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Clinical paper

A 2-year prospective evaluation of airway clearance devices in foreign body airway obstructions

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Abstract

Aim: To collect, analyze and report the first prospective, industry-independent, data on airway clearance devices as novel foreign body airway obstruction interventions.

Methods: We recruited adult airway clearance device users between July 1, 2021 and June 30, 2023 using a centralized website and email follow-up. The data collection tool captured patient, responder, situation, and outcome variables. Multi-step respondent validation occurred using electronic and geolocation verification, a random selection follow-up process, and physician review of all submitted cases.

Results: We recruited 186 airway clearance device users (LifeVac©:157 [84.4%]; Dechoker©:29 [15.6%]). LifeVac© was the last intervention before foreign body airway obstruction relief in 151 of 157 cases. Of these, 150 survived to discharge. A basic life support intervention was used before LifeVac© in 119 cases, including the 6 cases where LifeVac© also failed. We identified two adverse events using LifeVac© (perioral bruising), while we could not ascertain whether another 7 were due to the foreign body or LifeVac© (3 = airway edema; 3 = oropharyngeal abrasions; 1 = esophageal perforation). Dechoker© was the last intervention before obstruction relief in 27 of 29 cases and all cases survived. A basic life support intervention was used before Dechoker© in 21 cases, including both where Dechoker© also failed. We identified one adverse event using Dechoker© (oropharyngeal abrasions).

Conclusion: Within these cases, airway clearance devices appear to be effective at relieving foreign body airway obstructions. However, this data should be considered preliminary and hypothesis generating due to several limitations. We urge the resuscitation community to proactively evaluate airway clearance devices to ensure the public remains updated with best practices.

Keywords: FBAO, Anti-choking, Prehospital, Basic life support, Resuscitation, ACD

Introduction

Foreign body airway obstructions (FBAO or choking) remain a preventable injury with high mortality and morbidity.[1–4] Longstanding techniques taught for relief of FBAO include some combination of abdominal thrusts, back blows, or chest compressions/thrusts, yet limited contemporary data on these basic life support (BLS) interventions exists. Despite being studied since the 1970s, a recent systematic review found only six case series and one cross-sectional study evaluating these techniques.[5,6]

Recently, novel choking interventions are being promoted. Airway clearance devices (ACDs) are non-powered suction-based devices being marketed by manufacturers as an alternative to traditional choking interventions. Two manufacturers are the main suppliers of ACDs. LifeVac© (LifeVac LLC, Nesconset, New York, NY, USA) produces a device consisting of a facemask with a one-way valve connected to compressible bellows which are entirely non-invasive.[7] In contrast, Dechoker© (Dechoker© LLC, Wheat Ridge, CO, USA) has an intraoral component (in addition to a cylindrical plunger) that acts as a tongue depressor.[8]

Several studies have previously reported on FBAO cases intervened by ACDs.[9–12] However, these have had significant limitations that have bias-introducing potential including data collection conducted by manufacturers, being retrospective in nature, having small sample sizes, or incomplete case data to accurately describe the

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effectiveness of the intervention in detail.[13] To address these research gaps, we conducted the first prospective study on ACD interventions for FBAO with systematically collected, analyzed, and reported data independent from manufacturers.

Methods

Study design

This prospective, observational, international study recruited participants between July 1, 2021, and June 30, 2023. A detailed study protocol was published *a priori* and is briefly discussed below.[14] Prior to study launch, both ACD companies (LifeVac© and Dechoker©) agreed to assist solely with identification and recruitment of participants, and had no role in study design, data analysis or reporting. The study was approved by the Human Research Ethics Committee of the University of New South Wales (HC210242) on May 25, 2021. Reporting of the study adhered to all relevant sections of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[15]

Eligibility criteria and participant recruitment

We recruited eligible individuals, aged 18 years or older, who used an ACD to attempt to dislodge a FBAO during the study period. The only exclusion criterion was an inability to read and write in English or Spanish due to availability of the data collection tool in those languages.

We set up a centralized website for recruitment where eligible individuals could access the data collection tool (https://www.acdresearch.org). Both ACD companies included information on their own websites and social media accounts which made potential participants aware of the study and provided links to our study's independent website. Finally, a one-time standardized email was sent by the research team to any eligible individuals that the ACD manufacturers were made aware of via their own tracking systems.

Data collection and validation

We administered the data collection tool using digital survey software (Qualtrics, Provo, UT). The tool was developed by the research team, and then administered to 10 individuals without healthcare or research experience, to optimize its format and comprehension (e.g., added in examples following medical terms such as: conscious [*still awake, eyes open*] or unconscious [*passed out, eye closed, not responding to you*]). The final data collection tool is available in Appendix 1.

We performed a three-step data validation process. First, all responses were verified electronically (via unique IP address) and using geolocation technology within Qualtrics. We removed any responses with duplicate IP addresses which did not contain the same identifying information. Further, if the same person or same IP address reported a second choking incident, we only included their first entry in the final analysis. Using the geolocation technology in Qualtrics, we also removed any entry where the location that the response was submitted from did not match the approximate region where the choking was reported to have occurred. Next, we only included entries in the analysis where participants agreed to be contacted for follow up questions and/or interviews. Finally, we contacted (electronically via e-mail or video conferencing) a randomly selected 25% of these individuals to confirm identities and details of the case. A medical doctor (CD) with experience in Emergency Medicine, reviewed all case submissions for medical clarity, and participants were contacted if further details were required.

Outcome variables and analysis

Our primary outcome of FBAO relief was defined as resolution of the choking symptoms and signs, requiring no further intervention. Secondary outcomes included whether emergency medical services (EMS) attended the scene, whether the choking person attended the hospital for evaluation, whether the choking person was hospitalized, and if they survived the event (and to discharge if hospitalized).

A complete list of our collected variables and associated values is available in Appendix 2.

We calculated descriptive statistics on each variable. Age and number of ACD attempts were reported as median and interquartile range (IQR). Categorical data were expressed as proportions (*n* (%)). We narratively described cases where the obstruction was not relieved with the ACD, or those with device malfunctions or patient-related adverse events. We used Likert-response questions to obtain feedback on the ACD users' experience.

Results

During the study period, there were 288 completed data collection tool responses (Fig. 1). Eight hundred and sixty-six ACD uses had been reported to manufacturers, and subsequently our research team, during the study period who were notified of the study. Of the submitted responses, we excluded due to declined follow up questions (n = 69, 24.0%), failed electronic verification (n = 20, 6.9%), reporting a second FBAO or duplicate response (n = 9, 3.1%), and four responses did not describe a choking incident treated with an ACD (n = 4, 1.4%). Of the remaining 186 responses, 157 (84.4%) cases used LifeVac© and 29 (15.6%) cases used Dechoker©.

LifeVac©

Tables 1–3 report on the choking person, responder, and outcome details.

LifeVac© was the last intervention before resolution of FBAO symptoms and signs in 151 (96.2%) cases and in about half of the cases (n = 82, 54.3%) the foreign body was dislodged entirely without needing a finger sweep or patient roll. All cases with complete follow up survived, although one case did not have complete follow up (due to limits of EMS information). Most LifeVac© responders attempted at least one BLS technique prior to using the ACD (n = 119, 75.8%), with back blows being the most common (n = 84, 70.6%).

Among the six unsuccessful cases, all had back blows performed before ACD use. In one case, the FBAO was resolved during transitioning between ACD use and preparing for another technique, and another FBAO resolved after subsequent back blows were applied (despite initial ones pre-ACD use). Three other responders were uncertain whether the ACD or a traditional technique resolved the FBAO as they were doing both in sequence. Finally, one FBAO was not resolved before arriving at the hospital.

Device malfunctions and patient-related adverse events

Three cases involved device malfunctions, all of which involved disconnection of the mask with the plunging unit making seal formation

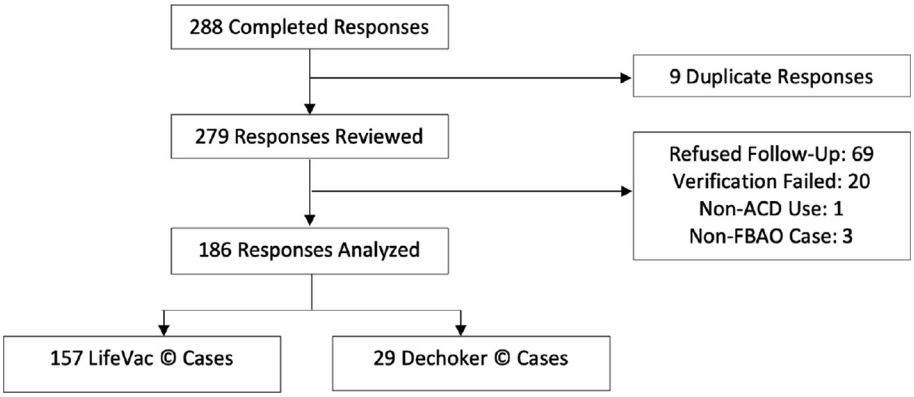

Fig. 1 – Flow of data collection tool responses.

Table 1 – Demographics of person with foreign body airway obstruction.

	LifeVac© N = 157 n (%)	Dechoker© N = 29 n (%)
Patient Gender		
M	88 (56.1)	18 (69.0)
F	69 (43.9)	9 (31.0)
Patient Age (median, IQR)	3 (1–32)	2 (0–36)
Patient Age Groups		
0–1 year	50 (31.8)	13 (44.8)
2–5 years	51 (32.5)	10 (34.5)
6–18 years	12 (7.6)	2 (6.9)
19–64 years	25 (15.9)	4 (13.8)
65+ years	19 (12.1)	0 (0)
Country		
England	1 (0.6)	0 (0)
New Zealand	1 (0.6)	0 (0)
United States of America	155 (98.7)	29 (100)
Medical Conditions: Cardiac[1]		
Present	13 (8.3)	0 (0)
Absent or Unsure	144 (91.7)	29 (100)
Medical Conditions: Respiratory[1]		
Present	14 (8.9)	1 (3.5)
Absent or Unsure	143 (91.1)	28 (96.5)
Medical Conditions: Neurologic[1]		
Present	35 (22.3)	3 (10.3)
Absent or Unsure	122 (77.7)	26 (89.7)
Medical Conditions: Other[1]		
Present	18 (11.5)	3 (10.3)
Absent or Unsure	139 (88.5)	26 (89.7)
History of Choking		
Present	43 (27.4)	9 (31.0)
Absent or Unsure	114 (72.6)	20 (69.0)
Foreign Body Airway Obstruction		
Emesis	3 (1.9)	1 (3.5)
Mucus	7 (4.4)	1 (3.5)
Object	29 (18.5)	6 (20.7)
Solid Food	112 (71.3)	21 (72.4)
Thickened Fluid	3 (1.9)	0 (0)
Unsure	3 (1.9)	0 (0)
Geographical Location		
Home	141 (89.2)	28 (96.5)
Long-term Care Facility	4 (2.5)	0 (0)
Public Space	11 (7.0)	1 (3.5)
School	2 (1.8)	0 (0)

IQR = Interquartile Range.

[1] **Appendix 3** includes a breakdown of specific medical condition frequency.

Table 2 – Demographics of responder who used the airway clearance device.

	LifeVac © N = 157 n (%)	Dechoker © N = 29 n (%)
Responder's Relationship to Choking Person		
Family or Friend	132 (84.1)	28 (96.5)
EMS or Fire First Responder	3 (1.9)	0 (0)
Nurse or Staff	6 (3.8)	0 (0)
Self	7 (4.5)	1 (3.5)
Unknown Bystander	9 (5.7)	0 (0)
Responder's Relevant Training		
Basic Life Support (BLS)	70 (44.6)	9 (31.0)
Nurse or Nurse Assistant	16 (10.2)	1 (3.5)
Paramedic or EMR	5 (3.2)	0 (0)
Physician	1 (0.64)	0 (0)
None	65 (41.4)	19 (65.5)
Airway Clearance Device Training		
Received In-person Training	14 (8.9)	3 (10.3)
Watched Online Training Video	104 (66.2)	13 (44.8)
Practiced On a Mannequin	24 (15.3)	5 (17.2)
Previously Used ACD	21 (13.4)	2 (6.9)

ACD = Airway Clearance Device; EMR = Emergency Medical Responder.

challenging. In all cases, the device was able to be reassembled and reused.

Respondents reported ten patient-related adverse events. We believe two cases of perioral irritation and bruising were likely to be caused by device application, whereas one case of subconjunctival hemorrhage was favoured to be related to the choking process. For the remaining seven events, we were unable to ascertain whether they were due to the FBAO or the device. These adverse events included: airway edema via inflammation (3 cases), intraoral abrasions/pain (3 cases), and esophageal perforation due to a plastic shard entrapped in mucosa. All airway edema cases resolved without intervention. The patient with an esophageal perforation also received back blows. This patient was temporarily admitted to the intensive care unit however has since been discharged from the hospital.

Dechoker©

Dechoker© was the last intervention before resolution of FBAO symptoms and signs in in 27 (93.1%) cases and did not require any additional maneuvers to remove the foreign body in 19 (70.4%) cases. Most users attempted at least one BLS technique prior to using the Dechoker© ($n = 21$, 72.4%), with back blows being the most common intervention ($n = 18$, 85.7%).

In both unsuccessful cases, the choking person ultimately resolved the FBAO while coughing. One of them did so in between device use and back blow alterations, and the other case after a single attempt of the ACD. Neither unsuccessful case was transported to hospital by EMS. One case had back blows and abdominal thrusts used before the ACD, while the other had just back blows.

Device malfunctions and patient-related adverse events

One device malfunction was reported, which involved the top of the pulley coming off and resulting in the air seal being lost. The responder was able to continue to use the device by covering the hole and maintaining a seal with their finger however it was one of the cases where the device did not remove the FBAO.

In one case, the choking person suffered abrasions to the oropharynx and gingiva because of the Dechoker© tube insertion.

ACD user experience feedback

Responses were similar among both devices (Fig. 2, Appendix 4). Almost all LifeVac© and Dechoker© respondents believed that ACDs were easy to use and should be a part of choking treatments. Three quarters of LifeVac© users reported if they had an intraoral component to their device, they would be more nervous to use the ACD and about 15% said this would make them not use it at all. Conversely, only one-quarter of Dechoker© users reported increased nervousness due to the intraoral component of the ACD.

Discussion

This study presents the first prospective evaluation of ACDs where data were collected, analyzed and reported independent of manufacturers. Within the reported cases, we find that LifeVac© and Dechoker© were effective at resolving FBAO with few, generally mild, adverse events. Further, most cases reported an unsuccessful BLS intervention prior to the ACD use.

The use of ACDs as an intervention for FBAO remains a controversial topic.[16,17] In fact, the rapid, widespread public interest and acceptance of ACDs with only case reports as supporting evidence has many parallels to the dissemination of the "Heimlich maneuver" (also known as abdominal thrusts) in the 1970s.[18,19] The data within our manuscript is like that presented by Redding in 1979 on traditional BLS interventions. Both describe a generous collection of cases, yet both are limited in their ability to make concrete conclusions (either statistical or theoretical) due to sampling bias from self-reporting recruitment strategies, and difficulties with precise outcome measurement (e.g., relief of obstruction). Despite these limitations, Redding's work remains the largest source of data on FBAO BLS interventions cited in present-day treatment recommendations.[6]

Table 3 – Airway clearance device use and outcome details.

	LifeVac © N = 157 n (%)	Dechoker © N = 29 n (%)
Initial FBAO Witnessed		
Witnessed	148 (94.3)	25 (86.2)
Unwitnessed	9 (5.7)	3 (10.3)
Unsure	0 (0)	1 (3.5)
Initial FBAO Severity		
Severe or Complete	108 (67.1)	18 (62.1)
Mild or Partial	41 (27.5)	11 (37.9)
Unsure	8 (5.4)	0 (0)
BLS Intervention Performed Before ACD	119 (75.8)	21 (72.4)
Abdominal Thrusts	39 (32.8)	4 (19.1)
Back Blows	84 (70.6)	18 (85.7)
Chest Compressions or Thrusts	9 (7.6)	2 (9.5)
Level of Consciousness When ACD Used		
Conscious	137 (87.3)	28 (96.6)
Unconscious	20 (12.7)	1 (3.5)
Number of ACD Attempts (median, IQR, range)	2 (1–2; 1–13)	2 (1–4; 1–15)
ACD Last Intervention Before Resolution of FBAO Symptoms / Signs (all cases)		
Yes	151 (96.2)	27 (93.1)
No or Uncertain	6 (3.8)	2 (6.9)
ACD Last Intervention Before Resolution of FBAO Symptoms / Signs (only severe cases)		
Yes	105 (97.2)	17 (94.4)
No or Uncertain	3 (2.8)	1 (0.6)
Foreign Body Removal		
ACD Removed Entirely	82 (54.3)	19 (70.4)
Required Finger Sweep or Rolling onto Side to Remove	51 (33.8)	8 (29.6)
Unsure	18 (11.9)	0 (0)
Other Outcome Indicators		
EMS Attended Scene	41 (26.1)	5 (17.2)
Sought In-hospital Evaluation	36 (22.9)	1 (3.5)
Admitted to Hospital	10 (6.4)	0 (0)
Admitted to Intensive Care Unit	3 (1.9)	0 (0)
Survived	150 (99.3)[1,2]	27 (100)[2]

ACD = Airway Clearance Device; BLS = Basic Life Support; EMS = Emergency Medical Services; FBAO = Foreign Body Airway Obstruction; IQR = Interquartile Range.

[1] One report from an EMS service did not have follow up information after admission to the intensive care unit.

[2] Proportion of cases which the ACD was the last intervention (LifeVac *n* = 151; Dechoker *n* = 27).

The difficulty identifying a study population is a prominent reason why data on traditional FBAO BLS interventions have not progressed significantly in decades. Our scientific basis for current recommendations includes abdominal thrusts (FBAO relief:417 case reports; survival:189 case reports; adverse events:52 case reports), and back blows (FBAO relief:75 case reports; survival:13 case reports; adverse events:4 case reports).[6] In comparison, LifeVac© ACD has 274 case reports of it being the final intervention before FBAO relief, with all patients with complete follow up subsequently surviving, and 9 reports of patient-related adverse events (including those analyzed in this study).[12]

The adverse events from ACDs published to date have been milder than those from abdominal thrusts, for example.[6] One notable exception from our study was the case of esophageal perforation where a plastic shard was entrapped in esophageal mucosa. The respondent mentioned that they were unsure what caused this injury as it could be due to the type of FBAO material, application of back blows or application of LifeVac©. Cases like this highlight why any new resuscitation intervention must be carefully assessed before use. As well, due to our inability to access health records for the patients assessed by medical providers in this study (25.1% of all cases), we need to strongly consider the likelihood of unaccounted adverse events given the reliance on layperson reporting.

Importantly, compared to other areas of evidence within resuscitation sciences, we are not concluding that the data quality for ACDs is sufficiently high, only that it is comparable to the present data for other FBAO interventions. There are additional reasons to pause however before considering a change of practice recommendations. Any benefit gained by introducing ACDs as standard interventions in resuscitation algorithms, must be balanced against potential barriers including implementation costs, equipment availability, and whether dispatchers would be able to instruct ACD use over the phone to providers.

There is also concern that laypeople will struggle with correct assembly of the devices and secure application of the face mask, resulting in a delay of other techniques.[5,16,17] Three mannequin studies have evaluated individuals' ability to use ACDs. Two mannequin studies assessed parents', educators', and healthcare learners' ability to correctly follow the steps provided by ACD manufacturers (written pamphlet) without other instruction.[20,21] Both studies found the

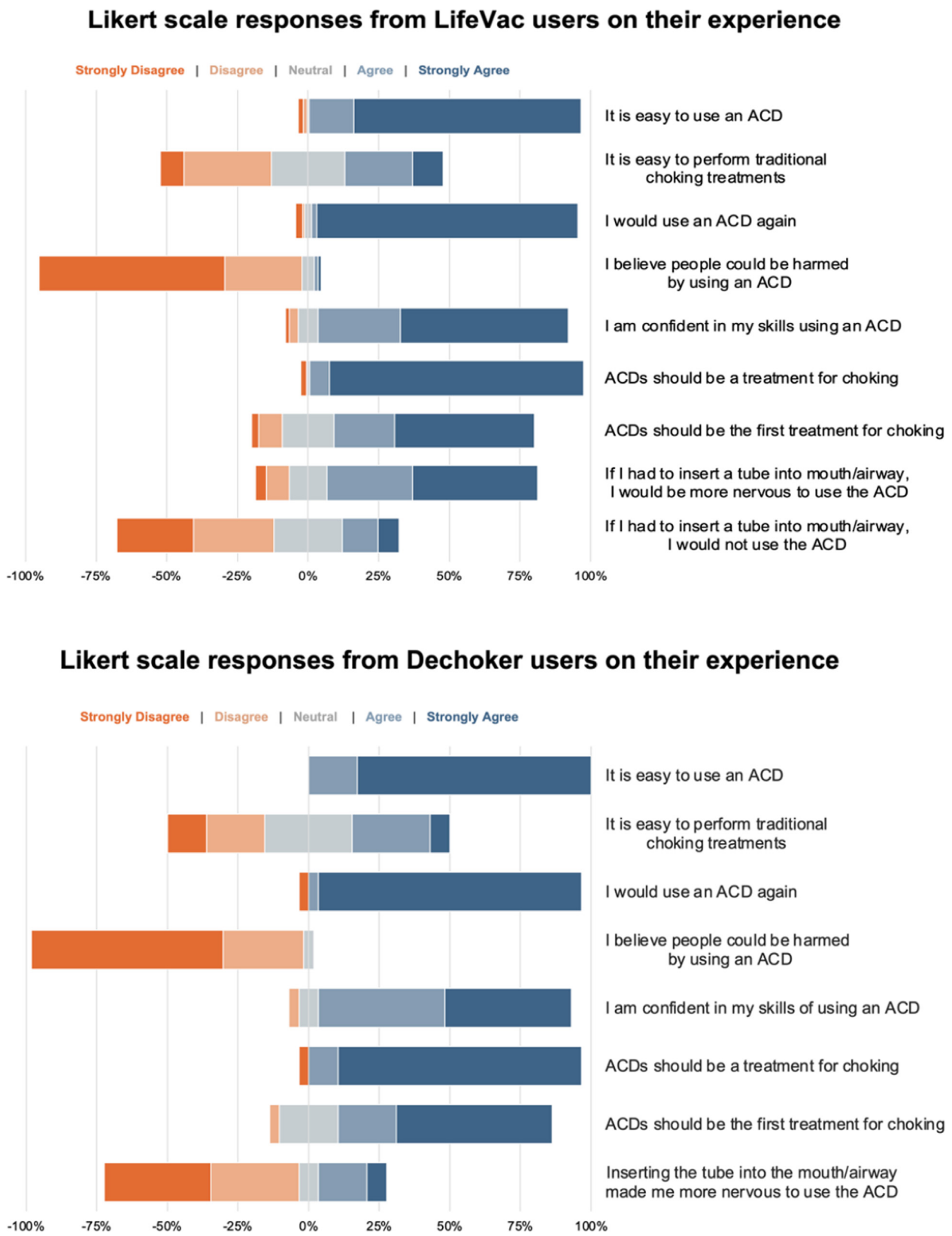

Fig. 2 – Comparison of Likert responses between LifeVac© (top) and Dechoker© (bottom) users describing their experience.

most common incomplete step was participants failing to keep the mask fixed to the face (performed correctly: LifeVac© 56.9–74.4%; Dechoker© 66.7–86.0%). LifeVac© was found to be more rapidly applied and executed then Dechoker© by 9–13.8 s.[20,21] When compared to applying current BLS interventions, both LifeVac© and Dechoker© had greater correct compliance rate than standard protocol (100% versus 50%), despite 72.1% of participants having prior training in FBAO BLS interventions.[21]

A third mannequin study evaluated efficacy of ACDs compared to abdominal thrusts. LifeVac© was found to be superior to abdominal thrusts at FBAO removal success (Odds Ratio [OR] 47.32 [95%CI 5.74–389.40]), whereas Dechoker© was not (OR 1.22 [95%CI 0.60–2.47]). Similar outcomes were also found when assessing rapidity of FBAO removal.[22] We were unable to find any studies assessing laypeople's ability to apply traditional FBAO BLS interventions correctly in the literature. Therefore, although widely adapted and taught, we remain uncertain of the effectiveness of these BLS interventions by laypeople.

FBAO intervention research has reached an impasse. On one side, our current FBAO BLS interventions have a weak scientific basis but have stood the test of time. On the other, a new intervention has now a similar body of evidence, but hesitation remains due to a shorter trial period and a number of barriers to widespread adoption that must be considered. With most case reports and simulation studies supportive of advancing ACD research further, traditional methods of research are unlikely to be helpful. As an example, querying health region databases will fail to capture enough (if any) events, as FBAOs are relatively infrequent, and ACDs as a FBAO intervention remain rarer to identify. We envision several ways forward.

First, further pre-clinical simulation research would be beneficial. This could include simulation trials, like Patterson's, investigating additional objectives such as comparing the effectiveness and usability of back blows versus ACDs, comparing different BLS interventions versus ACDs among untrained laypeople, comparing FBAO interventions in infant choking mannequins, and evaluating different instructional styles of ACDs (to see if the current model of watching an online video is sufficient for skill acquisition and retention).[21]

A next step for clinical data could be introducing ACDs into a highly controlled setting that sees a large volume of FBAOs and allow for detailed monitoring. This would allow initial ACD application by trained providers, with specific outcome and adverse event documentation, as well as comparison to other BLS interventions used in that setting.

Of note, we feel it is important to highlight that although both LifeVac© and Dechoker© fall under the umbrella term of ACD, they represent clinically different tools and should not be compared. The primary contrast is the tongue depressor attached to Dechoker© which is inserted intra-orally. Given Dechoker's© considerably fewer case reports in the literature, and industry-independent evidence suggesting inferior efficacy/usability, it is important guideline creators consider each device independently when making future recommendations.[9–13,22]

As clinicians and researchers, our concerns around safety and effectiveness are needed to protect our patients' interests, but we must also take a proactive approach to studying ACDs and guiding their introduction to the public, otherwise we will struggle to keep the public informed on best practices.

Limitations

There are several limitations relevant to our research including self-reporting sampling bias, reliance on layperson diagnosis of FBAO, and challenges attributing which intervention ultimately relieved the FBAO (where the last intervention is often only given credit). Self-reporting tends results towards exceptional outcomes (e.g., ACD cleared the FBAO or the patient had a severe adverse event such as death).[23] Cases where responders used an ACD and it did not clearly resolve the FBAO, responders may be less likely to seek out opportunities to submit an incident summary. This limitation highlights that our research does not have a denominator (i.e., total number of cases that a responder used an ACD worldwide). Therefore, we are unable to infer the proportion which ACDs are effective as we cannot account for the times when an ACD were used, and data were not collected. Further, in the cases where an ACD was used before a BLS intervention, we do not know if traditional intervention would have failed and negated the need for the ACD.

Although we employed multiple techniques to maximize validity (e.g., electronic and geographic verification, follow up with respondents, and physician review of all submissions), our study is still limited by lack of in-person medical assessment and documentation when the event occurred, similar to prior FBAO work.[18,23] Additionally, we did exclude 33.0% of all submitted cases, however, this was done based on pre-determined criteria which were selected to decrease other potential biases.

Conclusions

We report 157 LifeVac© and 29 Dechoker© airway clearance device uses, that were prospectively collected, validated, analyzed, and reported independent of industry. Within these reports, ACDs appeared to be effective at relieving FBAO with few adverse events, however, the results need to be interpreted within the context of their limitations. We urge resuscitation clinicians and researchers to be proactive in evaluating ACDs moving forward, to ensure the public remains informed and updated on best practices for FBAO management.

Disclaimer

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

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CRediT authorship contribution statement

Cody L Dunne: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing.

Kayla Viguers: Investigation, Formal analysis, Writing – review & editing. **Selena Osman:** Investigation, Formal analysis, Writing – review & editing. **Ana Catarina Queiroga:** Conceptualization, Methodology, Investigation, Writing – review & editing. **David Szpilman:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Amy E Peden:** Conceptualization, Methodology, Investigation, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors have no competing interests, financial or otherwise, to declare. The research team approached the manufacturers to seek their participation in this study. Manufacturers of airway clearance devices agreed to participate in the study in two areas: identification and recruitment of participants and distributing the research data collection tool as needed. Manufacturers were not involved in study design, nor do they have any financial involvement. Manufacturers do not have access to the collected data, nor have they been permitted to view the results or manuscripts prior to publication. Dr. Amy Peden is funded by a National Health and Medical Research Council (NHMRC) Emerging Leadership Fellowship (Grant ID: APP2009306) which supported open access publication. No funding was obtained for the conduct of the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resplu.2023.100496.

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