Quality of Life of Children with Otitis Media and Impact of Insertion of Transtympanic Ventilation Tubes in a Portuguese Population

Qualidade de Vida das Crianças com Otite Média e Impacto da Colocação de Tubos de Ventilação Transtimpânicos numa População Portuguesa

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ABSTRACT

Introduction: Quality of life is an important measure for health-outcome evaluation. Although otitis media is one of the most common childhood diseases, its impact on Portuguese children's quality of life is unknown. The aim of this study is to determine the quality of life of Portuguese children with chronic otitis media with effusion and/or recurrent acute otitis media and the short-term impact of transtympanic ventilation tubes, using the Portuguese version of the OM-6 questionnaire, a valid, reliable and sensitive instrument to evaluate the health-related quality of life in children with otitis media.

Material and Methods: This study was conducted in a tertiary referral center, to where children are referred from primary care and hospital pediatric consultations. The Portuguese version of the OM-6 questionnaire was applied to children with chronic otitis media with effusion and/or recurrent acute otitis media. The instrument was re-administered at two months postoperatively to a group of children who underwent tympanostomy tube placement, to evaluate the change in quality of life with the surgical procedure.

Results: The study involved a sample of 169 children, aged between 6 months and 12 years (mean: 4.20 ± 2.05 years). The average score in the survey was 3.3 ± 1.47, of a maximum of 7 (worst quality of life). The domains 'caregiver concerns', 'hearing loss' and 'physical suffering' had the highest scores. The domain 'hearing loss' was correlated with the domain 'speech impairment' (r_s = 0.41; p < 0.001) and the domain 'physical suffering' correlated with the domain 'activity limitation' (r_s = 0.47; p < 0.001). There was a correlation between the score on 'hearing loss' and the presence of conduction hearing loss (χ^2 (6) = 24.662; p = 0.022). Children with chronic otitis media with effusion had lower scores on the domain 'physical suffering', while children with recurrent acute otitis media had lower scores in the domain 'hearing loss' and higher scores in the domain 'emotional distress'. There was an improvement in the quality of life in all the dimensions studied by the questionnaire after surgery. The improvement was large in 55%, moderate in 15% and small in 10% of the cases. The presence of otorrhea postoperatively did not decrease the quality of life improvement achieved with surgery.

Conclusion: Otitis media has a negative impact on Portuguese children quality of life. Tympanostomy tubes improve quality of life related to the middle ear in most children. The application of validated disease-specific questionnaires allows an enhanced understanding of the impact of otitis media on Portuguese children quality of life and of the success of therapeutic measures.

Keywords: Child; Otitis Media/surgery; Portugal; Prostheses and Implants; Quality of Life; Surveys and Questionnaires

RESUMO

Introdução: A qualidade de vida é uma medida importante de avaliação de resultados em saúde. Embora a otite média seja uma das doenças mais comuns na infância, o seu impacto na qualidade de vida das crianças portuguesas não é conhecido. O objetivo deste estudo é determinar a qualidade de vida das crianças portuguesas com otite média crónica com efusão e/ou otite média aguda recorrente e o impacto a curto-prazo da colocação de tubos de ventilação transtimpânicos, utilizando a versão portuguesa do questionário OM-6, um instrumento válido, confiável e sensível para avaliar a qualidade de vida relacionada com saúde em crianças com otite média.

Material e Métodos: Este estudo foi realizado num hospital de nível terciário, para onde as crianças são referenciadas a partir dos cuidados de saúde primários e da consulta de pediatria hospitalar. O questionário OM-6 foi administrado em crianças com otite média crónica com efusão e/ou otite média aguda recorrente. O instrumento foi readministrado aos dois meses de pós-operatório a um grupo de crianças submetidas a colocação de tubos de ventilação transtimpânicos, para avaliar a alteração da qualidade de vida com o procedimento cirúrgico.

Resultados: O estudo envolveu uma amostra de 169 crianças, com idades entre os 6 meses e os 12 anos (média: 4,20 ± 2,05 anos). A pontuação média no questionário foi de 3,3 ± 1,47, num máximo de 7 (pior qualidade de vida). Os domínios 'preocupações do cuidador', 'perda auditiva' e 'sofrimento físico' apresentaram as pontuações mais elevadas. O domínio 'perda auditiva' correlacionou-se com o domínio 'alterações da fala' (r_s = 0,41; p < 0,001) e o domínio 'sofrimento físico' correlacionou-se com o domínio 'limitação da atividade' (r_s = 0,47; p < 0,001). Observou-se correlação entre a pontuação no domínio 'perda auditiva' e a presença de hipoacusia de condução (χ^2 (6) = 24,662; p = 0,022). Crianças com otite média crónica com efusão apresentaram pontuação mais baixa no domínio 'sofrimento físico', ao passo que crianças com otite média aguda recorrente apresentaram pontuação mais baixa no domínio 'perda auditiva' e pontuação mais alta no domínio 'sofrimento emocional'. Registou-se uma melhoria da qualidade vida em todas as dimensões estudadas pelo questionário após o procedimento cirúrgico. A melhoria foi considerada grande em 55%, moderada em 15% e pequena em 10% dos casos. A presença de otorreia no pós-operatório não mostrou comprometer a melhoria da qualidade de

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vida obtida com o procedimento cirúrgico.
Conclusão: A otite média tem um impacto negativo na qualidade de vida das crianças portuguesas. A colocação de tubos de ventilação transtimpânicos melhora a qualidade de vida na maioria das crianças. A aplicação de questionários validados doença-específicos permite uma melhor compreensão do impacto que a otite média apresenta na qualidade de vida das crianças portuguesas e do sucesso do tratamento.
Palavras-chave: Criança; Inquéritos e Questionários; Otite Média/cirurgia; Portugal; Próteses e Implantes; Qualidade de Vida

INTRODUCTION

Health-related quality of life is a multidimensional concept and domains related to physical symptoms, functional capacity and the psycho-social impact of illness are involved in its measurement. Quality of life has been increasingly recognized in medical research as an important measure for the assessment of health outcomes[1] and improved healthcare is the aim of the measurement in childhood.

Otitis media (OM) is a common occurrence in childhood and one of the major causes for medical examination in pre-school age.[2] The development of disease-specific instruments has allowed for the assessment of the impact of OM on children's quality of life.[3] Even though OM has been considered as an important cause for caregivers concern regarding other populations, as well as an association between OM and health-related quality of life,[4-7] its impact on Portuguese children's quality of life is still unknown.

Tympanostomy tube insertion is one of the most widespread surgical approaches to children with OM.[8] Great improvement in the quality of life of these patients has been described in previous studies on tympanostomy tube insertion.[3,9,10] However, no studies have yet been published on the systematic assessment of the subjective impact of this surgical approach in the Portuguese paediatric population.

This study aimed at the identification of the quality of life in Portuguese children with OM and the short-term impact of tympanostomy tube insertion.

MATERIAL AND METHODS

This was a prospective and longitudinal study carried out at the Department of Ear, Nose and Throat (ENT) Surgery of the *Hospital de Egas Moniz*, *Centro Hospitalar de Lisboa Ocidental, E.P.E.* and was approved by the Ethics Committee of the institution, in accordance with the Helsinki Declaration.

The Portuguese version of the OM-6 questionnaire, a valid, reliable and sensitive instrument for measuring health-related quality of life in children with OM, has been used for measuring ear-related quality of life.[11] The OM-6 questionnaire was developed by Rosenfeld *et al.* (1997)[3] and is the most widely used for measuring health-related quality of life in children with OM, aimed at children aged 6 months to 12 years with chronic otitis media with effusion (COME) (≥ 3 months) or recurrent acute otitis media (RAOM) (≥ 3 episodes over the past 12 months). The questionnaire has to be completed by the patient's caregiver and six domains regarding middle-ear infection or effusion are involved: physical suffering, hearing loss, speech impairment, emotional distress, activity limitations and caregiver concerns. OM impact on patient's quality of life during the past four weeks is estimated by the questionnaire and each domain is represented by questions on relevant symptoms and scores range from 1 - 7 (1 – no problem; 7 – extreme problem). Final score is obtained by taking the mean of the six domain scores and range from 1.0 - 7.0. The higher the final score the poorer the OM-related quality of life.

A change score was obtained by subtracting the final score obtained from the questionnaire that was postoperatively applied (follow-up score) from the final score obtained from the one that was preoperatively applied (baseline score) (baseline score – follow-up score). The change score allowed for measuring the response to a certain therapy within a four-week minimal interval. A negative change score corresponded to a clinical worsening and a positive to a clinical improvement. Intervals of change score were defined, aimed at measuring the level of change produced with a specific procedure: < 0.5 - trivial; 0.5 – 0.9 – mild; 1.0 – 1.4 - moderate; ≥ 1.5 – large change.

The OM-6 questionnaire was applied to a group of children attending the Department of ENT referred both from primary healthcare and paediatrics outpatient clinic. Inclusion criteria included (i) children aged 6 months to 12 years (ii) presenting with COME (≥ 3 months) or RAOM (≥ 3 episodes over the past 12 months), (iii) with a Portuguese speaking caregiver (European Portuguese). Exclusion criteria included the presence of (i) ruptured eardrum; (ii) tympanostomy tubes in situ at study onset; (iii) other middle-ear pathology (cholesteatoma, for instance); (iv) developmental impairment or neurological pathology; (v) syndromic disease or cleft palate; (vi) caregiver unable to read and/or understand the Portuguese language (European Portuguese). Children with a history of tympanostomy tube insertion were not excluded from the study.

The questionnaire was re-applied at two months postoperatively (follow-up score) to a group of children with an indication for tympanostomy tube insertion, aimed at measuring any change in quality of life with surgery. The questionnaire was self-administered and completed by caregivers throughout the study. Follow-up and baseline scores were obtained from the same caregiver in all cases.

Data regarding middle ear pathology and demographic data were obtained: age, gender, diagnosis (COME; RAOM; chronic otitis media with effusion and concomitant recurrent acute otitis media), results of tympanometry, presence of conductive hearing loss in pure-tone audiometry (air conduction isolated threshold elevation, with air-bone gap ≥ 15 dB), history of tympanostomy tube insertion associated to postoperative otorrhoea.

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

analysis.

Spearman's correlation coefficient has been used for the identification of a correlation between each of the OM-6 different domains and between patient's age and the likelihood of any perceived caregiver concerns regarding child's hearing loss. Chi-square association test has been used for the identification of a relationship (i) between diagnosis and the final score obtained from the OM-6 questionnaire, (ii) between diagnosis and the scores obtained from the different domains of the questionnaire and (iii) between the score obtained in 'hearing loss' domain and the presence of conductive hearing loss in pure-tone audiogram. Paired samples Student's t-test was used for the analysis of the difference between final scores obtained pre (baseline) and post-operatively (follow-up score). Non-parametric Wilcoxon two-sample test was used for the analysis of the difference between the scores obtained within the different domains of the OM-6 questionnaire on the two moments of the assessment. Pearson's correlation coefficient was used for the identification of a correlation between patient's age and change score with the OM-6 questionnaire. Chi-square association test was used for the identification of a relationship between change score and diagnosis, presence of conductive hearing loss and presence of post-operative otorrhoea, respectively. A 5% level of statistical significance has been considered.

RESULTS

A convenience sample of 169 patients and caregivers was involved in the study, with patient's age ranging 6 months to 12 years (M = 4.20; SD = 2.05), with a slight male predominance (53.3%; n = 90). Only 13.6% (n = 23) of the patients had a history of previous tympanostomy tube insertion.

COME was the most frequent diagnosis found (73.4% of the patients; n = 124), followed by recurrent acute otitis media concomitantly with chronic otitis media with effusion (16.0%; n = 27) and isolated RAOM (10.7%; n = 18). Most patients with COME presented with a bilateral disease (92.7%; n = 140).

Tympanometry was carried out in 53.8% (n = 91) of the patients and was more frequently requested for children diagnosed with COME (78.0%; n = 71) and with recurrent acute otitis media concomitantly with chronic otitis media with effusion (14.3%; n = 13). A type B tympanogram was obtained in 83.3% of these patients (n = 70) and type C in 16.7% (n = 14). A type A tympanogram was found in 57.1% (n = 4) of the patients with isolated RAOM and type C in 42.9% (n = 3). Pure-tone audiometry was carried out in 30.2% (n = 51) of the patients, 74.5% of whom presented with conductive hearing loss (n = 38).

A mean 3.3 final score was obtained (SD = 1.47), for a maximum seven-point score (poorest quality of life). The highest scores were obtained in 'caregiver concerns', 'hearing loss' and 'physical suffering' domains, followed by 'emotional distress', 'speech impairment' and 'activity limitations' (Table 1). At least some concern regarding patient's middle-ear infection or effusion was described by 57.4% of caregivers and great concern by 40.8%. Moderate concern regarding hearing loss and physical suffering were perceived by 58.6% and 49.1% of caregivers, respectively. Minimal concern regarding emotional distress and speech impairment were perceived by 58.0% and 43.8% of caregivers, respectively. At least minimal concern regarding patient's activity limitations was perceived by 39.6% of caregivers, while this was not described as a concern by 50.3% (Table 2) of caregivers.

A statistically moderate correlation was found between 'hearing loss' and 'speech impairment' domains ($r_s = 0.41$; $p < 0.001$), as well as between 'physical suffering' and activity limitations' domains ($r_s = 0.47$; $p < 0.001$). Positive and statistically significant correlation has been found between 'caregiver concerns' domain and all the remaining domains, with Spearman's correlation coefficients ranging between $r_s = 0.21$, $p = 0.006$ ('speech impairment') and $r_s = 0.66$; $p < 0.001$ ('physical suffering').

An association between the score from 'hearing loss' domain and the presence of conductive hearing loss in pure-tone audiogram ($\chi^2(6) = 24.662$; $p = 0.022$) has been found. Positive and moderate statistically significant correlation has been found between patient's age and 'hearing loss' domain score ($r_s = 0.43$; $p < 0.001$), showing that the

Table 1 – Mean score obtained from each domain of the Portuguese version of the OM-6 questionnaire (n = 169)

OM-6 domain	Domain content	Mean score (SD)*
Physical suffering	Ear pain, ear discomfort, ear discharge, ruptured ear drum, high fever, poor balance	3.4 (2.1)
Hearing loss	Difficulty hearing, questions must be repeated, frequently says 'what', television is excessively loud	3.8 (2.1)
Speech impairment	Delayed speech, poor pronunciation, difficult to understand, unable to repeat words clearly	2.7 (1.9)
Emotional distress	Irritable, frustrated, sad, restless, poor appetite	3.2 (2.0)
Activity limitations	Limitations with playing, sleeping, doing things with friends or family, attending school or day care	2.6 (1.9)
Caregiver concerns	Worry, concern or inconvenience because of the child's ear infections or fluid	4.1 (2.4)

* Responses were scored on a 1-7 ordinal scale (1 - no problem; 7 – extreme problem)

Table 2 – Level of awareness regarding the domains of the Portuguese version of the OM-6 questionnaire (n = 169)

	Level of awareness during the past 4 weeks, n (%)						
OM-6 domain	**Absent**	**Hardly**	**Minimal**	**Moderate**	**Significant**	**High**	**Very high**
Physical suffering	58 (34.3)	12 (7.1)	16 (9.5)	24 (14.2)	19 (11.2)	27 (16.0)	13 (7.7)
Hearing loss	42 (24.9)	10 (5.9)	18 (10.7)	28 (16.6)	26 (15.4)	27 (16.0)	18 (10.7)
Speech impairment	75 (44.4)	20 (11.8)	22 (13.0)	15 (8.9)	15 (8.9)	15 (8.9)	7 (4.1)
Emotional distress	57 (33.7)	14 (8.3)	25 (14.8)	25 (14.8)	20 (11.8)	16 (9.5)	12 (7.1)
Activity limitations	85 (50.3)	17 (10.1)	13 (7.7)	20 (11.8)	15 (8.9)	11 (6.5)	8 (4.7)
Caregiver concerns	45 (26.6)	16 (9.5)	11 (6.5)	18 (10.7)	10 (5.9)	27 (16.0)	42 (24.9)

older the patient the higher the likelihood of the caregiver describing a concern regarding child's hearing loss.

A statistically significant correlation between the final score obtained from the OM-6 questionnaire and patient's diagnosis has been found (χ^2 (12) = 23.318; p = 0.025). Children with RAOM showed higher scores with the OM-6 questionnaire, reflecting poorer ear-related quality of life, when compared to those presenting with COME.

An association between diagnosis and the scores in the following domains of the OM-6 questionnaire has been found: 'physical suffering' (χ^2 (12) = 27.154; p = 0.007), 'hearing loss' (χ^2 (12) = 21.320; p = 0.046) and 'emotional distress' (χ^2 (12) = 24.662; p = 0.017). A lower score in 'physical suffering' domain has been found in children with COME, while a lower score in 'hearing loss' and higher in 'emotional distress' were found in children with RAOM.

In total, 152 children in our group underwent tympanostomy tube insertion (89.9% of the patients). Response to recommended medical treatment for COME and/or RAOM was found in the remaining patients, with a positive outcome. Surgery was mostly associated with adenoidectomy (92.1%; n = 140). The indication for adenoidectomy in children under the age of 4 included the presence of nasal obstruction or chronic adenoiditis. The procedure revision was carried out in patients having already undergone adenoidectomy, whenever in the presence of adenoid hypertrophy.

The questionnaire was re-applied two months postoperatively to 60 caregivers for measuring any surgery-related change in patient's quality of life. Data regarding 29 male (48.3%) and 31 female (51.7%) patients aged 1-12 years (M = 3.82; SD = 2.11) were obtained. All the patients presented with unblocked tympanostomy tubes in situ.

Statistically significant differences between final baseline scores and follow-up scores have been found (t (59) = 10.104; p < 0.001). A 1.70 mean overall change score has been found (variation range: -0.7 to 4.3; SD = 1.30), corresponding to a significant improvement in postoperative ear-related quality of life. Overall, most patients (55.0%) presented with a significant improvement in their quality of life. Only 5% (n = 3) of the patients presented with poorer quality of life, all of these with a mild clinical worsening (Table 3).

Statistically significant differences were found between the two assessment moments (baseline and follow-up) regarding the scores obtained from OM-6 questionnaire domains, with p-value < 0.001 (Table 4). The results have shown an improved mean postoperative ear-related quality of life in all the dimensions of the OM-6 questionnaire. A significant improvement in quality of life has been found regarding 'hearing loss', 'caregiver concerns' and 'emotional distress' domains, with the following mean change scores: 'hearing loss' 2.4 (SD = 1.96); 'caregiver concerns' 2.0 (SD = 2.69); 'physical suffering' 1.9 (SD = 2.04); 'emotional distress' 1.5 (SD = 1.74). A moderate improvement in quality of life has been found in 'speech impairment' and 'activity limitations', with the following mean change scores: 'speech impairment' 1.3 (SD = 1.60); 'activity limitations' 1.1 (SD = 1.89). Poorer postoperative quality of life has been found in 0-11.7% of the patients regarding all the domains (Table 5, Fig. 1).

Over the study period, 25.0% (n = 15) of the patients having undergone tympanostomy tube insertion presented with postoperative otorrhoea and an association between this and change score has been found (χ^2 (4) = 11.600; p = 0.021). The results have shown that the presence of postoperative otorrhoea had no impact on the improvement in patient's quality of life obtained with tympanostomy tube insertion. No association has been found between the change score and patient's age, diagnosis or the presence of conductive hearing loss, respectively.

DISCUSSION

Most studies on the measurement of the impact of OM are based on objective measures regarding the middle ear. The relevance of health-related quality of life has been increasingly recognized in medical research on OM.[3] The measurement of the quality of life is even more relevant

Table 3 – Change in overall quality of life upon tympanostomy tube insertion (n = 60)

Level of change	Patients, n (%)
Significant improvement	33 (55.0)
Moderate improvement	9 (15.0)
Small improvement	6 (10.0)
Trivial change	6 (10.0)
Unchanged	3 (5.0)
Worsening	3 (5.0)

Change score = baseline score – follow-up score. Negative change score – clinical worsening. Positive change score – clinical improvement. Interpretation: < 0.5 - trivial; 0.5 - 0.9 – small; 1.0 – 1.4 - moderate; ≥ 1.5 – significant.

Table 4 – Difference between baseline and follow-up scores (n = 60)

	Baseline		Follow-up		
OM-6 domain	**M**	**SD**	**M**	**SD**	**W**
Physical suffering	3.30	2.03	1.37	0.86	-5.927***
Hearing loss	3.78	2.03	1.43	0.96	-5.933***
Speech impairment	2.83	1.85	1.52	1.16	-4.977***
Emotional distress	2.97	2.05	1.52	1.02	-4.872***
Activity limitations	2.45	1.88	1.32	0.65	-4.049***
Caregiver concerns	3.93	2.44	1.92	1.59	-4.563***
	M	**SD**	**M**	**SD**	**t**
Final score	3.21	1.44	1.51	0.62	10.104***

*** $p \leq 0{,}001$

regarding decision-making as well as therapy response considering the frequently found dissociation between middle ear status and the measurement of quality of life.[11] In fact, otitis media with effusion is frequently associated to scarce symptoms, even though the patient presents with obvious middle-ear signs. In addition, children with RAOM may present with normal middle ear while in remission and with a significant impact on the quality of life mainly related to clinical recurrence. Therefore, a combined use of objective measures of the middle ear status and measurement of the quality of life allows for a better understanding on the impact of the disease and subsequently for improved healthcare.

OM is one of the most common diseases in childhood, with a relevant impact on health-related quality of life.[4-7] This is the first study on the measurement of the impact of OM on the quality of life of Portuguese children and long-term outcome of tympanostomy tube insertion by using a disease-specific instrument which was validated for European Portuguese language.[11]

OM has shown a negative impact on the quality of life of Portuguese children and has been considered as an important cause for caregiver concerns. Physical suffering and caregiver concerns were two of the three most affected domains in children with OM, in line with previous studies.[3,7,9,10,12] A correlation has been found between caregiver concerns and all the other domains of the quality of life that were measured with the questionnaire. Previous studies have shown a correlation between total score in OM-6 questionnaire and the impact of OM on caregiver's quality of life.[6]

COME is usually associated to a 25-30 dB conductive hearing loss.[13] An association has been found in our study between the score obtained from 'hearing loss' domain and the presence of conductive hearing loss in pure-tone audiogram. However, studies that have used this questionnaire have shown a weak correlation between hearing loss awareness and audiology testing results.[3,12,14] In addition, our results have shown that the older the child the higher the likelihood of caregiver concerns related to patient's hearing loss. In fact, in earlier stages of its development, hearing loss may become difficult for caregivers to be aware of. Therefore, even though hearing awareness by caregivers is crucial for the identification of the quality of life in children with OM, it should always be supplemented with an audiology assessment.

Children with RAOM presented with higher mean scores with the OM-6 questionnaire, corresponding to a poorer quality of life, when compared to children with COME. Lowest scores in 'hearing loss' domain and highest in 'emotional distress' domains were found in children with RAOM, while children with COME presented with the lowest scores obtained from the 'physical suffering' domain. In fact, COME is associated to the presence of discharge to the middle ear and no signs or symptoms of infection, even though it may lead to long-term complications, such as hearing loss and

Table 5 – Change in quality of life per domain upon tympanostomy tube insertion (n = 60)

	Children, n (%)				
OM-6 domain	**Significant improvement†**	**Moderate improvement‡**	**Unchanged**	**Moderate worsening‡**	**Severe worsening†**
Physical suffering	31 (51.7)	7 (11.7)	20 (33.3)	1 (1.7)	1 (1.7)
Hearing loss	37 (61.7)	9 (15.0)	14 (23.3)	0 (0.0)	0 (0.0)
Speech impairment	26 (43.3)	9 (15.0)	22 (36.7)	2 (3.3)	1 (1.7)
Emotional distress	27 (45.0)	5 (8.3)	26 (43.3)	1 (1.7)	1 (1.7)
Activity limitations	20 (33.3)	6 (10.0)	29 (48.3)	3 (5.0)	2 (3.3)
Caregiver concerns	30 (50.0)	8 (13.3)	15 (25.0)	0 (0.0)	7 (11.7)

† Change score per domain ≥ 2; ‡ Change score per domain = 1

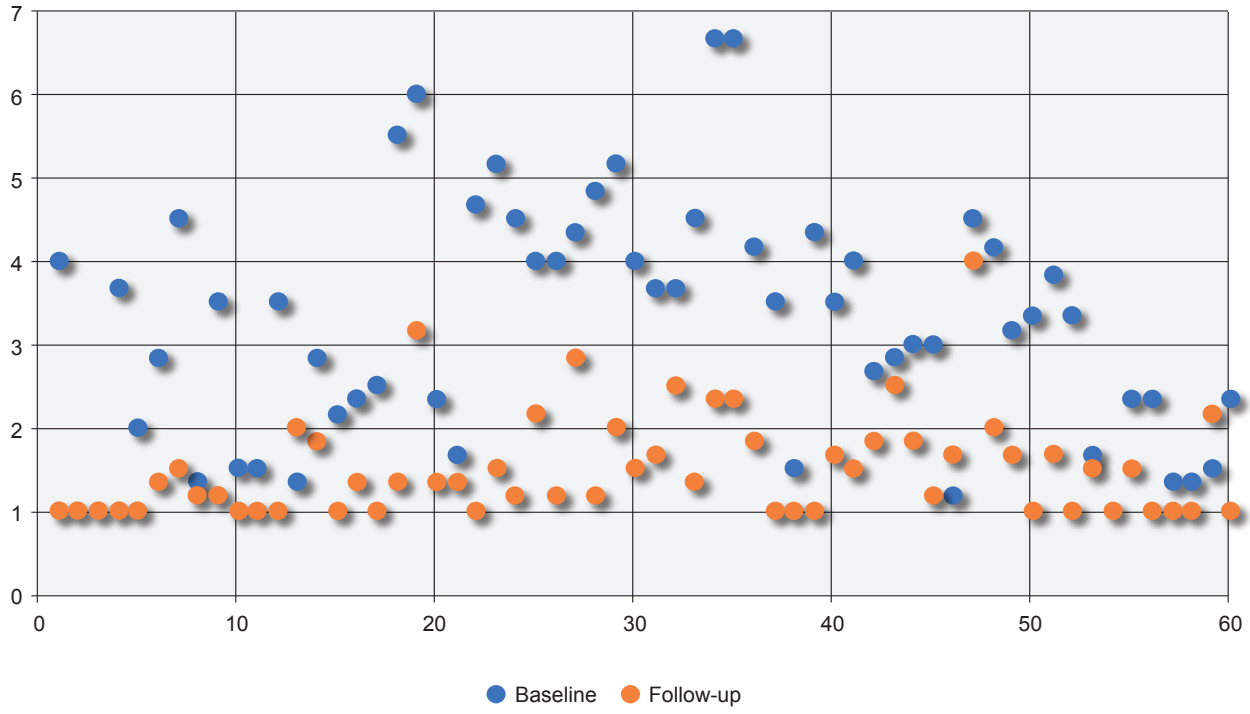

Figure 1 – Distribution chart of final baseline and follow-up scores (n = 60)

impaired language development.[15,16] In addition, acute otitis media clinically presents with otalgia, fever, general malaise and otorrhoea[17,18] and the recurrence of these symptoms, more than its severity, is associated to the impact on the quality of life of children with RAOM.[7]

A correlation between the scores in clinically-related domains has been shown by the results. A correlation between 'hearing loss' and 'speech impairment' has been found, which may be explained by the association between the presence of long-term hearing loss and delayed and/or impaired language development.[19] A correlation has been also found between 'physical suffering' and 'activity limitations', possibly due to the fact that an inability for the practice of normal activities is frequently found in children, including school or nursery attendance.

Improved short-term quality of life in Portuguese children with OM has been shown by the treatment with tympanostomy tube insertion, regarding all the domains that were assessed with the questionnaire and most patients have shown a significant improvement, in line with other studies.[9,11] However, our results were not aimed at explaining the general use of tympanostomy tube insertion, rather at understanding the impact of this surgery on the quality of life, whenever applied in patients with an indication for surgery.[20]

A slightly lower improvement in postoperative quality of life has been found in 'speech impairment' and 'activity limitations', when compared to the improvement found in the remaining domains of the questionnaire. A lower change in caregiver concerns was found in the 'speech impairment' domain, in line with the study by Rosenfeld *et al.* (2000).[9] Even though our results regarded a short-term measurement, other authors did not find any positive effect on language development of tympanostomy tubes 6 and 9 months postoperatively.[21,22]

A lower improvement in quality of life was found in 'activity limitations', which may have been due to the frequent recommendation by physicians regarding the prevention from water entering the ear canal, which is usually associated to a certain level of limitation or interruption in the practice of water activities. This has traditionally been recommended to children with ventilation tubes by most ENT physicians,[23] even though recent studies have shown that this recommendation is not usually required.[24-27] Apart from not producing any significant medical benefit, preventing exposure to water may be considered as socially inconvenient. Therefore, preventing from exposure to water is not included into current medical recommendations and it should be only recommended in patients presenting with active episodes of otorrhoea, recurrent or long-standing otorrhoea or with a history of problems with any previous exposure to water.[20]

Postoperative otorrhoea has been found in 25% of our patients, which is in line with literature in which a 26% mean incidence of otorrhoea (range, 4-68%) has been found.[28] Most patients present with a sporadic, brief and moderately symptomatic otorrhoea,[29] which may explain the fact that its occurrence is not associated to any significant impact on the quality of life obtained with the use of tympanostomy tubes.

Some limitations have been identified in our study, including the fact that a response-shift bias could not have been ruled out. Different studies have described that pretreatment health-related quality of life is overestimated by

patient caregivers (response shift). Postoperatively, caregivers perceived that pre-treatment quality of life was lower to what they have previously identified, due to the comparison between child's clinical status before and upon surgery (scale recalibration).[12] However, no impact has been shown on the estimated improvement in quality of life that was obtained with surgery.

Short-term results have been obtained, preventing from ruling out the impact on the quality of life of any subsequent adverse event or complication associated to tympanostomy tube insertion. However, complications are rare, miringosclerosis being the most frequent. This is not associated to any clear functional impairment (hearing loss < 0.5 dB) and therefore this should not limit the surgery approach whenever there is an indication for it.[30,31]

In addition, even though a postoperative improvement has been found in 90% of the patients regarding ear-related quality of life, a possible placebo effect associated to surgery or influenced by the natural history of the disease could not have been entirely ruled out.[32]

CONCLUSION

OM has a negative impact on the quality of life in Portuguese children and is an important cause for caregiver concerns. Improved quality of life has been found in most children with OM with the use of tympanostomy tube insertion.

The application of validated disease-specific questionnaires allowed for a better understanding on the impact of the disease and therapy outcomes, with subsequently improved healthcare.

OBSERVATIONS

Part of the study was presented as a free communication to the 64th *Congresso da Sociedade Portuguesa de Otorrinolaringologia e Cirurgia Cérvico-Facial*, held on the 7 May 2017 in Viana do Castelo and was awarded the 3th *SPORL de Otologia, Otoneurologia e Cirurgia da Base do Crânio* prize.

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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