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REVIEWER'S REPORT

Manuscript No.: IJAR-59023

Title: Endoscopic versus Microscopic Tympanoplasty : A Randomized Comparative Study

Recommendation:

Accept as it is .....

Accept after minor revision.....

Accept after major revision .....

Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		x		
Techn. Quality		x		
Clarity			x	
Significance			x	

Reviewer's ID: JPR-142

Detailed Reviewer's Report

The manuscript addresses an important and clinically relevant question by comparing endoscopic and microscopic tympanoplasty in patients with tubotympanic chronic suppurative otitis media and traumatic tympanic membrane perforation. The prospective comparative design, assessment of graft uptake, hospital stay, pure-tone audiometry, and air-bone gap are appropriate outcomes for this topic. The manuscript reports comparable postoperative hearing outcomes and apparently better graft uptake and shorter hospitalization in the endoscopic group. The principal concern is whether the reported superiority of endoscopic tympanoplasty can legitimately be attributed to the surgical approach because the groups appear substantially imbalanced with respect to perforation size. In addition, important information regarding randomization, sample-size justification, baseline characteristics, statistical methodology, outcome definitions, ethics, and reporting of complications is insufficient. The numerical presentation of graft uptake also requires correction.

1. Major concern regarding randomization and baseline comparability

The authors state that patients were "randomly allocated" using a periodic random number method, but the manuscript does not adequately describe how the random sequence was generated, whether allocation was concealed, or who performed the allocation.

More importantly, the results demonstrate a substantial imbalance in perforation size:

- 100% of large perforations were treated microscopically.
- 65% of medium perforations were treated microscopically.
- 89% of small perforations were treated endoscopically.
- The difference was statistically significant, reported as **p = 0.00**.

This is a major methodological issue because **perforation size is itself an important determinant of surgical difficulty and graft uptake**. Therefore, the higher graft uptake observed in the endoscopic

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group may partly or substantially reflect the greater proportion of small perforations rather than the superiority of the endoscopic technique.

Required revision

The authors should:-

1. Provide a complete baseline characteristics table for both groups.
2. Report the distribution of:

    - perforation size
    - site/location of perforation
    - CSOM versus traumatic perforation
    - age
    - sex
    - preoperative PTA
    - preoperative ABG
    - middle-ear statu;
    - duration of disease/perforation.

3. Explain why randomization resulted in such a substantial imbalance.
4. Perform an appropriate **stratified or multivariable analysis** adjusting for perforation size and other clinically relevant baseline factors.
5. Temper the conclusion if adjustment demonstrates that the graft-uptake advantage is attenuated after controlling for perforation size.

This is arguably the **most important issue in the manuscript**.

2. Sample-size calculation is absent

The study includes only **44 patients, with 22 patients in each group**.

No sample-size or power calculation is provided.

For a randomized comparative study, the authors should explain:

- the primary outcome;
- expected effect size;
- alpha level;
- statistical power;
- expected dropout rate;
- basis for selecting 44 participants.

Required revision

Add a formal sample-size calculation in the Methods section.

If this was a convenience sample and no prospective calculation was performed, this should be transparently acknowledged as a limitation.

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3. The graft-uptake percentage appears numerically inconsistent

The manuscript reports **94.45% graft uptake in the endoscopic group**, with 22 patients in that group.

This percentage does not correspond cleanly to an integer number of successful grafts among 22 patients.

For example:

- 21/22 = **95.45%**
- 20/22 = **90.91%**
- 16/22 = **72.73%**

The reported microscopic value of 72.7% is consistent with approximately 16/22, but **94.45% requires verification**.

Required revision:- Please provide:

- numerator and denominator;
- number of intact grafts;
- number of failures;
- percentage;
- exact statistical test;
- exact p-value.

The table should preferably report results as **n/N (%)**, rather than percentages alone.

4. Statistical analysis is insufficiently described

The Methods only state:

"Statistical analysis was done using SPSS software with appropriate statistical tools."

This is inadequate for a randomized comparative clinical study.

The authors should specify:

- SPSS version;
- tests used for categorical variables;
- tests used for continuous variables;
- normality assessment;
- paired versus independent statistical tests;
- whether Fisher's exact test was used when expected cell counts were small;
- definition of statistical significance;
- whether analyses were two-sided;
- whether confidence intervals were calculated.

Particularly important

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For postoperative PTA and ABG, it is unclear whether the reported p-values compare:

1. preoperative versus postoperative values within each group, or
2. postoperative values between groups.

The manuscript needs to clearly distinguish **within-group change** from **between-group treatment effect**.

5. Audiological results require considerably better statistical reporting

6 Definition and classification of perforation size is missing

The Results depend heavily on perforation size, yet the Methods do not define what constitutes:

- small;
- medium;
- large perforation.

This is particularly important because perforation size appears to be the strongest potential confounder in the study.

Required revision

Provide an objective classification system, preferably with:

- percentage of tympanic membrane involved, and/or
- standardized anatomical criteria.

The method used by the surgeon to classify perforation size should be stated.

7. Baseline characteristics table is necessary

There is no proper baseline Table 1. The current Table 1 is actually a postoperative outcome table.

For a randomized comparative study, a baseline table should be provided.

At minimum:

- age;
- sex;
- diagnosis;
- perforation size;
- perforation location;
- preoperative PTA;
- preoperative ABG;
- relevant clinical characteristics.

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This would allow readers to determine whether the groups were comparable before surgery.

8. CONSORT-style reporting should be improved

Because this is described as a **randomized prospective study**, the manuscript should report:

- number assessed for eligibility;
- number excluded;
- reasons for exclusion;
- number randomized;
- allocation to each arm;
- number receiving allocated intervention;
- losses to follow-up;
- number analyzed.

A participant flow diagram would significantly strengthen the manuscript.

9. Ethical approval and informed consent are not reported

The Methods do not mention:

- Institutional Ethics Committee/Institutional Review Board approval;
- ethics approval number;
- informed consent;
- adherence to the Declaration of Helsinki.

For a prospective randomized human surgical study, this information is essential.

Required revision

Add a dedicated **Ethical considerations** subsection.

10. Inclusion and exclusion criteria require clarification

The inclusion criteria are described as tympanic membrane perforation or conductive hearing loss caused by tubotympanic CSOM or trauma.

However, the authors should clarify:

- duration of perforation;
- whether the ear was dry before surgery;
- duration of dry ear;
- active infection status;
- Eustachian tube dysfunction;
- ossicular-chain status;
- previous ear surgery;
- smoking status if relevant;
- exclusion of cholesteatoma;
- exclusion of ossicular discontinuity;

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- other causes of conductive hearing loss.

11. The study combines two different disease etiologies

The study includes both:

- tubotympanic CSOM, and
- traumatic tympanic membrane perforation.

These are clinically different conditions and may have different prognostic characteristics.

The manuscript reports **30 CSOM patients and 14 traumatic perforation patients**.

Required revision

The authors should provide subgroup distributions between the two surgical groups and consider whether diagnosis acts as a confounder.

If sample size permits, a sensitivity/subgroup analysis should be performed.

At minimum, this should be acknowledged as a limitation.

12. Operative time is discussed but not measured

The Discussion states that previous studies reported shorter operative time with endoscopic surgery.

However, **operative time was not included among the study's outcome measures**.

Therefore, the manuscript should avoid implying that this study demonstrated shorter operative time.

The same applies to claims concerning:

- improved cosmesis;
- lower operative cost;
- improved educational utility.

These are discussed from the literature rather than demonstrated by the present study.

13. The claim of minimally invasive should be presented carefully

The manuscript states that the endoscopic technique avoids unnecessary incisions and soft-tissue dissection.

However, the Methods state that the temporalis fascia graft was harvested through a **separate incision approximately 1 cm above the helix**.

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Therefore, the authors should clarify that the **ear canal surgical approach** is transcanal/minimally invasive while graft harvesting still involved an external incision.

14. Complications are not adequately reported

The manuscript discusses the advantages and limitations of both techniques but does not provide a structured comparison of postoperative complications.

Important outcomes include:

- infection;
- otorrhea;
- graft lateralization;
- graft medialization;
- reperforation;
- canal stenosis;
- sensorineural hearing deterioration;
- postoperative pain;
- bleeding;
- facial nerve complications;
- other surgical complications.

Required revision

Add a complication table, even if **no complications occurred**.

If complications were not prospectively recorded, this should be stated.

The manuscript addresses a clinically important comparison between endoscopic and microscopic tympanoplasty and has potential value for ENT surgeons. However, the current version does not provide sufficient methodological and statistical information to support the strength of its conclusions. In particular, the substantial imbalance in perforation size between treatment groups raises a significant risk of confounding and makes it difficult to determine whether the reported difference in graft uptake is attributable to the surgical technique itself. The reported graft-uptake percentage also requires verification.