### Title

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ORIGINAL RESEARCH

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# The efficacy of two commercially available devices for airway foreign body relief: A cadaver study

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## Abstract

**Objective:** Foreign body aspiration events are frequent in young children and in the geriatric population. They may result in several complications such as hypoxia, edema, cardiac arrest, and death. Recently, two commercially available devices, the LifeVac and DeChoker, have entered the market with the claim of relieving foreign body aspiration. Both devices are portable, nonpowered, suction devices that are being considered for use in large public spaces such as schools, airports, and malls despite previous studies detailing variable efficacy. In this study, we aim to contribute further data on the safety and efficacy of these devices through a fresh cadaver model.

**Methods:** Commonly aspirated foods of three different sizes (saltines, grapes, and cashews) were placed at the level of the true vocal folds in a fresh cadaver. Three participants performed two trials with each food and device. Device use was performed to manufacturer specifications.

**Results:** The DeChoker resulted in gross injury to the tongue and failed to remove the obstruction in all trials. LifeVac was successful in removing the barium-moistened saltines but failed to remove all other foreign bodies. Both devices applied significant pressure to the tongue.

**Conclusion:** With the exception of the LifeVac removing saltine crackers, all trials were entirely unsuccessful in relieving foreign body aspiration. Additionally, both devices may cause significant pressure and injury to the oral cavity in a clinical setting. We conclude bystanders should continue to follow International Liaison Committee on Resuscitation's guidelines on resuscitation to aid with relieving foreign body aspiration.

**Level of Evidence:** 4

KEYWORDS

airway obstruction, aspiration, choking, commercial device, foreign body aspiration

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## 1 | INTRODUCTION

Foreign body aspiration is the fourth leading cause of unintentional death primarily affecting the very young and geriatric populations.[1] In the year 2015, over 5000 deaths were caused by choking, of which 56% occurred in individuals over the age of 74. The most commonly aspirated foods are small, compressible solids such as grapes or hot dogs. The population at risk is bimodal as the majority of cases occur in children under the age of four, although the risk again rises in the geriatric population.

The International Liaison Committee on Resuscitation (ILCOR) recommends back slaps as the initial treatment modality for foreign body airway obstruction (FBAO) removal and if ineffective, suggests abdominal thrusts.[2] However, it is recognized that both treatments have a very low certainty of evidence.

In recent years, several new products have come to the market with the claim of relieving airway obstruction from aspirated foods. Two commercially available choking devices, LifeVac and DeChoker, are among the most commonly available portable, non-powered suction devices (PNSDs). They work to remove FBAO through the application of negative pressure to the airway. The LifeVac is a noninvasive device with a valve that attaches to the patient's mouth similar to a plunger.[3] To use the device, one pushes down on the handle to create a one-way suction which, in theory, removes the foreign body. The DeChoker utilizes an oropharyngeal tube with a similar plunger mechanism. Currently, both devices are being marketed for use in public spaces and recommended for use in certain schools despite their variable efficacy.

Previous studies on PNSDs include cadaver studies, case reports, and mannequin trials, some of which report significant success in dislodging the foreign body upon an initial examination of the data.[4–10] A thorough systematic review by Dunne et al., however, details notable flaws in these studies namely a high risk of bias (industry involvement, and reporting bias), decreased generalizability of mannequin results, and a low certainty of evidence despite high success rates of dislodgement.[11] Therefore, it is commonly recognized that further independent studies must be conducted. The aim of this study is to contribute further data on the efficacy of the LifeVac and DeChoker in fresh frozen cadavers while involving a physician for examination of correlated anatomy.

## 2 | MATERIALS AND METHODS

A fresh cadaver (5′10″, Caucasian male) was utilized for all trials. Whole grapes (Columbine Vineyards red seedless), cashews (Aurora Organic), and barium-impregnated crackers (Premium Saltines) were placed at the level of the true vocal folds under visualization with a flexible endoscope (Olympus, Center Valley, PA). The choking relief devices were then used to manufacturer specifications by a PGY2 otolaryngology resident, a board eligible otolaryngologist, and a novice volunteer. The devices were reused between trials as there were no sanitary concerns. Each participant conducted two trials with each device and food for a total of 36 trials across the three participants. Extent of foreign body extrication was evaluated by flexible endoscopy and videofluoroscopy (GE Healthcare, Milwaukee, WI).

## 3 | RESULTS

Both the LifeVac and DeChoker failed to remove the cashews and grapes from the airway in all trials. The barium moistened cracker was moved from C2 at the level of the glottis to C1 at the level of the oropharynx by the LifeVac. After the first intervention with the DeChoker, we observed gross injury to the tongue with laceration of its dorsum. Both products exerted significant negative pressure on the tongue and soft palate manifesting as local blood pooling and edema in the cadaveric setting that might result in edema in the live clinical setting.

## 4 | DISCUSSION

This study aimed to test the efficacy of two PNSDs in removing a foreign body in an adult, male fresh cadaver. We recognize that our findings may not be generalizable to all ages, however, we suggest consumers strongly consider these findings prior to device use. Our primary findings were that the DeChoker was wholly unsuccessful in FBAO removal and the LifeVac made appreciable progress in removing barium moistened saltine crackers but failed to remove whole grapes and cashews. The LifeVac's increased success compared to the DeChoker is in line with current literature.

The main goal of FBAO intervention is to relieve airway obstruction without significant harm to the patient. Back blows and abdominal thrusts, the recommended first-line treatment, both have a low certainty of evidence and pose potential risks such as abdominal bruising and/or injury to the ribs.[2] A safe and universally accepted treatment with high efficacy is necessary for the management of this difficult problem.

The LifeVac and DeChoker both displayed safety concerns. The devices applied significant negative pressure to the tongue and oropharynx which risked edema as reported by an otolaryngologist. Additionally, gross injury to the tongue was observed following use of the DeChoker. A live video of both devices can be seen in video 1, which depicts the necessary force to generate the negative pressure. In a live situation, this could have resulted in bleeding and edema, potentially further complicating the clinical situation. This suggests PNSDs may pose additional complications to FBAO in an already time-critical event and distract bystanders from the recommended first-line treatments.

Within the literature found, there are multiple studies and case series, which report data that may find these two devices effective upon initial examination.[4,6–10] For example, multiple mannequin trials

report significant success in dislodgement with LifeVac use.[4,6,9,10] Although these studies represent optimistic outcomes, this data may not be generalizable. The application of negative pressure on a plastic mannequin largely differs from this same mechanism in humans. The soft tissue within the oral cavity of humans is prone to collapse in the setting of negative pressure, resulting in worse outcomes relative to a mannequin as observed in this study.

The literature also describes anecdotal evidence of success with both the LifeVac and DeChoker in two case reports.[7,8] Of note, there are a few relevant factors between the two studies that must be considered despite the reported high PNSD efficacy. For example, certain bystanders in these case reports received formal device trainings, one report did not include unsuccessful statistics, and there was also evidence of oral trauma and necessary emergent care. These variables undoubtedly have the potential to alter reported efficacy and the outcomes of a real-life choking event. It is concerning that consumers may be deterred from recommended ILCOR guidelines when these results are largely biased and/or not generalizable to the average bystander.

With both PNSDs, we identified oral trauma to be a significant concern that may further complicate the airway. Despite the risk to the oral cavity, there are few studies that mention the risk of soft tissue damage, edema, or injury to the tongue. We suggest all future studies include a physician for further examination of the oral cavity and associated injuries after administering these devices.

Additional cadaver studies should be performed to identify the safety of these devices and their implications to the oral cavity. Within the available literature, there is evidence of only one other cadaver study performed and there was no indication of it being a fresh frozen model.[5] This study found significant success in FBAO removal in supine cadavers. As stated by Dunne et al., transitioning a choking person from upright to the supine position may cause further complications to the airway.[11] Despite high rates of dislodgment reported in this study, a cadaver model cannot account for potential airway complications during this transition, which is a limitation of both cadaver studies. We speculate the difference in outcomes between the two cadaver studies may be due to differing cadaveric models. We stress the importance of using fresh frozen cadavers for their realistic tissue quality and generalizable outcomes.[12] Additionally, both cadaver studies included three distinctly sized commonly aspirated foods. We recognize the varying sizes of the foods may contribute to variable outcomes.

Our study contains several limitations. We do not have comparative data on the efficacy of PNSDs to traditional methods and therefore cannot conclude which has higher efficacy. Additionally, we cannot replicate the time-critical event that is choking. We also report comparatively fewer trials. However, it is recognized that increasing the number of trials performed by the same participants could yield skewed outcomes due to device familiarity. Of note, no training was conducted prior to using the devices. A formal training may yield better results. Finally, a live animal trial may provide a better model for tissue effects of these devices in more realistic clinical circumstances.

## 5 | CONCLUSION

Upon testing the efficacy of these two PNSDs in a fresh frozen cadaver, we find the LifeVac to be effective in removing only barium moistened saltines and the DeChoker to be wholly unsuccessful in relieving aspiration. Despite previous data indicating the potential efficacy of these PNSDs, we stress the very low certainty of this evidence and high risk of bias.[11] Our findings suggest that both the LifeVac and DeChoker should not replace abdominal thrusts and back blows as the treatment of choice for choking. Further independent studies must be conducted before these devices can be marketed as a secondary treatment option.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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