Received: 20 August 2023 | Revised: 31 October 2023 | Accepted: 15 November 2023

DOI: 10.1002/lio2.1218

Laryngoscope Investigative Otolaryngology

LETTER TO THE EDITOR

A response to a single cadaver study assessing the efficacy of two commercially available devices for airway foreign body relief

1 | BACKGROUND

Due to the preclusion of live human studies of choking on ethical grounds, and prior to going to market, LifeVac™, conducted tests including a single adult cadaver study[1] to assess the efficacy of the device in removing foreign bodies from the airway. Following this, there was criticism, that as a single study has so many variables, that the results could not be treated as definitive and only represented a low level of evidence. In June this year, a single cadaver study using LifeVac™ was also published[2] that has been quoted as a definitive (but similarly low evidence, Level 4) proof that the LifeVac™ airway clearance has little or no efficacy.

After its initial cadaver study, LifeVac™ sought out other forms of ethical evidence for the device, including a series of manikin-based independent studies all published in peer-reviewed journals showing efficacy and the involvement in a multi-institutional case series study of actual uses of the LifeVac™ device on human victims, almost exclusively when current first-aid measures had failed. All of these represent higher levels of evidence than the recently published single cadaver study.[3,4]

As the owner and director of LifeVac Australia and a clinician for over 35 years, studying the science of choking for most of this period, I believe it is important that the strength of the science and the conclusions drawn in this study are evaluated to ensure they have sufficient rigor, merit, and validity; after all, lives are at stake here.

2 | CAUTION IN DRAWING CONCLUSIONS

One must carefully examine the methodology, methods, process, conclusions drawn, and the potential bias of this latest study to determine its value in decision-making regarding the widespread adoption of the LifeVac™ device. At the outset it must be stated, the negative conclusions drawn in the study about the DeChoker™ (a wholly different device with a separate risk and efficacy profile and level of evidence) are not disputed as these are reflected in all past studies and evidence reviews. A consistent flaw in several studies has been the conflation of the LifeVac™ and the DeChoker™ as the "same" and therefore the illogical conclusion that is subsequently drawn is that if one fails all must lack efficacy. The study must also be examined for failures in logic in making unevidenced conclusions and statements, that is, opinions.

One must be very cautious when citations are made to the flawed conclusions of other authors (e.g., Dunne et al. and van der Voorde[4,5] on whom Dunne so heavily relied) as "proven" and where the opportunity for rebuttal was denied in the journal, they appeared in.

3 | SPECIFIC ERRORS IN THE RESEARCH

There were many errors in the research methodology, testing regime, and therefore the unsupported conclusion made by the authors.

1. The video attached to the publication as proof of testing regime, clearly shows that the application of the LifeVac™ was not in accordance with the manufactures instructions as claimed in the study; rather the device action was incorrect, and the repeated rapid sequencing of use is nowhere described in those instructions. The action demonstrated no review of the manufactures instruction in using a "push" followed immediately by a swift "pulling" action, rather the device was used with equal time spent on the "push and pull" phases, resulting in insufficient and incorrect operation. These huge variables account (almost entirely) for the negative findings of "poor efficacy" and "possible" (speculative as not observed) "injury" resulting from usage of the LifeVac™ device.
2. As with Dunne et al. and van der Voorde,[4,6] many of the conclusions made in these papers are highly speculative but are not based directly on the strength of the evidence reviewed or

presented. A claim that the LifeVac device "*may cause significant pressure and injury to the oral cavity*", or that *"it might result in oedema"* was not supported by evidence or the finding of these complications in the study or in any other studies or any documented case reports, anywhere in the world confirming this opinion and speculation.

3. Another common error in this and the previously cited papers such as Dunne et al. and van der Voorde, is the misrepresentation of the GRADE evidence review "*potential for bias*" as opposed to actual bias in research. All research and all studies under a GRADE review process have a level of possible bias but are not necessarily biased i.e. guilty of unethical manipulation of the outcome to satisfy an agenda unrelated to scientific truth. The quantum leap made in this paper to suggest the dismissal of one finding over another on the grounds of potential (but not actually proven) bias would represent libel and defamation, however in academic review "potentiality" is not regarded as an accusation or proof of impropriety. No research can be considered free of bias, but to suggest something more is akin to Ramaswamy et al. asserting that no doctor can publish any research on a drug they have prescribed or received any payment from a patient to prescribe that drug as this may influence their conclusions. The assumption also made here is that the authors of the study had no pre-conceived ideas or opinions that influenced the conclusions made, that is, were bias-free.
4. The call in the paper to "*strongly consider these finding prior to device use*" directly contradicts the status of the evidence, that is, GRADE 4—low-level opinion of an expert or group of experts, as previous studies (dismissed in the paper as "biased") are of equal or better standing as published scientific literature. The result of this unfounded opinion is likely to be inappropriate caution, leading to further choking deaths and injuries.
5. The claims made in the paper that the positive results of the previous cadaver study should be rejected based on the notion that there is a significant discrepancy between the accuracy of the research results using a fresh frozen cadavers (FFC) over other cadaver preparation methods used in research, is not supported by the cited research, that is, Song and Jo (2022) Current and potential use of fresh frozen cadaver in surgical training and anatomical education.[7] There are no suggestion or relevant conclusions in the research that can be drawn as to the accuracy or inaccuracy of cadaver studies using differing preparation methods in this research or any other research.
6. The study also misrepresents the unproven efficacy of first aid measures and the directions for the use of the LifeVac™ as contained in the device *Instructions for Use* (IFU). The use of LifeVac is recommended after the failure of the BLS measures as most obstructions are not severe (complete) and resolved using first-aid measures or no measures by the victim coughing. The efficacy of various first aid measures is assumed to be high, even though the evidence is cited here as of "low-quality." A central missing dimension to this single cadaver study is the bias created by the exclusion of a control group, that is, a group where first aid measures such as back- blows, abdominal thrusts, or chest thrusts were used to compare the validity of the conclusions and the strong (but unfounded) recommendations made in the paper to continue to use first aid measures in deference to the LifeVac™ device, even in cases where they have failed. Other studies have shown that abdominal thrusts (considered the most effective in the world for the management of upper airway obstruction after the failure of back-blows in all patients over the age of 1 year) are only effective in ≤71% of cases when used by health professionals (vs. LifeVac 97%–100%—Patterson, et al.).[5] For decades (until removed after being challenged) the Australian Resuscitation Council used the flawed conclusions of another similar cadaver study (Langhelle, 2000, *Resuscitation*, **44**, 2, 105–108),[8] as evidence for their own bespoke, unevidenced "chest thrusts" technique. The conclusion of the study when comparing abdominal thrusts with chest compression was simply that the airway obstruction is more easily removed postmortem, however, this was cited to prove that abdominal thrusts have likewise "no efficacy." Likewise, the study and conclusions drawn by Ramaswamy, merely highlight the variability and unsuitability of cadaver studies alone in assessing airway obstruction removal efficacy. In this single cadaver study, the object was placed in the in trachea of a deceased person where an obstruction is only removable with a laryngoscope and Magil forceps and not by any first-aid measures or LifeVac. In a cadaver, the upper sphincter muscles no longer function, so any suction is dissipated into the esophagus. Additionally, the two objects, where no efficacy was recorded, were likely to be too small to fully block an adult trachea and may not have resulted in an actual choking. No evidence was presented as to the relative size of the objects vs the anatomical dimension of the structures in the cadaver.
7. Although the study originated outside Australia, it has already been cited in Australia as "proof" that first aid measures are the preferred method for the removal of upper airway obstruction, exclusively. However, Australia (and New Zealand, i.e., ANZOR cooperative) are the only two countries in the world that do not recommend abdominal thrusts in the management of airway obstructions. This position is divergent to the international scientific consensus and detailed evidence reviews. Rather, the ARC has replaced these with unevidenced versions of "chest thrusts" that have no scientific basis, evidence of efficacy, or clinical evaluation, but are assumed to have absolute efficacy, but are less than 50% successful in severe upper airway obstructions, failing repeatedly and resulting in multiple deaths and permanent cerebral injuries. Australia does not have an evidence-based method for the relief of upper airway obstruction after the failure of back-blowback blows. LifeVac™ is backed by more published research and evidence of efficacy that these locally recommended measures.
8. A further indication of a lack of the quality of this research methodology and the extrapolation of false conclusions in this study is the suggestion by reference to a false assumption made by Dunne et al. (but accepted without question by the authors of this study) that "transitioning of a choking patient from upright to a supine position may cause further complications to the airway." However, there is no necessity or instruction for the LifeVac™ that requires

the application of the device with the patient placed in a supine position. This may be necessary if they have a decreased level of consciousness (LOC) but the LifeVac™ device (as per the IFU) can be used in a seated or standing position and even on oneself). Even if the patient must be transitioned to a supine position in the case of a decreased LOC it is mere speculation that this would cause complications in the airway. Presumably when using abdominal thrusts, the same requirement in the case of a decreased LOC is required to effectively apply the technique, however, the authors do not assert that this also "may" (speculative) create complications.

9. This recent study by Ramaswamy et al., also suffers a common problem in this type of literature. That is a poor understanding of the medical device regulatory process and risk management regime, and the resulting differences in methodology and risk between regulation and BLS recommendations. Medical devices are assessed and regulated under a risk management framework and are subject to evidence review and continuing surveillance, monitoring, and mandatory reporting of harm and/or failure. BLS guidelines (including choking guidelines) are all based low-quality evidence, and all considered to be weak recommendations at best. BLS treatment recommendation and guidelines are not subject to any surveillance, testing, reporting, or monitoring for efficacy and/or complications. Furthermore, resuscitation organizations and/or research academics are not regulators of medical devices (or anything else). The constant claim of these studies is invariably that "*more research needs to be conducted before the LifeVac is accepted*." It is not surprising therefore that such researchers have not yet been able to describe a study (short of an RCT on live subjects) that could be undertaken ethically that would satisfy the bar required to support the adoption of the LifeVac™ device. When continuing the attempt to solve a Rubik's cube with a baseball bat, you will never reach a logical conclusion. So too is trying to assess the efficacy of a device, based on opinion alone, considering the LifeVac™ has already shown efficacy and is monitored and controlled by actual regulators.

4 | CONCLUSIONS

With over 1600 documented case documented reports of saves using the LifeVac™ airway clearance device, including over 1000 of uses on children with no reports of failure or harm (including novice users and medical personnel conducting patient assessments after use) and used mostly by individuals who have been trained and implemented first aid measures (without success) prior to use of the LifeVac; it is anomalous that a single cadaver study of this type (low-level of evidence) should be considered definitive or that its results and conclusions are valid. The poor research methodology and methods used, coupled with the heavy reliance on the flawed conclusions and the errors of other previous authors (such as Dunne et al.) do not add to our understanding of the efficacy or role of the LifeVac™ device in severe upper airway obstructions.

FUNDING INFORMATION

No specific funding or gratuity has been received or directed for this manuscript. A rebuttal to LifeVac conclusions made in published article.

CONFLICT OF INTEREST STATEMENT

The author is the owner and director of LifeVac Australia.

Simon John Gould Dip. Paramedical Science

Australian Resuscitation Advisory Network, Belmont, New South Wales, Australia

Correspondence
Simon John Gould, Australian Resuscitation Advisory Network, Unit 7, 468 Pacific Highway Belmont, NSW, 2280 Australia.
Email: simon@lifevac.net.au

ORCID

Simon John Gould https://orcid.org/0000-0003-4082-922X

REFERENCES

1. Lih A III, Brody EP Jr, Millspaugh R, Lih-Brody L. LifeVac—A Novel Apparatus for the Resuscitation of a Choking Victim.
2. Ramaswamy A, Done A, Solis R, Srikanth M, Olinde L, Belafsky P. The efficacy of two commercially available devices for airway foreign body relief: a cadaver study. *Laryngoscope Investig Otolaryngol*. 2023;8(3):708-711.
3. Brody E Jr. (BS. Mech Eng, Cooper Union, MS. comp Sci, NYU Polytechnic). Vacuum generated by LifeVac apparatus in a closed system versus pressures generated by chest compressions and Heimlich manoeuvre in cadavers with complete airway obstruction.
4. Dunne CL, Peden AE, Queiroga AC, Gomez Gonzalez C, Valesco B, Szpilman D. A systematic review on the effectiveness of anti-choking suction devices and identification of research gaps.
5. Patterson E, Tang HT, Ji C, Perkins GD, Couper K. The efficacy and usability of suction-based airway clearance devices for foreign body airway obstruction: a manikin randomised crossover trial. *Resuscitation J*. 2020;5:100067.
6. van de Voorde P. A 'foreign body' in the 'foreign body airway obstruction' algorithm. Ghent University Hospital, Federal Department of health, Belgium. *Resuscitation J*. 2020;153:258-259. doi:10.1016/j.resuscitation.2020.05.030
7. Song YK, Jo DH. Current and potential use of fresh frozen cadaver in surgical training and anatomical education. *Anat Sci Educ*. 2022;15:957-969. doi:10.1002/ase.2138
8. Langhelle K, Sunde L, Wik PA. Steen, airway pressure with chest compressions versus Heimlich manoeuvre in recently dead adults with complete airway obstruction. *Resuscitation*. 2000;44(2):105-108.