INPLASY

Effects of rapid maxillary expansion on hearing: a systematic review

INPLASY202450110
doi: 10.37766/inplasy2024.5.0110
Received: 22 May 2024
Published: 22 May 2024

Leite, LAS; Granjeiro, JM; Maia, JAC.

Corresponding author:
Luciana Leite

lucianaleite_odonto@yahoo.com.br

Author Affiliation:
Fluminense Federal University (UFF).

ADMINISTRATIVE INFORMATION

Support - Does not have financial support.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450110

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2024 and was last updated on 22 May 2024.

INTRODUCTION

Review question / Objective In patients with conductive hearing loss caused by serous otitis media, does rapid maxillary expansion improve hearing when compared to hearing levels before intervention?

Rationale Check the literature whether there is improvement in hearing in patients with serous otitis media after rapid maxillary expansion.

Condition being studied The condition or domain being studied in the given question is conductive hearing loss caused by serous otitis media.

METHODS

Search strategy Electronic bibliographic databases: PubMed/Medline, Web of Science, Scopus, EBSCO, Scielo, Lilacs Cochrane, Science Direct. The gray literature was analyzed using the bases ProQuest e Google Academic.

Participant or population Patients aged 4 to 15 years with maxillary constriction and conductive hearing loss caused by serous otitis media.

Intervention Patients aged 4 to 15 years with maxillary constriction and conductive hearing loss caused by serous otitis media were treated with rapid maxillary expansion (RME). The treatment involved using an expander device designed to widen the maxilla. Initially, patients underwent a comprehensive diagnostic evaluation, including audiometric tests, to establish baseline hearing levels and confirm conductive hearing loss due to serous otitis media. The expander device, customized to fit each patient, was then anchored to the teeth and palate.
The activation protocol required gradual adjustments of the device, usually done daily by the patient or caregiver under the supervision of an orthodontist, to achieve the desired expansion of the maxillary arch. Regular follow-up visits were conducted to monitor progress, make necessary adjustments, and check for any potential side effects. Hearing levels were re-evaluated

immediately after the expansion and at specified intervals, such as one month, three months, and six months post-intervention, to assess the impact of the RME on hearing improvement.

Comparator In the context of this review, the control group comprises the hearing levels of the same patients before the intervention of rapid maxillary expansion. Specifically, this includes the baseline audiometric measurements taken prior to the commencement of the expansion treatment. This approach allows for a within-subject comparison, where each patient serves as their own control.

Study designs to be included Included studies are: randomized clinical trials, non-randomized controlled studies, cohort studies, case-control studies.

Eligibility criteria
Eligibility Criteria:
- Patients aged 4 to 15 years with maxillary constriction and conductive hearing loss caused by serous otitis media.
- Patients diagnosed and treated with rapid maxillary expansion.

Exclusion Criteria:
- Studies not involving rapid maxillary expansion.
- Studies not addressing conductive hearing loss due to serous otitis media.
- Studies involving interventions other than rapid maxillary expansion.

Information sources Electronic bibliographic databases and grey literature.

Main outcome(s) The main outcome is the improvement in hearing in patients with serous otitis media following rapid maxillary expansion. For to measure effect The patients' hearing will be analyzed before and after the intervention with an expander device.

Additional outcome(s) None.

Data management For study selection, two reviewers will independently and blindly apply the eligibility criteria to select studies for inclusion in the systematic review using Rayyan software to screen records. Each reviewer will screen the titles and abstracts of identified studies independently, followed by an independent assessment of the full-text articles of potentially relevant studies. Any disagreements regarding study inclusion will be resolved through consensus between the two reviewers, and if consensus cannot be reached, a third expert will be consulted to make the final decision. The decisions made during the study selection process will be recorded in Rayyan, ensuring an organized and traceable record of the inclusion and exclusion process.
Regarding data extraction, the reviewers will independently extract data from the included studies. This will include details on study design and methodology, participant demographics and baseline characteristics, intervention specifics related to rapid maxillary expansion, and measures of effect such as hearing levels before and after the intervention. One reviewer will perform the initial data extraction, while the second reviewer will check the extracted data for accuracy. Any discrepancies in data extraction will be resolved through discussion and consensus between the two reviewers, with an expert opinion sought if necessary. If data are missing or unclear, study investigators will be contacted to provide the unreported data or additional details. The extracted data will be recorded in an Excel spreadsheet and analyzed using RevMan 5.4 software, ensuring systematic and efficient management of the data. This approach maintains the integrity and reliability of the systematic review through a rigorous and transparent process for study selection and data extraction.

Quality assessment / Risk of bias analysis The risk of bias or quality assessment for the included studies will be conducted using various formal tools appropriate for different study designs. For randomized clinical trials, the Cochrane risk of bias tool will be used to assess characteristics such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. Non-randomized clinical trials will be assessed using the ROBINS-I (Risk Of Bias In Non-randomized Studies - of Interventions) tool. Cohort studies will be evaluated using the Newcastle-Ottawa Scale (NOS), while case-control studies will be analyzed with the Critical Appraisal Skills Program (CASP) tool.
The assessment of risk of bias will be performed independently by two reviewers at both the study and outcome levels. Disagreements between reviewers will be resolved through discussion and consensus, with a third expert consulted if necessary. The results of the risk of bias assessments will inform the data synthesis, providing a clear understanding of the potential limitations and strengths of the included studies.
The outcomes of the assessments will be presented both as a graph and a summary. The risk of bias graph will display the reviewers' judgments about each risk of bias item as

percentages across all included studies. The risk of bias summary will present the reviewers' judgments about each risk of bias item for each included study. This comprehensive approach ensures a rigorous and transparent evaluation of the quality and reliability of the evidence.
Unsolved disagreements between reviewers' judgments will be resolved with the intervention of the specialist. the included studies.
The outcomes of the assessments will be presented both as a graph and a summary. The risk of bias graph will display the reviewers' judgments about each risk of bias item as percentages across all included studies. The risk of bias summary will present the reviewers' judgments about each risk of bias item for each included study. This comprehensive approach ensures a rigorous and transparent evaluation of the quality and reliability of the evidence.
Unsolved disagreements between reviewers' judgments will be resolved with the intervention of the specialist.

Strategy of data synthesis The data synthesis for this systematic review will be conducted with a minimum of five included stuydies to assess hearing levels before and after the intervention of rapid maxillary expansion. The planned synthesis includes both narrative and quantitative components.
A narrative synthesis will be provided, structured around the type of intervention, the characteristics of the target population, the type of outcomes measured, and the content of the intervention. This will allow for a comprehensive understanding of the context and variations across the included studies.
For the quantitative synthesis, we will calculate summary effect measures for each study. Risk ratios will be calculated for dichotomous outcomes, while standardized mean differences will be used for continuous outcomes. Data from individual studies will be entered into RevMan 5 software for analysis.
To determine the consistency and appropriateness of pooling data, we will assess the heterogeneity of the studies using the I^2 statistic and chi^2 test. If heterogeneity is low ($I^2 < 50\%$), a fixed-effects model will be used to combine the data. If significant heterogeneity is detected ($I^2 \geq 50\%$), a random-effects model will be applied to account for variability among the studies.
This specific approach ensures that the synthesis is tailored to the data and objectives of the review, providing a robust and transparent analysis of the effects of rapid maxillary expansion on hearing levels in patients with serous otitis media.

Subgroup analysis None.

Sensitivity analysis In the context of this systematic review, sensitivity analysis will be conducted to assess the robustness of the findings and to explore the impact of various assumptions and decisions made during the review process. Sensitivity analysis will involve reanalyzing the data by systematically varying key parameters and inclusion criteria to determine how these changes affect the overall results.

Specifically, the sensitivity analysis will include the following steps:

1. **Exclusion of Studies with High Risk of Bias:** We will perform analyses excluding studies that are rated as having a high risk of bias according to the Cochrane risk of bias tool, ROBINS-I, NOS, CASP, or JBI tools, depending on the study design. This will help determine the influence of high-risk studies on the overall findings.

2. **Alternative Statistical Models:** If substantial heterogeneity is detected ($I^2 \geq 50\%$), we will compare the results of the random-effects model with those of a fixed-effects model to evaluate the consistency of the findings.

3. **Subgroup Analyses:** Sensitivity analyses will be conducted for different subgroups, such as age groups (e.g., younger vs. older children within the 4 to 15 years range) or severity of hearing loss, to investigate whether the intervention's effectiveness varies across different populations.

4. **Duration of Follow-Up:** We will analyze the impact of different follow-up durations by separately assessing studies with shorter follow-up periods (e.g., less than 6 months) and those with longer follow-up periods (e.g., 6 months or more).

5. **Inclusion Criteria Variations:** The analysis will be repeated by including and excluding studies based on variations in inclusion criteria, such as studies with different definitions of serous otitis media or different methods of audiometric assessment.

The results of the sensitivity analysis will be reported in detail, highlighting any significant changes in the effect estimates and the robustness of the overall conclusions. This comprehensive approach ensures that the findings of the systematic review are reliable and generalizable, taking into account potential sources of bias and variability in the included studies.

Language restriction None.

Country(ies) involved Brazil.

Other relevant information None.

Keywords Rapid Maxillary Expansion; Serous Otitis Media; Conductive Hearing Loss; Audiometric Assessment; Orthodontic Intervention.

Dissemination plans A paper will be submitted to a leading journal in this field.

Contributions of each author

Author 1 - Luciana Leite - Author 1 carried out the experimental design, data analysis and drafted the manuscript.
Email: lucianaleite_odonto@yahoo.com.br
Author 2 - José Granjeiro - The author 2 carried out the experimental design, data analysis, drafted the manuscript and performed a statistical analysis.
Email: jmgranjeiro@gmail.com
Author 3 - José Maia - The author 3 carried out the experimental design, data analysis and drafted the manuscript.
Email: josecalasans@gmail.com