**Table E-5. High risk of bias: Observational**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Bozkurt and Calguner, 200442  Study Design  Prospective cohort | Recruitment strategy differ across groups?  Unknown  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  Yes  I/E criteria equally applied in both groups?  Unknown  All outcomes pre-specified? All pre-specified outcomes reported?  Unknown | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Unclear or NR  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Retrospective comparison group - all tubes had been extruded by time study was done. No patient characteristics are provided other than age. Refers to SOM as an infection in discussion and so not confident this study is about OME rather than AOM. Data not provided on all participants. Unclear to what extent analysis is of ears compared to people. |

Abbreviations: AOM = acute otitis media; I/E = inclusion/exclusion; NA = not applicable; NR = not reported; OME = otitis media with effusion; SOM = secretory otitis media

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  D'Eredita, 200443  Study Design  Prospective cohort | Recruitment strategy differ across groups?  No  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  Unclear or NR | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  Unclear or NR  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No (Not accounted for or not identified) | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  Yes  I/E criteria equally applied in both groups?  Yes  All outcomes pre-specified? All pre-specified outcomes reported?  Unclear or NR | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Unclear or NR  Health outcome measures equal, valid and reliable?  Unclear or NR  Harms outcome measures equal, valid and reliable?  Unclear or NR | Risk of Bias  High  **Notes Explaining Risk of Bias**  Very small sample size. Information about subjects is extremely limited. The outcome of presence or absence of sclerosis of the TM was determined by visual assessment by one individual. Time period of outcome evaluation not specific and specific data on hearing or dysfunction of the TT. |

Abbreviations: I/E = inclusion/exclusion; NR = not reported; TM = tympanic membrane; TT = tympanostomy tubes

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Hassmann et al., 200444  Study Design  Prospective cohort | Recruitment strategy differ across groups?  Yes  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  No  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No (Not accounted for or not identified) | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  No  I/E criteria equally applied in both groups?  NA  All outcomes pre-specified? All pre-specified outcomes reported?  NA | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Yes  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Comparison groups taken from different time periods; followup period was 2 yrs in one arm but ~1 year in the 2 other arms. The groups have children of different ages. Some in each group received adnoidectomy so concurrent treatment was not controlled. TT group based on consistency of fluid and so different characteristics than myringotomy alone group resulting in groups not being comparable. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported; TT = tympanostomy tubes

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Hornigold et al., 200845  Study Design  Prospective cohort | Recruitment strategy differ across groups?  No  **Baseline characteristics similar between groups?**  Yes  If not, did the analysis control for differences?  NA | Outcome assessors blinded to the intervention or exposure status of participants?  No  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No (Not accounted for or not identified) | Maintain fidelity to the protocol?  NA  **Time of followup or time period between intervention/exposure equal in both groups?**  Yes  I/E criteria equally applied in both groups?  Yes  All outcomes pre-specified? All pre-specified outcomes reported?  Unclear or NR | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Yes  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  Yes | Risk of Bias  High  Notes Explaining Risk of Bias  Descriptive analysis of 7 participants from original sample of 150 children, after 20 years. No statistical analysis and sample too small to control for any intervening confounders. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Katz et al., 199546  Study Design  Retrospective cohort | Recruitment strategy differ across groups?  NA  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  Unclear or NR  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  NA  I/E criteria equally applied in both groups?  No  All outcomes pre-specified? All pre-specified outcomes reported?  No | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  NA  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  I/E criteria and outcomes not pre-defined; no baseline characteristics reported; study seems to be more of an exploratory analysis that measured hearing outcomes based on identifiable medical records at 6 to 12 months. Study did not control or identify any differences in groups that received different treatment options. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Marshak et al., 198047  Study Design  Retrospective cohort | Recruitment strategy differ across groups?  No  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  NA  I/E criteria equally applied in both groups?  Unclear or NR  All outcomes pre-specified? All pre-specified outcomes reported?  Yes | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Unclear or NR  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Similarity of groups based on age distribution only; otherwise no other baseline characteristics reported.Groups developed based on chart review of treatment received rather than also controlling for patient characteristics. Outcome is a composite measure of hearing and fluid and results for each of these outcomes is not provided. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Matt et al., 199148  Study Design  Retrospective cohort | Recruitment strategy differ across groups?  Unclear or NR  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  No  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No (Not accounted for or not identified) | Maintain fidelity to the protocol?  Yes  **Time of followup or time period between intervention/exposure equal in both groups?**  No  I/E criteria equally applied in both groups?  Unclear or NR  All outcomes pre-specified? All pre-specified outcomes reported?  No | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  NA  Health outcome measures equal, valid and reliable?  Unclear or NR  Harms outcome measures equal, valid and reliable?  Yes | Risk of Bias  High  Notes Explaining Risk of Bias  No characteristics of the groups were reported. Participants in one of the TT groups had more severe disease at baseline and had previous procedures done on the TM. Additionally, the outcomes were reported from different date ranges at the two institutions and within groups, followup period varied widely. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported; TM = tympanic membrane; TT = tympanostomy tubes

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Robinson, 198749  Study Design  Retrospective cohort | Recruitment strategy differ across groups?  NA  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  NA | Outcome assessors blinded to the intervention or exposure status of participants?  No  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  NA  I/E criteria equally applied in both groups?  No  All outcomes pre-specified? All pre-specified outcomes reported?  No | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  NA  Health outcome measures equal, valid and reliable?  Unclear or NR  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Unclear if this is a within person comparison or a comparison between ears with some individuals having 2 ears in same condition. Some of the patients had tumors in addition to OME. The population included teens and adults and there were no controls for comorbidities |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported; OME = otitis media with effusion

**Table E-5. High risk of bias: Observational**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Randomization**  **Groups** | **Masked**  **Statistical Analysis** | **Miscellaneous** | **Outcomes and Attritions** | Risk of Bias |
| Author, Year  Siegel and Chandra, 200250  Study Design  Prospective cohort | Randomization adequate?  NA  Allocation concealment adequate?  NA  Strategy for recruiting participants differ across study groups?  No  Groups similar at baseline?  Unknown  If not, did the analysis control for differences?  No | Providers masked?  No  Patients masked?  No  Outcome assessors masked?  Unclear or NR  Any impact from a concurrent intervention or exposure ruled out?  No  ITT analysis?  NA  Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?  No | Maintain fidelity to the protocol?  Unclear or NA  **Followup the same between the groups?**  Yes  I/E criteria equally applied in both groups?  No  All outcomes pre-specified? All pre-specified outcomes reported?  No | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately?  NA  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Group assignment chosen by parent; statistically significant age difference between groups and no other characteristics reported. Outcome is statisfaction with various treatment options but patients are self selected into one that they choose and so it is not possible to disentangle difference between the procedures from differences between the participants. |

Abbreviations: I/E = inclusion/exclusion; ITT = intent to treat; NA = not applicable; NR = not reported

Table E-5. High risk of bias: Observational

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | **Risk of Bias** |
| Author, Year  Slack, et al., 198720  Study design  Retrospective cohort | Recruitment strategy differ across groups?  Yes  Baseline characteristics similar between groups?  Unknown, NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  No  Any impact from a concurrent  intervention or exposure status ruled out?  No  Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?  No | Maintain fidelity to the protocol?  Unknown  Time of followup or time period between intervention/exposure equal in both groups?  Yes  I/E criteria equally applied in both groups?  Yes  All outcomes pre-specified? All pre-specified outcomes reported?  Unknown | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  NA  Health outcome measures equal, valid and reliable?  NA  Harms outcome measures equal, valid and reliable?  Yes | Risk of bias  High  Notes explaining risk of bias  This study examines differences in otorrhea rates by TT type. No data is provided about participant characteristics, except that they had OME. One type of TT was found to have a much higher rate. As stated by the authors, it’s possible that the group of patients who were given that type of TT had more long standing disease. We assume (authors did not say) if any of the patients also received adenoidectomies.  Study included in harms analysis. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported; OME = otitis media with effusion; TT = tympanostomy tubes

Table E-5. High risk of bias: Observational

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | **Risk of Bias** |
| Author, Year  Smyth et al., 198251  Study design  Retrospective cohort | Recruitment strategy differ across groups?  NR  Baseline characteristics similar between groups?  Unknown  If not, did the analysis control for differences?  No, analysis by ears and by participant | Outcome assessors blinded to the intervention or exposure status of participants?  No  Any impact from a concurrent  intervention or exposure status ruled out?  No, more than 1/3 of children also had adenoidectomy  Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?  No | Maintain fidelity to the protocol?  Unknown  Time of followup or time period between intervention/exposure equal in both groups?  No  I/E criteria equally applied in both groups?  Unknown  All outcomes pre-specified? All pre-specified outcomes reported?  Unknown | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Attrition unknown  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable? | Risk of bias  High  Notes explaining risk of bias  This study combined data from an NRCT to chart records to compare outcomes by TT type. However, the study did not control for potential differences between the children in the samples and a sizable percentage had a concurrent intervention. This is not controlled for in the analysis and the study does not report the percentage in each group. Possible baseline differences between participants receiving different types of TTs are not controlled for as well. |

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Groups** | **Masked and Statistical Analysis** | **Miscellaneous** | **Outcomes** | Risk of Bias |
| Author, Year  Strachan et al., 199652  Study Design  Retrospective cohort | Recruitment strategy differ across groups?  Unknown  **Baseline characteristics similar between groups?**  Unclear or NR  If not, did the analysis control for differences?  No | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No | Maintain fidelity to the protocol?  Unclear or NR  **Time of followup or time period between intervention/exposure equal in both groups?**  Unknown  I/E criteria equally applied in both groups?  Unclear or NR  All outcomes pre-specified? All pre-specified outcomes reported?  Yes | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  Unclear or NR  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  NA | Risk of Bias  High  Notes Explaining Risk of Bias  Matching between cases and controls only by age; I/E criteria not defined or pre-specifed and so not possible to determine why differences were observed between groups. Followup time varied within each group. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Randomization**  **Groups** | **Masked**  **Statistical Analysis** | **Miscellaneous** | **Outcomes and Attritions** | Risk of Bias |
| Author, Year  Yaman et al., 201053  Study Design  Retrospective cohort | Randomization adequate?  NA  Allocation concealment adequate?  NA  Strategy for recruiting participants differ across study groups?  No  Groups similar at baseline?  Unclear or NR  If not, did the analysis control for differences?  No | Providers masked?  NA  Patients masked?  NA  Outcome assessors masked?  Nnclear or NR  Any impact from a concurrent intervention or exposure ruled out?  No  ITT analysis?  NA  Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?  No | Maintain fidelity to the protocol?  Unclear or NR  **Followup the same between the groups?**  NA  I/E criteria equally applied in both groups?  Yes  All outcomes pre-specified? All pre-specified outcomes reported?  Yes | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately?  NA  Health outcome measures equal, valid and reliable?  NR  Harms outcome measures equal, valid and reliable?  Yes | Risk of Bias  High  Notes Explaining Risk of Bias  No baseline characteristics reported besides diagnosis and sex; potential confounding factors not accounted for in analysis. The analysis includes both children that had tubes in one ear and myringotomy in the other (used as their own control) and children who had just myringotomy or just tubes. Because of this, there is unknown confounding in the analysis. Analysis is conducted after different lengths of time in different groups. |

Abbreviations: I/E = inclusion/exclusion; ITT = intent to treat; NA = not applicable; NR = not reported

**Table E-5. High risk of bias: Observational (continued)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Identifiers** | **Randomization**  **Groups** | **Masked**  **Statistical Analysis** | **Miscellaneous** | **Outcomes and Attritions** | Risk of Bias |
| Author, Year  Zanetti et al., 200554  Study Design  Case control | Recruitment strategy differ across groups?  Unclear or NR  **Baseline characteristics similar between groups?**  NA  If not, did the analysis control for differences?  NA | Outcome assessors blinded to the intervention or exposure status of participants?  Unclear or NR  **Any impact from a concurrent  intervention or exposure status ruled out?**  No  **Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?**  No (Not accounted for or not identified) | Maintain fidelity to the protocol?  Yes  **Time of followup or time period between intervention/exposure equal in both groups?**  Yes  I/E criteria equally applied in both groups?  Unclear or NR  All outcomes pre-specified? All pre-specified outcomes reported?  No | If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?  NA  Health outcome measures equal, valid and reliable?  Yes  Harms outcome measures equal, valid and reliable?  Yes | Risk of Bias  High  Notes Explaining Risk of Bias  No characteristics about the case controls, or how they were chosen are reported. I/E criteria were not discussed and therefore could not determine if differences in outcomes were due to the different procedures or patient characteristics. |

Abbreviations: I/E = inclusion/exclusion; NA = not applicable; NR = not reported