Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.


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Supplementary Appendix


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Impedance Threshold Device: Function and Application

**Figure 1A:** Impedance Threshold Device Features

**Figure 1B:** Impedance Threshold Device Application with a Facemask
**Figure 1C:** Air flow through the inspiratory impedance threshold device (ITD) during the phases of cardiopulmonary resuscitation (CPR). During manual ventilation, respiratory gas bypasses the occlusion valve (silicone diaphragm) and flows into the lungs unimpeded. During chest compression or exhalation, expiration is not impeded by the valve and gas flows freely out of the lungs. During chest decompression the intrathoracic pressure within the chest falls below atmospheric pressure, causing the silicone membrane to occlude air flow through the valve. If the patient begins to breathe spontaneously, the safety valve opens, allowing inspiration. Reproduced from Lurie, KG, Barnes, TA, Zielinski TM, and McKnite SH. Evaluation of a Prototypic Inspiratory Impedance Threshold Valve Designed to Enhance the Efficiency of Cardiopulmonary Resuscitation. Respir Care 2003;48(1):52–57. (Figure 2, page 54) with permission from RESPIRATORY CARE and The American Association for Respiratory Care.

**Impedance Threshold Device Function**

The Impedance Threshold device (ITD; Figure 1A) is a small, 35mL device attached between any airway adjunct (e.g. facemask, supra-glottic airway, such as a Combitube®, laryngeal mask airway, or King LT, or endotracheal tube) and ventilation bag during CPR. (Figure 1B) When placed in the airway circuit, the ITD works as follows. (Figure 1C) During the compression phase of CPR, exhalation is unimpeded, and gas flows freely out of the lungs. During the decompression (or upstroke) phase of CPR, the intrathoracic pressure within the chest falls below atmospheric pressure, causing a silicone diaphragm in the device to occlude air entry into the lungs. This creates a vacuum within the thorax (approximately -3 to -10 mmHg) during the decompression phase of CPR, which has been demonstrated to have two primary physiologic effects.

1. First, the vacuum within the chest enhances venous return to the thorax, which increases systolic blood pressure and circulation, priming the heart for the next compression. 1 Second, use of the ITD reduces intracranial pressures at a faster rate (compared with no ITD use) providing a greater duration of time when intracranial pressures are at their lowest. Because intracranial pressure is a major determinant of resistance to forward blood flow to the brain, the more rapid reduction in intracranial pressure by the ITD further enhances cerebral circulation. 2 In this manner, with each chest compression and decompression, the chest serves as a bellows during CPR, creating a vacuum within the thorax during the upstroke of CPR, enhancing circulation to the heart and brain. 1, 2

With the ITD, the rescuer can ventilate the patient without encountering inspiratory resistance. The silicone diaphragm in the device does not block positive pressure ventilation or exhalation. Thus, rescue breathing is unimpeded. When the patient has been successfully resuscitated, the ITD should be removed from the respiratory circuit to allow the patient to breathe without inspiratory resistance. If the rescuer should fail to remove the device once the resuscitated patient begins to breathe, a built-in safety check valve opens, allowing spontaneous inspiration and exhalation. (Figure 1C) The ITD used in this trial had a safety check valve designed to open when airway pressures become <-16 cm H2O.
Impedance Threshold Device Application

Achieving the desired physiologic effects of the Impedance Threshold Device (lower mean intrathoracic pressure and resulting improvement in coronary and cerebral perfusion) is dependent on the circumstances of the cardiac arrest and rescuer CPR. Better outcome is associated with earlier CPR and device application. In one study using the ITD with active compression decompression CPR in humans, no patient survived cardiac arrest if CPR was initiated later than 10 minutes following the emergency call.\(^3\) When using the ITD with a facemask, the rescuer must keep a continuously tight seal during compressions and ventilations. Breaking the facemask seal during the chest compression/decompression cycle extinguishes the vacuum within the thorax.\(^4\) Animal studies have shown that excessive ventilation rates or excessive ventilation duration are associated with high mean intrathoracic pressure, decreased blood flow and decreased survival.\(^5\) Incomplete chest recoil results in continuously positive intrathoracic pressure, resulting in reduced blood flow and cerebral perfusion.\(^6\) In general, the better the quality of CPR delivered (e.g. chest compression rate, depth, complete chest recoil, chest compression fraction, and ventilation rate/duration) the greater achievement of the desired physiologic effect of the device.

For these reasons, the ROC consortium significantly invested in EMS training, retraining, and monitoring throughout the study. EMS personnel were trained in ITD physiology and all aspects of protocol implementation, emphasizing optimal CPR performance according to local guidelines. Training included the importance of early ITD placement, use of ventilation timing-assist lights (on both sham and active devices) with advanced airways and, when using the ITD with a facemask, a continuously tight seal using the “E-C” hand technique (one airway rescuer) or two-handed technique (two airway rescuers). (Figure 1C) To avoid impeding inspiration in patients with unrecognized spontaneous breathing, providers were instructed to remove the ITD immediately on return of spontaneous circulation, but re-apply it for recurrent cardiac arrest. Generating even a small amount of negative intrathoracic pressure carries with it the theoretical risk of generating or exacerbating pulmonary edema. For these reasons, if the device filled with fluid, it was removed and cleared, the patient was suctioned, and the device was re-applied. If the device filled with fluid again, use was discontinued. Use of the ITD was terminated on arrival at the hospital. Retraining occurred at periodic intervals throughout the trial. CPR process data were electronically recorded. An internal Study Monitoring Committee monitored the quality of CPR provided during the run-in phase (requiring demonstration of acceptable performance to advance to the main trial) and throughout the study.


Explanation of Relationship with Analyze Early versus Analyze Later Trial

The ROC PRIMED Impedance Threshold Device (ITD) trial was conducted simultaneously with the ROC PRIMED Analyze Early versus Later (AEvsAL) trial, thus halving the cost and time required to conduct these two trials. Furthermore, although no substantial interactive effect between the two interventions was anticipated, simultaneous implementation allowed assessment of the ITD under the early and later strategies for rhythm analysis, both of which were in common use. Potential difficulties caused by simultaneous implementation of two protocols were mitigated by not requiring EMS and fire personnel to actively perform randomization, which was accomplished by pre-determined cluster randomization or pre-randomized ITD kits. A full factorial design was not possible because not all agencies participated in both trials (Seattle Medic One did not participate in the AEvsAL trial and Multnomah county in Oregon did not participate in the ITD trial) and inclusion criteria for the two trials differed. In particular, EMS-witnessed cases were not eligible for the ALvsAE trial whereas enrolment in the ITD trial required opening the ITD kit which was not done in approximately 28% of cases (e.g., due to adverse scene conditions or early ROSC).

Of the 12,090 patients enrolled in at least one trial, 7283 (60%) were enrolled in both trials, 2870 (24%) were enrolled only in the AEvsAL trial, and 1937 (16%) were enrolled only in the ITD trial.

It is unlikely that co-implementation of the two trials influenced the outcome of the ITD trial. The estimated treatment effect of the active ITD within the Analyze Early group, Analyze Later group, and those not entered in the Analyze Early versus Analyze Later study was consistent with the overall study result, and the test for interaction was not significant (P=0.74).
**Figure 2: Patient Flow Chart**

Screened: includes treated cardiac arrests and cases with ITD opened; DNR: do not resuscitate orders; Non-ROC: treatment by non-Resuscitation Outcomes Consortium agency; DSE: drowning, strangulation, electrocution
<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Sham</th>
<th>Active ITD</th>
<th>Difference and 95% CI</th>
<th>Interaction p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>mITT Population</td>
<td>260/4345 (6.0%)</td>
<td>254/4373 (5.8%)</td>
<td>-0.1 (-1.1, 0.8)</td>
<td>0.0 (-0.9, 1.0)</td>
</tr>
<tr>
<td>ITT Population*</td>
<td>283/4776 (5.9%)</td>
<td>283/4766 (5.9%)</td>
<td>-0.0 (-0.9, 1.0)</td>
<td>0.0 (-0.9, 1.0)</td>
</tr>
</tbody>
</table>

**A Priori Subgroups**

| First Rhythm | VT/VF | 200/1096 (18.2%) | 199/1040 (19.1%) | 0.9 (-2.4, 4.2) | 0.76 |
| PEA | 40/1007 (4.0%) | 35/1080 (3.2%) | -0.7 (-2.3, 0.9) | 0.0 (-0.5, 0.4) |
| Asystole | 10/1946 (0.5%) | 9/1903 (0.5%) | 0.0 (-0.9, 1.0) | 0.0 (-0.9, 1.0) |
| Other | 7/290 (2.4%) | 10/345 (2.9%) | 0.5 (-2.0, 3.0) | 0.5 (-2.0, 3.0) |

| Witnessed Status | EMS witnessed | 24/331 (7.3%) | 31/367 (8.4%) | 1.2 (-2.8, 5.2) | 0.77 |
| Bystander witnessed | 177/1794 (9.9%) | 174/1754 (9.9%) | 0.1 (-1.9, 2.0) | 0.1 (-1.9, 2.0) |
| Unwitnessed | 51/2115 (2.4%) | 46/2122 (2.2%) | -0.2 (-1.1, 0.7) | -0.2 (-1.1, 0.7) |

| ALvE Study | Analyze later | 90/1634 (5.5%) | 91/1632 (5.6%) | 0.1 (-1.5, 1.6) | 0.71 |
| Analyze early | 98/1860 (5.3%) | 83/1815 (4.6%) | -0.7 (-2.1, 0.7) | -0.7 (-2.1, 0.7) |
| Not in ALvE | 72/825 (8.7%) | 80/889 (9.0%) | 0.3 (-2.4, 3.0) | 0.3 (-2.4, 3.0) |

**Exploratory Subgroups**

| Time to ITD Application | <5 minutes | 188/2589 (7.3%) | 176/2539 (6.9%) | -0.3 (-1.7, 1.1) | 0.74 |
| ≥5 minutes | 61/1525 (4.0%) | 63/1588 (4.0%) | 0.0 (-1.4, 1.3) | 0.0 (-1.4, 1.3) |
| Missing | 11/231 (4.8%) | 15/246 (6.1%) | 1.3 (-2.7, 5.4) | 1.3 (-2.7, 5.4) |

| Average CPR Fraction | ≤59.8% | 62/702 (8.8%) | 46/682 (6.7%) | -2.1 (-4.9, 0.7) | 0.006 |
| 59.9-71.0% | 30/698 (4.3%) | 58/674 (8.6%) | 4.3 (1.7, 6.9) | 4.3 (1.7, 6.9) |
| 71.1-82.0% | 49/698 (7.0%) | 40/710 (5.6%) | -1.4 (-3.9, 1.2) | -1.4 (-3.9, 1.2) |
| >82.0% | 35/693 (5.1%) | 33/710 (4.9%) | -0.2 (-2.5, 2.1) | -0.2 (-2.5, 2.1) |
| Missing | 84/1554 (5.4%) | 77/1630 (4.7%) | -0.7 (-2.2, 0.8) | -0.7 (-2.2, 0.8) |

| Epinephrine Dose | >3 mg | 30/1712 (1.8%) | 28/1735 (1.6%) | -0.1 (-1.0, 0.7) | 0.97 |
| ≤3 mg | 229/2622 (8.7%) | 226/2621 (8.6%) | -0.1 (-1.6, 1.4) | -0.1 (-1.6, 1.4) |

| Airway Management | Intubation | 197/3312 (5.9%) | 209/3332 (6.3%) | 0.3 (-0.8, 1.5) | 0.17 |
| Supraglottic | 14/465 (3.0%) | 12/470 (2.6%) | -0.5 (-2.6, 1.7) | -0.5 (-2.6, 1.7) |
| Facemask only | 48/562 (8.5%) | 33/569 (5.8%) | -2.7 (-5.7, 0.3) | -2.7 (-5.7, 0.3) |

Figure 3: Forest Plot of Primary Outcome (Survival to Hospital Discharge with mRS ≤ 3) in A Priori Subgroups and Post Hoc Exploratory Subgroups

ITD: impedance threshold device, mITT: modified intent to treat, ITT: Intent to treat, VT/VF: ventricular tachycardia or ventricular fibrillation, PEA: pulseless electrical activity, EMS: emergency medical services, ALvE: analyze later versus early trial.

*The ITT population (a total of 9542 subjects with an ITD package opened during the main trial) included 8718 subjects in the mITT population and an additional 824 subjects who were excluded from the primary analysis because they did not have an ITD applied; met study exclusion criteria; experienced cardiac arrest secondary to hanging, drowning, electrocution, or strangulation; or who had a response time of more than 15 minutes.
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