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Research Article

Clinical Outcomes of eXciteOSA Therapy: A Retrospective Chart Review

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Abstract

Obstructive sleep apnea (OSA) is a common disorder with significant health consequences. A widespread treatment for this disorder, continuous positive airway pressure (CPAP), often has low patient adherence. The eXciteOSA device, a neuromuscular electrical stimulation (NMES) therapy, offers a non-invasive alternative that aims to address the underlying cause of OSA. This retrospective chart review of 87 patients investigated the efficacy outcomes of adherent patients (defined as ≥50% usage over 6 weeks) to eXciteOSA therapy, specifically as measured by a decrease in the Apnea-Hypopnea Index (AHI 3%; events/hour). A subset of 37 patients with both baseline and follow-up AHI 3% data was analyzed for efficacy, including a more in-depth analysis of the adherent cohort (n=34) as a per-protocol analysis. Within the adherent cohort, 52.94% (n=18) of patients demonstrated improvement in AHI 3%, 35.29% (n=12) worsened, and 11.76% (n=4) showed no change in this metric. A paired-samples *t*-test revealed the mean reduction in AHI 3% from baseline to follow-up did not reach statistical significance ($p = 0.56$). Despite this, these findings provide valuable real-world data and demonstrate a positive trend that suggests patient adherence is a critical factor for successful outcomes. Furthermore, this study highlights the need for larger, controlled studies to confirm the association between NMES therapy and efficacy.

Keywords: *Obstructive Sleep Apnea (OSA), eXciteOSA Therapy, Neuromuscular Electrical Stimulation (NMES), Apnea-Hypopnea Index (AHI), Treatment Adherence*

Introduction

Apnea is defined as the periodic cessation of breathing for upwards of 20 seconds, commonly during sleep. [1] Within this general definition, a form of apnea known as obstructive sleep apnea (OSA) is characterized by the repeated collapse of the pharyngeal airway during sleep [2], consequently preventing consistent breathing for the patient. OSA is a serious, yet common disorder, with estimates from a 2019 study suggesting that nearly 1 billion adults worldwide between the ages of 30-69 have OSA with a cutoff of 5 events per h on the Apnea-Hypopnea Index (AHI 3%; events/hour). Moreover, greater than 45% of these individuals have an AHI of 15 or more events per h, indicating moderate to severe cases of the disorder. [3] The AHI measures frequency of respiratory events on an hourly basis, with the 3% oxygen desaturation threshold being classified as "Recommended" by the AASM over the "Alternative" 4% threshold due to the higher sensitivity in detecting hypopneas by the 3% metric. A higher sensitivity is essential for identifying symptomatic patients who may otherwise be underdiagnosed. [4] Additionally, the AHI metric was prioritized in this analysis as the primary clinical endpoint over the Oxygen Desaturation Index (ODI). AHI captures the full spectrum of respiratory disturbances that drive daytime symptoms as well as long-term cardiovascular risk, whereas the ODI metric is limited to events that result in significant oxygen desaturation. [5,6]

The condition typically occurs due to the relaxation of muscles meant to keep the airway open during sleep, as a result of decreasing muscle tone over time. Modern phenotyping has shown that though a physically small airway is a primary cause, around 20% of patients suffer from this lack of muscle control during sleep. [7] However, many additional factors are also commonly associated with OSA such as obesity, male sex, and increasing age. [8] Obstructive sleep apnea commonly leads to daytime fatigue, snoring, and headaches, however there is evidence for a link between OSA and cardiovascular disease, as OSA is often tied to systemic arterial hypertension, which can in turn lead to heart disease, strokes, aneurysms, and more. [9,10] OSA can also frequently have an impact on neurocognitive function, such as loss of memory and changes in mood regulation. [11] Beyond this clinical burden, untreated OSA now exceeds over USD 150 billion in annual societal cost, across medical expenses, loss in productivity, and accidents. [12] Due to the prevalence and severity of OSA, a few widespread treatments are available, such as continuous positive airway pressure (CPAP). This method involves the patient wearing a mask at night that connects to a compact machine that generates a pressurized stream of air that keeps the airway open. [13] Many patients struggle to adhere to this treatment due to the discomfort of the apparatus while in bed as well as symptoms such as dryness and irritation, which can be incredibly inconvenient especially for those with only mild OSA. [14] Broadly, CPAP non-adherence ranges from 46 up to 83%, with a specific study finding that fewer than half of OSA patients achieved high adherence to CPAP therapy in the long-term, 24 months after initiation. [15,16] Seeing this issue, Signifier Medical Technologies developed eXciteOSA, a neuromuscular electrical stimulation (NMES) device. This device applies gentle electrical stimulation to the genioglossus and upper airway muscles, strengthening them to reduce and even eliminate airway collapse during sleep. Low-frequency NMES like that in eXciteOSA has been otherwise shown to make muscles more fatigue-resistant by shifting fibers towards a slow-twitch direction over time. [17] The eXciteOSA protocol is much lighter than other treatments, with 20-minute applications per day for six weeks, and two times a week thereafter. Upon FDA approval, the device launched in the United States in 2021, being distinct in its methods for treating OSA, as well as going after the root cause of the condition rather than individual symptoms. [18] This advanced treatment allows patients to control their therapy sessions via a paired smartphone app and enables Signifier Medical Technologies to collect data on usage patterns through remote monitoring to further improve the model. [19] The primary purpose of this study is to investigate the efficacy of eXciteOSA therapy in adherent patients - defined as ≥50% usage over 6 weeks - by evaluating changes in the AHI 3% from baseline to follow-up.

Methods

This study was conducted as a retrospective chart review, a research design in which existing patient data previously gathered as part of routine clinical care were viewed and analyzed. No direct patient contact, data collection, or interventions were performed for the purpose of this study. All patient information and therapy data were sourced from electronic health records (EHRs) maintained within the AthenaHealth platform at Ohio Sleep Medicine Institute.

As part of the standard clinical process for eXciteOSA, patients consent to Signifier Medical Technologies monitoring and analyzing data collected via their HIPAA-compliant platform, remotely monitored via the paired app. This ensures that both descriptive patient information and objective therapy usage data are consistently recorded. Internet connectivity is a prerequisite for initiating an eXciteOSA therapy session, guaranteeing the completeness of all electronically captured usage data.

A de-identified dataset was extracted from the AthenaHealth Electronic Health Records (EHR) on September 3rd, 2024. The dataset included all U.S.-based patients who initiated eXciteOSA therapy on or before July 23rd, 2024. For each patient included, the following data points were collected: Demographic Information (self-reported age, sex, height, and weight); Baseline and Follow-up Sleep Study Metrics (Apnea-Hypopnea Index [AHI] and Oxygen Desaturation Index [ODI] values, indicative of sleep apnea severity); Oxygen Saturation Data (the lowest oxygen saturation recorded during the baseline and follow-up sleep studies); and eXciteOSA Therapy Adherence Data (usage data for the initial six weeks of therapy, highlighting percentage of days that therapy was used out of possible days).

For the purpose of data integrity, any calculated body mass index (BMI; kg/m^2) values that fell outside the range of 16 to 60 kg/m^2 were presumed as data entry errors. Outside of this and defined temporal constraints for patient inclusion, no further filters or exclusion criteria were applied in the data extraction process. When extracting the data, there was no minimum usage threshold applied to patient inclusion. However, a specific adherence threshold of 50% (defined as utilizing the device for at least 21 out of 42 prescribed days) was established for analysis purposes.

This threshold was chosen to evaluate outcomes in a larger sample of patients who achieved consistent neuromuscular stimulation, including those with sub-maximal adherence.

Descriptive statistics (mean ± SD) were calculated for demographic variables and all sleep metrics. A paired-samples t-test was performed using Microsoft Excel to evaluate the mean change in AHI 3% from baseline to follow-up within the adherent cohort. Statistical significance was defined as $p < 0.05$.

Results

Of the 87 participants initially enrolled in the chart analysis, descriptive information and baseline characteristics are presented in Table *1*. From the 79 evaluable patients with available adherence data, 75.95% (n=60) were classified as adherent (≥50% usage) to the eXciteOSA 6-week treatment regimen (Table *2*). Table *3* highlights the overall efficacy based on change in AHI 3% in the 37-patient subset that had both baseline and follow-up data for this metric, before and after the initial treatment period, including non-adherent patients as the intention-to-treat (ITT) analysis; within this group, 54.05% of patients demonstrated improvement. Table *4* depicts the clinical outcomes of overall efficacy within the adherent subset, as the per-protocol (PP) analysis (n = 34), which excluded three non-adherent individuals to evaluate efficacy when the device was used as directed. A paired-samples t-test was performed to evaluate the baseline to follow-up mean change in AHI 3% within the adherent subset; 52.94% (n=18) of patients showed categorical improvement, though the overall mean reduction did not reach statistical significance ($p = 0.56$). Finally, summary statistics of primary and secondary respiratory metrics are provided in Table *5*, showing means and standard deviations that overview the clinical parameters and physiological response to therapy experienced by patients.

Table 1. Baseline Characteristics of Study Participants.

Characteristics	Value
Age (years)	53.8 ± 17.4
BMI (kg/m^2)	27.1 ± 4.8
Sex	
Male	51 (58.6%)
Female	33 (37.9%)
Total	87

Values are presented as Mean ± Standard Deviation (SD) for continuous variables and n (%) for categorical variables. Three patients did not report gender, leading to a sum less than the number of total patients.

Table 2. Patient Adherence to eXciteOSA Treatment

Adherence	N	%
Yes	60	75.95%
No	19	24.05%
Total	79	100.00%

Adherence is defined as percentage of nights the device was used out of the total 42-day treatment period. Patients with ≥50% adherence were classified as “Yes”, and those with <50% adherence – including those who discontinued the study – were classified as “No”. Only the 79 patients with evaluable device usage data were considered for this table.

Table 3. eXciteOSA Overall Efficacy (based on AHI 3% change)

Overall Efficacy	N	%
Improved	20	54.05%
Worsened	15	40.54%
No Change	2	5.41%
Total	37	100.00%

AHI 3% change categories were defined as follows: Improved (>0.1 decrease from baseline), Worsened (<0.1 decrease from baseline), No Change (between -0.1 and 0.1 change from baseline). Only patients with sufficient data were considered for this table.

Table 4. Clinical Outcomes by Overall Efficacy (AHI 3%) in Adherent Patients

Clinical Outcome (AHI 3%)	Count (n)	Percentage (%)
Improved (Decrease > 0.1)	18	52.94%
Worsened (Increase > 0.1)	12	35.29%
No Change (Change ≤ 0.1)	4	11.76%

Only patients with data for baseline and follow-up AHI 3% values as well as adherence data were considered for this table. Percentages may not total 100% due to rounding.

Table 5. Baseline and Follow-up Clinical Outcomes

Variable	Baseline	Follow-up
AHI 3% (events/hour)	11.9 ± 9.2	11.2 ± 10.5
AHI 4% (events/hour)	5.0 ± 4.1	6.5 ± 6.1
ODI 3% (events/hour)	8.0 ± 7.0	9.2 ± 9.5
ODI 4% (events/hour)	4.3 ± 3.7	6.6 ± 6.0
Lowest Oxygen Saturation (%)	86 ± 5	86 ± 7

Values are presented as Mean ± Standard Deviation. A paired-samples *t*-test was conducted to compare baseline and follow-up AHI 3% scores; no statistically significant difference was found ($p = 0.56$). Statistical testing was only performed on the primary endpoint (AHI 3%).

Discussion and Conclusion

While this retrospective chart review initially reviewed 87 total patients using the eXciteOSA treatment to manage their obstructive sleep apnea, a subset of the 34 adherent patients with sufficient data was focused on to evaluate efficacy of eXciteOSA therapy over a six-week period. By prioritizing this cohort, the study aimed to assess clinical outcomes in a per-protocol analysis, ensuring that results reflect the treatment's impact when used as directed (≥50% usage). Particularly, an analysis of change in the AHI 3% statistic from baseline to follow-up was established as the primary endpoint to determine treatment efficacy. Results show that for the specified adherent cohort, 52.94% (n=18) of individuals showed improvement in AHI 3% data, while 35.29% (n=12) showed worsening, and 11.76% (n=4) experienced no change. A paired-samples t-test revealed that this mean reduction did not reach statistical significance (p=0.56).

This lack of statistical significance in mean AHI 3% reduction, despite the 52.94% (n=18) improvement rate, highlights a high degree of individual variability in response to treatment within the adherent cohort. The subset of patients that increased AHI 3% over the six-week period (35.29%; n=12) shows a split between responders and non-responders that suggests that NMES therapy efficacy may be highly dependent on specific patient phenotypes. Factors not accounted for in this study, such as baseline airway anatomy and obesity rates, may correlate significantly to treatment success. In a small sample size similar to that of this study (n=34), even a few individuals with increased AHI 3% at follow-up can mathematically mask the clinical progress of the majority, resulting in a non-significant p-value despite a positive trend. This is noteworthy, given our decision to utilize the AASM-recommended AHI 3% threshold to increase sensitivity in detecting clinical improvements that may have been overlooked with the more conservative 4% threshold. Ultimately, these results suggest that eXciteOSA efficacy may be highly individualized; consequently, a more targeted approach to patient selection may be necessary to optimize outcomes.

The findings of this study offer a real-world perspective on NMES therapy, specifically when placed in the context of larger clinical analyses. For instance, a similar study by Baptista et al. (2021) measured eXciteOSA effectiveness in a cohort of 115 patients, demonstrating a statistically significant reduction in mean AHI ($p < 0.001$). [20] This stark contrast in statistical outcomes between their findings and this study likely stems from differences in sample size and study design. With 115 participants, the Baptista study was able to overcome individual variability and identify a cohort-wide effect. Additionally, it utilized strict inclusion criteria and controlled monitoring to isolate effects in a prospective setting. Conversely, our retrospective review captures real-world clinical use, subject to unmeasured confounding variables that can add variation to the data. This comparison underscores the idea that while eXciteOSA has proven efficacy in controlled research settings, a localized population is more susceptible to individual variability that can obscure a treatment's broader clinical trend.

Beyond the aforementioned constraints limiting statistical power, several methodological limitations of this study must be considered as well. The retrospective design of this chart review relied entirely on pre-existing electronic health records, which precluded control of confounding external factors - such as fluctuations in BMI or seasonal allergies - that may have influenced AHI 3% results. The significant attrition from the initial enrollment period (n=87) to the final analyzed subset (n=34) suggests a potential for selection bias towards responders, as clinical trajectories of those lost to follow-up remain unknown. Furthermore, the categorical classification of adherence (% of days used) can be imprecise in comparison to a measurement such as % of minutes completed, as the 20-minute-long therapy can be paused at any time in the session. Finally, while this study prioritized the AASM-recommended AHI 3% threshold, the less pronounced changes observed in AHI 4% and both ODI metrics suggest that eXciteOSA therapy may primarily impact lower-threshold respiratory events. Further research is needed to determine how this divergence in metric sensitivity translates to long-term clinical outcomes.

This study, while not without its limitations, provides valuable insight into the real-world performance of eXciteOSA therapy within an adherent population. Unlike highly controlled clinical trials, this retrospective analysis captures the impact of the device in a setting where individual physiological variability and patient phenotypes play a significant role in outcomes. While the mean reduction in AHI 3% did not reach statistical significance, the observed improvement rate demonstrates that the device is a viable therapeutic option for a majority of patients who remain committed to the protocol. These results specifically highlight that in a real-world environment, clinical success may be highly individualized, necessitating a more targeted approach to patient selection. The limitations of this study, most notably the retrospective design and limited sample size, underscore the need for future research. Prospective, longitudinal studies are required to identify the key anatomical markers that predict high responsiveness, ultimately allowing clinicians to better tailor NMES therapy to the individual needs of the patient.

Conflict of Interest Statement

The authors are affiliated with the Ohio Sleep Medicine Institute, the clinical site where the data was collected and analyzed. No external funding was received from Signifier Medical Technologies for the conduct of this research, and the authors declare no other financial or personal conflicts of interest.

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