The Inspiratory Impedance Threshold Device For Treatment of Patients in Cardiac Arrest

a report by

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Introduction

In an effort to improve outcomes in cardiac arrest patients, new and novel technology has been developed that rediscovers and works to maximize the most important principles surrounding optimization of blood flow during resuscitation. Use of this new Impedance Threshold Device (ITD) enhances the changes in intrathoracic pressures during cardiopulmonary resuscitation (CPR) to double both blood flow to the heart and blood pressures, improve circulation to the brain, and significantly increase the chances for survival after an out-of-hospital cardiac arrest.(4, 6, 9-25) Additionally, recent clinical studies of this device punctuate the difficulty of performing CPR correctly; these studies have demonstrated that even mildly excessive ventilation rates and incomplete chest wall recoil during CPR can be lethal. Importantly, use of the ITD has enhanced our understanding of the essential elements needed to perform effective CPR and improve survival rates after cardiac arrest. While not a panacea, use of the ITD in efficient emergency medical systems increases the likelihood for survival after out of hospital cardiac arrest.

Conventional manual CPR (sCPR) is inherently inefficient, and provides only marginally adequate coronary perfusion pressures due to the sub-optimal pressure gradient between the aorta, the right atrium and left ventricle. During the decompression (or passive relaxation) phase of CPR, a small intrathoracic vacuum (relative to atmospheric pressure) develops with each chest wall recoil, promoting blood flow back to the heart. Myocardial perfusion predominantly occurs during this key decompression phase of CPR. The difference between the diastolic aortic and the right atrial pressures (coronary perfusion pressure) is a critical determinant of CPR efficacy.

With sCPR, much of the potential hemodynamic benefit of this intrathoracic vacuum is lost by the passive influx of inspiratory gas. Alternatively, the ITD (*Figure 1*), which is a small, lightweight device containing pressure sensitive valves, selectively impedes the influx of air during chest wall decompression, providing an augmented amplitude and duration of vacuum within the thorax.(13) When used with both sCPR and active compression decompression (ACD) CPR, the ITD prevents respiratory gases from entering the lungs during the decompression phase of CPR. By harnessing the kinetic energy of the chest wall recoil, thereby augmenting the "bellows-like" action of the chest with each compression-decompression cycle, the ITD draws more venous blood back into the heart. This results in increased cardiac preload, and thus, increased cardiac output, improved blood pressure and enhanced vital organ perfusion. The ITD also lowers intracranial pressure during the decompression phase of CPR, which, combined with increased cardiac output, results in greater cerebral perfusion. Because of the pressure sensitive valves, the ITD offers no resistance to active ventilation by a rescuer or to patient exhalation of respiratory gases. Clinical and animal studies, described in more detail below, have shown that the combination of an ITD with either sCPR or ACD CPR results in markedly higher blood flow to the heart and brain compared with either method alone.

> *Return of spontaneous circulation occurred more rapidly*

Device Use During CPR

During CPR, the ITD works effectively with either an endotracheal tube or facemask. Models designed for mouth to mask ventilation are available with a bacterial filter for rescuer protection.

The device instructions for use are very simple. The ITD is inserted into the respiratory circuit, between the endotracheal tube or facemask (*Figure 2*) and the

Figure 1. Impedance threshold device (ResQPOD®)

Figure 2. Impedance threshold device (ResQPOD®) on a facemask

ventilation source (mouth-to-mouth, bag-valve resuscitator, transport ventilator, etc). It should be removed after the patient has been successfully resuscitated. If the patient is gasping during the resuscitation effort, continue to use the ITD as long as the patient requires CPR to maintain a palpable blood pressure. When used with a facemask, it is important to continuously maintain a tight seal between the face and the mask during CPR in order to maintain the vacuum. This is best accomplished with a two-person ventilation technique where one person holds the facemask and a second person squeezes the resuscitator bag.(*Figure 2*)

The ITD is designed to prevent inspiratory gas exchange except with active rescuer ventilation or spontaneous patient breaths. It allows the rescuer to needed to allow for spontaneous inspiration through the device can be varied at the time of manufacturing. When used for sCPR, the cracking pressure is -10 cmH2O, which is a relatively small amount of resistance. At this low setting, the ITD is very safe, and there are no known adverse effects associated with using the ITD during CPR.

Recent studies have flagged three common errors during sCPR performance that decrease blood flow to vital organs and worsen the chances for survival.(2,3,5,26) These technique errors are hyperventilation, incomplete chest wall recoil, and interruption of chest compressions. While beyond the scope of this article, it is fundamental that CPR training courses emphasize these critical points in order to improve resuscitation outcomes. An

Studies have shown that use of the ITD with sCPR doubles blood flow to the heart

ventilate the patient without any resistance and permits unobstructed patient exhalation. The ITD is equipped with timing lights that flash 12 times/minute, prompting rescuers to ventilate at the proper rate and avoid hemodynamically detrimental and potentially lethal hyperventilation.(2,5) As described above, when CPR is not being performed because the patient has been successfully resuscitated, the ITD should be removed from the circuit. Spontaneous inspiration through the ITD is possible, but may be slightly difficult for a recently resuscitated patient. The cracking pressure, or inspiratory pressure

understanding of how the ITD works during CPR will help to focus on the criticality of avoiding these errors in order to generate an adequate vacuum during the chest wall recoil phase.

Preclinical Studies

Since 1995, there have been at least 10 animal investigations evaluating the ITD during CPR.(6,9-12,14,15,21,23,24) The first study established the importance of the concept.(11) Addition of the ITD in an animal model of ACD CPR results in an increase

Figure 3. Systolic blood pressure during cardiac arrest with standard CPR and an ITD

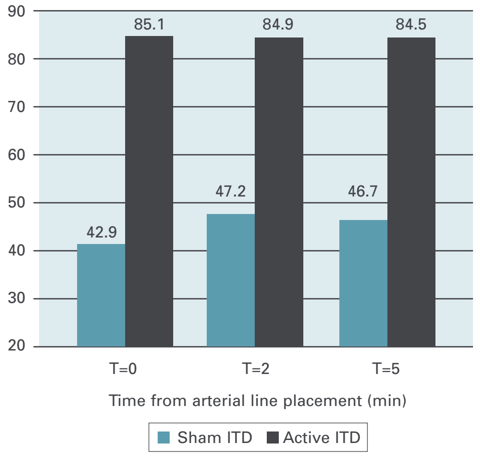
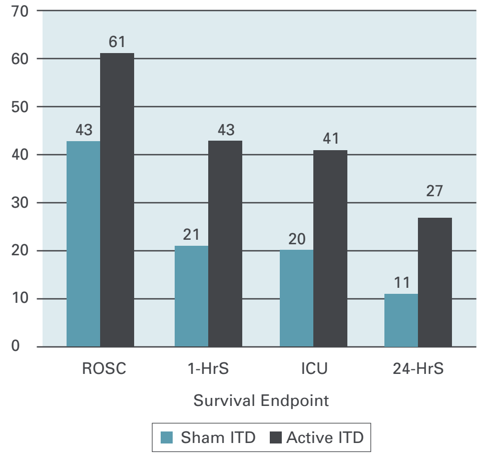


Figure 4. Survival from cardiac arrest in patients in PEA at any time during cardiac arrest



PEA = pulseless electrical activity; ROSC = return of spontaneous circulation; 1-HrS = survival to one hour; ICU = survival to intensive care unit admission; 24-HrS = survival to 24 hours

Use of the ITD has been shown to more than double 24-hour survival rates

in blood flow to the heart from 20% of normal in the control pigs treated with sCPR to 75% of normal in the animals treated with the ITD and ACD CPR.(11,12,14) Blood flow to the brain using the combined devices was >100% of normal, versus only 30% of normal with sCPR. Subsequent studies have shown that use of the ITD with sCPR doubles blood flow to the heart and, depending upon the experimental model, results in a >50% increase in blood flow to the brain.(9,12,14) In addition, animal survival studies have shown a remarkable increase in 24-hour survival rates and restoration of neurological function to normal with sCPR in combinations with the ITD.(15) Finally, studies in hypothermic animals have shown that the combination of the ITD and ACD CPR resulted in more rapid and greater circulation of vasopressor therapy and improved brain metabolism when compared with sCPR.(6,21) These data strongly support the increased circulation provided by the ITD technology.

Clinical Studies

ITD and sCPR

In Milwaukee, Wisconsin, Pirrallo et al studied acute hemodynamics (17) and Aufderheide et al studied survival rates (4) in the out-of-hospital setting using blinded, randomized clinical trial designs. The hemodynamic study involved 22 patients. Mean systolic blood pressures increased from 45 to 85 mmHg (P<0.001) when a sham vs. active ITD was used during sCPR as shown in *Figure 3*. T=0 was approximately 12 minutes after ITD placement. The clinical outcomes study enrolled 230 adult patients with out-of-hospital cardiac arrest. Intensive care unit (ICU) admission (the primary study endpoint) and 24-hour survival rates were: 17% and 12% in sham (n=116) versus 25% and 17% in active ITD patients (n=114), (P=NS). In patients with pulseless electrical activity (PEA) initially, survival to ICU admission and 24 hours was 20% and 12% in sham (n=25) versus 52% and 30% in active ITD patients (n=27) (P=0.018 and 0.123, respectively). Post hoc analysis of patients in PEA at any time during the cardiac arrest demonstrated that survival to ICU admission and 24 hours was 20% and 11% in sham (n=56) versus 41% and 27% in active ITD patients (n=49) (P=0.018 and 0.036, respectively). In this group comprising almost half of the patients in the study, the ITD increased 24-hour survival rates by nearly 250%. The results for patients with PEA at any time are shown in *Figure 4* (differences were statistically significant for 1-Hr, ICU, and 24-Hr survival). A third study in England confirmed the benefit of using the ITD in patients undergoing sCPR.(22) Use of the ITD in 105 patients in Staffordhire resulted in a 32% (23/71) survival to emergency department admission versus 17% in the control group (103/621) from the prior year (P=0.002).

ITD and ACD CPR

Four randomized human trials have also been performed to date to evaluate the efficacy and safety of using an ITD in combination with ACD CPR.(18-20,25) One of these studies, a randomized, blinded prospective hemodynamics study found that end tidal carbon dioxide (ETCO2) levels rose more rapidly and to higher levels with the active ITD. Significantly, systolic and diastolic blood pressures were nearly normal in the active ITD group (109/57 mmHg) versus the sham ITD group (89/35 mmHg), and return of spontaneous circulation occurred more rapidly in the active ITD group compared with the sham ITD group.(19) Based upon these data, use of an ITD with ACD CPR was recommended as an alternative to standard CPR in the AHA Guidelines in 2000.(1) A second study measured changes in intrathoracic pressures and demonstrated that use of the active ITD resulted in a significantly greater intrathoracic vacuum than ACD CPR with a sham ITD.(20)

The remaining studies assessed clinical outcomes, and demonstrated that use of the ITD during ACD CPR improves short-term survival rates after cardiac arrest. One prospective, controlled trial was performed in Mainz, Germany.(25) Patients with out-of-hospital arrest of presumed cardiac etiology were sequentially randomized to either ACD + ITD CPR or sCPR by the advanced life support team after intubation. Patients with an initial heart rhythm of ventricular fibrillation (42% of the total) who could not be resuscitated with automatic defibrillators by basic life support personnel were enrolled in this clinical trial, along with any patients with an initial rhythm of asystole or PEA. The primary endpoint was 1-hour survival after a witnessed arrest. With ACD + ITD CPR (n=103), return of spontaneous circulation and 1- and 24-hour survival rates were 55%, 51% and 37% versus 37%, 32% and 22% with sCPR (n=107) (P=0.016, 0.006, and 0.033) for the entire patient population. One and 24-hour survival rates in witnessed arrests were 55% and 41% with ACD + ITD CPR versus 33% and 23% in control subjects (P=0.011 and 0.019), respectively. One and 24-hour survival rates in patients with a witnessed arrest in ventricular fibrillation were 68% and 58% after ACD + ITD CPR versus 27% and 23% after S-CPR (P=0.002 and 0.009), respectively. For all patients, hospital discharge rates were 18% after ACD + ITD CPR versus 13% in control subjects (P=0.41). Overall neurological function trended higher with ACD + ITD CPR versus control subjects (P=0.07). These positive findings are supported by another 400 patient double blinded randomized control trial in France.(18) The group treated with ACD CPR and a functional ITD had a 32% 24-hour survival rate compared with a 22% 24-hour survival rate in the control population (P<0.05). It is noteworthy that the vast majority of these patients, including the survivors, had an initial heart rhythm of asystole.

Conclusions

Based on seven distinct, significant clinical trials, the ITD offers new hope for survival in patients experiencing cardiac arrest. By greatly increasing circulation during CPR, the ITD helps to deliver more nutrients to vital organs and increases the efficacy of intravenous vasopressor therapy. The specific, recently demonstrated clinical benefits of the ITD in these studies revealed that priming the pump prior to cardiac defibrillation with the ITD increases the chances for successful defibrillation. In patients not in ventricular fibrillation during out-of-hospital cardiac arrest, use of the ITD has been shown to more than double 24-hour survival rates. There was no increase in adverse events in the patient group receiving an active versus sham ITD in sCPR. Additionally, studies surrounding the ITD have helped to point out common but significant errors in the performance of CPR. One such error, delivery of excessive ventilation rates, was found to be lethal. Use of the ventilation timing lights on the ITD has been proven to reduce the frequent, lethal rescuer error of hyperventilation.

Despite the well-established benefits of the ITD in patients in cardiac arrest, it is important to note that, by itself, the ITD is not a panacea. Much has been learned in recent years about the importance of post-resuscitation care.(7,8,16) Without continued research and additional measures to help preserve brain and cardiac function in the post-resuscitation phase, many initially-resuscitated patients will continue to be lost.

In summary, the ITD can be easily and safely used with any method of CPR that involves external chest compression, either with a facemask or endotracheal tube. Based upon the studies performed to date, widespread use of this technology, when coupled with good CPR technique and post-resuscitation care, should significantly increase survival rates for patients suffering from sudden cardiac death, a major cause of morbidity in adults around the world.

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