Evaluation of a Prototypic Inspiratory Impedance Threshold Valve Designed to Enhance the Efficiency of Cardiopulmonary Resuscitation

Keith G Lurie MD, Thomas A Barnes EdD RRT, Todd M Zielinski PhD, and Scott H McKnite

OBJECTIVE: Assess a prototype inspiratory impedance threshold valve (ITV) designed to enhance vital organ circulation during standard and active compression/decompression cardiopulmonary resuscitation (CPR). BACKGROUND: The ITV attaches to commonly used airway assist devices and decreases intrathoracic pressure during the decompression (chest recoil) phase of CPR by creating a vacuum within the thorax, which increases venous blood flow to the heart and thus increases coronary perfusion pressure and blood flow to the brain. METHODS: The evaluation included laboratory bench testing, according to American Society for Testing and Materials (ASTM) and International Standards Organization (ISO) guidelines, and performance testing with pigs in cardiac arrest. A vacuum pull test was developed to determine the inspiratory impedance under various inspiratory flow conditions. RESULTS: The valve passed all minimum ASTM and ISO performance tests. During cardiac arrest in pigs the ITV decreased intrathoracic pressures by 6–8 mm Hg during the decompression phase. The vacuum pull test demonstrated that the prototype ITV functioned as intended. CONCLUSIONS: The prototype ITV passed all performance testing recommended by international guidelines and functioned effectively as intended for use. The animal study results, when combined with recent clinical data, suggest that an ITV inspiratory cracking pressure of 12 cm H_2O should be sufficient to decrease intrathoracic pressure during the decompression phase of standard CPR. Clinical studies are now underway. *Key words: cardiac arrest, cardiopulmonary resuscitation, inspiratory impedance threshold valve, ventricular fibrillation, active compression/decompression, CPR.* [Respir Care 2003;48(1):52–57]

Introduction

Despite widespread implementation of standard cardiopulmonary resuscitation (CPR), the survival rate for victims of cardiac arrest remains low. Many mechanical devices have been developed to enhance CPR efficacy by increasing intrathoracic pressure during the compression phase of CPR.[1] Recently, new devices have been created to increase negative intrathoracic pressure during the chest wall decompression phase, thereby enhancing venous return to the heart.[2–5]

To better appreciate the rationale for devices that lower intrathoracic pressure during CPR decompression, it is important to understand some of the basic mechanisms underlying standard CPR. Three essential mechanisms are thought to promote blood flow during standard CPR: (1) an increase in intrathoracic pressure during the compression phase to enhance blood flow out of the heart and to the brain and other extrathoracic vital organs, (2) direct cardiac compression in some patients, which serves to enhance forward blood flow, and (3) a slight negative intrathoracic pressure created by the natural elastic recoil of the chest during the relaxation/decompression phase, which draws venous blood back to the chest cavity, thereby

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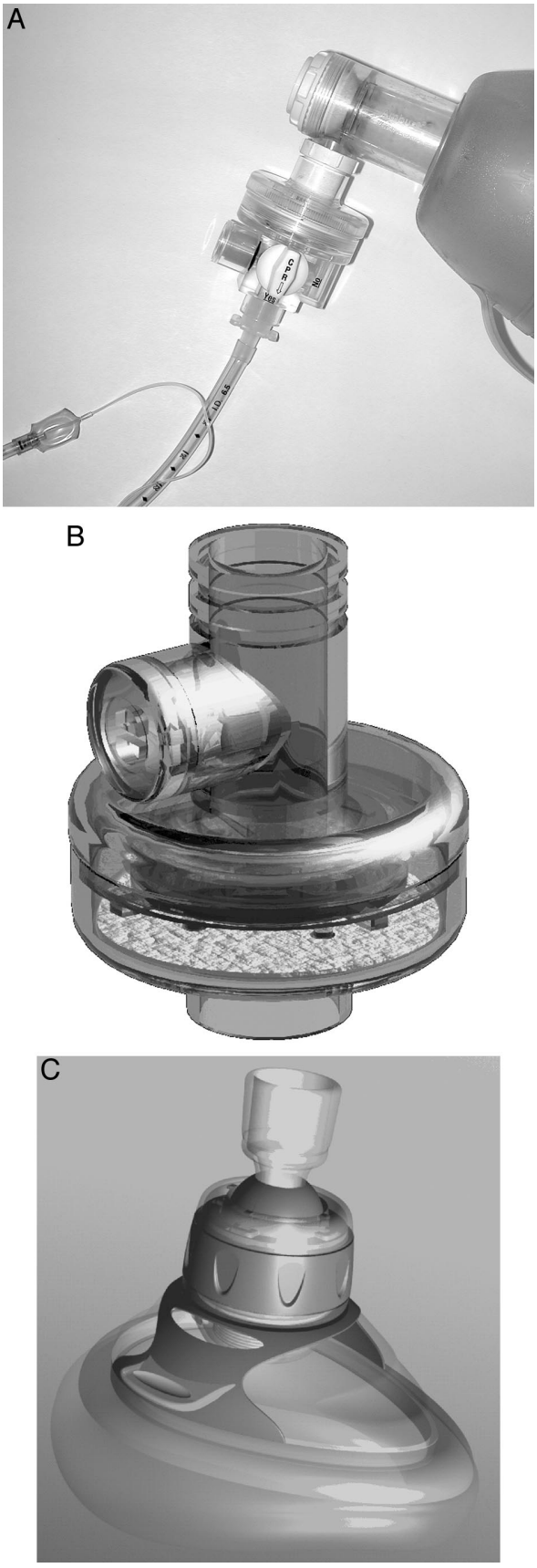

priming the heart for the subsequent compression.[1] During CPR the rescuer must allow the chest wall to relax and recoil back to its resting position. The importance of this decompression phase is highlighted in the American Heart Association's 2000 guidelines, which state, "Release the pressure on the chest to allow blood to flow into the chest to return to its normal position after each compression."[1] In this manner the chest serves as a bellows during CPR.

Both standard CPR and active compression/decompression (ACD) CPR enhance negative intrathoracic pressure during the decompression phase.[1–3] The ACD CPR approach uses a hand-held suction cup device that is attached to the chest over the sternum. The chest is compressed with the device, as with standard manual CPR, but then actively decompressed after each compression phase, which increases the intrathoracic vacuum and thereby increases minute ventilation and cardiopulmonary circulation. Building on these studies, further investigations with a porcine model of ventricular fibrillation, and, more recently, with patients, revealed that a prototype inspiratory impedance threshold valve substantially improves ventricular and cerebral blood flow, 24-hour survival, and neurological function during both standard and ACD CPR.[4–9]

An inspiratory impedance threshold valve impedes respiratory gas exchange when thoracic pressure is lower than atmospheric pressure. This creates a vacuum within the thorax during the decompression phase, which increases blood return to the heart each time the chest wall recoils. The temporary impedance of air flow into the chest during decompression causes the intrathoracic pressure to remain low long enough to enhance venous return to the thorax, which increases circulation and primes the heart for the next compression. Based on the promising results of the initial studies, a small, disposable inspiratory impedance threshold valve (ITV, CPRx, Minneapolis, Minnesota) was developed (Fig. 1).

With the ITV the rescuer can ventilate the patient without encountering inspiratory resistance. That is a unique feature of the ITV (Fig. 2). The valve does not block

Fig. 1. The inspiratory impedance threshold valve (ITV) is inserted within the respiratory circuit, between the ventilation bag and the endotracheal tube, face mask, Combitube, or LMA. The ITV enhances venous return during the chest recoil phase of cardiopulmonary resuscitation (CPR) and thus primes the heart for the subsequent CPR compression. A safety check valve attached to the side of the ITV opens if the patient begins to breathe independently. A: The original impedance valve prototype. B: The prototype disposable ITV studied for the present report (the ResQValve) includes a bacteria filter. C: The final version of the ITV (ResQPod), as it looks when attached to a face mask. This device was designed to fit onto an improved face mask. It includes a swivel mount to reduce tension between the resuscitator bag and the face mask or breathing tube, and an optional metronome that indicates the correct cadence for CPR.

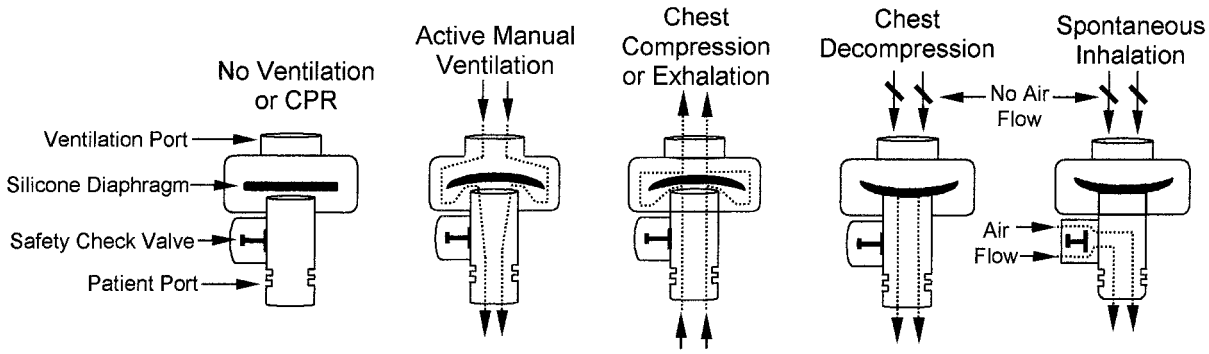

Fig. 2. Air flow through the inspiratory impedance threshold valve (ITV) during the phases of cardiopulmonary resuscitation (CPR). During manual ventilation, respiratory gas bypasses the occlusion valve (silicone diaphragm) and flows into the lungs unimpeded. During chest compression or exhalation, expiration 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.

exhalation of respiratory gas, and there is a built-in safety check valve that opens if the patient begins to breathe spontaneously. When the patient has been successfully resuscitated, the impedance valve must be removed from the respiratory circuit to allow the patient to breathe without substantial inspiratory resistance. The present report describes some of the animal and bench tests used to evaluate the safety and efficacy of the ITV and describes its potential use for treating shock.

Development of the Valve

The inspiratory impedance threshold valve was designed to be placed within a standard respiratory circuit. It can be used in conjunction with nearly all CPR techniques and devices (eg, standard CPR, ACD CPR, vest CPR, and interposed abdominal counterpulsation CPR) and airway devices (endotracheal tube, laryngeal mask airway, Combitube, face mask) presently recommended by the American Heart Association.[1] Currently the ITV is recommended for use with ACD CPR in the American Heart Association guidelines.[1]

The valve has gone through several engineering refinements since its inception. The first prototype (see Fig. 1A) was larger and heavier and included a stopcock that the rescuer was to turn from "CPR Yes" to "CPR No" when chest compressions were no longer needed. However, this made the valve too cumbersome, and the stopcock was removed. With the current design the rescuer must remove the valve from the circuit if there is a return of spontaneous breathing, since it is difficult to inspire through the impedance valve.

Each version of the valve has undergone extensive testing. In this report we describe some of the results of bench testing and animal testing of the prototype disposable valve (see Fig. 1B). A commercially available version was recently developed, based on the results with the prototype valve, that has a number of additional features, including a swivel mount, a metronome that indicates the correct cadence for CPR, and a means to create a better seal when used with a face mask (see Fig. 1C).

Bench Testing Methods

All medical devices in the United States are required to be designed and manufactured according to rigorous standards that provide guidance for their functionality and the ability to withstand the environmental conditions/stresses that would be encountered by the device, which can include being dropped, contamination with vomitus, extreme temperature and humidity conditions, and the degree of resistance when ventilating the patient and during expiration. The bench testing was performed on the prototype ITV according to American Society for Testing and Materials (ASTM) and International Standards Organization (ISO) guidelines.[10]

At present there are no standards for evaluating different degrees of inspiratory impedance in valves designed for resuscitation, so we developed a vacuum pull test to evaluate the cracking (triggering) pressure of the ITV's safety check valve at various inspiratory flows. The safety check valve allows the patient to breathe through the valve if he or she wakes up during CPR. Using a Rudolph 1-L syringe (Hans Rudolph, St Louis, Missouri) connected inline with a vacuum gauge (Ashcroft Dresser, Stratford, Connecticut), the vacuum pull test was used to evaluate the resistance through the ITV at flows ranging from 0 to 50 L/min through the valve.

Bench Testing Results

Table 1 shows the bench test results, which demonstrate that the prototype valve meets the ASTM and ISO standards

Table 1. Bench Testing and ASTM Standards Tests of the Inspiratory Impedance Threshold Valve

ASTM Method	ASTM Standard	Result
One-way valve function after extreme temperature and humidity storage	F920-93.A1.2.13	Passed
Safety check valve function after extreme temperature and humidity storage	F920-93.A1.2.13	Passed
One-way valve function after extreme temperature and humidity operation	F920-93.A1.5.19	Passed
Safety check valve function after extreme temperature and humidity operation	F920-93.A1.5.19	Passed
Drop test	F920-93.A1.5.4	Passed
Valve function after contamination with vomitus	F920-93.A1.5.3	Passed
Expiratory resistance (positive flow from patient port)	F920-93.A1.5.9.2	Passed
Inspiratory resistance (positive flow from ventilation port)	F920-93.A1.5.10.2	Passed
Delivered oxygen concentration	F920-93.A1.5.7	Passed
Tidal volume and cycle rate	F920-93.A1.5.13	Passed
Dead space measurement	F920-93.A1.5.12	Passed

ASTM = American Society for Testing and Materials

for dead space (< 45 mL) and expiratory resistance at flows of up to 120 L/min (resistance < 5 cm $H_2O \cdot s \cdot L^{-1}$). The valve operated well after exposure to extreme temperatures (– 40 to +70° C) and humidity (50–90%), after contamination with vomitus, and after mechanical shock (drop) testing.

The cracking pressure of the prototype safety check valve depends on its design and the intended use of the device. At intrathoracic pressures between 0 and – 10 cm H_2O, the valve remained closed. With greater inspiratory effort the valve opened, and the resistance through the valve depended on the design of the valve and the flow rate though the valve.

The degree of inspiratory resistance is flow-dependent and is partly determined by the spring tension and the size of the safety check valve orifice. We evaluated several different spring tensions and safety check valve orifice sizes. Enlarging the safety check valve orifice and decreasing the spring tension reduced the resistance through the safety check valve at higher flow rates (Fig. 3).

Animal Studies Methods

To determine the effect of the impedance valve on intrathoracic pressure, a study was performed to measure pressures generated during CPR with 6 pigs ventilated with a laryngeal mask airway (LMA, Intavent, Berkshire, United Kingdom). The LMA was used to create an adequate seal within the airway while allowing the vocal cords to move freely during CPR.[11] The studies were approved by the Animal Care Committee of the University of Minnesota. The protocol, including the anesthetic used, monitoring methods, and CPR method, was previously described.[5,7,9] The animals were anesthetized with pentobarbital, and ventricular fibrillation was induced via a right ventricular catheter.[5,7,9] Ventilations of 450 mL were delivered once per every 5 compressions. After 3 min of untreated ventricular fibrillation, CPR was performed continuously with an automated pneumatically driven device capable of delivering active compression only or ACD CPR, at a rate of 80 compressions/min.[5,7,9]

Animal Studies Results

During both standard and ACD CPR the impedance valve significantly increased negative intrathoracic pressure during the decompression phase (Table 2). The pigs remained apneic throughout the tests and did not overdrive the safety check valve. The maximum negative intrathoracic pressure measured was approximately –12 cm H_2O.

Discussion

Adequate venous return is essential for effective CPR, so techniques that enhance venous return during the decompression phase improve the efficacy of any CPR method. One way to increase circulation during CPR is to decrease negative intrathoracic pressure during chest recoil, thereby creating an intrathoracic vacuum. The inspiratory threshold valve accomplishes that objective.

The valve passed ASTM and ISO tests, functioned as intended, and was efficacious in both bench tests and animal model cardiac arrest. Bench testing revealed that the valve functioned within its intended specifications and withstood mechanical shock and extreme temperatures and humidity. The vacuum pull test helped to assess the relationship between flow and resistance through the impedance valve. By either decreasing the spring tension or widening the safety check valve orifice, the valve functioned well at low inspiratory pressures and had less resistance to flow once it was open. Furthermore, the animal studies revealed that the prototype valve reduced the intrathoracic pressure to –8.8 cm H_2O during standard CPR and to –10.2 cm H_2O during ACD CPR.

In the present study we used an LMA to ensure that the observed changes in intrathoracic pressure were independent of potential effects of the vocal cords.[11] The LMA does not impair vocal cord movement. The present study found that the seal was adequate with the LMA, the effect of the ITV was independent of vocal cord movement, and the intrathoracic pressures through the LMA were similar to what we recently observed in pigs ventilated via endotracheal tube.[7,9] It therefore appears that both the LMA

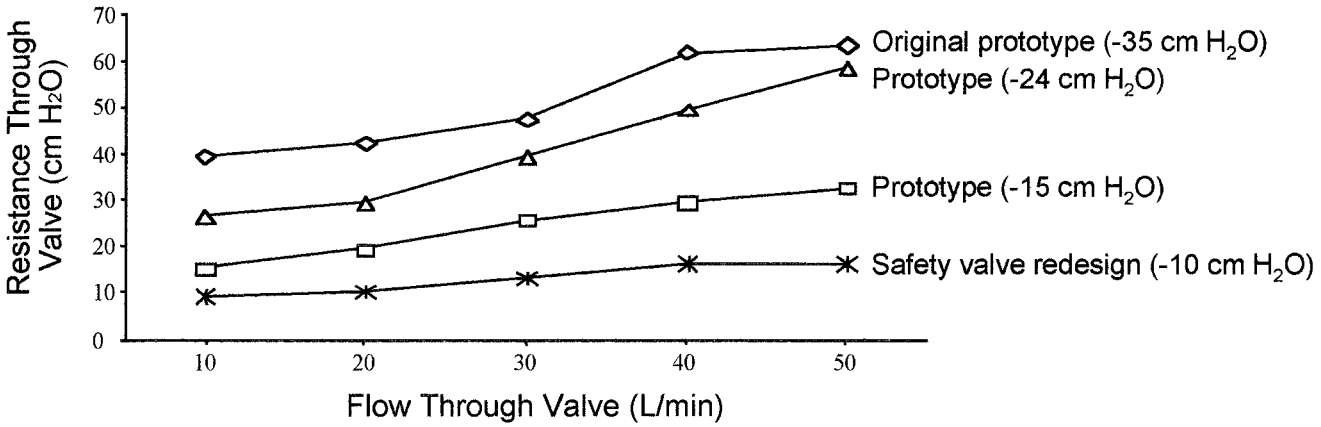

Fig. 3. Inspiratory flow versus resistance through several different inspiratory impedance threshold valves (ITVs). Increasing the safety check valve orifice and decreasing the spring tension reduced the resistance through the safety check valve at higher flow. The resistance was highest with the smallest safety check valve orifice and the highest spring tension (original prototype, –35 cm H_2O). The flow/resistance curve shifted lower with a reduction in the spring tension (–24 and –15 cm H_2O). When the spring tension was further lowered and the valve orifice was enlarged, the safety valved opened at –10 cm H_2O and there was minimal increased resistance at the higher inspiratory flow.

Table 2. Intrathoracic Pressure in Pigs During Standard CPR and Active Compression/Decompression CPR With and Without the Impedance Threshold Valve

Method	Compression Pressure (mm Hg)	Decompression Pressure (mm Hg)
Standard	0.50 ± 0.60	−3.37 ± 0.51
Standard + ITV	0.16 ± 0.63	−6.45 ± 0.81*
ACD	0.84 ± 0.68	−4.02 ± 0.49
ACD + ITV	0.46 ± 0.52	−7.50 ± 0.68*

CPR = cardiopulmonary resuscitation
ITV = impedance threshold valve
*$p < 0.05$ comparing standard CPR alone versus standard CPR with ITV, and ACD CPR alone versus ACD CPR with ITV
ACD = active compression/decompression

and the endotracheal tube provide an adequate seal when using the ITV. By contrast, we recently reported that intrathoracic pressure in patients in cardiac arrest decreased to –17 cm H_2O during ACD CPR, using either face mask or endotracheal tube.[12] Thus it is possible that the chest recoil properties of patients may be greater than that of pigs and that the intrathoracic pressures in patients may be lower than those in animals during the decompression phase of CPR.

These findings have important implications for the design of a safe and effective ITV. Because of the possibility of operator error (eg, the rescuer may forget to remove the ITV after there is a return of spontaneous circulation), it is important that the ITV have the lowest possible cracking pressure that achieves the hemodynamic benefit during CPR. The first clinical trial was performed with a safety check valve that had a cracking pressure of –35 cm H_2O at a flow of 20 L/min.[6] However, based on earlier clinical studies,[7,9] subsequent clinical trials were performed with a safety valve that had a –24 cm H_2O cracking pressure.[13,14] Based on the animal study evaluations described here, clinical evaluations with patients in whom intrathoracic pressure was measured during ACD CPR,[7,12] and an ongoing comparison (Aufderheide TP, Medical College of Wisconsin, Milwaukee, Wisconsin, 2002; personal communication) of standard CPR with and without the ITV, the cracking pressure was further reduced to –15 cm H_2O at 20 L/min. At that cracking pressure the ITV creates the intrathoracic vacuum necessary to enhance circulation, but if the rescuer forgets to remove the ITV upon return of spontaneous breathing, it is easier (than with previous versions of the ITV) to inspire through the ITV; this minimizes the potential risk of the device.

Use of the impedance valve during CPR has several potential limitations. First, the rescuer must remember to remove the valve once a pulse has been restored, since it would be difficult to breathe through the ITV unless the inspiratory resistance is reduced to $<$ 10 cm H_2O. Second, when the impedance valve is used with a face mask, the rescuer must maintain a complete mask-to-face seal throughout the resuscitation effort to optimize the benefit of the impedance valve. Third, when the impedance valve is used with ACD CPR, it is important that the rescuers are properly trained in the ACD technique. However, when performed correctly, the combination of the ITV and ACD CPR results in a $>$ 50% increase in coronary perfusion pressure, improved 24-hour survival, and improved neurological function in cardiac arrest patients.[13,14] Thus, despite the potential limitations, the valve can have a striking effect on the outcome of cardiac arrest patients. Finally, although there is strong support for the use of the impedance valve with standard CPR in animals,[7–9] at present

there are no clinical data. A trial comparing standard CPR with the ITV and a sham ITV is presently underway in Milwaukee, Wisconsin. No important adverse effects from the impedance valve have been observed in the animal models or in the clinical studies to date.

Future Directions

The importance of lowering inspiratory resistance during CPR has led to the discovery that the ITV might enhance circulation in other states of low blood pressure. The ITV was recently used as a circulatory enhancer in the treatment of shock secondary to hemorrhage and hyperthermia.[15–18] By increasing venous return to the right heart, an ITV with a safety valve cracking pressure of 5–15 cm H_2O substantially increases cardiac filling during inspiration and results in a sustained rise in blood pressure.[19] The ITV is particularly effective in spontaneously breathing animals and patients. In that setting an ITV with a low safety valve cracking pressure (5–15 cm H_2O) serves as a patient-powered pump that enhances circulation with each inspiration. Additional animal and clinical studies are underway to determine which shock patients benefit from ITV.

Conclusions

The results of the ASTM and ISO testing described here provide additional support for the safety and efficacy of the disposable ITV during CPR. The ITV provided relatively small but important decreases in intrathoracic pressure (6–8 cm H_2O) during the decompression phase. Recent clinical trials have demonstrated the safety and efficacy of the ITV when used during ACD CPR.[13,14] Building upon the current study and recent clinical trials, further investigations are ongoing in patients to determine the potential benefits of this new valve for patients receiving standard CPR and in spontaneously breathing patients in hemorrhagic shock.

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