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ORIGINAL PAPER

**David Greenberg · Natasha Bilenko · Zvika Liss
Tomer Shagan · Orly Zamir · Ron Dagan**

The burden of acute otitis media on the patient and the family

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Abstract The aim of our study was to determine the burden of acute otitis media (AOM) on patients and their families. Parents of children with AOM were interviewed with regard to the week preceding the AOM diagnosis and every 3 days henceforth for an additional 21 days. The interview included information on loss of workdays, use of health care services and impact on the patient's and family's quality of life. Parents of age- and neighbourhood-matched controls were interviewed in an identical manner. A total of 150 patients and 51 controls were included in the analysis. The following variables differed significantly ($P < 0.001$) between patients and controls (mean ± SD): non-routine days 18.5 ± 11.0 in patients versus 3.4 ± 6.5 in controls; number of visits to primary health centres 2.6 ± 1.6 versus 0.4 ± 0.6; number of emergency room visits 0.2 ± 0.5 versus 0.1 ± 0.02 and number of visits to an otolaryngology clinic 0.3 ± 0.6 versus 0. Days of antibiotic and over the counter drug use were 9.0 ± 5.6 versus 0.3 ± 0.9 and 7.0 ± 6.0 versus 4.9 ± 6.0, respectively per episode. The mean loss of workdays per child was 1.6 ± 1.8 in patients versus 0.25 ± 0.6 in controls, for working mothers and 0.6 ± 1.1 versus 0.1 ± 0.4 for working fathers; duration of absenteeism from day care facilities was 3.5 ± 2.5 versus 0.9 ± 2.7. *Conclusion*: Acute otitis media significantly reduces the quality of life of both child and parents, causes substantial use of medical services and significant loss of workdays.

Keywords Acute otitis media · Burden · Disease

Abbreviations *AOM* acute otitis media · OTC over the counter

D. Greenberg (✉) · T. Shagan · O. Zamir · R. Dagan
The Paediatric Infectious Disease Unit,
Ben-Gurion University of the Negev,
Soroka University Medical Centre,
Beer-Sheva, Israel
E-mail: dudi@bgumail.bgu.ac.il
Tel.: +972-8-6400547
Fax: +972-8-6232334

N. Bilenko
Department of Epidemiology, Faculty of Health Sciences,
Ben-Gurion University of the Negev, Beer-Sheva, Israel

Z. Liss
The Israel General Health Insurance Plan,
Faculty of Health Sciences,
Ben-Gurion University of the Negev, Beer-Sheva, Israel

Introduction

Acute otitis media (AOM) is the most common bacterial infection in children. By the age of 2 years, at least one episode of otitis media will have occurred in over 90% of children [12]. In addition, more than 75% of children will contract AOM before the age of 3 years and > 50% will have at least one recurrent episode before that age [10]. It is estimated that more than 10 million cases of AOM occur annually in the United States in children less than 5 years of age [6,12].

Childhood community-acquired infections have an important impact on society and are a frequent cause of visit to the physician, consumption of antibiotics and over-the-counter (OTC) drugs, work loss and reduction of quality of life. The direct cost of an episode of AOM may be measured by physician visits and consumption of antibiotic and OTC drugs. It varies and depends on the antibiotic prescribed as well as on the nature of the AOM episode (first or recurrent episode) [9]. The indirect cost is more difficult to estimate and includes: missing workdays to care for a sick child, hiring a babysitter and transportation [1, 4,9]. Indirect costs have a major impact on the total cost. In one study, 90% of the cost of AOM was due to parents' work loss [1].

Recently, a pneumococcal conjugated vaccine was introduced into the United States vaccination schedule. This vaccine may reduce the incidence and the severity of AOM in children [5, 8, 11, 13,16]. New viral vaccines such as vaccines against influenza and respiratory syncytial viruses may also be introduced in the future and may have an effect on the occurrence of AOM. Thus it is

important to estimate the specific cost and burden of AOM on the patients and their families since they may play a major role in decisions on the implementation of vaccines.

The aims of our study were to define the burden of AOM on patients, on their families as well as on health services.

Subjects and methods

Enrollment

Patients were enrolled in three primary paediatric clinics serving the Jewish population in Beer-Sheva. The primary physician made the diagnosis of AOM and provided the treatment. Research assistants were present in the clinics every workday for 4 h in the morning to enroll these patients.

Inclusion criteria

Patients diagnosed as having AOM were enrolled if: (1) they were younger than 3 years of age; (2) they did not have an episode of AOM diagnosed within the 7 days before enrollment; (3) they did not have any known immunological impairment or chronic diseases; (4) they were not receiving any acute or chronic medication; and (5) parents or legal guardians signed an informed consent.

Data collected

The initial questionnaire included the following variables: age, gender, chronological order of child in the family, number of children in household, total number of persons living at home, number of bedrooms, number of people sleeping with the child in the same room, patient or sibling's day care attendance as well as the number of children in the day care facility attended by the patient. In addition, parents' work place and information on their employment and years of schooling were recorded. Data on the occurrence of AOM during the 12 months before enrollment were obtained and the medical history and the symptoms related to AOM during the last 7 days before enrollment were recorded.

Follow-up

After completion of the initial questionnaire, telephone interviews were performed every 2–3 days for a total of 21 days of follow-up from the initial visit (total follow-up was in fact 29 days since questions about the 7 days before enrollment were also included). The follow-up questionnaire was designed to obtain details on the daily occurrence of temperature $>38°C$, vomiting, severe crying, loss of appetite, earache and insomnia (all according to the subjective judgment of the mother). Non-routine days were defined by the parents' judgment of the child's level of activity compared with that before the AOM episode or when the child had at least one of the following: severe crying, sleep disturbances and loss of appetite. In addition, data were obtained from parents about work loss, babysitting and travel related expenses. Visits to primary health care centres, paediatric emergency room visits, laboratory tests and procedures performed were recorded. Consumption of medications such as antibiotics and OTC drugs and visits to the emergency room and hospitalisations were recorded as well.

Control group

Each parent participating in the study was asked to provide the name of an acquaintance with a healthy child who could take part in the control group. The controls were matched to the cases by season, age and neighbourhood. The parents of the control group signed an informed consent and were interviewed and followed using a questionnaire and schedule identical to that of the patients.

This study was approved by the Soroka University Medical Centre Institutional Review Board and a written signed informed consent was obtained from the parents of all the children.

Data analysis

Data were recorded using the Access Microsoft Office software. Statistical analysis was performed using SPSS software. Continuous variables in cases and controls were compared by t-test and proportions were compared by the chi-squared or Fisher's exact test as needed. Multivariate logistic regression models were performed for prediction. A P value <0.005 was regarded as significant.

Results

Between November 4th 1999 and June 13th 2000, 160 children with AOM and 58 controls were enrolled. Ten children in the patient group and seven in the control group did not complete the study due to refusal to continue follow-up ($n=7$), or were lost to follow-up ($n=10$). Thus the final study group included 150 children in the patient group and 51 children in the control group.

There was no significant difference between the groups with regard to age and gender. A trend toward larger family size, number of subjects attending day care centre, number of children per family, and smaller number of bedrooms, suggested increased crowding among children with AOM compared with controls (Table 1). Statistically significant differences were found between the groups with regard to the mothers' years of schooling, 13.0 ± 2.6 and 14.7 ± 3.6 years in the patient and control groups, respectively ($P=0.002$), while no differences were noted in the fathers' years of schooling.

The patient group had suffered from a significantly higher number of episodes of AOM and underwent tympanocentesis more often in the 12-month period preceding the study than the controls (Table 2). Furthermore, patients were treated with more courses of antibiotics than controls during the 6 months preceding enrollment.

The final number of controls was lower than that of the patients for two main reasons: (1) it was difficult to find healthy children <3 years of age (not even suffering from upper respiratory infections) during the AOM season and (2) refusal to participate in the follow-up excluded a substantial number of controls.

During the follow-up period following the diagnosis of AOM, patients experienced a significantly higher number of days of diarrhoea, conjunctivitis and vomiting compared with controls. In addition they had additional days of fever, earache, severe crying, loss of appetite and sleep disturbances; those symptoms lasted a week in average (Fig. 1).

Compared with controls, patients had an additional mean of 15.2 non routine days (95% confidence interval:

Table 1 Selected demographic characteristics of the patient and control groups

Characteristic	Cases (n = 150)	Controls (n = 51)	P
Mean age ± SD (months)	14.8 ± 8.3	14.5 ± 9.7	0.83
Number of males (%)	87 (58)	30 (59)	0.92
Mean number of bedrooms in the house ± SD	2.8 ± 0.9	3.1 ± 1.0	0.11
Mean number of individuals in household ± SD[a]	4.5 ± 1.3	4.2 ± 1.1	0.07
Mean number of (< 5 years) children in household ± SD[a]	2.1 ± 1.0	1.9 ± 0.8	0.12
Patients or controls attending day care centre (%)	50 (33)	11 (22)	0.11
Mean number of children attending day care facility together with the child ± SD (for those attending day care centre)	7.1 ± 8.6	6.2 ± 9.6	0.05
Mean mother's years of schooling ± SD	13.0 ± 2.6	14.7 ± 3.6	0.002
Mean father's years of schooling ± SD	12.9 ± 2.9	13.0 ± 4.8	0.85
No. of mothers working out of home (%)	90 (60)	28 (55)	0.52
No. of fathers working out of home (%)	130 (87)	44 (86)	0.95

[a]Including the index child

Table 2 Medical history of the study children

Condition	Patient group (mean ± SD, n = 150)	Control group (mean ± SD, n = 51)	Difference		P
			Mean	95% confidence interval	
AOM in past 12 months	1.06 ± 1.3	0.22 ± 0.54	0.84	0.58; 1.08	< 0.01
Recurrent AOM[a]	0.22 ± 0.41	0.02 ± 0.14	0.20	0.12; 0.27	< 0.01
Number of episodes during which tympanocentesis was performed in past 12 months	0.39 ± 1.03	0.06 ± 0.24	0.33	0.16; 0.51	< 0.01
Antibiotic treatment courses in last 6 months	1.95 ± 2.11	0.55 ± 0.92	1.40	0.98; 1.82	< 0.01

[a]Defined as more than three episodes within the last 6 months or more than four episodes within the last year

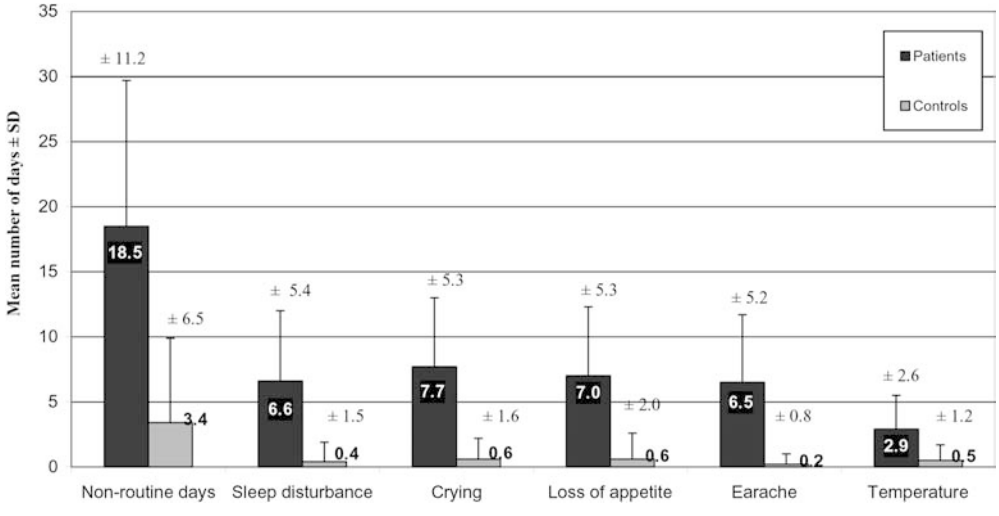


Fig. 1 Mean number of days with clinical signs and symptoms during a 1-month follow-up (± standard deviation). P = < 0.01 between case and controls for all parameters

12.65–17.6) as reported by parents, and 25% did not return to their regular routine at the end of the follow-up versus only 9.8% of the controls (P < 0.01).

Working mothers of AOM patients lost more workdays than fathers but both had a statistically significant increase in lost workdays compared with the control groups (Table 3). A multivariate logistic regression analysis revealed that parents in the patient group had a significantly higher rate of work loss due to an AOM episode when adjusted for age and day care facility attendance. An additional multivariate model showed that the subjects belonging to the patient group missed a significantly higher number of days at their day care facility than controls, irrespectively of other variables.

With regard to medical facility use, patients visited their primary physician 6.5-fold more than controls and the paediatric emergency room 10-fold more than controls. Approximately 33% of the patients visited an otolaryngologist and 15% underwent tympanocentesis during the AOM episode (Fig. 2). During the follow-up

Table 3 Loss of workdays and absenteeism from day care facility in the patient and control groups during a 1-month follow-up

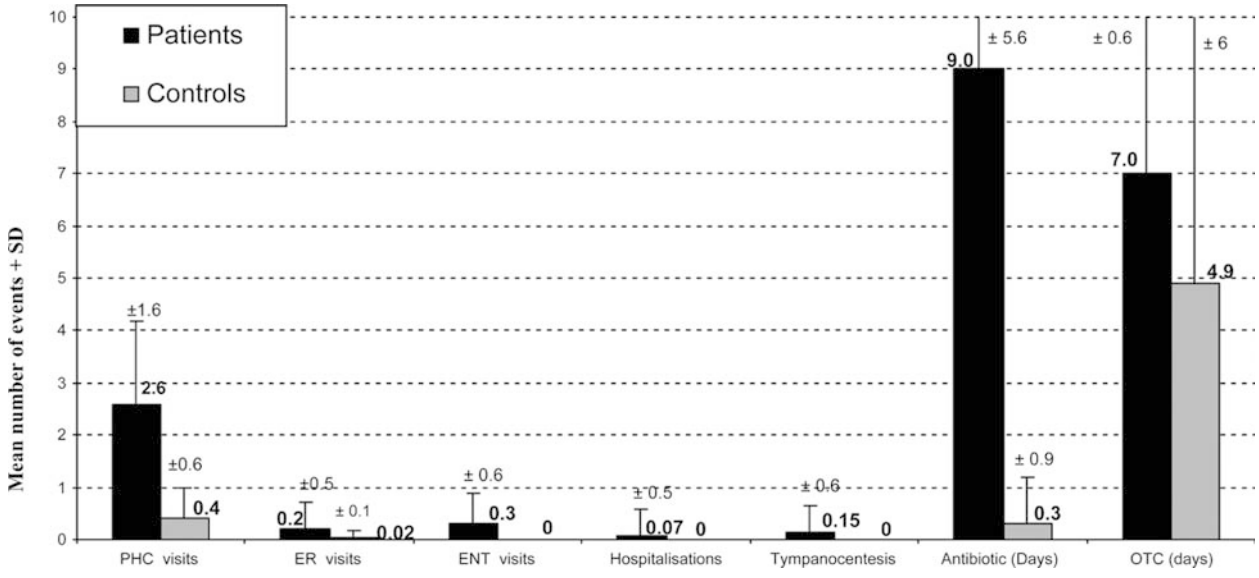
	Patient group (mean ± SD, n = 150)	Control group (mean ± SD, n = 51)	Difference		P
			Mean	95 confidence interval	
Number of workdays lost by mothers ± SD[a]	1.6 ± 1.8	0.25 ± 0.6	1.35	0.9; 1.7	< 0.01
Number of workdays lost by fathers ± SD[b]	0.6 ± 1.1	0.1 ± 0.4	0.5	0.25; 0.9	< 0.01
Number of days of absenteeism from day care facility[c]	3.5 ± 2.5	0.9 ± 2.7	2.4	1.2; 4.1	< 0.01

[a]For working mothers only
[b]For working fathers only
[c]For those attending day care centres

period, the patient group had on average 30-fold more antibiotic days and 1.4-fold more OTC drug days (Fig. 2).

Among our 150 patients, 31 (20.7%) had a previous history of recurrent AOM episodes (defined as three episodes within the last 6 months or four within the last 12 months). These patients underwent a significantly higher number of tympanocentesis (1.2 ± 1.9 versus 0.2 ± 0.4 respectively per episode; $P < 0.001$) and visited their primary physician more often than patients without a history of recurrent episodes (3.1 ± 1.7 versus 2.5 ± 1.5 respectively; $P < 0.001$). With regard to symptoms, in comparison with controls, patients with recurrent AOM episodes went through more days with loss of appetite (8.1 ± 5.2 versus 7.6 ± 5.3 respectively; $P = 0.19$), earache (8.4 ± 4.6 versus 6.0 ± 5.2 respectively; $P = 0.01$), and non-routine days (21.2 ± 12.0 versus 17.8 ± 10.7 respectively, $P = 0.12$). No significant differences were noted between patients with recurrent versus non-recurrent AOM episodes with regard to parents' work loss or absenteeism from day care facilities.

Fig. 2 Usage of medical services and drug consumption during a 1-month follow-up of cases versus controls. Values are given as mean (*columns*) and SD (*bold*). $P = < 0.01$ for all comparisons between case and controls, except hospitalisation. (*ENT* ear throat and nose physician, *ER* emergency room, *PHC* primary health care clinic)



Discussion

The aim of the present prospective study was to determine the direct burden of AOM on patients, their families and society, during a 1-month follow-up. The study was conducted in the southern region of Israel among the Jewish population, which is comparable to a developed country's mid-low socioeconomic class. In this study, subjects and controls were enrolled in the same geographic area and matched by season, age and neighbourhood. This approach gave us the opportunity to determine our population's baseline of events, such as parents' workday loss, which were not directly related to the AOM episode. Comparison between cases and controls with regard to each event shows the actual contribution of AOM to the burden of disease, since the controls determine the baseline of events among the population not affected by AOM.

We divided our findings into three separate categories: (1) the burden of AOM on the quality of life of the patient; (2) the burden of disease on the family and (3) the burden of an AOM episode on medical services and society.

With regard to the burden of AOM on patients, during the 1-month follow-up, children with AOM experienced more days with the following symptoms than controls: high temperature, severe crying, loss of appetite, earache and sleep disturbances. They also had a prolonged recovery process before returning to a normal routine life. Even after 29 days, about 25% of the patients did not go back to their routine, compared with only 10% among controls. This finding may also represent a long-term behavioural problem associated with middle ear effusion or residual symptoms. Furthermore, an AOM episode was associated in average with an increase in day care absenteeism of 2.4 days per child.

With regard to the family's quality of life, in addition to caring for a sick child, other family members lost additional routine days and parents had extra babysitting expenses. The costs associated with caring for an ill child (by a family member) may be underestimated. The time necessary to care for the patient could have been used by the caregiver for market work, non-market household work or for leisure [4,15].

Regarding the burden on society, the loss of workdays was striking. The implication of each episode in terms of work loss by both working parents was in average 1.6 days for working mothers and 0.6 days for working fathers. The burden associated with work loss is an important component of the total cost calculated in certain diseases [3, 7,14]. These findings are comparable to a previous report from Finland, where parents of children with AOM were absent from work for an average of 1.9 days per person per year [14].

Concerning the medical costs of AOM, the two most important aspects that contributed to the direct costs of AOM were medications and physician visits. Patients had an average of 2.6 visits to a primary physician versus 0.4 visits for controls over a 1-month follow-up. This finding is compatible with the finding previously reported of 2.1 visits to a primary physician for AOM in Finland and 2.4 visits per child over a 6-month period for common infections in infants attending day care centres [4,14]. In addition, a high frequency of visits to otolaryngology clinics and emergency rooms, as well as tympanocentesis procedures was documented in AOM patients. This is probably related to the fact that in our case group almost 21% of patients experienced recurrent episodes of AOM. It may also be associated with the ease of accessibility to medical care facilities and to otolaryngology clinics in our region.

The patient group consumed significantly more antibiotics than the controls. In our study, the primary care physician determined the antibiotic treatment for AOM. In our region the treatment of choice for AOM is amoxicillin (with or without clavulinic acid) or cefuroxime axetil. Patients in whom antibiotic treatment fails and who subsequently undergo tympanocentesis receive a different antibiotic treatment following the procedure. The frequent usage of OTC drugs by AOM patients as well as by controls may be related to the cultural behaviour of our specific population. Furthermore, physicians often recommend the use of OTC drugs in our region. The frequent usage of OTC for paediatric respiratory infections was also reported in previous studies [2,4].

The total cost of an AOM episode was not calculated in our study for several reasons: (1) the actual cost should take into consideration indirect costs such as workdays loss and babysitting expenses. These costs differ in various parts of the world and the figures from our country would not reflect the cost in other parts of the world. Therefore we chose to present our data in actual numbers such as antibiotic days and workday loss. Those data can then be extrapolated to each country; (2) since in our country all children are covered by the government health system, access to medical facilities including specialists is easy. This also varies from country to country and can lead to significant differences. Although drug treatment for AOM may differ in various countries, the direct costs can be extrapolated and calculated from our findings for an AOM episode taking into account all of these parameters and additional costs.

Our study had three important limitations. First, the choice of patients with AOM and controls is always problematic. On the one hand, AOM is not easy to determine and the only gold standard is tympanocentesis. By choosing patients with tympanocentesis-proven AOM, we run the risk of selecting the most severe cases or those not responding to antibiotic treatment. We therefore chose to include the patients diagnosed with AOM by their paediatrician. On the other hand, choosing appropriate controls poses a dilemma as in the case of choosing controls with upper respiratory tract infection without AOM, since AOM is often a complication of upper respiratory infections and that it is difficult to distinguish the symptoms of AOM from those of upper respiratory infection. Thus selecting patients with upper respiratory infections without AOM would result in comparing the burden of one disease with the burden of another. We therefore decided to choose healthy controls without any acute diseases. Second, our data rely on the parents' reports and therefore are subjective and cannot be measured or validated. Third, we followed our subjects for 21 days only following the first intervention. We believe, however, that the first two limitations cannot be overcome in any study, at least not with the technology available to date for the diagnosis of AOM in a primary care setting. To overcome the third limitation, additional studies with a longer follow-up period must be conducted in order to determine the exact period of recovery of AOM patients and the return to normal routine. This might not be easy to demonstrate since, as we have shown, a considerable proportion of AOM patients may experience additional AOM episodes that would limit the actual results.

We have shown that each episode of AOM caused a significant burden on the patient, on the patient's family and on society. The latter was expressed both by the loss

of productivity of working parents and by the extensive use of medical facilities and drugs. In addition, we have shown that each AOM episode is associated with a prolonged recovery period, which influences the quality of life of the patient and the family. Thus the estimated costs of AOM should take into consideration both the economic loss and the loss of quality time by patients and caregivers. These data should be used when considering the introduction of bacterial and viral vaccines that could have an impact on the occurrence or severity of AOM.

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