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Biphasic Truncated Exponential Waveform Versus Biphasic Rectilinear Waveform Monitor/Defibrillators: Clinical Effectiveness, CostEffectiveness, and Guidelines

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Authors: Ke Xin Li, Melissa Walter

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Research Questions

- 1. What is the comparative clinical effectiveness of biphasic truncated exponential waveform versus biphasic rectilinear waveform monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings?
- 2. What is the cost-effectiveness of biphasic truncated exponential waveform versus biphasic rectilinear waveform monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings?
- 3. What are the evidence-based guidelines regarding biphasic waveform monitor/defibrillator for patients at risk of arrythmia or cardiac arrest in emergency medical service settings?

Key Findings

Two relevant systematic reviews were identified regarding the comparative clinical effectiveness of biphasic truncated exponential waveform versus biphasic rectilinear waveform monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings. Three evidence-based guidelines were identified regarding the biphasic monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings. No relevant health technology assessments randomized controlled studies, non-randomized studies, or economic evaluations were identified.

Methods

A limited literature search was conducted by an information specialist on key resources including Medline, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were biphasic waveforms and defibrillation. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2010 and June 29, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

| Population | Patients of all ages at risk of arrythmia or cardiac arrest in emergency medical service settings |
|--------------|---|
| Intervention | Q1-2: Biphasic truncated exponential waveform monitor/defibrillators Q3: Biphasic waveform monitor/defibrillators (e.g., biphasic truncated exponential waveform, biphasic rectilinear waveform and biphasic pulsed waveform) |
| Comparator | Q1-2: Biphasic rectilinear waveform monitor/defibrillators Q3: Not applicable |



| Outcomes | Q1: Clinical effectiveness (e.g., patient safety; risk; side effects; morbidity; mortality) Q2: Cost-effectiveness (e.g., quality-adjusted life years) Q3: Recommendations regarding the use of biphasic waveform monitor/defibrillators |
|--------------|--|
| Study Design | Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines |

Results

Two relevant systematic reviews¹⁻² and four evidence-based guidelines³⁻⁶ were identified regarding the biphasic monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings. No relevant health technology assessments randomized controlled studies, non-randomized studies, or economic evaluations were identified.

References of potential interest that did not meet the inclusion criteria are provided in the appendix.

Overall Summary of Findings

Two of the included systematic reviews 1,2 compared the clinical effectiveness of biphasic truncated exponential waveform to biphasic rectilinear waveform monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings. Authors of one of the systematic reviews found that the biphasic defibrillators from PhysioControl ADAPTIV (biphasic truncated exponential waveform), Philips SMART(biphasic truncated exponential waveform) and ZOLL Rectilinear (biphasic rectilinear waveform) have similar efficacy, probability, energy and number of shocks required to achieve successful atrial fibrillation cardioversion. Authors of another systematic review reported that there were no statistically significant differences between the truncated and rectilinear protocols in restoration of the sinus rhythm.

A summary of the recommendations of the included evidence-based guidelines³⁻⁶ from the American Heart Association,³ the Malaysia Ministry of Health,⁴ the Canadian Cardiovascular Society,⁵ and the International Liaison Committee on Resuscitation⁶ are included in Table 2. Overall, biphasic waveforms monitor/defibrillators are recommended.³⁻⁶

No relevant literature was found regarding the cost-effectiveness of biphasic truncated exponential waveform versus biphasic rectilinear waveform monitor/defibrillators for patients at risk of arrythmia or cardiac arrest in emergency medical service settings.

Table 2: Summary of Relevant Recommendations in Included Guidelines

Recommendations and Supporting Evidence

American Heart Association, 2015³

Part 7: Adult Advanced Cardiovascular Life Support

"8. Management of Cardiac Arrest with Ventricular Fibrillation/Pulseless Ventricular Tachyardia (ie, "shockable" rhythms)... 8.1.1 Defibrillation Strategies for VF/pVT: Waveform Energy and First-Shock Success... Defibrillators (using Biphasic Truncated Exponential, Rectilinear biphasic, or monophasic waveforms) are recommended to treat atrial and ventricular arrhythmias. (Class I, LOE B-NR) (2015 Part 7)



Based on their greater success in arrhythmia termination, defibrillators using biphasic waveforms (Biphasic Truncated Exponential or Rectilinear biphasic) are preferred to monophasic defibrillators for treatment of both atrial and ventricular arrhythmias. (Class IIa, LOE B-R) (2015 Part 7)

In the absence of conclusive evidence that 1 biphasic waveform is superior to another in termination of VF, it is reasonable to use the manufacturer's recommended energy dose for the first shock. If this is not known, defibrillation at the maximal dose may be considered. (Class Ilb, LOE C-LD) (2015 Part 7)"

"18. Tachyarrhythmias...

18.3.1 Synchronized Cardioversion and Unsynchronized Shocks...

Monomorphic VT (regular form and rate) with a pulse responds well to monophasic or biphasic waveform cardioversion (synchronized) shocks at initial energies of 100 J. If there is no response to the first shock, it may be reasonable to increase the dose in a stepwise fashion. This recommendation represents expert opinion. (Class IIb, LOE C) (2010 Part 8)"

Part 11: Pediatric Basic Life Support and Cardiopulmonary Resuscitation Quality 6.10 Defibrillation

"It is reasonable to use an initial dose of 2 to 4 J/kg of monophasic or biphasic energy for defibrillation. (Class IIa, LOE C-LD), but for ease of teaching, an initial dose of 2 J/kg may be considered. (Class IIb, LOE C-EO) (2015 Part 12)"

Part 12: Pediatric Advanced Life Support

6.10 Defibrillation

"It is reasonable to use an initial dose of 2 to 4 J/kg of monophasic or biphasic energy for defibrillation (Class IIa, LOE C-LD) (2015 Part 12), but for ease of teaching, an initial dose of 2 J/kg may be considered. (Class IIb, LOE C-EO) (2015 Part 12)"

Malaysia Ministry of Health. 20114

"The recommended initial energy for synchronized cardioversion (see figure 6) is: ... 100J or greater with biphasic waveform... 10-50J biphasic waveform for AFL" (p. 23) Recommendation strength NR

"5.1.3.3 Cardioversion in patients with implanted pacemakers and defibrillators... Biphasic shocks are preferred because they require less energy for AF termination." (p. 24) Recommendation strength NR

Canadian Cardiovascular Society, 2010⁵

"We recommend that electrical cardioversion may be conducted in the ED with 150-200 joules biphasic waveform as the initial energy setting (Strong Recommendation, Low-Quality Evidence)" (p. 42)

International Liaison Committee on Resuscitation, 2010⁶

"For both defibrillation and AF cardioversion, when using biphasic defibrillators, self-adhesive defibrillation pads are safe and effective and are an acceptable alternative to standard defibrillation paddles." (p. e72) Recommendation strength NR

"There is insufficient evidence to recommend any specific biphasic waveform." (p. e73) Recommendation strength NR

AFL = atrial flutter; ED = emergency department; J/kg = joule/kilogram; LD = limited data; LOE = level of evidence; NR = not reported; pVT = pulseless ventricular tachycardia; VF = ventricular fibrillation; VT =. ventricular tachycardia.

References Summarized

Health Technology Assessments

No literature identified.



Systematic Reviews and Meta-analyses

 Secorun Inacio JF, dos Santos Gomes da Rosa M, Shah J, et al. Monophasic and biphasic shock for transthoracic conversion of atrial fibrillation: systematic review and network meta-analysis. *Resuscitation*. 2016 Mar;100:66-75.
 PubMed: PM26777209

 Al-Khatib SM, Allen Lapointe N, Chatterjee R, et al. Treatment of atrial fibrillation. (Comparative effectiveness review no. 119). Rockville (MD): Agency for Healthcare Research and Quality; 2013: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/atrial-fibrillation_research.pdf. Accessed 2020 Jul 10.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

No literature identified.

Economic Evaluations

No literature identified.

Guidelines and Recommendations

 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Dallas (TX): American Heart Association; 2015 [updated 2019]: https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/. Accessed 2020 Jul 10.

See: Part 7: Adult Advanced Cardiovascular Life Support:

 $\underline{https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/part-7-adult-advanced-cardiovascular-life-support/}$

8.1.1 Defibrillation Strategies for VF/pVT: Waveform Energy and First-Shock Success and 18.3 Electrical Cardioversion

See: Part 11: Pediatric Basic Life Support and Cardiopulmonary Resuscitation Quality: https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/part-11-pediatric-basic-life-support-and-cardiopulmonary-resuscitation-quality/

6.10 Defibrillation

See: Part 12: Pediatric Advanced Life Support:

https://eccguidelines.heart.org/circulation/cpr-ecc-guidelines/part-12-pediatric-advanced-life-support/

6.0 Defibrillation

4. Clinical practice guidelines on management of atrial fibrillation. Putrajaya (MY): Ministry of Health Malaysia; 2011:

http://www.moh.gov.my/moh/resources/Penerbitan/CPG/CARDIOVASCULAR/11.pdf. Accessed 2020 Jul 10.

See: 5.1.3 Direct Current Cardioversion



 Stiell IG, Macle L, CCS Atrial Fibrillation Guidelines Committee. Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010: Management of recent-onset atrial fibrillation and flutter in the emergency department. *Can J Cardiol*. 2011;27(1):38-46. https://www.onlinecjc.ca/action/showPdf?pii=S0828-282X%2810%2900015-2. Accessed 2020 Jul 10.

PubMed: PM21329861

See: Electrical cardioversion (p. 42)

Sunde K, Jacobs I, Deakin CD, et al. Part 6: Defibrillation: 2010 international consensus on cardiopulmonary resuscitation and emergency cardiovascular care science with treatment recommendations. *Resuscitation*. 2010;81(Suppl 1):e71-e85. https://www.resuscitationjournal.com/action/showPdf?pii=S0300-9572%2810%2900451-X. Accessed 2020 Jul 10.
 PubMed: PM20956034

See: Self-adhesive defibrillation pads compared with paddles (p. e72) Biphasic compared with monophasic defibrillation waveform (p. e73)



Appendix — Further Information

Previous CADTH Reports

 200J rectilinear biphasic waveform and 360J truncated biphasic waveform defibrillators: clinical effectiveness and equivalency. (CADTH Rapid response report: summary of abstracts). Ottawa (ON): CADTH; 2010: https://www.cadth.ca/200j-rectilinear-biphasic-waveform-and-360j-truncated-biphasic-waveform-defibrillators-clinical-0. Accessed 2020 Jul 10.

Systematic Reviews – Unclear Intervention

 Morrison LJ, Henry RM, Ku V, Nolan JP, Morley P, Deakin CD. Single-shock defibrillation success in adult cardiac arrest: a systematic review. *Resuscitation*. 2013;84(11):1480-1486. PubMed: PM23876982

Randomized Controlled Trial

Alternative Population

 Deakin CD, Connelly S, Wharton R, Yuen HM. A comparison of rectilinear and truncated exponential biphasic waveforms in elective cardioversion of atrial fibrillation: a prospective randomized controlled trial. *Resuscitation*. 2013;84(3):286-291. PubMed: PM22842285

Alternative Comparators

 Schmidt AS, Lauridsen KG, Adelborg K, et al. Cardioversion efficacy using pulsed biphasic or biphasic truncated exponential waveforms: a randomized clinical trial. *J Am Heart Assoc.* 2017;6(3):e004853.

Non-Randomized Studies – Alternative Comparators

 Lavignasse D, Trendafilova E, Dimitrova E, Krasteva V. Cardioversion of atrial fibrillation and flutter: comparative study of pulsed vs. low energy biphasic truncated exponential waveforms. *J Atr Fibrillation*. 2019;12(3):2172.
 PubMed: PM32435331

Guidelines

Recommendations Not Clearly Stated

- Brugada J, Katritis DG, Arbelo E, et al. 2019 ESC Guidelines for the management of patients with supraventricular tachycardia. The Task Force for the management of patients with supraventricular tachycardia of the European Society of Cardiology (ESC). Eur Heart J. 2020;41(5):655-720.
 https://academic.oup.com/eurheartj/article/41/5/655/5556821. Accessed 2020 Jul 10.
 PubMed: PM31504425
- Cardiac arrhythmias in coronary heart disease. (SIGN publication no. 152). Edinburgh (GB): Scottish Intercollegiate Guidelines Network (SIGN); 2018: https://www.sign.ac.uk/assets/sign152.pdf. Accessed 2020 Jul 10.
 See: 3.3 Defibrillation (p. 7)



14. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014;64(21):e-1-e76.

https://www.sciencedirect.com/science/article/pii/S0735109714017409?via%3Dihub. Accessed 2020 Jul 10.

PubMed: PM24685669

 Morrison LJ, Neumar RW, Zimmerman JL, et al. Strategies for improving survival after in-hospital cardiac arrest in the United States: 2013 consensus recommendations: a consensus statement from the American Heart Association. *Circulation*. 2013;127(14):1538-1563.

https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31828b2770. Accessed 2020 Jul 10.

PubMed: PM23479672

 Soar J, Nolan JP, Bottiger BW, et al. European Resuscitation Council Guidelines for Resuscitation 2015: Section 3. Adult advanced life support. *Resuscitation*. 2015:95:100-147.

See: p. 115

PubMed: PM26477701

Unclear Methodology

17. Lee CYF, Anantharaman V, Lim SH, et al. Singapore defibrillation guidelines 2016. Singapore Med J. 2017;58(7):354-359.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5523087/. Accessed 2020 Jul 10. PubMed: PM28741000