

BIBLIOGRAFÍA DEL INSTRUMENTO

Cuestionario de los Resultados Funcionales del Sueño (FOSQ)

Versión española del Functional Outcomes
Sleep Questionnaire (FOSQ)
adaptada por M. Ferrer, J. Alonso

Institut Municipal d'Investigació Mèdica (IMIM-Hospital del Mar)
Grupo de Investigación en Servicios Sanitarios
C/Doctor Aiguàder, 88 E-08003 Barcelona
Fax (+34) 93 316 0797
www.imim.es



BiblioPRO



Biblioteca Virtual de Instrumentos de Resultados Percibidos por los Pacientes

BiblioPRO es una página web desarrollada por el Grupo de Investigación en Servicios Sanitarios del Institut Municipal d'Investigació Mèdica (IMIM-IMAS) y financiada por el CIBER en Epidemiología y Salud Pública.

www.bibliopro.imim.es



Bibliografía de la adaptación española del FOSQ

1. Ferrer M, Vilagut G, Monasterio C, Montserrat JM, Mayos M, Alonso J. Medida del impacto de los trastornos del sueño: las versiones españolas del cuestionario del impacto funcional del sueño y de la escala de somnolencia de Epworth. **Med Clin (Barc)** 1999;113:250-5.
2. Monasterio C, Vidal S, Duran J, Ferrer M, Carmona C, Barbe F, Mayos M, Gonzalez-Mangado N, Juncadella M, Navarro A, Barreira R, Capote F, Mayoralas LR, Peces-Barba G, Alonso J, Montserrat JM. Effectiveness of continuous positive airway pressure in mild sleep apnea-hypopnea syndrome. **Am J Respir Crit Care Med** 2001;164:939-43.
3. Montserrat JM, Ferrer M, Hernandez L, Farre R, Vilagut G, Navajas D, Badia JR, Carrasco E, De Pablo J, Ballester E. Effectiveness of CPAP treatment in daytime function in sleep apnea syndrome: a randomized controlled study with an optimized placebo. **Am J Respir Crit Care Med** 2001;164:608-13.
4. Blanco J, Zamarron C, Abeleira Pazos MT, Lamela C, Suarez Quintanilla D. Prospective evaluation of an oral appliance in the treatment of obstructive sleep apnea syndrome. **Sleep Breath** 2005;9:20-5.
5. Masa JF, Jimenez A, Duran J, Capote F, Monasterio C, Mayos M, Teran J, Hernandez L, Barbe F, Maimo A, Rubio M, Montserrat JM. *Alternative methods of titrating continuous positive airway pressure: a large multicenter study.* **Am J Respir Crit Care Med.** 2004 Dec 1;170(11):1218-24
6. Barbe F, Mayoralas LR, Duran J, Masa JF, Maimo A, Montserrat JM, Monasterio C, Bosch M, Ladaria A, Rubio M, Rubio R, Medinas M, Hernandez L, Vidal S, Douglas NJ, Agusti AG. *Treatment with continuous positive airway pressure is not effective in patients with sleep apnea but no daytime sleepiness. a randomized, controlled trial.* **Ann Intern Med.** 2001 Jun 5;134(11):1015-23.

Bibliografía del desarrollo del cuestionario original

1. Weaver TE, Laizner AM, Evans LK, Maislin G, Chugh DK, Lyon K, Smith PL, Schwartz AR, Redline S, Pack AI, Dinges DF. An instrument to measure functional status outcomes for disorders of excessive sleepiness. **Sleep** 1997;20:835-43.
2. Faccenda JF, Mackay TW, Boon NA, Douglas NJ. Randomized placebo-controlled trial of continuous positive airway pressure on blood pressure in the sleep apnea-hypopnea syndrome. **Am J Respir Crit Care Med** 2001;163:344-8.
3. Massie CA, Hart RW. Clinical outcomes related to interface type in patients with obstructive sleep apnea/hypopnea syndrome who are using continuous positive airway pressure. **Chest** 2003;123:1112-8.



4. Gooneratne NS, Weaver TE, Cater JR, Pack FM, Arner HM, Greenberg AS, Pack AI. Functional outcomes of excessive daytime sleepiness in older adults. *J Am Geriatr Soc* 2003;51:642-9.
5. Reimer MA, Flemons WW. Quality of life in sleep disorders. *Sleep Med Rev* 2003;7:335-49.
6. Dinges DF, Weaver TE. Effects of modafinil on sustained attention performance and quality of life in OSA patients with residual sleepiness while being treated with nCPAP. *Sleep Med* 2003;4:393-402.
7. Schwartz JR, Hirshkowitz M, Erman MK, Schmidt-Nowara W. Modafinil as adjunct therapy for daytime sleepiness in obstructive sleep apnea: a 12-week, open-label study. *Chest* 2003;124:2192-9.
8. Steward DL, Weaver EM, Woodson BT. A comparison of radiofrequency treatment schemes for obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg* 2004;130:579-85.
9. Teixeira VG, Faccenda JF, Douglas NJ. Functional status in patients with narcolepsy. *Sleep Med* 2004;5:477-83.
10. Walker RP, Paloyan E, Gopalsami C. Symptoms in patients with primary hyperparathyroidism: muscle weakness or sleepiness. *Endocr Pract* 2004;10:404-8.
11. Reishtein JL, Pack AI, Maislin G, Dinges DF, Bloxham TJ, George CF, Greenberg H, Kader GA, Mahowald MW, Younger JB, Weaver TE. Sleepiness and relationships in obstructive sleep apnea. *Issues Ment Health Nurs* 2006;27:319-30.
12. Krakow B, Melendrez D, Sisley B, Warner TD, Krakow J, Leahigh L, Lee S. Nasal dilator strip therapy for chronic sleep-maintenance insomnia and symptoms of sleep-disordered breathing: a randomized controlled trial. *Sleep Breath* 2006;10:16-28.

Bibliografía relacionada con la versión española del FOSQ

1. Ferrer M, Vilagut G, Monasterio C, Montserrat JM, Mayos M, Alonso J. Medida del impacto de los trastornos del sueño: las versiones españolas del cuestionario del impacto funcional del sueño y de la escala de somnolencia de Epworth. *Med Clin (Barc)* 1999;113:250-5

BACKGROUND: Excessive daytime sleepiness is a frequent symptom and a public health problem due to its association with automobile and work related accidents. The aim of this study was to develop and carry out a preliminary assessment of the Spanish version of the functional outcomes sleep questionnaire and the Epworth sleepiness scale, two instruments designed to evaluate patients with sleep disorders. MATERIAL AND METHODS: For the adaptation, the forward and back-translation method by bilinguals was used with professional and lay panel. Once tested for feasibility and comprehension, 39 patients with obstructive sleep apnea syndrome completed the Spanish version of the FOSQ and the Epworth sleepiness scale, together with a question on self-rated health status. RESULTS: Difficulty of translation was assessed as low and the naturalness of Spanish expressions as high for all the items of the questionnaires except for the response options of the Epworth sleepiness scale. Both questionnaires showed higher reliability than the standard proposed for individual comparisons (Cronbach's alpha > 0.9). The FOSQ vigilance scale showed a high correlation with the Epworth score ($r = -0.79$), while for the other scales of the FOSQ correlations were moderate (r ranging from -0.52 to -0.68). Patients who reported "regular" or "poor" health had significantly worse scores for most of the FOSQ scales. CONCLUSION: These results suggest that the Spanish versions of both questionnaires are conceptually equivalent to the originals and that they show similar characteristics of reliability and validity. The FOSQ vigilante scale assess daytime sleepiness similarly to Epworth but the others scales of the FOSQ provide additional information for these patients.
2. Mar J, Rivero-Arias O, Duran-Cantolla J, Alonso-Alvarez ML, Gaminde I, de la Torre-Munecas G. [Effect on quality of life of nCPAP treatment in patients with obstructive sleep apnea] *Med Clin (Barc)* 2005;125:611-5.



BACKGROUND AND OBJECTIVE: The standard treatment of the obstructive sleep apnea syndrome (OSAS) is the nCPAP. There is evidence that its use improves the quality of life of patients. The objective of the study is to measure the effect of nCPAP on the quality of life of patients in a Spanish cohort. **PATIENTS AND METHOD:** We have used 3 quality of life questionnaires: SF-36, EuroQol 5D and FOSQ. OSAS patients were interviewed at baseline prior to the start of the treatment and at 3 months follow-up. Two measures were employed to analyze the data: distribution based measures such as the effect size and instruments that evaluate the sensitivity to change of the questionnaires such as the ROC curves. **RESULTS:** We interviewed 124 patients. The benefit in terms of utility of the nCPAP was 0.03 with SF-36 and 0.04 with EuroQol 5D. Effect size varies from small (0.21) with EuroQol 5D to moderate (0.51) with FOSQ. SF-36 obtained intermediate scores (0.35). EuroQol 5D was the questionnaire that obtained the biggest area under the ROC curve. Nevertheless, the area size was small in all cases. **CONCLUSIONS:** nCPAP improves significantly the quality of life of OSAS patients. The assessment of the quality of life of OSAS patients with the available instruments is only partially satisfactory.

3. Montserrat JM, Ferrer M, Hernandez L, Farre R, Vilagut G, Navajas D, Badia JR, Carrasco E, De Pablo J, Ballester E. Effectiveness of CPAP treatment in daytime function in sleep apnea syndrome: a randomized controlled study with an optimized placebo. *Am J Respir Crit Care Med* 2001;164:608-13.

Application of continuous positive airway pressure (CPAP) as the standard treatment for sleep apnea/hypopnea syndrome (SAHS) is a moot point. Studies on the effectiveness of this treatment have been challenged because of the lack of a suitable placebo. The recent description of a true placebo (sham CPAP) prompted us to conduct a randomized trial of CPAP or placebo to assess the effectiveness of CPAP in improving SAHS-related symptoms and daytime function in patients with moderate to severe SAHS. Forty-eight patients, stratified in four groups according to severity, were randomly allocated into two treatment groups (optimal and sham CPAP) for a 6-wk period. Of these, 45 completed follow-up (91% males; age: 54 +/- 10 yr; body mass index [BMI]: 32 +/- 6 kg/m²); apnea-hypopnea index [AHI]: 54 +/- 19 events/h; and Epworth Sleepiness Scale [ESS]: 16 +/- 5). The ESS, a questionnaire on SAHS-related symptoms, Functional Outcomes Sleep Questionnaire (FOSQ), and the Short Form Health Survey (SF-36) were completed at inclusion and after treatment. After 10 d of washout, the placebo group was treated with optimal CPAP and reassessed before and after optimal CPAP. The group receiving optimal CPAP when compared with the group with sham CPAP showed considerably greater improvement in the relief of sleepiness (-9.5 versus -2.3, $p < 0.001$), other SAHS-related symptoms (-18.5 versus -4.5, $p < 0.001$), vigilance (+8.5 versus +3.4, $p = 0.009$), and general productivity (+4.0 versus +0.5, $p = 0.04$) FOSQ scales. Both groups used a similar number of hours for the optimal and the sham CPAP (4.3 versus 4.5, $p = \text{NS}$). The patients initially treated with placebo CPAP improved significantly more when optimal CPAP was applied for ESS (-2.3 versus -6.7, $p < 0.001$) and other sleep apnea syndrome (SAS)-related symptoms (-4.5 versus -11.2, $p = 0.02$). Our study provides strong evidence of the effectiveness of CPAP treatment in improving symptoms and perceived health status in moderate to severe SAHS.

4. Monasterio C, Vidal S, Duran J, Ferrer M, Carmona C, Barbe F, Mayos M, Gonzalez-Mangado N, Juncadella M, Navarro A, Barreira R, Capote F, Mayorals LR, Peces-Barba G, Alonso J, Montserrat JM. Effectiveness of continuous positive airway pressure in mild sleep apnea-hypopnea syndrome. *Am J Respir Crit Care Med* 2001;164:939-43.

The aim of this trial was to evaluate the effectiveness of continuous positive airway pressure (CPAP) in patients with mild sleep apnea-hypopnea syndrome (SAHS). One hundred forty-two consecutive patients with mild SAHS (apnea-hypopnea index 10-30, without severe sleepiness) were randomly assigned to receive conservative treatment (CT)-sleep hygiene and weight loss- (65 patients) or CT plus CPAP (77 patients), and 125 patients (86% males, age: 54 +/- 9 yr, BMI: 29 +/- 4 kg/m², AHI: 20 +/- 6, ESS: 12 +/- 4) completed the follow-up. The following outcomes were assessed at inclusion and after 3 and 6 mo of treatment: sleepiness (Epworth scale, multiple sleep latency test [MSLT]), other symptoms related to SAHS, cognitive function, and perceived health status (Functional Outcomes of Sleep Questionnaire [FOSQ], Nottingham Health profile). The relief of SAHS-related clinical symptoms was significantly greater in the CPAP group than in the CT group; the Epworth scale and FOSQ also showed more improvement in the CPAP group but did not reach significance. There were no significant differences in the other tests performed probably because the baseline values were normal. CPAP compliance was 4.8 +/- 2.2 h and treatment continuation was accepted by 62% of the patients at the end of the study. These results suggest that CPAP can be considered in treating patients with mild SAHS on the basis of an improvement in symptoms.

5. Blanco J, Zamarron C, Abeleira Pazos MT, Lamela C, Suarez Quintanilla D. Prospective evaluation of an oral appliance in the treatment of obstructive sleep apnea syndrome. *Sleep Breath* 2005;9:20-5.

The purpose of this study was to investigate the effects of an oral appliance (OA), with and without mandible advance, in the treatment of obstructive sleep apnea syndrome (OSA). Twenty-four patients diagnosed with OSA agreed to participate in this study. The patients were treated for 3 months (with a removable soft elastic silicone positioner customized with thermoplastic silicone and with a 5-mm opening). Patients were selected, using a randomized design, to receive an OA model either with (12 patients) or without advance (12 patients). Before treatment, a snoring questionnaire, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), the Functional Outcomes of Sleep Questionnaire (FOSQ), the Epworth Sleepiness Scale (ESS), and polysomnography were completed. Fifteen subjects completed the protocol (13 men, two women). With respect to basal values, the mandible-advanced OA group presented a decrease in the mean apnea-hypopnea index (AHI) (33.8 +/- 4.7 versus 9.6 +/- 2.1; $p < 0.01$), number of arousals per hour (33.8 +/- 13.9 versus 16.0 +/- 1.5; $p < 0.05$), ESS score (14.7 +/- 5.1 versus 5.1 +/- 1.9; $p < 0.05$), snoring score (15.4 +/- 1.9 versus 10.1 +/- 3.2; $p < 0.05$), and total FOSQ score (78.1 +/- 22.6 versus 99.3 +/- 14.4; $p < 0.05$). After treatment, the non-advanced group presented a decrease in the mean AHI (24.0 +/- 12.2 versus 11.7 +/- 7.9; $p < 0.05$). However, no significant differences were found in the number of arousals per hour, ESS score, snoring, and total FOSQ score in the non-advanced group. Neither study group showed significant difference in mean SF36 scores. Oral appliances, especially those that advance the mandible, offer an effective treatment for OSA.