Otitis Media with Effusion (OME) is the commonest cause of hearing difficulty and one of the most frequent reasons for elective admission to the hospital for surgery during childhood. The condition starts with dysfunction of middle ear due to poor ventilation through Eustachian tube or extension of the inflammatory process from nasopharynx. In the natural history of the disease, there may be a period of the pre-clinical stage without symptoms or signs of OME. If the disease is identified in this stage, the further sequel of it (like persistent hearing difficulty or retraction pocket formation) may be prevented.

Materials And Methods
A hospital based analytical cross-sectional study was conducted among the children below 12 years of age to assess the middle ear function (by tympanometry) in children having upper respiratory tract infection (but no ear related complaints) and comparing them with the middle ear function in children not having such infection or any recent history of the same. Age and sex matched control group having no such symptoms was constructed. There were 25 children in both study and control group selected from Otorhinolaryngology and Pediatrics outpatient department (OPD). So total numbers of children were 50.

Result
There was no statistically significant difference in background characteristics (age, sex) of the of study and control groups. There was no statistically significant difference when the tympanic membrane retraction or middle ear pressure is taken into account. But significant difference found in the parameters like middle ear compliance (68% children have low compliance in the study group vs 20% in control, with df= 1, \( \chi^2 = 11.688 \) and p value was 0.001) and tympanogram curve type (48% in study group have B or C type and 8% have such in control group).

Conclusion
Early diagnosis of the middle ear dysfunction among the children with upper respiratory infection, by clinical examination and suitable audiological investigation in the pre-clinical stage with appropriate intervention can prevent further progression of the disease, causing hearing loss as well as retraction pocket formation.

Keywords
Middle Ear Dysfunction, Asymptomatic; Otitis Media with Effusion, Asymptomatic; Respiratory Tract Infection; Child; Cross Sectional Study
and having a continuous mucosal lining. Therefore, any inflammation in the upper aero-digestive tract may affect the middle ear either due to propagation of inflammation via continuous mucosal lining or due to blockage of Eustachian tube. Optimum performance of the middle ear mechanism requires equal pressures on the both surfaces of the tympanic membrane. Experimental observation showed that a loss of some 5 to 6 dB for frequency below 1kHz results from pressure changes of 10 cm of water, whether these changes are in the positive or the negative sense. OME may be associated with a conductive hearing loss of up to 30 to 35 dB. Most popular explanation is that due to low supply of the gas through the Eustachian tube. In born or acquired obstruction, or narrowing of the lumen, or obstruction of the nasopharyngeal opening by adenoid has often been suggested. But this theory lacks much evidence. Magnuson thought that the atelectatic condition was a result of middle ear gasses being sucked out along the Eustachian tube by the patients themselves, who were believed to sniff compulsively. The creation of negative pressure in middle ear cavity is compensated to some extent by mastoid air cell system, depending upon the amount of air reserve there.

The etiology of OME is thought to be multi-factorial and includes bacterial and viral infections, Eustachian tube obstruction in nasopharynx, environmental factors and possibly a familial predisposition. Acute Otitis Media (AOM) often complicates the condition of a child with upper respiratory infection, but it presents with obvious pain with hearing impairment. Considering the sterile nature of the effusion fluid, some investigators suggest that the OME fluid is a transudate and created due to negative middle ear pressure as a result of Eustachian tube malfunction. According to Bluestone and Klein, symptoms of OME are neither sensitive nor specific and most of the children with OME are asymptomatic, some may have hearing loss, tinnitus or ear fullness or parent/teachers may suspect a hearing difficulty. One thing is accepted anonymously that, upper respiratory infection in children is the one of the most important etiological factor responsible for Eustachian tube dysfunction and as a consequence middle ear dysfunction.

In existing literature, there is a lack of research on the asymptomatic middle ear dysfunction (or the pre-clinical stage of OME) in children with upper respiratory infection. The present analytical cross-sectional study was planned with the objective to assess the middle ear function (by tympanometry) in children having upper respiratory tract infection and comparing them with the middle ear function in children not having such infection or any recent history of the same.

Materials and Methods

A hospital based analytical cross-sectional study was conducted in a tertiary care hospital cum medical college from November 2019 to March 2020. Participants in study groups were selected from Otorhinolaryngology and Pediatrics outpatient department (OPD) with age below 12 years, diagnosed to have upper respiratory infection but no ear related symptoms. Age and sex matched controls were selected from those children attending OPD with problems other than upper respiratory tract infections. There were 25 children in both study and control group selected from Otorhinolaryngology and Pediatrics outpatient department (OPD). So total numbers of children were 50.

Congenital or other acquired conditions which may affect Eustachian tube functions (as craniofacial abnormalities, any syndromic conditions involving upper airway or head neck region, branchial cleft anomalies, etc.) were excluded from both study and control group. Informed consents were taken from all the parents/legal guardians (and age appropriate assents from children where applicable). Complete examination of the ears was done, and conditions of tympanic membranes were noted. Tympanometry was performed in all the children and data recorded regarding the shapes of tympanogram, middle ear compliance and middle ear pressure. Subjects were considered as patients and not as individual ear (abnormality in either ear is considered as Eustachian tube dysfunction in that patient).

Standard numeric values and units of measurement:

i) Static middle ear compliance: Measured in cubic centimeter(cc) with reference normal range within 0.35cc and 1.40cc.

ii) Middle Ear Pressure: Measured in Deka Pascal (daPa) unit with reference normal range +25daPa to
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-100 daPa up to 5 years of age and between +50 daPa to -100 daPa in Children > 5 years of age.\(^6\)

iii) Grade of Tympanic Membrane Retraction: As per Sade’s classification.\(^7\)

iv) Types of shapes of Tympanogram: As per coding system proposed by J. Jerger.\(^8\)

**Statistical Analysis:**

Data compiled on Microsoft Excel worksheet. Statistical Package for Social Sciences (SPSS-version 20.0) was used for analysis. Descriptive data was analyzed as frequency, percentage and presented in tables. Categorical characteristics were compared between groups with the use of Chi-square tests. For the entire statistical test applied p value less than 0.05 considered as statistically significant.

**Results**

There was no statistically significant difference in background characteristics (age, sex) of the participants of study and control groups. Majority in both the study (19 - 76%) and control groups (19 - 76%) were aged above 60 months. Numbers of participants in the age group 7 - 60 months in both the study and control groups were 5 (20%). Only 1 child (4%) in both study and control groups were below 6 months of age. (Table I)

Majority of the children (14 - 56%) in the study group had duration of upper respiratory infection more than 120 days (4 months). 8 (32%) patients had duration of disease 2-4 months and 3 (12%) have 1 month. (Table II)

In the study group 19 (76%) children and in the control group 22 (88%) children had no retraction of the right tympanic membrane and 6 (24%) in the study group and 3 (12%) in the control group had grade 1 retraction of the right tympanic membrane. In retraction grade of the right tympanic membrane, there is no statistically significant difference of study and control group with df= 1, \(\chi^2 = 1.220\) and p value was 0.269. In case of the left tympanic membrane, 18 (72%) patients in the study group and 24 (96%) in the control group had no retraction. 6 (24%) patients in study group and 1 (4%) in the control group had grade 1 retraction and only 1 (4%) patient had grade 2 retraction in the study group. There was no grade 2 retraction in the control group. In retraction grade of the left tympanic membrane, there was no statistically significant difference of study and control group with df= 2, \(\chi^2 = 5.429\) and p value was 0.066. Majority of patients had no retraction of the tympanic membrane in either ear [16 (64%)] in the study group and in the control group 21 (84%)]. In the study group 9 (36%) and in the control group 4 (16%) children had retraction in one or other ear. There was no statistically significant difference in the duration of upper respiratory infection among the participants of study and control groups with df= 2, \(\chi^2 = 0.556\) and p value was 0.760.

**Table I: Background characteristics of the study and the control groups (N=50)**

| VARIABLES | "STUDY GROUP (N=25) NO. (%)" | "CONTROL GROUP (N=25) NO. (%)" | CHI-SQUARE TEST, P VALUE |
|-----------|-------------------------------|-------------------------------|--------------------------|
| Age       |                               |                               |                          |
| 1- 6 month| 1 (4.00)                      | 1 (4.00)                      | df=2, \(\chi^2 = 0.000\), p= 1.000 |
| 7- 60 month| 5 (20.00)                    | 5 (20.00)                    |                          |
| > 60 month| 19 (76.00)                    | 19 (76.00)                    |                          |
| Sex       |                               |                               |                          |
| Male      | 12 (48.00)                    | 14 (56.00)                    | df=2, \(\chi^2 = 0.571\), p= 0.389 |
| Female    | 13 (52.00)                    | 11 (44.00)                    |                          |

**Table II: Duration of diseases of the study group (n1=25)**

| DURATION          | STUDY GROUP (N1=25) NO. (%) |
|-------------------|-----------------------------|
| 1-30 days (1 month)| 8 (32.00)                   |
| 31-120 days (2-4 months) | 3 (12.00)                   |
| > 120 days (4 months) | 14 (56.00)                   |
no statistically significant difference in overall tympanic membrane retraction in both ear of study and control groups with df= 1, χ² = 2.599 and p value of 0.196. (Table III)

In case of middle ear pressure 14 (56%) children in the study group and 9 (36%) in the control group had abnormal middle ear pressure. 11 (44%) children in the study group and 16 (64%) in the control group had normal middle ear pressure. There was no statistically significant difference in middle ear pressure of study and control groups with df= 1, χ² = 2.013 and p value was 0.156. (Table III)

In the study group majority of children [17 (68%)] had abnormal middle ear compliance and 8 (32%) had normal middle ear pressure. There was no statistically significant difference in middle ear compliance of study and control groups with df= 1, χ² = 11.688, p = 0.001.

Table III: Comparison of the study and the control group according to retraction of tympanic membrane and middle ear pressure (N=50)

| VARIABLES                        | STUDY GROUP (N1=25) NO. (%) | CONTROL GROUP (N2=25) NO. (%) | CHI-SQUARE TEST, P VALUE |
|----------------------------------|-----------------------------|-------------------------------|-------------------------|
| Retraction grade of Rt tympanic membrane* | No retraction 19 (76.00) | 22 (88.00) | df= 1, χ² = 1.220, p= 0.269 |
|                                 | Grade 1 6 (24.00)           | 3 (12.00)                     |                         |
| Retraction grade of Lt tympanic membrane # | No retraction 18 (72.00) | 24 (96.00) | df= 2, χ² = 5.429, p=0.066 |
|                                 | Grade 1 6 (24.00)           | 1 (4.00)                      |                         |
| Tympanic membrane retraction     | No retraction 16 (64.00%)   | 21 (84.00%)                   | df= 1, χ² = 2.599, p=0.196 |
|                                 | Retraction 9 (36.00%)       | 4 (16.00%)                    |                         |
| Middle Ear Pressure              | Normal 11 (44.00)           | 16 (64.00)                    | df= 1, χ² = 2.013, p=0.156 |
|                                 | Abnormal 14 (56.00)         | 9 (36.00)                     |                         |

*No grade 2 or grade 3 retraction of right tympanic membrane in both study and control groups.  # No grade 3 retraction of left tympanic membrane in both study and control groups

In case of middle ear pressure 14 (56%) children in the study group and 9 (36%) in the control group had abnormal middle ear pressure. 11 (44%) children in the study group and 16 (64%) in the control group had normal middle ear pressure. There was no statistically significant difference in middle ear pressure of study and control groups with df= 1, χ² = 2.013 and p value was 0.156. (Table III)

In the study group majority of children [17 (68%)] had abnormal middle ear compliance and 8 (32%) had normal middle ear compliance. 

Table IV: Comparison of the study and the control group according to middle ear compliance and Tympanogram curve (N=50)

| VARIABLES                        | STUDY GROUP (N1=25) NO. (%) | CONTROL GROUP (N2=25) NO. (%) | CHI-SQUARE TEST, P VALUE |
|----------------------------------|-----------------------------|-------------------------------|-------------------------|
| Middle ear compliance            | Normal 8 (32.00)            | 20 (80.00)                    | df= 1, χ² = 11.688, p= 0.001 |
|                                 | Abnormal 17 (68.00)         | 5 (20.00)                     |                         |
| "Tympanogram curve Type (Rt ear)" | A type 13 (52.00)           | 21 (84.00)                    | df= 2, χ² = 8.282, p=0.016 |
|                                 | B type 3 (12.00)            | 3 (12.00)                     |                         |
|                                 | C type 9 (36.00)            | 1 (4.00)                      |                         |
| Tympanogram curve Type, (Lt ear) | A type 13 (52.00)           | 23 (92.00)                    | df= 2, χ² = 10.566, p=0.005 |
|                                 | B type 5 (20.00)            | 0 (0.00)                      |                         |
|                                 | C type 7 (28.00)            | 2 (8.00)                      |                         |
normal middle ear compliance in one or the other ear. Where as in control group majority of patients [20 (80%)] had normal middle ear compliance and 5 (20%) had abnormal middle ear compliance in one or the other ear. There was statistically significant difference in middle ear compliance of study and control groups with df= 1, \( \chi^2 = 11.688 \) and p value was 0.001. In right ear, number of children with type A tympanogram (normal) were 13 (52%) in the study group and majority of patients 21(84%) in the control group. In the study group 3 (12%) had B type and 9 (36%) had C type tympanogram curves, and in the control group 3 (12%) had B type and only 1 (4%) had C type tympanogram curve in the right ear. Statistically significant difference present in right ear tympanogram curve of study and control groups with df= 2, \( \chi^2 = 8.282 \) and p value was 0.016. (Table IV)

Number of patients with tympanogram curve A type were 13 (52%) in the study group and majority of patients 23(92%) in the control group of left ear. In the study group 5 (20%) had B type and 7 (28%) had C type tympanogram curves and in the control group 2 (8%) had C type tympanogram curve of right ear. There was no type B curve in control group. There was statistically significant difference of study and control groups with df= 2, \( \chi^2 = 10.566 \) and p value was 0.005 of left ear tympanogram curve. (Table IV)

Discussion

Otitis media with effusion (OME) is the accumulation of mucus within the middle ear and sometimes the mastoid air cell system. Persistence of the fluid for the condition to be described as chronic is normally taken as 3 months or longer.\(^9\) Upper respiratory tract infection including inflammation involving adenoid is a well established etiology for otitis media with effusion. Biofilms were demonstrated in 92% of the middle ear mucosal specimens obtained during ventilation tube insertion for persistent OME.\(^10\) Similar types of Biofilms were reported from operated adenoid samples of the patients with OME, supporting the hypothesis that inflammation associated with the biofilm rather than adenoidal size per se blocking the Eustachian tube is the critical factor in etiology of OME.\(^11\) At least one episode of otitis media with effusion is experienced by 95% of children before their school admission.\(^12\) The condition may go unnoticed with subsequent spontaneous resolution. But it may affect language development process in early childhood or in the worse scenario may progresses to atelectasis or Chronic Otitis Media with retraction pocket formation. Early diagnosis of OME in pre-clinical stage may have the benefits in terms of preventing these long term complications. But there is a lack of researches about this pre clinical/asymptomatic stage of OME/ Middle ear dysfunction.

In the present study there is no significant deference in baseline characters (Age, Sex) across the study and control groups, which confirms the effective matching between the groups. None of the patients have any symptoms related to ears. On clinical examination, presence of tympanic membrane retraction is detected in 9(36%) children in the study group and in 4 (16%) among the controls. There is no statistically significant difference in this regard. While considering the middle ear pressure, 14 children (56%) in the study group having the pressure outside the normal range in one or other ears, where as in the control group it is 9(36%). Again this parameter fails to establish any statistical significance. But when the middle ear compliances are compared across the groups, 17 children (68%) have the values outside the normal range (in one or other ear) in the study group, and 5 children (20%) in the control group have such values. The difference is found to be statistically significant (df= 1, \( \chi^2 = 11.688 \) and p value 0.001). Similarly, significantly more children in the study group have abnormal tympanogram (type B or C) in compared to the control group. These findings can indicate the high prevalence of asymptomatic middle ear dysfunction among the children having upper respiratory tract infection when compared with matched controls. In their study among the children with adenoid hypertrophy, Bhat et al found asymptomatic middle ear dysfunction in 36% of the study population.\(^13\) Another study found more than 60% of episodes of symptomatic URI among young children were complicated by Acute Otitis Media or middle ear effusion.\(^14\) These asymptomatic middle ear dysfunction may eventually progresses to full blown OME, affecting the hearing of
the child and consequently language development (in early childhood). In worse scenario, it may progresses to retraction pocket formation and squamous variety of chronic otitis media.

**Conclusion**

Upper respiratory infection can causes middle ear effusion and dysfunction in children, which may be asymptomatic. Early diagnosis of the condition by examination and suitable audiological investigation in this preclinical stage with appropriate intervention can prevent further progression of the disease causing hearing loss as well as retraction pocket formation.

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