

Association of Laryngopharyngeal Reflux with Otitis Media with Effusion in Adults: A Hospital-Based Cross-Sectional Study

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Abstract:

Background: Laryngopharyngeal reflux (LPR) has emerged as a potential risk for otitis media with effusion (OME) through reflux-induced inflammation of the Eustachian tube and middle ear. However, evidence regarding this association in adults remains limited, particularly in the Indian population. Objective: To evaluate the association between laryngopharyngeal reflux and otitis media with effusion in adults presenting with chronic throat complaints.

Materials and Methods: This hospital-based analytical cross-sectional study was conducted over a period of 12 months in the Department of Otorhinolaryngology at a tertiary care teaching hospital. A total of 120 adults with chronic throat complaints were enrolled and classified into LPR-positive (n=60) and LPR-negative (n=60) groups using the Reflux Symptom Index (RSI) and Reflux Finding Score (RFS). All participants underwent detailed otorhinolaryngological examination, pneumatic otoscopy, and tympanometry. OME was diagnosed based on a Type B tympanogram with compatible otoscopic findings in the absence of acute infection.

Results: The mean RSI (18.6 ± 4.8 vs. 7.4 ± 3.1 ; $p < 0.001$) and RFS (10.3 ± 2.5 vs. 4.5 ± 1.8 ; $p < 0.001$) were significantly higher in the LPR-positive group. Globus sensation, throat clearing, hoarseness, ear fullness, and subjective hearing impairment were significantly more frequent among participants with LPR. Type B tympanograms were observed in 28.3% of participants with LPR compared with 6.7% of those without LPR ($p = 0.002$). OME was diagnosed in 17 (28.3%) participants with LPR and 4 (6.7%) participants without LPR, corresponding to a prevalence ratio of 4.25 ($p = 0.004$). Allergic rhinitis was also significantly associated with OME (39.3% vs. 10.9%; $p < 0.001$), whereas age, sex, and smoking status showed no significant association.

Conclusion: Laryngopharyngeal reflux is significantly associated with otitis media with effusion in adults presenting with chronic throat complaints. Patients with LPR are more likely to have middle-ear effusion, Type B tympanograms, and ear-related symptoms. Assessment for LPR should be considered in adults with unexplained OME, and further prospective studies are required to clarify the causal relationship and therapeutic implications.

Keywords: Adult; Laryngopharyngeal Reflux; Otitis Media With Effusion; Reflux Finding Score; Reflux Symptom Index.

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Introduction

Otitis media with effusion (OME) is a disease that is characterised by inflammation of the middle ear with fluid formation, without signs or symptoms of acute infection, and with intact tympanic membrane. This disease commonly occurs in children and can appear symptomless. [1] Diagnosis and management of OME are usually late and are associated with complications. OME is the most common cause of hearing loss in children

in developing countries and can impair the child's behavioural and language development. [2] Otitis media with effusion (OME) is a common condition in the pediatric population. It is associated with many factors, including adenoidal hypertrophy, upper respiratory tract infection, cleft palate, and exposure to cigarette smoke. In adults, OME is less prevalent, but still causes considerable morbidity. While adult OME was once a neglected subject in

terms of research effort, this is no longer the case. Over the last 20 years, a great deal of new information that sheds some light on the pathogenesis of this enigmatic condition has become available. [3,4] The possible aetiologies and risk factor of adult OME are local malignancy, sinonasal disease, gastroesophageal reflux, eustachian tube dysfunction, smoking, intensive care patients, human immunodeficiency virus (HIV), and sarcoidosis. Other common cause is allergy, which was reported in 41.9% of cases. [5] The worldwide prevalence rate of laryngopharyngeal reflux disease (LPRD) ranges from 5% to 30%. In 2022, research conducted on the Indian population revealed that the prevalence rate of LPR in the population was 11%. The prevalence rate of LPR was 11.2% in females and 10.6% in males. [6]

Laryngopharyngeal reflux (LPR) is also known as supra-esophageal reflux, extra-esophageal reflux, or silent reflux. It refers to a disease in which there is a backflow of gastric contents that rises through the esophagus affecting the aerodigestive tract and leading to throat symptoms, specifically those of the laryngopharynx. [7] In some patients, the gastroduodenal content may even reach the nasal cavities and ears through the Eustachian tubes, which can aggravate rhinitis, sinusitis, or otitis media. [8,9] While gastroesophageal reflux disease (GERD) has long been identified as a source of esophageal disease, laryngopharyngeal reflux (LPR) has only recently been implicated in causing head and neck problems. Reflux that advances to the laryngopharynx and, subsequently, to other regions of the head and neck such as the larynx, oral cavity, nasopharynx, nasal cavity, paranasal sinuses, and even middle ear could cause LPR. [10] The most common manifestation of LPR is reflux laryngitis. Other manifestations in the head and neck that have been reported include asthma, sinusitis, and otitis media. [11]

Despite the growing evidence, studies evaluating the relationship between laryngopharyngeal reflux and otitis media with effusion in adults remain limited, particularly in the Indian population.

Most available studies have been conducted in different populations using varying diagnostic criteria for both laryngopharyngeal reflux and otitis media with effusion, making comparison of results difficult. Therefore, further studies using standardized clinical assessment and objective middle ear evaluation are required to better understand the association between laryngopharyngeal reflux and otitis media with effusion. The present study was undertaken to evaluate the association between laryngopharyngeal reflux and otitis media with effusion in adult patients presenting with chronic throat symptoms.

Materials and Methods

This hospital-based analytical cross-sectional study was planned to assess the association between laryngopharyngeal reflux and otitis media with effusion among adults attending the outpatient department of Otorhinolaryngology and Head and Neck Surgery at a tertiary care teaching hospital. The study was conducted over 12 months. All eligible participants were informed about the study procedures, and written informed consent was obtained before enrolment. Adult patients presenting with chronic throat-related complaints were screened for participation. These complaints included hoarseness, frequent throat clearing, globus sensation, chronic cough, excessive throat mucus, sore throat, dysphagia, and cough after meals or while lying down.

Participants were classified into an LPR-positive group and an LPR-negative comparison group based on the Reflux Symptom Index and Reflux Finding Score. The study included 120 participants, with 60 individuals in each group.

The sample size was estimated using the formula for comparison of two independent proportions. The calculation was based on the article, which reported OME in 32.14% of patients with LPR and 7.14% of patients without LPR.

At a 95% confidence level, 80% statistical power, and a two-sided alpha error of 5%, the minimum calculated sample size was approximately 39 participants per group. After allowing for incomplete examinations, possible exclusions, and improved precision, the sample size was increased to 60 participants per group, giving a total sample of 120. Eligible participants were enrolled consecutively until the required sample size was achieved. The LPR-negative participants were selected during the same study period from patients presenting with throat complaints but not fulfilling the diagnostic criteria for LPR.

Inclusion Criteria

Adult patients aged 18 years or older presenting with one or more chronic throat complaints, including hoarseness, frequent throat clearing, globus sensation, chronic cough, excessive throat mucus, sore throat, dysphagia, or cough after meals or while lying down for a duration of at least four weeks, were considered eligible for the study. Participants were required to complete the Reflux Symptom Index (RSI) questionnaire, undergo a comprehensive otorhinolaryngological evaluation including flexible nasopharyngolaryngoscopy, pneumatic otoscopy, and tympanometry, and provide written informed consent before enrolment.

Exclusion Criteria

Patients were excluded if they had acute upper respiratory tract infection within the preceding two weeks, acute or chronic suppurative otitis media, tympanic membrane perforation, previous middle-ear or nasopharyngeal surgery, congenital craniofacial anomalies affecting Eustachian tube function, head and neck malignancy or prior radiotherapy, external ear conditions precluding otoscopic examination, neuromuscular disorders affecting swallowing, current use of proton pump inhibitors, H₂-receptor antagonists, or prokinetic agents within the previous four weeks, or incomplete clinical or tympanometric evaluation.

Data Collection: Information was collected using a predesigned case-record form. Demographic and clinical variables included age, sex, occupation, body mass index, smoking status, alcohol consumption, and duration of throat symptoms, allergic rhinitis, chronic rhinosinusitis, asthma, diabetes mellitus, and hypertension. A detailed history of throat and ear symptoms was obtained. Ear-related complaints included ear fullness, hearing impairment, tinnitus, intermittent ear discomfort, and a blocked-ear sensation. All participants underwent a complete ear, nose, and throat examination by an otorhinolaryngologist.

Assessment of laryngopharyngeal reflux

Reflux Symptom Index: Each participant completed the Reflux Symptom Index, which contains nine questions related to common symptoms of LPR. Each item is scored from 0, indicating no symptom, to 5, indicating a severe symptom. The total score ranges from 0 to 45.

The symptoms assessed were:

- hoarseness or voice disturbance,
- throat clearing,
- excessive throat mucus or postnasal drip,
- difficulty swallowing,
- coughing after eating or lying down,
- breathing difficulty or choking episodes,
- troublesome cough,
- globus or foreign-body sensation in the throat,
- Heartburn, chest discomfort, indigestion, or acid regurgitation.

An RSI score greater than 13 was considered abnormal.

Reflux Finding Score: Flexible nasopharyngolaryngoscopy was performed under topical anaesthesia. Laryngeal findings were graded using the Reflux Finding Score.

The following findings were evaluated:

- subglottic oedema,
- ventricular obliteration,
- laryngeal erythema or hyperaemia,
- vocal-fold oedema,
- diffuse laryngeal oedema,

- posterior commissure hypertrophy,
- granuloma or granulation tissue,
- Thick endolaryngeal mucus.

An RFS greater than 7 was considered abnormal. Participants were classified as LPR positive when both RSI was greater than 13 and RFS was greater than 7. Participants who did not fulfil both criteria were categorized as LPR negative.

Assessment of otitis media with effusion

Otосcopy and pneumatic otoscopy: Both ears were examined using conventional and pneumatic otoscopy. The tympanic membrane was assessed for colour, translucency, position, visible fluid level or air bubbles, and mobility.

Findings suggestive of OME included:

- dull or opaque tympanic membrane,
- retraction or outward bulging without acute inflammation,
- visible middle-ear fluid or air-fluid level,
- Reduced or absent tympanic membrane mobility.

Tympanometry: Tympanometry was performed in both ears using a calibrated middle-ear analyser. Tympanograms were classified according to the Jerger classification:

- Type A: normal middle-ear pressure and compliance;
- Type B: flat curve, suggestive of middle-ear effusion when the ear-canal volume was normal;
- Type C: negative middle-ear pressure, suggestive of Eustachian tube dysfunction.

OME was diagnosed when a participant had a Type B tympanogram with a normal ear-canal volume and compatible otoscopic or pneumatic otoscopic findings, in the absence of symptoms and signs of acute infection. The participant, rather than the individual ear, was treated as the unit of analysis. A participant was classified as having OME when either ear fulfilled the diagnostic criteria. When the findings differed between ears, the more abnormal ear was used for participant-level tympanometric classification.

Pure-tone audiometry: Pure-tone audiometry was performed in participants reporting hearing impairment or demonstrating abnormal otoscopy or tympanometry. Air- and bone-conduction thresholds were measured, and conductive hearing loss was identified by the presence of an air-bone gap.

Statistical Analysis: Data were entered into Microsoft Excel and analysed. Continuous variables were examined for normality using the Shapiro-Wilk test. Normally distributed variables were expressed as mean $\pm$ standard deviation.

Categorical variables were expressed as frequencies and percentages.

Group comparisons were performed using the independent-samples Student's *t* test for normally distributed continuous variables. The Pearson chi-square test was used to compare categorical variables when expected cell counts were adequate. The prevalence of OME was calculated separately in the LPR-positive and LPR-negative groups. The strength of association was expressed as a prevalence ratio with a 95% confidence interval. All statistical tests were two-sided, and a *p* value below 0.05 was considered statistically significant.

Results

[Table-1] The baseline demographic and clinical characteristics of the study participants were comparable between the LPR-positive and LPR-negative groups. Although participants with LPR tended to be older and had a higher prevalence of allergic rhinitis, these differences were not statistically significant. Similarly, no significant differences were observed with respect to sex distribution, body mass index, smoking status, chronic rhinosinusitis, or asthma (all *p* > 0.05).

[Table-2] Participants with LPR reported throat symptoms more frequently than those without LPR. Globus sensation, frequent throat clearing, and hoarseness were significantly more common in the LPR-positive group, whereas the frequencies of excessive throat mucus, chronic cough, dysphagia, and sore throat were comparable between the groups. Among ear-related symptoms, ear fullness, subjective hearing impairment, and the presence of any ear complaint were significantly associated with LPR. Although tinnitus and intermittent ear discomfort were reported more often in participants with LPR, these differences did not reach statistical significance.

The mean RSI was significantly higher in the LPR-positive group than in the LPR-negative group (18.6 ± 4.8 vs. 7.4 ± 3.1 , *p* < 0.001). Similarly, the mean RFS was significantly higher among participants with LPR compared to those without LPR (10.3 ± 2.5 vs. 4.5 ± 1.8 , *p* < 0.001).

[Table-3] Type A tympanograms were the most common finding in both groups but were observed more frequently in the LPR-negative group than in the LPR-positive group (91.7% vs. 65.0%). In contrast, Type B tympanograms, suggestive of middle ear effusion, were considerably more common among participants with LPR (28.3% vs. 6.7%). Type C tympanograms were infrequent in both groups (6.7% vs. 1.7%). Overall, the distribution of tympanogram types differed significantly between the two groups (*p* = 0.002).

[Table-4] OME was diagnosed in 17 of 60 participants with LPR and 4 of 60 participants without LPR. The prevalence of OME was therefore 4.25 times higher among participants with LPR than among those without LPR. The association was statistically significant.

[Table-5] Although OME was more common among participants aged ≥ 40 years than those aged <40 years (22.2% vs. 12.3%) and among females compared with males (20.0% vs. 15.7%), these differences were not statistically significant.

Similarly, the prevalence of OME was higher among current smokers than non-smokers (22.2% vs. 16.1%), but the association was not significant. Participants with allergic rhinitis had a significantly higher prevalence of OME than those without allergic rhinitis (39.3% vs. 10.9%, *p* < 0.001). Likewise, OME was observed more frequently among participants with LPR than among those without LPR (28.3% vs. 6.7%, *p* = 0.004).

Table 1: Baseline characteristics of the study participants

Characteristic	LPR positive (n=60)	LPR negative (n=60)	P value
Age (years)	42.8 $\pm$ 11.6	39.5 $\pm$ 12.2	0.132
Sex			
Male	34 (56.7)	36 (60.0)	0.711
Female	26 (43.3)	24 (40.0)	
BMI (kg/m ²)	25.7 $\pm$ 3.8	24.8 $\pm$ 3.4	0.174
Current smoking	15 (25.0)	12 (20.0)	0.512
Allergic rhinitis	18 (30.0)	10 (16.7)	0.084
Chronic rhinosinusitis	8 (13.3)	6 (10.0)	0.570
Asthma	5 (8.3)	4 (6.7)	1.000

Table 2: Distribution of throat and ear-related symptoms among participants

Variable		LPR positive n (%)	LPR negative n (%)	P value
Throat Symptom	Globus sensation	39 (65.0)	20 (33.3)	0.001
	Frequent throat clearing	36 (60.0)	22 (36.7)	0.011
	Hoarseness	31 (51.7)	18 (30.0)	0.016
	Excessive throat mucus	28 (46.7)	19 (31.7)	0.093
	Chronic cough	25 (41.7)	17 (28.3)	0.126
	Dysphagia	14 (23.3)	8 (13.3)	0.157
	Sore throat	12 (20.0)	10 (16.7)	0.637
Ear symptom	Ear fullness	18 (30.0)	5 (8.3)	0.003
	Subjective hearing impairment	16 (26.7)	6 (10.0)	0.018
	Tinnitus	8 (13.3)	5 (8.3)	0.378
	Intermittent ear discomfort	7 (11.7)	3 (5.0)	0.186
	Any ear complaint	25 (41.7)	10 (16.7)	0.003

Table 3: Participant-level tympanometric findings

Tympanogram type	LPR positive n (%)	LPR negative n (%)	Total n (%)
Type A	39 (65.0)	55 (91.7)	94 (78.3)
Type B	17 (28.3)	4 (6.7)	21 (17.5)
Type C	4 (6.7)	1 (1.7)	5 (4.2)
Total	60 (100.0)	60 (100.0)	120 (100.0)

Table 4: Prevalence of OME according to LPR status

LPR status	OME present n (%)	OME absent n (%)	Total
LPR positive	17 (28.3)	43 (71.7)	60
LPR negative	4 (6.7)	56 (93.3)	60
Total	21 (17.5)	99 (82.5)	120

Table 5: Bivariate association of demographic and clinical factors with OME

Variable		OME present n (%)	OME absent n (%)	P value
Age (Years)	<40 years	7 (12.3)	50 (87.7)	0.152
	≥40 years	14 (22.2)	49 (77.8)	
Sex	Male	11 (15.7)	59 (84.3)	0.542
	Female	10 (20.0)	40 (80.0)	
Smoking habit	Non-smoker	15 (16.1)	78 (83.9)	0.463
	Current smoker	6 (22.2)	21 (77.8)	
allergic rhinitis	Absent	10 (10.9)	82 (89.1)	<0.001
	Present	11 (39.3)	17 (60.7)	
LPR	Absent	4 (6.7)	56 (93.3)	0.004
	Present	17 (28.3)	43 (71.7)	

Discussion

The present study investigated the association between laryngopharyngeal reflux (LPR) and otitis media with effusion (OME) among adults presenting with chronic throat complaints. The principal findings demonstrated that participants with LPR had a significantly higher prevalence of OME than those without LPR (28.3% vs. 6.7%), corresponding to more than a fourfold increase in prevalence. In addition, LPR was associated with a higher frequency of ear-related symptoms and a significantly greater proportion of Type B tympanograms, supporting the hypothesis that reflux-related upper airway inflammation may contribute to middle-ear dysfunction.

The baseline demographic and clinical characteristics were comparable between the two

groups, with no significant differences in age, sex, body mass index, smoking status, chronic rhinosinusitis, or asthma. Although allergic rhinitis was more frequent among participants with LPR, the difference was not statistically significant. This similarity in baseline characteristics reduces the likelihood that the observed differences in middle-ear findings were attributable to major demographic or clinical imbalances between the study groups. As expected, participants with LPR had significantly higher Reflux Symptom Index (RSI) and Reflux Finding Score (RFS) values than those without LPR. Moreover, characteristic reflux-related symptoms such as globus sensation, frequent throat clearing, and hoarseness were significantly more common among individuals with LPR. These findings are consistent with the established clinical manifestations of LPR and

support the validity of the diagnostic criteria used in the present study. [12,13]

Ear-related complaints were also significantly more frequent among participants with LPR, particularly ear fullness and subjective hearing impairment. Although tinnitus and intermittent ear discomfort were reported more often in the LPR-positive group, these differences were not statistically significant. These findings suggest that middle-ear symptoms may represent an under-recognized manifestation of LPR and highlight the importance of considering reflux disease in patients presenting with unexplained otological complaints.

Objective middle-ear assessment further supported this association. Type A tympanograms predominated in both groups but were significantly less frequent among participants with LPR, whereas Type B tympanograms, which are highly suggestive of middle-ear effusion, were observed more than four times as often in the LPR-positive group. This finding indicates that LPR is associated not only with subjective symptoms but also with measurable abnormalities in middle-ear function. [14]

The most important finding of this study was the significantly higher prevalence of OME among participants with LPR. Similar observations have been reported by Karyanta et al [15], who found OME in 32.1% of adults with LPR compared with 7.1% of controls, corresponding to a prevalence ratio of approximately 4.5. The prevalence ratio observed in the present study (4.25) closely mirrors their findings, suggesting a consistent and clinically meaningful association between LPR and OME across different populations.

Our findings are also consistent with those of Restuti et al [16], who demonstrated a significantly higher prevalence of LPR among patients with OME than among healthy controls using RSI and RFS. Although their study evaluated reflux prevalence in patients with established OME, whereas the present study examined OME prevalence among patients with LPR, both investigations support a close relationship between reflux disease and middle-ear pathology.

Yeo et al [17], in a nationwide population-based cohort study, reported that patients with LPR had a significantly increased risk of developing chronic OME during follow-up. Although the magnitude of association in that longitudinal study was smaller than that observed in the present cross-sectional study, the direction of the association remained consistent.

The lower effect estimate reported by Yeo et al. is likely attributable to differences in study design, diagnostic criteria, follow-up duration, and adjustment for multiple confounding factors. A

systematic review by Miura et al [18] concluded that the available evidence supports an association between LPR and OME but remains insufficient to establish a definitive causal relationship because of heterogeneity in study designs, diagnostic criteria, and patient populations.

Direct reflux of gastric contents into the nasopharynx may expose the Eustachian tube mucosa to acid and pepsin, resulting in chronic inflammation, mucosal edema, and impaired mucociliary clearance. Eustachian tube dysfunction subsequently leads to persistent negative middle-ear pressure, impaired ventilation, and accumulation of sterile middle-ear effusion.

Experimental studies have demonstrated the presence of pepsin within middle-ear effusions, supporting the possibility that reflux material may directly contribute to middle-ear inflammation. In addition, chronic inflammatory changes induced by reflux may increase susceptibility to secondary infection and prolong the persistence of middle-ear effusion. Allergic rhinitis may contribute to Eustachian tube dysfunction through persistent nasal and nasopharyngeal mucosal inflammation, leading to impaired middle-ear ventilation. The coexistence of allergic inflammation and reflux-related mucosal injury may further increase the likelihood of middle-ear disease in susceptible individuals.

Adults presenting with persistent throat symptoms suggestive of LPR should be evaluated not only for laryngeal manifestations but also for associated middle-ear disease, particularly when ear fullness or hearing impairment is present. Likewise, patients with unexplained or recurrent OME may benefit from assessment for underlying LPR, as recognition of reflux could influence overall patient management.

Conclusion

This study demonstrated a significant association between laryngopharyngeal reflux (LPR) and otitis media with effusion (OME) in adults presenting with chronic throat complaints. Participants with LPR had a significantly higher prevalence of OME and were more likely to exhibit Type B tympanograms, along with a greater frequency of ear-related symptoms, particularly ear fullness and subjective hearing impairment. Allergic rhinitis was also significantly associated with the presence of OME, whereas age, sex, and smoking status showed no significant association. These findings suggest that LPR may contribute to middle-ear pathology and should be considered during the evaluation of adults with chronic throat symptoms and unexplained OME. Further prospective longitudinal studies incorporating objective reflux testing are warranted to clarify the causal

relationship and evaluate the impact of anti-reflux therapy on middle-ear outcomes.

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