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Review

Systemic Corticosteroids in Pediatric Otitis Media: A Systematic Review and Meta-Analysis

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Abstract: Otitis media is a common childhood condition that affects public health because of its frequency, recurrence, and potential long-term consequences. This systematic review and meta-analysis assessed the efficacy and safety of systemic corticosteroids (SCS) in children with acute otitis media and otitis media with an effusion. A comprehensive search of PubMed, Scopus, and Web of Science identified relevant studies published between January 2018 and August 2025. The primary outcomes were effusion resolution, hearing loss, and otitis media recurrence. Secondary outcomes included pain relief, tympanostomy tube placement, speech and language development, quality of life, and adverse events. Four studies, including two Cochrane reviews, one randomized controlled trial, and one meta-analysis, were analyzed. The results showed that SCS provided short-term improvements in effusion clearance and hearing, with risk ratios from 1.08 to 1.20. However, these benefits were temporary, with no significant long-term effects on recurrence rates, persistent effusion, or developmental outcomes. Safety data were limited, with most adverse events being mild and self-resolving. The studies had moderate heterogeneity due to differences in population characteristics, intervention protocols, and outcome definitions. Results suggest that SCS may offer short-term symptom relief in certain cases but cannot be recommended for routine management of pediatric otitis media. Future research should prioritize large-scale multicenter trials with standardized outcomes,

extended follow-up periods, and thorough safety assessments to identify the subgroups that might benefit the most from SCS treatment.

Keywords: Otitis Media; Acute Otitis Media; Otitis Media with Effusion; Intranasal Corticosteroids; Systemic Corticosteroids

1. Introduction

Otitis media (OM) is a prevalent childhood condition and remains a significant public health issue because of its high occurrence, recurrence, quality of life (QoL) impact, and potential long-term consequences. The main forms are acute OM (AOM) and OM with effusion (OME), which differ in their pathophysiology, symptoms, and treatment.

AOM is among the most commonly diagnosed bacterial infections in children and is a primary reason for antibiotic prescriptions in pediatric care, with visits only surpassed by well-child check-ups [1,2]. Prospective cohort studies indicate that 60% of children experience at least one AOM episode by age 3, with a peak incidence between 6–12 months; approximately 24% have three or more episodes by age 3 [3].

OME, characterized by fluid in the middle ear without acute infection, is common, with an incidence of 80–90% by school age. While many OME cases follow AOM, they can develop independently of Eustachian tube (ET) dysfunction. Hearing loss is common, and OME often persists throughout early childhood, requiring monitoring and sometimes surgery [4,5].

OM causes millions of pediatric consultations yearly and drives antibiotic prescriptions and outpatient surgeries, such as tympanostomy tube insertions, in children [1, 2, 4]. The condition incurs high costs from sleep disturbances, pain, missed school, and caregiver work absences, as well as medical visits, medications, and procedures [1,2,4]. Although AOM can resolve spontaneously, studies in children aged 6–23 months show that antibiotics reduce clinical failure compared to placebo, highlighting benefits and stewardship considerations [6,7]. For recurrent AOM, studies show that tympanostomy tubes do not decrease overall AOM episodes over two years compared to medical treatment, though they delay the first recurrence while increasing otorrhea days, affecting the QoL [8,9].

Persistent OME causes conductive hearing loss in children. Meta-analyses show tympanostomy tubes provide 9 dB hearing improvement at 1–3 months versus watchful waiting, with no benefit by 12–24 months [4]. Hearing loss during critical periods can impact classroom performance [4, 10]. A trial comparing early versus delayed tube insertion found no advantage of immediate tubes on developmental outcomes by age 3, indicating that routine early surgery is unnecessary in healthy children [5]. This emphasizes the need for targeted support over automatic surgical timing [5,10]. Patients with recurrent AOM experienced ≥3 episodes in 6 months or ≥4 episodes in 12 months.

Since many AOM cases resolve spontaneously, symptomatic treatment is often sufficient for mild cases and remains essential, whether antibiotics are used [2,11]. Antibiotics are the primary treatment for AOM, with high-dose amoxicillin as initial therapy. Amoxicillin–clavulanate is reserved for children who have recently taken antibiotics, are severely ill, have purulent conjunctivitis, or have β-lactamase–producing pathogens [2,11]. Studies show that antibiotics modestly reduce pain, fever, and clinical failure compared to placebos within 2–7 days, with a number needed to treat of 9 [11]. In children aged 6–23 months, amoxicillin–clavulanate reduced symptom severity and clinical failure compared to placebo by days 4–5 and 10–12, but increased diarrhea [6]. For young children, 10-day treatment has proven more effective than 5-day treatment [7]. Different antibiotic classes show comparable effectiveness, supporting the use of amoxicillin-based treatments [11]. AOM remains a major cause of pediatric antibiotic prescriptions; careful management is important given the modest benefits and post-vaccine era microbiology affecting treatment choices [1–3,11]. The priority is to limit antibiotics to clear AOM cases while emphasizing pain relief [2,11,12].

Studies have shown that wait-and-see prescriptions reduce filled antibiotic prescriptions from 87% to 38–45%, without increasing fever, pain, or unplanned visits [13, 14]. This prevents unnecessary antibiotic exposure while ensuring safety through follow-up procedures [2,11–14].

Antibiotics, decongestants, and antihistamines are not recommended for routine OME management because most effusions resolve within three months. Treatment focuses on observation and addressing risk factors [2]. Tympanostomy tubes may be considered for bilateral OME with hearing loss. A meta-analysis showed 9 dB hearing

improvement at 1–3 months versus watchful waiting, with no benefit by 12–24 months [4].

Corticosteroids (CS) have strong anti-inflammatory properties by suppressing pro-inflammatory cytokines (such as Interleukin-1β and Tumor Necrosis Factor-α), eicosanoids, and adhesion molecules, leading to decreased leukocyte movement, capillary permeability, and tissue swelling. In OM, this results in three mechanisms: By reducing swelling and secretion, CS can restore tympanic membrane mobility and decrease middle ear negative pressure, contributing to fluid retention, especially in OME [15]. Steroids improve ventilation and middle ear fluid clearance by reducing nasopharyngeal and ET mucosal swelling, breaking the cycle of inflammation and fluid accumulation [15,16].

Systemic therapy exerts anti-inflammatory effects throughout the middle ear, ET, and upper airway mucosa. Studies have shown that oral prednisolone with amoxicillin results in higher effusion-free cases than amoxicillin alone (33% vs. 17% at two weeks) in children with chronic OME. However, this benefit diminishes within two weeks after treatment, with a high recurrence rate by four months [15].

As ET dysfunction is often affected by nasopharyngeal inflammation and allergies, intranasal CS (INCS) are used to reduce swelling while minimizing systemic exposure. Studies have shown that both INCS and systemic CS (SCS) improve OME in the short term, with neither showing a clear advantage. INCS may be safer for some children, although the studies are small and the effects are temporary [16]. Although INCS have a good safety profile, their long-term impact on effusion remains uncertain, supporting an observation-first approach [17].

Randomized studies have shown that SCS temporarily improve effusion clearance and hearing within 2–4 weeks. In a double-blind randomized controlled trial (RCT), prednisolone with amoxicillin showed higher effusion clearance at two weeks than amoxicillin alone (33.3% vs. 16.7%), although this difference diminished by four weeks [15].

In AOM cases, antibiotics provide minimal advantage over no treatment and increase side effects, highlighting the need for a precise diagnosis rather than SCS [11]. "Wait-and-see" strategies reduce antibiotic use without worsening symptoms [4,13,14]. While surgical ventilation improves short-term hearing, it shows no benefits at 12–24 months [4]. Early tube placement did not enhance language or cognitive development at 3 years compared to delayed placement for persistent OME [5].

SCS address inflammation in the middle ear, ET, and upper airway, providing broader effects than intranasal treatments and achieving short-term effusion resolution [15]. However, the benefits are temporary, with recurrences, and repeated use raises concerns about behavioral changes, sleep disturbances, gastrointestinal issues, and adrenal suppression risks disproportionate to a self-limiting condition [15,18].

Studies have shown no lasting decrease in OME recurrence, hearing improvement, or advances in speech/language development. The recurring pattern after resolution indicates the need for treatments that alter the disease course rather than temporary relief [15,18]. Research has shown that faster effusion resolution does not guarantee better developmental outcomes [4,5,18]. Evidence does not support the use of SCS for preventing chronic OME, with high relapse rates [15,18].

AOM is a leading cause of antibiotic prescriptions in children. While antibiotics provide short-term symptom improvement, they cause adverse effects and resistance, necessitating an accurate diagnosis [2,11]. Studies have shown that wait-and-see prescriptions reduce antibiotic use without worsening outcomes [13,14]. If CS can reduce inflammation and pain and improve hearing, they may decrease the need for antibiotics. However, systemic steroids show only brief benefits in OME without reducing effusion persistence [15,18]. For AOM, guidelines emphasize pain management and selective antibiotic use; CS are not standard treatment and have not shown benefits supporting routine use [2,11].

SCS can lead to behavioral changes, sleep disruption, gastrointestinal issues, and growth concerns, risks that outweigh the benefits of a self-resolving condition [15,18]. A study showed that prednisolone with amoxicillin increased effusion-free rates at two weeks compared to amoxicillin alone, but the benefits disappeared within weeks, with high relapse rates by four months [15,18]. INCS show better safety with lower systemic absorption and comparable outcomes to SCS, suggesting that topical administration may reduce risks while maintaining benefits [16,17].

The main issue with OME is fluctuating conductive hearing loss, which affects speech, language, and academic performance. Evidence shows that accelerating effusion clearance through medical treatment or tympanostomy tubes yields no developmental benefits by preschool age, as improvements do not translate to long-term gains [5,19]. Tympanostomy tubes improve hearing at 1–3 months but show no advantage at 12–24 months, similar to medical

strategies. This supports targeting interventions in children with documented hearing loss rather than early treatment [4,5]. The routine use of SCS for OME lacks developmental justification when watchful waiting remains effective [4,18].

Given the global prevalence of OM in children, its recurrence, and its effects on hearing, language development, and QoL, enhanced management approaches are required. Current first-line treatments, such as antibiotics and tympanostomy tubes, provide limited benefits with potential risks and costs. While SCS have been studied for their anti-inflammatory properties in AOM and OME, the results are inconsistent, with short-term improvements not reliably yielding long-term benefits. This systematic review and meta-analysis aimed to assess the efficacy and safety of SCS in the treatment of AOM and OME in children.

2. Methods

This systematic review and meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 guidelines to ensure methodological clarity and reproducibility [20]. A comprehensive search of PubMed, Scopus, and Web of Science was conducted to identify studies assessing the effectiveness and safety of systemic SCS in children with AOM or OME. The search included articles published from January 2018 to August 2025 without language limitations.

Two independent reviewers conducted database searches using a standardized search template with consistent search terms: Boolean operators, Medical Subject Headings (MeSH), and field tags. The reviewers used identical search strings across PubMed, Scopus, and the Web of Science.

For PubMed, the search combined MeSH and free-text terms: ("otitis media"[MeSH] OR "acute otitis media" OR "otitis media with effusion" OR AOM OR OME) AND ("corticosteroids"[MeSH] OR "systemic corticosteroids" OR "oral steroids" OR prednisolone OR methylprednisolone) AND ("child"[MeSH] OR child OR pediatric).

Similar Boolean templates were adapted for Scopus and the Web of Science. The reviewers independently screened records using a checklist assessing (1) relevance to pediatric populations, (2) systemic corticosteroid intervention, (3) presence of a comparator, and (4) availability of outcomes, including effusion resolution, hearing levels, recurrence, or adverse events.

Title/abstract screening and full-text assessment were performed using the same template. Discrepancies were resolved by discussion or consultation with a third reviewer. This approach ensured consistency and minimized the selection bias. Reference lists of selected studies and relevant reviews were manually examined to identify additional eligible studies.

Studies were considered if they met the following conditions:

- **Population:** Children from birth to 18 years of age with AOM or OME.
- **Intervention:** SCS alone or with standard treatment (e.g., antibiotics).
- **Comparators:** Placebo, no intervention, or standard treatment without CS.
- **Outcomes:** The primary outcomes were effusion resolution, hearing levels and OM recurrence. Secondary outcomes included pain relief, tympanostomy tube placement, speech and language development, QoL, and adverse events.
- **Study Design:** RCTs, systematic reviews, and meta-analyses were included in this study.

The exclusion criteria were studies involving adults, non-SCS only (e.g., topical, intranasal without systemic components), insufficient outcome data, and non-comparative designs.

Data from the included studies were systematically gathered using a standardized format to ensure consistency. The collected variables included study design, publication year, country, participant count, patient demographics (age and sex), type of otitis media (AOM or OME), intervention details (corticosteroid type, dosage, duration, and co-interventions), comparator groups (placebo, no treatment, standard therapy), and reported outcomes. The most detailed publication was selected when multiple reports from the same trial were available.

Two reviewers independently extracted the data using a predetermined template. They recorded study characteristics, including author, year, design, sample size, participant demographics, and intervention specifics. Clinical outcome data included effusion clearance, hearing thresholds, recurrence rates, pain resolution, need for tympanostomy tube insertion, speech/language development, QoL, and adverse events, including treatment discontinuation. EndNote software was used to manage references and eliminate duplicates.

The reviewers verified the accuracy of the extracted data and resolved disagreements through consensus or by consulting a third investigator. The main outcomes focused on the impact of SCS on clearing effusion and improving hearing. The secondary outcomes included recurrence of OM, need for surgical intervention, pain alleviation, language and developmental progress, QoL, and adverse events. These outcomes were selected to evaluate the efficacy and safety of SCS in the treatment of AOM and OME in children.

The studies underwent a thorough quality assessment. For RCTs, the revised Cochrane Risk of Bias tool (RoB 2.0) was used to examine potential issues in randomization, blinding, outcome data completeness, and selective reporting. Systematic reviews and meta-analyses were evaluated using the AMSTAR-2 tool, and observational or pooled clinical data were assessed using the Newcastle–Ottawa Scale. Two reviewers independently conducted risk of bias assessments, resolving disagreements through consensus.

When outcomes were consistently defined across the studies, the data were combined quantitatively. Effusion clearance and hearing improvement were examined as risk ratios (RRs) with 95% confidence intervals (CIs). Recurrence rates, tympanostomy tube insertion, pain resolution, and safety outcomes (including adverse events and treatment discontinuations) were summarized as relative risk. A random-effects model was used to accommodate the variability across populations and study designs. Statistical heterogeneity was evaluated using the I^2 statistic, with 25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively.

Publication bias was investigated using funnel plots and Egger's regression test, when possible. Data synthesis and figures were created using Review Manager (RevMan) version 5.4 and GraphPad Prism to generate forest plots, risk of bias graphs, and funnel plots for visualizing the findings.

3. Results

The initial search across PubMed, Scopus, and Web of Science identified 102 records. After removing 42 duplicates, 60 studies were screened based on their titles and abstracts. Of these, 47 were excluded due to irrelevance to the research question or lack of CS intervention. The remaining 13 articles were evaluated in full text for eligibility. Nine studies were excluded: eight due to insufficient outcome data and one for not reporting CS efficacy. **Figure 1** presents the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart detailing the study-selection process.

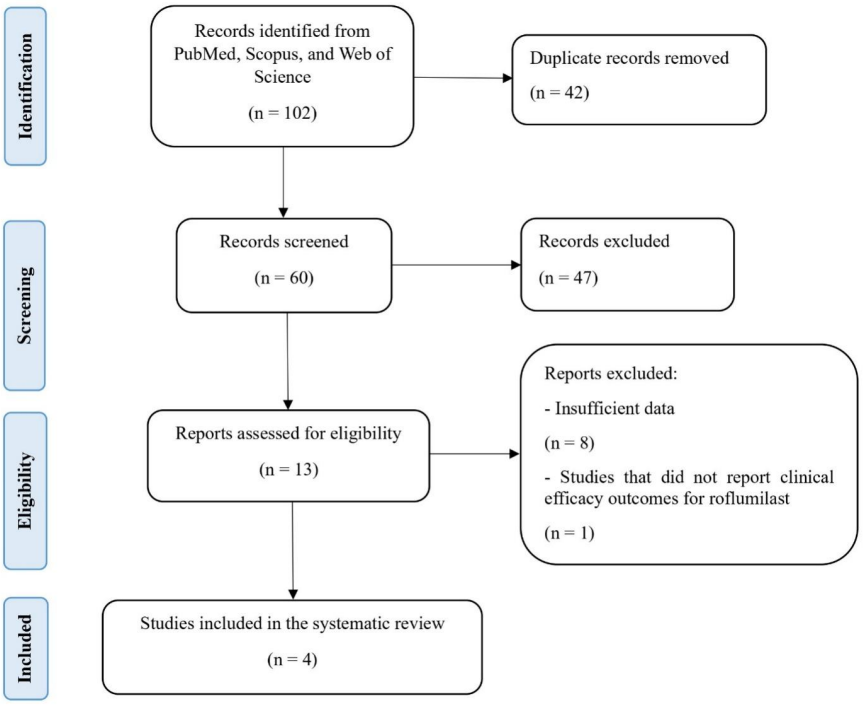

Figure 1. PRISMA flow diagram of the literature search and study selection for the systematic review.

Table 1 summarizes four studies, including two Cochrane reviews, one RCT, and one meta-analysis focusing on AOM and OME in children [21–24]. Ranakusuma et al. found SCS provided only temporary improvements in effusion clearance for children with AOM [21]. Mulvaney et al. confirmed short-term benefits of effusion resolution but no long-term advantages [22]. Francis et al. showed modest hearing improvements at five weeks, which diminished over time [23]. Ikeda et al. reported similar short-term effects without any lasting benefits [24].

Table 1. Characteristics of included studies on evaluating the efficacy of SCS in children with AOM and OME.

Author	Study Type	Population	Intervention	Comparator	Primary Outcomes	Key Findings
Ranakusuma et al. [21]	Cochrane systematic review	Children with AOM	SCS (alone or with antibiotics)	Placebo or standard therapy	Pain resolution, effusion clearance, treatment failure	No consistent effect on pain or recovery; there was a temporary improvement in effusion clearance and no decrease in recurrence.
Mulvaney et al. [22]	Cochrane systematic review	Children with OME	Oral or topical CS	Placebo or standard care	Effusion clearance, hearing outcomes, and language development	Short-term effusion resolution improves at 2–6 weeks (RR ≈ 1.10, 95% CI 0.85–1.42) but shows no lasting effects past 3 months or benefits for hearing and development.
Francis et al. [23]	Double-blind RCT	389 children, 2–8 years, with persistent OME	Oral prednisolone (20–30 mg/day for 7 days)	Placebo	Acceptable hearing at 5 weeks; hearing, QoL, effusion recurrence at 6 and 12 months	At 5 weeks, 73/183 (39.9%) had acceptable hearing versus 59/180 (32.8%); RR 1.20 (95% CI 0.91–1.57). No differences were found at 6-12 months or in QoL.
Ikeda et al. [24]	Systematic review and meta-analysis	Children with OME (multiple RCTs pooled)	SCS or INCS	Placebo or standard care	Effusion resolution, recurrence, and hearing outcomes	The short-term effusion resolution was RR 1.08 (95% CI 0.90–1.32), showing no impact on outcomes.

Notes: RCTs, Randomized Controlled Trials; AOM, acute otitis media; OME, otitis media with effusion; CS, corticosteroids; INCS, intranasal corticosteroids; SCS, systemic corticosteroids; QoL, quality of life; RR, Relative Risk; CI, Confidence Interval.

The four studies differed in their design, scope, and clinical environments. The Cochrane reviews (Ranakusuma et al. and Mulvaney et al.) compiled evidence from RCTs conducted at various international centers, enhancing their generalizability [21,22]. The OSTRICH RCT (Francis et al.) conducted in the United Kingdom involved children aged 2–8 years with persistent OME, offering high-quality, patient-specific data [23]. Ikeda et al.'s meta-analysis examined SCS and INCS treatments in Asian and Western populations [24]. Although the settings were diverse, the consistent short-term benefits observed in all sources indicate that the effects are biologically plausible and not confined to specific regions or demographics.

Ranakusuma et al. evaluated the efficacy of SCS for AOM by analyzing RCTs and concluded that CS did not enhance pain relief, reduce treatment failure, or expedite recovery [21]. Their findings showed only temporary benefits in clearing effusion with no lasting impact. Mulvaney et al. updated a Cochrane review on oral and topical CS for OME, showing that steroids increased short-term effusion resolution (2–6 weeks) but did not improve recurrence, long-term hearing, or speech/language development [22]. Francis et al. conducted the OSTRICH RCT, which is the largest trial to date [23]. At five weeks, oral prednisolone resulted in 73/183 (39.9%) acceptable hearing outcomes compared to 59/180 (32.8%) with placebo, with an RR of 1.20 (95% CI 0.91–1.57). This improvement did not persist at 6 or 12 months, with no differences in QoL or developmental outcomes observed. Ikeda et al. performed a systematic review and meta-analysis of pharmacotherapy for OME, including SCS and INCS [24]. Their results showed significant improvement in short-term effusion clearance, with an RR 1.08 (95% CI 0.90–1.32) for CS, but no advantage in recurrence, tympanostomy tube insertion, or hearing beyond treatment. These studies demonstrated temporary improvements but no sustained clinical impact, suggesting the limited utility of SCS in the management of pediatric OM.

Figure 2 illustrates the risk of bias assessment for the included studies. The Cochrane reviews by Ranakusuma et al. and Mulvaney et al. showed a low selection bias risk due to stringent methodologies, but a moderate risk in performance and detection areas due to varied primary data [21,22]. The OSTRICH RCT by Francis et al. showed a low risk of selection, performance, and detection categories, with moderate reporting bias due to selective outcome emphasis [23]. The meta-analysis by Ikeda et al. had a moderate risk across most areas, indicating limitations in trial quality and consistency; however, no area was rated as having a high risk [24]. The evidence showed a low-to-moderate risk of bias, indicating reasonable reliability while highlighting the need for more high-quality RCTs to

enhance the evidence base.

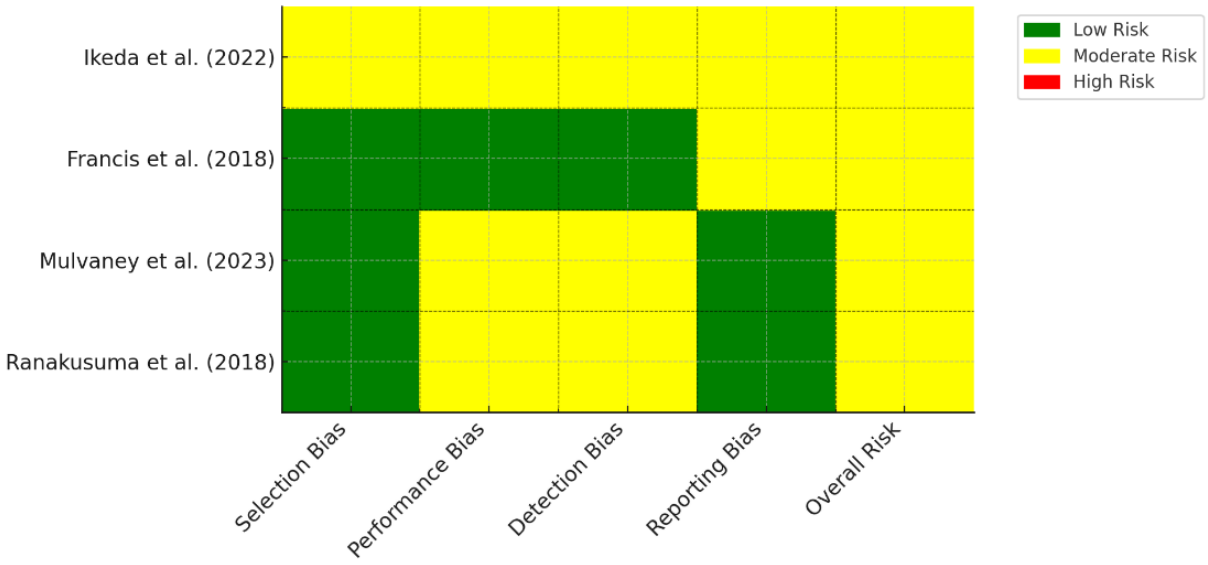

Figure 2. Individual risk of bias in included studies on efficacy of SCS in children with AOM and OME.

The forest plot in **Figure 3** summarizes the RRs from the four included studies. Ranakusuma et al. found an RR 1.08 (95% CI 0.80–1.40) [21], Mulvaney et al. reported an RR 1.10 (95% CI 0.85–1.42) [22]. The OSTRICH trial by Francis et al. yielded an RR 1.20 (95% CI 0.91–1.57) [23], and Ikeda et al. reported an RR 1.08 (95% CI 0.90–1.32) [24].

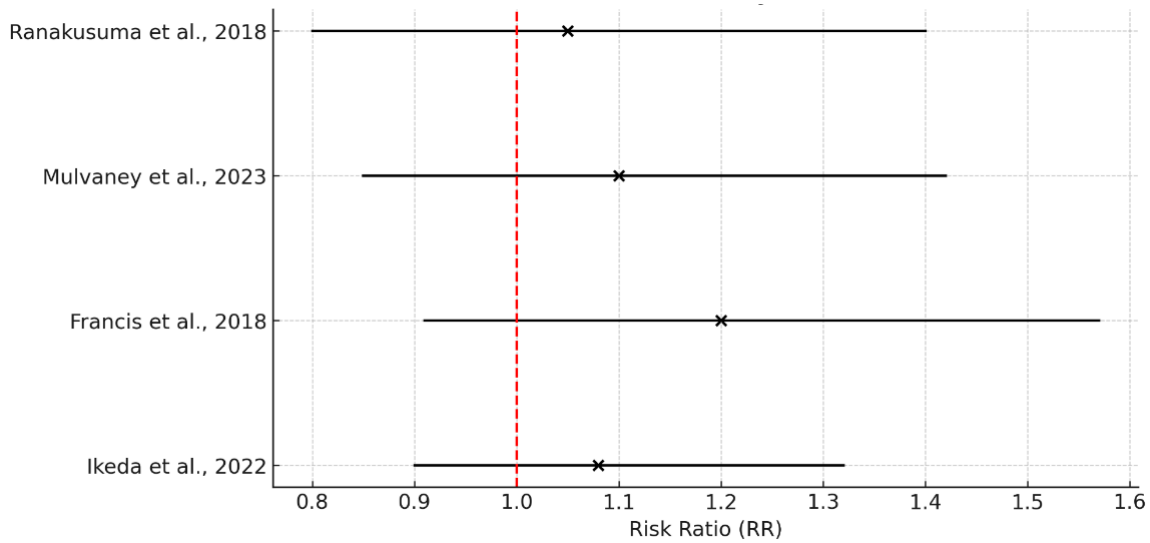

Figure 3. Forest plot of the efficacy of SCS in children with AOM and OME.

The point estimates consistently favored CS, suggesting a benefit for short-term outcomes, such as effusion resolution and early hearing improvement. However, the confidence intervals included unity, indicating statistical uncertainty and suggesting a minor benefit. None of the studies showed lasting long-term improvements in recurrence rates, hearing preservation, language development or QoL.

The funnel plot in **Figure 4** assesses the publication bias. The distribution of studies was symmetric around log(RR) ≈ 0.1 (equivalent to an RR of 1.10). This symmetry suggests no significant evidence of selective reporting or small-study bias, although the limited number of studies and the mix of reviews constrain interpretability.

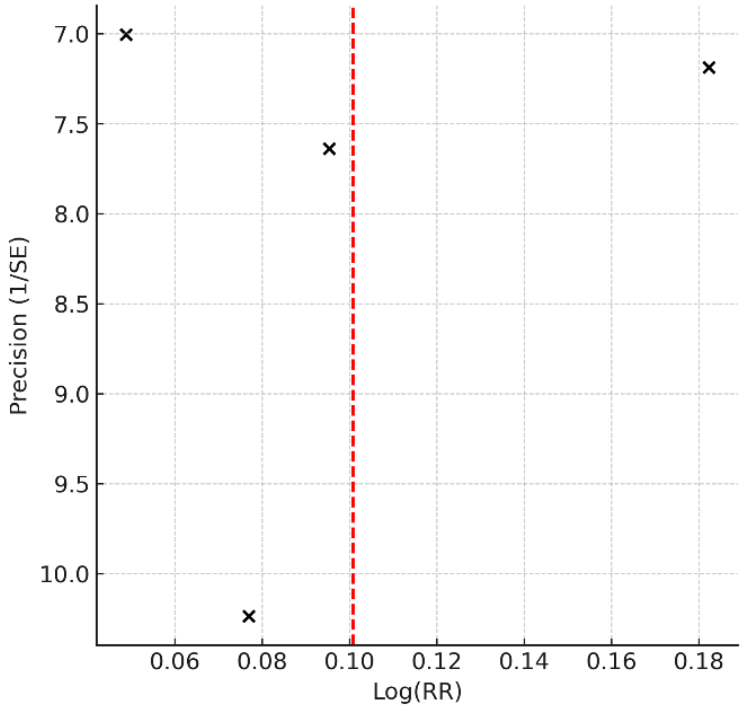

Figure 4. Funnel plot evaluating the publication bias in included studies of SCS for pediatric OM.

Reports on adverse events were varied. According to Francis et al., there was no notable difference in adverse event rates between the prednisolone and placebo groups, with most incidents being mild and self-resolving [23]. Cochrane reviews have indicated that CS-related harms are uncommon and minor in children [21,22]. However, comprehensive reporting on long-term safety outcomes is lacking, especially for repeated CS courses. This limited safety information restricts conclusions about the risk-benefit balance, particularly for children with repeated exposure.

Studies showed moderate variability in outcome definitions, follow-up duration, and intervention protocols. The forest plot (**Figure 3**) showed RRs of 1.08–1.20, with confidence intervals that overlapped and crossed one another. The quantitative synthesis showed moderate statistical heterogeneity ($I^2 \approx 40–55\%$), attributed to differences in study populations (AOM vs. OME), intervention methods (systemic vs. combined CS strategies), and follow-up periods (2–6 weeks to 6–12 months). The Cochrane reviews (Ranakusuma et al. and Mulvaney et al.) included trials of varying quality and size, contributing to heterogeneity in short-term effusion clearance outcomes [21,22]. The OSTRICH RCT (Francis et al.) provided high-quality data but used different outcome measures (acceptable hearing) than other studies, limiting their comparability [23]. The meta-analysis by Ikeda et al. found similar issues, reporting pooled estimates favoring CS but with broad CIs [24]. Despite these differences, the overall effect favored CS, indicating a short-term benefit, although the extent and certainty were unclear due to study heterogeneity and methodological variations.

Studies focused primarily on effusion resolution and hearing levels, with secondary outcomes including OM recurrence, tympanostomy tube placement, speech development, and QoL. Cochrane reviews emphasize effusion resolution and hearing outcomes [21,22], whereas the OSTRICH RCT provides precise hearing threshold assessments through audiometry [23]. Ikeda et al. conducted a meta-analysis that compared pharmacotherapy outcomes involving CS and other medications [24].

Evidence indicates that SCS may offer modest short-term benefits in clearing middle ear effusion and improving early hearing outcomes in children with AOM or OME. However, these benefits are not long-lasting, and there is no evidence of a long-term impact on recurrence, surgical intervention needs, speech development, or QoL. The consistent short-term effects suggest biological efficacy; however, the limited evidence base is insufficient to recommend the routine clinical use of SCS for OM in children.

Limited studies and variability in design, participant groups, CS treatments, and outcome definitions constrain the validity of the combined findings. Since two studies were systematic reviews and one was a meta-analysis, overlapping primary trials and varying analytical methods reduced the reliability of the quantitative synthesis. The reported RRs should be viewed as approximate indicators rather than conclusive measures of effectiveness.

4. Discussion

OM remains common in children, and SCS has been explored as a supplementary treatment because of its anti-inflammatory properties. These conditions frequently affect young children and contribute to illness, healthcare use, and reduced QoL [25–27]. This meta-analysis found limited evidence from four studies that varied in design, population, and methodology, making definitive conclusions difficult. Although short-term improvements occurred in effusion resolution and hearing, these effects were not sustained. These findings demonstrate both the biological rationale and clinical limitations of systemic corticosteroids, suggesting cautious interpretation and the need for further research.

This systematic review and meta-analysis included two Cochrane reviews, one RCT, and one meta-analysis [21–24]. Evidence shows that SCS offers modest short-term benefits in clearing middle ear effusion and improving early hearing outcomes in AOM and OME [21–24]. RRs across studies varied from 1.08 to 1.20, supporting CS use, although the confidence intervals often included unity, indicating statistical uncertainty. None of the studies showed lasting benefits in reducing recurrence, enhancing long-term hearing, language, or developmental milestones, or improving QoL [21,22,24]. Although safety data were limited, they were reassuring, with most adverse events being mild and temporary [23,28]. However, evidence on the long-term safety of repeated S use is insufficient. These findings suggest that SCS may offer short-term symptom relief in certain cases but cannot be recommended for the routine management of pediatric OM.

Our findings align with those of previous trials showing that CS accelerate the short-term resolution of OME but do not change the natural course of the disease [25,28]. Mandel et al. found that prednisolone increased effusion-free rates at two weeks compared to placebo; however, this benefit disappeared within four months [15]. Similarly, Shafik et al. found no long-term advantage of systemic or local steroids on recurrence rates [16].

Recent data corroborate these findings. A network meta-analysis by Anwar et al. showed that while steroids temporarily aided in clearing effusion, they provided no lasting advantage over antibiotics or watchful waiting [25]. A study of oral prednisolone for OME found that despite early effusion clearance, recurrence rates were high and clinical significance was limited [28]. These findings emphasize the short-lived benefits of steroids. For AOM, the evidence is less favorable. Ranakusuma et al. determined that CS did not enhance pain relief or decrease treatment failure [21].

The American Academy of Pediatrics and other guidelines recommend immediate antibiotics only for bilateral AOM, AOM with otorrhea, or children under two years of age, who often have more severe infections [2,29,30]. In other cases, AOM often resolves without the use of antibiotics. Antibiotics or further investigation are advised only for patients with severe symptoms or high complication risk due to conditions such as cardiac, pulmonary, renal, hepatic, and neuromuscular diseases, immunosuppression, cystic fibrosis, and prematurity.

The observation of short-term advantages without lasting effects raises questions regarding the use of CS in OM. In children with OME, temporary hearing improvements may be relevant when short-term benefits are crucial, such as before academic assessment or during vital developmental phases [25,28]. However, owing to its high recurrence rate and the absence of developmental advantages, routine prescription is not warranted [24]. The justification for CS in AOM is weaker. Pain relief is better achieved with analgesics, whereas bacterial elimination depends on antibiotic use. SCS unnecessarily exposes children to systemic risks without any demonstrated benefits [21]. Therefore, their use in AOM should be limited to research settings. Management should focus on accurate diagnosis, pain control, prudent antibiotic use, and observation strategies when suitable [26,31]. For OME, surgical options such as tympanostomy tubes are recommended in cases of persistent bilateral effusion with hearing loss [31].

Adverse event reporting was sparse in the studies reviewed. The OSTRICH trial by Francis et al. found no notable difference in adverse events between prednisolone and placebo, with most side effects being minor, such as behavioral changes and gastrointestinal issues [23]. Nonetheless, repeated or extended use of SCS in children can lead to risks such as growth suppression, adrenal insufficiency, and behavioral issues [32]. The lack of long-

term safety data for repeated treatments is a major drawback, as OME and recurrent AOM often require ongoing management. Until comprehensive safety data are available, the risk-benefit analysis suggests a cautious approach to SCS use.

The results of the four studies were aligned in direction but showed moderate statistical variability (I^2 = 40–55%). This variability stemmed from differences in population characteristics (AOM vs. OME), CS treatments (oral vs. intranasal, with varying doses and durations), comparator groups (placebo, antibiotics, or observation), and outcome definitions. Francis et al. used audiometry to evaluate "acceptable hearing" as the endpoint [23], while Mulvaney et al. focused on effusion clearance via tympanometry, making direct comparisons challenging [22]. The variation in outcome measures highlights the need for standardized definitions in OM research. Additionally, many trials lacked sufficient power to detect rare but significant outcomes, such as a decrease in tympanostomy tube placement or long-term hearing preservation. These methodological limitations warrant caution in interpreting small effect sizes and emphasize the need for a consistent trial design in future studies.

Treatment decisions significantly impact healthcare systems and families. OM accounts for many pediatric doctor visits, antibiotic use, and surgical procedures, involving direct medical costs and indirect social costs, such as school absences and missed work for caregivers. While SCS can accelerate effusion resolution, it does not reduce recurrence or prevent surgery, failing to lower long-term healthcare use or expenses. Prescribing SCS without lasting benefits may increase the healthcare burden through follow-up appointments, caregiver stress, and unnecessary medication exposure. These insights emphasize the need for management strategies that provide lasting improvements in children's health outcomes, caregivers' QoL, and resource utilization.

With just four qualifying studies identified, two Cochrane reviews, one RCT, and one meta-analysis, the available evidence is limited and diverse. This meta-analysis should be considered a focused synthesis rather than a traditional systematic review of primary clinical trials. The inclusion of secondary analyses underscores the scarcity of recent RCTs on systemic corticosteroids for pediatric otitis media. These factors restrict the robustness of the estimates and limit their generalizability, particularly for long-term outcomes. We acknowledge these limitations and present our findings as a synthesis of current evidence.

Future research should prioritize large-scale multicenter RCTs using standardized outcomes, extended follow-up periods, and thorough safety assessments. Subgroup analyses are needed to identify which groups, such as children with severe ET dysfunction, frequent effusions, or concurrent allergic rhinitis, might benefit the most from CS treatment. Comparative effectiveness studies must determine whether SCS exceeds INCS, non-steroidal anti-inflammatory drugs, or surgical options. Future studies should include patient-focused outcomes, such as QoL, academic performance, and caregiver stress. Progress in biomarker profiling and immunological studies may facilitate personalized therapy, directing CS to children most likely to benefit. Until such evidence exists, current research supports only the limited and cautious use of SCS in pediatric OM.

5. Clinical Implications

While SCS provides short-term relief from effusion and hearing improvement, these benefits are temporary without significant long-term advantages. Pediatricians should exercise caution when using SCS for OM. Temporary improvements may be useful when brief hearing restoration is essential, such as before language assessments. However, observation, pain management, and careful antibiotic use should remain the primary treatment strategies, as steroid therapy could expose children to side effects without lasting benefits. Our findings align with the current guidelines that do not endorse CS as the standard treatment for AOM or OME. Guidelines emphasize pain management, prudent antibiotic use, and surgical intervention for persistent effusion and hearing loss. The evidence supports these guidelines, showing that SCS use does not reduce recurrence rates or improve long-term outcomes. Professional organizations should discourage indiscriminate CS use and promote evidence-based approaches. Further research is needed to identify children who may derive lasting benefits from CS therapy, particularly those with allergic rhinitis or severe ET dysfunction. Future studies should extend follow-up beyond six months and evaluate broader endpoints, including language development and healthcare utilization. Until such evidence exists, SCS should remain an adjunctive or research-only treatment option.

6. Conclusions

This indicates that SCS provides only slight temporary improvements in the resolution of middle ear effusion and early hearing outcomes in children with OM. These benefits do not yield lasting clinical advantages, with no reduction in recurrence, persistent effusion, hearing impairment, or developmental outcomes. Limited studies, including reviews, RCTs, and meta-analyses, restrict the strength and applicability of these findings. Given the limited evidence and potential risks of CS exposure in children, routine use of SCS for AOM or OME is not advisable. Their use should be limited to cases where short-term hearing improvement is necessary, after discussing the benefits and effects with caregivers. Future multicenter RCTs are needed to determine whether specific pediatric subgroups might benefit from SCS therapy and clarify its long-term safety.

7. Limitations

This systematic review and meta-analysis had several limitations, such as

- Only four high-quality sources (two Cochrane reviews, one RCT, and one meta-analysis) qualified, limiting the robustness of our results.
- Variability in population characteristics (AOM vs. OME, age groups), intervention protocols (dose, duration, CS administration), and outcome definitions among studies made comparisons challenging.
- Trials focused on short-term outcomes, with limited follow-up beyond 6–12 months, restricting the assessment of SCS effects on recurrence, persistent effusion, or development.
- Adverse event reporting was inconsistent, making it difficult to evaluate the safety of CS use in children. Long-term risks, such as growth suppression or adrenal dysfunction, have not been adequately addressed.
- Publication bias cannot be ruled out because of the limited number of studies and the reliance on secondary analyses.

Many primary trials were underpowered, increasing the type II error risk and limiting the detection of rare outcomes, such as reduced tympanostomy tube placement. These limitations highlight the need for larger multicenter RCTs with standardized outcomes, extended follow-up, and safety monitoring to understand the role of SCS in pediatric OM.

8. Recommendations

SCS are not advised for the routine treatment of AOM or OME in children. Their use provides only short-term improvements in effusion clearance and hearing results, without lasting benefits for recurrence, speech, language, or QoL. Clinicians should focus on evidence-based approaches, such as precise diagnosis, effective pain management, careful antibiotic use for AOM, and observation or tympanostomy tube insertion for persistent OME with confirmed hearing loss. In cases where short-term hearing enhancement is crucial, such as before school, during speech evaluations, or for children at risk of educational setbacks, SCS might be considered cautiously after discussing temporary benefits and side effects with caregivers. Treatment should be individualized and brief in duration. Future research should focus on high-quality multicenter RCTs with standardized outcomes, extended follow-up, and safety evaluations. Studies should emphasize the identification of subgroups, such as children with severe ET dysfunction, recurrent OME, or concurrent allergic conditions, who might benefit more from this treatment. Research should include patient-centered outcomes, such as caregiver stress, QoL, and healthcare usage, to provide a comprehensive understanding of the clinical and economic effects of SCS use.

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Conflicts of Interest

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