Comparison of an Oxygen-Powered Flow-Limited Resuscitator to Manual Ventilation With an Adult 1,000-mL Self-Inflating Bag

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BACKGROUND: Positive-pressure ventilation of patients with unprotected airways during cardiopulmonary resuscitation can cause gastric dilation. OBJECTIVE: Determine if there is a significant difference in volume delivered to lungs and stomach while using an adult 1,000-mL disposable bag-valve-mask (BVM) device and the oxygen-powered, flow-limited Oxylator EMX resuscitator. METHODS: We used a bench model to simulate a patient with an unprotected airway, consisting of an intubation manikin, lung analog, and simulated lower esophageal sphincter set at an opening pressure of 20 cm H_2O. The BVM and the Oxylator were used to provide mask ventilation at a verbally prompted rate of 12 breaths/min. RESULTS: The volumes delivered with the BVM and the Oxylator to the lungs and stomach were not significantly different: 262 ± 112 mL versus 297 ± 99 mL and 227 ± 199 mL versus 159 ± 73 mL, respectively. CONCLUSION: Our study found no significant difference between the Oxylator and BVM when comparing tidal volume delivered to lungs and stomach during ventilation of a simulated unconscious nonintubated patient. More research on BVM use and the Oxylator should be done to validate the American Heart Association's guideline recommendations for ventilating unconscious patients with unprotected airways. Research on gastric dilation during cardiopulmonary resuscitation needs to be done with bench models using manikins that simulate chest excursion, bidirectional airway flow, lung impedance, and gastric compliance. *Key words: cardiopulmonary resuscitation, respirator, gastric dilation, devices, disposable equipment.* [Respir Care 2005;50(11):1445–1450.

Introduction

Gastric inflation is a complex problem that is frequently associated with positive-pressure ventilation of nonintubated patients.[1] Gastric inflation can precipitate other serious complications such as regurgitation,[2] aspiration,[3] and pneumonia.[4] The mechanism by which gastric inflation occurs depends on the compliance of the respiratory system and the lower-esophageal-sphincter opening pressure (LESOP).[1,5–8] Decreased respiratory system compliance can result in a dangerous cycle of decreasing lung ventilation[9] and increasing gastric inflation as gas is diverted to the stomach.[10] Following a cardiac arrest, LESOP has been shown in a porcine model to decrease over 7 min, from a mean baseline of 18.0 ± 3.0 cm H_2O to 3.3 ± 4.2 cm

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H_2O, thereby facilitating gas entry to the stomach.[11] The rapid drop in LESOP following cardiac arrest observed in animal models is very likely to occur in humans.[10] To reduce gastric inflation, it is important to follow the American Heart Association guidelines[12] for smaller tidal volumes (V_T) and to use the most appropriate equipment.[13]

New resuscitators need to be tested to evaluate their efficacy in providing adequate V_T to the lungs with a minimum of gastric inflation. The most popular type of manual resuscitator is the disposable self-inflating bag-valve-mask (BVM), because of its size and cost. A newly developed oxygen-powered flow-limited resuscitator, the Oxylator EMX, has shown potential to reduce gastric inflation.[5,6] Less gastric inflation was reported when a pediatric BVM (750 mL)[10,13] or a small adult BVM (1,100 mL)[14] was used to ventilate a bench model of a patient with a nonintubated airway.

Our hypothesis was that there would be no significant difference in volume delivered to the lungs and stomach when the Oxylator and BVM were evaluated on a previously described bench model[15] of a simulated nonintubated patient.

Methods

Institutional review board approval was obtained to enroll 10 respiratory therapy and nursing students who had current American Heart Association Basic Life Support Healthcare Provider certification. Following a 30-min in-service on the Oxylator (CPR Medical Devices, Markham, Ontario, Canada) and an adult 1,000-mL BVM, the 10 students were randomly scheduled to ventilate a simulated patient with an unprotected airway using the Oxylator or BVM for five 2-min trials, following the current American Heart Association guideline of 400–600 mL/breath.[12] A stopwatch was used during each trial to verbally prompt the subject to deliver a V_T every 5 seconds (12 breaths/min). A cross-over phase of the study tested the Oxylator or BVM not randomly assigned for the first set of trials. The Oxylator was used in manual mode, with pressure-release set at 25 cm H_2O. The Oxylator was factory-preset to provide a constant inspiratory flow of 30 L/min. The 1,000-mL adult BVM (cardiopulmonary resuscitation bag, Mercury Medical, Clearwater, Florida) had no pressure-release valve, and the volume delivered and speed of delivery was controlled by each subject. Inspiratory time with the Oxylator was controlled manually unless high inspiratory pressure ($>$ 25 cm H_2O) cycled the resuscitator to the expiratory phase. Instruction was given on proper hand placement to ensure a tight mask-seal around the face of the manikin (Airway Management Trainer, Laerdal Medical, Wappingers Falls, New York), and 2-rescuer ventilation was used. The head of the intubation manikin required both an adequate mask seal and jaw position to ventilate. A respiratory mechanics monitor (Ventcheck, Novametrix Medical Systems, Wallingford, Connecticut) (accuracy $\pm$ 3%) was placed between the Oxylator or BVM and mask to record V_T and flow delivered to the mask. The tracheal outlet of the airway management trainer was connected to the lung analog (VT-1, Bio-Tek Instruments, Winooski, Vermont) (accuracy $\pm$ 3%), with compliance set at 50 mL/cm H_2O, and airway resistance at 8 cm H_2O/L/s. The esophageal outlet of the airway trainer was connected with a 20-cm section of surgical drain (19-mm inner-diameter Penrose, Davol, Cranston, Rhode Island) to a water-column positive end-expiratory pressure (PEEP) valve (Emerson Company, Cambridge, Massachusetts). The PEEP valve was adjusted to 20 cm H_2O to simulate normal LESOP. A respirometer (Wright Panel-Mount Respirometer, Ferraris Medical, Louisville, Colorado) (accuracy $\pm$ 5–10%) was placed at the distal end of the PEEP valve to record the volume of air delivered to the stomach during each breath.

The Oxylator was connected to a 50-psig source of air, and 15 L/min of air was delivered to the oxygen reservoir of the BVM. The volumes delivered by the Oxylator or BVM to the mask, lungs, and stomach were recorded simultaneously for each ventilatory cycle. Mask leak was estimated by subtracting the total volume to lungs and stomach from the V_T delivered to the mask. The peak inspiratory flow (PIF) was measured during BVM ventilation with 7 subjects. The Oxylator's inspiratory flow is factory-preset at 30 L/min, and that flow was confirmed with 3 subjects. Peak inspiratory pressure was not measured in this study. A Mann-Whitney test was performed to compare the mean volumes delivered to the lungs, stomach, and mask, and the mask leak. A Spearman rank correlation test was performed to compare PIF to gastric inflation. Both tests were conducted with commercially available statistics software (InStat version 3.00 for Windows XP, GraphPad Software, San Diego California). Alpha was set at 0.05 for statistical significance.

Results

The V_T delivered to the lungs and stomach by the BVM and the Oxylator (Table 1), and the V_T delivered to the mask and mask leak with the BVM and the Oxylator (Table 2) were not significantly different (Fig. 1). PIF with the BVM measured on 7 subjects (3–9) was 52.0 $\pm$ 20.0 L/min and ranged from 28.7 L/min to 82.1 L/min (Fig. 2). The factory-preset inspiratory flow (30 L/min) from the Oxylator measured with 3 subjects (7–9) was 29.8 $\pm$ 0.3 L/min and ranged from 29.5 L/min to 30.1 L/min. The highest mean gastric inflation was 564 $\pm$ 49 mL, generated by subject 9, with a BVM, with mean PIF of 82.1 $\pm$ 11.5 L/min. A low mean gastric inflation of 42 $\pm$ 18 mL was generated by subject 7, with a BVM, with a mean inspira-

Table 1. Tidal Volumes Delivered to Lungs and Stomach*

Subject	Tidal Volume to Lungs (mL)				Tidal Volume to Stomach (mL)			
	Bag-Valve-Mask†		Oxylator EMX		Bag-Valve-Mask†		Oxylator EMX	
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
1	272 ± 48	130–300	301 ± 28	170–420	15 ± 25	0–240	172 ± 15	0–340
2	205 ± 12	150–300	430 ± 63	220–570	494 ± 26	200–540	221 ± 163	0–620
3	159 ± 24	90–290	350 ± 89	100–460	229 ± 85	0–500	110 ± 112	0–400
4	383 ± 23	250–490	290 ± 12	110–420	71 ± 38	0–460	79 ± 50	0–220
5	112 ± 19	50–890	268 ± 27	160–460	322 ± 46	100–460	135 ± 20	0–280
6	238 ± 29	120–360	308 ± 51	40–570	338 ± 55	0–580	103 ± 44	0–360
7	423 ± 20	210–520	340 ± 27	210–460	42 ± 18	0–360	283 ± 64	0–700
8	187 ± 65	70–330	52 ± 3	40–160	186 ± 204	0–600	68 ± 37	0–460
9	216 ± 28	130–300	360 ± 37	290–500	564 ± 49	180–680	247 ± 103	0–520
10	428 ± 21	50–500	267 ± 57	120–370	12 ± 7	0–200	170 ± 78	0–300
Overall	262 ± 112	50–890	297 ± 99	40–570	227 ± 199	0–680	159 ± 73	0–700

*The values were generated during five 2-min trials at a verbally prompted rate of 12 breaths/min. The range values are minimum and maximum for all the data points collected during the five 2-min trials. The overall values are for the entire group of 10 subjects.
†Adult, 1,000-mL bag-valve-mask

Table 2. Tidal Volume Delivered to Mask and Mask Leak*

Subject	Tidal Volume to Mask (mL)				Tidal Volume to Mask Leak (mL)			
	Bag-Valve-Mask†		Oxylator EMX		Bag-Valve-Mask†		Oxylator EMX	
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
1	421 ± 48	151–579	493 ± 46	270–721	109 ± 50	0–330	39 ± 15	0–294
2	663 ± 11	572–745	745 ± 148	315–1185	6 ± 5	0–206	112 ± 54	0–301
3	693 ± 70	85–833	678 ± 19	497–840	311 ± 38	0–669	220 ± 174	0–656
4	707 ± 43	579–872	487 ± 47	306–718	255 ± 32	0–489	123 ± 80	0–425
5	527 ± 27	458–631	430 ± 37	271–611	94 ± 23	0–274	37 ± 27	0–242
6	599 ± 25	185–700	465 ± 79	129–742	46 ± 28	0–399	65 ± 30	0–361
7	785 ± 10	461–931	688 ± 68	338–1083	313 ± 19	0–609	85 ± 18	0–446
8	664 ± 47	565–798	304 ± 36	166–703	299 ± 111	0–569	179 ± 49	0–508
9	804 ± 60	621–893	674 ± 56	543–982	31 ± 20	0–454	82 ± 113	0–462
10	580 ± 30	346–679	464 ± 94	177–640	140 ± 24	0–501	36 ± 34	0–235
Overall	644 ± 116	85–931	543 ± 144	129–1185	160 ± 123	0–669	98 ± 62	0–656

*These values were generated during five 2-min trials at a verbally prompted rate of 12 breaths/min. The range values are minimum and maximum for all the data points collected during the five 2-min trials. The overall values are for the entire group of 10 subjects.
†Adult, 1,000-mL bag-valve-mask

tory flow of 28.7 ± 1.5 L/min. There was a significant correlation ($r = 0.97$) between mean PIF and mean gastric inflation for subjects 3–9 with the BVM (see Fig. 2). The mean gastric inflation for all 10 subjects with the BVM and the Oxylator ranged from 12 ± 7 mL to 564 ± 49 mL and 68 ± 37 mL to 283 ± 64 mL, respectively.

Discussion

When ventilating an unprotected airway, it was difficult to prevent gastric inflation, regardless of whether a BVM or Oxylator was used. Applying cricoid pressure during ventilation of nonintubated unconscious patients is difficult to perform without sufficient personnel available.[16] In our study, the BVM and the Oxylator delivered a clinically important proportion of the V_T into the stomach: 35% and 29%, respectively. A review of individual performance in our study (see Tables 1 and 2) shows varying degrees of success at reaching the American-Heart-Association-recommended V_T of 400–600 mL. Only 2 subjects (7 and 10) delivered a V_T-to-lungs > 400 mL with BVM. The subgroup comprising subjects 1, 7, and 10, when using BVM,

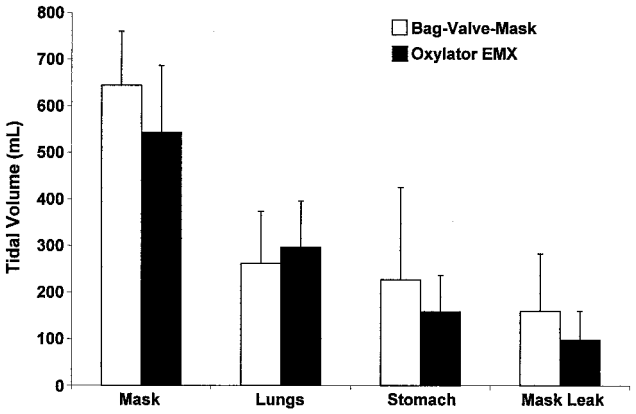

Fig. 1. Differences in mean ± SD tidal volume delivered to mask, lung, stomach, and lost to mask leak with the Oxylator EMX resuscitator and an adult 1,000-mL bag-valve-mask. Lower-esophageal-sphincter-opening pressure was set at 20 cm H_2O, pulmonary compliance was set at 50 mL/cm H_2O, and airway resistance was set at 8 cm H_2O/L/s. The ventilation rate was verbally prompted at 12 breaths/min. There were no significant differences for any of the Oxylator and bag-valve-mask comparisons.

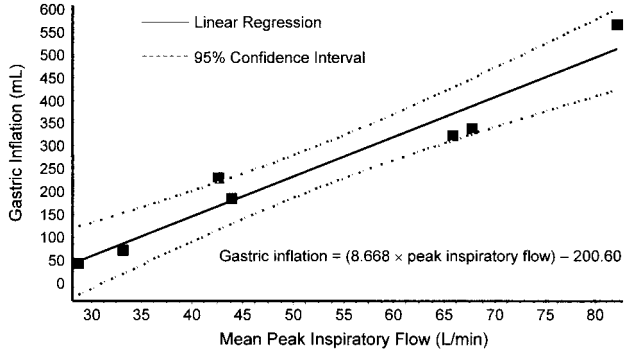

Fig. 2. Linear regression line of gastric inflation versus mean peak inspiratory flow for test subjects 3–9 when using an adult 1,000-mL bag-valve-mask. The ventilation rate was verbally prompted at 12 breaths/min. The equation for the regression line is gastric inflation = (8.668 × peak inspiratory flow) –200.60. The flow and gastric inflation data points have a Spearman rank correlation of $r = 0.9696$ and $r^2 = 0.9401$.

had a small gastric inflation (< 42 mL), compared to the group mean (227 mL) but did not demonstrate comparable skill with the Oxylator. Only one subject using the Oxylator was able to deliver a mean V_T to lungs > 400 mL, and mean gastric inflation was 221 mL. Further subgroup analyses of the volumes delivered to the lungs and stomach indicated that limited training with both devices may have affected individual performance. Subject fatigue and inability to evaluate adequate chest rise while performing BVM or Oxylator ventilation may have affected performance.

The retail price comparison of the Oxylator versus BVM is 39:1 ($835 and $21, respectively). Disregarding the cost involved with disinfecting the device between patients, the Oxylator would have to be used with 39 patients to recover the initial investment, compared to using disposable BVMs.

Stallinger et al, using a gastric-inflation model with LESOP of 5 cm H_2O, found that an adult BVM and the Oxylator delivered 21% and 15%, respectively, of the V_T into the stomach.[5] The difference in gastric inflation reported may have been a result of a large (40%) mask leak observed by Stallinger et al, versus the smaller (18–25%) mask leak observed in our study, which used 2-rescuer ventilation. The smaller 1,000-mL BVM used in our study, instead of the larger 1,500–1,600-mL BVM used by Stallinger et al,[5] may also have impacted the results, because less bag volume was available to compensate for mask leaks. In our study the Oxylator delivered a higher proportion of V_T to the stomach than was reported by 2 independent studies, by Stallinger et al[5] and Osterwalder and Schuhwerk.[6] Differences in volume delivered to lungs and stomach may have been the result of 2-rescuer ventilation decreasing mask leak, with a resultant increase in peak airway pressure. Mask leak has been reported to start when airway pressure reaches 15 cm H_2O.[17]

Osterwalder and Schuhwerk, using a different bench model than ours, reported less abdominal inflation with the Oxylator EM-100 than with the Ambu Mark 3 resuscitator.[6] We attribute lower gastric inflation in the Osterwalder-and-Schuhwerk study to the relatively high 30-cm H_2O LESOP they used, compared to the 20-cm H_2O LESOP in our study. Osterwalder and Schuhwerk found that the Oxylator EM-100 delivered a mean V_T of 1,196 mL, as compared to 543 mL observed in our study. We hypothesize that the large V_T reported by Osterwalder and Schuhwerk resulted from a higher maximum flow with the Oxylator EM-100 (36–40 L/min) than from the Oxylator EMX (30 L/min) and longer inspiratory time when subjects waited for full chest excursion to reach a V_T target of > 800 mL. Gastric inflation will progressively increase as LESOP drops from 20 cm H_2O to 5 cm H_2O.[1,5,8,10]

Wenzel et al studied gastric inflation using a bench model similar to ours to compare large and small V_T delivered with pediatric and adult BVMs.[10] The gastric inflation observed by Wenzel et al at LESOP of 15 cm H_2O with a pediatric 750-mL BVM was similar to that in our study with LESOP of 20 cm H_2O with an adult 1,000-mL BVM. The Wenzel et al study and our work show a mean V_T to lungs with BVM of 242 ± 73 mL and 262 ± 112 mL, respectively, and mean V_T delivered to the mask of 498 ± 121 mL and 644 ± 116 mL, respectively. Gastric inflation was significantly less in the Wenzel et al study, which used a pediatric 750-mL BVM, than with the adult 1,000-mL BVM in our study: 70 ± 96 mL versus 227 ± 199 mL, respectively. The lower gastric inflation seen by Wenzel et al with a pediatric BVM is related to a large mask leak (40% of V_T), compared to the smaller mask leak in our study (25% of V_T). Two-rescuer ventilation in our

study allowed the mask to be held tightly to the face, with 2 hands, versus 1 hand. Based on mask-leak and gastric-inflation data seen in our study, compared to other similar studies,[1,5,6,8] the issue of 1-rescuer versus 2-rescuer BVM ventilation should be revisited by resuscitation councils that issue cardiopulmonary resuscitation guidelines.

Johannigman et al used a bench model similar to ours for comparing techniques of emergency ventilation and for evaluating V_T delivered to the lungs, gastric inflation, and peak airway pressure.[8] They concluded that, when ventilating a nonintubated patient in a prehospital setting, using a ventilator to control V_T, respiratory frequency, inspiratory flow, pressure limit, and inspiratory time held promise for reducing gastric inflation.[8]

Our study found no clinically important difference between the Oxylator and an adult 1,000-mL BVM when comparing V_T delivered to lungs and stomach with a simulated nonintubated unconscious patient. However, our research establishes a foundation for future study based on observed differences in inter-participant and intra-participant capability to use the BVM and the Oxylator without causing gastric inflation. Consequently, future research with BVMs and the Oxylator should be conducted with a dynamic decrease of LESOP, to mimic cardiac arrest. The PEEP valve should be adjusted to levels of 20, 15, 10, and 5 cm H_2O during each 2-min trial, to simulate the decrease of LESOP during cardiac arrest. Significant increases in volume delivered to the stomach are expected during prolonged cardiac arrest in patients with unprotected airways.

The best indicator of delivery of the American-Heart-Association-recommended small V_T with oxygen during cardiac arrest has been reported to be adequate chest excursion.[18] A V_T of approximately 400 mL has been observed to make the chest begin to rise.[18] In order for each subject to deliver adequate V_T that is not too large or small, a full chest-torso manikin should be used in future studies. Finally, in addition to PIF, the peak airway pressure of each breath should be measured in future studies of gastric inflation. Gastric inflation would be expected to rise proportionally, with the increase of peak airway pressure and peak flow.

Limitations

Our gastric-inflation study and others[1,5,8] were limited by the bench model used, because subjects were unable to observe chest excursion during V_T delivery. Gastric inflation is very likely to occur with high inspiratory flow during BVM ventilation of nonintubated patients, because of high peak airway pressure that exceeds LESOP.[1,5,6,14] The risk of gastric inflation, regurgitation, aspiration, and severe lung damage is increased if the BVM is cycled rapidly with short inspiratory time and high PIF.[5] Our study was limited by having inspiratory flow data from only 7 of the 10 subjects and no data on peak airway pressure. Although our study simulated a nonintubated unconscious patient with a widely accepted bench model,[5,6,8,14] we were unable to duplicate dynamic physiologic changes in compliance and LESOP that occur in animal models and patients. Lung compliance decreases rapidly, from 0.1 L/cm H_2O to 0.02 L/cm H_2O, in patients in cardiac arrest.[9] Porcine models have demonstrated that LESOP also rapidly decreases, from 18 cm H_2O to 3 cm H_2O, after cardiac arrest.[10,11] The PEEP valve used for simulating the lower esophageal sphincter in our bench model had no systemic compliance, as would be expected in a human with a stomach and intestines.[5] The effect of back-pressure on LESOP, created as a result of reaching the volume capacity of the stomach and gastrointestinal tract, has not been studied in humans. The varying amount of positive pressure downstream from the lower esophageal sphincter in humans is different from the mechanical valve used in our bench model, which opened directly to the respirometer and the atmosphere.

Conclusions

Our study found no significant difference between the Oxylator and the BVM when comparing V_T delivered to lungs and gastric inflation during ventilation of a simulated unconscious nonintubated patient. More research on BVM and the Oxylator should be done to validate the American Heart Association guideline recommendations for ventilation of unconscious patients with unprotected airways. Research on gastric inflation needs to be done on bench models using manikins that simulate chest excursion, bidirectional airway flow, lung impedance, and gastric compliance.

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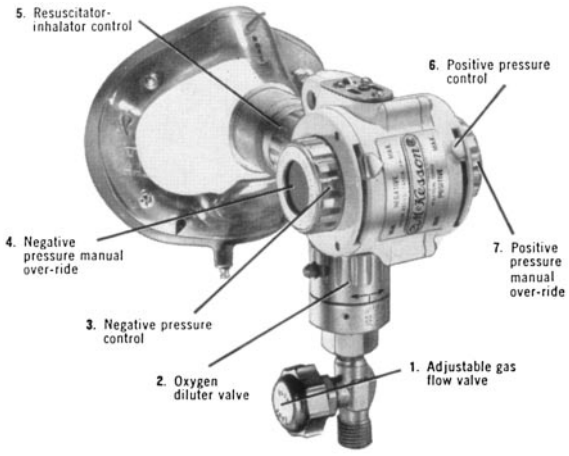

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