Consensus Conference on Long-Term Oxygen Therapy; and a recommendation was made that when PDODs are prescribed, they should be appropriately titrated to the specific patient and PDOD device.[14]

Advanced technology, advanced home care

It is clear that the advances in oxygen technology are helping change the way we provide oxygen in the home. PDOD device use is now a normal part of LTOT therapy in the home and an integral part of most modern oxygen technologies. This use is supported by a growing body of published clinical and anecdotal evidence. Appropriately employed, PDOD technologies can be both clinically efficacious and economically sound additions to the LTOT tool box of physicians and home oxygen providers. Concurrently, PDOD devices provide LTOT users with an abundance of new technologies that help improve their lives by encouraging frequent ambulation, freedom, and independence, including travel. A key to optimizing the benefit of these important technologies is understanding the technical foundation, performance, and clinical data surrounding them.

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OXYGEN CONSERVING DEVICES:

Optimizing the Benefit

by Joseph S. Lewarski, BS, RRT, FAARC

For more than 30 years, long-term oxygen therapy (LTOT) in the home has been a standard and accepted treatment for patients with severe COPD demonstrating stable, chronic hypoxemia. Oxygen is the only noninvasive therapy shown to prolong the life of COPD patients with severe hypoxemia, as was evidenced in the two major randomized, controlled studies in this area. The well-known and frequently referenced Nocturnal Oxygen Therapy Trial (NOTT) and the British Medical Research Council report on domiciliary oxygen use set the scientific basis for the use of LTOT in the treatment of chronic hypoxemia. Both of these studies demonstrated significant mortality improvement with prolonged oxygen therapy.[1,2]

Over the last 10 years, there have been a number of technological advancements aimed at enhancing the provision of LTOT in the home. Pulse-dosed oxygen delivery (PDOD) systems, commonly referred to as oxygen conserving devices or OCDs, are some of the most prevalent of the new and advancing home oxygen technologies. Two prominent issues helping to stimulate the rapid acceptance and use of PDOD have been the steady decline in Medicare (and other payor) payment, and a significant rise in the demand for lightweight and ambulatory home oxygen systems.

Oxygen payment reductions

It has been said by numerous health care scholars that economics helps to drive health care practice. There is clear evidence of this as it relates to the home oxygen therapy benefit and the use of PDOD devices. Since the implementation of the Omnibus Budget Reconciliation Act of 1987 and the "Six Point Plan," Medicare oxygen payments have faced a steady decline. In 1989, Medicare introduced the "modality neutral" payment methodology, which imposed a Diagnosis Related Group-like, prospective payment method for home oxygen technologies. This was followed by the Balanced Budget Act of 1997, which imposed an unprecedented and draconian 30 percent cut to the home oxygen payment. The Medicare Modernization Act of 2003 introduced competitive bidding, along with the implementation of the Federal Employees Health Benefits Plan cuts, which imposed another 10 to 12 percent reduction in the Medicare home oxygen payment. When aggregated and adjusted for inflation, the Medicare payments for home oxygen therapy have been reduced by approximately 60 to 65 percent since 1989. The current average Medicare payment for home oxygen therapy (combined payment for stationary and portable devices) is approximately $232 per month, or roughly $7.63 per day. This is a fairly modest amount of money to provide patients with essentially an unlimited supply of oxygen 24 hours per day.

Demand for lightweight and ambulatory oxygen systems

Despite the significant payment reductions and challenges faced by home oxygen providers, the modern home oxygen consumer has become a more informed and

educated consumer. This new model of informed oxygen user, in conjunction with the earlier identification of chronic hypoxemia, has produced what many believe to be a new breed of LTOT user. Many modern LTOT users are considered highly active and ambulatory when compared to their historic counterparts, who often were considered truly homebound. Today's LTOT users may still work, travel frequently, and participate in other activities of daily living that keep them away from their stationary oxygen systems for extended periods of time throughout the day. They are very aware of their need for oxygen, their desire and need for freedom and independence, and the growing availability of the technologies that can fulfill these requirements.

> "PDOD devices provide an abundance of new technologies that help LTOT users improve their lives by encouraging frequent ambulation, freedom, and independence, including travel."

The recent Federal Aviation Administration approval of portable oxygen concentrators for use on board aircraft is a milestone event in the brief history of LTOT use in the home. It is also public testimony to the impact LTOT users have had on society.

These new variables have been considered catalysts for many of the technological advancements in oxygen technology, especially the PDOD devices. PDOD is now an integral part of nearly all modern LTOT delivery systems. The PDOD technology is part of most lightweight compressed gas, liquid, and portable oxygen concentrator systems.

Overview of pulse-dosed oxygen delivery

PDOD is a logical extension and application of low-flow oxygen delivery. Although oxygen therapy prescriptions are typically written in liters per minute (L/min), all low-flow oxygen devices actually deliver a *volume* of oxygen to the patient. The volume of oxygen delivered is simply a result of the fixed flow of the gas over time. As an example, a patient prescribed 2 L/min of oxygen via nasal cannula does not actually breathe two full liters of oxygen. The net volume of the inspired oxygen delivered to a patient over the course of a minute is a product of the oxygen flowrate, the patient's respiratory rate, inspiratory time, and the tidal volume minus anatomical deadspace (V_{Dant}).

PDOD technology has been around for more than 20 years, although its widespread acceptance and dramatic rise in utilization have only been observed in the United States over the last five to 10 years. This class of oxygen technology is most commonly referred to as OCDs because of the effect these devices have on reducing oxygen consumption in fixed volume oxygen systems, such as compressed cylinders or liquid vessels. More accurately, most modern PDOD devices actually "conserve" oxygen as a result of the bolus-style, volume-based oxygen delivery methodology.

Modern PDOD devices are normally either electronic or mechanical (pneumatic) and typically operate on demand, responding to a pressure drop triggered by the user's inspiratory effort and then delivering a predetermined bolus of oxygen. The clinical basis of PDOD relies on the assumption that the oxygen participating in gas exchange in the lungs is that which enters the airways quickly, during the first two-thirds of the inspiratory cycle. Oxygen flowing at the end of the inspiration, during exhalation, and during the pause prior to the next inspiration, is considered wasted since it plays no role in gas exchange. Approximately one-third of a person's inspiration is gas that remains in the larger airways, sinuses, nose, and mouth (V_{Dant}).

There are a few key elements associated with efficient PDOD technology, including bolus size, sensitivity, and bolus speed/delivery. A common assumption with PDOD promotes the theory that the earlier the oxygen bolus is delivered into the inspiratory cycle, the more efficient the oxygen delivery will be. Oxygen boluses delivered late in inspiration may be less effective in improving blood oxygen levels, as portions of the bolus may fall into the anatomical deadspace. Early work by Tiep and Lewis noted that the efficiency of pulsed oxygen therapy can be improved by focusing the oxygen delivery to early inspiration.[3]

PDOD use with ambulation

Oxygen demand and breathing patterns normally change with exercise. A patient's specific physiologic response to exercise will vary based on conditioning; but common clinical responses will include increased heart rate, increased blood pressure, and increased cardiac output. There is adequate scientific and anecdotal data to support the use of PDOD in ambulating and exercising patients. Bower et al studied a group of hypoxemic COPD patients using a demand PDOD device during rest, exercise, and sleep and concluded the demand PDOD produced arterial oxygenation equivalent to continuous flow oxygen under all conditions while using substantially less oxygen.[4] Tiep et al studied the effect of using an electronic demand PDOD system with exercising patients and concluded that the device maintained adequate oxygen levels during rest and exercise but noted that patients should be titrated during exercise to the ideal PDOD setting.[5] Fuhrman et al compared the performance of four different PDOD devices at rest and exercise and concluded that all devices improved patient oxygenation and saved oxygen but noted that devices that delivered a rapid bolus of oxygen at the onset of inspiration yielded better clinical performance.[6]

In a small study looking at the clinical efficacy of PDOD providing concentrator-produced gas (about 93 percent) to exercising LTOT patients, Lewarski et al concluded there were no clinical or statistical differences in blood oxygenation and heart rate between PDOD oxygen produced by a concentrator and United States Pharmacopeia continuous flow oxygen.[7] Cuvelier et al also studied the clinical efficacy of concentrator-produced gas delivered via PDOD and concluded concentrator-produced oxygen was as efficient as traditional cylinder gas in exercising patients.[8]

PDOD use and sleep

There are many theories surrounding COPD patients, oxygen use, and sleep; yet there are but limited controlled studies in this area. Some COPD patients who are normoxic during the day may experience clinically significant nocturnal desaturation. This also holds true for some LTOT users considered well managed on their prescribed LTOT setting while awake.

The American Thoracic Society (ATS) defines clinically significant nocturnal oxygen desaturation as a SpO_2 (saturation measured via pulse oximetry) of less than 90 percent for more than 30 percent of the sleep time.[9] The ATS goal for effective oxygen therapy is to maintain a SpO_2 above 90 percent for 70 percent of the time. Current research suggests that as many as 20 to 50 percent of current LTOT users with corrected daytime hypoxemia may desaturate to less than 90 percent for more than 30 percent of their sleep time while on their prescribed continuous flow oxygen setting.[10] This is likely a result of a reduced inspired minute volume of oxygen secondary to diminished minute ventilation.

There are a number of favorable scientific studies that have examined the performance and clinical efficacy of PDOD devices among LTOT users during sleep. One of the largest is a hospital-based study by Kerby et al that evaluated a PDOD against continuous flow oxygen in 100 hospitalized oxygen-dependent patients. They concluded that a PDOD system produced clinically equivalent SaO_2 to that of continuous flow oxygen during all activities, including sleep.[11]

Cuvelier et al used polysomnography to study the nocturnal sleep tolerance of a demand PDOD in COPD patients with hypoxemia and concluded that a demand PDOD device does not induce any significant alteration in nocturnal neurophysiologic and ventilatory profiles.[12]

In a recent study evaluating the clinical efficacy of a portable oxygen concentrator (POC) that delivers a fixed minute volume of oxygen per setting, Chatburn et al observed that a POC with integrated PDOD oxygen delivery produced nocturnal SpO_2 levels of continuous flow oxygen; and they also concluded that for the particular POC studied, daytime PDOD titration setting appeared to be an effective determinant of nocturnal oxygen needs in their study group.[13]

Most recently, PDOD was discussed during the Sixth

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available resources

Many educational resources are available through "The Respiratory Catalog" from the AARC, such as training modules on CD or Professor's Rounds on DVD. Some of these products offer CRCE credits, too. Visit www.aarc.org/store.cfm to take advantage of the online search engine that will search titles and descriptions by word or topic. Or contact AARC Customer Service at (972) 243-2272.