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LITERATURE REVIEW

Management of acute otitis media in children: an umbrella review of clinical practice guidelines and systematic reviews

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ABSTRACT

BACKGROUND. Acute otitis media (AOM) is a frequent cause of paediatric care and antibiotic prescription, affecting up to 75% of children under 5 years of age. Despite the available clinical guidelines, variations in its diagnosis and management persist.

OBJECTIVE. To synthesize current evidence on the treatment of childhood AOM, highlighting effective interventions and gaps in clinical knowledge.

MATRIAL AND METHODS. An umbrella review of systematic reviews and clinical guidelines published between 2000 and 2025 was conducted. PubMed, Cochrane Library, Virtual Health Library and Epistemonikos were consulted, following PRISMA criteria. We included studies in English (and Spanish in the case of local guides). Two review authors applied the inclusion criteria independently using Rayyan. Methodological quality was assessed with AMSTAR-2.

RESULTS. 33 studies were analysed. Eighteen reviews evaluated treatments (antibiotics, surgery, complementary therapies), five addressed prevention (vaccines, xylitol), and the rest epidemiological and implementation aspects. Short-acting antibiotics were as effective as longer-acting antibiotics, with fewer adverse effects. Pneumococcal vaccines significantly reduced the incidence. Xylitol showed moderate benefit. Amoxicillin remains a first-line treatment, with surveillance in mild cases. Gaps persist in the use of corticosteroids, education for caregivers, and monitoring of adverse effects.

CONCLUSION. There is strong evidence for the rational use of antibiotics and vaccines. However, more studies are needed on complementary interventions and strategies to improve adherence to clinical guidelines.

KEYWORDS: otitis media, child, disease management, therapeutics.

INTRODUCTION

Acute otitis media (AOM) is characterized by sudden inflammation and fluid accumulation in the middle ear, accompanied by local (otalgia, otorrhea) and systemic (fever, irritability) signs and symptoms. It is extremely common in childhood: it affects approximately 75% of children before 5 years of age, being most common between 6 and 24 months[1,2]. Reported incidence rates vary widely, due to differences in diagnostic definitions, study designs, populations assessed, and geographical/seasonal factors. However, AOM remains the leading cause of antibiotic prescribing in paediatrics in many countries. For example, in the United States, AOM traditionally represented the first indication of antimicrobials in children. Following awareness efforts and the introduction of the pneumococcal conjugate vaccine, AOM visits decreased from 950 to 634 per 1000 children between 1995–1996 and 2005–2006[1]; in the same period, antibiotic prescriptions for AOM fell from 760 to 484 per 1000. However, the proportion of consultations for AOM treated with antibiotics remained high (barely decreasing from 80% to 76%). This suggests that, although the incidence of AOM may have been slightly reduced (possibly thanks to vaccines and better recognition of viral pictures), the practice of prescribing antibiotics for any AOM has hardly changed[1,2].

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Despite the availability of evidence-based clinical practice guidelines (e.g., 2004 and 2013 American Academy of Pediatrics guidelines, European and other national guidelines), numerous studies show a gap between recommendations and actual practice. Vernacchio et al.[3] surveyed 469 primary care paediatricians about their management of AOM in four clinical settings, shortly after the publication of the 2004 American Academy of Pediatrics (AAP) guideline, and found no significant changes from previous surveys. In their study, most physicians were aware of the guideline, but many did not follow its recommendations, especially in diagnosis (only 16.2% used routine pneumatic otoscopy) and in "watchful observation" (applied in only 10–15% of cases, mainly due to fear of complications or parental pressure)[3]. From the treatment point of view, only 17.9% followed the guidelines recommendations of prescribing high-dose amoxicillin-clavulanate in severe acute otitis media. Accordingly, Coco et al.[4] analysed data from the U.S. National Ambulatory Medical Care Survey (2002–2006, n=1114) and found no significant difference in antibiotic prescribing rates before and after the 2004 guideline was released (p=0.103). Similarly, in Italy a lack of impact of guidelines on physicians' conduct was observed, with 81% of antibiotic prescribing versus 82% prior to the guidelines[5]. A study in Israel reported that between 2002 and 2009 the proportion of physicians who chose not to prescribe an antibiotic at the outset of AOM remained low; paediatricians and otolaryngologists showed a slight tendency to postpone antibiotics, while family doctors even increased their early prescribing in that period[6].

These findings highlight the resistance to changing established practices and the influence of factors such as parental concern, expectations during the consultation, and the logistics of follow-up, despite evidence supporting more conservative management in certain cases[7].

AOM continues to represent a major challenge in child health: it is a very frequent reason for consultation and generates considerable use of antibiotics, with the consequent impact on health costs and microbial resistance. At the same time, notable variations persist in their handling; for example, there are differences between countries in antibiotic regimens, in the use of diagnostic procedures such as tympanocentesis or pneumatic otoscopy, and in the indication for surgeries (myringotomy with ventilation tubes, adenoidectomy). A report by Tamir et al.[8] compared AOM guidelines from different countries and concluded that, although most share common pillars (promoting initial observation when safe, ensuring coverage with amoxicillin as the first line, and encouraging pneumococcal vaccination), there are significant variations in the duration of recommended treatment, the role of topical analgesia, and the management of complications. All of the above highlights the need to integrate the body of available evidence to outline a current consensus and detect which questions remain unanswered. In this context, an umbrella review, which brings together results from multiple systematic reviews and guidelines, is particularly useful.

The objective of this work is to provide a panoramic and updated view of the management of childhood AOM, strengthening the scientific bases of clinical recommendations and identifying knowledge gaps that guide future research and improvements in care.

MATERIAL AND METHODS

Study design: An umbrella review was carried out, understood as an integrative second-level review that synthesizes the evidence from previous systematic reviews and clinical practice guidelines. This design is appropriate for drawing global conclusions on a broad topic – such as the management of acute otitis media (AOM) – from the best evidence compiled to date. The review is reported following the PRISMA guidelines for overviews where applicable[9,10].

Eligibility criteria: Systematic reviews, meta-analyses or high-level narrative reviews, as well as clinical practice guidelines, that addressed aspects of treatment, diagnosis or prevention of AOM in the paediatric population (≤18 years) were included. Since the most relevant literature in health sciences is published in English, the language was restricted to English for primary sources of evidence (and Spanish only if it corresponded to high-impact local guidelines; in the end, all eligible guidelines were in English). Publications from 2000 to May 2025 were considered to ensure topicality (many key changes, such as the introduction of conjugate vaccines and the dissemination of guidelines, occurred from that decade onwards).

We excluded: individual primary studies (clinical trials, cohorts, etc.) that were not part of a review; low-quality narrative reviews or without explicit methodology; technical reports and theses not published in peer-reviewed journals; and articles in languages other than English or Spanish. In terms of practice guidelines, both national guidelines and consensus of relevant scientific societies were included, as long as they were based on evidence review.

Literature search: We searched PubMed (MEDLINE), Cochrane Database of Systematic Reviews, Virtual Health Library, and Epistemonikos, from 1 January 2000 to 10 May 2025. The strategy combined MeSH terms and free text in English, grouping concepts of: acute otitis media ("acute otitis media", "AOM"), pediatric population ("child", "infant", "children", "pediatric"), interventions ("antibiotics", "antibacterial agents", "watchful waiting", "tympanostomy", "vaccination", "xy-

litol", etc.), and outcomes ("treatment outcome", "symptom resolution", "recurrence", "adverse effects", "hearing loss"). Equivalent terms were adapted for the other databases. In addition, reference lists of relevant articles obtained were reviewed to identify potentially uncaptured studies, and "similar articles" functions in PubMed were used to expand sensitivity. No restriction was applied by country or type of publication (except for the aforementioned eligibility criteria). The last search was conducted on 10 May 2025.

Study selection: Search results were managed with Rayyan® software. First, duplicates were removed. Subsequently, two review authors independently screened titles and abstracts, discarding those that were clearly irrelevant based on inclusion/exclusion criteria. The records that passed this initial filter were evaluated in full text. Each review author kept a record of the reasons for exclusion for studies read in full text (e.g., 'ineligible design – primary study', 'topic out of scope – otitis media with effusion, not acute', etc.). Discrepancies at any stage were resolved by discussion and consensus. If disagreement persisted, a third author was consulted for the final decision.

Data extraction and synthesis: An ad-hoc form was designed in Excel to extract the key data of each included study. We extracted: (a) bibliographic data (author, year, country or region of evidence, type of publication), (b) scope and main question (e.g., "Are prophylactic antibiotics effective in preventing recurrent AOM?"), (c) design of summary studies (number of trials included in each review, etc.), (d) main outcomes and recommended care, (e) authors' conclusions, and (f) stated limitations. For clinical practice guidelines, their relevant specific recommendations (e.g., first line therapy, duration of treatment, diagnostic criteria) were also extracted. Two authors performed the extraction in parallel in a cross-sectional manner (each article was extracted by one reviewer and verified by the other), resolving differences of interpretation by consensus. Given the narrative and integrative nature of the umbrella review, the synthesis of results is presented in a descriptive and qualitative manner, grouping findings by themes (e.g., antimicrobial therapies, surgical interventions, preventive measures, etc.). Where relevant, quantitative measures of effect reported in the original reviews (relative risks, mean differences, etc.) were incorporated to illustrate the magnitude of the findings. We did not perform a new meta-analysis combining results from different reviews, as each review largely included different studies, and combining estimates could lead to duplication of primary data. Instead, it was privileged to summarize the conclusions with the highest level of evidence available.

Assessment of the quality of the evidence: The AMSTAR-2 (A Measurement Tool to Assess Systematic Reviews 2) tool was applied to each included systematic review, to assess its methodological rigor (domains such as a priori protocol, completeness of the search, consideration of publication biases, synthesis methods, etc.). The overall quality of each review was categorised as high, moderate, low or critically low, according to AMSTAR-2 criteria[11,12].

Clinical practice guidelines were evaluated informally, considering their degree of support in evidence (all the guidelines included were based on systematic reviews and had explicit levels of evidence and degrees of recommendation, so they were considered reliable). However, for future research, it is proposed to apply a formal tool, such as the Appraisal of Guidelines for Research & Evaluation II (AGREE II), to systematically assess the methodological quality of the clinical guidelines included. To graphically synthesize the strength of the evidence in each sub-theme, an *Evidence Gap Map* was developed. In this map, the horizontal axis represents the relevant interventions (e.g., antibiotics, vaccines, ventilation tubes, xylitol, corticosteroids, etc.) and the vertical axis represents the different outcomes or aspects (e.g., resolution of symptoms, recurrences, adverse effects, adherence to guidelines, etc.). Each 'bubble' on the map indicates the amount of evidence available on that intervention-outcome combination (size of the bubble proportional to the number of studies) and the average quality (colour indicating high, moderate or low-quality evidence). This made it possible to visually identify where the evidence is abundant and robust, and where gaps exist.

Further analysis (publication bias and heterogeneity): As results from multiple reviews were compiled, we assessed whether there might be publication bias at the global level of the evidence. To do this, we constructed a funnel *plot* by taking, from each included quantitative systematic review, a primary effect estimator (e.g., the overall effect of antibiotic vs. placebo on cure, the effect of vaccine vs. non-vaccine, etc.) and its standard error. Although mixing different outcomes in the same *funnel* is methodologically approximate, we use it as a general indicator of asymmetry. In addition, we applied Egger's test on this funnel plot to detect significant asymmetry, and we calculated the I^2 statistic as an estimate of the heterogeneity between the results of the reviews (due to the diversity of outcomes and populations, high heterogeneity was anticipated). These analyses were performed using RevMan v5.4 software (Cochrane).

RESULTS

The selection process is outlined in Figure 1 (PRISMA flow diagram). A total of 1,171 unique records were identified, of which 118 full-text articles were reviewed. Ultimately, 33 studies focusing on the management of acute

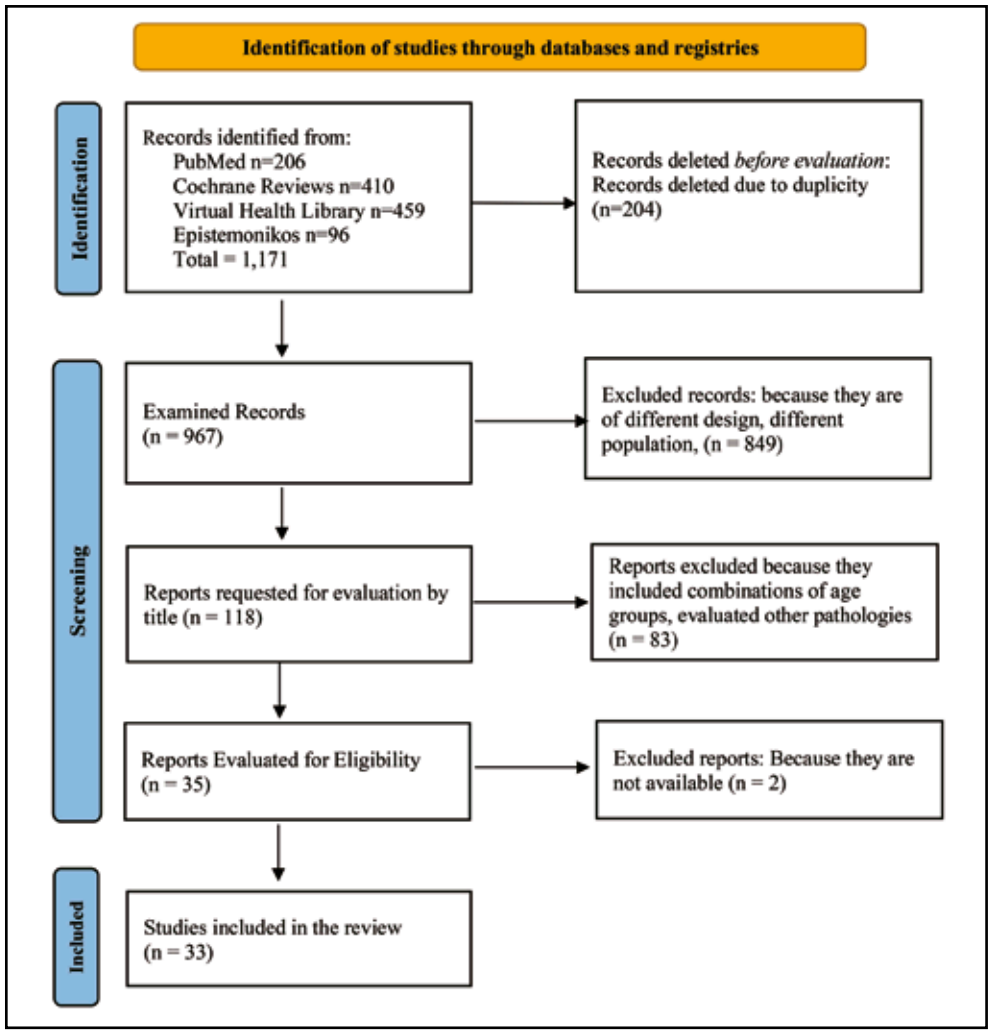

Figure 1. PRISMA flowchart. Management of acute otitis media in children: umbrella review.

otitis media (AOM) in pediatric populations were included[8,13-44]. The majority were systematic reviews with or without meta-analyses (n=23), several of which were Cochrane reviews or employed robust methodological frameworks such as GRADE (Grading of Recommendations Assessment, Development, and Evaluation), ROBIS (Risk of Bias in Systematic Reviews), and AMSTAR-2. Additionally, four clinical guidelines based on national or international consensus were included, along with two narrative reviews, one qualitative systematic review, and three studies evaluating specific therapeutic interventions (e.g., xylitol, corticosteroids, phytotherapy). This methodological heterogeneity provides a comprehensive and evidence-based perspective on antibiotic stewardship, clinical efficacy, prevention strategies, and complementary approaches in the pediatric care of AOM.

Table 1 presents a summary of each (authors, year, title, objective, population scope, main method, key findings, strengths/limitations, and quality rating according to AMSTAR-2). The reviews came from various regions (North America, Europe, Asia and Latin America), as did the guidelines (USA, Canada, Europe, Asia). In terms of approach, 18 reviews focused on therapeutic interventions (antibiotics, surgical procedures, alternative treatments), 5 on preventive measures (vaccines, xylitol, antibiotic prophylaxis), 3 on risk factors and epidemiology, and 2 on educational aspects or the implementation of guidelines. The clinical guidelines included corresponded to: the 2013 American Academy of Pediatrics (AAP) guideline, European guidelines (e.g., Danish 2016, British 2015 summary by Siddiq et al., Italian 2010), Israeli 2016, the Canadian Guide (2016) and Asian guidelines (Korean 2012, Japanese 2014 and its 2018 update)[13-19].

According to AMSTAR-2, in this umbrella review, 17 reviews were judged to be of high quality, 13 of moderate quality, and 2 of low quality (see Table 1, the last column). Two reviews were rated as of low quality: one on herbal medicine (Son et al.[20]) and another on adherence to management guidelines (Siddiq et al.[19], 2015), due to limitations in the strategy for finding and evaluating biases.

Table 1. Articles included in the review.

Author(s), year	Objective of the study	Study setting, participant details	Included method: study design	Results	Strengths and limitations	Quality Rating (AMSTAR-2)
Gattinara et al.[25], 2025	To provide recommendations on the use of antibiotics in AOM and RAOM in previously healthy Italian children	Italy, children >3 months with AOM/RAOM; revision of NICE and SIP guidelines	Systematic review and Delphi consensus; application of GRADE-ADOLOPMENT	Initial use of amoxicillin; observation 48-72h; clavulanate or cephalosporins in selected cases	Strengths: interdisciplinary consensus, updated evidence Limitations: based on previous guidelines	High
Conesa et al.[30], 2024	To review the clinical and economic burden of AOM caused by S. pneumoniae post-introduction of PCV	31 European countries, children ≤5 years old; Literature since 2011	Systematic review; tools ISPOR-AMCP-NPC, ECOBIAS, ROBIS	Reduction in hospitalizations and antibiotic resistance after PCV; Methodological variability	Strengths: multinational approach, economic evaluation Limitations: data heterogeneity	Moderate
Lee et al.[14], 2012	Establish Korean guidelines for the diagnosis and treatment of otitis media in children under 15 years of age	Korea, children <15 years old; national survey and literature review	Adaptation of previous guidelines; national review; expert consensus	Recommendations for diagnosis, treatment, and prevention of AOM/OME	Strengths: local adaptation Limitations: limited evidence in some respects	Moderate
Lieberthal et al.[13], 2013	Update AAP and AAFP guidelines for AOM management in children 6 months to 12 years	USA, children 6 months - 12 years; development with AHRQ and clinical experts	Systematic review; GRADE methodology	Strict definitions, recommendations for observation, antibiotic treatment, and prevention	Strengths: strong methodological basis Limitations: variable applicability in diverse environments	High
Gulani et al.[24], 2009	To compare efficacy of short (<4 days) vs long (≥4 days) antibiotic treatment in children	India; children 4 weeks - 18 years; 35 trials	Systematic review of RCTs; meta-analysis by antibiotic type	There is no major failure with short treatments; lower risk of adverse effects	Strengths: analysis by subgroups Limitations: variability between studies	High
Azarpazhooh et al.[31], 2016	To assess the efficacy of xylitol in preventing AOM in children under 12 years of age	5 RCTs (n=3405), mainly Finland	Cochrane Review; Xylitol vs Control Comparison	Xylitol reduces the incidence of AOM; Lower adherence in children under 2 years of age	Strengths: good methodological quality Limitations: limited general applicability	High
Bardach et al.[29], 2011	To describe the epidemiology of AOM in children in Latin America and the Caribbean	Regional studies, various countries; paediatric population	Systematic review and meta-analysis	High incidence and variability in diagnosis, treatment and etiological agents	Strengths: regional focus Limitations: heterogeneous quality of studies	Moderate
Heidemann et al.[17], 2016	Update Danish guidelines for the management of AOM and OME in preschoolers	Denmark, preschoolers; Evaluation of multiple methodological tools	Review with GRADE, AGREE II, AMSTAR	Recommendations for diagnosis, surgical treatment (tubes, adenoidectomy)	Strengths: rigorous methodology Limitations: indirect evidence in some areas	High
De Sevaux et al.[28], 2020	To assess the effectiveness of PCV in preventing AOM in children under 12 years of age	11 RCTs (n=60.733), various countries	Cochrane Review; GRADE; PCV vs. vaccine control comparison	Reduction of general and pneumococcal AOM, lower recurrence; mild side effects	Strengths: large sample size Limitations: heterogeneity between studies	High
Dissanayake et al.[27], 2024	Review PCV's impact on reducing AOM-resistant strains	International Studies, children <18 years old; 5 databases	Systematic review with PRISMA criteria 2020	ABR reduction S. pneumoniae; increase in serotypes not included	Strengths: current and focus on resistance Limitations: lack of meta-analysis	Moderate
Mather et al.[43], 2019	To assess bacterial prevalence and antimicrobial resistance in pediatric acute otitis media	48 studies, 15,871 samples from children with AOM, various countries	Systematic review and meta-analysis (MEDLINE, EMBASE, Cochrane)	S. pneumoniae (30%) and H. influenzae (23%) were prevalent; 15% resistance to amoxicillin	Strengths: high volume of data Limitations: crop heterogeneity	High
Holm et al.[22], 2020	Determining the real benefit of antibiotics in AOM in the post-vaccine era	5 RCTs (n=1862) in countries with pneumococcal vaccination programmes	Systematic review of RCTs; Outcomes: Pain, adverse effects, recurrences	Antibiotics with limited effect; NNT 7–28; AE in 1 in 13 patients	Strengths: focused on post-vaccination population Limitations: few RCTs	High
Marchisio et al.[18], 2010	To provide diagnostic and therapeutic recommendations for AOM in Italian children	Italy, children 2 months to 12 years, multidisciplinary development	Clinical guideline based on systematic review and consensus	Recommendations on accurate diagnosis, use of antibiotics, vaccines	Strengths: broad support from medical societies Limitations: No meta-analysis	Moderate

Author(s), year	Objective of the study	Study setting, participant details	Included method: study design	Results	Strengths and limitations	Quality Rating (AMSTAR-2)
Siddiq et al.[19], 2014	Review and compare the 2013 AAP guidelines on the diagnosis and management of AOM	Narrative Review Comparing AAP Guidelines with NICE and SIGN	Critical synthesis of official clinical guidelines	AAP allows for initial observation; Better diagnostic definition	Strengths: comparative clarity Limitations: not systematic study	Low
Tsergouli et al.[26], 2023	Comparing efficacy of antimicrobials and placebo vs amoxicillin-clavulanate	12 RCTs (children 6 months to 12 years), Europe and Asia	Systematic review with meta-analysis (RevMan 5.4)	AMX-CLV more effective than placebo, cefdinir, penicillin V; comparable to others	Strengths: direct benchmarking Limitations: heterogeneity	High
Kitamura et al.15, 2015	Update Japanese guidelines for the diagnosis and treatment of AOM in children	Japan, children <15 years old; 2006-2012 revision	National evidence-based clinical guideline; severity stratification	Amoxicillin for mild/moderate cases; alternatives according to resistance	Strengths: adaptation to local resistance Limitations: lack of external validation	High
Lous et al.[33], 2011	To assess the effect of ventilation tubes in children with recurrent AOM	5 RCTs (n=519), Denmark and others	Systematic review; studies with different control groups	Reduction of one episode in 6 months; same efficacy as prolonged antibiotics	Strengths: direct evidence Limitations: heterogeneity, no meta-analysis	Moderate
Neto et al.[41], 2006	Identify modifiable risk factors for recurrent AOM in children	Review of studies from 1966 to 2005, multiple countries	Systematic Review of Observational Studies and RCTs	Pacifier use and daycare increase risk; Breastfeeding is protective	Strengths: preventive approach Limitations: biases in included studies	Moderate
Meherali et al.[37], 2020	Explore information needs and parent experiences about AOM	21 qualitative studies in high-income countries	Qualitative systematic review (PRISMA)	Frequent misinformation; Negative impact on family management and well-being	Strengths: user perspective Limitations: subjectivity and lack of interventions	Moderate
Son et al.[20], 2017	To evaluate the efficacy of phytotherapy in childhood AOM	7 RCTs in Asia (China, Korea, Japan)	Systematic review; Comparison between phytotherapy + antibiotic vs antibiotic alone	Major clinical improvement with combination, but low-quality studies	Strengths: first review of the topic Limitations: high bias, few studies	Low
Hayashi et al.[16], 2020	Update the 2013 Japanese guidelines for the management of AOM in children under 15 years of age, incorporating vaccines and bacterial resistance	Japan, children <15 years old; 2013–2016 Literature Review and National Consensus	Clinical guideline with a focus on otoscopy, gravity and antibiotics according to local bacteriology	Selective use of antibiotics with otoscopic criteria; Amoxicillin-clavulanate effective in severe cases	Strengths: Japanese and global evidence assessment Limitations: international applicability	High
Davies et al.[32], 2025	To assess efficacy of antimicrobial chemoprophylaxis in children with recurrent AOM	20 studies, n=2210; 9 pre-PCV studies quantitatively analyzed	Systematic review and meta-analysis; relative risk with 95% CI; Random-effects models	RR 0.59 (95% CI 0.45–0.77); no controlled trials after introduction of PCV	Strengths: robust meta-analysis Limitations: pre-PCV data, current low applicability	High
van den Aardweg et al.[35], 2010	To assess the effectiveness of adenoidectomy in paediatric AOM/OME	14 RCTs, n=2712; children with AOM/OME	Cochrane systematic review comparing adenoidectomy vs non-surgical management	Adenoidectomy reduces persistent OME; Modest effect on AOM episodes	Strengths: Cochrane evidence Limitations: clinical heterogeneity	High
Deniz et al.[39], 2018	To examine the effect of AOM clinical guidelines on antibiotic and analgesic prescribing	7 observational studies in 6 countries (n=200 – 4.6 million)	Systematic review with ROBINS-I tool	Modest decrease in antibiotic prescribing (5%–12%); Increased painkillers	Strengths: international analysis Limitations: high risk of bias	Moderate
Fichera et al.[38], 2023	Review cases of facial paralysis associated with AOM and propose a therapeutic algorithm	15 studies, n=120; Median age 4.96 years	Descriptive systematic review	88% complete recovery with antibiotic and corticosteroid treatment	Strengths: novel revision Limitations: lack of controlled trials	Moderate
Ranakusuma et al.[42], 2018	To determine effects of systemic corticosteroids in children with AOM	2 RCTs, n=252; children 3 months–6 years	Cochrane Systematic Review; comparison with placebo	No consistent clinical benefits; lack of evidence for routine use	Strengths: rigorous methodology Limitations: few studies	High
Rovers et al.[21], 2006	Identify paediatric subgroups that benefit most from antibiotic treatment	6 RCTs, n=1643; children 6 months–12 years	Meta-analysis with individual data	Significant benefit in children under 2 years of age with bilateral AOM and otorrhea	Strengths: analysis by subgroups Limitations: old data	High

Author(s), year	Objective of the study	Study setting, participant details	Included method: study design	Results	Strengths and limitations	Quality Rating (AMSTAR-2)
Segal et al.[44], 2005	Update guidelines considering antibiotic resistance in AOM	Israel; children with AOM; Narrative Review	Evidence-based guidance and clinical experience	Promotes observation 48–72h; Rational use of amoxicillin and vaccination	Strengths: updated clinical approach Limitations: no systematic review	Moderate
Steele et al.[34], 2017	Synthesizing evidence on ventilation tubes in AOM and OME	147 studies reviewed, random-effects network analysis	Comparative meta-analysis of intervention vs. observation	Initial hearing benefit (1–3 months); No long-term effect	Strengths: broad reach Limitations: limited applicability to healthy children	High
Tamir et al.[8], 2017	Compare global clinical guidelines for the treatment of AOM	International review of guiding documents	Comparative analysis of diagnostic and therapeutic criteria	General consensus on initial observation, use of NSAIDs, and preventive vaccination	Strengths: global review Limitations: Not systematic	Moderate
Venekamp et al.[23], 2015	To evaluate the efficacy and safety of antibiotics in children with AOM	13 RCTs (3401 children); high-income countries; ages 2 months to 15 years.	Cochrane systematic review of RCTs.	Antibiotics slightly reduce pain in later days and some complications; more adverse effects than placebo	Strengths: high methodological quality Limitations: limited to developed countries, no impact on severe complications	High
Michel[36], 2021	To review the role of analgesic ear drops in the treatment of AOM-related pain.	Narrative review including 11 clinical studies, 2 guidelines, 5 reviews; no specific geographic restriction.	Narrative systematic review (2000–2020).	Analgesic ear drops offer rapid onset but short duration; may be considered first-line for pain management.	Strengths: good evidence compilation Limitations: lack of standardized protocols beyond single-dose use.	Moderate
NICE[40], 2022	To update recommendations on the antimicrobial prescribing strategy for AOM in children.	UK; children and adolescents under 18 with AOM; guideline developed with Public Health England.	Evidence-based clinical guideline developed from systematic reviews, meta-analyses, and expert consensus.	Antibiotics offer limited pain relief (NNT=24 at 2–3 days); risk of adverse events (NNH=13); back-up or no antibiotics recommended for most cases. Amoxicillin is first-line.	Strengths: robust methodology, integration of updated evidence and risk-benefit analysis. Limitations: limited direct evidence for certain subgroups and practices.	Not applicable

AOM – acute otitis media; RAOM – recurrent acute otitis media; NICE - National Institute for Health and Care Excellence; SIP - Italian Society of Pediatrics; GRADE - Grading of Recommendations Assessment, Development, and Evaluation; PVC - Pneumococcal conjugate vaccines; OME – otitis media with effusion; AAP - American Academy of Pediatrics; AAFP - American Academy of Family Physicians; AHRQ - Agency for Healthcare Research and Quality; RCTs – randomized controlled trials; NNT - number needed to treat; AE – adverse events; SIGN - Scottish Intercollegiate Guidelines Network; AMX-CLV - amoxicillin-clavulanate.

Antibiotic management of AOM: A central issue addressed in multiple reviews was the efficacy and optimization of antibiotic therapy. Synthesized evidence confirms that antibiotics offer a modest but significant benefit in uncomplicated AOM, shortening pain duration compared to placebo, although many children improve spontaneously within a few days.

A seminal meta-analysis performed by Rovers et al.[21] in 2006, on 1643 children aged 6 months to 12 years, estimated that antibiotics produce a slightly higher cure rate at 3–7 days than no treatment (number needed to treat, NNT=8; i.e., treating 8 children so that 1 more is cured quickly). This benefit is more pronounced in children under 2 years of age with bilateral AOM or otorrhea. On the other hand, in older children with unilateral AOM and mild symptoms, the difference between immediate antibiotic therapy versus watchful waiting is minimal in terms of short-term clinical resolution. For this reason, the guidelines promote initial observation in these mild cases[21,22].

Another review by Venekamp et al.[23] noted that 84% of children with AOM improve spontaneously within 2–3 days without antibiotics, although antibiotics slightly reduce the risk of persistent pain at day 3 (30%, 95% CI 14% to 43%). Regarding the duration of antibiotic treatment, the review by Gulani et al.[24] provided strong evidence that short courses (<4 days) are comparable in efficacy to traditional courses of 7–10 days. In 35 trials analyzed, there was no significant increase in failures when using abbreviated regimens (at 1-month follow-up, RR=1.06; 95%CI 0.95–1.17; p=0.298). In addition, short regimens had a lower incidence of gastrointestinal adverse effects (RR=0.58; 95%CI 0.48–0.70). However, there were exceptions: antibiotics with a very short half-life given only for 2–3 days (e.g., penicillin V for 3 days) did have

more relapses than standard regimens. In contrast, short-course azithromycin was associated with similar (or greater) success than traditional regimens, as was ceftriaxone at 1–2 doses, which showed comparable efficacy to 10 days of amoxicillin. Based on this, modern guidelines usually recommend courses of 5–7 days of amoxicillin in most children (and even 3 days in >2 years with a favourable evolution), reserving 10 days only for <2 years or severe cases[23-25].

Regarding the choice of antibiotic, practically all the guidelines included converge in recommending amoxicillin at high doses (80–90 mg/kg/day) as first-line therapy in the vast majority of cases of acute uncomplicated AOM. This is due to its adequate spectrum (it covers *S. pneumoniae*, the main pathogen, and *Haemophilus influenzae* that does not produce beta-lactamase) and its safe profile. The amoxicillin-clavulanic acid combination is suggested as a first choice only if there are risk factors for beta-lactamase-producing bacteria (e.g., recent antibiotic treatment, concomitant purulent conjunctivitis suggestive of resistant *H. influenzae*) or in severe-onset AOM. The AAP 2013 guideline[13] emphasizes differentiating between severe AOM (defined by moderate to severe otalgia or fever ≥39°C) – in which case it urges immediate treatment with antibiotics (amoxicillin-clavulanate in severe cases, amoxicillin in non-severe cases) – versus non-severe AOM in >2 years – where it endorses observing 48–72 hours before deciding to start antibiotics. Other guides, such as the Italian and Japanese, agree with this direction, emphasizing adapting the handling according to gravity. Tsergoulli et al.[26] state that amoxicillin-clavulanate should be considered the treatment of choice for children between 6 months and 12 years of age diagnosed with acute otitis media. In recurrent AOM or one that does not respond to the first course of amoxicillin (if there is no improvement after 2–3 days), it is recommended to escalate to amoxicillin-clavulanate, and if this fails, consider intramuscular ceftriaxone. These algorithms are derived from studies showing that with each therapeutic step, recovery is achieved for most patients, although the initial failure rate with amoxicillin is low overall (10–20%). It should be noted that macrolides (e.g., azithromycin) are reserved for penicillin-allergic patients, as *S. pneumoniae* exhibits significant macrolide resistance in many regions[13,15,16,25]. In summary, this integrative review confirmed that the optimal antibiotic strategy is to treat in a targeted manner (amoxicillin) only those who need it (according to age and severity), with the shortest possible duration, and to switch to broad-spectrum drugs only if there is therapeutic failure or specific risk factors. This balances clinical efficacy and minimizes the risk of adverse events and bacterial resistance[27].

Pneumococcal vaccines and prevention of AOM: The introduction of pneumococcal conjugate vaccines (PCV7 since 2000; PCV10/13 since 2010) has substantially modified the epidemiology of AOM. Two systematic reviews evaluated its preventive impact. De Sevaux et al.[28] (Cochrane 2020) included 11 trials (60,733 children) and confirmed that vaccination reduces the incidence of AOM: in <1 year vaccinated with PCV7, the relative risk of having ≥1 episode of AOM decreased by about 6–7% in absolute terms; the reduction was greater for recurrent AOM (up to 24% lower risk of recurrences). The PCV10 vaccine (which adds serotypes not covered by PCV7) showed additional reductions in countries with high disease burden.

Dissanayake et al.[27] specifically analyzed the vaccine effect on resistant strains: after the adoption of PCV13, they found a significant decrease in penicillin-resistant *S. pneumoniae* isolates in AOM exudates, with RR 0.5 to isolate resistant strains in vaccinated children versus the pre-vaccination era. However, they also highlighted the phenomenon of serotype replacement: serotypes not included in vaccines (such as 19A at the time of PCV7, or others after PCV13) increased their proportion in post-vaccination AOM. Still, the net impact is positive: the global burden of AOM decreased (for example, in some countries AOM visits fell by 20% after PCVs) and global resistance was reduced, supporting universal vaccination as a highly effective preventive measure.

Another review (Bardach et al.[29]) focused on Latin America and the Caribbeans prior to the introduction of PCV and found a very high incidence of AOM (on average, 3 episodes/year in <5 years), underscoring the potential benefit of vaccination in these regions. They reported an annual incidence of approximately 1,171–36,000 episodes per 100,000 children. Currently, with PCV13/15/20, this downward trend in otitis is expected to continue. However, updated studies are required to quantify the effect of new expanded conjugate vaccines (PCV15, PCV20) on AOM, as they could cover some emerging serotypes.

Conesa et al.[30] assessed the burden of acute otitis media due to *Streptococcus pneumoniae* in European children after widespread pneumococcal vaccination. A total of 107 studies from 31 countries were included. Findings showed reductions in hospitalizations and antibiotic resistance, but a rise in non-vaccine serotypes. A residual disease burden remains, highlighting the need for standardized methods and improved surveillance.

As non-immunological preventive measures, the use of xylitol has generated interest. The Cochrane Review performed by Azarpazhooh et al.[31] reviewed 5 clinical trials in Finland (including 3,405 children) and concluded that xylitol (given in gum or syrup several times a day) modestly reduces the incidence of AOM in healthy children attending day care (relative risk reduction of 25%, from 30% to 22% of children with AOM; RR 0.75, 95%CI 0.65 to 0.88). This effect was mainly observed in children older than 2 years with no

history of recurrent otitis. In infants or children with very frequent infections, the benefit was not significant. In addition, adherence to xylitol was often suboptimal (it is difficult to administer gum or syrup several times daily). Thus, although xylitol is safe and could be recommended as an aid in certain cases (for example, children with recurrent respiratory infections, when they tolerate chewing gum), the evidence does not position it as a generalized preventive policy of high impact.

Another preventive measure discussed is continuous antibiotic chemoprophylaxis in children with recurrent AOM (usually defined as ≥3 episodes in 6 months or ≥4 per year). This practice, common decades ago, has fallen into disuse due to resistance concerns. Davies et al.[32] included in the qualitative analysis twenty studies involving 2,210 children, and nine in the meta-analysis (n = 1,087). Antimicrobial chemoprophylaxis significantly reduced the incidence of recurrent acute otitis media (RAOM) with a pooled risk ratio of 0.59 (95%CI: 0.45–0.77), and a number needed to treat (NNT) of approximately six. Trimethoprim-sulfamethoxazole showed the greatest effect, followed by amoxicillin. Subgroup analysis showed limited evidence of benefit in children ≤5 years or in males. Adherence was high and adverse effects were minimal, but overall evidence quality was moderate to very low with notable publication bias. However, no trials were conducted in the post-pneumococcal vaccine era, and most reported a rebound in otitis after stopping the antibiotic. In addition, adverse events (mainly diarrhoea, rashes) were common and the impact on resistance, although not measured in those old studies, is a tangible risk. Consequently, current guidelines no longer recommend routine continuous antibiotic prophylaxis; rather, they suggest considering surgical measures (ventilation tubes) in children with very frequent recurrences rather than exposing them to prolonged antibiotics.

Surgical interventions (myringotomy with tubes, adenoidectomy): Surgical management has a role in recurrent AOM or otitis media with persistent effusion (OME, which may accompany acute episodes). Several included reviews explored its effectiveness. The review by Lous et al.[33] collected trials on tympanostomy tube placement in children with recurrent AOM (5 studies, 519 children). They found that the tubes reduce the number of AOM episodes in the following year per child by about 1 (on average). This benefit was clearer in the first 6 months post-placement; then the differences are attenuated, in part because many tubes have already been expelled spontaneously or have become clogged. In terms of hearing, in children with persistent effusion, the tubes improve hearing by 5–12 dB in the short term, but there is no evidence of long-term impact on language development.

Steele et al.[34], in a review performed on 147 articles, concluded that the effectiveness of tubes is transient and that the indication should be individualized – which aligns with guidelines, which recommend tubing primarily if there are persistent effusions with hearing loss or language delay, rather than isolated recurrent AOM without effusion. Children with tympanostomy tubes presented a decrease in mean hearing levels of 9.1dB at 1 to 3 months when compared to watchful waiting group, with no difference by 12 to 24 months. In recurrent AOM without effusion, the tubes can space out otitis, but with the cost of anaesthesia, possible otorrheas through the tube (occur in 20% of children), and small tympanic scars. The 2013 AAP/AAO guidelines discourage tubing solely for recurrent AOM unless parents have a good understanding of the risk/benefit balance.

For adenoidectomy, the Cochrane Review by van den Aardweg et al.[35] evaluated 13 studies and found that adenoidectomy – especially in combination with tube placement – significantly reduces AOM recurrences: the NNT was 9 to prevent a child from having recurrent AOM at 12–24 months. The benefit was greater at >2 years and in the presence of concurrent serous otitis. In children under 2 years of age, efficacy was minimal. This suggests that in very young children the adenoids do not yet play an important role, but in older preschoolers with obvious adenoid hypertrophy, surgery helps. Consequently, some European guidelines contemplate adenoidectomy if there is recurrent AOM plus hypertrophied adenoids that obstruct nasal breathing or with concomitant OME, after conservative measures have failed. In summary, the evidence suggests that surgeries should be reserved for selected cases: ventilation tubes improve quality of life by reducing episodes in children with very frequent otitis or chronic effusions, and adenoidectomy adds benefit in subgroups with adenoid hypertrophy. But they are not interventions to be applied indiscriminately to all children with recurrent AOM, since many outgrow the stage of recurrences with age and these procedures carry risks.

Complementary therapies and other interventions: Although of lesser weight in the literature, alternative approaches have been studied. A review by Son et al.[20], investigated the Chinese herbal medicines at AOM: it included 6 small trials in China with heterogeneous results. Some herbal combinations given together with antibiotics appeared to relieve fever and pain more quickly than antibiotics alone, but the quality of the studies was low and no regimen was tested outside Asia. Therefore, there is insufficient evidence to recommend any specific phytotherapy in AOM.

For topical analgesics, some guidelines mention the use of anaesthetic ear drops (e.g., lidocaine) to relieve pain, but no specific systematic review was identified in our search. However, the general recommendation is to use systemic analgesics (ibuprofen, acetaminophen) as a base. Although paracetamol and ibuprofen could relieve pain in the short term in children with AOM, the evidence is limited and of low quality. If the eardrum is intact, lidocaine drops could be used

for moderate pain; if otorrhea (perforated eardrum) is present, drops with ototoxic anaesthetics should be avoided[36].

An important aspect is **the education and expectations of parents**. The review by Meherali et al.[37] evaluated 21 collected studies on the information needs of parents before the AOM**.** It found that many parents are unaware of the self-limiting nature of many AOM episodes, leading them to push for antibiotics. It also showed that they feel uncertainty about how to manage pain or recognize complications. Simple educational interventions (explanatory leaflets, clear instructions during consultation) improve satisfaction and can reduce immediate demand for antibiotics. Therefore, the guidelines emphasize explaining the management plan (either observation or antibiotic) to caregivers and ensuring adequate follow-up. Another qualitative study found that parents who understand the option of watchful waiting are more willing to accept it, especially if they are provided with a "delayed prescription" to fill only if the child does not improve. All of this points to addressing parents' perceptions as key to successfully implementing evidence-based recommendations.

Finally, literature on AOM in special situations was identified. A review by Fichera et al.[38] on **AOM complicated by facial paralysis** in children showed that it is a very rare condition (<0.5% of AOM), generally related to subclinical mastoiditis. Most cases in the literature were managed with intravenous antibiotics and myringotomy, with complete recovery of facial function in more than 90% of the cases, without the need for mastoid surgery. This supports the fact that, in the face of the unusual complication of facial paralysis due to AOM, management can be conservative but energetic (adequate systemic antibiotic and drainage of the middle ear) with a good prognosis – valuable information for clinical guidelines on this topic.

Publication bias and heterogeneity: When plotting the main results of the included reviews (Figure 2), some asymmetry was observed. There seem to be more studies with 'positive' results than 'negative' results than would be expected in a symmetrical graph, suggesting that there may be publication bias (e.g., reviews with no findings may not have been published). Egger's test was statistically significant (p = 0.00013), reinforcing this suspicion. This implies that conclusions should be taken with caution, as the published literature could overrepresent beneficial effects. However, given the diverse nature of the data (different outcomes in different

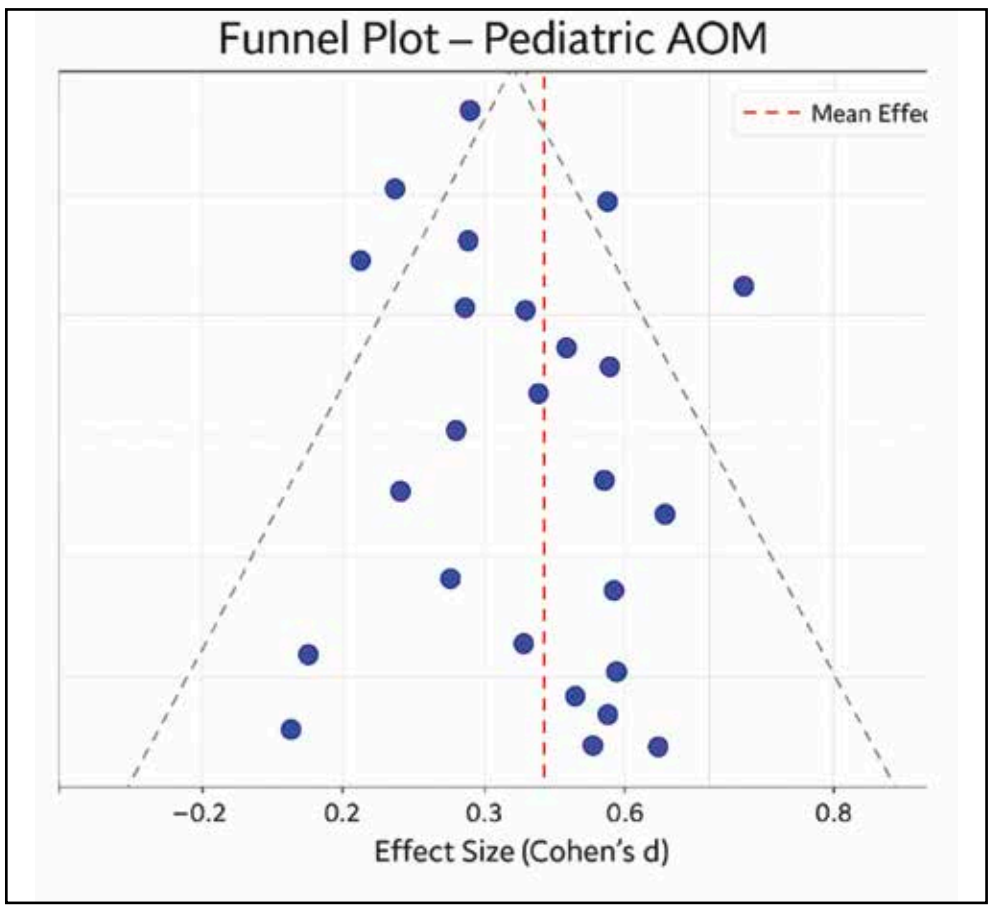

Figure 2. Funnel plot for the assessment of publication bias in the 33 quantitative data series on pediatric AOM. The horizontal axis represents the size of the effect (Cohen's d) and the vertical axis represents the inverted standard error. The red dotted line indicates the combined average effect. The grey diagonal lines correspond to the 95% pseudo-confidence limits. The observed asymmetry suggests the possible presence of publication bias, which was confirmed by the Egger test (p = 0.00013).

populations), this analysis is only exploratory. In terms of heterogeneity, the differences between studies were notable – something to be expected given that we combined everything from guidelines to meta-analyses with different focuses. We did not seek to quantify global statistical heterogeneity beyond the aforementioned $I^2 = 59\%$, but qualitative heterogeneity was identified in: populations (age, thresholds to define recurrent AOM), interventions (variable doses and durations) and measured outcomes. This sometimes made it difficult to directly compare results between reviews. To mitigate this effect, in our synthesis we focus on consistent trends supported by multiple sources.

Evidence Gap Map (Figure 3): This map visually summarized the evidence landscape. It was noted that the "antibiotics versus placebo in AOM" domain is widely studied (multiple large "bubbles" in outcomes of healing, pain, etc., with green colour indicating good quality evidence). The same goes for "pneumococcal vaccines versus AOM incidence" (multiple RCTs, large green bubble). On the other hand, for "systemic corticosteroids versus pain/recurrence" there was only one study (very small yellow bubble). "Parent education versus clinical outcomes" also showed gaps (only qualitative studies, no RCTs evaluating impact on recurrences or adherence). "Xylitol versus prevention" had moderate evidence (a couple of trials, medium yellow bubble). In bacterial resistance outcomes, few reviews directly addressed emerging resistance after interventions, except in the case of vaccines. All of the above indicates that, while we have strong evidence on the pillars of management (antibiotics, vaccines, and ventilation tubes where necessary), there are opportunities for research in complementary strategies (e.g., validating whether structured parent education reduces inappropriate antibiotic use or improves quality of life; evaluating non-anti-inflammatory drugs in AOM; developing vaccines against non-pneumococcal pathogens such as *H. influenzae* nontypeable, etc.).

DISCUSSIONS

This umbrella review provides a comprehensive view of the management of acute otitis media (AOM) in children, integrating findings from 33 synthesis studies (systematic reviews) and clinical guidelines. The results confirm and update several key trends. First, it is reaffirmed that the vast majority of AOM episodes are satisfactorily resolved with conservative management that includes adequate analgesia and close monitoring, reserving antibiotics only for necessary cases. This is supported by robust evidence: meta-analyses with thousands of patients show that, while antibiotics modestly accelerate improvement, the difference is clinically significant primarily in infants and in bilateral or complicated otitis[22].

This knowledge has underpinned the paradigm shift in the last two decades: from treating practically all AOM with immediate antibiotics, to a more selective strategy where initial observation is considered in low-risk cases. Our findings show that guidelines around the world have adopted this approach. For example, North American, European and Asian guidelines agree in recommending active surveillance without an initial antibiotic in older children with

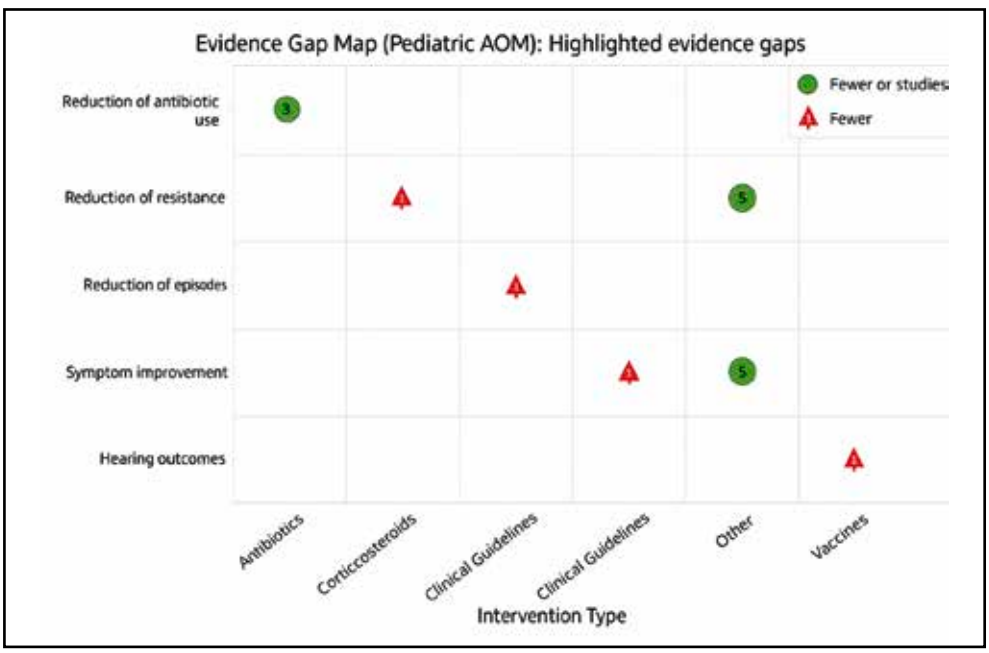

Figure 3. Evidence Gap Map on interventions in pediatric acute otitis media. The X-axis represents the types of interventions, while the Y-axis shows the types of clinical outcomes observed. Each bubble indicates the number of studies that evaluated a specific combination, with its colour indicative of the level of certainty of the evidence (● high, ● moderate, ● low). The symbol ▲ indicates combinations with fewer than two studies, considered relevant evidence gaps.

mild AOM. However, a major challenge remains in implementation: physicians' adherence to these recommendations has been limited, as evidenced by real-world practice studies such as those by Vernacchio et al.[3] and Deniz et al.[39]. The reasons are multifactorial: clinical inertia, concern about complications (although these are rare, such as mastoiditis, whose post-guideline incidence did not increase) and perceived pressure from parents. Addressing these barriers requires educational interventions aimed at both professionals and caregivers.

An outstanding finding is the clear convergence of international guidelines on the central points of management: accurate diagnosis (ideally with pneumatic otoscopy and strict AOM criteria to avoid confusing it with serous otitis), targeted treatment (high-dose amoxicillin as the gold standard) and consideration of severity/age for the therapeutic decision. The review by Tamir et al.[8] remarked that, despite minor differences, practically all the guidelines of different countries emphasize the initial observation and judicious use of antibiotics as common pillars. This is encouraging, as it indicates an evidence-based global consensus. However, they also noticed variations: for example, some European guidelines recommend topical analgesia with lidocaine, while others do not; The definition of "severity" may vary; and only certain guidelines (e.g., the British NICE) formally advise against the use of macrolide antibiotics in view of resistance[40]. These differences reflect local adaptations and areas where the evidence may be weak or interpreted differently. An international harmonization of guidelines could be beneficial, although always considering local contexts (local resistance patterns, monitoring systems, etc.)[8,40].

In terms of prevention, our results underscore the enormous positive impact of pneumococcal vaccination. The burden of AOM has decreased in the post-PCV era[13], and our data reinforce that vaccinated children have less otitis and require fewer antibiotics. This is a clear message for public health policies: maintaining high PCV vaccination coverage is essential, not only to prevent invasive diseases but also to reduce AOM and its consequences. Likewise, the inclusion of the annual influenza vaccine could be explored as a strategy to reduce the incidence of AOM, given that many AOM follow viral respiratory tract infections; some studies suggest that the influenza vaccine modestly reduces the incidence of AOM during flu season. On the other hand, the review revealed that general measures, such as avoiding pacifier use in infants older than 6 months and encouraging exclusive breastfeeding until at least 6 months, could help prevent recurrent AOM. It would be convenient for the guidelines to emphasize these preventive aspects more (several already do so, such as the AAP 2013 that recommends not using a pacifier from the second semester of life to prevent AOM[13,27,41].

A valuable contribution of this review is the identification of evidence gaps. For example, we found that the use of systemic corticosteroids in AOM, under the hypothesis of reducing inflammation and pain, has been very little studied. We found only one 2018 Cochrane review, Ranakusuma et al.[42], which found no clear benefits. Given that corticosteroids are useful in other pediatric infections (croup, pharyngitis), it would be interesting to investigate their role in AOM further, perhaps in cases with significant edema of the tubal mucosa or very intense pain. However, for now its use is not supported by evidence.

Another gap identified is parent education: while qualitatively we know this is crucial, there is a lack of clinical trials that measure whether educational interventions (e.g., explanatory videos in the waiting room, 24-hour telephone support lines) reduce unnecessary consultations or improve compliance with watchful observation. Given the key role of parental expectations in antibiotic prescribing, investing in medical social science studies could have a high return[13].

In relation to adherence to guidelines, the review by Deniz et al.[39], although focused on antibiotic therapy and post-guideline analgesia, showed that the publication of AOM guidelines had a "modest at best" effect in reducing the use of antibiotics and increasing the use of adequate analgesics. This indicates that publishing guides alone does not substantially change practice. Dissemination and implementation strategies (workshops, electronic reminders, clinical audits) are required to achieve effective change. This situation mirrors what has been observed in other fields of medicine, but clear pre- versus post-guideline measurements are available at AOM that show little variation. Therefore, our recommendations should not only focus on *what* to do based on the evidence, but on *how to get* it done. For example, incorporating modules on evidence-based AOM management into continuing medical education, and providing clinicians with tools (e.g., fact sheets to give to parents explaining and justifying observation), among other measures.

Another emerging aspect is antimicrobial resistance. Although pneumococcal vaccination has mitigated resistance in *S. pneumoniae*, we still face resistant bacteria (e.g., certain strains of *non-typable H. influenzae*, not affected by PCV). The review by Mather et al.[43] showed relevant rates of resistance: 15% penicillin-resistant pneumococci in post-PCV samples, and 30-40% beta-lactamase-producing *H. influenzae* in some studies. This justifies continuing with the prudent prescription of antibiotics. The guidelines emphasize the use of high doses of amoxicillin precisely to overcome the relative resistance of pneumococci with decreased sensitivity, and the addition of clavulanate to cover beta-lactamase-producing *H. influenzae*. The fact that the proportion of AOM visits receiving antibiotics remains around 75–80% in the US suggests that there is room for improvement in reducing antibiotic use without impairing outcomes, which would have benefits in terms of bacterial resistance[29].

Finally, it is worth mentioning the quality of the evidence. Many of the conclusions expressed here are supported by randomized clinical trials and meta-analyses of good quality (level of evidence I). However, we note areas with lower-level evidence (IV or V) that nevertheless appear in the guidelines by expert consensus – for example, the recommendation to avoid pacifiers comes from observational studies. Prospective

studies in these areas would be desirable to strengthen the evidence base. Equally, some current practices could be re-evaluated: for example, is 10 days of antibiotics really necessary in children <2 years? Perhaps a study in the PCV era could validate 5-day courses even in infants with good evolution, which would further reduce the antibiotic load. Gulani et al.[24] did not have the power to analyse subgroups by age. Non-antibiotic adjuvant treatments might also be worth exploring: analgesic ear drops with anaesthetics or anti-inflammatories could improve comfort without systemic effects, but robust research is scarce (a 2019 trial in Australia with lidocaine drops showed less pain at 30 minutes compared to placebo). Integrating optimal pain management is critical. Our review found that parents are often dissatisfied if they are only told to "watch" without a clear plan for symptomatic relief. Guidelines should emphasize the importance of offering a schedule of analgesia at home for the first 1–2 days[1,24].

In terms of strengths, this study compiled a wide range of high-level sources, providing a global synthesis that could hardly be obtained from a single focused systematic review. In addition, the use of tools such as evidence gap mapping and publication bias analysis adds a meta-level perspective on the available evidence. Being written in Spanish, it can be particularly useful for disseminating evidence in Spanish-speaking countries where access to so many scattered sources is sometimes limited.

However, there are also limitations. This umbrella review depended on the quality and biases of the original reviews. Although we evaluated their quality with AMSTAR-2, if any contained biases, they are carried over to our work. For example, several non-systematic narrative reviews (e.g., Siddiq et al.[19]) were included because they provided interpretations of guidelines, but did not meet strict methodological rigor. We try to mitigate this effect by prioritizing the findings of formal systematic reviews in the discussion. Another limitation is the possible lack of completeness: despite extensive searching, there may be revisions or guides not captured (e.g., local guides in other languages). However, we consider that the most influential ones were included (e.g., the AAP guide, some European ones, etc.). In addition, the heterogeneity of topics made it difficult to delve into all of them in equal detail; the clinical relevance of each section was prioritized. Finally, the identified publication bias suggests caution: there may be unpublished evidence of negative outcomes (e.g., studies of interventions that did not demonstrate benefit and never saw the light of day). This could oversize the perception of effectiveness of some measures.

CONCLUSIONS

This umbrella review provides a comprehensive update on the management of acute otitis media in the pediatric population, integrating evidence from multiple systematic reviews and clinical guidelines from diverse sources. It is confirmed that the current recommendations — prudent use of antibiotics, initial observation in selected cases, targeted treatment with amoxicillin, shorter courses, universal pneumococcal vaccination, and judicious use of surgical interventions — are supported by robust evidence and have contributed to improving the prognosis and reducing complications of AOM. At the same time, important gaps in knowledge are emerging: there is an urgent need to investigate adjuvant strategies to control symptoms (e.g., topical analgesia), address adherence to guidelines (possibly through education and decision support systems for clinicians and families), and explore interventions in understudied areas (such as non-antibiotic anti-inflammatory therapies).

It is essential to advance in the effective implementation of evidence-based clinical guidelines, promoting their application through educational strategies aimed at health professionals, as well as through audits that allow monitoring their compliance in daily practice. This approach will contribute to reducing the gap between scientific knowledge and its clinical application. It is also key to strengthen communication with parents during the medical consultation, clearly explaining the nature of acute otitis media, its expected clinical course, and therapeutic alternatives, including vigilant observation in selected cases. This education can encourage more rational use of antibiotics and improve adherence to treatment.

In the preventive field, it is recommended to maintain and even expand pneumococcal vaccination coverage, while promoting healthy practices at home, such as breastfeeding, reducing exposure to tobacco smoke and responsible pacifier use. On the other hand, clinical guidelines should be reviewed and updated periodically to incorporate new findings, especially those related to changes in the epidemiology of the disease after the introduction of new generations of vaccines.

Finally, the need to direct future research towards areas where evidence is still insufficient is underlined, through clinical trials and population-based studies that evaluate emerging interventions. Together, these actions will consolidate a more uniform and effective approach to the management of AOM, ensuring quality and equitable care for all children.

Study limitations: This umbrella review was based on the evidence available in published reviews and clinical guidelines, so its conclusions depend on the quality and scope of these sources. Although a broad search strategy was used, there is a possibility that some relevant reviews or guidelines may not have been included. We focused mainly on studies in English (and local guides in Spanish), which could have excluded evidence in other languages. It is worth mentioning that two potentially relevant studies could not be obtained in full text, preventing their evaluation. We also detected indications of publication bias in the literature (funnel plot asymmetry), suggesting that studies with negative results might be underrepresented. We did not perform a meta-analysis of our own due to the marked heterogeneity of the available data. Despite these limitations, we believe that our findings offer a robust synthesis of current evidence and provide valuable

guidance for clinical practice in pediatric otolaryngology.

Clinical implications and recommendations: The findings of this review support several concrete measures to optimize the management of childhood AOM.

Implementation of evidence-based guidelines: It is critical to strengthen the dissemination and adoption of current recommendations (e.g., delayed use of antibiotics in mild cases, amoxicillin as the first line, initial observation) through continuing medical education, in-practice reminders, and clinical decision support systems. Improving practitioners' adherence to guidelines will reduce variability in care and unnecessary antibiotic use.

Education for parents and caregivers: Develop effective communication strategies for parents to understand the self-limiting nature of many AOMs and the importance of appropriate symptomatic management. Simple educational materials (handouts, infographics) and clear conversations during the consultation can decrease caregiver anxiety and increase acceptance of watchful watching when indicated.

Prevention and general measures: Maintain high coverage of pneumococcal vaccination in the pediatric population, given its effectiveness in reducing the incidence of AOM and resistant strains. Likewise, promote measures such as exclusive breastfeeding for the first 6 months of life, avoid passive exposure to tobacco smoke and limit the use of pacifiers in children over 1 year of age, since these interventions are associated with a lower risk of recurrent otitis.

Regular updating of guidelines: Clinical practice guidelines should be reviewed and updated as new evidence emerges (e.g., efficacy of expanded conjugate vaccines, new antibiotics, or therapeutic alternatives). Integrating the findings of this review, such as identified gaps in corticosteroids or family education, would help future versions of the guidelines address these areas of uncertainty.

Future research agenda: It is recommended to direct research efforts towards the gaps detected, through clinical trials and robust studies evaluating: (1) complementary therapies (e.g., non-antibiotic anti-inflammatory drugs) to alleviate AOM symptoms; (2) educational or public health interventions to improve adherence to treatments and guidelines; (3) the long-term impact of surgical options on hearing and language outcomes; and (4) strategies to monitor and mitigate post-vaccination antimicrobial resistance. Generating evidence in these areas will strengthen the comprehensive management of the WCO in the coming years.

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