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Re-evaluation of local anesthesia trans-tympanic electrical auditory brainstem response in cochlear implant candidacy

An objective promontory stimulation test using electrical auditory brainstem response to check patients' integrity of the auditory pathway preoperatively

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Abstract: Introduction: The trans-tympanic electrically evoked auditory brainstem response measurement in local anesthesia (= LA-TT-EABR) has been shown as a useful tool in doubtful CI candidacy to objectively evaluate the excitability of the auditory pathway up to the brainstem. Previous studies in this matter were of relatively low subjects number. To update the knowledge of the reliability of LA-TT-EABR, we re-evaluated the latest results from a bigger subjects dataset from our clinic and follow up regarding hearing sensation post-operatively. Methods: LA-TT-EABR was performed, as described in previous publications, with a trans-tympanic golf-club electrode in the round window niche for pre-operative stimulation in local anesthesia and with an evoked potential device for EABR recording. Hearing sensations were monitored in the implanted CI subjects. Results: 39 of 40 planned subjects were included in this study. In 22 subjects, a positive LA-TT-EABR was recorded. In 11 subjects, the response was insecure. In 6 subjects, no response was recorded. One subject was excluded because of pain during the paracentesis. Among them, 19 were implanted with a CI, and 18 had hearing sensations with a hearing prosthesis post-operative. The sensitivity and specificity of LA-TT-EABR in estimating the excitability of the auditory nerve pre-operatively are both 100%. Conclusion: LA-TT-EABR was shown as a reliable pre-operative test to objectively evaluate the auditory brainstem response. In addition to LA-TT-EABR, an analysis of the auditory cortex using LA-TT-EALR may provide correlation and confirmation of LA-TT-EABR results and additional information about cortical reorganization after long deafness.

Keywords: promontory stimulation, electrical stimulation, electrical auditory brainstem response, trans-tympanic, cochlear implant, auditory nerve.

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1 Introduction

The trans-tympanic (TT) electrically evoked auditory brainstem response (EABR) measurement in local anesthesia (= LA-TT-EABR) consists of a pre-operative electrical stimulation at the promontory/round window and short latency evoked potential recording. This procedure is applied to difficult cochlear implant (CI) candidates, who has a doubt presence and excitability of the auditory nerve, providing essential electrophysiological information for good hearing outcomes with CI.

A few years ago, the first results about LA-TT-EABR have been reported in an earlier publication [1]. In Germany, this testing is typically called PromBERA being a symbiosis of promontory testing and auditory brainstem response recording. In those days, we tested eleven subjects with PromBERA, and the first comparisons to intra-operative EABR using cochlear implant stimulation (= CI-EABR) had been shown [1].

Over the last few years, we were able to recruit nineteen patients and especially verify the results of the LA-TT-EABR via intra-operative CI-EABR and speech understanding with the CI [2]. This publication shows data about the waveform classifications, brainstem response latencies, stimulation impedance, and stimulation charge of the trans-tympanic electrode. Within a group of nineteen patients, a positive response by the PromBERA was confirmed in fourteen patients.

These two publications' results showed that LA-TT-EABR is a tool for objective testing of the auditory pathway in a clinical pre-operative scenario using local anesthesia in contrast to general anesthesia's so-called "pre-operative" EABR testing. In summary, they recommended the use of PromBERA in doubtful CI candidates.

In this work we investigate the predictive value of LA-TT-EABR in determine auditory nerve excitability and forecasting hearing sensation with CI, expanding the number of included subjects compare to previous works. This may be helpful for who is interested in using such test in clinical routine for difficult CI candidates.

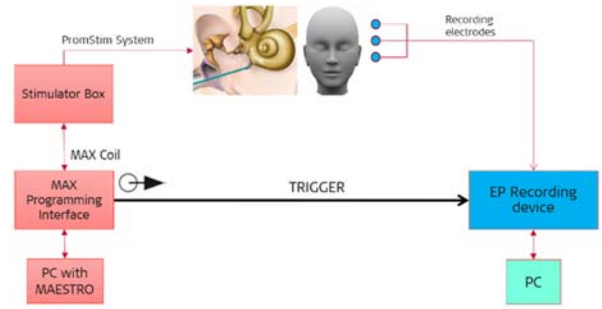

Figure 1: Setup for LA-TT-EABR. Stimulation is provided by the MED-EL clinical software MAESTRO, the MED-EL clinical programming interface MAX connected to the "golf-club" electrode via the MED-EL stimulator box. Recording is performed by an EP-System, surface electrodes on the subject's head and trigger signal sent by MAX.

Figure 2: Photo of the golf club PromStim electrode with round-bent tip.

2 Methods

Subjects were evaluated for potential LA-TT-EABR testing. Only those subjects were selected for the LA-TT-EABR where CI candidacy was uncertain due to the doubt presence or excitability of the auditory nerve.

CI candidates were evaluated using the standard audiological tests. Subjects with doubt presence or excitability of the auditory nerve were included for LA-TT-EABR test.

For method detail, see previous publications [1]. Briefly, under local anesthesia, myringotomy on the posterior-inferior quadrant was performed and a trans-tympanic rounded-bent tip electrode was placed temporarily on the round window niche (**Figure 1**) under the view of a microscope. The surface ground electrodes were placed on the zygomatic bone, and the angle of the mandible; electrical impedance was checked and electrical stimulation was provided with the MED-EL Stimulator Box and the MED-EL clinical Maestro v9.0 software (**Figure 2**).

Electrode placement was confirmed with MED-EL Impedance Field Telemetry (IFT) and MED-EL Expert Impedance Field Telemetry (eIFT). The IFT is the clinically used tool to test implant integrity and impedance values. For LA-TT-EABR, IFT was used to measure the electrode impedance value in kΩ. If the impedance was over 5 kΩ, the electrode position was optimized. The eIFT offers a continuous impedance measurement, useful to detect not stable electrode placement.

For LA-TT-EABR stimulation, we used an alternating biphasic pulse at a stimulation rate of 34 Hz. The stimulation amplitude started at an amplitude of 100 cu (≈ 100µA) and was increased in 100 cu steps till a possible response. Afterward, smaller steps between this step size were taken individualized. The pulse width was set to 100 µs as a standard setting. In case stimulation was too high, leading to activation of non-auditory structures, as facial nerve, pulse width was reduced to 60µs.

The recording of LA-TT-EABR was performed by a Nihon Kohden Neuropack S1 MEB9400 evoked potential system. The MED-EL MAXs' trigger output was connected to the trigger input of the EP system. Ambu® Neuroline 720 surface electrodes were applied on the contralateral mastoid (inverting), high forehead (non-inverting), and lower forehead (ground). We used a band-pass filter of 50 Hz to 3000 Hz. Per waveform, 1000 sweeps were collected and averaged. The rejection level was set to +/- 100 µV.

For a subgroup of subjects, CI implantation was performed and hearing sensation at the CI activation was established as clinical routine (pitch, loudness discrimination). Finally sensitivity and specificity of EABR in prediction hearing sensation was calculated, using Maximum Likelihood Chi-Square statistical test (STATISTICA, TIBCO Software Inc. (2020). Data Science Workbench, version 14) and results were defined statistical significant when $p\text{-val} < 0.05$.

3 Results

39 of 40 subjects were included in this study (**Table 1**). One subject (S33) had been excluded because myringotomy was not possible due to pain. In these 39 subjects, 22 left and 17 right ears were tested. The etiology of hearing loss was unknown in 17 cases and in thirteen cases a tumor or the removal of a tumor was associated with deafness. The included subjects were 48.31 ± 20.58 years old.

Table 1: Subject demographics. (S33 was excluded).

Subject	Side	Etiology	Age at test
S01	Left	Unknown	40
S02	Right	Unknown	83
S03	Right	Neuritis of CN VIII	79
S04	Left	Craniocerebral injury, tumor, and resection	53
S05	Left	Traumatic head injury	22
S06	Right	Siderosis	72
S07	Right	Tumour	74
S08	Left	Unknown	60
S09	Right	Unknown	77
S10	Left	Unknown	23
S11	Left	Head trauma	41
S12	Right	Head trauma	21
S13	Right	Unknown	19
S14	Left	Jannetta surgery	66
S15	Right	Unknown	23
S16	Right	Tumor removal	60
S17	Left	Existing tumor	77
S18	Left	Existing tumor	55
S19	Left	Tumor removal	48
S20	Left	Tumor removal	32
S21	Left	Unknown	68
S22	Left	Tumor removal	59
S23	Left	Syndrome	55
S24	Right	Unknown	62
S25	Right	Unknown	18
S26	Left	Unknown	22
S27	Right	Unknown	22
S28	Left	Unknown	42
S29	Right	Unknown	22
S30	Left	Unknown	27
S31	Right	Unknown	28
S32	Left	Herpes Zoster	78
S34	Left	Tumor removal	36
S35	Right	Tumor	52
S36	Left	Unknown	59
S37	Right	Existing tumor	61
S38	Left	Tumor removal	25
S39	Right	Tumor	57
S40	Left	Multiple strokes	66

In most subjects (56 %, n = 22) LA-TT-EABR could be recorded successfully which means that a response was secure and reproducible. In 11 subjects, an insecure response was recorded. In these cases, amplitude variation and or latency variation was too high between averaged waveforms. In 6 subjects, there was no response for LA-TT-EABR (**Figure 3**). In LA-TT-EABR, the response changes slightly compare to the CI-EABR, due to a broad cochlea stimulation from a temporary placed electrode and stimulation of multiple generators at the level of brainstem; this leads to waves II and III gathering into an eII/III complex and waves IV and V gathering into an eIV/V complex (**Figure 3**).

Among the 39 subjects, 19 of them were implanted with a CI. On 18 of them, intra-operative and/or post-operative EABR could be recorded and subjects had hearing sensations,

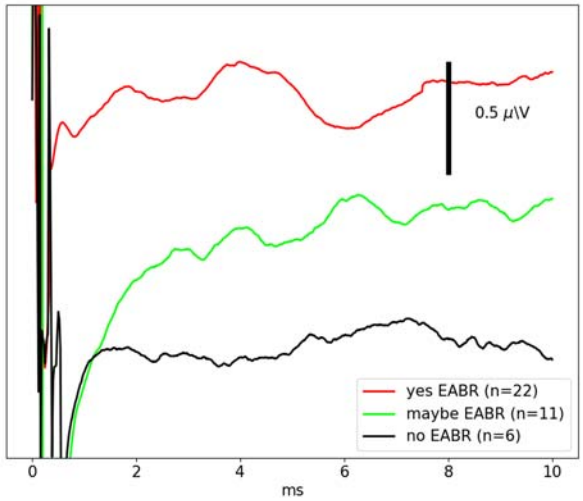

Figure 3: Grand average of response waveforms in LA-TT-EABR splitted in three sub-groups: a) secure response (red) b) insecure response (green) c) no response (black). Voltage scale on the top-left black bar. Clear and evident response are the peaks eII/eIII and eIV/eV on the red curve (present EABR), while these peaks are missing on the black line (missing EABR).

which were classified as true positive. Only one implanted subject had no hearing sensation, had a negative LA-TT-EABR and was classified as true negative.

Overall, the sensitivity and specificity of LA-TT-EABR on estimating the excitability of the auditory nerve pre-operatively on this subset of patients are both 100% (n = 19). Applying Maximum Likelihood Chi-Square test with 6 degrees of freedom (possible EABR response: yes/no/maybe/not-available and possible hearing sensation: yes/no/not-available) there was a significant relationship between pre-operative LA-TT-EABR and hearing sensation with the CI post-operatively, ML-X^2 (6, N = 19) = 12,85, p = 0.045.

4 Conclusion

Together with established clinical pre-operative tools like AEP by acoustical stimulation [4, 5], we have shown with these results that LA-TT-EABR, having high reliability in terms of sensitivity and specificity to forecast the auditory nerve excitability and hearing sensation. Finally it can support clinical centers in cochlear implantation candidacy. To our knowledge this is the largest database of LA-TT-EABR from one unique center at the time of the writing.

Although pre-operative assessment is a strongly suggested tool from the ADANO group in Germany [5], LA-TT-EABR is not yet established in clinical practice, therefore this measurement database may give a baseline reference to other centers interested in such procedure. A detailed analysis regarding response amplitudes and latencies is not yet possible as given in measurements in general anesthesia [7, 8] or post-operative cochlear implant EABR testing [9]. Despite that, it was possible to see on TT-EABR morphology similar peaks seen in CI-EABR. One advantage of LA-TT-EABR is the possibility to test the patient in local anesthesia, therefore avoid risk and cost of anesthesia equipment and facility in subjects with unknown or difficult etiology.

In case of insecure or no response in LA-TT-EABR, decision to proceed with CI implantation has to be discussed with the clinical team and patient, taking in consideration all the pre-opeartive assessment. In alternative, intra-opeartive tools may be used in addition, such as intra-opeartive test electrode [10].

Author Statement

Research funding: The authors state that there was no funding involved. Conflict of interest: G. Mandruzzato and M. Polak are employed by MED-EL. Informed consent: Informed consent was obtained from all individuals included in this study. Ethics approval: The research related to human subjects complies with all relevant national regulations, institutional policies, and was performed following the Declaration of Helsinki, and has been approved by the Ethic Commission of the faculty of Medicine, LMU Munich, Germany Project n. 412-13.

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