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Use of an impedance threshold device improves short-term outcomes following out-of-hospital cardiac arrest☆

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Abstract

Introduction: An impedance threshold device (ITD) has been developed for the treatment of cardiac arrest to augment circulation to the heart and brain during cardiopulmonary resuscitation (CPR). The ITD has ventilation timing lights that flash at 12 min^{-1} to discourage excessive ventilation rates.
Hypothesis: Implementation of the ITD during conventional manual CPR in a large emergency medical services (EMS) system (Staffordshire, UK) is safe, feasible and will improve short-term survival.
Methods: ITD use was implemented by the Staffordshire Ambulance Trust, which treats 1600 cardiac arrests per year with 90 advanced life support (ALS) units and an average response time of 6.3 min. During training, rescuers learned to use the ventilation timing lights to discourage hyperventilation. Rescuers applied the device after tracheal intubation. They were trained to allow the chest to recoil fully after each compression. Prospective ITD use in adults receiving conventional manual CPR for non-traumatic cardiac arrest was compared to matched historical controls receiving conventional manual CPR without inspiratory impedance. All received similar ALS care. The primary endpoint was admission to the emergency department (ED) alive following cardiac arrest. Chi-square, Fisher's exact and Kolmogorov–Smirnov tests were used for statistical analyses.
Results: Survival (alive upon ED admission) in all patients receiving an ITD (61/181 [34%]) improved by 50% compared to historical controls (180/808 [22%]) ($P < 0.01$). Survival in patients presenting in asystole tripled in the group receiving an ITD (26/76 [34%]) compared with historical controls (39/351 [11%]) ($P = 0.001$). There were no significant adverse events.
Conclusions: The ITD was used safely and effectively in a large, diverse EMS system and markedly improved short-term survival for adult patients in non-traumatic cardiac arrest.

Keywords: Asystole; Cardiac arrest; Cardiopulmonary resuscitation; Emergency medical services; Impedance threshold device; Out-of-hospital CPR; Sudden cardiac death

1. Introduction

An impedance threshold device (ITD) was developed recently to enhance circulation during cardiopulmonary resuscitation (CPR) [1–12]. This device impedes inspiratory gas exchange during the decompression (or chest wall recoil) phase of CPR, thereby generating a greater vacuum in the thorax and enhancing blood flow back to the heart. The device works by impeding inflow of respiratory gases into the lungs during the chest wall recoil phase of CPR. During the decompression phase of CPR the reduced intrathoracic pressures create a vacuum to enhance blood flow back to the heart. Rescuer-assisted ventilations override the impedance valve within the device and allow resistance-free ventilation. The device has been tested in animals and in humans in cardiac arrest and found to increase vital organ perfusion and survival rates in patients undergoing conventional manual CPR and active compression decompression (ACD) CPR [1–14]. Based upon those studies, ventilation timing lights

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were added to discourage hyperventilation, thereby further augmenting vital organ perfusion [15].

The purpose of this current study was to describe the initial experience associated with the clinical deployment of this new CPR adjunct in a well-established emergency medical services (EMS) system. Using historical data as controls, we evaluated prospectively the key elements associated with training and effective implementation of the ITD for use by basic life support (BLS) and advanced life support (ALS) providers in a model system for British prehospital cardiac arrest care.

2. Material and methods

This was a prehospital implementation trial comparing survival in adult patients receiving an impedance threshold device (ResQPOD®; ZOLL Medical Corp. and Advanced Circulatory Systems, Inc.) (Fig. 1) during cardiac arrest with a historical control group who had not received the device. It was performed by the Staffordshire Ambulance Trust, which, with 90 ambulances, provides the primary emergency response in the country of Staffordshire and the surrounding area. The Staffordshire Ambulance Trust is operated by the National Health Service and provides a full-time, two-tiered response with both BLS and ALS personnel, operating under treatment protocols consistent with European Resuscitation Council and American Heart Association guidelines.

The Staffordshire Ambulance Trust attempts resuscitation in approximately 1600 patients from both urban and rural areas each year. Those who are transported from the scene are brought to one of three hospitals in the area; however, survival data after the patient is received in the emergency department are unknown as hospitals do not provide outcome data due to concerns for patient privacy. For this reason, investigators selected the variable with the highest degree of reliability, survival (alive with a perfusing pulse) to hospital emergency department (ED), as the primary endpoint.

Training prior to introduction of the ITD was performed according to EMS guidelines for the introduction of new devices. All personnel underwent a 2-h training programme that included special emphasis on: (a) use of the timing lights on the device to avoid the deleterious effects of excessive ventilation rates; (b) the importance of full chest wall recoil after each chest compression; (c) the importance of removing the ITD once there has been a return of spontaneous circulation (ROSC) and CPR is discontinued; (d) use of low dose adrenaline (epinephrine); (e) performance of CPR with the ITD for 30 min, regardless of the presenting arrest rhythm; (f) the importance of rotating the person performing chest compressions frequently (every 3–5 min) to avoid fatigue.

All cardiac arrest patients from presumed non-traumatic aetiology received BLS (including automated external defibrillation if indicated) and ALS resuscitation care according to European Resuscitation Council (ERC) and American Heart Association (AHA) Guidelines [16]. Conventional manual

Fig. 1. Impedance threshold device (ResQPOD®).

CPR was performed on adults at 100 min^{-1} using a 15:2 compression to ventilation ratio if the airway was unsecured, with ventilations being administered with a bag-valve resuscitator. Upon arrival of the ALS unit, adult (≥21 years) patients still in cardiac arrest were intubated and an ITD was applied. Once the airway was secured, chest compression and release were performed at 100 min^{-1} and ventilations were provided at a rate of 12 min^{-1}, using the ITD ventilation timing lights as a guide.

Prospective data on patients who received an ITD were collected over an 11-month period and compared to data on a matched set of historical patients from the previous year (2003) who did not receive an ITD during their cardiac arrest care. Those from the matched historical control group who achieved ROSC prior to tracheal intubation were excluded to provide a comparable control to the experimental group, who were ventilated with the ITD after tracheal intubation. The only treatment difference between the prospective and historical phases was that patients in the prospective phase were ventilated with an ITD during CPR.

An independent biostatistician performed all analyses. The two groups (control and experimental) were compared by student's *t*-test with respect to continuous variables, such as response time, and by Chi-square tests in the case of categorical variables. Specifically, in the case of two categories, a Chi-square test with Yates' correction, and for subgroups, Fisher's exact tests were used. In the case of more than two categories, the Chi-square test was applied. For the comparison of the two groups with respect to age, the Kolmogorov–Smirnov test was employed. Since the categories labeled 'unknown' were likely to contain a mix of the defined categories, they were dealt with separately. The *P*-value for overall survival results was adjusted for the witnessed status because the distribution of the witnessed status was different between the two groups. A *P*-value of <0.05 was considered statistically significant.

3. Results

The training programme, which emphasized the use and rationale of the ITD, was well received by EMS personnel. They were able easily to learn how to use the ITD and the basic physiological concepts on which the technology is based.

During the historical phase in the year prior to ITD introduction, the ambulance service responded to 1847 patients in reported cardiac arrest; of these, resuscitation was attempted in 956. Of those with attempted resuscitation, 148 were excluded from the matched historical data set due to: likely traumatic cardiac arrest aetiology (84), ROSC prior to intubation (40), and age less than 21 years (24).

During the prospective field implementation phase, a total of 181 adults were ventilated with an ITD for their presumed non-traumatic cardiac arrest. Introduction of the ITD was phased in systematically as more and more rescuers were trained. Thus, there were some patients in the first part of the prospective who did not receive an ITD. These patients were excluded from the analyses.

Patient characteristics from both groups are summarized in Table 1. The groups did not differ significantly in terms of age, sex, bystander CPR, initial cardiac rhythm, and EMS response intervals. The group that was ventilated with an ITD did have a higher percentage of patients who experienced a witnessed arrest.

Comparison of the primary endpoint, alive (perfusing pulse in the absence of CPR) on admission to the emergency department, is shown in Table 2. In all patients, use of the ITD resulted in significantly higher ROSC rates, as reflected by the number of patients with spontaneous pulse-perfusing circulation upon ED admission compared to controls (61/181 [34%] versus 180/808 [22%], respectively; $P < 0.01$). In an

Table 1
Patient characteristics

	Conventional CPR ($n = 808$)	Conventional CPR + ITD ($n = 181$)	*P*-value
Age (years)			0.19
21–31	11 (1%)	2 (1%)	
31–40	23 (3%)	6 (3%)	
41–50	48 (6%)	11 (6%)	
51–60	107 (13%)	22 (12%)	
61–70	154 (19%)	50 (28%)	
71–80	258 (32%)	47 (26%)	
81–90	172 (21%)	40 (22%)	
91–100	28 (3%)	3 (2%)	
Not known	7 (1%)	0 (0%)	0.444
Males (%)	524 (65%)	115 (64%)	0.804
Initial cardiac rhythm (%)			0.146
V-fib or pulseless V-tach	229 (28%)	65 (36%)	
Asystole	351 (44%)	76 (42%)	
PEA	203 (25%)	38 (21%)	
Unknown	25 (3%)	2 (1%)	0.218
Witnessed cardiac arrest (%)			0.0043
Witnessed by Bystander	438 (54%)	122 (67%)	
Witnessed by EMS	79 (10%)	12 (7%)	
Unwitnessed	253 (31%)	39 (22%)	
Unknown	38 (5%)	8 (4%)	1.0
EMS response time (min ± S.D.)	6.20 ± 3.58	5.95 ± 2.84	0.30
Bystander CPR (%)	303 (38%)	74 (41%)	0.399

CPR, cardiopulmonary resuscitation; EMS, emergency medical services; ITD, impedance threshold device; N/A, not applicable; PEA, pulseless electrical activity; S.D., standard deviation; V-fib, ventricular fibrillation; V-tach, ventricular tachycardia.

Table 2
Alive (with ROSC) upon emergency department admission

	Conventional CPR ($n = 808$)	Conventional CPR + ITD ($n = 181$)	P-value
All patients with ROSC (%)	180/808 (22%)	61/181 (34%)	0.005
Patients with ROSC based upon initial cardiac rhythm (%)			
V-fib or pulseless V-tach	72/229 (31%)	24/65 (37%)	0.454
Asystole	39/351 (11%)	26/76 (34%)	0.001
PEA	50/203 (25%)	11/38 (29%)	0.549
Unknown	19/25 (76%)	0/2 (0%)	0.080
Witnessed arrest patients with ROSC (%)	143/517 (28%)	49/134 (37%)	0.055
Unwitnessed or unknown witnessed patients with ROSC (%)	37/291 (13%)	12/47 (26%)	0.042

CPR, cardiopulmonary resuscitation; ITD, impedance threshold device; PEA, pulseless electrical activity; ROSC, return of spontaneous circulation; V-fib, ventricular fibrillation; V-tach, ventricular tachycardia.

analysis of survival based upon initial presenting rhythm, the patients in the group who presented in asystole and who were ventilated with an ITD had a three-fold improvement in survival (26/76 [34%]) compared to historical controls (39/351 [11%]) ($P = 0.001$). In patients presenting in other rhythms (ventricular fibrillation, pulseless ventricular tachycardia and pulseless electrical activity) and in those presenting in witnessed arrest regardless of initial rhythm, there were trends towards improvement but these differences were not statistically significant. For patients with a witnessed arrest, 27% survived to emergency department admission historically versus 37% with the ITD ($P = 0.055$). In the group of patients with either an unwitnessed arrest or an unknown witnessed arrest status, survival to the emergency department was 13% in the historical group compared with 26% in the group who were ventilated with an ITD ($P = 0.042$).

The ITD was compatible with existing resuscitation equipment and protocols. There were no clinically significant adverse events or complications reported to result from ITD use. There was, however, a problem with the timing lights on some ITDs. Some lights did not illuminate at all and in other cases the lights stopped flashing before the CPR attempts were completed. These issues were brought to the attention of the manufacturer who has since remedied this problem.

4. Discussion

Results from this first clinical evaluation of the ITD during conventional manual CPR in a European EMS system demonstrated that this new CPR adjunct: (a) was easy to teach and use, (b) could be readily integrated into the standard care for cardiac arrest patients, and (c) increased the short-term survival rates by 50% compared to historical controls. The survival benefit was proportionally greatest in patients presenting in asystole, a rhythm that been associated with a very poor prognosis. We observed no adverse events or complications from use of the ITD in our study.

Introduction of this new technology into our EMS system provided the opportunity to retrain all EMS personnel in several essential CPR principles. To maximize CPR efficacy and the effectiveness of the ITD, the training included emphasis on the importance of limiting the ventilation frequency to 12 min^{-1}, reducing the overall time used for delivery of a breath, and the importance of complete chest wall recoil [15,17–19]. The concepts underlying the physiology of the ITD were conveyed effectively with a small training aid that demonstrated the impact of impeding inspiration on blood return to the heart during CPR. As such, introduction of the ITD enabled EMS educators to relay these important principles rapidly, based upon a new and more complete understanding of the science of blood flow during CPR [15,17–19].

In addition to augmenting circulation by enhancing the negative intrathoracic pressure during the chest wall recoil phase, the ITD served as a useful tool to guide ventilation rates. Based upon the findings of Aufderheide et al, which demonstrated that excessive ventilation rates were common in the field and result in a marked decrease in coronary perfusion pressures and decreased survival rates during CPR, we used the new timing lights on the ITD to help prevent this natural tendency to hyperventilate patients during CPR [15]. Based upon monitoring of some of the resuscitation efforts by the investigators and their staff, the timing lights have served as an effective means to help regulate ventilation frequency and duration.

Intrigued by the positive results of recent studies combining the ITD with active compression decompression CPR [12–14], we have also recently begun to explore whether adding an ITD to the performance of ACD CPR with an automated device that actively compresses and decompresses the chest would further improve short-term survival rates in our EMS system. We intend to continue to study this treatment combination as we try to improve the quality of care for our cardiac arrest patients.

The study is limited as current government regulations made it difficult to follow longer-term endpoints for patients in cardiac arrest. In addition, we used historical controls for the primary basis of comparison of the ITD. Despite these limitations, we have made use of the ITD the standard of care for the Staffordshire EMS system based upon results from our study and the studies of Aufderheide et al. [20] and Pirrallo et al. [21]. We have observed no significant device failures, with the exception of some timing light failures that have been corrected recently by the manufacturer. Finally, as we retrained all EMS providers on the importance of limiting ventilation rates to 12 breaths/min and the importance of full chest wall recoil, we cannot separate the beneficial effects of the ITD from the benefit derived from the proper performance of CPR. Nonetheless, based upon blinded prospective animal and clinical studies performed with either a sham or active ITD, where blood flow to the heart and systolic blood pressures were found to double with use of the ITD, we believe that the ITD provides a significant benefit by improving the blood flow during CPR.

5. Conclusions

Based upon the observations related to the introduction of the ITD in this study, we conclude that the ITD is easy to use, easy to teach, and should become the standard of care for the treatment of prehospital patients in cardiac arrest. We have since expanded use of the ITD to BLS personnel, who attach the device to a facemask or Laryngeal Mask Airway (LMA) prior to intubation by ALS personnel. This permits the inspiratory impedance technology to be initiated earlier in the "chain of survival".

Adding an impedance threshold device to standard resuscitation care improved overall short-term survival by 50% and tripled survival in patients with traditionally the poorest outcomes, those with asystole. Given the size, cost of the ITD and issues associated with its introduction, we believe that it is a very cost-effective way to increase survival rates for patients in cardiac arrest, especially for those who have asystole. From this perspective, we expect to observe even higher survival rates in the near future as we explore the synergistic benefits of combining inspiratory impedance with active compression decompression CPR.

Conflict of interest

None.

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