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, MN, 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 Aneuenea, 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 safety 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 representatives 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.

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

Dr. Colin Sullivan, the Australian inventor of the CPAP machine, delighted those present at a lunch 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 1980s 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 the National Transportation Safety Board, 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.

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. Proven 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 exhalation 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 series of patient testing and further refining the nasal valves. Founding a company, Ventus Medical, to do several rigorous...
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 special summit meeting to be held 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 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 among diabetes, cancer, and cardiovascular disease, I can’t help but wonder about sleep apnea, a disease that may be 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 approvingly a remark by Dr. Margaret Chan, secretary-general of the World Health Organization, at a preparatory meeting in April. Speaking

The development of the Provent device has added a new letter to the growing alphabetical of PAP possibilities. Along with the established CPAP, APAP, BiPAP and VPAP acronyms, comes now another, PAP, a device that eliminates the need for a pressure. But EPAP, as represented by Provent, differs significantly from each of its PAP brethren. It does not require electricity. It is simple to use. It is disposable. For the moment, it is relatively cheap, at around $60 a month compared to prices in the 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 before a patient is identified with sleep apnea, the Provent is a sleep lab, a do-it-yourself test 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 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.

A sleeping OSA patient poses with no mask or hose, just two small Provent stick-ons, one over each nostril. Provent, continued on p. 2

The DOT creation of the registry of certified examiners will have a major impact on all operations of truck and buses.

Every one of the nearly 9 million commercial motor vehicle operator’s license, a card, is required to be purchased by a physician as evidence of the need for PAP therapy. The DOT’s plan is to sell that card, a personalized card, for $25.

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 regulatory program. 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 reach the OMB clearance by Nov. 28, and to be published in the Federal Register, making it law, Dec. 9.

The provisions of the rule, which aim to streamline examination to make 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.

At last, the ME registry

A letter from Executive Director Edward Grandi

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 $40 million, or approximately $5 million a month. To Doshi, Ventus Medical’s largest single investor is Johnson & Johnson, the maker of among others many Band-Aids.

The effectiveness of Provent therapy has been supported by the findings of six published clinical studies that were the first 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. Mass, M.D., 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 first 3 months. Polysomnography of other patients who did not comply found that 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 4.4, 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 (AHI of higher than 30) at week one. Among these, 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 he had found the initiation of Provent therapy “much more difficult” for patients than he “would have you believe.” Coppola is president and chief medical officer of the ASA.

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 email 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 is not like CPAP, he cautioned, and the actual reason it works is complicated.

Three key elements are important. First, the increased expiratory pressure during a night without the devices to 18.9 with them. Among these 17, the median AHI dropped from 48.2 breathing events during a night without the devices to 18.9 with them.

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Among the speakers and panel participants expected at the conference who represent this broadening are Bernard Anseau, 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 are being 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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ASAA in Brief ............................................... p. 2
Letter from the Executive Director ............... p. 2
Editor and Ask the Doctor .................................. p. 2
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Rajiv Doshi, M.D.

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