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# Role of immunoglobulin E and gastro-esophageal reflux disease in the development of otitis media with effusion

*Mohammed A. Gomaa* *, *Abdel Rahim Ahmed Abdel Karim*, *Yaser Makram Elsherbeny*

*Faculty of Medicine, Minia University, Egypt*

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ABSTRACT

**Introduction:** The role of allergy in chronic otitis media with effusion (OME) is controversial. **Aim of the work:** To study the role of allergy and gastroesphogeal reflux diseases in the etiology of OME. **Materials and methods:** It is a prospective study that was done on 43 cases; 30 patients suffer from OME with mean age 6.8 years and 13 control child with mean age 8.3 years. Blood sample were taken from patients and control children for assay of total Immunoglobulin E (IgE) and serum pepsinogen 1 (PG1). Effusion fluid samples were taken from middle ear of the patients during myringotomy and ventilation tube insertion; IgE and PG1 were assayed in the effusion samples. Total IgE and PG1 were assayed by enzyme-linked immunosorbent assay. **Results:** Our results showed that, there is a correlation between serum IgE and Effusion IgE in the patients group, there is a significant negative correlation between PG1 in the effusion and serum of the studied patients. **Conclusion:** Allergy is a possible risk factor for the development of OME. The level of PG1in the effusion is one tenth of its level in the serum of the patients.



## Introduction

Otitis media with effusion (OME) is defined as chronic inflammation of the middle ear mucosa characterized by the retention of fluid behind an intact tympanic membrane (TM) within the middle ear space without signs or symptoms of an acute ear infection [1–3]. The most common complication of OME is hearing loss, and it is the commonest cause of hearing loss in children [4]. Allergy and otitis media (OM) are both very common conditions and are linked epidemiologically and mechanistically [5]. Only recently oesophago-laryngo-pharyngeal reflux has been taken into consideration as a possible risk factor for Eustachian tube dysfunction [6].

## Patients and methods

The studied population includes 43 individuals, patients and controls were selected from ENT department, Minia university hospital in the period from March 2011 to October 2011.

* *Corresponding author at*: Minia University Hospital, Minia 61111, Egypt. Tel.: +20 1227339776.
E-mail address: magomaa@yahoo.com (M.A. Gomaa).

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The study sample was divided into 2 groups:-

Group I (cases): It includes 30 diseased children with OME (resistant to medical treatment or recurrent after successful medical treatment). Patients were subjected to myringotomy with insertion of tympanostomy tube (Grommet or T-tube). Their age ranged from 1.5 to 15 years (14 males and 16 females).

Group II (control): It includes 13 diseased children with ENT disease other than OME mostly adenoidal or tonsillar hypertrophy. Their age ranged from 3 to 14 years (6 males and 7 females)

## Exclusion criteria

1. Acute otitis media.
2. Perforated tympanic membrane.
3. Sensorineural hearing loss.
4. Immunodeficiency diseases.
5. Down's disease.
6. Cleft palate.
7. Patients with gastric problems.
8. Craniofacial abnormalities.
9. Chronic underlying medical disease.

Each group was subjected to:

(1) Careful history taking, including history suggesting allergy – such as symptoms suggesting allergic rhinitis, asthma, eczema, urticaria, conjunctivitis, food sensitivity and anaphylaxis – or history suggesting GERD such as heart burn,
(2) General examination,
(3) Clinical otorhinolaryngologic examination,
(4) Audiological evaluation in the form of pure tone audiometry and tympanometry,
(5) Effusion fluid sample obtained from patients by wide bore syringe during myringotomy and tympanostomy tube insertion under complete aseptic conditions, middle ear effusion obtained from one or both ears of the same case was considered a single sample; assay of Immunoglobulin E (IgE) and pepsinogen I by ELISA,
(6) Blood sample obtained by Sterile venipuncture from both patients and control subjects for Assay of serum total IgE and pepsinogen I by ELISA.

IgE kits supplied by D.S. I. Italy and PG1 kit supplied by D.R. G. International, Inc., USA.

## Results

The current study is a prospective study, that was done between March and October 2011, at Otorhinolaryngology department, Minia University Hospital. The study was approved by the research Ethics committee of Minia University and written informed consent was signed by parents of enrolled children.

The study was done on thirty patients who suffer from OME and 13 control subjects. The age range of the patients was 18 months to 15 years, with mean age 6.8 years. The gender of patients was 16 females and 14 males (Tab. I). The control sample had 6 males and 7 females who did not suffer from OME; the mean age was 8.3 years, as shown in Table II.

**Table I – Sex distributions for patient's group**

| Sex | No. | % |
|---|---|---|
| Male | 14 | 46.5 |
| Female | 16 | 53.5 |
| Total | 30 | 100% |

Regarding IgE, the IgE in the serum of the patients was 40–932.11 IU/mL with mean value 315 IU/mL While IgE in the serum of control samples was 55–400 IU/mL with mean value 153.5 IU/mL. Our results showed that, IgE is higher in the serum of the patients than in control subjects, and there is a significant correlation between IgE in the serum of patients and that of control cases as $P = 0.05$, while serum PG1 in both groups did not correlate as shown in Table III.

As regard of pepsinogen 1(PG1), our results showed that its level in the serum of the patients was 20.1–245.2 ng/ml. With mean value 89.5 ng/ml, while in the control group, it ranged from 5 ng/ml to 248.1 ng/ml with mean value 97 ng/ml. The level of PG1 in the effusion of the studied patients was 5–18 ng/ml with mean value 9.2 ng/ml.

The study revealed that there is a correlation between total serum IgE and effusion IgE in patient's group as $P = 0.00$, while Serum PG1 correlates with effusion PG1 as $P = 0.00$. Our data also showed that serum total IgE correlates with serum PG1 and effusion PG1 as $P = 0.00$, also there is a correlation between effusion total IgE and effusion PG1 as shown in Table IV.

## Discussion

The study was done to shed a spot of light on the role of allergy and gastroesphogeal reflux on the etiology of secretory otitis media.

OME is known as the presence of fluid in the middle ear without signs or symptoms of acute middle ear infection. The persistence of the middle ear effusion (MEE) for at least 3 months is defined as chronic otitis media with effusion (COME). It is a multifactorial disease and still remains as the most common cause of deafness in children. The causes of COME include eustachian tube dysfunction, upper respiratory tract infection, insufficient aeration of the mastoid cells, mucociliary clearance abnormalities, adenoid disease, allergic rhinitis, and immunologic disorders. Gastroesophageal reflux (GER) has also been implicated as a possible associated factor in the pathogenesis of COME. It has been demonstrated that pepsin and pepsinogen were present in the MEE of patients with COME [7]. The role of allergy in COME is controversial [8].

**Table II – Sex distributions for control group**

| Sex | No. | % |
|---|---|---|
| Male | 6 | 46.5 |
| Female | 8 | 53.5 |
| Total | 13 | 100% |