

Wake-up Call

from the American Sleep Apnea Association

CELEBRATING OUR 21ST YEAR

SUMMER 2011

ASAA A.W.A.K.E. NETWORK NEWS

Dr. Colin Sullivan, the Australian inventor of the CPAP machine, delighted those present at a June gathering of **Park Nicollet A.W.A.K.E.**, Minneapolis, MN, with a surprise appearance. Sullivan was in Minneapolis for the annual Sleep Meeting sponsored by the Associated Professional Sleep Societies.

Reminiscing about those early days of dealing with obstructive sleep apnea, Sullivan said it was as a stopgap measure that he came up with his 1981 device to keep blocked airways open by blowing air into the nose. His hope was to bring some temporary relief to OSA patients awaiting tracheostomies or other major surgery, then the only treatment for severe OSA. But it soon became clear that for most patients regular use of the machine made surgery unnecessary.

The A.W.A.K.E. gathering, cosponsored by the ASAA, was a special event held to launch the association's CPAP Assistance Program (see *related story, p. 3*). The key organizers were Barb Feider and Colleen Bazzani of Park Nicollet Health Services.

Also assisting was Tracy Nasca, a member of the ASAA board and vice president of Talk About Sleep, who is a frequent participant in Park Nicollet A.W.A.K.E.

Feider, the lead technologist for sleep disorders at Park Nicollet-Methodist Hospital, recalled in an interview that Dr. Mark Wedel, then medical director of the hospital's respiratory care department, read Sullivan's article about his vacuum-cleaner-powered device in *The Lancet* and called for such a machine to be built for the hospital. One was cobbled together, using an anesthesia mask and valves from a ventilator, and in early 1982 tried out on a patient with severe OSA who weighed 408 pounds.

The patient awoke in the morning "totally ecstatic" with the results, she said. ■

A.W.A.K.E. — ALERT, WELL, AND KEEPING ENERGETIC

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2 Band-Aids for your sleep apnea? Here comes a cheaper, no-machine airway opener

Obstructive sleep apnea patient, just imagine this scenario. It's nighttime and you're preparing for bed. Teeth brushed, nightwear on, you slip between the sheets, and you reach for...not for the face mask and long hose that tethers you to a PAP machine.



Rajiv Doshi, M.D.

No, you reach for a package that contains what look like a pair of inch-and-a-half-long oval Band-Aids with smaller oval plastic sieve-like devices inset in their centers. You stick one Band-Aid over each nostril, lie back against your pillow, and prepare for sleep. Provent therapy for your OSA is underway.

The little "sieves" that the Band-Aids hold over your nostrils are in fact valves that open and close depending on the direction the air is moving.

Inhalation is easy, exhalation much more difficult.

The resulting increased pressure from the exhaling lungs to force out the breath serves to open the airway in an odd mirroring of the action of a PAP machine.

The inventor of the Provent system, Rajiv Doshi, M.D., was trained initially as an engineer at Stanford University (B.S.E., 1994, M.S.E., 1998). Then he enrolled in Stanford Medical School, and was awarded his M.D. in 2001. As he pursued medicine, Doshi explained in a telephone interview from India, where he was traveling, the young physician became increasingly interested in the mechanics of breathing, and the phenomenon of sleep apnea.

"Wouldn't it be great if someone came up with a simpler system of keeping the airway open?" he said to himself, simpler, that is, than the cumbersome equipment array of even the best-designed positive airway pressure device.

Working in an emergency room during his medical training, Doshi recalled, he had assisted a patient in a crisis with chronic obstructive pulmonary disease. He noticed that as the patient struggled to breathe, there was a distinct pursing of the lips during exhalation. And he wondered why this was. In subsequent years, Doshi learned much more about the effects of breathing against resistance and its therapeutic benefits. He then had the counterintuitive notion that in obstructive sleep apnea, the effect of increased resistance during exhalation could linger long enough in the airway to ease the inhalation that follows. (The blocked airway that leads to obstructive sleep apnea generally obstructs inhalation, not exhalation.)

As he tells the story, he mentioned his thought to Jed Black, M.D, a professor at the Stanford Sleep Disorders Clinic, and received an encouraging response: "Hey, it's worth trying out."

So he did, working, like most inventors, on himself. Doshi was a chronic snorer. He knew that he was on the right track when he found with his wife's reporting assistance that the prototype design he'd come up with had cured his snoring. He concluded that if it worked on his snoring, it would likely also work on obstructive sleep apnea.

From that point on followed a swarm of activity. Patenting and further refining the nasal valves. Founding a company, Ventus Medical, to do several rigorous

Provent, continued on p. 2

A letter from Executive Director Edward Grandi



Preventable noncommunicable diseases, of which sleep apnea is one, are major killers and are wreaking economic havoc in the world, particularly in poor countries. In a significant shift in international health strategy, the

United Nations General Assembly has called a summit meeting to gather in New York Sept. 19 and 20 to explore how to respond.

The convening of the summit, or more exactly in U.N. speak, the “high-level meeting with the participation of heads of state and government,” is aimed at rolling back the killing impact of cancer, cardiovascular disease, chronic respiratory disease, and diabetes around the globe. It’s estimated that three out of every five deaths worldwide is attributable to one or another of these four principal noncommunicable diseases, or NCDs, and that many of the deaths could have been prevented or delayed.

Despite this heavy toll, international health attention up till now has been mainly focused on HIV/AIDS, malaria, and tuberculosis, all communicable diseases. Indeed, according to the NCD Alliance, the world’s donor nations have a policy of not funding efforts to battle noncommunicable diseases. (The NCD Alliance is a collaboration that claims a network of 2,000 health organizations around the world.)

As I look over the list of killer diseases to be considered at the summit as one concerned about sleep apnea, I can note that sleep apnea is known to be directly related to three of the four. And there are hints it may be related to the fourth, cancer, as well.

Having succeeded in getting NCDs on to a high-level international agenda, the NCD Alliance is now seeking to ensure that the summit goes beyond mouthing good intentions to engendering real change. The organization quotes approvingly a remark by Dr. Margaret Chan, secretary-general of the World Health Organization, at a preparatory meeting in April. Speaking critically of an initial list of vague objectives for the summit, she said: “Without global goals or targets, this is not going to fly—what gets measured gets done.”

The major measure to which the alliance hopes the world’s nations will commit is to reduce preventable deaths from the four main classes of NCDs 25 percent by 2025. And it’s pushing specific steps on how to get there.

—Edward Grandi

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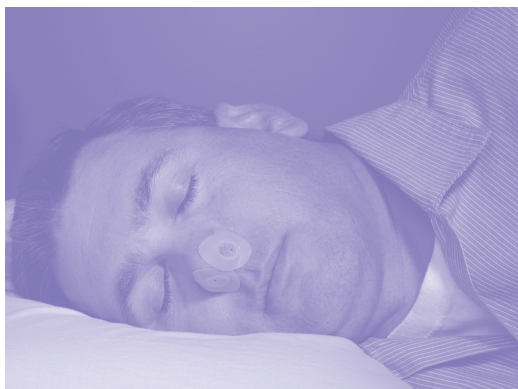
clinical studies and to manufacture and sell the one-time-use stick-ons. Seeking and obtaining approval of Provent by the Food and Drug Administration. Building a staff. Raising capital, which now totals \$62 million. According to Doshi, Ventus Medical’s largest single investor is Johnson & Johnson, the maker of among other things Band-Aids.

The effectiveness of Provent therapy has been supported by the findings of six published clinical studies including most recently the largest effort so far, a double-blind, sham-controlled study of 229 patients in 19 sleep centers scattered across the United States.

That study, authored by Richard B. Berry, M.D., Meir H. Kryger, M.D., and Clifford A. Massie, Ph.D., and published in the April 2011 issue of *Sleep* (34:4, 479-485), showed significant improvements in the Provent-using patients and an impressively high compliance rate, a median of 88.2 percent for all-night usage for the three months. Polysomnography of the test patients during the first week of Provent therapy showed the median AHI of the group dropping from 13.8 events per hour to 5.0, and a median reduction of 52.7 percent. At the end of three months of Provent therapy, the group registered a median AHI of 14.4 during a night without the devices in place compared to 5.6 during a night with them, and a median reduction of 42.7 percent.

The researchers reported similar significant positive effects of Provent use among the 17 in the patient group who had severe OSA (AHIs of higher than 30) at week one. Among these 17, the median AHI dropped from 48.2 breathing events during a night without the devices to 18.9 with them

Despite the high patient compliance rate reported in the Berry study, Michael Coppola, M.D., a sleep physician in practice in Springfield, MA, said



A sleeping OSA patient poses with no mask or hose, just two small Provent stick-ons, one over each nostril.

he had found the initiation of Provent therapy “much more difficult” for patients than its backers “would have you believe.” Coppola is president and chief medical officer of the ASAA.

David M. Rapoport, M.D., director of the sleep medicine program at New York University School of Medicine, who has studied Provent in operation in two clinical studies, said in an e-mail that the device appears

to cause a marked reduction in sleep apnea in about 50 percent of OSA patients who use it. The expiratory pressure generated by the Provent valve is not like CPAP, he cautioned, and the actual reason it works is complicated.

“We believe it may have three mechanisms of action. First, it inflates the lungs and at the end of expiration there is an increased pull on the structures of the upper airway, which may stiffen it, reducing the tendency to collapse and cause apnea,” Rapoport wrote. “Second, the elevated pressure at the end of expiration may slightly dilate the upper airway and this may carry over into inspiration despite the fact that there is no longer any pressure then (differing from CPAP, which maintains a continuous airway pressure). Third, the valves cause people to ‘underbreathe’ a little, which raises the CO₂ in the blood, and this may act to stimulate the upper airway muscles and stiffen them slightly.

“All three of the above appear to happen, but it is not clear which, if any, is the most important for the therapeutic effect.”

Rapoport, who is a member of the board of directors of the American Sleep Apnea Association, also noted that while breathing through the nose is mildly uncomfortable after one applies the Provent devices, breathing through the mouth removes all discomfort. “When you fall asleep, breathing spontaneously switches to the nose and appears to be tolerated well by most people,” he added.

The development of the Provent device has added a new letter to the growing alphabet of PAP possibilities. Along with the established CPAP, APAP, BiPAP and VPAP acronyms, comes now EPAP, or expiratory positive airway pressure. But EPAP, as represented by Provent, differs significantly from its PAP brethren. It does not require electricity. It is easily portable. It is simple to use. It is disposable. For the moment, it is relatively cheap, at around \$60 a month compared to price tags of hundreds or thousands of dollars for other PAP machines and their accessories.

Some observers believe Provent therapy may well alter the whole structure of how sleep apnea treatment is delivered. Unlike PAP machines, which are almost always prescribed by sleep physicians after a patient is tested in a sleep lab, a 10-day test supply of Provent therapy can be easily prescribed by a primary care physician or a sleep physician in combination with a home sleep study “to see if it works.” If it doesn’t, no harm done. If it does, another case of OSA has been brought under control much more directly and at much lower cost.

Coppola, however, questioned the appropriateness of primary care physicians prescribing Provent therapy on the basis of home sleep studies. Better that Provent therapy, if used, be at the direction of sleep specialists, he said. ■

At last, the ME registry

By coincidence, the long-awaited U.S. Department of Transportation rule creating a National Registry of Certified Medical Examiners seems likely to come into effect almost concurrently with the ASAA’s forthcoming Sleep Apnea and Multimodal Transportation Conference.

NEWS FROM



WASHINGTON

The conference, to be held Nov. 8 and 9 in Baltimore, MD, is designed to share the latest information on obstructive sleep apnea as the disease affects all sectors of commercial transportation: highway, rail, maritime, and air. The DOT creation of the registry of certified examiners will have a major impact on all operators of trucks and buses.

Everyone who holds a commercial motor vehicle operator’s license, known as a CDL, is required to be found physically qualified to drive by a medical examiner. After the proposed rule is published and its requirements phase in, the conducting of such examinations will be limited to health care professionals listed in the national registry and certified as to their knowledge of the health needs of commercial drivers.

A key concern of such medical examiners must be detecting undiagnosed OSA in license holders and obtaining a continuing assurance that drivers with OSA are fully compliant with an effective therapeutic regimen, in most cases PAP therapy.

The creation of the national registry has been a long time coming. It was originally mandated by legislation passed by Congress and signed by President Bush in 2005. Since that time the Federal Motor Carrier Safety Administration, a unit of the Department of Transportation, has labored over fleshing out the law into a fully developed rule. Publication of the rule has been delayed several times.

As of early August, however, the final language was in the hands of the office of Ray LaHood, the secretary of transportation, with the schedule calling for it to be submitted to the Office of Management and Budget for White House approval by Aug. 29, for it to receive OMB clearance by Nov. 28, and to be published in the Federal Register, making it law, Dec. 9.

The centrality of an effective medical examination to making highways safer is well established. In addition to its attention to other causes of disability, the examination increases the likelihood that commercial drivers will achieve healthier sleep, thereby reducing the number of sleepy drivers behind the wheel.

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ASAA IN BRIEF



Mark Seager

Donated PAP machines, some new, some “gently used” by their previous owners, piled into the Marriott West Hotel in St. Louis Park, MN, in June as the ASAA launched CAP, its CPAP Assistance Program.

Through the program, a needy obstructive sleep apnea patient can obtain a machine on nothing more than his or her physician’s statement that the patient needs a CPAP and can’t afford one. Details on applying for assistance (and for making donations) are available at www.donatedcpap.org.

The program is headquartered in Tracy, MN, a town of just over 2,000 residents that’s 160 miles southwest of the Minneapolis/St. Paul metropolitan area. Mark Seager, who runs the program, is a volunteer. A sleep apnea patient himself, he is a pulmonary technologist who makes his living as proprietor of SecondWindCPAP.com, a vendor of reconditioned used PAP machines, and of Prairie Home Medical, which retails a general array of durable medical equipment.

Seager got into the business of secondhand PAP machines after receiving his diagnosis of OSA, he said in an interview. As it happened, his medical insurance covered the testing that established he had sleep apnea but provided no funding for purchase of the device he needed to treat it.

“Then I discovered what new machines cost,” Seager observed dryly.

He also discovered that no company he could find specialized in the sale of used machines. So he decided to start one. Not surprisingly, given Tracy’s remoteness, SecondWindCPAP and the CPAP Assistance Program are operations conducted almost entirely by internet and by mail.

Seager and his family previously lived in Phoenix, AZ, but decided seven years to opt for small town life. They chose Tracy because Seager’s wife is a native of Walnut Grove, MN, an even smaller town (population 871) eight miles east of Tracy.

One of CAP’s first moves after it was organized was to ship 30 gift CPAP machines to tornado-devastated Joplin, MO, for distribution to tornado victims needing them. ■

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News From Washington, continued from p. 3

The broadening of the agenda of this year's ASAA transportation conference, which last year focused on highway transportation alone, signals a widening awareness of the risks posed by sleepy operators at the controls. The 2009 incident in which a Northwest Airlines flight bound for Minneapolis-St. Paul flew 150 miles beyond its destination before turning back, possibly because the pilots were asleep, made its mark.

Among the speakers and panel participants expected at the conference who represent this broadening are Bernard Arseneau, D.O., M.D., medical director of the Federal Railroad Administration; Laura Gillis, M.D., medical director of the U.S. Coast Guard; Peter Gimbrere, a lawyer on the staff of the National Air Traffic Controllers Association who specializes in occupational fatigue issues; Jeff Moller, assistant vice president of the Association of American

Railroads; and Quay Snyder, M.D., president of the Aviation Medicine Advisory Service.

They will be joined by various officials of the National Transportation Safety Board, the Federal Motor Carrier Safety Administration, and other agencies of the Department of Transportation; by representatives of a wide variety of firms and other organizations within the transportation industry; and by professionals from the sleep medicine community experienced in occupational safety issues in transportation. ■

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FROM THE AMERICAN SLEEP APNEA ASSOCIATION

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