

# Serous otitis media: Clinical and therapeutic considerations, including dexamethasone (C<sub>22</sub>H<sub>29</sub>FO<sub>5</sub>) intratympanic injection

CRISTIAN MÂRTU<sup>1,2\*</sup>, SEBASTIAN COZMA<sup>1,2\*</sup>, BOGDAN COBZEANU<sup>1,2</sup>, DOINA VESA<sup>3</sup>,  
CORINA BUTNARU<sup>1,2</sup>, DRAGOȘ BULARDA<sup>2</sup>, ADELINE CUMPĂȚĂ<sup>1,2</sup> and LUMINIȚA RĂDULESCU<sup>1,2\*</sup>

<sup>1</sup>ENT Department, 'Grigore T. Popa' University of Medicine and Pharmacy, 700115 Iasi;

<sup>2</sup>ENT Clinic, Clinical Rehabilitation Hospital, 700613 Iasi; <sup>3</sup>Clinical Surgical Department, Faculty of Medicine and Pharmacy, 'Dunarea de Jos' University of Galati, 800008 Galati, Romania

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**Abstract.** Serous otitis media (SOM) occurs in children and constitutes one of the most significant causes of hearing loss in young age, posing as an important risk factor for long-term hearing loss. SOM is underdiagnosed, most frequently in infants, or the appointment to the ENT doctor is delayed due to non-acute symptomatology. The aim of the present study was to assess 285 patients with SOM diagnosed within a two-year span. The etiology and pathology of hearing loss in patients with different age groups were examined. The importance of a clinical examination and tympanometry was emphasized as absolutely necessary for a correct diagnosis. Treatment targeted Eustachian Tube permeabilization for satisfactory long-term middle ear aeration. Nasal drops with vasoconstrictor drugs (phenylephrine) and disinfectant (colloidal silver 1%) were commonly used, but some patients also benefitted from dexamethasone intratympanic injection. Patients were evaluated at the end of the treatment and follow-up occurred at one month, one year and three years later.

## Introduction

Serous otitis media (SOM) is a common inflammatory process of the middle ear, frequent in early childhood. It is commonly accompanied by mild to moderate hearing loss (HL), alongside a sensation of pressure in the ear that infants cannot always

describe or indicate. The functional deficiencies of the auditory organ, especially if it is bilateral, can have an important influence in the development of a small child. SOM is defined as the presence of fluid (effusion) in the middle ear, with no signs or symptoms of acute ear infection (1,2). This is usually due to Eustachian tube dysfunction.

The presence of serous fluid in the middle ear acts like a barrier in sound conduction, accompanied by a decrease in the efficiency of transmitting sound to the middle ear (ear drum and ossicles) (1). If we consider SOM to be a continuous dynamic process, there are several factors that influence and transform the character of the effusion such as time, the body's reaction and repeated infections. There are different stages of serous otitis, varying from tubotympanic catarrh, acute serous otitis, chronic serous otitis or progression to fibro-adhesive otitis (3).

From a functional point of view, the final stage of these conditions can be hearing impairment. Regarding the impact and importance of this condition, in the USA, 2.2 million episodes of common serous otitis are diagnosed annually, with a cost of \$4 billion (3).

In fact, indirect costs are much higher, because the average serous otitis is usually asymptomatic, and many episodes remain undetected, including children with hearing impairments and reduced school performance (3).

There are many risk factors associated with SOM development. Some are related to inflammatory and immune reactions against rhinopharyngeal infections leading to cytokine production and the secretion of an exudate rich in protein and inflammatory mediators, allergy, genetic conditions, pollutants, biofilm formation and persistence, and gastro-esophageal reflux (4).

Different treatment options are available, including medical treatment (anti-inflammatory, antihistaminic, mucolytic, antibiotic), mechanic inflation through the Eustachian tube (Poltzer maneuver), surgery (intratympanic injections and grommet placement), with various results, being also influenced by the individual particularity of the pathology and patient (4).

The aim of the study was to investigate the frequency of SOM by age groups, in relation with different possible etio-pathogenic causes, considering early and correct diagnosis, as well as obtaining optimal therapeutic results.

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*Correspondence to:* Dr Sebastian Cozma or Dr Bogdan Cobzeanu, ENT Department, 'Grigore T. Popa' University of Medicine and Pharmacy, 16 Universitatii Street, 700115 Iasi, Romania  
E-mail: scozma2005@yahoo.com  
E-mail: bcobzeanu@gmail.com

\*Contributed equally

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## Patients and methods

**Patient characteristics.** The present study was conducted on 285 patients diagnosed with SOM that were hospitalized in the ENT Department, Clinical Rehabilitation Hospital and the ENT Department, 'Sf. Andrei' Emergency Hospital Galati (Galati, Romania), over a period of two years (2016-2017) and followed up for a minimum of three years after initial management.

Each patient underwent general ENT evaluation that included audiometry and tympanometry with an Interacoustics AA222 AudioTraveller (SC Sonorom SRL). This study was approved by the Ethics Committee of 'Grigore T. Popa' University of Medicine and Pharmacy (Iasi, Romania). Written informed consent was obtained from all patients and/or guardians prior to publication.

**Inclusion and exclusion criteria.** The design of the study was based on a retrospective analytical investigation with etiopathogenesis analysis of all patients.

Inclusion criteria were patients with type B tympanogram and positive otomicroscopic image of SOM. Exclusion criteria were patients with atelectatic ear pathology, otosclerosis, acute or chronic suppurative otitis media, external otitis, or foreign bodies in the external ear canal. Patients referred for grommet insertion or failing to return for follow-up were also excluded.

**Methods.** The treatment for SOM included nasal drops with decongestant drugs up to 3 times a day. Phenylephrine was commonly used for short periods (3-5 days) in acute episodes and colloidal silver 1% solution. In some patients, this treatment was inefficient, with SOM persistence for more than 3 months; for this situation, intratympanic dexamethasone (DXM) (ITD) injection treatment was performed under sedation (for the majority of cases), with the placement of 0.5 ml/4 mg/mm DXM directly into the antero-inferior quadrant of the tympanic membrane through a small tympanotomy. The procedure was performed during day hospitalization, with patients leaving the hospital 3 h after the ITD placement.

## Results

**SOM and various parameters.** Results showed a higher frequency of SOM in female patients (58.6%), but without any explanation regarding sex preference.

Out of the total number of patients, 59.3% of the SOM cases were bilateral and 40.7% of cases were unilateral (Fig. 1).

In regards to the patients with SOM, 220 patients (77.2%) were between 2 and 14 years; 53 patients (18.6%) were in the age range of 15-30 years, while 12 patients (4.2%) were over 31 years of age (Fig. 2).

Most patients claimed HL as first symptom (58.57% bilateral, 30% unilateral); in small children, this was reported by the parents, or educators. Other local symptoms included ear fullness with autophony (20%), mild otalgia (33%), tinnitus (2.85%) and mild dizziness (15.7%) (Fig. 3).

Recorded symptoms associated with SOM were nasal obstruction with oral breathing (44.2%), rhinorrhea (8.5%), dysphagia (4.3%), cough (2.85%) and hyponasality (15.7%) (data not shown).

**Physical examinations.** Through the physical examination of the children, retrostilian, submandibular and laterocervical adenopathies were observed. The nodes were elastic, painless and mobile with an average diameter of 3x1cm. Other patients had nasal pyramid dysmorphism.

The otoscopic diagnosis (in 97.15% of cases, the aspect of the tympanic membrane was modified) was more evident in adults than in children. In adults, the presence of liquid with or without air bubbles was most often observed behind a slightly retracted eardrum (10% of cases). In children, the observation of fluid level was exceptional.

Audiometric testing was performed on children >5 years of age. Audiometric results showed bilateral conductive HL in 34.37% of patients, unilateral conductive HL in 37.53% of patients, 24% showed bilateral mixed HL and 4.1% showed unilateral mixed HL and conductive HL in the contralateral ear. HL was greater at low frequencies, in most cases around 30-40 dB.

**Treatment methods.** In 208 patients (73%), SOM healed within 3 months, with just local nasal treatment and ET permeabilization methods: ET anemizations, mechanical exercises (positive pressure in the rhinopharynx). In 40 cases (14%), nasal decongestant and disinfectant drops were accompanied by antihistaminic short-time treatment (loratadine, levocetirizine) and mucolytic (active substance acetylcysteine) treatment (Fig. 4).

In 37 cases (13%), SOM did not resolve unless transtympanic aspiration of the sero-mucous fluid was performed under sedation and corticosteroid medication (DXM) was placed in the tympanic cavity (Fig. 4).

Tympanic membrane perforation usually healed primarily between 5 and 10 days. There were no cases of persistent tympanic membrane perforation, and audiometric testing at 1 month showed improvement of hearing thresholds. Follow-up was performed at one and three years. Most of the patients showed full recovery, however, a group of 23 patients (8%) showed recurrent SOM and needed further treatment.

## Discussion

The study followed the frequency of SOM by age groups in parallel with its possible etiopathogenesis. Regarding children (aged <14 years), there was an increased frequency of 52% in younger children (2-6 years of age) and only 25.2% in older children (7-14 years of age).

Data from literature confirm this fact. It is reported that 90% of children have severe serous otitis before school age (5). The frequency of common SOM episodes is particularly high, averaging about four episodes per year (6).

In the first year of life, >50% of children have SOM which can reach >60% by the age of 2 (7). One out of eight children aged five to six, in preschool, have fluid in one or both ears (8).

Most episodes of SOM heal spontaneously within 3 months, but 30-40% of children have repeated episodes and 5-10% have SOM lasting over a year or more (1,5,9).

The etiopathogenic factors, according to the medical files of the patients (anamnesis and personal medical history), most commonly incriminated in the age group 2-14 years were acute and chronic adeno-amygdalitis 83.18% (183 out of 220 patients),

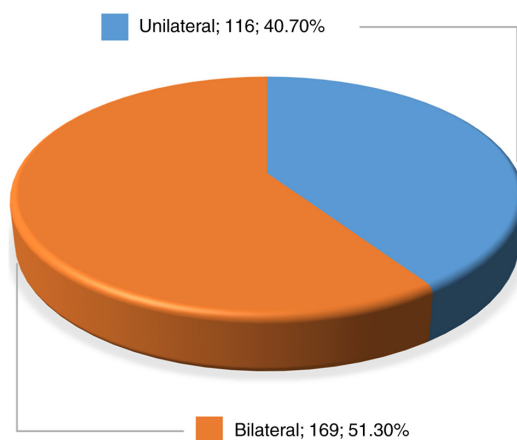


Figure 1. SOM distribution bilateral/unilateral. SOM, serous otitis media.

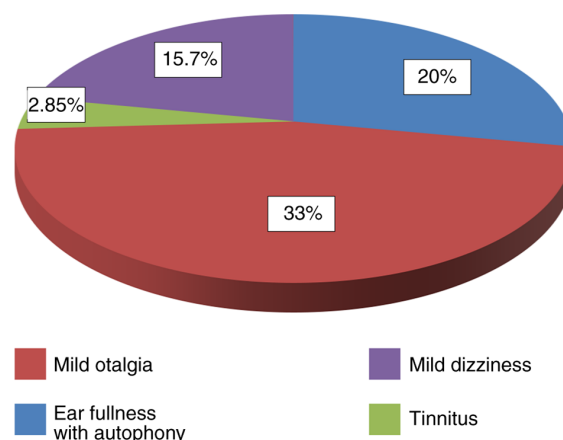


Figure 3. Other local symptoms.

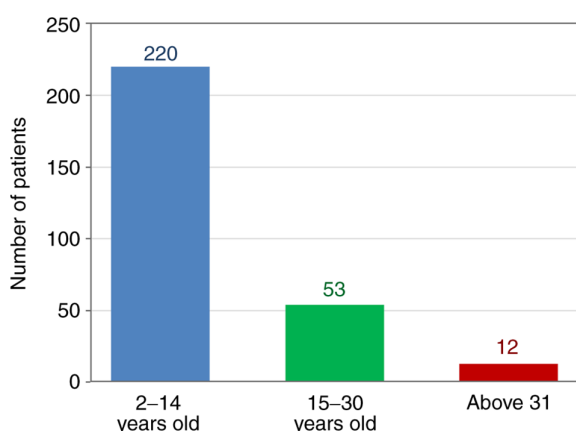


Figure 2. Age group distribution.

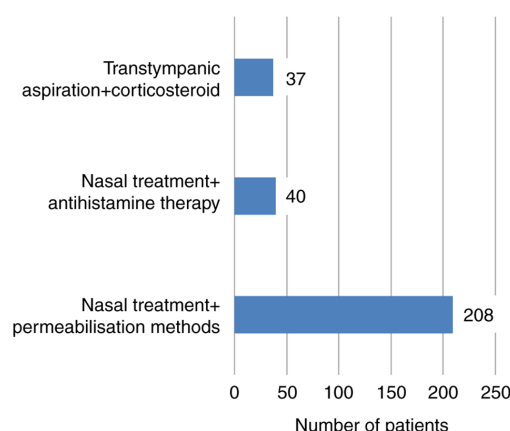


Figure 4. Distribution of treatment stages needed in treating SOM in the study group. SOM, serous otitis media.

acute and chronic rhinosinusitis 51.81% (114 patients out of 220), septal deviations and inferior turbinate hypertrophy 32.72% (72 out of 220 patients).

Most factors for the 15- to 30-year age group were: acute and chronic adeno-amygdalitis 77.35% (41 out of 53 patients), acute and chronic rhinosinusitis 69.81% (37 out of 53 patients), septal deviations and turbinate hypertrophy, especially posteriorly 73.58% (39 out of 53 patients).

Patients in the latter age group presented septum deviation and chronic hypertrophic rhinitis 83.33% (10 out of 12 patients), rhinosinusitis allergy 33.33% (4 out of 12 patients), chronic otitis media 25% (3 out of 12 patients), acute untreated rhinopharyngitis 25% (3 out of 12 patients) and rhinopharyngeal carcinoma 16.66% (2 out of 12 patients).

An increased frequency in symptomatology was observed during the spring period (40% of cases) and the months with increased incidence of SOM were March, April, May, September and October. An explanation can be the increased frequency of viral rhinopharyngeal inflammation, considerable temperature variations and sudden changes in atmospheric pressure.

Patient origin was recorded and a higher percentage of SOM was observed in socio-economically deprived urban neighborhoods (42.45%, 121 patients), compared to rural areas (26.66%, 76 patients) and 30.87% in urban areas. This

could be explained by a lower medical addressability, crowded dwellings and increased exposure to risk factors, such as passive smoking.

According to literature, the average duration of a SOM episode is 17 days (6). Common symptomatology is discrete and minimal eardrum changes were observed (10).

If the SOM persists for >3 months (present in 25% of cases), symptoms such as HL, vestibular dysfunction, poor school performance and ear fullness or behavioral changes may occur (11). SOM can transform into acute suppurated otitis, which needs antibiotic treatment in order to avoid further complications (12,13).

Patients included in the study had associated symptoms as well, such as nasal obstruction with oral breathing, rhinorrhea, dysphagia, cough, hyponasalality, increased frequency of retrosternal, submandibular, laterocervical adenopathy and sometimes nasal pyramid dysmorphism. For a correct diagnosis, an audiometric examination was essential and could be performed on children after the age of 5.

The audiometric examination should be completed with tympanometry. This technique has the advantage of objectifying the variations of acoustic impedance. Tympanometry is a non-invasive technique that can be achieved in young children and usually a B- or C-type curve is recorded in SOM.

This examination is especially useful in young children, where otoscopy is often difficult or inconclusive. Another advantage of tympanometry is the possibility of observing the dynamic of middle ear pathology. Performed routinely, tympanometry would allow a greater detection of SOM.

Targeted treatment is needed for rhinopharyngeal disobliteration and ET permeabilization in order to establish normal anatomic and physiologic conditions, hearing improvement and the prevention of recurrences and development of chronic condition of the middle ear (chronic SOM, atelectatic ear, cholesteatoma).

Vasoconstrictor and nasal disinfectants, such as Phenylephrine and Colloidal Silver, were used after nasal secretions were aspirated or eliminated by correct nose blowing. Most of the patients that presented with fresh symptomatology onset benefited from decongestant substances at the rhinopharyngeal tubal orifices applied by cotton swabs (34% of cases).

Nasal mucosa hypertrophy is influenced by local anatomical mechanical obstruction and inflammation, air quality and allergic terrain of the child. Although studies show a limited efficacy of antihistaminic medication in ET function prognosis (14,15), in some cases it may be effective in nasal decongestion and ET permeabilization (especially in patients with allergic conditions) (16). In select cases, before initiating transtympanic function treatment protocol (performed under sedation during continuous hospitalization), antihistaminic drugs were used 5-7 days with some favorable results (6% of cases).

Second-generation H (1)-antihistamines (loratadine or levocetirizine) have high selectivity for H (1)-receptors with improved efficacy and minimal side effects compared to first-generation molecules and can provide improvement of ET mechanics (16).

After ITD, some of the patients complained about ear fullness 26.31% (75 patients), sometimes light dizziness 10.87% (31 patients) and discrete ear discharge 19.65% (56 patients). Symptoms can persist several hours and are related to the presence of the liquid in the middle ear. Myringotomy healed in all patients.

DXM has been used due to good local dispersion with the ability to inhibit inflammation and reduce edema, satisfactory absorption in the middle ear and no side effects locally and generally. Previous findings also found DXM to be effective in the reduction of granulation tissue, more than antibiotic therapy alone (17). Mucosal hypertrophy reduction and possible permeabilization improvement through ET is expected.

SOM is a disorder found more commonly in childhood, with recurrent episodes and a higher frequency of viral rhinopharyngeal infections.

Most frequent etiopathogenic factors were found to be ET dysfunction, infection, and allergy.

SOM can be relatively asymptomatic with uni- and even bilateral conductive HL. An audiometric examination is indispensable in adults and children.

Surgical interventions for associated diseases can indirectly treat SOM and the inherent ear affliction. The General Practitioner is familiar with SOM, as well as its treatment. SOM is especially frequent in school-aged children. If not treated, it can lead to repeated episodes of SOM and other complications in time.

Upper respiratory tract mucosa inflammation and edema should be addressed by complex medical treatment (vasoconstrictor, disinfectant, corticosteroid, mucolytic, antihistaminic), although sometimes SOM has to be addressed by myringotomy. The placement of DXM in the middle ear is an effective method for localized corticosteroid drug delivery with minimal local and general side effects.

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## Availability of data and materials

All data and materials supporting the results of the present study are available in the published article.

## Authors' contributions

All authors contributed to the acquisition of the data and critical revision of manuscript for important intellectual content. CM contributed to the design of the study, data analysis and edited the manuscript. SC contributed to the design of the study and data acquisition. BC analyzed and interpreted the data. DV designed the study, provided archive data and wrote the main manuscript text. CB contributed to the data analysis and to the design of the study. DB contributed to the data acquisition and data interpretation. AC provided archive data, contributed to data acquisition and edited the manuscript. LR contributed to the data analysis, data interpretation and edited the manuscript. All authors read and approved the final version of the manuscript. CM and BC are responsible for confirming the authenticity of raw data.

## Ethics approval and consent to participate

This study was approved by the Ethics Committee of 'Grigore T. Popa' University of Medicine and Pharmacy (Iasi, Romania)- Nr.4/13.09.21. Written informed consent was obtained from all the patients and/or guardians prior to publication.

## Patient consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

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