Author's response to reviews

Title: Occurrence of a round window membrane rupture in patients with sudden sensorineural hearing loss

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Author's response to reviews: see over
Dear Dr. Foote,

First of all we would like to thank the Editor and the Reviewers for their important comments on our manuscript “Incidence of a round window membrane rupture in patients with sudden sensorineural hearing loss”.

Please find our comments and revisions below.

Kind regards,

Frank Haubner
EDITOR:
A author contribution section was added to the manuscript.

REVIEWER 1:

Material and methods.

“Please provide more data of the 69 patients (treatment prior to explorative surgery, duration of hearing loss, preexisting hearing loss).”

There was no evaluation of pure-tone audiometry values prior the event of sudden deafness. All patients were treated simultaneously with high-dose steroids. The exploratory tympanotomy was performed within 48 h after diagnosing the severe hearing loss if no improvement of hearing was observed. (this passage was added to the material and methods section)

Results.

“Was there a correlation between the mentioned factors* and the recovery rate?”

Only patients with no hearing recovery after 48 h and a persisting severe hearing loss were included into the study. Preexisting hearing test data were not available in this retrospective analysis. That is why a correlation analysis concerning the mentioned factors is not possible.

“With regard to the surgical technique, did the surgeons exposure the round window membrane by drilling the bone overhang during exploratory tympanotomy or was fluid in the round window niche a criterion for a rupture? Did the surgeons also observed the stapes footplate during surgery (micro-fissures etc.)?”
Using the operation microscope, the chorda tympani was preserved and the auditory ossicles were inspected. In some cases it was necessary to remove parts of the lateral attic wall to obtain a complete overview of the stapes foot plate and the round window niche. The round window membrane is mostly hidden in the depth of the round window niche. That is why false membranes and mucosal folds were removed by the surgeons routinely. Drilling bony overhangs was not part of the procedure regularly.

A clearly visible rupture of the RWM with persisting fluid in the round window niche after suctioning was the criterion for a “definite fistula”. Due to the difficulties to categorize a definite fistula in case of missing overview of the complete RWM, the category of “doubtful fistula” was integrated to the study according to Maier for subjects with persisting fluid in the round window niche instead of suctioning.

(page 7)

“Please provide the mean values for each frequency separately. “

Table 3 including the mean values for each frequency was added to the manuscript.

“Did the authors recognize a worsening of air conduction after surgery?”

Bone and air conduction were evaluated 3 weeks after surgery. There was no worsening observed postoperatively. (page 7)

Discussion.

“The number of patients with a round window membrane fistula varies among the
studies depending on many factors (patients history, surgical procedure with exposure of the round and oval window niche, imaging modalities to identify a rupture). This retrospective study shows that 3 out of 7 patients with a typical history had a fistula, one patient a doubtful fistula and 3 had no fistula, while 38% of patients without a typical history had either a fistula or a doubtful fistula. With regard to indication and hearing outcome, the authors should emphasize and discuss the indication for exploratory tympanotomy more in detail.

Do the authors recommend performing exploratory tympanotomy regardless the patients history prior to steroid medication in patients with a sudden hearing loss and if yes, when?"

The occurrence of a round window membrane rupture in SSNHL patients was under 20% in our study population. The patients’ history did not predict the finding of an intraoperative round window membrane rupture. Thus the anamnesis concerning a predisposing incident is not a reliable indication for the surgery. We found no correlation between the hearing recovery of SSNHL patients with and without perilymphatic leak. Nevertheless exploratory tympanotomy is a safe procedure that might be a useful addition to intravenous steroids in severe cases of SSNHL. Our indication for an exploratory tympanotomy persists for patients with no improvement of hearing within 48 h after treatment with intravenous steroids and a SSNHL of more than 50 dB in three contiguous frequencies. Further prospective studies that compare different treatment regimens are necessary to identify the benefit of an exploratory tympanotomy in patients with sudden deafness.

(discussion, page 10).
REVIEWER 2:
Major comments and compulsory revisions:

A retrospective chart review has limitations for evaluating an „incidence“. Only a percentage of those patients who received a tympanoscopy for suspected round window membrane rupture can be established that way. The term “incidence” should be changed to “occurrence” or a similar term.

The term “incidence” was changed to “occurrence” in the entire manuscript.

Methods, from 2nd paragraph: The definition of sudden hearing loss is somewhat arbitrary. Give references, where the chosen definition for sudden hearing loss comes from.

There exist several studies concerning the evaluation of the outcome after exploratory tympanotomy. Ul-Mulk et." included patients with SSNHL of more than 40 dB. Other authors report about 60 dB as definition for a unilateral deafness¹. Therefore, we decided to use 50 dB SSNHL in at least three contiguous frequencies to define a severe hearing loss and as indication for an exploratory tympanotomy.

(page 5)

How did the authors quantify non-measurable thresholds in audiograms („out-of-limits“)? How did they calculate improvement in these cases?

To calculate the out-of-limits the PTA value was set to 120 dB hearing loss. The improvement was calculated with respect to this value in each frequency.
How did you calculate threshold? If a PTA was used does the frequencies used for the PTA correlate with the frequency range of the definition for sudden hearing loss?

PTA was used to calculate the thresholds. Sudden deafness was defined as sensorineural hearing loss of more than 50 dB HL in three or more contiguous frequencies in pure-tone audiometry as compared to the normal hearing ear. (page 5)

What were the criteria for a “suspected round window membrane rupture“ or what were the criteria for surgery?

All patients were treated simultaneously with intravenous steroids. The exploratory tympanotomy was performed within 48 h after diagnosing the severe hearing loss if no improvement of hearing was observed. (page 5)

Results, 1st paragraph: How many patients with sudden hearing loss were suggested surgery and refused to have surgery? If this cannot be established retrospectively, this will impose bias on the „incidence“ and should be mentioned, e.g. in the results section.

There is a possible bias because only patients who consented to perform surgery were included to this study. (page 10)

In general: The concept of an intraoperative assignment of “no fistula”, “doubtful fistula” and “definite fistula” should be specified in more detail. In the methods section, criteria for these categories should be outlined. (Fluid in the RW niche
alone does not appear a definite sign of a RW lesion without full inspection of the RW membrane.)

All patients obtained an exploratory tympanotomy under local anesthesia and received a sealing of the round window niche. The procedures were done via an endaural approach to the middle ear after raising a tympanomeatal flap. Using the operation microscope, the chorda tympani was preserved and the auditory ossicles were inspected. In some cases it was necessary to remove parts of the lateral attic wall to obtain a complete overview of the stapes foot plate and the round window niche.

Clear signs of a rupture of the round window membrane with persisting fluid after suctioning the local anesthetic fluid was the criterion for a “definite fistula”. Due to the difficulties to categorize a definite fistula the category of “doubtful fistula” was integrated to the study according to Maier.

How many different surgeons were performing the procedure and it should be stated that they adhered to the same criteria for evaluations.

All procedures were done by three experienced otological surgeons who used the criteria mentioned above for their diagnosis. (page 6)

Results, 4th paragraph: The RW membrane in most case is hidden in the depth of the RW niche and in some cases covered by false membranes and mucosal folds (see Alzamil and Linthicum 2000 and other authors). Therefore it is often not visible by tympanoscopy before these false membranes are removed and more importantly the promontorial ridge over the RW niche has been removed. Please state whether and how this was done and of so in how many cases it was
The round window membrane is mostly hidden in the depth of the round window niche. That is why false membranes und mucosal folds were removed by the surgeons routinely. Drilling bony overhangs was not part of the procedure regulary. Exact data on this technical detail were not possible to evaluate retrospectively.

(page 6)
Assessment of perilymphatic fistulas remains a diagnostic problem. In our study we had a rate of 22% of doubtful fistulas. Visualizing the round window membrane often demands the removal of false membranes and bony ridges. Exact data on this technical detail were not possible to evaluate retrospectively in all cases. Indirect signs as the observation of persisting fluid in the round window niche were therefore considered as a criterion for the diagnosis of a doubtful perilymphatic fistula in the present study.

(page 10)

*How differed the patients with fat seal from those with a fibrin glue combination sealing with respect to outcome?*

The three patients covered with fibrous glue showed an improvement of hearing of more than 20 dB. Due to the small sample size there was no significant correlation between the different techniques and the outcome. (p. 7)

*Please give a reference for your criterion of hearing improvement (<20dB).*

*The hearing recovery in a major recent sudden hearing loss study (Rauch et al. 2011, JAMA) showed an average improvement of approx. 30dB in the PTA.*

*Please discuss this (or results from other sudden hearing loss studies) with*
respect to your findings.

The specific definition of what constitutes improvement or recovery after a SSNHL is not uniform among studies and reports. One interpretation is an improvement of 20 dB in pure-tone audiometry. Other authors use an improvement of 30 dB as definition for a relevant hearing recovery.

(page 12)

Minor comments and essential revisions:

Is citation (1) correct, if so, use only „Simmons“, not „Blair Simmons“. The citation was corrected. (p. 4)

p.5., 2nd paragraph: Include the Ethics Committee approval number.

The approval number 11-101-0232 was added.

p.7., last paragraph: Change to: “were not observed” This phrase was corrected.