

# SLEEP-GOAL: A multicenter success criteria outcome study on 302 obstructive sleep apnoea (OSA) patients

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## ABSTRACT

**Objective:** To demonstrate SLEEP-GOAL as a more holistic and comprehensive success criterion for Obstructive Sleep Apnoea (OSA) treatment.

**Methods:** A prospective 7-country clinical trial of 302 OSA patients, who met the selection criteria, and underwent nose, palate and/or tongue surgery. Pre- and post-operative data were recorded and analysed based on both the Sher criteria (apnoea hypopnea index, AHI reduction 50% and <20) and the SLEEP-GOAL.

**Results:** There were 229 males and 73 females, mean age of 42.4±17.3 years, mean BMI 27.9±4.2. The mean VAS score improved from 7.7±1.4 to 2.5±1.7 (p<0.05), mean Epworth score (ESS) improved from 12.2±4.6 to 4.9±2.8 (p<0.05), mean body mass index (BMI) decreased from 27.9±4.2 to 26.1±3.7 (p>0.05), gross weight decreased from 81.9±14.3kg to 76.6±13.3kg. The mean AHI decreased 33.4±18.9 to 14.6±11.0 (p<0.05), mean lowest oxygen saturation (LSAT) improved 79.4±9.2% to 86.9±5.9% (p<0.05), and mean duration of oxygen <90% decreased from 32.6±8.9 minutes to 7.3±2.1 minutes (p<0.05). The overall success rate (302 patients) based on the Sher criteria was 66.2%. Cross-tabulation of respective major/minor criteria fulfilment, based on fulfilment of two major and two minor or better, the success rate (based on SLEEP-GOAL) was 69.8%. Based solely on the Sher criteria, 63 patients who had significant blood pressure reduction, 29 patients who had BMI reduction and 66 patients who had clinically significant decrease in duration of oxygen <90% would have been misclassified as “failures”.

**Conclusion:** AHI as a single parameter is unreliable. Assessing true success outcomes of OSA treatment, requires comprehensive and holistic parameters, reflecting true end-organ injury/function; the SLEEP-GOAL meets these requirements.

## KEY WORDS:

*OSA, sleep apnoea, surgical outcomes, success rate, AHI*

## INTRODUCTION

Obstructive sleep apnoea (OSA) is a common illness affecting 9% of middle age men and 3% of women in North America.<sup>1</sup> It is a condition that affects the patient's cardio-vascular, psychomotor and neurological systems. It is estimated that up to 93% of females and 82% of males with moderate to severe OSA remain undiagnosed.<sup>2</sup> There is a link between OSA and hypertension,<sup>3</sup> cardiovascular diseases,<sup>4</sup> and congestive heart failure.<sup>5</sup> Neurologic function in OSA patients are also affected, they are less resistant to hypoxia and may be more prone to the effects of sleep disruption.

The gold standard diagnostic test for OSA is overnight polysomnography (PSG). Where the frequency of obstructive events is reported as the apnoea hypopnea index (AHI); the severity of the OSA is classified based on the number of apnoea and hypopnea events per hour. As a consequence, the effectiveness of each and/or combined surgical interventions for OSA is almost exclusively based on the reported changes in AHI post-operatively, based on a specific arbitrarily 50% reduction in AHI and an AHI below 20. This is commonly known as the Sher's success criteria.<sup>6</sup> However, recent evidence has shown that there is a consistent discordance between the levels of AHI used to denote outcomes/success of therapy and real-world clinical outcomes such as quality of life (QoL), patient perception of disease, cardiovascular measures (e.g., blood pressure, oxygen saturation, and/or survival).<sup>7</sup> Moreover, in many areas of medicine patient-reported outcome measures and QoL assessments are gaining substantial traction as priority items to assess, when gauging effect of therapy for all manner of diseases;<sup>7</sup> yet in the case of OSA the AHI remains paradoxically persistent as the main, and frequently the only, outcome measure. The issues with utilising purely the AHI from a “one-night only” sleep study, include its night-to-

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night variability,<sup>8,11</sup> the first night-effect, patient anxiety, the restriction of movements from the abundance of monitoring wires, and the use of different definitions of hypopnea in the laboratory systems, and in addition, the use of different monitoring equipment.<sup>12</sup>

Hence, the method sleep specialists measure success of any OSA therapy needs re-evaluation considering these points, the need for more holistic and comprehensive parameters of success instead of the single parameter AHI. The parameter AHI is nebulous to the patient; no patient would seek a consult with a sleep specialist complaining that “my AHI is high”. There is too much weightage given to a single parameter (AHI) that has too much variability. Parameters that affect the patient as a whole and/or those that measure the effects of the end-organs due to the disease process, are more accurate.

We propose the SLEEP-GOAL as a more comprehensive and appropriate means of success measure. The objective of this study was to align the SLEEP-GOAL parameters, demonstrate that the SLEEP-GOAL is more holistic, comprehensive and inclusive compared to AHI alone, and determine the level at which is success rate is acceptable for the SLEEP-GOAL.

## MATERIALS AND METHODS

### *Study Design*

This was a non-randomised prospective multi-centre clinical trial of consecutive patients seen in the ENT clinic for complaints of bothersome snoring and/or symptoms of OSA, who met the inclusion criteria, and subsequently underwent either nose, palate and/or tongue surgery of the upper airway. Patients were recruited from nine tertiary clinical centres from seven countries, including Singapore, Canada, India, Spain, Poland, Israel and Korea, from June 2016 to February 2018.

### *Patient Selection*

All patients underwent a comprehensive clinical assessment including a thorough physical examination, nasoendoscopy, and an overnight polysomnography (PSG) pre- and post-surgery. Parameters collated were the duration of oxygen saturation below 90%, AHI, sleep latency and lowest oxygen saturation (LSAT).

It was ensured that all patients could read English and/or had an English translator to help translate to their native language when answering the questionnaires. Patients completed the Epworth Sleepiness Scale (ESS) and a visual analogue scale (VAS) for snoring pre- and post-surgery. The sleep partner completed a similar VAS scale for snoring. Quality of Life (QoL) was assessed using at least one of the following instruments the 36-Item Short Form Survey (SF36), the Functional Outcomes of Sleep Questionnaire (FOSQ10), Sleep Apnea Quality of Life Index (SAQLI), and/or the Pittsburgh Sleep Quality Index (PSQI) questionnaires. The reaction/execution times was assessed using the [www.humanbenchmark.com/tests/reactiontime](http://www.humanbenchmark.com/tests/reactiontime) website; which simulates a driving episode.

Clinical examination included height, weight, neck circumference, body-mass index (BMI), and blood pressure (pre- and post-operative); an endoscopic assessment of the nasal cavity, posterior nasal space, oropharyngeal area, soft palatal redundancy, uvula size and thickness, tonsillar size and Mallampati grade. Flexible nasoendoscopy was performed for all patients and collapse during a Mueller's manoeuvre was graded for the soft palate, lateral pharyngeal walls and base of tongue.

Inclusion criteria was adult patients (>18 years old), AHI >5, all Friedman stage, all Mallampati grades, all multi-level collapse, all BMI, and nose, palate and/or tongue surgery. All patients were offered continuous positive airway pressure (CPAP) therapy, and those patients who chose CPAP were subsequently excluded from the study. We excluded patients who had previous upper airway surgery and/or had any pillar implants or hypoglossal nerve implant inserted previously or currently.

The study protocol and methodology was reviewed and approved by the hospital Ethics Committee/Institutional Review Board of their respective countries.

### *Study Intervention*

All patients enrolled had either nasal, palatal and/or tongue surgery performed at the same sitting. Nasal surgery included either functional endoscopic sinus surgery, septoplasty, turbinate reduction and/or turbinoplasty. Palate surgery was performed either in the form of the uvulopalatopharyngoplasty, anterior palatoplasty, z-plasty, uvulo-palatal flap and/or the expansion sphincter pharyngoplasty. Tongue surgeries included radiofrequency tongue base ablation, midline tongue glossectomy, or tongue base coblator channelling. Surgeries were decided by surgeon discretion, standard practice, and the anatomy of the patient.

### *Outcome Measures*

#### SLEEP-GOAL

The SLEEP-GOAL is an acronym that relates intimately with the OSA patient's end-organ effects and its parameters. It measures the cardiovascular and neuro-cognitive effects of the OSA disease process and the OSA disease load. The parameters are presented Box 1:

Based on the medical evidence on these parameters, we assigned SLEE as minor criteria and PGOAL as the major criteria. The data on each parameter was collected at pre-surgery and at one-year post-surgery.

### *Statistical Analysis*

All analyses were performed using SPSS 24.0 with statistical significance set at  $p < 0.05$ . Descriptive statistics for the measured parameters were presented as mean $\pm$ sd. The change in the pre-post measurements was compared using paired T test.

## RESULTS

A total of 302 patients were recruited from the nine tertiary clinical centres in seven countries. There were 229 males and 73 females, with an average age of 42.4 $\pm$ 17.3years. The mean height was 1.71 $\pm$ 0.08metres, mean weight was

**Box 1: The parameters of SLEEP-GOAL**

S = **Snoring** – VAS reduction by 50%  
 L = sleep **Latency** – increase by 50%-time latency  
 E = **ESS** – a reduction of 50% and below 10  
 E = **Execution** time – an improvement by 50%  
 P = **blood Pressure** – reduction of either SBP or DBP by 7mmHg or both by 5mmHg  
 G = **Gross weight / BMI** – reduction of GW by 8% or drop in BMI by 2 points  
 O = **Oxygenation** (duration of oxygen < 90%) – improvement by 50%  
 A = **AHI** – reduction by 50%  
 L = **Life quality** (QOL) score – improvement by 50%

**Table I: Changes in Selected Pre-operative and Post-operative parameters (N=302)**

| Parameters                      | Pre-op Mean±SD | Post-op Mean±SD | p-value |
|---------------------------------|----------------|-----------------|---------|
| Body Mass Index (BMI)           | 27.9±4.2       | 26.1±3.7        | p>0.05  |
| Gross Weight (kg)               | 81.9±14.3      | 76.6±13.3       | p>0.05  |
| Snore VAS                       | 7.7±1.4        | 2.5±1.7         | p<0.05  |
| Epworth Sleepiness Score (ESS)  | 12.2±4.6       | 4.9±2.8         | p<0.05  |
| Apnoea Hypopnea Index (AHI)     | 33.4±18.9      | 14.6±11.0       | p<0.05  |
| Lowest oxygen saturation (LSAT) | 79.4±9.2       | 86.9±5.9        | p<0.05  |
| Oxygen duration <90% (min)      | 32.6±8.9       | 7.3±2.1         | p<0.05  |

**Table II: Cumulative percentage and success rates based on the various major and minor criteria fulfilled**

| Criteria Fulfilled | Cumulative Percent | Success Rate (%) |
|--------------------|--------------------|------------------|
| None               | .4                 | 100.0            |
| 1 minor only       | 3.3                | 100-0.4=99.6     |
| 2 minor only       | 5.8                | 100-3.3=96.7     |
| 1 major only       | 6.2                | 100-5.8=94.2     |
| 1 major + 1 minor  | 10.7               | 100-6.2=93.8     |
| 1 major + 2 minor  | 16.9               | 100-10.7=89.3    |
| 1 major + 3 minor  | 17.8               | 100-16.9= 83.1   |
| 2 major + 1 minor  | 30.2               | 100-17.8=82.2    |
| 2 major + 2 minor  | 42.1               | 100-30.2=69.8    |
| 2 major + 3 minor  | 46.7               | 100-42.1=57.9    |
| 3 major + 1 minor  | 58.7               | 100-46.7=53.3    |
| 3 major + 2 minor  | 71.9               | 100-58.7=41.3    |
| 3 major + 3 minor  | 77.3               | 100-71.9=28.1    |
| 4 major + 1 minor  | 83.1               | 100-77.3=22.7    |
| 4 major + 2 minor  | 95.5               | 100-83.1=16.9    |
| 4 major + 3 minor  | 100.0              | 100-95.5=4.5     |

Note: Minor goal: Snoring VAS score reduction by 50%; sleep Latency - increase by 50% time-latency; Epworth Sleepiness Scale (ESS) - a reduction of 50% and below 10; Execution time – an improvement by 50%. Major goal - blood pressure (BP) - reduction of either Systolic BP or Diastolic BP by 7mmHg or both by 5mmHg; Gross weight - reduction by 8%; body-mass index (BMI) drop by 2 points; Oxygenation (duration of oxygen <90%) - improvement by 50%; apnoea hypopnea index (AHI) - reduction by 50%; Quality of Life score - improvement by 50%.

**Table III: Blood pressure, gross weight, body-mass index (BMI) and oxygen saturation changes and Apnoea Hypopnea Index (AHI) reduction by 50% and AHI<20**

| Changes in parametres          | AHI reduction by 50%<br>AHI<20 |            | Total      |
|--------------------------------|--------------------------------|------------|------------|
|                                | No (n, %)                      | Yes (n, %) | (n, %)     |
| SBP/DBP <sup>a</sup>           | YES                            | 63, 20.9%  | 147, 48.7% |
|                                | NO                             | 39, 12.9%  | 53, 17.5%  |
| Gross weight <sup>b</sup>      | YES                            | 25, 8.3%   | 96, 31.8%  |
|                                | NO                             | 77, 25.5%  | 104, 34.4% |
| BMi <sup>c</sup>               | YES                            | 29, 9.6%   | 106, 35.1% |
|                                | NO                             | 73, 24.2%  | 94, 31.1%  |
| Oxygen saturation <sup>d</sup> | YES                            | 66, 21.8%  | 154, 51.0% |
|                                | NO                             | 43, 14.4%  | 39, 12.8%  |

a) reduction of either systolic blood pressure (SBP) or diastolic blood pressure (DBP) by 7mmHg or both by 5mmHg

b) reduction of gross weight by 8%

c) drop in BMI by 2 points

d) Oxygen saturation <90% duration, reduction by 50%

81.9±14.3kg, with mean BMI 27.9±4.2. There was statistically significant improvement in the post-operative snore VAS score, ESS, AHI, LSAT, and mean oxygen duration of less than 90%. (Table I). There was also improvement in the BMI, gross weight and mean sleep latency, however, the results were not statistically significant. (Table I)

The overall success rate based on the Sher's criteria was 66.2%. Based on the Sher's criteria of 66.2%, as stipulated in our objectives, we set out a target range of within 65 to 69% (approximate) as a reasonable success range for the SLEEP-GOAL. The cumulative percentage and success rates based on the various major and minor criteria is presented in Table II. The fulfilment of at least two major and two minor criteria was deemed successful as treatment for patients with OSA as it has achieved the Sher's criteria of 66.2%.

#### Major Criteria – (PGOAL)

The achievement of the major criteria in the SLEEP-GOAL is presented in Table III.

Around 70 per cent achieved the reduction in SBP and/or DBP of  $\geq 7$ mmHg, 40.1% had a reduction of gross weight by 8%, 44.7% had a reduction of BMI by two points, and 72.8% had their oxygen  $< 90\%$  duration reduced  $\geq 50\%$  (Table III). Based on the old Sher's success criteria only 48.7% has achieved reduction of SBB and/or DBP, 31.8% reduction in gross weight, 35.1% reduction in BMI and 51.0% had their oxygen  $< 90\%$  duration reduced  $\geq 50\%$ , which would have been deemed as "unsuccessful" (Table III).

#### Apnoea Hypopnea Index

There was a 66.2% reduction in AHI by 50% and less than 20 in this group of 302 patients. When considering the sole reduction of AHI by 50%, there was a 74.8% (226 out of 302 patients) who met the criteria; taking note that this was only an 8.2% increase in number (not significant statistically).

#### Quality of Life

Only 256 patients completed any of the QoL questionnaires, and due to the non-standardisation of the instruments used in different centres, hence, analysis of the data was not meaningful. However, based on the SLEEP-GOAL criteria of improvement by 50% in QoL scores, only 42.9% (110 out of the 256 patients) had an improvement of at least 50% in their respective pre-operative and post-operative QoL scores.

#### Minor Criteria – (SLEE)

**Snore VAS** – The mean pre-operative snore VAS improved from 7.7±1.4 to 2.5±1.7 ( $p < 0.05$ ). In terms of the snore VAS improving by at least 50%, there were 42.9% of the 302 patients had a reduction of their snore VAS by 50% or more. **Latency – Sleep Latency** – Based on the SLEEP-GOAL criteria of sleep latency increasing but 50% between the pre-operative and post-operative result, only 70 patients out of the 302 (23.1%) had their sleep latencies increased post-intervention.

**Epworth Sleepiness Score** – The mean pre-operative Epworth sleepiness score (ESS) improved from 12.2±4.6 to 4.9±2.8 ( $p < 0.05$ ). In terms of the ESS reducing by 50% and below 10 post-operatively, there were 195 patients out of 302 (64.6%) who met these criteria.

**Execution Time** – There were only 212 patients with data on execution time pre-operative and post-operative. Only 71 patients out of 212 (33.5%) had their execution/reaction times improved by 50%.

## DISCUSSION

This article has an arduous task of illustrating how and why the old traditional single parameter AHI is far from ideal and that there should be a clear paradigm shift away from the old Sher's success criteria as the sole success rate indicator. Our discussion objective would be to highlight the association between OSA and with blood pressure, gross weight, BMI, quality of life, hypoxemia, neuro-cognitive and the cardiovascular systems. This will support the utilisation of the SLEEP-GOAL as a suitable outcome measure and to illustrate the inadequacies of the single parameter AHI.

#### OSA and the Blood Pressure

In patients with OSA, during the night, there are BP surges that can be observed in both the systemic and pulmonary circulation,<sup>13</sup> unlike in normal people where there is a nocturnal 10-20% dip; occasional cyclical variations of the heart rate may also be evident; i.e., sinus tachycardia/bradycardia, extreme cases of arrhythmias have also been documented.<sup>14</sup> It is also believed that through these arrhythmias, OSA may cause sudden cardiac death.<sup>15</sup> Detrimental effects of OSA on the cardiovascular system are carried over into daytime hours, resulting in arterial hypertension, and a high percentage of hypertension. Mainly through its pressor effects, OSA increases the risks for stroke, heart failure, and myocardial infarction.<sup>16</sup> Patients with OSA have a higher incidence of hypertension, as high as 1.5 to 2.7 times.<sup>17-19</sup> Treatment of OSA patients with CPAP have consistently and reliably showed a decrease in blood pressure, likely due to the improvement of vascular function.<sup>20</sup> A randomised controlled trial (RCT) conducted by Weaver et al., showed patients with OSA on CPAP has a significant reduction in DBP values from baseline by -1.93mmHg (95%CI; -3.8 to 0.0).<sup>21</sup>

In a meta-analysis published by Bratton et al., in which the individual data of 1,206 patients from four RCTs were evaluated. Although CPAP treatment reduced OSA severity and sleepiness, overall it did not to have a beneficial effect on BP, except in those patients who used CPAP for  $> 4$  h/night; suggesting that a minimum of 4 hours use per night is needed.<sup>22</sup>

These literatures illustrate that effective therapy for OSA would result in a decrease in the blood pressure of the patient.

#### OSA and BMI

Obese patients have a higher incidence of OSA, however, patients with OSA may not be obese.<sup>23</sup> Simplistically, the anatomy of the upper airway is essentially a balance between the soft tissues and its skeletal framework. These patients have a "local" problem (i.e., a localised problem in their upper airway) versus patients who have a "global" problem (i.e., generalised obesity). There have been papers illustrating the use of clinical prediction models as prediction of OSA and its severity, these all include BMI.<sup>24,25</sup> Studies have

also showed that in Asian patients a cranio-facial restriction (small jaw, retrognathia) is commonly associated with OSA (making gross weight a better reflection compared to BMI), compared to Caucasian patients where fat deposition is common.<sup>22</sup> Research also demonstrate that a BMI >40 is also a predictor of poorer surgical outcomes,<sup>26</sup> and that obesity is significantly associated with fat deposition in the posterior tongue.<sup>27</sup> Kim et al., had recently showed that the tongue fat percentage was higher in OSA patients compared to normal (matched BMI) subjects (42% versus 24%).<sup>28</sup> Parapharyngeal fat pads have also been shown to be enlarged in apneics and to contribute to airway narrowing.<sup>29</sup> Therefore, it is important for the sleep specialist to appreciate that a reduction in BMI would not only reduce the overall oxidative metabolic stress but also, inadvertently also increase the upper airway space in totality.

#### *OSA and the Epworth Sleepiness Scale*

The ESS is a self-reported questionnaire that evaluates the tendency to fall asleep in eight daily situations. The ESS score ranges from 0 to 24, and a score equal to or greater than 10 indicates excessive daytime sleepiness.<sup>30</sup> The ESS is sensitive for sleepiness but not specific for any particular sleep disorder.

#### *OSA and Quality of Life*

QoL is considered one of the most fundamental patient-reported outcomes in healthcare. The improvement in QoL is used to determine whether any intervention should be considered as useful, beneficial or standard of care. For most patients with OSA, a reduction in their QoL is often reflected by symptoms such as excessive daytime sleepiness or fatigue, poor sleep quality, irritability, poor concentration, low work productivity, reduced libido, loss of interest and inability to sleep in the same bedroom with their bed partner. Hence, any successful form of treatment for OSA should result in an improvement in the QoL for these patients.

#### *The AHI*

The overnight in-hospital polysomnogram has its short-comings, namely it is resource intensive, including the need of recording beds, high cost, long waiting lists and intense labour requirements. Many sleep specialists recognise the likelihood of a low sleep efficiency due to the first night-effect, patient anxiety, the restriction of movements from the abundance of monitoring wires. Hence, one needs to be cognisant of the night to night variability in these cumbersome and uncomfortable sleep tests.

Night-to-night variability may drastically affect the AHI of a patient being assessed either pre or post-surgery. Chediak et al.,<sup>8</sup> reported that 32% of their patients had a difference of AHI  $\geq 10$  in two consecutive nights of PSG. Levendowski et al.,<sup>10</sup> reported a fairly weak correlation ( $r = 0.44$ ) between overall AHI from the two PSG studies conducted approximately 40 days apart with a seven event/hour bias. However, Stepnowsky et al.,<sup>11</sup> did show in 1091 patients that the night-to-night Pearson correlation coefficients ranged between 0.88 and 0.90 for each pair of nights.

Another consideration would be the use of home-based sleep studies; e.g., the Watch PAT device versus the in-laboratory sleep tests.

The third and major confounder, and perhaps the most common and widely debated factor, is the use of different definitions of hypopnea in the laboratory systems, and in addition, the use of different monitoring equipment; e.g., the use of nasal thermistors versus the use of nasal airflow pressure sensors. Studies also have reported that the depth of desaturation varies by equipment manufacturer,<sup>31</sup> and the criteria based on a 4% desaturation may not be the same at different sleep laboratories. Apnoea definition is fixed, it refers to a pause in respiration for more than 10 seconds and is seen in both central sleep apnoea (CSA) and OSA. Hypopnea is usually defined as reduction in ventilation of at least 50% that results in a decrease in arterial saturation of 4% or more due to partial airway obstruction. Some sleep centres define hypopnea as clinically significant when there is a  $\geq 30\%$  reduction in nasal airflow lasting for 10 seconds or longer with an associated  $\geq 4\%$  oxygen desaturation and/or if this results in an arousal or a fragmentation of sleep.

Therefore, it would be prudent to note that there can be huge test-retest variability from the different available sleep tests in the market, and this is a confounding factor in assessing treatment outcomes, purely by using AHI alone. Guidelines developed to standardise the scoring of sleep and detection of related events; i.e., accreditation by the American Academy of Sleep Medicine, appears ineffective in controlling the inherent variability of OSA when measured by PSG. The suggestion of multi-night PSG studies is both difficult for subjects and very expensive. Sleep specialists using solely the AHI from the PSG for assessing treatment outcomes should factor in the increased variability, with perhaps high level of inaccuracy and discordance with the actual patient benefit as a whole.

#### **SLEEP-GOAL as a Holistic Success Criteria**

No sleep specialist has ever had a patient walk into the office and complained of a raised/elevated AHI. To the patient, the AHI is a nebulous concept, while other clinical outcomes measures are more relevant, including subjective sleepiness, snoring level and level of performance. In addition, most OSA treatment is aimed at preventing long-term deleterious effects of the disease; e.g., high blood pressure and cardiovascular morbidity, yet paradoxically, such parameters are notably underutilised and relatively invisible to both medical and surgical studies evaluating treatment outcomes. When AHI is utilised, sleep specialists may not be familiar of its short-comings and accept that the archaic criteria of 50% reduction in AHI and an AHI <20 tends to be gospel truth. This criterion, based on historical literature was arbitrarily developed, it did not stratify any patients nor had any clinical data, parameters or assessments.

Hobson et al., recently showed in a creative study that differences even in the definition of AHI severity cut-off can greatly influence reported efficacy of surgery in patients with OSA.<sup>32</sup> For example, let us consider patient A with a pre-operative AHI of 95 who, after surgery, has a post-operative PSG of AHI 21; this patient would likely experience measurable symptomatic and clinical improvement with a huge decrease in disease burden; in terms of obesity, hypertension, cardiovascular effects and oxidative stress, even though this is not defined as a successful surgical outcome by the numerical old Sher's AHI criteria, whereas

consider another patient B with baseline pre-operative AHI of 35, and who had reduced post-operatively to under 14, this is considered a successful AHI outcome even though the likelihood of clinical cardiovascular or QoL impact may be minimal, as compared to patient A. Intuitively, one would agree that patient A benefitted significantly more than patient B, but yet was labelled as a “surgical failure”. Moreover, not forgetting, that in much of the reported literature, the pre- and post-surgery sleep test may have been done in different sleep laboratories, using different definitions of hypopnea and different sleep diagnostic devices, all of which can confound reporting.

Hence, employing AHI as the single variable with which to gauge success of therapy, either medical or surgical, is flawed and allows it to hold too much weight in the field of sleep medicine. Other metrics of OSA measurement such as quality of life, subjective sleepiness, performance, and biological measures must evolve to play a larger role to study outcomes.<sup>33</sup> Validated subjective measurements, such as QoL scores, sleepiness scores, and performance testing, better reflect the patient clinical manifestation than does AHI. Objective measures such as blood pressure more directly measure important long-term goals that OSA interventions aim to treat than does the sole AHI. OSA is more than just local airway pathology reflected by the number of apnoea and hypopneas per hour,<sup>33</sup> it is the effects on the end-organs.

This SLEEP-GOAL criterion best represents the end-organ “damage” of the airway obstructions (apnoea and hypopnea). From our study, we demonstrated that the overall success rate in our 302 patients, based on the Sher’s criteria was 66.2%. In order to maintain a success rate as stringent as the old Sher’s criteria, we set out a target of within 65 to 69% (approximate) as a reasonable success range for the SLEEP-GOAL. Based on the list of SLEEP-GOAL clinical outcomes, and the respective major/minor criteria fulfilment (Table I), based on a fulfilment of two major and two minor criteria, the cumulative frequency equivalent to a post-operative success rate of 69.8%. With a fulfilment of two major and one minor, the success rate would be 82.2%, and with two major and three minor fulfilled, the success rate would be 57.9%.

Hence, based on these validated parameters from the list of SLEEP-GOAL, we propose that any patient who meets the criteria of at least any of the two major and two minor is deemed clinical success of that respective intervention.

In addition, we also illustrated that if we had applied the old Sher’s criteria to these 302 patients, who would have “misclassified” many patients as “failures”, those who actually had good post-intervention results in terms of blood pressure decrease, BMI and gross weight reduction, and significance reductions in the duration below 90% oxygen saturations. Based on the old Sher’s criteria, we would have classified these as “failures”:

We acknowledge and recognise some short comings of this paper: As with most multi-centre surgical studies, the surgeon performing the procedure is slightly different and may contribute to each individual patient’s success rates. There

are many different surgical techniques that may be employed by each surgeon; however, this paper’s objective was not to analyse the technique’s success rates but the type of outcome measures used. As with most multi-centre studies, the method and device used for assessing sleep may vary. The device software may have slightly different definitions of hypopnea and oxygen desaturation definitions in each country. However, this is precisely the objective of this study to illustrate the need on over-reliance of one parameter AHI. As with most multi-centre studies, language of the questionnaires could be a confounding factor. Attempts were made to decrease the confounding by providing translators where needed. We are aware that not all the enrolled patients had completed the questionnaires, however, this would reflect a realistic environment where not all patients are keen to or would oblige to fill up questionnaires; where this is a concern, other major criteria from P-GOAL may be used.

## CONCLUSION

We recognise that implementing such criteria would complicate rather than simplify the management of OSA, but this would be more realistic and holistic, in contrast to the gross oversimplification of the disease management that currently occurs by the use of AHI alone. From this study, it would be fair to conclude that the use of a single AHI parameter as the only outcome measure for the treatment intervention for OSA, would be not only misleading but extremely inadequate.

Treatment intervention need not be surgery, CPAP use, and/or an oral appliance, it could be a simple weight loss/dietary program; with the loss of the extra kilograms, the patient’s BMI or gross weight would decrease, the patient’s quality of life would improve, blood pressure would be lowered, sleep parameters and quality improved and the overall body’s oxidative stress would be lowered. It would be plausible to state that the paradigm of OSA treatment outcomes need to be better thought through, redefined and shifted to a more holistic, comprehensive and realistic parameter, like the SLEEP-GOAL.

## DISCLOSURE

This study was not funded. There are no financial disclosures and no conflict of interest for all the above authors

## ETHICAL APPROVAL

Ethical approval: This article does not contain any studies with animals performed by any of the authors. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. There were no recognisable data or patient/human profiles within the article.

## CONFLICT OF INTEREST

All the authors declare that he/she has no conflict of interest.

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