



Simulation and education

Comparative performance assessment of commercially available automatic external defibrillators: A simulation and real-life measurement study of hands-off time[☆]



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ABSTRACT

Purpose: Early and good quality cardiopulmonary resuscitation (CPR) and the use of automated external defibrillators (AEDs) improve cardiac arrest patients' survival. However, AED peri- and post-shock/analysis pauses may reduce CPR effectiveness.

Methods: The time performance of 12 different commercially available AEDs was tested in a manikin based scenario; then the AEDs recordings from the same tested models following the clinical use both in Pavia and Ticino were analyzed to evaluate the post-shock and post-analysis time.

Results: None of the AEDs was able to complete the analysis and to charge the capacitors in less than 10 s and the mean post-shock pause was 6.7 ± 2.4 s. For non-shockable rhythms, the mean analysis time was 10.3 ± 2 s and the mean post-analysis time was 6.2 ± 2.2 s. We analyzed 154 AED records [104 by Emergency Medical Service (EMS) rescuers; 50 by lay rescuers]. EMS rescuers were faster in resuming CPR than lay rescuers [5.3 s (95%CI 5–5.7) vs 8.6 s (95%CI 7.3–10)].

Conclusions: AEDs showed different performances that may reduce CPR quality mostly for those rescuers following AED instructions. Both technological improvements and better lay rescuers training might be needed.

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Introduction

Automated external defibrillators (AEDs) have a key role in out-of-hospital cardiopulmonary resuscitation (CPR). Convincing data supporting the relationship between the widespread use of AEDs and the increase of survival of out-of-hospital cardiac arrest victims have been recently published.^{1,2} Non-professional first responders or lay rescuers are guided in their hands-off/on time by automatic messaging given by AED. However interruption of chest

compression over a substantial period of time is often observed, in order to allow the AED shock advisory system to analyze the patient's rhythm for artifact free electrocardiogram (ECG). This processing results in an accurate indication for shock or immediate chest compression resumption and, during discharge time prevent rescuer from electrocution.^{3–5} Decreasing the duration of pre-shock and immediate post-shock analysis would help to minimize interruptions in chest compression. Indeed, it is well known that pre-shock and peri-shock pauses are independently associated with a decrease in defibrillation success,⁶ with a lower probability of return-to spontaneous circulation (ROSC)⁷ and ultimately, with survival.^{8,9} Variations of even a few seconds produce large effects on survival outcome.⁸ As such, current clinical practice guidelines recommend to reduce as much as possible the hands-off time to less than ten seconds per cycle.^{10,11}

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In 2004, Snyder and Morgan¹² showed that various AEDs models impose wide variations in the hands-off interval, due to differences in AED voice prompting, ECG analysis capabilities, and defibrillator charge times. They concluded that protocol guidance offered by modern AED models varies considerably in ways that may offset the benefits of substantial gains in defibrillation efficacy. They also demonstrated that out of seven different tested models of commercially available AEDs, only one achieved an interruption interval of <10 s. Also, previous studies using AED recordings have shown a median time from last compression until attempted defibrillation, and from shock delivery until resumed chest compression of 20 s and 38 s, respectively.^{13,14} However, current guidelines neither prescribe nor recommend maximum ECG analysis time and capacitor charging time in AEDs to maintain hands-off time within the recommended 10 s time.¹⁰

Some technical improvements have been developed to mostly shorten the pre-shock pauses with promising results: an algorithm that recognizes chest compression interruption allows for faster rhythm analysis.¹⁵ Also, modification in the capacitors charging algorithm during the rhythm analysis could result in shorter hands-off time.¹⁶ However, shortening of post-shock pauses has not been improved. Consequently, our aim was to conduct a comparative performance assessment of 12 modern commercially available AEDs in a manikin model and to compare the bench data with analysis of AED recordings, with particular emphasis to post shock-pauses.

Materials and methods

This study consists of 2 independent parts: the former performed on a manikin, where 12 different commercially available AEDs were tested against the same rhythm scenario; the latter consisted in the analysis of AEDs recordings following the clinical use of the AED (same manufacturers as in the benchmark testing) to evaluate the post-shock and the post-analysis pauses in both lay rescuers and EMS rescuers. The post-shock pause was the time from the delivery of the shock to the first chest compression after the shock. The post analysis pause was the time from the end of rhythm analysis to the first chest compression after the analysis.

AEDs tested

Twelve commercially available AEDs were tested: Rescue SAM and Rescue life AED (Progetti, Turin, Italy); FR2, FR3 and Heartstart (Philips, Eindhoven, Netherlands); 3G Plus (Cardiac Science, Bothell, WA, USA); FRED Easy and FRED Easypoint (Schiller AG, Baar, Switzerland); Lifeline AED (Defibtech, Guilford, CT, USA); HeartSave AD (Primedic, Rottweil, Germany); i-PAD (CU Medical System, Korea); and finally, BeneHeart D1 (Mindray Medical, China). Every AED was equipped with a new battery before the beginning of the study, and the initial automated test was successfully passed. Each AED was updated with the 2015 guidelines. For comparative assessment goals, the benchmark analysis was limited to those AEDs that are mostly used by the local rescue vehicles or that are freely accessible on the territory.

Manikin preparation

An ALS trainer (Laerdal Medical, Norway) was utilized: the manikin was equipped with a rhythm simulator capable of reproducing the following rhythms: ventricular fibrillation (VF), asystole, normal sinus rhythm at 60 bpm, slow monomorphic ventricular tachycardia (Slow VT) at 125 bpm and fast monomorphic ventricular tachycardia (Fast VT) at 225 bpm. For each AED, a set of pads was used and prepared to be connected to the cable of the manikin using

clip connectors. The rhythm was selected and turned on before attaching the AED pads.

Time performance

According to the guidelines, after turning on the AED, the cables were connected to the manikin and the performance for both shockable and non-shockable rhythm was tested. VF, slow VT and fast VT were considered as shockable rhythms, while asystole and normal sinus rhythm were considered as non-shockable rhythms. Moreover, the AED ability to discriminate between shockable vs non-shockable rhythm just before shock delivery was tested. To do so, at the end of the analysis once the shock was indicated, a sudden rhythm change (from VF to normal sinus rhythm) was introduced.

For each of the 3 shockable rhythms (VF, fast VT and slow VT), the analysis time (the time from the cable connection to the message "shock needed" or "not needed"), the charging time (from the message "shock needed" to the lighting of the shock button), the post-shock pause (the time elapsing from the shock delivery to the instruction to resume CPR) and the pads to CPR time (the time from pads connection to the instruction to resume CPR) were recorded.

For non-shockable rhythms, the analysis time (the time from cable connection to the message "shock needed" or "not needed"), the post-analysis pause (the time passing from the end of the analysis to the instruction to resume CPR) and the pads to CPR time (the time from the pads connection to the instruction to resume CPR) were computed.

Each evaluation was repeated three times and the mean performance was then considered for statistical analysis. All the tests were filmed and the time analysis was performed by 2 independent investigators in a blinded fashion. In case of time discrepancy or difference in interpretation, a third investigator was involved and results were determined by consensus.

Real world use of AED

All the consecutive reports available generated by the use of an AED during out-of-hospital cardiac arrests occurred between October 2014 and December 2015 at 2 different sites (Pavia and Ticino) were analyzed and included in this study. Only reports generated by those AED models included in the bench test were considered for analysis. Post-shock and post-analysis pauses were measured from the shock administration or from the notification of shock not needed to the recovery of chest compression, as assessed by ECG artefacts (Fig. 1), respectively. These time intervals were computed and then compared to those measured during the bench tests.

Statistical analysis

Statistical analysis was performed using MedCalc version 11.2.1.0 (MedCalc software bvba). Values are presented as mean \pm standard deviation (SD). T-test and Chi-square test were used for the comparison of continue and categorical variables, respectively. A p value <0.05 was considered as statistically significant.

Results

Rhythm classification

In the manikin simulations, each AED was able to recognize and to correctly diagnose ventricular fibrillation, asystole, normal sinus rhythm and fast ventricular tachycardia (225 bpm); in contrast only 3 out of 12 (25%) AEDs correctly classified a slow VT (125 bpm) as shockable rhythm. When testing the rapid rhythm change during

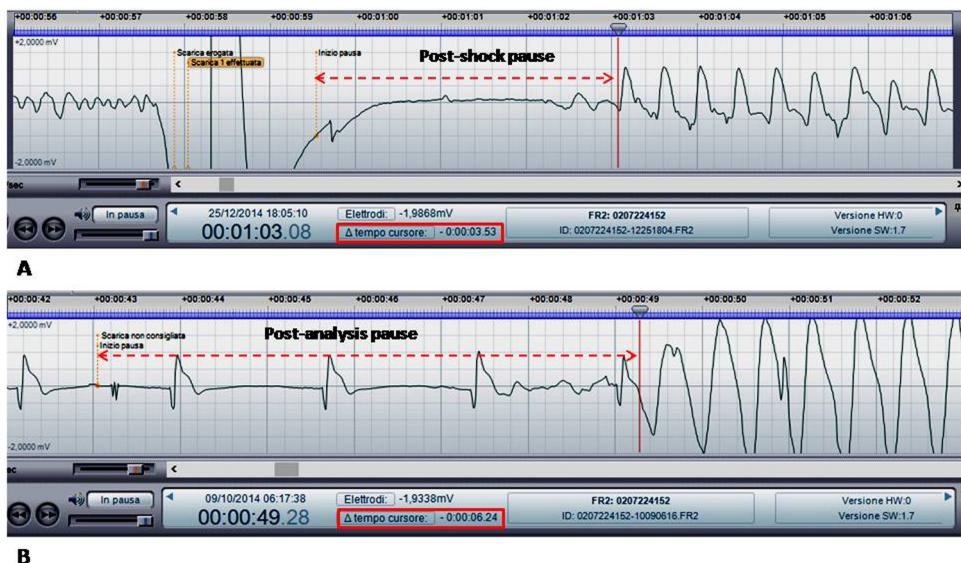


Fig. 1. This figure shows two examples of a Philips FR2 AED report. In panel A, there is a real life example of a shockable rhythm. The third vertical dotted line indicates the end of the shock's artefact. The post-shock pause was measured from this point to the first artefact which most likely represents the resumption of chest compressions. The time indicated in the red rectangle represents the length of the pause (seconds). Panel B depicts an example of a non-shockable rhythm. The dotted vertical line indicates the end of the rhythm analysis. The post-analysis pause was calculated from this point until the first artefact due to CPR resumption. In the red rectangle it is reported the length of the pause (seconds). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

the charging phase from a shockable to a non-shockable rhythm, only 5/12 (41.7%) AEDs appropriately detected the non-shockable rhythm (Table 1).

AED performance for shockable and non-shockable rhythms

There was no difference in the analysis time between shockable and non-shockable rhythms (9.7 ± 1.5 s vs 10.3 ± 2 s; $p = 0.37$).

As far as shockable rhythms is concerned, none of the tested AEDs was able to complete the analysis and to charge the capacitors in less than ten seconds. The mean analysis time was 9.7 ± 1.5 s; the mean charging time was 6.9 ± 3.8 s; the mean post-shock pause was 6.7 ± 2.4 . Therefore the mean pads to CPR time was 23.3 ± 4.2 s. No difference was found between the analysis time during VF or fast VT (9.7 ± 1.5 s vs 9.8 ± 1.3 s, $p = 0.88$).

In 8 out of 12 AEDs (67%), the analysis time was ≤ 10 s during a non-shockable rhythm. The mean analysis time was 10.3 ± 2 s, the mean post analysis pause was 6.2 ± 2.2 s resulting in a mean pads to CPR time of 16.3 ± 3.5 s. The analysis time was similar when testing normal sinus rhythm or asystole (10.4 ± 1.9 s vs 10.3 ± 2 s, $p = 0.91$). Fig. 2 reports the performance for each tested AED model according to shockable and non-shockable rhythms.

Analysis of the post-shock/analysis pauses in the real world use of AED

A total of 154 AED consecutive records were analyzed, where 104 records were generated by AED utilized by EMS rescuers, and 50 records were generated by AED utilized by lay rescuers. The records showed 56 post-shock pauses and 394 post-analysis pauses. The post-shock pauses were significantly shorter than the post-analysis pauses [3.1 s (95%CI 2.6–3.7) vs 5.4 s (95%CI 5–5.7) $p < 0.001$]. Comparing EMS rescuers to lay rescuers, EMS rescuers were faster in resuming CPR as compared to lay rescuers [5.3 s (95%CI 5–5.7) vs 8.6 s (95%CI 7.3–10) $p < 0.001$].

When the AED was utilized by EMS rescuers, the post-shock pauses were significantly shorter than the post-analysis ones [2.8 s (95%CI 2.4–3.3) vs 5.6 s (95%CI 5.4–5.9) $p < 0.001$]. Their post-shock and post-analysis pauses were considerably shorter than

the ones suggested by AEDs: 2.8 s (95%CI 2.4–3.3) vs 6.6 s (95%CI 6.2–6.9) ($p < 0.001$), and 5.6 s (95%CI 5.4–5.9) vs 6.6 s (95%CI 6.5–6.8) ($p < 0.001$), respectively (Fig. 3). In contrast, the utilization of AED by lay rescuers resulted in post-shock and post-analysis pauses [7.3 s (95%CI 5–9.6) vs 8.9 s (95%CI 7.3–10.5) $p = 0.23$] of similar duration. Moreover, their post-shock and post-analysis pauses were close to the pause duration suggested by the respective AED manufacturer: 7.3 s (95%CI 5–9.6) vs 6.3 s (95%CI 2.5–10.1) ($p = 0.62$), and 8.9 s (95%CI 7.3–10.5) vs 7.6 s (95%CI 6.8–8.4) ($p = 0.14$), respectively (Fig. 4).

Discussion

The objective of this study was to systematically assess the hands-off time in modern AEDs in both a simulated clinical scenario and during real-life use. To our knowledge, this is the most comprehensive assessment of post-shock and post-analysis pauses to date. Indeed, our analysis covered the largest number of AEDs so far tested, different clinical situations (shockable and non-shockable rhythm), and different AED user groups, namely EMS rescuers and lay rescuers. Our study showed that none of the tested AEDs was able to complete a pre-shock analysis and charge time in less than the recommended 10 s,¹¹ thus resulting in a prolonged hands-off time between pads application and CPR time. Importantly, in the post-shock phase AED voice prompting resulted in a long time to resume CPR, in particular when AED was used by lay rescuers, the most important group of AED users. As a result, the quality of CPR is significantly affected by technological elements, which however could be improved.

This study confirms previous observations but also expands the current understanding of the present AEDs performance. As already shown by Snyder and Morgan,¹² with the exception of one single manufacturer, none of the tested AEDs had a pre-shock pause shorter than 10 s, but as the name of the manufacturers was not reported, it is not possible to provide a direct comparison with our results. Regrettably, more than 10 years after this publication not much has changed; indeed, in a much larger sample size than the one by Snyder and Morgan, our data indicate that the time to shock delivery is on average 16 s with significant variations among man-

Table 1

Appropriate rhythm classification by each of the tested AED: Rescue SAM and Rescue life AED (Progetti, Turin, Italy); FR2, FR3 and Heartstart (Philips, Eindhoven, Netherlands); 3G Plus (Cardiac Science, Bothell, WA, USA); FRED Easy and FRED Easypoint (Schiller AG, Baar, Switzerland); Lifeline AED (Defibtech, Guilford, CT, USA); Heartsave AD (Primedic, Rottweil, Germany); i-PAD (CU Medical System, Korea); and finally, BeneHeart D1 (Mindray Medical, China).

AED	VF diagnosis	Fast VT at 225 bpm diagnosis	Slow VT at 125 bpm diagnosis	Sinus rhythm at 60 bpm diagnosis	Asystole diagnosis	Rhythm change during charging
Rescue SAM by progetti	✓	✓	□	✓	✓	□
Rescue Life by progetti (AED mode)	✓	✓	□	✓	✓	□
FR2 by Philips	✓	✓	□	✓	✓	□
FR3 by Philips	✓	✓	□	✓	✓	✓
Heartstart by Philips	✓	✓	□	✓	✓	□
3G plus by Cardiac Science	✓	✓	✓	✓	✓	✓
FRED Easy by Schiller	✓	✓	□	✓	✓	□
FRED Easypoint by Schiller	✓	✓	□	✓	✓	✓
Lifeline AED by Defibtech	✓	✓	✓	✓	✓	□
Heartsave by Primedic	✓	✓	✓	✓	✓	□
i-PAD by CU Medical System	✓	✓	□	✓	✓	✓
BeneHeart D1 by Mindray Medical	✓	✓	□	✓	✓	✓

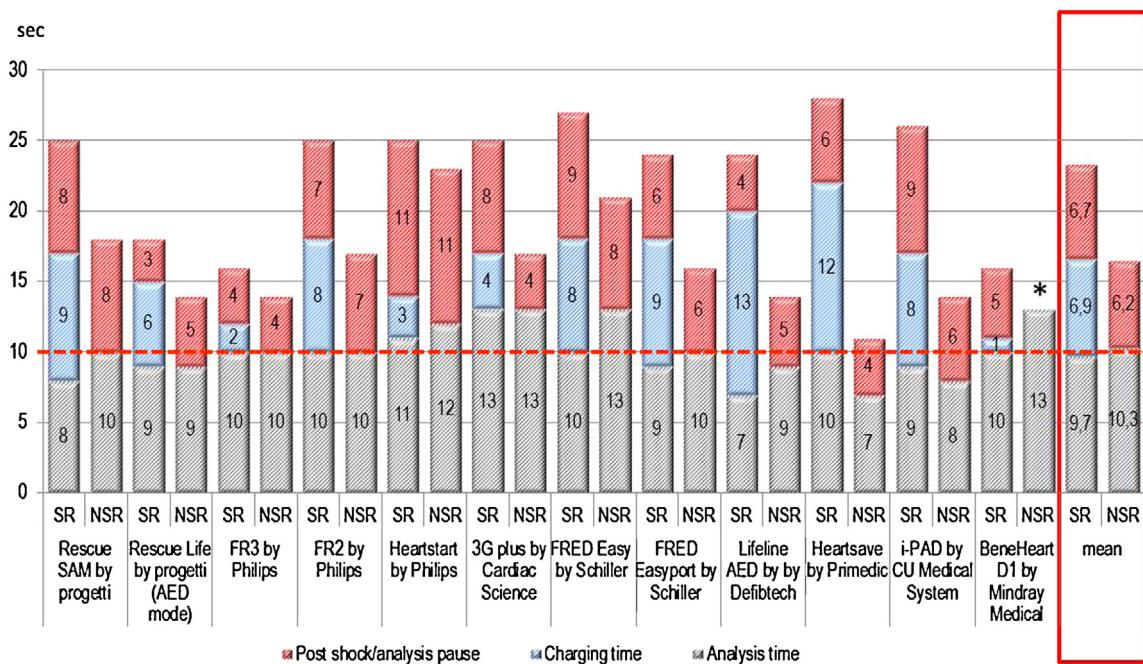


Fig. 2. This figure depicts the time performances of the twelve tested AEDs—in the manikin model. For each AED time performances concerning shockable rhythms (SR) and non shockable rhythms (NSR) are reported. The mean values are also reported at the top of the figure in the red box. A dotted red horizontal line indicates the recommended ten seconds.

*This machine did not give the instruction to resume CPR at the end of the analysis of a non-shockable rhythm but only to take care of the patient. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

ufacturers. Therefore, it is wishful that scientific societies reinforce the recommendation about the maximum time requirements, and eventually consider conducting regular, independent benchmark testing on commercially available AEDs.

Previous studies comparing AED performance focused on technical AED aspects, such as energy, current, first and second phase waveform duration in 18 AEDs,¹⁷ or performed an extensive evaluation of the speed of untrained lay rescuers to deliver a shock and initiate CPR after a shock.¹⁸ On the contrary, we addressed the ability of AEDs to perform accurate rhythm discrimination dur-

ing charging, as well as to evaluate the hands-off time as part of AED performance because automatic AED messaging is governing CPR delivery. As far as AED performance in rhythm discrimination is concerned, only 3 out of 12 AEDs appropriately classified a slow ventricular tachycardia (125 beats per minute) as a shockable rhythm which could be a rare cause of a cardiac arrest. More important and worrisome, only 5 of out 12 AEDs were able to recognize a change in rhythm (from a shockable to a non-shockable one) during capacitor charging. Although uncommon, spontaneous termination of ventricular arrhythmias has been well documented^{19,20}; in this

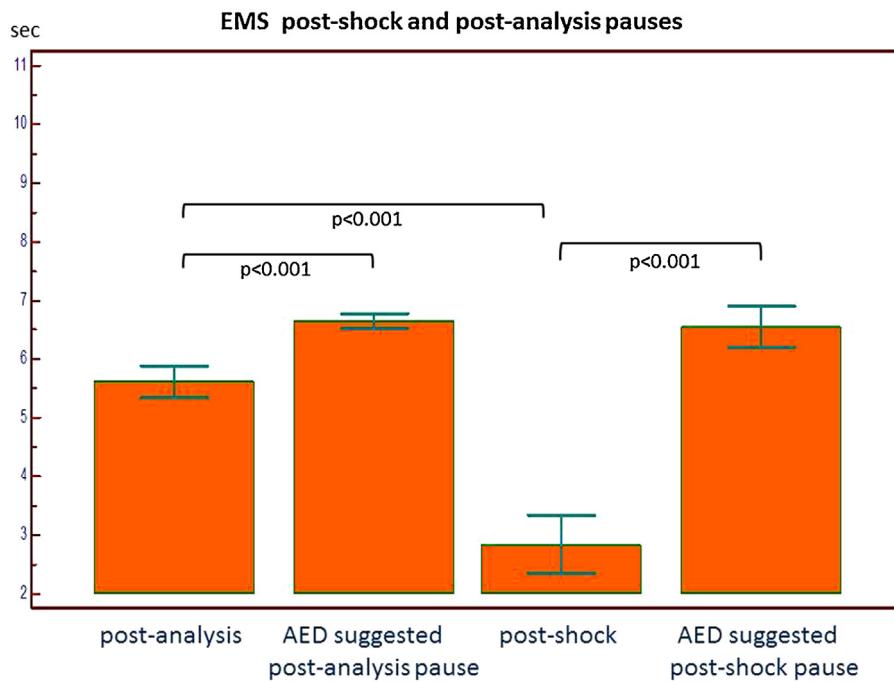


Fig. 3. This figure shows the real life post-shock and post-analysis pauses of EMS rescuers compared to the AEDs suggested pauses both for shockable and non shockable rhythms.

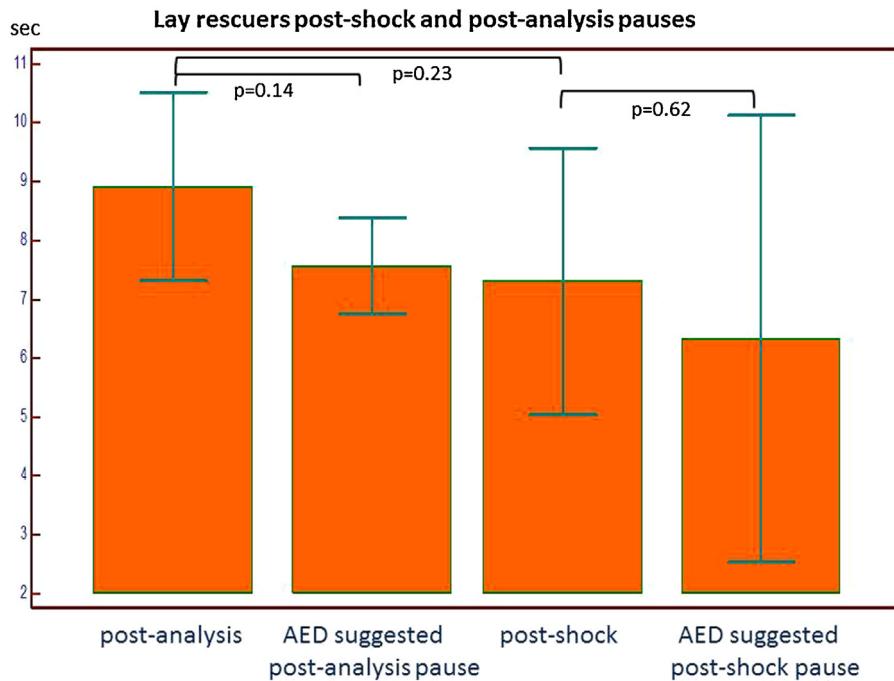


Fig. 4. This figure depicts real life the post-shock and post-analysis pauses of lay rescuers compared to the AEDs suggested pauses both for shockable and non shockable rhythms.

respect, the delivery of an unsynchronized shock during an organized rhythm may induce ventricular fibrillation.^{21,22}

Our study significantly expands the work by Snyder and Morgan, because for the first time the presence of major post-shock pauses, leading to prolonged hands-off time, has been evaluated. Our data strongly advise to instruct lay rescuers to resume CPR already during capacitor charging, and to minimize the AED confirmation time for shock delivery. Current international guidelines recommend resuming CPR as soon as the shock has been delivered, or as soon as

the rhythm analysis by AED has been completed. Unlike EMS rescuers who are familiar with AED use and do not need instructions about when to resume CPR after a shock, untrained lay rescuers follow closely AED instructions and, as a result, post-shock pauses up to 10 s have been observed. Such long pauses affect survival outcome, as demonstrated by Cheskes et al.⁸ in a large population, where a sigmoidal relationship between outcome and post-shock pauses with major reduction in survival was observed within the range of post-shock pauses reported in our study. Although train-

ing might help to overcome some of the current AEDs limitations, it will be probably more costly and less effective than efforts by AED manufacturers to reduce hands-off time at different stage of the AED use. Therefore, charging the capacitors during analysis time,¹⁶ maintaining the charged energy for longer time, and improvements in rhythm analysis algorithm represent potential technical ameliorations easy to be implemented that could have significant impact on survival outcome by decreasing CPR time by at least 10–12 s for each shock cycle.

An interesting observation is the fact that lay rescuers have equally long post-shock and post-analysis time, which strongly indicates how this user group is highly dependent from recorded and precise instructions given by the AED. In contrast, EMS rescuers who are well trained in the AED use, immediately resume CPR without waiting the AED notification or message mostly during a shockable rhythm. This observation further stresses the importance both of training and of improving the performance and the vocal instructions of current AEDs and eventually to develop novel telecommunication platform for real-time assistance to first responders during CPR.

Limitations

As regards the AED models, we tested those models that are routinely used by rescue vehicles or publically available on the territory. We are well aware that our selection does not fully cover all commercially available models or manufacturers that could be utilized in other geographical areas. Although the number of tested AEDs may appear limited, the current group represents the largest one available in literature so far.

Conclusions

AEDs have different performance that often result in prolonged hands-off time exceeding the currently recommended by guidelines 10 s limit, especially when an AED is used by lay rescuers who are routinely trained to strictly follow AED vocal instructions. It is wishful that scientific societies reinforce the recommendation about the maximum time requirements, and eventually consider conducting regular, independent benchmark testing on commercially available AEDs and to publish the respective results. Technological improvements are therefore needed to significantly improve AEDs' performances. A better training of lay rescuers is probably needed, potentially including basic technical background information about ECG interpretation by AED, in order to minimize hands-off time and possibly overcome some limitations of the current AEDs.

Conflict of interest statement

All authors have no potential conflict of interest to disclose.

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