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

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Abstract

Objective

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

Methods

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

Results

Physiologic data from adult and pediatric human, non-human, and simulation studies show pressure generation ranging from 5.4 to 179 cm H₂O using well-established resuscitative maneuvers. Laboratory testing demonstrated that a prototypic PNSD demonstrated peak airway pressures of 434.23 ± 12.35 cm H₂O. 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.

Keywords

Airway; foreign body; choking; aspiration; device design; pre-hospital

1. Introduction

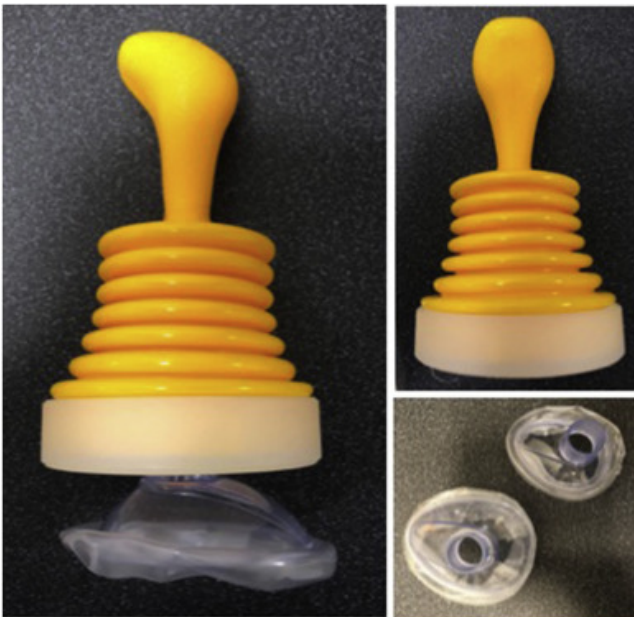
Aerodigestive tract foreign body aspiration causes thousands of deaths per year, particularly in patient populations that have difficulty protecting their airway, such as children, the elderly, and adults with dysphagia. In pediatric patients, the overall in-hospital mortality rate for airway foreign body aspiration has been estimated at 2.5%.¹ In the United States, choking is the fourth leading cause of unintentional injury death, responsible for 5,051 deaths, more than half of which occurred in adults older than 74 years.²

While operative techniques have been described for patients stable enough for transport to a medical facility, opportunity exists for improvement in pre-hospital management. Patients who have foreign body removed in the pre-hospital setting have improved neurologic outcomes.^{3,4} In a large pediatric database review, approximately 50% of all airway foreign bodies in pediatric patients were located at the laryngeal level, and overall in-hospital mortality for this group was reported at 1.8%.¹ This cohort of patients also was significantly younger in age (mean of 2.27 ± 4.20 years) with indication that time prior to foreign body removal negatively affected outcomes.¹ Here we perform a literature review of emergent pre-hospital management of patients suffering acute respiratory distress from foreign body aspiration into the oropharyngeal or supraglottic airway, and present a potential novel addition to the cadre of resuscitation techniques in the form of a portable, non-powered, suction-generating device (PNSD).

2. Materials and Methods

The PubMed and MEDLINE databases were comprehensively screened using broad MeSH terms, including “airway obstruction,” “foreign body,” “emergency medical services,” and “suction device.” After excluding non-English abstracts, all identified citations between 2008-2018 were reviewed for relevance. Further studies were obtained by examining bibliographies of selected articles. A literature review of pre-hospital management of acute aerodigestive tract obstruction and foreign body was performed.

Next, a prototypic model of a PNSD created by an independent manufacturer (LifeVac LLC, Springfield Gardens, NY) was examined ([Figure 1](#)). The device is registered with the United States Food and Drug Administration. It consists of a mask to allow seal around the lips, similar to bag valve masks commonly used by emergency medical personnel, with adult and pediatric sizes ([Figure 2](#), [Figure 3](#)). The mask connects to a second, suction-generating component with simple plunger-like deployment. The connection between the two components contains a one-way valve to control direction of pressure in an outward direction in order to ensure the foreign body is not further lodged. Independent laboratory testing results and anecdotal case reports related to the device were obtained from the manufacturer, which were serially reviewed. A summary of this data is herein provided, in the context of a larger literature review. The authors have no disclosures, conflict of interest, nor association with the device manufacturer.



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Figure 1. Prototypic design of a portable, non-powered, suction-generating device (PNSD), including mask component to allow seal (bottom right), pressure-generating component with inferior one-way valve to dissipate undue downward force (top right), and assembled device for adult use (left).



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Figure 2. Demonstration of portable, non-powered, suction-generating suction device rescue technique on adult simulator.



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Figure 3. Demonstration of portable, non-powered, suction-generating suction device rescue technique on infant simulator.

3. Results

3.1. Pressure-generation of various resuscitative techniques

Comparison of peak airway pressures by chest compressions versus abdominal thrusts in twelve recently deceased people demonstrated statistically significantly ($p = 0.0005$) lower mean peak airway pressure during abdominal thrusts (26.5 cm H₂O) as compared to chest compressions (49.9 cm H₂O).⁵ Another study examined four maneuvers in four consenting adults, using esophageal and gastric balloon catheters. In this study, horizontal abdominal thrusts and upward-directed abdominal thrusts (Heimlich maneuver) generated similar pressures, 53±11 cm H₂O and 57±17 cm H₂O, respectively.⁶ Forward thrusts of the abdomen against a chair generated significantly higher esophageal pressures of 115±27 cm H₂O. These authors also performed additional measurements of different maneuvers (esophageal pressure) in one participant: back slaps (7 cm H₂O); chest compressions when supine (42 cm H₂O); Heimlich maneuver (64 cm H₂O); voluntary cough (179 cm H₂O); supine abdominal thrusts (86 cm H₂O). In seated adults, Day and colleagues demonstrated superior pressure generation for the Heimlich maneuver (36.7 cm H₂O) as compared to back blows (17.7 cm H₂O).⁷ They also demonstrated possible harm related to back blows, specifically worsening dislodgement of supraglottic foreign bodies, due to straightening of the spine, with movement of the head and neck upward and forward. In six anesthetized, healthy adult males, airway pressures with endotracheal manometers showed highest pressures for: low-chest thrusts in the horizontal lateral position (34.0 cm H₂O) and mid-chest thrusts in the sitting position (46.2 cm H₂O).⁸ A study in anesthetized pigs measured the mean (SD) thrust pressures generated for the anterior, lateral and abdominal techniques were 120.9 (11.0), 135.2 (20.0), and 142.4 (27.3) cm H₂O, respectively ($p < 0.0001$). The mean (SD) peak expiratory airway pressures were 6.5 (3.0), 18.0 (5.5) and 13.8 (6.7) cm H₂O, respectively ($p < 0.0001$). The mean (SD) peak expiratory intrapleural pressures were 5.4 (2.7), 13.5 (6.2) and 10.3 (8.5) cm H₂O, respectively ($p < 0.0001$).⁹ While data in pediatric models are scarce, a study examined peak chest pressures in two different neonatal mannequin models, with different chest compliances, each intubated with a leak-free system. Clinicians, including neonatologists, nurses, and respiratory therapists, adjusted peak inflation pressure based on what they subjectively felt would be required based on chest excursions, and peak pressures were measured. The median pressures (range) were 18 cm H₂O (16-25) and 26 cm H₂O (19-33), for the two respective models.¹⁰ These measurements, while only in a simulation model, indicate peak airway pressures that are relatively safe in a neonatal model. A summary of these findings is presented in [Table 1](#).

Table 1. Comparison of airway pressure generation by various resuscitative techniques.

Study	Subjects	Abdominal thrusts (Heimlich) (cm H ₂ O)	Chest compressions (cm H ₂ O)	Back blows (cm H ₂ O)
Brugada et al, 2011 ¹⁰	Neonatal mannikin		18 (Range 16-25)	
	Neonatal mannikin		26 (Range 19-33)	
Langhelle et al, 2000 ⁵	Deceased human	26.5	49.9	—
Pavitt et al, 2017 ⁶	Living human	53 - 57	42.0	7.0
Day et al, 1982 ⁷	Living human	36.7	—	17.7
Guildner et al, 1976 ⁸	Living human	—	34 - 46.2	—
Lippmann et al, 2013 ⁹	Living pig	142.4	120.9	—

3.2. Pressure-generation by a PNSD

An independent laboratory performed vacuum verification testing on ten PNSD devices provided by the manufacturer, with three serial readings per device (Retlif Testing Laboratories, Ronkonkoma, New York). This analysis demonstrated mean pressure (SD) generation of 434.23 (12.35) cm H₂O on thirty measurements. Similarly, measurement of mean pressure (SD) while deploying the plunger downward prior to applying suction was 0.13 (0.10) cm H₂O on thirty serial analyses. While these data have not been verified in physiologic human or cadaver studies, the preliminary data is compelling, in comparison to what has been quantified regarding existing and widely used maneuvers to treat foreign body airway obstruction.

3.3. Application of a PNSD in simulated cases of foreign body airway obstruction

Efficacy of a PNSD was demonstrated on an adult cadaver model.¹¹ A piece of clay simulated a food bolus, varying in size from two to three centimeters, and was placed seven to ten centimeters past the lips, into the patient's airway. On fifty serial attempts at deploying the PNSD, the food bolus was dislodged into the mouth or mask forty-nine times (98%) on the first attempt. A single trial required tighter seal and the food bolus was dislodged on a second deployment.

Efficacy of a PNSD was also demonstrated on a simulated model of a choking victim.¹² Although a manuscript of this study has not been published, an abstract and primary data was reviewed. The investigators used the Choking Charlie simulator system (Laerdal Medical, Wappinger Falls, New York), designed for training Heimlich maneuver abdominal thrusts, with half of a piece of sausage (Nathan's Cocktail Franks) inserted seven centimeters past the lips to simulate airway foreign body. On 500 serial simulations, the self-generating suction device dislodged the object into the mouth or mask 470 out of 500 simulations on the first attempt, 498 out of 500 simulations after two attempts, and 500 out of 500 simulations on three attempts.

3.4. Application of a PNSD in actual cases of foreign body airway obstruction

There have been several case reports of successful application of a PNSD in real foreign body aspiration situations. These anecdotal reports were reviewed. A total of eight individual cases are reported, ranging in age from 31 to 80 years. Six cases were at nursing home facilities, while two were in a home setting. In half of these cases, the patient had an underlying swallowing or neurodegenerative disorder, such as Parkinson's disease or dementia. In all cases, the PNSD was attempted after exhausting recommended interventions, such as finger sweep, Heimlich maneuver, chest thrusts, and back blows. In each case, the food bolus was dislodged immediately, or on less than four attempts, providing anecdotal support of what is seen in the laboratory studies above.

4. Discussion

Accidental foreign body aspiration carries high morbidity and mortality in high-risk populations, specifically young children, disabled adults, and the elderly. The American Heart Association recommends use of abdominal thrusts, or Heimlich maneuver, in rapid succession until the foreign body obstruction is relieved. If these are ineffective, the rescuer may consider back blows, chest thrusts, or extraction of foreign body with forceps.^{13,14} Recommendations for children are similar. Importantly, none of these maneuvers may be feasible in wheelchair or bed-bound individuals. Abdominal thrusts are not recommended in infants (<1-year-old), due to risk of intra-abdominal injury. Blind finger sweeps are not recommended routinely, due to risk of further dislodgement and injury to the pharynx.¹⁵

The pre-hospital presentation and management of foreign body airway obstruction has largely been studied in retrospective or anecdotal fashion. A large retrospective case series examined the San Diego County prehospital database and identified 513 cases of choking in adults over a 17-month period. This study demonstrated 3.3% mortality rate, and successful application of the Heimlich maneuver in 86.5% of cases.¹⁶

A reported case series of three pediatric patients who had choked on a grape demonstrated one fatality and two near-fatalities, with sequelae of pulmonary edema and lobe collapse requiring intensive care unit monitoring and operative intervention.¹⁷ Whole seedless grapes measure approximately two to three centimeters in size, roughly comparable to the food bolus used in simulation studies with a PNSD. Further, according to Feltbower et al, multi-disciplinary review of the fatal case concluded that extraction of the foreign body at the scene, with a Magill forceps or other means, could have altered the outcome for that child. The ability to extract a foreign body with

specially adapted forceps, Magill forceps, or Kelly clamp have also been described by other authors as a life-saving pre-hospital intervention for choking victims when Heimlich maneuver and other interventions fail.^{16,18, 19} Use of a Magill forceps in the pre-hospital setting has even significantly correlated to a neurologically favorable survival after choking episode.⁴ However, these types of interventions require special medical instruments, as well as higher level training in their proper use, which are not readily available in the pre-hospital setting. They are also seemingly invasive, may further lodge food boluses in the airway, or cause trauma to the laryngopharynx. While these are acceptable risks versus asphyxiation, they may still present barriers to immediate intervention by lay persons. In these situations, a PNSD, with safeguards to prevent causing harm, such as a one-way valve when deploying the device to prevent worsened obstruction, may represent a suitable alternative to instrumentation. Unlike forceps extraction, minimal training is required to use a PNSD.

Most resuscitative techniques commonly described involve specific positioning of the rescuer in relation to the choking victim. Abdominal thrusts require the rescuer to encircle the patient with both arms, which may be prohibitive in an obese or wheelchair-bound patient.¹⁹ Chest compressions require the patient to be supine. Preparing the patient for a maneuver may waste precious time between onset of hypoxemia and cardiac arrest. A PNSD can be quickly applied to patients regardless of their position, requiring only access to the face.

While the pressure generated by a PNSD is several factors greater than that generated by traditional resuscitative techniques, the transmission to lung parenchyma is not thought to be equivalent. External maneuvers, such as chest or abdominal compressions, apply positive intrathoracic pressure to push a foreign body out of the airway like a cork under pressure; thus, this peak airway pressure is felt by the lower airway and alveoli and transmitted to the point of obstruction. In contrast, the high negative pressure generated by a PNSD is applied at and above the level of the foreign body obstruction, without significant transmission to the lower airways. In reported cases of PNSD application, there were no known complications of pulmonary hemorrhage, airway collapse or other sequelae of high intrathoracic pressures. Future studies are warranted in cadaveric models to determine if high suction forces do indeed cause any undue morbidity. However, limiting the amount of time suction is applied and ceasing application of suction once the foreign body is expelled or is visible in the oral cavity would mitigate this risk. Further, in the absence of known anatomic abnormality, airway collapse is unlikely to persist after the negative pressure application is ceased. A potential modification to future prototypes could be a pressure-sensitive release valve to dissipate pressures above a certain level, without affecting the efficacy of the device in dislodging foreign body obstructions. This could act similarly to the existing one-way valve action of the plunger that ensures that no undue positive pressure is applied to the airway when the plunger is being deployed downward prior to applying suction pressure, to prevent worsening dislodgement of foreign body into the airway.

Importantly, if a patient with foreign body aspiration is stable for transport, he or she should be evaluated in a hospital setting, where the airway can be secured and the foreign body retrieved in a controlled fashion. Converting an esophageal to an airway foreign body is certainly dangerous if it occurs, especially in a child, and should not be risked if the patient is not in immediate respiratory distress. This possibility is also difficult to quantify as it cannot easily be replicated in a cadaver or mannequin.

Given the lack of prospective data or consensus on a single resuscitative technique, many have advocated for a broad approach to dealing with foreign body airway obstruction, including educating the lay person on recognition of upper airway obstruction, and utilization of a variety of techniques in successive order to alleviate the obstruction, up to and including direct laryngoscopy and instrumentation.²⁰ Early intervention by by-standers has been shown to significantly correlate with improved outcomes after choking.²¹ Early intervention by parents rendered 59% of foreign body aspirations resolved prior to paramedic arrival.²² Further, most cases of choking in adults, and even children, are due to food objects.^{23,24} Some have demonstrated wide variability in availability of life-saving equipment, proposing standardized protocols across health care facilities, including universally available equipment lists and staff training for medical professionals, specifically in the management of pediatric airway foreign bodies.²⁵ In designing a systematic approach to pre-hospital management of foreign body airway obstruction, with emphasis on early lay person or parental involvement, a PNSD may offer a complementary and effective adjunct to existing techniques, especially in high-risk, targeted areas such as restaurants, schools, nursing facilities and basic life support vehicles.

5. 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, safety, and reproducibility in larger cadaveric or simulation studies mimicking physiologic conditions is indicated.

Conflicts of Interest

None.



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