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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Wearable defibrillator

May 2008



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID

S000075

NAME OF TECHNOLOGY

WEARABLE DEFIBRILLATOR

PURPOSE AND TARGET GROUP

TO PROVIDE HEART MONITORING AND DEFIBRILLATION FOR PATIENTS AT RISK OF SUDDEN CARDIAC DEATH

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany	✓		
United States	✓		

IMPACT SUMMARY

ZOLL Lifecor Corporation manufactures a wearable defibrillator system, consisting of a vest-like garment and monitoring unit, that monitors a patient's heart rhythm and provides defibrillation if life threatening arrhythmia occurs. The device is designed for patients at risk of sudden cardiac death. The wearable defibrillator is not currently available in Australia.

BACKGROUND

Sudden cardiac death is a term used to describe the unexpected death of a person due to an abrupt loss of heart function. Sudden cardiac death can occur in individuals who may or may not have been diagnosed with cardiac disease (Sovari et al. 2006). In many (but not all) cases, sudden cardiac death is preceded by sudden cardiac arrest, when the heart suddenly and unexpectedly stops beating (Feldman et al. 2004).

Sudden cardiac arrest and sudden cardiac death can both result from any disease that affects the heart. However, the most common cause of sudden cardiac death is coronary heart disease, which accounts for approximately 80% of all occurrences (Zipes and Wellens 1998). Predisposing factors for sudden cardiac death include cigarette smoking, hypertension, diabetes mellitus, and dyslipidaemia, all of which are modifiable risk factors for cardiovascular disease (Sinha et al. 2005).

Ventricular arrhythmias are present in the majority of cases of sudden cardiac arrest (Schott 2002). In such instances, the heart's electrical impulses become rapid (ventricular tachycardia; VT) or chaotic (ventricular fibrillation; VF), leading to an irregular heart rhythm (arrhythmia), which can cause the heart to suddenly stop beating (Schott 2002). Sudden cardiac death generally occurs within one hour of symptom onset (Sovari et al. 2006). The most obvious symptoms of sudden cardiac arrest include a loss of consciousness and the absence of a palpable pulse. In most patients, cardiac arrest can be reversed with the prompt administration of an electric shock to the heart (defibrillation), which restores the heart's normal rhythm (Zipes and Wellens 1998). An automatic external defibrillator is the most common way to defibrillate a heart.

An implantable defibrillator, also known as an implantable cardioverter defibrillator, may be implanted in some patients to monitor heart rhythm and provide defibrillation, if required (Sovari et al. 2006). The implantable defibrillators have leads surgically attached to the heart which are also attached to a pulse generator implanted in a pouch under the skin of the chest or abdomen. Implantable defibrillators are designed for patients who are at high risk of sudden cardiac death and there are strict indications for their use (Schott 2002; Sinha et al. 2005). As a result, many patients are ineligible to receive an implantable defibrillator and remain at substantial risk of sudden cardiac death (Feldman et al. 2004). In addition, there are a number of issues associated with the use of implantable defibrillators. These include the cost of the device (and the associated implantation and support required), as well as the risk of infection, blood clots, myocardium or blood vessel perforation, and inappropriate shock, among others (Kron et al. 2001, Pinski 2000, Rosenqvist et al. 1998). Additionally, the battery must be replaced every three to five years, which involves another invasive procedure (Schott 2002).

ZOLL Lifecor Corporation (Pittsburgh, PA, USA) manufactures a wearable defibrillator, or wearable cardioverter defibrillator, that monitors, identifies and treats life threatening arrhythmias (Zoll Lifecor Corporation 2007). The LifeVest® defibrillator system, which is worn underneath a patient's clothing, consists of an electrode belt and a monitoring unit. The electrode belt is a soft cotton vest-type garment that keeps the monitoring electrodes in contact with the skin. The electrode belt has a grounding plate and three

therapy pads, which deliver an electrical shock if a life threatening arrhythmia is detected. Prior to an applying an electric shock, the therapy pads deploy a conductive gel to aid in the conduction of current. The monitoring unit, which contains a digital signal processing computer to detect VT or VF, the capacitors and a battery, is carried in a holster that can be worn as a fanny pack or using a shoulder strap. The device can be programmed to recognise the patient's heart rhythm and deliver electric shocks according to the patient's individual characteristics. The monitor also has a display unit, an alarm module, a speaker and buttons for patient interaction. When VT or VF is detected, the patient is warned via tactile stimulation from the ground plate, audible tones and voice prompts instructing the patient how to prevent the electric shock. If there is no response, the monitor alerts the patient and bystanders that an electrical shock will be administered and to stay clear. The system can deliver up to five subsequent shocks if needed.

There are various indications for the wearable defibrillator (Table 1), including patients who do not meet the guidelines for an implantable defibrillator and those with an increased risk of sudden cardiac death who do not require long-term treatment (Schott 2002).

Table 1. Potential applications for the wearable defibrillator (Beuregard 2004)

Bridge to transplantation, implantable device or clinical improvement
Post-bypass with ejection fraction less than 30% or ventricular arrhythmia or syncope within 48 hours of surgery
Post-myocardial infarction with ejection fraction less than 30% or ventricular arrhythmia within 48 hours of surgery
After implantable defibrillator removal - during antibiotic treatment for device-related infection or non-device related systemic infection
During treatment of other medical illnesses which temporarily prevent device implantation
Drug-related arrhythmias
While awaiting revascularisation
Patients too ill to undergo device implantation
Patients who refuse implantation of a device

CLINICAL NEED AND BURDEN OF DISEASE

Approximately 350,000 people each year in the United States die as a result of sudden cardiac death (Schott 2002). No Australian specific data regarding sudden cardiac death was found in the literature search.

It has been estimated that coronary heart disease affects approximately 334,500 Australians (AIHW 2006).

DIFFUSION

The wearable defibrillator was approved (PMA approval, P010030) by the United States Food and Drug Administration in 2001. The LifeVest defibrillator system is not currently listed in the Australian Register of Therapeutic Goods.

COMPARATORS

The main comparator to the wearable defibrillator is the implantable defibrillator.

SAFETY AND EFFECTIVENESS ISSUES

Feldman et al. (2004) reported a multicentre trial on the use of the wearable defibrillator in two patient populations at risk of sudden death. The study consisted of two single-arm studies (the WEARIT and BIROAD studies), which were combined. The WEARIT group included patients (n = 177, mean age 52 ± 11 years) with symptomatic heart failure and an ejection fraction of less than 30%. The WEARIT patients used the wearable defibrillator for a mean duration of 3.4 months. The BIROAD group was more diverse and consisted of patients (n = 112, mean age 60 ± 11 years) who had recently experienced a myocardial infarction or undergone bypass surgery and had arrhythmia, syncope or, an ejection fraction of less than 30%. Discharged patients who were unable to receive an implantable defibrillator for at least four months and patients who were eligible for an implantable defibrillator but had refused were also included. The BIROAD group used the wearable defibrillator for a mean period of 2.6 months, after which therapy was discontinued or patients received an implantable defibrillator. In both groups, the wearable defibrillator used a monophasic waveform with a maximum output of 285 joules.

Auricchio et al. (1998) investigated the use of the wearable defibrillator during VF induction in an electrophysiology laboratory setting. The case series study included 15 prospectively selected patients who had survived cardiac arrest due to VT or VF. Five of these patients had an implantable defibrillator, but the device was inactivated during the study period. The study was conducted during a routine electrophysiologic study or during the testing period following defibrillator implantation. Two methods of inducing VF were used. Programmed electrical stimulation with a temporary pacing catheter was used in patients who did not have an implantable defibrillator, whereas in patients with an implanted defibrillator the current delivered by the device was alternated. The wearable defibrillators were altered so that they could be armed and discharged manually by the physician. The electric shock was a monophasic waveform that delivered 230 joules of energy.

Reek and colleagues (2003) investigated the use of the wearable defibrillator in a group of 12 patients (mean age 60 ± 10 years) with ischemic cardiomyopathy and a history of at least one myocardial infarction in the setting of an electrophysiologic testing laboratory. While both Feldman et al. (2004) and Auricchio et al. (1998) used a monophasic waveform for the defibrillation shocks, this study used a wearable defibrillator capable of delivering a biphasic waveform shock, which yields equivalent defibrillation success

rates to the monophasic waveform but uses significantly less energy (Bardy et al. 1996). While wearing the wearable defibrillator, patients underwent programmed stimulation to induce VF. The charging of the capacitors, gel release and shock delivery of the wearable defibrillator was manually controlled by a clinician. Each patient received two induction/defibrillation attempts. The administered shocks delivered either 70 or 100 joules of energy. A randomisation table was used to determine which shock intensity was administered first.

Safety

Twelve deaths were reported by Feldman et al. (2004). No deaths were reported in patients who were correctly wearing the device. Six of the 12 deaths were non-sudden (causes of death not reported). Sudden death occurred in five patients who were not wearing the device and in one patient who had reversed the leads. Other than unnecessary shocks (described in the effectiveness section), there were no serious device-related adverse events reported. Development of a skin rash and/or itching was reported in 17 patients.

Sixty-eight of the 289 patients withdrew from the study. The reasons cited for withdrawal by patients in the WEARIT group included comfort or lifestyle issues (30%), heart transplantation (16%) and implantation of a defibrillator (20%). In the BIROAD group, 42% had reached the four month study endpoint or no longer required the wearable defibrillator, 23% received an implantable defibrillator (23%) and 11% withdrew because of comfort and lifestyle issues.

Auricchio et al. (1998) did not report any device-related adverse effects resulting from the use of the wearable defibrillator.

No persistent electrographic changes or functional impairment was reported by Reek et al. (2003) following administration of electric shocks by the wearable defibrillator. A skin inspection of the patients immediately following the electric shocks revealed mild redness without tenderness in some patients (number of patients not reported). No other adverse events were observed.

Effectiveness

Feldman et al. (2004) reported six successful defibrillations out of eight attempts: two successful defibrillations in the WEARIT population (both in the same patient) and four successful defibrillations in the BIROAD group (two occurring in the same patient). Both unsuccessful defibrillations occurred in patients who had placed the therapy electrodes incorrectly. In one case the patient received successful external defibrillation and the event was non fatal.

A total of six unnecessary shocks (shock in the absence of ventricular arrhythmia) in six different patients were reported. Taking into account that there were 901 months of use of

the wearable defibrillator, this equates to a rate of 0.67% per month of patient use or 8% per year.

Auricchio et al. (1998) were able to induce VF or VT in 10 out of 15 patients. The mean duration of the induced VT/VF was 32 ± 15 seconds (range 12 to 60 seconds). In each of the 10 patients, the 230 joule shock from the wearable defibrillator successfully terminated the arrhythmia. In all but one instance, the wearable defibrillator correctly identified and classified the induced arrhythmias. In the patient in whom the arrhythmia was not detected, the sensing electrodes were disconnected at the time of induction.

Reek and colleagues (2003) induced 22 episodes of VF in 12 patients. In two patients, VF was only induced once and each patient received only one shock from the wearable defibrillator (in both the energy of the shock was 70 joules). In all 22 instances of electrically induced VF, the first shock administered by the wearable defibrillator terminated the arrhythmia. The time between arrhythmia induction and shock delivery was similar for both the 70 joule (22 ± 6 seconds) and 100 joule setting (21 ± 6 seconds) (*P*-value not significant). Therefore, the biphasic waveform was determined to be 'efficacious'.

COST IMPACT

The cost of the wearable defibrillator and its associated support is US\$3200 per month (Beuregard 2004). The estimated average cost of implanting and testing an implantable defibrillator is US\$110,500. Since the average lifespan of such devices is between four and five years, at approximately 2.5 years the raw cost of a wearable defibrillator and an implantable defibrillator are approximately the same (Beuregard 2004). Therefore, based on these estimates, the wearable defibrillator compares favourably in terms of cost over a short period of time. However, in the studies presented, the longest time the wearable defibrillator has been used is 3.4 months with many patients citing lifestyle issues as the main reason for not wearing the device. The feasibility of wearing the wearable defibrillator for 2.5 years or longer must be determined before more complex cost effectiveness calculations can be made.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

Patients who receive the wearable defibrillator undergo extensive training in assembling, maintaining and interacting with the system (Schott 2002). Despite this, as demonstrated by the studies presented, there is a risk that patients may not always wear the wearable defibrillator appropriately.

Two of the studies presented, Auricchio et al. (1998) and Feldman et al. (2004), had two co-authors (M. Stephen Heilman and Steven J. Szymkiewicz) who worked for Zoll Lifecor Corporation, one of whom (M. Stephen Heilman) is the founder. In both of the studies, the funding sources for the studies were not disclosed.

SUMMARY OF FINDINGS

The evidence on the wearable defibrillator suggests that when the device is worn correctly, it is able to successfully detect and reverse arrhythmia in patients at risk of sudden cardiac death. Two of the studies presented, however, were performed under laboratory conditions where the investigators could manually trigger defibrillation. Therefore, further studies outside of the laboratory setting are needed to confirm the ability of the wearable defibrillator to consistently detect arrhythmias and assess issues related to patient compliance and training. Furthermore, the wearability of the device over the long term of the device must also be assessed in order to determine its cost effectiveness.

HEALTHPACT ACTION

Based on the limited evidence available and the fact that the majority of studies were conducted in laboratory conditions, this device will be archived.

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level III-3 intervention evidence	1
Level IV intervention evidence (laboratory feasibility study)	2

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

defibril\$

wearable

external

sudden cardiac death

SCD

Sudden cardiac arrest

SCA