Novel Oxygen-Concentrator-Based Equipment: Take a Test Drive First!

Patient incidents can teach us shocking and amusing lessons. The lesson may be obvious, but sometimes there is a second, subtler lesson. A recent incident involving new concentrator-based O_2 equipment provided both.

About 6 months ago, the afternoon therapist paged one of us to see a patient who was upset because the therapist would not fill his portable O_2 cylinder. His request and response were odd, because the practice of transferring *liquid* O_2 from large to small (portable) reservoirs at home is common, but that of transfilling *gaseous* O_2 from large to small cylinders has virtually disappeared.[1] While some local retailers fill their own small cylinders, none offers "while-you-wait" service. We, like everyone else, exchange full for empty cylinders. Our patient refused because his cylinder was special—a tiny size "A" and made of lightweight aluminum, it had an integrated *demand* valve and proprietary filling port that was incompatible with the threaded (CGA-540) and post-type (CGA-870) connectors on our large and small cylinders (Fig. 1).[2] Unsatisfied, he demanded to see a concentrator. When we showed how the tiny Diameter Index Safety System outlet also did not fit, he said he understood—we did not have the special pump. He grudgingly accepted the loan of an old-fashioned continuous-flow regulator and several full cylinders. We chatted as the therapist assembled the equipment for his drive home. He had spent most of the day at the center, visiting specialists. Suddenly, we realized that he had left home with a 3-hour O_2 supply for a 19-hour outing! He knew from his limited experience that the cylinder would last 3 hours, he had no spare (backordered from the manufacturer), and he extended his supply by shutting *off* flow while driving and sitting and used 1 L/min while walking, not the prescribed 2 L/min at rest and 3 L/min walking.

We will never forget our patient who was so enamored by the novelty of his home-filled O_2 cylinder that he *purposely* under-treated his hypoxemia. We smiled, reviewed the importance of complying with his prescription, discussed options for arranging adequate supplies, and sent him home with conventional equipment. Later, a report[3] about concentrator-produced O_2 raised concerns that we had missed a second, subtler lesson, namely, that clinicians and patients may *inadvertently* under-treat hypoxemia with this new equipment. We would like to discuss this potential problem: first, by describing novel concentrator-based equipment; next, by reviewing limitations of concentrators and associated demand valves; and last, by providing calculations to demonstrate these potential limitations.

Fig. 1. Invacare HomeFill II high-pressure cylinder with integrated demand valve and proprietary connector. The outlet nipple is not visible. The cylinder is placed horizontally before connecting to the high-pressure compressor. See Reference 2 for more details.

Novel Concentrator-Based Equipment. O_2 Cylinders Filled From Concentrators. For decades, home concentrators have provided O_2 at low pressure. Recently, some vendors have used O_2 concentrators instead of cryogenic generators with *high-pressure compressors* to fill high-pressure cylinders. Now patients may use concentrators with high-pressure compressors to fill their cylinders at home.[2,4,5] One high-pressure compressor is an option for a proprietary concentrator, and a second is integrated with its proprietary concentrator. Both use cylinders with pro-

Fig. 2. Chad Total O_2/Oxylite high-pressure cylinder, showing back of integrated pressure gauge, proprietary inlet hole (above cylinder neck to the right; plastic cover moved aside for illustration). Note that the CGA-870 post has 2 standard holes (Pin Index Safety System positions 2 and 5) for O_2 and a proprietary pin for use with proprietary demand valves. The cylinder is placed horizontally before connecting to the high-pressure compressor. See Reference 4 for more details.

prietary connectors (see Figs. 1 and 2). The time to fill an empty cylinder varies considerably (eg, from about 75 min for a small "A" cylinder to more than 20 hours for an "E" cylinder) and depends on concentrator output, compressor capacity, and cylinder size. Cylinders can be used with a demand valve or conventional continuous-flow regulator.[5]

Portable O_2 Concentrators. Nearly 2 decades ago, a prototype briefcase-size, battery-powered O_2 concentrator that weighed less than 10 pounds amazed practitioners.[6] It provided 30% O_2, so it would be considered an "enricher" today.[1] Recent technical advances have led to the production of 2 truly portable concentrators (ie, $\leq$10 pounds). Both can use an internal rechargeable battery, automobile 12-volt direct-current adaptor, or household alternating current, and they deliver *pulses of O_2* with settings equivalent to continuous L/min flow.[7]

Two Known Limitations of O_2 Delivery Equipment. First, concentrators do not provide 100% O_2. Under the best conditions, concentrators provide 96% O_2.[8] Depending on design, state of repair, and *how close flow is set to the maximum rated flow*, the O_2 concentration can drop substantially.[8] Some concentrators have sensors and alarms to indicate when concentration drops to a specific value, often in the range of 85–90%. Clinicians have ignored the consequences of less-than-pure O_2, because of the shape of the hemoglobin-O_2 dissociation curve, limitations of pulse oximetry, and the ease of raising flow to compensate. In a recent report, half of the hypoxemic patients with chronic obstructive pulmonary disease (COPD) needed at least 1 (some 2 or 3) L/min *additional* O_2 flow from a concentrator to achieve the same P_{aO_2} they had with cryogenically produced, 100%, "wall" O_2.[3] This observation is relevant because many patients are assessed with 100% O_2 in a medical center but are sent home to use concentrator-provided O_2.[3]

Second, equivalent-flow settings on O_2-conserving pulse-dose demand valves are a fallacy.[9] Manufacturers take different approaches to determine the volume of the O_2 pulse (bolus) and *how the valve responds to changes in respiratory rate*. At the same "continuous O_2 equivalent-flow setting," 3 different demand valves may deliver different O_2 volumes at a commonly observed respiratory rate (often 15 or 20 breaths/min), and as the respiratory rate increases, one valve *reduces*, a second *maintains*, and a third *increases* O_2 bolus volume. Experienced clinicians recognize that many hypoxemic patients must raise O_2 flow during exercise[10] to overcome the effects of increased demand and dilution with room air (air entrainment). In a recent bench evaluation, nearly all demand valves set at maximum flow demonstrated air entrainment with higher respiratory rate (ie, the delivered O_2 concentration dropped).[11]

In summary, compact and miniature O_2 concentrators will have less capacity than large traditional stationary concentrators and may provide less-than-pure O_2. Depending on design, adding a conserving demand valve can mitigate or aggravate reduced O_2-generating capacity. An unfortunate combination of low O_2 concentration and low O_2 bolus volume may lead to inadvertent under-treatment of hypoxemia, especially during exercise. Finally, it may not be possible to raise true (as opposed to equivalent) flow. That is, raising the equivalent flow may fail to achieve the desired effect. This potential limitation may be intuitively obvious to experienced clinicians. It will take time for bench and clinical studies to support or refute these concerns.

Until such studies are reported, one approach is to calculate the expected effects of air dilution on supplemental O_2 therapy with the *gas mixing equation*[12] (and personal communication, Alexander B Adams MPH RRT FAARC, Regions Hospital, St Paul Minnesota, and Peter L Bliss BME, Techniflow, Prior Lake, Minnesota; and OxyTec Medical, Anaheim Hills, California).

Table 1. Calculated Oxygen Concentrations Delivered by a Demand Valve With Pure Oxygen at Rest, Less-Than-Pure Oxygen at Rest, and Less-Than-Pure Oxygen With Reduced Volume During Exercise

L/min flow*	A 20 breaths/min at rest			B 20 breaths/min at rest			C 30 breaths/min during exercise		
	V_{ox} (mL)	C_{ox} (%)	C_f (%)	V_{ox} (mL)	C_{ox} (%)	C_f (%)	V_{ox} (mL)	C_{ox} (%)	C_f (%)
"1"	10	100	22.6	10	95	22.5	06	95	21.9
"2"	20	100	*24.2*	20	90	23.8	12	90	22.7
"3"	30	100	25.7	30	85	*24.8*	18	85	23.3
"4"	40	100	27.3	40	85	26.1	24	85	24.1
"5"	50	100	28.9	50	80	26.9	32	80	*24.8*

The effect of dilution by air on calculated oxygen concentration (C_f) is shown using an efficient demand valve (5:1 savings) with 100% O_2 (column A) and less-than-pure (O_2 (column B) at rest, and, as designed, smaller volumes of less-than-pure O_2 (column C) during exercise. Note that C_f is remarkably low when using an efficient demand valve (5:1 savings). One may draw a line to connect 3 similar C_f values (italicized): 24.2% at equivalent flow "2" in column A, 24.8 at "3" in column B, and 24.8 at "5" in column C. The values for C_f imply that using less-than-pure O_2 (eg, from a concentrator) requires at least one higher setting at rest than using pure O_2. Of concern is that C_f fails to rise during exercise, despite raising the "equivalent flow" by 3 settings, to the maximum "5". This is unfortunate because many patients have to raise true O_2 flow during exercise. This failure to provide higher O_2 concentration may under-treat hypoxemia.

*L/min = equivalent flow setting

V_{ox} = volume of oxygen delivered per breath

C_{ox} = percent concentration of oxygen delivered per breath

C_f = final concentration of oxygen delivered after considering dilution with air

Tidal volume = 500 mL = V_{ox} plus inhaled air. See text for formula.

$$C_f = \frac{V_{ox} \times C_{ox} + V_{air} \times 21}{V_f}$$

where C_f is the final O_2 concentration after accounting for air dilution, V_{ox} is the volume (in mL) of delivered supplemental O_2, C_{ox} is the O_2 concentration (as a percent [eg, 100 for pure O_2]), V_{air} is the volume (in mL) of air entrained, 21 is the O_2 concentration (as a percent) of air, and V_f is the sum of the volumes of supplemental O_2 and entrained air (ie, $V_f = V_{ox} + V_{air}$ = tidal volume).

For simplicity, we will fix tidal volume at 500 mL, so V_{air} = 500 mL – V_{ox}. If we plan to use a *hypothetical* demand valve that provides a 10-mL O_2 bolus at "1 L/min," 20 mL at "2 L/min," et cetera, up to 50 mL at "5 L/min," as determined by the manufacturer at 20 breaths/min (a commonly observed resting respiratory rate in patients with COPD), we may quickly calculate the final concentrations at each setting when using pure O_2 (C_{ox} = 100). The results are summarized in Table 1 (column A).

The calculated final O_2 concentrations (C_f) are remarkably low, ranging from 23% at setting 1 to 29% at setting 5. This is characteristic of an efficient O_2-conserving demand valve that offers a 5:1 savings (eg, at setting 1, the valve provides 10 mL/breath × 20 breaths/min or 200 mL/min, a *fifth* of 1 L/min (1,000 mL/min) continuously flowing O_2.

Next we can calculate the effect of using this efficient conserving demand valve with a *hypothetical* concentrator of limited capacity (ie, the O_2 concentration drops as flow setting rises). This might be either a portable concentrator or a high-pressure cylinder filled from a compact concentrator. Comparing C_f with less-than-pure O_2 (column B in Table 1) and with pure O_2 (column A in Table 1) suggests that flow will have to be raised by 1 setting; also, C_f at setting 5 (maximum) using less-than-pure O_2 barely matches C_f at setting 4 using pure O_2 (27%).

Last, we can calculate the effect of using less-than-pure O_2 with a demand valve that is designed to *reduce O_2 bolus volume* as respiratory rate rises (eg, at 30 breaths/min, a commonly observed respiratory rate during exercise in patients with COPD). The bolus is only 60% of that provided at 20 breaths/min (column C). Maximum C_f, which is barely 25% at setting 5 (column C) matches C_f at rest with setting 3 using less-than-pure O_2 (column B) and setting 2 using pure O_2 (column A). This *double reduction* of supplemental O_2 concentration and volume is *contrary* to the clinical experience that many patients with lung disease require higher O_2 flow during exercise to maintain arterial oxygen saturation.[10] This unfortunate combination may under-treat patients during exercise, despite raising equivalent flow to the maximum setting.

A more practical approach is to verify that the selected novel equipment provides adequate oxygenation during rest and exercise.[10] Manufacturers can design safety controls with sensors, alarms, and feedback circuits to provide minimum O_2 concentrations, but it is difficult to predict from published specifications if those less-than-pure O_2 concentrations, coupled with a demand valve, will actually provide what individual patients need.

Some buyers examine published fuel-economy ratings from the Environmental Protection Agency, while others scrutinize manufacturer's published performance specifications, but nearly all will take the chosen automobile for a test drive to see if it meets expectations. We think pa-

tients also deserve a "test drive" with the chosen novel compact and convenient O_2 equipment!

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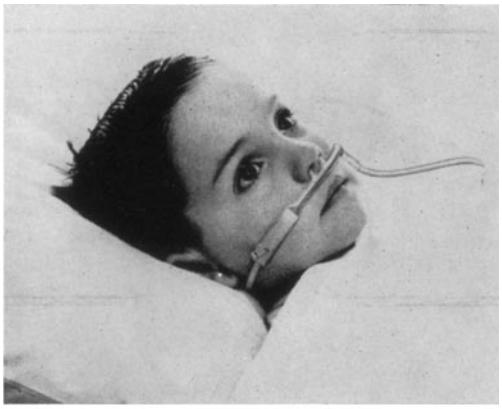

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