Beaty

By Medical Feedback Technologies Ltd.

Literature Review

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"Beaty"- Real time CPR feedback device

Literature review

Introduction

Sudden Cardiac Arrest (SCA) refers to the sudden cessation of cardiac mechanical activity with hemodynamic collapse. This usually occurs in patients due to coronary artery disease and patients with other cardiac problems such as arrhythmias, valvular abnormalities, congenital cardiac abnormalities etc. Irreversible brain damage occurs within 5 minutes from complete cardiac arrest.

According to the World Health Organization (WHO) data[1], collected in 2012, cardio vascular diseases are the leading cause of death worldwide, accounting for 17.5 million deaths yearly. Of these deaths, an estimated 7.4 million were due to Coronary Heart Disease (CHD) and 6.7 million were due to strokes. During a 38-year follow up of subjects in the Framingham Heart Study[2], the annual incidence of sudden cardiac death increased dramatically with age and underlying cardiac disease.

Each year, approximately 350,000 out-of-hospital cardiac arrests occur in the US itself. Survival rates from SCA are less than 10% but can be doubled or even tripled if cardio-pulmonary resuscitation (CPR) is initiated by a bystander or EMS, respectively[3,4].

CPR is an emergency procedure that combines chest compressions and artificial ventilation (mouth-to-mouth or mechanical ventilation) that was first developed in the late 1950s and 1960s[4]. Delaying tissue death and preventing permanent brain damage by restoring partial flow of oxygenated blood to the brain and heart is its main goal. The onset of CPR and its quality are the main prognostic factors in the survival rates given above[3,4,6].

In 2010, The American Heart Association (AHA) published its guidelines[5] for CPR based upon extensive evidence performed by the International Liaison Committee on Resuscitation (ILCOR). The new guidelines were most notable for the conceptual change in the previously known CPR algorithm. The 2010 guidelines emphasized the importance of rapid identification of cardiac arrest and the importance of high quality chest compressions. The universal, well known CPR sequence has been reoriented from A-B-C (Airway-Breathing-Circulation) to C-A-B (Circulation-Airway-Breathing) as an expression of the importance of rapid initiation of chest compression and thus restoration of partial blood flow to the brain and heart, preventing irreversible damage. As for the quality of compressions, the AHA recommendations addressed the rate, depth and adequate recoil of the chest between compressions. Compression rate and depth were set to be at least 100/min and 2 inches (5cm) respectively. According to the *"Highlights of the 2010 guidelines for CPR and ECC"* published by the AHA[5], the given compression rate and depth, were associated with higher survival rates, while lower numbers were associated with lower survival rates. Compression fraction (the portion of time during which compressions are made, out of the total CPR time) was also mentioned in correlation with survival, advocating the importance of chest compressions in CPR[5,9].

For untrained bystanders, "Hands-only" (compression only) CPR algorithm was developed based on similar survival rates with either "Hands-only" CPR or CPR with both compressions and mouth-to-mouth ventilation[5]. These findings were supported by many studies[7,8]; however it's important to understand that compression-only CPR is only recommended for untrained rescuers while trained rescuers should adhere to the routine CPR and perform rescue breaths as well. Interestingly, in a large multicenter, randomized trial published by D. Rea et al. it was shown, that compression-only CPR increased survival rates among patients with cardiac cause of arrest and those with VF[8].

The role of CPR in VF

Arrhythmic Mechanisms, account for 20-35% of sudden cardiac deaths. Among these, Ventricular Fibrillation (VF) is responsible for the majority of episodes.

VF is a rapid, disorganized ventricular arrhythmia, resulting in no uniform ventricular contraction and thus impairment in cardiac output. Early defibrillation is an AHA (based on ILCOR) class 1 recommendation in cases of VF as data suggesting 8-10% decrease in survival with each passing minute[10]. Moreover, as the importance of immediate defibrillation has been substantiated, worldwide governmental laws have been enacted requiring placement of AEDs in public places.

Recent data suggested a 3 phase model for VF cardiac arrest referring the approximate time since cardiac arrest: (1) electrical phase, 0-4 min (2) circulatory phase, 4-10 min (3) metabolic phase, extending beyond 10 min after cardiac arrest. Based on this model, the role of CPR in each phase has been studied. The "3 phase model" challenged the "uniform" way of treatment proposed by the AHA (immediate defibrillation regardless the time since cardiac arrest occurs)[10,11]

During the electrical phase, immediate defibrillation indeed showed improvement in survival rates. The major conceptual change was regarding the circulatory phase in which chest compressions took priority over immediate defibrillation. It has been shown that delaying defibrillation by 1-3 minutes while providing oxygen delivery (chest compressions according to guidelines) results in higher success in terms of Return of Spontaneous Circulation (ROSC), hospital discharge and 1-year survival[10,11]. The exact underlying mechanism is unknown although it is suggested that restoration of substrates as oxygen along with washout of deleterious metabolic factors accumulated during ischemia may explain the findings. As for the metabolic phase (>10 min after cardiac arrest), the extensive brain and cardiac cell injury may attenuate the survival benefit of CPR[10]. In general, regardless the time-to-shock discussed above, it is recommended to immediately resume adequate chest compressions following attempted defibrillation for two more min[12].

Updated 2015 guidelines

In 2015, the AHA updated its guidelines[13]. The previous concept of the importance of high quality chest compressions, presented in the 2010 guidelines, has been substantiated as more data became available[16]. Many studies have indicated higher survival rates from cardiac arrest for high quality chest compressions (adequate depth, rate, chest recoil etc.)

The main changes presented in the 2015 were in setting an upper limit for chest compressions rate and depth. For compressions rate, upper limit of 120/min was set suggesting that excessive rate may prevent an adequate chest recoil and impair the desirable compression depth. As for compressions depth, upper limit of 2.4 inches (6cm) was set based on a report associating increased non-life-threatening injuries with excessive compression depth.

It is worth mentioning several things relating to the changes mentioned above:

i. The addition of an upper limit for compressions rate and depth was based on 1 publication each.
ii. In the 2010 guidelines, only 1 value for rate/depth was given suggesting that confusion may result when a range is recommended.
iii. Evaluating the precise depth of compression by an untrained bystander or even a trained rescuer may be challenging. With this in mind, the 2010 AHA recommended the concept of *"Push Hard, Push Fast"*. The new recommendations are inconsistent with the given statement and force a precise evaluation of a tight range (0.4 inches), which may be impossible in the absence of feedback devices. The extra precautions taken by a rescuer in avoiding deviation from the given range, may lead to inadequate compressions depth.

Emerging needs

Assessing CPR quality and adherence to the CPR guidelines was the objective of many studies and a high frequency of inadequate chest compression depth and rates compared to guidelines has been reported[14,15]. Wik et al.[14] studied the quality of CPR during out of hospital cardiac arrest and used the international CPR guidelines for outcome measure. In their study, Wik et al. used defibrillators to record chest compressions via a sternal pad fitted with an accelerometer. The mean compression depth was found to be 34 mm (95% CI, 33-35 mm), 28% (95% CI, 24%-32%) of the compressions reached 38-51 mm depth and more than half of the compressions were less than 38 mm.

Since the development of CPR in the late 1950s and it's evolution through the years, the limited improvement in survival rates following cardiac arrest has led to the development of several CPR assisting devices. These devices were introduced to trained rescuers and are widely used nowadays (Bag and Mask ventilator, Cardio-Pump, Lucas CPR device etc.).[17]

Moreover, the importance of early initiation of CPR put focus on educating the general population about the subject and CPR assisting devices were also introduced to the "untrained" population targeting its needs (mobility, simplicity etc.).

The emphasis on the importance of chest compressions and the findings of inadequate chest compression depth and rate, even among professionals, has led to further research and development of CPR feedback devices.

With the technological advances over the years, many assisting feedback devices have been developed based on different technologies (pressure sensors, accelerometers, metronomes) both for training and real life CPR. The efficacy of these devices became the subject of many studies.

A systemic review[18] found evidence that feedback devices may be helpful for rescuers to improve CPR performance in both training and clinical setting. Yeung et al.[19] conducted a single blinded, randomized controlled trial in which different feedback devices were compared. The primary outcome was compression depth. Secondary outcomes were compression rate, proportion of chest compressions with inadequate depth, incomplete release and user satisfaction. The difference between the feedback devices was the technology used for its purpose. It was found that pressure sensor device improved compression depth (37.24-43.64mm, p-value=0.02) while the accelerometer device reduced chest compression depth (37.38-33.19mm, p-value=0.04).

Another open, prospective, randomized, controlled trial compared other CPR feedback devices found no significant improvement and the overall BLS quality was suboptimal in all groups.[20]

To summarize, the studies described above and many others, studied the quality of chest compressions during CPR while little is known about the outcome and survival rates since the introduction of CPR assisting and feedback devices. Such a study[21] is now being conducted, assessing the effect of real-time CPR feedback and post event debriefing on patient's outcomes.

Since the evolvement of CPR assisting devices there has been an insignificant improvement in compressions quality and the survival rates following CPR on cardiac arrest victims remained constant[20,22]. This may be explained, in our opinion, by several factors. First, the current studies regarding the existing CPR feedback devices used trained caregivers (EMS) or medical students as participants. This population is already well trained and major improvement in the quality of chest compressions was expected to be low. Regarding compression depth as an example, even if was suboptimal in comparison to the AHA guidelines, was probably better than compression depth achieved by lay population before arrival of trained teams. In the later, significant improvement in compressions quality is expected if feedback devices will be used. Secondly, the onset of high quality chest compressions is an important factor. As shown before, survival rates are doubled or even tripled if CPR is initiated before the arrival of EMS[3,4]. These numbers may be even higher by improving the quality of chest compressions before arrival of EMS, by introducing feedback devices to first aiders and untrained population (12 million people are trained by the AHA annually). Such devices would also increase sense of capability among the general population when facing a cardiac emergency as data from the AHA shows that 70% of Americans feel helpless to act in such cases.[23]

Several principles should be taken into consideration when introducing such devices to the general population-

1. Affordable price
2. Portable and small dimensional
3. Simplicity – no buttons or features that would confuse the user and/or postpone the initiation of CPR

The existing devices (CPRmeter by Laerdal, Pocket CPR by Zoll etc.) use number of sensors and provide feedback regarding compression depth, rate and other parameters associated with quality of CPR. Theoretically, these devices have had to make a meaningful change in quality of CPR and survival rates following cardiac arrest. Practically, their high price and complexity made them unaffordable by the general population and thus limited their potential. In the current outlines, these devices are excellent for training purposes.

Our solution

We developed a CPR feedback device that refers to the principles mentioned above. "Beaty" is a small dimensional, easy for use, and affordable device that allows the user to get a real time feedback regarding CPR performance.

We used a pressure sensor that transforms the pressure force applied on a victim's chest into a desired depth and gives an audible output as a feedback. This kind of sensor is more accurate than other sensors (i.e. accelerometer) that are used for depth evaluation.

A study published in 2006[24], provided comprehensive information concerning the elastic properties of the human chest during chest compressions and described the forces needed in order to achieve adequate compressions depth.

We do understand that in certain victims the sternum would be displaced more than 6cm depth. Several concerns regarding consequences of deep compressions have been raised, therefore we have reviewed the literature about chest compression complications

Various rates of skeletal and non-skeletal injuries were reported in several studies[25,26]. In one study[27], the association of CPR- related thoracic and abdominal injuries and compression depth was investigated. According to this study, the incidence rate of injuries in mean compression depth categories <5cm, 5-6cm,>6cm was 28%, 27%, 49% respectively. The correlation between compressions depth and related injuries was shown in males only, while no such association was observed in females. Nevertheless, the study concluded that the injuries were in by and large non-fatal and that it is important to remember that deeper compressions increase survival. The authors also mentioned that exaggerated fear of injuries related to deeper compressions depth would lead to a reduction in depth below recommendations. Even in the AHA 2015 guidelines, the addition of an upper limit to chest compression recommended depth was based on one publication that showed potential harm from excessive chest compression depth. In the same document, it has been claimed that compression depth may be difficult to judge without use of feedback devices, and identification of lower and/or upper limit may be challenging.

It is worth mentioning that we guide the users to allow full recoil, immediately as they reach the adequate depth as provided by the device. Without the use of assisting devices, CPR providers can be divided into 3 main groups regarding compression depth: most of them provide suboptimal chest compressions, some provide adequate compressions and some provide compressions that are too deep. The use of a feedback device will help the first group in reaching the adequate depth and would also help the last group, preventing them from compressing too deep. For the second group, feedback devices could ascertain their actions thus increase their sense of capability.

We believe that by creating an "effective" bystander community and strengthening the first links of the "survival chain" more lives can be saved each day.

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