Objective: To determine the effect of passive smoking on otitis media with effusion (OME) and recurrent otitis media (ROM).

Design: A case-control study of children who received ventilation tubes and who were followed up for 1 year to determine the risk of developing postoperative otorrhea and early extrusion in relation to exposure to passive cigarette smoke.

Setting: Otorhinolaryngology Clinic of Istanbul School of Medicine, Istanbul, Turkey.

Patients: A total of 166 children 3 to 7 years old who required tympanostomy tubes because of OME and ROM (case group) compared with an age-matched control group of 166 children. The control group consisted of children who did not meet and never had met criteria for insertion of tympanostomy tubes.

Main Outcome Measures: Statistical analysis of factors associated with a higher prevalence of OME or ROM, postoperative otorrhea, and early tube extrusion.

Results: Passive smoking was a significant risk factor for OME and ROM. The case group was exposed to a mean of 19.6 cigarettes per day vs 14.4 cigarettes per day for the control group ($P<.004$). Only maternal smoking was a significant factor ($P<.001$); no association was found with paternal smoking. Prospective follow-up of the case group showed no significant difference in the clinical course of OME and ROM between maternally exposed and non-maternally exposed children.

Conclusions: Passive smoking increases the risk of OME and ROM in children between 3 and 7 years old. The avoidance of daily exposure to domestic tobacco smoke could have a public health impact.

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Everal studies show that passive smoking may aggravate some diseases. Most of these studies suggest that young children are at particular risk for health problems as a result of passive smoking.\textsuperscript{1,2} In exposed children there is a risk of increased infections,\textsuperscript{3,4} sudden infant death syndrome,\textsuperscript{5} asthma,\textsuperscript{6,7} and adenoidectomies and tonsillectomies.\textsuperscript{8}

Middle ear disease is considered by many investigators to be associated with passive smoking. Otitis media with effusion (OME) is one of the most common illnesses of childhood, with an incidence of 3.6% in 5-year-olds.\textsuperscript{9} Recurrent otitis media (ROM) is also common; it has been reported that, by their seventh birthday, 24%, 12%, and 2% of children had made at least 3, 5, and 10 visits, respectively, to a physician because of this disorder.\textsuperscript{10} The importance of childhood middle ear disorders derives in part from their negative effects on the linguistic, auditory, and communication skills of children.\textsuperscript{11} Furthermore, OME and ROM are well known to carry the possibility of otologic sequelae, including permanent perforation of the tympanic membrane, cholesteatoma, and sensorineural hearing loss.\textsuperscript{12}

Management of OME and ROM may consist of medical therapy or surgery. The surgical treatment is insertion of ventilation tubes with or without adenoidectomy. Ventilation tube placement is the most common operation performed in young children\textsuperscript{13}; therefore, it has an important economic impact.

It is unclear whether exposure to environmental tobacco smoke increases the risk of OME and ROM in the pediatric age group. The aim of this study was to determine the effect of passive smoking on the incidence of OME and ROM by comparing children with inserted ventilation
SUBJECTS AND METHODS

A prospective study of 166 cases and an equal number of controls was undertaken. The case group was identified from the patients who had ventilation tubes inserted under general anesthesia between May 1, 1993, and November 30, 1996, in the Otorhinolaryngology Clinic of Istanbul School of Medicine, Istanbul, Turkey. Children between the ages of 3 and 7 years who had OME or ROM were included in the case group if they fulfilled either of the following criteria14,15: (1) existence of otitis media with effusion not responding to medical management for at least 3 months when bilateral or 6 months when unilateral, marked hearing loss, retracted tympanic membranes on microscopic otoscopy, and type B configuration on tympanogram; or (2) recurrent acute otitis media, especially when antimicrobial prophylaxis fails to prevent frequent, severe, and long-lasting disease, with a minimum of 3 episodes during the previous 6 months or 4 or more attacks during the previous year (1 being recent), red or bulging tympanic membranes on microscopic otoscopy, and type B tympanogram. Middle ear diseases were diagnosed by otolaryngologists, and tympanometric measurements were performed by a certified audiologist (O.C.I., N.K., K.D., or I.S.).

During the study period, a control group similar in age to the case group was selected from patients attending the Orthopedic Clinic at the same hospital. The control group consisted specifically of children who did not meet criteria for insertion of tympanostomy tubes, nor had they at any previous time. There was no socioeconomic bias, since 89% of the case group and 92% of the control group were members of Government Health Insurance, which represents a moderate-income population.

A standard questionnaire was administered to the parents of the children in both groups to assess the effect of indoor environmental factors. The questionnaire included questions about the type of housing (single family or apartment), the year in which the home was built, heating system (central or wood stove), number of persons residing in the same household, the cigarette smoking habits of household members and of frequent visitors, the amount of time the child spent in the home (months per year and average hours per day), other places the child may live part of the year or spend a great deal of time visiting, and any other regular sources of cigarette smoke. No bias of the questionnaire toward OME, ROM, or smoking status was presented, and interviewers were not told the purpose of the study.

The 166 children in the case group were followed up for 1 year after insertion of tympanostomy tubes to evaluate postoperative complications, such as otorrhea and early extrusion (<6 months), in case a significant risk factor was found. The χ², Fisher exact, and Student t tests were used to evaluate the relationships. Confidence limits were calculated by means of the test-based method with an α level of 5%, 95% confidence intervals (CIs), and associated P values.

tubes with normal controls while controlling for other potential risk factors.

RESULTS

The characteristics of the study group are shown in Table 1. The age and sex distributions and mean number of persons in the household were similar between the cases and controls. Mean ages of the case and control groups were 5.8 and 5.7 years, respectively. Compared with control subjects, the case subjects were more likely to be male (60.2% vs 54.2%). This difference was not significant (P = .32; odds ratio [OR], 1.28; 95% CI, 0.83-1.98); however, this finding was consistent with previous studies that demonstrated male preponderance in middle ear disease in children.13,16,17 There were 112 wood-burning stoves (67.5%) in the case group vs 101 (60.8%) in the control group (P = .25; OR, 1.34; 95% CI, 0.85-2.09). The age of the home was less than 10 years for 32 children (19.3%) in the case group vs 41 children (24.7%) in the control group (P = .29; OR, 0.73; 95% CI, 0.43-1.23). The type of home was an apartment for 111 children (66.9%) in the case group and 109 children (65.7%) in the control group (P = .91; OR, 1.06; 95% CI, 0.67-1.66). None of these characteristics (mean age, sex, age of current home, type of home, or wood-burning stove) had a significant effect on OME and ROM.

The children in the study group spent at least 18 hours per day at home. Since smoking in public areas is strictly forbidden by law, none of the children was exposed to smoking in school or in school vehicles. Figure 1 shows the quantitative relationship of the exposure rates in the case and control groups. The case group was exposed to 19.6 cigarettes per day, while the control group was exposed to 14.4 cigarettes per day. This difference was significant (P < .004; t = 2.89; 95% CI, −8.82 to −1.68). Figure 2 compares the smoking histories of the mother, father, and other people (residing in the same household or frequent visitors) in the case and control groups. Families in the case group had maternal smoking in 82 (49.4%) compared with 33 (19.9%) in the control group. This finding was statistically significant (P < .001; OR, 3.93; 95% CI, 2.42-6.41). For paternal smoking, we found a rate of 108 (65.1%) in the case group and 90 (54.2%) in the control group. This excess was not significant (P = .06; OR, 1.57; 95% CI, 1.01-2.45). Among other people residing in the same household or frequent visitors, we found smoking histories for 64 (38.6%) in the case group and 59 (35.6%) in the control group. This result also was not statistically significant (P = .65; OR, 1.14; 95% CI, 0.73-1.78).

Table 2 gives the maternal level of smoking in the case and control groups. Mean number of cigarettes per day was 7.87 in the case group and 7.01 in the control group. We did not find a clear association between increasing numbers of cigarettes smoked by mothers and the likelihood of children having OME or ROM.

The 166 children in the case group were prospectively followed up, and the 82 children exposed to maternal tobacco smoke were compared with the 84 non–maternally exposed children to evaluate whether the children exposed had more postoperative problems. Figure 3 focuses on the case group to compare early extrusion and persistent otorrhea rates of maternally exposed and non–maternally exposed groups. Early extru-
tion of tubes appeared more likely in exposed children; however, the numbers were small and not significant (11 maternally exposed children vs 9 non–maternally exposed children; \( P = .77; \text{OR, 1.29; 95\% CI, 0.50-3.30} \)). Persistent otorrhea occurred in 10 of the 82 of maternally exposed children and in 14 of the 84 of non–maternally exposed children (\( P = .55; \text{OR, 0.69; 95\% CI, 0.29-1.67} \)).

**COMMENT**

Findings of this study confirm the previously reported association between middle ear diseases and maternal smoking.\(^{18,19}\) Exposure to tobacco smoke is considered a risk factor for middle ear disease by some investigators, but others reported the opposite finding. Such studies differed from each other by the following observations: (1) some of these investigators studied acute otitis media (AOM) and others studied OME or ROM; (2) they studied children of different age groups; (3) often there was no distinction between maternal and paternal smoking; (4) methods to determine exposure to tobacco were varied as to whether they were objective or subjective; (5) sample sizes varied among the studies, in that some were big and others were small; and (6) OME, ROM, and AOM were not diagnosed by otolaryngologists and tympanometric assessments were not done.

An important highlight of this study was to find a clear definition for parental smoking histories used in the questionnaire. In some of the previous studies, parental smoking was expressed as “primary or secondary caretaker”\(^{20}\) or “one of the parents,”\(^{21}\) or the type of the exposure was not described.\(^{22}\) Only a few of these studies made a distinction between paternal and maternal smoking status.\(^{17,18}\) Evaluation of parental smoking status without that distinction may be adequate for Western countries, which represent a different culture. In such countries, the rates of working women are higher, whereas in our study group only 14 of the 166 mothers in the case group and 17 of those in the control group were working. As a result, most of the children in the study group stayed with their mothers nearly the whole day.

**STUDIES FINDING POSITIVE CORRELATIONS BETWEEN PARENTAL SMOKING AND MIDDLE EAR DISEASE**

Teele et al.\(^{21}\) in their follow-up study, investigated children from birth to 7 years of age. They showed a significant effect of parental smoking in children less than 1 year old but did not find the same correlation in older children. However, their study differed from ours in that the subjects were children with AOM, not ROM or OME, and they studied a different age group.


