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Review

Effectiveness of ultraportable automated external defibrillators: A scoping review



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Abstract

Background: Ultraportable automated external defibrillators (AEDs) are a new generation of defibrillators that are small, lightweight, easy to carry on one's person, and affordable for personal and home use. They offer the opportunity to increase AED availability in case of out-of-hospital cardiac arrest (OHCA) and therefore improve outcomes.

We aimed to review evidence supporting the potential effect on outcomes and the performance of these ultraportable AEDs.

Methods: We searched Ovid Medline, Embase and Cochrane databases from 2012 to July 4th, 2024 to identify any studies related to ultraportable AED. The population was adult and children with OHCA who were treated with an ultra-portable AED. All outcomes were accepted. We limited study designs to randomized controlled trials and non-randomized studies. Data charting was done by the primary author using standardized data abstraction forms.

Results: The search strategy identified 54 studies (Pubmed = 26, Embase = 28, with 19 duplicates). We included three articles in the final review. One study was a medico-economic simulation study including 600,000 simulated patients, one is the study protocol of cluster randomized trial of providing ultraportable AEDs to first responders and one is an abstract with preliminary results of this trial reporting 1805 community responders recruited, 903 allocated to ultraportable AED. No studies to date have reported patient outcomes.

Conclusion: This review found no evidence of ultraportable AED device performance, clinical or safety outcomes. There is an urgent need for further research to determine the safety and effectiveness of ultraportable AEDs.

Keywords: Cardiopulmonary resuscitation, Heart arrest, AED

Introduction

Early defibrillation is associated with a large increase in survival from out-of-hospital cardiac arrest (OHCA).^{1–4} If defibrillation occurs within 3 to 5 min of collapse, survival rates as high as 50–70% have been reported.^{3,4} Emergency medical services (EMS) response time rarely allows defibrillation to occur in such a short time.⁵ To date, public access defibrillation (PAD) programs are ineffective on their own, with low rates of OHCA patients receiving defibrillation by bystanders.⁶ A paradigm shift in automatic external defibrillator (AED) deployment is needed to improve outcomes.^{7,8}

Current strategies to decrease time to defibrillation in OHCA include using drones to delivery the AEDs and use of community volunteer responders dispatched by mobile apps to perform early bystander CPR and defibrillation.^{9–11} Recently, several companies have started advertising “ultraportable” AEDs for personal use by lay people or equipping community volunteer responders. They advocate that, compared to standard AEDs, these devices offer a lower cost and weight, allowing for easier portability and availability in homes, where most OHCA occur. However, these devices may be limited to a certain number of shocks and lower energy outputs (e.g., restricted to up to 20 shocks and a maximum of 85 J).

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We aimed to review evidence supporting the potential effect on patient outcomes and the performance of ultraportable AEDs.

Methods

Arksey and O'Malley's methodological steps for scoping reviews, with the refinements proposed by Levac were followed to develop the protocol and conduct this review.^{12,13}

The international database of prospectively registered systematic reviews in health and social care (PROSPERO), Medline, google scholar, and open science framework were checked to confirm that no systematic, scoping, or narrative reviews on a similar topic have been published.

This review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR)¹⁴ (Supplement A). The review process followed the written protocol (Supplement B) and applied data screening steps and a standard data abstraction form available on Covidence.¹⁵ Our scoping review comprised of the following steps:

Identifying the research question

The research question was: In adults and children who are in cardiac arrest outside of a hospital does the use of an ultra-portable AED improve patient outcomes?

Identifying relevant studies

The search strategy was developed with assistance from an information specialist from University of Toronto. Key search terms and the search strategy are provided in Supplement C.

After review from the ILCOR BLS Task Force, the search strategy was run on July 4th, 2024. Articles for review were obtained through Ovid MEDLINE(R), EMBASE and Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials from 2012 to July 4th, 2024. We did not search grey literature. Since ultraportable AED are relatively new devices we limited the search to start from 2012.

Study selection

Table 1 explains the eligibility criteria for selecting appropriate articles for this review. The population was adults and children with OHCA who were treated with an ultra-portable AED. All outcomes were accepted. We limited study designs to randomized controlled trials (RCTs) and non-randomized studies (non-randomized controlled trials, interrupted time series, controlled before-and-after studies, cohort studies, conference abstracts and trial protocols).

All citations were uploaded into the Covidence website for screening and duplicates were removed. Included manuscripts described any studies related with ultraportable AED. Manuscripts that did not describe the use or the development of ultraportable AED and articles which described AEDs deliver by drones were excluded. We also excluded manuscripts that were not available in English.

First, two authors (GD, TN) reviewed all titles and abstracts against inclusion and exclusion criteria. For initial screening, limited exclusion criteria were employed to have broader inclusion. After initial screening, all potential eligible full texts were retrieved and further reviewed by two authors (GD, TN) against the same eligibility criteria. Additional citations were searched through hand search of the refer-

Table 1 – Summary of defined inclusion criteria for selecting articles.

| | |
|---------------------|---|
| Population | In adults and children in out-of-hospital cardiac arrest |
| Intervention | the use of an ultra-portable / pocket AED |
| Comparison | |
| Outcomes | all outcomes were accepted |
| Study Design | Randomized controlled trials (RCTs) and non-randomized studies (non-randomized controlled trials, interrupted time series, controlled before-and-after studies, cohort studies) are eligible for inclusion. Non-peer reviewed studies, unpublished studies, conference abstracts and trial protocols are eligible for inclusion. Studies which describe the use of mobile AEDs associated with drone technology are excluded. |
| Timeframe | January 2012 – July 2024 |

ence list of included studies following the initial review. Whenever there was uncertainty about a potentially eligible study, the final decisions were achieved by discussion and consensus.

Data extraction and charting the data

The primary author extracted the data using standardized data abstraction forms and guided by JBI (Joanna Briggs Institute) methodology.¹⁶ The following information was extracted for each included study: year and origin of publication, study design, population and number of included patients, intervention, comparator, outcome, if reported.

Collating, summarizing and reporting the results

An overview of all material reviewed was performed. The authors reviewed the outputs and developed a narrative summary describing the main results, qualities and limits of the evidence identified.

Results

The search strategy identified 54 studies to screen (Pubmed = 26, Embase = 28, with 19 duplicates). We identified 4 articles for full-text review (Fig. 1). One was excluded due to wrong setting (standard AED).¹⁷ We included three articles in the final review.^{18–20} One study was a medico-economic simulation study, one is the study protocol of cluster randomized trial and one is an abstract with preliminary results of this trial (Table 2.). No papers reported on the potential effect on patient outcomes or the performance of ultraportable AEDs.

Health-economic simulation study (n = 1)

A health-economic analysis modeled the impact of a Small AED for Rapid Treatment of a Sudden Cardiac Arrest (SMART) strategy on a simulated patient database (n = 600,000) at low, moderate, and high-risk for OHCA.²⁰ Their results suggest that a SMART approach to prevent fatalities related to OHCA is cost-effective in patients with elevated sudden cardiac arrest risk (annual cardiac arrest risk > 1.5%). They described a smartphone-enabled pocket AED, but as a simulation study, they estimated the performance of the device from conventional AED studies, which limited the applicability of the results to ultraportable AEDs.

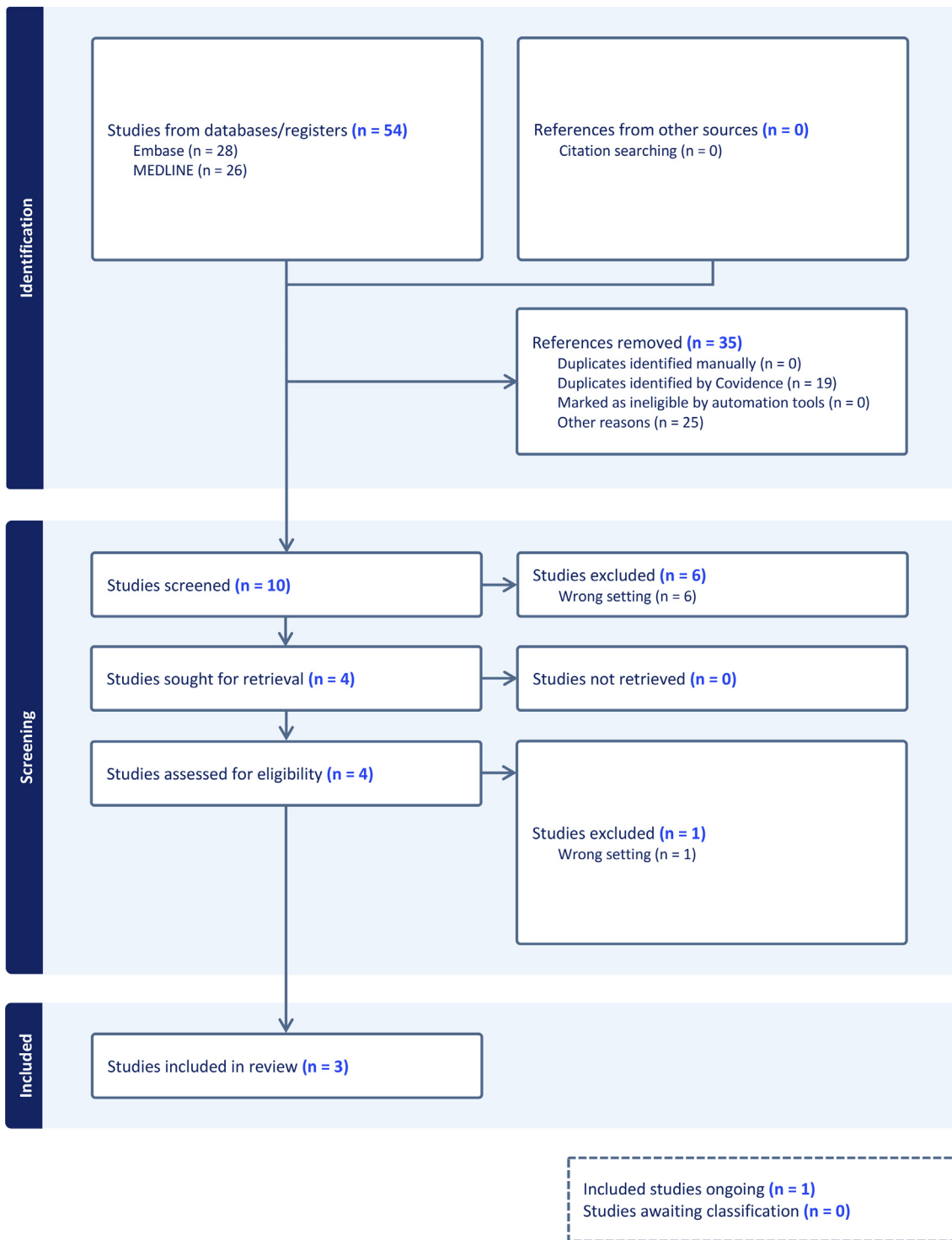


Fig. 1 – PRISMA flowchart. EBM: Evidence-based medicine. Embase: Excerpta Medica Database.

Real world studies with use of ultraportable AED (n = 2)

In two papers, Todd et al. presented the study protocol and preliminary results of the First Responder Shock (FIRST) cluster random-

ized trial.^{18,19} FIRST aims to examine if providing frequently responding volunteer community responders with an ultraportable AED can increase OHCA survival at 30-days.^{18,19} In their abstract

Table 2 – Summary of results.

| Study Details | Study Design | Population | Intervention | Comparator (s) | Outcome measure |
|-----------------|--|--|--|---|--|
| Shaker, 2022; 9 | Economic analysis | 600,000 simulated patients at low, moderate, and high-risk for SCA | Small AED for Rapid Treatment of SCA (SMART) strategy | No SMART strategy | At a 1.6% SCA annual risk, SMART strategy was associated with \$95,251/QALY (societal perspective) and \$100,797/QALY (healthcare perspective). At a 3.5% SCA annual risk, SMART strategy was associated with \$53,925/QALY (societal perspective) and \$59,672/QALY (healthcare perspective). SMART prevented 1,762 fatalities across risk strata (1.59% fatality relative risk reduction across groups). |
| Todd, 2023; 16 | Cluster-randomised controlled trial – Study protocol | Sample size calculation of 714 (357 per arm) | Community responder dispatched with GoodSAM app equipped with an ultraportable AED | Community responder not equipped with AED | Primary outcome will be survival to 30 days. Aim to detect a 7% increase in survival (9% to 16%) |
| Todd, 2023; 19 | Cluster randomized intervention – preliminary trial results (abstract) | 1805 community responders recruited, 903 allocated to CellaAED | Community responder dispatched with GoodSAM app equipped with an ultraportable defibrillator (CellAED) n = 903 | Community responder not equipped with AED | Unfinished study. 1,788 alerts to CellaAED participants, 104 arriving before EMS. |

AED: Automated External Defibrillator, QALY: Quality Adjusted Life Year, SCA: Sudden Cardiac Death.

1,788 alerts have been sent to CellaAED participants, with 104 responders arriving before EMS. No data on the performance of the device or patient outcomes were reported.

Discussion

Ultraportable AEDs are a new generation of defibrillators that offer an opportunity to enhance public access defibrillation and community volunteer responder programs, increase home AED availability with potential to improve patient outcomes. However, in this review we found no evidence of device efficacy or real-world evidence of their use or impact.

The use of AEDs by trained lay responders in community-based PAD programs has been shown to increase survival after sudden cardiac arrest. When sudden cardiac arrest is witnessed and an AED is immediately available impressive survival with favorable neurologic outcome results have been reported.^{3,4,21} Programs to develop layperson-enacted CPR-response plan by adding AEDs and AED training can increase the number of survivors of OHCA in public locations.²² Unfortunately, the large majority of cardiac arrest occur at home, and to date access to home AED has not been shown to be associated with improved outcomes.²³

Bystander CPR before EMS arrival has increased in industrialized countries and can be observed up to 70% of OHCA. Despite these improvements, community defibrillation rates usually remain low (less than 10%).²⁴ In a systematic review and meta-analysis, Squizzato et al. observed that dispatching citizen first responders using mobile phone technologies is associated with an increase of AED use.²⁵ The strategy assessed in the FIRST trial to improve volunteer community ability to provide early defibrillation is novel.¹⁸ Volunteer community responders alerted using mobile apps could,

in addition to providing early CPR, be the carriers of small, affordable AED and decrease time to first shock. A recent RCT and observational research shows AED use does not improve when responders are sent to retrieve an AED on the way to the scene.²⁶ Further research is required to explore if the widespread deployment of ultraportable AED to volunteer community responders will increase AED use before EMS arrival on scene and translate to improved patient outcomes.

This review highlights the lack of available data on the effectiveness and safety of such devices. Device registration with regulatory authorities alone does not provide evidence of device performance in real-world settings. As the success of defibrillation is related to several factors including shock energy, transthoracic impedance, defibrillator pad size and anatomical location, diagnostic accuracy for shockable rhythms and the duration the person has been in cardiac arrest. Clinical research is required to demonstrate the clinical efficacy of ultraportable AEDs.

Limitations

This scoping review has some limitations that should be considered when interpreting the findings. This review focused on peer-reviewed studies and excluded gray literature which may have restricted the number of included studies. We limited our review to include only publications which had an English language abstract available. As such, it is possible that we missed studies published in other languages and not translated.

Conclusion

This review found no evidence of ultraportable AED device performance, clinical or safety outcomes. There is an urgent need

for further research to determine the safety and effectiveness of ultraportable AEDs.

Disclosure statement

The authors declared no conflict of interest related to this work. GDP is an Editor and JEB an Editorial Board Member of Resuscitation. GDP is Editor-in-Chief, JEB an Editor and KD and TO are Editorial Board Members of Resuscitation Plus.

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CRedit authorship contribution statement

G. Debaty: Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **GD. Perkins:** Writing – review & editing, Visualization, Validation, Methodology, Investigation, Data curation, Conceptualization. **K.N. Dainty:** Writing – review & editing, Methodology, Investigation, Conceptualization. **T. Norii:** Writing – review & editing, Visualization, Investigation, Data curation, Conceptualization. **T.M. Olasveengen:** Writing – review & editing, Visualization, Validation, Supervision, Methodology, Conceptualization. **J.E. Bray:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.resplu.2024.100739>.

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