

Ventus gets ‘bullet-proof’ data that Provent works

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Even the very best therapeutic device won't work if the patient refuses to use it.

Physicians who treat obstructive sleep apnea (OSA) have faced this dilemma for years; continuous positive airway pressure (CPAP) therapy – the current gold standard – works, but a lot of patients refuse to use it, or won't use it as long as they need to.

“We're talking about a chronic disease, and the person that treats the chronic disease is the patient, and if the patient doesn't use the device then it's worthless,” Philip Westbrook, MD, told *Medical Device Daily* from a noisy gathering of sleep experts in San Antonio on Monday.

According to **Ventus Medical** (Belmont, California), two studies were presented this week at the Sleep 2010 meeting of the **Associated Professional Sleep Societies** (APSS; Westchester, Illinois) in San Antonio – including one that was a randomized, multi-center trial – that confirm the clinical efficacy of the company's Provent sleep apnea device.

“With the large randomized multi-center clinical trial we finally have bullet-proof clinical data that this thing really works, and works very well,” said Westbrook, the chief medical officer at Ventus.

He said the studies presented at the Sleep meeting show that the Provent device works – not for everyone, but for a large percentage of patients – and that the compliance to the therapy is “excellent.”

“It's an easy disease to diagnose, but it's a very difficult disease to treat, and now we have another [device] in our toolbox,” Westbrook said.

At the Sleep meeting, James Walsh, PhD, executive director of the Sleep Medicine and Research Center at **St. Luke's Hospital** (St. Louis, Missouri) reported that patients using Provent therapy had clinically meaningful and statistically significant decreases in the apnea-hypopnea index (AHI) – a measure of breathing disruptions during sleep. The therapy was accepted by 80% of patients who had previously refused CPAP therapy or used CPAP fewer than three hours a night on average. The study also found that Provent therapy use improved blood oxygen saturation, and resulted in less daytime sleepiness as measured by the

Epworth sleepiness scale, the company noted.

“Current treatment options for obstructive sleep apnea are suboptimal,” Walsh said. “When used properly, CPAP essentially eliminates sleep apnea, but a large percentage of patients are non-compliant and express significant dissatisfaction with CPAP. These data provide evidence that Provent is a treatment option for many patients who were unable to tolerate or unwilling to try CPAP therapy.”

Ventus describes the Provent therapy as a “simple, non-invasive prescription treatment that works across mild, moderate, and severe OSA.” The treatment uses nasal expiratory positive airway pressure (EPAP) and the device incorporates a valve design that is placed over the nostrils and secured with hypoallergenic adhesive, the company said. During inhalation the valve opens, allowing nearly unobstructed airflow, and during exhalation the valve closes, directing airflow through two small openings, which increases expiratory airway pressure.

After Walsh presented his study findings Monday, the Ventus booth at the meeting was buzzing with interest from the physician attendees, according to Meir Kryger, MD, a clinical professor of medicine at the **University of Connecticut** (Storrs) and director of Sleep Medicine Research and Education at **Gaylord Hospital** (North Haven, Connecticut).

“I'm standing in front of the program booth and it's crawling with people who are interested in this thing, and they're asking for samples and more information so there's a lot of interest in it,” Kryger told *MDD* during a phone interview from the meeting.

Although many of the patients involved in the study responded very well to the treatment, Kryger said, “we don't know exactly yet how to identify the ideal patient.” He said the treatment is so new that “all of us are [still] learning” how best to implement the therapy.

Kryger also emphasized the importance of patient compliance when treating patients with OSA.

“People who use [Provent] use it every night and they use it all night, and that's always been a problem with CPAP,” he said. “Compliance is not fabulous and a certain percentage of people simply will not use CPAP.”

Also during the Sleep meeting, Richard Berry, MD, from the **University of Florida** (Gainesville), reported results

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from a multi-center, randomized, controlled trial of Provent versus a placebo (or sham) device for OSA. This study also showed that Provent therapy significantly reduced AHI, improved oxygen saturation in the blood as well as reduced daytime sleepiness when compared to the sham device.

“Many OSA patients are inadequately treated due to adherence or efficacy issues with current therapy. Alternative effective treatments for OSA are needed,” Berry said. “The results of the study suggest that Provent therapy is an effective treatment alternative for a substantial percentage of OSA patients.”

The Provent device received FDA clearance in 2008, but the company has been used mostly at trial centers rather than being aggressively marketed while Ventus builds phy-

sician confidence, and a payor foundation, by developing clinical evidence of the device’s effectiveness (*MDD*, June 15, 2009).

Kyger said he is “delighted” that there are now other options to treat OSA patients besides CPAP.

“The main thing is . . . with any disease you have to move forward with new treatments and there really have not been a lot of options with CPAP,” Kryger said. “CPAP is an excellent treatment, but for some people it’s not the best fit.” ■

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