Use of an inspiratory impedance threshold device on a facemask and endotracheal tube to reduce intrathoracic pressures during the decompression phase of active compression–decompression cardiopulmonary resuscitation

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Introduction: **Use of an inspiratory impedance threshold device (ITD) significantly increases coronary perfusion pressures and survival in patients ventilated with an endotracheal tube (ETT) during active compression–decompression cardiopulmonary resuscitation. We tested the hypothesis that the ITD could lower intratracheal pressures when attached to either a facemask or ETT.**

Methods: **An active and sham ITD were randomly applied first to a facemask and then to an ETT during active compression–decompression cardiopulmonary resuscitation in 13 out-of-hospital cardiac arrest patients in a randomized, double-blinded, prospective clinical trial. The compression-to–bag-valve ventilation ratio was 15:2. Airway pressures (surrogate for intrathoracic pressure) were measured with a pressure transducer. A sham and an active ITD were used for 1 min each in a randomized order, first on a facemask and then on an ETT. Statistical analyses were made using Friedman's and Wilcoxon's rank-sum tests.**

Results: **For the primary end point, mean ± SD maximum negative intrathoracic pressures (mm Hg) during the decompression phase of cardiopulmonary resuscitation were -1.0 ± 0.73 mm Hg with a sham vs. -4.6 ± 3.7 mm Hg with an active ITD on the facemask ($p = .003$) and -1.3 ± 1.3 mm Hg with a sham ITD vs. -7.3 ± 4.5 mm Hg with an active ITD on an ETT ($p = .0009$). Decompression phase airway pressures with the facemask and ETT were not statistically different.**

Conclusions: **Use of an active ITD attached to a facemask or an ETT resulted in a significantly lower negative intratracheal pressure during the decompression phase of active compression–decompression cardiopulmonary resuscitation when compared with controls. Airway pressures with an ITD on either a facemask or ETT were similar. The ITD–facemask combination was practical and enables rapid deployment of this life-saving technology. (Crit Care Med 2005; 33:990–994)**

KEY WORDS: cardiac arrest; active compression–decompression; cardiopulmonary resuscitation; impedance threshold device; emergency medical services; ventilation

Use of an inspiratory impedance threshold device (ITD) with conventional manual or active compression–decompression (ACD) cardiopulmonary resuscitation (CPR) has been shown to significantly increase coronary perfusion pressures and survival rates in animals and patients when compared with ACD CPR alone (1–7). The ITD augments the vacuum created within the thorax during the decompression phase of standard and ACD CPR. ACD CPR and an ITD are synergistic: the suction cup of the ACD device sticks on the anterior chest wall and begins the creation of the vacuum (decreased intrathoracic pressure) when actively pulling up its handle during decompression, whereas the ITD in the ventilatory circuit impedes the influx of inspiratory gas generated by the ACD device, thereby enhancing the amplitude of the vacuum.

Studies to date have focused on animals and patients ventilated using an endotracheal tube (ETT) during advanced life support (ALS) care. To increase the likelihood of survival with a better neurologic outcome, hemodynamics should be optimized as early as possible. The present study tested the hypothesis that the ITD would function effectively when attached to either a facemask or ETT, enabling rescuers to use it during basic life support (BLS).

MATERIALS AND METHODS

This prospective, randomized, blinded clinical trial was performed in a single out-of-hospital setting on an intention-to-treat basis. The study was approved by the Consultative Council for the Protection of Persons Volunteering for Biomedical Research of Lariboisière Saint-Louis University, Paris. This ethical committee waived the requirement for informed consent because it was not possible under clinical circumstances.

A two-tiered emergency medical services system is responsible for responding to all emergency calls in France (2, 3). The first-tier response consists of fire rescue personnel equipped with BLS equipment and automatic external defibrillators. They practice CPR regularly and perform ACD CPR as the primary

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Supported, in part, by Advanced Circulatory Systems of Eden Prairie, MN.

K. G. Lurie is a co-inventor of the impedance threshold device and the active compression-decompression cardiopulmonary resuscitation devices.

DOI: 10.1097/01.CCM.0000163235.18990.F6

initial resuscitation technique. The second-tier response provides ALS care, including advanced airway support, pharmacologic therapy, and manual defibrillation. It is standard practice for both BLS and ALS to be performed on the scene until the patient is successfully resuscitated or until the physician on the ALS team decides to stop the resuscitation efforts. Resuscitated patients are transported by the ALS medical team directly to an intensive care unit.

Patients >18 yrs of age with a witnessed out-of-hospital cardiac arrest and for whom basic cardiac life support was already started by firefighters before the arrival of the medical team were enrolled in the study. Patients with unwitnessed cardiac arrest, presumed irreversible death, known terminal illness, traumatic injuries, do-not-resuscitate orders, and those in whom a spontaneous palpable carotid or femoral pulse was restored before the arrival of the medical team were excluded from the study.

During BLS care, bag-valve ventilation was performed with 100% supplemental oxygen at 15 L/min using a compression-to-ventilation ratio of 15:2, as recommended by current American Heart Association and European Resuscitation Council guidelines (8). First response teams were not equipped with the ITD but did perform ACD CPR on all patients. Personnel had been previously trained in ACD CPR and had used it for many years. For the purposes of this study, no additional ACD CPR training was provided.

At arrival of the ALS team, subjects were treated with both an active (functional) and sham (nonfunctional) ITD (ResQValve, Advanced Circulatory Systems, Eden Prairie, MN) in random order, based on a computer-generated randomization list. Sham devices were created by the manufacturer specifically for this study by removing the silicone diaphragm and occluding the diaphragm venting ports; as such, the sham devices functioned as hollow conduits. Furthermore, all ITDs were colored dark blue so that rescuers were blinded to device function. All devices were labeled with a unique serial number, and the code was held by an independent statistician (E. Vicaut). This code remained unknown to all investigators until after study enrollment was completed. Investigators were instructed to use the ITDs sequentially for each patient in cardiac arrest who required ongoing CPR with ALS and to remove it as soon as there was return of spontaneous circulation.

Both a sham and active ITD were evaluated sequentially during ACD CPR with bag-valve ventilation, first through the facemask for 2 mins and then through an ETT for the next 2 mins. At arrival of ALS personnel, the emergency medical services team prepared for intubation, placed an intravenous catheter, and administered medications as indicated. ACD CPR (100/min) was performed by the BLS team with the aid of a metronome. Just before intubation, the investigator placed the first ITD within the ventilation circuit between the facemask and the ventilation bag. An oral airway was placed and a head strap was used to maximize the facemask seal and minimize air leak. Each ITD (one active and one sham) was used for 1 min in a randomized, blinded order. The subject was then intubated orotracheally, and both ITDs were connected in the same sequence to the ETT for 1 min each. During the 4-min procedure, the facemask and ETT were connected to a monitor (Propaq Encore, PhysioControl, France) via a pressure transducer (Sorensen Transpac III, Abbott Systems, Chicago, IL) to continuously measure upper airway pressures, a surrogate for intrathoracic pressures (Fig. 1). The same rescuer performed chest compressions throughout the 4-min evaluation.

Data collection forms were collected on each subject according to Utstein template guidelines (9). The primary end point was maximum negative intrathoracic pressures achieved during the decompression phase of ACD CPR with an active vs. sham ITD on a facemask and ETT. The secondary end point was maximum negative intrathoracic pressures induced by an active ITD during the decompression phase of ACD CPR on the facemask vs. the ETT. Data from individual tracings were measured by investigators in a blinded fashion. The data were analyzed to provide mean ± SD and median (range) minimum and average intratracheal pressures. In addition, we tracked the rate of vomiting and aspiration during ITD use in each patient.

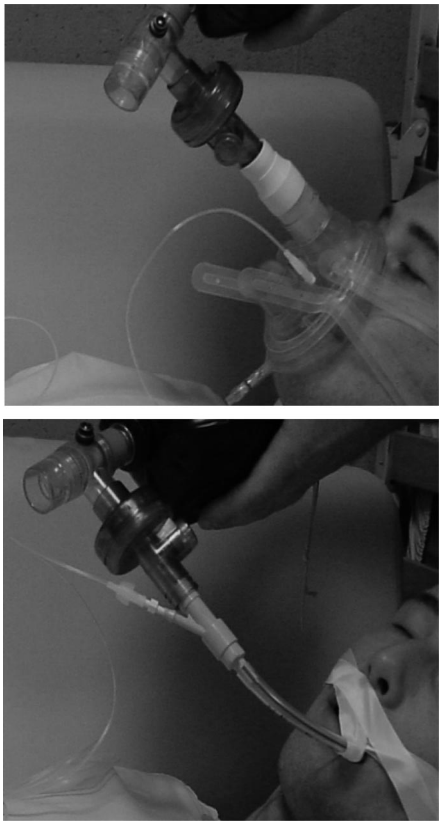

Figure 1. *Top*, typical test configuration for subjects receiving facemask ventilation with the inspiratory impedance threshold device; *bottom*, typical test configuration for subjects receiving endotracheal ventilation with the inspiratory impedance threshold device.

Data were analyzed on an intention-to-treat basis. Sample size was determined on the following basis: data obtained in animals suggested a SD for intrathoracic pressure close to 1 mm Hg (1, 5, 10). Investigators wanted to be able to detect an approximate 3-mm Hg difference due to the ITD. However, no data were available on the statistical distribution of intrathoracic pressure in humans under study conditions. Thus, the sample size was based on the use of nonparametric Wilcoxon's tests. A sample size equal to eight would allow a 90% power to detect a difference between the values obtained with or without the ITD corresponding to a probability $P(X < Y) = 0.98$ for values X measured with the ITD to be smaller than values Y obtained without the ITD (note that this probability corresponds for a Gaussian variable to a difference to be detected equal to 3 mm Hg for a variable with a SD equal to 1 mm Hg). Comparisons between values obtained in the presence or absence of the ITD or between facemask and endotracheal intubation were made using Wilcoxon's test for matched pairs. Significance level was fixed at 5%. Statistical analyses were made using Friedman's and Wilcoxon's rank-sum tests.

RESULTS

A total of 16 consecutive patients were eligible for the study protocol. Two were excluded because of pulmonary hemorrhage and vomiting before endotracheal intubation, respectively, making the measurement of airway pressures inaccurate. A total of 14 subjects were prospectively enrolled. One subject had a return of spontaneous circulation within the first 2 mins of the protocol. Only 12 patients were studied with both a facemask and an ETT, as one patient had a return of spontaneous circulation after the facemask portion of the protocol was completed and just before intubation. General characteristics of the 13 subjects, such as age, sex, percentage of bystander CPR, initial cardiac rhythm, and time intervals from collapse to arrival of BLS and ALS are shown in Table 1. No patient developed vomiting or aspirated during use of the ITD.

Figure 1 demonstrates the typical test configuration for subjects receiving facemask and endotracheal ventilation with the ITD. Mean and median (range) minimum and average airway pressure values during the decompression phase of ACD CPR with the sham ITD vs. active ITD during ventilation through the facemask and an ETT are shown in Table 2. The mean ± SD maximum negative intrathoracic pressures (in millimeters of mercury) during the decompression phase of CPR were −1.0 ± 0.73 with a sham vs. −4.6 ± 3.7 with an active ITD on the facemask ($p = .003$) and −1.3 ± 1.3 with a sham ITD vs. −7.3 ± 4.5 with an active ITD on an ETT ($p = .0009$), respectively. Decompression phase airway pressures with the facemask and ETT were not statistically different. Representative tracings of the upper airway pressures acquired during ACD CPR with a sham vs. active ITD on a facemask are shown in Figure 2 (*top*) and on an ETT in Figure 2 (*bottom*).

DISCUSSION

The main end point of the present study was the evaluation of the maximum effect of an active ITD on airway pressures during the decompression phase of ACD CPR. Use of an active ITD significantly decreased decompression phase airway pressures with both a facemask and an ETT, as compared with a sham ITD. To our knowledge, this study is the first evaluation of the vacuum effect generated in patients with out-of-hospital cardiac arrest, with or without an ITD, during CPR. Previous studies measured intrathoracic pressures during ACD CPR with and without an ITD in animals (1, 11). The results from those animal studies and from the current study are similar. The maximum negative intrathoracic pressure generated in animal studies with use of the ITD and ACD CPR ranged from −4 to −8 mm Hg. In the current study, negative intrathoracic pressures as low as −13 mm Hg were measured in some patients undergoing ACD CPR.

In the present study, the maximum negative intrathoracic pressure generated with ACD CPR was −4.0 mm Hg with a sham ITD in an intubated patient vs. −13.0 mm Hg with an active ITD; thus, the present study showed, for the first time, a significant enhancement in negative airway pressures when the ITD was added to the ventilatory circuit during ACD CPR. The active ITD was similarly effective when the patient was ventilated with a facemask, but the effect was more variable. We speculate that this variability may be due to the challenges of creating a perfect seal during facemask ventilation. Nonetheless, in this study with 13 patients, the vacuum created with the active ITD was statistically similar when using either the facemask or ETT. It is important to note that any negative intrathoracic pressure generated during CPR is clinically important. The right heart operates under very low pressure gradients, under normal conditions and during CPR. This is particularly true during the filling phase of the heart. As such, a pressure differential between the intrathoracic and extrathoracic compartments of even −2 mm Hg is clinically important, as blood flows into the heart even with such a small pressure gradient.

The ITD functioned as intended in this study to impede inspiratory flow when intrathoracic pressures become lower than atmospheric pressure. There were no complications from the use of the ITD in this study. The ITD did not impede rescuer ventilation or patient exhalation, as is shown in the pressure curves.

The maximum negative intrathoracic pressure achieved during CPR is dependent on many factors. During manual chest compression with conventional CPR, intrathoracic pressure becomes negative due to the natural recoil of the chest, as long as the recoil is not impeded (12, 13). Broken ribs, a rigid chest, chest wall configuration, chest wall remodeling, and poor CPR technique can all contribute to the inability of the chest to recoil back to its resting position during both conventional manual and ACD CPR (14). As such, the beneficial hemodynamic effect of chest wall recoil may vary from patient to patient. Despite this variability, use of the ITD harnesses the kinetic recoil energy of the chest wall during the decompression phase of CPR, thereby preventing respiratory gases from entering the lungs. This results in a similar hemodynamic effect as a Muller maneuver. This maneuver, which is an inspiratory effort with the glottis closed, is known to decrease intrathoracic pressures and enhance venous return to the heart (15). Santamore et al. (16) showed a significant increase in right ventricular end-diastolic volume by ventriculography during the Muller maneuver as compared with its measurement during normal inspiration (10.4 ± 2.3 vs. 2.3 ± 0.7 mL, $p < .05$). Based on the current study, we

Table 1. Subjects' characteristics (n = 14)

Age ± SD, yrs	54 ± 18
Sex, n	
Male	11
Female	3
Bystander CPR, n	0
Initial rhythm, n	
Asystole	8
PEA	3
Unknown	3
Return of spontaneous circulation, n	3
Time intervals ± SD, mins	
Collapse to BLS arrival	12.4 ± 10.7
Collapse to ALS arrival	22.0 ± 13.7

CPR, cardiopulmonary resuscitation; PEA, pulseless electrical activity; BLS, basic life support; ALS, advanced life support.

Table 2. Maximum and mean negative airway pressures during the decompression phase of active compression–decompression cardiopulmonary resuscitation with a sham and active impedance threshold device (ITD) attached to a facemask or endotracheal tube (ETT)

	Sham ITD			Active ITD			
	n	Mean, mm Hg (SD)	Median, mm Hg (Range)	n	Mean, mm Hg (SD)	Median, mm Hg (Range)	*p* Value
Facemask							
Maximum	13	−1.0 (0.73)	−1 (−2.5, 0)	13	−4.6 (3.7)	−3 (−11, −1)	.003
Mean	13	−0.5 (0.65)	0 (−2, 0)	13	−3.4 (3.2)	−2 (−9, −0.5)	.003
ETT							
Maximum	12	−1.3 (1.25)	−1 (−4, 1)	12	−7.3 (4.53)	−8 (−13, −1)	.0009
Mean	12	−0.8 (1.26)	0 (−3, 1)	12	−5.8 (4.33)	−6.3 (−12, 0)	.002

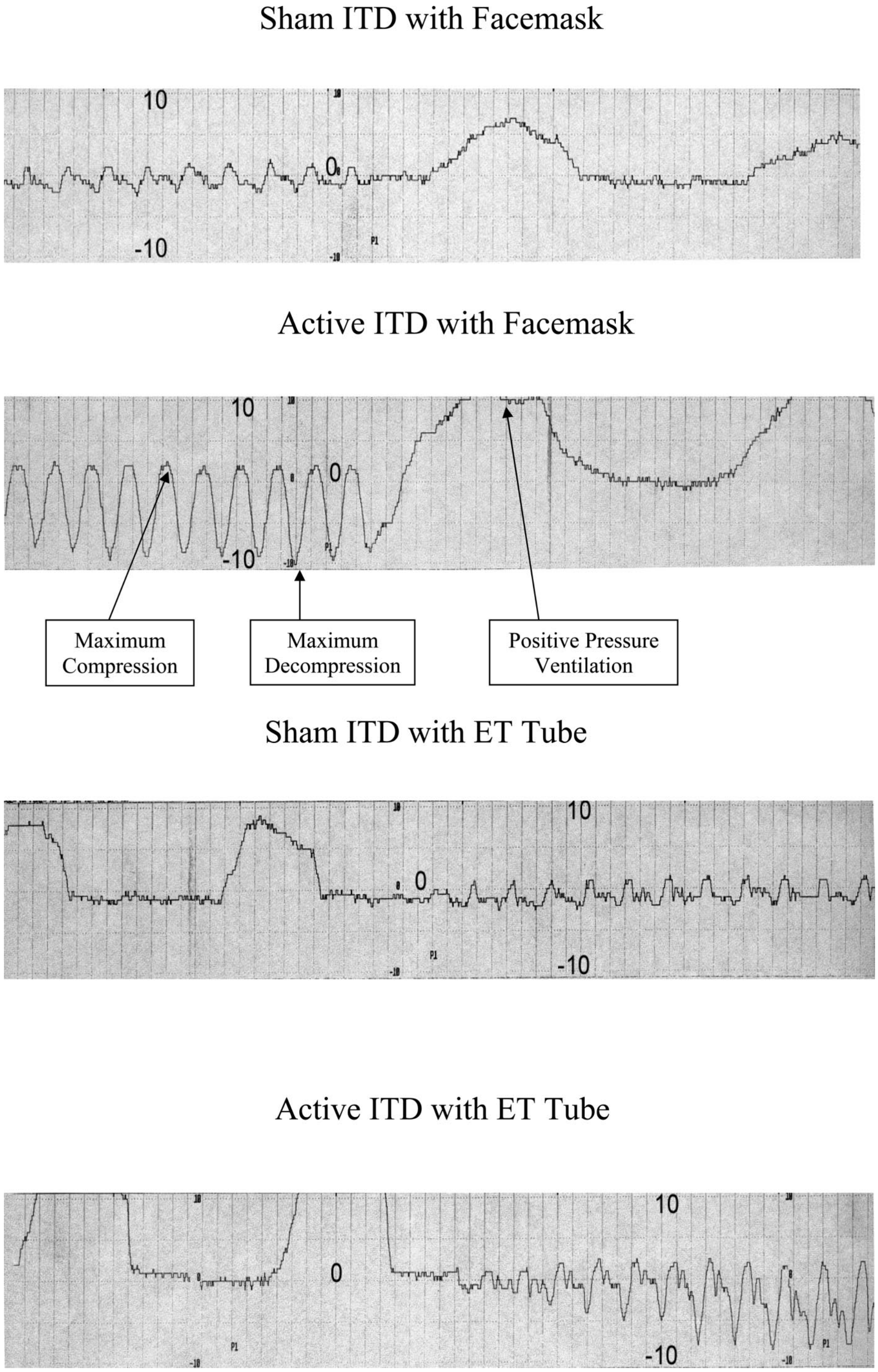

Figure 2. *Top*, representative tracing of upper airway pressures (in millimeters of mercury) acquired during active compression–decompression cardiopulmonary resuscitation with a sham vs. active impedance threshold device (*ITD*) on a facemask. *Bottom*, representative tracing of the upper airway pressures (in millimeters of mercury) acquired during active compression–decompression cardiopulmonary resuscitation with a sham vs. active ITD on an endotracheal (*ET*) tube.

Use of an active impedance threshold device attached to a facemask or an endotracheal tube resulted in a significantly lower negative intratracheal pressure during the decompression phase of active compression–decompression cardiopulmonary resuscitation when compared with controls.

speculate that use of the ITD also results in an increase in right ventricular end-diastolic volume during ACD CPR.

This study has limitations. One was that intrathoracic pressures were measured at the level of a facemask and the proximal tip of the ETT. The optimal measurement of intrathoracic pressures should be made from an esophageal probe or with a pressure transducer within the pleural space; however, these more ideal approaches are more difficult to perform during CPR in out-of-hospital cardiac arrest patients. They are also more invasive, time consuming, and risky for patients in cardiac arrest. Nevertheless, as the trachea is an intrathoracic structure, the airway pressures generated during the recoil phase reflect the intrathoracic pressures in other intrathoracic compartments, especially during the decompression phase of CPR. However, although negative intrathoracic pressures may be accurate, positive intrathoracic pressures could not be obtained as the airway was open and respiratory gases were expelled without restraint with each compression.

Another limitation relates to extrapolation of the airway pressure measurements at the level of the facemask. There are two methodologic concerns. First, the hypotonicity of the pharyngolaryngeal area observed in unconscious people could lead to overestimated pressures measured at the level of the facemask compared with the one measured more distally, due to upper airway collapse, especially with the application of the ITD. As a preliminary evaluation, we simultaneously measured pressures through the facemask and subglottic pressures by means of a catheter inserted through the intercricoid membrane in three out-of-hospital cardiac arrest patients ventilated with a facemask with and without an ITD. We observed similar airway pressure values at both sites. Based on these pilot studies, we determined that there was no need to delay the time of endotracheal intubation by a transcricoid catheter to measure airway pressures with the facemask. The second problem concerns the leak between the facemask and the face. We reduced this leak by using a strap around the head of the patient and by ventilating with the bag-valve mask using a two-rescuer technique; one to squeeze the ventilation bag and one, using both hands, to maintain a face seal as recommended by the international guidelines (8). This approach resulted in a satisfactory seal.

CONCLUSIONS

ACD CPR combined with an ITD is known to improve hemodynamics, vital organ blood flow, and survival by enhancing negative intrathoracic pressure during the decompression phase of CPR. Previous studies have shown that use of an ITD with ACD CPR enhances hemodynamics during ALS, resulting in increased survival rates. The present study is the first to measure the intrathoracic vacuum generated during the decompression phase of ACD CPR with an ITD in patients in out-of-hospital cardiac arrest. The vacuum generated with the active ITD was significantly greater, both when using a facemask and when using an ETT, compared with controls. Moreover, use of the ITD attached to the facemask during CPR was practicable and effective in the BLS setting. As such, application of an ITD to a facemask may enable more rapid deployment of this lifesaving technology.

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