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Artificial Intelligence-Based Diagnostic Models for Pediatric Secretory Otitis Media: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Faculty of Data Science, City University of Macau.

Review Stage at time of this submission - The review has not yet started.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 August 2026 and was last updated on 9 August 2026.

INTRODUCTION

Review question / Objective To systematically review and meta-analyse the diagnostic accuracy of artificial intelligence (AI)-based models—including machine learning and deep learning algorithms—for the diagnosis of secretory otitis media (otitis media with effusion, OME) in children.

PICOS framework:
- P (Population): Children aged ≤18 years with suspected secretory otitis media. Mixed-age studies will be included if child-subgroup data are extractable.
- I (Index test): AI/ML/DL diagnostic models (e.g., convolutional neural networks, ResNet, support vector machines, random forests, transfer learning), with inputs including otoscopic images, tympanometry, audiometry, or acoustic reflexes.
- C (Comparator / Reference standard): Clinical reference standard—tympanometry (Jerger type B/C), specialist otoscopy, audiological assessment, or myringotomy/tympanocentesis (single or combined).
- O (Outcomes): Primary: sensitivity and specificity. Secondary: area under the receiver operating characteristic curve (AUC-ROC), diagnostic odds ratio (DOR), positive and negative likelihood ratios (+LR / −LR).
- S (Study designs): Diagnostic accuracy studies—cross-sectional, case-control, and cohort (retrospective or prospective).

This review will provide the first comprehensive evidence synthesis of AI-based diagnostic models for pediatric OME, guiding clinical adoption and future research.

Condition being studied Secretory otitis media (otitis media with effusion, OME) — a collection of non-purulent fluid in the middle-ear cleft without signs of acute infection — in children aged ≤18 years.

METHODS

Participant or population Children aged ≤18 years with suspected secretory otitis media (otitis media with effusion, OME). Mixed-age studies will be included if pediatric subgroup data can be extracted separately. No restrictions on sex, ethnicity, or clinical setting (primary, secondary, or tertiary care).

Intervention Artificial intelligence / machine learning / deep learning–based diagnostic models for OME. Eligible algorithms include, but are not limited to: convolutional neural networks (CNN), ResNet, VGG, support vector machines (SVM), random forests, k-nearest neighbors, transfer learning, ensemble methods, and hybrid deep-learning architectures. Input modalities may include otoscopic images, tympanometric curves, pure-tone audiometry data, acoustic reflex data, or multimodal combinations. Threshold- or rule-based methods without a machine-learning component, simple logistic regression without feature engineering, and qualitative expert diagnosis will be excluded.

Comparator Clinical reference standard: pneumatic otoscopy or specialist otoscopy by an ENT/pediatric otolaryngologist; tympanometry (Jerger type B or C); audiological assessment; or myringotomy/tympanocentesis with fluid confirmation. Single reference standards or combinations of these (e.g., tympanometry + otoscopy) are both accepted. Studies without an explicit reference standard will be excluded.

Study designs to be included Diagnostic accuracy studies: cross-sectional studies, case-control studies (nested or traditional), and cohort studies (retrospective or prospective). Both single-gate and two-gate designs are acceptable. Animal studies, conference abstracts, narrative reviews, editorials, case reports, and studies without extractable 2×2 contingency data will be excluded.

Eligibility criteria Inclusion criteria (additional to PICOS):
- Peer-reviewed original diagnostic accuracy studies (full-text articles)
- Published in English or Chinese
- Sufficient data to construct a 2×2 contingency table (TP, FP, FN, TN), or reported sensitivity and specificity with denominators

Exclusion criteria:
- Conference abstracts and conference papers (even if full data obtainable)
- Narrative reviews, systematic reviews, meta-analyses, editorials, letters, case reports
- Animal or in-vitro studies
- Studies not using AI/ML/DL methodology (e.g., simple threshold or logistic regression without feature engineering)
- Studies of adult-only populations (≥18 years) without extractable pediatric subgroup data
- Studies without an explicit clinical reference standard
- Duplicate publications (most comprehensive version retained)
- Studies with insufficient data for 2×2 table and no response from authors after contact.

Information sources We will search the following twelve electronic databases from inception to [search date, please fill]: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science Core Collection, Scopus, IEEE Xplore, CINAHL, ProQuest Dissertations & Theses, China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP (CQVIP), and SinoMed (CBM). No language restriction will be imposed at the search stage (English and Chinese studies will be eligible).

The search strategy will combine three concepts: (1) secretory otitis media and related middle-ear conditions (e.g., otitis media with effusion, glue ear, middle ear, tympanic membrane); (2) artificial intelligence / machine learning / deep learning diagnostic models; and (3) diagnosis / classification / detection. MeSH, Emtree, CINAHL Headings, and Chinese thesauri will be used for controlled vocabulary; free-text terms and truncations will be combined with OR within each concept and AND across concepts. Search strategies will be peer-reviewed by a second information specialist using the PRESS checklist.

Grey literature will be searched via ProQuest Dissertations & Theses, conference proceedings indexed in the databases, and Google Scholar. The reference lists of all included studies and relevant systematic reviews will be hand-searched. Citation chasing (forward and backward) will be performed via Web of Science and Scopus. Clinical trial registries (ClinicalTrials.gov, ChiCTR) will be checked for unpublished or ongoing studies.

Authors of included studies will be contacted (up to three attempts) to obtain missing data (e.g., 2×2 contingency tables). The full search strategies for each database are available from the corresponding author on reasonable request and will be provided as a supplementary file in the final publication.

Main outcome(s) The primary outcomes are the sensitivity and specificity of AI-based diagnostic models for pediatric secretory otitis media, expressed as pooled point estimates with 95% confidence intervals. From these, the diagnostic odds ratio (DOR), positive likelihood ratio (+LR), and negative likelihood ratio (–LR) will be derived.

Quality assessment / Risk of bias analysis Methodological quality and applicability concerns of each included study will be independently assessed by two reviewers using the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) tool. QUADAS-2 evaluates four domains: (1) patient selection, (2) index test(s), (3) reference standard, and (4) flow and timing. Each domain is rated for risk of bias, and the first three domains are additionally rated for applicability concerns. Disagreements will be resolved by consensus or by consulting a third reviewer. Risk-of-bias judgments will be summarized in graphical displays (traffic-light plot and summary bar chart) generated in RevMan 5.4 (The Cochrane Collaboration).

Strategy of data synthesis From each included study we will extract or reconstruct a 2×2 contingency table (true positives, false positives, false negatives, true negatives). Sensitivity and specificity will be pooled using a bivariate random-effects model (the Reitsma model), which accounts for the inherent trade-off between the two measures and is the standard approach for diagnostic test accuracy meta-analysis. Summary operating points with 95% confidence ellipses and a hierarchical summary ROC (HSROC) curve will be produced.

Heterogeneity will be assessed through visual inspection of forest plots and SROC curves, complemented by Cochran's Q test and the I^2 statistic. Where substantial heterogeneity is observed, potential sources will be explored through prespecified subgroup and sensitivity analyses (see Fields 23 and 24). When pooling is not appropriate (e.g., very few studies, extreme heterogeneity, or non-overlapping thresholds), findings will be reported narratively in structured tables.

Publication bias will be examined using Deeks' funnel plot asymmetry test, which is the recommended test for DTA reviews. All analyses will be performed in Stata (release 17 or later) using the midas and metandi packages, or in R (version 4.3 or later) using the mada package.

Subgroup analysis Prespecified subgroup analyses will be performed to explore potential sources of heterogeneity, including:
- Input modality: otoscopic images only; tympanometry only; pure-tone audiometry only; multimodal combinations.
- Algorithm type: deep learning (CNN family) vs. classical machine learning (SVM, random forest, k-NN, etc.).
- Reference standard: single test (otoscopy or tympanometry alone) vs. combined reference standard.
- Age group: infants (<2 years), preschoolers (2–6 years), school-age children (7–12 years), adolescents (13–18 years).
- Study setting: primary/secondary care vs. tertiary/specialist center.
- Study design: cross-sectional vs. case-control vs. cohort.
- Risk of bias (overall low vs. high/unclear).
- Training data size and external validation status (internal validation only vs. external validation).

Subgroup differences will be tested formally by including interaction terms in the bivariate model or by comparing pooled estimates across strata.

Sensitivity analysis The robustness of the pooled estimates will be tested through the following sensitivity analyses:
1. Excluding studies rated as high risk of bias in any QUADAS-2 domain.
2. Excluding studies with fewer than 30 participants or events in either group (small-study effects).
3. Restricting to studies using a single, well-defined reference standard (otoscopy alone or tympanometry alone).
4. Restricting to prospective studies only.
5. Excluding studies without external validation of the AI model.
6. Excluding studies that contributed disproportionately to heterogeneity (leave-one-out sensitivity analysis).
7. Re-analysis using a univariate random-effects model for sensitivity and specificity separately, to compare with the bivariate results.
8. Re-analysis using a fixed-effect (Mantel–Haenszel) model as a sanity check.

Findings of the sensitivity analyses will be reported alongside the primary pooled estimates, and any substantial changes in the direction or magnitude of the effect will be discussed.

Country(ies) involved Macao, China (first affiliation: City University of Macau) and Hangzhou, China (second affiliation: Hangzhou Medical College).

Keywords artificial intelligence; machine learning; deep learning; diagnostic accuracy; otitis media with effusion; pediatric; sensitivity and specificity; systematic review; meta-analysis.

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