QUALITY OF LIFE ANALYSIS OF HYPOGLOSSAL NERVE STIMULATION WITH INSPIRE® DEVICE IN THE TREATMENT OF PATIENTS WITH OBSTRUCTIVE SLEEP APNEA INTOLERANT TO CONTINUOUS POSITIVE AIRWAY PRESSURE THERAPY

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BACKGROUND

Standard treatment of obstructive sleep apnea (OSA) is continuous positive airway pressure (CPAP) in patients with an apnea-hypopnea index (AHI) ≥15/h, excessive daytime sleepiness (Epworth scale >10), impaired sleep-related quality of life (QoL), and/or or high blood pressure. Up to 35.5% of patients do not tolerate CPAP requiring surgical alternatives. A minimally invasive option is the **hypoglossal nerve stimulation** (HNS) with the **Inspire® device**, which the Spanish Health System does not currently finance.

OBJECTIVE

Estimate the **impact on QoL (IQoL)**, under real practice conditions, associated with HNS in patients with moderate or severe OSA who do not tolerate CPAP.

METHODS

A retrospective **observational study** was carried out with patients diagnosed with moderate or severe OSA and intolerants to CPAP. At that time, all of them were offered the **possibility of implanting an HNS device** (paying it out if their pockets).

To participate in the study, patients met the following *inclusion criteria*: over 18 years, Diagnosis of OSA by polysomnography, and AHÍ > 15/hour. CPAP intolerance. Likewise, they were not included if they met any exclusion criteria: pregnancy, concentric collapse in the palate región, psychiatric disease, insomnia, and body mass index >35.

METHODS (cont.)

The intervention group (IGr) included all of the patients implanted in our hospital (3/2016 to 3/2021); *the control group* (CGr) was extracted from patients who did not accept the device (2:1). Patients were followed up for three months

The primary outcome was the impact on quality of life (IQoL) in the 3 monts after accepting/rejecting the device:

IQoL = QoLI_post – QoLC_post) – (QoLI_pre – QoLC_pre)

QoL was adjusted by multivariant regression:

QoLiT=*β1 + β2*device + β3*time + δ*(device*time)*

RESULTS

Table 1. Basal characteristics of patients

Variable	Total (n:66)	IGr (n=22)	CGr (n=44)	P
Sex, male (%)	84.8 (4.4)	90,9 (6,1)	81,8 (5,8)	*0,476*
Age (years)	53,5 (13.0)	51.7 (11.2)	54,0 (13,9)	*0,490*
BMI (kg/m^2)	28,7 (4,6)	28.1 (3.7)	29.0 (5.0)	*0,456*
AHI (events/h)	39,7 (20,1)	42,9 (21,1)	43,7 (24,7)	*0,928*
ESS (SD)	11.0 (5.3)	12.2 (5.1)	10.4 (5.4)	*0.227*
HTN, % (SD)	40.9 (6.1)	50.0 (10.7)	36.4 (7.3)	*0.304*
MD, % (SD)	21.2 (5.0)	18.2 (8.2)	22.7 (6.3)	*0.759*
MI, % (SD)	9.1 (3.5)	9.1 (6.1)	9.1 (4.3)	*1,000*
Asthma, % (SD)	21.2 (5.0)	27.3 (9.5)	18.2 (5.8)	*0.524*
COPD, % (SD)	6.1 (2.9)	9.1 (6.1)	4.5 (3.1)	*0,596*
CRF, % (SD)	6.1 (2.9)	4.5 (4.4)	6.8 (3.8)	*1,000*
Dyslipidemia, % (SD)	47.0 (6.1)	50,0 (10.7)	45.5 (7.5)	*0,797*
Cognitive failure, % (SD)	4.5 (2.6)	4.5 (4.4)	4.5 (3.1)	*1.000*
Chronic pain, % (SD)	18.2 (4.7)	31.8 (9.9)	11.4 (4.8)	*0.086*
RLS, % (SD)	21.2 (5.0)	22.7 (8.9)	20,5 (6.1)	*1,000*
CPAP previous, % (SD)	78,8 (5.1)	86.4 (7.3)	75.0 (6.5)	*0,354*
Daily use of CPAP, % (SD)	21.2 (5.0)	13.6 (7.3)	25.0 (6.5)	*0.354*

BMI: body mass index; AHI: apnea hypopnea index; ESS: Epworth sleepiness scale; HNT: arterial hypertension; MD: mellitus diabetes; COPD: chronic obstructive pulmonary disease; CRF: chronic renal failure; RLS: restless legs syndrome; CPAP: continuous positive airway pressure

RESULTS (cont.)

- 82% of patients rejected the implant for economic reasons
- The estimated IQoL was +0,177 (95% CI: 0.044-0.310); after adjusting for ESS, MD, MI, COPD, CRF, cognitive failure and chronic pain, IQoL was +0.062 (95% CI: 0.017-0.107) (**Figure 1**).
- At t: 3 months, the proportion of patients without problems in any QoL dimension was higher in IGr (**Figure 2**).
- The mean EQ-5D utility index of the Spanish population (0.923; SE: 0.01) showed no significant difference with that of the IGr at 3 months, but it was higher than that of the CGr (**Figure 3**).

Figure 1. Variation of the adjusted EQ-5D utility index pre-post

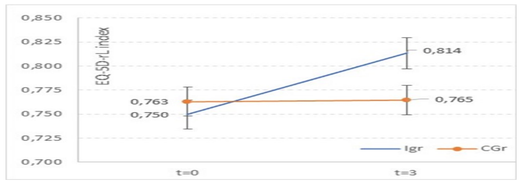
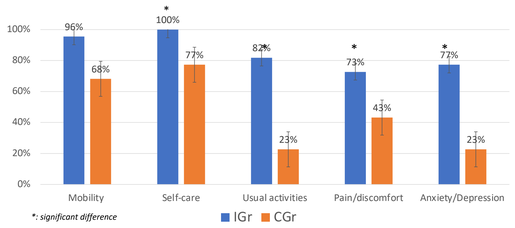
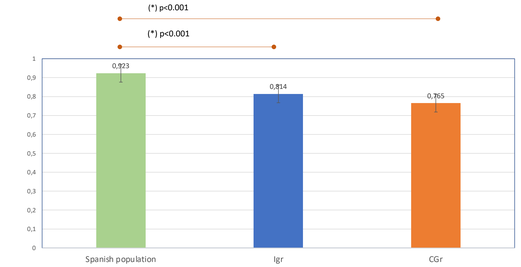


Figure 2. Patients withouth problems at final time



RESULTS (cont.)

Figure 3. Estimated EQ-5D utility index (t:3 months)



CONCLUSIONS

Patients with moderate/severe obstructive sleep apnea who are intolerant or do not accept standard treatment with continuous positive airway pressure showed a positive association between hypoglossal nerve stimulation (Inspire® device) and improved quality of life. In addition, they reached values equivalent to those of the general population.

Patients who cannot afford the device remain with a reduced quality of life.