Resuscitation 88 (2015) 68–74

Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Clinical Paper

Inaccurate treatment decisions of automated external defibrillators used by emergency medical services personnel: Incidence, cause and impact on outcome☆

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ARTICLE INFO

Article history:
Received 25 June 2014
Received in revised form
21 November 2014
Accepted 11 December 2014

Keywords:
Automated external defibrillators
Outcome
Quality assurance

ABSTRACT

Background: The rhythm analysis algorithm (RAA) of automated external defibrillators (AEDs) may be deceived by many factors. In this observational study we assessed RAA accuracy in prehospital interventions. For every rhythm analysis judged to be inaccurate, we looked for causal factors and estimated the impact on outcome.

Methods: In 135 consecutive patients, two physicians reviewed 837 rhythm analyses independently. When they disagreed, a third physician made the final decision.

Results: Among 148 shockable episodes, 23 (16%) were not recognized by the RAA due to external artifacts ($n = 7$), fine ventricular fibrillation (VF; $n = 7$), RAA error without external artifacts ($n = 4$) or a combination of factors ($n = 5$). In six cases the omitted/delayed shock was judged to be of clinical relevance: survival with some neurological deficit ($n = 4$), death without regaining consciousness ($n = 1$) and no restoration of spontaneous circulation ($n = 1$).

In 689 non-shockable episodes, the RAA decided "shockable" 25 times (4%). This wrongful decision was due to external artifacts ($n = 9$), a concurrent shock of an internal cardioverter defibrillator ($n = 1$), RAA error without external artifacts ($n = 13$) or a combination of factors ($n = 2$). Fifteen spurious shocks were delivered. As these non-shockable rhythms did not deteriorate after the shock, we assumed that no significant harm was done.

Conclusions: Up to 16% of shockable rhythms were not detected and 4% of non-shockable rhythms were interpreted as shockable. Therefore, all AED interventions should be reviewed. Feedback to caregivers may avoid future deleterious interactions with the AED, whereas AED manufacturers may use this information to improve RAA accuracy. This approach may improve the outcome of some VF patients.

1. Introduction

Cardiac arrest victims with a shockable rhythm have a much better prognosis than patients with a non-shockable rhythm, provided defibrillation is performed timely.[1] The introduction of automated external defibrillators (AEDs) had a major impact on the outcome of patients with ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT) as they allow defibrillation to be performed before the arrival of medical professionals equipped with a manual defibrillator.[2–6] Consequently, the in-built rhythm analysis algorithm (RAA) of AEDs plays a crucial role. On the one hand, defibrillation can only be initiated if the AED detects a shockable rhythm. On the other hand, delivery of a shock to a patient with a non-shockable rhythm may be harmful, either directly by inducing VF via a shock delivered during the vulnerable ventricular repolarization period, either indirectly by the interruption of chest compressions.[7] Unfortunately, many factors such as external artifacts (e.g. chest compressions and a moving ambulance), pacemaker spikes and quickly changing heart rhythms (e.g. torsades de pointes and in patients with an internal cardioverter defibrillator or ICD) have an impact on the

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at http://dx.doi.org/10.1016/j.resuscitation.2014.12.017.

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http://dx.doi.org/10.1016/j.resuscitation.2014.12.017
0300-9572/

RAA accuracy.[8–13] The American Heart Association has considered these issues and has determined performance goals for the RAAs of AEDs.[14] It should, however, be stressed that these standards deal with artifact-free ECG tracings, and therefore the accuracy figures of RAAs may not reflect performance under real-life conditions.

The aim of this observational study was to assess the accuracy of the RAA of AEDs used in the emergency medical services (EMS) system. For every analysis judged to be inaccurate, we looked for factors potentially misleading the device's RAA and estimated the impact of the inappropriate decision on the patient's outcome.

2. Methods

2.1. AED program and EMS system in the Ghent area

Belgium has a two-tiered EMS system. The first tier ambulances are staffed with emergency medical technicians (EMTs). By law, the basic training (including the use of AED) of these EMTs is confined to 160 h. The second tier units, also called Mobile Emergency Teams (METs) are staffed by emergency physicians (EPs) and nurses. The MET is free to use its own manual defibrillator or to continue with the AED, either in the semi-automatic mode, or switched to manual mode.

Since 1990, AEDs were gradually introduced in the first tier services of the Ghent area. All EMTs initially attended an AED provider course (with exam) followed by mandatory annual refresher courses. Each AED intervention is assessed by an EP and, if necessary, discussed with the EMTs and/or MET members involved. Since 1992, this local quality assurance program is performed by one of the authors (PC).[10,13,15]

In February 2012 the three first tier units of the Ghent Fire Brigade started using ZOLL AED PRO® devices. In November 2012 the Wetteren Fire Brigade (with two units) made the same switch. All EMTs were given an introductory course for their new AED devices.

Special features of the ZOLL PRO® devices used in both first tier services are:

- Full compliance with the 2010 CPR guidelines, including a rhythm analysis after every 2 min basic life support episode.
- Programmed in semi-automatic mode, with only MET members allowed to convert to manual mode. In the manual mode the RAA is disabled.
- Use of CPR-D-padz®, i.e. a one-piece, pre-connected adjunct with integrated electrodes using the lower part of the sternum as the landmark. The three main components are the CPR sensor (to be placed on the lower part of the sternum) and two self-adhesive pads for the conventional sternal–apical position.
- A real-time feedback system (metronome and voice prompts) based on accelerometer measurements of the CPR-D-padz®, helps the caregiver to improve compression depth and rate.
- The RAA sequence takes approximately 9 s, divided into 3-s segments. For the differentiation between shockable and non-shockable segments, the RAA combines (after filtering of noise, artifacts and baseline wander) several elements: (1) measurements of the baseline content of the signal, (2) QRS rate, width and variability, and (3) amplitude and temporal regularity of peaks and troughs. Only if multiple (but not necessarily all) 3-s segments are judged to be shockable, the AED starts charging and ECG analysis is stopped. This explains why a first 3-s segment with many external artifacts (i.e. a non-shockable segment) followed by some 3-s segments showing VF (i.e. shockable segments) as a rule gives rise to a shock.
- The detection limit for VF is an amplitude of 0.1 mV, and for VT (i.e. a regular broad complex tachycardia) a rate of 150/min.
- If the caregiver does not deliver the shock within 30 s of full charge, the device automatically disarms itself, and resumes ECG analysis.
- If the AED is unable to analyze the ECG signals (mainly due to poor contact of the pads or external artifacts) the analysis is halted, voice prompts are given to optimize the conditions and a new ECG analysis is started immediately.
- The AED automatically and continuously stores ECG tracings, voice prompts and data on shocks and chest compression quality.

2.2. Study design

As the routine prospective quality assurance program revealed a rather high number of inaccurate decisions of the RAA without apparent external cause, a thorough evaluation was conducted in October 2013. All AED applications from February 2012 on were retrospectively reviewed and all subsequent AED applications until March 2014 were prospectively assessed.

In each case, we assessed all ECG strips analyzed by the RAA, irrespective of the number of analyses, the circulatory status (i.e. before and after return of spontaneous circulation), the presence of a MET and the age of the patient. Analyses aborted by the device itself were also included. We excluded analyses terminated early due to a device switch-off by the caregivers.

For every RAA analysis, the AED decision (i.e. "shock advised" versus "no shock advised") was re-assessed by the first author (PC). Whenever PC disagreed with the AED decision on shockable versus non-shockable, we looked for factors potentially misleading the RAA (mainly external artifacts, but also pacemaker spikes or shocks by an ICD). For every inaccurate AED decision (irrespective of the cause), we estimated the impact on the outcome of the patient.

The assessments of PC were repeated by the second author (NM), except for cases in whom all analyses were classified as non-shockable by the AED and by PC. NM was blinded to the interpretations of PC. The assessments of PC and NM were compared by the third author (SC); all discrepancies were discussed by PC and NM. If no consensus could be found, the case was presented to the fourth author (KM) who made the final decision. The physicians were not blinded to the RAA decision.

Since all data were gathered as parts of an ongoing quality assurance program, the Ethics Committee of the Maria Middelares General Hospital decided that analysis of these data was exempt from the usual requirement for informed consent.

2.3. Rhythm definitions

VF was defined as uncoordinated ventricular depolarizations with a minimum of five complexes with a peak to peak amplitude >0.2 mV during a three seconds window.[15]

Fine VF was defined as uncoordinated ventricular depolarizations with a minimum of five complexes with a peak to peak amplitude >0.1 mV and <0.2 mV.

3. Results

In 135 patients 860 ECG tracings were evaluated by the RAA of the ZOLL devices. Twenty-three of these 860 analyses were aborted by the AED itself because of external artifacts ($n = 12$) or poor contact of the pads ($n = 11$). All but one of these ECG tracings showed non-shockable rhythms. As these 23 aborted analyses were immediately repeated (and therefore could be considered as duplicated), we excluded them in the sensitivity/specificity/accuracy calculations.

The reviewers classified 148 of 837 (18%) ECG tracings as shockable. This involved 35 patients (with a maximum of 12 tracings