Tone-pip frequency-specific auditory brainstem response via loudspeakers in ossiculoplasty: a tool in predicting long-term hearing improvement intra-operatively

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Abstract

Objective: In this study, we aimed to establish a frequency-specific ABR (fs-ABR) system via loudspeakers to assess the hearing improvement in ossiculoplasty intra-operatively and observe its efficiency and accuracy in predicting the long-term outcome. Setting Blackman-gated 1kHz tone-pips with 1ms, 2ms and 3ms duration were used in normal hearing (NH) subjects to calibrate the system and the standard ABR threshold and wave V latency for this system were established. All subjects would take four hearing tests: Pure tone audiometry (PTA) before and six-month after the surgery, fs-ABR under anesthesia before surgery and right after the ossicular chain reconstruction intra-operatively. PTA was used as the standard test to measure hearing. Bland-Altman analysis and linear correlation analysis were used to compare the agreement between PTA and fs-ABR results. Participants Forty-two conductive hearing loss (CHL) subjects. Results: For NH and CHL subjects in operating room before surgery, the fs-ABR threshold showed a high linear relation with the PTA results ($r=0.88$, $P<.0001$). For CHL follow up results: for 1ms group, PTAI showed a better correlation with fs-ABRI ($r=0.67$, $P<.01$) with the equation: PTAI=2.15*fs-ABRI-3.49; for 3ms group, PTA showed a better correlation with fs-ABR ($r=0.76$, $P<.01$) with the equation PTA=0.93*fs-ABR+3.48. Bland-Altman analysis showed no difference between PTA and fs-ABR in all above analysis. Eustachian tube malfunction would negatively affect the prediction efficacy, for subjects with normal ETF, the correlation between fs-ABRI and PTAI was even higher: PTAI=1.6*fs-ABRI+12.48 with $r=0.77$ ($P=.0407<0.05$). Conclusions This system could monitor the function of the reconstructed ossicular chain intra-operatively and predict the post-surgical 6-month hearing improvement efficiently and accurately. The average testing time for the fs-ABR was short, about 10 to 15 minutes. This system would serve as a promising tool clinically to help surgeons optimize the efficacy of ossiculoplasty. Besides, ETF should be taken into consideration as a risk factor that would negatively influence the hearing impairment.

Abstract

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Methods

Observational studies

Setting

Blackman-gated 1kHz tone-pips with 1ms, 2ms and 3ms duration were used in normal hearing (NH) subjects to calibrate the system and the standard ABR threshold and wave V latency for this system were established. All subjects would take four hearing tests: Pure tone audiometry (PTA) before and six-month after the surgery, fs-ABR under anesthesia before surgery and right after the ossicular chain reconstruction intra-operatively. Bland-Altman and linear correlation analysis were used to compare the agreement between PTA and fs-ABR results.

Participants

Forty-two conductive hearing loss (CHL) subjects.

Results: For CHL follow up results: for 1ms group, PTAI showed a better correlation with fs-ABRI (r=0.67, P<.01) with the equation: PTAI=2.15*fs-ABRI-3.49; for 3ms group, PTA showed a better correlation with fs-ABR (r=0.76, P<.01) with the equation PTA=0.93*fs-ABR+3.48. Bland-Altman analysis showed no difference between PTA and fs-ABR in all above analysis. Eustachian tube malfunction would negatively affect the prediction efficacy, for subjects with normal ETF, the correlation between fs-ABRI and PTAI was even higher: PTAI=1.6*fs-ABRI+12.48 with r=0.77 (P=.0407<0.05).

Conclusions

This system could monitor the function of the reconstructed ossicular chain intra-operatively and predict the post-surgical 6-month hearing improvement and would be a promising tool clinically to help surgeons optimize the efficacy of ossiculoplasty.

Keywords: ossiculoplasty, frequency-specific-ABR system, intra-operative monitoring, hearing improvement

Key points

- Objective monitoring of reconstructed ossicular chain during ossiculoplasty remains challenging.
- Intra-operative 1kHz tone-pip fs-ABR threshold after the ossicular reconstruction showed high correlation with post-surgery PTA result.
- This fs-ABR system was suggested to be an efficient tool to monitor and predict the hearing outcome of ossiculoplasty intra-operatively.

Introduction

Patients with conductive hearing loss(CHL) present hearing and communication hardship which greatly lower their life quality. Ossiculoplasty has been proved to be the most effective way to improve hearing and minimize the air-bone gap(ABG). However, post-surgery hearing improvement(HI) are influenced by several factors, among which positioning and coupling of ossicular prosthesis are prerequisites of long-term HI. However, the revision surgery rate remains a risk both for patients and surgeons ranging from 8%(1) to 13.2%(2). The reason that long-term HI presents great variety is that it mainly depends on the surgeon's subjective judgments.

Various mechanical and acoustical intra-operative measurements of ossiculoplasty efficiency had been tried: Laser-Doppler Vibrometry(LDV) (3), electromagnetic field stimulation(4), electrocochleography(ECochG)(5), auditory brainstem response(ABR)(6), auditory steady-state responses(ASSR) and Chirp-ASSR(7). Instead of stimulating the tympanic membrane (TM), mechanical methods directly tested the ossicular chain(OC) movement which ignored the TM changes which could lead to the overestimation of the hearing ability(4). Additionally, nearly all experiments were carried out in cadaver temporal bones, few of them confirming the usage of these methods in patients.

ABR is an objective and noninvasive hearing measurement widely used clinically and is rarely being affected by sleep, anesthesia and environmental noise. Tone-burst ABR was reported to have a high linear correlation with PTA threshold and hearing threshold at 1kHz could estimate low-frequency PTA thresholds accurately(8). Griffith S. Hsu firstly applied intra-operative ABR in stapedectomy and demonstrated that ABR monitoring could reduce the revision surgery rate(6). However, those studies mainly focused on stapes surgery with intact and uninjured tympanic membrane, few reported eligible follow-up results, and enrolled limited subjects. Another obstacle is that insert sponge earphones are not suitable for middle-ear surgeries.

On one hand, the sponge will absorb blood and effusion during surgery, causing the change of stimulus sound intensity and threshold shift. On the other, CHL often involves leisured mastoid and TM needed to be repaired, which leaves changed middle-ear cavity and reconstructed TM after the surgery. The sponge insert earplug fail to seal the external canal after the reconstruction, leading to the leakage of the sound intensity and artificial unknown threshold shift.

In response to these obstacles, we firstly used the loudspeaker to replace the insert earplug. The Blackman-gated 1kHz tone-pip was demonstrated efficient and accurate in measuring hearing threshold in both normal hearing(NH) and CHL patients both in OR and standard sound-proof chamber(SPC) in our previous work(9). In this paper, we modified previous fs-ABR system, test its efficiency in predicting the long-term post-surgery HI intra-operatively and explore the effect of ETD on post-surgery HI and fs-ABR system monitoring efficiency.

Material and Methods

Ethical considerations

This study was approved by the Ethics Committee of [blinded for review] before the commence of the experiment. A written consent was signed by all the participants before enrollment.

Participants

Eight subjects (16 ears, 4F4M, average age 21.88 years old) whose pure tone audiometry (PTA) thresholds were less than 25 dB HL at each frequency from 250 Hz to 8 kHz (average PTA of 0.5/1/2/4kHz was 4.38 ± 4.96) were enrolled to undergo fs-ABR in SPC and OR to standardize the system. Forty-two CHL subjects who were determined to take ossiculoplasty in our hospital were enrolled from 2016 to 2019 whose etiologies were listed in the Supplemental table1. Four hearing tests were required: the pre-operative and 3 to 6-month post-surgery PTA tests in SPC; pre-operative fs-ABR test under general anesthesia before the surgery in OR; intra-operative fs-ABR test right after the reconstruction with recovered external canal skin flap.

Signal Presentation System and ABR Testing

International Acoustic Eclipse 25 (Denmark) were used as the recording system. Blackman gated 1kHz tone-pips with three different durations of 1ms (S1), 2ms (S2) and 3ms (S3) were used with stimulus repetition rate of 27.1/second, sweep number of 1024, amplifier gain of 100k and band pass filter from 300 to1500Hz. Non-invasive button electrodes were used: recording electrode was at the forehead hair line, the reference electrode on ipsilateral cheek of the tested ear and ground electrode on the nasion. Skin was wiped with 95% alcohol to ensure the inter-electrodes impedance was lower than 3kΩ. The sound source was put 30cm away from the external ear canal whose central axis was in line with that of the loudspeaker.

Signal Calibration

Output levels of the signals were calibrated at the reference point which was 30 cm away from the loudspeaker using a sound level meter (Norsonic, Lierskogen, Norway) both in SPC and OR by a step of 10dB. Procedure of calibration was illustrated in our previous paper, and the averaged background noise level was 20.59 A-weighted dB in SPC and 48.46 A-weighted dB in OR(9).

ABR Threshold Determination

ABR threshold was determined in accordance with ABR Guidance (version 2.1) issued by British Newborn Hearing Screening Program (NHSP) in 2013(15). For NH subjects, 70 dB SPL was used to elicit a clear response (CR). A CR was defined as the amplitude of the response exceeded 40nV and at least 3 times of background noise level(15). For CHL subjects, a higher start stimulation level of 80 to 90 dB SPL was used according to their PTA results to gain a CR. The intensity level was then decreased by10 dB until there was no repeatable response, then smaller increment and decrement were implemented to determine the real threshold in a precise step of 5dB. Two experienced audiologists analyzed the results independently to ensure exact recognition of the threshold.

Eustachian tube function testing

Eustachian tube function (ETF) was measured by Tubomanometer (Spiggle&Theis, Medizintechnik). An extended test of Eustachian Tube Score (ETS-7) was used which combines subjective (clicking sound when swallowing, Valsalva) and objective (tubomanometry, tympanometry) measures of ETF (Supplemental table2). The total score of ETS-7 is 10 points and ETS-7[?]7 would be diagnosed as ETD.

Statistics analysis

Prism version 8 was used. Statistical methods: 1) Bland-Altman analysis was used to measure the agreement between fs-ABR and PTA results. This method is more accurate in comparing the agreement between clinical measurements(11). 2) Linear regression analysis was used to find out the correlation between post-surgery PTA and intra-fs-ABR, PTAI and fs-ABRI results. 3) Paired and unpaired Student's t-tests were used and values of p less than 0.05 was considered as statistically different.

Results

Signal Calibration

All facilities were integrated into a custom-made test cart with a flexible arm holding the loudspeaker (Figure1). All stimuli showed linear correlation between the dial value and measured sound pressure level at the reference point, the difference between those two points was significantly (P<0.001). The average dial to reference point difference (DRD) of sound pressure level is near 0 dB (Table 1). Dynamic range of the loudspeaker output was 20-100 dB SPL in SPC and 40-100 dB SPL in OR.

System standardization: Results of NH Subjects in SPC and OR

For NH subjects in SPC, the wave V latency at 70dB SPL was 7.305ms, 7.54ms and 8.79ms for S1, S2 and S3 respectively. One-way ANOVA showed statistical difference (p <0.0001). Further multiple comparisons showed no statistical difference between S1 and S2 (p_{latency}=0.77) while both S1 (p <0.0001) and S2 (p= 0.0008) were statistically different from S3 (Figure2A). The fs-ABR thresholds were 31.25, 31.25 and 37.36 dB for group S1, S2 and S3 respectively. One-way ANOVA showed statistical difference (p =0.0033<0.05). Further multiple comparisons revealed that S1 and S2 had no statistical difference ($p_{threshold}$ >0.99) while the S3 was statistically different from S1 and S2 (Figure2B).

Bland-Altman analysis showed no statistical difference between PTA and fs-ABR threshold for S1 and S2 in SPC (Figure2 C and D). Since the mean bias of S1 group was smaller than that of S2 group, S1 and S3 were chosen for further study in the OR.

For NH subjects in OR, the wave V latencies for group S1 was 7.33±0.39ms, and no statistical difference between wave V latency in SPC and OR was found by two-sided paired t-test (p =0.63>0.01) (Figure2E). Bland-Altman analysis showed no statistical difference between PTA and fs-ABR in OR. The fs-ABR threshold in OR was 37.33dB SPL, 6.08 dB higher than in SPC (p =0.0039<0.01) (Figure2F).

Results of all enrolled subjects in OR

The fs-ABR data of all subjects (16 NH and 42 CHL ears) were analyzed, Bland-Altman analysis showed that all dots except one were within the 95% confidence interval (CI). This dissociative dot might be caused by the poor corporation of the patient in PTA test. The correlation between $\text{PTA}_{(1\text{kHz})}$ (X) and fs-ABR (Y) thresholds was high (r =0.88, p <0.0001) with Y=0.46*X+34.25(Figure3B). We also analyzed the correlation between the PTA average threshold of 0.5/1/2kHz ($\text{PTA}_{(0.5/1/2\text{kHz})}$)(X) and the fs-ABR threshold (Y): Y=0.41*X+35.38 (r =0.84,p <0.0001) (FigureS1). Accordingly, when fs-ABR threshold was lower than 45.58 dB SPL, $\text{PTA}_{(0.5/1/2\text{kHz})}$should be within normal hearing range.

For the CHL group in OR before surgery, Bland-Altman analysis did not show difference between two methods (Figure3C). Linear regression analysis also showed high correlation: fs-ABR =0.50* $PTA_{(1kHz)}$+32.17 (r= 0.66,p <0.0001) (Figure3D), and fs-ABR = 0.40*$PTA_{(0.5/1/2kHz)}$+35.66 (r =0.80,p <0.0001)(FigureS1).

Correlation between Intra-operative fs-ABR and Follow-up PTA Result

Among the forty-two CHL patients (16 males and 26 females), 15 subjects were tested by S3 and 27 by S1. Thirty-seven patients (88.10%) completed the 6-month follow-up. Two subjects of S3 group and 3 subjects of the S1 group were excluded from the analysis because of living remote from the hospital (Supplemental Table3). The ABG improvement (ABGI), fs-ABRI and PTAI were was the difference of pre- and post-surgery ABG, fs-ABR and PTA.

For all 42 CHL subjects, the post-surgery $PTA_{(1kHz)}$ and $PTA_{(0.5/1/2kHz)}$ was 37.65±18.06 dB HL and 38.52±16.67 dB HL with the average HI of 19.41±21.2 dB and 13.37±21.74 dB, respectively. The post-surgery ABG at 1kHz ($ABG_{(1kHz)}$) and 0.5/1/2kHz ($ABG_{(0.5/1/2kHz)}$) was 25.15±14.93 dB and 19.15±15.39dB with an average ABGI of 18.97±18.66 dB and 22.79±18.21dB respectively. Bland Altman analysis showed no difference between the two methods for $PTA_{(1kHz)}$(Figure4B) and $PTA_{(0.5/1/2kHz)}$(FigureS2A). The linear relation was $PTA_{(1kHz)}$ (Y) =0.58* intra-fs-ABR +9.56 (r =0.42,p =0.014<0.05) and $PTA_{(0.5/1/2kHz)}$=0.44* intra-fs-ABR +17.44 (r =0.34,p =0.04<0.05). $PTAI_{(1kHz)}$=1.31*fs-ABRI+1.74 (r =0.48,p <0.01) and $PTAI_{(0.5/1/2kHz)}$=1.44*fs-ABRI-2.956 (r =0.52,p <0.01) (FigureS2).

For S1, post-surgery $PTA_{(1kHz)}$, $PTA_{(0.5/1/2kHz)}$, $ABG_{(1kHz)}$ and $ABG_{(0.5/1/2kHz)}$ were 36.67+-19.13dB HL, 37.22+-17.53dB HL, 24.5+-15.3dB and 19.11+-14.67dB respectively; for S3, 37.92+-16.85dB HL, 41.92+-16.17dB HL, 26.15+-14.88dB and 21.54+-11.42dB respectively. Two-sided unpaired T test showed no statistical difference between group S1 and S3 post-surgery PTA follow-up results for each above parameter (p =0.68, p =0.95, p =0.38, p =0.95 respectively) (Figure4A).

For S1 and S3, Bland-Altman analysis showed no difference between two methods for both $PTA_{(1kHz)}$ and $PTA_{(0.5/1/2kHz)}$. In S1, $PTA_{(1kHz)}$=1.22*intra-fs-ABR-30.35 with r =0.5 (p =0.02<0.05) and $PTA_{(0.5/1/2kHz)}$=1.01*intra-fs-ABR-18.37 with$r$ =0.46 (p =0.03<0.05). $PTAI_{(1kHz)}$=2.15* fs-ABRI-3.49 with r =0.67 (p =0.0063<0.01) for and $PTAI_{(0.5.1.2kHz)}$=2.43*fs-ABRI-8.76 with r =0.69 (p =0.0042<0.01) (Figure4 and FigureS2). In S3, $PTA_{(1kHz)}$ =0.93*intra-fs-ABR+3.48 with r =0.76 (p =0.0026<0.05) and $PTA_{(0.5/1/2kHz)}$=0.83*intra-fs-ABR+9.92 with$r$ =0.71 (p =0.0068<0.01). For PTAI and fs-ABRI, p value was 0.22 and 0.1 for $PTA_{(1kHz)}$ and $PTA_{(0.5/1/2kHz)}$ respectively (Figure4E and FigureS2D).

Impact of Eustachian tube function on long-term recovery

Patients in S1 was divided into two subgroups according to the ETF score (ETS) with the cutoff point of 7. Eleven subjects with ETS[?]7 were in Subgroup1(Sub1) and the rest with ETS>7 were in Subgroup2(Sub2). Sub1 and Sub2 were statistically different in post-surgery PTA (p =0.036<0.05), PTAI(p =0.0012<0.05) and ABGI(p =0.037<0.05) by t-test (Figure5 and S3). For Sub2, the mean post-surgery PTA, ABG, ABI and PTAI were 28.5dB HL, 19dB, 31.50dB and 36dB and for Sub1, 46.5dB HL, 30.56dB, 17.22dB and 10dB respectively. The PTAI in Sub1 was 26dB smaller than that of Sub2, and the ABG in Sub1 was 27.5dB higher than that of Sub2 (Figure6A).

For Sub1, there was no clear linear relation between post-surgery PTA and intra-fs-ABR (p =0.47>0.05), the PTAI and fs-ABRI (p >0.99). For Sub2, PTA=3.22*intra-fs-ABR-162.7 with$r$ =0.65 (p =0.042<0.05) (Figure5B); PTAI=1.6*fs-ABRI+12.48 with r =0.77 (p =.0407<0.05) (Figure5C).

Discussion

ABR is an objective hearing measurement rarely affected by anesthesia, sleep and environmental noises. Blackman-gated tone-burst ABR had been reported to predict the PTA thresholds for a wide range of frequencies while click evoked ABR only focused on 2kHz to 4kHz PTA thresholds. Compared to click-ABR, Blackman-gated 1kHz tone-pip ABR worked better in assessing low-to-mid hearing frequencies which are mainly impaired in CHL patients. The pre- and intra-fs-ABR only prolonged the surgery for 10 to 15 minutes. Instead of insert earplug, loudspeaker was better in maintaining sound intensity and aseptic principle.

In terms of different stimuli, both S1 and S3 worked well in OR. The wave V latency of S3 was longer than that of S1 because longer rise phase activates less nerve fiber compared to shorter rise phase. In S1, fs-ABRI and PTAI showed better correlation and in S3, the absolute intra-fs-ABR value was better in predicting the long-term HI.

Background noise of the air conditioner and anesthesia machine, magnetic and electronic influence of various machines might affect the monitoring. Therefore, only the anesthesia machine was left open while testing. We noticed that the mean hearing threshold of fs-ABR of NH in OR was 6.08dB higher than that in SPC, but it was not clinically significant, and would pose little impact on the efficiency of prediction.

Additionally, the mean bias between post-surgery PTA and intra-fs-ABR was smaller than that of the pre-PTA and pre-fs-ABR, and the difference between the two biases were 6.024dB and 14.09dB for S1 and S3 respectively. That meant intra-fs-ABR underestimated the post-PTA for 6.024 and 14.09 in average for S1 and S3 respectively which might be caused by the following factors: firstly, the revised tympanic membrane and the underneath cartilage would increase the mass of acoustic transducer system. It usually took 3-6 months for the cartilage to be absorbed which was unavoidable. Secondly, blood and serum would pile up in the external canal during monitoring, which would cause artificial conductive hearing loss. Necessary steps had been taken to minimize the impact of local errhysis, like using gelatin sponge with hemostatic at the external ear canal before testing.

ETD was a known etiology for CHL with a prevalence of 1% in adult and presented in 70% of patients undergoing tympanoplasty caused by chronic otitis media or cholesteatoma(10). Most otologists agree that better ETF is critical for the better long-term HI of middle ear surgery(11). We also observed that ETD affected the HI in a negative way. ETS-7 had been demonstrated to be valuable as a diagnostic follow-up method(12). Subjects with ETS[?]7 showed better HI outcome and the coefficient factor between post-surgery PTA and intra-fs-ABR rose to 0.8, higher than that of whole S1 (r=0.5). We didn't find any statistically significant correlation among parameters in Sub1(ETS<7). Therefore, it is recommended to pay attention to ETF to optimize the HI.

However, there are several conditions should be taken into consideration in future work. Firstly, more subjects should be enrolled to test the feasibility of this method among different kinds of ossiculoplasty. Secondly, the impact of errhysis on the threshold shift should also be studied in animal models. Thirdly, an automatic threshold determination method is now under study and we are trying to further minimize the testing time to optimize patients' benefit.

Conclusion

The Blackman-gated 1kHz tone-pip ABR intra-operative monitoring system via loudspeakers showed high efficiency and accuracy in optimizing the position of prosthesis and predicting the post-surgery long-term HI both for PTA at 1kHz and average of 0.5/1/2kHz intra-operatively. This system may help otologists improve HI and reduce revision surgery rate which is clinically to the patients' interest.

6. Data availability statement

Parts of the data are available at [blinded for review].

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