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Middle ear disease in Danish toddlers attending nursery day-care – Applicability of OM-6, disease specific quality of life and predictors for middle ear symptoms



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ABSTRACT

Objectives: Otitis media (OM) is a very common childhood disease and impacts child quality of life (QoL) to different extents. The aim of this study was to investigate the difference in quality of life between three groups of children; Children with symptoms of ear disease within the last 4 weeks, children without any ear disease and children scheduled for ventilating tube treatment. Furthermore, we investigated predictors for experiencing middle ear symptoms. Lastly, we assessed psychometric properties of OM-6 used to assess QoL.

Methods: Four hundred ninety-four children attending nursery day-care aged 6–36 months were enrolled in the study. Caregivers were asked to recall the child's history of symptoms related to middle ear infection. The Danish version of otitis media-6 questionnaire was used to measure the children's quality of life. Data from children treated with ventilating tubes were included from a previously published study. Logistic regression was applied for determining possible predictors for experiencing ear related symptoms.

Results: The study had an 87% response rate, with a total of 342 children included. At the inclusion 32 (9%) children were included in the 4-week group and, while 307 children were allocated to the non-4 week group. The children in the 4-week group were significantly younger and were more likely to have siblings with a history of middle ear infection than the non-4week group. Furthermore, QoL was significantly worse in the 4-week group compared to the non-4week group. Only subtle differences were found between children with acute symptoms compared to children scheduled for tube treatment.

Conclusions: As expected, children with acute symptoms of OM experience lowered QoL compared to children with no symptoms and young age as well as having siblings with a history of middle ear problems were found to be possible predictors for experiencing middle ear symptoms. Children with acute symptoms differed from children scheduled for ventilating tubes on domains related to long-term problems from OM. OM-6 has shown to be a valid instrument for assessing disease specific QoL in children with OM, however a more large-scale instrument might be necessary for detecting subtle differences between subgroups of children with OM.

1. Introduction

The disease burden of otitis media (OM) in pre-school children is well known. 70–80% of children will have experienced one or more episodes of OM by the age of three years [1,2]. Symptoms vary greatly depending on severity and diagnostic subgroup with overlap between groups. Acute otitis media (AOM) is characterized by acute episodes of ear pain, fever and sometimes otorrhea [3]. Children with Otitis media with effusion (OME) on the other hand, are more likely to experience general discomfort, sleep disturbances, lower appetite and even temporary hearing loss [4]. Studies have shown that OM affects quality of life (QoL), especially when the disease progress to a more chronic state

as either chronic OME (COME) or recurrent AOM (RAOM) [5,6].

Multiple factors are associated with the risk of developing OM. Host factors include age and genetic predisposition. Furthermore, environmental factors such as siblings, season and daycare attendance also play an important role [7]. The latter has been attributed to the frequent exposition to various infections [8].

Daycare attendance varies greatly in the western world and Denmark has one of the highest rates with more than two thirds of pre-school children attending any kind of daycare [9]. Most attend public nursery daycare, which makes Denmark ideal for conducting research on these children.

The objectives of this study were to investigate the difference in QoL

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Table 1
Demographic data of the total sample and subgroups after excluding children treated with VT.

	Total	4w group	Non-4w group	VT group Heidemann et al. ^b [5]
Distribution ^a	342	32 (9%)	307 (90%)	106
Male	164 (48%)	17 (53%)	146 (48%)	59 (56%)
Female	178 (52%)	15 (47%)	161 (52%)	47 (44%)
Age in months, mean (SD)	21.1 (7.5)	16.3 (4.6)	21.5 (7.5)	19.1 (6.3)
Number of children in household, mean (SD)	1.6 (0.8)	1.7 (0.9)	1.6 (0.8)	1.9 (0.8)
If more than 1 child in the household: siblings' history of middle ear problems, n (%)	71 (38%)	11 (73%)	60 (35%)	40 (57%)
Pacifier use, n (%)	263 (77.3%)	25 (80.6%)	236 (76.8%)	90 (85%)

^a 3 children could not be allocated to the subgroups and were excluded from the analysis.

^b Only data from children aged 36 months or less were included in order to ensure comparability.

in children with symptoms of ear disease within the last 4 weeks compared to children without any ear disease, excluding children with a history of ventilation tube (VT). We also compared the QoL in the above two groups of children to a group of children scheduled for VT. Furthermore, we investigated predictors for experiencing middle ear symptoms. The validated Danish version of the otitis media-6 questionnaire was used for assessing QoL [10]. This version has only been applied in children with severe OM scheduled for VT. Hence, psychometric properties were assessed as the instrument was applied in children who were assumed to present with a wider spectrum in QoL scores compared to children scheduled for VT.

2. Material and methods

In this cross-sectional study we included children attending nursery day-care aged 6–36 months. Children were included from 12 public centers with a total of 494 children. The authors (SA or JI) visited the centers on afternoons when the children were picked up by their caregivers from February 24th to March 28th, 2014. We excluded children with other significant disease that might have an impact on QoL as well as children who had a history of ventilating tube insertion.

Caregivers were asked to recall the child's history of symptoms related to middle ear infection (ear pain in combination with fever) and QoL was measured using the Danish version of the Otitis Media-6 questionnaire (OM-6). This disease specific instrument contains six items and respondents (parents) are asked to recall symptom history pertaining to the previous four weeks [11]. The OM-6 covers the child's physical suffering, hearing loss, speech impairment, activity limitations, emotional distress and caregiver concern. Each of the items is scored on a Lickert-type scale ranging from 1 to 7, with 7 representing worst score [11]. The Danish version has shown good reliability and validity in a population of pre-school children with COME and RAOM [10]. However, basic psychometric properties were investigated in this study as the instrument is used in a population of children which may have less severe or no ear related symptoms. Floor and ceiling effects were considered present if more than 15% achieved the highest or the lowest possible score [12,13]. Internal consistency was assessed by calculating Cronbach's alpha for the subgroups. Alpha was analysed for the both subgroups and should be between 0.70 and 0.95 [12]. Construct validity was assessed by analysing correlations between the OM-6 summary score and having middle ear symptoms for the past 4 weeks. In addition, for both subgroups we analysed correlations between the summary score and scores of an 11-point numerical rating scale representing global ear related QoL (NRS) included for these analyses. We hypothesized that all correlations would be strong ($r > 0.50$) [14]. Discriminant validity was evaluated by statistical difference between subgroups of children.

For all analyses OM-6 scores were adjusted to 0–100 scales and summary scores were calculated based on the method of proportional recalculation [15]. As the OM-6 is completed based on symptoms pertaining to the past four weeks, we dichotomized the study sample in children with and without middle ear symptoms in the past 4 weeks

(4w group vs. non-4w group) for comparison. We also included data from a previously published study on children scheduled for ventilating tube treatment for COME and/or RAOM (VT group) [5]. This enabled further analysis on possible differences between groups of children with acute disease (4w group) and chronic disease (VT group). Only data from children attending nursery day-care and from the same age group was included. Student's t-test was used for testing statistical difference in scores between subgroups. Lastly, logistic regression was applied for determining possible predictors for experiencing ear related symptoms. Independent variables included gender, age, number of children in the household, siblings' history of middle ear problems and pacifier use. Non-binomial variables were dichotomized at the median.

The study was approved by the Danish Data Protection Agency. According to the rules and regulations of the Danish Scientific Ethical Committee approval is not required for studies that are purely observational.

3. Results

3.1. Participants

Parents of 424 children accepted participation (87% response rate). Two children were excluded due to other significant diseases and 80 children were excluded as they had been treated with ventilating tubes. This left 342 children eligible for inclusion. 32 (9%) were included in the 4-week group, while 307 were allocated to the non-4 week group. 3 could not be allocated to either group and were excluded from the comparative analysis. Mothers completed 74% of the questionnaires, whereas fathers completed only 19%, and 8% chose to fill in the questionnaire together. Table 1 displays basic demographic descriptives of the study sample. The study sample consisted of 52% females. The mean age of the participating children was 21 months. Children in the 4w group were significantly younger than children in the non-4w group (mean difference 0.44 months, 95% confidence interval (CI): 0.21–0.66, $P < 0.001$). There was no significant difference in the number of children in the household ($P = 0.716$). However, children in the 4w group were more likely to have siblings with a history of middle ear problems (mean difference 0.37, CI: 0.12–0.63, $P = 0.004$).

3.2. Quality of life

QoL as measured by the OM-6 was significantly worse in the 4w group compared to the non-4w group (Table 2). A statistically significant difference between subgroups was found for all individual items except item 3 (speech impairment). Physical suffering was the parameter showing the greatest difference, followed by caregiver concerns and emotional distress. A small respectively no difference were seen in hearing loss and speech impairment. Children with chronic disease (VT group) had worse QoL compared to children in the 4w group. However, there were no statistical difference in items related to physical suffering, emotional distress and activity limitations (Table 3).

Younger age (median = 20.1 months, OR = 4.94, $p = 0.018$) and

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