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Automated External Defibrillators for Home Use

Summary

- ✓ **The Philips HeartStart Home Defibrillator is an automated external defibrillator (AED) that is approved for home use by untrained users.**
- ✓ **Most cardiac arrests occur in the home, so a rapid response with cardiopulmonary resuscitation (CPR) and defibrillation is critical for survival.**
- ✓ **No prospective studies demonstrate that the use of AEDs in the home by untrained persons improves health outcomes. Further investigation is needed to determine the benefit and harm of AEDs in the home.**

The Technology

The Philips HeartStart Home Defibrillator (Philips Medical Systems, Markham ON) is an AED that is designed for consumer use in the home. The technology is similar to that of other Philips AED models intended for use in public areas,¹ but it has additional features that allow its use without special training. After switching the unit on, the operator is prompted by voice instructions to attach defibrillation pads to the patient's bare skin. An electrocardiogram analysis system determines if defibrillation is appropriate. If a shockable rhythm is detected, the defibrillator uses biphasic waveform technology (as opposed to monophasic, where the current flows in one direction) and impedance-based defibrillation to deliver the energy to shock the patient's heart. The defibrillator will inform the operator if the defibrillator pads are incorrectly positioned; if a nonshockable rhythm is present; and if the operator should

avoid touching the patient. When CPR, rather than a shock, is required, the defibrillator will instruct the operator on how to perform CPR.

The HeartStart Home Defibrillator is powered by lithium camera batteries, which have an operating time of approximately three hours and a shelf life of approximately four years. The unit weighs approximately 3.3 lbs (1.5 kg).

AEDs from other manufacturers are intended for use in non-hospital settings; and may be used in the home with minimal training. Examples of these units include the LIFEPAK[®] CR^{Plus} (Medtronic), AED 10 (Welch Allyn Canada), AED@Home Defibrillator (Zoll Medical Corporation), FRED[®] easyport[®] (Schiller), LifeLine AED (Defibtech) and Samaritan[®] AED (HeartSine Technologies).

Regulatory Status

The Philips HeartStart Home Defibrillator received a Medical Device License from Health Canada in June 2003 (Kathleen Savage, Therapeutic Products Directorate, Health Canada, Ottawa: personal communication, 2005 Feb 24). The device is a class III (i.e., potentially hazardous) medical device. It is intended for use on patients (adults and children who are ≥ 8 years old or who weigh ≥ 24.9 kg) who are believed to be in cardiac arrest, do not respond when shaken and are not breathing normally. Special defibrillation pads that deliver less voltage (50 joules) than the standard pads (150 joules) are available for use with infants and young children.

The US Food and Drug Administration (FDA) granted marketing clearance for the sale of this defibrillator in 2004.

Patient Group

Cardiac arrest results from the sudden cessation of efficient mechanical cardiac activity, which is accompanied by electrical cardiac dysfunction, most commonly ventricular fibrillation. The most common underlying cause of cardiac arrest is coronary heart disease, but it may also be caused by respiratory arrest, electrocution, drowning, choking or trauma. AEDs may be used to successfully defibrillate patients with ventricular fibrillation or ventricular tachycardia.

Among the approximately 55 out of every 100,000 Canadians who suffer an out-of-hospital cardiac arrest annually, 2.5% to 12.0% survive to hospital discharge.² Approximately 80% of cardiac arrests occur in the patient's home and about half of these are witnessed by another person.² Most patients who undergo an out-of-hospital cardiac arrest have no prior history of heart disease.³ A Canadian study indicates that there is a 23% relative improvement in survival for every minute that is saved in the defibrillation response time.^{4,5}

Current Practice

The standard protocol for cardiac arrest is the Chain of Survival, which was originally developed by the American Heart Association⁶ and adopted by the Heart and Stroke Foundation of Canada. The four links in the chain are early access to emergency medical services (i.e., calling 911 or an emergency number), early initiation of CPR, rapid defibrillation and early advanced cardiac life support.

The Evidence

No published studies evaluated the use of the Philips HeartStart Home Defibrillator in the home. Approval of the device for home use was based on data obtained from clinical studies of the technology in other settings.⁷ A review of the field performance demonstrated the safety history of more than 150,000 Philips AEDs that have accumulated more than 160,000 service years collectively.⁷ The Home Automatic

External Defibrillator Trial (HAT)⁸ is examining whether defibrillation with the Philips HeartStart Home Defibrillator by a lay responder is effective in the home of a cardiac arrest survivor. This study will compare outcomes when the home companion has been trained in AED use and CPR and when he or she has been trained in CPR alone. The primary endpoint will be all-cause mortality. Secondary endpoints include economics and quality of life, survival free of neurological injury and predictive factors from the baseline ECG. The trial plans to enrol 7,000 patients during the first two and a half years, then patients will be followed for an additional two years.

Two published studies have evaluated the use of AED units in the home.^{9,10} One of these is a case-control study that evaluated the use of an AED (Heart Aid 80, Cardiac Resuscitator Corp.) in the homes of 97 heart attack survivors during a 57-month period.¹⁰ The authors conclude that they cannot demonstrate a survival benefit for AED treatment, because the study is limited by the small number of cardiac arrests that occurred and the even smaller number of resuscitations. The other study is a telephone survey. Of the 73 homes that had owned a Philips AED for ≥ 12 months,⁹ the device had been used in four. Information regarding AED use was reported in two of these cases; in both cases, no shock was delivered.⁹

Another study evaluated the use of an AED by an untrained person in a public setting. This two-year prospective cohort study examined AED use [Philips HeartStart/Heartstream ForeRunner (FR) model E] by random bystanders at three Chicago airports.¹¹ During a two-year period, 18 patients with ventricular fibrillation received defibrillator shocks from an AED. With two exceptions, the operators of the AEDs were Good Samaritans who used the device correctly despite having no previous training with it. Ten of the 18 patients (56%) were alive and neurologically intact at one year. Of the 12 patients who underwent defibrillation within five minutes, eight (67%) were alive with a good neurologic outcome one year later. Survival rates of 5% have been observed with

the use of traditional “rapid response,” which is the response and treatment of patients, on scene, by emergency medical service providers.²

A small 2003 study compared the ease of use of three automated external defibrillators by untrained lay people.¹² Three different AEDs [AEDPlus™, (Zoll Medical Corporation); Physio-Control LIFEPAK® CR^{plus} (Medtronic), and HeartStart OnSite (Philips/Laerdal)] were used by 24 individuals with no prior training in the use of these devices. The researchers found that most people in the study group were able to use the equipment safely and effectively, and within an acceptable timeframe. However, the Physio-Control LIFEPAK® CR^{plus} and the HeartStart OnSite devices were rated as easier to use.

Adverse Effects

The Philips HeartStart Home Defibrillator was used safely by all participants in a simulation study that compared the use of the device by video-trained volunteers (n=61) with untrained (n=63) volunteers.¹³ There were no reports of harm due to inappropriate, intentional or unintentional shocks resulting from the use of a Philips AED.¹⁴

Administration and Cost

The Canadian list price for the Philips HeartStart Home Defibrillator is \$2,165 (Élisabeth Deschênes, Philips Medical Systems, Montreal: personal communication, 2005 Jan 18).

Concurrent Developments

Defibrillators, such as the LifeVest™ wearable cardiac defibrillator system (Lifecor), may offer an option for individuals who have a known risk of sudden cardiac arrest and who, for various reasons, do not receive an implantable defibrillator.¹⁵

Rate of Technology Diffusion

A study of 124 volunteer participants found that training did not have a significant impact on the volunteer’s ability to successfully use the device (89% success rate for the video-trained group versus 87% success rate for the untrained group, $p < 0.79$).¹³ One study indicated that untrained sixth graders used an AED (Hewlett-Packard Heartstream FR) proficiently and safely, with a speed of use slightly slower than that of professionals.¹⁶ Another study found that untrained third-grade students could use an AED (FirstStar AED Trainer Model, SurvivaLink) successfully. Students who received training significantly decreased their time in administering the first shock.¹⁷ Widespread diffusion of the Philips HeartStart Home Defibrillator may be limited by the absence of evidence to support its use in the home and by its relatively high cost. An additional barrier to diffusion may be a general lack of awareness of this strategy.

Implementation Issues

Cardiac arrest survivors and their significant others were interviewed for a study after a CPR/AED course.¹⁸ Participants indicated that they considered the AED (Laerdal HeartStart FR, AED Trainer™) to be generally acceptable and easy to use, but approximately one-third of them said that having the device in their home would make them feel anxious. However, another similar study indicated that most participants felt the AED gave them a feeling of security and control; and there was no evidence that in-home AEDs created excessive anxiety or stress.¹⁹

The individuals who are most likely to benefit from a home defibrillator are patients who are at a higher risk of experiencing a sudden cardiac arrest, including individuals with known coronary artery disease or those with multiple risk factors for coronary heart disease (e.g., >45 years old, diabetes, obesity, inactivity).²⁰

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