Clinical Otolaryngology

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SYSTEMATIC REVIEW OPEN ACCESS

The Prognostic Value of Active Otitis Media on Tympanoplasty Success Rate—A Systematic Review

Hanae Fumiyo Namba[1] | Mariëlle Bernadette Plug[1] | Adriana Leni Smit[2,3]

[1]Faculty of Medicine, University of Utrecht, Utrecht, The Netherlands | [2]Department of Otorhinolaryngology—Head and Neck Surgery, University Medical Center Utrecht, Utrecht, The Netherlands | [3]Department of Neurology, UMC Utrecht Brain Center, University Medical Center Utrecht, Utrecht, The Netherlands

Correspondence: Adriana Leni Smit (a.l.smit-9@umcutrecht.nl)

Received: 7 August 2023 | **Revised:** 9 July 2024 | **Accepted:** 13 July 2024

Funding: The authors received no specific funding for this work.

Keywords: chronic otitis media | myringoplasty | success rate | tympanoplasty | wet versus dry ear

ABSTRACT

Objectives: The aim is to investigate the influence of an active otitis media on the success rate of tympanoplasty in patients with a chronic otitis media (COM) and a tympanic membrane perforation.

Databases Reviewed: PubMed, Embase and the Cochrane Library.

Methods: The inclusion criteria were studies on closure rates of tympanoplasty performed in COM patients of any age with a tympanic membrane perforation caused by COM. The exclusion criteria were studies on patients undergoing concomitant mastoidectomy, ossicular chain reconstruction, tuboplasty, adenoidectomy, revision tympanoplasty, patients with perforations due to other conditions than COM, and letters to editors, commentaries, conference abstracts and case reports. The included articles were critically appraised using the QUIPS tool. Data on tympanic membrane closure rate were extracted, odds ratio (OR) and 95% confidence intervals (CI) of the closure rate with a wet versus a dry ear were calculated.

Results: The search was performed on 1 February 2023. Of 4671 articles, 16 studies were included and critically appraised. Of these observational studies (nine prospective, seven retrospective), with a total of 1509 patients (dry ear group $n = 1003$; wet ear group $n = 506$), two studies stated a significant difference in success rate, one in favour of a dry ear and one in favour of a wet ear at time of surgery. All other studies did not show a statistically significant difference. Overall, the risk of bias was considered moderate to high.

Conclusions: We found no significant prognostic value of having an active otitis media during tympanoplasty on tympanic membrane closure rates. Because the overall risk of bias was considered moderate to high, no strong conclusions can be made. To be able to answer this question with higher levels of evidence, high-quality prospective or randomized studies are needed.

1 | Introduction

Chronic suppurative otitis media (CSOM), also referred to as chronic otitis media (COM), is a chronic inflammation of the middle ear and mastoid cavity, characterized by ear discharge through a perforated tympanic membrane [1]. The prevalence of COM varies between countries and populations. Previously, the World Health Organization estimated that between 65 and 330 million people suffer or have signs of COM [2]. To be noted, otitis media is not only the main cause of preventable hearing loss but also can have a big impact on quality of life [3]. Patients with persistent tympanic membrane perforations are at risk for middle ear infections which can lead to further hearing damage. Besides this, tympanic membrane perforations can also lead to

Summary

- For patients with a tympanic membrane perforation due to chronic otitis media, tympanoplasty is an important treatment option.
- Up to this day, evidence lacks on timing of tympanoplasty, that is, whether closure rates differ between an active versus inactive infection (or wet vs. dry ear).
- In this systematic review including 16 studies, one study showed a statistically significant closure rate in favour of a wet ear, one study showed a statistically significant closure rate in favour of a dry ear and all other studies showed no difference.
- Based on the QUIPS tool, overall risk of bias was considered moderate to high.
- Further high-quality prospective or randomized studies are needed for conclusive evidence.

epithelial migration to the middle ear resulting in cholesteatoma formation and damage to the ossicles of the middle ear [4].

In case of a discharging ear, otorrhoea can often be treated successfully by topical or oral antibiotics. In case of a persistent tympanic membrane perforation, a Type 1 tympanoplasty can be considered to reduce the risk of recurrent ear inflammations and restore hearing. Type 1 tympanoplasty, or myringoplasty, is a common procedure applied in children and adults with reported success rates up to 86% [5]. Several factors have been found to be related to the chance of successfully closing the tympanic membrane in Type 1 tympanoplasty, such as the age of the patient, the size of the perforation and the graft material used [5, 6]. Previously, it has been stated that stopping an ongoing active otitis media is necessary to enhance the success rate of this procedure [6–9]. However, so far it is unclear if there is any evidence to support this statement. Therefore, a systematic review of literature on the prognostic value of an active otitis media on the tympanic closure rate after tympanoplasty is needed to facilitate decision making whether to perform Type 1 tympanoplasty in patients with active otitis media at time of surgery.

2 | Materials and Methods

We used PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines for this systematic review [10]. See Appendix 1 for the PRISMA checklist. The protocol for this study was registered in Prospero (registration number CRD42021250780).

2.1 | Search Strategy

Original studies reporting on tympanic membrane closure rates and otitis media were considered eligible for inclusion. A systematic search of the literature was performed on 1 February 2023 in PubMed, Embase and the Cochrane Library. A search syntax was built using MeSH terms and synonyms of 'tympanoplasty' and 'active otitis media' (see Appendix 2) in title/abstract, medical subject headings (MeSH) terms and Emtree fields. In addition to electronic database searches, reference lists were scanned to identify additional studies. There was no restriction in publication year.

The participants were patients with a tympanic membrane perforation due to chronic otitis media; the intervention was tympanoplasty; the comparison was wet versus dry ear at time of surgery; the outcome was tympanic membrane closure rate; the timing was any time point; and the types of studies included were all except for letters to editor, commentaries, conference abstracts and case reports.

2.2 | Study Selection

The articles found were deduplicated in Mendeley, manually checking the duplicate pair with a low confidence indication. After this, two authors (H.F.N. and M.B.P.) independently scanned the initial search results on title/abstract, using Rayyan. The retrieved studies were then reviewed full text using the predefined inclusion and exclusion criteria. Duplicates, studies in different languages other than English and Dutch and reports about non-original studies were excluded. Articles in the English and Dutch languages were included due to the screening authors' proficiency in these languages. If an article was not available in full text, the author was contacted by ResearchGate e-mail to request the full text article. In case of no response, studies were excluded. Differences in opinion regarding the inclusion of studies were resolved by discussions by the research team to reach consensus. Cross reference checking of included studies was performed.

2.3 | Study Inclusion and Exclusion Criteria

Inclusion criteria were studies reporting on closure rates or graft uptake rates of tympanoplasty performed in COM patients of any age with a tympanic membrane perforation caused by COM. Exclusion criteria were studies on patients undergoing concomitant mastoidectomy, ossicular chain reconstruction, tuboplasty, adenoidectomy, revision tympanoplasty, or patients with tympanic perforations related to other conditions than chronic otitis media (e.g., after ventilation tube extrusion or trauma). Furthermore, letters to editors, commentaries, conference abstracts and case reports were excluded (Table 1).

2.4 | Quality Assessment of the Studies

The included studies were critically appraised on the risk of bias (RoB) by two reviewers (H.F.N. and M.B.P.) independently. The QUIPS tool [11] was used to assess the following six domains for each individual study: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding and statistical analysis and reporting. For each domain the risk of bias was judged and categorized as low, moderate or high risk of bias. The scoring system is specified in Appendix 3. Differences in opinions were solved by discussion in the research team to reach consensus. For the domain 'study confounding', covariates that were considered relevant were age, size of the perforation, graft material and pre-, peri-, and post-operative antibiotic treatment [5].

TABLE 1 | Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Population: COM patients, any age, with tympanic membrane perforation due to COM	Concomitant mastoidectomy, ossicular chain reconstruction, tuboplasty, adenoidectomy
Intervention: tympanoplasty procedure	Tympanic membrane perforation due to other cause than COM (e.g., after ventilation tube extrusion, trauma)
Outcome: closure rate, graft uptake rate	Revision tympanoplasty
	Study type: letter to editor, commentary, conference abstract, case report

2.5 | Outcome Measures, Data Extraction and Synthesis

The primary outcome of the current study was the closure rate of the tympanic membrane perforation stated within the first 5 years of follow-up after surgery. For this, variables were extracted in an Excel file from the included studies by one author (H.F.N.), to be converted in tables for summary of outcomes. The following data were retrieved: study design, country of the study, the sample size in the wet (having an active otitis media at time of surgery) and dry ear group (having no active otitis media at time of surgery) per study, the age range, the method to determinate whether an active otitis media was present at time of surgery, the method used to determine the closure rate of the tympanic membrane, the type of graft used, the graft uptake rate and the length of follow-up after surgery. The second author (M.B.P.) checked the extracted data.

2.6 | Statistical Analysis

The odds ratio (OR) and 95% confidence intervals (CI) for the prognostic value of active otitis media on success rate of surgical tympanic membrane closure were extracted for all studies. In case this number was not provided in the article, the OR was calculated by our study team. As we anticipated considerable heterogeneity between studies (differences in age, pre- or peri-operative antibiotic treatments, surgical procedures and methods to assess active otitis media and tympanic membrane closure), we did not intend to perform a meta-analysis.

3 | Results

3.1 | Study Search and Selection

The electronic search yielded a total of 6824 articles. After deduplication, 4671 remained for title/abstract screening (see Figure 1 for the flowchart). One hundred thirty articles were selected for full text screening. A total of 115 studies were excluded due to various reasons: no full text available ($n = 47$), wrong language ($n = 4$), wrong study type ($n = 14$), wrong determinant ($n = 25$), wrong domain ($n = 24$) and wrong outcome ($n = 1$). Finally, 16 studies were included in this review, of which one through cross-reference checking.

3.2 | Study Characteristics

Baseline characteristics of the included studies are shown in Table 2. Of the 16 studies included, nine were prospective cohort studies [12, 13, 15–18, 23, 24, 26] and seven were retrospective cohort studies [14, 19–22, 25, 27]. The articles were published between 1998 and 2023. Most of the studies (11 out of 16; 69%) were conducted in Asia [12, 15, 16, 18–20, 23–27], with seven of these 11 from India [12, 15, 16, 23–26] and five out of 16 (31%) studies were conducted in Europe [13, 14, 17, 21, 22]. Two studies included only paediatric patients [14, 21], 11 studies included non-paediatric patients (with a definition varying between 15+ and 16+ years of age) [15–18, 20, 22–27], one study did not specify the age of included patients [14] and two studies included both paediatric and non-paediatric patients [12, 13]. A total of 506 patients were included in the active otitis media group ('wet ear' group) and 1003 in the control group ('dry ear' group). The sample size per study varied from two/15 to 123/171 (participants in the wet/dry group, respectively). In 10 studies, a temporal fascia graft was used for tympanoplasty [12–17, 21, 24–26]; in two studies, a cartilage graft was used [18, 27]; in one study, both temporal fascia and cartilage grafts were used [22] and in three studies, the type of graft used was unclear [19, 20, 23]. The length of follow-up reported in included studies varied between 3 and 68 months. Otoscopy was most often used to define whether the tympanic membrane was successfully closed after surgery, that is, in seven of 16 studies [12, 14, 15, 18, 20, 26, 27]. In the other nine studies, the method to assess the outcome was not specified [13, 16, 17, 19, 21–25].

3.3 | Risk of Bias Assessment

The risk of bias assessment of included studies can be found in Table 3. The predefined criteria are described in Appendix 3. For the domain 'study participation', four studies scored a low risk of bias [15, 22, 24, 27]. The other studies scored a moderate or high risk of bias, since in nine of 16 studies, it was unclear how patients were included [13, 16–21, 23, 26]. Furthermore, 11 out of 16 articles did not include a baseline characteristics table [12–14, 16, 17, 19–21, 23, 25, 26]. All studies scored a low risk of bias on 'study attrition' since there was no loss to follow-up in 15 of 16 studies, and in one study, patients with loss to follow-up were excluded from statistical analyses [13]. 'Prognostic factor measurement' was only rated low risk of bias in Deosthale et al. [15], Shankar et al. [24] and Yang et al. [27], because the other studies did not specify how and when the presence of otorrhoea was investigated. In the domain 'outcome measurement', in nine of 16 studies, it was unclear which method was used to determine whether the tympanic membrane was closed at follow-up [13, 16, 17, 19, 21–25]. Furthermore, two studies did not state when the outcome would be measured [13, 19]. Besides Salvador et al. [22], all studies were considered as having a high risk of bias on 'study

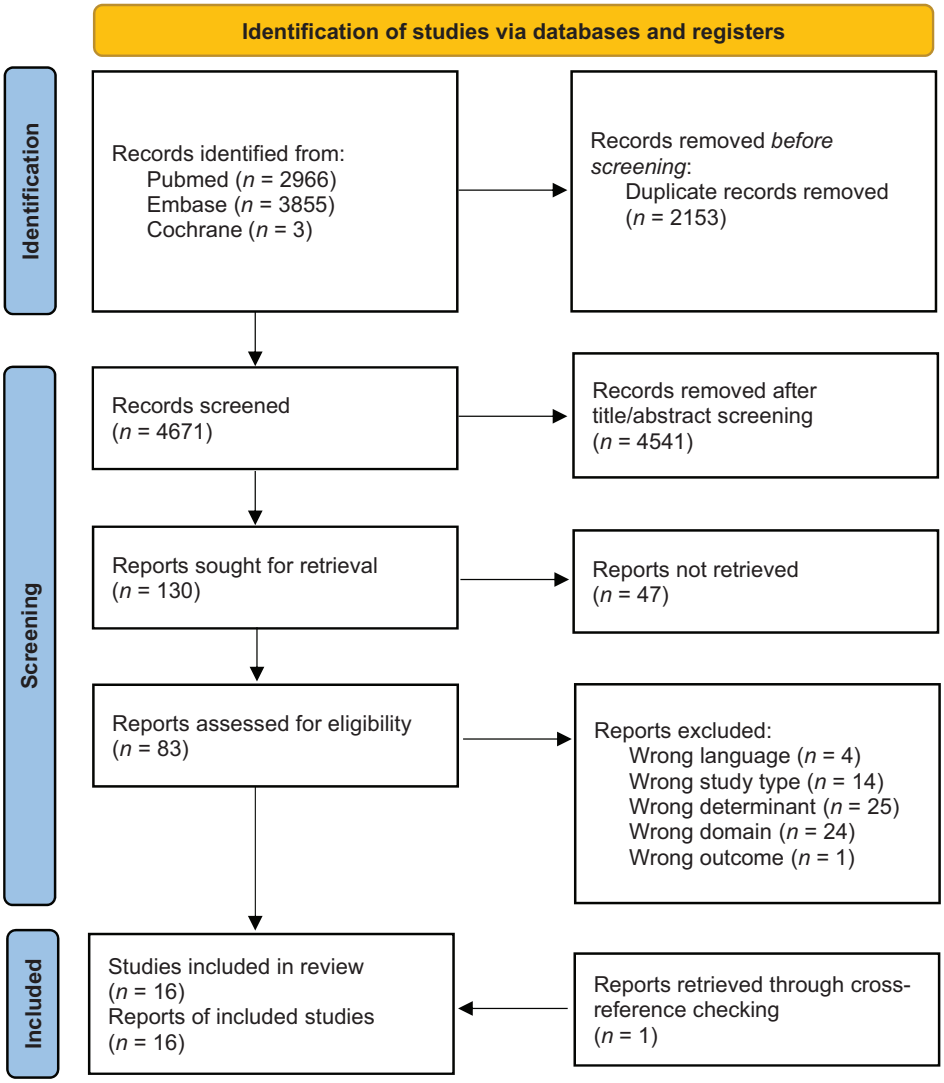

FIGURE 1 | PRISMA flowchart of systematic literature search [10].

confounding' since potential confounders were not described and/or taken into consideration in statistical analyses. All articles provided raw data on the amount of successful tympanic membrane closures and, therefore, were all rated as low risk of bias on 'statistical analysis and reporting'.

3.4 | Primary Outcome

The reported OR with 95% CI for successful closure of the tympanic membrane of included studies are presented in Table 4 and in a forest plot in Figure 2, generated using RevMan [28]. In two out of 16 included studies, the calculated OR was in favour of the wet ear group, without reaching statistical significance (reported OR wet vs. dry 1.66 [95% CI, 0.54–5.05] and 1.03 [95% CI, 0.30–3.52]) [13, 18]. One study, Aggarwal and Dev, showed a statistically significant difference in favour of the wet ear group with OR 7.17 (95% CI, 2.1–24.46) [12]. In one study, there was no calculated difference in success rate between the wet and dry ear groups [25]. All other studies ($n = 12$) displayed an OR in favour of the dry ear group with a reported OR range wet versus dry between 0.31 (95% CI, 0.07–1.30) and 0.69 (95% CI, 0.12–3.79), without reaching statistical significance. Only in the study of Pignataro et al., a statistically significant OR in favour of the dry ear group was found (wet vs. dry OR 0.06 [95% CI, 0.01–0.47]) [21].

4 | Discussion

The aim of this systematic review was to determine the prognostic value of an active otitis media on the success rate of a tympanoplasty in COM patients. Of the 16 observational studies included (nine prospective, six retrospective), two studies stated a significant difference, one in favour of a dry ear [21] and one in favour of a wet ear [12]. All other studies did not show a statistically significant difference in closure rates comparing patients with and without an active otitis media at time of surgery. Overall, the risk of bias was considered moderate to high.

Current statements in literature so far suggest that operating on an ear with an active otitis should be avoided to improve tympanoplasty success rates [6–9]. Based on the outcomes of the current study, there seems no robust evidence to base

TABLE 2 | Baseline characteristics of included studies.

Study	Country	Study design	Sample size (*n*) (wet/dry ear)	Study participants	Determination of active otitis media status	Outcome (measurement method)	Follow-up length
Aggarwal and Dev [12]	India	Prospective cohort	47/35	Patients 8–40 years of age with (suppurative) COM undergoing tympanoplasty using temporal fascia graft	Discharging ear pre-operatively	Graft uptake rate (otoscopy)	4 months
Albera et al. [13]	Italy	Prospective cohort	41/171	Patients 3–73 years of age undergoing myringoplasty using temporal fascia graft	Otorrhoea at time of surgery	Graft uptake rate (undefined)	68 months
Caylan et al. [14]	Italy	Retrospective cohort	15/36	Patients aged 16 years or younger with recurrent/persistent otitis media undergoing Type 1 tympanoplasty with temporal fascia graft	Discharging ear defined as presence of mucopus in middle ear cavity with/without hyperemic "wet" looking and swollen mucosa	Graft uptake rate (otoscopy)	4 years
Deosthale et al. [15]	India	Prospective cohort	40/46	Patients 16–60 years of age with COM undergoing Type 1 tympanoplasty using temporal fascia graft	Wet ear defined as minimal mucoid middle ear discharge with no microorganisms on culture	Graft uptake rate (otoscopy)	3 months
Dhanajkar et al. [16]	India	Prospective cohort	31/31	Patients 16–50 years of age with COM undergoing Type 1 tympanoplasty using temporal fascia graft	Minimal mucoid discharge in the middle ear which on culture and sensitivity showed no microorganisms	Graft uptake rate (undefined)	3 months
Dispenza et al. [17]	Italy	Prospective cohort	14/58	Patients 16+ years of age with COM undergoing Type 1 tympanoplasty using temporal fascia graft	Pre-operative drainage of ear	Graft failure rate (undefined)	12 months
Lou and Li [18]	China	Prospective cohort	29/78	Non-paediatric patients (not specified) with COM undergoing Type 1 tympanoplasty using cartilage graft	Wet ear (mucoid, oedematous, or purulent discharge) pre-operatively	Graft uptake rate (otoscopy)	6 months
Mishiro et al. [19]	Japan	Retrospective cohort	14/90	Patients with non-cholesteatomatous COM treated by tympanoplasty without mastoidectomy	Discharging ear at operation	Graft uptake rate (undefined)	32 months

(Continues)

TABLE 2 | (Continued)

Study	Country	Study design	Sample size (*n*) (wet/dry ear)	Study participants	Determination of active otitis media status	Outcome (measurement method)	Follow-up length
Naderpour, Shahidi and Hemmatjoo [20]	Iran	Retrospective cohort	30/30	Patients 15–60 years of age with COM undergoing tympanoplasty with medial graft technique	Discharging ear at the time of surgery	Graft uptake rate (otoscopy)	3 months
Pignataro et al. [21]	Italy	Retrospective cohort	6/35	Patients 8–14 years of age undergoing Type 1 tympanoplasty with temporal fascia graft	Discharging ear at operation	Graft uptake rate (undefined)	39 months
Salvador et al. [22]	Portugal	Retrospective cohort	2/153	Patients ≥18 years of age undergoing Type 1 tympanoplasty with either temporal fascia graft or cartilage graft	Active otorrhoea with middle ear discharge at the time of surgery	Graft uptake rate (undefined)	1.3 years
Santosh, Prashanth and Rao [23]	India	Prospective cohort	15/15	Patients 15–45 years of age with COM of the mucosal type undergoing Type 1 tympanoplasty	Wet ear (mucoid or mucopurulent) pre-operatively	Graft uptake rate (undefined)	3 months
Shankar et al. [24]	India	Prospective cohort	35/35	Patients 15+ years of age with COM undergoing Type 1 tympanoplasty using temporal fascia graft	Wet ear with discharge at time of presentation and operation	Graft uptake rate (undefined)	12 months
Srinivasa et al. [25]	India	Retrospective cohort	24/24	Patients 15–45 years of age with COM undergoing Type 1 tympanoplasty using temporal fascia graft	Mucoid ear discharge pre-operatively	Graft uptake rate (undefined)	3 months
Tiwari et al. [26]	India	Prospective cohort	123/123	Patients 15–50 years of age with COM undergoing Type 1 tympanoplasty using temporalis fascia graft	Mucoid middle ear discharge with no microorganisms on culture pre-operatively	Graft uptake rate (otoscopy)	3 months
Yang et al. [27]	China	Retrospective cohort	40/43	Patients ≥16 years of age with COM (suppurative) underdoing Type 1 tympanoplasty with cartilage graft	Wet ear at the time of surgery defined as mucoid/mucopurulent discharge or oedematous middle ear mucosa	Graft uptake/failure rate (otoscopy)	6 months

Note: *n* = sample size.
Abbreviation: COM = chronic otitis media.

TABLE 3 | Risk of bias assessment according to the QUIPS tool.

Study	Study participation	Study attrition	Prognostic factor measurement	Outcome measurement	Study confounding	Statistical analysis and reporting
Aggarwal and Dev [12]	🟡	🟢	🔴	🟢	🔴	🟢
Albera et al. [13]	🔴	🟢	🟡	🔴	🔴	🟢
Caylan et al. [14]	🟡	🟢	🟡	🟢	🔴	🟢
Deosthale et al. [15]	🟢	🟢	🟢	🟢	🔴	🟢
Dhanajkar et al. [16]	🔴	🟢	🟡	🟡	🔴	🟢
Dispenza et al. [17]	🔴	🟢	🔴	🟡	🔴	🟢
Lou and Li [18]	🟡	🟢	🟡	🟢	🔴	🟢
Mishiro et al. [19]	🔴	🟢	🔴	🔴	🔴	🟢
Naderpour, Shahidi and Hemmatjoo [20]	🔴	🟢	🔴	🟢	🔴	🟢
Pignataro et al. [21]	🔴	🟢	🔴	🟡	🔴	🟢
Salvador et al. [22]	🟢	🟢	🟡	🟡	🟢	🟢
Santosh, Prashanth and Rao [23]	🔴	🟢	🟡	🟡	🔴	🟢
Shankar et al. [24]	🟢	🟢	🟢	🟡	🔴	🟢
Srinivasa et al. [25]	🟡	🟢	🔴	🟡	🔴	🟢
Tiwari et al. [26]	🔴	🟢	🟡	🟢	🔴	🟢
Yang et al. [27]	🟢	🟢	🟢	🟢	🔴	🟢

Note: 🔴 indicates high risk of bias; 🟡 indicates moderate risk of bias; 🟢 low risk of bias (See Appendix 2).

TABLE 4 | Graft uptake rate and OR of included studies.

Study	Graft uptake rate (%) (wet/dry ear)	OR (95% CI)
Aggarwal and Dev [12]	91/78	7.17 (2.1–24.46)
Albera et al. [13]	90/85	1.66 (0.54–5.05)
Caylan et al. [14]	100/75	—[a]
Deosthale et al. [15]	80/87	0.60 (0.19–1.91)
Dhanajkar et al. [16]	74/90	0.31 (0.07–1.30)
Dispenza et al. [17]	71/83	0.52 (0.14–2.00)
Lou and Li [18]	86/86	1.03 (0.30–3.52)
Mishiro et al. [19]	86/94	0.35 (0.06–2.03)
Naderpour, Shahidi and Hemmatjoo [20]	93/97	0.48 (0.04–5.63)
Pignataro et al. [21]	33/89	0.06 (0.01–0.47)
Salvador et al. [22]	50/75	0.33 (0.02–5.41)
Santosh, Prashanth and Rao [23]	73/80	0.69 (0.12–3.79)
Shankar et al. [24]	80/89	0.52 (0.14–1.95)
Srinivasa et al. [25]	83/83	1.00 (0.22–4.56)
Tiwari et al. [26]	89/93	0.54 (0.22–1.34)
Yang et al. [27]	90/95	0.44 (0.08–2.54)

Abbreviations: CI = confidence interval, OR = odds ratio.
[a]No OR provided/no data are available to calculate the OR.

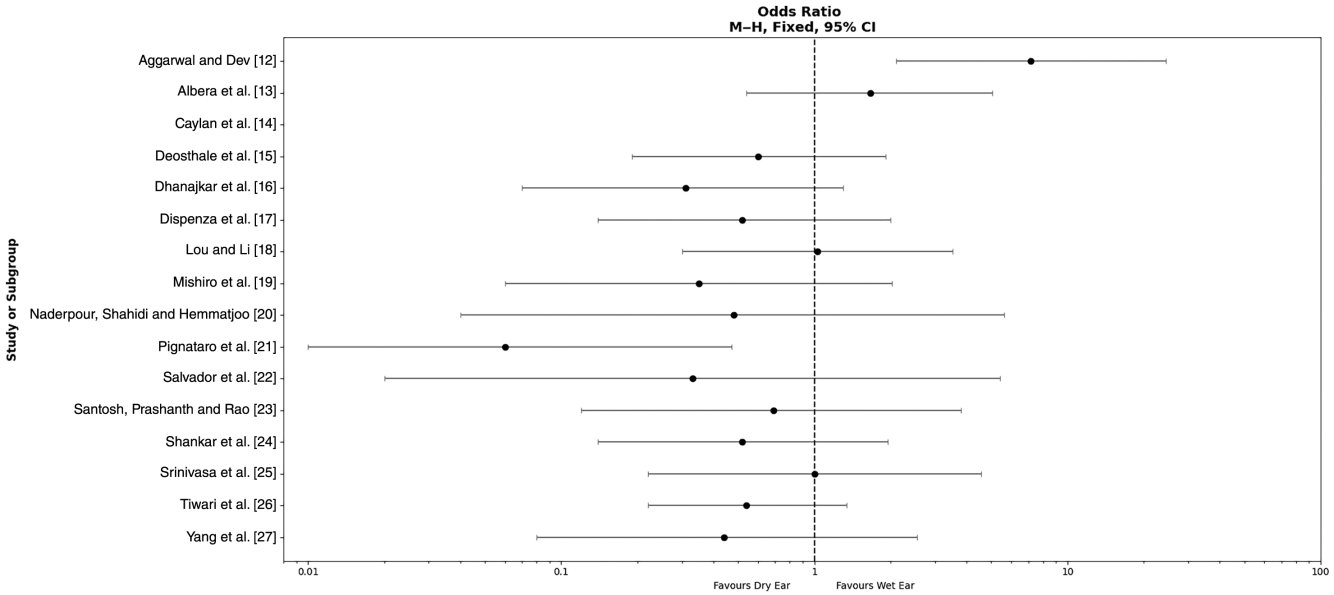

FIGURE 2 | Forest plot of OR (95% CI) of included studies. CI, confidence interval; M–H, Mantel–Haenszel; OR, odds ratio.

this statement on. This is in line with the findings of a meta-analysis published in 2016 by Tan et al., studying factors influencing closure rates of Type I tympanoplasty in adult and paediatric populations. In the study by Tan et al., adult surgery, smaller perforation size and the use of cartilage as a graft were associated with improved closure rates, while ears that were operated on while still discharging did not have significantly different outcomes [5]. However, it is important to note that not only closure of the tympanic membrane to avoid or reduce recurrent otitis media, but also hearing improvement and cessation of otorrhoea are clinically relevant outcomes of such procedures. These outcomes have not been assessed in this systematic review. Moreover, having an active otitis media at time of surgery could also influence complication rates such as wound infections. To date, this has not been reported in detail.

The quality of included studies varied widely and overall showed moderate to high risk of bias. This was mainly related to the chance of bias by indication and selection. Most studies did not specify their criteria for diagnosing active otitis media and how and when the outcome was assessed. Additionally, in most of the included studies it was unclear if the patients' stage of disease influenced the indication for surgery and if patients in the wet and dry ear group received equal treatment pre-operatively. The equal group sizes in five of the studies suggest inappropriate patient selection. Moreover, none of the studies adjusted their results for other prognostic factors. Lastly, we found that overall, considerably more patients were included in the dry ear group than in the wet ear group ($n = 1003$ vs. $n = 506$, respectively). This might be the result of the preference and beliefs of surgeons to perform tympanoplasty procedures on dry ears rather than on wet ears. Based on this overall moderate to high risk of bias, outcomes of this study need to be interpreted cautiously. Preferably, randomized controlled trials with a sound protocol on indication and patient selection and assessment of confounding factors is needed to provide definitive answers on the prognostic value of an active otitis media on the success rate of a tympanoplasty in COM patients.

The strength of this study is the systematic search of available literature on this topic. However, there are a few limitations to be mentioned. First, we excluded studies in languages other than English or Dutch, resulting in four studies (all Chinese) that were not included in our study. This could introduce selection bias and affect the overall outcome of this review. Second, studies were very heterogenous in the age of participants, graft materials used, methods to assess the status of the otitis media and outcome measurements. Third, we excluded patients undergoing concomitant mastoidectomy and/or ossiculoplasty to create a more homogenous population which limits the generalizability of outcomes to these groups. Furthermore, although we intended to include a wide age range, overall, more adults than children were included. This could influence overall success rates of the described procedures and the reported outcomes per group. Potentially, as described earlier, children might have a lower success rate of tympanoplasty due to a relative immaturity of the immune system, higher incidence of upper airway infections and poor Eustachian tube function [12]. Moreover, in children with active otorrhoea, it has been speculated that vascularization is more substantial, while atrophic quiescent ears have poor blood supply [20]. Therefore, children might display a lower tympanoplasty success rate in the dry ear group compared to the wet ear group [14]. In addition, as stated earlier, the majority of participants included in this review were categorized in the dry ear group, suggesting introduction of selection bias. Lastly, the limited sample sizes in the included studies, with two studies containing groups consisting of <10 patients, poses challenges in interpreting the results and drawing conclusions. This underlines the need for future studies on this topic to draw robust conclusions taking analyses per age group into account.

5 | Conclusion

In this systematic review including 16 studies, we found no significant prognostic value of having an active otitis media during tympanoplasty on tympanic membrane closure rates. Overall, the included studies were scored as moderate risk of bias and reports were mainly based on adult patients, with the majority having a dry ear at time of surgery. On this basis, no strong conclusions can be made. To be able to answer this question with higher levels of evidence, future high-quality prospective or randomized studies are needed with larger samples sizes, standardized outcome measurement and analyses adjusted for confounders.

Author Contributions

A.L.S. and H.F.N. designed the work. H.F.N. and M.B.P. acquired and analysed data. H.F.N., M.B.P. and A.L.S. drafted, revised and approved the manuscript. H.F.N., M.B.P. and A.L.S. agree to be accountable for all aspects of the work.

Acknowledgements

This research has received no external funding.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Peer Review

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/coa.14205.

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Appendix 1

PRISMA 2020 Checklist

Section and topic	Item #	Checklist item	Location where item is reported
Title			
Title	1	Identify the report as a systematic review	Page 1
Abstract			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 1
Introduction			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 2
Methods			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 3
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 3
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 1
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g., for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pages 3–4
	10b	List and define all other variables for which data were sought (e.g., participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 4
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently and, if applicable, details of automation tools used in the process.	Page 4 + Appendix 2
Effect measures	12	Specify for each outcome the effect measure(s) (e.g., risk ratio, mean difference) used in the synthesis or presentation of results.	Page 4

(Continues)

Section and topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g., tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Pages 3–4
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pages 3–4
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity and software package(s) used.	Page 4
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g., subgroup analysis, meta-regression).	NA
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	NA
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 3
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Page 3
Results			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Figure 1 + page 4
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded and explain why they were excluded.	Figure 1 + page 4
Study characteristics	17	Cite each included study and present its characteristics.	Page 5 + Table 2
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 5 + Table 3
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g., confidence/credible interval), ideally using structured tables or plots.	Pages 5–6
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Page 5
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g., confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pages 5–6
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pages 4–5 + Table 2
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	NA

(Continues)

Section and topic	Item #	Checklist item	Location where item is reported
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pages 5–6 + Table 4
Discussion			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 6–7
	23b	Discuss any limitations of the evidence included in the review.	Pages 6–7
	23c	Discuss any limitations of the review processes used.	Pages 6–7
	23d	Discuss implications of the results for practice, policy and future research.	Pages 6–7
Other information			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Page 2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	NA
Support	25	Describe sources of financial or non-financial support for the review and the role of the funders or sponsors in the review.	Title page
Competing interests	26	Declare any competing interests of review authors.	Title page
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Title page

Appendix 2

Search Syntax

PubMed

(((myringoplasty[MeSH Terms]) OR (tympanoplasty[MeSH Terms]) OR (tympanoplast*[Title/Abstract]) OR (myringoplast*[Title/Abstract])) OR (((eardrum*[Title/Abstract]) OR (tympanic membrane*[Title/Abstract])) AND ((operation*[Title/Abstract]) OR (surger*[Title/Abstract]) OR (reconstruct*[Title/Abstract]) OR (closure*[Title/Abstract]) OR (repair*[Title/Abstract]))))

AND

((((otitis media[MeSH Terms]) OR (otitis media[Title/Abstract]) OR (wet ear*[Title/Abstract])) OR (((infect*[Title/Abstract]) OR (inflam*[Title/Abstract])) AND (middle ear*[Title/Abstract]))))

Embase

('otitis media'/exp OR 'otitis media':ti,ab,kw OR 'wet ear':ti,ab,kw) OR (('infect*':ti,ab,kw OR 'inflam*':ti,ab,kw) AND 'middle ear':ti,ab,kw)

AND

('myringoplasty'/exp OR 'tympanoplasty'/exp OR 'tympanoplast*':ti,ab,kw OR 'myringoplast*':ti,ab,kw OR (('eardrum*':ti,ab,kw OR 'tympanic membrane*':ti,ab,kw) AND ('operation':ti,ab,kw OR 'surger*':ti,ab,kw OR 'reconstruct*':ti,ab,kw OR 'closure*':ti,ab,kw OR 'repair':ti,ab,kw)))

Cochrane

('otitis media'/exp OR 'otitis media':ti,ab,kw OR 'wet ear':ti,ab,kw) OR (('infect*':ti,ab,kw OR 'inflam*':ti,ab,kw) AND 'middle ear':ti,ab,kw)

AND

('tympanoplast*':ti,ab,kw OR 'myringoplast*':ti,ab,kw OR (('eardrum*':ti,ab,kw OR 'tympanic membrane*':ti,ab,kw) AND ('operation':ti,ab,kw OR 'surger*':ti,ab,kw OR 'reconstruct*':ti,ab,kw OR 'closure*':ti,ab,kw OR 'repair':ti,ab,kw)))

Appendix 3

Predefined QUIPS Criteria

Study Participation

- Low risk of bias: patients with a chronic otitis media eligible for Type 1 tympanoplasty, description includes location, time period and method of inclusion, inclusion and exclusion criteria and baseline table.
- Moderate risk of bias: one of the above missing.
- High risk of bias: two or more of the above missing.

Study Attrition

- Low risk of bias: no loss to follow-up or adequate description and imputation of missing data.
- Moderate risk of bias: few patients lost to follow-up or inadequate description/imputation of missing data, or suspected non-reporting of loss to follow-up.
- High risk of bias: many patients lost to follow-up without adequate description/imputation of missing data.

Prognostic Factor Measurement

- Low risk of bias: wet ear group defined as presence of otorrhoea during physical examination using otoscopy prior to or during surgery.
- Moderate risk of bias: definition missing one of the aspects mentioned above.
- High risk of bias: definition of prognostic factor absent, or missing more than one of the aspects mentioned.

Outcome Measurement

- Low risk of bias: graft uptake rate/tympanic membrane closure rate or perforation recurrence rate objectified with otoscopy/microscopy/endoscopy, follow-up at least 2 months or more.
- Moderate risk of bias: method or moment of measurement of outcome not specified.
- High risk of bias: definition of outcome absent, or method or moment of measurement of outcome not specified.

Study Covariates

- Low risk of bias: statistically adjusted outcome for clearly described and adequately calculated relevant covariates (age, size of perforation and graft material).
- Moderate risk of bias: partial adjustment for aforementioned covariates.
- High risk of bias: no statistical adjustment for covariates.

Statistical Analysis and Reporting

- Low risk of bias: surgical outcome percentage, relative risk or odds ratio with a χ^2 test and raw data are presented to assess the adequacy of the analysis.
- Moderate risk of bias: insufficient presentation of data.
- High risk of bias: inadequate or no statistical analysis.