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Allergic Rhinitis and Allergic Sensitization in Pediatric Otitis Media with Effusion: A Systematic Review and Meta-Analysis with Narrative Synthesis of Eustachian Tube Dysfunction

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Abstract

Background
Otitis media with effusion (OME) is a common pediatric middle-ear disorder with multifactorial pathogenesis. Allergic rhinitis and allergic sensitization have been proposed as contributing factors, but previous evidence remains heterogeneous. This systematic review and meta-analysis aimed to clarify the association between allergic rhinitis, allergic sensitization, and pediatric OME, while separately considering Eustachian tube dysfunction (ETD) and middle-ear dysfunction.
Methods
A systematic search was conducted in PubMed/MEDLINE, Scopus, and the Cochrane Library. Observational studies evaluating allergic rhinitis, rhinitis, atopy, IgE sensitization, or allergy-related symptoms in relation to OME, ETD, abnormal tympanometry, or middle-ear dysfunction were considered eligible. Random-effects meta-analyses were performed separately for allergic rhinitis/rhinitis–OME and atopy/IgE sensitization–OME. ETD and middle-ear dysfunction outcomes were synthesized narratively because of methodological heterogeneity.
Results
After removal of duplicates, 956 records were screened, 46 reports were assessed for eligibility, and 20 studies were included in the qualitative or narrative synthesis. Nine studies contributed to at least one quantitative synthesis. Allergic rhinitis/rhinitis was significantly associated with OME in the primary meta-analysis (OR = 3.73, 95% CI 1.79–7.74, $p < 0.001$; $I^2 = 69.7\%$). The association remained significant in an expanded sensitivity analysis including one additional community-based study (OR = 3.46, 95% CI 1.92–6.23, $p < 0.001$; $I^2 = 63.7\%$). Atopy/IgE sensitization was also associated with OME (OR = 5.45, 95% CI 1.33–22.35, $p = 0.018$; $I^2 = 86.0\%$), although this analysis included only two studies.
Conclusions
Allergic rhinitis/rhinitis and allergic sensitization are associated with increased odds of pediatric OME. However, the available evidence is mainly observational and heterogeneous. Allergic disease should be considered a potential contributing factor in selected pediatric OME phenotypes, rather than a universal or isolated cause. A phenotype-based approach involving both otolaryngology and allergy/immunology may be clinically useful.

Highlights

What are the main findings?

• Allergic rhinitis/rhinitis was significantly associated with pediatric otitis media with effusion, with a pooled odds ratio of 3.73 in the primary random-effects meta-analysis.

• Atopy or IgE sensitization was also associated with OME, but the evidence was based on fewer studies and showed high heterogeneity.

What are the implications of the main findings?

• Allergic rhinitis and allergic sensitization should be considered potential contributing factors in selected pediatric OME phenotypes, especially when persistent nasal symptoms coexist with ear complaints, hearing concerns, or abnormal tympanometry.

• The findings support phenotype-based ENT and allergy/immunology assessment, but do not justify treating all pediatric OME as allergy-driven disease.

1. Introduction

Otitis media with effusion (OME) is a common pediatric middle-ear disorder defined by the presence of non-purulent fluid behind an intact tympanic membrane, without signs or symptoms of acute infection [1,2]. It represents one of the most frequent causes of acquired conductive hearing loss in childhood and may affect speech development, school performance, and quality of life when persistent or recurrent [1]. Although many episodes resolve spontaneously, persistent OME remains clinically important because it may require audiological monitoring, medical follow-up, or surgical intervention in selected cases [1,2].

The pathogenesis of OME is multifactorial. Eustachian tube dysfunction (ETD), recurrent upper respiratory tract infections, adenoid hypertrophy, immature immune responses, environmental exposures, and host susceptibility have all been implicated [2,3]. Among these potential contributors, allergic rhinitis and allergic sensitization have attracted long-standing interest because of the anatomical and immunological continuity between the nose, nasopharynx, Eustachian tube, and middle-ear cavity [3–5]. Allergic inflammation may promote nasopharyngeal mucosal edema, impaired mucociliary clearance, altered mucus properties, and functional obstruction of the Eustachian tube, thereby contributing to negative middle-ear pressure and effusion formation [4,5].

However, the relationship between allergic disease and OME remains controversial. Previous studies have used heterogeneous definitions of allergic rhinitis, nasal allergy, atopy, IgE sensitization, and middle-ear outcomes, which complicates interpretation and quantitative synthesis [1–3]. Some studies have reported a high prevalence of allergic rhinitis or atopy among children with chronic or recurrent OME, whereas others have found weak or non-significant associations [1,2]. Moreover, allergic rhinitis and allergic sensitization are often treated as interchangeable exposures, despite being clinically distinct constructs. Allergic rhinitis implies symptomatic nasal disease related to allergen exposure, whereas atopy or IgE sensitization may exist without clinically relevant rhinitis.

Previous meta-analytic evidence suggested that allergic rhinitis and allergy are risk factors for OME [6]. Nevertheless, several limitations remain relevant for current clinical interpretation. First, allergic rhinitis, nonspecific rhinitis, atopy, and IgE sensitization are frequently pooled together despite differences in diagnostic meaning. Second, OME, ETD, abnormal tympanometry, and middle-ear pressure abnormalities are sometimes discussed together, although they

are not equivalent outcomes. Third, newer studies have become available, including community-based, birth-cohort, and ETD-focused studies, which justify an updated synthesis.

The ETD literature is particularly relevant from an otolaryngological perspective. Recent reviews suggest that allergic mechanisms may contribute to ETD through Th2-mediated inflammation, mucosal swelling, impaired clearance, surfactant alterations, and extension of nasopharyngeal inflammation toward the tubal mucosa [4]. At the same time, experimental evidence indicates that allergen exposure alone may be insufficient to induce OME, supporting a more nuanced model in which allergy acts as one contributor among several interacting mechanisms rather than as a universal isolated cause [5,7].

Therefore, this systematic review and meta-analysis aimed to update and refine the evidence regarding the association between allergic rhinitis, allergic sensitization, and pediatric OME. We specifically separated clinically defined allergic rhinitis/rhinitis from atopy or IgE sensitization and treated ETD and middle-ear dysfunction as secondary narrative outcomes because of methodological heterogeneity. By doing so, we aimed to provide a synthesis that is more directly useful for pediatric ENT and allergy practice.

2. Materials and Methods

2.1. Study Design and Reporting

This systematic review and meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 statement [8]. The review was designed to evaluate the association between allergic rhinitis, allergic sensitization, and otitis media with effusion (OME), with a secondary narrative synthesis of Eustachian tube dysfunction (ETD) and broader middle-ear dysfunction outcomes.

The primary quantitative analysis focused on the association between allergic rhinitis/rhinitis and OME. A secondary quantitative analysis evaluated the association between atopy or IgE sensitization and OME. ETD and middle-ear dysfunction outcomes were analyzed narratively because the available studies used heterogeneous definitions, populations, and diagnostic methods.

2.2. Eligibility Criteria

Studies were considered eligible if they evaluated human participants and reported data on allergic rhinitis, rhinitis, nasal allergy, atopy, IgE sensitization, or allergy-related symptoms in relation to OME, ETD, abnormal tympanometry, altered middle-ear pressure, or related middle-ear dysfunction outcomes.

Eligible designs included observational cohort, case-control, cross-sectional, school-screening, community-based, and population-based studies. Studies were considered for quantitative synthesis when they provided extractable 2 × 2 data or effect estimates allowing calculation or interpretation of odds ratios.

Studies that were clinically relevant but unsuitable for pooling were retained for qualitative or narrative synthesis. This included non-comparative cohorts, treatment-response studies, mechanistic studies, studies with heterogeneous outcomes, and studies without extractable comparative data.

Studies were excluded if they were reviews, editorials, case reports, animal or in vitro studies, studies focused exclusively on acute otitis media, studies without an allergy-related exposure, studies without an OME/ETD-related outcome, duplicate or overlapping cohorts, reports without verifiable bibliographic details, or studies lacking sufficient data for either qualitative or quantitative synthesis.

2.3. Information Sources and Search Strategy

A systematic literature search was performed in PubMed/MEDLINE, Scopus, and the Cochrane Library. Manual screening of relevant references and eligible articles was also performed.

The search strategy combined terms related to allergic disease and sensitization with terms related to OME and ETD. Search concepts included allergic rhinitis, rhinitis, allergy, atopy, IgE sensitization, otitis media with effusion, middle-ear effusion, Eustachian tube dysfunction, tympanometry, and middle-ear dysfunction.

No date restriction was applied during the initial search. Records were imported into a screening workbook, and duplicate records were removed before title and abstract screening. The final search was performed on 8 June 2026. The complete search strategy is provided in Supplementary Table S1. The review protocol was not registered.

2.4. Study Selection

After deduplication, records were screened by title and abstract. Reports considered potentially relevant were sought for retrieval and assessed for eligibility. Studies were categorized as eligible for quantitative synthesis, eligible for qualitative or narrative synthesis only, excluded after eligibility assessment, duplicate or overlapping cohort, or not retrievable. Screening and eligibility assessment were performed by the first author, with uncertain records discussed with the senior authors.

When multiple reports appeared to describe overlapping populations or closely related datasets, only the most complete or methodologically suitable report was retained for synthesis. Reports with insufficient bibliographic information or unverifiable source details were excluded.

2.5. Data Extraction

For each eligible study, the following data were extracted: first author, year of publication, country, study design, population characteristics, age group, sample size, exposure definition, outcome definition, diagnostic methods, comparator group, 2 × 2 data where available, reported odds ratios, adjusted odds ratios where available, and relevant methodological notes.

For quantitative synthesis, data were extracted using the following convention:

- a = exposed participants with outcome;
- b = exposed participants without outcome;
- c = unexposed participants with outcome;
- d = unexposed participants without outcome.

Individual odds ratios were calculated as:

OR = (a × d) / (b × c).

Allergic rhinitis/rhinitis studies were extracted separately from atopy or IgE sensitization studies. This separation was prespecified to avoid pooling clinically expressed allergic rhinitis with immunological sensitization alone.

2.6 Outcomes

The primary outcome was the association between allergic rhinitis/rhinitis and OME.

The secondary quantitative outcome was the association between atopy or IgE sensitization and OME.

Additional secondary outcomes included ETD and middle-ear dysfunction, including abnormal tympanometry, altered middle-ear pressure, ETDQ-7 abnormalities, tubomanometry findings, mastoid pneumatization abnormalities, or otologic history. These outcomes were synthesized narratively.

2.7. Risk of Bias Assessment

Risk of bias and methodological quality were assessed at study level using a structured domain-based approach adapted for observational studies. Because the included studies had heterogeneous designs, including cross-sectional, case-control, cohort, school-screening, community-based, and mechanistic studies, a single rigid scoring system was not considered appropriate.

The following domains were assessed: selection and representativeness, exposure ascertainment, outcome ascertainment, comparability and confounding, statistical reporting, and overall risk of bias. Studies were categorized as having low risk of bias, some concerns, or high risk of bias.

Exposure ascertainment was judged more favorably when allergic rhinitis was clinically defined using compatible symptoms and allergy-related assessment, or when atopy/IgE sensitization was objectively assessed using skin-prick testing, CAP-FEIA, or specific IgE testing. Outcome ascertainment was judged more favorably when OME was assessed using otoscopy and tympanometry, or when ETD/middle-ear dysfunction was evaluated using objective or validated methods.

Particular attention was given to potential confounding, including age, adenoid hypertrophy, recurrent upper respiratory tract infections, daycare exposure, smoke exposure, previous acute otitis media, and other known risk factors for OME. Studies with clearly defined populations, objective outcome assessment, and adjustment or matching for relevant confounders were considered at lower risk of bias. Small, highly selected, referral-based, non-comparative, or poorly adjusted studies were considered at higher risk of bias or retained only for qualitative interpretation.

2.8 Statistical Analysis

For studies providing extractable 2 × 2 data, crude odds ratios and 95% confidence intervals were calculated. Data were extracted using a consistent convention: **a** = exposed participants with outcome, b = exposed participants without outcome, **c** = unexposed participants with outcome, and d = unexposed participants without outcome. Individual odds ratios were calculated as:

OR = (a × d) / (b × c).

Meta-analyses were performed on log odds ratios using inverse-variance weighting under a random-effects model, because clinical and methodological heterogeneity was expected across studies. Heterogeneity was quantified using the I^2 statistic. No continuity correction was required because none of the included 2 × 2 tables contained zero cells.

The primary meta-analysis pooled studies evaluating allergic rhinitis/rhinitis and OME. An expanded sensitivity analysis additionally included one recent community-based study using a broader clinical symptom-based definition of allergic rhinitis. This study was considered separately because allergic rhinitis did not remain an independent predictor of OME in multivariable analysis.

A secondary random-effects meta-analysis pooled studies evaluating atopy or IgE sensitization and OME. Studies reporting adjusted odds ratios without extractable 2 × 2 data were not pooled directly with crude odds ratios in the main analysis but were considered in narrative or sensitivity interpretation.

ETD and broader middle-ear dysfunction outcomes were not pooled quantitatively because of heterogeneity in definitions, diagnostic methods, and outcome measures. These outcomes were synthesized narratively.

3. Results

3.1. Study Selection

The database and manual searches identified 1201 records. After removal of 245 duplicates, 956 records were screened by title and abstract. Of these, 906 records were excluded as clearly irrelevant, leaving 50 reports sought for retrieval. Four reports could not be retrieved. Therefore, 46 reports were assessed for eligibility.

After eligibility assessment, 26 reports were excluded for reasons including absence of an eligible comparator, lack of extractable data, duplicate or overlapping cohorts, non-eligible outcomes, qualitative/background-only design, or insufficiently verifiable bibliographic information. Overall, 20 studies were included in the qualitative or narrative synthesis, and 9 studies contributed to at least one quantitative synthesis.

The study selection process is shown in Fig. 1.

The diagram summarizes the identification, screening, eligibility assessment, and inclusion of studies in the systematic review and meta-analysis. Background-only references used solely for contextual discussion were not counted as included studies.

3.2. Characteristics of Included Studies

The studies included in the quantitative synthesis were published between 1998 and 2024. Additional qualitative and mechanistic studies used for narrative interpretation covered a broader period, from 1985 to 2024. The included studies were predominantly observational and included cross-sectional, case-control, prospective case-control, birth cohort, school-screening, community-based, and nationally representative cross-sectional designs.

Most studies focused on pediatric populations. Adult or mixed-age studies were retained only when they were relevant to Eustachian tube dysfunction or broader middle-ear dysfunction. The main quantitative synthesis evaluated the association between allergic rhinitis/rhinitis and otitis media with effusion. Six studies contributed to the primary allergic rhinitis/rhinitis–OME meta-analysis [9–14]. One additional community-based study was included in an expanded sensitivity analysis because allergic rhinitis was clinically defined and the adjusted association was not statistically significant [15]. Two studies contributed to the secondary atopy/IgE sensitization–OME meta-analysis [16,17].

OME was most commonly assessed using otoscopy and tympanometry. Some studies used type B tympanograms as the main objective marker, whereas others also considered type C tympanograms, negative middle-ear pressure, absent acoustic reflexes, or persistent effusion criteria. Allergic rhinitis was variably defined using clinical symptoms, physician assessment, nasal findings, questionnaires, or combinations of symptoms and allergy-related history. Atopy and IgE sensitization were assessed more objectively, typically through skin-prick testing, CAP-FEIA, or specific IgE testing.

Studies addressing Eustachian tube dysfunction or middle-ear dysfunction used heterogeneous outcomes, including ETDQ-7 scores, tympanometry, tubomanometry, middle-ear pressure, abnormal tympanogram patterns, mastoid pneumatization, and otologic history. Because of this heterogeneity, these studies were synthesized narratively rather than pooled quantitatively.

The characteristics of included studies are summarized in Table 1.

Table 1
Characteristics of studies included in the systematic review and synthesis.

Study	Country	Design	Population	Exposure	Outcome	Assessment / diagnostic method	Role in synthesis
Pau and Ng, 2016	Hong Kong	Cross-sectional	Children aged 4–12 years	Allergic rhinitis	OME	Pneumatic otoscopy and portable tympanometry	Primary AR/rhinitis–OME meta-analysis
Fasunla et al., 2017	Nigeria	Case-control	Children aged 2–7 years	Allergic rhinitis	OME	AR diagnosed by symptoms and nasal cytology; OME by Jerger tympanometric patterns	Primary AR/rhinitis–OME meta-analysis
Sharifian et al., 2019	Iran	Case-control	37 children with OME and 52 controls	Allergic rhinitis	OME	OME diagnosed by otoscopy and/or type B tympanogram; AR by clinical assessment and allergy testing where indicated	Primary AR/rhinitis–OME meta-analysis
Caffarelli et al., 1998	Italy	Case-control	172 children with OME and 200 controls	Allergic rhinitis / atopic symptoms	OME	OME by otoscopy and type B/C tympanograms; allergic disorders assessed by questionnaire, clinical examination, and skin-prick testing	Primary AR/rhinitis–OME meta-analysis
Yeo et al., 2007	South Korea	Prospective case-control	123 children with chronic OME and 141 controls	Allergic rhinitis	Chronic OME	OME by otoscopy and tympanometry; AR by history, examination, skin testing and/or MAST-CLA	Primary AR/rhinitis–OME meta-analysis
Kayhan et al., 2002	Turkey	Case-control	22 children with OME and 21 controls	Allergic rhinitis	OME	OME by physical examination and tympanometry; AR by symptoms, IgE, skin-prick testing and nasal smear	Primary AR/rhinitis–OME meta-analysis
Adekanye et al., 2024	Nigeria	Community cross-sectional	320 children aged 1–10 years	Clinically defined allergic rhinitis	OME	AR by rhinological symptoms plus allergy/family/asthma history; OME by otoscopy and tympanometry	Expanded sensitivity analysis
Kreiner-Møller et al., 2012	Denmark	Prospective birth cohort	COPSAC children assessed at 6 years	Allergic rhinitis	OME	AR defined by symptoms, sensitization and relevant exposure; OME by otoscopy and tympanometry	Adjusted-OR / narrative sensitivity
Chantzi et al., 2006	Greece	Case-control	88 children with OME and 80 controls, aged 1–7 years	IgE sensitization	OME	OME by symptoms, otoscopy and tympanometry; sensitization by SPT and/or CAP-FEIA	Atopy/IgE–OME meta-analysis
Martines et al., 2010	Italy	School cross-sectional screening	310 primary school children aged 5–6 years	Atopy by SPT	OME	OME by pneumatic otoscopy, type B/C tympanogram, absent acoustic reflex and conductive hearing loss	Atopy/IgE–OME meta-analysis
Ma et al., 2020	China	Prospective controlled cross-sectional study with treatment follow-up	59 adults with house dust mite allergic rhinitis and 59 controls	House dust mite allergic rhinitis	ETD / middle-ear dysfunction	ETDQ-7, tympanography, nasal endoscopy and tubomanometry	ETD narrative synthesis
Adams et al., 2023	USA	NHANES cross-sectional	Adolescents aged 12–19 years	Allergic and non-allergic rhinitis	ETD-related history and tympanometry	Serum IgE, rhinitis classification, tympanometry and otologic history	ETD narrative synthesis
Alles et al., 2001	United Kingdom	Referral-clinic observational study	209 children aged 3–8 years with chronic/recurrent OME	Atopic disorders / allergic rhinitis	Chronic/recurrent OME	Allergy history, examination, nasal smear and SPT	Qualitative synthesis only
Bemanian et al., 2020	Iran	Prospective cross-sectional / treatment-response study	122 children with adenoid hypertrophy and/or OME	Atopy / allergic symptoms	AHT and OME symptoms	OME by otoscopy, audiometry and tympanometry; allergy assessment by symptoms, IgE and SPT in selected patients	Qualitative synthesis only

Study	Country	Design	Population	Exposure	Outcome	Assessment / diagnostic method	Role in synthesis
Kaymakçı et al., 2014/2015	Turkey	Prospective controlled study	33 atopic adults and 30 non-atopic controls	Atopy	Abnormal tympanometry / mastoid pneumatization	Atopy by SPT; tympanometry and 3D temporal CT mastoid volume measurement	Secondary qualitative ETD/middle-ear dysfunction synthesis
Norhafizah et al., 2020	Malaysia	Observational study	Children with OME	Allergic rhinitis	OME	Otologic and audiologic assessment as reported	Qualitative synthesis only
Hurst, 1996	USA	Mechanistic / clinical observational study	Patients with persistent OME	Atopy / allergy	OME and middle-ear inflammation	Skin testing, effusion markers and mucosal biopsy assessment	Mechanistic qualitative synthesis
Boedts et al., 1984	Belgium	Mechanistic observational study	Patients with OME / secretory otitis media	Atopic allergy / IgE	Middle-ear effusion	IgE assessment in effusion and serum	Mechanistic qualitative synthesis
Knight et al., 1992	USA	Seasonal exposure study	Patients with seasonal allergic rhinitis	Seasonal allergic rhinitis / pollen exposure	ETD / middle-ear pressure	Eustachian tube function and middle-ear pressure assessment	ETD qualitative synthesis
Osur et al.	USA	Small seasonal exposure study	Children with ragweed hay fever	Ragweed allergic rhinitis	ETD	Eustachian tube obstruction/function assessment	ETD qualitative synthesis

Footnote: AR, allergic rhinitis; AHT, adenoid hypertrophy; CAP-FEIA, fluorescence enzyme immunoassay; ETD, Eustachian tube dysfunction; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7; IgE, immunoglobulin E; MAST-CLA, multiple allergosorbent chemiluminescent assay; NHANES, National Health and Nutrition Examination Survey; OME, otitis media with effusion; SPT, skin-prick test.

3.3. Primary Meta-Analysis: Allergic Rhinitis/Rhinitis and OME

Six studies were included in the primary random-effects meta-analysis evaluating allergic rhinitis/rhinitis and OME [9–14]. The pooled analysis showed that allergic rhinitis/rhinitis was significantly associated with increased odds of OME:

OR = 3.73, 95% CI 1.79–7.74, $p < 0.001$; $I^2 = 69.7\%$.

The direction of effect generally favored a positive association between allergic rhinitis/rhinitis and OME. Individual study effects varied, contributing to moderate-to-substantial heterogeneity. Yeo et al. reported a weaker, non-significant association than the other studies and was therefore identified as an important contributor to heterogeneity [13].

Individual study-level effect estimates and 2 × 2 data are shown in Table 2, and the forest plot is presented in Fig. 2.

Table 2
Quantitative synthesis data and study-level effect estimates.

Study	Analysis	Exposure	Outcome	a	b	c	d	OR	95% CI	Weight RE (%)	Use / caveat
Pau & Ng 2016	Primary AR/rhinitis–OME	Allergic rhinitis	OME	12	147	3	182	4.95	1.37–17.88	14.7	Patient-level full text
Fasunla et al. 2017	Primary AR/rhinitis–OME	Allergic rhinitis	OME	39	47	8	78	8.09	3.48–18.79	19.7	Patient-level full text
Sharifian et al. 2019	Primary AR/rhinitis–OME	Allergic rhinitis	OME	9	3	28	49	5.25	1.31–21.01	13.6	Case-control full text
Caffarelli et al. 1998	Primary AR/rhinitis–OME	Allergic rhinitis / rhinitis symptoms	OME	28	11	144	189	3.34	1.61–6.94	21.1	SPT positivity not pooled as AR
Yeo et al. 2007	Primary AR/rhinitis–OME	Allergic rhinitis	Chronic OME	35	34	88	107	1.25	0.72–2.17	23.2	Counts explicitly reported; heterogeneity driver
Kayhan et al. 2002	Primary AR/rhinitis–OME	Allergic rhinitis	OME	5	1	17	20	5.88	0.62–55.38	7.6	Small study
Pooled random-effects	Primary AR/rhinitis–OME	-	-	-	-	-	-	3.73	1.79–7.74	-	I^2 = 69.7%; p = 0.0004266
Adekanye et al. 2024	Expanded sensitivity AR/rhinitis–OME	Clinically defined allergic rhinitis	OME	12	33	32	243	2.76	1.30–5.88	-	Added in expanded sensitivity; adjusted association not significant
Pooled random-effects incl. Adekanye	Expanded sensitivity AR/rhinitis–OME	-	-	-	-	-	-	3.46	1.92–6.23	-	I^2 = 63.7%; p = 0.0000365
Chantzi et al. 2006	Secondary atopy/IgE–OME	IgE sensitization	OME	28	12	60	68	2.64	1.24–5.66	49.7	SPT and/or CAP-FEIA; adjusted OR 2.52
Martines et al. 2010	Secondary atopy/IgE–OME	Atopy by SPT	OME	24	32	16	238	11.16	5.36–23.20	50.3	School screening; objective OME criteria
Pooled random-effects	Secondary atopy/IgE–OME	-	-	-	-	-	-	5.45	1.33–22.35	-	I^2 = 86.0%; p = 0.01846

a = exposed participants with outcome; b = exposed participants without outcome; c = unexposed participants with outcome; d = unexposed participants without outcome. Individual odds ratios were calculated as OR = (a × d)/(b × c). Dashes indicate not applicable for pooled random-effects estimates. AR, allergic rhinitis; CAP-FEIA, fluorescence enzyme immunoassay; CI, confidence interval; IgE, immunoglobulin E; OME, otitis media with effusion; OR, odds ratio; RE, random effects; SPT, skin-prick test.

Random-effects analysis of studies evaluating allergic rhinitis/rhinitis and OME. Odds ratios greater than 1 indicate higher odds of OME among children with allergic rhinitis/rhinitis. CI, confidence interval; OME, otitis media with effusion; OR, odds ratio.

3.4. Expanded Sensitivity Analysis Including Adekanye et al. 2024

An expanded sensitivity analysis was performed by adding one recent community-based study that used a clinical symptom-based definition of allergic rhinitis [15]. In this study, children with allergic rhinitis had a higher prevalence of OME than children without allergic rhinitis; however, allergic rhinitis did not remain an independent predictor of OME in multivariable analysis [15]. Therefore, this study was not used as a primary driver of the main pooled estimate but was included in an expanded sensitivity model.

After inclusion of this additional study, the association remained statistically significant:

OR = 3.46, 95% CI 1.92–6.23, $p < 0.001$; I^2 = 63.7%.

Compared with the primary analysis, the pooled effect changed only modestly, and heterogeneity decreased from 69.7% to 63.7%. This supports the stability of the association between allergic rhinitis/rhinitis and OME.

3.5. Secondary Meta-Analysis: Atopy/IgE Sensitization and OME

Two studies were included in the secondary random-effects meta-analysis evaluating atopy or IgE sensitization and OME [16,17]. This analysis was kept separate from the allergic rhinitis/rhinitis analysis because allergic sensitization and clinically expressed allergic rhinitis are related but distinct constructs.

The pooled analysis showed a significant association between atopy/IgE sensitization and OME:

OR = 5.45, 95% CI 1.33–22.35, p = 0.018; I^2 = 86.0%.

This result suggests that allergic sensitization may be associated with increased odds of OME. However, the finding should be interpreted cautiously because the analysis included only two studies and heterogeneity was high.

The study-level data and pooled estimate are shown in Table 2, and the forest plot is presented in Fig. 3.

Random-effects meta-analysis of studies evaluating atopy or IgE sensitization and OME. Odds ratios greater than 1 indicate higher odds of OME among children with atopy or IgE sensitization. CI, confidence interval; IgE, immunoglobulin E; OME, otitis media with effusion; OR, odds ratio.

3.6. Narrative Synthesis of Eustachian Tube Dysfunction and Middle-Ear Dysfunction

The evidence regarding allergic rhinitis, ETD, and middle-ear dysfunction was synthesized narratively because the included studies used heterogeneous populations, diagnostic tools, and outcomes. Some studies assessed Eustachian tube function using ETDQ-7, tympanometry, tubomanometry, or middle-ear pressure measurements, while others evaluated abnormal tympanograms, otologic history, tympanostomy tube placement, or mastoid pneumatization.

Overall, the ETD and middle-ear dysfunction literature supported biological plausibility for a relationship between allergic rhinitis or atopy and altered middle-ear physiology. Controlled and observational studies suggested that allergic rhinitis may be associated with abnormal Eustachian tube function, negative middle-ear pressure, abnormal tympanometric patterns, or history of otologic disease [18–20]. However, the outcomes were not sufficiently homogeneous to allow a robust pooled estimate.

Therefore, ETD and middle-ear dysfunction were retained as secondary narrative outcomes rather than as a main quantitative endpoint.

3.7. Qualitative and Mechanistic Evidence

Several studies were retained for qualitative synthesis because they were clinically relevant but unsuitable for quantitative pooling. These included OME-only referral cohorts, adenoid hypertrophy/OME mixed cohorts, treatment-response studies, mechanistic studies, and studies assessing allergic inflammation or middle-ear dysfunction without a clean comparator group [21–28].

OME referral-clinic studies reported high prevalences of allergic rhinitis, asthma, eczema, or positive skin-prick testing among children with chronic or recurrent OME, but these studies lacked non-OME comparator groups and were therefore not included in the main meta-analysis [21]. Other studies examined allergic inflammation, middle-ear effusion mediators, or Eustachian tube physiology and were used to support mechanistic interpretation rather than quantitative risk estimation [24–28].

Adult or mixed-age studies evaluating atopy and abnormal tympanometry were also considered relevant for the broader concept of middle-ear dysfunction, but they were not pooled with pediatric OME studies because their outcomes were not equivalent to clinically diagnosed OME [23].

3.8. Risk of Bias

The risk of bias assessment is summarized in Table 3. Overall, most studies had some concerns due to observational design, variable definitions of allergic rhinitis or allergy, referral-based sampling, small sample size, and incomplete adjustment for confounding.

The main sources of bias were heterogeneous exposure definitions, especially when allergic rhinitis was defined only by symptoms or questionnaire; variable OME diagnostic criteria across studies; incomplete adjustment for age, adenoid hypertrophy, upper respiratory tract infections, daycare exposure, smoke exposure, and previous acute otitis media; referral bias in clinic-based OME cohorts; and small sample sizes in some older case-control studies.

Studies using objective OME assessment and clearer allergic sensitization definitions were judged as having lower risk of bias. In contrast, small, older, or highly selected referral-based studies were judged as having higher risk of bias or were retained only for qualitative synthesis.

Table 3
Risk of bias summary for studies included in quantitative and qualitative synthesis.

Study	Design	Analysis role	Selection	Exposure	Outcome	Confounding	Reporting	Overall RoB	Main rationale
Pau & Ng 2016	Cross-sectional	Primary AR/rhinitis–OME meta-analysis	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns	AR clinically/questionnaire assessed; OME by otoscopy/tympanometry; limited adjustment.
Fasunla et al. 2017	Case-control	Primary AR/rhinitis–OME meta-analysis	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns	AR by symptoms and nasal cytology; OME by tympanometry; hospital-based sample.
Sharifian et al. 2019	Case-control	Primary AR/rhinitis–OME meta-analysis	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns	Small sample; OME objectively assessed; limited adjustment.
Caffarelli et al. 1998	Case-control	Primary AR/rhinitis–OME meta-analysis	Some concerns	Low	Low	Some concerns	Low	Some concerns	Allergy evaluated clinically with SPT; OME objectively defined; older design.
Yeo et al. 2007	Prospective case-control	Primary AR/rhinitis–OME meta-analysis	Some concerns	Low	Low	Some concerns	Some concerns	Some concerns	Objective OME diagnosis; non-significant association; heterogeneity contributor.
Kayhan et al. 2002	Case-control	Primary AR/rhinitis–OME meta-analysis	High	Some concerns	Some concerns	High	Some concerns	High	Very small sample and limited reporting; unclear adjustment.
Adekanye et al. 2024	Community cross-sectional	Expanded sensitivity analysis	Low	Some concerns	Low	Some concerns	Low	Some concerns	Community sample; AR clinically defined; adjusted association not significant.
Kreiner-Møller et al. 2012	Prospective birth cohort	Adjusted-OR / narrative sensitivity	Low	Low	Low	Low	Low	Low	Prospective birth cohort; clear definitions; adjusted for relevant confounders.
Chantzi et al. 2006	Case-control	Atopy/IgE–OME meta-analysis	Some concerns	Low	Low	Low	Low	Low to some concerns	Matched groups; objective sensitization and OME; multivariable analysis.
Martines et al. 2010	School cross-sectional screening	Atopy/IgE–OME meta-analysis	Low	Low	Low	Some concerns	Low	Some concerns	School screening with SPT-defined atopy and strict audiological OME criteria.
Ma et al. 2020	Controlled cross-sectional + follow-up	ETD narrative synthesis	Some concerns	Low	Low	Some concerns	Low	Some concerns	Objective ETD assessment; single-center and heterogeneous outcomes.
Adams et al. 2023	NHANES cross-sectional	ETD narrative synthesis	Low	Some concerns	Some concerns	Low	Low	Some concerns	National data and adjusted models; ETD inferred from tympanometry/history.
Alles et al. 2001	Referral-clinic observational	Qualitative only	High	Some concerns	Some concerns	High	Some concerns	High	Selected clinic cohort with no non-OME comparator.
Bemanian et al. 2020	Prospective cross-sectional / treatment response	Qualitative only	Some concerns	Some concerns	Some concerns	High	Some concerns	High	Mixed AHT/OME cohort; no clean comparator.
Kaymakçı et al. 2014/2015	Prospective controlled	Secondary qualitative ETD/middle-ear dysfunction	Some concerns	Low	Some concerns	Some concerns	Low	Some concerns	Outcome was abnormal tympanogram/mastoid volume, not OME.

Risk of bias was assessed across the following domains: selection and representativeness, exposure ascertainment, outcome ascertainment, comparability and confounding, and statistical reporting. Studies were categorized as low risk, some concerns, or high risk of bias. AR, allergic rhinitis; ETD, Eustachian tube dysfunction; OME, otitis media with effusion

Study	Design	Analysis role	Selection	Exposure	Outcome	Confounding	Reporting	Overall RoB	Main rationale
Knight et al. 1992	Seasonal exposure cohort	ETD qualitative synthesis	High	Low	Low	High	Some concerns	High	No non-AR comparator; mechanistic support only.
Osur et al.	Small seasonal exposure study	ETD qualitative synthesis	High	Low	Low	High	Some concerns	High	Very small ragweed hay fever cohort without classical comparator.

Risk of bias was assessed across the following domains: selection and representativeness, exposure ascertainment, outcome ascertainment, comparability and confounding, and statistical reporting. Studies were categorized as low risk, some concerns, or high risk of bias. AR, allergic rhinitis; ETD, Eustachian tube dysfunction; OME, otitis media with effusion

4. Discussion

4.1. Main Findings

In this systematic review and meta-analysis, allergic rhinitis/rhinitis was significantly associated with pediatric otitis media with effusion. The primary random-effects analysis showed that children with allergic rhinitis or rhinitis had higher odds of OME than children without allergic rhinitis/rhinitis. The pooled estimate was OR = 3.73, with a 95% confidence interval of 1.79–7.74. Although heterogeneity was moderate to substantial, the direction of effect was generally consistent across the included studies [9–14].

The expanded sensitivity analysis, which added the recent community-based study by Adekanye et al., showed a similar result. The pooled estimate remained significant, with OR = 3.46, 95% CI 1.92–6.23, and heterogeneity decreased slightly [15]. This supports the stability of the overall association. At the same time, the Adekanye study deserves a cautious interpretation because allergic rhinitis was clinically defined and did not remain an independent predictor of OME after multivariable adjustment [15].

A separate secondary meta-analysis showed that atopy or IgE sensitization was also associated with OME, with OR = 5.45, 95% CI 1.33–22.35 [16,17]. This finding is clinically relevant, but it should not be overinterpreted. Only two studies were included in this analysis, and heterogeneity was high. Therefore, the result supports a possible association between allergic sensitization and OME, but it does not provide strong evidence of causality.

The evidence regarding allergic rhinitis and Eustachian tube dysfunction or broader middle-ear dysfunction was more heterogeneous. Studies used different outcomes, including ETDQ-7, tympanometry, tubomanometry, middle-ear pressure, abnormal tympanogram patterns, mastoid pneumatization, and otologic history [19,20,23,27,28]. For this reason, ETD and middle-ear dysfunction were not pooled quantitatively.

4.2. Interpretation in Relation to Previous Literature

Our findings are broadly consistent with previous evidence suggesting that allergic rhinitis and allergy are associated with OME [6]. However, the present review adds a more clinically structured interpretation. Rather than pooling all allergy-related exposures together, we separated allergic rhinitis/rhinitis from atopy and IgE sensitization. This distinction is important because allergic rhinitis is a symptomatic inflammatory disease of the nasal mucosa, whereas sensitization may exist without clinically relevant nasal disease.

Previous reviews have emphasized that the reported prevalence of allergic rhinitis or atopy in children with OME varies widely, partly because of differences in diagnostic criteria, referral setting, age group, and OME definitions [1–3]. This variability was also evident in the present review. Some studies reported a clear positive association between allergic rhinitis and OME [9–12,14], whereas Yeo et al. found no significant difference in allergic rhinitis prevalence between children with OME and controls [13]. The inclusion of this weaker study is important because it prevents an overly selective interpretation of the evidence.

The moderate-to-substantial heterogeneity in the primary analysis is therefore not surprising. It probably reflects real differences between study populations and diagnostic methods, not only statistical noise. Studies differed in how allergic rhinitis was defined, whether objective allergy testing was used, how OME was diagnosed, and whether confounders such as age, adenoid hypertrophy, daycare exposure, or recurrent upper respiratory infections were considered.

4.3. Allergic Rhinitis and Atopy Should Not Be Treated as the Same Exposure

One of the main methodological choices in this review was to avoid combining allergic rhinitis, atopy, and IgE sensitization into a single exposure category. This matters clinically. A child may have positive skin-prick testing or specific IgE without having symptomatic allergic rhinitis. Conversely, a child may have rhinitis symptoms in a clinical study without a complete allergological workup.

This separation helped keep the interpretation more precise. The primary analysis evaluated allergic rhinitis or rhinitis in relation to OME [9–15]. The secondary analysis evaluated atopy or IgE sensitization in relation to OME [16,17]. The stronger pooled odds ratio in the atopy/IgE analysis should be interpreted carefully, because it was based on only two studies. It may reflect a true biological association, but it may also reflect differences in design, case definition, and outcome assessment.

Chantzi et al. reported that IgE sensitization remained independently associated with OME after multivariable analysis [16]. Martines et al. found a markedly higher prevalence of OME among atopic children than among non-atopic children in a school-screening population [17]. These findings support the relevance of allergic sensitization, but they do not prove that sensitization alone is sufficient to produce OME.

4.4. Biological Plausibility

Several mechanisms may explain the observed association between allergic rhinitis and OME. The Eustachian tube links the nasopharynx to the middle-ear cavity and is essential for ventilation, pressure regulation, and clearance. Allergic inflammation in the nose and nasopharynx may promote mucosal edema around the pharyngeal opening of the Eustachian tube, impair tubal opening, and contribute to negative middle-ear pressure [4,5].

The concept of a continuous upper-airway inflammatory pathway is also relevant. Yu et al. described several mechanisms through which allergic inflammation may contribute to ETD, including Th2-mediated inflammation, mucosal swelling, impaired mucociliary clearance, surfactant alterations, and extension of inflammation from the nasopharynx toward the Eustachian tube [4]. These mechanisms are compatible with the association observed in the present meta-analysis.

At the same time, the mechanism is unlikely to be simple or universal. Doyle et al. investigated whether the middle ear could behave as an allergic “shock organ” in a passively sensitized rhesus monkey model, but allergen challenge did not induce OME [7]. Fireman also emphasized that intranasal antigen or histamine challenge may induce transient Eustachian tube obstruction without necessarily producing middle-ear effusion [5]. These findings support a more cautious interpretation: allergic inflammation may contribute to OME in susceptible children, but it is unlikely to be sufficient as an isolated cause in all cases.

This interpretation fits the clinical reality of OME. Age, adenoid hypertrophy, viral infections, daycare exposure, smoke exposure, craniofacial factors, and previous acute otitis media may all influence OME risk. Allergic rhinitis may interact with these factors rather than act independently in every patient.

4.5. Eustachian Tube Dysfunction and Middle-Ear Dysfunction

The narrative ETD findings support biological plausibility, but they should be interpreted separately from OME. Ma et al. evaluated patients with house dust mite allergic rhinitis using ETDQ-7, tympanometry, nasal endoscopy, and tubomanometry, and found evidence of altered Eustachian tube function in allergic rhinitis [19]. Adams et al., using NHANES data, reported associations between rhinitis and otologic history in adolescents, although not necessarily with abnormal tympanometry at the time of assessment [20].

These studies are relevant because they suggest that allergic rhinitis may affect middle-ear physiology even when OME is not the immediate endpoint. However, ETD is not measured uniformly across studies. Symptoms, tympanometric patterns, tubomanometry results, middle-ear pressure, and tympanostomy history are related but not identical outcomes. Pooling these data would risk producing a statistically neat but clinically weak result. For that reason, we treated ETD and middle-ear dysfunction as narrative outcomes.

4.6. Clinical Implications

The results support a phenotype-based approach rather than a universal allergy-based explanation for OME. Children with persistent allergic rhinitis, nasal obstruction, recurrent ear symptoms, suspected hearing loss, speech delay, or abnormal otoscopy may benefit from tympanometric evaluation and closer ENT follow-up.

However, this review does not show that all children with OME should receive allergy-directed treatment. OME remains multifactorial, and most included studies were observational. In addition, spontaneous resolution is common, which makes treatment-response studies difficult to interpret without adequate controls [1]. Allergy treatment is clinically appropriate when allergic rhinitis is present, but OME management should still follow otologic principles, including watchful waiting when appropriate, hearing evaluation, tympanometric monitoring, and surgical referral when indicated.

A practical implication is that pediatric ENT and allergy/immunology should not work in isolation in selected cases. Children with persistent OME and clear allergic rhinitis symptoms may require both middle-ear assessment and proper rhinitis phenotyping. This does not mean that allergy explains every case of OME, but it may identify a subgroup in whom nasal inflammation contributes to middle-ear dysfunction.

4.7. Strengths

This review has several strengths. It provides an updated synthesis including studies published up to 2024, and it incorporates both classic controlled studies and more recent community-based evidence. It also separates allergic rhinitis/rhinitis from atopy or IgE sensitization, which improves clinical interpretability.

Another strength is the conservative handling of heterogeneous outcomes. OME, ETD, abnormal tympanometry, and middle-ear dysfunction were not treated as interchangeable endpoints. ETD-related evidence was summarized narratively, which is more appropriate given the variability in diagnostic tools and outcome definitions.

The review also included sensitivity analysis. The primary AR/rhinitis–OME association remained significant after adding Adekanye et al. [15], suggesting that the finding was not dependent on a single narrow set of studies. Finally, unverifiable records and studies without adequate extractable data were not forced into the meta-analysis.

4.8. Limitations

The main limitation is the observational nature of the included evidence. Most studies were case-control or cross-sectional, so causality cannot be inferred. The association between allergic rhinitis and OME may be influenced by shared risk factors, referral patterns, or residual confounding.

Heterogeneity was also important. Definitions of allergic rhinitis varied across studies, ranging from clinical symptoms to physician diagnosis, questionnaires, nasal cytology, or allergy testing. OME definitions also varied, with some studies using type B tympanograms alone and others including type

C tympanograms, persistent effusion criteria, absent acoustic reflexes, or surgical indications.

Confounding was inconsistently addressed. Age, adenoid hypertrophy, upper respiratory tract infections, daycare exposure, smoke exposure, previous acute otitis media, and socioeconomic factors may all influence the risk of OME. Some studies adjusted for these factors, but many did not. Small sample size and older reporting standards also limited the reliability of some studies, particularly in older case-control designs.

The atopy/IgE analysis was limited to two studies and showed high heterogeneity. Therefore, that pooled estimate should be considered supportive rather than definitive. The ETD literature was too heterogeneous for pooling, and the conclusions in that area should be regarded as hypothesis-generating.

4.9. Future Research

Future studies should use standardized definitions of both allergic rhinitis and OME. Ideally, allergic rhinitis should be diagnosed using compatible nasal symptoms, evidence of sensitization, and relevant allergen exposure. OME should be confirmed using otoscopy and tympanometry, with clear separation between type B tympanograms, type C tympanograms, negative middle-ear pressure, and persistent effusion.

Future research should also adjust for major confounders, including age, adenoid hypertrophy, recurrent upper respiratory infections, daycare attendance, smoke exposure, previous acute otitis media, and craniofacial or developmental risk factors. For ETD, studies should combine validated symptom scores with objective measures such as tympanometry, tubomanometry, sonotubometry, or pressure-equilibration testing.

Clinical trials of allergy-directed treatment should focus on children with clearly defined allergic rhinitis phenotypes and should use objective middle-ear outcomes. Without this type of design, it will remain difficult to distinguish true treatment effect from spontaneous resolution or nonspecific improvement.

5. Conclusions

This systematic review and meta-analysis found that allergic rhinitis/rhinitis is significantly associated with pediatric otitis media with effusion. The association remained stable in sensitivity analysis, suggesting that the finding is not dependent on a single study or on a narrowly defined dataset. Atopy and IgE sensitization also appear to be associated with OME, although this evidence is more limited and heterogeneous.

The available data support a biologically plausible link between allergic inflammation, Eustachian tube dysfunction, and middle-ear disease. However, the evidence does not support allergy as a universal or isolated cause of OME. OME remains a multifactorial condition, influenced by age, upper-airway infections, adenoid-related factors, environmental exposures, and host susceptibility.

From a clinical perspective, allergic rhinitis and allergic sensitization should be considered potential contributing factors in selected pediatric OME phenotypes, particularly when persistent nasal symptoms coexist with hearing complaints, recurrent ear symptoms, speech delay, or abnormal tympanometry. A phenotype-based approach involving both otolaryngology and allergy/immunology is therefore more appropriate than routine allergy-directed treatment for all children with OME.

Abbreviations

AOM	Acute otitis media
AR	Allergic rhinitis
CI	Confidence interval
ENT	Ear, nose, and throat
ETD	Eustachian tube dysfunction
ETDQ-7	Eustachian Tube Dysfunction Questionnaire-7
IgE	Immunoglobulin E
MEP	Middle-ear pressure
NHANES	National Health and Nutrition Examination Survey
OME	Otitis media with effusion
OR	Odds ratio
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SPT	Skin-prick test
URTI	Upper respiratory tract infection

Declarations

Author Contributions: Conceptualization, A.-M.P.; methodology, A.-M.P.; formal analysis, A.-M.P.; data curation, A.-M.P.; writing—original draft preparation, A.-M.P.; writing—review and editing, A.-M.P., R.C. and I.A.; supervision, R.C. and I.A. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest: The authors declare no conflicts of interest.

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Figures

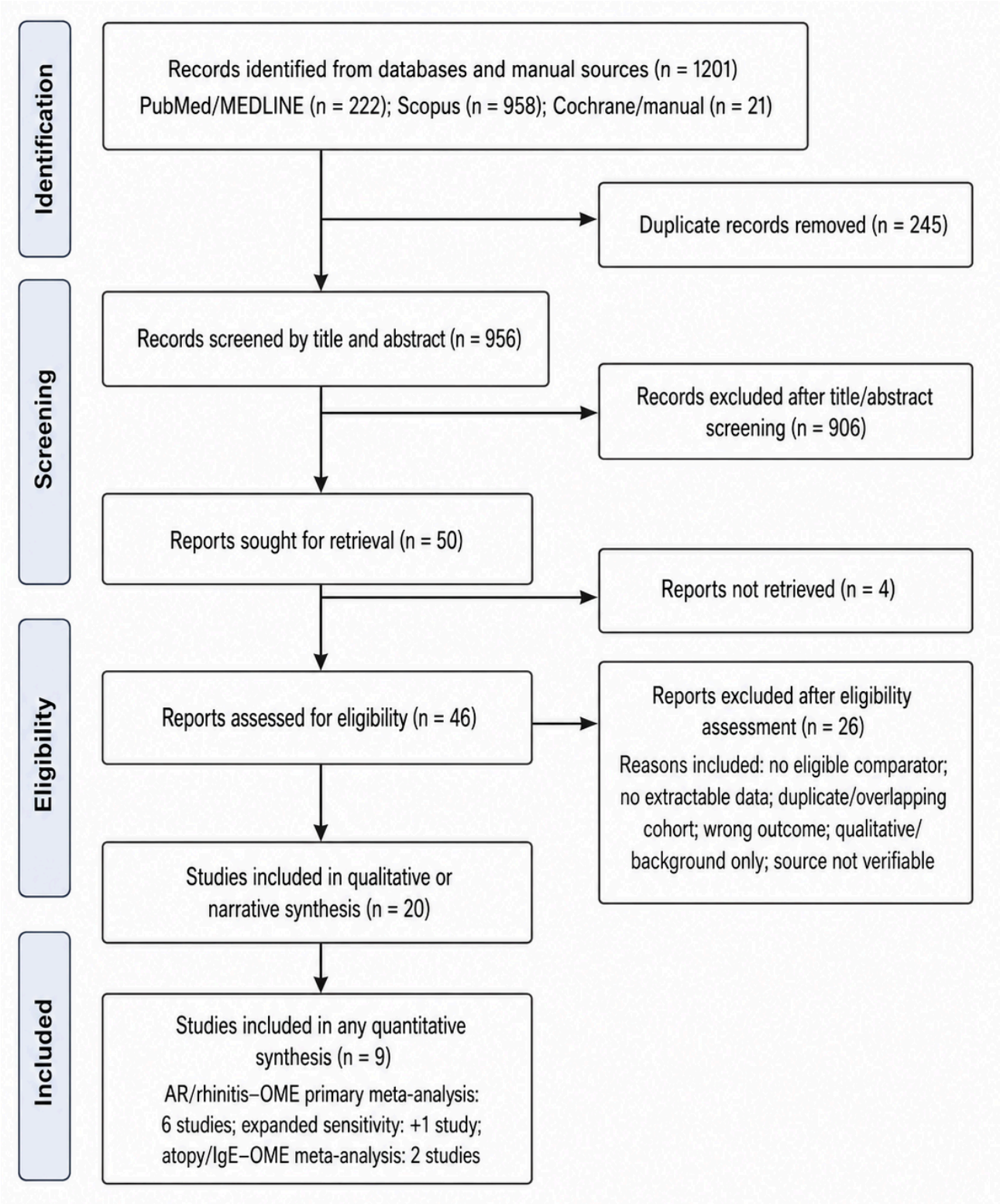


Figure 1

PRISMA 2020 flow diagram of study selection.
The diagram summarizes the identification, screening, eligibility assessment, and inclusion of studies in the systematic review and meta-analysis. Background-only references used solely for contextual discussion were not counted as included studies.

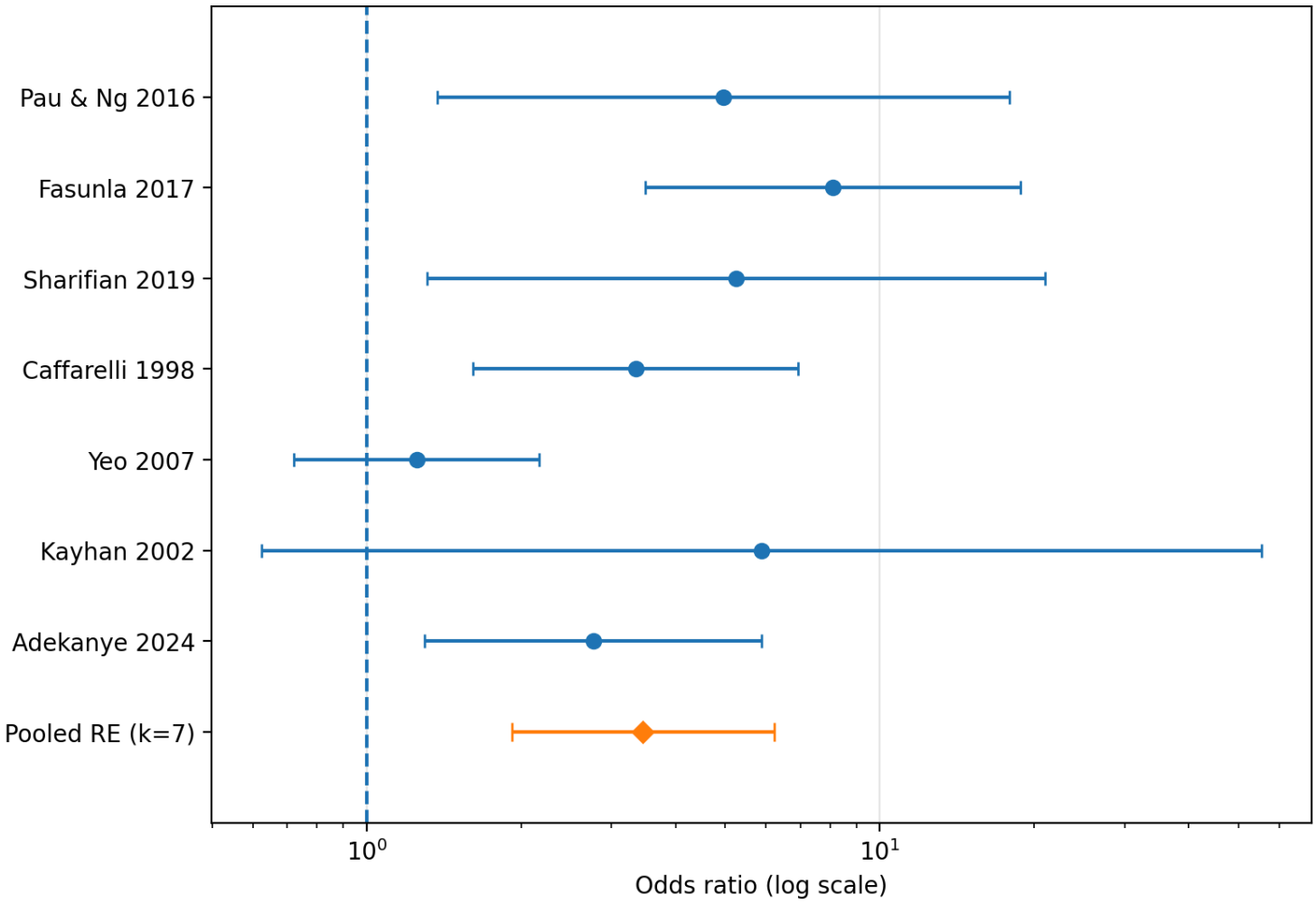


Figure 2

Forest plot of the association between allergic rhinitis/rhinitis and pediatric otitis media with effusion, including the expanded sensitivity analysis

Random-effects analysis of studies evaluating allergic rhinitis/rhinitis and OME. Odds ratios greater than 1 indicate higher odds of OME among children with allergic rhinitis/rhinitis. CI, confidence interval; OME, otitis media with effusion; OR, odds ratio.

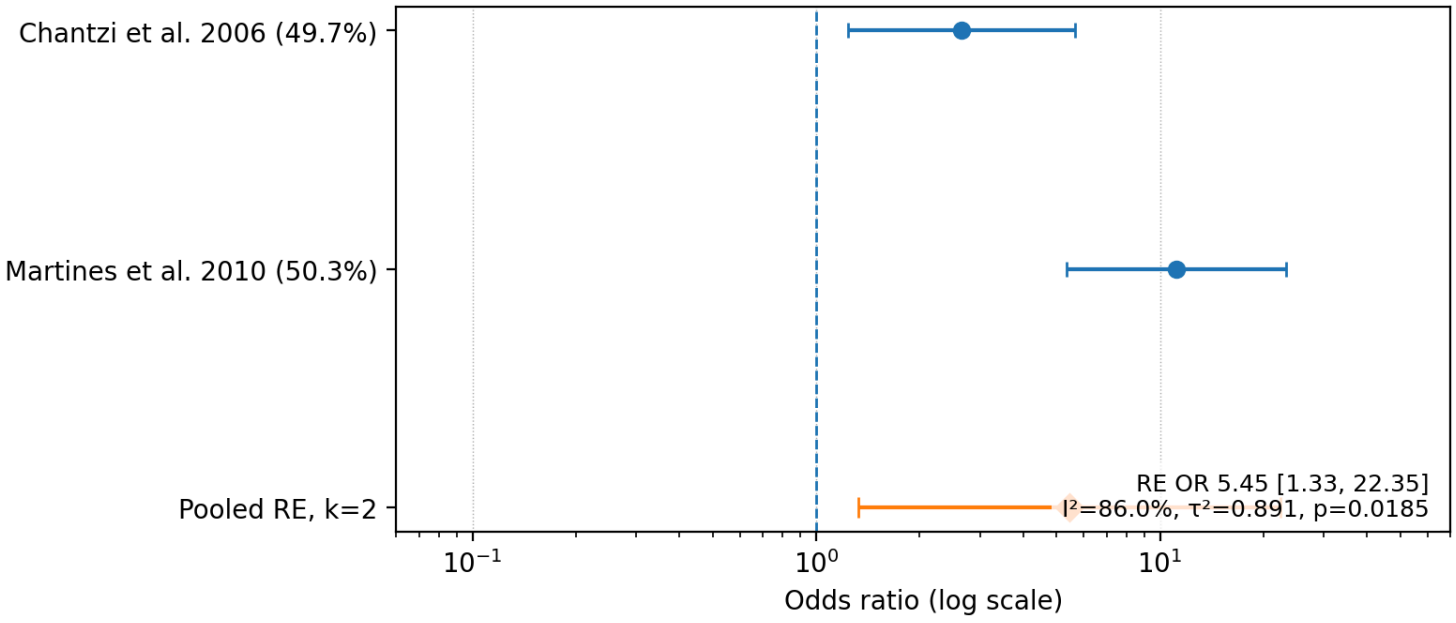


Figure 3

Forest plot of the association between atopy/IgE sensitization and pediatric otitis media with effusion.

Random-effects meta-analysis of studies evaluating atopy or IgE sensitization and OME. Odds ratios greater than 1 indicate higher odds of OME among children with atopy or IgE sensitization. CI, confidence interval; IgE, immunoglobulin E; OME, otitis media with effusion; OR, odds ratio.

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