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SCIENTIFIC INVESTIGATIONS

Does race-ethnicity affect upper airway stimulation adherence and treatment outcome of obstructive sleep apnea?

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Study Objectives: Untreated obstructive sleep apnea (OSA) is associated with excessive daytime sleepiness, decreased quality of life, and cardiovascular disease. Positive airway pressure is the first-line therapy for OSA; however, adherence is difficult. Upper airway stimulation is a Food and Drug Administration-approved treatment of OSA. The objective of this study was to evaluate for a difference in treatment efficacy and adherence of upper airway stimulation therapy for OSA between individuals who are White and non-White using data from the ADHERE registry.

Methods: ADHERE registry is a multicenter prospective study of real-world experience of upper airway stimulation for treatment of OSA in the United States and Europe. Propensity score matching was used to create a balanced dataset between the White and non-White groups. *t*-Tests at a significance level of 5% were used to compare numeric values between groups.

Results: There were 2,755 participants of the ADHERE registry: 27 were excluded due to not having a race identified, 125 participants identified as non-White, 2,603 identify as White, and 27 did not provide race information. Propensity score matching was used to select 110 participants, with 55 White and 55 non-White for the noninferiority analysis. We did not find a difference in adherence, treatment apnea-hypopnea index, changes in Epworth Sleepiness Scale score, or clinical global impression after intervention score between White and non-White individuals.

Conclusions: Our study found that there was no statistically significant difference in adherence or efficacy with upper airway stimulation therapy between White and non-White individuals. However, the percent of non-White people implanted is low, which suggests a need to expand access to this therapy for non-White populations with OSA who cannot tolerate positive airway pressure therapy.

Keywords: obstructive sleep apnea, positive airway therapy, upper airway stimulation, hypoglossal nerve stimulation, apnea-hypopnea index, Epworth Sleepiness Scale, adherence, health care disparities

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Untreated obstructive sleep apnea is associated with decreased quality of life and cardiovascular disease. Non-White patients with obstructive sleep apnea have shown to have low adherence to positive airway pressure treatment. The association of race-ethnicity on utilization of upper airway stimulation for obstructive sleep apnea has not been clearly established.

Study Impact: Analyzing the real-world ADHERE registry, we found non-White patients accounted for 5% of total upper airway stimulation recipients, reflecting possible health disparities related to race-ethnicity. Non-White patients showed similar efficacy and adherence of upper airway stimulation as matched White patients.

INTRODUCTION

Obstructive sleep apnea (OSA) is a condition of intermittent closure of the upper airway during sleep leading to arousals and hypoxemia. Untreated OSA is associated with excessive daytime sleepiness, decreased quality of life, and cardiovascular disease. Positive airway pressure (PAP) is the first-line therapy for moderate to severe OSA. However, adherence is less than 50% in most studies.[1,2] Prior studies have shown that Black men and women have more severe OSA disease as measured by the apnea-hypopnea index (AHI), hypoxemia burden, and symptoms of poor sleep and daytime sleepiness compared to White people.[3,4] They also have younger age of onset and higher rates of hypertension compared to White people.[5] Despite this, Black men represent a small cohort of patients obtaining sleep studies compared to Black women and White men and women.[6]

Prior studies have indicated that Black race is associated with low adherence to PAP.[7–12] There have been far fewer studies reporting PAP adherence in Hispanics and Asian/Pacific Islanders, with the limited data demonstrating no significant difference relative to White patients.[10–14] The adherence issue is concerning because the prevalence of OSA is higher among minorities, who bear a higher burden of OSA-related comorbidities relative to White patients.[4,15–17]

Blacks have, on average, 1 hour lower mean daily PAP usage and use PAP on fewer nights relative to White patients.[9,11,12] They are also less likely to return to clinics for follow-up and have owned their PAP machines for less time.[11,18,19] Minorities are also seen less frequently by a sleep specialist prior to sleep testing, which negatively impacts PAP acceptance and adherence.[7,20] When controlling for poverty and education, neighborhoods in the United States with a higher proportion of Black and Hispanic residents have objectively measured lower PAP adherence.[21] In addition to enhancing resources to help patients adhere to PAP, alternate treatment of OSA can also be explored.

Upper airway stimulation (UAS) of the hypoglossal nerve has been established as an effective treatment option for patients with OSA who are nonadherent to PAP. The hypoglossal nerve is a pure motor nerve that innervates the genioglossus muscle, which is the largest upper airway dilator muscle.[22] Activation of the genioglossus muscle leads to tongue protrusion, stiffening of the anterior pharyngeal muscle wall, and enlargement of the pharynx.[22,23] The Stimulation Treatment for Apnea Reduction (STAR) trial was a multicenter prospective study looking at the effects of hypoglossal nerve stimulation on the treatment of OSA. The study showed that 12 months postimplant, the AHI was reduced by 50% with a treatment AHI of < 20 events/h in 66% of the 126 participants.[24] There was also improvement in self-reported sleepiness and sleep-related quality of life as assessed by the Epworth Sleepiness Scale (ESS) and the Functional Outcomes of Sleep Questionnaire. Five-year data showed 75% of participants had a 50% reduction of AHI from baseline with a treatment AHI of < 20 and ESS and Functional Outcomes of Sleep Questionnaire score improvements persisted.[25] This study evaluates for a difference in treatment efficacy and adherence of upper airway stimulation therapy for OSA between White and non-White individuals using data from the ADHERE registry which is an ongoing international, multi-center prospective observational study of patients implanted with UAS.

METHODS

ADHERE registry

The ADHERE registry is a multicenter prospective study of real-world experience of UAS for treatment of OSA in the United States and Europe.[26] After providing informed consent, registry participants reported adverse events related to UAS, daytime sleepiness using ESS, and treatment satisfaction during the post-titration visit (approximately 6 months postoperatively) and final visit (approximately 12-month postop). Care providers collected baseline demographics, OSA treatment history, preoperative and postoperative AHI from either polysomnography or home sleep apnea test, and therapy usage.

Propensity score matching

To create a balanced dataset between the White and non-White groups, propensity score matching using nearest neighbor with 1:1 matching was performed. Logistic regression was used as the matching algorithm with the following variables: age, sex, baseline body mass index (BMI), and baseline AHI. *t*-Tests with α of .05 were used to determine the balance between the 2 groups after matching.

Statistical analysis

t-Tests at a significance level of 5% were used to compare numeric values between groups unless otherwise noted. Chi-square tests of independence with a significance level of 5% were used to compare categorical variables between the two groups.

A 1-sided *t*-test with 2.5% significance level and noninferiority margin of 0.5 h/night was used to test noninferiority in therapy use. Noninferiority was also tested for change in AHI at posttitration with a noninferiority margin of 7.5 events/h. A noninferiority margin of 7.5 events/h was chosen based on the recent American Academy of Sleep Medicine guideline on OSA treatment with PAP, which defined a ≥ 15 events/h reduction of AHI to be clinically significant.[27] The noninferiority margin is typically smaller than the observed clinical differences between treatment options. For this analysis, half of a clinically significant reduction of 15 events/h was chosen for the noninferiority margin to compare therapy efficacy between White and non-White individuals. Both non-inferiority tests were performed on the matched dataset.

Numeric results are presented in mean ± standard deviation and 95% confidence interval unless otherwise noted, and categorical results are presented in total sample size and percentages.

RESULTS

Patient selection

The current report included 2,755 participants of the ADHERE registry between 2016 and 2021 from 53 sites in the United States and Europe: 27 participants were excluded due to not having a race identified, leaving 2,728 participants for the analysis; 636 participants were from Europe; and 2,092 were from the United States. Among them, 125 participants identified as non-White and 2,603 identify as White; 1.6% of participants from European centers identified as non-White and 4.6% from US centers. A total of 55 non-White participants had a complete set of age, sex, AHI, BMI at baseline, and AHI as well as usage at posttitration (**Table 1**).

We used propensity score matching to select 110 participants, with 55 White and 55 non-White people for the noninferiority analysis of the following variables between the 2 groups: AHI reduction and therapy usage; and difference in time from baseline to the post-titration follow-up visit.

Comparison between White vs non-White participants using propensity matching

A total of 55 non-White participants had a complete set of age, sex, AHI, and BMI at baseline and AHI and usage at posttitration.

Table 1—Baseline characteristics of all patients prior to matching.

	Non-White (n = 125) (4.6%)	White (n = 2,603) (95.4%)	*P*
Age, y	58.7 ± 11.6 (117)	60.1 ± 11.1 (283)	.2
Male, n	84*	189*	.2
BMI, kg/m^2	29.9 ± 4.4 (110)	29.3 ± 4.0 (274)	.2
AHI	34.1 ± 18.1 (119)	35.2 ± 15.4 (214)	.5
ESS	11.2 ± 5.3 (106)	11.2 ± 5.6 (223)	.9

*A total of 8 patients did not have sex entered into the database: 1 non-White patient and 7 White patients. AHI = apnea-hypopnea index, BMI = body mass index, ESS = Epworth Sleepiness Scale.

We matched 55 White patients and the non-White cohort with the complete dataset for comparison. There were no significant differences between the 2 groups in baseline variables of age, sex, BMI, and AHI that were matched. There was also no difference in baseline ESS between the 2 cohorts (Table 2).

There was no significant difference in therapy use between White and non-White patients. However, we could not rule out a small usage reduction of 0.27 h/night with a confidence interval from −1.06 to 0.53 among non-White patients to be noninferior to the usage among White patients using a noninferior margin of 0.5 h/night.

The mean difference in AHI decrease from baseline to posttitration between White and non-White patients was 1.08 with a confidence interval from −6.14 to 8.31. The lower limit of the confidence interval was within the noninferiority margin of −7.5 events/h. This suggests that non-White patients have no worse outcomes than White patients regarding the reduction of AHI (Table 3).

For secondary analysis, there were no difference in posttreatment AHI, changes of ESS from baseline, and AHI response rate using Sher criteria (at least 50% reduction from baseline and AHI less than 20 events/h) between White and non-White patients at the post-titration visit (Table 4).

Patient symptom improvement with UAS was measured using the Clinical Global Impression–Improvement Scale (CGI-I) and was found to be similar between White and non-White individuals.

Table 2—Baseline variables for matched patients.

Variable	Non-White (n = 55)	White (n = 55)	*P*
Age, y	60.2 ± 11.1	61.2 ± 9.7	.61
% Male (n)	70.9 (39)	61.8 (34)	.42
Baseline BMI, kg/m^2	29.7 ± 4.5	29.4 ± 4.5	.67
Baseline AHI	36.0 ± 17.5	33.7 ± 12.4	.4
Baseline ESS	10.8 ± 6.2	11.4 ± 5.6	.6

AHI = apnea-hypopnea index, BMI = body mass index, ESS = Epworth Sleepiness Scale.

Both groups had approximately 80% of the participants with their symptoms rated as either very much or much improved at the post-titration visit (Table 5).

When evaluating post-implant adherence, there was no difference between White and non-White patients in terms of completing the titration sleep study or post-titration follow-up visit. 75.1% of White and 74.0% of non-White patients completed the sleep study and 77.6% of White and 76.9% of non-White patients completed the post-titration visit. There was no difference in visit (P = .96) and sleep study (P = .9) adherence between the 2 groups based on the chi-square tests of independence. In addition, the average time from implant to post-titration follow-up was similar between White and non-White patients with 21.1 ± 18.0 and 21.4 ± 19.1 weeks (P = .98) timeframe, respectively.

DISCUSSION

Although a real-world assessment of the actual number of patients with UAS therapy in White and non-White patients is difficult, the ADHERE registry provides a potential way to explore this question. The registry overall has 5% of patients enrolled who identify as non-White, of whom the majority (92%) were from US centers. Given that nearly one-quarter of Americans identify as non-White (US Census Bureau 2019), this demonstrates a potential health care disparity. The study results presented here demonstrate that in groups of matched White and non-White patients with OSA, there was no difference in the efficacy, usage, or satisfaction with UAS therapy for OSA. The reduction in AHI from baseline to posttitration for non-White patients is noninferior compared to White patients using a noninferiority margin of −7.5 (mean difference of 1.08, lower limit of −6.14). The mean difference in therapy use between White and non-White patients is 0.27, with confidence interval between −1.06 and 0.53, although we cannot rule that therapy use among non-White patients is lower compared to White patients using the noninferiority margin of −0.5 h/night. Moreover, we did not see a significant difference in Clinical Global Impression Scale between White and Non-White patients based on physician assessment. Given these findings, UAS therapy has the same therapeutic benefits for non-White as it does for White patients and could provide an avenue for treatment in those unable to tolerate continuous PAP therapy. From a population health standpoint, the non-White population with its burden of OSA could potentially receive great benefit from UAS therapy for OSA. However, the percentage of non-White people receiving therapy is low.

Our group attempted to explore possible barriers for referral and implant of UAS therapy in non-White populations. One potential factor for lack of referral of non-White people for UAS may be the BMI criteria for UAS therapy. The STAR trial, which led to Food and Drug Administration approval had the inclusion criteria of a BMI less than and equal to 32 kg/m^2. The average BMI is 32.2 kg/m^2 among Blacks with moderate to severe OSA,[28] while the average recipient of UAS had a BMI of 29 kg/m^2.[26] Another possible barrier for UAS therapy for

Table 3—Noninferiority analysis: outcome data for matched patients.

Variable	Non-White (n = 55)	White (n = 55)	Difference [CI]
Therapy use, h	6.08 ± 1.87	6.35 ± 2.29	−0.27 [−1.06, 0.53]
Decrease in AHI, events/h	21.9 ± 19.4	20.8 ± 18.9	1.08 [−6.14, 8.31]

AHI = apnea-hypopnea index, CI = confidence interval.

non-White people could be lack of access to sleep medicine clinics for initial diagnosis and management of OSA. Blacks with OSA are significantly underdiagnosed.[29] Among 24% with moderate to severe OSA, 95% were not diagnosed. Blacks who are unable to tolerate continuous PAP are less likely to receive continuous care for OSA. Blacks are less likely to return to clinics for follow-up and own their PAP machines for less time.[11,18,19] Given that UAS is only offered as a treatment option for those intolerant of continuous PAP, the lower follow-up rate could lead to decreased discussion and referral for UAS therapy in this patient population.

Systemic barriers, including decreased health literacy and English language proficiency, decreased educational opportunities, health care system distrust, and a lack of culturally adapted and reading level-appropriate health information all likely contribute as well.[30–34] In 1 study, only about one-half of Hispanics reported that their sleep study results had been explained to them in their language.[35] Providers are likely unaware of the degree of the gap in health literacy, and their personal biases may unintentionally impact their recommendations and follow-up.[24] Minorities are also vulnerable to miscommunication affecting the perception of the need and benefits of treatment.[35,36]

Among limited data addressing disparities in surgical treatment for OSA, UAS is not the only surgical option that is associated with potential disparities across income and certain ethnicities. Non-White people are less likely to receive mandibular advancement surgery as treatment for OSA compared to White people.[37] Black children with OSA are less likely to receive adenotonsillectomy than White children,[38] and more likely than non-Black children to be lost to follow-up after referral for polysomnography.[39]

In addition, there can be factors of poor enrollment of non-White patients into the ADHERE registry. Enrollment is voluntary and even though the vast difference between White and non-White participants is striking and most likely due to a low level of implanted patients, disparities in enrollment of non-White participants may be at play as well. There are issues regarding recruitment of participants in clinical research with diverse backgrounds and whom English is not the primary language.[40] A study looking at participants in cardiac studies showed a low percentage of Blacks although the Black population has a higher burden of disease compared to other racial groups.[41] There may also be an element of hesitancy among non-White patients to participate in research. A survey study asking about perception of participation in biomedical research and cancer screening showed that Black and Hispanic people perceive higher risks and worries of "being taken advantage of" compared to White people.[42]

There are limitations to our study. This is a retrospective study with a low number of participants. While there was not a significant difference in therapy use between White and non-White patients, we could not rule out the small reduction of 0.27 h/night among non-White participants to be noninferior to White participants using the noninferiority margin of 0.5 h/night. We also did not have final AHI (defined as residual AHI on UAS at the final visit, which is typically 12 months after implant) for several participants to compare if there is a significant difference between White and non-White patients. Moreover, systematic collection of data regarding structural racism, social determinants of health, and reasons for barriers to access to care were not collected to be able to elucidate the rationale behind the sleep health care disparities observed.

In summary, our study found that there was no significant difference in adherence or efficacy with UAS therapy for OSA between White and non-White patients. However, the percent of non-White people in the ADHERE registry was low, which

Table 4—Secondary analyses: other outcome results.

Variable	Non-White (n = 55)	White (n = 55)	*P**
Post-treatment AHI, events/h	14.1 ± 15.6	12.9 ± 13.54	.9
	Median: 9.9	Median: 10.1	
Change in ESS	3.6 ± 4.6	3.4 ± 5.4	.9
Response rate (Sher)	65.4% (36)	65.4% (36)	1

*Wilcoxon rank sum test at a significance level of .05. AHI = apnea-hypopnea index, ESS = Epworth Sleepiness Scale, Sher = criteria for treatment success defined as of 50% reduction in AHI and treatment AHI <20.

Table 5—Secondary analyses: clinical global impression after intervention results at post-titration.

Answer	Non-White (n = 55)	White (n = 55)	*P*
Very much improved	12 (33.3%)	17 (39.5%)	.957*
Much improved	17 (47.2%)	18 (41.9%)	
Minimally improved	4 (11.1%)	3 (7.0%)	
No change	2 (5.6%)	3 (7.0%)	
Minimally worse	1 (2.8%)	1 (2.3%)	
Very much worse	0 (0%)	1 (2.3%)	

Data are presented as n (%). *Fisher's exact test.

indicates a possible health care disparity and the need to expand access to this therapy for non-White populations. This study also brings to light potential issues with enrollment of non-White participants into the registry, which is another aspect that should be explored when looking at recruitment sites and processes for the ADHERE registry. Research has demonstrated that culturally tailored approaches toward education, evaluation, and treatment can significantly improve outcomes especially when developed with the input and approval of the targeted communities.[43,44] Currently, promotional materials for the only Food and Drug Administration-approved UAS therapy (Inspire) are in English and Spanish. However, development of more culturally tailored materials could be considered for UAS to expand this OSA treatment option to non-White patients and reduce disparities in health.

ABBREVIATIONS

AHI, apnea-hypopnea index
BMI, body mass index
ESS, Epworth Sleepiness Scale
OSA, obstructive sleep apnea
PAP, positive airway pressure
UAS, upper airway stimulation

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SUBMISSION & CORRESPONDENCE INFORMATION

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