Spotlight on Innovation

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A medical student's perspective on the future of obstructive sleep apnoea management

BY KATHY BACH

Obstructive sleep apnoea remains an immensely challenging condition to treat. Many treatments have been used over the years, but no single management strategy has proven significantly better than the others. We hear about some technological innovations in the field of sleep medicine.

As a medical student, I have the luxury of having more time to spend at the patient's bedside. In these interactions, I have had the opportunity to listen to my patient's success stories and satisfaction with patient care, but also, most importantly, their understanding of their health conditions and concerns with their disease management. Occurring more frequently, I will walk into a fatigued patient's room only to find their sleep apnoea equipment neglected in a corner. Even to a medical student, it is clear that there is room for improvements in sleep apnoea management.

Obstructive sleep apnoea (OSA) is the most common sleep-related breathing disorder defined by recurrent episodes of apnoea and hypopnoea due to pharyngeal collapse. OSA severity is classified by the number of apnoea and hypopnoea events recorded by polysomnography. It is estimated that 936 million adults aged 30-69 worldwide have OSA, with almost 50% of cases classified as moderate to severe OSA [1]. These numbers continue to increase as obesity and old age become more prevalent in the population.

Affected individuals are negatively impacted in their daily lives, with symptoms of daytime sleepiness, fatigue, and poor concentration, as well as long-term consequences, with a higher risk of developing hypertension, metabolic disease, cardiovascular disease, and neurocognitive impairments [2]. These symptoms also contribute to serious, life-threatening events such as motor vehicle collisions and workplace accidents that further add to the annual economic burden of OSA due to increased healthcare utilisation and management of associated comorbidities [3]. Despite our better understanding of the disease pathogenesis, the clinical implications on health, and the public health impacts, many cases of OSA remain undiagnosed or misdiagnosed [1]. Factors that contribute to this include the involvement of multiple anatomical parts and patient risk factors. To address varying presentations of OSA, various treatment options have been developed over the last several decades.

Invented by Dr Collin Sullivan in 1980, continuous positive airway pressure (CPAP) remains the gold standard for sleep apnoea medical management [4]. However, its

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effectiveness is often limited by patient compliance due to complaints of discomfort, inconvenience, frequent nighttime awakenings, and patient complaints [5]. For patients who struggle with CPAP compliance, surgical treatment seems like an appealing next option. However, frustrated patients may not even be recommended surgery as they must be carefully evaluated. To undergo the most effective surgical option, maxillomandibular advancement, patients must be young, non-obese, and without comorbidities [6]. The most commonly performed surgery for obstructive sleep apnoea (OSA), uvulopalatopharyngoplasty, was previously thought to have poor success rates, but has more recently been shown to have up to 80% success rates with appropriate patient selection based on Friedman staging [7]. As with all surgeries, these options pose concern for postoperative disability and possible long-term complications, in addition to the nuisances of patient selection to achieve good outcomes.

Alternatives to CPAP and surgical management include lifestyle changes like weight loss, positional therapy, tongue and throat exercises, and oral appliance use [8]. Unsurprisingly, these lead to similar non-compliance issues as seen with CPAP. With the goal of addressing these issues, several innovations have drawn interest and attention, and provided hope for having a wider range of medical management options that can encompass differences in patient scenarios.

Currently still in development, Airing's micro-CPAP claims to potentially become the world's first maskless, hoseless, and cordless CPAP device, avoiding most of the common complaints with using a traditional CPAP machine [9]. This battery-powered micro-blower would have nose buds to hold the device in position, while producing pressures up to and exceeding those of traditional CPAP machines. In order to hold enough power while maintaining its small size, it would be designed for single use. To ensure affordability, it is estimated to cost $3 per device and even less with insurance reimbursement. The device's effectiveness will depend on its motor's ability to produce high enough pressures to stent open the upper airway while maintaining its compact size. Patient compliance and tolerability with wearing the device nightly while being able to keep it in position throughout the night, will be crucial. With ongoing research and development since 2015, it seems it will still be some time before Airing will have a prototype that meets its highly-anticipated promised specifications. Traditional CPAP users and hopeful patient consumers are supportive of this idea, as evidenced by eager donations to Airing's crowdfunding.

A new removable tongue muscle stimulation device called eXciteOSA was developed by Signifier Medical Technologies. The device was FDA approved February 2021 [10]. A prescription is required to purchase the device. Unlike the standard training devices that patients use while they are asleep, this is the first device designed to be used while the patient is awake. The awake patient wears the reusable training device mouthpiece for 20 minutes daily for the first six weeks, and then once a week thereafter. The device delivers electrical pulses to improve tongue muscle function with the goal to prevent posterior displacement of the tongue and subsequent airway obstruction during sleep. After eight weeks of use, patients with mild OSA were seen to have an average apnoea-hypopnoea index (AHI) reduction by almost 50%. Side effects reported included excessive salivation, tongue and tooth discomfort, metallic taste, and gagging. This device requires careful patient selection as it is only indicated for snoring and mild OSA. It is also limited by its contraindications for patients with mouth lesions or implants, pacemakers, or pregnancy.

Used for decades by anaesthesiologists, nasopharyngeal techniques have been utilised to prevent upper airway obstruction in patients with facial burns or airway compromise [11]. Several physicians realised that this concept drew parallels to OSA management. The goal was to mechanically splint open the upper airway to aid in breathing. Walsh and colleagues pioneered this concept in 1972 without polysomnographic (PSG) data [12], and Guilleminault and colleagues in 1975 with PSG data [13]. Unfortunately, their studies showed no impact in reducing OSA events. In 1981, Afzelius and colleagues finally reported complete cessation of severe OSA in two patients after six months using a 30 French nasopharyngeal airway [14]. The translation of a nasopharyngeal airway to everyday OSA management understandably sparked concern for patient compliance and tolerability, anatomical considerations, and side effects resulting from daily insertion and removal of a tube in the nasal passages [15,16]. In 2019, a case report described a patient with mild nasal septal deviation who achieved improvement in sleep quality and snoring after six years of using a nasopharyngeal stent [17].

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Developed by Seven Dreamers Laboratories in Japan, Nastent is a daily disposable silicone tube inserted through a nostril with the tip at the level of the soft palate and secured with an external nasal clip [18]. The tubes can be ordered online and each tube costs about $6. The device is not currently available in the United States. There is scarce data that shows the tube improving snoring and increasing the lowest oxygen saturation levels measured in OSA patients up to one week [19-20]. However, patient compliance remains an alarming issue with the Nastent, as a recent study shows poor tolerability in healthy BMI, mild to moderate OSA patients [21]: 33.3% of patients did not tolerate the tube at all. Only 29.4% of patients consistently used the tube daily for a duration of one month. In addition, the tube is contraindicated in patients with upper respiratory disorders.

The AlaxoStent is an FDA registered, reusable nitinol-braided stent originally designed in Germany [22]. It is placed with a plastic introducer, advanced as far as the lower oropharynx, and secured in position with an external plastic disk taped to the ala. The 15cm-long, cone-shaped stent expands to a lumen of 1cm at the distal end and 5mm at the proximal end. A training period is required in which the user learns to tolerate the stent for longer periods of time over several days. This process is described as being analogous to a new contact lens wearer. A prescription is required for the first order, with the stent costing about $2 per day of use. Efficacy was greatest for isolated palatal collapse with complete resolution of apnoeic episodes [23-24]. Multisegmental airway collapse showed partial to complete resolution. The stent is also useful in determining patient selection for OSA surgeries. The AlaxoStent reduced the average AHI less than CPAP, but both could reduce the average number of obstructive apnoeas by greater than 94% [25]. The AlaxoStent also showed comparable responder rates to those of traditional surgical interventions. While these initial studies show hope for an alternative to current management methods, further research is needed to further evaluate the stent's efficacy in treating sleep apnoea and nasal obstruction long term, and in patients with higher BMIs. Similar to the Nastent, it will be interesting to see future research on patient compliance and tolerability as patient buy-in would be crucial for finding a competitive alternative to CPAP.

Great strides have been made in the development of unique medical devices and medical alternative options for OSA management. OSA remains a complex disease to treat owing to its involvement of many anatomical and patient factors. However, this complexity gives rise to a wide range of possibilities for future innovations and opportunities, as demonstrated by the different medical devices mentioned above. As more research continues to be performed and new technology developed, it is of utmost importance that they embody the ideal of patient-centred care and approaches to treatment while remaining cost effective. Without adequate patient acceptance, cooperation, compliance, and health literacy, we end right back where we started with decreased quality of life and high morbidity due to ineffective OSA management. Fortunately, OSA management is headed in the right direction with the potential for effective and patient-friendly management options. I look forward to seeing how these innovations will benefit millions of patients worldwide in the near future as I start my career in medicine.

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