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Horizon Scanning Technology

Prioritising Summary

ResQPOD® impedance threshold device for cardiac arrest

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PRIORITISING SUMMARY

REGISTER ID: **000393**

NAME OF TECHNOLOGY: **RESQPOD® IMPEDANCE THRESHOLD DEVICE**

PURPOSE AND TARGET GROUP: **USED TO PROVIDE NEGATIVE THORACIC PRESSURE DURING CARDIOPULMONARY RESUSITATION (CPR) ON CARDIAC ARREST PATIENTS, IMPROVING PERFUSION.**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

The ResQPOD® was registered on the TGA as a Class I device. This registration has lapsed and First Response Australia is currently seeking to have the device registered as a Class II device (personal communication First Response Australia).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA		✓	
France	✓		
Germany	✓		
UK	✓		

IMPACT SUMMARY:

Advanced Circulatory Systems Inc (United States) markets the ResQPOD®, which is distributed in Australia by First Response Australia. The ResQPOD® is an impedance threshold device for use during cardiopulmonary resuscitation (CPR) performed on patients who are having a cardiac arrest. The ResQPOD® would be used by emergency medical services staff during routine resuscitation attempts.

BACKGROUND

Cardiac arrest is a leading cause of death in Australia and CPR is used to resuscitate these patients. CPR chest compressions are designed to force blood out of the heart during the compression phase and negative pressure in the chest cavity during the recoil phase facilitates the flow of blood back into the heart ready for the next compression. In normal CPR the influx of air into the lungs lessens the intra-thoracic vacuum reducing the blood flow backing to the heart. The ResQPOD® is designed to transiently impede the flow of air into the lungs during chest wall recoil, maintaining the intra-thoracic negative pressure. This should facilitate greater blood flow back to the heart allowing a higher rate of blood flow to occur during compression. The ResQPOD® device is a small device with pressure sensors and valves that can be attached to an endotracheal tube or a facemask (Figure 1). The device does not impede normal exhalation and can be used in conjunction with the normal ventilation of the patient. In addition, the device has lights which can assist the timing of compressions.

Figure 1 The ResQPOD® attached to a face mask and ventilator bag (First Response Australia 2007)

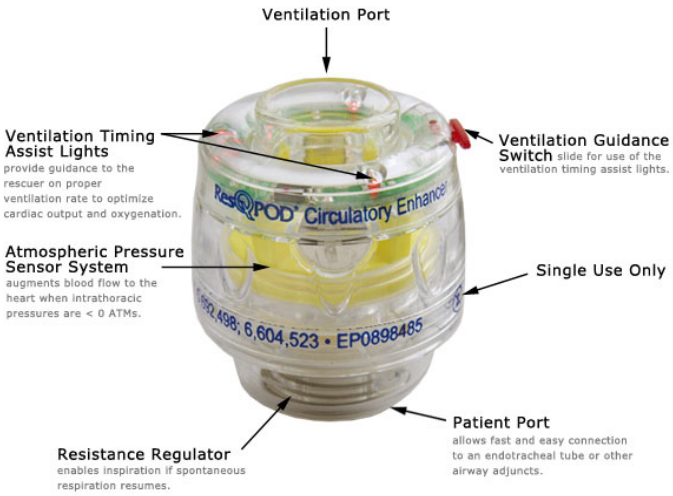

Figure 2 ResQPOD features (First Response Australia 2007)

CLINICAL NEED AND BURDEN OF DISEASE

The causes of cardiac arrest are diverse, including cardiovascular disease, electrophysiological abnormalities, toxins and shock. A study conducted in Victoria by Jennings et al (2006) reported an out of hospital cardiac arrest survival rate of 7.4 and 1.9 per cent in urban and rural areas, respectively. Another larger Victorian study in 2002-2005 found the survival rate of 18, 827 out-of-hospital cardiac arrests to be 3.8 per cent (Fridman et al 2007). When extrapolated to the Australian population of 2004 (20.1 million at June 2004 (ABS 2006)) out-of-hospital cardiac arrests are responsible for an estimated 18,000 deaths per year. Although the underlying cause of cardiac arrest can be diverse, a major attributable factor is cardiovascular disease. A need exists for better treatment of cardiac arrest to increase the survival rate and also to improve the outcomes of the patients who do survive as they often have a significant level of disability resulting from hypoxia during cardiac arrest.

During the period 2006-07, the number of public hospital separations in Australia for the ICD code I46 cardiac arrest was 1,435. Of these, 314 were for I46.0, cardiac arrest with successful resuscitation. The average length of stay for these patients was 6.2 days. During the same period there were 174 separations sudden cardiac deaths (I46.1) and 947 separations for cardiac arrest, unspecified (I46.9) (AIHW 2008).

No data on the number of cardiac arrest events in New Zealand were identified. There were many studies published on measures to improve outcomes after cardiac arrest, however these studies combined data from Australian and New Zealand hospitals. In addition, published morbidity and mortality data from New Zealand combined ICD codes I30-I52, other forms of heart disease into one category.

DIFFUSION

The ambulance services of Queensland, New South Wales and the Australian Capital Territory are currently investigating the use of the ResQPOD® device and are awaiting further guidance from the Australian Resuscitation Council (personal communication First Response Australia).

COMPARATORS

Manual CPR is the gold standard for resuscitation of cardiac arrest patients. The quality of compressions is critical to the rate of survival (Abella et al 2005). Blood flow rates to the heart and brain are also critical to the survival rates of patients treated with normal CPR. Blood flow from the heart during compression is partly determined by the return of blood to the heart during the decompression phase of CPR. Return blood flow is facilitated by the negative pressure formed by the recoil of the chest wall once external pressure is removed. The negative intra-thoracic pressure achieved in normal CPR averages -3mm Hg (Frascone et al 2004).

SAFETY AND EFFECTIVENESS ISSUES

Several studies have investigated the use of ResQPOD® in real out of hospital cardiac arrest situations. Most of the studies are small to medium and only investigate short term surrogate markers of survival.

Several randomised controlled trials (RCTs) have been conducted using the ResQPOD®. An initial RCT to test the ability of the ResQPOD® to induce negative pressure during CPR, prospectively enrolled 13 patients who were being treated for cardiac arrest. A ResQPOD® device and sham ResQPOD® were used to investigate whether negative pressure formed intra-thoracically. The devices were used for one minute each with a facemask and one minute each with an endotracheal tube (ETT). The sham ResQPOD® plus facemask achieved -1.0 ± 0.73 mmHg, while the ResQPOD® plus facemask achieved -4.6 ± 3.7 mmHg (p=0.003). The sham ResQPOD® plus ETT achieved 1.3 ± 1.3mmHg compared to 7.3 ± 4.5 mmHg for the ResQPOD® plus ETT (p=0.0009).The authors note that differences of 2mmHg are clinically important and this small change will cause blood to flow into the heart. There was no significant difference in pressure between the face mask and endotracheal tube (Plaisance et al 2005) (level II intervention evidence).

A blinded RCT with 200 sham ResQPOD® treated and 200 active ResQPOD® treated patients investigated survival to 24 hours as its primary end point. The 24 hour survival rate for the sham ResQPOD® was 22 per cent (44/200) versus 32 per cent (62/200) for the active ResQPOD® (p=0.02). Secondary endpoints were also recorded. Rate of ROSC was 39 per cent for the sham ResQPOD® compared to 48 per cent for the active ResQPOD®. Sham ResQPOD® treated patients survived to intensive care unit (ICU) admission in 29 per cent of cases and 40 per cent of active ResQPOD® treated cases survived to ICU admission. There was no significant difference between the two groups in hospital discharge rates with four per cent of sham ResQPOD® treated and five per cent of active ResQPOD® treated patients surviving to discharge. There was also no significant difference in normal neurological function at discharge between the two groups (Plaisance et al 2004) (level II intervention evidence).

Aufderheide et al (2005) conducted a double-blinded RCT using a sham ResQPOD® versus an active ResQPOD® on a population of 230 patients. ICU admission was the primary endpoint. Although there was an increase in the number of patients surviving to admission in the active ResQPOD® treated patients (25%) compared to the sham ResQPOD® treated group (17%), this difference was non-significant (p=0.13). When patients were divided *post hoc* into categories based on cardiac arrest presentation, those patients with pulseless electrical activity showed significantly higher ICU admission rates (sham ResQPOD® = 20% vs active ResQPOD® = 41%; p = 0.018). Twenty-four hour survival rates were also significantly higher (sham ResQPOD = 11% vs active ResQPOD® = 27%; p = 0.037). There were no significant differences between the hospital discharge and normal neurologic function rates between the active and sham ResQPOD® treatments (level II intervention evidence).

A double-blinded RCT investigating invasive femoral arterial blood pressure as the primary end-point, reported on 22 patients being treated for an out of hospital cardiac arrest. The study showed a significant increase in systolic blood pressure in patients in the active ResQPOD® group compared to those in the sham ResQPOD® group. Blood pressure was measured at 2, 5, and 7 minutes after initial blood pressure reading. The systolic blood pressure readings were significantly higher at all time points in the active ResQPOD® group compared to the sham group ($p < 0.01$). The first blood pressure reading was an average of 14 minutes after initiation of CPR using either the sham or active ResQPOD®, which explains the difference in zero minute blood pressures (85 ± 29 vs 43 ± 15 mmHg). The study was too small to determine any effect on short term survival. (Pirrallo et al 2005) (level II intervention evidence).

The ResQPOD® was used in a study on 104 cardiac arrest patients, with 143 cardiac arrest patient's records used as a historical control. The two groups were matched on several parameters including gender, age and emergency medical response time. The primary endpoint was return of spontaneous circulation (ROSC). A significant increase in ROSC rates were observed in the patients treated using the ResQPOD® (59% vs 45% in the historical control group; p=0.03). There was a non-significant improvement in neurological status of patients treated using the ResQPOD® (17% neurologically intact) versus historical controls (10% neurologically intact) (Vartanian et al 2006) (level III-3 intervention evidence).

A second study using historical controls in the UK enrolled 181 patients prospectively in the ResQPOD® group and 808 patients analysed as historical controls (historical controls treated for cardiac arrest in the year 2003, prior to ResQPOD® testing). Survival to emergency department admission was the primary endpoint. There was a 50 per cent increase in survival to admission in the ResQPOD® treated patients compared to the historical control group (ResQPOD® survival in 68/181 (34%) versus historical survival in 180/808 (22%) patients, p<0.01). Additionally a significant increase in survival to admission was reported in patients treated with ResQPOD® who presented with asystole, a presentation normally associated with significantly lower survival rates (34% of ResQPOD® treated patients vs 11% of historical controls survived to admission, p=0.001) (Thayne et al 2005) (level III-3 intervention evidence).

No adverse effects of the ResQPOD® were reported in the examined literature.

Overall the ResQPOD® shows some promising improvements in short-term surrogate markers of survival. It has not yet been demonstrated whether this translates into improved patient survival at a meaningful stage eg hospital discharge. Larger studies are required to investigate whether there is a significant difference in longer term survival and/or if those that do survive have less impairment.

COST IMPACT

The recommended retail price for the single-use ResQPOD® is $229 (personal communication First Response Australia).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

It may be detrimental to the patient's quality of life to prolong short term survival if there are no subsequent long term survival and neurological outcome improvements. Increased short term survival, without long term improvements, potentially increase pain and distress, and require extra health system resources for no additional benefit. To date no study has investigated these issues for the ResQPOD®.

OTHER ISSUES

A large trial of the ResQPOD® device, which hopes to enrol 15,000 cardiac arrest patients, is currently underway in Canada (personal communication First Response Australia).

SUMMARY OF FINDINGS

The ResQPOD® has shown some promise in early trials improving surrogate markers of survival. As so few patients in either normal or ResQPOD® treated groups survive to hospital discharge, the studies reviewed here lack the power to elucidate any long term survival changes. Further studies are required to investigate the changes to hospital discharge rates and also the effect of the ResQPOD® on the rate of neurological impairment of survivors.

HEALTHPACT ACTION:

Due to the lack of evidence supporting any long term benefits of the ResQPOD®, HealthPACT has recommended that further assessment of this technology is no longer warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level II intervention evidence	4
Level III-3 intervention evidence	2

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SEARCH CRITERIA TO BE USED:

Cardiopulmonary Resuscitation/adverse effects/ instrumentation/statistics & numerical data

Double-Blind Method

Emergency Medical Services/ methods/statistics & numerical data

Heart Arrest/ therapy