A comparison of cardiopulmonary resuscitation with standard manual compressions versus compressions with real-time audiovisual feedback: A randomized controlled pilot study

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ABSTRACT

Background: Strategies that improve cardiopulmonary resuscitation (CPR) guideline adherence may improve in-hospital cardiac arrest (IHCA) outcomes. Real-time audiovisual feedback (AVF) is one strategy identified by the American Heart Association and the International Liaison Committee on Resuscitation as an area needing further investigation. The aim of this study was to determine if in patients with IHCA, does the addition of a free-standing AVF device to standard manual chest compressions during CPR improve sustained return of spontaneous circulation (ROSC) rates (primary outcome) or CPR quality or guideline adherence (secondary outcomes).

Methods: This was a prospective, randomized, controlled, parallel study of patients undergoing resuscitation with chest compressions for IHCA in the mixed medical-surgical intensive care units (ICUs) of two academic teaching hospitals. Patients were randomized to receive either standard manual chest compressions or compressions using the Cardio First Angel™ feedback device.

Results: Sixty-seven individuals were randomized, and 22 were included. CPR quality evaluation and guideline adherence scores were improved in the intervention group ($P = 0.0005$ for both). The incidence of ROSC was similar between groups ($P = 0.64$), as was survival to ICU discharge ($P = 0.088$) and survival to hospital discharge ($P = 0.095$).

Conclusion: The use of the Cardio First Angel™ compression feedback device improved adherence to publish CPR guidelines and CPR quality. The insignificant change in rates of ROSC and survival to ICU or hospital discharge may have been related to small sample size. Further clinical studies comparing AVF devices to standard manual compressions are needed, as are device head-to-head comparisons.

Key Words: Cardiopulmonary resuscitation, chest compression, in-hospital cardiac arrest, medical device

INTRODUCTION

In-hospital cardiac arrest (IHCA) is common and carries high patient morbidity and mortality. Data from the American Heart Association’s (AHA) Get with the Guidelines-Resuscitation Registry indicates an annual incidence of 292,000 cases per year in the U. S., or roughly 1 per 100 admissions.[1] IHCA outcomes vary...
Cardiopulmonary resuscitation (CPR) with effective chest compression remains the cornerstone of acute management, and international guidelines emphasize the importance of compression position, rate, force, depth, interruptions, recoil, no-flow time, flow fraction, and avoiding excessive ventilation.[3‑8] Even so, evidence suggests that compressions administered by medical practitioners in real time may be suboptimal.[9,10] The AHA and the International Liaison Committee on Resuscitation (ILCOR) have made cautious recommendations supporting real-time audiovisual feedback (AVF) use to aid educational and clinical resuscitation efforts by improving compression quality.[5,7,11]

AVF devices may be free-standing or linked to automated external defibrillators (AED) or other monitoring equipment. Free-standing devices are generally applied between the victim’s chest and the rescuer’s hands. The reliant technology ranges in complexity from a metronome to tensile springs, accelerometers, pressure sensors, and triaxial magnetic sensing.[2,12‑14] The feedback may be given (singular or in combination) in audio, visual, or tactile format.

Despite an abundance of products released to market, only two devices (Ambu CardioPump, Cardio First Angel™) have published randomized controlled trials for IHCA.[2,13,14] The objective of this pilot feasibility RCT was to determine if in patients with IHCA (population), does the addition of a free-standing AVF device to standard manual chest compressions during CPR improve outcomes including sustained ROSC (primary outcome) or CPR quality or guideline adherence (secondary outcomes).

**METHODS**

**Study design and settings**

This was a prospective, randomized, controlled, parallel study of patients undergoing resuscitation with chest compressions for IHCA in the mixed medical-surgical Intensive care units (ICUs) of two academic teaching hospitals in Tehran, Iran, from December 1, 2013, to March 1, 2014. The protocol was approved by the Investigational Review Board at Baqiyatallah University of Medical Sciences (IR. BMSU. REC.1394.419). Informed consent was required and covered both study participation and consent to publish the findings. Consent by the patient’s surrogate or designated health-care proxy was permitted in cases where the patient did not have decision-making capacity. The crossover was not allowed. Patients were blinded to the randomization group. The health-care provider was not blind during the resuscitation, as it was considered unethical to employ a sham device. The data analyzer was blinded to group randomization and was not present during resuscitation.

Block randomization (groups of 4) was performed using a random number list generated by Random Allocation Software © (RAS; Informer Technologies, Inc., Madrid, Spain). The allocation, consignment, and blinding methodology is described elsewhere.[2] Enrollment and randomization occurred in the emergency department (ED) from available admitted ICU patients on a convenience basis. Patients consented to enrollment in a study on cardiac arrest treatment should that event occur during the ICU stay; otherwise, the treatment was according to usual care. There were no important changes to methods after trial commencement. The study ended because it achieved the necessary sample size.

**Patient population**

Inclusion criteria were as follows: (1) age ≥18 years, (2) admitted to the ICU from the ED, (3) resuscitation status full-code, and (4) willing and able to provide written informed consent by the patient, legal guardian, or health-care surrogate prior to cardiac arrest event. Exclusion criteria were as follows: (1) pregnant or (2) any code status other than full code, and (3) any out-of-hospital cardiac arrest or ED cardiac arrest prior to enrollment. Patients were excluded from the final analysis for (1) revoked consent or (2) lost or incomplete data due to logistical impediment to data collection. Decisions to cease resuscitation efforts were made in accordance with the AHA and European Resuscitation Society Guidelines and included (1) asystole for >20 min in the absence of a reversible cause (e.g., hypothermia at time of arrest, cardiac tamponade, tension pneumothorax, distributive shock from anaphylaxis, and chemical intoxication/overdose [e.g., opioid]), (2) >30 min of resuscitation with no occurrence of ventricular fibrillation (VF) or ventricular tachycardia (VT) at any point (initial or subsequent rhythm), (3) injury not compatible with life, (4) severity of comorbidities, and (5) normothermia.[15,16] For those patients in persistent pulseless VF or VT not responsive to CPR, defibrillation, and medications, the determination to cease resuscitation efforts was made by the resuscitation team leader based on clinical parameters including time to CPR initiation, CPR duration, comorbid disease, and pre-arrest state.

**Intervention**

Prior to the study deployment, all ICU nurses at approved study sites received standardized CPR training in accordance with published guidelines in addition to formal training with the CFA device.[17] All arrests were significantly worldwide, with the return of spontaneous circulation (ROSC) rates reported to range from 20% to 73%.[2]
Data collection
Utstein variables were published after data collection; however, all available Utstein variables are reported. The primary outcome was sustained ROSC (>30 min). The secondary outcomes were CPR quality and guideline adherence. Recorded data included age, sex, invasive mechanical ventilation status on code onset, ICU length-of-stay, diagnoses, initial cardiac rhythm, defibrillation, and administered drugs. Data for invasive arterial monitoring and waveform capnography were not routinely available for patients and were not reported. Time of resuscitation occurrence (morning, mid-day, evening, and night), and nurse’s level (years) of critical care nursing experience was recorded.

CPR effectiveness and guideline adherence were both evaluated using checklists with an assigned score ranging from 0 (lowest) to 10 (highest). Derivation and validation of the assessment tools have been described elsewhere. Those items assessing for CPR effectiveness included patient position, CPR event frequency, presence of a working intravenous catheter, use of a CPR-board (or deflation of air mattress), environmental management, CPR duration, and ROSC. Items assessed for CPR guideline adherence included timeliness of compression initiation, effective team coordination and observation of pre-assigned roles, compression rate, compression depth, rescuer position, airway management, medication administration, and appropriate use of defibrillation and pacing. The tool was developed by AVA and validated using a three-round Delphi technique by a 19-person panel including anesthesiologists (n = 3), cardiologists (n = 5), intensivists (n = 2), internists (n = 4), and ICU nurses (n = 5). Both checklists were validated based on content validity ratio = 0.54 and content validity index = 0.89 as previously reported. The scoring tools were administered by the principal investigator and two ICU nurses not involved in the project. Inter-rater reliability yielded a Kendall agreement coefficient score of 0.91.

Sample size and data analysis
All analyses were performed using SPSS 22.0 (SPSS Inc., Chicago, IL, USA). Frequency (percent; %) and mean (standard deviation) are presented for qualitative and quantitative variables. The normality of study variables was assessed through One-Sample Kolmogorov–Smirnov Test. Median (Quartile1 to Quartile 3) was presented as summary statistic for non-normative variables including CPR duration, nurse satisfaction with CPR quality, CPR evaluation, and observation of CPR guidelines. The frequency was presented as summary statistic for ROSC. Non-Gaussian variables were compared through Mann–Whitney U, Chi-square, and Fisher’s exact test as appropriate. Demographic variables were compared using t-test, Chi-Square, or Fisher’s exact test as appropriate. Statistical significance was defined as P < 0.05.

The sample size was based on ROSC data from a pilot cohort of patients not included in the study. The analysis was performed using STATA® 14 (StataCorp LLC, College Station, TX, USA). Assuming an alpha of 0.05 and a power of 0.9, the necessary sample size per group was 9. Accounting for anticipated 10% attrition, the final sample size needed was 11 per group.

RESULTS

Of 67 consecutive eligible patients for study enrollment, 45 were excluded, and 22 were included [Figure 1]. The patient demographics were similar between groups [Table 1]. The percentage of female patients was similar between groups (P = 0.67) as was patient age (P = 0.32). Admission diagnoses were similar between groups and included (CFA vs. Control): trauma (2 vs. 1; P = 1.0), Neuro (5 vs. 4, P = 1.0), renal (0 vs. 0), cancer (0 vs. 1, P = 1.0), respiratory (2 vs. 1; P = 1.0), and abdominal infection (2 vs. 4; P = 0.63). All cases of cardiac arrest occurred in the ICU. Identified initial rhythms compared between intervention and control groups included asystole (9% vs. 9%; P = NS), VT (36% vs. 55%; P = 0.67), VF (9% vs. 18%; P = 1.0), and pulseless electrical activity (PEA)/brady-arrhythmia (45% vs. 18%; P = 0.36).

The use of resuscitation therapies was similar between groups [Table 2], including total electricity dose (P = NS), and dose of epinephrine, vasopressin, atropine, amiodarone, calcium gluconate, lidocaine, or sodium bicarbonate [Table 2]. CPR guideline adherence and quality were both improved in the intervention group [P = 0.0005; Table 3]. No
A large gap exists between current knowledge of CPR quality and its optimal implementation, contributing to preventable deaths attributable to cardiac arrest.\textsuperscript{[19]}

**Table 1: Summary statistics and the results of the tests for comparing groups for demographic variables**

| Variable                        | Total (n = 22) | Intervention (n = 11) | Control (n = 11) | Significance P |
|---------------------------------|----------------|-----------------------|------------------|---------------|
| Age, mean ± SD                  | 66.4 ± 14.5    | 62.1 ± 12.5           | 70.6 ± 15.7      | 0.32          |
| ICU length-of-stay (days), mean ± SD | 37.3 ± 21.4    | 29.5 ± 22             | 45.1 ± 18.7      | 0.09          |
| Nurse ICU experience (years), mean ± SD | 21.7 ± 4.9    | 20.4 ± 4.6            | 23.1 ± 5.1       | 0.37          |
| Sex (female), n (%)             | 10 (45)        | 6 (55)                | 4 (36)           | 0.67          |
| Intubated prior to CPR event, n (%) | 12 (54)        | 7 (64)                | 5 (45)           | 0.67          |
| Multi-organ dysfunction (yes), n (%) | 11 (50)        | 5 (45)                | 6 (55)           | 1.0           |
| Invasive mechanical ventilation at onset of code (yes), n (%) | 10 (45)        | 6 (55)                | 4 (45)           | 0.39          |

*One-way ANOVA, \textsuperscript{a}Fisher’s exact test, \textsuperscript{b}Pearson χ², SD: Standard deviation, ICU: Intensive care unit, CPR: Cardiopulmonary resuscitation

**Table 2: Comparison of resuscitation treatments**

| Treatment administered          | CFA, n (%) | Control, n (%) | P \textsuperscript{a} | Treatment dose* | CFA, median (mean) | Control, median (mean) | P \textsuperscript{b} |
|---------------------------------|------------|----------------|------------------------|-----------------|-------------------|-----------------------|------------------------|
| Electricity, total (joules)      | 11 (100)   | 11 (100)       | NS                     | Electricity, total (joules) | 600 (582)         | 600 (636)             | NS                     |
| Epinephrine                     | 11 (100)   | 11 (100)       | NS                     | Epinephrine (mg) | 3 (3)            | 4 (3)                 | 0.45                   |
| Vasopressin                     | 3 (27)     | 3 (27)         | NS                     | Vasopressin (units) | 40 (40)           | 40 (40)               | NS                     |
| Atropine                        | 7 (64)     | 3 (27)         | 0.20                   | Atropine (mg)   | 1 (0.65)         | 0.75 (0.75)           | 0.17                   |
| Lidocaine                       | 3 (27)     | 3 (27)         | NS                     | Lidocaine (mg)  | 200 (183)        | 150 (150)             | 0.90                   |
| Amiodarone                      | 4 (36)     | 7 (64)         | 0.39                   | Amiodarone (mg) | 450 (412)        | 450 (386)             | 0.37                   |
| Sodium bicarbonate              | 2 (18)     | 2 (18)         | NS                     | Sodium bicarbonate (mEq) | 89 (89)         | 89 (89)               | NS                     |
| Calcium gluconate               | 2 (18)     | 2 (18)         | NS                     | Calcium gluconate (g) | 1 (1)             | 1 (1)                 | NS                     |
| Magnesium sulfate               | 1 (9)      | 1 (9)          | NS                     | Magnesium sulfate (g) | 1 (1)            | 1 (1)                 | NS                     |

*Due to small sample size and low treatment numbers for any given therapy, the mean and median doses only include patients who received the treatment. The sample size for those calculations is reported on the left-hand side of the table, \textsuperscript{a}Fisher’s exact test, \textsuperscript{b}Wilcoxon test. CFA: Cardio first angel, NS: Not significant

**Table 3: Summary statistics and the results of the tests for comparing the groups for four study variables**

| Variable                          | Intervention (n = 11) | Control (n = 11) | Significance P |
|-----------------------------------|----------------------|------------------|---------------|
| CPR duration, min, mean ± SD      | 46.9 ± 2.9           | 51.6 ± 2.9       | 0.29\textsuperscript{a} |
| CPR evaluation score, mean ± SD   | 8.54 ± 0.8           | 5.63 ± 0.5       | 0.0005\textsuperscript{a} |
| CPR guideline observation score, mean ± SD | 8.64 ± 0.7           | 5.18 ± 0.6       | 0.0005\textsuperscript{a} |
| Sustained ROSC, n (%)             | 4 (36)               | 2 (18)           | 0.64\textsuperscript{a} |
| Survival to ICU discharge, n (%)  | 9 (82)               | 5 (46)           | 0.088\textsuperscript{a} |
| Survival to hospital discharge, n (%) | 8 (73)               | 4 (36)           | 0.095\textsuperscript{a} |

\textsuperscript{a}Wilcoxon test, \textsuperscript{b}Pearson, \textsuperscript{c}Fisher’s exact test, \textsuperscript{d}Binary logistic regression. SD: Standard deviation, ICU: Intensive care unit, CPR: Cardiopulmonary resuscitation, ROSC: Return of spontaneous circulation

A significant difference in CPR duration was observed between groups [P = 0.29; Table 3]. The incidence of ROSC was similar between groups [P = 0.64; Table 3], as was survival to ICU discharge (P = 0.088) and survival to hospital discharge (P = 0.095).
defibrillation (when appropriate) and initiation of CPR with quality chest compressions are keys to survival. Strategies that improve guideline adherence may improve IHCA outcomes. The real-time AVF is one strategy identified by the AHA and the ILCOR as an area needing further investigation.\cite{9,16,20,21} In the 2015 International Consensus on CPR and Emergency Cardiovascular Care Science with Treatment Recommendations, AVF use was recommended (weak recommendation and low-quality evidence) to provide directive feedback on compression rate, depth, release, and hand position during training. In addition, tonal guidance during training is recommended (weak recommendation and low-quality evidence) to improve the compression rate. However, clinical data were lacking at the time of these recommendations.

In this pilot study, we did not observe an improvement in sustained ROSC. This may be due to the small sample size as our subsequent larger validation RCTs did show improvements in sustained ROSC and survival to hospital discharge,\cite{2,13} as did a prior RCT by Cohen et al.\cite{14} Conversely, CPR guideline adherence and quality were both improved in the intervention group, finding upheld in our follow-up study.\cite{13} No other published studies were identified that compared overall CPR guideline adherence or compression quality in health-care providers with AVF compared to standard compressions. However, several medical simulation studies of healthcare providers have reported on components of quality compressions with AVF use. Improvements in compression rate,\cite{22,27} depth,\cite{12,22,25,26,28,29} and fewer ineffective compressions have been noted.\cite{22,26,30,31} The results on AVF on allowing for full chest recoil have been mixed,\cite{12,25,28} and no-flow time has not been reported to improve.\cite{12}

As the medical community appraises the free-standing AVF devices, there are some important points to consider. At least 15 non-AED AVF devices have been released to market, but only 2 have published human RCTs for IHCA: Ambu Cardiopump (Ambu Inc., Columbia, MD, USA) and Cardio First Angel\textsuperscript{TM} (Inotech Gruppe, Neuberg, Germany).\cite{2,13,14} Moreover, many do not even have published simulation studies. In addition, they are not all created equal; the reliant technology and feedback method may vary significantly. Both the Ambu Cardiopump and the CFA utilize tensile springs, whereas the most readily available commercial products utilize accelerometers or pressure sensors including: Beaty, CPR-1100 CPR Assist, CPRCard\textsuperscript{TM}, CPREye\textsuperscript{TM}, CPR-plus\textsuperscript{TM}, CPRmeter 2\textsuperscript{TM}, LinkCPR\textsuperscript{TM}, and Pocket CPR\textsuperscript{TM}. In addition, some devices in the literature are no longer manufactured: CPR-plus\textsuperscript{TM}, CPR PRO\textsuperscript{TM}, and CPRMeter\textsuperscript{TM}. Further investigations are needed before routine implementation of compression AVF devices is adopted into clinical practice. We encourage investigators to consider that whereas further clinical trials are needed, head-to-head comparisons are needed as well.

**Limitations**

A significant limitation of compression feedback device studies is the inability to blind the clinical providers. Blinding the subject, the investigator, and the data analysts is easy and was done in this case. Sham device use was deemed to be unethical. One criticism of the compression feedback devices is that they do not account for complex changes that occur during CPR. Like other AVF feedback devices, the CFA neither accounts for changes in chest wall compliance and elasticity nor the compressibility of the surface the patient is lying on (e.g. mattress).

This study did not enroll patients with primary cardiac conditions; such patients were admitted to the cardiac ICU. This study was not designed to follow neurologic outcomes as such data regarding the functional outcome are not available. Moreover, for invasive arterial monitoring and waveform capnography were not routinely available at the time of the study and are not reported. In addition, this study was not powered to detect a difference in survival to ICU or hospital discharge.

\section*{CONCLUSION}

The use of the Cardio First Angel\textsuperscript{TM} compression feedback device improved adherence to published CPR guidelines and CPR quality. The insignificant change in rates of ROSC and survival to ICU or hospital discharge may have been related to small sample size. Further clinical studies comparing AVF devices to standard manual compressions are needed, as are device head-to-head comparisons.

\section*{Research quality and ethics statement}

The authors of this manuscript declare that this scientific work complies with reporting quality, formatting, and reproducibility guidelines set forth by the EQUATOR Network. The protocol was approved by the Investigational Review Board at Baqiyatallah University of Medical Sciences (IR. BMSU. REC.1394.419). The trial was not registered in a trial registry as it was performed before trial registration was standard practice in Iran. The subsequent validation studies were both registered in Clinicaltrials.gov (NCT02394977; NCT02845011).

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\section*{Conflicts of interest}

There are no conflicts of interest.
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