Validation of the Otitis Media-6 Questionnaire for European Portuguese

Validação do Questionário *Otitis Media-6* para Português Europeu

Ana Rita LAMEIRAS✉[1], Deodato SILVA[1], Assunção O'NEILL[1,2,3], Pedro ESCADA[1,3]
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ABSTRACT

Introduction: Otitis media is one of the most prevalent childhood diseases. The impact of otitis media on quality of life of Portuguese children is unknown, because of the unavailability of a tool validated in European Portuguese to assess this consequence of otitis media. The Otitis Media-6 questionnaire (Otitis Media-6) is the most frequently used tool to assess health-related quality of life in children with otitis media. This study aims to create a version in the Portuguese language and culturally adapted to Portugal of the otitis media-6 questionnaire.

Material and Methods: The Otitis Media-6 questionnaire was translated and culturally adapted to the Portuguese language and population. Then, to assess the instrument psychometric properties, it was applied to a sample of Portuguese children with chronic otitis media with effusion or recurrent acute otitis media.

Results: The Portuguese version of Otitis Media-6 questionnaire demonstrated the following psychometric properties: construct validity for baseline (r_s = 0.98) and change scores (r_s = 0.97), internal consistency (α = 0.780), test-retest reliability (r_s = 0.89) and responsiveness to clinical change (t(59) = 10.104).

Discussion: The simplicity and brevity of application of the instrument make it ideal for use in research and in clinical practice, enabling a more objective assessment of the extension of the otitis media impact in children quality of life and a more targeted therapeutic decision.

Conclusion: The Portuguese version of the Otitis Media-6 questionnaire is a valid, reliable and sensitive instrument to evaluate the health-related quality of life in Portuguese children with otitis media.

Keywords: Child; Otitis Media; Portugal; Quality of Life; Surveys and Questionnaires

RESUMO

Introdução: A otite média é uma das doenças mais prevalentes na infância. O impacto da otite média na qualidade de vida das crianças portuguesas não é conhecido, devido à indisponibilidade de um instrumento validado em português europeu capaz de avaliar esta consequência da otite média. O questionário *Otitis Media-6* é o instrumento mais frequentemente usado para avaliar a qualidade de vida relacionada com a saúde em crianças com otite média. Este estudo tem como objetivo criar uma versão em língua portuguesa e culturalmente adaptada a Portugal do questionário *Otitis Media-6*.

Material e Métodos: O questionário *Otitis Media-6* foi traduzido e culturalmente adaptado à língua e à população portuguesa. Em seguida, para avaliar as propriedades psicométricas do instrumento, o mesmo foi aplicado a uma população de crianças portuguesas com otite média crónica com efusão ou otite média aguda recorrente.

Resultados: A versão portuguesa do questionário *Otitis Media-6* demonstrou as seguintes propriedades psicométricas: validade de construção para os scores basal (r_s = 0,98) e de mudança (r_s = 0,97), consistência interna (α = 0,780), confiança teste-reteste (r_s = 0,89) e resposta a alteração clínica (t(59) = 10,104).

Discussão: A simplicidade e brevidade de aplicação do instrumento tornam-no ideal para utilização em investigação e na prática clínica diária, possibilitando uma avaliação mais objetiva da extensão do impacto da otite média na qualidade de vida da criança e a tomada de decisões terapêuticas mais orientada.

Conclusão: A versão portuguesa do questionário *Otitis Media-6* é um instrumento válido, confiável e sensível para avaliação da qualidade de vida relacionada com a saúde em crianças portuguesas com otite média.

Palavras-chave: Criança; Inquéritos e Questionários; Otite Média; Portugal; Qualidade de Vida

INTRODUCTION

Otitis media (OM) is one of the most prevalent childhood diseases and one the major causes for medical examination in preschoolers.[1] Chronic otitis media with effusion and acute otitis media are the two most relevant forms of OM, showing a continuum between these two clinical entities.[2]

Most studies assessing the impact of OM are based on physiological measurements such as hearing thresholds, the rate of recurrent OM, the assessment of middle-ear status and tympanic membrane integrity. However, the relevance of quality of life has been increasingly recognised in OM clinical research.[3] In fact, recurrent otalgia, fever and general malaise[4,5] or long-term consequences of OM such as hearing loss and language development disorders[6,7] may have an impact on health-related quality of life of children with OM.

The *Otitis Media-6* (OM-6) questionnaire was originally developed in English by Rosenfeld *et al*.,[3] has been widely used for the assessment of health-related quality of life in

1. Serviço de Otorrinolaringologia. Hospital de Egas Moniz. Centro Hospitalar de Lisboa Ocidental. Lisboa. Portugal.
2. Departamento de Anatomia. NOVA Medical School. Universidade Nova de Lisboa. Lisboa. Portugal.
3. Departamento de Otorrinolaringologia. NOVA Medical School. Universidade Nova de Lisboa. Lisboa. Portugal.
✉ Autor correspondente: Ana Rita Lameiras. rita_lameiras@hotmail.com
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children with OM and was already translated and validated into different other languages.[8-10] This study aimed at the development of a culturally-adapted Portuguese version of the questionnaire as well as the assessment of its consistency and reliability.

MATERIAL AND METHODS

This was a longitudinal prospective study carried out at the Department of ENT (Ear, Nose & Throat) of the *Hospital de Egas Moniz, Centro Hospitalar de Lisboa Ocidental* and was developed into two stages: Stage I – translation and cultural adaptation of the OM-6 questionnaire; Stage II – application of the Portuguese version (European Portuguese) of the questionnaire to Portuguese children with OM, aimed at the assessment of its consistency and reliability. A written consent for translation and application has been obtained from the first author of the original version of the OM-6 questionnaire.[3]

This study has been approved by the Ethics Committee of the institution where it took place, according with the Helsinki Declaration.

Characterisation of the questionnaire

The OM-6 questionnaire has been aimed at patients aged between 6 months and 12 years with chronic otitis media with effusion (and at least three-month duration) or recurrent acute otitis media (at least 3 episodes over the past 12 months, with full otoscopic recovery between episodes). It has been completed by the researcher and six domains related to the OM have been assessed: physical suffering, hearing loss, speech impairment, emotional distress, activity limitation and caregiver concerns. Each domain is addressed by a single 7-point question allowing for the assessment of the impact of OM on health-related quality of life over the past four weeks. Responses were scored 1 to 7 (1 – no problem; 7 – extreme problem). The final score (ranging 1.0-7.0) has been obtained by taking the mean of the 6 domain scores. The highest the final score the poorer the health-related quality of life.

Change scores can be obtained by subtracting post-intervention final score (follow-up score obtained upon myringotomy tube placement, for instance) from the pre-intervention final score (baseline score) (change score = baseline – follow-up score) and allowed for the assessment of clinical outcomes with a minimum four-week time gap between clinical examinations. A negative score corresponds to a poor clinical outcome and a positive score to a clinical improvement. The level of change related to a specific intervention can be assessed by pre-defined change score intervals: < 0.5 - trivial; 0.5 – 0.9 – small; 1.0 – 1.4 - moderate; ≥ 1.5 - large.

Stage I

The original English version of the OM-6 questionnaire has been assessed by two bilingual (Portuguese and English) native Portuguese (European Portuguese) speaker specialist physicians and English (level B2) independent users and an initial Portuguese version has been developed. This has been assessed by a panel including two translators and other three specialist physicians, leading to the adaptation of three words and expressions that were considered as inadequate for the Portuguese reality: the word '*fluid*' (consensually translated as 'fluido') has been replaced by 'derrame (liquid)'; the word '*discharge*' regarding physical suffering (consensually translated as 'descarga') has been replaced by 'purgação (supuração)' and the issue of '*poor pronunciation*' regarding speech impairment (consensually translated as 'pronúncia pobre') has been replaced by 'alteração da pronunciação (alteração da articulação da fala)'.

This Portuguese first version has been called 'primeira tradução de consenso' (first consensus translation) and was analysed by two professional bilingual (Portuguese and English) native English speaker translators for the translation into English. The translators were unaware of the aims of the study, as well as the original version of the questionnaire and have had no contact with each other. These two retro-translations have been analysed and compared to the original English version by the two Portuguese translators who have produced the second consensus translation ('segunda tradução de consenso').

This version ('segunda tradução de consenso') was applied to a group of parents/caregivers of patients with OM and was divided into a first part (i) including the instruction guide of the instrument and a second part (ii) which was subdivided into six sections (II 1-6) corresponding to the six domains. Each parent/caregiver has been requested to give his/her opinion on the clarity of the text: 'percebo muito bem', 'percebo bem', 'percebo mal' or 'percebo muito mal' ('I understand very clearly', 'I understand clearly', 'I understand poorly' or 'I understand very poorly'). A revision of the items of the second version of the questionnaire would have been carried out beyond a cut-off of at least 15% responses as 'percebo mal' or 'percebo muito mal' ('I understand poorly' or 'I understand very poorly').

The following criteria have been considered (inclusion criteria): (1) patients aged between 6 months and 12 years; (2) patients diagnosed with unilateral or bilateral chronic otitis media with effusion (at least three-month duration) or with recurrent acute otitis media (at least 3 episodes over the past 12 months, with full otoscopic recovery between the episodes); (3) native Portuguese speaker caregivers (European Portuguese). Exclusion criteria: (1) presence of perforated tympanic membrane; (2) myringotomy tube placement at study onset; (3) other pathology of the middle ear (such as cholesteatoma, for instance); (4) developmental delay or neurological pathology; (5) syndromic disorders or cleft palate; (6) parent/caregiver unable to read and/or understand the Portuguese language (European Portuguese). Children with a history of myringotomy tube placement were not excluded from the study.

The diagnosis of the different types of OM was based on the presence of the classical signs in otoscopy when observed by a specialist, as well as on the results of

tympanometric findings.

Stage II

The Portuguese version of the questionnaire has subsequently been applied to patients and their parents/caregivers according with the abovementioned criteria, aimed at the assessment of its consistency and reliability. The questionnaire has been self-administered and self-completed by parents/caregivers.

The construct validity of the instrument has been assessed by the comparison between the final score obtained with the OM-6 questionnaire and the overall assessment of quality of life related to the middle-ear status on a 10-point visual analogue scale (0 – worst possible quality of life; 10 – best possible quality of life), using Spearman's correlation coefficient.

Internal consistency has been assessed through the analysis of any association between the items of the questionnaire. Cronbach's alpha method has been used and good consistency has been defined for a value of Cronbach's alpha beyond 0.70.

Test-retest reliability has been assessed by the application of the Portuguese version of the questionnaire over a seven-day interval to a subgroup of patients with stable disease, defined by the presence of clinical stability (absence of any clinical change). The normal distribution of both scores (initial and retest final score) has been confirmed by using the Kolmogorov-Smirnov test. Pearson's correlation coefficient has been used to assess test-retest reliability and good reliability has been defined by a correlation coefficient of at least 0.70 between the initial and retest final score.

The response to clinical change has been assessed in a group of patients with an indication for myringotomy tube placement as part of the clinical follow-up and a significant improvement had been expected as regards patient's quality of life, shown by the recognised efficacy of the procedure for the treatment of chronic otitis media with effusion and recurrent acute otitis media.[11,12] The OM-6 questionnaire and the 10-point visual analogue scale were applied to parents/caregivers before surgery and at two months upon surgery. Paired-sample Student's t-test has been used for the analysis of the difference between the final scores obtained with the OM-6 questionnaire before (baseline score) and upon myringotomy tube placement (follow-up score). The follow-up score of both instruments was obtained from the same parent/caregiver who had completed the baseline score.

Change score of the OM-6 questionnaire (baseline – follow-up score) was obtained for this group of patients and its construct validity has been assessed by comparing the change score with the 10-point visual analogue scale (follow-up – baseline score) using Spearman's correlation coefficient.

Data were introduced into an Excel® spreadsheet and Statistical Package for The Social Sciences® (SPSS) version 21.0 Windows® software has been used for statistical analysis.

RESULTS

Stage I

The second consensus translation ('segunda tradução de consenso') has been applied to a group of 50 parents/caregivers of patients with OM. The assessment made by this group of parents/caregivers using this version did not show more than 15% of responses as 'percebo mal' or 'percebo muito mal' ('I understand poorly' or 'I understand very poorly') in any of the items and therefore no revision has been necessary (Table 1). Based on the results, the Portuguese version of the OM-6 questionnaire has been developed (Appendix 1) [http://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/7921/5045].

Stage II

Data were collected over a six-month period of time and a convenience sample of 216 patients and parents/caregivers has been involved in the study (average age range between six months and 12 years [M = 4.12; SD = 2.22], male predominance [53.7%; *n* = 116]).

OM-6 questionnaire has been self-completed by parents/caregivers, preventing from any bias due to an interaction with the interviewer. All parents/caregivers have successfully completed the Portuguese version of the questionnaire over a two-minute completion average time.

The assessment of the construct validity of the Portuguese version of the OM-6 questionnaire showed Spearman's correlation coefficients above 0.97 for all the

Table 1 - Results of the assessment of the 'second consensus translation' by the group of translators

	I	II1	II2	II3	II4	II5	II6
'Percebo muito bem' (I understand very clearly)	33 (66%)	28 (56%)	31 (62%)	33 (66%)	32 (64%)	32 (64%)	33 (66%)
'Percebo bem' (I understand clearly)	15 (30%)	22 (44%)	17 (34%)	13 (26%)	17 (34%)	16 (32%)	16 (32%)
'Percebo mal' (I understand poorly)	2 (4%)	0 (0%)	2 (4%)	3 (6%)	1 (2%)	1 (2%)	1 (2%)
'Percebo muito mal' (I understand very poorly)	0 (0%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)	1 (2%)	0 (0%)

Table 2 - Assessment of the construct validity of the Portuguese version of the OM-6 questionnaire

	OM-6			Change Score		
	n	r_s	*p*	n	r_s	*p*
Total	216	- 0.98	< 0.001	60	0.97	< 0.001
Per gender						
Male	116	- 0.97	< 0.001	29	0.93	< 0.001
Female	100	- 0.98	< 0.001	31	0.99	< 0.001
Per age						
< 5 years	132	- 0.98	< 0.001	42	0.96	< 0.001
≥ 5 years	84	- 0.97	< 0.001	18	0.99	< 0.001

Table 3 - Assessment of the internal consistency of the Portuguese version of the OM-6 questionnaire

	Cronbach's alpha	Inter-item correlation	Item-total correlation	Cronbach's alpha when item is removed
OM-6	0.780	0.369		
Physical suffering			0.644	0.717
Hearing loss			0.276	0.805
Speech impairment			0.367	0.783
Emotional distress			0.663	0.715
Activity limitation			0.615	0.727
Caregiver concerns			0.632	0.719

groups ($p < 0.001$), showing a strong correlation between the final score obtained with the Portuguese version of the OM-6 and the scores obtained with the 10-point visual analogue scale. A negative correlation has been found, as the highest score with the OM-6 corresponded to a poorer quality of life in patients with OM within the 10-point visual analogue scale (Table 2).

The assessment of the internal consistency of the Portuguese version of the OM-6 showed a 0.780 Cronbach's alpha value for the whole domains and, even though the analysis showed a mild improvement in the instrument's internal consistency with the removal of the domains of 'hearing loss' and 'speech impairment', the overall assessment of the Portuguese version of the OM-6 showed an adequate Cronbach's alpha (Table 3).

A second questionnaire has been completed by parents/caregivers included into a second convenience sample of 34 patients (19 female – 55.9%; aged 2-12 [M = 4.85; SD = 2.55]) over a seven-day time period aimed at the evaluation of test-retest reliability. The Kolmogorov-Smirnov test has been used for the assessment of the normality of both scores (initial and retest final score). Both variables followed a normal distribution ($z = 0.958$; $p = 0.318$ and $z = 0.880$; $p = 0.421$, respectively). Pearson's correlation coefficient has been used for the assessment of test-retest reliability and a positive, robust and statistically significant correlation has been found between final scores on both evaluation moments, in the whole sample and in all the groups, with values ranging between $r = 0.82$; $p < 0.001$ (male) and $r = 0.89$; $p < 0.001$ (group of patients aged 5 years or above) (Table 4).

The questionnaire has been completed by sixty parents/caregivers (31 female patients [51.7%], aged 1-12 [M = 3.82; SD = 2.11]). All the patients presented with in situ myringotomy tube placement and with patent lumen at the time of follow-up assessment. Statistically significant differences were found between both moments of the assessment, with t (59) = 10.104; $p < 0.001$, showing a postoperative improvement in the quality of life of children with chronic otitis media with effusion and recurrent acute otitis media (Table 5). A 1.70 mean global change score (variation: 0.7 to 4.3; SD = 1.30) has been found, showing an overall important improvement in post-operative middle-ear related quality of life.

The assessment of the construct validity of change scores with the OM-6 questionnaire showed a strong positive correlation ($r_s = 0.97$, $p < 0.001$) between change scores with the OM-6 questionnaire and the 10-point visual analogue scale. The results have shown that higher change scores with the questionnaire corresponded to higher scores with the 10-point visual analogue scale (Table 2).

Table 4 - Assessment of test-retest reliability of the Portuguese version of the OM-6 questionnaire

	n	r_s	*p*
Total	34	0.89	< 0.001
Per gender			
Male	15	0.82	< 0.001
Female	19	0.87	< 0.001
Per age			
< 5 years	20	0.84	< 0.001
≥ 5 years	14	0.89	< 0.001

Table 5 - Assessment of the response to clinical change of the Portuguese version of the OM-6 questionnaire

	Baseline		Follow-up		*t*	*p*
	M	SD	M	SD		
Final score	3.21	1.44	1.51	0.62	10.104	< 0.001

DISCUSSION

Quality of life has been increasingly recognized in clinical research and is an important measure for the evaluation of health outcomes. The scientific interest in the measures of quality of life in children, shown by its subsequent conceptual and methodological refinement aims at the improvement of healthcare practice focussed on this population.

OM is one of the most common diseases in childhood, with a relevant impact in health-related quality of life.[13-16] The burden of OM on the quality of life of Portuguese children is unknown due to the absence of a disease-specific validated instrument in Portuguese. Therefore, a culturally adapted Portuguese version of the OM-6 questionnaire seemed relevant[3] as this is the mostly used instrument worldwide for the assessment of health-related quality of life of children with OM.

Health-related quality of life is a multi-dimension concept and its assessment involves physical symptoms, functional ability and psychological and social impact of the disease. Six domains regarding the OM are included in this questionnaire: physical suffering, hearing loss, speech impairment, emotional distress, activity limitation and caregiver concerns and allows for a quick assessment of the perceived impact of OM on the patient by parents/caregivers, as well as for the identification of the most relevant domains for the quality of life related to the middle ear and the level of caregiver concerns.

The method of translation adopted for the Portuguese version of the questionnaire OM-6, involving translations and retro-translations, has been considered as adequate due to the fact that different independent assessments were involved.[17] The fact that the questionnaire has been applied to a convenience sample from a single hospital should be considered as a possible limitation to the process of cultural adaptation of the instrument. This must be considered in further studies, in order to ensure an optimal content validity of the questionnaire when applied in different regions.

The Portuguese version of the OM-6 questionnaire has been shown to be a valid method for the assessment of health-related quality of life in children with chronic otitis media with effusion or recurrent acute otitis media, as scores have shown a strong correlation with those obtained with the visual analogue scale (construct validity). This scale is an adequate measure for the assessment of construct validity of the Portuguese version of the OM-6 questionnaire, as it is a valid, reliable and sensitive instrument, comparable to the questionnaires with multiple assessment items and is recommended for the overall assessment of the quality of life in clinical trials.[18] The scale has been shown in previous studies to be an adequate instrument for pre and postoperative overall assessment of quality of life in children with OM and it may be used as a simplified method for the outcome analysis in this group of patients.[19]

The Portuguese version of the OM-6 questionnaire showed a correlation between the results of similar items (internal consistency), even though a mild improvement in the internal consistency of the instrument has been found when 'hearing loss' and 'speech impairments' domains were removed. This may be explained by patient's age, as many patients were in earlier stages of speech development (61.1%), which may have led to a greater difficulty for parents/caregivers to accurately assess any speech impairment. In addition, the ability of parents/caregivers to assess the presence of any hearing loss is also questionable. Hearing loss is an important symptom of otitis media with effusion and is one of the domains that were assessed by the OM-6 questionnaire. However, other studies that have applied this questionnaire found a weak correlation between hearing perception by parents/caregivers and the results of audiological testing.[3,8,20] The perception of a change in auditory acuity did not show any correlation with an effective audiological change either.[3] Therefore, even though the perception of the auditory acuity by parents/caregivers is extremely important for the determination of quality of life in children with OM, it must be always supplemented by the audiological assessment. Despite a possible limitation of 'hearing loss' and 'speech impairment' domains, the removal of any of these domains in the Portuguese version of the OM-6 questionnaire was not considered; the loss of content has not been compensated by any other domain and the global assessment of the instrument has shown an adequate Cronbach's alpha.

Relatively stable results were also found with the Portuguese version of the OM-6 questionnaire when re-applied to patients with stable disease (test-retest reliability) in the whole group of patients and in all the groups and the test-retest reliability has been highly dependent on the clinical stability of our group of patients.

A significant improvement in the quality of life related with the middle ear has been found in the patients who underwent myringotomy tube placement as part of the clinical follow-up. The Portuguese version of the OM-6 questionnaire has allowed for the quantification of clinically significant changes in quality of life over time in the same patient (response to clinical changes). The results were not intended to support the efficacy of myringotomy tubes and rather aimed at showing the clinical usefulness of the OM-6 questionnaire through change scores, an easily interpretable measure of clinical outcome and its dimension (< 0.5 trivial change; 0.5 – 0.9 mild; 1.0 – 1.4 moderate; ≥ 1.5 great).

Child's perspective has been increasingly considered

by the most recently developed instruments for the assessment of quality of life in childhood and children have been more directly involved in the decisions. However, the construction of instruments for the assessment of quality of life in children has some limitations. Children's self-assessment on their quality of life is influenced by the ability of oral comprehension, i.e., children must understand what has been asked in order to be able to respond. In addition, many measures of the quality of life require responses to be based on experiences over a specific period of time, as in OM-6 questionnaire and the ability for children to respond to the questionnaire regarding the time is influenced by the development of memory and time perception.[21] Therefore, the only way that we can mostly obtain any information on the quality of life is by using alternative sources such as by using parents/caregivers and asking them to reflect on the perception of child's quality of life, which may not necessarily be concordant.[22] However, previous studies have found that the assessment of the quality of life by parents/caregivers is adequately correlated with children's self-assessment regarding physical suffering and other observable symptoms, suggesting that close caregivers are acceptable in order to respond to questionnaires assessing such domains, as is the case of the OM-6 questionnaires.

The fact that the indicators of quality of life can vary according to patient's age should also be considered.[21] Each item of the OM-6 questionnaire is designed as a complete domain, with which parents/caregivers may rank the impact of symptoms according with the age, allowing for the avoidance of limitations due to the assessment in different stages of development.

Different studies have found that parents/caregivers overestimate pre-treatment health-related quality of life in children with OM (response shift). Upon therapy, parents/caregivers understand that pre-treatment quality of life was poorer than what they have considered, through the comparison between pre and postoperative child's clinical status (scale recalibration). The results suggested that the dynamic nature of the instruments for the assessment of quality of life should be considered, at the risk of an underestimation of the therapeutic effect.[8]

A dissociation between tympanic membrane status and the assessment of quality of life is expectable. Chronic otitis media with effusion is commonly characterised by a scarcity of symptoms and lower scores in the questionnaire, despite the presence of obvious middle ear signs. In addition, children with a normal middle ear status may show higher scores in the presence of recurrent acute otitis media due to its significant impact, although transitory, on the quality of life. Therefore, objective measures of middle ear status and subjective measures of quality of life must be considered both within the clinical assessment of children with OM and in the determination of the clinical outcome.

The OM-6 questionnaire is not a discriminatory instrument as its final score and the individual domains are not valid for the comparison between patients. Even though each domain assesses a set of symptoms and the response of parents/caregivers is hardly based on the same symptoms, repeated responses of the same parents/caregivers of a specific patient can be compared, corresponding to a valid measure for the assessment of the clinical response of that patient.

The questionnaire allows for the identification of objective data on quality of life related with the middle ear. The instrument's ease of use makes it optimal for the assessment of the quality of life in routine clinical practice and not only in clinical trials and observational studies.

CONCLUSION

The Portuguese version of the OM-6 questionnaire is a valid, reliable and sensitive instrument for the evaluation of health-related quality of life in children with OM. Its use in clinical practice as in research will allow for the characterisation of the impact of this pathology in quality of life in Portuguese children and for the assessment of clinical outcome, leading to subsequent improvements in healthcare.

OBSERVATIONS

Part of the study has been presented as a free communication to the *63º Congresso da Sociedade Portuguesa de Otorrinolaringologia e Cirurgia Cervico-Facial*, in 24 Apr 2016, in Coimbra.

HUMAN AND ANIMAL PROTECTION

The authors declare that the followed procedures were according to regulations established by the Ethics and Clinical Research Committee and according to the Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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