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LifeVac Europe Ltd are the manufacturers of LifeVac for the UK and EMEA.

LifeVac ACD is a Class I medical device. LifeVac is MHRA, FDA registered and CE marked. LifeVac is registered with all relevant authorities in all countries sold.

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LIFEVAC COMPREHENSIVE TEST DIAGRAM

Retliff Force Test	Outbound
Retliff Force Test	Inbound
Retliff 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 Real Life Saves (10)
SEMES	Summary Real Life Saves
International Journal of Pediatric Otorhinolaryngology	Peer Review World leading Physician Pediatric Airway Management
Journal of Clinical Gastroenterology	Submitted
American Academy of Pediatrics Poster Presentation	Worldwide Real Life Saves
Pediatrics & Therapeutics	Peer Reviewed - Real-World Data (21)
European Resuscitation Council	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
Frontiers	Peer reviewed - Use of a Novel Portable Non-Powered Suction Device in Patients with Oropharyngeal Dysphagia During a Choking Emergency

LIFEVAC

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Our Ref: CA014885

MHRA

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Mr Eric Banagan
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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

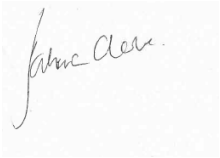
Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address 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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Not having an Airway Clearance Device (LIFEVAC) violates the following laws:

For employees:
OSHA Law

United States DEPARTMENT OF LABOR

OSHA

The **General Duty Clause** of the United States Occupational Safety and Health Act (Federal OSHA) states: (1)

29 U.S.C. § 654, 5(a) 1: **Each employer** shall furnish to each of his employee's employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

Application of the General Duty Clause

The general duty provisions are used in inspections only where there are no specific standards applicable to the particular hazard involved. Any recognized hazard created in part by a condition not covered by a standard may be cited under the general duty clause. (2) A hazard is recognized if it is a condition that is (a) of a common knowledge or general recognition in the particular industry in which it occurred, and (b) detectable (1) by means of the senses (sight, smell, touch, and hearing), or (2) is such wide, general recognition as a hazard in the industry that even if it is not detectable by means of the senses, there are generally known and accepted tests for its existence which should are generally known to the employer. In addition, "Voluntary Standards" also meet the preceding criteria for identifying a hazard. Citations based on the general duty clause are limited to alleged serious violations (including willful and/or repeated violations which would not otherwise qualify as serious violations, except for their willful or repeated nature.

United States DEPARTMENT OF LABOR

OSHA

Appendix A to § 1910.151- First aid kits (Non-Mandatory)

First aid supplies are required to be readily available under paragraph § 1910.151(b). An example of the minimal contents of a generic first aid kit is described in American National Standard (ANSI) Z308.1-1998 "Minimum Requirements for Workplace First-Aid Kits." The contents of the kit listed in the ANSI standard should be adequate for small worksites. When larger operations or multiple operations are being conducted at the same location, employers should determine the need for additional first aid kits at the worksite, additional types of first aid equipment and supplies and additional quantities and types of supplies and equipment in the first aid kits.

In a similar fashion, employers who have unique or changing first-aid needs in their workplace may need to enhance their first aid kits. The employer can us the OSHA 300 log, OSHA 301 log, or other reports to identify these unique problems. Consultation from the local fire/rescue department, appropriate medical professional, or local emergency room may be helpful to employers in these circumstances. By assessing the specific needs of their workplace, employers can ensure that reasonably anticipated supplies are available. Employers should assess the specific needs of their worksite periodically and augment the first aid kit appropriately.

For Student/Patrons:
Premises Liability at Schools

There are a growing number of lawsuits arising out of some school's failure to keep students safe while on school property. Under the theory of "premises liability", occupiers and owners of land (including schools) are legally required to keep premises safe for those who are legally allowed to be there. The law generally requires owners and occupiers of land to exercise a "reasonable amount of care" in providing a safe environment on their premises. However, because schools are typically utilized by young children, the law requires a greater amount of care to be taken in situations where students are present. Parents of children who are injured may file a claim against a school or school district for contributing to a student's harm or failing to keep premises safe at school. This may include common situations where a child falls or injures themselves in some way due to a school's negligence, but may also include situations where a child is bullied, harassed, or becomes ill and the school fails to come to the aid of the student, or control the situation.

Premises Liability: Who Is Responsible?

Property owners (or non-owner residents) have a responsibility to maintain a relatively safe environment so that people who come onto the property don't suffer an injury. This responsibility is known as "premises liability," which holds property owners and residents liable for accidents and injuries that occur on their property. The types of incidents that may result in premises liability claims can range from a slip and fall on a public sidewalk to an injury suffered on an amusement park ride. For example, a courier delivering a package may sue you for injuries if he slips and falls on an oil slick in the driveway although if the courier acted in an unsafe way, he or she may not have a valid claim.

Accepted Manuscript

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

Mimi Juliano MA, CCC-SLP, Robert Domingo PHD, Mary S. Mooney PT, DPT, Alex Trupiano

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ACCEPTED MANUSCRIPT

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

Mimi Juliano, MA, CCC-SLP
Robert Domingo, PHD
Mary S. Mooney PT, DPT
Alex Trupiano, Paramedic, E.M.T.

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.

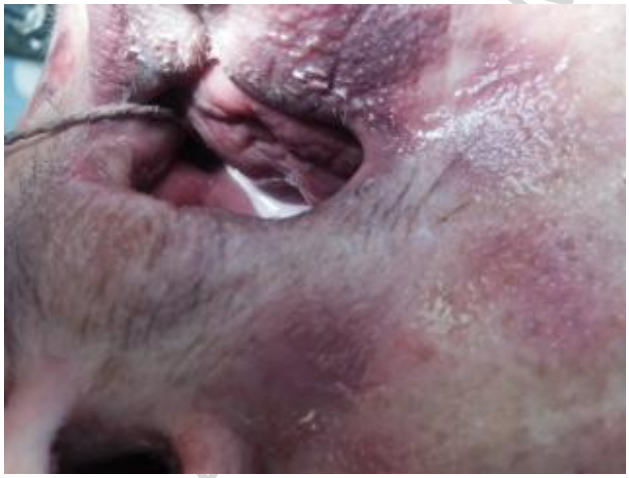
Each year, approximately 3,000–4,000 Americans die from choking. Children and the elderly present much higher risks for choking. At least one child dies from choking on food every five days in the U.S., and more than 10,000 children are taken to hospital emergency rooms each year for food-choking incidents.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

ACCEPTED MANUSCRIPT

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.



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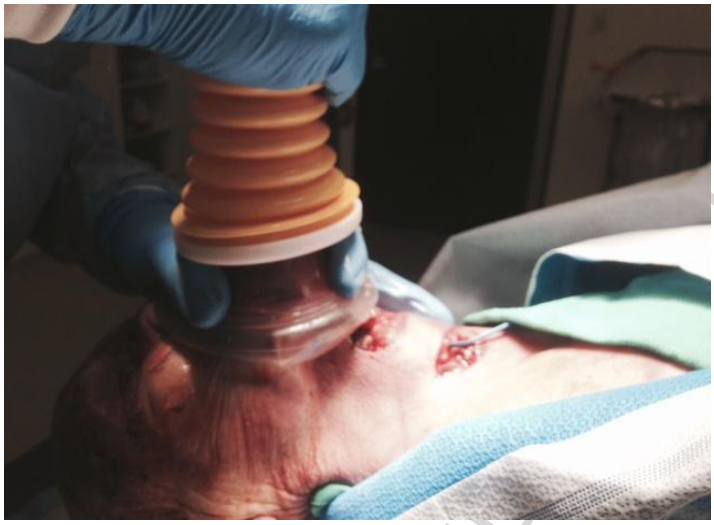

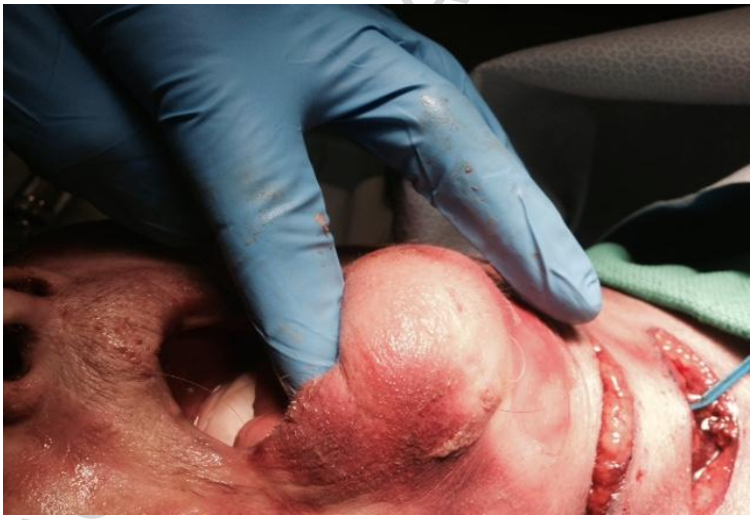

The American Red Cross' recent first-aid protocol de-emphasizes the use of the Heimlich for treating a conscious choking victim. The new protocol recommends calling 9-1-1, then giving the person several sharp blows to the back, right between the shoulder blades, with the heel of the hand. If this doesn't 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.

ACCEPTED MANUSCRIPT

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.

ACCEPTED MANUSCRIPT

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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.

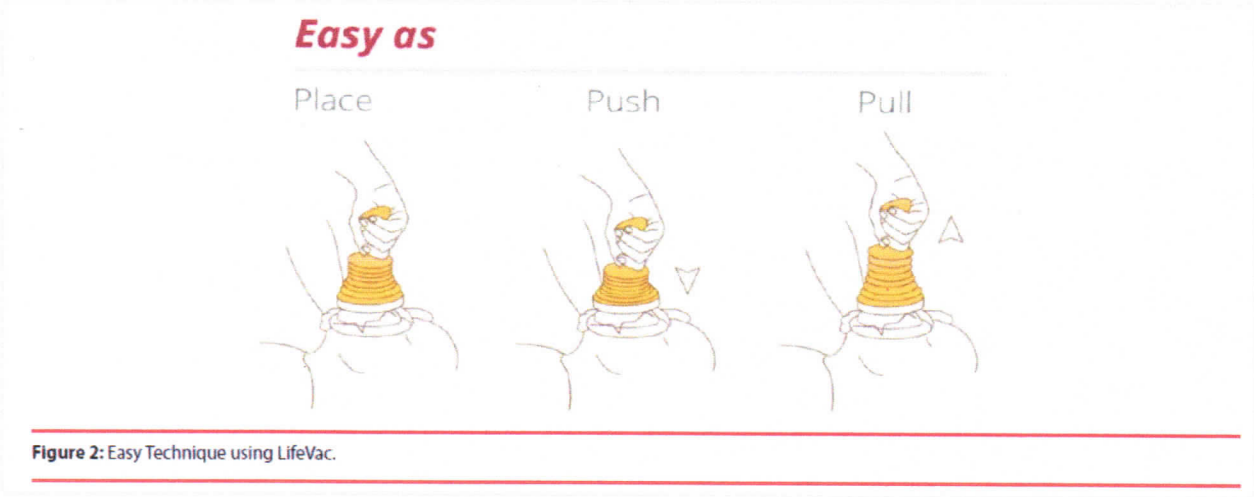

Figure 2: Easy Technique using LifeVac.

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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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Available online xxx

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

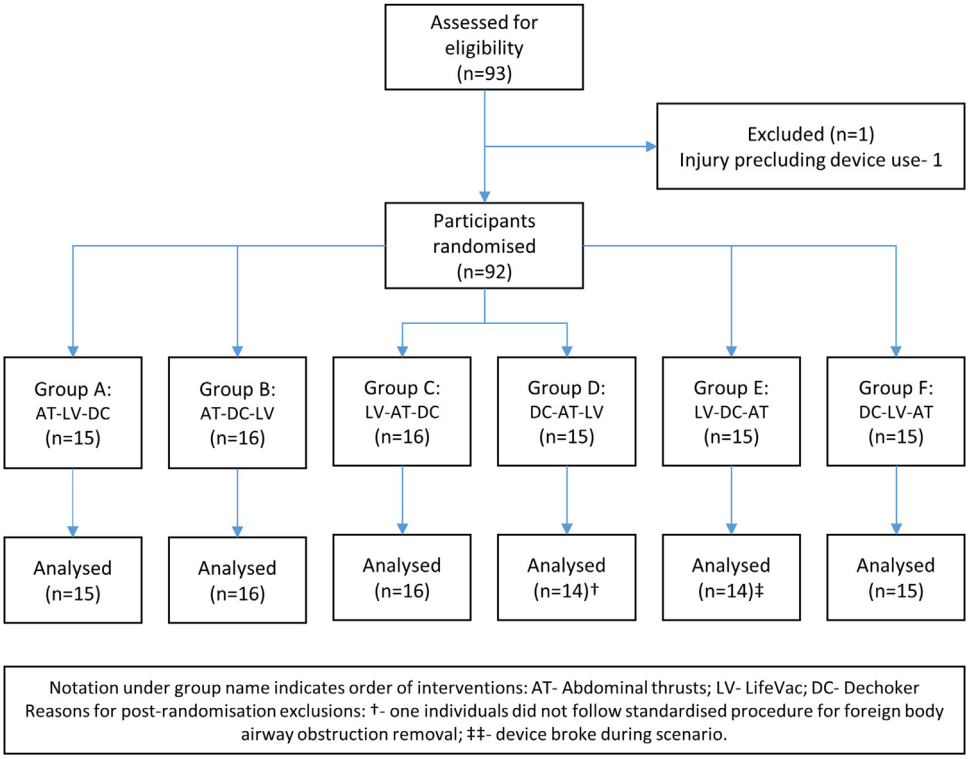

Fig. 1 – CONSORT participant flow diagram.

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.

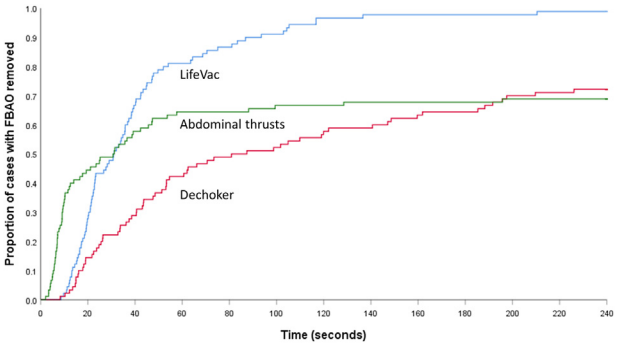

Fig. 2 – Time to removal of foreign body for study interventions.

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

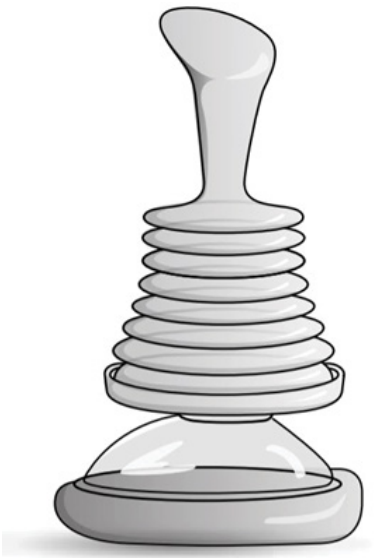

Figure 1: The device attached to a standard adult facemask.

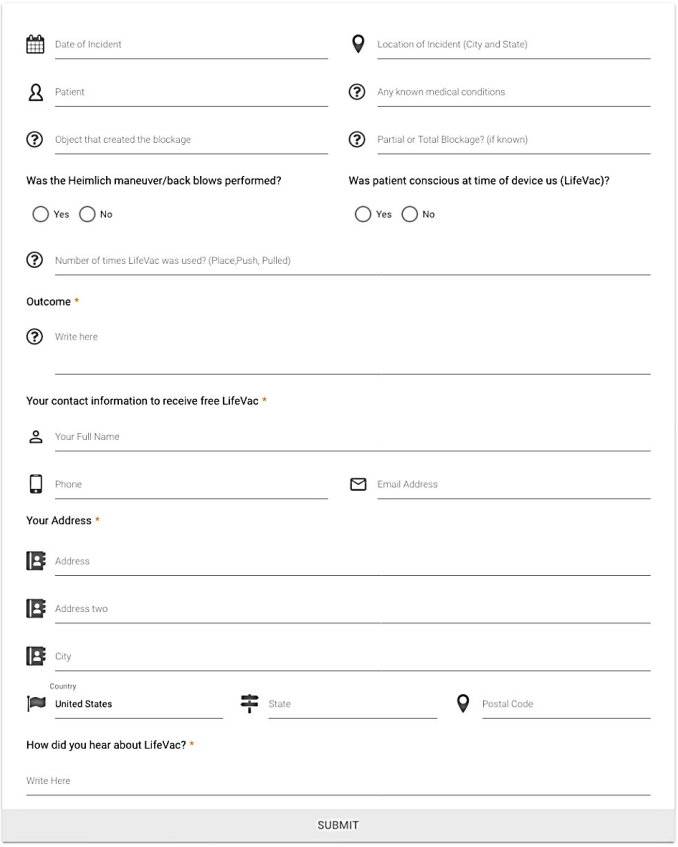

Figure 3: The online feedback form.

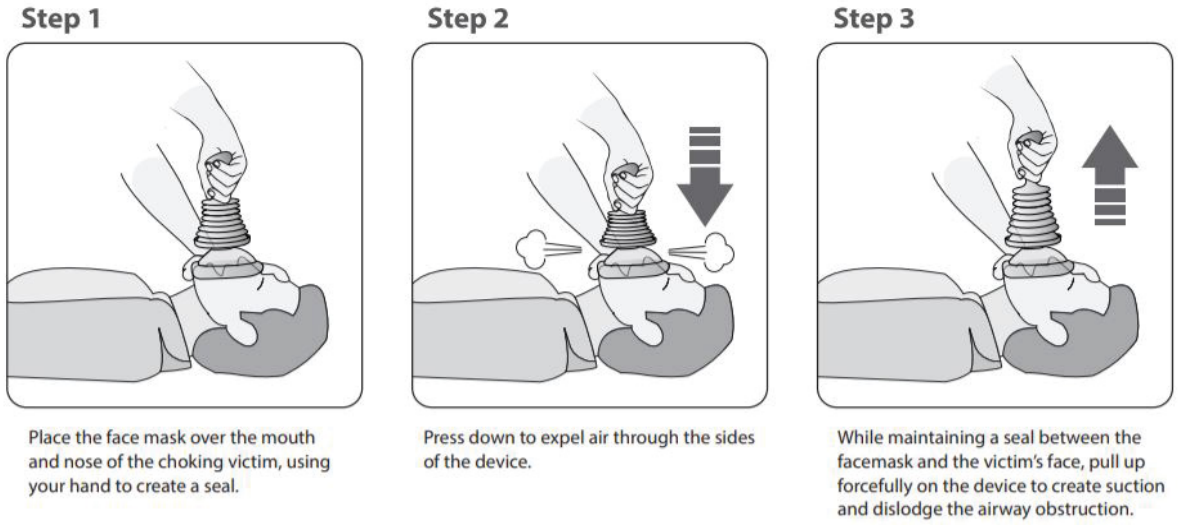

Figure 2: Instructions for use.

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
https://doi.org/10.1016/j.ijporl.2018.12.014Get rights and content

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

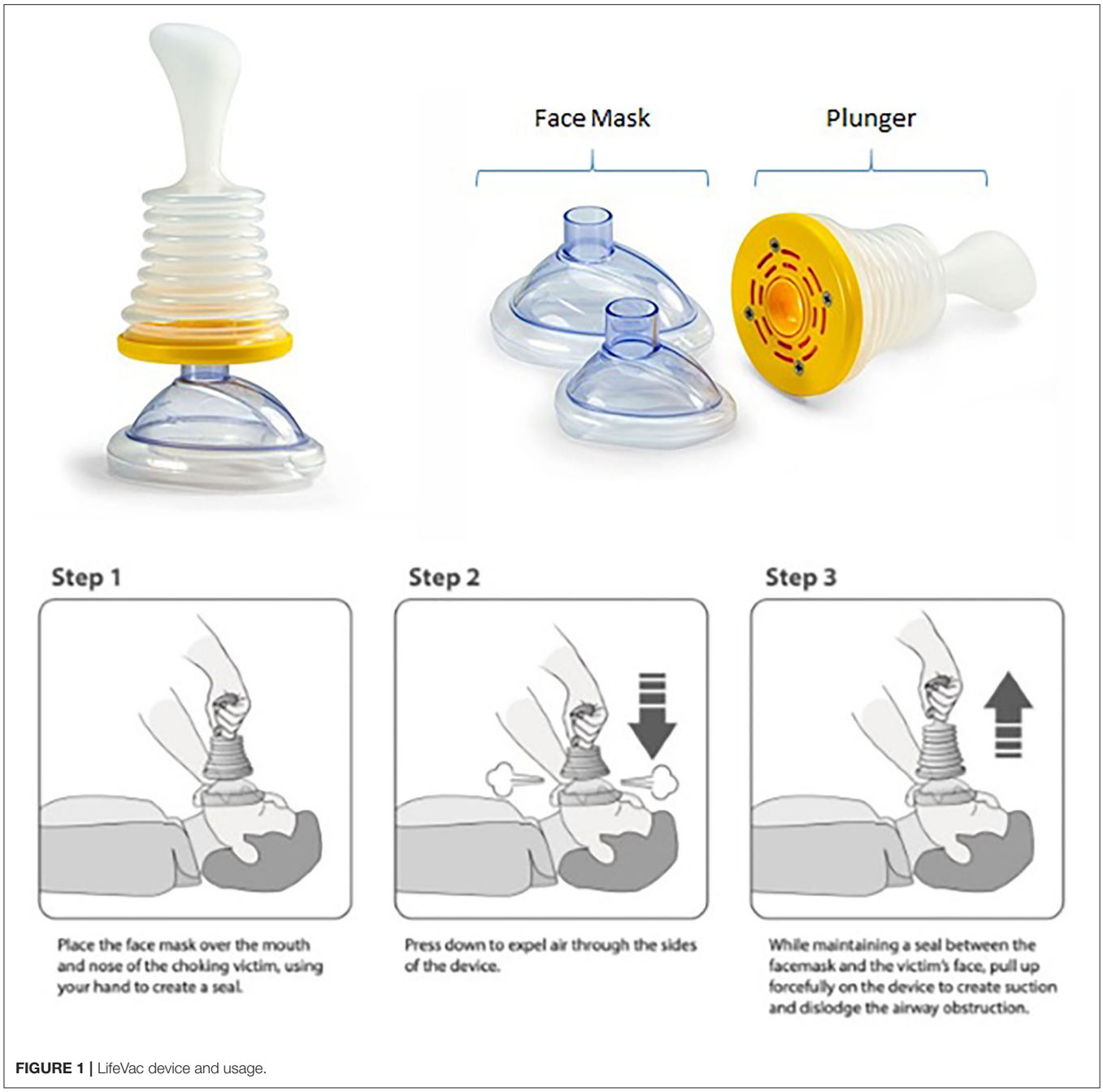

FIGURE 1 | LifeVac device and usage.

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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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?

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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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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.

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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

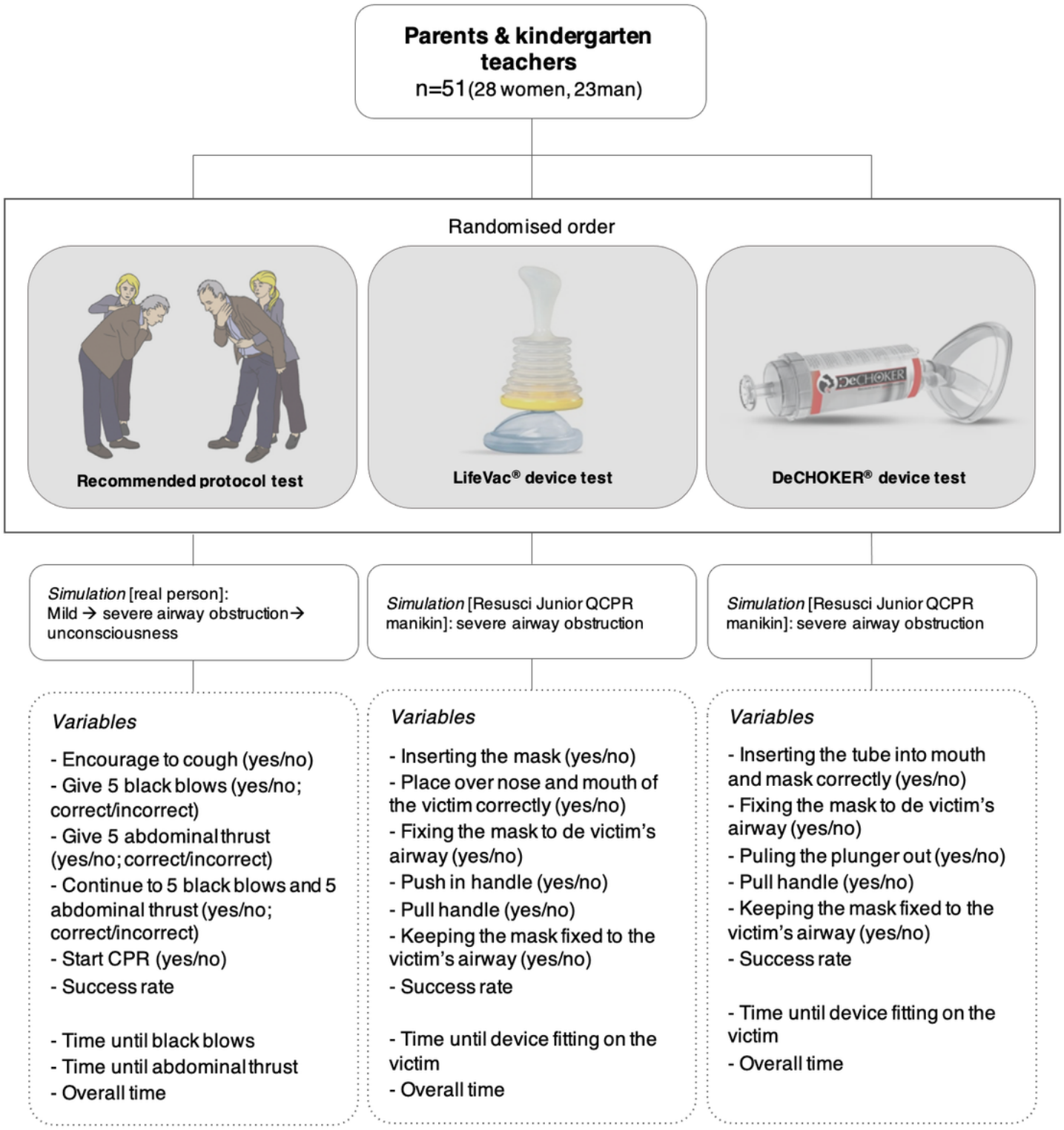

Figure 1

Flow chart of the design of the study.

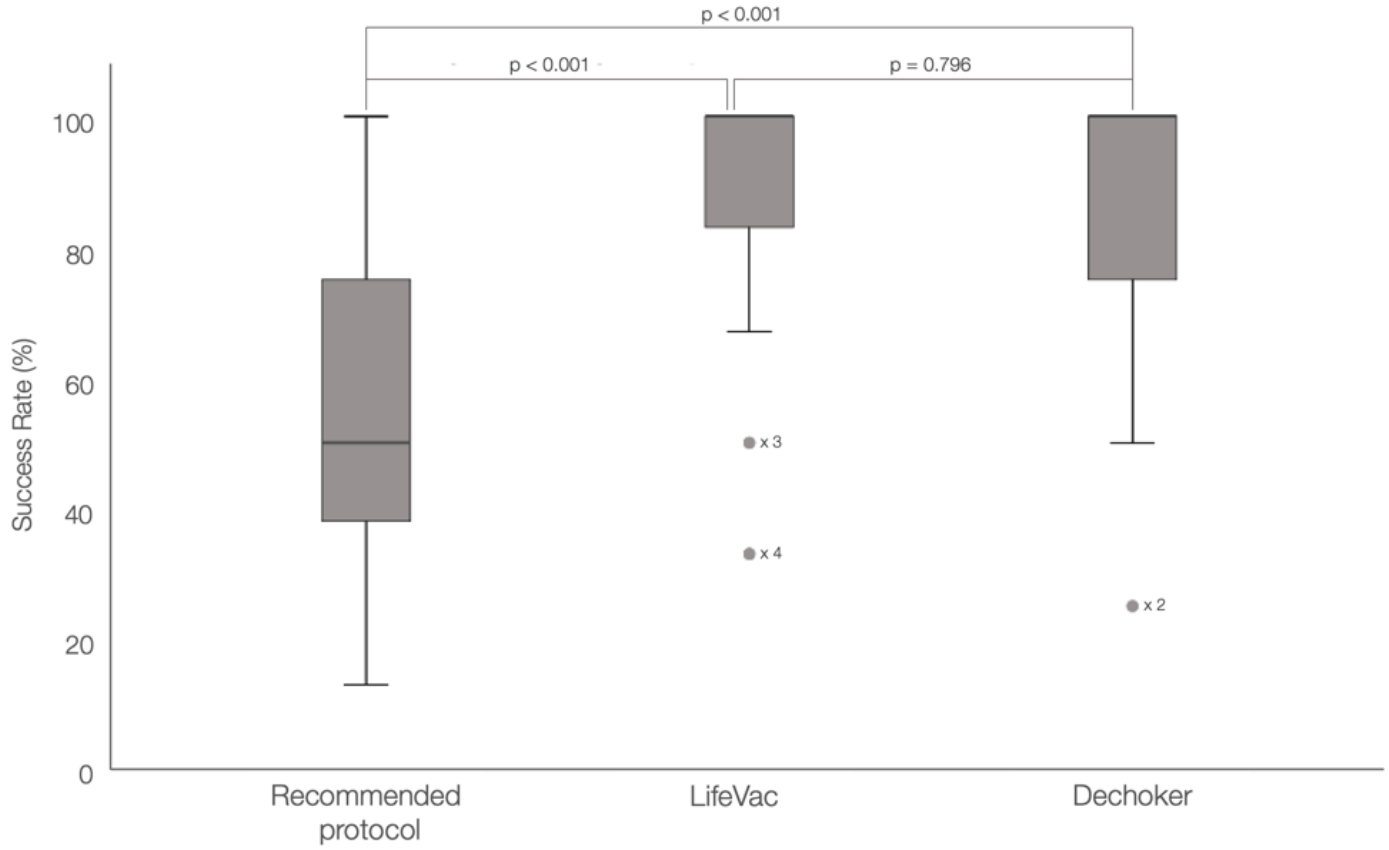

Figure 2

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.

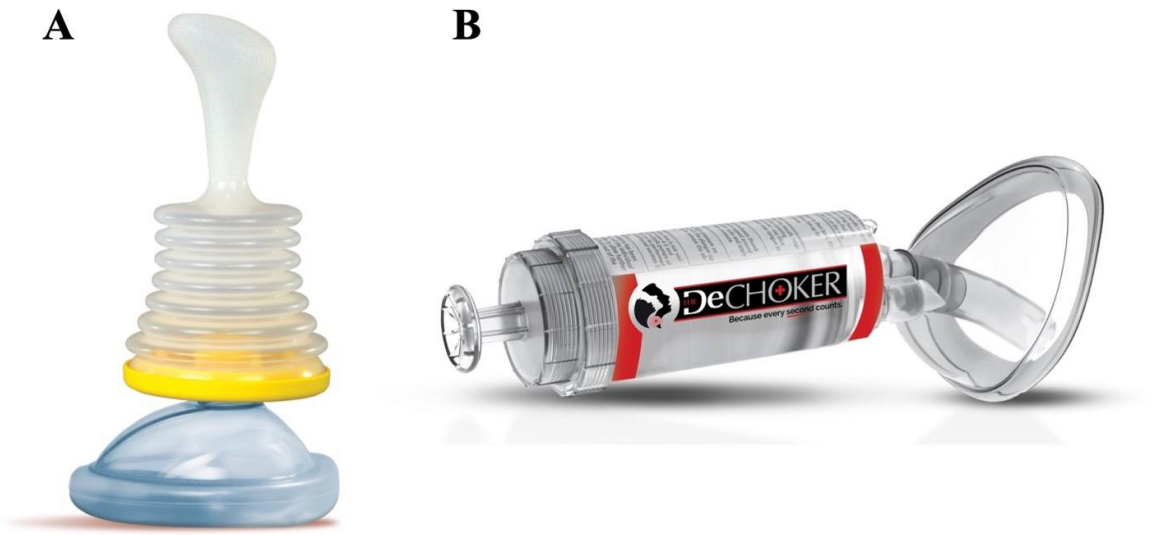

Figure 1. (**A**) LifeVac© airway clearance device (**B**) DeChoker© airway clearance device [images supplied by the respective manufacturers with permission to include].

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].

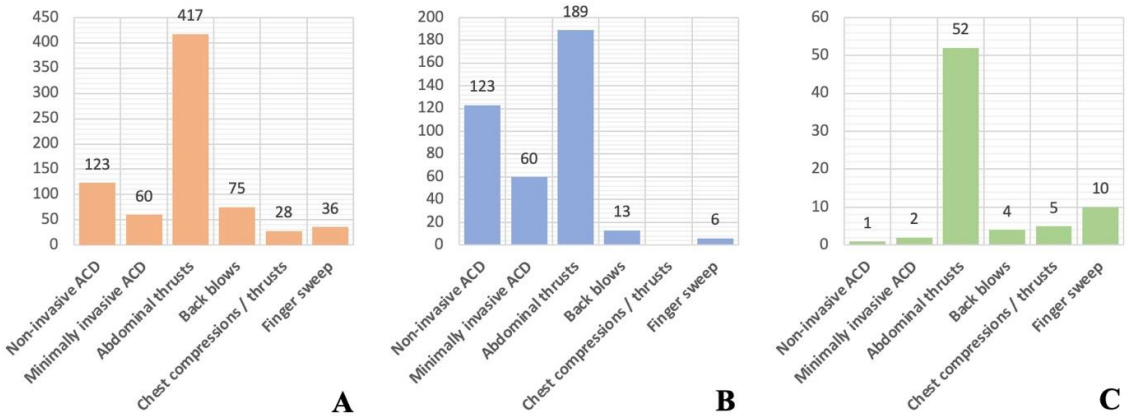

Figure 2. Reported counts in academic literature of effectiveness and safety outcomes for airway clearance devices and traditional FBAO interventions: (**A**) Relief of FBAO (**B**) Survival* (**C**) Adverse events [8,9]. * *Chest compressions/thrusts had survival with good neurological outcome reported, 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.

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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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Pressure Verification Test Report

On

(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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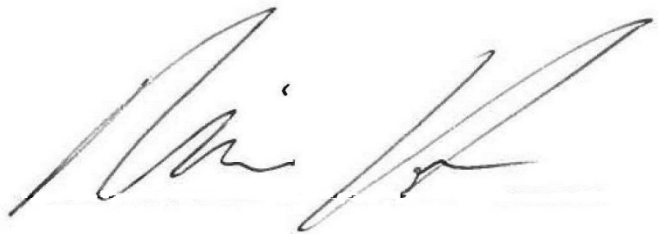
Victor Rondon
Lead Environmental Test Technician



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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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RETLIF TESTING LABORATORIES | Put Us To The Test™

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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

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3942 North Upland Street
Arlington, VA 22207 USA
Tel (703) 533-1614
Fax (703) 533-1612

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.

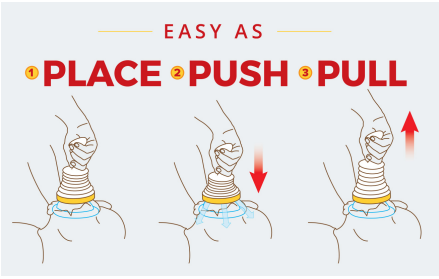
Units 3, 4, 7, 8, 9, and 10 did not undergo functional test by Retlif but will be tested at LifeVac by pulling a blockage from the airway of a Laerdl Charlie simulator in order to demonstrate functionality after being exposed to temperature extremes.

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 non-invasive, portable airway clearance device.
- Interchangeable sized masks, clearly identified by colour coded rings.
- No risk of pushing the tongue or obstruction back in a panic situation.
- No risk of oral damage.
- Generates over 326mm Hg of suction, safely and effectively dislodging the obstruction.
- Can be used for full and partial obstructions.
- Saved many 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 three different variations, Standard Home LifeVac Kit, EMS LifeVac Kit and Wall mounted LifeVac Kit.
- LifeVac is FDA registered, MHRA registered as a class one medical device and CE accredited.

❖ Extra Large Adult

❖ Large Adult

❖ Medium Adult

❖ Small Adult/Child

❖ Easy to hold handle for secure grip.

- LifeVac is equipped in over 3500 care and nursing homes across the UK.

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

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

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

From £59.95

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