The Usability of Five Automated External Defibrillators by Minimally Trained Bystanders

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Objective - Public deployment of Automated External Defibrillators (AEDs) can potentially improve survival from Sudden Cardiac Arrest (SCA) by enabling more timely access to defibrillation. An AED should ideally be designed so that minimally trained bystanders can effectively and safely operate the device and deliver the necessary shock. This study evaluates the usability of five AEDs by bystanders with only a basic understanding of AED functionality and use.

Methods - 125 subjects were recruited to participate as bystander rescuers. Each of the five AEDs was evaluated by a different set of 25 randomly assigned subjects. Subjects were first asked to review a brief memo that provided generic AED instructions. Subjects then deployed the assigned AED and delivered a shock to a simulated victim of cardiac arrest. The principle outcome was successful use of the AED, defined as safe and effective defibrillation shock delivery. The secondary outcome was time to shock, defined as the time from first contact with the AED to delivery of defibrillation shock. Subjects also completed a questionnaire to evaluate their experience using the AED.

Results - The successful use rates for the Defibtech Lifeline (92%), Philips HeartStart OnSite (84%), Medtronic LifePak CRPlus (72%), and Zoll AED Plus (72%) were statistically equivalent (p>0.05 for all comparisons), while the successful use rate for the Cardiac Science PowerHeart G3 (36%) was substantially lower (p<0.05) due to inaccurate pad placement. Time to shock for the Medtronic LifePak CRPlus (63 sec), Defibtech Lifeline (64 sec), Cardiac Science PowerHeart G3 (69 sec), and Philips HeartStart OnSite (79 sec) were statistically equivalent (p>0.05 for all comparisons), while time to shock for the Zoll AED Plus (114 sec) was substantially greater (p<0.05). Subjects rated the Zoll AED least favored in terms of clarity of pad placement and ease of use (p<0.05).

Conclusion - Properly designed AEDs can be used by bystanders with only basic AED knowledge and training to safely deliver an effective defibrillation shock and do so in a timely manner. The Defibtech, Medtronic, and Philips AEDs were more successfully used by minimally trained bystanders than the Cardiac Science and Zoll AEDs, and were therefore more suitable for deployment in public settings.

Approximately 340,000 people die from Sudden Cardiac Arrest (SCA) in the United States annually. The majority of SCA cases are due the development of a cardiac arrhythmia, the most common of which is ventricular fibrillation (VF). The most effective intervention for VF is early defibrillation. For victims of VF, time to defibrillation is crucial, since every minute of delay until defibrillation decreases the chances of survival by 7-10%.

SCA often occurs outside of the medical setting. In this case the victim is reliant on the rapid response of Emergency Medical Services (EMS) or on the timely actions of bystanders. This is why the American Heart Association (AHA) strongly advocates for placing Automated External Defibrillators (AED) in targeted public areas² and supports government sponsored AED community deployment programs.³ Increased AED prevalence in public locations

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enables a broader range of people to successfully assist a victim of SCA.

Rapid EMS response in large office complexes or high-rise buildings is a challenge. SCA is more likely to occur in these work environments due to the large number of people present in one place. To address this challenge many employers are initiating AED deployment programs. It is unrealistic and cost prohibitive to expect that all employees would receive comprehensive AED training, yet they may need to use an AED in a critical situation to resuscitate a co-worker.

Previous studies indicate that untrained bystanders can effectively use an AED⁴, however concern has been raised that not all AEDs are equally effective when used by untrained bystanders. ^{5,6,7} The purpose of this study is to assess the usability of five commercially available AEDs in a work environment by bystanders who have not received formal training, but do have a basic understanding of AED functionality and use.

Methods

AEDs

Five commercially available AED models were utilized in the study (Figure 1). To eliminate the risk of injury due to defibrillation shock, training defibrillators and training pads with no electrical energy delivery capabilities were used.

Cardiac Science Powerheart G3 (180-3010-002)

Two adhesive pads (9035) affixed to a single plastic liner are stored in the device; AED deployment scenario is controlled through an infrared remote control (Cardiac Science, Irvine, CA).

Defibtech Lifeline (DDU-100A)

Two adhesive pads (DDP-100TR-V1) affixed to a single plastic liner stored on the back of the device; AED deployment scenario is controlled through an infrared remote control (Defibtech, Guilford, CT).

Medtronic LifePak CRPlus (3201804-000)

Two adhesive pads (3201805-004) affixed to a single plastic liner are stored in the device; AED deployment

scenario is controlled through an infrared remote control (Medtronic Physio-Control, Redmond, WA).

Philips HeartStart OnSite (M5085A)

Two adhesive pads (M5093A) affixed to a single plastic liner stored in a cartridge that is part of the device; AED deployment scenario is controlled by device itself through recognition of electrode attachment via an impedance simulating metallic strip on the manikin's chest (Philips Medical Systems, Seattle, WA).

Zoll AED Plus (8008-0104-01)

Single large adhesive electrode (8900-0803-01) affixed to two plastic liners is stored in the device; AED deployment scenario controlled trough a wired remote control (Zoll Medical, Chelmsford, MA).

Subject Recruitment

125 subjects between the ages of 18 and 75 years were recruited to participate in the study as bystander rescuers. None of the subjects had prior AED training nor had previously used an AED.

Upon arrival each subject received a subject number



Figure 1. The five commercially available Automated External Defibrillators (AED) used in the study. Rear row (left-right): Medtronic LifePak CRPlus, Defibtech Lifeline, Zoll AED Plus. Front row (left-right): Cardiac Science Powerheart G3, Philips HeartStart OnSite.

representing the sequence of their arrival. Prior to the study one of the 5 AED models had been randomly assigned to each subject number. The assignment made certain that each AED model was used by 25 subjects. The AED assigned to a particular subject number was the AED used by that subject for the study.

Protocol

The study scenario was designed to represent AED deployment in the work environment where the bystander rescuer has no formal AED training or AED experience. Subjects were informed that they would be asked to deploy an AED and deliver a defibrillation shock to a co-worker suffering from SCA. Subjects were instructed to take every action that they thought would be helpful to this simulated victim and to act quickly since the victim's life was in jeopardy. The subjects were asked to read a standardized 200-word memo from the corporate safety office about the AEDs that were recently deployed in the work place (Figure 2). The memo provided generic instruction on AED functionality and use. The subjects were then permitted to request clarification of the memo, however specific questions related to AED use were not allowed. After all questions were answered, no further interaction between the investigators and subjects was permitted.

The trial was performed in an isolated room, so that other

From: Safety Office

Sent: Friday, March 4, 2005 10:36AM

To: All Employees

Subject: Automated External Defibrillator (AED)

Each year Sudden Cardiac Arrest claims the lives of more than 300,000 people.

We have recently purchased several Automated External Defibrillators (AED) to resuscitate employees suffering from cardiac arrest. AEDs automatically analyze the heart rhythm and if necessary shock the heart back into a normal rhythm. AEDs provide simple voice commands that instruct anyone how to correctly use the device.

An AED has been placed at every entrance to our facility. Safety officers have been trained in the use of AEDs. However, in the event that you need to use an AED we are providing basic instructions. Please review these instructions so that you are ready to resuscitate a victim of cardiac arrest.

If you find a collapsed person call for help and get the AED. Then,

- 1) Turn on the AED or open AED lid
- 2) Expose victim's chest
- 3) Find attached pads package and open
- 4) Peel liner from pads
- 5) Follow pictures to apply pads to the victim's bare chest
- 6) Follow all voice commands

We anticipate that Safety Officers will quickly respond in the event of any emergency. However, we also want you to be prepared to use the AED if necessary.

Thank you for your cooperation.

John Franks Director, Safety Office

Figure 2. Memo provided to subjects prior to trial providing basic instruction on AED functionality and use.

subjects would not be aware of actions taken by previous subjects. Upon entering the room the subject discovered a fully clothed CPR manikin (victim of SCA) on the floor in a supine position. Within 2 feet of the victim the subject also found the randomly assigned AED. The AED was prepared for use according to AED manufacturer instructions.

Experimental data was documented by the investigators on a standardized data collection form. The investigators documented the time from start to successful shock delivery, the positioning of the electrode pads, and other aspects of AED deployment and use such as whether pads were applied to the bare chest, whether pads were peeled from the liner, whether the victim was touched during ECG analysis or defibrillation shock delivery. The trial was stopped after the first shock was delivered or censored at 5 minutes if the subject was unable to successfully deliver the defibrillation shock.

After conclusion of the trial the subjects were requested to complete a brief questionnaire and rate their experience using the AED device. All 125 trials were also videotaped enabling subsequent trial review and analysis.

Data Analysis

The principle outcome was successful use of the AED. Success was defined as safe and effective defibrillation shock delivery and was comprised of three required elements: 1) proper positioning of electrode pads on the victim's bare chest, 2) pressing of the SHOCK button when instructed and 3) staying clear of the victim during charging of the AED and shock delivery. Positioning of the right infraclavicular pad was considered to be correct if at least half of the pad area was within the area defined by the clavicle (superior border), costal margin (inferior border), right of mid-sternal line (medial border), and anterior axillary line (lateral border). Positioning of the left apical pad was considered to be correct if at least half of the pad area was within the area defined by the top of the axilla (superior border), costal margin (inferior border), left of mid-sternal line (medial border), and posterior axillary line (lateral border). The number of subjects who successfully used the AED was compared for the five AED models using Fisher's exact test. A two-sided p-value of 0.05 was considered to be statistically significant.

The secondary outcome was time to shock (T_{shock}) . Time to shock was defined as the time that the subject first makes physical contact with the AED to the time that the SHOCK button was pressed by the subject when instructed by the AED. T_{shock} was compared for all five AED models by oneway ANOVA, testing the null hypothesis that there was no difference between the AEDs. Post-test analysis was also

performed to compare T_{shock} results for individual AED pairs of interest. Again, a two-sided p-value of 0.05 was considered to be statistically significant.

Statistical analysis was also performed to determine whether gender or age influence the principle and secondary outcomes. The rate of successful AED use and T_{shock} was compared for male and female subjects as well as for subjects 50 years or less and those greater than 50 years old using Fisher's exact test and T-test analysis respectively.

Finally, subject responses provided on the post trial questionnaire were compared for the five AED models. Subjects used a rating scale of 1 ("Strongly Disagree") to 5 ("Strongly Agree") to respond to each presented question. Kruskall Wallis tests were utilized to assess whether the difference in responses for the 5 AEDs was statistically significant.

Results

Subject Characteristics

Demographics of the 125 study participants are shown in Table 1. The subjects range in age from 18 to 70 years with an average age of 37 years. The average age of subjects for each of the five AED models ranges from 35 to 38 years. Eighty-four (67%) of the 125 subjects were female. The percentage of female subjects for each of the five AED models ranges from 56% to 76%. The difference in subject age and gender for the five AED models was not statistically significant.

| AED | Number of subjects | Avg age (yrs) | % female |
|-----------------|--------------------|------------------|-------------|
| Cardiac Science | 25 | 36 | 60 |
| Defibtech | 25 | 35 | 72 |
| Medtronic | 25 | 38 | 76 |
| Philips | 25 | 36 | 72 |
| Zoll | 25 | 38 | 56 |
| ALL | 125 | 37 | 67 |

 Table 1. Demographics of study subjects for each AED model.

Success Rate

The percentage of subjects who safely delivered an effective defibrillation shock for each AED model is shown in Figure 3. The highest success rate was achieved with the Defibtech AED (92%). Subjects using the Cardiac Science AED had the most difficulty with pad placement resulting in the lowest success rate (36%). Two Zoll subjects touched the victim during shock delivery negatively impacting the success rate (72%) and posing a risk to the rescuer. The

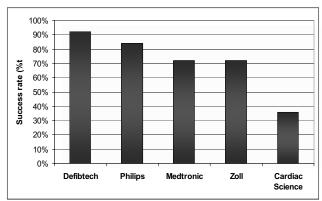


Figure 3. AED model and success rate. 92% of Defibtech subjects safely delivered an effective defibrillation shock, while difficulties with pad placement resulted in a 36% success rate for Cardiac Science subjects.

| AED | Success rate (%) | Difference in success rate significant (p<0.05)? | | | |
|--------------------|---------------------|--|---------|-----------|-----------|
| | | Zoll | Philips | Medtronic | Defibtech |
| Cardiac Science | 36 | Yes | Yes | Yes | Yes |
| Defibtech | 92 | No | No | No | |
| Medtronic | 72 | No | No | | |
| Philips | 84 | No | | | |
| Zoll | 72 | | | | |

Table 2. Percentage of subjects that successfully achieved safe and effective defibrillation shock delivery. Analysis indicated a statistically lower success rate for the Cardiac Science AED (p<0.05).

success rates for the Philips AED (84%) and the Medtronic AED (72%) were impacted by the accuracy of electrode pad placement on the victim's chest. Statistical analysis results for all AED pairs presented in Table 2 indicate that the success rate for the Cardiac Science AED was statistically worse than that for the Defibtech, Medtronic, Philips, and Zoll AEDs.

Time to Shock

The median time to shock (T_{shock}) for all AED models is shown in Figure 4. The shortest median T_{shock} was achieved with the Medtronic AED (63 sec), while the longest median T_{shock} with the Zoll AED (114 sec). As indicated in Figure 5, 24% of subjects using the Defibtech AED (6) achieved a T_{shock} less than 60 sec. 20% of Medtronic and Cardiac Science AED subjects (5) and 12% of Philips AED subjects (3) also achieved T_{shock} less than 60 sec, while no Zoll AED subjects were able to deliver a defibrillation shock within 60 sec. ANOVA analysis indicates that the AED model has a significant influence on T_{shock} results (p<0.0001). As shown in Table 3 post test statistical analysis verifies that T_{shock} for the Zoll AED was statistically greater than that of all other AEDs (p<0.05), while T_{shock} for all other AEDs was statistically equivalent.

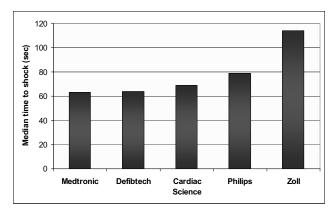


Figure 4. AED model and median time to shock. The Medtronic AED resulted in the fastest time to shock (63 sec), while the Zoll AED resulted in the slowest time to shock (114 sec).

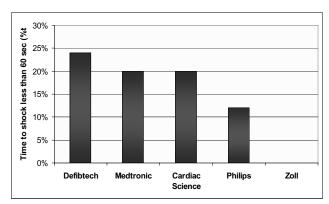


Figure 5. AED model and percentage of subjects with time to shock less than 60 sec. No Zoll subjects were able to deliver a defibrillation shock within 60 sec.

| AED | Median T _{shock} (sec) | Difference in T _{shock} significant (p<0.05)? | | | |
|--------------------|---------------------------------------|--|---------|-----------|-----------|
| | | Zoll | Philips | Medtronic | Defibtech |
| Cardiac Science | 69 | Yes | No | No | No |
| Defibtech | 64 | Yes | No | No | |
| Medtronic | 63 | Yes | No | | |
| Philips | 79 | Yes | | | |
| Zoll | 114 | | | | |

Table 3. Median time to shock for all AEDs. Analysis indicated a statistically greater time to shock for the Zoll AED (p<0.05).

The data indicates that gender and age impact the speed with which the rescuer was able to deliver the defibrillation shock. The median $T_{\rm shock}$ for female subjects was 71 sec, while median $T_{\rm shock}$ for male subjects was 79 sec (p<0.05). The median $T_{\rm shock}$ for subjects of age 50 years or less was 71 sec and 87 sec for subjects greater than 50 years (p<0.05).

Subject Responses

Medtronic

Philips

Zoll

The average satisfaction scores from the post-trial questionnaire is shown in Table 4. For each of the questions the average score for all AED models is provided. The responses provided by the Zoll subjects result in the lowest satisfaction score among all the AEDs. Statistical analysis results for all AED pairs presented in Table 4 indicate a statistically significant lower level of satisfaction with the Zoll AED when compared to the Cardiac Science, Defibtech, Medtronic, and Philips AEDs.

| Question: The location for placing the pads was clearly indicated? | | | | | | |
|---|--------|-------------------------------------|---------|-----------|-----------|--|
| 4 | Avg | Statistically significant (p<0.05)? | | | | |
| AED | rating | Zoll | Philips | Medtronic | Defibtech | |
| Cardiac Science | 4.5 | Yes | No | No | No | |
| Defibtech | 4.3 | Yes | No | No | | |
| Medtronic | 4.3 | Yes | No | | | |
| Philips | 4.5 | Yes | | | | |
| Zoll | 3.6 | | | | | |
| Question: The AED was easy to use? AED Avg Statistically significant (p<0.05)? | | | | | | |
| AED | rating | Zoll | Philips | Medtronic | Defibtech | |
| Cardiac Science | 4.5 | Yes | No | No | No | |
| Defibtech | 4.5 | Yes | No | No | | |
| | | | | | | |

Table 4. Average subject AED ratings regarding clarity of pad placement and ease of use. Analysis indicated a statistically lower subject preference for the Zoll AED (p<0.05).

No

Yes

Yes

4.7

4.5

3.9

Discussion

The study scenario represented an office environment where employees had already received basic information regarding AED functionality and use through a memo distributed by the corporate safety office. It is likely that the study subjects paid considerable attention to this particular memo, because they understood that the subsequent task was related to the information presented in the memo. One can surmise that given the volume of memos and emails distributed in typical work environments today, a memo describing AED use would have been read with less diligence. However, any impact of decreased attentiveness to the training memo would impact all AEDs equally and therefore was not considered a factor in our comparative study.

All of the subjects were able to deploy the AED and deliver a defibrillation shock within 5 minutes, therefore none of the trials were censored by the investigators. All subjects removed the clothing from the manikin's chest before applying the electrode pads, however some subjects did not initially recognize that the pads need to be peeled from the liner before applying to the manikin. While liners were still affixed to the pads the investigators did not allow the AED to progress with the resuscitation effort. These subjects did eventually understand that pads must be peeled from the liner, however this initial confusion did extend the elapsed time to shock delivery.

Previous studies that evaluate the usability of AEDs by untrained rescuers^{5,6,7} emphasize time to defibrillation shock as the primary outcome. Time to defibrillation has been shown to be an important factor in cardiac arrest survival, however small differences in time to defibrillation have not been proven to result in significant differences in survival. We prefer to evaluate AED usability emphasizing the effectiveness and safety of the delivered shock. Expedient delivery of a shock that is not effective and safe does not help the victim of cardiac arrest, and may even result in the rescuer unintentionally becoming a victim themselves.

The AED success rate was largely determined by the number of subjects who properly positioned both electrode pads on the victim's chest. Proper positioning of the pads ensures that the AED will accurately assess the victim's ECG signal and if necessary deliver an effective defibrillation shock. All five AEDs provide diagrams on the pad package and the pads themselves indicating where pads should be placed on the victim's chest. The Cardiac Science AED uses the same black and white only pad placement diagram on the pad package and the pads themselves. The diagram concurrently indicates the correct position of both the right and left pad. The Defibtech, Medtronic, Philips, and Zoll AEDs use pad specific diagrams enhanced with color to assist the rescuer in pad positioning. The diagram on the right pad indicates the proper position of the right pad only, while the diagram on the left pad indicates the position of the left pad only. Our results suggest that pad specific diagrams positively impact pad placement accuracy. Subjects using the Cardiac Science AED had the most difficulty with pad placement. Only 36% of the Cardiac Science subjects properly positioned the pads on the simulated victim's chest, as compared to the 92% pad placement accuracy achieved by the Defibtech subjects.

The Zoll user interface design does not facilitate easy and efficient AED use. Several Zoll subjects had problems locating and activating the on/off switch, while others expected that removing the Zoll AED cover would activate the device. Four of the Zoll subjects (16%) had trouble

simply turning on the Zoll device. Seven of the Zoll subjects (28%) had difficulty orienting and correctly using the one-piece electrode. Subjects appeared confused by the Zoll visual interface with graphical icons and LED indicator lights, resulting in five Zoll subjects (20%) unnecessarily pressing these icons. Four Zoll subjects (20%) could not initially locate the "treatment" button to deliver the necessary shock.

These usability challenges experienced by the Zoll subjects were evident in the results for time to shock as well as in the subject preference ratings. Time to shock for the Cardiac Science, Defibtech, Medtronic, and Philips AEDs were statistically equivalent, while Zoll AED time to shock was nearly 75% greater than that of the other AEDs. Our results were consistent with those published in previous studies in which shock times for the Zoll AED were 40-120% greater when compared to the other AEDs. Subject preference scores from the post-trial questionnaire also reflect the Zoll usability challenges. Subjects expressed the greatest dissatisfaction with the Zoll AED, while subject satisfaction with all other AEDs was statistically equivalent.

Limitations

The scenario utilized in the study was that of a co-worker suffering from cardiac arrest. Even though many subjects did report experiencing stress as they deployed the AED and delivered a defibrillation shock, all subjects understood that this was only a simulated emergency situation. Therefore, relevance of these results to real cardiac arrest situations is unclear. However, given the limited data available on AED use in the field by untrained bystanders, studies with simulated scenarios are an appropriate manner to study AED usability.

All subjects received basic instructions about AED deployment and use through the memo provided immediately prior to the trial. This study did not consider the impact of information retention and whether a longer elapsed time between training and use would impact AED usability. In addition, the training memo was designed to be generic and not AED-specific. One would expect that even basic AED training provided to employees would be tailored to the specific AED model deployed in the work environment.

Since the manikin does not simulate human impedance, the investigators were required to use a remote control for the Cardiac Science, Defibtech, Medtronic and Zoll AEDs to simulate the attachment of electrodes and advance the scenario. Despite great care to make certain that delays were not introduced, this may have minimally impacted the

time to shock results.

The Philips AED used in the study requires that a metallic strip adapter be affixed to the manikin's chest positioned from upper right to lower left. This conductive strip was used by the trainer AED to determine that both pads have been applied to the manikin's chest. It was likely that the silver strip influenced the placement of the pads on the victim's chest.

Conclusions

This study indicates that there are significant differences between the various AED models impacting the ability of bystanders with only basic AED knowledge and training to safely deliver an effective defibrillation shock and to do so in a timely manner. These differences are a reflection of the AED user interface design including all voice commands, diagrams, labeling, buttons, and indicator lights. This study indicates that the Defibtech, Medtronic, and Philips AEDs can be more successfully used by minimally trained bystanders than the Cardiac Science and Zoll AEDs, and are therefore more suitable for deployment in public settings.

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Thank you for reading this data sheet.

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