

## 10.1 Summary of chapter 1

The relation between an idiopathic sudden sensorineural hearing loss (ISSNHL) and a perilymphatic fistula (PLF) resulting in a leak between inner and middle ear with a flow of perilymphatic fluid into the tympanon is explained. In a historical review the explorative tympanoscopy with sealing of the round/oval windows, which is able to treat PLF successfully, is described as a therapy which also has been applied more frequently during the last decades in cases of acute profound or severe hearing loss as well as in deaf patients.

A survey is given of the diagnostic and therapeutic methods and procedures which will be presented in the following chapters of this book. The treatment of patients with ISSHL by using systemic steroids and an explorative tympanoscopy is described in detail.

Our group of 51 patients with ISSNHL treated by explorative tympanoscopy was combined with data of patients treated by the same therapeutic procedure from 4 other studies collected from literature ( $n=357$  patients). In this combined pool of patients epidemiologic, anamnestic und clinical findings are examined on their influence on the extent of initial hearing loss. In addition post-operative development of hearing is evaluated in 42 of our patients by using average hearing losses in the frequencies 0,5 kHz, 1 kHz, 2 kHz and 4 kHz ( $PTA_4$ ) and the modified Kanzaki criteria and the results are compared to data from other published studies. It is evaluated if specific individual data of patients can predict the success of the surgical procedure (prognostic value) and the results are reflected in context to the findings of other authors.

Hearing results following an explorative tympanoscopy with sealing of the round/oval window are compared to hearing results drawn from literature in patients who received intratympanal applications of corticosteroids ( $n=1404$ ).

Student's t-test, Chi-squared test and correlation analysis are used to investigate statistically significant differences/relations between subgroups of patients suffering from ISSNHL or specific parameters which are interesting. Post-hoc Bonferroni and Li corrections/adjustments are performed to verify significant results when the influence of different parameters in relation to the initial or final hearing levels are compared within a patient group. In cases where the independent variable is scaled in a nominal form and the dependent variable is scaled in a metric the statistical analysis was performed by ANOVA. Where also the dependent variable is scaled nominally Kruskal-Wallis test was used. To compare the results of different patient groups weighted averages were formed which took the different sizes of each patient population into account.

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## 10.2 Summary of chapter 2

At the Carl-Thiem-Clinics in Cottbus during a decade (2006–2015) explorative tympanoscopy with sealing of the round/oval window was performed in 76 patients. After using selection criteria the hearing data of 51 of these patients are used for statistical analysis. Epidemiologic data, anamnestic informations and clinical findings of these patients was collected and we investigate if these were related to the initial hearing loss. The results are compared to the data of patients published by other studies.

In our population men predominated by 62,7 % and average age of patients was 65 years. 2/3 of the hearing impairments occurred in April to September, only 1/3 during the rest of the year. 22,5 % of patients suffered from an earlier lesion at the same inner ear or an earlier brain injury. In 29,5 % hearing loss occurred in a situation which was able to raise the intracranial pressure and therefore is typical for the development of a PLF between the inner and middle ear (trigger elicitor situation). Hearing loss was in 57,0 % accompanied by dizziness and in 54 % by tinnitus. Hearing impairment was spread over all frequencies (pancochlear), average PTA<sub>4</sub> level was 101,3 dB (0,5, 1, 2 and 4 kHz). Mean latency between onset of hearing loss and admission to hospital was 2,8 days and mean latency between treatment by systemic steroids and tympanoscopy was 5,3 days.

In patients who reported a trigger elicitor situation accompanying the development of hearing loss the hearing level before therapy was significantly worse (114, dB) than in patients who did not describe such a situation (96,6 dB).

Dizziness also showed a significant influence on initial hearing losses. Patients who suffered from dizziness started with a mean hearing loss of 107,0 dB, those without loss of balance with a hearing loss of 93,0 dB. These results were confirmed by Maier et al. Some authors reported a close correlation between age and initial hearing levels of patients. In our study we could not detect such a correlation.

Influence of age on the level of hearing loss before starting therapy is described contradictingly in literature. We could not find a statistically close correlation between these two parameters.

### 10.3 Summary of chapter 3

In a group of 41 patients suffering from ISSNHL (hearing loss >60 dB) and treated at the ENT-Department of the Carl-Thiem-Clinics in Cottbus between 2005 and 2014 it was investigated if latency between onset of hearing loss and explorative tympanoscopy with obliteration of the round/oval window influences the gain of hearing after operation. Additionally the time course of hearing gain before and after tympanoscopy was pursued at different time intervals.

Hearing loss after admission to hospital differed significantly from hearing loss in a follow-up examination in average 2,3 years after tympanoscopy. Up to day 16 after onset of the inner ear lesion the operation can be followed by a good final result in hearing. If the operation was performed during the first six days after admission to hospital (first line mode) improvement in hearing was lower (23,4 dB) than in cases where surgery was performed after 10 days of systemic application of steroids (second line mode, hearing gain: 38,1 dB).

During the first 7 days of i.v. application of steroids no signs of change in hearing were detected. After the operation it took a period of 10–20 days before hearing restored clearly visible. During the following 2,3 years no additional hearing gain was detected. Therefore recovery of hearing appears to be completed 3 weeks after tympanoscopy. In pure tone audiogram the improvement in hearing was more accentuated in low than in high frequencies.

Explorative tympanoscopy with sealing of the round/oval window is a valuable method in treating ISSNHL when systemic application of steroids has not been effective. So far the operation cannot be recommended convincingly as a first line treatment. More studies are needed to work out the value of early performed tympanoscopies in treating ISSNHL and the results have to be compared with other worldwide used therapies like intratympanic steroid injections.

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### 10.4 Summary of chapter 4

Formerly explorative tympanotomies including sealing of the round/oval window have only been used in treating perilymphatic fistulas. In the last years this operation has more and more been performed in patients suffering from ISSNHL especially in middle European countries. This chapter presents the effect of this operation combined with a simultaneous systemic steroid therapy on hearing levels from data collected in literature, the results will be presented by means of a systematic review. The survey also includes results of this operative procedure in 41 patients who have been treated in our clinic.

From 19 publications dealing with the above mentioned topic only 6 (4 with information about hearing loss at the time of admission to hospital and an additional follow-up examination, n=309) have been included in this study. Another 2 studies in which hearing gains (regardless of initial hearing loss) were evaluated according to the modified Kanzaki criteria (n=288), have been used for

assessing the therapeutic effects of tympanoscopy with sealing of the round/oval window in patients with sudden deafness.

The follow-up examination had to exceed a 3 weeks interval from the time of operation. Several methods to evaluate median hearing loss ( $PTA_4$  and  $PTA_5$ ) in pure tone audiograms are demonstrated to be acceptable for the analysis of hearing losses when we compare the results of the treatment.

In each patient group collected from literature and two patient groups of our own study the hearing loss before therapy was significantly higher than the hearing loss measured at the follow-up examination.

Patients treated with tympanoscopy in combination with systemic steroids in a first line mode ( $n=79$ ) showed a hearing loss of 94,1 dB. Their hearing improved to a hearing level of 70,7 dB at the follow-up examination (hearing gain: 23,4 dB;  $n=79$ ). Patients who were first treated with systemic steroids followed by tympanoscopy (second line mode) had an initial hearing loss of 105,1 dB and a hearing gain of 38,6 dB. Their final hearing level reached 66,5 dB ( $n=197$ ).

Median hearing thresholds rose after detamponation of the external ear canal which was usually done 10 days after operation up to the follow-up examination.

Based on modified Kanzaki criteria 58,7 % of patients presented a recovery of their hearing exceeding 30 dB. In 18,7 % of cases hearing improvement was between 10 dB and 30 dB. 23,1 % of patients didn't benefit from tympanoscopy.

References for the decision to perform an explorative tympanoscopy which are mentioned in literature are collected and discussed.

Explorative tympanotomy including sealing of the round/oval window is a very valuable method in the treatment of sudden hearing loss especially if hearing loss was severe, profound or patients were completely deaf and if the therapeutic procedure was performed sequentially (first systemic steroids, secondly operation). Further studies should investigate if tympanoscopy used in a first line mode can result in hearing gains which are successful enough that this form of therapy can also be recommended.

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## 10.5 Summary of chapter 5

Prognostic expectations in reaching a hearing gain differ in patients who are treated with explorative tympanoscopy and sealing of the round/oval windows with autologous fibrous tissue according to their epidemiologic, anamnestic and clinical findings. This chapter relates influences of patient associated parameters to hearing gains and levels of hearing threshold after operation.

In 42 patients of our own study and 539 patients published in 7 studies with a comparable study design the results of hearing gains following a tympanoscopy were collected and analyzed statistically by means of Chi-squared test, student's t-test, ANOVA and Krsukal-Wallis test. The influence of epidemiologic, anamnestic and clinical parameters on hearing outcome in cases of sudden deafness is assessed. To compare the results the mean hearing loss was estimated

by using the average hearing level formed by four frequencies of the pure tone audiogram (PTA<sub>4</sub>).

Neither sex, side of hearing loss, oral therapy before admission to hospital, a previous lesion of the inner ear or previous brain damage, a so-called elicitor situation at the time of onset of hearing loss, a tinnitus occurring simultaneously to the hearing impairment nor the operative findings of the middle ear structures did show a significant influence on the development of hearing after operation.

Only one author reported that elderly patients were not able to reach as good hearing results as younger ones. This result can not be confirmed by the hearing data of our patients.

Some studies including our own revealed that dizziness occurring simultaneously with the hearing impairment was connected with significant lower expectations in postoperative hearing development. A spontaneous nystagmus and a directional preponderance evaluated by the nystagmus reactions could not be correlated with the hearing improvement nor the subjectiv feeling of vertigo.

The initial level of hearing loss in patients of our study as well as in patients in studies from literature influenced the hearing gain in such a way that patients with lower hearing at the time of admission to hospital would not reach such good hearing results as those with better hearing before the start of therapy.

Some authors reported that in their patient groups latency between onset of hearing impairment and date of tympanoscopy correlated with the hearing gain in such a way that an earlier performed operation influenced the hearing improvement in a positive way. We were not able to confirm these results in our patients.

Patients with initial hearing losses representing a pancochlear type did recover in a better way than those who had developed an apico- or basocochlear form of hearing impairment.

Different results on the prognostic value of epidemiologic, anamnestic and clinical findings were found in literature according to their influence on hearing improvement after an explorative tympanoscopy with sealing of the round/oval window in cases of a severe, profound sudden hearing loss as well as in completely deaf patients. Prognostic evaluations appear mostly to depend on dizziness occurring simultaneously with hearing loss and on initial levels of hearing impairment. In our opinion this phenomenon should be discussed with the patients who have to consent to the operation in advance.

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## 10.6 Summary of chapter 6

In this chapter it is analyzed if some subgroups of our patients with ISSNHL which in some particular features stood out of the normal range differ according to their epidemiologic, anamnestic and clinical findings in their initial hearing loss as well as the hearing gain after having performed a tympanoscopy with sealing

of the round/oval window/s on from another subgroup of patients which did not fulfill these selection criteria.

1. Patients with surditas vs. patients with an initial hearing loss <120 dB.
2. Patients who reported about a trigger elicitor situation which is assumed to be typical for the development of a perilymphatic fistula at the onset of hearing loss vs. patients who denied such a situation.
3. Patients who reported a simultaneous development of vertigo at the onset of sudden hearing loss vs. patients without any problems of imbalance.
4. Patients with a hearing gain far above the average of that from other patients (>50 dB) vs. patients who had no or nearly no improvement in hearing after tympanoscopy (<10 dB).

Age, sex, location of the lesion, a history of previous inner ear disease or head injury, an outpatient treatment and the development of tinnitus simultaneously to the sudden deafness did not differ significantly in the above mentioned subgroups of patients.

In patients with surditas vertigo correlated significantly more often with the onset of ISSNHL than in patients with an initial hearing loss <120 dB. Patients with surditas differ in their final hearing loss evaluated in follow-up examinations significantly from those patients who started therapy with an impairment of hearing <120 dB.

In patients with trigger elicitor situations initial hearing losses were significantly more marked than in patients without elicitor situations.

Patients with dizziness had significantly worse initial hearing losses as well as lower hearing gains and more pronounced final hearing losses than patients without problems of their vestibular system.

It did not surprise that final hearing losses of patients with hearing gains of  $\geq 50$  dB were significantly lower than those of patients who did not recover (<10 dB) so successfully.

In summary, especially the simultaneous onset of sudden deafness and vertigo showed a significant negative influence on the outcome of tympanoscopy and sealing of the round/oval window. These results have to be considered and discussed with patients in whom an operation is planned to treat ISSNHL.

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## 10.7 Summary of chapter 7

During explorative tympanoscopy in patients with ISSNHL some showed pathoanatomical abnormalities of tympanon and/or a PLF was verified by a flow of perilymphatic fluid into the round and oval window niches (IOP-positives). In the present study the epidemiological and anamnestic data as well as the clinical findings of IOP-positive patients are compared with the data of IOP-negative patients who showed normal structures of tympanon. In addition the prognostic value on the one side of trigger elicitor situations which are typical for the development of a PLF

and on the other side of the onset of dizziness simultaneous with hearing loss is assessed. The amount of hearing gain after sealing the oval/round window niches with autologous fibrous tissue is compared in the group of IOP-positive patients and in patients with normal anatomical middle ear structures in our own study as well as in studies reported in literature.

In our study the epidemiological and anamnestic data as well as the clinical findings didn't differ in the two subpopulations of IOP-positive and IOP-negative patients.

In patients who reported a trigger elicitor situation the predictive value in the summarized data from a study by Maier et al. and our own patients is 30,2 % and the sensitivity value is 59,3 %. The odds ratio was 1,05. The Chi-square test revealed a highly significant difference ( $p=0,0008$ ) between the two subpopulations of IOP-positive and IOP-negative patients according to the prevalence of the existence of a trigger elicitor situations.

Based on the results of three studies dizziness has a predictive value of 55,4 % for the existence of a PLF and a sensitivity of 56,6 %. The odds ratio was 2,01. There is a probability of  $p=0,002$  that IOP-positive and IOP-negative patients do not belong to the same population.

Belonging to different results in multiple studies the so-called trigger elicitor situations and the dizziness combined with acute hearing loss are not safe parameters in predicting a PLF and therefore didn't appear to be very effective for making the decision to perform an explorative tympanoscopy.

Independent of the method how hearing levels were evaluated in all the study groups IOP-positive patients gained much more hearing improvement from the operation than IOP-negative patients. Hearing gain in the frequencies 0,5 kHz ( $p=0,05$ ) and 1 kHz ( $p=0,033$ ) differed significantly in IOP-positive patients at the follow-up examination compared to patients with normal anatomical structures of the tympanon.

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## 10.8 Summary of chapter 8

Based on our investigation only 3 publications exist up-to-date which deal with explorative tympanoscopy in which corticoid-soaked autologous tissue was used for sealing the round/oval window niches in patients being treated for ISSNHL. In this chapter the success of this form of operative therapy is assessed and compared to tympanoscopy in which untreated tissue was used for obliteration of the round/oval window niches. In addition the time course of hearing improvement is examined in both forms of operative therapy and compared to intratympanic corticoid injections for treatment of sudden deafness.

The three existing studies which deal with the sealing of the round/oval window with corticoid-soaked tissue used different criteria for analyzing the hearing data of their patients and therefore could not be used for a comparison (median hearing loss vs. arithmetical average of hearing loss, follow-up time of 1–5 days after tympanoscopy vs. follow-up-time of 3–6 months; using frequencies

0,5, 1, 2 and 3 kHz vs. using 0,5, 1, 2 and 4 kHz). To compare the hearing data of our patients to those reported in literature we had to adapt our results to the criteria of the different studies.

In a long-term follow-up examination (>90 days) patients of a study group whose round and oval window niches have been sealed with steroid-soaked tissue showed a median hearing improvement of 26,3 dB and reached a final median hearing loss of 86,7 dB. Three weeks after operation this group of patients reached a hearing gain of 15 dB in average (57,0 % of total hearing gain). In our patients in whom no pretreated fibrous tissue had been used the median gain in hearing was 31,2 dB and at follow-up examination the patients reached a hearing level of 76,3 dB.

In the postoperative days 1–5 patients in whom steroid-soaked tissues had been used showed a mean hearing gain of 31 dB. In average they had a final hearing loss of 42 dB. The team of authors also had a study group in which they used untreated autologous tissue for sealing the oval and round window niches. In these patients hearing gain after tympanoscopy was 18 dB. Five days after operation patients had a mean loss of hearing of 58 dB. In contrast to these results our patients only had a hearing improvement of 2,1 dB during the first 5 days after surgery and their hearing impairment during the first 5 days after operation was 97,2 %. This represented only 6,5 % of the total hearing gain which patients could reach after more than 120 days.

Using the modified „Kanzaki“-criteria for describing the effect of therapy in patients recruited from literature who have got steroid-soaked fibrous tissue obliteration of the window(s)– independently from the time interval between operation and follow-up examination– could reach in 52%, 69%, and 83% of the cases a hearing gain of Typ 1-2 (>10 dB improvement in hearing). In contrast patients in whom untreated fibrous tissue had been implanted a hearing gain belonging to Typ 1–3 could be seen in 32,3 % in one study group and in 63 % in another study group.

In patients who had been treated with intratympanic corticoid injections (n=436) a hearing improvement was detected directly after the 2 weeks course of intratympanic application of steroids. In patients who had been treated by tympanoscopy and sealing of the round/oval window with autologous fibrous tissue the recovery in hearing started later and could clearly be observed in the second week after operation.

Looking at the time course of the 3 mentioned studies (2 of them had been published by the same main author) in which steroid-soaked tissue had been used a very quick improvement of hearing after tympanoscopy is detected in two study groups. This result contrasts to a delayed improvement in hearing in another study group.

In our opinion up-to-date not enough valid data exist to get a serious evaluation of the effect of sealing the round and oval window with steroid-soaked autologous fibrous tissue. The outcome of this form of therapy can statistically not be compared to the therapy using untreated tissue for implantation. We expect that more and more clinicians will use the method of steroid-soaked material in the future.



## 10.9 Summary of chapter 9

Application of steroids in many variations and tympanoscopies with sealing the oval/round window are the most often reported methods for treating ISSNHL. In the present study the results of different treatment methods using the above mentioned therapies are collected from literature in addition to our own group of patients. The therapies are compared in a systematic review.

A total of 27 publications (42 study groups) is presented in this review comprising 2117 patients in the years 2006 to 2015 who either had received systemic steroids and/or intratympanic injections/infusions of dexamethasone/prednisolone or a tympanoscopy with sealing of the round/oval window. Hearing loss was calculated by two different methods of forming a PTA<sub>4</sub> and one with a PTA<sub>5</sub> including the frequencies of 0,25 kHz and 4 kHz of the pure tone audiogram. In addition a quantitative description of the hearing gain according to the so-called Kanzaki criteria was performed.

There was a population of patients who received

1. only intratympanic injections in a first line mode (ISTS; n=525) or
2. a treatment with systemic steroids concomitant with intratympanic injections/infusions (COMB-ITST; n=437) or
3. a sequential treatment of systemic steroid application followed by intratympanic steroid applications (SEQ; n=306).

Additionally there were patients who

4. had been operated in a first line mode in combination with a systemic steroid application (COMB-TYMP-FL; n=79) or
5. received in a second line mode initially systemic steroids followed by tympanoscopy with sealing of the round/oval window(s) (TYMP-SL; n=247).

The variation of initial hearing losses as well as those of hearing levels which were documented at a follow-up examination showed a wide range throughout the study groups.

All patients who had received steroids intratympanally had a less profound initial hearing loss than those who had been operated (ITST: 769,8 dB; COMB-ITST: 73,2 dB; SEQ: 75,2 dB; COMB-TYMP-FL: 94,1 dB; TYMP-SL: 104,2 dB). Hearing of the patient groups with intratympanic steroid injections improved between 18,4 dB (SEQ group) and 31,7 dB (COMB-ITST group). The hearing gain in the tympanoscopy first line group was 23,4 dB. The best improvement was accomplished in the TYMP-SL group with 38,1 dB. The final hearing was 47,3 dB in the ITST-group, 41,5 dB in the COMB-ITST group and 56,8 dB in the SEQ group. In the two study groups who had received a tympanoscopy the final hearing level was 70,7 dB (COMB-TYMP-FL group) resp. 66,1 dB (TYMP-SL group). Patients who had been operated in second line

mode started from a far lower hearing level than all others patients but nearly reached a final hearing level as those who had got intratympanal steroids. Relative gain in hearing – related to the initial hearing loss – was best in the COMB-ITST group (43,3 %), followed by the TYMP-SL group (36,6 %) and the ITST group (32,2 %).

The extent of initial hearing loss appears not to influence the degree of hearing improvement in patients with a conservative or surgical therapy if the initial hearing loss exceeds 60 dB.

Statistical analysis of the different hearing gains in study groups which were all treated with one of the described modes of intratympanal steroid injections/infusions showed very inconsistent results in relation to the question if one form of therapy did overtop the others significantly in its therapeutic effects.

Explorative tympanoscopy with sealing of the oval/round window is a very valuable method in treating sudden hearing loss especially if the hearing loss was severe, profound or patients even were completely deaf and if the operation was performed in second line mode. More studies with larger patient populations are needed to evaluate tympanoscopy in first line mode as treatment of ISSNHL.

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