How Appropriate Is the OM6 as a Discriminative Instrument in Children With Otitis Media?

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**Background:** The OM6 is a 6-item condition-specific handicap measure developed in the United States for children with recurrent acute otitis media and otitis media with effusion. Easy and quick to use, it has high test-retest repeatability and is sensitive to change after ventilation tube insertion.

**Objectives:** To explore aspects of the validity of OM6 in a United Kingdom population and to specifically address the instrument’s ability to discriminate between children with different burdens of disease.

**Design:** The parents of 179 consecutive newly referred children with otitis media with effusion or recurrent acute otitis media completed the OM6 on their first visit to the hospital. The parents of 72 children with sore throats completed the OM6 for comparison. Scores were compared with markers of disease severity, demographic variables, and generic quality-of-life measures.

**Results:** Poorer scores were found in those with ear complaints than in those with sore throats. The OM6 scores were not associated with age, sex, socioeconomic class, or respondent (mother vs father). The OM6 scores did not correlate with frequency of otalgia, frequency of otorrhea, or time off school in the recurrent acute otitis media group. In the otitis media with effusion group, poorer scores were associated with bilateral B or C2 tympanometric findings but not with a better ear threshold of more than 20 dB. Correlation with a global 10-cm visual analog scale for quality of life and with the Health Utilities Index Mark III was good.

**Conclusions:** The OM6 scores correlate well with global quality-of-life measures and are free from many potential biases. However, OM6 does not adequately reflect disease severity, which may limit its usefulness as a discriminative measure.

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OTITIS MEDIA IS ONE OF THE most common diseases of childhood in the developed world and causes a significant burden for children, their parents, and health care systems. A tool to assess the impact of otitis media on the child’s life would be useful in research and clinical practice. Although many such instruments are beginning to appear, few have been widely used and validated beyond the work of their originators.

The OM6 (Figure 1) is a short instrument whose great advantage is speed and ease of use. It has been developed for use in children with recurrent acute otitis media (AOM) and otitis media with effusion (OME). Six domains (physical suffering, hearing loss, speech impairment, emotional distress, activity limitation, and caregiver concerns) are each addressed by a single question. The question gets a positive response if any one of a list of symptoms is present. Answers are given on a 7-point categorical scale, and a total score is calculated by taking the mean of the 6 domain scores. A visual analog scale is also included for a global assessment of ear-related problems. In 186 children with ear symptoms, the test-retest reliability was high and the correlation between the overall score and a global assessment on the visual analog scale was high.

In a prospective study of 248 children undergoing ventilation tube insertion for OME, the OM6 scores before and after surgery showed a significant change, demonstrating the instrument’s sensitivity to change. Similar benefits were shown in a pilot study of 14 children in Liverpool, England, undergoing ventilation tube insertion. The grouping of symptoms into only 6 questions, however, is likely to reduce the sensitivity of the instrument. In addition, the inclusion of a question on caregiver concerns may introduce bias because it reflects the effect of the illness on the parents, not the child.

This study was performed to assess the applicability of OM6 to a United King-
dom otitis media population and to assess aspects of its validity not addressed in studies to date. Specifically, we studied the influence of variables extraneous to the instrument, such as age, sex, and social class, and the extent to which OM6 scores correlate with measures of overall quality of life.

Although OM6 was designed specifically to be used as an evaluative instrument, particularly for measuring change in ear-related handicap after treatment, we were interested in whether such a popular and easy-to-use instrument could have a wider application. We wanted to see its effectiveness as a discriminative instrument, by studying the ability of OM6 to discriminate between a reference group of children with no ear problems and children with OME or recurrent AOM, and to determine the degree to which OM6 scores increase with disease severity. The use of OM6 in this context goes beyond its originator’s intentions, but we believe that, as the instrument seems destined to be more widely used, it is inevitable that people will seek to use it in various situations and it is important to demonstrate what is and is not appropriate use.

METHODS

The study was conducted in the pediatric otolaryngology clinics at a large children’s hospital (The Royal Hospital for Sick Children, Yorkhill, Glasgow) and 2 district general hospitals (Ayr Hospital and Crosshouse Hospital, Kilmarnock). All children were examined by the same otolaryngologist (H.K.). Prior approval for the study was obtained from the relevant research ethics committees.

The OM6 questionnaire was completed at the time of the first hospital appointment by the parents of a consecutive series of children referred with a presumptive diagnosis of otitis media. These children were labeled as having suspected OME if the complaint was of hearing impairment or speech delay or as having recurrent AOM if the complaint was of recurrent otalgia and fever with or without otitis media.

The questionnaire was also completed by a comparison group, comprising a consecutive series of children, also at their first visit, having been referred with sore throats thought to be due to recurrent tonsillitis. Any children in the comparison group with reported hearing impairment, speech delay, otalgia, or otitis media were excluded.

All parents also completed the Health Utilities Index Mark III (a 16-item generic quality-of-life measure) and a global rating of quality of life on a 10-cm visual analog scale. Clinical data were recorded, including tympanometric and audiometric findings for the children with ear complaints. Tympanometric traces were classified according to Fiellau-Nikolajsen,5 with type B (flat trace) and type C2 (highly negative middle ear pressure) denoting a strong likelihood of middle ear fluid and an associated hearing impairment being present.6

Statistical analyses were performed by computer using a commercially available software program (SPSS for Windows, version 11.0; SPSS Inc, Chicago, Ill).

RESULTS

Two hundred seventy-seven families were invited to participate in the study, but 26 declined. Thus, the OM6 was completed by the parents of 251 children, of whom 179 had ear complaints and 72 had sore throats. Of the ear complaints group, 84 had suspected OME, 49 had recurrent AOM, and 46 had OME and recurrent AOM. Most of the children (n=209) were referred to the hospital by their general practitioner, while 38 were referred by community pediatric services and 4 by other departments within the hospital. One hundred eighty-five children were seen at The Royal Hospital for Sick Children, and the remainder were seen at Crosshouse Hospital (n=37) and Ayr Hospital (n=29).

Overall, there were 132 boys and 119 girls, with no sex difference identified between any of the diagnostic groups. The socioeconomic status of the families, as judged by the main wage earner’s occupation (manual vs nonmanual) and by area of residence (categorized by the Carstairs Deprivation Index7,8), also did not differ for any of the diagnostic groups.

Overall, the children ranged in age from 1 to 14 years (mean, 5.3 years; median, 5 years). However, the recurrent AOM children were significantly younger than the other diagnostic groups (mean age, 3.5 years; median age, 4 years) (Kruskal-Wallis test, P<.001).
A wide range of OM6 scores was encountered in the children with ear complaints, ranging from 1.0 (the lowest [best] score possible) to 6.2 (of a maximum possible of 7.0). This reflects the wide range of disease severity seen in the children referred, including many who had minimal complaints and normal examination and audiometric findings. The scores were not affected by the sex of the child (Mann-Whitney test, \( P = .55 \)), the occupation of the parents (Mann-Whitney test, \( P = .08 \)), the deprivation index (Kruskal-Wallis test, \( P = .12 \)), the sex of the parent completing the form (Mann-Whitney test, \( P = .76 \)), or the age of the child (Kruskal-Wallis test, \( P = .21 \)).

The OM6 scores in those children with sore throats were significantly lower than in the children with ear complaints, as expected (Mann-Whitney test, \( P < .001 \)). However, there was much overlap in the scores, with some surprisingly high values (as high as 6) in the children with sore throats and reportedly no ear complaints (Figure 2). The situation was similar for the 6 domain scores, with lower scores in the children with sore throats than in those with ear complaints. The differences were most marked for the hearing loss and caregiver concerns domains (Mann-Whitney test, \( P < .001 \) for both) but were also statistically significant for the physical suffering and speech impairment domains (\( P = .04 \) and \( P = .03 \), respectively).

For the 128 children with OME, there was some evidence of an association between disease severity and OM6 score. Those who had bilateral B or C2 tympanometric findings on the day of their hospital visit had worse OM6 scores than those with other tympanometric patterns (\( n = 64 \) in each group) (Mann-Whitney test, \( P = .004 \)) (Figure 3). However, those with a better ear threshold of more than 20-dB hearing level (the median threshold) did not score significantly differently from those with worse hearing (\( \geq 20 \)-dB hearing level) (\( n = 83 \) and \( n = 45 \), respectively) (Mann-Whitney test, \( P = .42 \)) (Figure 4).

For the 95 children with recurrent AOM, there was no evidence of an association between disease severity and OM6 score. There was no correlation between OM6 score and mean number of episodes of otalgia per month (Spearman \( \rho = .013 \), \( P = .22 \)) or mean number of episodes of otorrhea per month (Spearman \( \rho = .017 \), \( P = .31 \)). In those of school age (\( \geq 5 \) years), scores were no worse in those who had lost time from school as a result of their ear infections compared with those who had not (\( n = 24 \) and \( n = 35 \), respectively) (Mann-Whitney test, \( P = .45 \)) (Figure 5). The OM6 score correlated well with global quality of life, as measured on a 10-cm visual analog scale (Spearman \( \rho = .55 \), \( P < .001 \)) (Figure 5) and with the Health Utilities Index Mark III (Spearman \( \rho = -.61 \), \( P < .001 \)) (Figure 6).

**COMMENT**

Quality of life is a broad concept that reflects a person’s experience across the whole range of social, psychological, and physical aspects of day-to-day life. Quality-of-life measures are, therefore, broad in scope and allow comparisons to be made between different conditions and interventions. They lack sensitivity, however, because their broad nature limits the extent to which they can focus on any individual aspect of life. Measures that are more specific to one condition allow more sensitive measurements to be made and can be used alone or to complement the broader quality-of-life instruments. By definition, a measure that is condition specific cannot be addressing the more general concept of quality of life, so these measures should be referred to by a term such as condition-specific handicap measures.

The children referred to the hospital for a specialist consultation range in the severity of their condition from...
those who are within the range of normal to those who are severely affected and require surgery. This spectrum allows us to compare disease severity against its impact on day-to-day life. In general, we would expect that the children with the more severe manifestations of disease would report a greater disease-related handicap. Of course, the correlation between parent reports of disease severity and objective measures will never be perfect; we know, for example, that parent reports of hearing impairment correlate poorly with audiometric thresholds. The fact that associations between disease severity and handicap can be difficult to show serves to emphasize the huge variability in reported handicap and quality of life from one child to another. It is precisely because of such variability that we need to attempt to measure these things at all. However, the lack of an association between OM6 scores and markers of disease severity, such as frequency of otalgia and otorrhea and audiometric threshold, means that OM6 is unlikely to be useful for comparing groups of children. The grouping of responses into symptom clusters means that responses for different children may well be based on different symptoms. Responses for the same child before and after treatment, however, are more likely to be based on the same symptoms, and OM6 has previously been shown to be effective as a measure of change.

To our knowledge, no data have previously been published on scores obtained in healthy children to be used for comparison. Children with sore throats who are free of any ear-related complaints were, therefore, chosen as a potentially useful comparison group. The large overlap between scores in children with ear complaints and scores in those without ear complaints reflects the same lack of discriminant validity previously described. The high OM6 scores occasionally obtained in the comparison group were unexpected as OM6 refers explicitly and exclusively to ear-related problems. It is possible that some parents were misled by the context in which OM6 was administered and answered the questions with their child’s sore throats in mind. This may have falsely elevated the OM6 scores obtained in the comparison group. It is clear, however, that the large spread of results obtained in any group of children means that large numbers would be required in any research study that aims to show a difference between groups.

Demographic variables, such as age, sex, and socioeconomic class, together with the sex of the parent completing the questionnaire, do not seem to bias the scores obtained with the OM6. This serves to confirm the robustness of OM6 as a measure that has already been shown to have a low test-retest error and good responsiveness to change.

In the original description of OM6 by Rosenfeld et al, only children with proven persistent OME or at least 3 episodes of AOM were studied, so their series is not directly comparable with our unselected series. The median OM6 score (2.8) in that group was, therefore, slightly higher than in ours (2.3). Further comparison with data in the article by Rosenfeld et al shows that the higher range of reported values is similar (10th percentile score of 4.5 compared with 4.3 in our series) but that there are more children in our series with low scores (90th percentile score of 1.7 compared with 1.0 in our series). Data on the domain scores from the subsequent study by Rosenfeld et al also show some differences from our own (Table). The scores for physical suffering, emotional distress, activity limitations, and caregiver concerns are considerably higher than in our series, while hearing loss scores are lower. The variability of responses is similar, however, with all domain scores having an SD of 1.6 to 1.9. The differences may reflect cultural differences and differences in the proportion of AOM vs OME and in the severity of disease in the populations studied.

A Comparison of OM6 Domain Scores in 2 Studies

<table>
<thead>
<tr>
<th>Domain</th>
<th>Study by Rosenfeld et al 2</th>
<th>Present Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical suffering</td>
<td>4.6 (1.8)</td>
<td>2.7 (1.7)</td>
</tr>
<tr>
<td>Hearing loss</td>
<td>2.7 (1.8)</td>
<td>3.6 (1.8)</td>
</tr>
<tr>
<td>Speech impairment</td>
<td>2.3 (1.8)</td>
<td>2.2 (1.6)</td>
</tr>
<tr>
<td>Emotional distress</td>
<td>4.0 (1.8)</td>
<td>2.5 (1.6)</td>
</tr>
<tr>
<td>Activity limitations</td>
<td>3.4 (1.9)</td>
<td>2.3 (1.7)</td>
</tr>
<tr>
<td>Caregiver concerns</td>
<td>4.9 (1.7)</td>
<td>3.1 (1.6)</td>
</tr>
</tbody>
</table>

Figure 5. Scatterplot of global quality of life, as rated on a 10-cm visual analog scale, and ear-specific handicap, as rated by the OM6.

Figure 6. Scatterplot of global quality of life, as rated on the Health Utilities Index Mark III, and ear-specific handicap, as rated by the OM6.

Table: A Comparison of OM6 Domain Scores in 2 Studies
In conclusion, OM6 scores correlate well with global assessments of quality of life and are free from many potential biases. However, the scores themselves have little relationship with disease severity in children with either AOM or OME, and the high scores in the children with sore throats may reflect a lack of specificity to otitis media. While changes in OM6 score have previously been shown to be effective in measuring change in ear-related handicap after treatment, care should be taken not to assign too much meaning to isolated OM6 scores. Ideally, the OM6 should be supplemented with the use of appropriate measures of disease severity and should not be used on its own as a discriminative measure.

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