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Review

A systematic review on the effectiveness of anti-choking suction devices and identification of research gaps

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Abstract

Aim: Despite an obstructed airway (choking) being a relatively preventable injury, it has a considerable mortality burden globally, with increasing incidence. Given new technologies in choking management, this systematic review aimed to assess current literature on the effectiveness of anti-choking suction devices at relieving obstructions.

Methods: Ovid MEDLINE, Embase, PubMed, The Cochrane Library, SCOPUS, Web of Science, CINAHL Plus and the English websites of the devices were searched on September 23, 2019. Studies were included if they reported the anti-choking devices' dislodgment success rate (primary outcome) or associated adverse events (secondary outcome). Articles, conference abstracts or technical reports were included if peer reviewed. Certainty of evidence was assessed in accordance with GRADE.

Results: Five studies satisfied the inclusion criteria for this review. Two studies (40%) reported findings of a single centre mannequin trial, one (20%) of a single centre cadaveric trial, and two (40%) were case series. Cohen's Kappa for the first and second round of screening was 0.904 and 0.674 respectively. Although several devices have been manufactured worldwide, the LifeVac© has been most extensively studied, with a combined dislodgement success rate of 94.3% on first attempt. However, certainty of evidence for the primary outcome was evaluated as very low.

Conclusions: There are many weaknesses in the available data and few unbiased trials that test the effectiveness of anti-choking suction devices resulting in insufficient evidence to support or discourage their use. Practitioners should continue to adhere to guidelines authored by local resuscitation authorities which align with ILCOR recommendations.

Keywords: Airway management, Airway obstruction, Choking, Basic life support, Layperson intervention, Systematic review, Suction device, Anti-choking device

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Introduction

A foreign body airway obstruction (FBAO), resulting in choking, represents a life-threatening emergency. Despite being a preventable injury, it has a considerable mortality burden globally and some studies show that its incidence is on the rise.[1,2] The risk of injury applies to both young and old, as data from the United States of America demonstrated that choking was the third leading cause of unintentional death between 2000 and 2013 for adults older than 65, and also a significant cause of mortality/morbidity among children less than 3.[3,4]

Those responding to first aid injuries need to be aware that individuals may present with varying degrees of airway obstruction requiring different interventions. If left untreated, individuals suffering from severe obstructions will quickly progress to unresponsiveness and death.[5,6] Due to this short time-to-mortality once the airway is obstructed, public intervention by bystanders is a critical aspect to prevent adverse outcomes.

The quest to find a universally accepted and successful technique dates back decades.[7] In 1975, Dr. Heimlich outlined his proposed technique of using sub-diaphragmatic pressure to forcefully expel objects from a patient's airway. Before this maneuver, the accepted technique was tracheotomy or bronchoscopy — both of which required a skilled physician to be in your dining room at the moment of obstruction. The public resorted to uninformed, untrained back slaps in hopes of saving their loved ones. Heimlich's maneuver (which later became known as abdominal thrusts) gained quick public acceptance as the anecdotal evidence began to pour in.[7,8]

Four and a half decades later, much has changed in our medical system, and how new interventions are scrutinized before becoming evidence-based recommendations, yet little has changed about our response to a foreign body in the airway.

Influenced by the Consensus on Science with Treatment Recommendations (CoSTR) produced by the International Liaison Committee on Resuscitation (ILCOR), regulatory authorities form evidence-based guidelines for the management of a FBAO.[5,6] Such content is included in their basic life support or first aid programs. Abdominal thrusts are still one of the first-line techniques for a severe obstruction, combined with focused back blows and chest thrusts.[5,6]

There is some anecdotal and retrospective evidence to support these recommendations.[9–15] One review of a prehospital database studied obstructed airway injuries that Emergency Medical Services (EMS) responded to. In that study, 50% of the obstructions were relieved before the paramedic services arrived and intervention by EMS with abdominal thrusts increased the success rate to greater than 85%.[9] Through advanced intervention by EMS, this study reported less than 4% mortality.[9,16]

It is in the public interest for new interventions to be developed and, if rigorously demonstrated to be effective and safe, then be incorporated in future guidelines and introduced into practice. One proposed intervention for the management of a FBAO is anti-choking suction devices. Several developers have manufactured these externally applied, non-powered, portable suction devices. The premise is to generate a negative pressure system in the oral airway proximal to the obstruction in contrast to the positive pressure force from below that is currently recommended (e.g., abdominal thrusts) with the aim of producing the same result — relief of the airway obstruction.

As these emerging technologies become more widely available to the public, it is important that the existing evidence regarding their use is readily evaluated. Through this systematic review, the authors aim to assess the current literature available on the effectiveness of anti-choking suction devices on relieving foreign body airway obstructions in humans to ensure best practice in airway management.

Methods

A systematic review of both peer-reviewed and grey literature was undertaken to identify the evidence around the effectiveness of negative pressure anti-choking devices. The methodology utilized is outlined below. The protocol was registered with PROSPERO: CRD42019150977.

PICO question

The PICO (Population, Intervention, Comparator, Outcome) framework was used to define the review. The question posed by the researchers was: for humans (>1 year old), mannequins or cadavers with foreign body airway obstructions (P), do externally applied, negative pressure, anti-choking devices (I), when compared to traditional techniques (C), have similar dislodgment success rates (O)? Traditional techniques were defined as abdominal thrusts, chest compressions (or thrusts), and/or back blows. The number of attempts required to achieve the primary outcome and any comments regarding delay of advanced life support as a result of the devices' use was noted as well.

The authors recognized that as these devices are still novel, comparison data may be limited; to capture as much information regarding their results, studies without comparison data were also accepted. For the same reason, mannequin and cadaver studies were included to help provide context for any support of these devices in humans (this is an extension of the evidence presented in the ILCOR CoSTR by Couper et al.).[17]

A secondary outcome was identified as adverse events (e.g., further injuries, hospitalizations, etc.) related to the use of the devices.

Study eligibility

Peer reviewed studies were included if they explicitly reported on the defined primary or secondary outcomes. It was decided a priori that peer reviewed conference abstracts/presentations, case series and technical reports would be included in the final discussion due to the new nature of the subject in question and likelihood that few experimental studies would have been conducted. Articles were excluded if they discussed infants only (<1 year old), used animal models, only reported pressure values generated by the devices, were reviews (e.g., literature, systematic, narrative) or were of non-English language.

Search strategy

Ovid MEDLINE, Embase, PubMed, The Cochrane Library, SCOPUS, Web of Science and CINAHL Plus databases were searched from inception to September 23, 2019. Combinations of subject headings and keywords were used for each database and included: "airway obstruction", "foreign bodies", "respiratory aspiration", "choking",

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"lifevac", "lifewand", "dechoker", and "anti-choking" amongst others. The complete search strategy is outlined in Supplementary material 1.

Additionally, English language websites associated with the devices' manufacturers were searched on September 23, 2019 to capture any additional research not published. Supplementary material 2 includes a complete list of websites searched.

Study selection and processing

Titles and abstracts were screened independently by two authors (CD & ACQ) to identify studies that met inclusion criteria. Following this, a full-text reading was conducted to determine which studies would be included in the final analysis (CD & CGG). In the case of a disagreement between authors, a third reviewer assessed the abstract/article and reached a final decision (AP).

Data collection and analysis

Data from each study was extracted and collated by one of the authors (CD) while another independently assessed for accuracy (CGG). From the experimental studies which reported the primary outcome, data was extracted which was relevant to the PICO question and subsequently, these studies were then evaluated for their overall certainty of evidence using the GRADE system.[18] Randomized interventional trials were to be assessed for bias in terms of the primary outcome using the suggested method described in the Cochrane handbook.[19] Non-randomized trials were assessed using the RoBINS-I tool (with the additional element of risk of bias due to industry involvement).[20]

Extracted data from the case reports included what was reported regarding the patient demographics, medical comorbidities, device used, results of the intervention (and of any comparison techniques), and adverse events. For included case series, the risk of bias was assessed using the tool described by Murad et al. and assigned a low, moderate or high rating in accordance with GRADE recommendations.[18,21]

Results

Search results

A total of 258 articles were identified using the above search strategy. 234 of these were from the electronic databases, and the remaining articles were identified from a review of the devices' international websites. The initial abstract screening for relevance yielded 21 articles which were potentially applicable to the research objective.

Full-text analysis yielded five studies that met inclusion criteria for the review (with eight excluded for studying the incorrect population, six for not reporting data relevant to the primary or secondary outcomes and two for not meeting study eligibility criteria).[22–26] Fig. 1 (PRISMA diagram) summarizes the results of the article search and selection.[27]

Publication characteristics

Of the five studies that satisfied the inclusion criteria: two studies reported the findings of a single centre mannequin trial, one of a single

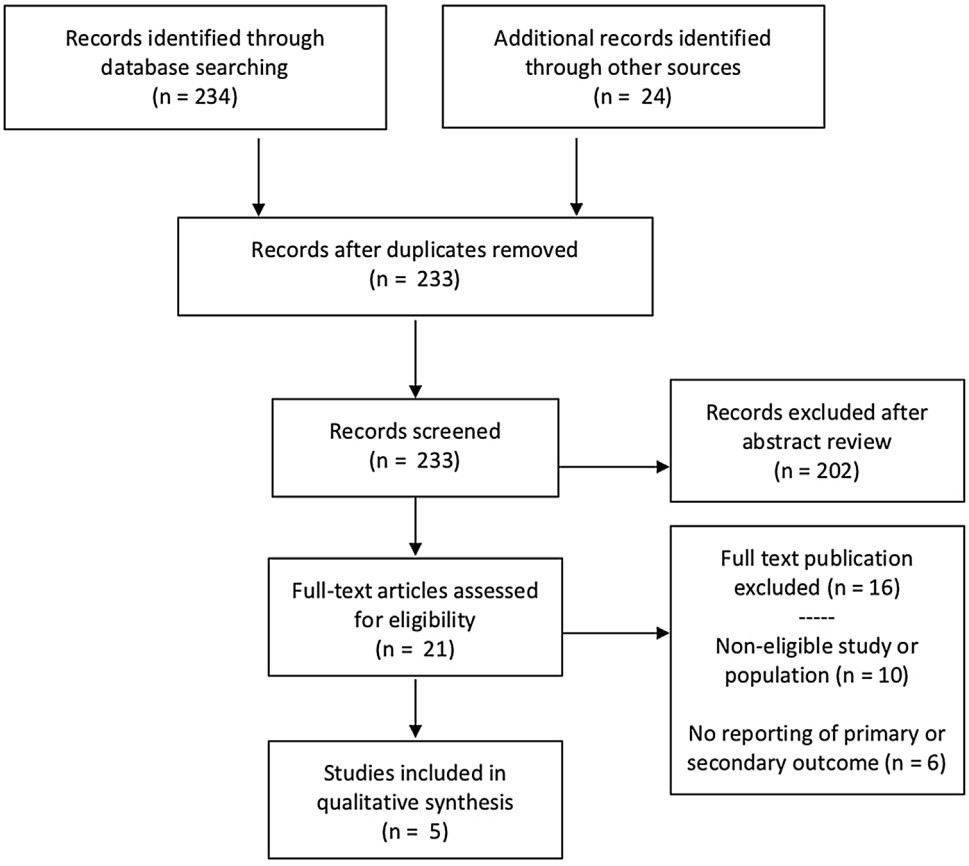

Fig. 1 – Adapted PRISMA diagram outlining the search strategy.[27]

centre cadaveric trial, and two were case series. As there were different reviewers for the first and second rounds of screening, Cohen's Kappa was calculated independently for both, and equated 0.904 and 0.674. This indicates near-perfect and substantial agreement in each round, respectively.

Table 1 outlines the results of any experimental trials from the included studies that measured the frequency which an anti-choking suction device was successful at dislodgement. Combined, the articles document attempted removal of 1050 total airway obstructions with a dislodgement success rate of 94.3% on first attempt with the LifeVac© device.[22–24] No trials reported whether there was a delay in advanced life support occurring as a result of using the devices.

Table 2 outlines the case reports that were identified in the review. Two articles discuss a total of 10 unique case reports, all of which utilized the Lifevac© model to successfully relieve an airway obstruction.[25,26]

Table 3summarizes pertinent data extracted from each individual report included in the case series. Cases 1–3 were deemed by reviewers to be duplicate reports described in both case series. No adverse events were detailed in any of the case reports. However, the reports contain limited/incomplete data and a significant variation exists between each case report relative to the extent of details included.

Risk of bias assessment

No randomized trials were identified in the review. As a result, only the ROBINS-I tool was utilized to assess risk of bias of the non-randomized experimental studies.[20] The results of this assessment are summarized in Table 4.

The critical confounder that was identified was the training of the device operator. One trial (Juliano 2016) acknowledged that a paramedic is the participant in the trial, which likely biases the outcome towards the device, as someone who is experienced with other airway techniques (such as bag-mask-ventilation) would be of higher skill level than the general population.[24] The remaining studies do not clarify who operated the device for the trial.[22,23]

The outcome assessor was not clearly identified in two trials and was the primary investigator in one (Juliano 2016).[22–24] Regardless of their identity, they were unlikely to be blinded as the studies only involved one intervention arm. If the assessor was invested in the trial, coaching could have occurred after unsuccessful attempts which would bias towards more favourable intervention results. In one trial, Juliano (2016), it stated that coaching was provided.[24]

Bias due to industry involvement was present in a number of the included studies. The founder of LifeVac©, A. Lih, is the co-author of one of the trials.[22] Additionally, his relative (L. Lih-Brody) is the primary author of others.[22,23,26] Although this does not eliminate the potential effects of the devices, it does support the need for more independent researchers to conduct their own evaluations.

Based on several categories with concerns for a serious risk of bias from the ROBINS-I tool, the evidence for the primary outcome overall was considered to have a high likelihood of bias.[20]

As shown in Table 2, both case series were also determined to have a high risk of bias. They were assigned this rating due to several identified areas including: unclear selection method of reported patients, incomplete description of the intervention (and co-interventions) received, inadequate outcome reporting, and overall lack of consistent, relevant details regarding patient demographics, interventions and adverse events to allow replication or inference (questions 1–3 and 8 of the tool).[21]

Certainty of evidence

Utilizing the GRADE system, the evidence reported for the primary outcome is summarized in Table 5. Downgrading of the evidence was due to likelihood of significant bias, indirectness of the results and

Table 1 – Summary of experimental studies included in the review.[22–24]

Author (Year)	Title	Device	Population	Primary outcome	Study design & sample size	Results (% [95% CI])
Lih-Brody (2015)	Lifevac: A novel apparatus to resuscitate a choking victim	LifeVac©	Mannequin (Laerdal Choking Charlie)	Number of attempts to successful dislodgement of object	Single centre mannequin trial n = 500	1st Attempt: 94.0% [91.5%, 95.9%] 2nd Attempt: 99.6% [98.5%, 99.9%] 3rd Attempt: 100.0% [CI not reported]
Lih-Brody (2017)	Lifevac: A novel apparatus for the resuscitation of the pediatric choking victim	LifeVac©	Mannequin (Laerdal Choking Adolescent Simulator)	Number of attempts to successful dislodgement of object	Single centre mannequin trial n = 500	1st Attempt: 94.2% [92.0%, 96.0%] 2nd Attempt: 99.4% [98.0%, 100.0%] 3rd Attempt: 100.0% [99.0, 100.0%]
Juliano (2016)	Assessment of the LifeVac, an anti-choking device, on a human cadaver with complete airway obstruction	LifeVac©	Cadaver (F, 71 y/o, BMI 25, Recently deceased, PMHx = Breast Cancer)	Number of attempts to successful dislodgement of object	Single centre cadaveric trial n = 50	1st Attempt: 98.0% [CI not reported] 2nd Attempt: 100.0% [CI not reported]

BMI = Body mass index; Ca = Cancer; CI = Confidence interval; F = Female; n = Number of times foreign body dislodgement was attempted; PMHx = Past medical history; y/o = years old.

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Table 2 – Summary of case series included in the review.[25,26]

Author (Year)	Title	Device	No. of case reports	Risk of bias assessment[21]
Saperstein (2018)	Successful use of a novel device called the LifeVac to resuscitate choking victims - worldwide results	LifeVac©	10	High
Lih-Brody (2015)	Successful resuscitation of choking victims using a Lifevac, a non-powered portable suction device: real world experience	LifeVac©	3	High

No. = Number.

publication bias. As a result, the primary outcome was considered to have very low certainty of evidence.

Discussion

Despite existing for at least five years, there was scarce literature available testing the portable, non-powered, anti-choking suction devices. Of the ones that have been manufactured worldwide, the LifeVac© was the only with peer reviewed data available (a summary of the available devices can be found in Supplemental material 3). Although there was other data available online that was assessed during the screening phase of the review, it was excluded as a result of being published directly by the manufacturers without peer-review oversight.[28,29]

On initial review of the data, there appeared to be some support for the utility of the device in relieving foreign bodies from the airway. However, a more detailed review of the studies demonstrated a very low certainty of evidence for its use.

The prior training of the device operator was considered a critical confounder as no formal certification is provided to use these devices as is provided for other practical techniques learned through First Aid courses. In theory, this device could be purchased and used by someone with no medical knowledge. If the trials were conducted by someone with advanced medical training or who had received instruction/practice on the specific device prior to the trial, this would

Table 3 – [a] A summary of data extracted from case series detailing the use of anti-choking devices.[25,26]

Year	Age/gender	Medical comorbidities	Foreign body	Intervention data	Comparison data	Adverse events
[b]N.d.	80 F	Dementia	Food bolus	Removed with one attempt of LifeVac©	Back slaps twice before device	No adverse events
[b]N.d.	80 F	Dementia	Not reported	Success with LifeVac© (attempts unknown)	Not reported	Not reported
[b]N.d.	70 M	Parkinson's disease	Food	Success with LifeVac© (attempts unknown)	Not reported	Not reported
2015	31 F	Wheelchair bound, "dysphagia"	Tuna sandwich	Success with LifeVac© (attempts unknown). Patient supine.	Abdominal thrusts (attempts unknown) before device	Not reported
2017	60 F	"No medical issues"	Piece of meat	Removed with one attempt of LifeVac©. Patient supine.	Abdominal thrusts (attempts unknown) before device	No adverse events
2017	80 M	Parkinson's disease	Meat	Removed with four attempts of LifeVac©	5 back blows before 5 abdominal compressions before device	Not reported
2017	"Elderly" M	In a wheelchair	Sandwich	Success with LifeVac© (attempts unknown).	Reports unable to do abdominal compressions due to wheelchair	No adverse events noted following a medical exam
2017	40 F	Not reported	Piece of garlic	Removed with three attempts of LifeVac©	Abdominal thrusts and back blows before device (attempts unknown)	No adverse events
N.d.	70 F	Huntington's disease	Sandwich	Removed with three attempts of LifeVac©	Not reported	Required CPR but no adverse events reported in hospital and returned to the home the next day
N.d.	68 M	"Downs Syndrome" (Trisomy 21), Wheelchair	Piece of chocolate	Removed with two attempts of LifeVac©	Not reported	No adverse events

CPR = cardiopulmonary resuscitation; F = female; M = male; N.d. = No date.
[a] *Note*: data reported here is drawn directly from case series using the same language, and is not verified/corrected for medical accuracy.
[b] Indicates that these case reports appear in both Saperstein (2018) and Lih-Brody (2015).

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Table 4 – Risk of bias assessment utilizing the ROBINS-I tool.[20]

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviation from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selected reporting of results	Industry involvement (other potential sources)
Lih-Brody (2015)	Serious	N/A	Serious	Low	Low	Serious	Low	Serious
Lih-Brody (2017)	Serious	N/A	Serious	Low	Low	Serious	Low	Serious
Juliano (2016)	Serious	N/A	Serious	Low	Low	Serious	Low	No information

Table 5 – Summary of findings for the primary outcome.

Anti-choking suction devices versus traditional methods at relieving foreign body airway obstructions

Outcome	Comparative success		Number of participants (studies)	Certainty of evidence (GRADE[a])	Comments
	Anti-choking suction device	Traditional methods			
Dislodgement success rate on first attempt (%)	Cadaver or Mannequin 94.3%	–	1050 (3)	+OOO Very Low[b]	No comparison arm included in any trial
	Human –	–	0	–	

High certainty — We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty — We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty — Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low certainty — We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the.
[a] GRADE Working Group Grades of Evidence.[17]
[b] All studies were evaluated to have multiple high risk of bias, as well as being not generalizable to humans as conducted on cadavers or mannequins (indirectness). Two studies had potential publication bias due to involvement of industry.

trend the data towards a higher success rate as the device learning curve would be minimized.

The indirectness of evidence presented by the two mannequin trials was another indication for downgrading of certainty.[22,23] When considering the soft tissues of a human airway, there exists a number of physiological and mechanical differences from a rigid plastic mannequin. These create the possibility of a difference in effect seen in the mannequin studies compared to living humans and makes the data less generalizable. Even the relative comparability between preserved cadavers and live human, may be variable based on specimen preservation technique and the directness of evidence can be questioned for them as well.

It is worth noting that none of the experimental trials included a comparison arm.[22–24] It is not clear if the foreign bodies were lodged in such a way that traditional methods (e.g., abdominal thrusts, back blows and chest thrusts) would be unsuccessful. The anti-choking devices are frequently cited for use only when standard resuscitation efforts have failed.[30–32] If the objects were lodged in such a way that standard protocols would have worked then the results generated do not represent situations where the device is being promoted to be used.

The foreign bodies studied in these experimental trials all were solid.[22–24] While these likely represent the leading causes of obstructed airway in adults and children, food tends to be semi-solid as mastication and partial digestion has begun by the time it passes the oropharynx. It would be beneficial to study the effect of the negative pressures generated from the anti-choking devices on partially digested material (or semi-solid).

Each experimental trial, using either mannequins or cadavers, studied the anti-choking device's success with a patient in the supine position.[22–24] The studies frequently compare the utility of the device to traditional methods, all of which are performed on a standing person who has a severe obstruction. Transitioning a conscious, standing individual who is choking to a supine position to use the device may be difficult and could lead to greater respiratory distress. If such a device were to be used supine, it would be in direct comparison to CPR on an unconscious person as per guidelines.[6,7] Delaying CPR to retrieve the device and attempt another technique to alleviate the obstruction is against current recommendations. This may further exacerbate hypoxic injury (as by beginning CPR you not only perform an obstruction alleviating technique, you may get partial oxygenation through ventilation attempts).[6,7]

For the 10 case reports, the lack of specifics in medical follow up is concerning. As an example, one report claims that a person had CPR performed on them (without a discussion on length, or other medical interventions) but states that no adverse effects were caused as a result. It is not clear from the report whether this detail is via word-of-mouth or a review of medical records.[25]

Anecdotal, self-reporting data is associated with a voluntary response bias which tends towards extremes of opinions.[33]

Saperstein (p.1) comments that, "... the unit has been used successfully 100% of the time with limited to no side effects".[25] As these devices are being placed in more ambulances, nursing care homes, etc. this is an impossible claim to quantify as there exists no mandatory reporting of the device's use to the manufacturers.

It is concerning that the same websites promoting anti-choking devices are actively advising people that it is okay to diverge from their first aid training because their product is registered as a medical device with certain agencies (e.g., the Food and Drug Administration [FDA-USA], or Health Canada).[31,32] One website goes further to encourage instructors of first aid programs to incorporate these devices into their first aid courses despite not being in the curriculum.[31] First aid regulatory organizations, instructors and participants should be aware of this claim and its inaccuracy. If instructors or providers of first aid diverge from their published course content/guidelines and insert their own curriculum, then they could be exposed to risk in the event of a negative outcome.

Although the data is presently insufficient for the authors to make a recommendation to support or discourage the use of the anti-choking devices in clinical use, there is the potential that further research in this area would be of benefit. This recommendation for use in research only settings is in accordance with the GRADE system.[18] Future studies should have a clear protocol described prior to initiation, include a comparison/control arm, have a systematic outcome & adverse events reporting strategy and be independent of industry. Until such time when the uncertainty regarding the devices is clarified through research, they should not be used regularly outside of this context.[18]

Limitations

This systematic review was limited by the examination of peer-reviewed literature from seven databases and the websites of manufacturers in the English language only. There may be additional relevant literature published in the non-peer reviewed literature and in other languages. Conference abstract and technical report data was included in the review as a way of capturing as much detail as possible regarding these new technologies, however, the information available within is more limited and may not include all pertinent details.

Conclusion

There exist minimal systematic, unbiased trials that test the effectiveness of anti-choking suction devices and current case report data is incomplete and tended towards a positive voluntary reporting bias. No studies were found which compared the devices to traditional techniques used to intervene on foreign body airway obstructions.

As a result, there is no high-quality medical evidence at present to support or discourage the use of negative-pressure anti-choking devices by bystanders providing basic life support (BLS) or healthcare providers intervening with advanced life support (ALS).

Disclaimer

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

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Conflict of interests

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.resuscitation.2020.02.021.

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