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Cardiac rhythm analysis during ongoing cardiopulmonary resuscitation using the "Analysis During Compressions with Fast Reconfirmation" (ADC-FR) technology

Short title: Rhythm analysis during compressions

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Abstract

Background. Pauses in chest compressions (CCs) have a negative association with survival from cardiac arrest (CA). ECG rhythm analysis and defibrillator charging are significant contributors to CC pauses.

Objective. Accuracy of the "Analysis During Compressions with Fast Reconfirmation" (ADC-FR) algorithm, which features automated rhythm analysis and charging during CCs to reduce CC pauses, was retrospectively determined in a large database of ECGs from 2,701 out-of-hospital CAs.

Methods. The ADC-FR algorithm generated a total of 7,264 advisories, of which 3,575 were randomly assigned to a development dataset and 3,689 to a test one. With ADC-FR, a high-pass digital filter is used to remove CC artifacts, while the underlying ECG rhythm is automatically interpreted. When CCs are paused at the end of the 2-min CPR interval, a 3 sec reconfirmation analysis is performed using the artifact-free ECG to confirm the shock/no-shock advisory. Sensitivity and specificity of the ADC-FR algorithm in correctly identifying shockable/non-shockable rhythms during CCs were calculated.

Results. In both the datasets, the accuracy of the ADC-FR algorithm for each ECG rhythm exceeded the recommended performance goals, which apply to a standard artifact-free ECG analysis. Sensitivity and specificity were 97% and 99%, respectively, for the development dataset, and 95% and 99% for the test dataset.

Conclusion. The ADC-FR algorithm is highly accurate in discriminating shockable and non-shockable rhythms and can be used to reduce CC pauses.

Key words. Cardiac arrest; rhythm analysis; automated external defibrillation; pre-shock pauses; chest compression; defibrillation.

Introduction

Cardiopulmonary resuscitation (CPR) in conjunction with prompt electrical defibrillation can re-establish spontaneous circulation (ROSC) after cardiac arrest (CA) from ventricular fibrillation (VF) and pulseless ventricular tachycardia (VT).[1] Nevertheless, resuscitative efforts are often unsuccessful and poor outcomes may result from ineffective and/or frequently interrupted chest compressions (CCs).[2-6]

Among the different causes for interrupting CCs during CPR, are the pre-shock pauses mandated by automated external defibrillators (AEDs). CCs create artifacts on the electrocardiographic (ECG) signal, such that interruptions are mandatory for rhythm analysis prior to a defibrillation attempt.[7-9] Limiting the frequency and the duration of such CC interruptions may improve outcomes of CA.[10-14]

A novel technology was developed to limit CC interruptions required for both rhythm analysis and defibrillator charging. This technology, called "Advisory During CPR with Fast Reconfirmation" (ADC-FR), features automated ECG analysis and defibrillator charging during ongoing CCs, with a 3 sec ECG rhythm reconfirmation analysis.[15] The purpose of the present study was to investigate the sensitivity and specificity of the ADC-FR analysis algorithm on a large dataset of ECG traces with CC artifacts obtained from prehospital CAs.

Methods

A database of defibrillator records (AED Pro®, AED Plus®, E Series) collected during prehospital CPR was used to develop and test the ADC-FR algorithm. The database, managed by

ZOLL Medical Corporation (Chelmsford, MA), included field case submissions from multiple emergency medical services (EMS) agencies between 2004-2014. The electronic data did not contain any patient's identifiable information, in compliance with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

ECG was recorded at a sample rate of 250 Hz. CCs were detected using an accelerometer and acceleration data were sampled at 125 Hz. The acceleration records associated with the ECG traces were manually inspected to identify CC intervals (continuous CCs ≥ 15 sec) and subsequent pauses (pauses in CCs ≥ 11 sec, regardless of the reason for the pause). All ECG segments matching the above criteria were included. The included ECG traces were blindly and randomly partitioned into a development dataset and a test dataset, and subsequently processed by the ADC-FR algorithm, which generated a shock/no shock decision for each ECG trace. Sensitivity and specificity of the ADC-FR algorithm were calculated based on comparison of the automated analysis results with a corresponding expert reviewers' rhythm annotation (QT, NZ, GR). ECG rhythms were evaluated and coded according to the recommendations for specifying and reporting arrhythmia analysis algorithm performance from the American Heart Association (AHA).[16] Since the aim of the ADC-FR algorithm was to discriminate between shockable and non-shockable rhythms, a simplified rhythm categorization was used, as detailed in Table 1. Methods details are reported in the Supplemental Methods.

ADC-FR Technology

The ADC-FR technology uses the signal from the accelerometer embedded in the defibrillation pads (CPR-D padz® or CPR-stat padz®), to identify the presence of CCs. When CCs are detected, a high-pass digital filter is used to minimize CC artifacts from the ECG signal. A previously validated algorithm for ECG analysis during ongoing CCs is then applied to the filtered trace in order to determine whether or not the patient's rhythm is shockable.[17] Subsequently, upon interruption of CCs and settling of the ECG, the ADC-FR algorithm performs a 3 sec analysis using the compression-free ECG trace to reconfirm the decision determined during CCs. This reconfirmation analysis is compared against the previous analysis during CCs and the shock/no-shock decision is immediately made if both match. For the clinical implementation of the feature, the ADC-FR algorithm is applied only at the end of the pre-configured 2-min CPR interval, as detailed in Figure 1. The capacitor of the defibrillator is automatically charged 4 sec before the end of the 2-min CPR interval, allowing for immediate defibrillation after the reconfirmation pause, if a shockable rhythm is confirmed. The same 3 sec analysis during CC pause occurs in the instance of a non-shockable rhythm. In this case, the AED issues a "no shock advised" order and CCs can restart promptly (Figure 1).

If a shock/no shock decision cannot be made using the combination of analysis during CCs and the 3 sec reconfirmation analysis, an additional segment of ECG is analyzed. In the instance that a shock/no-shock decision cannot be made after two ECG segments, a final ECG segment is analyzed. In summary, the ADC-FR algorithm makes the shock/no-shock determination during CCs based on three 3 sec segments (9 sec total); then, when CCs are paused, the algorithm performs the reconfirmation analysis, again based on a 3 sec segment (requiring from a minimum of one up to three, i.e. 3-9 sec). Supplemental Figure 1 provides more details on the ADC-FR algorithm, while Supplemental Figure 2 describes the logical decision algorithm of the ADC-FR technology. Samples of raw ECG traces for different rhythms, correctly interpreted by the ADC-FR algorithm, are reported in Figure 2.

Statistical analysis

The performance of the ADC-FR algorithm was evaluated in terms of accuracy of the shockable or non-shockable decision. Accuracy was defined as the number of correct advisories (shockable or non-shockable) divided by the total number of advisories for each ECG rhythm. Sensitivity was defined as the number of ECG rhythms correctly classified as shockable divided by the total number of shockable rhythms. Specificity was defined as the number of ECG rhythms correctly classified as non-shockable (Table 1) divided by the total number of non-shockable rhythms. Accuracy of the ADC-FR algorithm for each rhythm was compared to the AHA recommendations for arrhythmia algorithm performance.[16] Calculation of confidence intervals (CI) is reported in the Supplemental Methods.

Results

A total of 7,264 CC intervals with one of the ECG rhythms listed in Table 1, from 2,701 CA patients were included in the analysis (3.8±2.9 segments/patient). Of these, 3,575 were randomly assigned to the development dataset, while the remaining 3,689 to the test one. The different ECG rhythms included in the development and test datasets are reported in Table 2. For both datasets, the number of intervals analyzed for each ECG rhythm exceeded the minimum required sample size from the AHA recommendations.[16]

The ADC-FR algorithm accuracy for each rhythm exceeded the recommended arrhythmia algorithm performance goals, even though these were set for artifact-free ECGs.[16] The accuracy of the ADC-FR in identifying non-shockable rhythms (i.e. normal sinus rhythm, asystole, and other non-shockable rhythms) ranged between 99% and 100% (Table 2). Similarly, the accuracy for identification of shockable rhythms (i.e. coarse VF or rapid VT) was between 99-100%. For the rhythms without specific performance goal recommendations, i.e. fine VF and other VTs, the accuracy ranged between 91-100%. Even the 90% lower CI for each rhythm exceeded the performance goals.[16]

The overall performance of the ADC-FR algorithm yielded a sensitivity of 97% and 95% in the development and test dataset respectively, while the specificity was 99% in both the datasets. Considering only coarse VF and rapid VT and excluding fine VF, the sensitivity increased to 100%, in both datasets.

The algorithm accuracy was re-evaluated considering only one interval of any ECG rhythm from each patient (n=4,544), as suggested in the AHA recommendations[16] and the results are reported in the Supplemental Table. Again, accuracy exceeded performance goals,[16] ranging between 98-100% for coarse VF, rapid VT, NSR, asystole, and other non-shockable rhythms, and between 89-100% for fine VF and other VT, in the development and test datasets. Specificity remained at 99% in both databases and sensitivity was 96% and 94% in the development and test datasets, respectively.

The majority of ECG rhythms (81% in the development dataset and 83% in the test one), were correctly identified using a combination of analysis during CCs and one 3 sec reconfirmation analysis (median=3 sec, IQR=3, 3 sec; Table 3). In 16% of the instances in both datasets, an additional analysis was needed. A third analysis was necessary in 3% of cases in the development dataset and in 1% of the test dataset. Overall, fine VF, other VT, and asystole represented the rhythms that required more re-analyses.

Discussion

This study demonstrated that the newly developed ADC-FR algorithm, which features ECG rhythm analysis during CCs with the need for a brief pre-shock CPR pause for rhythm reconfirmation, is highly accurate in discriminating shockable and non-shockable rhythms. The ADC-FR algorithm yielded a sensitivity greater than 95% and a specificity greater than 99% for identification of a shockable/non-shockable rhythm. The accuracy of the ADC-FR algorithm for each ECG rhythm exceeded the arrhythmia analysis performance goals recommended by the AHA, which apply to a standard artifact-free ECG analysis.[16] Moreover, in 83% of the instances, the ECG rhythm was correctly identified and a shock/no shock decision was made with one 3 sec reconfirmation analysis.

Although some randomized clinical trials comparing 2000 vs. 2005 CPR Guidelines showed that shortening pre-shock and post-shock CC pauses and increasing the CC fraction (CCF) did not improve survival,[18, 19] more recent evidence suggests that when controlling for the effects of other resuscitation interventions, higher CCF was predictive of survival.[20] Moreover, in several other studies, it has been demonstrated that during CPR, greater CCFs were associated with higher likelihood of ROSC and survival after out-of-hospital cardiac arrests.[4, 6, 10-14, 21] However, CC pauses as long as 32 sec have been recently described during pre-hospital CPR. Among these, peri-shock pauses accounted for the longest CC interruptions, with more than 23 sec.[6] In a study of more than 800 CA patients with a shockable rhythm, the odds of survival were significantly lower for patients with pre-shock pauses > 20 sec, while pre-shock pauses < 10 sec and CCF > 60% were associated with improved survival.[11]

Implementing the proposed ADC-FR algorithm in a defibrillator can significantly reduce pre-shock pauses. With a standard AED algorithm, CCs have to be interrupted after each 2-min CPR cycle for rhythm analysis, charging of the defibrillator capacitor, warning the rescuer to stand clear from the patient, and delivering of the shock.[7] The ADC-FR technology, instead, allows for accurate automated rhythm analysis during ongoing CCs and for automatic charging of the defibrillator at 4 sec before the end of the timed CC interval, with a 3 sec reconfirmation analysis once the ECG is free of CC artifacts. Compared to the earlier algorithm we published in 2008,[17] the ADC-FR one includes the capability to quickly detect the end of the CC interval, to perform the reconfirmation analysis, and to compare its result against the previous analysis during CCs to achieve the shock/no-shock decision. These adjuncts contribute to the higher accuracy of the ADC-FR technology compared to the earlier one,[17] as shown from this study in a large and complex (for the variety of rhythms) ECG dataset.

An earlier study investigated the duration of CC pauses in simulated CPR on manikins with the use of a defibrillator set either to a standard AED mode or to the ADC-FR mode.[15] Although the rescuers received no specific information or training on ADC-FR apart from the instruction to perform CPR following the defibrillator prompts, overall CC interruptions at the end of each CPR interval were significantly reduced by almost 5 sec, for both shockable and non-shockable rhythms, when the new technology was employed. In our database, more than 80% of ECG rhythms were correctly identified during CCs, and thus required one 3 sec reanalysis period prior to the shock/non-shock prompt. A rescuer trained in the use of a defibrillator equipped with ADC-FR technology can use this brief pause to assure nobody is touching the patient and to prepare for immediate shock delivery. In the other 20% of instances, the ECG rhythm identified during CCs was not confirmed, suggesting that either the rhythm changed between CCs and the subsequent pause or the analysis during CCs was wrong due to excessive artifacts. Nevertheless, only in 1-3% of instances, 2 additional reconfirmations were necessary, supporting the hypothesis that overall this algorithm would greatly reduce the pre-shock pauses.

The duration of CC interruptions to interpret ECGs might be particularly severe since some AED can require more than 20 sec of “hands off” in order to perform a reliable rhythm analysis and charging the capacitor.[9, 22] The purpose of filtering compression artifacts from the ECG signal is to enable rhythm analysis during uninterrupted CCs, shortening the pre-shock pause and ultimately improving resuscitation outcome.[6, 10-14] Human ECG and CPR artifacts, however, show a large spectral overlap that makes the filtering approach difficult.[7] Over the years, considerable effort has been dedicated to developing more sophisticated methods of rhythm analyses during CCs. The numerous signal processing techniques can be summarized into two major approaches, either based on adaptive filters for the suppression of artifacts or on algorithms for analyses performed directly on the corrupted ECG.[23-29] However, overall the proposed algorithms achieved a sensitivity > 90%, but a specificity ranging from 79.9% to 93%. Although the sensitivity of the shock advisory algorithms greatly improved over time, the specificity for identification of non-shockable rhythms remained below the recommended level. Indeed, achieving a high specificity is a major determinant for the clinical use of a new algorithm for rhythm analysis during CPR, because an insufficient specificity may erroneously cause inappropriate shock delivery to patients with non-shockable rhythms.[23] The performance goals recommended by the AHA task force on AEDs require a sensitivity > 90% for VF and a specificity > 95% for non-shockable rhythms.[16] Our study validated the ADC-FR algorithm in CC-corrupted ECG traces from 2,701 CA patients. The ADC-FR algorithm, with rhythm analysis during CCs and a quick reconfirmation analysis during CC pause, demonstrated a very high accuracy in rhythm identification, with a sensitivity greater than 95% for identification of a shockable rhythm and a specificity greater than 99% for identification of a non-shockable one. Only in the instance of fine VF was the algorithm accuracy lower (i.e. 91-93%); however, fine VF is considered to be a rhythm for which the benefits of defibrillation are limited or uncertain.[16] For this reason, when the rhythm did not meet any shock or no shock criteria, for safety reasons the ADC-FR algorithm considered it as non-shockable. Thus, the accuracy of the ADC-FR technology for each rhythm exceeded the recommended performance goals.[16] The 3 sec pre-shock analysis for rhythm reconfirmation allows to discriminate those cases misinterpreted during CCs and those in which a change in the rhythm might occur during CCs,[30] while being short enough to not negatively affect outcomes. In a small retrospective analysis of data on pre- and post-shock CC pauses from 36 VF patients, a pre-shock pause as brief as 3 sec was associated with a 6-fold increase in the likelihood of ROSC, compared to longer pauses.[14] Similarly, with all the limitations related to animal protocols, in a swine model of cardiac arrest, a 100% ROSC was documented with pre-shock intervals of 3 sec, while a 0% ROSC occurred when the pre-shock pauses increased to 15 sec.[10]

Several approaches have been employed to reduce the pre-shock pause. The use of the defibrillator in manual mode, as opposed to AED mode, has been tested because hands-off time for rhythm analysis and defibrillator charging can be shorter when a defibrillator is operated in manual mode.[31, 32] However, analysis accuracy has been reported to be lower with manual compared to automatic analysis.[32] Moreover, only advanced life support providers are trained and allowed to perform manual rhythm analysis, while for basic life support providers, the hands-off time for cardiac rhythm analysis associated with an AED operation is unavoidable. Pre-shock pauses have been also reduced by 42% in the prehospital setting using a technology that featured automated charging during compressions.[33] To reduce the impact of long charging times, resumption of CPR during the charging process has been also suggested.[4] Finally, rhythm analysis during pauses for ventilations has been proposed, but the accuracy of this approach was lower than standard AED analysis.[34] The ADC-FR technology enables rhythm analysis during ongoing CCs while maintaining high accuracy; CC interruptions are further reduced by pre-charging of the defibrillator capacitor. A combination with algorithms to predict defibrillation success,[35] reducing the number of futile defibrillation attempts, may further improve outcome of CPR.

We acknowledge several limitations of this study. It was a retrospective data analysis; however, the randomized bifurcation of the database into a development and a test one, as recommended by the AHA,[16] eliminates some possibility of bias. No assessment was performed on how the effect of CPR quality may have influenced algorithm performance. Nevertheless, the high accuracy of the proposed technology has been demonstrated in a large database of ECG traces from multiple EMS, which should guarantee the representativeness of the data and the normal distribution of CPR quality usually encountered in the field. Finally, the application of the ADC-FR algorithm depends on the availability of a CC-sensor for detecting of compressions, and currently this may limit its use in both manual defibrillators and AEDs.

Conclusions

The ADC-FR is a highly accurate shock decision algorithm, which may be incorporated and used in defibrillators to greatly reduce pre-shock pauses in CCs during CPR. Clinical studies are required to investigate the impact of the ADC-FR algorithm on interruptions in CPR and outcome.

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Table 1. ECG rhythm categories identified by the "Analysis During Compressions with Fast Reconfirmation" (ADC-FR) algorithm

ECG rhythm categories
Shockable
Coarse ventricular fibrillation (Coarse VF)
Ventricular tachycardia with rate ≥ 150 beats/min (Rapid VT)
Non-shockable
Normal sinus rhythm (NSR)
Asystole
Any other non-shockable rhythms: atrial fibrillation, atrial flutter, supraventricular tachycardia, sinus bradycardia, premature ventricular contractions, second- or third-degree heart block, idioventricular rhythm
Intermediate rhythms
Fine ventricular fibrillation (Fine VF)
Ventricular tachycardia with rate < 150 beats/min (Other VT)

Table 2. “Analysis During Compressions with Fast Reconfirmation” (ADC-FR) algorithm accuracy in the development and in the test datasets

	Recommendations[16]		**ADC-FR Development Dataset**				**ADC-FR Test Dataset**			
Rhythms	**Minimum test sample size**	**Performance Goal (%)**	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Accuracy (%) [90% low CI]**	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Accuracy (%) [90% low CI]**
Coarse VF	200	> 90	276	275	1	99 [97]	342	338	4	99 [96]
Rapid VT	50	> 75	58	58	0	100 [91]	58	58	0	100 [91]
NSR	100	> 99	341	341	0	100 [98]	419	419	0	100 [99]
Asystole	100	> 95	926	920	6	99 [98]	841	839	2	100 [99]
Other non-shockable	30	> 95	1590	1569	21	99 [98]	1631	1618	13	99 [98]
Fine VF	25	Report only	346	324	22	94 [89]	347	316	31	91 [86]
Other VT	25	Report only	38	38	0	100 [87]	51	49	2	96 [83]
Overall Performance										

	ADC-FR Development Dataset			**ADC-FR Test Dataset**		
	No Shock Advised	**Shock Advised**	**(%) [90% low CI]**	**No Shock Advised**	**Shock Advised**	**(%) [90% low CI]**

Non-Shockable	2868	27	99% [99] (Specificity)	2925	17	99% [99] (Specificity)
Shockable	23	657	97% [94] (Sensitivity)	35	712	95% [93] (Sensitivity)

CI, 90% lower confidence interval; VF, ventricular fibrillation; VT, ventricular tachycardia; NSR, normal sinus rhythm.

Table 3. Overall reconfirmation analysis duration by the "Analysis During Compressions with Fast Reconfirmation" algorithm for each ECG rhythm

	Development Dataset			**Test Dataset**		
	1 ECG segment	**2 ECG segments**	**3 ECG segments**	**1 ECG segment**	**2 ECG segments**	**3 ECG segments**
Coarse VF	240 (87)	35 (13)	1 (0)	298 (87)	42 (12)	2 (1)
Rapid VT	46 (79)	11 (19)	1 (2)	44 (76)	10 (17)	4 (7)
NSR	323 (95)	18 (5)	0 (0)	391 (93)	26 (6)	2 (1)
PEA	1357 (85)	211 (13)	22 (1)	1393 (85)	221 (14)	17 (1)
Asystole	728 (79)	185 (20)	13 (1)	656 (78)	171 (20)	14 (2)
Fine VF	228 (58)	106 (27)	58 (15)	229 (66)	104 (30)	14 (4)
Other VT	29 (76)	8 (21)	1 (3)	35 (69)	14 (27)	2 (4)
Total	2951 (81)	574 (16)	96 (3)	3046 (83)	588 (16)	55 (1)

Data presented as n (%); VF, ventricular fibrillation; VT, ventricular tachycardia; NSR, normal sinus rhythm; PEA, pulseless electrical activity.

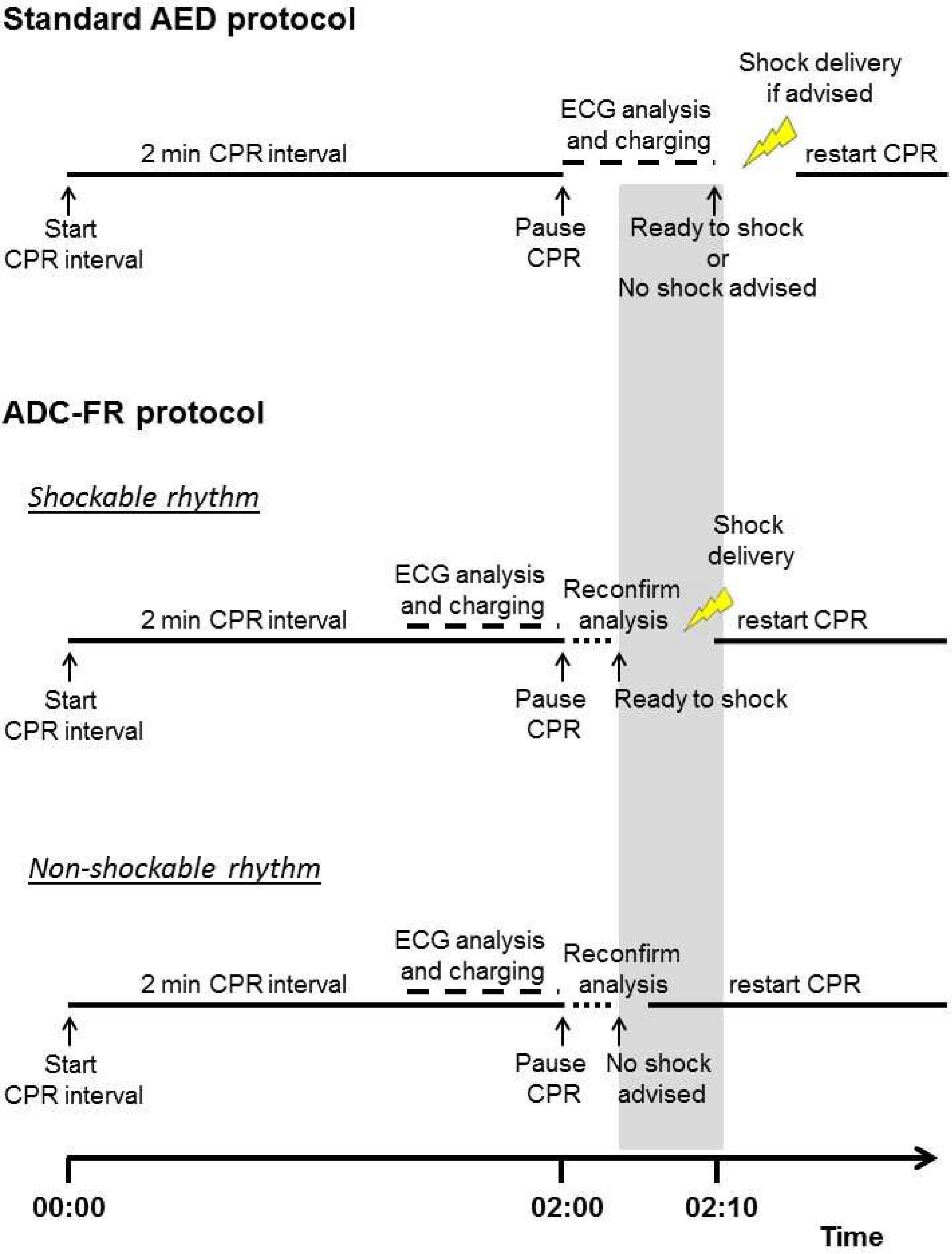
Legends to figure

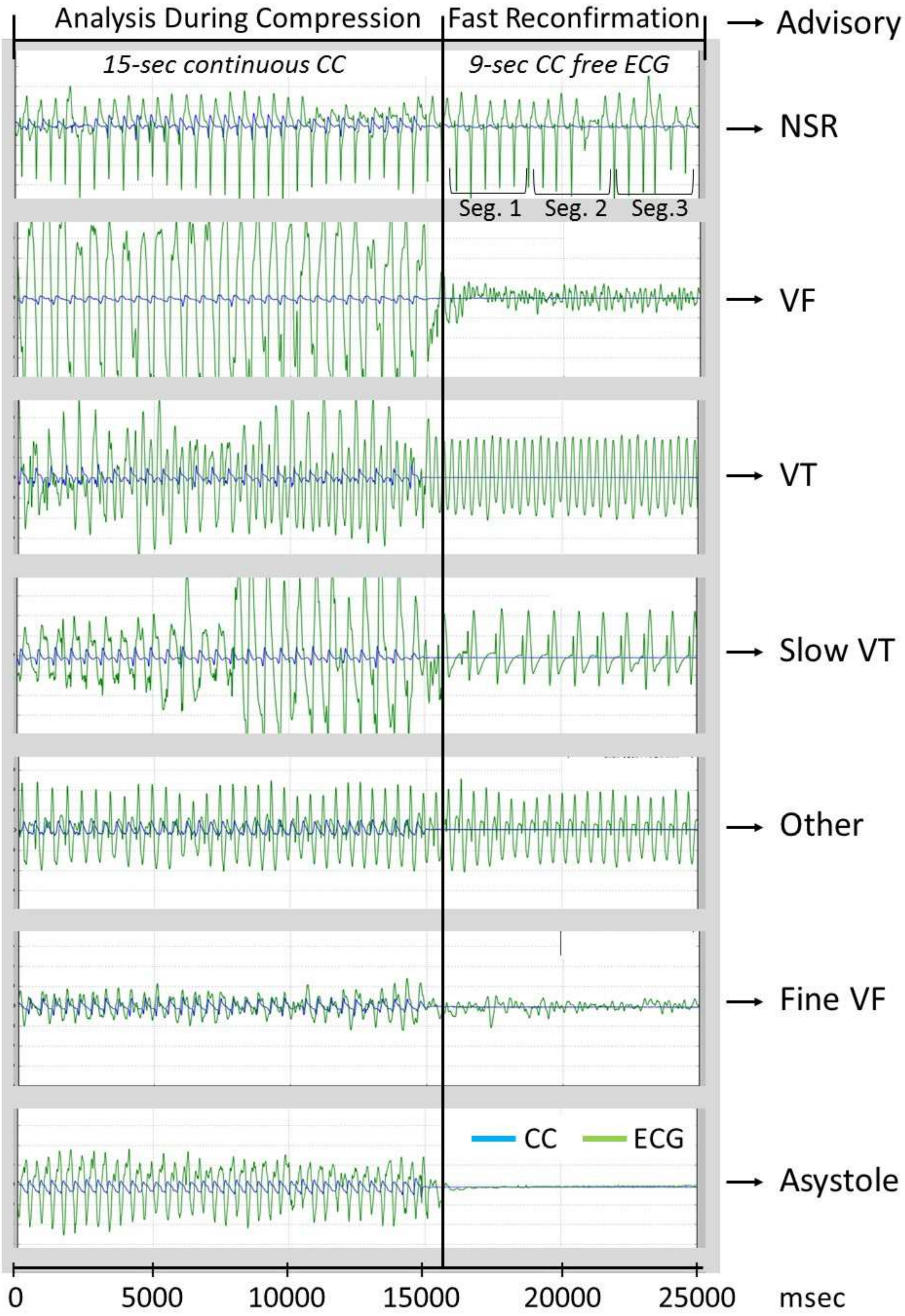
Figure 1. The "Analysis During Compressions with Fast Reconfirmation" (ADC-FR) technology can shorten chest compression pauses.

The standard automated external defibrillator (AED) algorithm requires interruption of cardiopulmonary resuscitation (CPR) for ECG rhythm analysis and defibrillator charging (dash line). In the ADC-FR algorithm, ECG rhythm analysis and defibrillator charging occur during the 2-min CPR interval, requiring only a 3 sec pause for reconfirmation analysis prior to the shock delivery (dotted line). The gray area represents the pause shortening when the ADC-FR is used compared to the standard AED protocol. The ADC-FR algorithm does not apply to the first AED application at the arrival to the patient, in which an immediate rhythm analysis is performed and a shock delivery prompted if necessary, as recommended by guidelines.

Figure 2. Samples of raw ECG tracings for different rhythms generated by the automated external defibrillator and correctly interpreted by the "analysis during chest compression with fast reconfirmation ADC-FR" algorithm. The algorithm analyzes the ECG trace during chest compression (CC) and then requires up to three 3-sec segments (seg.) of artefact-free ECG for reconfirmation.

NSR, normal sinus rhythm; VF, ventricular fibrillation; VT, ventricular tachycardia.


Standard AED protocol
Shock delivery if advised
ECG analysis and charging
2 min CPR interval
restart CPR
Start CPR interval
Pause CPR
Ready to shock or No shock advised
ADC-FR protocol
Shockable rhythm
Shock delivery
ECG analysis and charging
Reconfirm analysis
2 min CPR interval
restart CPR
Start CPR interval
Pause CPR
Ready to shock
Non-shockable rhythm
ECG analysis and charging
Reconfirm analysis
2 min CPR interval
restart CPR
Start CPR interval
Pause CPR
No shock advised
00:00
02:00
02:10
Time


Analysis During Compression
Fast Reconfirmation
→ Advisory
15-sec continuous CC
9-sec CC free ECG
→ NSR
Seg. 1
Seg. 2
Seg.3
→ VF
→ VT
→ Slow VT
→ Other
→ Fine VF
CC
ECG
→ Asystole
0
5000
10000
15000
20000
25000
msec