

Tympanic Cavity Packing in Tympanoplasty Type 1: A Meta-Analysis

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ABSTRACT

Packing of tympanic cavity is generally considered an essential step in myringoplasty. However, each packing material comes with one or another side effect. The objective of this meta-analysis was to compare the results of Type 1 myringoplasty with or without packing. Pubmed, Cochrane database, Embase, Google Scholar, and clinicaltrials.gov were searched using 'tympanoplasty or myringoplasty and packing' as the search query. All RCTs / quasi-RCTs comparing tympanoplasty Type 1 with packing (control) *versus* without packing (intervention) of tympanic cavity in the human population were included. For dichotomous and continuous outcomes, relative risks (RR) and mean differences (MD) were calculated with 95% confidence interval, respectively. Heterogeneity was assessed using I^2 statistics. Publication bias was checked using funnel plot and Egger's test, if applicable. Quality of evidence was assessed for each outcome using GRADE approach. Eleven studies were deemed eligible. For graft uptake and functional success rate, RR of 1.01 and 1.05 were obtained, respectively, showing no significant differences between the intervention and control groups. At 1st and 3rd postoperative month, no-packing group showed 3.86 dB and 2.08 dB better air-bone gap (ABG) closure than the packing group, respectively. Also, intervention with no-packing was 9.28-minute shorter procedure. With RR 0.35, no-packing had significantly lesser postoperative aural fullness. Type 1 tympanoplasty performed with or without packing show comparable results in terms of graft uptake and functional success rate. However, if performed without packing, it takes shorter time, provides early hearing improvement and causes less aural fullness.

Key Words: Tympanoplasty Type 1, Packing, Gelfoam, No-packing, Meta-analysis, Endoscopic myringoplasty.

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INTRODUCTION

Tympanoplasty, without any doubt, can be regarded as the heart of otology. Regardless of approach, technique or graft material used, the aim of tympanoplasty is to repair the tympanic membrane (TM) abnormality, ensure improvement in hearing ability, and keep the tympanic cavity well-aerated.¹

Type-1 tympanoplasty also known as myringoplasty, is a surgical technique, which involves placement of graft material in order to stimulate, facilitate, and direct the regeneration of TM and thus result in the healing of the defect.^{1,2} Various absorbable materials, such as gelfoam, biodegradable polyurethane foam, nasopore, hyaluronic acid, etc. are commonly used to pack the tympanic cavity before implantation of the graft,³⁻⁶ with the intention to prevent graft displacement and maintain the integrity of the cavity.⁷

However, packing comes with some inherent adverse effects, including ototoxicity, fibrosis, inflammation, subepithelial thickening, and early postoperative conductive hearing loss.^{5,7} An ideal material for packing would be the one with optimum durability, expandability, complete resorption, leaving no remnant behind, and the ability of ensuing no inflammation or adverse reaction in the middle ear cavity. With no such material available up till now, questions have been raised concerning the necessity of this step in tympanoplasty. Since the study conducted by Ghiasi *et al.* reported comparable rates of graft uptake in tympanomastoidec-tomy with and without packing, so far several trials have been conducted in this regard.⁸

This current analysis was conducted to collect and analyse the available literature addressing the role of packing of the middle ear cavity, to put light on the query of whether this step is even needed for the success of myringoplasty. The current paper aimed to combine all the currently available level 1 evidence in order to determine the effect and role of packing of middle-ear cavity during tympanoplasty Type 1, irrespective of the type of graft or technique used during the intervention.

METHODOLOGY

This meta-analysis was conducted in accordance with preferred reporting items for systematic reviews and meta-analyses guidelines (PRISMA).⁹ The current project was prospectively registered with Open Science Framework on 23rd December

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2022 (accessible at <http://doi.org/10.17605/OSF.IO/29JKA>), which was done before any data collection.

The patient / population, intervention, comparison, and outcomes (PICO) framework consisted of patients with chronic otitis media (COM) in whom Tympanoplasty Type 1 was indicated; intervention-no packing of tympanic cavity; comparison-packing of tympanic cavity. Primary outcomes were graft uptake and audiological improvement and secondary outcomes included postoperative ear fullness and operative time.¹⁰

A literature search was performed in Medline (using PubMed), Cochrane database, Google Scholar, Embase, and ClinicalTrials.gov up to 31st December 2022. The search was done using query 'tympanoplasty or myringoplasty and packing'. No restrictions were applied regarding date of publication or language. Inclusion criteria applied were randomised or quasi-randomised studies, tympanoplasty Type 1, comparing packing of tympanic cavity with no-packing at all. Exclusion criteria consisted of studies involving non-human subjects, designs other than RCT / quasi-RCT, and studies with their interventions including any otologic procedure additional to tympanoplasty Type 1.

All records found were transferred to citation managing software-EndNote (X7,7, Thomson Reuters). Duplicate records were omitted. All the leftover records were screened by title, abstract, and full-text. The screening and selection were done by the authors IUH and SU. In case of any dispute or disagreement, the author IUD was consulted for settlement.

All the studies which were deemed eligible for the meta-analysis were thoroughly reviewed by authors IUH and SU. Data including study design, year of publication, number of participants, type of graft, type of technique, size of perforation, mean age, gender distribution, follow-up period etc., was extracted and entered in Microsoft Excel, and later exported to the Review Manager (RevMan). Data regarding primary and secondary outcomes were also extracted. Disagreements were resolved through mutual discussion with author IUD.

Cochrane Risk of Bias Tool (version 2) was used to assess the risk of bias in individual studies. Two authors i.e. IUH and SU independently judged and estimated the risk of bias, in compliance with random sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment: Both self-reported and objective measures (detection bias), incomplete outcome data (attrition bias), and selective reporting (reporting bias).¹¹ For each domain, low-risk, some concern, and high-risk scores were assigned and later, based on these scores, an overall assessment was done. Wherever the above-mentioned authors faced any conflict or disagreement, the author IUD's consultation was adopted for settlement.

Statistical analysis was performed using Review Manager (RevMan version 5.4), (Nordic Cochrane Centre, Copenhagen, Denmark). The authors used random effects model for the meta-analysis to account for between-studies variance and potential heterogeneity. For dichotomous outcomes (graft uptake, functional success rate, and postoperative aural fullness), risk ratio was calculated using the Mantel-Haenszel methodology with 95% confidence interval

(CI). For continuous outcomes (postoperative mean ABG after the first and 3rd month, operating time taken), weighted mean difference (MD) was calculated with 95% CI, using inverse variance (IV) methodology.

I² statistics was used to determine statistical heterogeneity. Forest plots were inspected visually for any asymmetry and thus, the publication bias was assessed. Wherever applicable, Egger's test was applied to check publication bias quantitatively, using Stata 11 SE (StataCorp). For sensitivity analysis, by excluding each study turn by turn, the individual study impact was investigated on the overall estimate. A $p < 0.05$ was defined as statistically significant. Subgroup analysis was performed wherever necessary.

The grading of recommendations, assessment, development, and evaluation (GRADE) was used to assess the quality of evidence.¹²

RESULTS

A detailed flowchart of study search, selection, and inclusion has been described in Figure 1. Almost 4,452 records were identified through database searching. All the records found were transferred to Endnote and duplicate records were removed. After screening the title, abstract, and full text and applying the predefined inclusion and exclusion criteria, 12 articles were collected. One article was dropped due to the surgical intervention being tympano-mastoidectomy. Eleven articles were deemed eligible for inclusion. Characteristics of each study have been described in Table I and II.

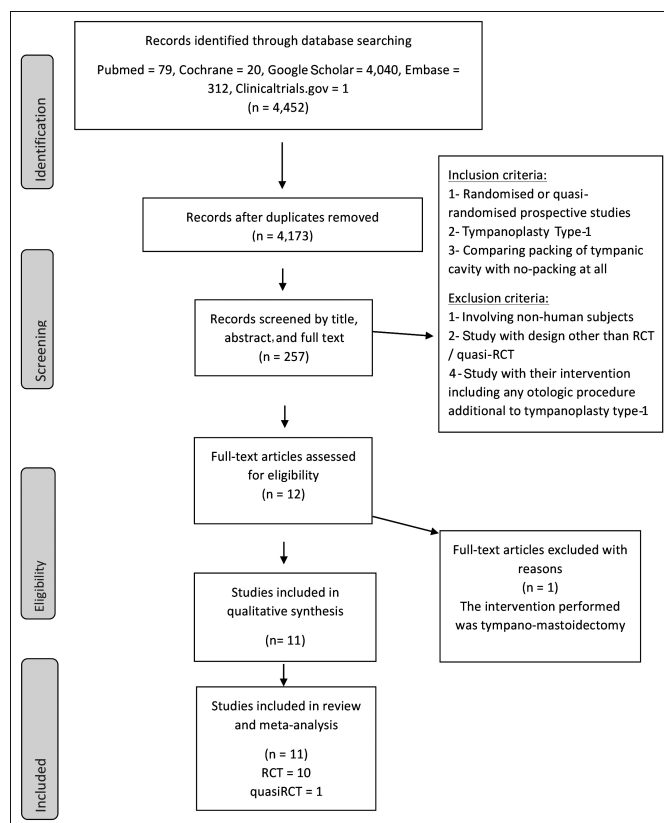


Figure 1: Flowchart of the study's inclusion and exclusion criteria.

Table I: Characteristics of studies.

Study	Year	Country	Sample size	Technique	Graft material	Packing material	Adhesive used	Anaesthesia
Bahavana <i>et al.</i> ¹³	2022	India	72	NR	NR	Gelfoam	None	NR
Han <i>et al.</i> ¹⁴	2021	Korea	57	Swing door overlay	TF	Gelfoam	None	GA
Kiran <i>et al.</i> ¹⁵	2021	India	80	Underlay	TF	Gelfoam	None	LA
Kumar <i>et al.</i> ¹⁶	2021	India	100	Underlay	TF	Gelfoam	None	LA
Li <i>et al.</i> ¹⁷	2018	China	67	Anterosuperior anchoring	TF	Gelfoam	Cyanoacrylate glue	GA
Lou <i>et al.</i> ⁵	2022	China	70	Over-underlay	Modified cartilage	Nasopore	None	GA
Malick <i>et al.</i> ¹⁸	2017	India	61	Underlay	TF	Gelfoam	None	LA
Pimparkar <i>et al.</i> ²²	2020	India	60	Overlay	TF	Gelfoam	Fibrin glue	LA
Ramalingam <i>et al.</i> ¹⁹	2019	India	80	Underlay	TF	Gelfoam	None	LA
Sahoo <i>et al.</i> ²⁰	2021	India	80	Underlay with 360° TMF	TF	Gelfoam	None	GA/MAC
Wang <i>et al.</i> ²¹	2020	China	70	Underlay	Tragal perichondrium	Gelfoam	None	GA

GA: General anaesthesia; LA: Local anaesthesia; MAC: Monitored anaesthesia care; NR: Not reported; TF: Temporalis fascia; TMF: Tympanomeatal flap.

Table II: Characteristics of studies.

Study	Groups	Sample size (n)	Gender		Age (Mean ± SD)	Size of perforation					Lost to follow-up (n)	Follow-up period (months)
			Male (n)	Female (n)		Small (n)	Medium (n)	Large (n)	Subtotal (n)	Total (n)		
Bahavana <i>et al.</i> ¹³	PG	36	NR	NR	NR	9	18	4	1	-	0	6
Han <i>et al.</i> ¹⁴	NPG	36	NR	NR	NR	10	11	10	0	-	0	3
	PG	30	9	21	49.9 ± 16.99	Reported as mean percentage					0	3
Kiran <i>et al.</i> ¹⁵	NPG	27	6	21	53.19 ± 17.87						0	3
	PG	40	24	26	NR	NR					0	3
Kumar <i>et al.</i> ¹⁶	NPG	40	27	23	NR						0	3
	PG	50	33	17	NR	NR					0	3
Li <i>et al.</i> ¹⁷	NPG	50	27	23	NR						0	3
	PG	37	18	19	NR	-	-	-	31	6	0	6
Lou <i>et al.</i> ⁵	NPG	32	17	15	NR	-	-	-	28	4	2	12
	PG	35	14	21	41.2 ± 2.36	-	24	11	-	-	0	3
Malick <i>et al.</i> ¹⁸	NPG	35	16	19	40.8 ± 3.97	-	22	13	-	-	0	3
	PG	31	20	11	NR	NR					0	3
Primparkar <i>et al.</i> ²²	NPG	30	16	14	NR						0	3
	PG	30	16	14	32.17 (SD NR)	NR					0	3
Ramalingam <i>et al.</i> ¹⁹	NPG	30	17	13	30.97 (SD NR)						0	3
	PG	40	13	27	NR	6	23	-	11	-	0	2
Sahoo <i>et al.</i> ²⁰	NPG	40	15	25	NR	3	24	-	13	-	0	3
	PG	40	18	22	32.25 ± 9.3	NR					0	3
Wang <i>et al.</i> ²¹	NPG	40	15	25	33.35 ± 8.49						0	3
	PG	35	17	18	49.5 ± 9.76	6	20	9	-	-	-	6
	NPG	35	16	19	44.05 ± 10.87	8	19	8	-	-	-	6

NPG: No-packing group; NR: Not reposted; PG: Packing group; SD: Standard deviation

Table III: Postoperative complications.

Study		Complications	PG (n/N)	%	NPG (n/N)	%
Bahavana <i>et al.</i> ¹³	1	Tinnitus	2/36	5.55%	3/36	8.33%
Li <i>et al.</i> ¹⁷	1	Infection	1/37	2.7%	1/30	3.33%
	2	Retractions	1/37	2.7%	2/30	6.66%
	3	OME	1/37	2.7%	0/30	0
	4	Myringitis	2/37	5.4%	2/30	6.66%
	5	Tinnitus	1/37	2.7%	0/30	0
Lou <i>et al.</i> ⁵	1	ME infection	1/35	2.85%	0/35	0
Malick <i>et al.</i> ¹⁸	1	Atelectasis	1/31	3.22%	1/30	3.33%
	2	Retractions	3/31	9.67%	2/30	6.66%
Primparkar <i>et al.</i> ²²	1	Anterior blunting	1/30	3.33%	0/30	0
	2	SNHL	0/30	0	1/30	3.33%
	3	EAC infection	1/30	3.33%	1/30	3.33%
Ramalingam <i>et al.</i> ¹⁹	1	Myringosclerosis	2/40	5%	0/40	0

EAC: External auditory canal; ME: Middle ear; OME: Otitis media with effusion; SNHL: Sensorineural hearing loss.

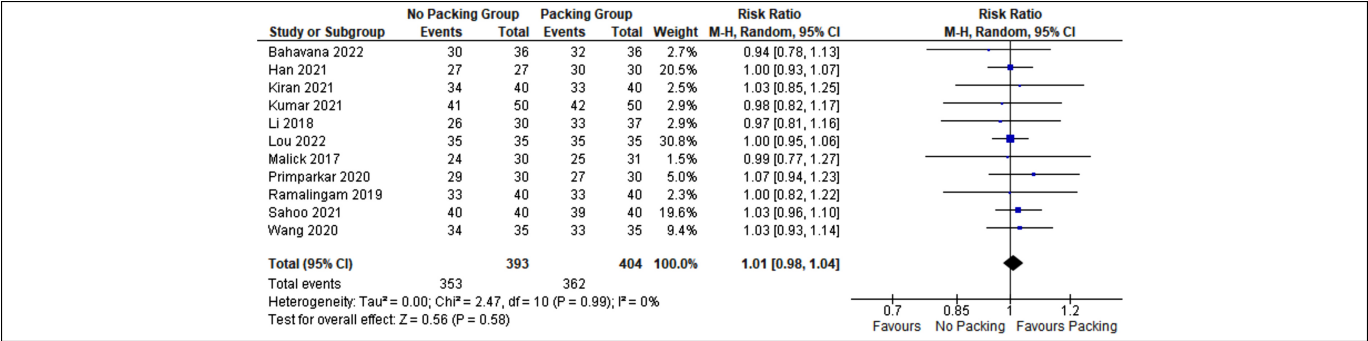


Figure 2: Forest plot of graft success rate.

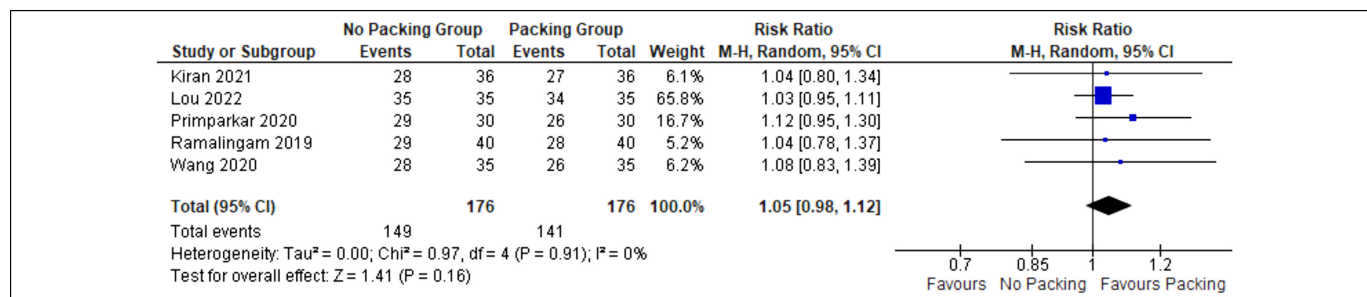


Figure 3: Forest plot of audiological success rate.

Table IV: GRADE approach.

Question: Is tympanic cavity-packing necessary in Tympanoplasty Type-1, irrespective of graft or technique used?

Participants (studies) follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	Study event rates (%)		Relative effect (95% CI)	Anticipated Absolute effects	
							With packing	With no packing		Risk with Packing	Risk difference with No packing (95% CI)
Graft success rate (Critical outcome; assessed with: Otoscopy)											
797 (11 studies)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Undetected	⦿⦿⦿⦿ High	362/404 (89.6%)	353/393 (89.8%)	RR 1.01 (0.98 to 1.04)	Study population	
										90 per 100	1 more per 100 (from 2 fewer to 4 more)
										Moderate	
										89 per 100	1 more per 100 (from 2 fewer to 4 more)
Functional success rate (Postoperative ABG ≤20dB) (Critical outcome; assessed with: Audiometry)											
352 (5 studies)	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Undetected	⦿⦿⦿⦿ High	141/176 (80.1%)	149/176 (84.7%)	RR 1.05 (0.98 to 1.12)	Study population	
										80 per 100	4 more per 100 (from 2 fewer to 10 more)
										Moderate	
										75 per 100	4 more per 100 (from 1 fewer to 9 more)
Mean postoperative air-bone gap after 1 month (Important outcome; measured with: Audiometry; better indicated by lower values)											
207 (3 studies)	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious ¹	Undetected	⦿⦿⦿⦿ Moderate ¹ due to imprecision	105	102	-	-	The mean postoperative air-bone gap after 1 month in the intervention groups was 3.86 lower (4.67 to 3.04 lower)
Mean postoperative air-bone gap after >3months (Critical outcome; measured with: Audiometry; better indicated by lower values)											
518 (7 studies)	No serious risk of bias	Serious ²	No serious indirectness	No serious imprecision	Reporting bias strongly suspected ³	⦿⦿⦿⦿ Low ^{2,3} due to inconsistency, publication bias	261	257	-	-	The mean postoperative air-bone gap after >3months in the intervention groups was 2.08 lower (3.66 to 0.5 lower)
Postoperative ear stuffiness (Important outcome; assessed with: Subjective assessment)											
220 (3 studies)	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious ⁴	Undetected	⦿⦿⦿⦿ Moderate ⁴ due to imprecision	87/110 (79.1%)	30/110 (27.3%)	RR 0.35 (0.25 to 0.48)	Study population	
										79 per 100	51 fewer per 100 (from 41 fewer to 59 fewer)
										Moderate	
										83 per 100	54 fewer per 100 (from 43 fewer to 62 fewer)
Average operating time taken in minutes (Important outcome; measured with: Time record; better indicated by lower values)											
140 (2 studies)	No serious risk of bias	Serious ⁵	No serious indirectness	Serious ¹	Undetected	⦿⦿⦿⦿ Low ^{1,5} due to inconsistency, imprecision	70	70	-	-	The mean average operating time taken in minutes in the intervention groups was 9.28 lower (11.87 to 6.69 lower)

¹ Cumulative sample size <400. ² High heterogeneity (I² = 86%). ³ Uncertain. ⁴ Cumulative sample size <300. ⁵ High heterogeneity (I² = 77%).

For graft uptake, 11 studies comprising of 797 patients were included in the analysis.^{5,13-22} A total of 797 interventions were included, among these 393 had no packing, while 404 had tympanic cavity packing during tympanoplasty. The graft uptake-rate in the no-packing group was 89.82% (353/393) while in the packing group, it was 89.6% (362/404). The meta-analysis indicated that tympanoplasty without packing was equally as effective as tympanoplasty with packing of tympanic cavity (RR: 1.01, 95% CI: 0.98-1.04; $I^2 = 0\%$, $p = 0.58$, Figure 2). It was graded as high grade of evidence (Table IV). Funnel plot was visually analysed to determine publication bias which showed symmetrical distribution of the outcome. For quantitative assessment of asymmetry in the funnel plot, Egger's test was performed which indicated no evidence of publication bias ($p = 0.685$). Sensitivity analysis was performed which revealed that omitting any study from the analysis did not affect the overall results.

For functional success rate, five studies consisting of 352 interventions were deemed eligible.^{5,15,19,21,22} Among these, 176 tympanoplasties had no packing while 176 had packing of the tympanic cavity. The functional success rate was 84.65% (149/176) in the no-packing group while it was 80.11% (141/176) in the packing group. The meta-analysis indicated that the tympanoplasty without any packing of middle-ear cavity was equally as effective as that with packing of the cavity (RR: 1.05, 95% CI: 0.98-1.12; $I^2 = 0\%$, $p = 0.16$, Figure 3). It was graded as high grade of evidence (Table IV). Sensitivity analysis was performed which revealed that omitting any study from the analysis did not affect the overall results.

For postoperative mean ABG after 1 month, three out of eleven RCTs reported the mean ABG at postoperative first month.^{14,20,21} Consisting of 207 participants, 102 underwent tympanoplasty with no-packing while 105 had packing of their middle-ear cavities. Based on the analysis, the mean ABG at 1st postoperative month in the no-packing group was 3.86 dB better than packing group (WMD: -3.86, 95% CI: -4.67 to -3.04; $I^2 = 0\%$, $p < 0.001$). By GRADE approach, it came out to be moderate grade of evidence (Table IV). Sensitivity analysis showed that if any of the included studies was omitted, the overall result remained in the favour of tympanoplasty with no-packing.

For postoperative mean ABG after ≥ 3 months, seven RCTs reported mean ABG at or after 3 months.^{5,14-16,18,20,21} A total of 518 interventions, consisting of 257 with no-packing and 261 with packing of tympanic cavities were included. Analysis showed that postoperative mean ABG after ≥ 3 months in no-packing group was 2.08dB better than packing group (WMD: -2.08, 95% CI: -3.66 to -0.50; $I^2 = 86\%$, $p = 0.01$). It was regarded as low grade of evidence by the GRADE approach (Table IV). Sensitivity analysis showed that if any of the included studies was omitted, the overall result remained in favour of tympanoplasty with no-packing.

Postoperative ear stuffiness or fullness was observed and reported by three RCTs, including 220 participants.^{5,20,21} Among them, 110 belonged to the no-packing group while 110 belonged to the packing group. Thirty out of 110 patients (27.27%) of the no-packing group and 79.09% (87/110) of the packing group reported postoperative ear stuffiness. Pooled analysis favouring no-packing group showed that without any packing of tympanic cavity, the patient-reported ear stuffiness was significantly lesser than those with packing (RR: 0.35, 95% CI: 0.25-0.48; $I^2 = 0\%$, $p < 0.001$). It was regarded as moderate grade of evidence (Table IV). Performing sensitivity analysis, it was indicated that excluding any study from the analysis did not affect and the results remained quite unchanged.

Only two out of 11 RCTs, comprising of 140 participants, reported the mean operating time taken by each intervention in minutes.^{5,21} Among these, 70 participants underwent tympanoplasty without packing while 70 had their middle-ear cavities packed. Based on the pooled analysis, tympanoplasty without any packing required shorter time, an average difference of 9 minutes, as compared to packing group (WMD = -9.28; 95% CI: -11.87 to -6.69; $I^2 = 77\%$, $p < 0.001$) and was regarded as low grade of evidence.

A subgroup analysis was performed for graft uptake-rate. Nine out of 11 studies did not use any adhesive / glue while 2 studies i.e. Li *et al.* and Pimparkar *et al.* used cyanoacrylate and fibrin glue, respectively, after graft-implantation in no-packing group.^{17,22} The subgroup analysis revealed no significant difference in the rate of graft uptake between the 2 techniques ($p = 0.62$, $I^2 = 0\%$).

Six studies reported postoperative complications (Table III).^{5,13,17-19,22} Due to discrepancy among results, a meta-analysis could not be conducted. All the studies concluded the rate of complications among the two groups to be insignificant.

Risk of bias assessment done with Cochrane RoB2 tool revealed that only 2 studies had high-risk of bias, while the rest 9 studies had unclear or no risk of bias.

DISCUSSION

This systematic review with meta-analysis has analysed the role and necessity of tympanic cavity packing during Type 1 tympanoplasty. Eleven studies (ten RCTs and 1 quasi-RCT) comprising of 797 participants were included. Among these, 393 underwent no-packing and the rest of 404 patients underwent packing of tympanic cavity with absorbable material (gelfoam was used in 358 subjects, nasopore in 35 subjects). In 8 studies, temporalis fascia was used as graft material. Modified cartilage and tragal perichondrium were

used in one study each, while no graft material was reported in one study (Table I). Only two studies i.e. by Li *et al.* and Primpakar *et al.* used cyanoacrylate and fibrin glue as adhesive, respectively. A variety of surgical techniques were used including underlay (most common i.e. six studies), overlay, over-underlay, swing door overlay, and anterior anchoring. No significant difference was found between the techniques in terms of graft uptake or audiological improvement. However, the tympanoplasty done without packing was found to be quicker procedure with earlier improvement in hearing and lesser postoperative ear fullness.

With new advancements and techniques, the success rate of conventional tympanoplasty has reached up to 90%.^{23,24} But the unquenchable desire of humans to achieve perfection is constantly compelling the researchers to explore new and better techniques. Packing of tympanic cavity has been considered as an essential step in myringoplasty, but the side effects have made the otologists enquire its role and necessity.⁷

Addressing and comparing the basic aim of myringoplasty, the anatomical graft uptake-rate and healing of TM defect were comparable between the packing and no-packing group. In the postoperative period, one would anticipate temporary conductive hearing loss in patients who had their tympanic cavities packed. It has been shown through pooled analysis, that the mean ABG in no-packing group was better by 3.86dB after 1st month and 2.08dB after 3rd month as compared to the packing group. However, the audiological aim to get mean postoperative ABG ≤ 20 dB was comparable between the two groups.

Temporary sense of postoperative aural fullness was significantly more common in the packing group. Also, packing of the tympanic cavity with absorbable material takes extra time, thus extra medical cost and finances. This meta-analysis has shown that the packing group takes, on an average, 9 minutes more than the no-packing group.

Packing is done with the aim of making a supportive bed for the implanted graft and to prevent its displacement. To avoid packing, biological glues have also been used to adhere the graft with the remnants of TM.^{17,22} However, conducting subgroup analysis, the authors compared the outcome of graft uptake between studies using glue with those using no glue / packing at all. The results were comparable and statistically insignificant.

This review has got several strengths. It is the first meta-analysis addressing the role of tympanic cavity packing during tympanoplasty Type 1. Its protocol was prospectively registered with Open Science Framework as standard pre-data collection registration. A detailed and extensive systematic search was done to identify and include all

available evidence. Including only randomised or quasi-randomised controlled trials to assess outcomes and draw conclusions is also one of the strengths of this study. The authors also assessed each study individually for risk of bias using the Cochrane RoB tool. Wherever applicable, publication bias was checked and sensitivity analysis was also performed.

Regarding limitations, the major one was the small number of studies i.e. 11 and thus the limited sample size. Two out of six outcomes were heterogeneous thus decreasing the analytical power of the analysed results. Due to limited number of studies included, publication bias could not be assessed for all outcomes. The studies assessed the size of TM perforation using different criteria. Thus, due to lack of universality in assessment, the perforation size could not be assessed for any confounding effect.

CONCLUSION

This present review suggests that tympanoplasty Type 1 without any packing of tympanic cavity is equally as effective as that performed with packing of the cavity in regards of graft uptake and functional success rate. However, no-packing provides the authors with a quicker operative technique, earlier audiological improvements, and lesser postoperative ear fullness as compared to tympanoplasty with packing of middle-ear cavity.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

NL, ZL: Study conception, statistical analysis, and manuscript preparation.

IUD: Study conception, design, and interpretation of the results.

IUH, SU: Data collection and manuscript drafting.

IK: Interpretation of the results and critical revision of the manuscript.

All authors approved the final version of the manuscript to be published.

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