LIFEVAC EUROPE LTD

Condensed Medical Folder

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 CREDENTIALS

The Airway clearing device (LifeVac) has over gone thorough testing and has published in medical journals. Retlif Force Testing (Obound & Inbound), Retlif Durability/Environmental Test Report, The Journal College of Gastroenterology – Adult Simulation Study (***LifeVac - A Novel Apparatus to Resuscitate a Choking Victim),*** The American College of Emergency Physicians – Adolescent Simulation Study (***A Novel Device for the Resuscitation of the Adolescent Choking Victim),*** The American Journal of Emergency Medicine – Human Cadaver Study (***Assessment of LifeVac, an anti-choking device, on a human cadaver with complete airway obstruction -***An independent study of the LifeVac on a human cadaver has been peer reviewed and published in the American Journal of Emergency Medicine. Results of this study suggest that the LifeVac be included as part of the guidelines used for basic life support management, World College of Gastroenterology – Real Life Saves (2) (***Successful Resuscitation of Choking Victims Using a LifeVac, a Non-powered Portable Suction Device: Real World Experience),*** American Broncho-Esophagological Association – Summary & Real life saves (***Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims- Worldwide Results),*** The International Journal of Clinical Skills (2018) – Peer reviewed study & 11 real life saves - ***Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims- Worldwide Results***

LifeVac has been approved and is adopted into Suffolk County, NY EMT – Adult Obstructed Airway BLS Protocol also Nassau County, NY has written internal letter from David Kugler, MD, Chairman Nassau REMAC stating LifeVac can be used at approval of Medical Director

LifeVac has been vetted with medical expertise and is implemented in 34 Fire Departments/Rescue Squads, 3 police departments, 135 schools, 8 major disability/special need facilities, 8 hospitals, 19 eldercare/long term homes, 15 medical practices, 13 dental/oral surgeon practices, 16 corporations, plus restaurants, churches, country clubs/camps along with over **eleven thousand (11,000)** homes having LifeVac on hand if an emergency was to arise.

LifeVac is endorsed and has articles written by the following doctors, medical experts… Dr. Keith Johnson- MD is Board Certified in both Pediatrics and Internal Medicine, Dr. William Holt - Board Certified Neurologist, Senior Medical Director, Dr Nina Shapiro - Director of Pediatric Ear, Nose, and Throat at the Mattel Children's +Hospital UCLA and Professor at the David Geffen School of Medicine at UCLA, Coauthor of the LifeVac study in The American Broncho-Esophagological Association & author of a new book "Hype", Dr. Cynthia Paulis – MD Emergency Room physician, Dr. James Kalyvas - Neurosurgeon of the Barrow Neurological Institute, Dr. Robert Domingo – PH.D,

Dept of Communication Sciences & Disorders LIU Post, Nassau Univ. Medical Center, Dr Louis Philip Rotowitz – MD FAAFP City Medical Specialist – Bureau of Medical Affairs/Online Medical Control Fire Dept. – City of NY, Dr. Sheeba Mesghali, MD, Internal Medicine, FL, Saperstein DM*, Pugliesi PR, Ulteig C, Schreiber N, Dr. Suzanne Fuchs – MD, Podiatry, Palm Beach, FL, Mimi Juliano, MA, CCC-SLP (Author) , Mary S. Mooney, PT, DPT, Alex Trupiano, EMT, Amy Benenson, BS- (Presenting Author), Rashawn Chin, PA-C (Author), Pratik B Patel, (Author), Saperstein, DM (Corresponding Author), RPALee Burns – Director, NY State Dept. of Health Bureau of Emergency Medical Services & Trauma Systems, Robert Delagi – MA, NREMT-P Director, EMS & Public Health Emergency Preparedness, Rodney Millspaugh, NREMT/Paramedic, Lisa-Lih Brody, MD, FACG

LIFEVAC

COMPREHENSIVE TEST DIAGRAM

Retliff Force Test	Retiliff Force Test	Retliff Durability Test	The American Journal of Gastroenterology	The American College of Emergency Physicians	The American Journal of Emergency Medicine	World College of Gastroenterology	American Broncho-Esophagological Association	International Journal of Clinical Skills
Outbound	Inbound	Durability	Adult Simulation Study	Adolescent Simulation Study	Human Cadaver Study	(2) Real life Saves	Summary Real life saves	Peer Review (11) Real life saves

This chart represents that all aspects of vestability have been covered.

LIFEVAC

SAVED LIFE DIAGRAM

Female Resident w MS Eldercare Home	Male Resident w Parkinson's Eldercare Home	Female resident w MS Eldercare Home	Female Adult w special needs	Female in her 60's	Male patient w Parkinson's in Parkinson Center	Male patient with CP	Female in her 40's	Female resident w Huntington's Disease in elder care	Male Patient w Down Syndrome	Male patient in eldercare home	Male adult in wheelchair
Saved by Nurse	Saved by staff member	Saved by staff member	Saved by Mother	Saved by Son	Saved by nurse	Saved by staff member	Saved by EMS	Saved by staff member	Saved by staff member w nurses assistance	Saved by EMS	Saved by Mother

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Abstract

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

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

Keywords

Choking, Resuscitation, Anti choking device, Lifevac

Introduction

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

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

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

Case Report

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

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

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

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

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

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

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

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

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

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

Discussion

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

Figure 1: The LifeVac Device.

Figure 1: The LifeVac Device.

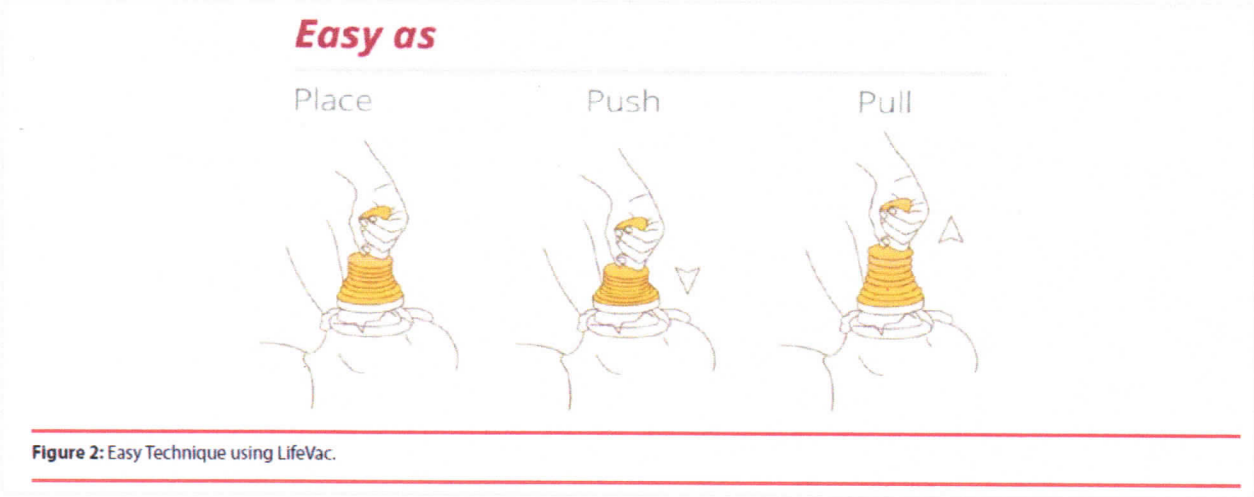

Figure 2: Easy Technique using LifeVac.

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Simulation and education

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

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Abstract

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

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

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

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

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

Introduction

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

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

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

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

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

Methods

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

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

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

Setting and participants

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

Randomisation

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

Interventions and study process

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

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

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

Outcomes

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

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

Sample size

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

Statistical methods

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

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

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

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

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

Results

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

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

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

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

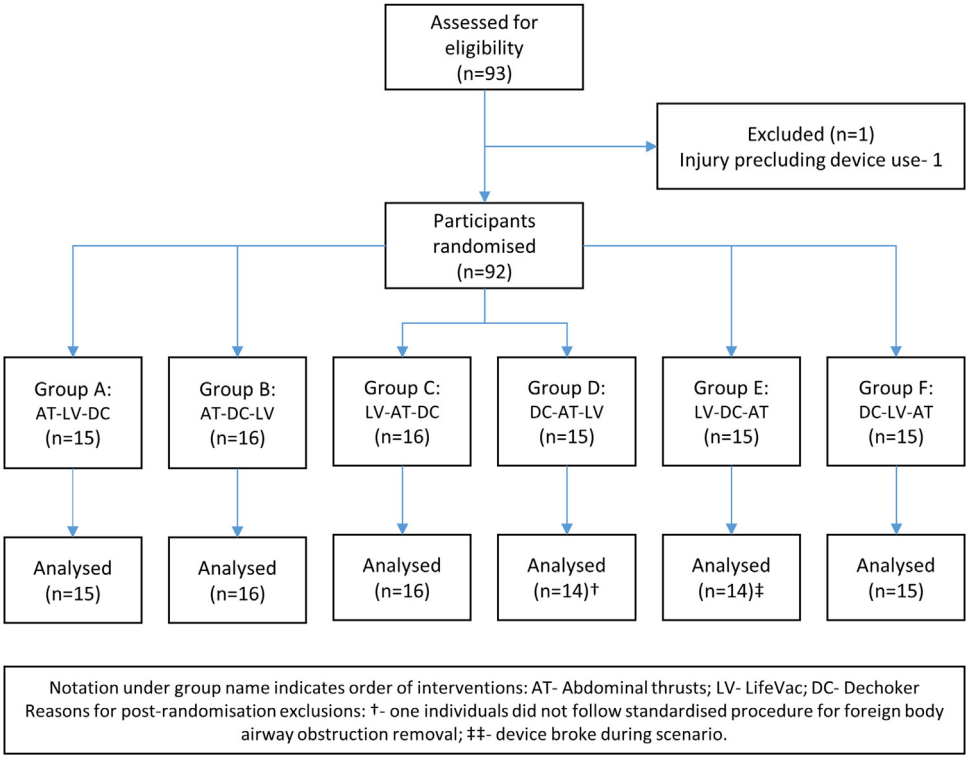

Fig. 1 – CONSORT participant flow diagram.

Table 1 – Participant characteristics.

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

[a] One participant declined to answer.

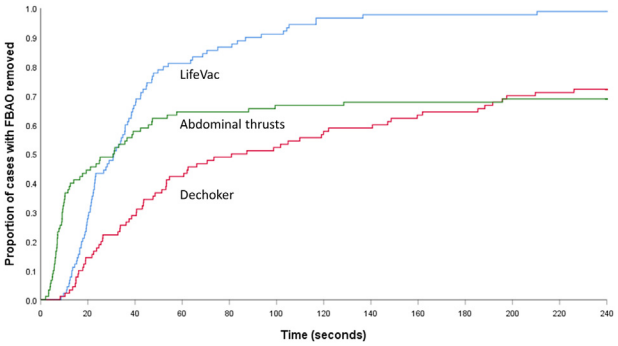

Fig. 2 – Time to removal of foreign body for study interventions.

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

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

Discussion

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

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

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

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

Table 2 – Study outcomes.

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

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

Table 3 – usability outcomes.

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

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

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

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

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

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

Conclusion

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

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Conflict of interests

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

CRediT authorship contribution statement

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

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

Appendix A. Supplementary data

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

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Poster Tours (PT)

PT1

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

Lafcadio Robert Rusu

CH Clavary, Grasse, France

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

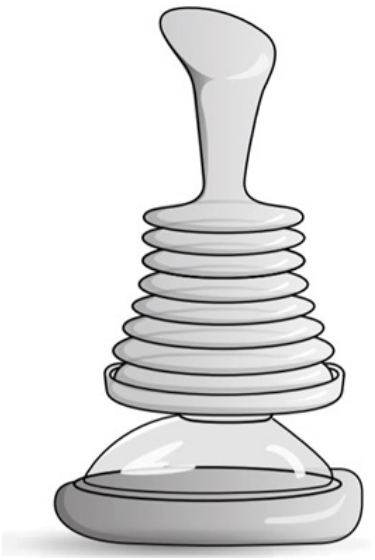

Figure 1: The device attached to a standard adult facemask.

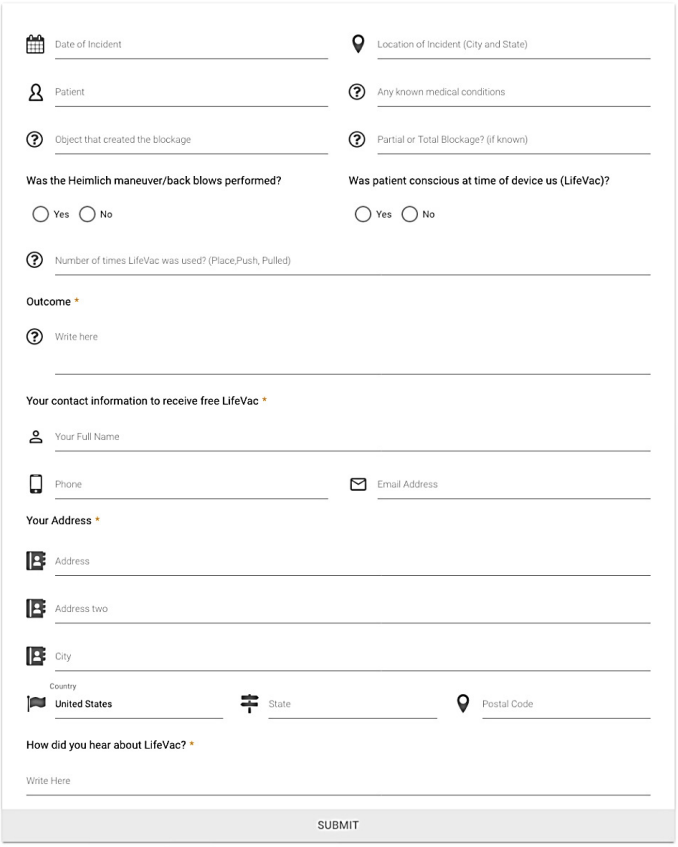

Figure 3: The online feedback form.

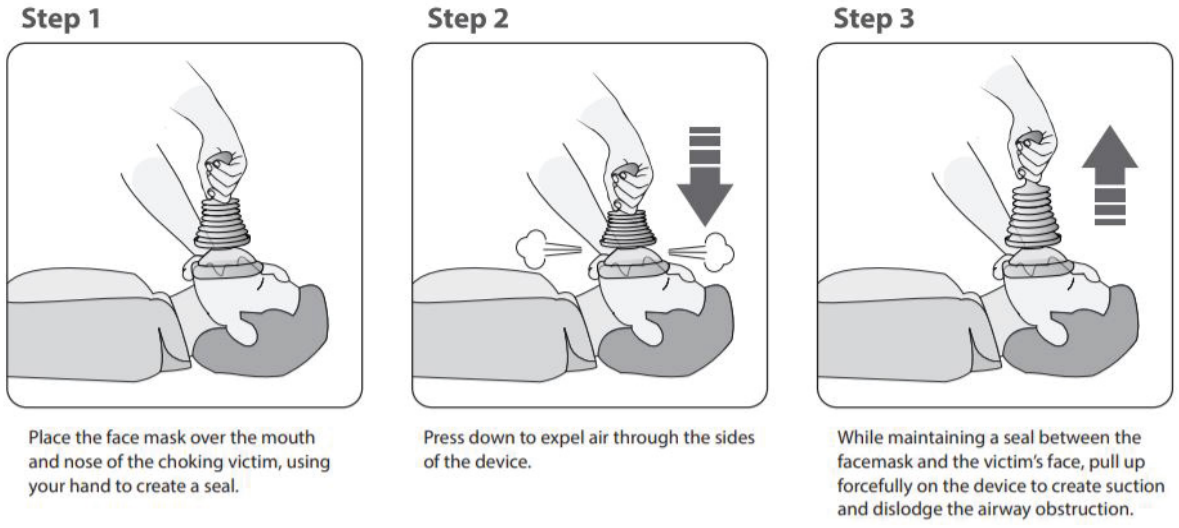

Figure 2: Instructions for use.

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.

ACKNOWLEDGEMENTS

The authors would like to thank Diana Bowman, PhD, for her editorial assistance.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

FUNDING

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International Journal of Pediatric Otorhinolaryngology

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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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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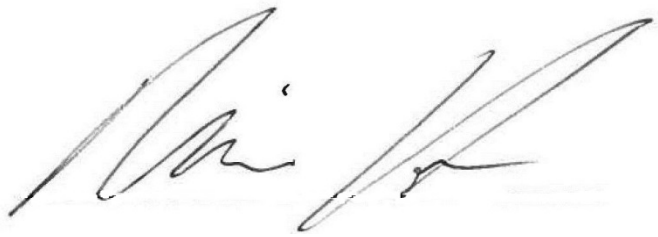
Certification and Signatures

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

Victor Rondon
Lead Environmental Test Technician



Michael Hull
Environmental Laboratory Supervisor

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

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

Revision History

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

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

Test Program Summary

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

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

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

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

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

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

Acceptability Criteria
The following was considered EUT acceptability:

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

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

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

Table 1 - Test Sequence and Results

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

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

Pressure Verification
Test Data

TEST DATA SHEET

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

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

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

	14:25	Test Complete.

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

Test Photographs
Pressure Verification

Test Setup

Equipment List
Pressure Verification

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

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Vacuum Verification Test Report

On

(10) Anti-Choking Devices

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

Test Program Summary

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

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

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

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

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

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

Acceptability Criteria
The following was considered EUT acceptability:

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

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

TEST DATA SHEET

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

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

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

Sheet 1 of 1

LIFEVAC

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.

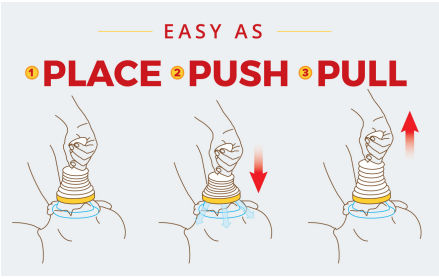
Units 3, 4, 7, 8, 9, and 10 did not undergo functional test by Retlif but will be tested at LifeVac by pulling a blockage from the airway of a Laerdl Charlie simulator in order to demonstrate functionality after being exposed to temperature extremes.

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

FDA

MHRA
Regulating Medicines and Medical Devices

CE