ❖ Large Adult
- ❖ Medium Adult
- ❖ Small Adult/child
- ❖ Pediatric

❖ Interchangeable sized masks to fit a casualties facial features, as one size does not fit all.

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