

Research Article

Health-related quality of life in obese patients with isolated obstructive sleep apnea and obstructive sleep apnea with obesity hypoventilation syndrome on home non-invasive ventilation

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Summary

Introduction: It is well known that sleep-related breathing disorders like obstructive sleep apnea (OSA) and obesity hypoventilation syndrome (OHS) decrease quality of life and increase morbidity and mortality. OSA patients with good adherence to nighttime CPAP report improvement of their daily functioning, social interactions, emotional functioning, daytime sleepiness, and other symptoms. In OHS, both CPAP and non-invasive ventilation (NIV) show improvement in quality of life if prescribed accurately.

Methods: We recruited 60 newly diagnosed obese patients with OSA and divided them into two groups: isolated – iOSA (n = 32) and OHS-OSA (n = 28). The health-related quality of life of all subjects was measured at baseline and after 3 months of treatment via the Interviewer Administered version of the EQ-5D-5L questionnaire.

Results: The baseline EQ-5D value of the iOSA group (Median: 0.836; IQR: 0.113) was significantly higher than that of the OHS-OSA overlap syndrome (Median: 0.67; IQR: 0.209) ($p < 0.001$). Three months after treatment, both groups had increased their EQ-5D value significantly: The iOSA group from median: 0.836 with IQR: 0.113 to median: 1 with IQR: 0 ($p < 0.001$), and the OHS-OSA group from median: 0.67 with IQR: 0,209 to median: 0.874 with IQR: 0.137 ($p < 0.001$) respectively. When we compared the EQ-5D values after treatment between the two groups, we observed the same statistically significant difference as before treatment ($p < 0.001$).

Conclusion: NIV therapy makes a huge difference in the HRQoL of OHS-OSA patients, though it does not reach a subjective perception of full health like in subjects with iOSA.

Key words: EQ-5D-5L, OSA, OHS, non-invasive ventilation, quality of life



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Introduction

Modern medicine has reached a stage where a lot of chronic diseases cannot be cured completely, but can be stabilized for long periods of time. People living with chronic illness experience some degree of discomfort and decline in their overall health because of their condition. All treatments for chronic diseases

aim not only to delay death but to improve the quality of life of patients as much as possible during the disease course that can last months (some aggressive forms of cancer) or years (COPD, breast cancer, diabetes mellitus). It is important how a patient perceives their own health. This perception is called health-related quality of life (HRQoL). According to the US Center for Disease Control, it is defined as "a multidomain concept that represents a patient's general perception of the effect of illness and treatment on physical, psychological, and social aspects of life" (Sitlinger and Zafar 2018). It can be measured via different questionnaires aimed either at the general population or at patients with a specific diagnosis or age groups.

Obstructive sleep apnea (OSA) is a condition characterized by repetitive upper airway collapse during sleep with recurrent oxygen desaturation, multiple arousals, and fragmented sleep, leading to poor sleep quality and symptoms of excessive daytime sleepiness (Mohammadi et al. 2017). Obesity hypoventilation syndrome (OHS) is another respiratory disorder characterized by obesity, daytime hypercapnia, and sleep disordered breathing in the absence of other conditions that cause alveolar hypoventilation. In order to diagnose OHS, the patient must have a body mass index $\geq 30 \text{ kg}\cdot\text{m}^{-2}$ and an arterial partial pressure of carbon dioxide (PaCO_2) $\geq 45 \text{ mmHg}$ (Masa et al. 2019).

It is well known that sleep-related breathing disorders like OSA and OHS deteriorate life quality and increase morbidity and mortality. (Chang et al. 2020) Patients with moderate and severe sleep apnea show improved quality of life after initiation of continuous positive airway pressure (CPAP) treatment (Battool-Anwar et al. 2016). OSA patients with good adherence to nighttime CPAP report improvement of their daily functioning, social interactions, emotional functioning, and daytime sleepiness, among other symptoms (Avlonitou et al. 2012). In OHS, both CPAP and non-invasive ventilation (NIV) improve quality of life if prescribed accurately (Masa et al. 2019). After 6 months of treatment, newly diagnosed severely impaired patients show the most improvement (Valko et al. 2020).

A Japanese study from 2003 compared the HRQoL of obese OSA, OHS-OA, and non-obese OSA patients. Its results showed that, before treatment, OHS-OA subjects had the worst quality of life, followed by obese OSA and non-obese OSA patients without hypoventilation. After 3–6 months of treatment, the quality of life of all three groups had leveled off (meaning that all three groups had a comparable HRQoL a few months after treatment initiation, regardless of the baseline differences) (Hida et al. 2003).

Several other studies confirm that long-term mechanical ventilation (invasive or non-invasive) improves the HRQoL in patients with chronic hypercapnic respiratory failure. However, they do not focus primarily on OHS and also include COPD, kyphoscoliosis, and neuro-muscular disease patients as well (Windisch et al. 2003; Budweiser et al. 2007; Markussen et al. 2018; Valko et al. 2020; Windisch and Quality of life in home mechanical ventilation study group 2008; Chang et al. 2010; Tsolaki et al. 2011; Yüksel et al. 2020).

Our literature search in the PubMed, Scopus, EMBASE, and Web of Science databases found no other research except for the 2003 Japanese study that compared the HRQoL of OSA and OHS-OA patients before and after treatment. Therefore, we conducted a study that evaluated the HRQoL in a cohort of obese OSA and OHS-OA patients before and after initiation of appropriate treatment.

Materials and methods

This observational dual-centric study was conducted in a specialized center for ambulatory patients with pulmonary and cardiovascular diseases and a specialized unit for pulmonary diseases in a University Hospital in Sofia, Bulgaria.

We recruited only newly diagnosed obese patients with OSA with and without daytime hypercapnia. Inclusion criteria were: 1. Body mass index $\geq 30 \text{ kg}\cdot\text{m}^{-2}$; 2. Five or more obstructive respiratory events per hour of sleep during a cardio-respiratory polygraphy test with symptoms of excessive daytime sleepiness or disordered sleep, or fifteen or more obstructive respiratory events per hour of sleep during a respiratory polygraphy test. Obstructive respiratory events include apneas, hypopneas, or respiratory effort-related arousals. Patients previously treated with CPAP or NIV were excluded from the study.

For OSA detection, we used a respiratory polygraph that records respiratory movements, airflow through a nasal cannula, oxygen saturation (SpO_2), and heart rate. Interruption of the amplitude of nasal airflow $> 90\%$ for at least 10 sec. was interpreted as apnea. Hypopnea was identified as a decrease $\geq 50\%$ in the amplitude of oronasal airflow compared with the pre-event chest excursion, lasting at least the equivalent of two respiratory cycles and accompanied by a SpO_2 decrease $\geq 3\%$ (Masa et al. 2011). Apnea-hypopnea index (AHI) was measured automatically. It is the combined average number of apneas and hypopneas that occur per hour of sleep and is used for the interpretation of OSA severity. AHI of 5–15 means mild OSA, 15–30 means moderate OSA, and > 30 indicates severe OSA (Asghari and Mohammadi 2013).

After an OSA diagnosis had been made, we performed an arterial blood analysis on all patients. We divided them into two groups based on the results. The ones with (PaCO_2) $\geq 45 \text{ mmHg}$ were considered to have OHV and were labeled as OSA-OHV, and the others formed the isolated OSA (iOSA) group.

The iOSA patients underwent a CPAP trial and titration. Those who failed to maintain an AHI below 5, had $\text{SpO}_2 < 90\%$ on CPAP of 20 mm H_2O , or experienced discomfort from the high positive airway pressure, were switched to NIV. The end goal was to abolish or have minimal apneas and reach a sufficient $\text{SpO}_2 > 90\%$ through the night.

In accordance with the most recent recommendations (Ramírez Molina et al. 2020), OHS-OSA patients were split into two groups: with predominant hypercapnia and with predominant obstructive events. Those with predominant hypercapnia were put directly on NIV. Those with predominant obstructive events underwent a trial of CPAP and, if their symptoms and hypercapnia did not respond properly, they were also referred for NIV.

The ventilation modes we used for our patients were as follows: fixed CPAP, automatic CPAP, fixed Bilevel Positive Airway Pressure (BPAP), automatic BPAP, and S/T mode. Fixed CPAP is the most basic ventilation mode. It provides a set pressure throughout the whole night regardless of the changes in the patient's respiration. Automatic CPAP is a form of automatic CPAP titration through the night. It starts with a set low CPAP value and starts to increase every time the ventilator detects a respiratory event until there are no more respiratory events, or a set maximum CPAP value is reached. BPAP is a form of NIV. It delivers two pressures – inspiratory airway pressure (IPAP) and expiratory airway pressure (EPAP). When the patient has an inspiratory effort, a breath is triggered, and

the ventilator assists the patient with the IPAP. During expiration, the ventilator delivers the EPAP to maintain airway and alveolar patency through the respiratory cycle. A fixed BPAP has fixed EPAP and IPAP. Every breath is assisted with the same pressures regardless of the breathing pattern. The automatic BPAP, similar to the automatic CPAP, starts with a set EPAP and IPAP, and they increase simultaneously when a respiratory event occurs. BPAP modes only assist the patient's own breathing efforts. S/T mode is a classic NIV mode where the ventilator assists the patient's efforts like a fixed BPAP. However, the physician can also set a certain number of mandatory breaths per minute. If the patient's respiratory rate falls below this number, the ventilator will deliver a machine-triggered breath with set IPAP and EPAP.

The ventilators that all patients used recorded their average ventilator use, all respiratory events, AHI, and mask leak. The data was recorded on an SD card and sent to the cloud via the built-in 3-G sim card of the devices. Both groups were monitored for ventilation compliance and AHI through an online platform that extracts data from the cloud.

The HRQoL of all subjects was measured at baseline and after 3 months of treatment with the Interviewer Administered version of EQ-5D-5L questionnaire created by the EuroQol Group (Devlin et al. 2020). The questionnaire is composed of 5 questions addressing 5 dimensions of HRQoL – Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression. They all have 5 levels (items) that can be arranged in an ordinal scale from 1 to 5, where 1 represents no problems, and 5 represents severe impairment in the respective dimension.

The answers to these 5 questions create the EQ-5D profile, which then can be summarized as a single number – the EQ-5D value. It can have a value between 1 and 0, where 1 means full health and 0 means a state so bad, as being dead. Rarely, the EQ-5D value can be a negative number, representing a health state worse than death. This index is calculated via country-specific value sets. They weigh the value of each item of the questionnaire according to the specific national mindset. Unfortunately, there is no value set developed for Bulgaria. According to the EuroQuol Group recommendations, we used the value set for Romania (Olariu et al. 2022) because Bulgaria and Romania are neighboring countries, both are in Eastern Europe, and became members of the European Union in the same year.

The second part of the EQ-5D questionnaire is a visual-analogue scale (VAS) presented as a ruler with the numbers from 0 to 100. The patient is asked to evaluate his/her health today and mark it on the scale with a cross. The VAS provides additional information to the EQ-5D profile and is reported separately.

The HRQoL at baseline was assessed with an in-person interview, and at 3 months, the interview was repeated via a telephone call. Data was recorded and summarized in Microsoft Excel.

After all data were obtained, we compared the HRQoL before and after treatment in the iOSA and OHS-OSA groups separately to see if there was an improvement in the quality of life perception after treatment initiation in each patient population individually. Then we compared the HRQoL of the two groups at the two time points to test if NIV treatment alone can level off the quality of life of both groups, similar to the study of Hida et al. (2003).

Statistical analysis was conducted with the IBM SPSS package v.25. Data are presented as absolute values, percentages, medians, and interquartile ranges

(IQR). Independent samples were compared with the Mann-Whitney U test and chi-square test, and dependent samples with the Wilcoxon signed-rank test. A p-value of ≤ 0.05 was considered to be statistically significant.

Results

A total number of 60 subjects participated in the study: 32 (53.3%) obese iOSA patients and 28 (46.7%) patients with OHS-OSA overlap syndrome. The most important characteristics of both groups are shown in Table 1.

The median baseline EQ-5D value of the iOSA group was 0.836; IQR: 0.113. Three months after treatment initiation, it had increased to a median of 1 with IQR: 0 ($p < 0.001$). The median baseline EQ-5D value of the OHS-OSA group was 0.67; IQR: 0.209. Three months after treatment initiation, it has increased to a median of 0.874 with IQR: 0.137 ($p < 0.001$). More detailed information about the values of the individual items of the EQ-5D-5L questionnaire, grouped in their respective dimensions, before and after treatment for both groups, is presented in Table 2.

Table 1. Characteristics of the study participants.

	OSA (n = 32)	OHS/OSA (n = 28)	p
Age (median;IQR)	58 (IQR: 27)	61 (IQR: 16.75)	0.97
Sex (n)			
Male	26 (81.3%)	15 (53.6%)	
Female	6 (18.8%)	13 (46.4%)	
Smoking status (n)			
Smokers	21 (65.6%)	13 (46.4%)	
Non-smokers	7 (21.9%)	10 (35.7%)	
Ex-smokers	4 (12.5%)	5 (17.9%)	
BMI (median; IQR)	35.7 (IQR: 9.7)	39.85 (IQR: 7.7)	0.022
AHI before treatment (median; IQR)	51 (IQR: 37.3)	41.5 (IQR: 19.65)	0.26
AHI after treatment (median; IQR)	1.1 (IQR: 1.47)	2.4 (IQR: 2.8)	0.01
Average use per day in min (median; IQR)	424 (IQR: 91.5)	480 (IQR: 75.5)	0.002
Ventilation mode (n)			
CPAP (fixed)	1	1	
CPAP (automatic)	24	1	
BPAP (fixed)	0	10	
BPAP (automatic)	7	12	
S/T mode	0	6	
Comorbidities (n)			
Ischemic heart disease	6	14	
Hypertension	25	24	
Pulmonary hypertension	1	9	
Atrial fibrillation	4	1	
Congestive heart failure	1	9	
History of pulmonary embolism	0	6	
Mild COPD	1	6	
Asthma	0	3	
Bronchiectasis	0	1	
Hypothyroidism	1	5	
Insulin resistance	6	7	
Diabetes	7	10	
Cirrhosis	2	1	
Gout	3	5	
None	2	0	

Table 2. Frequencies of the EQ-5D-5L questionnaire items before and after treatment.

	OSA before treatment	OSA after treatment	p	OHS/OSA before treatment	OHS/OSA after treatment	p
Mobility (n; %)						
1	21 (65.63%)	28 (87.5%)	0.006	1 (3.6%)	12 (42.86%)	< 0.001
2	7 (21.88%)	3 (9.38%)		10 (35.71%)	13 (46.43%)	
3	2 (6.25%)	1 (3.13%)		7 (25%)	3 (10.71%)	
4	1 (3.13%)	0 (0%)		9 (32.14%)	0 (0%)	
5	1 (3.13%)	0 (0%)		1 (3.6%)	0 (0%)	
Self-Care (n; %)						
1	28 (87.5%)	29 (90.63%)	0.18	7 (25%)	15 (53.57%)	< 0.001
2	3 (9.38%)	3 (9.38%)		12 (42.86%)	13 (46.43%)	
3	0 (0%)	0 (0%)		5 (17.86%)	0 (0%)	
4	1 (3.13%)	0 (0%)		3 (10.71%)	0 (0%)	
5	0 (0%)	0 (0%)		1 (3.6%)	0 (0%)	
Usual activities (n; %)						
1	7 (21.88%)	28 (87.5%)	< 0.001	0 (0%)	10 (35.71%)	< 0.001
2	16 (50%)	3 (9.38%)		8 (28.57%)	14 (50%)	
3	7 (21.88%)	1 (3.13%)		11 (39.29%)	3 (10.71%)	
4	2 (6.25%)	0 (0%)		7 (25%)	1 (3.6%)	
5	0 (0%)	0 (0%)		2 (7.14%)	0 (0%)	
Pain and Discomfort (n; %)						
1	0 (0%)	27 (84.38%)	< 0.001	1 (3.6%)	12 (42.86%)	< 0.001
2	2 (6.25%)	4 (12.5%)		3 (10.71%)	15 (53.57%)	
3	14 (43.75%)	1 (3.13%)		7 (25%)	1 (3.6%)	
4	14 (43.75%)	0 (0%)		12 (42.86%)	0 (0%)	
5	2 (6.25%)	0 (0%)		5 (17.86%)	0 (0%)	
Anxiety and Depression (n; %)						
1	28 (87.5%)	29 (90.63%)	0.317	17 (60.71%)	20 (71.43%)	0.011
2	4 (12.5%)	3 (9.38%)		6 (21.43%)	7 (25%)	
3	0 (0%)	0 (0%)		4 (14.29%)	1 (3.6%)	
4	0 (0%)	0 (0%)		1 (3.6%)	0 (0%)	
5	0 (0%)	0 (0%)		0 (0%)	0 (0%)	

If we make a side-by-side comparison of the EQ-5D values in both groups before and after treatment, we can see that there is a statistically significant difference, both at baseline ($p < 0.001$) and at three months ($p < 0.001$).

The results for the VAS were similar to those for the EQ-5D value: The baseline self-reported quality of life measured with the VAS was significantly better in the iOSA group (Median: 50; IQR: 20) than that of the OHS-OSA group (Median: 30; IQR: 20) ($p = 0.001$). After treatment, the median VAS value increased by 30 points in both groups – 80 with IQR: 15 ($p < 0.001$) in the iOSA patients and 60 with IQR: 10 ($p < 0.001$) in the OHS-OSA patients, respectively. This 30-point increase after treatment in both groups leads to a similar intergroup VAS value difference as before treatment, with $p < 0.001$.

Discussion

As can be seen in the data summary in Table 1, there are some statistically significant but clinically negligible differences between the study groups (higher BMI, AHI before treatment, and average ventilator use per day in the OHS-

OSA group). The BMI of OHS-OSA patients was higher than that of isolated OSA patients. However, as demonstrated, both medians fall in the range of 35–39.5, which is classified as moderate obesity.

The average ventilator use per day was significantly higher in the OHS-OSA group, but converted to hours, both medians were above 5 h, which means that all patients included in the study demonstrated good compliance with the therapy. The average use per day was very high for both groups and was achieved with a good support and motivation program, and weekly monitoring of the ventilator compliance and respiratory events using the online platform to which the devices were connected. If there were a problem with the compliance, the healthcare provider would reach out to the patient to address the issue.

The AHI after treatment of the OHS-OSA group was worse than that of the iOSA group. Nevertheless, both were below 5, which means that from a clinical standpoint, this statistically detected significance is clinically irrelevant. All patients had a very high AHI before treatment, and after CPAP/NIV titration, apneas were almost absent.

There were more males and more smokers in the iOSA group than in the OHS-OSA group. The difference is not unexpected because male gender is a prominent risk factor for OSA (Huh et al. 2022), while the role of gender in OHS (especially in postmenopausal women) is still a topic of discussion (Barbage-lata et al. 2022). A higher number of female patients in the OHS-OSA group is considered a clinically relevant difference between groups because female subjects are known to have a significantly worse quality of life in OSA (Tasbakan et al. 2018). Since the majority of the subjects in the iOSA group were male, their smoking status is not surprising: in Bulgaria, 43.6% of men are smokers in contrast to 26.9% of women. (World Health Organisation 2016).

The most important difference between our study groups was the one related to the comorbidities. The OHS-OSA group has a higher prevalence of heart disease, such as ischemic heart disease and congestive heart failure, as well as pulmonary embolism and pulmonary hypertension. Endocrine diseases associated with obesity (diabetes, insulin resistance, and gout) were also more prevalent amongst the OHS-OSA patients. It is well known that heart disease diminishes HRQoL (Soleimani et al. 2020). Diabetes also contributes to a lower quality of life (Rodríguez-Almagro et al. 2018; Al-Matrouk and Al-Sharbaty 2022; Amin et al. 2022). These differences in the level of comorbidity are probably the main cause of the gap observed in the EQ-5D values and the VAS between groups, not only before but after CPAP/NIV institution as well.

The HRQoL before treatment, measured with the EQ-5D-5L questionnaire, was better in the iOSA group than the OHS-OSA group, analogous to the Japanese study from 2003 (Hida et al. 2003). Three months after initiation of proper treatment, the EQ-5D and the VAS of both groups increased: the median EQ-5D value after treatment of OSA patients was 1, representing full health with a corresponding VAS value of 80. This change means that correction of apneas significantly improved the quality of life of these patients to the point of normal social functioning and a subjective feeling of normal physical health. In contrast to the findings of Hida et al. (2003), the OHS-OSA patients in our study had lower HRQoL than the iOSA group even after correction of their respiratory disturbances. There might be two reasons for this occurrence. First, gender is a significant confounding factor. Female subjects with

OSA seemed to have a worse quality of life than their male counterparts. Also, the OHV-OSA group had more comorbidities that cannot be treated with NIV, which diminished their quality of life.

It is worth examining the answers to the individual questions in each domain of the EQ-5D-5L questionnaire before and after treatment. (Table 2) The everyday life of the iOSA patients had improved through better mobility, increased ability to perform usual activities, and a decline in pain and discomfort. The OHV-OSA patients also experienced improved mobility, performance during usual activities, and a decline in pain and discomfort levels, as well as improved ability to take care of themselves and relief of anxiety and depression symptoms. The progress the OHV-OSA patients made in those two domains is very important for their everyday functioning, meaning that NIV treatment makes a huge difference in the HRQoL of OHS-OSA patients, even though they did not reach a subjective perception of full health.

Conclusion

Sleep disordered breathing in obese patients with or without daytime hypercapnia reduces one's quality of life. Isolated OSA patients had a better HRQoL than OSA patients with accompanying OHV at baseline and 3 months after institution of proper treatment. Correction of apneas and hypercapnia with CPAP/NIV increased the EQ-5D values and VAS values of both iOSA and OHS-OSA syndrome patients. However, it did not level them off.

Further research is needed in order to correct the results for confounding factors, such as gender and comorbidities.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that experiments on humans or human tissues were performed for the present study.

Informed consent from the humans, donors or donors' representatives: Pecialised Hospital for Pulmonary diseases St. Sofia.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

Use of AI

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Author contributions

Conceptualization: YY, VI. Data curation: YY. Formal analysis: VI. Investigation: YY. Methodology: YY, VI. Project administration: VI. Resources: YY. Validation: YY. Writing - original draft: VI. Writing - review and editing: YY.

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Data availability

All of the data that support the findings of this study are available in the main text.

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