New Long-Term Oxygen Therapy Technology: The Transition Continues

The process of providing domiciliary long-term oxygen therapy (LTOT) is undergoing a radical transformation. Traditionally, 2 types of equipment have been used to deliver LTOT. The first is the large stationary unit for in-home use. A stationary unit can be either an electrically powered oxygen concentrator or a large, refillable liquid-oxygen dewar. When ambulation is required beyond the physical limits of the stationary unit, a smaller portable system is used. A portable system can be either a compressed-gas cylinder (an E-size or smaller cylinder) or a liquid-oxygen canister that can be refilled from the larger stationary dewar.

Under this traditional scheme, patients receive the majority of their daily oxygen from the stationary system, set at the physician-prescribed continuous flow (eg, 2 L/min). Conversely, the amount of oxygen received from a traditional portable system is limited by the amount of oxygen (gaseous or liquid) in the portable canister, which determines how long patients can remain away from the stationary unit before realizing their greatest fear: running out of oxygen!

Because of the physical attributes of liquid oxygen, portable liquid-oxygen devices last longer than do compressed-oxygen cylinders. This is especially true when operating in the continuous-flow mode. Portable liquid-oxygen units also offer several advantages over the ubiquitous standard aluminum E cylinder system (ie, cylinder, cart, and regulator). Standard portable liquid-oxygen units are smaller, weigh much less (4 kg vs 9 kg), and, unlike the E cylinder, can be carried by the patient. For subsequent excursions, patients can refill their liquid-oxygen portable unit from the stationary liquid-oxygen dewar, whereas patients who use the standard E-cylinder system have to replace the empty cylinder from their limited inventory of full cylinders.

Disadvantages of both stationary and lightweight liquid portable oxygen systems include higher equipment acquisition costs, periodic refills of the dewar necessitating repeat home deliveries using expensive and highly regulated cryogenic equipment and the difficulty some patients have using liquid oxygen equipment safely. Another major disadvangage is the fact that the monthly reimbursement allowed by most third-party insurance payers is the same for either system, notwithstanding the fact that it costs more to supply liquid oxygen.

Since the lightweight liquid portable oxygen system offers greater flexibility in replacing depleted contents, we might suspect that patients using these systems would ambulate more than those using the more traditional E-cylinder systems. Theoretically, daily ambulation with ample protection from arterial desaturation reflects better disease-control, and should result in lower health-care utilization, especially for patients with stable, chronic arterial hypoxemia secondary to chronic obstructive pulmonary disease (COPD).

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In this issue of RESPIRATORY CARE, Mapel and colleagues, from the Lovelace Clinic Foundation in Albuquerque, address this question from a unique perspective.[1] They studied whether the total cost of care for patients with COPD was higher among patients who used the more expensive lightweight liquid portable oxygen system than among those who used the less-costly standard aluminum E-cylinder system.

Mapel et al collected data from the period January 1, 1999, through December 30, 2004, from the health records of 2,725 patients with COPD enrolled in their closed, managed health-care plan, who had a prescription for supplemental oxygen and met their inclusion criteria. Oxygen equipment was dispensed by one of several contracted home-care providers at a predetermined monthly reimbursement rate that was the same for both the lightweight liquid portable (code E0434) and the standard E-cylinder (code E0431) oxygen systems.

Of the 2,725 patient records selected, 83% (2,268) used the standard E-cylinder system, 7.5% (203) used a lightweight liquid portable oxygen system, and the remaining 9.3% used both (ie, started on the E-cyclinder system but later switched to the lightweight liquid portable system). The reason 83% received an E-cylinder system and only 7.5% received a lightweight liquid portable oxygen system was because the contracted LTOT providers only dispensed the more expensive liquid portable equipment when the referring physician specifically prescribed it, or when the patient specifically requested it.

Not surprisingly, the findings led Mapel et al to conclude that there were no significant difference in total

health care costs between the patient groups based on the type of oxygen system. Specifically, patients who used the liquid-oxygen system did not have higher overall costs of care than did the patients who used the E-cylinder system. However, though Mapel et al did find a $2,988 difference in the unadjusted annual mean total health care costs in favor of the portable liquid-oxygen users, the difference did not reach statistical significance. While the health plan did not see increased costs based on equipment type, I suspect that the contracted LTOT providers would argue that their costs were indeed higher for those patients who did receive the lightweight liquid portable equipment.

As Mapel et al note, there are several limitations to their study that will be obvious to those in home respiratory care, but I have a few more to add. First, though Mapel et al indicate that "the most common" lightweight portable oxygen system dispensed was a continuous-flow device, the reader is left to wonder if, unknown to the researchers, some of the patients actually received a liquid-oxygen portable device employing pulse-dose oxygen-conserving technology. Second, are we also to assume that all the patients who received the E-cylinder system used only continuous flow, or did some use pulse-dose technology? Third, is it absolutely certain that all patients who received the E0431 equipment received an aluminum E cylinder, and not one of the smaller M6 cylinders typically used with an oxygen-conserving device?

These are important questions, especially as we now embark on a new era of providing both stationary and ambulatory LTOT with a single device, which is a radical departure from using 2 different types of equipment to meet stationary and ambulatory LTOT needs. The availability of an LTOT device that provides both stationary and ambulatory oxygen will surely lead to studies of its effectiveness and efficacy in protecting patients from arterial desaturation in various settings and types and intensities of activity. It will therefore be incumbent on future investigators to succinctly describe the equipment being studied and the parameters set for the delivery of supplemental oxygen.

The use of a single device to provide both stationary and ambulatory LTOT is commonly referred to as "deliveryless technology," implying that the home-care provider no longer has to make repeat home deliveries. Deliveryless technology describes a self-sustaining oxygen system that affords the patient a new degree of freedom from home deliveries. However, the various deliveryless technologies are based on different engineering platforms, each with advantages and limitations. It will therefore be incumbent on future investigators to clearly describe the performance characteristics of the device(s) being studied, as well as certain patient variables to be listed shortly.

One engineering approach to deliveryless technology involves using a standard oxygen concentrator that has been modified to refill a small aluminum cylinder with compressed gaseous oxygen while also supplying the continuous-flow prescription. Patients can then use the refilled cylinders to ambulate while breathing concentrated oxygen that is delivered in a preset bolus via pulse-dose. A variation on this approach is the recently introduced liquifier, which takes concentrated gaseous oxygen from a standard concentrator and converts it into liquid oxygen, which is then used to refill a small, lightweight pulse-dose liquid oxygen device.

The portable oxygen concentrator is the second engineering approach to deliveryless LTOT technology. A portable concentrator is nothing more than a scaled version ($\leq$4.5 kg) of a standard pressure-swing adsorption concentrator—they both employ air-separation technology. Portable concentrators can produce oxygen concentrations $\geq$90% (therapeutic oxygen) and are able to operate on standard household alternating current (AC), on direct current (DC), as found in most motor vehicles, or from a rechargeable battery. However, the small size of portable concentrators limits the total amount of therapeutic oxygen that can be produced in one minute. At this writing, the maximum oxygen production capabilities of the five portable oxygen concentrators on the market range from a low of 480 mL/min to a high of 1040 mL/min. This limited oxygen production capability necessitates that portable oxygen concentrators can only operate in the pulse-dose mode, whether they are used for stationary or ambulatory purposes.

The third approach to deliveryless technology is the portable ambulatory oxygen system, a variation on the aforementioned portable concentrator that employs a unique proprietary air-separation technology. The portable ambulatory oxygen system is similar to a portable concentrator in terms of power supply (AC, DC or rechargeable battery), but is slightly larger at 7.7 kg. However, in terms of oxygen production capabilities, the personal ambulatory oxygen system can produce up to 3,000 mL/min of therapeutic oxygen, enabling it to operate in both the continuous flow mode (up to 3 L/min) or in the pulse-dose mode during ambulation.

Central to all 3 of the aforementioned deliveryless technologies is the use of pulse-dose during ambulation, either to conserve oxygen contents when using one of the refillable cylinders or, in the case of the portable concentrator and personal ambulatory oxygen system, to conserve battery life. As with all oxygen-conserving technology, the important clinical objective is to ensure that the selected pulse-dose setting provides the same degree of protection from arterial desaturation as does the physician's original continuous-flow prescription.

One misconception that must be avoided is that a setting of "2" on a pulse-dose device is the same as a continuous-flow setting of 2 L/min. The settings on any pulse-dose device are more or less arbitrary—the settings could just as easily be letters instead of numbers—and they only reference the size of the delivered bolus. Moreover, with portable oxygen concentrators that have very limited oxygen-production capabilities, patients who are protected at a certain setting at a specific activity level and certain breathing rate may desaturate if their breathing rate increases. Simply stated, a patient's demand for oxygen may at times exceed the maximum output of therapeutic oxygen of a given portable oxygen concentrator. Further, the safety and efficacy of using pulse-dose-only portable oxygen concentrators during sleep remains to be more fully explored.

So what information needs to be collected, tracked, and reported in studies of the efficacy and effectiveness of deliveryless LTOT technology? First, with any pulse-dose device the original continuous-flow prescription should be reported, followed by the selected corresponding pulse-dose setting and the way the setting was determined. One would hope that pulse oximetry, as stipulated in the proceedings of the 6th Oxygen Consensus Conference,[2] is used to establish the appropriate pulse-dose setting, and pulse-oximetry readings should likewise be reported.

However, as discussed previously, the breathing rate is another important variable and should also be included in the data set. The bolus size for each setting of the pulse-dose device(s) studied should also be included (if that information is available from the manufacturer), because no 2 portable oxygen concentrator models have the same performance characteristics.

As the evolution of deliveryless LTOT technology continues, the use of pulse-dose technology is certain to increase. It is therefore essential that patients using this approach to having their daily oxygen needs met with a single device retain the same degree of protection from arterial desaturation as is provided with the physician's original continuous-flow prescription. As Mapel et al remind us, the need for LTOT itself is going to increase, as will the demand for new LTOT technology. For this new technology to be embraced, benefits must accrue to patients, providers, and payers alike. However, given the important operational and performance differences between the various deliveryless technologies available today, it is incumbent that home-care therapists understand these differences and choose deliveryless equipment accordingly. Our patients deserve no less. Equally important, whenever deliveryless LTOT equipment is used, specific set-up and titration protocols must be used to ensure that adequate oxygenation occurs at all times. Otherwise, the full clinical and economic advantages of deliveryless LTOT technology will not be realized, with the potential for patient harm more real than remote.

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Mr Dunne is a consultant for SeQual Technologies. He reports no other conflicts of interest in the content of this editorial.

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