Original Article

Automatic Transport Ventilator Versus Bag Valve in the EMS Setting: A Prospective, Randomized Trial

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Purpose: The primary objective of this study was to compare Emergency Medical Technicians-Paramedics (EMT-P) perceptions of the usefulness of an automatic transport ventilator (ATV) compared with bag valve (BV) ventilation for intubated patients.

Methods: Cardiopulmonary resuscitation or assisted ventilation patients were randomly assigned by day to the ATV or BV arm of the study. Questionnaires were completed by the EMT-Ps at the conclusion of each patient enrollment. EMT-Ps were asked to rate the modality used (ATV versus BV) on ease of use, time of setup, expedition of transport, additional tasks completed, documentation, overall patient care, and patient comfort.

Results: Twenty-eight patients were entered into the study, 14 in the BV arm and 14 in the ATV arm. There were significant differences in favor of the ATV in ability to accomplish additional tasks (P = 0.01), ability to document (P = 0.04), and ability to provide patient care (P = 0.03)

Conclusions: EMT-Ps were able to accomplish more tasks, document more completely, and provide better patient care with the use of the ATV.

Key Words: emergency medical services, ventilation, end-tidal CO_2, critical care

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Safe, effective airway management is the single most important skill performed by prehospital personnel. In the past, most mechanical ventilators were electronically driven.[1] More recently, a number of devices that are gas-driven have appeared on the marketplace.[2,3] These devices are simple to use, effective, and inexpensive.[2] Previous studies have shown that transport ventilators are better at maintaining minute volume[4] and pre/postarterial blood gas results.[2,5] However, no one has evaluated ongoing oxygen saturation and the ability of Emergency Medical Service (EMS) crews to perform other functions. We are seeking to determine whether a gas-powered ventilator is a valuable asset to EMS once a definitive airway has been established.[1,3,5–10] If a gas-powered ventilator could be used for airway support, the result could be an improvement in patient ventilation, patient care, and oxygenation during transport.

The hypotheses of this study were that (1) paramedics prefer the use of a gas-powered respirator over the use of a bag valve (BV) and that (2) measures of ventilation and oxygenation can be successfully recorded by EMS personnel during transport

Materials and Methods

This was an unblinded, randomized, prospective study comparing two ventilatory methods in intubated patients.

The study device used was the Vortran Automatic Resuscitator (VAR), which is a single-patient, disposable, gas-powered, automatic resuscitator. The VAR provides constant-

Key Points

- Use of an automatic transport ventilator allowed EMTs to accomplish extra tasks, document better, and provide better patient care.
- Side effects are no different between the automatic transport ventilator and the bag valve.
- Physiological data can be effectively gathered during field care of intubated patients.

flow, pressure-cycled ventilation. It can be used in either the pressure support or pressure control modes. A manometer provides real time airway pressure figures. The device includes a 60 cm H_2O pop-off valve that will actuate in the unlikely event of a pressure overload. For clarity, the VAR will be called an automatic transport ventilator (ATV) for the remainder of this report. Both the ATV and the BV were FDA-approved devices for ventilatory management that were used successfully in other environments. The cost of the VAR is less than $100. Figure 1 shows the ventilator.

Patients were included if they were at least 18 years of age and endotracheal intubation was successful. Patients under the age of 18 or those weighing less than 40 kg were excluded, as the ATV is not approved for those patients. Entry included those intubated for either CPR or assisted ventilation.

The independent variable was the use of either the ATV or the BV to ventilate a patient. The dependent variables were the following: (1) successful management, as determined clinically by ease of use of the device, ability to accomplish additional tasks, ability to complete additional monitoring, ability to provide more thorough documentation, and overall assessment of the performance of the device as measured by a Likert scale completed by paramedics after transport; and (2) effectiveness of oxygenation and ventilation, as determined by pulse oximetry and capnometry.

All cases were analyzed with the use of an intention-to-treat methodology. Ambulance units were assigned to use the ATV or the BV resuscitator as their method of ventilatory support for a 24-hour period, based on a list of random numbers. The device unpacked and packaged for use is shown in Figure 2, A and B.

After random assignment, the data collection device was connected to all subjects to collect physiological data. Pulse, oxygen saturation, respiratory rate, and end-tidal CO_2 were collected every 5 seconds and converted into an Excel file for analysis.

At the receiving hospital, the intervention phase of the study ceased and the hospital management was based on physician choice of care. The study information form was filled out for each patient, indicating condition of the patient, activities of the paramedics, and outcome. The questions determined paramedic opinion on the ventilation method used in comparison to the other method (-2 = much worse, -1 = worse, 0 = the same, 1 = better, 2 = much better). Complications were followed in an ongoing manner, and the study would be stopped if there was a significant difference in complications between the two groups. In the event that the gas-powered ventilator was not working successfully, the patient's airway management reverted to ventilatory management with a BV.

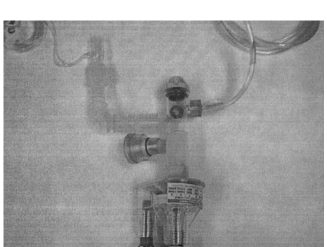

Fig. 1 **Vortran disposable pressure-powered ventilator used in the study.**

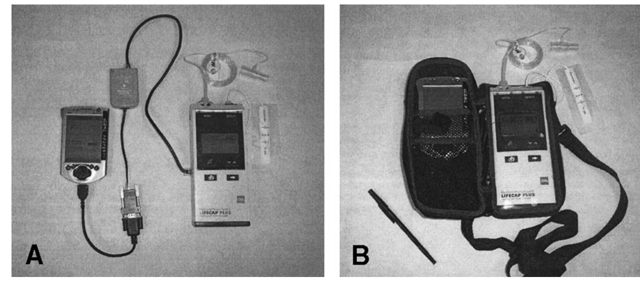

Fig. 2 **Data collection device laid out to show all of the parts (*A*) and packed for use by the EMS providers (*B*). Comparison with a Bic pen in *B* shows the relatively small size of the packet carried by EMS.**

Confounding variables of experience with BV and variation from standard techniques in placement were avoided by training everyone equally and using a break-in period at the beginning of the study to allow EMS personnel to gain familiarity in using the gas-powered ventilators.

The University Investigational Review Board approved the study. This study was waived from informed consent, based on minimal risk. We were unable to obtain consent because patients entered into the study had extreme distress at the time when the study device was used. Both the BV and the ATV are FDA-approved devices for patient ventilation. This study qualified for a waived consent for the following reasons: (1) there was minimal risk associated with either device; (2) the waiver would not adversely affect the rights or welfare of the subjects; (3) the study could not be practically performed without the waiver; (4) whenever possible, the subjects were provided with additional pertinent information after participation, if warranted.

Although multiple manufacturers funded the study and loaned the devices to the investigators, none had any say in study design, implementation, write-up, or publication. No study investigator was associated with any of these companies or received any compensation.

Statistical analysis was performed by using a Mann-Whitney U test for nonparametric data and a Pearson χ^2 for dichotomous data. All values were considered significant at a value of $P < 0.05$.

Results

Twenty-eight patients were entered into the study, 14 in the BV arm and 14 in the ATV arm. The reason for device use was assisted ventilation in 7 of 28 (25%) cases and CPR in 21 of 28 (75%) cases.

There were no significant differences in the EMS perception of ease of use ($P = 0.08$), time of setup ($P = 0.14$), expedition of transport ($P = 0.27$), or overall patient care ($P = 0.59$). There were significant differences in favor of the ATV in ability to accomplish additional tasks ($P = 0.01$), ability to document ($P = 0.04$), and ability to provide patient care ($P = 0.03$). These are illustrated in Table 1.

Problems occurred only rarely and did not affect the outcomes of any of the patients. Table 2 lists the problems and percentages for each of the groups. More of the problems were with charging or recording properly on the data collection unit. These were not listed in the table because they did not pertain to the ATV or BV ventilation devices.

The data collection unit was able to record ongoing physiological data on 15 of 28 (54%) patients during EMS transport. Reasons for lack of data collection were run times that were too short and inability to operate the data collection unit. Table 3 lists the patients who had data successfully recorded, data type, and period of time.

Case studies

The following two cases illustrate the results obtained and the utility of noninvasive physiological monitoring of patients during EMS transports.

Patient 1: ATV

EMS was called to the house of a 58-year-old male for the complaint of the patient being unresponsive (Fig. 3). The patient was found slumped over in a friend's vehicle when the friend drove him to the firehouse. He was placed on a backboard and gurney. Because he was pulseless and apneic, CPR was initiated and the patient was intubated. En route, the patient went through multiple rhythm changes, including asystole, pulseless electrical activity, and ventricular fibrillation. He received 1 mg epinephrine × 2, 1 mg atropine × 2, and electric shocks × 3. At arrival to the Emergency Department (ED), he had a strong carotid pulse without any change in level of consciousness or respirations. The graphic results, shown in Figure 3, illustrate the high values for end-tidal CO_2 and how they increase dramatically on restoration of a pulse. The patient survived.

Patient 2: Bag valve

EMS was called for a 79-year-old diabetic male for complaint of unresponsiveness (Fig. 4). The patient was found lying unresponsive on the ground. Because he was pulseless and apneic, CPR was initiated and the patient was intubated. En route, the patient received 1 mg epinephrine × 3, and 1 mg atropine × 2. There were no changes in the patient's condition during transport. At arrival to the ED, he was declared dead on arrival by the ED staff. The graphic results shown in Figure 4 illustrate how a rhythm appeared for a short time, but end-tidal CO_2 never increased significantly, and the patient died.

Discussion

We found that EMT-Ps perceived that certain aspects of their job (tasks, documentation, and patient care) were easier when ATV was attached to the patient. We also found a trend toward perceived ease of use and time to setup in favor of the BV. This was not surprising, considering that ATV use was a newly learned skill. Both end-tidal CO_2 and oxygen saturation could be monitored during EMS transport.

There is a great deal of literature on the use of end-tidal CO_2 during CPR and mechanical ventilation.[11–18] Most have suggested that a low CO_2 has prognostic value during CPR. Garnett et al[18] say that end-tidal CO_2 with ventilation held

Table 1. Likert scale comparison for EMT-P perceptions of the two airway management devices used in this study. Higher mean scores and higher mean ranks represent more paramedics favorably rating that device (see text for scoring system)

	Automatic transport ventilator (ATV)		Bag valve (BV)		
	Mean score	Mean rank	Mean score	Mean rank	P
Ease of use	−0.8	11.89	−0.4	17.11	0.08
Amount of time to set up ventilation equipment	−0.6	12.36	−0.2	16.64	0.14
Expedition of transport	0.3	15.93	0.0	13.07	0.27
Accomplishing additional tasks	0.6	18.21	−0.3	10.79	0.01*
Ability to document activities clearly and quickly during the transport	0.2	17.36	−0.3	11.64	0.04*
Patient comfort	0.0	16.50	−0.4	12.50	0.20
Ability to provide overall patient care	0.4	16.36	0.0	12.64	0.03*

**Significant at $P < 0.05$.*

Table 2. **Comparison of problems with the ATV and BV ventilatory devices**

	For automatic transport ventilator (ATV) (N = 14)	For bag valve (BV) (N = 14)	*P**
Loss of airway before ED (up to when patient turned over to ED physician)	0 (0%)	0 (0%)	1.00
Evidence of aspiration	3 (21%)	0 (0%)	0.22
Evidence of device failure	2 (14%)	0 (0%)	0.48
Inability to correctly use device	3 (21%)	0 (0%)	0.22
Oxygen ran out	0 (0%)	0 (0%)	1.00
Difficulty performing CPR	2 (14%)	0 (0%)	0.48

Pearson χ^2 ($P < 0.05$ is significant).

Table 3. **Table of physiological data recorded during EMS transport for each of the four variables in the 28 patients entered into the study. Plus (+) indicates acceptable data was recorded; minus (-) indicates unacceptable or no data recorded[a]**

Ventilation group	CPR or assisted ventilation (AV)	Patient No.	ET CO_2	Resp rate	O_2 sat	Heart rate	Minutes recorded
ATV	CPR	1	+	+	−	−	3
		2	−	−	−	−	nd
		9	−	−	−	−	nd
		10	−	−	−	−	nd
		14	+	+	+	+	10
		15	−	−	−	−	nd
		16	+	+	−	−	9
		17	−	−	−	−	nd
		20	+	+	+	+	13
		21	−	−	+	+	8
		26	−	−	−	−	nd
		27	−	−	−	−	nd
	AV	8	+	+	+	+	9
		18	−	−	−	−	nd
BV	CPR	3	−	−	−	−	nd
		4	+	+	−	−	3
		6	+	+	+	+	15
		13	−	−	+	+	8
		22	−	−	−	−	nd
		23	+	+	+	+	7
		24	+	+	+	+	9
		25	−	−	−	−	nd
	AV	5	+	+	+	+	16
		12	+	+	+	+	12
		19	+	+	+	+	1
		28	+	+	+	+	5

[a]nd, no data were collected in these cases.

constant tracked changes in perfusion and that the real-time tracking of events with this device led to rapid and successful pharmacological intervention in the case they describe. The two cases described in this report differed primarily in the end-tidal CO_2 ($ETCO_2$) values, the other three variables were minimally different. The survivor (patient 1) had higher $ETCO_2$ during the entire transport. Then, just before the documentation of spontaneous circulation, there was a rise in the $ETCO_2$ to values greater than 60. On the other hand, the nonsurvivor had very low $ETCO_2$ levels except for an in-

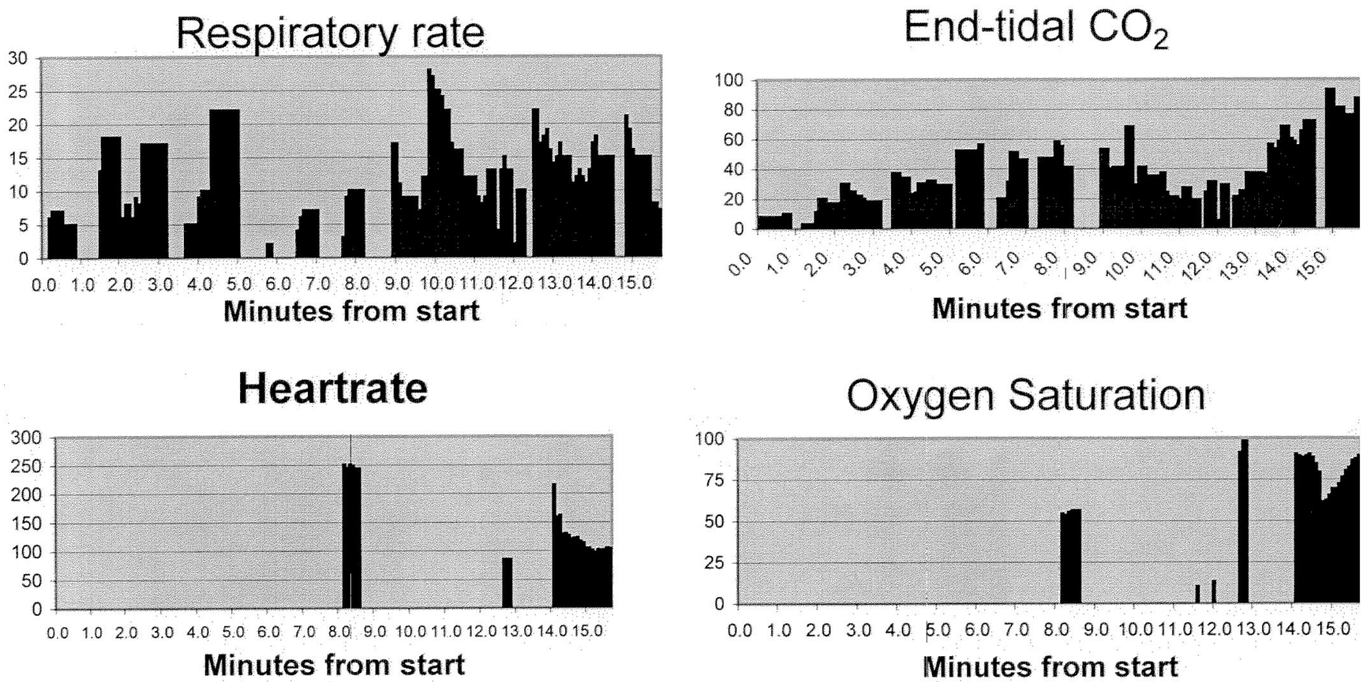

Fig. 3 **Results shown using data collection device with monitor in a case using the automated transport ventilator.**

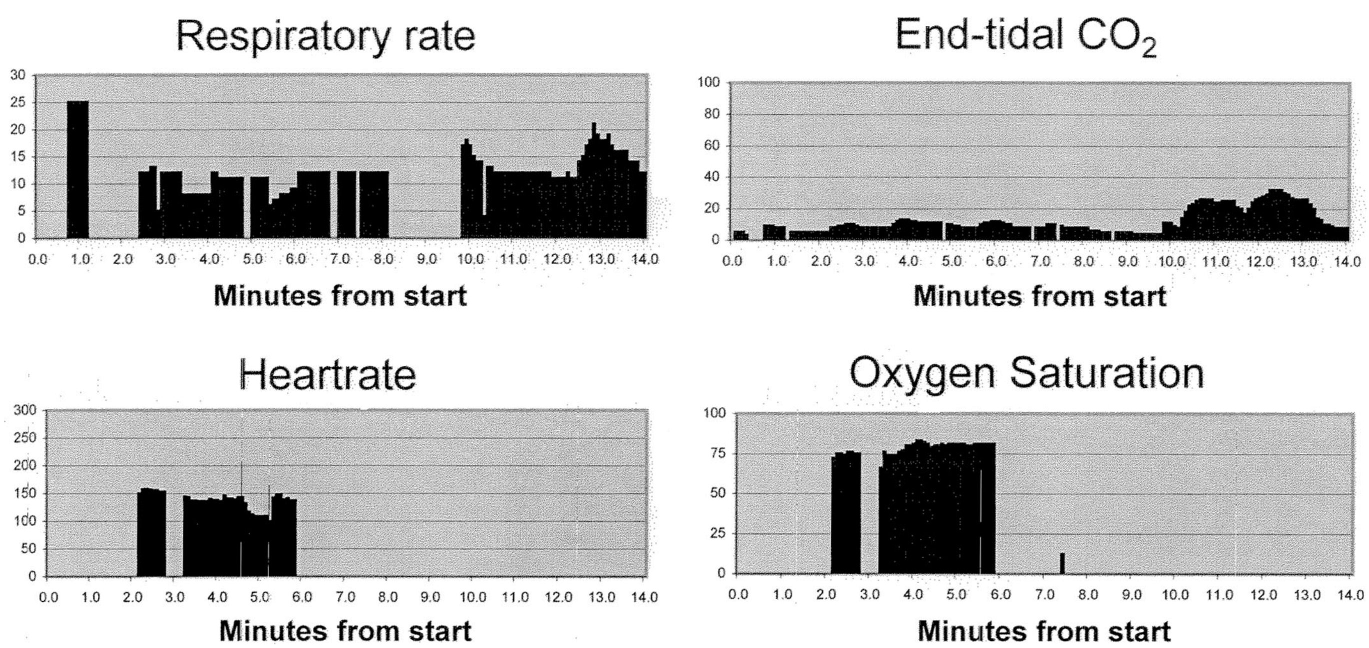

Fig. 4 **Results shown using data collection device with monitor in a case using the bag valve ventilator.**

crease in values to 35 about 1 to 2 minutes before ED arrival. Our results agree with these other studies that the differences in outcome seem to be related to $ETCO_2$; however, the graphs indicate that a single level and a particular time would be oversimplifying the results and could lead to the wrong conclusion. Following $ETCO_2$ over time would lead to more appropriate use of the results.

The difficulties associated with BV ventilation during scene management are important to describe. Any time a patient requires positive-pressure ventilation in the prehospital setting, at least one member of the EMS team must manually operate the BV resuscitator. This loss of a team member to such a crucial, singular duty can add difficulty to the transport. Delays can occur due to the loss of manpower to tasks such as extrication, patient portage over obstacles such as stairs, and even due to the difficulty of moving the gurney into and out of the ambulance. The utilization of resources is suboptimal when a skilled provider is dedicated solely as the ventilator. Clearly, this strain on manpower is most acute for two provider teams, which require one team member to drive while the other shoulders the entire burden of patient care. In this case, management of the resuscitator completely monopolizes the provider's time to the exclusion of intravenous access, secondary survey, management of injuries, and additional patient assessment.

It is unknown how lapses in optimal ventilation affect patient oxygenation. During these instances when manpower is short, patient ventilation is relegated to a secondary concern. Hurst et al[19] examined 28 patients requiring transport in a prospective, randomized fashion, comparing manual ventilation with ventilation provided by a transport ventilator. After manual ventilation, all patients showed a marked respiratory alkalosis, whereas after ventilation with the transport ventilator there were no appreciable changes in pH or $PaCO_2$. Based on these results, the authors suggested the superiority of automated transport ventilators in this setting.

In addition to the extra tasks that could be accomplished and the stabilization of acid-base status, there is an advantage to transport ventilators in stabilizing the ventilatory rate. Dockery et al[8] found that during intrahospital transport, BV ventilation resulted in greater fluctuation of ventilatory parameters from an established baseline than did use of a transport ventilator, which was important for adequate resuscitation.

A critical outcome of this study was to determine whether we could successfully move the laboratory into the prehospital setting and monitor patient data during EMS transport. We were able to successfully monitor patients for up to 18 minutes of transport times, only limited by the length of our longest call. The machines worked well at collecting every 5-second heart rate, respiratory rate, end-tidal CO_2, and oxygen saturation. Using this technology, the number of studies assessing the outcome of prehospital interventions could increase dramatically.

We only found a few problems with the ATV, none of which reached statistical significance. There was an inability to correctly use the device by a number of the paramedics. Four cases in which "device failure" or "inability to use the device" was recorded were actually failure of the data collection device. These were not recorded as outcome problems because they were unrelated to the ventilator use. Many were charging problems because both the monitor and the data collection device required frequent charging cycles and stayed charged for only short periods of time.

A limitation of the study was the complexity of the setup required for data monitoring. The setup included a fairly complex monitoring system that itself took additional time, energy, and knowledge. The system required not only the placement of the monitoring devices, one on the airway and one on the patient's finger, but also required the EMT-P to turn on both the data collector and the monitor and wait for both to warm up and set up correctly. It then required verification that data were being produced and exported by the monitor and that the data were received and recorded on the data collector. Although these steps were necessary for the research collection, in general these multiple complex steps would not be part of the setup and therefore resulted in study bias. We believe that our compliance level was lower because of this difficult set of steps. Newer marketed devices can monitor this information internally and may offer a better solution in the future.

Operators' preexisting bias for or against each device is unavoidable in a study such as this. The study could not be blinded. However, we found that the opinions of the paramedics at the outset of the study were mixed, suggesting no particular bias on their part.

Finally, our ability to generalize these results to other systems is limited by the technology available to that system and the training of the EMS responders.

Conclusion

EMT-Ps were able to accomplish more tasks, document more completely, and provide better patient care with the use of the ATV. The ATV can be used successfully during field resuscitation and transport. The data collector was able to collect physiological data, time-mark it, and store it for subsequent retrieval in a majority of cases. This type of monitoring system is feasible to collect physiological data in the EMS setting.

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> *Think not those faithful who praise all thy words and actions; but those who kindly reprove thy faults.*
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> —Socrates