Journal of Neuroradiology 46 (2019) 307–311

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Original Article

Quantitative analysis of cochlear signal intensity on three-dimensional and contrast-enhanced fluid-attenuated inversion recovery images in patients with Meniere's disease: Correlation with the pure tone audiometry test

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ARTICLE INFO

Article history:
Available online 3 April 2019

ABSTRACTS

Purpose. – The purpose of this study was to correlate the quantitative analysis of cochlear signal intensity (SI) on 3-dimensional fluid-attenuated inversion recovery (3D-FLAIR) and contrast-enhanced (CE) 3D-FLAIR images with results of the pure tone audiometry (PTA) test in patients with Meniere's disease (MD).

Materials and methods. – Over a 3-year period, 123 patients with MD underwent 3-Tesla (3 T) temporal magnetic resonance imaging (MRI), including 3D-FLAIR and CE-FLAIR sequences. The SI of membranous labyrinth of the cochlea in both ears of each patient was measured by drawing a region of interest (ROI) with a seed growing technique. The correlation between measured cochlear SIs on 3D-FLAIR and CE-FLAIR images, contrast enhancement index (CEI), and contrast enhancement ratio (CER) and clinical findings and pre- and post-treatment PTA results were assessed.

Results. – Cochlear signal ratios of symptomatic ears on 3D-FLAIR and CE-FLAIR images were significantly higher than those of asymptomatic ears ($P < 0.001$). The area under the curve, from the receiver operating characteristic curve of cochlear SIs on 3D-FLAIR and CE-FLAIR images for discrimination between symptomatic and asymptomatic ears, was 0.729 and 0.728, respectively. Cochlear SIs on 3D-FLAIR and CE-FLAIR images were significantly correlated with patients' sex ($P < 0.05$ and $P < 0.01$, respectively), symptomatic ear (both $P < 0.0001$), and pre-treatment PTA ($P < 0.0001$ and $P < 0.005$, respectively), but were not significantly correlated with patients' age, post-treatment PTA or hearing threshold level at 0.5, 1.0, 2.0, or 4.0 kHz.

Conclusion. – Quantitative analysis of cochlear SI on 3D-FLAIR and CE-FLAIR images may be a helpful diagnostic adjunct for MD, but may be of little value in predicting the prognosis of MD.

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Introduction

Meniere's disease (MD) is defined as a chronic inner ear disorder, which is characterized by recurrent episodes of spontaneous vertigo, fluctuating sensorineural hearing loss, tinnitus, and aural fullness [1,2]. Diagnosis of MD is done mainly based on the patient's symptoms and audiometry results.

Recently, endolymphatic hydrops in MD have been identified by magnetic resonance imaging (MRI) fluid-attenuated inversion

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https://doi.org/10.1016/j.neurad.2019.03.010
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recovery(FLAIR) sequence, based on increased signal intensity (SI) of the cochlea and vestibule [3,4] It is also known that contrast enhancement of the perilymphatic compartment can be observed on FLAIR images in patients with various inner ear diseases owing to disruption of the blood-labyrinthine barrier and faster transfer of high molecular weight substances from blood into perilymph [4–8]. Although the causes of MD are very diverse, such as labyrinthitis, cholesteatoma, cochlear otosclerosis, and vestibular schwannoma [5]. Many previous studies have demonstrated that MRI sequences are useful in diagnosing MD. However, they have reported conflicting results in predicting the prognosis of MD after treatment.

The purpose of this study was to correlate the quantitative analysis of cochlear SIs on 3-dimensional FLAIR(3D-FLAIR) and contrast-enhanced(CE) 3D-FLAIR with results of pre- and post-treatment pure tone audiometry (PTA) testing in patients with MD.

Materials and methods

Patients

The study protocol was approved by the Institutional Review Board, and informed consent was waived because of the retrospective study design.

Between May 2013 and December 2015, 123 patients with MD who underwent temporal MRI including 3D-FLAIR and CE-FLAIR were included in the study. The demographic characteristics and PTA results of patients are summarized in Table 1. The population consisted of 69 male and 54 female patients, with a mean ± standard deviation (SD) age of 45.9 ± 16.1 years (age range, 11–78 years).

We evaluated MRI findings of 246 inner ears (right and left) of the 123 patients. Of these patients, 95 and 28 suffered from unilateral and bilateral MD, respectively. Unilateral MD was defined as an increase in the pure tone thresholds for bone-conducted sound that are higher (i.e., worse) in the symptomatic ear by at least 30 dB hearing loss, at each of two contiguous frequencies below 2.0 kHz [9]. In cases of bilateral MD, the absolute thresholds for bone-conducted sound must be 35 dB hearing loss or higher, at each of two contiguous frequencies below 2.0 kHz, in both ears [9]. The mean ± SD time interval between the first visit and MRI was 2.8 ± 2.8 days. The mean ± SD hearing level in pre-treatment PTA and post-treatment PTA in the symptomatic ear was 65.3 ± 30.5 dB and 53.2 ± 33.9 dB, respectively.

Audiometric evaluation

Pre-treatment PTA results were obtained at the time of MD diagnosis. Hearing loss was defined by the PTA test, calculated by using thresholds of 0.5, 1.0, 2.0, and 4.0 kHz, following the standards of the National Institute on Deafness and Other Communication Disorders [10]. The severity of the initial hearing loss was classified as mild (26–40 dB), moderate (41–55 dB), moderately severe (56–70 dB), severe (71–90 dB), or profound (> 90 dB). If the patient did not respond to the maximum sound level, hearing loss was classified as profound plus 5 dB. All patients were treated with oral methylprednisolone at a dosage of 48 mg/day for 7 days, and then tapered off over 4 subsequent days. After 3 months of steroid therapy, post-treatment PTA was performed to evaluate the therapeutic effects. The degree of recovery was evaluated according to the Siegel criteria [11] as follows:

- complete recovery: final hearing better than 25 dB;
- partial recovery: more than 15 dB gain and final hearing in the range of 25–45 dB;
- slight improvement: more than 15 dB gain and final hearing poorer than 45 dB, and;
- no improvement: less than 15 dB gain and final hearing poorer than 75 dB.

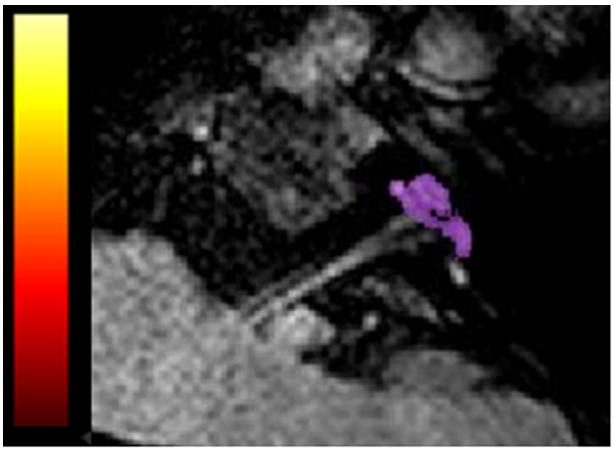

Fig. 1. Measurement of cochlear SI on 3D-FLAIR MRI. The 3D-FLAIR image demonstrates the measurement of cochlear SI by drawing a region of interest with a seed growing method at the cochlea. The cochlea is indicated in purple.

Imaging protocols

MRI was performed using a 3 T MRI system (Achieva; Philips Healthcare, Best, the Netherlands) with a 32-channel head coil. The protocols included axial and coronal view of 3D T1-weighted image, 3D T2-weighted image, 3D-FLAIR images, CE-FLAIR images and CE T1-weighted images. A volume isotropic TSE acquisition (VISTA) technique, comprising a 3D TSE sequence by using a non-selective refocusing pulse and refocusing control, was used for 3D FLAIR imaging. CE-FLAIR images were acquired 5 minutes after injection of gadobutrol (Gadovist; Bayer Healthcare, Berlin, Germany) at a dose of 0.1 mmol/kg of body weight. Axial 3D-FLAIR imaging was performed with the following parameters; TR/TE_{eff}/TI: 4800/272/1650 ms, flip angle: 90°, number of averages: 2, fat saturation: spectral presaturation with inversion recovery, echo-train length: 140, number of encoding steps: 256, FOV: 180 × 180 mm, matrix: 256 × 256 (reconstruction matrix: 512 × 512), voxel size: 0.7 × 0.7 × 0.8 mm, section thickness: 1.6 mm, spacing between sections: 0.8 mm, acquisition time: 8 minutes 25 seconds and sensitivity encoding factor: 2. Axial CE T1-weighted imaging was performed with the following parameters; TR/TE_{eff}: 25/2.3 ms, flip angle: 30°, number of averages: 2, number of encoding steps: 257, FOV: 180 × 180 mm, matrix: 256 × 256 (reconstruction matrix: 512 × 512), voxel size: 0.7 × 0.7 × 0.8 mm, slab number: 1, slab thickness: 60 mm, section thickness: 1.6 mm, spacing between sections: 0.8 mm, acquisition time: 4 minutes and sensitivity encoding factor: 2.

Image analyses

Two neuroradiologists (J.H.L and E.S.K) reviewed the 3D-FLAIR and CE-FLAIR images to determine the presence of labyrinthine abnormality in both ears of each patient. They were blinded to the clinical findings and PTA results. The 3D-FLAIR and CE-FLAIR MRI were processed by using pixel analysis methods with manual and seed growing segmentation for quantitative analysis (Fig. 1), using a commercial software (Nordic ICE; NordicNeuroLab, Bergen, Norway).

The cochlear SI on 3D-FLAIR and CE-FLAIR images were measured by placing a large region of interest (ROI) within basal, mid, and apical turns of the cochlea. The final cochlear SI was set as the mean value of measurements by two neuroradiologists. Circu-

lar 15-mm^2 ROI was placed within cisternal space of the temporal convexity where CSF flow is less common and less intense than ventricular system to diminish CSF flow artifact. And the cochlear SNR was calculated. The cochlear SIs of ears on CE-FLAIR images were compared with those on 3D-FLAIR images by using the two following indices [12]:

Contrast Enhancement Index (CEI): $\hat{I} = I\text{-}I_0$ and

Contrast Enhancement Ratio (CER): $I' = [100\times(I\text{-}I_0)]/I_0$,

Where $\hat{I}$ is CEI, I' is CER, I is the cochlear SI on CE-FLAIR after contrast agent administration and I_0 is the cochlear SI on 3D-FLAIR before contrast agent administration.

Statistical analysis

We evaluated inter-observer agreement between the 2 readers using Pearson's Correlation Coefficient (r). The cochlear signal ratios of symptomatic ear group and asymptomatic ear group on both 3D-FLAIR and CE-FLAIR were compared by using Mann-Whitney test. Receiver operating characteristic (ROC) analysis was used to determine the performance of cochlear SIs on 3D-FLAIR and CE-FLAIR images for identifying MD and determining the optimal cut-off values for predicting MD. The correlation between cochlear SIs on 3D-FLAIR and CE-FLAIR images and age, sex, symptomatic ear, pre-treatment PTA, post-treatment PTA, and hearing threshold level at each kHz were assessed using the mixed model analysis. We assessed correlation of CEI and CER with age, sex, symptomatic ear, pre-treatment PTA, difference between pre- and post-treatment PTAs, and hearing threshold level at each kHz using the mixed model analysis. Relationship between cochlear SIs on 3D-FLAIR and CE-FLAIR images, CEI, and CER was analyzed using Pearson's Correlation Coefficient (r). All statistical analyses were performed using the statistical software package SPSS version 21.0. (SPSS Inc., IBM Company, Chicago, IL, USA). A P-value of < 0.05 was considered statistically significant.

Results

Inter-observer agreements were excellent for both 3D-FLAIR and CE-FLAIR (r value, 0.849 vs. 0.903). The cochlear signal ratios of symptomatic ear were significantly higher than those of asymptomatic ear on both 3D-FLAIR (mean ± SD, 6.4 ± 1.3 vs 7.6 ± 1.4, $P < .001$) and CE-FLAIR images (mean ± SD, 4.7 ± 1.1 vs 5.9 ± 1.3, $P < .001$) (Fig. 2). The ROC curve of the cochlear SIs on 3D-FLAIR (area under the curve (AUC) = 0.729) and CE-FLAIR (AUC = 0.728) images demonstrated moderate discriminatory power for the diagnosis of MD (Fig. 3). The sensitivity and specificity in the diagnosis of MD was 64% and 66%, respectively, at the cut-off value of cochlear SI (= 20.8) on 3D-FLAIR images. The sensitivity and specificity was 66% and 68%, respectively, at the cut-off value of cochlear SI (= 30.4) on CE-FLAIR images.

Cochlear SIs on 3D-FLAIR and CE-FLAIR images were significantly correlated with patients' sex ($P < 0.05$ and $P < 0.01$, respectively), symptomatic ear ($P < 0.0001$ for both), and pre-treatment PTA results ($P < 0.0001$ and $P < 0.005$, respectively), but were not significantly correlated with patients' age, post-treatment PTA results, and hearing threshold level at 0.5, 1.0, 2.0, and 4.0 kHz (Table 2, Fig. 4). CEI and CER were significantly correlated with patients' sex ($P < 0.05$ and $P < 0.01$, respectively), symptomatic ear ($P < 0.0001$ for both), and pre-treatment PTA results ($P < 0.0001$ and $P < 0.005$, respectively), but were not significantly correlated with patients' age, difference in hearing loss between pre- and post-treatment PTAs, and hearing threshold level at 0.5, 1.0, 2.0, and 4.0 kHz. In addition, CER was significantly correlated with pre-treatment PTA results ($P < 0.05$; Table 3).

The cochlear SI on 3D-FLAIR images showed a statically significant relationship with cochlear SI on CE-FLAIR and CEI images

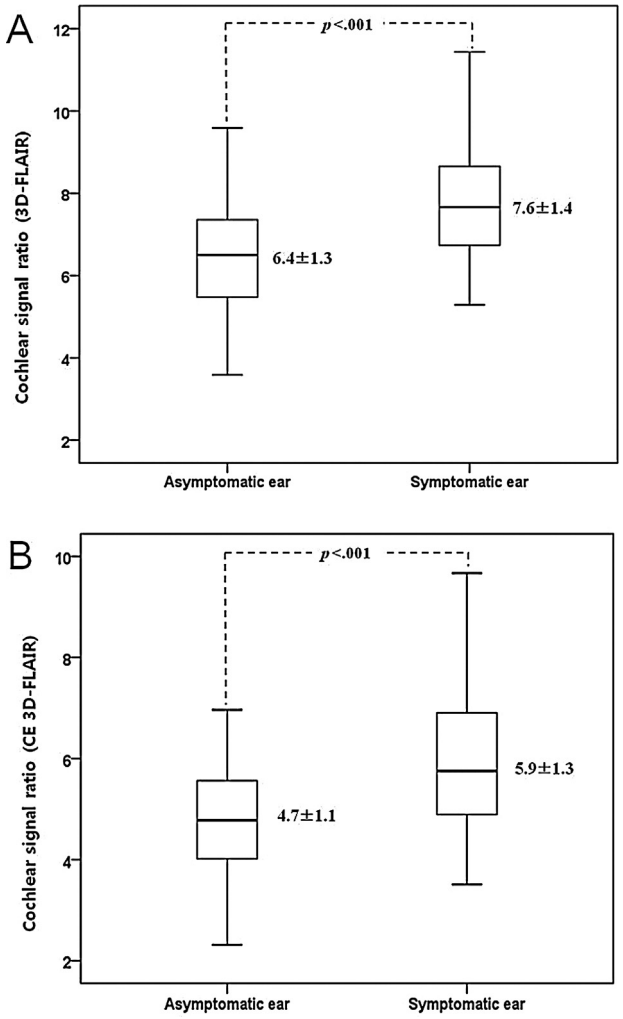

Fig. 2. Comparison of the cochlear signal ratios on 3D-FLAIR(A) and CE-FLAIR(B) between symptomatic and asymptomatic ears. The cochlear signal ratio of symptomatic ear were significantly higher than asymptomatic ear on both 3D-FLAIR and CE- FLAIR.

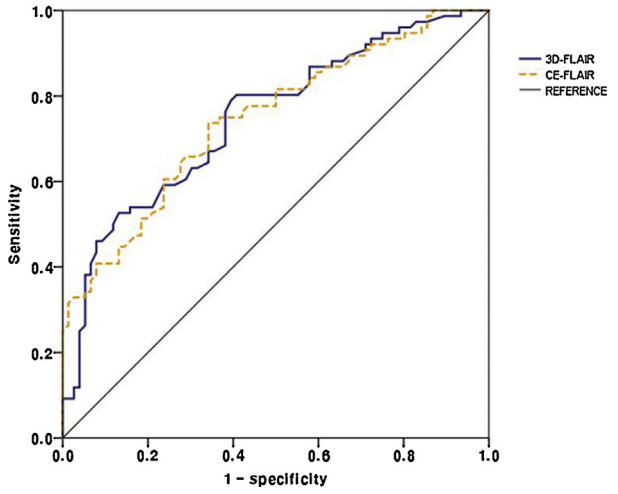

Fig. 3. Receiver operating characteristic curves of cochlear SI on 3D-FLAIR (dotted line, the area under the curve = 0.729) and CE-FLAIR (solid line, the area under the curve = 0.728) for differentiating symptomatic from asymptomatic ears in patients with MD.

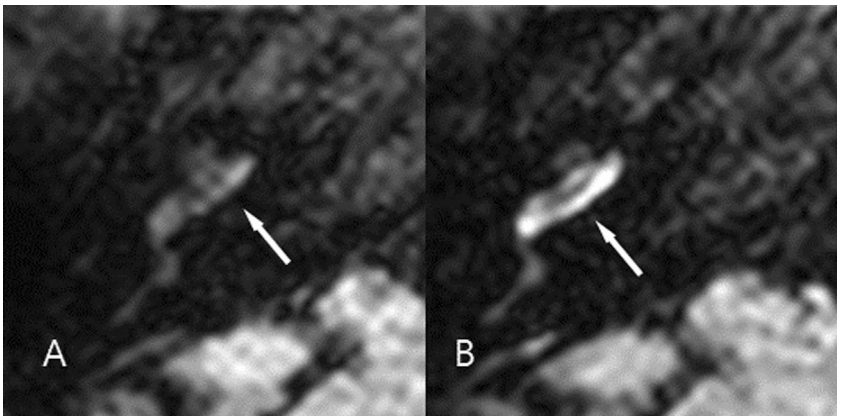

Fig. 4. Temporal MRI of a 20-year-old woman with MD in the right ear. The pre-treatment pure tone audiometry of the right ear revealed a 62 dB hearing loss. (A) Axial 3D-FLAIR image shows high signal intensity (mean ± SD, 33.3 ± 8.2) in the right cochlea (arrow). (B) Axial CE-FLAIR image shows strong contrast enhancement (mean ± SD, 87.7 ± 28.5) at the basal and mid turns of the cochlea(arrow). The post-treatment pure tone audiometry of the right ear revealed that hearing loss had improved to 21 dB.

($P < 0.0001$ for both). The cochlear SI of CE-FLAIR images showed a statically significant relationship with CEI and CER ($P < 0.0001$ for both), and there was a statically significant relationship between CEI and CER ($P < 0.0001$; Table 4).

Discussion

With continued technologic advances and efforts to investigate optimized imaging techniques, it is possible to visualize endolymphatic hydrops in patients with MD using high resolution MRI scans [13]. In the 3D-FLAIR MRI sequence, presence of high-intensity signal in 3DFLAIR images, owing to the increased protein content in the membranous fluid secondary to the presence of protein exudates, while T1 sequences did not show any signal alteration, potentially consistent with acute inflammatory process. Especially, the perilymphatic fluid creates a high SI due to compositional changes in response to pathologic conditions, such as increased concentration of protein due to increased permeability BLB permeability rather than the endolymphatic compartment which is usually impermeable [14–16]. Therefore, the high SI within the affected labyrinth can be identified on a 3D-FLAIR image, which is more sensitive than T1- and T2-weighted images for the diagnosis of MD [17]. Moreover, abnormal contrast enhancement can be observed after intravenous injection of gadolinium contrast agent into the membranous labyrinth of the affected ears in patients with MD, which indicates breakdown of the blood-labyrinth barrier with associated increased contrast permeability [1,17]. Therefore, the 3D-FLAIR and CE-FLAIR images may potentially enhance diagnostic accuracy, guide clinicians regarding treatment decisions, and inform prognosis of patients with MD [16].

Recently, there has been a report of a paper to evaluate blood-labyrinthine barriers (BLB) by distinguishing endolymph and perilymphatic space from 10 minutes after injection of contrast agent and 4 hour delay in MR image among patients with unilateral inner ear symptoms [18].

And 3D-FLAIR imaging 24 hours after intratympanic gadolinium injection has been reported to visualize perilymph and endolymph fluid separately and to enable preliminary prediction of drug distribution to the inner ear, such as gentamicin and steroids [13,19]. In our study, it was impossible to divide the labyrinthine space into endolymph and perilymphatic space with the 5-min delayed image after contrast injection. The unenhanced endolymphatic space is difficult to distinguish from bone on the 3D FLAIR images. However, we have found that fusion of the 3D-FLAIR sequence with a volume isotropic TSE acquisition (VISTA) technique can help differentiate the enhanced perilymphatic space from bone, and using a color map overlay in the areas of increased signal on the FLAIR sequence can increase the conspicuity of the abnormal endolymphatic space in patients with MD [20]. And, measurement of the labyrinthine fluid on CE-FLAIR without taking the 4-hour delayed image showed the breakdown of blood-labyrinthine barrier of MD. It can be used as an indirect measure of disease activity and treatment, using existing data as means of evaluation. This assumes that BLB decay is a marker of active disease in the MD presented in recent literature. In addition, direct comparative studies using same technique after 4-hour delay in CE- FLAIR will be required.

Various subjective, semi-quantitative, and quantitative analyses using FLAIR MRI have been used to detect the labyrinthine abnormality in patients with MD or sensorineural hearing loss [4,5,16]. The majority of previous studies have performed subjective evaluation of the SI of perilymphatic fluid after contrast material administration [5,17]. Some studies used the cochlea/medulla ratio, calculated as the SI of the basal turn of cochlea divided by the SI of the medulla with freehand ROIs [4]. This is the first quantitative analysis of cochlear SI on 3D-FLAIR and CE-FLAIR images using a seed growing technique for the identification of endolymphatic hydrops in patients with MD. The seed growing technique we used offered advantages over freehand ROI methods, such as the ability to evaluate all areas within the boundary of cochlea/vestibule for diagnosis of endolymphatic hydrops. Moreover, this quantitative assessment of endolymphatic hydrops can be replicated and reproduced by other studies. We found that our quantitative method differentiated the membranous labyrinthine space from the bone more clearly using a color map overlay in the areas of high SI on the FLAIR sequence, and increased the conspicuity of the abnormal membranous labyrinthine space in patients with MD.

We compared 3D-FLAIR and CE-FLAIR images for the diagnosis of MD and found no significant difference between these two MRI sequences. Although the sensitivity and specificity of CE-FLAIR were slightly higher than those of 3D-FLAIR, AUC values of both sequences in the ROC curve were almost the same. These results suggest that we should be cautious in interpreting both sequences to minimize the missing information. On the basis of our group data, the sensitivity and specificity calculated at the optimal cut-off values were 64% and 66% for 3D-FLAIR and 66% and 68% for CE-FLAIR. Our sensitivity of 3D-FLAIR and CE-FLAIR for endolymphatic hydrops in clinically involved MD ears is similar to or marginally higher than that of previous studies, which used 3D-FLAIR to identify inner ear abnormality in patients with sudden sensorineural hearing loss: Yoshida et al (64.5%) [16], Berrettini et al. (57%) [17], and Cadoni et al. (57%) [21]. Our 3D-FLAIR MRI protocol had no significant technical differences from those used in the studies of

Yoshida et al. [16] and Berrettini et al. [17]. However, this time interval between first visit to hospital and MRI exam was not consistently reported by all authors. The time factor may be an element that significantly affects 3D-FLAIR MRI findings, which may be negative within 90- 150 days after the onset of sudden sensorineural hearing loss [16]. In fact, as Ramos et al. [22] suggest, a certain number of normal-appearing MRIs might provide better information if they were performed before the start of steroid therapy. Spontaneous evolution of auditory function in MD patients presenting with hydrops is highly variable, and the effect of steroid therapy remains controversial [23]. If the diagnostic and prognostic value of 3D-FLAIR MRI in MD is to be further confirmed and validated, the interval between the onset of symptom, the execution of the MRI, and the beginning of the therapy must be reduced to a minimum.

Previous studies showed inconsistent results regarding the prognostic value of abnormalities in labyrinthine MRI. The majority of studies [5,16,17,24] demonstrated that cochlear high SI on 3D-FLAIR images were associated with a poor prognosis in sudden sensorineural hearing loss. Another study [1] showed that cochlear SI on 3D-FLAIR or CE-FLAIR images did not significantly influence hearing improvement in patients with sudden hearing loss. In our study, both 3D-FLAIR and CE-FLAIR could not predict prognosis for hearing recovery; there were no significant correlations between cochlear SIs on both sequences and post-treatment PTA results. These inconclusive and conflicting results may be partially due to differences in study populations, criteria for severity based on MRI findings, time intervals between disease onset and MRI, or protocols of steroid treatment.

Especially, in our study, hearing loss was more frequent in males and statistically significant. It is likely that men should suspect that the probability of exposure to the cause of hearing loss such as environmental factors of noisy, male-dominated occupations such as construction and factory work, infection or ototoxic drugs is high [6].

Our study has several limitations. First, this is a retrospective study involving patients with MD treated in a single institution; thus, the findings in our study may be subject to selective bias. Second, our control group of asymptomatic ear in patients with MD may be affected given the systemic processes that likely affect blood-labyrinth barrier permeability in both ears. Third, because most of our patients had not undergone a follow-up MRI examination, it was impossible to investigate the association between cochlear SIs on follow-up 3D-FLAIR and CE-FLAIR images with post-treatment PTA results. In our institution, post-treatment MRI is not routinely performed except in cases where symptoms are exacerbated or new symptoms develop. Future studies with more extensive data should be pursued to clarify these issues.

Conclusion

Quantitative analysis of cochlear SI on 3D-FLAIR and CE-FLAIR images may be helpful in the diagnosis of MD, but may not provide reliable prognostic information regarding the clinical course of MD.

Disclosure of interest

The authors declare that they have no competing interest.

Acknowledgement

This work was supported by Hallym University Research Fund (HURF-2016-39).

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