

Peer Review File

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Reviewer A

While this paper describes a consecutive series of a good number of patients with temporal bone fractures and hearing losses, there are several issues with the methodology, analysis, and discussion that need to be addressed before it can be published.

1. It is cited as a retrospective cohort. However, there is a lack of stating the period of follow up and hearing outcome. Otherwise, it is more likely a retrospective analysis.
2. In such an analysis, the variables identified will be described statistically. Further, comparative statistics and if possible a regression model be generated;
3. This is not an interventional study and comments on treatment such as steroid is invalid; it could be listed as a variable for analysis but generalization is not possible

I do find a reference that is worth referencing with the correct methodology:

<https://www.mdpi.com/2673-4087/3/1/4>

Reply 1:

Thank you for your comments.

We agree that retrospective analysis is the most accurate way to describe our study, and have amended our methods accordingly.

We have reviewed our statistical methods at length and feel that the tests utilized are the most accurate means of assessing our heterogeneous data; a multiple regression model incorporating presence or absence of fracture, haemotympanum, and tympanic membrane perforation was generated, but the latter two factors were not significant within that model, and as such only simple linear regression using presence or absence of fracture as a dummy variable could be generated. We felt this data was better understood when categorized in terms of the means and medians within each group; however we did overlook our use of the student's paired t-test in our description of our methods; the paired t-test can be validly applied to our non-parametric BCT data given the high numbers (122) of included patients. Logistic regression as utilized in the study you kindly included is of course not possible with our data, as no dependent variable was categorical.

We agree that use of 'Generalisability' as the subheading describing our steroid analysis was poorly applied; we have removed this heading,

Changes in the text:

Please see page 2, line 36 – amended to “we performed a retrospective analysis”.

Page 5, line 103 onwards – the 'Statistical Methods' section outlines the rationale for paired t-test analysis of relevant data.

Page 12, line 259 – subheading 'Generalisability' has been deleted.

Reviewer B

This is a well-written and well-conducted retrospective study of otic capsule sparing temporal bone fractures looking at the effect on sensorineural hearing loss.

The premise is reasonable that a force significant enough to fracture the temporal bone might cause additional damage to the inner ear.

There are a few subtle issues with the methodology. One is that the two ears are not separate entities but obviously part of the same skull and therefore the traumatic impact causing fracture of the ipsilateral side is also imparting potentially damaging energy to the contralateral ear as well. Therefore, looking at the difference between the two sides may not be a fair representation of whether the trauma caused SNHL if it caused a degree of SNHL on both sides. However, without pre-injury and post injury audiograms there would be no way to confirm this. So it is reasonable that you chose to use the contralateral side as your control group, but I feel this point does warrant mention in your limitations.

Given your assumption that the contralateral side was not affected, it is also important that in your comparisons (e.g., administration of steroid) you were comparing the *difference* in BCT between the two ears, not just looking at the BCT of the fractured side. I assume this was the case, but can you confirm this.

Another issue relates to the Carhart's effect which is not mentioned. In patients with additional CHL there will be an impact on the bone line due to the Carhart's phenomenon (most noticeable in otosclerosis, but present with any CHL). This gives an artifactual lower bone lines, particularly at the higher frequencies, where you report the bigger difference. Ideally you should exclude those with mixed hearing loss or at least look at the pure SNHL group in isolation as a separate group analysis.

Finally, there is definitely an issue with the timing of the audiograms. I note a mean time of 3 weeks (23 days) to audiological testing and the range is huge - almost a year in one case (305 days!). It is hard to compare groups if some had audiology months after the injury and others were on the day of the injury.

So, the data is messy and perhaps too heterogeneous to make any firm conclusions but I still think it is worthy of publication, so long as those significant limitations are clearly outlined. Your institution clearly has a lot of presentations of temporal bone fracture and so you are very well placed to run a prospective study (as you mention) where you can address these shortcomings, e.g., timing of audiology and follow up audiology, especially in the presence of steroid administration.

I certainly feel it is a subject we need to look more closely at in a prospective manner as perhaps we should be considering SNHL as a more common phenomenon after otic sparing fractures and it would be interesting to see if early steroid application (as used in SSNHL) is otoprotective in these cases.

Reply 2:

Thank you for your comments.

We agree with your assertion that trauma may affect both fractured and paired unfractured ears; we have included reference to this within a newly created, more comprehensive 'Limitations'

subsection. For further explicitly define the relationship between paired ears, we have also included a correlation analysis regarding the hearing of paired fractured and unfractured ears; as expected, they are highly correlated.

Our initial comparisons only examined the mean BCT of fractured ears with special properties (steroid use, haemotympanum, tympanic membrane perforation) against other fractured ears. We have updated our results to also compare the change in paired BCT difference within such groups, but find that our results in either case are concordant with each other. We also feel that the initially included results are more intuitive to the reader, and so have retained these.

We have included reference to Carhart's effect in our 'Key Results' subsection, amongst discussion of the postulated pathophysiologic mechanisms consistent with our results.

We have also made more particular mention of the problematic nature of the wide discrepancy in time to audiogram within our dataset in the 'Limitations' subsection, and reiterated at the close of this section the necessity for prospective data in addressing many of the confounding influences present in our study.

Changes in the text:

Please see page 12, line 269 onwards – subsection 'Limitations' has been created (also relevant to point 4). Page 7, line 153 makes explicit statistical reference to the correlation between paired ears.

See page 8, lines 162-164, 168-169, and 175-177 regarding the effect of adjustment for BCT difference within paired ears for subgroup analysis of tympanic membrane perforation, haemotympanum, and steroid effect.

See page 11, lines 244-246 referencing the influence of Carhart's effect.

Editorial Comments

1. Readers should be able to easily identify the design that was used from the Title or Abstract. Thus, please indicate the study type in the Abstract or Title. This should include not only the reported "a retrospective analysis", also whether it is a cohort (retrospective/prospective), case-control or cross-sectional study. Kindly take note of the unique characteristics of each type of research design.

Reply: We have more precisely defined our study as an observational analytic study.

Changes in the text: See page 2, line 39 and page 5, line 110

2. Abstract - Methods: Specify how "followed-up with audiometry" was defined – was there a specific time frame post-injury when the audiometry had to be performed?

Reply: This has been clarified; included cases underwent audiometry within 365 days of injury

Changes in the text: See page 2, line 41-42

3. Abstract - Results: “Thirty-three individuals (27.0%) had a bone conduction threshold >25 dB in their petrous temporal bone fracture-affected ear”, clarify if the “bone conduction threshold >25 dB” is a standard measure of hearing loss in this context.

Reply: Routine interpretation of audiometry dictates that air or bone conduction thresholds above 25 decibels are suggestive of mild hearing loss, with values below this level within the normal population range. Given we expect our study to be of greatest interest to otologists and audiologists, rather than a broader clinical cohort, we suggest that to rationalize the use of this accepted audiometric threshold within our abstract would reduce the readability of this section. We have however included citations to support our hearing loss threshold in the Methods section – see comment 7.

Changes in the text: None made.

4. Introduction: Ensure that all technical terms are clearly defined for the reader. For instance, what constitutes an “otic capsule-sparing” versus “otic capsule-violating” fracture could be briefly explained.

Reply: The anatomy of the otic capsule has been explicitly outlined for greater clarity regarding fracture types.

Changes in the text: See page 4, lines 87-90

5. Introduction: Discuss why it is particularly important to study sensorineural hearing loss in the context of otic capsule-sparing fractures. What are the potential long-term impacts on patients?

Reply: We have included a reference to the protracted natural history of SNHL, and to the known quality of life deficits experienced by those with hearing loss, which are further expounded upon in our discussion section.

Changes in the text: See page 4, lines 93-95

6. Methods: Please further explain “prior known hearing impairment” to provide clarity regarding the specific scenarios that are excluded from this study.

Reply: This has been explained in greater detail; given the uniformly emergent nature of presentations, without clinical referral letters or other forms of corroborative clinical information, patient’s self-reported medical histories were relied upon for inclusion or exclusion according to the criteria of premorbid hearing impairment. Any report of poor hearing, as well as more precise medical diagnoses, were considered sufficient for exclusion from subsequent analysis.

Changes in the text: See pages 5-6, lines 126-136

7. Methods: Explain the rationale or cite the references for choosing the specific frequencies for BCT assessment.

Reply: We have referenced the WHO grades of hearing impairment as a common standard for delineation of hearing loss severity.

Changes in the text: See page 6, lines 140-142

8. Methods: Clarify the timeframe within which the post-injury audiograms were obtained.

Reply: This has been clarified; included cases underwent audiometry within 365 days of injury

Changes in the text: See page 6, line 136

9. Methods: Explain the process of independent review by a radiologist, including any blinding or standardization procedures to ensure objective assessment. Additionally, how are discrepancies in findings resolved?

Reply: We have expanded upon our CT review process.

Changes in the text: See page 5, lines 119-123

10. Figure 1: Consider adding data labels above each bar to display the exact percentage of patients affected, providing quick and precise information without the need to cross-reference the y-axis.

Reply: We have made the requested changes.

Changes in the text: See page 21, Figure 1

11. Figure 2&3: Bone conduction thresholds typically do not have negative values. If negative values are present due to calibration or other reasons, this should be explained. And consider adding a horizontal reference line to denote the clinical threshold for normal versus impaired hearing, if applicable.

Reply: Audiometric hearing values rely upon normative data for human hearing thresholds, meaning that 0 dB is the loudness at which most people can perceive a sound 50% of the time; individuals that can hear better than average may, therefore, have hearing thresholds that are lower than 0 dB. We feel that a line dividing normal from mild or greater hearing loss would be visually confusing, given the individual lines of sample medians within each population.

Changes in the text: None made.

12. Please thoroughly proofread the text for grammatical and spelling errors to ensure the report's readability and accuracy. Below are some examples:

(1) Abstract - Background: "The sequelae of otic capsule-violating fractures on hearing outcomes has long been appreciated", please change "has" to "have" to agree with the plural subject "sequelae".

(2) The phrase " $p= < 0.0001$ " should be corrected to " $P < 0.0001$ ".

(3) Methods - Participants & Main Outcome Measures: The phrase "images were also reviewed by an independent radiologist to determine concordance of findings to those reported", consider rephrasing to "images were also reviewed by an independent radiologist to determine the concordance of findings with those reported".

(4) Discussion: "Noise induced hearing loss will follow the same pattern" could benefit from a hyphen for clarity: "Noise-induced hearing loss...".

(5) Discussion: "Carhart effect in those with co-existing CHL will raise BCTs," may be clearer as "Carhart effect, in those with co-existing CHL, will raise BCTs," to denote the insertion of an additional detail.

Reply: The above changes have all been made and the remainder of the text has been carefully proofread for grammatical and spelling errors.

Changes in the text: As mentioned above.