

# Course and long-term outcome of ‘refractory’ secretory otitis media

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## Abstract

**Objective:** The course and the long-term outcome of ‘refractory’ secretory otitis media (SOM), defined as continuous SOM for more than 6 years, were studied in 52 young patients. They had during childhood been treated for bilateral SOM on average for 12 years (range 6 to 26 years). The mean interval between resolution of SOM and examination was 7 years.

**Methods:** At follow up the patients’ medical records were scrutinized with regards to transmyringal ventilation tubes, adenoidectomy, sequelae and complications, and a questionnaire was filled in to document other diseases.

**Results:** The onset of SOM showed two peaks, one at the age of one year and one at the age of 3.5 years. Patients whose onset of SOM was related to an episode of acute otitis media (AOM) were younger at SOM onset than those who had no such relation. Otorrhoea and AOM episodes were more frequent during the SOM periods, with blocked or expelled tubes, than during periods with patent tubes. Cholesteatoma were seen in 3 per cent and perforations in 5 per cent of patients.

**Conclusions:** Extremely long-standing SOM does not necessarily result in myringal perforation or cholesteatoma to a greater extent than that seen in patients with shorter durations of SOM. However, at follow up one-third of the patients reported hearing impairment and a majority felt discomfort when flying or diving.

**Key words:** Otitis Media with Effusion; Complications; Disease Progression; Outcome Assessment (Health Care)

## Introduction

Secretory otitis media (SOM) is defined as middle-ear effusion without signs or symptoms of acute infection. Most preschool children (57 to 91 per cent) are reported to experience at least one episode.<sup>1–3</sup> Fifteen per cent of all children have uni- or bilateral SOM more than half the time during their first 3 years of life.<sup>4</sup> The prevalence of SOM decreases with age;<sup>1,5</sup> thus, at screening of school children 8 to 13 years of age, only 1.5 per cent were found to have SOM.<sup>6</sup> It is well known from screening studies of preschool populations that most cases of transient SOM resolve spontaneously; two-thirds of the ears are resolved within one month of detection<sup>2</sup> and within 6 months the effusion has undergone spontaneous resolution in 85 to 95 per cent of the ears.<sup>2,7</sup>

A subset of children have a lower rate of spontaneous resolution; in reports of children with SOM for a period of one to 3 months prior to the study only 20 per cent of the SOM are resolved within 6 months; after 2 years 31–37 per cent and after 4 years only 59 per cent had recovered

spontaneously from SOM.<sup>8–9</sup> Several risk factors for protracted SOM have been reported: previous acute otitis media (AOM) episodes,<sup>10,11</sup> attending day-care centres,<sup>1,3,11–13</sup> parental smoking,<sup>3,10,14</sup> heredity,<sup>13,15,16</sup> young age,<sup>14</sup> autumn season,<sup>11</sup> male gender,<sup>3,11</sup> older siblings<sup>13</sup> and atopy.<sup>10</sup>

Protracted SOM and/or frequent tube insertions and myringotomies are risk factors in the development of complications and sequelae such as hearing impairment,<sup>17,18</sup> retraction,<sup>8,17–19</sup> tympanosclerosis,<sup>17–20</sup> perforation,<sup>17,19</sup> atrophy of the tympanic membrane<sup>19,20</sup> and middle-ear cholesteatoma.<sup>17,19</sup> Protracted and recurrent SOM during early childhood has been reported in some studies to have an adverse effect on higher-order auditory abilities and to cause delay in language, speech and cognitive development in childhood,<sup>21,22</sup> and also to cause behavioural problems and deficiencies in reading ability in late childhood and early teens,<sup>23</sup> although other authors have expressed doubts about these statements.<sup>24,25</sup>

The aim of the present study was to map out the

TABLE I  
DATA ON 52 SUBJECTS WITH REFRACTORY SOM

	Men (n = 30)	Women (n = 22)	Mean (range) (n = 52)
Age at follow-up (years)	21	20	20 (15–36)
SOM duration (years)	12	12	12 (6–26)
Tube insertions (n/child)	14	13	14 (3–29)
Myringotomies (n/child)	4	3	4 (0–13)
AOM episodes (n/child)	14	16	15 (5–30)
ENT doctor visits (n/child)	76	82	78 (38–228)

Mean values are shown.

clinical course and the long-term outcome, sequelae and complications of refractory SOM in a group of patients who had been treated in accordance with the policy at the time and clinically examined every 3 to 6 months.

## Subjects and methods

### Definitions

Secretory otitis media was defined as effusion in the middle-ear space in the absence of signs and symptoms of an acute infection.

Refractory SOM was in the present study defined as middle-ear effusion persisting continuously for at least 6 years, interrupted only by treatment with transmyringal ventilation tubes.

Acute otitis media was defined as an acute episode of earache in a child with red bulging eardrum(s), occasionally febrile and with signs of upper respiratory tract infection. More than 70 per cent of the AOM episodes were diagnosed otomicroscopically by an ENT specialist.

The duration of SOM was calculated using (1) the total time between two visits if SOM (or inserted ventilation tubes) was present at both visits, and (2) the midpoint between visits if SOM recurred or had resolved. The tube functioning time was calculated using (1) the total time between two visits if the tube was present and patent at both visits, and (2) the midpoint between visits if the tube protruded or was occluded.

### Subjects

One of the authors (OK) noted that some of his child patients suffered a protracted course of SOM. During the 1980s he subsequently listed all patients with long-standing SOM. Out of the listed patients, treated during 1967 to 1999, 56 fulfilled our criteria for refractory SOM. Two patients were excluded because they had siblings in the group and two declined to participate in the study.

Fifty-two former patients, 22 women, with a mean age of 21 years (range 16 to 36 years), and 30 men, with a mean age of 22 years (range 15 to 34 years) filled in a questionnaire and gave permission for their medical records to be examined. The follow-up study took place 10 to 33 years after the initial myringotomy and/or tube insertion. All the patients had had documented bilateral middle-ear effusion, diagnosed by otomicroscopic, tympanometric and audiometric examinations. They had all been treated

several times with myringotomy as well as with insertion of transmyringal ventilation tubes. During the SOM period(s) the ears were regularly examined at 3- to 6-month intervals, mainly by the same ENT specialist (OK), at the ENT clinic at the University Hospital, Lund, Sweden. Some of the patients recovered from SOM and then had a relapse, but exhibited at least one period of SOM exceeding 6 years. At follow up none of the patients was receiving any further treatment for SOM.

### Methods

The patients were asked to fill in a questionnaire regarding their former and present state of health and any discomfort in their ears or hearing disorders. The patients, or when appropriate their parents, signed an informed consent form to participate in the study. The medical records from the ENT clinic, other hospital clinics and from the health-care centres were retrospectively scrutinized. For every visit, the examination findings regarding the ears and/or surgery were noted, as well as complications, other illness or allergy.

### Statistical methods

Significance was tested using non-parametric tests as described by Siegel since many of the variables in the present study proved to have distributions deviating significantly from those of normal distributions, as shown by the Kolmogorov–Smirnov test. Independent samples were tested (two-tailed tests) with Spearman's rank correlation test, the Mann–Whitney U test, Fisher's exact probability test or the chi-square test with correction for continuity.

The study was approved by the Ethics Committee of the Medical Faculty of Lund University, Sweden.

## Results

The 52 patients previously had suffered from bilateral refractory SOM for a period of 6 to 26 years (mean 12 years) and the mean interval from the resolution of SOM to follow up was 7 years (range one to 15 years). The patients had had a mean of 78 visits to the ENT department (range 38 to 228 visits) (Table I). Sixty-five per cent of the patients had parents or siblings with middle-ear disease.

### Age at onset

The mean age at SOM debut was 2.6 years (range half to 9 years). Two peaks of onset were observed, one at the age of one year and another at the age of 3.5 years (Figure 1). In 65 per cent of the cases an episode of AOM was associated with the onset of refractory SOM, whereas in the other 35 per cent no such episode was observed. The patients with AOM-associated SOM were younger at SOM onset, mean 1.9 years (range 0.5 to 8.9 years), than those with no AOM relation, mean age 3.7 years (range 0.8 to 8.5 years) ( $p < 0.001$ ). No difference in age at the onset of SOM was observed between the sexes. No correlation was found between age at SOM onset and duration of SOM.

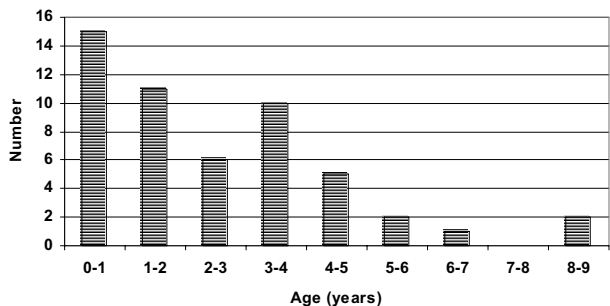


FIG. 1

Age at onset in 52 children with refractory SOM for at least 6 years.

*Tubes*

In the 104 ears of the SOM patients 697 tube insertions had been performed, a mean of seven tubulations in each ear. Myringotomy without tube insertion (*n* = 213) was performed once, or repeatedly, without lasting improvement in 62 per cent of the ears before the first tubulation. Eight of the 104 ears (8 per cent) had had tubes inserted once or twice, 38 ears (36 per cent) three to five times, 28 ears (27 per cent) six to eight times, 13 ears (12 per cent) nine to 11 times, 10 ears (10 per cent) 12 to 14 times and in four ears (4 per cent) 15 or more tubes had been inserted (Figure 2). The highest number of tube insertions was 20. Three ears (3 per cent) in three individuals were treated with repeated myringotomy without any tube insertion. On average, the patients had patent tubes 5.2 years in the left ears and 4.8 years in the right ears (44 and 40 per cent of the total SOM time, respectively).

Two kinds of tubes were used, a short-term tube (Shepard and similar) and a long-term tube (the T-tube). When T-tubes were inserted, the ears had previously been ventilated on at least one occasion by short-term tubes. Only in one patient were T-tubes inserted before the age of 4 years. The 590 short-term tubes were ventilating, on average, 5.5 months (0.5 to 46 months). No difference was seen

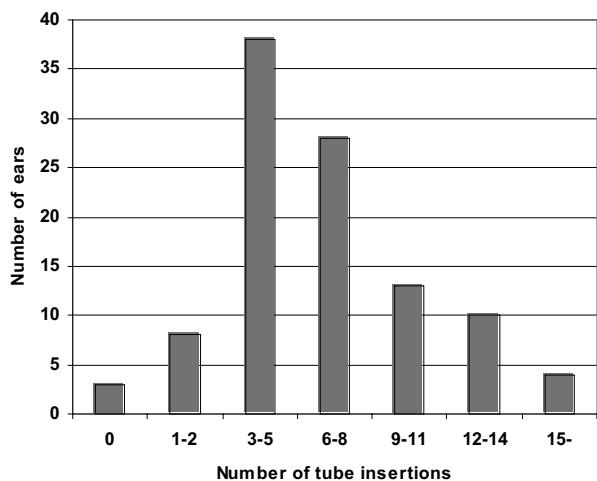


FIG. 2

Number of tube insertions in 104 ears with SOM.

TABLE II

INDICATIONS FOR TUBE EXTRACTION

	Short-term tubes ( <i>n</i> )	T-tubes ( <i>n</i> )
Otorrhoea	13 (72%)	6 (16%)
Granulations	1 (6%)	2 (6%)
Blocked tube	2 (11%)	2 (6%)
Poor hearing	0 (0%)	1 (3%)
Presumed healed	2 (11%)	25 (69%)
Total	18 (100%)	36 (100%)

between the sexes. Eighteen short-term tubes (3 per cent) were actively extracted; the others (97 per cent) were expelled spontaneously. The mean ventilation time of the 107 T-tubes was 22 months (range one to 96 months). Seventy-one T-tubes (66 per cent) were expelled spontaneously after a mean of 18 months, and 36 T-tubes (33 per cent) had to be extracted after a mean of 33 months. Table II shows the number of tubes removed and the indications for removal. Of the 27 ears from which patent tubes were extracted when SOM was presumed to have healed, 14 ears were retubulated later. No tube displacement into the middle ear was observed.

*Complications and sequelae*

Three patients had long-lasting perforations during the SOM period, all of them after insertion of T-tubes; one healed spontaneously and the others were corrected surgically. Another three asymptomatic perforations were found at follow up in patients who were otomicroscopically examined before a hearing examination (in 34 out of the 52).<sup>26</sup> One of these three patients had earlier had myringoplasty twice with temporary healing. No observations or complaints of otorrhoea were reported in the questionnaires. Two of the 52 patients underwent surgery due to cholesteatoma, one bilaterally and the other on the left ear. One of them had undergone repeated treatment with T-tubes, the other one with short-term tubes. Another man underwent surgical exploration due to suspicion of cholesteatoma, which, however, was not found.

*Acute otitis media and otorrhoea*

The patients had a mean of eight episodes of purulent AOM and otorrhoea in the right ear (range one to 22) and nine episodes in the left ear (range one to 28). During the SOM periods 617 AOM episodes occurred, 225 of the episodes (36 per cent) as otorrhoea with a patent tube in place. The mean age at the first AOM episode was 23 months (range 2 to 94 months).

Otorrhoea episodes were more frequent in springtime (Figure 3). Transient otorrhoea, within one week post-operatively, was documented in 3.3 per cent of tubulations. In all, the 225 episodes of otorrhoea were found in 24 per cent of the tubes (136 episodes with short-term tubes and 89 episodes with T-tubes), with means of one episode of otorrhoea in 24 months with short-term tubes and one episode in 26 months with T-tubes. Seventy-nine

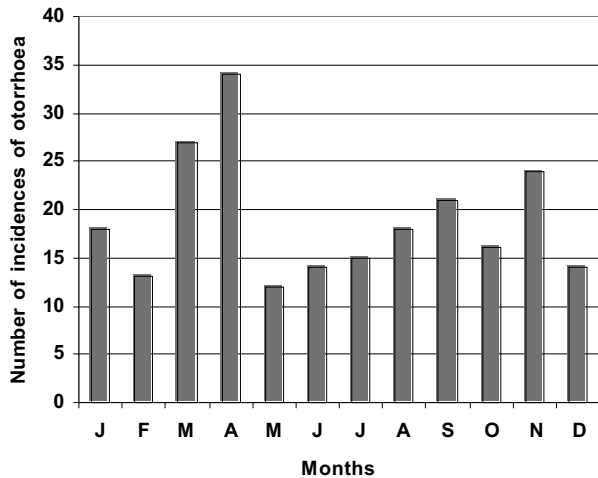


FIG. 3

The seasonal distribution of otorrhoea in patients with patent tubes.

of the 104 ears (76 per cent) in the SOM patients exhibited otorrhoea at least once. One of the patients who had never had any otorrhoea was later operated on for bilateral cholesteatoma.

During the SOM periods without tubes or with a blocked tube there were significantly more AOM/otorrhoea episodes (mean 1.1 episodes per year) than during the SOM periods with a patent tube in place (mean 0.5 episodes per year) ( $p < 0.001$ ).

#### Adenoidectomy

Almost half [24/52 (46 per cent)] of the patients were treated with adenoidectomy at a mean age of 5 years (range 1.5 to 14.5 years). Two children underwent surgery more than once; one had three operations, the other two operations. No differences were seen in the duration of SOM between those who had undergone adenoidectomy and those who had not. The adenoidectomized group exhibited more myringotomies and tubulations (means of 10 in the right ear and 11 in the left ear) than did the group that had not been adenoidectomized (means of seven in the right ear and eight in the left ear) (findings not significant in the right ears and  $p < 0.05$  in the left ears).

#### Allergy and other illness

Nineteen per cent (10/52) of the subjects suffered from allergic manifestations or bronchial asthma, in childhood or later in life. One child had Henoch–Schönlein purpura, another had parotitis with viral meningitis and meningoencephalitis (but no AOM at the same time), another one was operated on due to an ovarian cyst, and yet another had a cataract. No other chronic diseases were reported in the group.

#### Persisting discomfort

At follow up, 83 per cent (43/52) of the patients reported that they had some kind of discomfort in

their ears. Thirty-one per cent (16/52) considered themselves as having poor hearing and 55 per cent (26/47) of those who had had experience of air travel at the time of the questionnaire had complaints; most common were earache or pain, difficulty in pressure equilibration, and blocking of the ears, which in some cases persisted for several days. Thirty-eight per cent (20/52) avoided diving, partially or completely, because of severe pain in their ears or because of difficulty in compensating the pressure difference in the middle ear.

#### Discussion

This retrospective study addressed patients with extremely long-standing ‘refractory’ SOM. The patients with AOM-related onset of SOM showed an earlier onset of disease than did those without such a relation. The SOM patients had more AOM or otorrhoea episodes during the SOM periods with blocked or expelled tubes than during periods with patent tubes. Although these patients had had refractory SOM they did not show tympanic membrane perforation or cholesteatoma to a high degree. One-third of the patients with persistent SOM for many years at follow up reported hearing impairment, and the majority also had ear problems when flying and diving.

We do not claim that this is a representative SOM population. Instead this is a study of 52 patients treated for bilateral SOM of extremely long duration. We contacted all patients who were listed and who fulfilled our criteria of refractory SOM, but of course we cannot be sure that no patients were missed from the list. The strength of this paper is that the patients were seen mostly by the same ENT specialist, the population in the area was stable, with little immigration, and the health record of every one of the patients was available and up-to-date. We have found no documentation in the literature of patients with refractory SOM over such a long period. In a British report on patients with bilateral SOM, 5 to 28 per cent of the ears still showed signs of SOM 10 years after the first myringotomy or tube insertion, but some of these patients had had effusion-free periods between the SOM periods.<sup>9</sup>

Persistent SOM often follows an episode of purulent AOM in the youngest children,<sup>10,11</sup> but may also arise without any known history of AOM.<sup>4</sup> The two prevalence peaks reported in other studies<sup>1,27,28</sup> are in accordance with the two onset peaks observed in our findings; we could relate the first peak to AOM-related onset and the second to non-AOM-related onset of SOM.

Otorrhoea was noted at least once in 76 per cent of the ears, which is far more than the 17 per cent reported in a meta-analysis of tube treatment sequelae,<sup>29</sup> and the number of tubes requiring extraction due to otorrhoea was 3 per cent in our study, compared with 4 per cent in the meta-analysis. Our patients had tubes for long periods, which is probably the reason for the higher frequency of otorrhoea. However, there were fewer AOM and

otorrhoea episodes during periods with patent tubes than during periods without a tube or with a blocked tube. In the meta-analysis<sup>29</sup> more otorrhoea episodes, perforations and cholesteatomata were observed with T-tubes than with short-term tubes. Our findings showed an increase in the number of perforations only. We certainly found more episodes of otorrhoea per T-tube, but when this was related to the duration of the tubulations no differences were seen between the short-term tubes and the T-tubes. The number of cholesteatomata was not high enough to evaluate differences between different types of tubes. The duration of transmyringal tube patency seemed to be on a par with other reports.<sup>30</sup> More than two-thirds of the T-tubes extracted were in ears presumed to have healed. In this group of patients with a history of extremely long-standing SOM it is not surprising that more than half of the ears required retubulation.

On the one hand, tubes have not been proved beneficial in preventing complications arising from SOM in the middle ear<sup>31</sup> but, on the other hand, there were no more complications (perforations or cholesteatomata) in our SOM group than in SOM patients with fewer tube insertions. Thus, in a group of Finnish patients with protracted SOM who were re-examined on average 8 years after first tube insertion, with a mean of two tube insertions per ear, perforations or cholesteatomata were seen in 10 per cent of the ears,<sup>19</sup> and in a study on long-term follow up of an unselected group of SOM patients, with a mean of one tube insertion, 3 per cent was reported to have perforations and 3 per cent to have cholesteatoma 10 to 14 years after their first tubulation.<sup>17</sup>

The majority of our SOM patients reported in the questionnaire that they experienced ear discomfort when flying and/or diving. This information is difficult to evaluate as we do not have similar data from a normal healthy population, in which a certain percentage may also experience ear discomfort when they fly or dive. However, it may reflect the fact that many of the SOM patients have difficulties in pressure regulation of the middle ear due to poor active function of the Eustachian tube. The active tubal function was tested in a subgroup of our SOM population; 57 per cent had poor active tubal function,<sup>32</sup> compared with 7 to 10 per cent in a normal adult population.<sup>33,34</sup>

More than a third of the SOM patients had self-reported hearing impairment. Studies carried out by other authors have shown high reliability of self-reported hearing impairment.<sup>35</sup> The majority of the patients had parents or siblings with middle-ear disease, an observation which is in accordance with the theory of a genetic influence on the development of SOM.<sup>13,15,16</sup>

The results of this retrospective study of patients with refractory SOM show that, with meticulous follow up and treatment with myringotomy and tube insertions when appropriate, extremely long-standing SOM does not result in myringal perforation or cholesteatoma to a greater extent than that seen in patients with shorter durations of

SOM. However, the majority still experienced discomfort in their ears, and almost one-third reported impaired hearing.

- **Subjects who had previously suffered from 'refractory' SOM for many years during childhood were retrospectively studied**
- **Patients with AOM-associated SOM onset were younger at SOM onset than those without AOM relation**
- **AOM and otorrhoea were not more frequent in association with T-tubes than short-term tubes and were less frequent during periods with a patent tube in place**
- **Cholesteatoma and perforation were not more common in subjects with refractory SOM than in subjects with shorter SOM duration**
- **The majority reported ear discomfort when flying or diving, and over 30 per cent considered themselves as having poor hearing at follow up**

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