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Automatic External Defibrillators (AED)

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Executive Summary

Automatic external defibrillators (AED) are able to automatically perform an analysis of the heart, determine if defibrillation is required, and deliver electrical shocks to the heart. AED has the potential for improving survival in persons with ventricular fibrillation (VF). The trend is toward wide AED placement in public and private settings. However, an evaluation of AED usefulness, placement, and cost effectiveness should be done to determine if widespread use is appropriate. Additional issues concern implementation, control, and data collection for AED. The purpose of this report is to assist those who are considering purchasing and installing AED in their setting, or making them a component part of their first response team.

There are many examples from hospital settings, EMS responders and actual victims, that verify the life saving attributes of cardiac defibrillation. For successful defibrillation, quick response is a basic requirement. Studies have shown that without defibrillation within ten minutes, heart attack victims with ventricular fibrillation have little chance for survival. Field trials in Rochester, Minnesota, and Seattle, Washington, have shown the effectiveness of AED. However, other randomized trials report AED had a non significant impact on survival rates. All studies have emphasized the importance of having cardiopulmonary resuscitation (CPR), and AED associated with an effective first response dispatch system.

HTAC recommends that widespread public deployment of AED should not proceed until ambulances, police units, highway patrol units, fire rescue units, ambulatory centers that see high risk patients, and hospitals are equipped with AED, and their effectiveness in these settings is established. Data should be collected on their use. Their effectiveness should be evaluated before AED are routinely placed in other settings such as stadiums, airplanes, theaters, schools, retirement homes, churches, and casinos.

A successful AED program should have five main parts:

1. An evaluation to determine appropriate placement
2. A plan for implementing personnel training and retraining
3. Medical oversight
4. Data collection protocols
5. Follow-up of outcomes

The American Heart Association's "Chain of Survival" could be used as a cornerstone for a successful AED program. The "Chain of Survival" has four crucial links:

1. Early Access to Care is the first link;
2. Early Cardiopulmonary Resuscitation, if defibrillation is indicated, gives a victim additional time until defibrillation can be performed;
3. Early Defibrillation is a critical link for treating victims with ventricular fibrillation;
4. Early Advanced Care is important because some patients will require more advanced treatments, including airway control or drugs.

Introduction

Nationally, sudden cardiac arrest (SCA) strikes 350,000 people a year making it the single most common event leading to death. [7,10, 11, 23, 31] In Minnesota, during 1996, approximately 13,000 people died of SCA.[17] It is not known how many of these Minnesotans may have been saved by an AED device. Industry estimates indicate 100 Minnesotans may have been saved by AED technology since 1995. It is not known how many times AED have been used.

A majority of SCA is due to abnormal heart rhythm. Called arrhythmias, of which, ventricular fibrillation (VF) is the most common. During VF the heart's electrical signals become scrambled and ventricular contractions cease. The heart then stops pumping, causing a victim to collapse and quickly lose consciousness. Death follows within minutes if normal heart rhythm is not restored. In the United States, one adult dies of SCA every one to two minutes. [28]

The underlying cause of SCA is not well understood and victims may or may not have had a history of heart disease. Only 30 percent of SCA can be conclusively attributed to acute myocardial infarction. A normal cardiac rhythm can be achieved after SCA by the application of an electric shock to an arrested heart. This shock can be given through the chest wall by external defibrillation.[27]

Statistics are not available on the total number of Minnesota emergency team calls responding to cardiac arrest for individuals in ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT).

Between 50 and 80 percent of SCAs occur in the home, often without prior warning or witnesses, thus making AED use a greater challenge. This makes the victim's chance for survival before reaching a hospital less than one in 20.[7, 11] Although the average SCA victim's age is 65, younger people in their 30s and 40s can also be stricken.[7] It is generally misconstrued that cardiac attacks occur only to adult males; however, the ratio of male to female victims is relatively equal. Minnesota 1996 data showed 7,314 male deaths to 5,911 female deaths. [17]

Early defibrillation is the single most important therapy for the treatment of adults in VF.[26] For each minute VF persists, the likelihood of successful resuscitation decreases by 10 percent. After 10 minutes there is very little chance that resuscitation will succeed.[28] In Seattle, Washington, it was found that the survival rate (hospital release) increased to as much as 30 percent when early CPR and early defibrillation were provided.[7, 14] This compares to a national survival rate of 5 percent or less. [18, 23]

Nationally, it is estimated that less than 50 percent of ambulances, 30 percent of fire department vehicles, and 10 percent of police vehicles are equipped with any kind of defibrillator.[7, 30] In Minnesota, the Minnesota Emergency Medical Services Regulatory Board (MEMSB) estimates 450 of the 765 licensed ambulances are equipped with AED.[4] The MEMSB, which licenses ambulance services, requires advanced service providers to carry a defibrillator. A basic ambulance service must apply for a variance to use defibrillators and then the defibrillators may only be used by trained Emergency Medical Technicians (EMTs). The board has proposed legislation to have all basic ambulance services carry AED, not just the primary 911 responders. In 1998, the Minnesota Legislature passed a bill allocating $450,000 for the one-time purchase of AED by local law enforcement agencies.[12] This appropriation is being administered by the Commissioner of Public Safety.

Presently, AED are mainly used by EMTs in ambulances and fire rescue vehicles; however, some hospitals are now starting to augment their crash carts with AED devices. The technology is also starting to proliferate into the nonhealthcare sector, which leads to concern. The importance of equipping 911 responders with the best methods available is recognized by the American Heart Association (AHA) and National Society of Cardiology (NSC), but as AED technology grows outside of the emergency medical services sector, cost effectiveness and liability issues arise.

A 1997 poll showed that only half of the states allow non-EMT first responders to defibrillate.[30] The poll also showed that less than one half of EMTs and less than one quarter of non-EMT first responders are trained and equipped to defibrillate. The AED training currently done in Minnesota is being performed by the manufacturers, the American Red Cross and the National Safety Council. The AHA will be incorporating AED training into their "Chain of Survival" program. In order for maximized AED effectiveness, well-planned training and retraining programs must be implemented.

One of the most important issues is training on the use of the devices. Over the last few years, improvements have been made by the manufacturers which make the devices easier to use. Manufacturers have built in self-help, self-explanatory directions and emphasized ease of use. Ease of use is a critical consideration when a decision about unit placement is being made. If an individual or individuals are going to be provided with training on the device, not only the type of training has to be considered but a plan for refresher training or continuing training should be in place. The AHA training recommendations are the standards which should be followed. The AHA Instructor's Manual for Basic Life Support contains good training guidelines. Other training guidelines have been developed by EMS agencies and the American Red Cross. Training and retraining should also include continuing education about CPR. Professional and public education on the use of and about AED must continue in order for Minnesota to achieve the maximum benefit from the technology. There are multiple organizations like the American Red Cross, other AHA approved training, private training, and hospital trainings that will fill this educational need.

Technology and Alternative Technologies

How Does AED Work?
The AED evolved from the experiences gained with portable defibrillators and from implantable defibrillator technology. The device is built with an electronic microprocessor (the brain of the device) which controls the analysis and defibrillation

functions. Through electrodes placed on the patient's chest, the AED unit senses and analyzes the cardiac rhythm of the heart and makes a decision based upon that information. Semi-automated devices require more decision making on the operator's part. If defibrillation is indicated, the unit will then alert operators that a shock is needed. During this time, lithium batteries charge a capacitor to a preset level and the unit then waits for the command by the operator to shock. The amount of energy delivered to the heart is measured in joules (1 joule = work done when one amp is passed through resistance of one ohm for 1 second). The maximum delivered amount can be 360 joules. If shock is initiated, the electrical energy is sent through the electrodes, into the chest cavity and the heart receives an electrical pulse. Another analysis is then performed by the device to determine if another higher energy shock is required. This sequence is followed until a nonshockable rhythm is attained or life support efforts are ended. [3, 26]

Patient Selection Criteria

A potential patient is selected by determining whether he or she is unconscious, has no pulse or heartbeat, and is not breathing. The patient is then connected to the AED so that the device can evaluate the individual's electrocardiogram (ECG). At this time, the unit also performs an evaluation on the quality of connection between the unit and electrodes, and the electrodes and paddles. If the unit determines a shock is needed, it will alert the rescuer and prepare to deliver a shock. If the unit determines that a shock is not required, it will not be able to deliver a shock. The automatic external defibrillator's ability to perform this type of analysis and make the decision of whether to shock is one of its most appealing features. Unlike manual defibrillation, where a trained person is required to read the unit's output (an electrocardiogram strip), AED does the evaluation. However, an individual still has to make the final decision forshock delivery when an AED is used.

The need for defibrillation is uncommon in the pediatric age group. When an unconscious child is found, airway obstruction or trauma is more common. Also, AED units are not capable of delivering energy levels low enough to treat pediatric patients. The AHA recommends only using AED on patients in cardiac arrest who are more than 12 years of age and weigh more than 90 pounds. [26, 14]

Description of Procedure

Adhesive pads are attached to the defibrillator cables (some units contain prepackaged, already attached cables and pads). Once the cables and pads are joined and connected to the unit, the rescuer attaches them to the patient's chest. The leads are placed in a modified lead II position (upper-right sternal border and lower-left ribs over the heart). After pad attachment, CPR is stopped and the unit is allowed to do an analysis. All contact with the patient during analysis must be avoided in order to obtain accurate readings. Depending upon the brand of device, assessment can take from five to fifteen seconds. The device will then notify the responder that shock is indicated by written message, visual display, or a synthesized or recorded voice. If the patient is to be shocked, the responder must then announce, "Clear the patient," "I'm clear," or some other notification that the patient is to be shocked. The shock control is then initiated and shocking completed.

CPR is not restarted until another analysis is performed by the device. This sequence of analysis, notification, shock, and CPR is continued until up to three shock cycles have been completed. Between cycles, CPR should be resumed for 60 seconds. Repeated shocking can go on until Advanced Life Support (ALS) arrives or as specified by the medical director. [26]

Formulated protocols should be followed; however, if none are available, the following treatment sequence is suggested:

1. If no pulse, do the ABCs of life saving; (A-check Airway, B-make sure Breathing, C-check Circulation)
2. Perform CPR until defibrillator is attached;
3. Attach AED only to people in apparent cardiac arrest;
4. Always shock according to the AED instructions;
5. Perform CPR for one minute between shock attempts;
6. Continue to shock until a "no shock" indication is received or until the patient is transported to a hospital.

Effectiveness
The AHA minimum standards for AED should be 90 percent sensitive for ventricular fibrillation and 99 percent specific for other heart rhythms.[15] AED now have a reported sensitivity range of 94-98 percent and a specificity range of 98-100 percent for VF.[11,27]

Alternatives
The most widely known alternative treatment to AED devices for VF, is CPR. CPR is the first method that should be used, but should not be used by itself. CPR is considered life sustaining (keeps victims alive until effective treatment can be given) and not necessarily life saving (victim's breathing and heart functions continue without assistance after treatment) when used for sudden cardiac arrest victims. CPR should be considered only as an interim method, which gives the victim life support until defibrillation can take place.

If an Emergency Medical Service (EMS) team is at the scene, a manual defibrillator (one with an EKG strip) is oftentimes available and put into use. These are highly effective but because of their size, weight, and complexity, operators have been found to be slower in delivering shock. Studies have shown an average of one minute faster response time with AED.

Patient Outcome

The earlier the response to a cardiac arrest, the higher the chance of survival. In hospital studies where cardiac arrest is witnessed and early defibrillation is a method of treatment, survival rates as high as 89 percent have been reported.[8, 31] The survival rate of 19 percent reported in Iowa or the 25 plus percentage rates of southeastern Minnesota, northeastern Minnesota and Wisconsin are a realistic goal.[32, 33]

A study conducted by Roger White and Associates in Rochester, Minnesota, of police cars and emergency medical technician-paramedics equipped with automatic defibrillators showed 41 of the 84 persons (49 percent), who had an out-of-hospital cardiac arrest and were shocked by an AED device, survived until hospital discharged. By comparison 26 out of 2,329 victims survived using normal treatment methods (CPR) in New York City.[32, 33]

One of the best known completed AED studies done in Seattle, Washington, and surrounding King County showed that a combination of aggressive public education in CPR, having a fully functional 911 network, two-tiered emergency response

systems (basic response followed by more advanced care like paramedics), and policies which allowed early defibrillation by EMTs resulted in a 30 percent resuscitation success rate. This high success rate can be attributed to a number of different factors. For example, Seattle is a community that has a dense population and a small land area, which makes response times short. Seattle is also known for its 20-year commitment to CPR and EMS.

A study of the Memphis, Tennessee Fire Department showed that AED were effective in treating and terminating VF and VT, but AED treated victims were no more likely to survive than those treated by using CPR (32% vs. 34%) and survival to hospital discharge had similar outcomes (14% to 10%).[13] Conclusions of a study done in Charlotte, North Carolina, showed that "there was not enough of a statistical difference between the AED group and the CPR group to recommend blindly adopting AED without having the other parts of The Chain of Survival optimized." [25]

The actual patient survival rates of any AED program will depend on the strength of all its parts. The effectiveness of the technology is in direct correlation to the rapidity of the response. There is only a ten minute window of time in which any therapy will be found to be effective. The importance of a quick response is best shown by the following graph which shows the 10 percent less chance for survival for each minute of delay until defibrillation. [24, 30]

By sampling the average or estimated response times of EMS teams across the United States, a better understanding of who should be AED equipped can be achieved. Responses of ten minutes for ambulance service, five minutes for fire rescue, and two to three minutes for police are considered typical. [13, 25, 28, 33] These response times point to the importance of first having police trained and equipped for first response, followed by fire rescue units, and then ambulance services. It should also be noted that emergency vehicles response times in rural areas and large cities, like New York City, usually go beyond ten minutes.[28]

Costs

Equipment Cost
The cost of an AED was once between $5,000 and $10,000 but with improvements in circuitry, device design changes, volume production and battery improvements, the cost per unit has dropped to between $2,500 and $4,000.

Other Costs
The major cost associated with AED, other than the cost of the equipment, is the cost of training and retraining of personnel on the use of the device. It generally takes several hours of time to learn the operation and use of an AED device. Retraining would require less time and cost would be affected by the frequency of retraining. Some recommend retraining every six months, but no less than once a year.

Although AED devices will operate by themselves, it is recommended that a playback unit, data collection unit, special software or increased memory should be added at the time of purchase if the basic unit doesn't have sufficient memory. These add an additional cost to a program, but will ensure better event records and may assist in the overall AED program administration.

Cost Effectiveness

The cost per EMS life saved from sudden cardiac arrest was estimated between $2,100 and $2,300. This estimate included the cost of a $7,000 defibrillator and a $40,000 ambulance. Another study put the estimated cost at $8,000. This estimate included the training of paramedics, personnel, equipment, and response time maintenance.[7] Costs are, however, dependent on frequency of use.

Other

There are many incidents where the lifesaving ability of AED technology has been documented. The AHA is recommending that the devices be available to all first response personnel, and support their placement in private homes and business. The AHA has made early defibrillation the third step in their "Chain of Survival" program. The AHA and the National Institutes of Health (NIH) are planning a national study to determine AED value.

Between 1994 and 1997, the Prudential Insurance Company pledged $2.5 million in grants to more than 1,000 EMS squads in 13 states. This assisted many squads in acquiring AED devices. In 1997, they pledged an additional $1 million to help another 500 EMS squads across the United States and in all 50 states.[21]

The United States Department of Transportation has incorporated defibrillation into their EMT Basic National Standard Training Curriculum. In 1994, they added a section to their curriculum which requires EMTs to be trained on the use of AED.

Issues of Controversy

AED usage raises concern about the use of the device by poorly trained or untrained personnel, differences between devices, the number of devices needed, battery life, liability, and device placement.

Critics express reservations about having poorly trained individuals using AED. Some of this concern has lessened since the newer AED devices have failsafe mechanisms built into them. They are now designed to protect a victim against unneeded shocks to the heart, but the potential for inappropriate use is still apparent and still an issue which can only be overcome by effective training and education.

The time period between training and actual unit use may also cause confusion, with a responder not knowing how to use the device correctly. Refresher training may never take place, and the individual using the device may not receive the latest information on defibrillation. The importance of a retraining program cannot be over emphasized.

Differences between machines may cause a delay and confusion when it comes to the use of an available device. Several manufacturers have addressed this issue by including voice instructions within the units. Newer units now have no more than three buttons, making them easier to use.

A major concern has always been about a battery's longevity. There is a fear that the unit may sit on the shelf for long periods of time and regular maintenance will be forgotten. Later, at a most crucial time, the batteries would be dead and the unit would be rendered inoperable. This concern is somewhat negated by the use of lithium batteries, which have a longer shelf life (up to five years) and a predictable

depletion curve. Newer units have been designed so that self-testing takes place on a daily basis. The units are also equipped with alert indicators if further maintenance is required. One manufacturer has built an electronic chip into their battery unit, which performs self diagnostics on the battery and maintains a battery history.

There are concerns that the time needed in trying to locate and the usage of an AED may hinder CPR. This concern can be overcome by stressing the importance of first performing the "ABCs" of CPR (airway, breathing, and circulation) which helps determine whether the problem is a cause other than SCA. CPR and AED are complementary to each other and when used together better patient outcomes can be achieved. It should be stressed that one minute of CPR between AED analysis is an optimal part of SCA treatment.

Some may be concerned about liability issues. In 1998, Minnesota amended the Good Samaritan Law (Minnesota Statutes, section 604A.01, subdivision 2)12 in order to address issues relating to civil actions and provide immunity from civil liability for the use of AED under certain circumstances. The new definition of "emergency care" now includes "providing emergency medical care by using or providing an automatic external defibrillator, unless the person on whom the device is to be used objects." The section goes on to define what is needed in order to meet the requirements for an AED:

1) FDA approval;
2) capable of determining the presence or absence of ventricular fibrillation or rapid ventricular tachycardia without the intervention by an operator and whether defibrillation should be performed; and
3) upon determining that defibrillation should be performed, automatically charges and requests delivery of an electrical impulse to an individual's heart.

One major cost concern is whether the cost of widespread AED placement will translate into better patient outcomes, especially when cost is compared to a possible lack of use because of poor AED placement.

Conclusions/Recommendations

AED are being used in many healthcare systems, are beginning to move into the public setting, and will be used by nonmedical personnel. First response teams, hospitals and ambulatory centers that have a patient population that is at high risk should be equipped with AED before they are placed outside of the emergency medicine system, (e.g. stadiums, theaters, schools).

HTAC recommends that widespread public deployment of AED should not proceed until ambulances, police units, highway patrol units, fire rescue units, ambulatory centers that see high risk patients, and hospitals are equipped with AED, and their effectiveness in these settings is established. Data should be collected on their use. Their effectiveness should be evaluated before AED are routinely placed in other settings such as stadiums, airplanes, theaters, schools, retirement homes, churches, and casinos. In order to effectively use the AED as a part of a life saving program, a first response team should include the following components in its program:

1. A plan of implementation that has looked at the best placement and most likely potential for use.
2. It should have procedures in place for the use of, maintenance,

training/retraining, and replacement of AED devices.
3. An effective training and retraining program that link AED and CPR.
4. Available medical supervision.
5. A method of data reporting and collection so that program evaluation can continually be done.
6. A plan for follow-up after an event. Obtaining knowledge about a program's effectivity indicates whether a life has been saved, and whether the ultimate goals were reached.

The American Heart Asociation's "Chain of Survival" could be used as a cornerstone for a successful AED program. The "Chain of Survival" has four crucial links:

1. Early Access to Care is the first link;
2. Early Cardiopulmonary Resuscitation, if defibrillation is indicated, gives a victim additional time until defibrillation can be performed;
3. Early Defibrillation is a critical link for treating victims with ventricular fibrillation;
4. Early Advanced Care is important because some patients will require more advanced treatments, including airway control or drugs.

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