The Effect of a Bellows Leak in an Ohmeda 7810 Ventilator on Room Contamination, Inspired Oxygen, Airway Pressure, and Tidal Volume

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We investigated the effect of a small bellows leak (bellows full at end-expiration) on inspired oxygen fraction (FIO_2), exhaled tidal volume (VT), airway pressure, and room contamination in an oxygen-driven anesthesia ventilator (Ohmeda 7810, Madison, WI). CO_2 concentration at the ventilator exhalation valve, FIO_2, VT, and airway pressure were measured ($n = 3$) while ventilating a CO_2-producing test lung at 8 breaths/min and an inspiratory/expiratory ratio of 1:2, with and without a bellows leak (4-mm-long tear). Set VT was 400, 600, 800, and 1000 mL. Fresh gas flow (FGF) was 0.3 L/min O_2 and (a) 5.0 L/min air, (b) 2.0 L/min air, and (c) 0.2 L/min nitrogen. There was no clinical difference in FIO_2, VT, PIP (peak inspiratory pressure) and PEEP (positive end-expiratory pressure), with and without a 4-mm bellows tear, at all FGFs and VT settings. CO_2 at the ventilator exhalation valve was always nonzero with a bellows leak, indicating that CO_2-laden circuit gas was contaminating the drive gas via the bellows leak. A 4-mm bellows tear in an Ohmeda 7810 ventilator allows anesthetic gases to contaminate ambient air but does not cause clinically significant changes in FIO_2, exhaled VT, PIP, or PEEP.

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The gas used to "squeeze" the bellows in an anesthesia ventilator is called the "drive gas" and may be oxygen, air, or an O_2/air mixture, depending on the ventilator model. Anesthesia textbooks suggest that, with an air-driven bellows, a bellows leak might cause (a) drive gas to enter the patient circuit (1–5), (b) alveolar hyperventilation (2,5,6), (c) barotrauma (5,6), (d) decreased inspired oxygen fraction (FIO_2) (2,4–6), (e) hypoxemia (2), and (f) an increase in N_2 concentration which could be misinterpreted as an air embolism (4). With an O_2-driven bellows, a leak increased FIO_2 (4–6). Bellows leaks have also been suggested as a cause for decreased anesthetic concentrations (1,2,4), and loss of gas from the breathing circuit (1).

We performed this study because existing literature on the effects of bellows leaks seemed to address outdated, instead of contemporary, anesthesia ventilators. Preliminary experiments using the widely used 7810 ventilator (Datex-Ohmeda, Madison, WI) seemed to contradict the findings and observations of prior publications. The objective of our study was to determine the effects of a small bellows leak in a contemporary anesthesia ventilator.

Methods

The size of the bellows tear had to be small enough that the bellows filled completely at end-exhalation with a fresh gas flow (FGF) as low as 0.5 L/min. In other words, the bellows leak rate had to be, on average, <0.5 L/min. After a trial and error process, we made a 4-mm-long horizontal incision along the top outer fold of a 7810 ventilator bellows to create the bellows leak. A mechanical test lung (MI Instruments Training Test Lung, Grand Rapids, MI), modified to produce CO_2 (7), was used with compliance set at 0.1 L/cm H_2O and airway resistance at 20 cm H_2O/L/s. CO_2 bleed rate into the test lung was adjusted to produce an end-tidal CO_2 ($ETCO_2$) concentration of 40 mm Hg when ventilated at a rate of 8 bpm, set tidal volume (VT) = 1000 mL, I/E = 1:2, and FGF of 5.3

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Table 1. FGF = 5.0 L/min Air and 0.3 L/min O_2 (Set $FIO_2 = 0.25$); $n = 3$

Set VT (mL)	Exhaled VT (mL)		Measured FIO_2 (%)		PIP (cm H_2O)		PEEP (cm H_2O)		CO_2 at ventilator exhaust (mm Hg)		$ETCO_2$ (mm Hg)	
400	434 (2)	421 (2)	25.3 (0.6)	25.7 (0.6)	8 (0)	8 (0)	3 (0)	3 (0)	22* (1.5)	0* (0)	111 (16)	120 (0)
600	608 (5)	591 (21)	25 (0)	24.7 (0.6)	10 (0)	10.3 (0.6)	3 (0)	3 (0)	19† (0)	0† (0)	68 (2)	65 (3)
800	789* (12)	763* (6)	25 (0)	25 (0)	12.3 (0.6)	12.7 (0.6)	3 (0)	3 (0)	15† (0)	0† (0)	51* (2)	47* (0.6)
1000	978 (2)	963 (11)	25 (0)	25 (0)	15 (0)	15 (0)	3 (0)	3 (0)	10† (0)	0† (0)	41 (1.2)	39 (0.6)

Data are mean values (SD). Right-hand columns denote data collected with an intact bellows.

FGF = fresh gas flow, VT = tidal volume, FIO_2 = inspired fraction of oxygen, PIP = peak inspiratory pressure, PEEP = positive end-expiratory pressure, $ETCO_2$ = end-tidal carbon dioxide.

* Significant difference ($P < 0.05$).

† Significant difference is believed to exist in those instances in which the standard deviation is zero for both groups and standard statistical techniques do not apply.

Table 2. FGF = 2.0 L/min Air and 0.3 L/min O_2 (Set $FIO_2 = 0.3$); $n = 3$

Set VT (mL)	Exhaled VT (mL)		Measured FIO_2 (%)		PIP (cm H_2O)		PEEP (cm H_2O)		CO_2 at ventilator exhaust (mm Hg)		$ETCO_2$ (mm Hg)	
400	335 (7)	323 (5)	30 (0)	30 (0)	6 (0)	6 (0)	2 (0)	2 (0)	31* (1.2)	0* (0)	120 (0)	120 (0)
600	499 (21)	487 (23)	30 (0)	30 (0)	8.3 (0.6)	8.7 (0.6)	2 (0)	2 (0)	23* (1)	0* (0)	101 (14)	87 (11)
800	652 (5)	653 (7)	29.3 (0.6)	30 (0)	10 (0)	10.3 (0.6)	2 (0)	2 (0)	17† (0)	0† (0)	61.3 (0.6)	57 (2.6)
1000	858 (22)	825 (3)	30 (0)	30 (0)	13 (0)	13 (0)	2 (0)	2 (0)	10* (0.6)	0* (0)	47* (0.6)	44* (1.2)

Data are mean values (SD). Right-hand columns denote data collected with an intact bellows.

FGF = fresh gas flow, VT = tidal volume; FIO_2 = inspired fraction of oxygen, PIP = peak inspiratory pressure, PEEP = positive end-expiratory pressure, $ETCO_2$ = end-tidal carbon dioxide.

* Significant difference ($P < 0.05$).

† Significant difference is believed to exist in those instances in which the standard deviation is zero for both groups and standard statistical techniques do not apply.

L/min (5 L/min air, 0.3 L/min O_2). CO_2 was used as a marker to differentiate between CO_2-laden patient circuit gas and CO_2-free drive gas and $ETCO_2$ as an indirect redundant monitor of VT.

The test lung was connected via an adult circle breathing circuit (SIMS-Portex, Ft. Myers, FL) to a 3-gas (O_2, N_2O, air) Modulus II anesthesia machine (Datex-Ohmeda) incorporating a 7810 ventilator. The ventilator bellows was mounted directly on the CO_2 absorber using a GMS absorber interface mounting kit. Respiratory rate was fixed at 8 breaths/min and I/E ratio at 1:2. Exhaled VT was measured with a turbine respirometer (Ohmeda 5410 volume monitor) placed on the expiratory port of the CO_2 absorber, FIO_2 from a sidestream paramagnetic oxygen analyzer (Ultima; Datex Medical Instrumentation, Inc., Helsinki, Finland) sampling gas from the Y-piece, and peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP) from pressure measured by the Datex Ultima, at the Y-piece. Additionally, the CO_2 concentration in the exhausted ventilator drive gas (exhaustCO_2) was monitored using an aspirating capnograph (Capnogard; Novametrix, Wallingford, CT) configured to display the average CO_2 concentration over the last 10 s. The tip of the Capnogard sampling line was taped next to the exhaust louvers at the back panel of the 7810 ventilator control module. FIO_2 measured by the gas analyzer was recorded at 0.1 Hz via a serial port using a personal computer. Before the study, the anesthesia machine and ventilator with intact bellows were checked according to the 1993 Anesthesia Apparatus Checkout Recommendations (8) and passed all the tests.

Exhaled VT, FIO_2, PIP, PEEP, and exhaustCO_2 were measured during mechanical ventilation of the test lung with, and without, a bellows leak at 3 FGFs (5.3, 2.3, and 0.5 L/min). The O_2 flowmeter was always set at its lowest setting (0.3 L/min for the anesthesia machine used). For the FGFs of 5.3 and 2.3 L/min, the balance gas was air whereas for the 0.5 L/min FGF, N_2 was the balance gas.

Because there was no low-flow flowmeter for measuring 0.2 L/min air on the anesthesia machine, we used the 0.2 L/min mark on the N_2O low-flow flowmeter to measure N_2 flow. We used N_2 instead of N_2O because N_2O would have leaked into the room when collecting data on a leaky bellows, even with a scavenging system present because the bellows leak causes the scavenging system to be bypassed. Any error from measuring N_2 flow with an N_2O flowmeter would be consistent while comparing data from the two different groups. We found the error to be minimal; FIO_2 was stable at exactly 0.60 when measured at the common gas outlet for 5 min.

Four VT settings were used (400, 600, 800, and 1000 mL). The order of VT settings was randomized in each group. The FGF was changed to 15 L/min

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Table 3. FGF = 0.2 L/min N_2 and 0.3 L/min O_2 (Set F_{IO_2} = 0.6); n = 3

Set VT (mL)	Exhaled VT (mL)		Measured F_{IO_2} (%)		PIP (cm H_2O)		PEEP (cm H_2O)		CO_2 at ventilator exhaust (mm Hg)		$ETCO_2$ (mm Hg)	
400	311 (16)	327 (6)	58.7 (0.6)	59.7 (1.2)	5 (0)	5 (0)	2 (0)	2 (0)	34.3* (4.7)	0* (0)	119 (0)	119.7 (0.6)
600	488 (21)	491 (19)	58.7 (0.6)	58.7 (0.6)	7 (0)	7.3 (0.6)	1.7 (0.6)	2 (0)	21.7* (2.1)	0* (0)	119.3 (0.6)	117 (2.6)
800	651 (34)	666 (9)	60.3* (0.6)	59* (0)	9 (0)	10 (0)	2 (0)	2 (0)	12* (1)	0* (0)	68.3 (6.1)	67.3 (1.2)
1000	847 (20)	868 (17)	59.3 (0.6)	59 (0)	11.7 (0.6)	12 (0)	2 (0)	2 (0)	8* (1.7)	0* (0)	50.7 (3.1)	47 (1.7)

Data are mean values (SD). Right-hand columns denote data collected with an intact bellows.
FGF = fresh gas flow, VT = tidal volume, F_{IO_2} = inspired fraction of oxygen, PIP = peak inspiratory pressure, PEEP = positive end-expiratory pressure, $ETCO_2$ = end-tidal carbon dioxide.
* Significant difference ($P < 0.05$).

air and 0.3 L/min O_2 between each set of measurements until the baseline F_{IO_2} at the start of each new set of measurements was always 0.22 to remove any potential influence of the previous experiment on current data collection. After each change of settings, the measurements were recorded after the values, especially F_{IO_2}, had stopped changing. In practice, the data were collected after 3, 5, and 60 min for FGFs of 5.3, 2.3, and 0.5 L/min, respectively. Each measurement was repeated 3 times ($n = 3$).

The statistical analysis was performed with SigmaStat (version 2.03.0; SPSS, Inc., Chicago, IL). At each combination of VT and FGF settings, the data between 2 groups (with, or without, a bellows leak) were compared using a *t*-test if the data passed the normality test. If the data were not normally distributed and the standard deviation was not zero for both groups, the Mann-Whitney ranked sum test was used. When the standard deviation was zero for both groups, there was an absence of any measure of variability, which made it impossible to run a meaningful statistical test. These situations are marked by the † symbol in those instances in which there is clearly a significant difference. $P < 0.05$ was considered statistically significant.

Results

The experimental data collected with, and without, a 4-mm bellows tear at a FGF of 5.3, 2.3, and 0.5 L/min are shown in Tables 1–3. Statistically significant differences ($P < 0.05$) are indicated by a asterisk (*) in Tables 1–3.

The value of exhaustCO_2 was always zero with no bellows tear and nonzero with a bellows tear, indicating that breathing circuit gas was contaminating the drive gas and exhausting directly into room air. There was a statistically significant difference ($P < 0.05$) in exhaustCO_2 between groups. There was no difference in measured F_{IO_2} with, or without, a bellows tear except at an FGF of 0.5 L/min and a set VT of 800 mL. There was no difference in PIP or PEEP with, or without, a bellows tear. There was no difference in exhaled VT between groups except at an FGF of 5.3 L/min and a set VT of 800 mL. There was no difference in $ETCO_2$ between groups except at 2 settings: FGF 2.3 L/min, VT 1000 mL; FGF 5.3 L/min, VT 800 mL.

Plots of F_{IO_2} versus time (not shown) had the characteristic shape of a first order system, with no overshoot, both with, and without, a bellows tear. Because the leak rate was sized to be less than FGF, the bellows was always full at end-exhalation.

Discussion

An intact bellows provides a barrier that prevents mixing of drive gas and circuit gas, i.e., gas in the breathing circuit. If a bellows leak has a lower opening pressure than the ventilator pressure relief valve (VPRV) in an ascending bellows (nominally 3 cm H_2O), circuit gas will exit through the path of least resistance, i.e., the bellows leak instead of the scavenging system. We confirmed this hypothesis by intermittently sampling gas in the ventilator scavenging hose. CO_2 was present with an intact bellows and absent with a 4-mm bellows tear and a FGF of 0.5 L/min, indicating that the VPRV remained closed, such that all excess circuit gas exited directly into ambient air. At more rapid FGFs of 2.3 and 5.3 L/min with a 4-mm bellows tear, CO_2 was present in the ventilator scavenging hose and at the ventilator exhaust valve. Large FGFs flowing through the flow resistance of the 4-mm bellows tear generated higher pressures sufficient to open the VPRV such that circuit gas exited through both the scavenging system and bellows tear. CO_2 first appeared in the scavenging system at an FGF of 0.6 L/min with a 4-mm bellows tear.

Step 12f of the Food and Drug Administration Anesthesia Apparatus Checkout Recommendations (8) (mechanical ventilation of a 3-L bag with minimal O_2 flow and checking that the bellows fills completely during expiration) will not detect a 4-mm tear in a bellows because the minimal O_2 flow of about 200 mL/min in some machines (including the Modulus II used in the study) compensates for the leak. The threshold appears to be a 10-mm horizontal tear whereupon the bellows will refill completely for 5

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breaths after the O_2 flush and thereafter progressively collapse. The horizontal tear was located on an outer fold based on wear and tear observed on a bellows used during extensive experimentation. The study was performed with an ascending bellows ventilator, representative of contemporary anesthesia ventilators in the United States. A descending bellows ventilator may behave differently because drive gas may be entrained into the bellows during exhalation, as a result of the weight of the hanging bellows; therefore, our data and conclusions may not apply. The CO_2-producing test lung had no equivalent of a physiological buffer resulting in high CO_2 levels during hypoventilation. CO_2 was used as a tracer gas, not to simulate gas exchange. Within the limitations described above, our experimental data identify contamination of the operating room environment as an effect previously not associated with a bellows leak.

In the case of North American Dräger (Telford, PA) ventilators, such as the AV-E, the drive gas is a mixture of O_2 and entrained room air such that the drive gas volume can be much larger than set V_T, especially at slow respiratory rates and I/E ratios close to 1:1. Thus, this study is likely not applicable to ventilators that use entrained room air as the drive gas. The results of this study should be applicable to the older, but still used, Ohmeda 7000 and the newer 7900 ventilators because, similar to the 7810 ventilator, they feature upright bellows driven with pure O_2. When drive gas is scavenged in O_2-driven bellows ventilators, such as the 7900 (9), fires in the oil-lubricated scavenging vacuum pumps have resulted from large O_2 concentrations in the presence of oil (10). Medical air drive gas is mentioned as a solution and our data should alleviate any potential concerns that air might reduce F_{IO_2} in the presence of a bellows leak.

To summarize, the experimental data indicate that, with a 4-mm bellows tear in an Ohmeda 7810 ventilator, drive gas will not affect airway pressure, F_{IO_2}, and anesthetic concentrations for FGFs of ≥0.5 L/min. With larger bellows leaks (>10 mm), unintended alteration of the inspired gas mixture may occur especially at low FGF and large V_T and the bellows will likely collapse. However, the widespread use of multigas analyzers will readily measure changes of F_{IO_2}, N_2O, and anesthetic concentrations caused by a large bellows leak. Use of these monitors should help avoid awareness under anesthesia caused by dilution of the inhaled anesthetic by the drive gas. User vigilance will detect the collapsed bellows. Most of the symptoms of a bellows leak can be detected by current standard monitoring equipment and vigilance, except for room contamination.

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