Abstract

Objectives Endoscopic approaches constitute a newly introduced and promising technique in the field of stapes surgery, presenting favorable outcomes, so far. This study aims to compare endoscopic and microscopic stapes surgery based on current literature evidence, in terms of their efficacy and safety characteristics.

Design We conducted a systematic literature search of three medical databases (Pubmed, Cochrane Library, and Scopus). We focused on randomized controlled studies or observational studies comparing microscopic to endoscopic stapes surgery. Data related to the efficacy and safety of each technique were extracted. Outcome data were summarized using the pooled mean differences or pooled odds ratio along with their 95% confidence intervals, according to the available data. The quality of evidence was assessed according to the GRADE recommendations.

Results Thirteen studies with 705 patients were included in the meta-analysis. Success rate was evaluated by estimating air-bone gap improvement, resulting in comparable outcomes for the two techniques (mean difference: -0.20; 95% CI: -0.53, 0.14). No statistically significant difference was detected concerning postoperative complications, except for dysgeusia that was in favor of the endoscopic approach (OR: -1.46; 95% CI: -2.45, -.047). The overall quality of evidence was assessed to range from "Low" to "Very Low".

Conclusion Endoscopic stapes surgery is an innovative alternative to the microscopic technique, resulting in commensurate outcomes in terms of success rate and complications. Further high-quality studies are needed, to adequately compare the two approaches, particularly in terms of operation time, learning curve, cost-effectiveness, and otology surgical skills acquisition.

Key points

1. Endoscopic and microscopic stapes surgery have comparable results regarding hearing improvement.

2. No statistically significant differences were observed in terms of postoperative pain and dizziness.

3. Endoscopic stapes surgery is shown to be associated with lower dysgeysia rates.

4. ENT trainees should receive training in both endoscopic and microscopic otologic surgery.

5. Future RCTs providing concrete evidence are essential for robust results.

Keywords : endoscopy, stapedectomy, microscope, otology, otosclerosis

Introduction

Binocular vision utilizing a microscope for improved visualization while performing otologic surgery, first developed in 1952, offered a plethora of advantages, such as ambidextrous hand mobility and clear view of the middle ear anatomy, except for the retrotympanic space.[1] Since its initial employment, the microscope has been established as a powerful instrument towards treating the majority of middle ear lesions. Alternatively, endoscopic ear surgery was first described by Ohnsorge in 1977, offering a more transparent view of the middle ear cavity, disadvantages including single-hand surgical maneuvers and two-dimensional view. During the last half-century, endoscopic approaches for middle ear pathologies have shifted from diagnostic-only to operative procedures, including tympanoplasties, cholesteatoma removal, and stapes surgery. [2]

Multiple studies have been conducted, regarding the comparability of the microscopic versus the endoscopic technique, otologic outcomes and complication rates. Besides each study's quality, ample evidence is needed, which cannot be drawn from individual studies and trials. Thus, we moved forward as we feel that a systematic review and meta-analysis of the aforementioned parameters of each approach is of great importance, drawing sturdy conclusions apropos the best technique for the patients' benefit.

Design

We prospectively designed search methods, eligibility criteria, and data extraction process. No patient informed consent or IRB/ethics committee approval was required due to the nature of the current study, which was based on published records. This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis Protocol (PRISMA).[(3)]

Search strategy

Two review authors performed an electronic literature search looking for published studies comparing microscopic to endoscopic stapedectomy (E.G and K.T.D.). The electronic search involved three medical databases (Pubmed, Cochrane Library, and Scopus). We used the following MeSH terms: "otosclerosis" AND "endoscopic stapedectomy" OR "endoscopic stapedotomy" OR "endoscopic stapes surgery" AND "microscopic stapedectomy" OR "microscopic stapedotomy" OR "microscopic stapes surgery" AND "success rate" OR "complication" OR "length of hospitalization" OR "cost". The search process was limited in the English literature and the search period extended from 1964 until July 2020. The literature was last accessed in January 2021. Additional records were traced in the reference list of the gathered studies.

Eligibility criteria

We primarily focused on randomized controlled studies and secondarily on observational studies comparing the endoscopic to the microscopic stapes surgery in terms of success rate, complications, length of hospitalization, and cost-effectiveness. We discarded case-series, case-reports, editorials, reviews and systematic reviews, and studies without data suitable for quantitative analysis. We also excluded studies reporting on surgical interventions other than stapes surgery.

Data extraction

Each study was identified by the name of the first author and the year of publication. The following data were collected: 1) the size of the endoscopic stapes surgery group, 2) the size of the microscopic stapes surgery group, 3) the success rate measured in mean and standard deviation in each group, 4) the counts of individual complications in endoscopic and microsurgery groups, 5) the length of hospitalization in endoscopic and microsurgery groups, and 6) the costs of endoscopic and microsurgery groups.

Individual Studies Quality Appraisal – Overall Quality of Evidence

Quality appraisal for individual studies, as well as assessment of the overall quality of evidence in the current analysis, was conducted by 2 independent review authors (K.T.D. and E.G.). Individual quality appraisal for each included study was conducted using the ROBINS-I[4] tool for the non-randomized studies and the RoB-II[5] tool for the randomized controlled trials. ROBINS-I and RoB-II tools assess studies in 7 and 4 domains, respectively. Both individual RCTs and Non-RCTs were considered bearing a “High”, “Moderate” or “Low” risk of bias, based on the evaluation. The overall quality of the gathered evidence was assessed according to the GRADE working group recommendations[6], and it was categorized as "High" (Grade 4), "Medium" (Grade 3), "Low" (Grade 2), or "Very-Low" (Grade 1) quality of evidence.. In cases of disagreement, the 2 authors reached a consensus after consultation by the senior author (J.H.).

Data synthesis

The comparison of the two treatment options, was conducted through a meta-analysis for every parameter under study. The outcomes of continuous measurements were pooled in mean differences and their 95% CI, whereas the outcomes of count measures were summarized in odds ratio along with their 95% confidence intervals (CI), through a paired meta-analysis. In addition, a proportion meta-analysis was performed to estimate the incidence of the complication in each arm, independently. Inter-study heterogeneity was evaluated using the significance of the Cochran's Q-metric (pQ) and quantified by the Higgins I^2 statistics. Significance was set at $p<0.05$, and we used continuity correction equal to 0.5 for metrics associated with zero events. The pooled estimate was assessed using the random-effects model in the presence of inter-study heterogeneity ($I^2>50\%$), or else with the fixed-effects model. A sensitivity analysis would be considered, only in the co-existence of significant statistical heterogeneity and more than three studies per stratum. Publication bias was eyeballed by funnel plots and assessed using the fail-safe N analysis, also known as file-drawer analysis. All statistical analyses were executed using the Jamovi project for the R-statistical environment.(7,8)

Results

Study selection and characteristics

In total, 159 articles were identified through database searching, of which 125 were excluded because of duplication. After the title and abstract evaluation, 117 articles were further removed. Subsequently, the full text of the remaining 17 articles was reviewed and 4 more articles were excluded. Finally, 13 articles were considered eligible and were included in the quality assessment, while only 9 of them were included in the quantitative synthesis, due to the paucity of statistics (Figure 1). Characteristics of the encompassed studies are presented in Table I. All selected articles included 705 patients (711 ears), who underwent endoscopic or microscopic stapes surgery, were written in English and were published between 2014 and 2019. One was a randomized control study, while the remaining were observational. A summary of our analysis results can be seen in Tables II and III.

Quality Assessment (Individual Studies/Overall Evidence)

Regarding the observational studies, all 12 of them (100%) were considered to have a "Moderate" risk of bias. In concern to the randomized controlled study, "Low" risk of bias was ascertained in all domains. Evaluation of observational studies is presented in Table IV[1,9-19], while for the randomized controlled trial in Table V.[20] The overall quality of evidence was found to be “Very-low” for 3 outcomes evaluated (Pain, Dysgeusia, Dizziness) and “Low” for 1 outcome (Success Rate). Quality of evidence was downgraded largely due to the presence of risk of bias, indirectness and inconsistency issues (Table VI)

Success rate

Based on five studies, the pooled air-bone gap after endoscopic and microscopic stapes surgery was 9.08 (95% CI = 7.06-11.10) and 10.79 (7.82-13.75), respectively. In the absence of statistical heterogeneity (I^2 = 51.57%, pQ=0.08), there was no difference in terms of success rate between the two treatments (pooled mean difference -0.20; 95% CI -0.53, 0.14) (Figure 2). In addition, the regression test for funnel plot asymmetry failed to detect publication bias (p=9.79).

Complications

The available data permitted the pooling of the evidence regarding three postoperative complications associated with stapes surgery; dysgeusia, pain, and dizziness (Figure 3-5). Dizziness was the most frequent postoperative complication with an estimated pooled incidence rate as high as 41% (5-77%) and 45% (12-79%). There was no statistically significant difference between the two modalities (OR= -0.46 [-1.31, 0.38]). Conversely, the difference between the two modalities regarding dysgeusia was in favor of the endoscopic surgery (OR=-1.46; 95% CI=-2.45, -0.047). In fact, dysgeusia occurred with an estimated pooled incidence rate as high as 14% (8-21%) and 42% (22%-62%) after endoscopic and microscopic stapes surgery, respectively. Likewise, postprocedural pain was more frequent (OR= -2.00; 95% CI=-2.97, -1.04) after microscopic (28%; 95%CI=6,50%) than endoscopic (4%; 95% CI=0,8%) stapes surgery.

Operation time

Operation time ranged from 45 min (SD=8.4 min) to 128 min (SD=27min) and from 36.5min (SD=8.2) to 132min (SD=38.7min) for the endoscopic and microscopic technique, respectively. Based on four studies, there was no significant difference, between the two, regarding the operation time (mean difference= -1.92, 95% CI= -5.88, 2.03); I^2 =99.22%).

Discussion

Otosclerosis is a multifactorial disorder affecting the hearing ability of patients, due to pathological bone resorption and deposition of the otic capsule. Stapes surgery is the gold-standard method for the treatment of this disease. While the microscopic approach has traditionally been the preferable technique, remarkable progress has been achieved utilizing specially designed endoscopes, providing a powerful asset to Otorhinolaryngologists, aiming to improve any inadequacy eventuated by the microscopic approach. Offering excellent visualization of the middle ear cavity, the endoscopic technique permits a multi-angle-view of every "corner", combined with improved accessibility to fine structures. Furthermore, the endo-aural approach is feasible through endoscopes even for narrow or curved external auditory canals, allowing for minimally invasive operations. Thus, hearing improvement accomplished by endoscopic stapedectomy is considered comparable to its microscopic counterpart. This conclusion is supported by the current's study results, but also by those of the previous meta-analyses encountered in the literature and particularly those of Hall et al., Nikolaos et al., Koukkoulis et al.(21–23) Exceptionally, Fang et al. observed a statistically significant difference in favor of the endoscopic technique, evincing its eminence.(24)

Moreover, the improved visualization of the surgical field, provided by the endoscope accounts for less bony auditory canal drilling and, consequently, for limited manipulation or injury of the chorda tympani, leading to better rates regarding postoperative dysgeusia.(21) Furthermore, less or no scutum curetting, alongside minimal incisions, offers the advantage of minimum postoperative pain.(23,24) In compliance with this aspect are the outcomes of the present study, where postoperative pain was in favor of the endoscopic approach. On the contrary, Koukkoulis et al. presumed that, regardless of the slightest external auditory canal injury, no statistically significant difference was evaluated between the two treatment modalities, in terms of pain (OR = 0.84; 95% CI: 0.36, 1.96; I^2=64.2%, $p=0.039$).(23) Nonetheless, dizziness was the most frequent complication to be observed in the present study, however, with no significant difference reported between the two approaches (*p=0.14* [0.08, 0.21]),while dizziness was also to endoscopic technique's advantage.

As far as the operation time is concerned, there was no sufficient evidence that the endoscopic was inferior to the microscopic technique, in the present analysis. Nonetheless, Das et al. in their original study reported a statistically significant difference in favor of the endoscopic technique, since its operation time was 31 minutes shorter compared to the microscopic method ($p<0.05$).[20] Moreover, Ianella and Magliulo, mentioned that, in absence of statistical difference between the two approaches, regarding operation time, during their last study period, the surgical execution time of the endoscopic stapedectomy appeared to be significantly improved, comparing the first 10 to the last 10 patients.[25]

Apart from its efficacy in ear surgery results, the endoscopic approach appears to be rather beneficial concerning middle ear anatomy teaching and ear surgery skills acquisition, since both the surgeon and his assistants have an unimpeded view of the surgical field and the procedure, through the uniformly used monitor. Nevertheless, just like any other newly-introduced technology, this innovative approach has a learning curve for every surgeon not acquainted with endoscopic otology.[14,15,17,19,20]In conformity with this view, Ianella and Magliulo mention that operative duration seems to reduce as experience is obtained.[25] However, as long as microscopic technique is of great importance and cannot be entirely substituted, ENT trainees should be enrolled in optimized learning curricula, combining microscopic and endoscopic ear surgery teaching, aiming for optimal performance in otologic surgery to be achieved.

Given its proven predominance so far in terms of the aforementioned parameters, endoscopic surgery seems to be the frontrunner, possibly replacing microscopes in most common otologic cases in the near future.[23,24] Besides, digitally developed surgical instruments, as well as the anticipated wide use of robots in ear surgery are expected to improve 3D visualization and overcome the endoscopic technique's demerits mentioned before. Undoubtedly, microscopes will still be available for advanced and more complex occurrences.

Study Limitations

The current study is characterized by some important limitations, affecting its power to arrive at extensively applicable conclusions. Only one RCT was included in the current analysis, while clinical heterogeneity and inconsistency in numerous factors contributed to the downgrade of risk of bias score, including revision surgery, the number, and experience of the operating surgeon(s), follow-up periods, methods and diagnostic tools of complication evaluation and assessment, sample size as well as the retrospective nature of data collection. Furthermore, lack of systematic complication assessment and evaluation methods limited the number of studies which were included in the final statistical analysis. Additionally, data regarding length of hospitalization and cost were insufficient, thus pertinent results in regard to these parameters could not be achieved. These aforementioned factors should be addressed appropriately in futurerobusts studies.

Conclusions

Endoscopic stapes surgery is a promising innovative alternative to the microscopic technique, resulting in commensurate outcomes regarding hearing improvement. In terms of postoperative complications, pain, dysgeusia, and dizziness appear to be less frequent using the endoscopic approach. Further studies need to be conducted, including wider sample sizes, in order to draw widely applicable conclusions concerning operation time, learning curve, and otology surgical skills acquisition.

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Studies	Study Design	Age Group	No Patients (Female/Male)	No Ears (Endoscopic/Microscopic)	Outcomes	Follow-Up Time (Endoscopic/Microscopic)	Anesthesia
Kojima2014[9]	Retrospective Cohort	Pediatric + Adult	50 (32/18)	56 (15/41)	Postoperative ABG, Dysgeysia, Dizziness, Pain, Facial Paralysis, Corda Tympani Injury	6-12 (months) / 9 (months) - 10 (years)	General
Gulsen2019[11]	Retrospective Cohort	Adult	61 (34/27)	61 (32/29)	Postoperative ABG, Dysgeysia, Dizziness, Pain, Tympanic Membrane Perforation, Corda Tympani Injury	8-12 (months) / 9-15 (months)	Local
Daneshi2016[12]	Retrospective Cohort	Adult	34 (24/10)	34 (19/15)	Postoperative ABG, Dizziness, Facial Nerve Paralysis, Corda Tympani Injury	1-15 (months) / 1-15 (months)	General
Ianella2016[13]	Retrospective Cohort	Adult	40 (25/15)	40 (20/20)	Postoperative ABG, Dysgeysia, Dizziness, Pain, Tympanic Membrane Perforation, Facial Nerve Paralysis, Tinnitus, Corda Tympani Injury	6-15 (months) / 6-15 (months)	General
Surmelioglu2017[15]	Retrospective Cohort	Adult	46 (17/29)	46 (22/24)	Postoperative ABG, Dysgeysia, Dizziness,	12-28 (months) / 12-48 (months)	Local
Ardiç2018[16]	Retrospective Cohort	Adult	94 (37/57)	94 (37/57)	Postoperative ABG	3rd, 12th (month) / 3rd, 12th (month)	General
Bhardwaj2018[17]	Retrospective Cohort	Adult	40 (17/23)	40 (20/20)	Postoperative ABG, Dygeysia, Dizziness, Pain, Tympanic Membrane Perforation, Corda Tympani Injury	1st, 3rd, 12th, 24th (week) / 1st, 3rd, 12th, 24th (week)	Local
Moneir2018[19]	Retrospective Cohort	Adult	42 (?/?)	42 (14/28)	Postoperative ABG, Dysgeysia, Dizziness, Tympanic Membrane Perforation, Sensoneural Hearing Loss	4-6 (weeks) / 4-6 (weeks)	Local
Das2019[20]	Randomized	Adult	64 (60/4)	64 (32/32)	Postoperative ABG Dysgeysia	1st (week)	Local

	Controlled			/ 1st (week)
Total		471 (246+?/183+?)	477 (211/266)	

Table I. Summary table of the eligible studies.

Footnote: Data for quantitative statistical analysis were drawn from 9 out of the 13 eligible studies (ABG, air-bone gap).

Complications	No. Included Studies	No. Events/No. Patients (Endoscopic)	No. Events/No. Patients (Microscopic)	Incidence (Endoscopic, 95% CI)	Incidence (Microscopic, 95% CI)	Pooled Analysis OR (95% CI)	Heterogeneity (I2, %)	Publication Bias (p value)
Postoperative Pain	4[9,11,13,17]	6/87	30/110	0.04 (0.00, 0.08)	0.28 (0.06, 050)	-2 (-2.97, -1.04)	0	<0.001
Postoperative Dizziness	6[9,11,12,13,17,19]	47/120	70/153	0.41 (0.05, 0.77)	0.45 (0.12, 0.79)	-0.46 (-1.31, 0.38)	0	0.192
Postoperative Dysgeysia	4[11,13,19,20]	16/98	48/109	0.14 (0.08, 0.21)	0.42 (0.22, 0.62)	-1.46 (-2.45, -0.47)	47%	<0.001

Table II. Summary-of-evidence table regarding the complications of stapes surgery.

Footnote: Results occurring from the proportion and the paired meta-analysis in regards to postoperative complications of the 2 modalities.

Primary Outcome	No. Included Studies	Mean ABG Difference (CI 95%)	Heterogeneity (I2, %)	Publication Bias (p value)
Success Rate	5[11,15,16,17,20]	-0.20 (-.53, 0.14)	51.75%	0.044

Table III. Summary-of-evidence table regarding the success rate of stapes surgery. (Postoperative ABG <20dB)
Footnote: Results occurring from the pooled meta-analysis in regards to postoperative ABG considered successful (ABG, air-bone gap).

Studies	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Domain 7	Overall
Sproat2017[1]	−	+	+	+	+	−	+	−
Kojima2014[9]	+	+	+	+	+	−	+	−
Cornejo-Suarez2019[10]	−	+	+	+	+	−	+	−
Gulsen2019[11]	+	+	+	+	+	−	+	−
Daneshi2016[12]	+	+	+	+	+	−	+	−
Ianella2016[13]	−	+	+	+	+	−	+	−
Plodpai2017[14]	−	+	+	+	+	−	+	−
Surmelioglu2017[15]	−	+	+	+	+	−	+	−
Ardic2018[16]	−	+	+	+	+	−	+	−
Bhardwaj2018[17]	−	+	+	+	+	−	+	−
Kuo2018[18]	+	+	+	+	+	−	+	−
Moneir2018[19]	+	+	+	+	+	−	+	−

Table IV. ROBINS – I Individual Study (Observational) Risk of Bias Evaluation

Footnote: Domain 1: Bias due to confounding, Domain 2: Bias due to selection of participants, Domain 3: Bias in classification of intervention, Domain 4: Bias due to deviations from intended interventions, Domain 5: Bias due to missing data, Domain 6: Bias in measurement of outcomes, Domain 7: Bias in selection of the reported result, (-): Moderate Risk of Bias, (+): Low Risk of Bias

Studies	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Overall
Das2019[20]	+	+	+	+	+	+

Table V. RoB – II Individual Study (RCT) Risk of Bias Evaluation

Footnote: Domain 1: Bias arising from the randomization process, Domain 2: Bias due to deviation from intended intervention, Domain 3: Bias due to missing outcome data, Domain 4: Bias in measurement of the outcome, Domain 5: Bias in selection of the reported result, (+): Low Risk of Bias

Outcomes	Starting Grade	Risk of Bias	Imprecision	Indirectness	Inconsistency	Publication Bias	Large Effect	Dose Response	Confounding factors	Final Grade	Quality of Evidence
Success Rate	4	-1	0	0	-1	0	0	0	0	2	LOW
Pain	2	-1	0	-1	0	0	0	0	0	1	VERY LOW
Dysgeusia	4	-1	0	-1	-1	0	0	0	0	1	VERY LOW
Dizziness	2	-1	0	-1	0	0	0	0	0	1	VERY LOW

Table VI. Quality assessment of the overall evidence according to the GRADE recommendations.
Footnote: Starting grade was 4 in outcomes where a RCT was included in the studies. Starting grade was 2 for outcomes where only observational studies where included.

Figure 1. PRISMA Flowchart of the current study.
Legend: From the initial 159 records, nine studies fulfilled our eligibility criteria and were included in our data synthesis.

PRISMA 2009 Flow Diagram

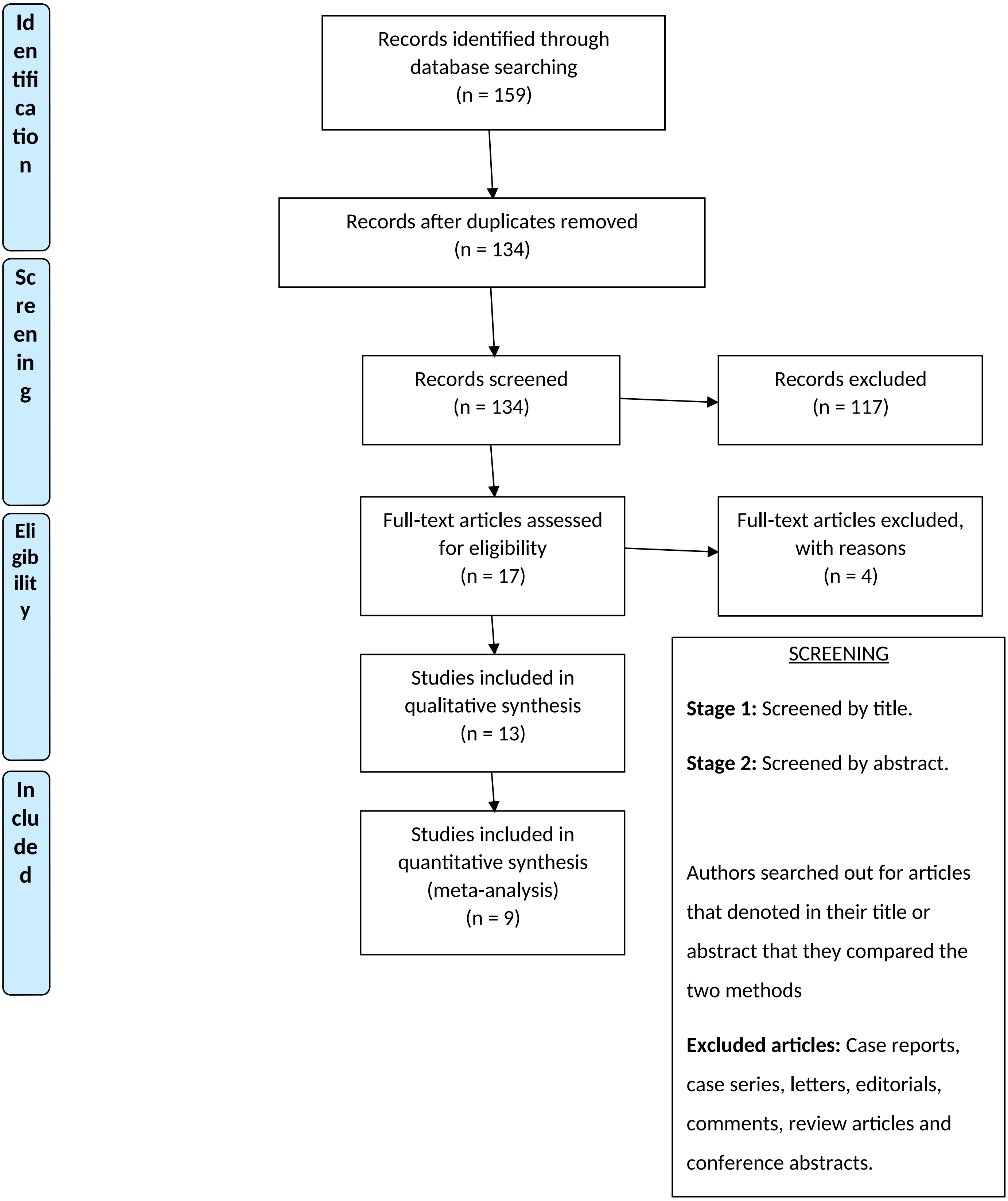
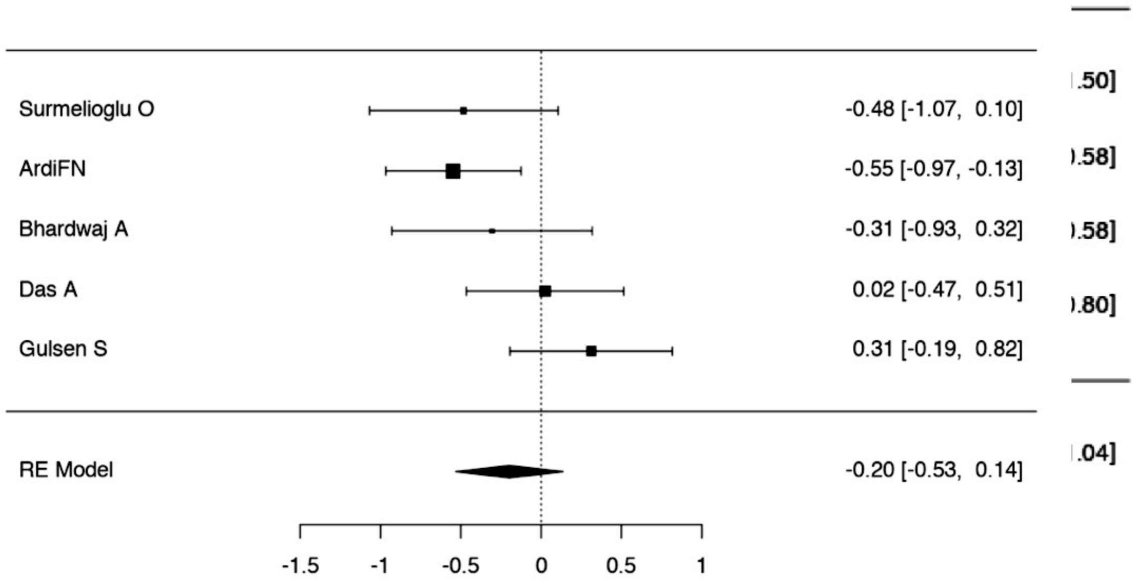


Figure 2. Success Rate Forest Plot
Legend: The current meta-analysis showed that here was no difference in terms of the success rate between the two treatments (Forest plot depicting standardized mean difference along with its 95% CI between microscopic and endoscopic approaches).



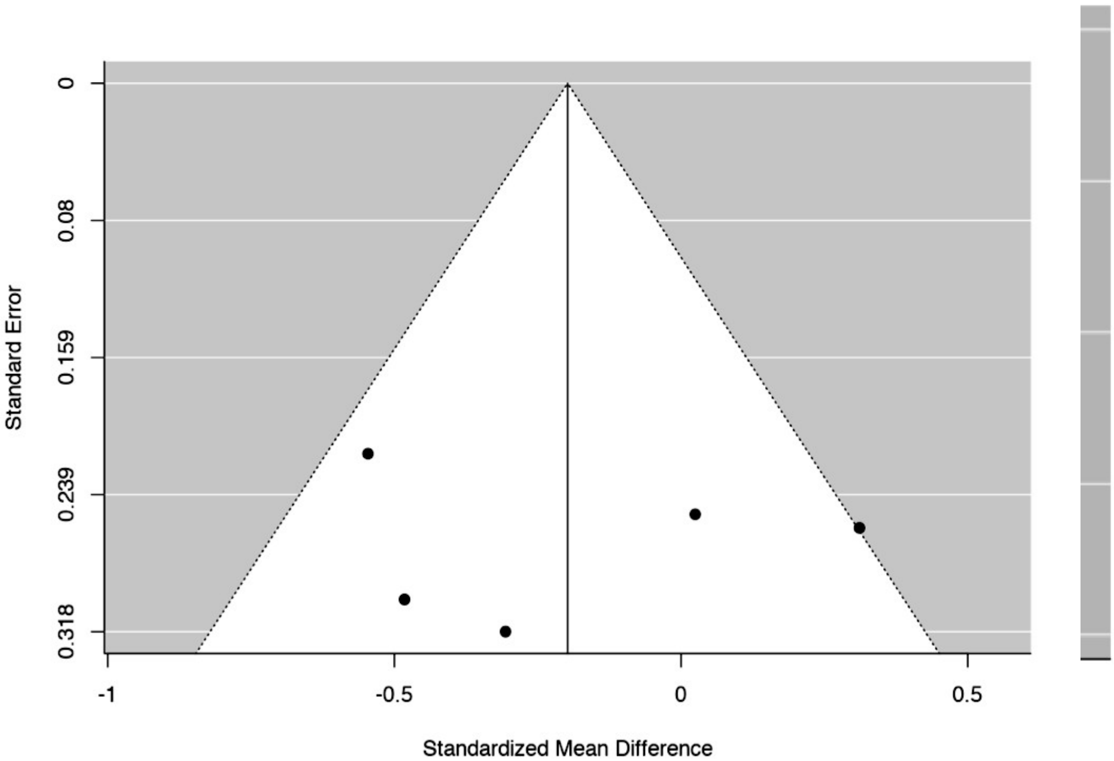
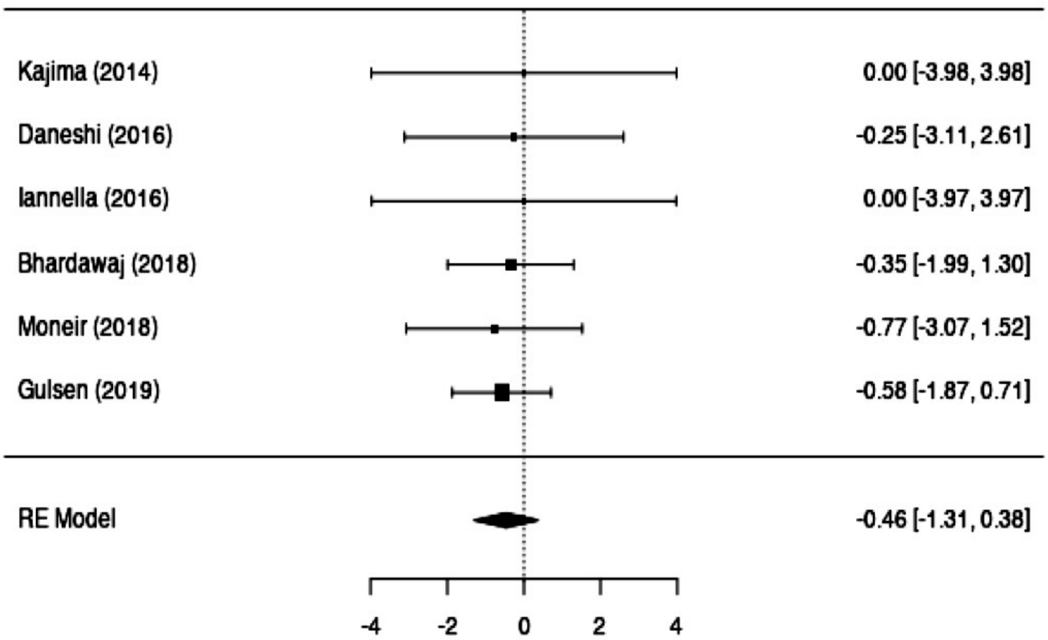


Figure 3. Postoperative Pain Forest Plot.
Legend: The current meta-analysis showed that the postprocedural pain was more frequent after microscopic than endoscopic stapes surgery.

Figure 4. Postoperative Dizziness Forest Plot
Legend: The current meta-analysis showed that there was no statistically significant difference between microscopic and endoscopic approach regarding the postoperative dizziness.


Kajima (2014)
Daneshi (2016)
Iannella (2016)
Bhardawaj (2018)
Moneir (2018)
Gulsen (2019)
RE Model
0.00 [-3.98, 3.98]
-0.25 [-3.11, 2.61]
0.00 [-3.97, 3.97]
-0.35 [-1.99, 1.30]
-0.77 [-3.07, 1.52]
-0.58 [-1.87, 0.71]
-0.46 [-1.31, 0.38]
-4
-2
0
2
4

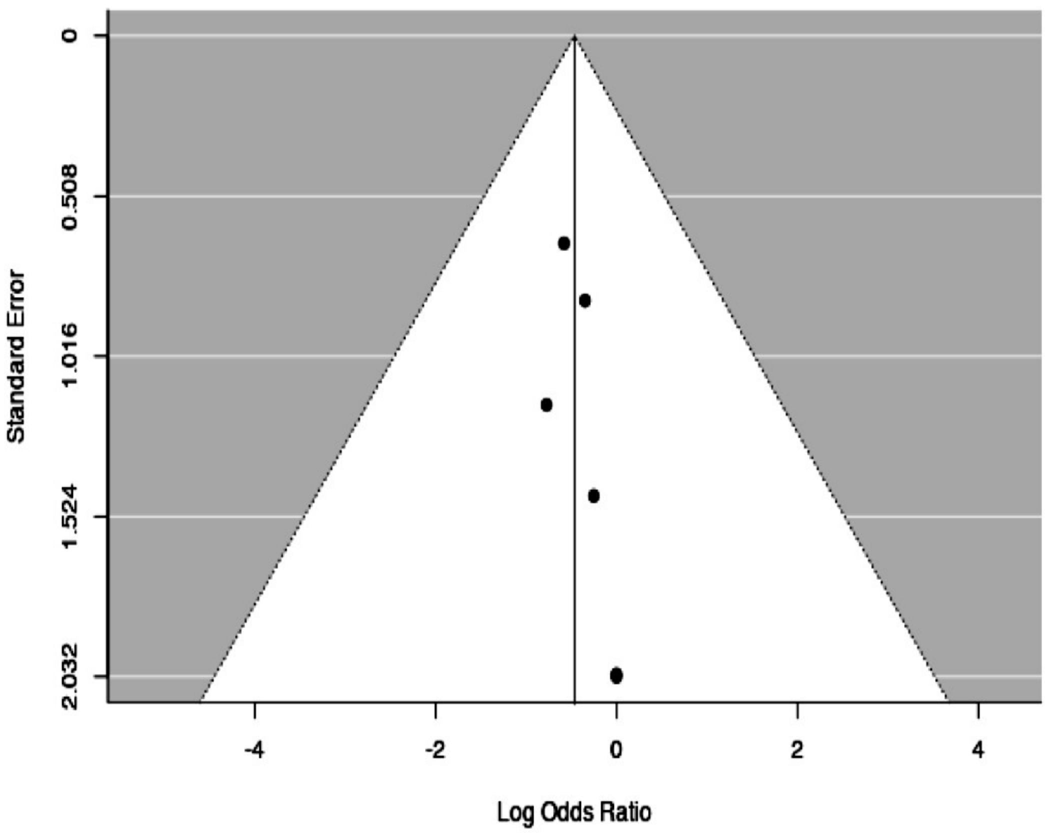

Standard Error
0
0.508
1.016
1.524
2.032
-4
-2
0
2
4
Log Odds Ratio

Figure 5. Postoperative Dysgeysia Forest Plot
Legend: The current meta-analysis showed that the difference between the two modalities regarding dysgeusia was in favor of endoscopic surgery