Evaluation of 16 Adult Disposable Manual Resuscitators

Daniel G Mazzolini Jr RRT and Nancy A Marshall RRT

INTRODUCTION: Disposable manual resuscitators are commonly used to ventilate patients during cardiopulmonary resuscitation, suctioning, and intrahospital transport, and their clinical performance is critical. METHODS: We bench-tested 16 adult disposable manual resuscitators from 9 different manufacturers. We performed a series of tests and made observations using testing industry standards as a guideline. Each resuscitator was tested for fraction of delivered oxygen (F_{DO2}), tidal volume delivery, drop test, and patient valve lock-up. We also made observations about reservoir style, ease or difficulty of attaching the positive end-expiratory pressure valve, size, texture, carbon dioxide detector, and if the resuscitator was labeled "latex free." RESULTS: Reservoir style and manufacturer design significantly affected F_{DO}. In general, the resuscitators with reservoir bags provided better F_{DO_2} than did the resuscitators with tubing reservoirs (large-bore or small-bore). Delivered tidal volumes were acceptable for all the resuscitators tested. All the resuscitators passed a standard drop test. None of the resuscitators had a patient valve lock up at high flow. With all but one resuscitator, attaching the positive end-expiratory pressure valve was easy and the valve attached securely. Most resuscitators were average in size and had good texture, but some were large, somewhat slippery, and difficult to handle. Only 2 resuscitators came with carbon dioxide detectors already attached. All but one of the resuscitators were labeled "latex free," and the one that was not was found not to contain latex proteins. CONCLUSIONS: Resuscitator reservoir style and manufacturer design significantly affect F_{DO}. Some resuscitator models may not deliver adequate oxygen in certain clinical circumstances. Each institution should evaluate and choose the resuscitator that best fits its needs, while meeting established performance criteria. Key words: manual resuscitator, fraction of delivered oxygen, tidal volume, resuscitation. [Respir Care 2004;49(12):1509–1514. © 2004 Daedalus Enterprises]

Introduction

Disposable manual resuscitators are handheld devices used to manually assist a patient's breathing. These devices are commonly used during cardiopulmonary resus-

citation, suctioning, and intrahospital transport of patients who require breathing assistance. Disposable manual resuscitators were first introduced in the United States in 1985.¹ Since then many new resuscitators have been marketed, and a wide variety of styles are now available. Several studies have documented the performance differences of various resuscitators in various clinical settings.1-4 Although disposable manual resuscitators claim to meet industry testing standards, they have different characteristics, and it is important that clinicians understand those differences. Some of the differences can be identified using simplified laboratory testing. Our health system, made up of 8 hospitals, wanted to standardize to a single manufacturer of disposable manual resuscitator. Since we could find no recent comparisons in the published literature, we subjected single samples of 16 disposable manual resuscitators to comparative testing, to aid in our purchasing decision. Table 1 lists the manufacturer names and locations.

Daniel G Mazzolini Jr RRT and Nancy A Marshall RRT are affiliated with the Department of Respiratory Care Services, Advocate Lutheran General Hospital, Park Ridge, Illinois.

The following companies supported this research by providing samples of their products: Allegiance Healthcare, Ambu, Engineered Medical Systems, Hudson RCI, Mercury Medical, Nellcor, Portex, Ventlab, and Vital Signs.

Correspondence: Daniel G Mazzolini Jr RRT, Department of Respiratory Care Services, Advocate Lutheran General Hospital, 1775 Dempster Street, Park Ridge IL 60068-1174. E-mail: dan.mazzolini@ advocatehealth.com.

Table 1. Manufacturers of Disposable Resuscitators

Manufacturer	Location
Allegiance Healthcare Corporation	McGaw Park, Illinois
Ambu Inc	Linthicum, Maryland
Engineered Medical Systems Inc	Indianapolis, Indiana
Hudson RCI	Temecula, California
Mercury Medical	Clearwater, Florida
Nellcor	Pleasanton, California
Portex Inc	Keene, New Hampshire
Ventlab Corporation	Mocksville, North Carolina
Vital Signs Inc	Totowa, New Jersey

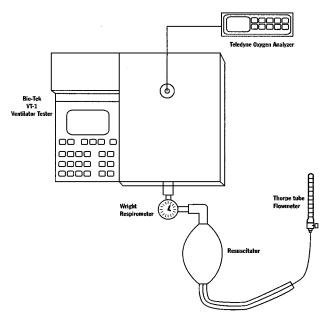


Fig. 1. Test equipment setup.

Methods

To evaluate each resuscitator, we performed a series of tests and made observations using the methods of the American Society for Testing and Materials and the International Organization for Standardization as a guideline.^{5,6} Figure 1 shows our test equipment setup. We used an adult ventilator tester (VT-1, Bio-Tek Instruments, Winooski, Vermont); all the tests were performed with the ventilator tester set at a compliance of 0.02 L/cm H₂O and a resistance of 20 cm H₂O/L/s. Each resuscitator was tested once for fraction of delivered oxygen (F_{DO_2}), tidal volume (V_T) delivery, drop test, and patient valve lock-up. We also made observations about reservoir style, positive end-expiratory pressure (PEEP) valve attachment, size, texture, carbon dioxide detection, and if the resuscitator was labeled "latex free."

Fraction of Delivered Oxygen

We tested the F_{DO2} of each resuscitator under 4 simulated clinical conditions: breathing rate of 12 breaths/min using 1 hand, breathing rate of 20 breaths/min using 1 hand, breathing rate of 12 breaths/min using 2 hands, and breathing rate of 20 breaths/min using 2 hands. An oxygen analyzer (TED200, Teledyne Analytical Instruments, City of Industry, California) was attached to the ventilator tester. Each resuscitator was connected to a Timeter-compensated Thorpe-tube flow meter (Allied Healthcare Products, St Louis, Missouri) and the flow rate was set to 15 L/min. The accuracy of the flow meter was verified using a calibration analyzer (Timeter RT-200, Allied Healthcare Products, St Louis, Missouri). Each resuscitator was then connected to the ventilator tester and the test lung was ventilated for 3–5 min to allow the F_{DO_2} to stabilize. The F_{DO_2} , once stable, was recorded. We performed a 2-point calibration of the oxygen analyzer between each trial. We used the ventilator tester display to verify that consistent breath rate and V_T were delivered during each simulated clinical condition. The same individual performed all the F_{DO_2} tests to minimize the variability in delivered $\boldsymbol{V}_{\mathrm{T}}$ that could be created by different hand sizes.

Tidal Volume Delivery

Each resuscitator was tested for average V_T delivery using 1 hand and 2 hands. A respirometer (Wright Mark 14, Ferraris Medical Limited, Hertford, England) was connected to the ventilator tester to allow breath-by-breath V_T measurement. Each resuscitator was connected to the ventilator tester, and the test lung was ventilated for 3–5 min, during which the average V_T was recorded.

Drop Test

Each resuscitator was dropped 5 times from a height of 4 feet onto a concrete floor. That height was chosen because it is the average height at which our resuscitators are stored at the bedside. The unit was dropped so that it landed on the patient valve assembly, which is the critical component of each resuscitator. The resuscitator was thoroughly visually inspected for damage and connected to the ventilator tester to test whether it operated properly after being dropped. Any visually apparent damage and/or deficit in performance were recorded.

Patient Valve Lock-Up

Each resuscitator was tested to determine whether its patient valve would lock up at high flow. The resuscitator was connected to a Thorpe-tube flow meter and the flow was set to "flush" (\geq 35 L/min). The flow rate was veri-



Fig. 2. Left: Bag style reservoir. Center: Large-bore tubing reservoir. Right: Small-bore tubing reservoir.

fied with the Timeter RT-200 calibration analyzer. The resuscitator was then connected to the ventilator tester and ventilated in a standard fashion to see whether the patient valve would lock up and thus cause the resuscitator to stop functioning. We recorded any change in resuscitator function during high flow.

Reservoir Style

The oxygen reservoirs attached to disposable manual resuscitators are available in 3 different configurations (Fig. 2). There is a bag style reservoir, large-bore tubing reservoir, and small-bore tubing reservoir. The tubing length differs among the tubing style reservoirs. We recorded the reservoir style of each resuscitator and measured the length of each small-bore-tubing style reservoir.

PEEP Valve Attachment

All resuscitators should allow the attachment of a PEEP valve. We attached standard disposable PEEP valves (Ambu, Linthicum, Maryland, or Vital Signs, Totowa, New Jersey) to each resuscitator and recorded the ease or difficulty with which the valves were attached, how securely

they connected, and whether an adaptor was needed to attach the PEEP valve.

Size and Texture

After handling each resuscitator under simulated clinical conditions, we subjectively graded the size of the resuscitator as large, average, or small, and the texture as good, fair, or poor, with and without gloved hands.

Carbon Dioxide Detection

For each resuscitator we recorded whether a carbon dioxide detection device was already attached to the unit.

Labeled "Latex Free"

For each resuscitator we recorded whether the product or its packaging were labeled "latex free."

Results

Table 2 shows the results of all our tests and observations. Manufacturer design and reservoir style significantly affected F_{DO_2} . The Ventlab BT5000 with reservoir bag

Manufacturer and Model	Reservoir Style	F _{DO2} (%) at 12 breaths/min 1 hand	F _{DO2} (%) at 20 breaths/min 1 hand	F _{DO2} (%) at 12 breaths/min 2 hands	F _{DO2} (%) at 20 breaths/min 2 hands	V _T (L) 1 hand	$V_{T}(L)$ 2 hands	Drop Test	Valve Lock- up?	PEEP Valve Attachment	Size	Texture	CO ₂ Detector Attached?	Latex Free?
Allegiance AirLife	small-bore tubing (101 cm)	86	86	78	78	0.60-0.65	0.70-0.75	Pass	No	Attaches easily	Average	Fair	No	Yes
Allegiance AirLife	reservoir bag	76	94	96	92	0.60-0.65	0.70-0.75	Pass	No	Attaches easily	Average	Fair	No	Yes
Ambu MediBag	reservoir bag	76	96	96	06	0.65-0.70	0.75-0.80	Pass	No	Attaches easily	Average	Fair	No	Yes
Ambu SPUR	small-bore tubing (101 cm)	96	86	84	80	0.65-0.70	0.75–0.80	Pass	No		Average	Fair	No	Yes
Engineered Medical Systems VentiSure	reservoir bag	88	88	82	82	0.55-0.60	0.70-0.75	Pass	No	Attaches easily	Large	Fair	Yes	Yes
Hudson RCI LifeSaver	reservoir bag	100	98	98	98	0.60-0.65	0.75-0.80	Pass	No	Attaches easily	Average	Good	No	Yes
Mercury Medical CPR Bag	large-bore tubing	91	88	06	88	0.60-0.65	0.75-0.80	Pass	No	Attaches easily	Average	Good	No	No*
Mercury Medical CPR Bag	reservoir bag	66	66	66	66	0.60-0.65	0.75-0.80	Pass	No	Attaches easily	Average	Good	No	No*
Nellcor INdGO	large-bore tubing	98	98	96	96	0.60-0.65	0.70-0.75	Pass	No	Attaches easily	Large	Fair	Yes	Yes
Portex 1st Response large-bore tubing	large-bore tubing	66	98	98	96	0.60-0.65	0.70-0.75	Pass	No	Attaches easily	Average	Good	No	Yes
Portex 1st Response	small-bore tubing (101 cm)	88	88	82	78	0.60-0.65	0.70-0.75	Pass	No	Attaches easily	Average	Good	No	Yes
Portex 1st Response	reservoir bag	78	74	72	78	0.60-0.65	0.70-0.75	Pass	No	Attaches easilv	Average	Good	No	Yes
Ventlab BT5000	small-bore tubing (188 cm)	100	98	96	96	0.65-0.70	0.80-0.85	Pass	No	SI	Large	Fair	No	Yes
Ventlab BT5000	reservoir bag	100	100	100	100	0.65-0.70	0.80-0.85	Pass	No	Needs adaptors	Large	Fair	No	Yes
Vital Signs Code Blue II	small-bore tubing (188 cm)	98	76	98	96	0.55-0.60	0.70-0.75	Pass	No	Attaches easily	Average	Good	No	Yes
Vital Signs Code Blue II	reservoir bag	98	98	98	98	0.55-0.60	0.70-0.75	Pass	No	Attaches easily	Average	Good	No	Yes
$\overline{F}_{DO_2} =$ fraction of delivered oxygen V _T = tidal volume PEEP = positive end-expiratory pressure *Product is labeled as containing dry natural rubber but has been independently tested and does not contain latex proteins	ed oxygen ratory pressure aining dry natural rubber	but has been independ	ently tested and does n	ot contain latex protei	su									

EVALUATION OF 16 ADULT DISPOSABLE MANUAL RESUSCITATORS

Test Results

Table 2.

outperformed all other resuscitators, maintaining an F_{DO2} of 100% under all tested conditions. In contrast, the Portex 1st Response with reservoir bag provided the lowest F_{DO_2} under all tested conditions. All the resuscitators provided acceptable delivered V_{T} . All the resuscitators passed our drop test. No resuscitator demonstrated a patient valve lock-up, despite being tested at very high flow rates. The Ventlab BT5000 was the only resuscitator that required additional adaptors for PEEP-valve attachment. Most resuscitators tested were of average size, but the Nellcor INdGO, Engineered Medical Systems VentiSure, and Ventlab BT5000 were slightly larger and a little more difficult to handle. Half of the resuscitators had good texture while the other half had fair texture and were somewhat slippery. The Nellcor INdGO and Engineered Medical Systems VentiSure were the only resuscitators that offered carbon dioxide detectors already attached. All resuscitators were labeled "latex free" or "free of latex proteins."

Discussion

 F_{DO_2} is arguably the most important aspect of a disposable manual resuscitator. We found that F_{DO_2} was significantly affected by reservoir style and manufacturer design. In general, bag style reservoirs provided better F_{DO_2} than either large-bore or small-bore tubing reservoirs. The American Society for Testing and Materials and the International Organization for Standardization specifications call for an $F_{DO_2} \geq$ 85% when a reservoir is in place, delivered V_T is 0.600 L, and oxygen flow is set at 15 L/min. Eleven of the 16 resuscitators tested met those specifications under all tested conditions. Three resuscitators that did not meet the specifications had small-bore tubing reservoirs of only 101 cm in length. The smaller overall volume of those reservoirs could account for their lower FDO2. Two resuscitators, Portex and Engineered Medical Systems, had reservoir bags that were observed to kink during use, which resulted in slow and only partial inflation of the reservoirs, which would account for their lower F_{DO₂}. Previous studies also found that resuscitator design, reservoir style, and oxygen flow rate affect the F_{DO2} of manual resuscitators.^{7–9} Our results confirm those findings.

All the resuscitators we tested delivered adequate V_T of approximately 0.6 L when squeezed with 1 hand. The Ventlab and Ambu resuscitators delivered slightly larger V_T (0.65–0.70 L) with a 1-handed squeeze. The Ambu resuscitator had a slow refill after being squeezed and did not fully refill at higher breathing rates. The Ventlab resuscitator delivered slightly larger V_T (0.80–0.85 L) with a 2-handed squeeze, which might be because of its larger size and more compliant material.

All the resuscitators passed our drop test. There was no visually apparent damage or post-drop change in perfor-

mance with any of the resuscitators we tested. Standard oxygen flow meters set to "flush" (≥ 15 L/min) can deliver ≥ 35 L/min. Incidents have been reported in which the patient valve locked up at high oxygen flow.¹⁰ Resuscitators should function properly at high flow. It is theoretically possible that a practitioner could accidentally set a flow meter to the "flush" setting during clinical use, which could cause the patient valve to lock up and thus make the resuscitator nonfunctional. None of the resuscitators we tested had a patient valve lock up, even with flows ≥ 35 L/min.

We found that the PEEP valves were easily attached to all but one of the tested resuscitators. The Ventlab resuscitator needed additional adaptors to attach the PEEP valve. Most of the resuscitators were subjectively graded as average in size and fairly easy to handle with 1 hand. Three resuscitators were subjectively graded as large and a little more difficult to handle, especially with 1 hand. Half of the resuscitators were subjectively graded as having good texture, whereas the other half were graded fair and were somewhat slippery when handled. Carbon dioxide detection following intubation to confirm endotracheal tube placement has become extremely popular. Only 2 resuscitators (Nellcor and Engineered Medical Systems) offered carbon dioxide detectors already attached to their resuscitators. We did not evaluate the quality or accuracy of the carbon dioxide detection devices. All but one of the resuscitators were clearly labeled "latex free"; the Mercury Medical resuscitator is labeled as containing dry natural rubber, but it has been independently tested and does not contain latex proteins.

We have identified a couple of important limitations of our study. First, we tested only one resuscitator of each type. A larger sample size would have allowed for a statistical comparison of each resuscitator type and more valid scientific results. However, although we tested only one of each type, we believe clinically relevant results can still be elucidated from our study. Second, we made every effort to include all manufacturers who offer disposable manual resuscitators in our service area, but we may have missed some. Our results should be interpreted with those limitations in mind.

Conclusions

The clinical performance of disposable manual resuscitators is critical, especially during resuscitation. The American Association for Respiratory Care's clinical practice guideline for resuscitation in acute care hospitals states that, "manual resuscitators must be capable of providing an F_{DO_2} of 1.0 even when large volumes are delivered."¹¹ Our findings suggest that F_{DO_2} is significantly affected by reservoir style and resuscitator design. Some reservoir styles and resuscitator designs may not deliver adequate oxygen under certain clinical circumstances. Disposable manual resuscitators look, feel, and perform differently. Each institution should evaluate and choose the resuscitator that best fits its needs, while meeting established performance criteria.

REFERENCES

- 1. Barnes TA, McGarry WP 3rd. Evaluation of ten disposable manual resuscitators. Respir Care 1990;35(10):960–968.
- Hess D, Spahr C. An evaluation of volumes delivered by selected adult disposable resuscitators: the effects of hand size, number of hands used, and use of disposable medical gloves. Respir Care 1990; 35(8):800–805.
- 3. Barnes TA, Stockwell DL. Evaluation of ten manual resuscitators across an operational temperature range of -18 degrees C to 50 degrees C. Respir Care 1991;36(3):161–172.
- Hess D, Goff G, Johnson K. The effect of hand size, resuscitator brand, and use of two hands on volumes delivered during adult bag-valve ventilation. Respir Care 1989;34(9):805–810.

- American Society for Testing and Materials. Standard specification for performance and safety requirements for resuscitators intended for use with humans F-920–85. Philadelphia: Am Soc Testing & Materials; 1993.
- International Organization for Standardization. International Standard ISO 8382: 1988(E). Resuscitators intended for use with humans. New York: American National Standards Institute, 1988. Available at http://www.iso.org. Accessed September 21, 2004.
- Barnes TA, Potash R. Evaluation of five adult disposable operatorpowered resuscitators. Respir Care 1989;34(4):254–261.
- Barnes TA, Watson ME. Oxygen delivery performance of four adult resuscitation bags. Respir Care 1982;27(2):139–146.
- Fitzmaurice MW, Barnes TA. Oxygen delivery performance of three adult resuscitation bags. Respir Care 1980;25(8):928–933.
- Emergency Care Research Institute. Pulmonary resuscitators: preventing cross contamination. Tech Respir Ther 1990;10(10):1–6.
- American Association for Respiratory Care. AARC Clinical Practice Guideline. Resuscitation and defibrillation in the health care setting—2004 Revision & Update. Respir Care 2004;49(9):1085–1099.



Sylvester's method of artificial respiration: expiration. From: A Complete Handbook for the Hospital Corps of the US Army and Navy and State Military Forces. Charles Field Mason, Major and Surgeon, US Army. New York, W. Wood and Company, 1906 Courtesy Health Sciences Libraries, University of Washington