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The future of sleep medicine and the business of sleep

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Over 12 years ago, an editorial in the *New England Journal of Medicine* [1] asserted that untreated sleep-disordered breathing (SDB) and particularly its major manifestation, obstructive sleep apnea (OSA), was a major public health problem equivalent to smoking. It was further suggested that it was time for the nation to wake up to sleep. Sadly, while this was an apparent clarion cry to action, there has been a marked reluctance on the part of the medical establishment to address this issue with the sense of urgency required.

In the ensuing decade, the links between SDB/OSA and such serious comorbidities as hypertension, stroke, congestive heart failure, and diabetes have become better appreciated and defined. No person who keeps abreast of the clinical literature in any of the medical specialties could remain ignorant of the impact of untreated SDB. As a result, the sleep industry will play an increasingly pivotal role in treating the leading causes of morbidity and mortality in the developed world.

Cardiovascular disease alone costs the United States healthcare system more than US\$200 billion annually. Clinical data [2–7] show that 30–80% of patients with hypertension and other cardiovascular diseases have SDB. In fact, the National Institute of Health's Joint National Committee on High Blood Pressure lists sleep apnea as the first of nine identifiable

causes of hypertension (JNC 7, May, 2003). Perhaps more importantly, data show that cardiovascular outcomes can be improved by treatment with nasal continuous positive airway pressure (CPAP). Effective CPAP therapy reduces arterial blood pressure by 10 mmHg after 9 weeks of therapy [8]. One month of CPAP improves daytime blood pressure, heart rate, and left ventricular function [9]. As mentioned, of the order of US\$200 billion is spent annually in the United States on treating cardiovascular disease. One could speculate at length as to how many of these dollars could be saved by increased treatment of SDB/OSA, but it could well be in the vicinity of several billions of dollars. Time will tell.

In addition to well-established cardiology data, studies in endocrinology have begun to emerge, such as a recent study on SDB/OSA prevalence in type 2 diabetics, presented by Erman at the Associated Professional Sleep Societies' annual meeting in June of 2005. The study, conducted at the Scripps Whittier Institute for Diabetes in La Jolla, showed that 72% of 62 type 2 diabetic patients had some form of SDB (apnea-hypopnea index greater than five), based on full polysomnography (PSG). In addition, James Herdegen and colleagues in Chicago [10] found that postprandial glucose levels could be reduced by as much as 40% when diabetic patients are successfully treated with nasal

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CPAP. This dramatic fall in post-prandial sugar might not be seen in all cases, particularly in those type 2 patients who have been receiving insulin for an extended period of time, but the data are somewhat compelling. Furthermore, the data suggest the need to evaluate the level of SDB in all type 2 diabetic patients, particularly as nasal CPAP treatment appears to treat both the diabetes and the SDB.

As we look to the future of healthcare and to the opportunities for the sleep business, our industry must transition from an excessive focus on lab-based diagnosis of SDB towards efforts to more simply detect and manage the millions of patients who suffer from this condition, the vast majority of whom remain unaware, and therefore, untreated. We must consider, with appropriate circumspection, the current diagnosis and treatment paradigm. First, a conventional history and physical, if done by a properly trained physician, should result in an 80% probability of a correct diagnosis of SDB, so a confirmatory diagnosis should rarely require full PSG but far simpler screening procedures. Second, nasal CPAP is arguably one of the safest treatments available to the medical community. Average CPAP pressure throughout the world is less than 10 cm of water or about 1% of atmospheric pressure. In fact, based on recently published prospective data from Spain in a suitably large group of patients, Dr. John Stradling at Oxford suggested full PSG should be reserved for patients who do not respond to CPAP [11].

To ease the overwhelming healthcare burden of SDB, our industry must increase both the number of patients who are treated and the percentage of patients who remain on therapy. The first half of this equation requires that we reach the tens of millions of untreated OSA sufferers through awareness, education, and increased diagnostic capacity. The second half of the equation requires that once a patient is successfully initiated on to treatment,

there needs to be a focus on both compliance and efficacy and a total commitment to better patient care.

Since ResMed was founded in 1989, we have been dedicated to addressing the challenge of untreated SDB by increasing awareness among both the general public and physicians and by concomitantly improving technologies to increase patient comfort, compliance, and efficacy. To address awareness, we have set up ResMed Foundations in both Australia and the United States to help lift the veil of ignorance about the serious consequences of untreated SDB/OSA. In addition, we are jointly funding a national public relations program (together with Respiroics) to publicize the dangers and pitfalls of undiagnosed SDB/OSA. To address comfort, compliance and efficacy, we have developed fully automatic CPAP devices based on a preemptive measure of flow limitation; published data [12–20] do show that our AutoSet technology does indeed improve acceptance of therapy, compliance, and concomitantly permits determination of efficacy.

Raising awareness and promoting education

Unfortunately, there is an appalling lack of education about sleep and SDB/OSA in medical schools. As a consequence, physicians often incorrectly refer patients with SDB to urologists (for nocturia), gastroenterologists (for reflux), cardiologists (for atrial fibrillation and bradyarrhythmias), neurologists (for morning headaches), psychiatrists (for depression) and so on, without any appreciation for the underlying SDB pathology. For several years, ResMed has been investing in educating primary care physicians and specialists on the connection between SDB and such serious comorbidities as the potential for perioperative deaths, diabetes, stroke, congestive heart failure, and hypertension. By partnering with sleep specialists to educate

their physician colleagues on the importance of treating SDB, we hope our industry can overcome the unfortunate lack of formal sleep education in medical schools. We view this approach as the *Hub and Spoke Model* (Fig. 1). The focus is to drive patients to the center of the “wheel” by educating physicians and the general population to refer patients in need of a sleep evaluation to sleep specialists.

Through the aforementioned Foundations, we also supply funds for clinical studies, and we attempt to provide education on sleep-related symptoms to physicians who deal directly with patients at high risk for SDB. Sleep specialists have an opportunity to lead the way in this educational process, and in so doing, improve patients’ health and increase standards of care by having more patients initiated on to therapy.

Increasing treatment capacity

Awareness of SDB is growing rapidly, yet today, less than 20% of the estimated 24% of the American adult population affected with SDB (~5% of the adult population) have been diagnosed. The vast majority of SDB sufferers are undiagnosed and are unaware of the serious health risks they may be facing. As awareness continues to accelerate, we must develop more innovative methods to treat millions of additional patients each year. In this vein, John Stradling of the Oxford Center for Respiratory Medicine in England (referenced above) stated in a recent editorial:

It has been realized by many that the purpose of the sleep study is really to detect sleep fragmentation due to upper airway obstruction or, even more pragmatically, ‘CPAP-responsive disease’...There is now a real acceptance by most that simplified tests are clearly the way of the future in routine clinical practice, particularly in the face of increasing disease burden [11].

Lending further practicality to this paradigm is the fact that nasal CPAP is an amazingly safe and effective treatment. At a pressure level of 1% of atmospheric pressure, one might argue that CPAP therapy is safer than aspirin. Many sleep specialists are embracing the paradigm of doing ambulatory or at-home diagnosis/screening of SDB/OSA as a way to increase the number of patients that they are able to help, thereby, growing their business in the process. In short, a growing number of sleep specialists have incorporated into their practices, the latest technologies that provide an alternative to full-night PSG for straightforward cases of OSA, and their patients have benefited. These sleep specialists are leading a profound evolution in our industry by focusing their efforts on treating more patients more efficiently and more effectively. These physicians are leading a changing paradigm, not only by helping more patients but, based on a growing list of peer-reviewed publications, also by most likely improving outcomes in serious comorbidities, such as cardiovascular disease and diabetes, as well as easing the financial burden of untreated SDB patients on the health-care system.

Increasing compliance and ensuring efficacy

In addition to providing expanded care to more SDB sufferers, it is critical to provide better care to the relatively small fraction of patients who have been diagnosed and are currently being treated. Studies have shown the importance of patient compliance and effective therapy, yet nearly all prospective studies in the clinical literature do not measure efficacy along with compliance; it tends to be assumed. In our efforts to continue to demonstrate improvement in the serious comorbidities associated with SDB, we need to ask ourselves, what

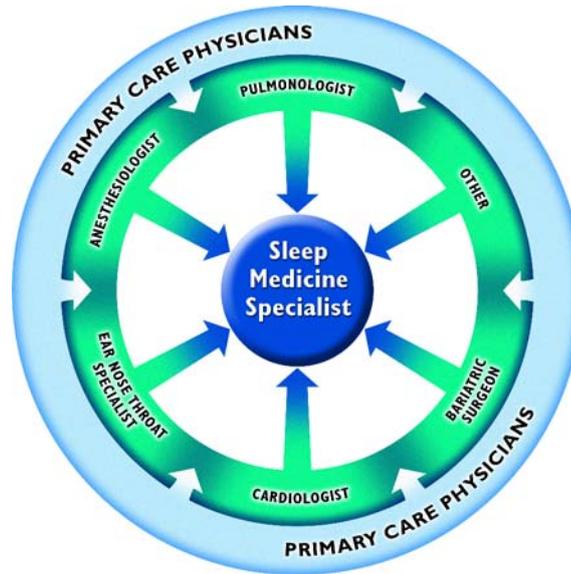


Fig. 1 The hub and spoke referral model for SDB

is the point of doing a prospective study if one does not absolutely know that the treatment is therapeutically effective? These issues are equally important in a clinical setting, where compliance without proper efficacy can have serious negative implications for patient health. Unfortunately, if patient service and follow-up are neglected, both the patient and the industry will lose. A patient's health will suffer over the long term and those in the sleep "business" will lose a long-term customer. Our industry needs to advocate treatment paradigms that support ongoing patient care if the business of sleep is to grow and continue to help patients in a way that is both clinically and economically sound.

Summary

Industry and ResMed, in particular, will address the challenge of untreated SDB by increasing awareness among the general public, as well as physicians, and by continuing to develop better technologies to increase both compliance and efficacy. We are promoting a *Hub and Spoke Model* as

one sensible approach to "The Business of Sleep." The concept is a reflection of our commitment to waking people up to sleep and breathing and to improving patients' lives.

Sleep specialists can have a tremendous impact on the progress and growth of the industry by educating fellow physicians and the public about the serious health consequences of untreated SDB, increasing the treatment capacity of their practices, and advocating better patient care by the caregivers with whom they deal. Our industry has made much progress, but we cannot be satisfied until the millions of undiagnosed SDB patients have been given the opportunity to receive treatment. Too many lives are at stake, and countless healthcare dollars are being wasted by too many people failing to address the underlying health problems associated with untreated SDB, which, more than a decade ago, was classified as a major public health problem. It still is, and the issue requires serious and concerted attention by all of us who have a stake in better health care through better sleep.

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