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GENERAL INFORMATION

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INDEX

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Product

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DON'T BECOME A STATISTIC

USA CHOKING FACTS

- A leading cause of death in children.
- 4,000 deaths yearly.
- One child dies every five days from choking.
- Leads to 100,000 visits to the ER yearly.
- Over one million Americans have no defense against choking due to pregnancy, disability, obesity or being alone.
- More people die from choking than fires, drowning or accidental shootings.
- A leading cause of accidental deaths of persons over the age of 65.
- Of all choking deaths in 2000, 41% were caused by food, 59% by nonfood items (balloons, etc).
- Candy is associated with 19% of ER visits for choking- 65% due to hard candy and 35% to candies such as gummy bears, chocolate, caramel, etc.
- Coins were responsible for 18% of ER visits for children aged 1 to 4 years old.

TIME IS OF THE ESSENCE

- 0-4 minutes brain damage unlikely.
- 4-6 minutes brain damage possible.
- 6-10 minutes brain damage probable.
- 10 minutes brain death probable.
- Average response time is 7-10 minutes.

UK CHOKING STATISTICS

- According to the St John Ambulance website nearly 900 hundred people choke to death yearly and 2500 people die from asphyxiation due to a blocked airway.

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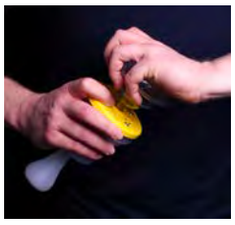
FOLLOW ALL STANDARD PROTOCOL FIRST AND DIAL 999

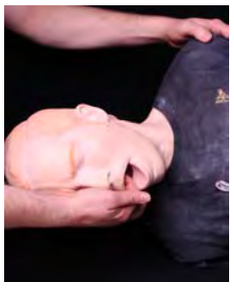


INSERT MASK INTO THE UNIT WITH A TWISTING MOTION WHILST APPLYING PRESSURE.
MAKE SURE YOU CHECK THE MASK TO ENSURE IT IS ATTACHED TO THE UNIT

PLACE MASK OVER NOSE AND MOUTH, HOLDING CHIN UPWARDS.
MASK MUST BE HELD FIRMLY OVER NOSE AND MOUTH WITH HAND

HOLDING MASK IN PLACE WITH ONE HAND AND CHIN HELD UPWARDS, PUSH HANDLE DOWN WITH THE OTHER HAND TO COMPRESS UNIT

ONCE HANDLE IS DEPRESSED, PULL HANDLE UPWARD WITH A SHORT, SWIFT TUG WHILST HOLDING THE MASK FIRMLY IN PLACE



ROLL PERSON ONTO THEIR SIDE AND SWEEP THE MOUTH TO CLEAR ANY DEBRIS.
ALSO CHECK UNIT FOR DEBRIS
REPEAT STEPS AS NECESSARY.

IF NO SPONTANEOUS RESPIRATION IS NOTED, THEN FOLLOW STANDARD ACLS CPR PROTOCOL

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LIFEVAC IS SAFE

LifeVac is designed with a patented valve to prevent any air from exiting through the mask. This patented designed valve prevents air from pushing food or objects downward. This creates a one-way suction to remove the lodged food or object.

- No prescription required
- Generates over 326 mmhg of suction

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FDA Registration
FDA Classification
MHRA Registration
And Health Canada License

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2014-2025

Certificate of Registration

This certificates that:

LifeVac Corp.
83 Rome Street
Farmingdale, NY 11735

Is registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date hereof by Registrar Corp.

U.S. FDA Registration No.: **3011053282**

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CFR - Code of Federal Regulations Title 21

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart G--General Hospital and Personal Use Miscellaneous Devices

Sec. 880.6740 Vacuum-powered body fluid suction apparatus.

(a) *Identification.* A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9. [45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

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Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: CA014885

Mr Eric Banagan
LifeVac Europe Limited
Carnanton
King Street
Combe Martin
Devon
EX34 0AD
United Kingdom

MHRA
151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

16 June 2015

Dear Mr Eric Banagan,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19

Registration of Persons Placing General Medical Devices on the Market

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

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

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

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

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

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

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

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

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

Please inform us of the following chargable changes:

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

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

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Thank you for registering the following generic groups of devices:

Class I Devices:
Airway Devices/Monitoring Equipment And Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

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

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

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

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

Yours sincerely

Barbara Clarke
Regulatory Affairs Administrator
Tel: 020 3080 7318
Fax: 020 3118 9809
Email: barbara.clarke@mhra.gsi.gov.uk

Confman Vers 3 June 2015

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Health Canada / Santé Canada

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments

Licence Number 6376 Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

LIFEVAC LLC

137 ALLEN BOULEVARD
FARMINGDALE, NEW YORK
UNITED STATES
11735

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, réglement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made :

Attestations faites :

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant
• distribution records	[N]	• les registres de distribution
• complaint handling	[N]	• les plaintes
• recalls	[N]	• les rappels
• mandatory problem reporting	[N]	• rapports d'incident obligatoires
• handling, storage, delivery	[N]	• la manutention, le stockage, la livraison
• installation	[N]	• l'installation,
• corrective action	[N]	• les mesures correctives
• servicing	[N]	• l'entretien

Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2014-12-08

Minister of Health / Ministre de la santé	Countersigned: Director General, Health Products & Food Branch Inspectorate or delegated authority / Contresigné par: Directeur Général, Inspectorat de la Direction générale des produits de santé et des aliments ou autorité déléguée
	Sharon Mullin

This licence is the property of the Health Products & Food Branch Inspectorate and must be returned upon demand.
Cette licence appartient au programme d'inspectorat de la Direction générale des produits de santé et des aliments et doit être retournée sur demande.

Canada

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments
Establishment Licence
Licence d'établissement
Health Canada / Santé Canada
Canada

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Studies and Medical Papers

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LifeVac
Simulation Study

A novel apparatus for the resuscitation of a choking victim

Background

Patients with oropharyngeal dysphasia 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 trachea if the Heimlich maneuver fails.

Methods

The Laerdel choking simulator system was used in order to simulate a choking victim. The Laerdel ALS Megacode Kelly, Megacode kid, and were all evaluated. Items most frequently leading to choking deaths include grapes, hot dogs, popcorn, and toy cars and these items were therefore tested. The item was pushed into the airway in order to create an obstruction. The LifeVac unit was then used per standard protocol and the frequency of dislodging the object was recorded.

Results

Using ALS Megacode Kelly with a grape inserted into the airway the LifeVac successfully moved the object 15 out of 19 tries (79%). It was successful in dislodging a hot dog in line with the airway 16 out of 16 tries or 100%. When the hot dog was perpendicular 4/5 or 80% were successful. Popcorn was removed in 8 of 8 tries or 100%, and 5 out of 5 toy cars in line with the airway or 100% were removed. Using the Laerdel Megacode kid with SIM pad 12 out of 12 grapes were removed (100%), 10 of 10 hot dogs were removed as well. 5 cars however did not move. Using the Laerdel airway trainer 14 hot dogs were all removed successful.

Conclusion

LifeVac is a promising apparatus that is simple to use and appears to be an effective method in successfully dislodging an object lodged in the airway of a choking victim. Further pilot studies in humans are warranted in the hopes of saving lives when the Heimlich maneuver fails.

Edward P. Brody Jr. MS, Lisa Lih-Brody, MD, FACG, Rodney Millspaugh, NREMT

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Vacuum generated by LifeVac apparatus in a closed system versus pressures generated by chest compressions and Heimlich maneuver in cadavers with complete airway obstruction

E.Brody Jr. (BS. Mech Eng, Cooper Union, MS. Comp Sci, NYU Polytechnic)

Abstract

In a previous study conducted in Norway in 1999, Langhelle et. al. [1], airway pressure generated by the Heimlich maneuver, and by chest compression were measured in 12 recently dead cadavers. In order to compare the recently developed Lifevac apparatus' effectiveness to chest compressions and the Heimlich, the following test was performed. The LifeVac apparatus was connected to a vacuum test device, and 5 test pulls were performed. Vacuum measurements were made and recorded. This was repeated using 12 different LifeVac units in order to arrive at an average value for vacuum. The mean peak vacuum generated by LifeVac was 232.2 cmH2O. The published mean peak airway pressure measured for chest compressions was 40.8 +/- 16.4 cm H2O, and for abdominal thrusts were 26.4 +/- 19.8 cmH2O. The Lifevac unit can generate more force on an airway obstruction by pulling from above the obstruction, than either chest compressions or abdominal thrusts generate from below. Therefore the LifeVac unit has the potential of being more effective at removing a foreign object from the airway of a choking victim.

Introduction

In the study performed by Langhelle [1], it was demonstrated that chest compressions are potentially more effective at removing a foreign body from an airway than the Heimlich maneuver, generating significantly more airway pressure to force the foreign body out. With the introduction of the new LifeVac apparatus, we now have the potential to improve upon the performance of both the Heimlich and chest compression for this purpose. While the Heimlich and chest compression generate the airway pressure by compressing and forcing the air out of the subjects lungs and thereby pushing the foreign object from below, the LifeVac takes the opposite approach. It is placed over the subject's nose and mouth, and when operated it generates a vacuum in the airway, effectively sucking the foreign object out from above. We therefore performed a test of the LifeVac unit to determine the magnitude of the vacuum generated, and to compare these values to the pressures generated by chest compression in the Langhelle [1] study.

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Materials and methods

The purpose of this study was to obtain results from the LifeVac apparatus which could be compared directly to those reported in the Norwegian study. In that study 12 recently dead cadavers were used as test subjects. All of these subjects had a tracheal tube still in place from intubation. The cuff was inflated to create an airtight seal between the airway and the tube. The tracheal tube was connected to a sensor to measure airway pressure, and the proximal end of the sensor was plugged to simulate a complete airway obstruction. In essence a closed system was created where a fixed volume of air was compressed by either the Heimlich maneuver or chest compressions.

Materials and methods - continued

The pressure exerted by this compressed air was measured by the sensor (see figure 2). In the study performed on the LifeVac apparatus, the unit was connected to a fitting with a sized boss and o-ring seal. This fitting was connected by tubing to a vacuum gauge (Druck DPI 104 by GE). This system simulates a completely obstructed airway, with the LifeVac unit covering a choking victim's nose and mouth. It is a closed system with a fixed volume of air. In this scenario the bellows assembly of the LifeVac is used to generate the pressure, or in this instance, vacuum. The magnitude of the vacuum is measured by the vacuum gauge (see figure 3). Twelve different LifeVac units were were tested to account for any manufacturing inconsistencies. Each LifeVac unit was installed on the vacuum test fixture (see Figure 1). Five compress/pull cycles were performed for each, and the values for vacuum were recorded for each cycle. This was repeated for each LifeVac unit. The person performing the test had no medical training whatsoever, and is therefore more representative of the type of person who would be using the LifeVac in an emergency situation in a public place, or a home.

Figure 1.

Figure 1. Vacuum testing fixture used in LifeVac testing.

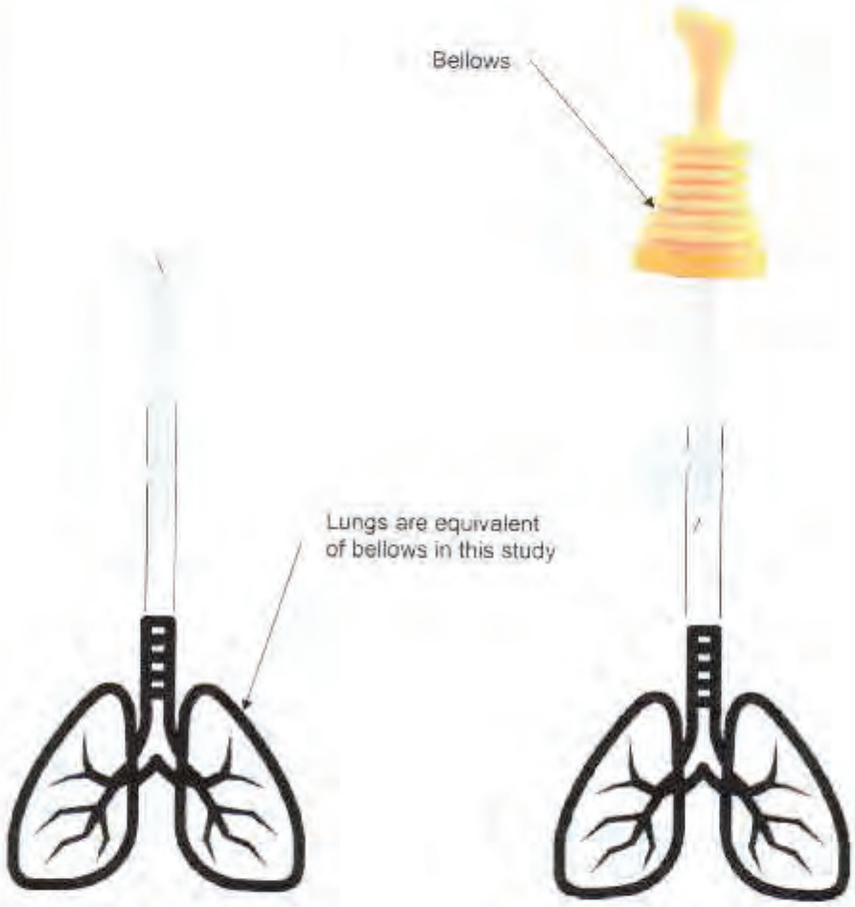

Figure 1. Simplified drawing of test setup for Norwegian study (Langhelle)

Figure 2. Test setup for LifeVac testing.

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Discussion

In this test we obtained vacuum values using the LifeVac unit which were much higher than airway pressures previously published by Langhelle et. al. [1]. We have demonstrated that the results of this test can be compared directly to the Langhelle study, since both tests took place in a closed, fully blocked, system. In the Langhelle study a cuff was inflated around a tracheal tube, and a sensor with the proximal end blocked off was inserted into the airway. The lungs were essentially the bellows which, when compressed, generated the pressures which were measured. In the LifeVac test, the closed system consists of the LifeVac unit connected to a vacuum gauge with flexible tubing. The LifeVac unit itself contains the bellows which, when compressed then pulled up rapidly, generates a vacuum. In a real world choking situation this vacuum will suck the foreign object from the airway. We can also state that the LifeVac results would be the comparable if the test was performed on cadavers, since the airway would be totally blocked off, and the vacuum is generated by the LifeVac bellows and is independent on the anatomy of the cadaver.

In conclusion, the findings of this test indicate that the LifeVac unit generates much higher pressures than either the Heimlich maneuver or chest compressions without the possibility of broken ribs or other physical damage, and is a more effective way to treat subjects with complete airway obstruction by a foreign body.

Results

Twelve LifeVac units were tested, and five vacuum readings were taken for each unit. The mean peak vacuum obtained was 233.2 cm H2O. This is in comparison to a mean peak airway pressure of 40.8 +/- 16.4 cmH2O for chest compression and 26.4 +/- 19.8 cmH2O for the Heimlich maneuver. The vacuum values recorded during testing are shown on Chart 1 below. The results from the Langhelle [1] study are reprinted in Chart 2.

Chart 1. Mean vacuum values obtained with Lifevac

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Chart 1. Mean vacuum values obtained with Lifevac

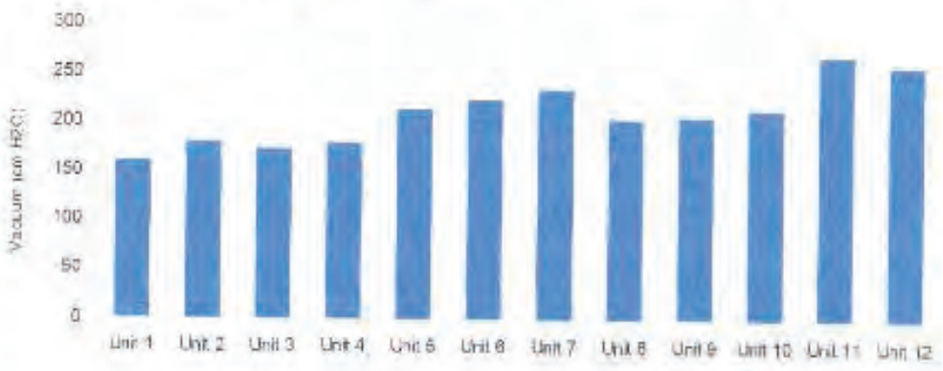

Chart2. Reprint of results from Norwegian study (Langhelle)

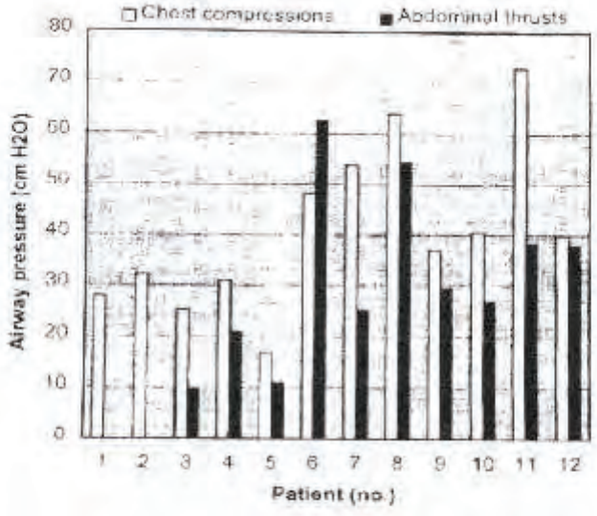

Fig. 1. Airway pressures with chest compressions and abdominal thrusts on twelve recently dead adults with complete airway obstruction. The airway pressure is significantly lower with abdominal thrusts than chest compressions ($P = 0.005$).

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

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

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Reference: YAJEM 55696

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

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

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

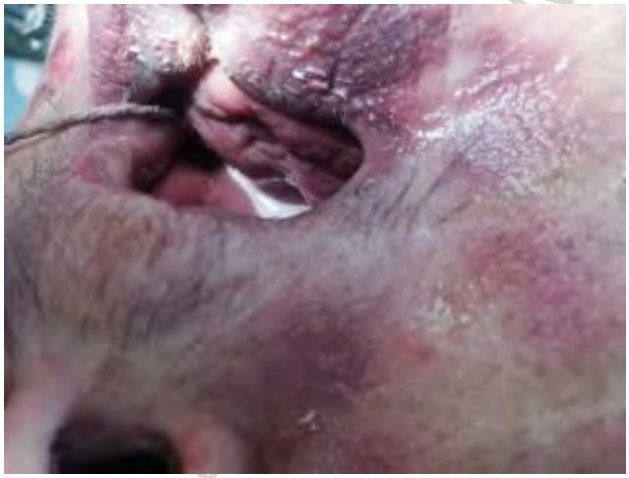
The LifeVac is a non-powered, single patient, portable suction apparatus (anti-choking device) developed for resuscitating choking victims when standard current choking protocol has been followed without success. The LifeVac is designed with a patented valve to prevent air from exiting through the mask.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

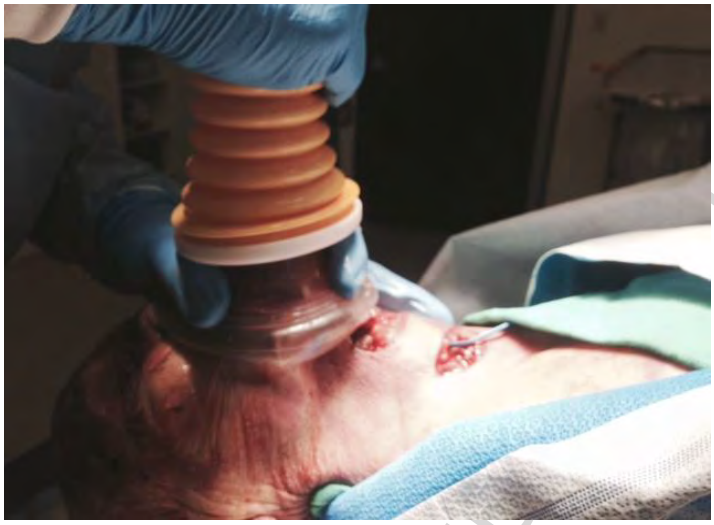
Each year, approximately 3,000–4,000 Americans die from choking. Children and the elderly present much higher risks for choking. At least one child dies from choking on food every five days in the U.S., and more than 10,000 children are taken to hospital emergency rooms each year for food-choking incidents.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

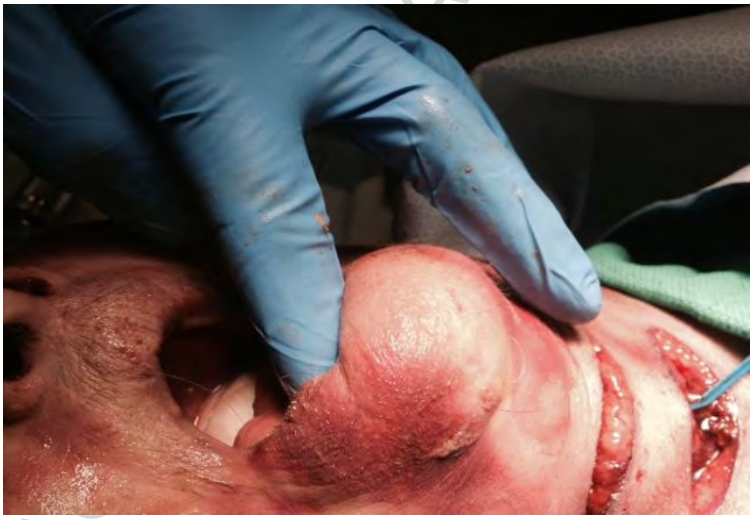
This study was conducted at Fusion Solutions, a cadaver based training center in New York. An unselected, recently diseased individual was employed in the study. The subject was a 71 year old, Caucasian female, 153 pounds, 65 inches with a Body Mass Index of 25. Medical history was remarkable for breast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

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

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







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

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

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

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

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

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

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

Correspondence

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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

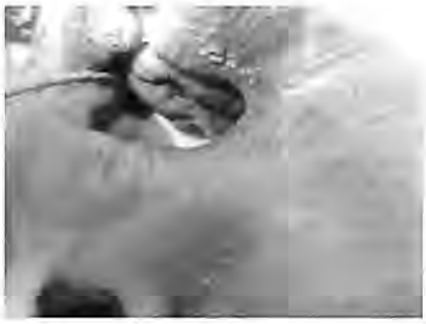

Figure 1. Placement of large simulated bolus (3 cm) 7–10 centimeters past tongue base into upper airway of subject.

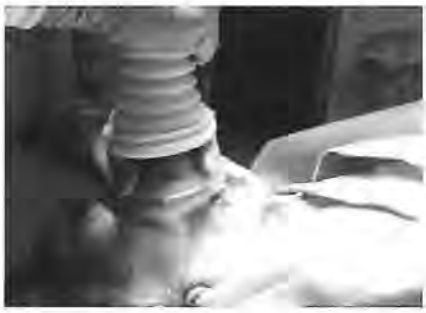

Figure 2. Placement of LifeVac device on the cadaver using guideline protocol to achieve proper seal to operate device.

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

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Abstract

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

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

Keywords

Choking, Resuscitation, Anti choking device, Lifevac

Introduction

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

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

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

Case Report

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

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

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

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

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

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

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

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

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

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

Discussion

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

Figure 1: The LifeVac Device.

Figure 1: The LifeVac Device.

Figure 2: Easy Technique using LifeVac.

Figure 2: Easy Technique using LifeVac.

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STUDIES AND RESEARCH

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Summary of Environmental Testing – Ed Brody

Testing Lab: Retlif Testing Laboratories

795 Marconi Ave

Ronkonkoma, NY11779

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

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

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

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

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

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

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

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

All four units passed this test.

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

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

Official test report from Retlif Testing Laboratories is expected in the first week of July

** Old Units: 8 pin press fit construction with large o-ring, no o-ring on valve seat.

New Units: 4 stainless screws and 4 pins, with large o-ring in a molded groove. Also a small o-ring on valve seat, to improve sealing.

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CADAVER TEST

Conducted at Fusion Technologies, Hicksville, NY

June 24th 2015, 9am

Trial #	No. of pulls to clear airway
1	2
2	1
3	1
4	1
5	1
6	1
7	1
8	1
9	1
10	1
11	1
12	1
13	1
14	1
15	1
16	2
17	2
18	1
19	1
20	1

Cadaver 58/C/Female 66 inches, 200 lbs, 32 BMI, COD-Lung Cancer, Chronic Bronchitis, Asthma, GER D, Gastritis
3cm diameter obstruction, simulated food
Food was placed 7 to 10 cm into throat

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Resuscitation 44 (2000) 105–108

RESUSCITATION

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Airway pressure with chest compressions versus Heimlich manoeuvre in recently dead adults with complete airway obstruction

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Accepted 22 November 1999

Abstract

In a previous case report a standard chest compression successfully removed a foreign body from the airway after the Heimlich manoeuvre had failed. Based on this case, standard chest compressions and Heimlich manoeuvres were performed by emergency physicians on 12 unselected cadavers with a simulated complete airway obstruction in a randomised crossover design. The mean peak airway pressure was significantly lower with abdominal thrusts compared to chest compressions, 26.4 ± 19.8 cmH_2O versus 40.8 ± 16.4 cmH_2O, respectively ($P = 0.005$, 95% confidence interval for the mean difference 5.3–23.4 cmH_2O). Standard chest compressions therefore have the potential of being more effective than the Heimlich manoeuvre for the management of complete airway obstruction by a foreign body in an unconscious patient. Removal of the Heimlich manoeuvre from the resuscitation algorithm for unconscious patients with suspected airway obstruction will also simplify training.

Keywords: Airway obstruction; Basic Life Support (BLS); Cardiopulmonary resuscitation (CPR); Chest compression; Education; Guidelines

1. Introduction

Foreign body airway obstruction is an uncommon but preventable cause of cardiac arrest, with an incidence of 0.65–0.9/100.000 [1,2] as a cause of death. In choking victims who stop breathing the European Resuscitation Council (ERC) recommends up to five sharp slaps between the shoulder blades, followed by abdominal thrusts (the Heimlich manoeuvre) if this fails. If the victim becomes unconscious, this is to be followed by 'the sequence of life support' [3]. The American Heart Association (AHA) recommends the Heimlich manoeuvre with alternating finger sweeps as the only technique [4], arguing that back blows may not be as effective as Heimlich manoeuvre in adults [5,6]. The AHA also claims that this will simplify training [4].

Based on a single case report Skulberg [7] suggested that standard chest compressions could be a better technique. If this is true, two additional goals might be achieved. It would simplify what needs to be learned for CPR and reduce the time without circulation from chest compressions in patients with cardiac arrest. We have therefore conducted a study of the airway pressure generated by chest compressions compared to abdominal thrusts in recently dead patients. Human cadavers were selected instead of animals, as the shape of the chest is different between animals and humans which makes extrapolation of data from one to the other unreliable.

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2. Materials and methods

The study was approved by the Regional Committee for Medical Research Ethics and performed in the Emergency Medical Service System of Oslo. Cadavers are not covered by the Helsinki declaration, and the ethics committee did not require informed consent from relatives. Twelve unselected recently dead adults of either sex were studied immediately after unsuccessful resuscitation from prehosptial cardiac arrest. While still intubated and with the cuff inflated to create an airtight seal, the tracheal tube (ID 8.0 mm) was connected to a handheld pneumotachograph (VentCheck™, model 101, Novametrix Medical Systems, CT, USA) for airway pressure measurements. The proximal end of the sensor was plugged to stimulate complete airway obstruction.

The peak pressures achieved with five standard chest compressions were compared with peak pressures achieved with five abdominal thrusts (Heimlich manoeuvre) in a randomised, crossover design. Before starting each procedure it was ensured that the lungs were in the resting expiratory position. Four male emergency physicians weighing 80–90 kg performed the procedures. All were advanced life support instructors with many years of practical CPR experience. Both procedures were performed according to the European Resuscitation Council guidelines [3]. The abdominal thrusts were given kneeling astride the supine cadaver. Two paramedics controlled the performance of the procedures and recorded the results. The physicians received no feedback and were blinded from the results. Patient sex, age, particulars about their size/shape and complications during CPR such as rib fractures or lung aspiration were recorded.

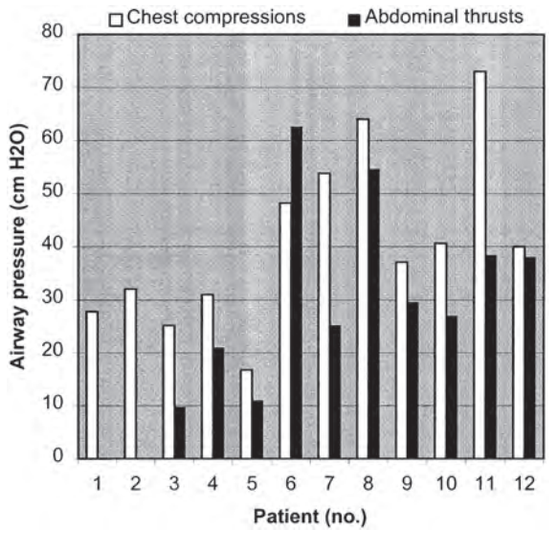

Fig. 1. Airway pressures with chest compressions and abdominal thrusts on twelve recently dead adults with complete airway obstruction. The airway pressure is significantly lower with abdominal thrusts than chest compressions ($P = 0.005$).

The mean pressures generated by the five chest compressions were compared to the mean pressures generated by the five abdominal thrusts using Jandel SigmaStat© statistical software (Erkrath, Germany). Each cadaver served as its own control. After assessing the distribution of the data distribution, a paired t-test was used. Data are presented as means $\pm$ SD.

3. Results

Ten recently dead men and two women with a mean age of 68 ± 15 years and mean body weight of 80 ± 15 kg were studied. Rib fractures were noted in three patients and pulmonary aspiration in one during the preceding resuscitation. One patient was very thin and the physician noted that he felt very little resistance in the epigastric region during abdominal thrusts before he felt the vertebral column. One corpse was extremely obese with a potbelly.

The mean peak airway pressure was significantly lower during abdominal thrusts compared to chest compressions, 26.4 ± 19.8 cmH_2O versus 40.8 ± 16.4 cmH_2O ($P = 0.005$, 95% confidence interval for the mean difference 5.3–23.4 cmH_2O) (Fig. 1). In all but one cadaver, the extremely obese subject, the mean airway pressure was higher with chest compressions compared to abdominal thrusts. In two cadavers, the very thin subject, and an 80 kg woman with pulmonary aspiration, there was no detectable airway pressure change at all with abdominal thrusts (patients 1 and 2, Fig. 1)

4. Discussion

In this study we achieved higher airway pressures with standard CPR chest compressions than with abdominal thrusts in recently dead subjects with complete airway obstruction.

Since the introduction of abdominal thrusts by Heimlich in 1974 [6] there has been debate and controversy regarding which manual rescue technique is most efficient in choking victims. Most studies have compared abdominal thrusts, various chest thrusts and back blows [5,8–10]. For unconscious patients the suggested technique has been the Heimlich manoeuvre with rescuer sitting astride the patient. In the unconscious, markedly obese victim the AHA advocates chest thrusts (the hand position being identical to that for chest compressions) as an option. This is in contrast to our findings, where the noticeably corpulent subject was the only one where abdominal thrusts generated a higher airway pressure. In 1992 Skulberg [7] suggested that chest compressions might be more effective than the Heimlich manoeuvre in the unconscious subject. This was based on a case where the Heimlich manoeuvre failed to dislodge a foreign body in an unconscious patient. As the patient also was pulseless, CPR was then started, and the airway was cleared with the first chest compression. The present study confirms Skulberg's hypothesis. We are aware of only one study of standard CPR chest compressions for foreign body removal. Gordon et al. [8] compared chest compressions with the Heimlich manoeuvre in six adult, anaesthetised volunteers and found pressures in the same range for the two methods (23 versus 17 cmH_2O, respectively). Their findings have, to our knowledge, never been published in a peer-reviewed journal and there is no specific description of the way they performed the chest compression other than 'standard external compression'. It is not known if chest compressions were done according to the current recommended guidelines. It would not be ethical to do 4–5 cm compression of the sternum in healthy volunteers because of the significant risk of causing damage such as rib fractures, and the pressures achieved by Gordon et al. were lower with both techniques than in the present study.

In 1978, Ruben et al. [10] compared the Heimlich manoeuvre with sternal thrusts on six cadavers and found higher pressure with the latter, median 18 (range 0–62) versus 30 (range 16–40) cmH_2O, respectively.

It has been speculated that the removal of a foreign body is dependent both on the pressure required to dislodge it and the ability to maintain pressure and potential air flow over time [8,11]. Thus, while a precordial thump might give a high peak pressure, it is sustained for only a very brief period with low flow rates [8]. The pressure is applied for a longer time with chest compressions. In the study by Gordon et al. [8] the airflows both with a partial airway obstruction and an open airway were similar for the Heimlich manoeuvre and chest compressions.

Substituting chest compressions for the Heimlich manoeuvre in unconscious patients has potential advantages in addition to creating a higher airway pressure. It will remove one step in managing an unconscious patient with cardiac arrest. The patient will be treated identically whether or not there is a foreign body airway obstruction. This should reduce confusion and improve training and practical performance. There is much evidence in the literature that the learning and retention of CPR skills is not very efficient [12–14]. There are many psychomotor skills to achieve, and there has been a drive towards simplifying CPR in the hope that this will reduce rescuer confusion and improve performance [15]. If removal of a foreign body can be achieved by chest compressions, this will also reduce the time without circulation in the patient with cardiac arrest.

In conclusion, the present findings indicate that standard chest compressions are more effective than the Heimlich manoeuvre for treating complete airway obstruction by a foreign body.

Acknowledgements

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Management of the choking victim

David Montoya, MD, MCFP, FRCPC

Current recommendations for the management of the choking victim have arisen from a long history of anecdotal experience and controver- sial experimental and clinical data. The author reviews the available literature on the various maneuvers and discusses the existing controver- sies. He also gives brief recommendations for the management of the choking victim.

Les conduites a tenir actuellement conseillees devant une personne en train de s'etouffer repo- sent sur l'experience de cas isoles et des travaux diniques ou experimentaux sujets a discussion.
Apres avoir passe en revue la litterature dispo- nible sur les diverses manoeuvres et les contro- verses qui les entourent, l'auteur esquisse le traitement qu'il recommande.

The first written description in English of a foreign body in the airway was published in 1677.[1] In an attempt to cure his colic, a man tried to swallow three pistol balls. One of the balls was aspirated into a bronchus, and, despite such treatments as being suspended head down, inhaling fumes, to promote coughing, and receiving "concussions to the body", it was not expelled and pulmonary infection developed. This account prompted Sir Christopher Wren to relate a similar case, in which inversion, coughing and blows to the back were successful in expelling a foreign body from the tracheobronchial tree.

It was not until nearly 200 years later that Gross[2] published *A Practical Treatise on Foreign Bodies in the Air Passages,* the classic reference on the subject. The work was based on an analysis of 200 cases collected from the literature or known to Gross personally. He was also among the first to recognize the confusion that so often occurs when diagnosing the cause of complete airway obstruction and to implicate the glottis as the site of obstruction.

Interestingly, many of the accounts of obstruction detailed by Gross are actually cases of aspiration of foreign matter into the distal tracheobronchial tree that caused coughing or choking spells. The spells "subsided" only after complete obstruction produced by inversion, blows to the back or other maneuvers that lodged the foreign body against the underside of the vocal cords. In one case, emergency tracheostomy (clearly below the level of the cords) produced relief, with expulsion of the foreign body. As a result, Gross advised against the use of inversion, shaking or blows to the back. This has been one of his most misinterpreted statements, regularly being taken out of context. Gross also warned against probing with the finger.

From 1917 to 1973 the Chevalier Jackson Clinic, Philadelphia, recorded more than 6000 cases of airway obstruction by foreign bodies; again, many authors warned against the use of blows to the back and inversion in such cases.[1-3]

In 1963 Haugen[4] coined the term "cafe coronary" in describing nine cases of sudden death in restaurants due to obstruction of the upper airway by meat. He also made the association between choking and excessive intake of alcohol as well as poorly fitted dentures.

Since 1933 the Red Cross had been teaching the use of blows to the back for choking victims. In 1969 Tucker5 persuaded the American Red Cross that blows to the back were inappropriate and could worsen the situation. As a result, from 1973 to 1978 official Red Cross textbooks on first aid

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made the following recommendations:[6]

Do not allow anyone to slap you on your back if you choke, and do not try to dislodge an object from another person 's throat by this means except as a last, desperate effort to save his life.

In 1974 Heimlich [7,8] introduced the abdominal thrust (Heimlich maneuver). He proposed that forceful upward displacement of the diaphragm was the method of choice in treating the choking victim. He urged that this procedure receive wide public dissemination and asked for reports of cases in which his maneuver was used. The lay press gave his maneuver widespread coverage, and he was soon deluged with anecdotal reports, all of which confirmed the usefulness of the maneuver.

In 1976 the Red Cross, under direction of its adviser, Dr. Archer Gordon, changed its recommendations to include blows to the back in the initial management of the choking victim.[9] A controversy began that prompted Heimlich [10] to denounce blows to the back as "death blows", which sparked the continuing debate over the appropriate management of the choking victim.

Epidemiologic considerations

Epideiniologic study of accidental deaths from choking has been difficult because, as pointed out by Haugen,[4] this phenomenon is often misinterpreted and misdiagnosed. Approximately 3000 deaths froin choking are reported annually in the United States;[7,11,13] however, this may be a gross underestimate, as many additional deaths due to choking could be mistakenly ascribed to other causes, such as myocardial infarction. This led Heimlich to propose his "universal choking sign":[11,14] victims grasp their necks with the thumb and index finger.

Choking is more common in children and the elderly. Of the 3106 people who died from choking in the United States in 1975-76, approximately 500 were aged 5 years or less and approximately 1050 were aged 65 to 85 years (Fig. 1).[12] Choking is the leading cause of accidental deaths in the hoe among children under 1 year of age,[11] who tend to put a variety of objects in their mouths. Choking in the elderly may be attributed to poorly fitted dentures and a high incidence of excessive intake of alcohol. Choking is the sixth most common cause of accidental deaths overall.[5]

There has been no significant change in the incidence of reported deaths from choking since the introduction of the Heimlich maneuver. Explanations have included a possible increase in reporting due to more public and professional awareness. The ·proportion of deaths from choking has actually decreased, given the increase in population over the years. The Arizona Department of Health Services reported a decrease of 45% in deaths from choking,[15] and figures from the University of Virginia's medical school showed a decrease of 10% in the United States from 1973 to 1976, despite a population increase of 5 million.[16]

Pathophysiologic features of choking

A number of factors influence the prognosis of the choking victim. The first is the site of obstruction. Therapeutic maneuvers give better results when objects are lodged in the larynx, at or above the vocal cords, than when they are lodged below the vocal cords, where they may be difficult to remove except by instrumentation. The degree of obstruction is important since partial obstruction allows some passage of air around the object, which makes it easier to expel.[17] The degree of obstruction is partly related to the size of the foreign body, with larger objects being harder to expel.[12] The type of foreign body is also important. Ruben and MacNaughton [17] showed that pieces of orange were easier to expel than pieces of meat.

Spasm and edema are likely related to the duration of obstruction. As time passes, the degree or intensity of spasm and the amount or severity of edema increase, while the victim's efforts decrease, which makes spontaneous expulsion of the object progressively less likely. Several studies have shown that the amount of air trapped in the lungs at the time of obstruction can greatly influence the amount of pressure generated by the various maneuvers to stimulate an artificial cough.[17-19] However, none of the maneuvers gen- erate pressure levels or airflow rates comparable to those produced by a natural cough.[9] The medical condition before choking may play a role in the outcome, particularly in the older person.

Experimental data

In 1974 Heimlich[7,8] studied the value of the abdominal thrust in anesthetized dogs whose endotracheal tube had been blocked by a rubber stopper and the cuff inflated to simulate total

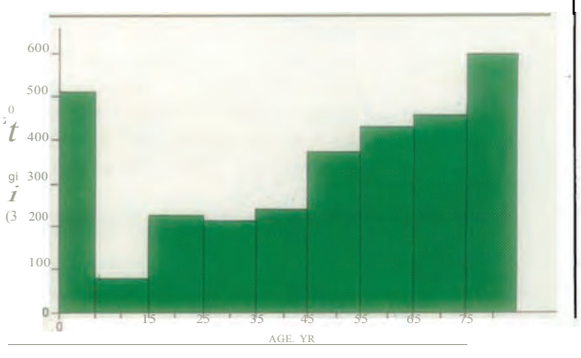

Fig. 1 — Age distribution of 3106 people who died from choking in the United States in 1975-76. Adapted from Hoffman.[12]

obstruction. The maneuver, repeated 10 times on each of four dogs, was consistently successful, even when the endotracheal tube was replaced by a piece of ground beef.

In 1975 Heimlich and colleagues[18] measured airflow generated by the Heimlich maneuver at various phases of respiration in 10 healthy, conscious volunteers. They were able to show increased airflow with larger lung volumes. The study, however, did not take into account the person's cooperation or voluntary expiratory effort.

In 1977 Guildner and associates[19] studied various artificial-cough maneuvers in anesthetized volunteers. They found that blows to the back were "ineffective in creating air flow or increased pressure in the chest". They did, however, find that chest thrusts produced higher pressure and peak airflow than did abdominal thrusts. They recommended that treatment consist of blows to the back followed by chest thrusts. The basis for this recommendation remains obscure.

Gordon and coworkers[9] completed extensive work in 1977 on anesthetized apneic volunteers and found that blows to the back generated significantly higher pea}< pressure than did abdominal or chest thrusts, but over a shorter period. They confirmed Heimlich's initial findings that correlated airflow and pressure with lung volumes. They found that none of the artificial-cough maneuvers could generate pressure levels or airflow rates equal to those produced by a natural cough. They concluded that blows to the back would dislodge foreign bodies but would not create enough airflow to move them any great distance; on the other hand, chest and abdominal thrusts would at times not generate enough pressure to dislodge objects but would create greater airflow to move them. Therefore, Gordon and coworkers recommended a protocol of combined maneuvers, beginning with blows to the back.

In 1978 Ruben and MacNaughton [17] studied the obstructive quality of various foods. They attached silicone-rubber casts of the larynx to the endotracheal tube of anesthetized apneic volunteers and then obstructed the laryngeal casts with various foods. They found that the pressure required to expel the food lodged in the larynx depended on the degree of obstruction and the type of food. They also found that inverting the victitn made ejection of the food easier and that pressure applied in a series of jolts was more successful than pressure applied steadily. Their results showed that none of the maneuvers were successful in expelling a tightly wedged piece of meat, but in cases of partial obstruction, both blows to the back and chest thrusts generated the peak and total pressure levels necessary to move the object; abdominal thrusts generated considerably less pressure. They emphasized the positive effects of inverting the patient.

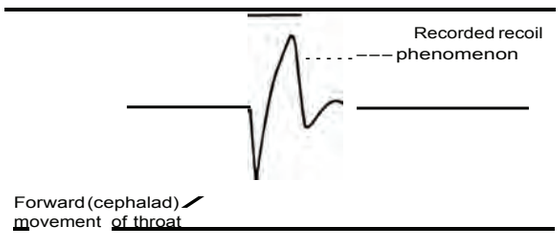

Fig. 2 — Accelerometer tracing, depicting cephalad and recoil movements of thyroid cartilage during blows to back. Adapted from Day.21

In. 1982 Day and collaborators[20] applied Newton's third law of motion (to every action there is always opposed an equal reaction) to supraglottic foreign bodies. They constructed a model of the upper airway and rested a metal ball-bearing on the vocal cords. Vigorous, repeated blows to the back failed to move the ball, whereas a single, more gentle downward blow on the shoulders moved the ball into the posterior pharynx. Other materials behaved similarly.

Day[21] attached an accelerometer externally to the thyroid cartilage of volunteers and recorded a cephalad movement of the throat during blows to the back (Fig. 2). He concluded that this movement would result in a caudad movement of a foreign body (according to Newton's third law of motion), which would further impact it against the cords. He also measured pressure levels and lung volumes generated by blows to the back and abdominal thrusts with body plethysmography. He found that blows increased pressure by 7 to 13 mm Hg, while the Heimlich maneuver increased it by 27 mm Hg. He also compared the efficacy of the two maneuvers in displacing ball-bearings in a glass column connected to the volunteers' mouth and found that blows to the back consistently gave inferior results.

This interpretation and application of Newton's third law of motion raises some questions. In the accelerometer recording, the initial downward deflection caused by the forward movement of the throat supposedly forces the foreign body further down against the vocal cords. However, the recording also revealed an upward deflection, which indicates an immediate recoil after the initial forward movement of the throat. This opposite movement of the throat more accurately reflects Newton's law: if, in fact, the forward motion of the throat further forces a foreign body against the vocal cords, the recoil should dislodge the object.

In addition, Day and coworkers assumed that the throat and the foreign body move independently. Given the degree or intensity of spasm and the amount or severity of edema evoked by an obstructing foreign body, the throat and the object may actually move as a single unit. Newton' s law, when applied in the pure sense, may not reflect the physiologic reality of the situation.

The available experimental data on pressure levels and airflow rates generated by the various maneuvers are shown in Table I. The discrepancies in the results are not easily explained. Neverthe-

less, most of the figures seem to support the concept that blows to the back produce higher peak pressure levels and lower airflow rates than do abdominal or chest thrusts.

Clinical data

Redding[22] and other investigators [21,23,24] have commented on the available clinical data and the difficulties with their interpretation, No controlled prospective studies of the treatment of acute upper airway obstruction have been reported: given the nature of the problem, setting up such a study would be very difficult. Analysis of the efficacy of the various therapeutic maneuvers must therefore be based on isolated reports. These reports tend to be anecdotal and retrospective and are often related by lay rescuers, who are likely to document only successful cases and to ascribe success to the last procedure used when more than one was attempted.

In 1976 Hughes[25] presented a series of 428 cases of choking on food to the American Society of Anesthesiologists. He later expanded the series to 536 and presented it to the US National Research Council (NRC). Not surprisingly, his results were similar to those of Heimlich, from whom he obtained all his cases. After prolonged debate at the NRC's Conference on Emergency Airway Management, in 1976, current recommendations were developed. Current recommendations of the Canadian Heart Foundation for the management of choking in adults before admission to hospital are shown in Table II.[26] There remains no clear basis for recommending a sequence of four repeated maneuvers.

Redding[22] reviewed 225 cases of choking on food that were reported to the Emergency Cardiac Care Committee of the American Heart Association in 1978-79. He found that each therapeutic maneuver was more efficacious when used in combination with other maneuvers (Table III).

In 1980 Patrick [27] evaluated the treatment outcome of 1164 choking victims by means of a detailed questionnaire. Outcomes in 972 people in whom the Heimlich maneuver had been carried out alone or initially were significantly better than those in 192 people who had initially been treated with blows to the back. There are a number of

Table II — Current recommendations of the Canadian Heart Foundation[26] for management of choking in adults

- Conscious victim
  - If victim cannot speak, assume total upper airway obstruction and administer four blows to the back
  - If unsuccessful, administer four chest or abdominal thrusts
  - If unsuccessful, repeat sequence until successful; stop if victim becomes unconscious
- Unconscious victim
  - Attempt to ventilate
  - If unsuccessful, administer four blows to the back with the person in a semiprone position
  - If unsuccessful, administer four chest thrusts with the person in a supine position
  - Lift tongue and jaw and scoop out foreign body with finger
  - If unsuccessful, repeat sequence

Table III — Success rates of maneuvers used alone or in combination[22]

Maneuver	Success rate, %	
	Alone	In combination
Blows to the back	20	50
Abdominal thrust	44	80
Chest thrust	36	65

Table I — Experimental pressure levels and airflow rates generated by maneuvers for management of choking victims

Maneuver; investigator	Pressure, mm Hg: Maximal change measured at the mouth	With lungs fully inflated	Airflow, L/min
Chest thrust			
Gordon et al[9]	18	19	276
Ruben et al[17]	15	22	
Guildner et al[19]	32		99
Abdominal thrust			
Gordon et al[9]	11	15	264
Ruben et al[17]	7	12	
Heimlich et al[18]	31		205
Guildner et al[19]	19		65
Day et al[20]	25		
Blows to the back			
Gordon et al[9]	25	45	39
Ruben et al[17]	18	24	
Day et al[20]	13		
Natural cough			
Gordon et al[9]	72	115	198

problems with this study. Less than 10% of the questionnaires were filled out, and 900 cases (77%) were provided by Heimlich. Since negative outcome was poorly defined, it is unclear whether this referred to death, unconsciousness, collapse or any complications attributed to the maneuver. No attempt was made to compare the two groups for other prognostic factors. There were no figures on the number of deaths or neurologic outcome in either group. Also, no mention was made of the number of patients in whom the Heimlich maneuver was applied unsuccessfully and who required a second maneuver.

Complications

Shortly after Heimlich introduced his maneuver, he received reports that detailed some of the complications.[14] The most common and earliest complications included abdominal tenderness, bruising, nausea and vomiting, and fractured ribs.[12,14] More serious, although less frequent, complications have been reported over the years, including retinal detachment,[12] pneumomediastinum[28] and rupture of the stomach.[29] Only recently have fatal complications been reported: abdominal aortic thrombosis, due to improper application of the maneuver,[30] and rupture of the stomach following the maneuver, which eventually resulted in death.[31] Heimlich maintains that complications arise only when the maneuver is applied improperly.[12]

Few complications have been ascribed to blows to the back. The main problem seems to be local trauma, including bruised back or ribs and, occasionally, nausea and vomiting.[12] Critics of this maneuver claim that it worsens obstruction. Heimlich misinterpreted Gross[2] and implicated blows to the back as a dangerous maneuver that could worsen obstruction.[32] However, Gross specifically condemned the maneuver in cases of partial or complete subglottic obstruction. All clinical and experimental data, including Heimlich's, pertain to supraglottic obstruction, which accounts for most choking episodes. The debate on the leading complications from blows to the back continues.

The most limited experience has been with the chest thrust. Although there is little in the literature, one might reasonably assume that complications of this maneuver are similar to those of cardiopulmonary resuscitation,[12] which include fractures of the sternum and ribs, myocardial contusion, pneumothorax and various intra-abdominal injuries.[33]

Probing with the finger should be done only to remove visible material from the oropharynx. Complications include oropharyngeal trauma and further impaction of the foreign body.[17]

The true incidence of complications of the various maneuvers is unknown since reporting is sporadic and anecdotal, and controlled trials are nonexistent.

Conclusions

Definitive management of the unconscious choking victim, whether in hospital or in the field, should include removal of the foreign body by instrumentation under direct visualization. However, there is debate as to the best management of the conscious victim with an obstructed upper airway and of the unconscious victim for whom such definitive instrumentation is not available. Which artificial-cough maneuver is the most efficacious in clearing the obstructed airway? Which maneuver should be used first? What are the complications of the various techniques? Is any maneuver dangerous or deleterious? To date there is no consensus on any of these issues.

There are significant discrepancies in the literature as to which technique produces the highest intrathoracic pressures and airflow rates. Most of the data seem to support the conclusion that blows to the back generate the highest intrathoracic pressure, whereas chest or abdominal thrust produces the highest airflow rate. Clinically, all the maneuvers are somewhat efficacious in clearing the obstructed airway when used alone; however, each maneuver seems to be substantially more efficacious when used in combination with another maneuver. Also, the results appear to be more successful when pressure is applied as a series of jolts rather than applied steadily.

The claim that blows to the back worsen obstruction has not been clearly proved. Presumably, any partial obstruction can be worsened by any artificial-cough maneuver. Therefore, I recommend that none of these techniques be administered to anyone who can still phonate. No maneuver is as effective as a natural cough, and some evidence suggests that inversion may indeed be helpful.

Application of Newton's third law of motion to foreign bodies obstructing the upper airway is suspect and may not be physiologically sound.

I feel that, when applied properly, each maneuver is acceptable on the basis of its risk/benefit ratio.

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Experimental pressure levels and airflow rates generated by maneuvers for management of choking victims

Maneuver	Investigator	Pressure MM Hg		
		Maximal Change Level at mouth	Volume (cc)	Airflow, L/min
Cough	Gordon et al	72/115*	550/1,650*	198/378*
Back Blow	Guidlner et al	----	----	----
	Gordon et al	25/45*	25	39
	Ruben & Macnaughnton	18/24*	----	----
Abdominal Thrusts	Heimlich et al	31	940	205
	Guidlner et al	19	380	65
	Gordon et al	11/15*	283	264
	Ruben & Macnaughnton	7/12*	----	----
Chest Thrust	Guidlner et al	32	520	99
	Gordon et al	18/19*	240	276
	Ruben & Macnaughnton	15/22*	----	----
LifeVac	Brody and Lih	350	225	13.5

* Values of lung volume recorded at end of inspiration.

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 VAC STARTER KIT £89	✓	✓	✓	✗	✓
 LIFEVAC £59.95	✓	✓	✓	✓	✓

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 S SCORT III SUCTION KIT £700+	✗	✗	✗	✗	✓
 SSCOR QUICKDRAW £349	✗	✗	✗	✗	✓
 AEROS TORTE-L-VAC £495+	✗	✗	✗	✗	✓

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Dr. William Holt, Board Certified Neurologist, Senior Medical Director-Global Product Development, PPD.

"If you have a serious neurological condition such as Parkinson's, MS, Alzheimer's, ALS or Stroke you are at increased risk for choking. LifeVac is a significant advance for preventing choking-related deaths and I recommend it to all my patients."

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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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5 THOUGHTS ON "A NEW INNOVATION TO SAVE LIVES AND PROVIDE HOPE FOR MSERS WITH DYSPHAGIA" LIFEVAC.NET

James Kalyvas says:
As a neurosurgeon who deals daily with patients suffering from neuromuscular disorders affecting their upper respiratory tract and their ability to swallow, I am acutely aware of the choking risks these patients face, as well as the psychosocial stress it puts on them and their caregivers. It is true that there are few intervention options for a choking patient after the Heimlich maneuver has failed, especially outside the hospital setting, which may be a bit surprising given how far technology has come in other treatment areas. Though I have not tried LifeVac yet, it does seem to make good physiological sense, especially if it can generate supraphysiological expulsion pressure at the oropharynx to compensate for the weak musculature in these patients. Overall, I think this is a refreshingly simple idea that holds promise.

JULY 10, 2014 AT 2:18 PM

Jo-Ann Gardner, ARNP says:
As a nurse practitioner I find this information and product to be of extraordinary benefit to not only my patients but their families as well. Such an inspiring story!!

JULY 10, 2014 AT 4:10 PM

Omar Y. Cooper says:
This has to be the most touching and amazing story that I have ever read! I am truly inspired by the author's selfless attitude to share her family's experiences and challenges with the rest of the MS community to offer a way that can bring ease to their loved ones. This article truly is saving and will save lives! LifeVac should be eternally thankful that Jane's passion, spirit, and servant mindset was presented to them. I would further urge LifeVac to partner closely with Jane as her closeness to the matters expressed in the article will undoubtedly do so much more in getting the word out about all of the benefits that LifeVac can offer so very many MS patients, their families, friends, and loved ones for years and years to come! This

article has even made me take a look at myself and how I share information that could assist or even save a life and definitely encouraged/inspired me to do more. I wish many blessings to Jane and her family and the thousands of lives that may be changed for the better from reading about her experiences and how LifeVac changed her situation. To the author: please let your heart keep bleeding for the MS community and it's many struggles. Because it takes a devoted, driven, and committed individual like yourself to help unlock so many answers and even ultimately find a cure. Don't ever stop and best wishes to you!

JULY 11, 2014 AT 12:58 PM

Sheeba mesghali says:
Jane ,
That was such a beautiful and well written story with very informative literature. You are a great writer and amazing and caring person who will be and already is a huge asset to this world. You have a huge kind loving heart and i see you doing bigger things in your future for others !!! You have a great passion for learning and helping to find improvements in ways to make peoples's lives the best they can be. You should have been a doctor for the Chronically ill as you have such a care taking capacity!! Super proud of your efforts and hope this takes you even further into finding a cure or even just comfort measures for the chronic illnesses that exist!!!!
Sheeba Mesghali

JULY 15, 2014 AT 12:04 AM

Lauren Mazer says:
I am so moved by your tireless commitment to help not only your own parents with their health struggles but also the global MS community at large. You are truly an inspiration, Jane. If only there were more people like you in the medical field!

JULY 24, 2014 AT 12:54 AM

LIFEVAC EUROPE LTD

MS Caregiver shares about LifeVac

Both my mother and father live with MS in Sarasota, FL. My mother lives with primary progressive MSand my father was initially diagnosed with relapsing-remitting MS which has now progressed to secondary progressive MS . Despite the variances in their disease-related impairment and progression, they both share difficulties with swallowing, even early on post-diagnosis. My mom has experienced several episodes of choking and several months ago choked on a donut, turned blue, and fell unconscious. Despite many efforts, the several caregivers present at the time could not effectively perform the Heimlich maneuver. It took a large 6'4 gentleman from EMS to perform the Heimlich six times before the food was slowly dislodged. She was approximately 30 seconds away from dying. Luckily, she is doing well now, however based on her history of swallowing and choking issues coupled with the natural pulmonary decline in some MS patients, I am constantly faced with the anxiety that she will choke again, and regardless of how well the Heimlich is performed, will not survive. I share this story with you because I know that at various stages of MS, including early on in the course of the disease, dysphagia (difficulty swallowing), pulmonary dysfunction and muscle weakness arise. When these impairments occur early on most are unaware that there is a problem.

Dysphagia may cause the individual to cough after drinking liquids, or choke when eating certain foods, especially those with a crumbly texture. There is an imaging procedure called a modified barium swallow (videofluoroscopy) that is used to evaluate a person's ability to swallow liquids of various thickness and solids. Speech therapists perform a thorough evaluation, diagnosis and treatment of dysphagia with strategies and techniques designed to achieve better eating and swallowing. There are three main swallowing strategies they try to implement: 1) Postural Changes 2) Swallow Maneuvers and 3) Behavioral Strategies. The speech therapist may adjust posture while eating through activities such as with chin tuck, head turn to weak side, head tilt to stronger side, head back, and chin tuck with head turn. They will also incorporate swallowing maneuvers such as the Mendelsohn Maneuver, Effortful Swallow, Supraglottic Swallow, and Super Supraglottic Swallow. There are also behavioral strategies that allow the individual to incorporate certain techniques while eating particular foods. These behaviors include Liquid Wash which alternates bites of solids with sips of liquids. The Larger Bolus Strategy is used to enhance the sensory input in order to reduce the delay triggering the pharyngeal swallow. For those with significant residue of food in mouth after trying to swallow, the Swallow/Bolus has the individual swallow 2-3 times with each bite/sip. These types of compensatory management techniques are helpful, yet obviously they do not slow or prevent the progression or course of the swallowing incompetency.

Whether you live with MS or are a caregiver for someone living with it you can empathize with the array of swallowing challenges and the subsequent psychological toll that it creates for all. Unfortunately, if the swallowing challenges turn into a choking episode there is a chance the individual may aspirate, or inhale fluid or solids into the upper respiratory tract, resulting in aspiration pneumonia. This condition can be serious, requiring treatment with antibiotics, or

could even be fatal. Choking on food without aspirating can be just as deadly whether the Heimlich is performed correctly or not. Think back to my mother's recent choking episode. The natural question is….Why so many unsuccessful Heimlich attempts and why did the food barely dislodge? Pulmonary compromise may be one of the main culprits. MSers rarely complain of pulmonary dysfunction, however upon pulmonary testing, dysfunction is commonly found during the mild phase of the disease. Muscle weakness in the diaphragm, changes in muscle tone, motor incoordination, and postural abnormalities all contribute to the reduced pulmonary function and essentially contributing to an ineffective Heimlich. If the Heimlich is unsuccessful the outcome is grim.

These ultimate, final outcomes and the potential for an unsuccessful Heimlich due to muscle weakness and pulmonary decline are exactly why I am so excited to learn about an apparatus that is specifically designed to save someone from choking. It's called LifeVac.

The inventor/founder, Arthur Lih, created this product after hearing a story about the death of an 8 year-old boy after he had choked on a grape. He has professed, "How in this world of tremendous widespread innovation and achievement are we not able to save a child from dying on a grape!" It has become his mission to save as many lives, from this senseless type of death, as possible.

The LifeVac is a non-powered single patient portable suction apparatus developed for resuscitating a choking victim when standard ACLS protocol has been followed without success. The negative pressure generated by the force of the suction is 3 times greater than the highest recorded choke pressure. The duration of suction is minimal so LifeVac is safe and effective. It will be available to the public in the coming weeks and there is a waiting list on the website to register to receive it upon its release.

My anxiety level, along with that of my parents' caregivers, about my parents' risk of choking has been drastically reduced just since finding out about this apparatus. I can't begin to express how critically important LifeVac will be not just for the MS population globally but for the relief of the psychological toll their dysphagia has on their family and caregivers. There is now hope.

Jane Mascola Bio

Jane Mascola is a graduate of Southern Methodist University (Dallas, TX) with a full-merit psychology Ph.D. scholarship to Tulane University (New Orleans, LA). She is currently employed as a pharmaceutical healthcare professional in Southwest Florida and resides in Venice, FL. She has a keen passion for learning as much as possible about MS and the subsequent impact the disease has on their families and caregivers. Both her mother and father live with MS in Florida and were under her direct care for approximately four years. She has a particular interest in helping other MSers and caregivers cope with MS-related swallowing and choking issues. Jane is married with a 2 year-old daughter.