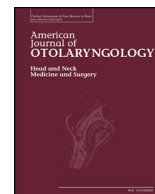




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## Comparison of intratympanic dexamethasone therapy and hyperbaric oxygen therapy for the salvage treatment of refractory high-frequency sudden sensorineural hearing loss

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### ABSTRACT

**Objective:** This study aimed to compare the efficacy of intratympanic dexamethasone (ITD) therapy and hyperbaric oxygen (HBO) therapy for the salvage treatment of patients with high-frequency sudden sensorineural hearing loss (SSNHL) after the failure of conventional therapy.

**Materials and methods:** 104 refractory high-frequency SSNHL patients were enrolled in our study. Among them, 31 received ITD alone (ITD group), 32 received HBO alone (HBO group) and 41 received no salvage therapies (control group). Hearing outcomes were determined by pure-tone average measured by audiometry. The total effective rates in the hearing recovery and improvement of tinnitus were calculated before and after salvage treatment.

**Results:** There was no significant difference of the total effective rates in the hearing recovery between ITD and HBO group ( $p = 0.368$ ). However, ITD therapy showed much better improvements of tinnitus than HBO therapy ( $p = 0.039$ ). After ITD and HBO therapy, there were no significant differences in hearing gains at 2 and 4 KHz between ITD and HBO group ( $p = 0.468$  and  $0.934$ , respectively). Nevertheless, ITD therapy showed significant improvements of hearing gains at 8 KHz ( $p = 0.049$ ) compared to that of HBO therapy.

**Conclusion:** ITD therapy may have better improvements of tinnitus and hearing gains at 8 KHz than HBO therapy in patients with refractory high-frequency SSNHL.

### 1. Introduction

Sudden sensorineural hearing loss (SSNHL) is a common disease defined as sudden hearing loss of more than 30 dB over at least three continuous frequencies in 72 h [1]. Although the definite mechanism of SSNHL is unknown by far, there is still a consensus that the earlier diagnosis is, the better therapeutic treatment of SSNHL. Usually, SSNHL is treated as emergency in clinical practice [2]. Based on possible pathogenesis, the following approaches are attempted with varying degrees of success: corticosteroids, vasodilators, and hyperbaric oxygen [3–5]. Among them, systemic steroids, either alone or in combination with other medications, are regarded as conventional option for the treatment of SSNHL [6]. At present, many studies have demonstrated that according to hearing loss at different frequencies there may be different mechanisms for development of SSNHL [7]. Low-frequency SSNHL (250, 500 and 1000 Hz) may be correlated with membranous labyrinthine hydrops of the cochlear, whereas high-frequency SSNHL (2, 4 and 8 KHz) may be resulted from injury of cochlear hair cells or

the blood-supplying insufficiency of spiral ligament of cochlear. Moreover, all-frequency SSNHL (250, 500, 1000, 2000, 4000 and 8000 Hz) may be associated with blood-supplying insufficiency (the average hearing threshold at 500, 1000, 2000 and 4000 Hz is < 81 dB) or embolism or thrombosis of cochlear artery (the average hearing threshold at 500, 1000, 2000 and 4000 Hz is > 81 dB). Therefore, it can be more reasonable to make corresponding treatment regimes according to different types of SSNHL. However, there are still some patients, especially those suffering from high-frequency hearing loss, being poorly responsive to the standard therapy.

Some studies have showed that as a salvage treatment, intratympanic steroid (ITS) therapy can treat some patients who fail to the conventional treatment. A meta-analysis study including five randomized and controlled trials reveals that salvage ITS therapy is able to improve hearing levels of SSNHL patients who have responded poorly to systemic steroid therapy [8]. Another similar meta-analysis study shows that there is no serious side effect with ITS therapy. Furthermore, for patients who have failed initial treatment with systemic steroids,

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additional treatment with salvage intratympanic dexamethasone (ITD) injections demonstrates significant reduction in the hearing threshold [9].

Since HBO was first applied for the treatment of SSNHL in the late 1960s [10], some studies have showed the outcomes of HBO therapy in the treatment of SSNHL. Bennett et al. reviewed data from six published randomized and controlled trials concerning HBO therapy for patients with SSNHL, and made a conclusion that HBO therapy could improve hearing recovery [11]. However, no convincing evidences show that HBO therapy is recommended as the first-line treatment option. In contrast, HBO therapy can be used for treating patients of SSNHL after the failure from common regimens [12, 13]. According to the Chinese guideline of prognosis and treatment for SSNHL, HBO therapy is recommended as a salvage treatment [14].

However, previous studies for HBO or ITS therapy as a salvage treatment weren't on the basis of concrete type of SSNHL. Furthermore, there has been still a research gap by far for the salvage treatment of high-frequency SSNHL. Therefore, the aim of the present study is to compare the efficacy of ITD and HBO therapy as a salvage treatment for patients with refractory high-frequency SSNHL.

## 2. Materials and methods

### 2.1. Subjects

The medical records of 163 high-frequency SSNHL patients admitted to the Yin zhou hospital were reviewed. The high-frequency SSNHL was defined as the average hearing loss > 30 dB at 2, 4 and 8 KHz. All patients were treated initially with intravenous injection of 10 ml lidocaine (0.1 g/5 ml) once a day for 10 days and intravenous injection of methylprednisolone (80 mg per day in the initial 3 days, followed by tapering to 40 mg/day for another 3 days). After the therapy, patients were determined to be given further therapy according to their responses to the standard treatment. Refractory high-frequency SSNHL was defined as effective with no more than 15 dB in average hearing gains at 2, 4 and 8 KHz. If some of them were not content with therapeutic effect and would rather accept further therapy, there were two treatment options including ITD and HBO therapy.

Before the ITD or HBO therapy was performed, patients were counseled regarding the advantages and disadvantages in details. Consequently, they were divided into ITD group and HBO group with informed consent. The patients who refused salvage treatment were treated as the control group. Meanwhile, to meet the design of our study, all patients must meet the criterion as follows: (1) older than 18 but < 70 years old; (2) no history of diabetes; (3) unilateral SSNHL; (4) no contraindication of HBO therapy; (5) complaining of tinnitus. Ultimately, there were 31 patients in ITD group, 32 patients in HBO group and 41 patients in control group. Therefore, the study was based on the data with the approval of the hospital ethics committee. Their information was reviewed: age, gender, interval between onset and treatment initiation and severity of tinnitus.

### 2.2. Salvage treatment

ITD therapy was administered once every 3 days for a total of 6 times. Before administration, the external auditory canal was sterilized with iodophor for 10 min. Next 0.5 ml dexamethasone (4 mg/ml) was injected into the posterior-inferior quadrant of the tympanic membrane under the endoscope. The mucosa in the tympanic cavity avoided being damaged. Then the head of patient was tilted about 60° toward the healthy side for 30 min. The patient also should avoid speaking and swallowing during this period.

HBO therapy was administered once a day for 3 weeks. Patients stayed in a hyperbaric chamber and breathed 100% oxygen for 90 min at 2.0 atmospheric pressure. The patients needed to swallow once

fullness or pain in ears was felt.

All patients should be given the tests of pure tone audiometry (PTA) and acoustic immittance for 1 month after the end of treatment. The patients in control group were performed with only observation. After one month they were also given the test of PTA and acoustic immittance.

### 2.3. Evaluation of hearing recovery and improvement of tinnitus

The average hearing threshold at 2, 4 and 8 KHz was used to evaluate hearing recovery. According to the changes of hearing levels before and after treatment, hearing recovery was divided into four grades (complete recovery, excellent recovery, partial recovery and no change) [15].

Complete recovery: average hearing returns to the normal level or to a level equal to that of the unaffected contralateral ear.

Excellent recovery: improvements in average hearing gains are > 30 dB.

Partial recovery: improvements in average hearing gains are > 15 dB but < 30 dB.

No change: improvements in average hearing gains are < 15 dB.

The evaluation of therapeutic effect in tinnitus was based on subjective feeling. Severity of tinnitus ranging from grade 0 to grade 6 could reflect subjective feeling of tinnitus [15]. For evaluation of tinnitus, this approach is very popular in china. Grade 0 represents no tinnitus. Grade 1 is defined as occasional tinnitus but no painful feeling. Grade 2 represents persistent tinnitus, which gets worse when it's quiet. When patients feel persistent tinnitus in a noisy environment, we define it as grade 3. If tinnitus is up to standard of grade 4, it means that persistent tinnitus can lead to dysfunction of attention and sleep. When persistent tinnitus is so severe that patients are unable to work, it is regarded as grade 5 and grade 6 represents the most serious tinnitus which can lead to suicidal tendency. According to frequently-used Chinese criteria, the improvement of tinnitus was also divided into four grades (complete recovery, excellent recovery, partial recovery and no change).

Complete recovery: the tinnitus disappears.

Excellent recovery: improvements of the tinnitus are > 2 grades.

Partial recovery: improvement of the tinnitus is only one grade.

No change: the tinnitus shows no improvement.

The total effective rates of hearing recovery and improvement of tinnitus were calculated using the following equations: the number of patients who got (complete recovery + excellent recovery + partial recovery) / the number of all patients in each group.

## 3. Statistical analysis

Comparison of ages, interval between onset and treatment initiation and severity of tinnitus among three groups were analyzed by one-way ANOVA. *t*-test was used for the analysis of measurement data between any two groups. Numeric and percent data analysis were performed by  $\chi^2$  test or Fisher's exact test. *F* test was used for repeated measurement data analysis of variance. SPSS 13.0 software was used in the statistical analyses. *p* < 0.05 was considered significant.

## 4. Results

The profile of patients was summarized in the Table 1. A total of 104 patients were enrolled in the study. There were no significant differences in the age, sex, interval between onset and treatment initiation and severity of tinnitus of patients between any of two groups.

Fig. 1 compared the results among three groups in the hearing recovery and improvement of tinnitus. There was a no significant difference in the total effective rate of hearing recovery among the three groups (*p* = 0.213). Although the total effective rate in ITD group (4/31) was much better than that in HBO group (2/32) and control group

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