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Effect of vaccination on quality of life in children with recurrent acute otitis media

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Abstract

Background: Knowledge about the effect of recurrent acute otitis media (rAOM) and its treatment on health-related quality of life (HRQoL) and functional health status (FHS) in children with rAOM is limited. The current study aims to assess the effect of pneumococcal vaccination on HRQoL and FHS in children aged 1–7 years with rAOM. *Methods*: In a double-blind randomized controlled trial, 383 children aged 1–7 years with rAOM were vaccinated with either heptavalent pneumococcal conjugate vaccine followed by pneumococcal polysaccharide vaccine (pneumococcal group, $n = 190$), or hepatitis A or B vaccine (control group, $n = 193$). At baseline, age-adjusted HRQoL and FHS scores of all children were compared to those of reference populations. Subsequently, scores of the pneumococcal and control vaccine group were compared at baseline and at 7, 14, and 26 months follow-up. Data are presented for two instruments, NRS Child and FSQ Generic, assessing HRQoL and FHS, respectively. *Results*: Scores on the FSQ Generic of children with rAOM were lower than those of healthy children and comparable to those of children with asthma. After vaccination, no differences on the FSQ Generic or NRS Child were found between the pneumococcal and the control group at baseline and during follow-up. *Conclusions*: Recurrent acute otitis media has a considerable

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impact on the HRQoL and FHS of children; however, pneumococcal vaccination had no beneficial effect on their HRQoL and FHS.

Keywords: Functional health status; Randomized controlled trial; Pneumococcal vaccination; NRS Child; FSQ Generic

1. Background

Acute otitis media (AOM) is one of the most common childhood infections. Five percent of all children suffer from recurrent ear infections (i.e., more than four episodes per year) [1,2]. So far, research has been focused on conventional clinical indices such as symptoms of acute illness [3–7], and on clinical efficacy of interventions [8–10]. Consequently, knowledge about the effect of recurrent acute otitis media (rAOM) on health-related quality of life (HRQoL) or functional health status (FHS) in children is limited. Likewise, studies on effect of interventions on HRQoL and FHS of children with rAOM are sparse [11–13].

Since the effectiveness of current treatment strategies for rAOM appears limited and antibiotic resistance increases [14,15], attention has shifted to the prevention of AOM, such as by pneumococcal vaccination. The clinical efficacy of pneumococcal vaccination regarding AOM appears to be modest [16]. The effect of vaccination on HRQoL or FHS in children with rAOM, however, has not yet been studied. This study aims to assess:

– both FHS and HRQoL of children with recurrent OM; and
– the effect of pneumococcal vaccination on FHS and HRQoL.

2. Methods

In a double-blind randomized controlled trial, 383 children aged 1–7 years with rAOM were vaccinated with either heptavalent pneumococcal conjugate vaccine followed by pneumococcal polysaccharide vaccine (pneumococcal group, $n = 190$), or with hepatitis A or B vaccine (control group, $n = 193$).

Parents completed validated Dutch versions of eight HRQoL/FHS instruments assessing generic FHS (RAND, FSQ Specific, and FSQ Generic), OM-specific FHS (OM-6), OM-specific child HRQoL (NRS Child), family functioning (FFQ), and OM-specific caregiver HRQoL (NRS Caregiver). All instruments had been validated for this population (data not shown).

To assess the impact of rAOM and the effectiveness of pneumococcal vaccination on FHS and HRQoL:

– age-adjusted total and subscale scores of all children at baseline were compared to those of reference populations. Reference populations consisted of children from the general population ($n = 117$) and children with asthma in general practices (n = 64); and

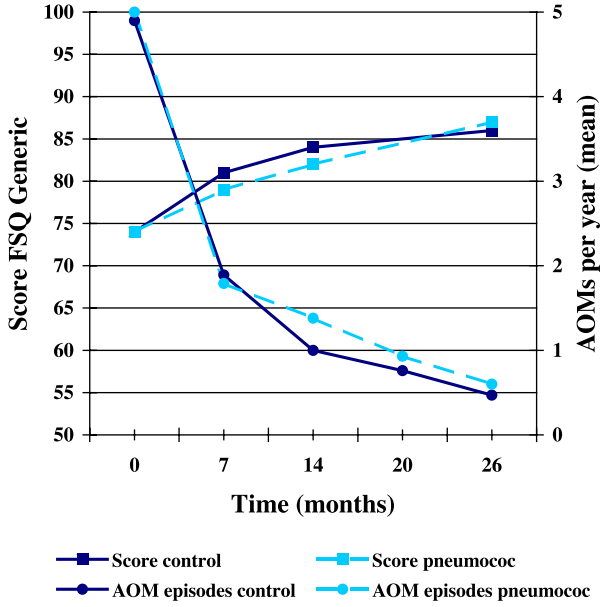
Score FSQ Generic
AOMs per year (mean)
Time (months)
100
95
90
85
80
75
70
65
60
55
50
5
4
3
2
1
0
0
7
14
20
26
Score control
Score pneumococ
AOM episodes control
AOM episodes pneumococ

Fig. 1.

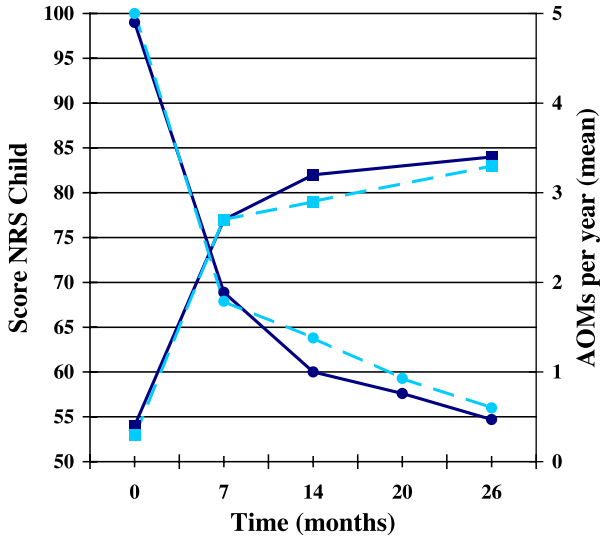
Score NRS Child
AOMs per year (mean)
Time (months)
100
95
90
85
80
75
70
65
60
55
50
5
4
3
2
1
0
0
7
14
20
26

Fig. 2.

– scores between the pneumococcal and control groups were compared at baseline and at 7, 14, and 26 months follow-up.

3. Results

We will present the results for two measures (i.e., the FSQ Generic and the NRS Child).

In general, scores of all children in the study population were low for subscales assessing physical problems, emotional distress, problem behaviour, and parental concern. For the FSQ Generic, the study population had poorer scores than healthy children (74 vs. 89, $p < 0.01$). Results of the study population were similar to those of children with asthma (74 vs. 76, $p = 0.32$).

No substantial differences on the FSQ Generic or NRS Child were found between the pneumococcal group and the control group at baseline, and at 7, 14, and 26 months follow-up. AOM frequency decreased in both groups, with considerable and comparable improvement on these two measures of HRQoL and FHS (Figs. 1 and 2).

4. Conclusion

In this study, we set out to quantify the impact of recurrent OM as well as the effect of pneumococcal vaccination on children's FHS and HRQoL.

For two measures of FHS and HRQoL, the burden of rAOM seems to be considerable; scores of the present study population on the FSQ Generic were similar to those of children with asthma. Pneumococcal vaccination compared to control vaccination, however, had no beneficial effect on either of these two measures of health-related quality of life or functional health status in children aged 1–7 years with rAOM.

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