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AerSleep™ for the treatment of Obstructive Sleep Apnoea

Keywords: medical device, continuous negative external pressure, cNEP collar, OSA, sleep-related breathing disorder

SUMMARY OF TECHNOLOGY

AerSleep™ is a portable, non-invasive device indicated to treat obstructive sleep apnoea (OSA). This device was developed by Sommetrics Inc., USA.

The device uses aer™ technology [formerly known as continuous negative external pressure (CNEP)] which uses the application of negative external air pressure on the submental area to gently open the airway from outside. It consists of silicone rubber collar which is lightweight and has a quiet air/vacuum pump that automatically regulates and maintains therapy.

The usage of aerSleep to treat OSA was approved by Health Canada on 8 June 2017 as Class II medical device which requires a prescription from a physician.[1]

The concept of continuous external pressure has been used in previously manufactured device produced by the Sommetrics Inc. known as aerFREE™ Airway Management System (AMS). AerFree has received approval by U.S FDA as de novo class II medical device on August 18, 2014. The device consists of a single patient use, soft, flexible collar and vacuum tubing. The external negative pressure is

supplied by a regulated external vacuum source in the operating range of -40 to -48 cm H2O (-29 to -35 mm Hg). The aerFree is indicated to be used as an aid for maintaining the patency of the upper airway in spontaneously breathing adults undergoing medical procedures less than two hours in duration, where the patient is intended to have mild to moderate sedation with non-propofol containing medications.[2]

POTENTIAL FOR IMPACT

According to WHO, obstructive sleep apnoea syndrome is a clinical disorder marked by frequent pauses in breathing during sleep usually accompanied by loud snoring.[3] Patient suffers a series of symptoms, such as apnoea, snoring, sleep fragmentation, daytime sleepiness with cognitive and attention deficit, which seriously reduce the quality of life of the individuals.[4]

Prevalence of OSA in general adult population ranges from 9% to 38%. Obstructive sleep apnoea prevalence was also greater among obese adults.[5] Locally, a cross-sectional study conducted at Northern part of Malaysia, evaluated the prevalence of snoring and breathing pauses during sleep in an adult population reported that 43.7% were habitual snorers. The prevalence of clinically suspected OSA increases with age, as categorically reported below:[6]

- 30–39 years, 5.2%
- 40–49 years, 7.6%
- 50–59 year, 8.1%
- ≥60 years, 7.2%

Presently, OSA is now recognised as an emerging major health problem and a high burden disease attributed to its contribution as independent risk factor for cardiovascular disease, metabolic and psychiatric disorder.[5] It has been shown that OSA patient also has a two- to-sevenfold increased risk of being involved in motor vehicle accidents (MVAs).[7] It was attributed to excessive daytime sleepiness (EDS) as part of the symptoms of OSA.[8]

After thorough evaluation, several options are available for treatment of OSA. The treatments can be divided into two major categories which are non-surgical and surgical therapy. Conservative treatment is usually the first line of management for sleep apnoeas unless they are severe and frequent. Weight reduction has been recommended on the basis that it should decompress the upper airway and promote its patency, particularly for obese patient. Advices for lifestyle modification includes

improve the sleep environment, avoid caffeinated drinks in the evening and other stimulants, increase physical activity during the day to improve the sleep/wake patterns and avoid daytime naps and also avoid excessive alcohol intake in the evening. According to a Cochrane review, there was lack of randomised controlled trial data with regards to the effectiveness of weight loss, exercise and sleep hygiene techniques in the treatment of OSA.[9] Other non-surgical treatments include positive airway pressure (PAP), positional therapy, oral appliances (OA), drug therapy and transcutaneous electrical stimulation. Whereas, surgical treatments include nasal surgery, oral/palate surgery, hypopharyngeal surgery and other operations, such as orthognathic surgery, hypoglossal nerve stimulation, tracheostomy and multi-lateral surgery.[10]

This new technology is an option of non-surgical treatment which has been proposed to treat OSA particularly for those who are non-compliant to CPAP therapy.

There were only two retrievable evidence found regarding the described technology.

A prospective, open-labeled pilot study evaluated the effect of continuous external negative pressure on 15 OSA patients recruited from American Academy of Sleep Medicine (AASM) accredited sleep clinic who have apnoea-hypopnoea index (AHI) > 15 events per hour on polysomnography (PSG) or home sleep apnoea testing. The mean age was 55.5 years, and the mean body mass index (BMI) was 34.8 kg/m^2 . The mean AHI prior to the application of cNEP was 43.9 events/h, with a range of 15.5 to 79.6 events/h. Response to cNEP was categorised in a manner similar to AASM standards for CPAP. “Excellent response” was defined as an AHI < five events/h and a “partial response” was defined as a reduction of AHI of > 50% from baseline and a AHI of < 15 events/h. Subjects who did not meet either criteria were considered non-responders. The result showed that nine (60%) of the patients exhibited an excellent response and four (27%) had a partial response. Two subjects (13%) did not respond. For responders, the mean negative pressure required to minimise the AHI during cNEP titration was 29.2 cm H_2O. Adverse events were observed in three subjects. Two had mild cutaneous erythema where the cNEP collar was in contact with skin and one had mild blistering at the contact site. All adverse events resolved without the need for clinical intervention.[11]

Another prospective study conducted in Chiba Japan measured the effect of negative external pressure on pharyngeal airway collapsibility among obese and non-obese women executed under anaesthesia and paralysis. A total of 21 women were recruited who undergone elective surgery, mostly for breast cancer and they were divided into obese group which was defined as body mass index (BMI) ≥ $25kg/m^2$ and non-obese group with BMI < $25kg/m^2$. After paralysing the patients, the patients were ventilated through a modified nasal CPAP mask with positive pressure

through an anaesthetic machine. A slim endoscope was inserted through the center of a soft silicone cork in the nasal CPAP mask without air leakage to visualise the retropalatal (RP) and retroglossal (RG) airways. The inserted endoscope was moved to visualise the different pharyngeal segments but insertion length of the endoscope was kept constant for each pharyngeal segment. A closed-circuit camera connected to the endoscope recorded pharyngeal images on a videotape along with pressure readings from a water manometer. The appropriate-sized cNEP collar was applied and connected to a vacuum source to produce preselected constant negative pressures inside the collar. The measurement calculated at zero pressure (NEP_{ZERO}), -25cmH_20 negative external pressure (NEP_{25}) and -50cmH_20 (NEP_{50}). The result showed that in non-obese subjects, application of submental negative pressure (-25 and -50 cmH_2O) significantly decreased closing pressures at the RP airway by 2.3 ± 3.2cmH_2O and 2.0 ± 3.0 cmH_20, respectively. Similarly it decreases closing pressure of RG airway by 2.9 ± 2.7 cmH_2O (NEP_{25}) and 3.7 ± 2.6 cmH_2O (NEP_{50}). It also showed that the application of -50 cmH_2O submental NEP increased the airway size, particularly at lower lumen in both RP and RG airways in the nonobese subject with a BMI of 19.8 kg/m^2. Among the obese group, there was no significant mechanical changes observed during application of submental negative pressure. It was postulated that the displacement of fatty tongue base in obese subjects is expected to be difficult because of relative higher Young's elastic modulus at the tongue base, accounting for no collapsibility changes in obese subjects during submental NEP.[12]

The price of this device is still unknown. Comparatively, the price of positive airway pressure device ranges from RM2000 to RM3000 depending on the producing company.

There was only one study found showing promising benefit from the technology described. The study mentioned had very small sample size. The other evidence showed proven benefit only among non-obese patient. Therefore, more high-quality evidence is needed on the effectiveness, safety and cost-effectiveness of this device.

EVIDENCE

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Kato S, Isono S, Amemiya M et al. Submental negative pressure application decreases collapsibility of the passive pharyngeal airway in nonobese women. Journal of Applied Physiology. 2015;118(7):912-920.

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