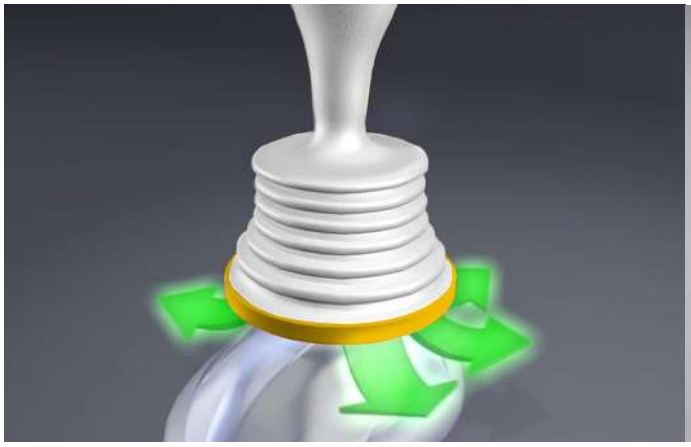
LIFEVAC

120 LAKE AVENUE SOUTH, #26
NESCONSET, NY 11767
516-962-2554 – 877-LIFEVAC
WWW.LIFEVAC.NET

The LifeVac is a non-invasive, non-powered, portable ACD (Airway Clearance Device) developed to remove an object/food from a victim with an airway obstruction when standard choking protocol has been followed without success. It is designed with a patented one-way valve which prevents air from pushing the object/food downward. This creates a one-way suction to remove the obstruction and clear the airway of the victim**.** The negative pressure generated by the force of the suction is 3 times greater than the highest recorded choke pressure.

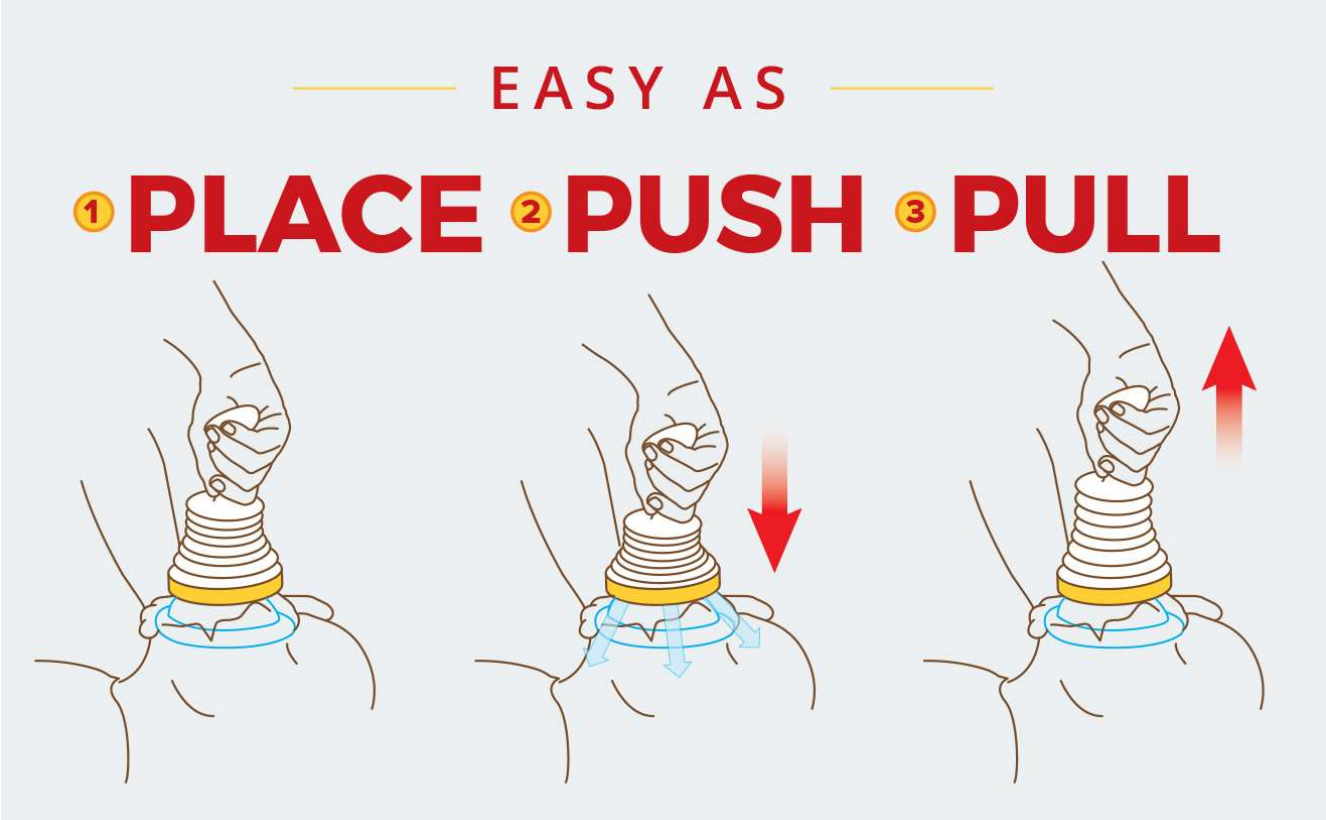
LifeVac is FDA registered

This patented designed valve will prevent air from pushing food or an object downward. Air is vented outside the unit. This creates a one-way suction to remove the lodged food or object



LifeVac is simple to use. Anyone can use it.

It's as easy as placing over the nose & mouth, pushing down, & pulling up



Protect yourself

Protect your family

- **Choking is the 4th leading cause of accidental death**
- **A leading cause of death under the age of 14 and over 65**
- **One child dies every 5 days**
- **Over 5,000 choking deaths per year in the US alone**
- **Thousands choke to death in their own HOMES every year**
- **Extremely dangerous for individuals in wheelchairs**
- **Particularly dangerous within the Neurological community**

LIFEVAC
CREDENTIALS

- LifeVac is FDA registered- Registration Class II medical devices are exempt from pre-market clearance. FDA does not require premarketing review.
- Retlif Pressure Test (Force Inbound & Outbound)
- 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 & 10 real life saves** - ***Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims- Worldwide Results***
- Spain National Congress Society Of Emergency Medical Services (SEMES) June 6, 7, 8, 2018, Post #655 of Chapter 7 – ***LifeVac - New Device For Clearing An Airway Obstructed By A Foreign Object***
- International Journal of Pediatric Otorhinolaryngology – **Peer reviewed study**
  Portable, non-powered, suction-generating device for management of life-threatening aerodigestive tract foreign bodies: Novel prototype and literature review
- Pediatrics & Therapeutics – **Peer reviewed study**– ***21 real life saves - Resuscitation of Choking Victims in a Pediatric Population Using a Novel Portable Non-Powered Suction Device: Real-World Data***

- European Resuscitation Council – ***Poster Tour - Device for the resuscitation of the choking victim***

- Resuscitation Plus- ***Peer reviewed study*** - ***The efficacy and usability of suction-based airway clearance devices for foreign body airway obstruction: a manikin randomised crossover trial***

- *Frontiers* ***-Peer reviewed study- Use of a Novel Portable Non-Powered Suction Device in Patients with Oropharyngeal Dysphagia During a Choking Emergency***

- *International Journal of Environmental Research and Public Health* ***- Peer-reviewed - Phase One of a Global Evaluation of Suction-Based Airway Clearance Devices in Foreign Body Airway Obstructions: A Retrospective Descriptive Analysis***

- LifeVac is adopted into Suffolk County, NY EMT – Adult Obstructed Airway – BLS Protocol

- LifeVac is adopted into Fennimore Wisconsin Airway Obstruction protocol

- Nassau County, NY internal letter from David Kugler, MD, Chairman Nassau REMAC stating LifeVac can be used at approval of Medical Director

- The LifeVac rescue suction device has been reviewed, purchased and implemented in **Thousands of schools, Hundreds of Fire Departments, Police departments and Medical Centers**, as well as numerous hospitals, disability facilities, eldercare homes, medical offices, dental practices, restaurants, corporations, churches etc. and over 100,000 homes across the globe. It has also been implemented by the Nassau County Police Department, Cerebral Palsy Association of Nassau County, CURE SMA, Cerebral Palsy of NYS Day Habilitation Programs and residences throughout the Five Boroughs of New York, United Cerebral Palsy of California, The Viscardi Center, the University Hospitals Elyria Medical Center in Ohio, Orlando VA Medical Center, Eldercare homes, Hatzolah Volunteer Ambulance, etc.

- The **Sarasota Police Department** was the first government agency to implement LifeVac. See link: http://www.prnewswire.com/news-releases/sarasota-first-in-us-to-equip-emergency-vehicles-with-lifevac-300065166.html

- In March of 2021 LifeVac was utilized by the **Prairie Du Chien Police Department** in Wisconsin when law enforcement officers responded to a choking related emergency. When arriving on the scene the elderly gentleman was immediately attended to using the Heimlich maneuver. When choking rescue procedures were unable to dislodge the hamburger that caused a total blockage LifeVac was utilized and cleared the victim airway.

"Thank you to LifeVac for helping us better serve our community. We police a rural area of Wisconsin that requires us to be first responders to most medical calls. On March 20, 2021 our Officers responded to an adult male who had a fully obstructed airway. Officers arrived on scene prior to our full-time EMS service and they were able to successfully use the LifeVac to break-up and dislodge the obstruction. Proper training and equipment make all the difference between being able to save lives and feeling helpless or hopeless in our efforts. Our entire patrol fleet was equipped with LifeVac devices in 2019 and two years later they have proven themselves to be an essential, lifesaving, tool for our department. Thank you again!" Chief of Police, Prairie Du Chien Police Department

LIFEVAC CREDENTIALS

- **All Nassau County PD** vehicles (350 patrol cars located in New York) are equipped with LifeVac. It has been reported that in October of 2019 an officer was called to the scene at Point Lookout Ale House to a choking incident. "I was the officer that used the LifeVac at the scene. I was so amazed by how it worked. The victim was clearly unconscious at the time of arrival. The civilian at the scene was performing CPR by himself while the victim was on his side. The first time used LifeVac the obstruction was stuck while the victim on their side Used a second time after adjusting the victim on their back and a piece of meat came out. The victim quickly gained consciousness and color to his face. Was talking within a minute of clearing obstruction. Was then transported by Point Lookout fire department ambulance and treated at a local hospital." For the full testimonial: https://lifevac.net/police-office-saves-man-from-choking-with-lifevac-150th-life-saved/

- Most recently the **City of Jacksonville**, Florida vetted and implemented 200 LifeVac device into the Jacksonville Fire and Rescue Department.

- **Doctors**:
  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.Timothy Coakley is a Board-Certified Emergency Medicine Physician who proudly served in the US States Navy for 30 years. He had medical oversight for thousands of active duty personnel. 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), RPA Lee 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, Michelle Rockwell, MD (Sports & family medicine)-mommy blogger, ARC Albanian Resuscitation Council

LifeVac Comprehensive Research & General Recap

Retliff Force Test	Downward Compression
Retliff Force Test	Suction
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
International Journal of Environmental Research and Public Health	Peer reviewed -Phase One of a Global Evaluation of Suction-Based Airway Clearance Devices in Foreign Body Airway Obstructions: A Retrospective Descriptive Analysis

LIFEVAC

KEY ELEMENTS

- There are over 5,000 choking deaths a year in the US alone
- One child dies every 5 days from a choking tragedy
- LifeVac is the **only non-invasive** airway clearance device
- LifeVac is the only airway clearance device that with third party independent testing. (vacuum verification, durability, pressure verification, environmental testing)
- LifeVac in the USA is registered with the FDA as a Class 2 Suction Apparatus. It is exempt from pre-market clearance. The FDA does not require a pre-market review of the LifeVac device.
- LifeVac is designed with a **one-way valve system** to prevent the airway obstruction from being pushed further into the victim. On the downward compression all air is vented outside the unit, not through the mask This creates a one-way suction to remove the lodged food or object.
- LifeVac has been published in 12 medical journals (**6 peer-reviewed**).
- LifeVac has documented & recorded over **342** post market clinical reports on lives saved worldwide.
- LifeVac has been used by Emergency Services, Nurses, Support workers and lay people. The airway clearance device is implemented in fire departments, police departments & rescue squads all over the US and worldwide.
- There have been no adverse effects when LifeVac was administered.
- LifeVac can be used on adults and children. LifeVac can be utilized starting at 22 pounds based on the mask manufacturers general guidelines for a proper fit.
- One unit provides safety for the entire family. LifeVac home kit comes equipped with 3 masks (1 adult, 1 pediatric & 1 practice mask) We provide customers with a practice mask so you can become familiar with how the rescue device works before an emergency situation occurs.
- The LifeVac device is a one-time use only airway clearance device. If the LifeVac device is used in a choking emergency we request to be contacted through our website to fill out a "Life Saved" report. We will make contact and send a new unit free of charge.
- The LifeVac device will **NOT** have to be replaced unless used to save the life of a choking victim. Only the masks will need to be replaced every 2-3 years. Replacement masks can be purchased on our website.
- LifeVac is simple to use and can be used by anyone
- LifeVac can also be administered on oneself
- Training is available online at www.lifevac.net.

LifeVac
Medical Journal Information

American Journal of Emergency Medicine 34 (2016) 1673–1730

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

Correspondence

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

We performed an independent study to 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 ($P = .005$, 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 3000–4000 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 departments 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 a second pull was required to ensure a tighter seal 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

Figure 1. Placement of large simulated bolus (3 cm) 7-10 centimeters past tongue base into upper airway of subject.

Figure 2. Placement of LifeVac device on the cadaver using guideline protocol to achieve proper seal to operate device.

Figure 3. Picture of large simulated bolus (3 cm) lifted from airway.

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 by 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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THE AMERICAN JOURNAL OF GASTROENTEROLOGY

LifeVac submission in the AJG (American Journal of Gastroenterology), Volume 110, Supplement 1, October 2015, Abstracts, page, S695, Section #1624

of effect measure (odds or risk ratio), was original, used the individual as the unit of analysis and published after 2000. Each study was weighted according to its inverse variance. The distribution of effect measures were examined using visual and tabular displays as well as tests of homogeneity to reveal variation in the risk estimates of histologic BE occurrence between AA and nHw using a DerSimonian-Laird random-effects method. Odds ratio was calculated along with 95% confidence interval estimates. Forest plots were conducted and summary odds ratio with 95% CI of histologic BE was reported. Heterogeneity was quantified using the I2 statistic. A sensitivity analysis was performed comparing results with and without case control studies. Software used to conduct the meta-analysis was the open source OpenMetaAnalyst platform.

Results: A total of 8 eligible studies reporting histologic confirmation of BE in either AA or nHw. Analysis including the case control study demonstrated a nearly 400% increased risk for nHw patients having histologic BE compared to AA (OR 3.949, 95% CI 3.069-5.082, figure 1). In the random effects model without the case control study, the risk of histologic BE remained elevated at approximately 360% in nHw compared to AA (OR 3.618, 95% CI 2.769-4.726, figure 2). Heterogeneity was not present in either model (case control included I2=17%, p=0.296, figure 1; without case control I2=0%, p=0.42, figure 2).

Conclusion: In a meta-analysis of studies that examined histologic confirmation of BE between AA and nHw, we observed that nHw had a risk of histologic BE between 3.6 and 4 times higher than AA. Investigation into understanding any molecular/genetic mechanisms underlying this risk disparity is warranted.

1624

LifeVac: A Novel Apparatus to Resuscitate a Choking Victim

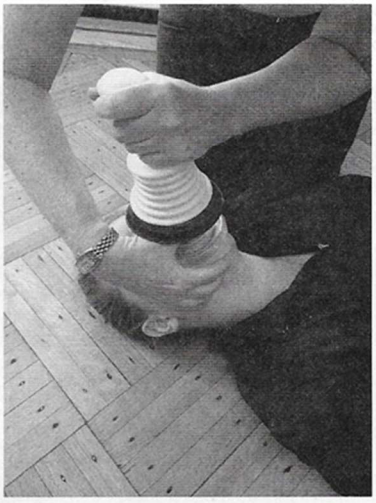
Lisa Lih-Brody, MD, FACG[1], Arthur Lih[2], Edward Brody, Jr., MS[3], Michael Singer[4]. 1. ProHealth Care Associates, Rockville Centre, NY; 2. Lifevac, Massapequa, NY; 3. Lifevac, Rockville Centre, NY; 4. Lifevac, Nesconset, NY.

Introduction: Patients with oropharyngeal dysphagia are at increased risk for choking which can be a leading cause of death in this population. Currently there are no methods to remove an inhaled object if the traditional Heimlich maneuver fails. We have developed an apparatus which is simple to use in order to remove an object lodged in the upper airway if the Heimlich maneuver fails.

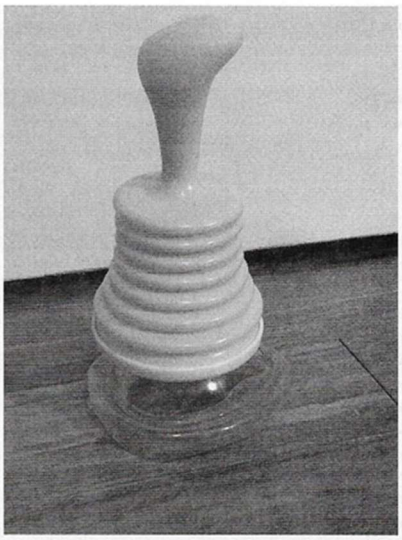
Methods: The Laerdaltm Choking Charlie simulator system designed specifically for training for the Heimlich abdominal thrust maneuver was used in order to simulate a choking victim. A Nathans Cocktail Frank cut in half was utilized as this food is responsible for many choking deaths. The item was pushed into the airway 7 cm from the lips in order to create an obstruction in the airway. The Lifevac unit was then utilized per the products instruction manual to attempt to dislodge the object and the frequency of dislodging the object was recorded.

Results: Using Laerdal Choking Charlie with a hot dog piece inserted into the airway the Lifevac successfully removed the object 470 out of 500 attempts in one useage, in 498 out of 500 attempts with two useages, and was successful 500 out of 500 attempts in three useages. The 95% confidence interval for the probability of success (S) of the device (when defining success as removal in one usage) = 91.5% < S < 95.9%. The 95% confidence interval for the probability of success (S) of the device (when defining success as removal in two or fewer usages) = 98.5% < S < 99.9%.

Conclusion: Lifevac is a promising apparatus that is simple to use and appears to be an extremely effective method in successfully dislodging an object lodged in the ariway of a choking victim. Further studies with cadavers and subsequent pilot studies in humans are warranted in the hopes of saving lives when the Heimlich maneuver fails.



[1624A] Figure 1.



[1625B] Figure 2.

1625

Lower Oropharyngeal Acid Exposure and Higher Psychological Distress Exists Amongst Subjects With Laryngeal Symptoms and Response to PPI Therapy

Rena Yadlapati, MD[1], Bruce Tan[1], Nadine Shabeeb[1], Diana Jaiyeola[1], Christopher Adkins[1], Neelima Agrawal[1], Andrew Gawron[2], Alcina Lidder[1], Caroline Price[1], Stephanie Smith[1], Michiel Bove[1], John E. Pandolfino, MD, MS[1]. 1. Northwestern University, Chicago, IL; 2. University of Utah, Chicago, IL.

Introduction: Predicting therapeutic response in patients with laryngopharyngeal reflux (LPR) symptoms is challenging. Consequently, patients with suspected LPR often receive empiric proton-pump inhibitor (PPI) therapy and up to 50% may not respond. The Restech Dx-pH probe is a transnasal catheter that measures oropharyngeal pH. We hypothesized that higher oropharyngeal acid burden is associated with a greater PPI response. The aims of this study were to (1) correlate oropharyngeal pH probe parameters with PPI response and (2) evaluate if alternative clinical surrogates predict PPI response.

Methods: This was a physician blinded prospective cohort study conducted at a tertiary care teaching institution between 1/2013 and 10/2014. Adult subjects with laryngeal symptoms >1 month and a Reflux Symptom Index score (RSI) ≥13 off PPI therapy 2 weeks prior to study were recruited from an otolaryngology clinic. Laryngoscopy and oropharyngeal pH assessment with the Restech Dx-pH system were first performed, followed by an 8 to 12 week trial of omeprazole 40 mg once daily. Prior to, and following PPI therapy, subjects completed various symptom questionnaires [Table 1]. PPI response was defined as > mean delta RSI (difference between pre- and post-PPI therapy RSI).

Results: Of 34 subjects, 15 (44%) had a PPI response. Percent time of oropharyngeal pH below 5.0 did not correlate with change in RSI (Spearman's rho -0.07, P=0.7); similar trends were seen for pH < 4.0, 5.5 & 6.0. Low acid exposure (< 1%) was significantly associated with PPI response when compared to high acid exposure (≥1%) [Figure 2]. PPI responders had higher psychological distress scores prior to treatment and a significantly greater reduction in post-treatment Brief Symptom Index, Negative Affect, and Heartburn Vigilance Scale scores. Baseline and delta GerdQ scores were significantly higher in the PPI responder group.

Conclusion: Contrary to our hypothesis, low oropharyngeal acid burden was associated with PPI symptom response, suggesting a non-acid mechanism of laryngeal symptoms in this group. PPI responders had higher psychological distress, indicating an association between cognitive affective symptoms and laryngeal complaints and supporting the placebo effect of PPI therapy. The etiology of laryngeal symptoms is undoubtedly complex, and the role of oropharyngeal pH testing to predict PPI response remains unclear.

1626

Interference With Daily Activities and Major Adverse Events During Esophageal pH Monitoring With Bravo® Wireless Capsule Versus Conventional Intranasal Catheter: A Systematic Review of Randomized Controlled Trials

Anthony Iluyomade, MD[1], Abiola Olowoyeye, MD, MPH[2], Opeyemi Fadahunsi, MD, MPH[3], Lia Thomas, MD[1], Christelle Nong Libend, MD[1], Karthik Ragunathan, MD[1], Jay Fenster, MD, FACG[1], Shivakumar Vignesh, MD, FACG[4]. 1. St. John's Episcopal Hospital, Far Rockaway, NY; 2. Children's Hospital Los Angeles, Los Angeles, CA; 3. Reading Health System, Reading, PA; 4. St. John's Episcopal Hospital, Far Rockaway, NY; 5. University of Illinois College of Medicine, Orange, IL; 6. SUNY Downstate Medical Center, Brooklyn, NY.

Introduction: For three decades, ambulatory 24-hour intranasal pH monitoring has been the established gold standard for detecting acid reflux in patients with refractory gastroesophageal reflux disease. However, device-associated adverse events and unpleasant experiences, reported by patients

The World Congress of Gastroenterology

Successful Resuscitation of Choking Victims Using a Lifevac, a Non-powered Portable Suction Device: Real World Experience

Abstract Category: Esophagus
Abstract Type: Clinical Vignettes/Case Reports

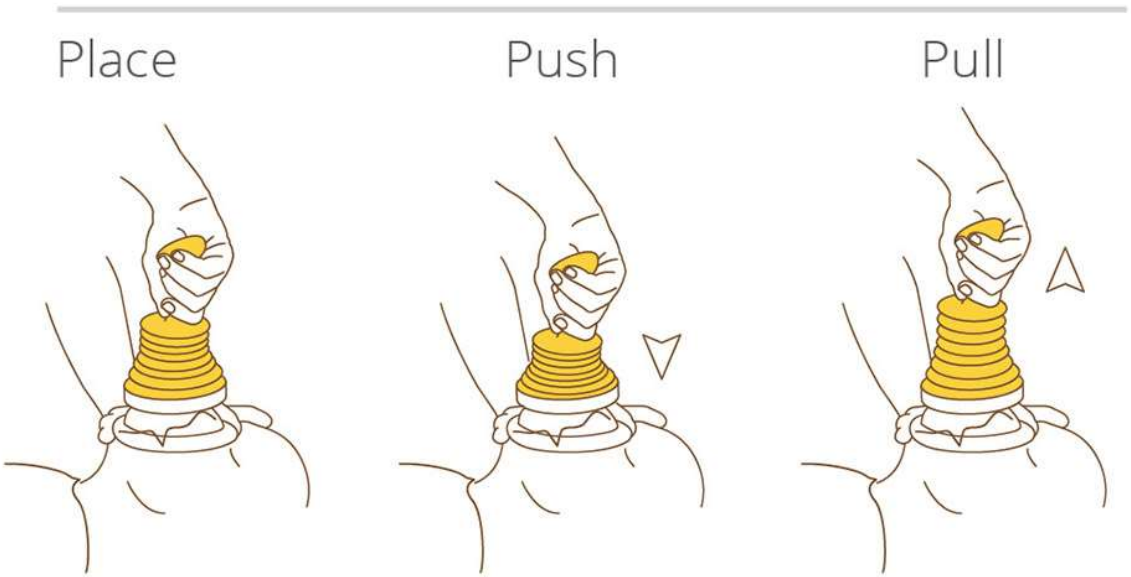
Abstract body:

Choking is a leading cause of accidental death worldwide and in the United States. Patients with oropharyngeal dysphagia are at a high risk for aspiration of food and thus, choking. Although there have been great technological advances, currently, there is no approved device to assist in the resuscitation of a choking victim when abdominal thrusts fail. Recently, a portable, non-powered suction device called LifeVac has been developed and introduced globally. This device consists of a one-way valve and a plunger attached to a standard face mask. When the plunger is pushed down, air escapes out the sides of the valve and not into the victim's airway; when the plunger is pulled back, negative pressure is generated and it suctions out the lodged material. Here we report several real-life cases in which this apparatus has been successfully used to resuscitate a choking victim.

A care home in Wales obtained several LifeVac devices for their residents. During lunch, a resident of this care home began choking on a piece of meat, lost consciousness, began turning blue. A nurse in the home attempted usual methods of assistance without any success. Therefore, the LifeVac device was used according to directions, and with one pull, the meat piece was dislodged. A physician was then called. The physician examined the patient and noted no adverse effects. Additionally, no further intervention was required. The same care home reported that 1 week later, another patient suffered a similar episode and the device was again successfully used to dislodge a meat piece through suctioning into the unit.
In addition, a LifeVac device was obtained by a family in Idaho and was kept at home in case of a choking emergency. On April 23, 2017, a woman in her late 60s with no underlying medical condition began choking at the dinner table on a meat piece. She was unable to speak and was wheezing. Her son unsuccessfully attempted the Heimlich maneuver; thus the LifeVac device was used as per instructions, and with one pull the meat piece was dislodged into her mouth. She did not require further medical attention.

These dramatic real-life case reports demonstrate the utility of this non powered suction device. Certainly, these testimonials show that lives were saved and major morbidity and mortality avoided.

Further studies are urgently needed as there is a need for such a suction device when abdominal thrusts fail to address choking.



https://www.conferenceabstracts.com/cfp2/login.asp?EventKey=KYUMLKAZ

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Role: Author
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THE AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

LIFEVAC- A NOVEL DEVICE FOR THE RESUSCITATION OF THE ADOLESCENTCHOKING VICTIM

Author Block: *Lisa Lih-Brody*, *Michael Singer*, *Edward Brody Jr.*. ProHealth Care Associates, Rockville Centre, NY, Lifevac LLC, Springfield Gardens, NY

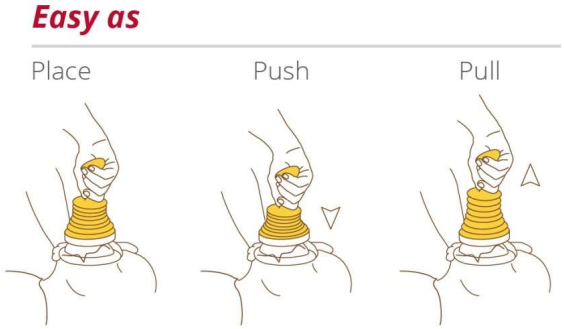
Abstract:

Study Objective- Choking remains a leading cause of tragic death in children and adolescents. Currently there are no devices that are accepted to assist in the resuscitation of an adolescent choking victim. Therefore we studied the 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 Laerdel choking adolescent simulator system was utilized and a hot dog piece was inserted one and one half inches into the airway. The Lifevac was then used per operating guidelines with the pediatric mask attached to attempt to remove the lodged object and the outcome was recorded.

Results- The Lifevac successfully removed the obstructing hot dog in 472 out of 500 attempts in one attempt, in 497 out of 500 in two attempts, and all obstructions were removed in three attempts. The 95% 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: $0.92 \leq S \leq 0.96$, success 2 attempts: $0.98 \leq S \leq 1.0$, success 3 attempts: $0.99 \leq S \leq 1.0$ 99% confidence intervals for the point estimate of the probability that the device will remove the obstruction (call the point estimate "S") shown for three scenarios depending on how you define success: success 1 attempt: $0.91 \leq S \leq 0.97$, success 2 attempts: $0.98 \leq S \leq 1.0$, success 3 attempts: $0.99 \leq S \leq 1.0$

Conclusion- The Lifevac is an apparatus that can successfully remove a hot dog, which is a food that commonly leads to choking, lodged in an adolescent choking victims 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.



Author Disclosure Information:

L. Lih-Brody: ; Lifevac LLC. **M. Singer:** ; Lifevac LLC. **E. Brody:** Lifevac LLC.

THE PROGRAM

OF

THE NINETY EIGHTH ANNUAL MEETING

OF

The American Broncho-Esophagological Association

Wednesday, Thursday, and Friday

April 18-20, 2018

The American Broncho-Esophagological Association (ABEA)

Novel use of a portable, non-powered, suction-generating device for management of life-threatening aerodigestive tract foreign bodies

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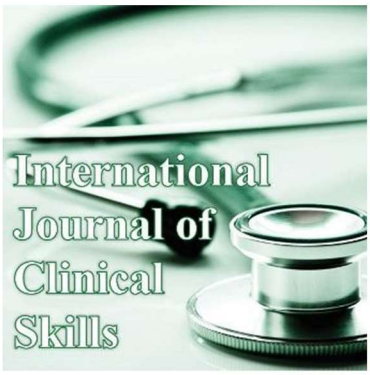
Abstract:
Objective: Foreign body aspiration causes thousands of deaths every year, particularly in children, the elderly, and adults with dysphagia. While operative techniques have been described for patients stable enough for transport to a medical facility, opportunity exists for improvement in pre-hospital management. Here we summarize data assessing a portable, non-powered, high suction-generating device which can be applied in the emergent resuscitation of patients suffering acute respiratory distress from foreign body aspiration.

Methods: The PubMed and MEDLINE databases were comprehensively screened using broad search terms. All identified citations were reviewed systematically. Further product testing materials, published abstracts, and anecdotal case reports related to the device were reviewed. A summary is herein presented.

Results: Laboratory testing demonstrated that this device generates peak airway pressures 8 to 10 times that of standard chest compressions and abdominal thrusts. A simulation study showed 94% reliability in retrieving upper aerodigestive tract foreign body. In a similar cadaveric study, there was 98% reliability in retrieving foreign bodies of varying sizes from the upper airway. The rate of success in both studies approached 100% with multiple attempts. Several case reports have also shown successful application in the emergent management of airway foreign body in elderly and dysphagia patients.

Conclusion: Portable suction-generating devices 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.

INTERNATIONAL JOURNAL OF CLINICAL SKILLS



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Successful Use of a Novel device called the LifeVac to Resuscitate Choking Victims- Worldwide Results

May 11, 2018
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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 back blows 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 minutes 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, non-powered 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, 2, 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 began performing abdominal thrusts. With the 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-year-old 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 Downs 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.

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Figure Legend

Fig (1). The LifeVac Device

Fig (2). Easy Technique Using LifeVac

SPAIN NATIONAL CONGRESS

SOCIETY OF EMERGENCY MEDICAL SERVICES

JUNE 6, 7, 8, 2018

Post #655 of Chapter 7

LIFEVAC

NEW DEVICE FOR CLEARING AN

AIRWAY OBSTRUCTED BY A FOREIGN OBJECT

URGENCIAS EXTRAHOSPITALARIAS; REANIMACION CARDIOPULMONAR; CATASTROFES, IMV

AREAS TEMATICAS

1. **Urgencias Medicas I**
   (Arritmias, Insuficiencia Cardiaca, Sindrome coronario agudol
2. **Urgencias Medicas II**
   (Enferme dadtromboemb6 lica. patologia respiratoria,
   enfermedades infecciosasl
3. **Urgencias Medicas III**
   (Diabetes y urgencias endocrinas. patologia neurol6gica,
   patologia digestiva y otras patologias medicasl
4. **Urgencias Traumatologicas, Quinirgicas y Ginecologicas**
5. **Urgencias por Toxicos y Agentes Externos**
6. **Diagnostico por Imagen, Ecografia en Urgencias**
7. Urgencias Extrahospitalarias, Reanimacion Cardiopulmonar, Catastrofes, IMV
8. Via Aerea, Vmni, Tecnicas enMedicina de Urgencias, Monitorizacion No Invasiva
9. Gestion de Urgencias y Emergencias, Seguridad Clinica y Calidad, Etica
10. Experiencias en Formacion, Simulacion Clinica, Investigacion
11. Enfermeria de Urgencias
12. Tecnicos en Emergencias Sanitarias
13. Miscelanea, Urgencias Geriatricas, Urgencias Pediatricas

P-0655

LIFEVAC®: NUEVO DISPOSITIVO PARA LA PERMEABILIZACIÓN DE VÍA AÉREA EN OBSTRUCCIÓN POR CUERPO EXTRAÑO

A Etxebarría Capellán (1), C Fernández Sánchez (2), R Rodríguez Hernández (3), IA Vilches Pincheira (4)

(1) Emergentziak Osakidetza. (2) Servicio de Urgencias. Hospital Santiago Apostol. Vitoria-Gasteiz, Araba. Osakidetza. (3) Larrialdiak. (4) Punto de Atención Continuada (PAC) de la Organización Sanitaria Integrada (OSI). Araba. Osakidetza

Palabras clave: obstrucción de las vías aéreas-vacío-equipos y suministros

INTRODUCCIÓN:

La Obstrucción de la Vía Aérea por Cuerpo Extraño (OVACE) o atragantamiento es una causa potencialmente tratable de muerte accidental. Dado que las víctimas inicialmente están conscientes y responden, en la mayoría de los casos, existe la oportunidad de intervenir precozmente para disminuir dicha mortalidad.

La obstrucción de la vía aérea (VA) puede ser leve o grave. Las recomendaciones de la European Resuscitation Council (ERC) y de la American Heart Association (AHA) indican cómo actuar y los pasos a seguir ante la obstrucción parcial o completa de la vía aérea.

Para realizar las dos técnicas recomendadas por la ERC y la AHA (compresiones abdominales y torácicas) hay que formarse, debido a que pueden potencialmente causar lesiones internas graves.

En 2012, tras conocer el caso de un niño de 7 años que había muerto por atragantamiento, el neoyorkino Arthur Lih, inventó un dispositivo de desobstrucción de la vía aérea llamado "LifeVac®" para ayudar a su desobstrucción. Este dispositivo salió al mercado en agosto de 2014, pero debido al poco tiempo que lleva y los pocos estudios que hay sobre él, no está incorporado en las recomendaciones de la ERC ni de la AHA.

OBJETIVOS:

Dar a conocer el dispositivo "LifeVac®" así como la técnica de utilización en situaciones de OVACE.

MATERIAL O PACIENTES Y MÉTODO:

Se realizó una revisión sistemática de documentos de diferentes sociedades científicas dedicadas a la salud tras la formulación de la pregunta PICO.

Una primera búsqueda se realizó en PubMed con diferentes ecuaciones de búsqueda sin aplicar ningún filtro. Con la primera-"Airway Obstruction"[Mesh] AND "Vacuum"[Mesh] – utilizando un lenguaje controlado, obtuvimos un total de 5 resultados. En otras dos búsquedas se utilizó un lenguaje libre sin filtros – "LifeVac" y "choking AND device AND vacuum" – obteniendo 2 y 5 resultados respectivamente. Tras la lectura de los documentos encontrados, sólo se pudo seleccionar uno común en las tres búsquedas.

También se realizó una búsqueda en Cochrane Library con lenguaje libre – "Airway Obstruction" AND (vacuum OR device) – obteniendo 175 resultados de los cuales ninguno trataba sobre nuestro tema.

Finalmente, se revisó la literatura gris utilizando como fuente de datos la propia página del dispositivo (https://lifevac.net/) y el contacto con el creador obteniendo 2 resultados válidos.

RESULTADOS:

En la documentación encontrada se refleja el fácil uso del dispositivo "LifeVac®", el cual consiste en la creación de una presión negativa en la VA mediante la adaptación de una mascarilla de resucitador manual auto-hinchable al dispositivo.

Los estudios presentaron una efectividad del 100% de este dispositivo, aunque los resultados no son concluyentes, debido a que sólo se han documentado 11 casos a nivel mundial.

En uno de los estudios realizados en cadáveres, se realizaron 50 obstrucciones simuladas con bolus de entre 2 y 3 cm de diámetro obteniendo una efectividad del 100% en la extracción del bolus requiriendo un segundo intento en sólo uno de los ensayos.

Otro de ellos, realizado en un simulador de un adolescente con OVACE (Laerdal®) se obtuvo un 94.4% de efectividad con un intento, 99.4% con dos intentos y 100% con tres intentos en un total de 500 simulaciones con un intervalo de confianza del 99%.

CONCLUSIONES:

Pese a escasa documentación encontrada, en la misma se refleja la facilidad de utilización de este dispositivo, por lo que se cree que es conveniente profundizar y analizar la efectividad de dicho producto con el fin de poder implantarlo en todas las unidades de trabajo en las que exista riesgo de atragantamiento haya o no una figura sanitaria; así como la necesidad de crear un registro de utilización del dispositivo.

Urgencias: Ciencia, Arte y Cultura 30º Congreso Nacional SEMES Toledo 6, 7 y 8 junio 2018

LIFEVAC®: NUEVO DISPOSITIVO PARA LA PERMEABILIZACION DE VIA AEREA EN OBSTRUCCION POR CUERPO EXTRAÑO

A Etxebarria Capellán, C Fernández Sánchez, R Rodríguez Hernández, IA Vilches Pincheira

INTRODUCCIÓN

Obstrucción de la Vía Aérea por Cuerpo Extraño (OVACE) o atragantamiento es una causa potencialmente tratable de muerte accidental. Las recomendaciones de la European Resuscitation Council (ERC) y de la American Heart Association (AHA) indican cómo actuar y los pasos a seguir ante la obstrucción parcial o completa de la vía aérea.

En 2012, tras conocer el caso de un niño de 7 años que había muerto por atragantamiento, el neoyorkino Arthur Lih, inventó un dispositivo de desobstrucción de la vía aérea llamado "LifeVac®" para ayudar a su desobstrucción. Este dispositivo salió al mercado en agosto de 2014.

DEFUNCIONES EN ESPAÑA 2016

OBJETIVO

Analizar la efectividad del dispositivo "LifeVac®" en personas con obstrucción de la vía aérea por cuerpo extraño en relación con la disminución la mortalidad.

METODOLOGÍA

Se realizó una revisión sistemática de documentos de diferentes sociedades científicas dedicadas a la salud tras la formulación de la pregunta PICO.

P	Personas que sufren OVACE
I	Uso del dispositivo "LifeVac®"
C	No uso del dispositivo
O	Disminución de la mortalidad

Fuentes de búsqueda	Ecuación de búsqueda	Filtros	Documentos obtenidos	Documentos usados
Pubmed	"Airway Obstruction"[Mesh] AND Vacuum [Mesh]	No	5	1
Pubmed	LifeVac	No	2	1
Pubmed	choking AND device AND vacuum	No	5	1
Cochrane Library	"Airway Obstruction" AND (vacuum OR device)	No	175	0
Literatura gris	https://lifevac.net/ Contacto con el autor	No	2	2

RESULTADOS

REPETIR HASTA RETIRAR LA OBSTRUCCIÓN O 5 VECES.

CASOS REALES DOCUMENTADOS		ESTUDIO CON CADÁVERES			ESTUDIO CON SIMULADOR				
Nº VECES USADO	EFECTIVIDAD	SIMULACIONES	EFECTIVIDAD 1º INTENTO	EFECTIVIDAD 2º INTENTO	SIMULACIONES	EFECTIVIDAD 1º INTENTO	EFECTIVIDAD 2º INTENTO	EFECTIVIDAD 3º INTENTO	INTERVALO DE CONFIANZA
11	100%	50	98%	100%	500	94,4%	99,4%	100%	99%

Limitaciones: El estudio 1 fue realizado sobre un solo cadáver y todos los intentos fueron hechos por los dos mismos investigadores, lo que dificulta saber si el estudio tiene validez externa.
El estudio 2 fue realizado íntegramente sobre el mismo simulador y no describe si todos los intentos están realizados por el mismo o por diferentes investigadores, lo que nos ocasiona el mismo problema que el anterior.

CONCLUSIONES

Pese a la escasa documentación encontrada, en la misma se refleja la facilidad de utilización de este dispositivo por parte de las personas con escaso o nulo conocimiento en el ámbito de la salud, por lo que se cree que sería conveniente profundizar y analizar la efectividad de dicho producto con el fin de poder implantarlo en todas las unidades de trabajo en las que exista riesgo de obstrucción de vía aérea por cuerpo extraño o atragantamiento haya o no una figura sanitaria; además de la necesidad de crear un registro de utilización del dispositivo para poder evaluar a largo plazo la efectividad del mismo a través de un estudio observacional prospectivo.

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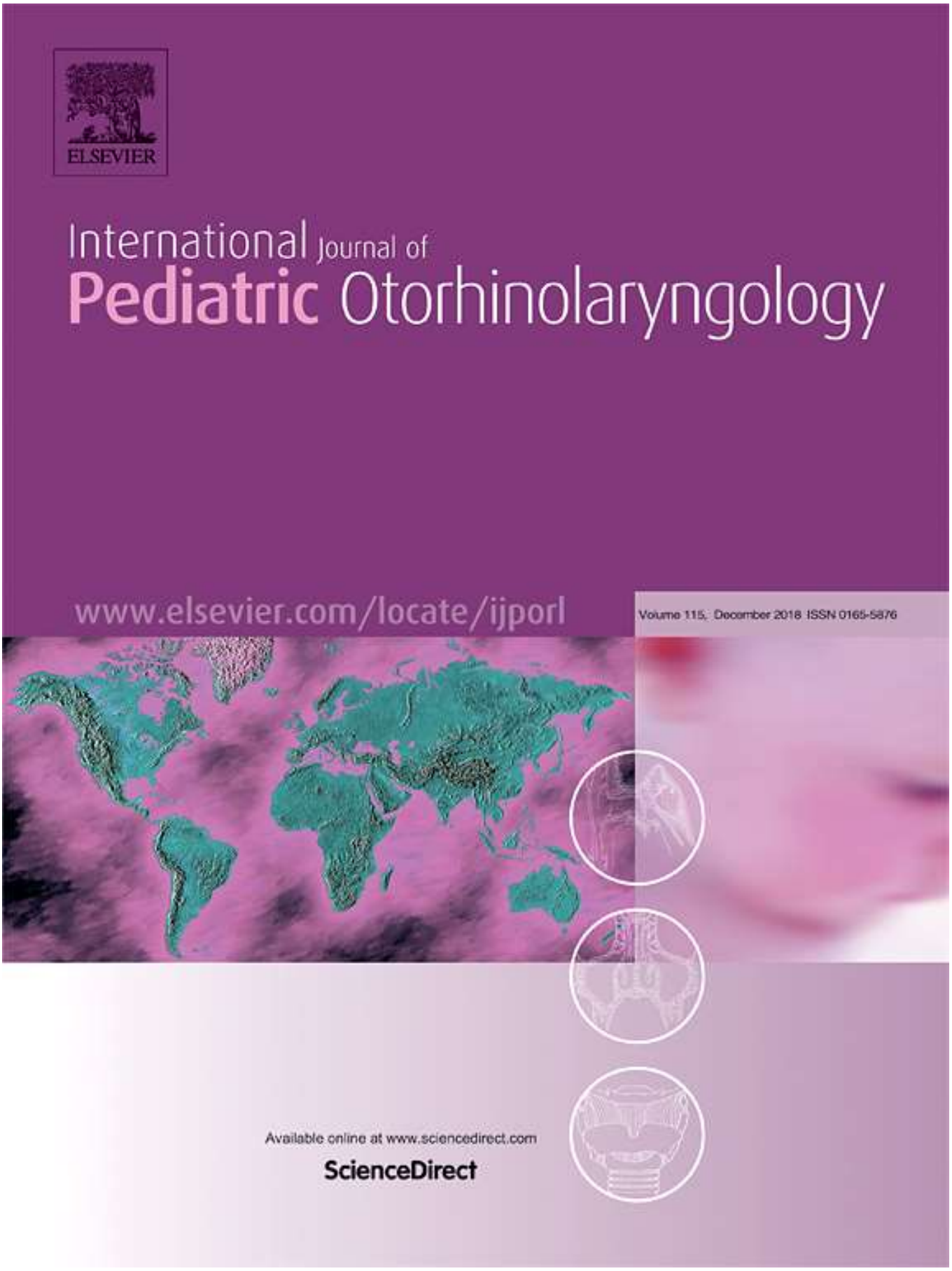
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Peer Reviewed

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.2018.12.014

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.

Pediatrics & Therapeutics

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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

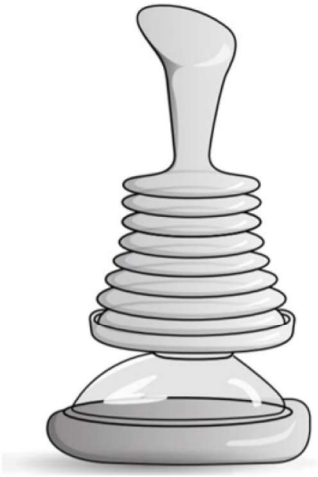

Figure 1: The device attached to a standard adult facemask.

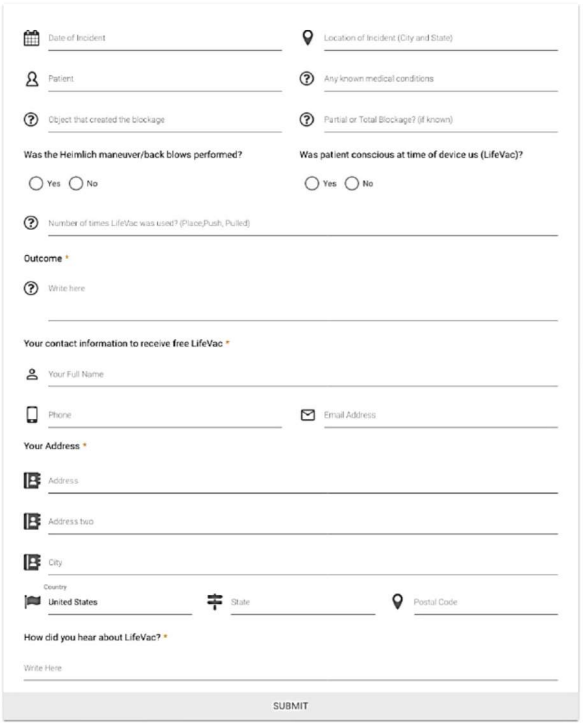

Figure 3: The online feedback form.

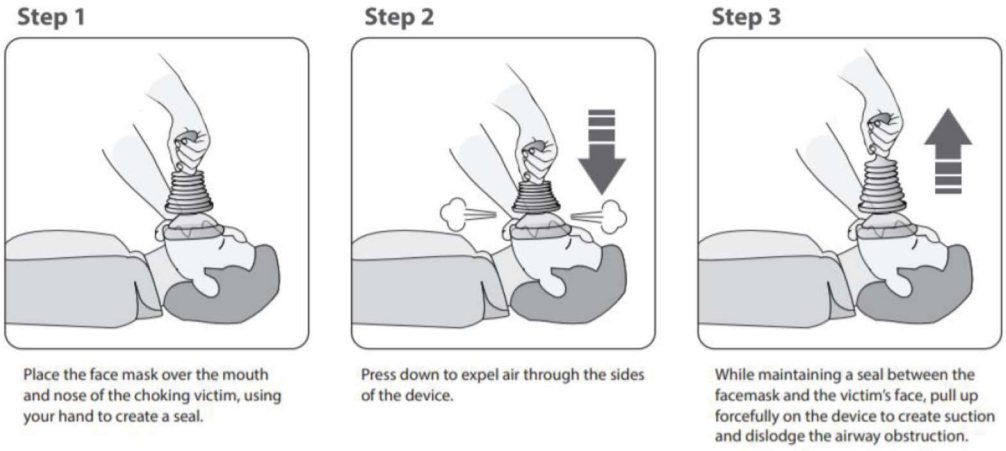

Figure 2: Instructions for use.

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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Poster Tours (PT)

PT1

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

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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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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

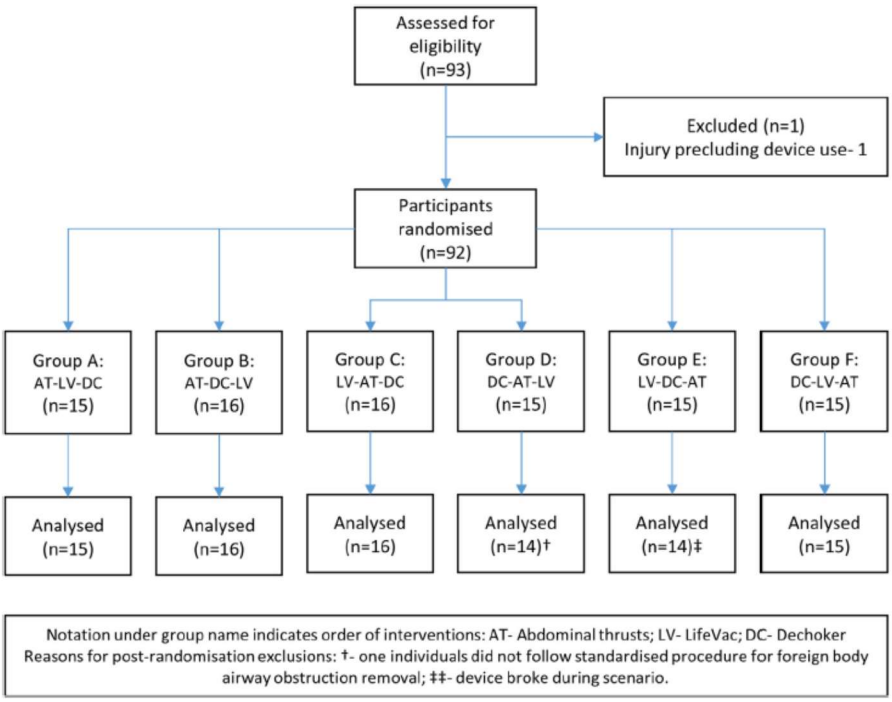

Fig. 1 – CONSORT participant flow diagram.

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.

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.

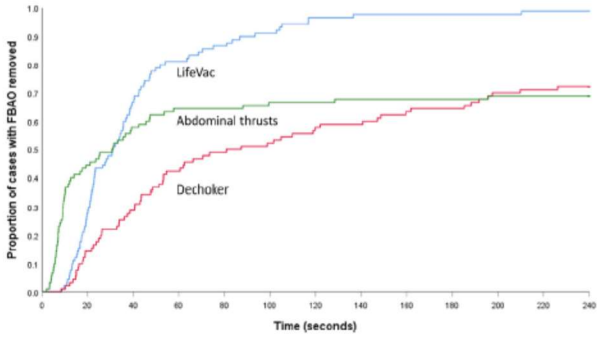

Fig. 2 – Time to removal of foreign body for study interventions.

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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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.

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.

FIGURE 1

Figure 1. LifeVac device and usage.

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.

TABLE 1

Characteristic	Value
Age range, years	20-90
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

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

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 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 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.

Conflict of Interest

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

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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 [1,2,3,4,5]. 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 [8,9,10]. 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 [1,2,3,4,5]. 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.

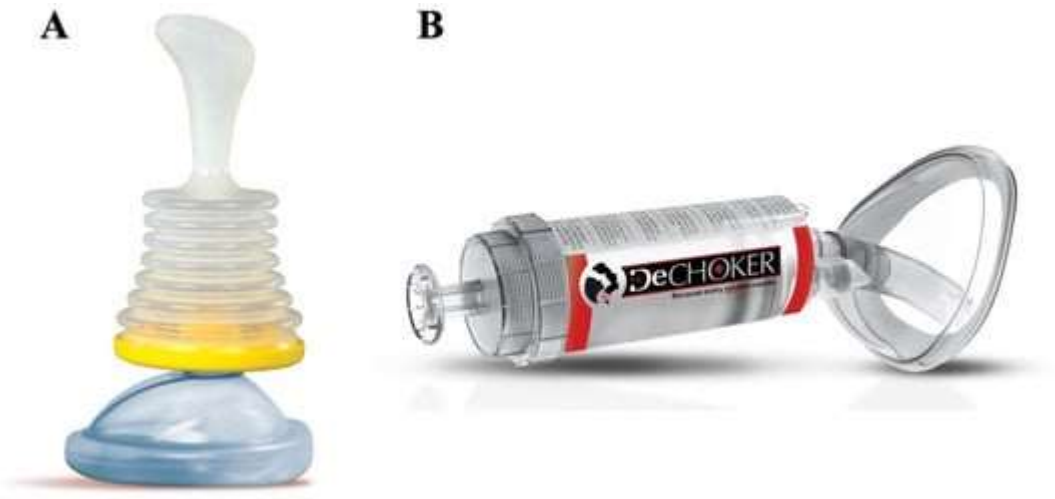


Figure 1. (**A**) LifeVac© airway clearance device (**B**) DeChoker© airway clearance device [images supplied by the respective manufacturers with permission to include].

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.

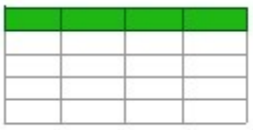
It was decided *a priori* that, for a record to be included in the final analysis, three clinical data points were required: the patient's age, a description of the foreign body material and commentary on the primary outcome. There were 140 LifeVac© interventions recorded, of which 124 (88.6%) were eligible 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.

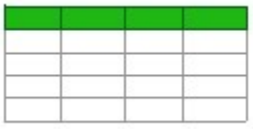


LifeVac© ACDs have a wide representation across the age span (median age, IQR = 40, range = 2–80 years) with about one-third of the interventions being younger than five years and another third aged 65 years and older. Pre-existing medical co-morbidities were common (59.6% having at least one), with 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%).

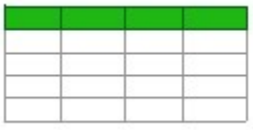
For both ACD types, females were more commonly treated (LifeVac©-53.2%; Dechoker©-59.0%) and a relatively small number of patients had a known history of dysphagia or aspiration (13.7%; and 4.8%). Similarly, food was the predominant foreign body for both ACD types (84.7%; and 91.8%). Besides food and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



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.

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



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.

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 [23,24,25]. 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 [23,24,25].

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.

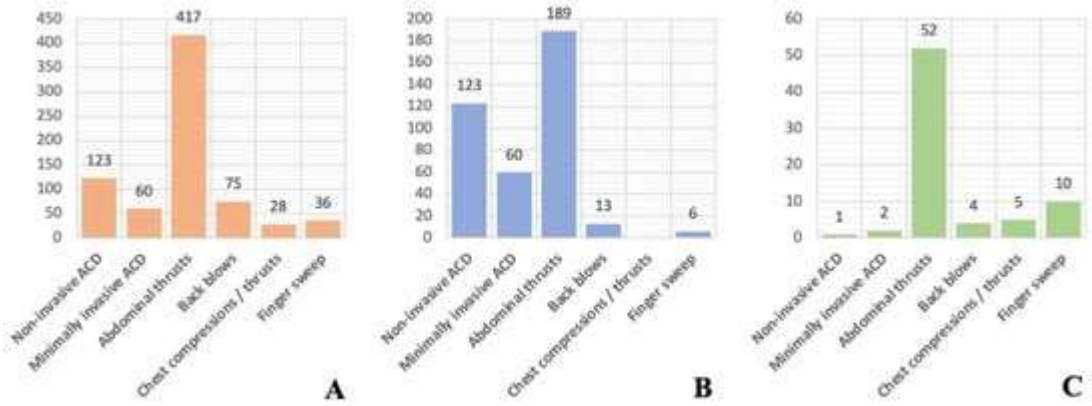


Figure 2. Reported counts in academic literature of effectiveness and safety outcomes for airway clearance devices and traditional FBAO interventions: (**A**) Relief of FBAO (**B**) Survival* (**C**) Adverse events [8,9]. ** Chest compressions/thrusts had survival with good neurological outcome reported,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

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].

6. Conclusions

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

Supplementary Materials

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

Author Contributions

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

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Institutional Review Board Statement

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

Informed Consent Statement

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

Data Availability Statement

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

Conflicts of Interest

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

Disclaimer

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

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(retired)
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"LifeVac is the only device that can free an airway obstruction in a life-threatening choking emergency that everyone can use. It provides the right amount of suction to free an airway obstruction without causing an adverse effect.

As an emergency physician, I recommend this product be available in schools, hospitals, nursing homes, daycare facilities, ambulances, with law enforcement officers, and anywhere there is emergency medical equipment."

Keith Johnson, MD is Board Certified in both Pediatrics and Internal Medicine and is trained on the current ACLS Protocol.

Dr. Keith Johnson is a pediatrician in Venice is shown on LifeVac's site demonstrating how the device is used. "It should be CPR, back slaps, Heimlich maneuver, and this is your next tool," Dr. Johnson said. "Create a seal on their face by firmly holding and pushing down," Dr. Johnson said while demonstrating LifeVac on a patient. "Then pull up hard. Turn the body immediately, opening the airways and sweeping out ...."

"LifeVac should be available in homes, schools, airports, wherever the situation will arise you never know when you are going to need one".

Rodney Millspaugh, NREMT/Paramedic

"As a Paramedic and CPR Instructor with a swallowing disorder, I highly recommend LifeVac. Not only do I teach my students how to use the LifeVac (when the Heimlich maneuver isn't successful) I keep one in my home to give my family peace of mind, you should too.
Using LifeVac is as simple as 1-2-3."

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