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Treatment Management of Sudden Sensorineural Hearing Loss Patients: Timing and Efficacy of Hyperbaric Oxygen Intervention

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ABSTRACT

Background: The Chinese guidelines for sudden sensorineural hearing loss (SSNHL) (published 2015) do not recommend hyperbaric oxygen (HBO) as a routine treatment option. The objective is to investigate the timing and efficacy of HBO in the treatment of SSNHL by a retrospective study.

Methods: The 398 patients with unilateral SSNHL were assigned to 6 groups according to the onset symptoms to initial treatment within (14^-) or over 14 days (14^+), and treatment type (medicine alone or combined with HBO). Using Pure Tone Average (PTA) threshold to evaluate the efficacy of treatment by HBO after 2, 4, and 12 weeks.

Results: The efficacy rate in treatment was statistically different between the single medicine and combined with HBO in the 14^- and 14^+ groups (respectively, 53.01% and 67.95%, $P < .05$; 35.37% and 50.35%, $P < .05$), while the change in PTA of the combined with HBO 14^- group or single HBO was significantly more favorable than the 14^+ group or Observer group ($P < .01, .01$).

Conclusion: Early use of HBO alone or in combination with medicines can achieve better therapeutic effects in SSNHL.

Keywords: Efficacy, hyperbaric oxygen, management, sudden sensorineural hearing loss, timing

Introduction

The estimated incidence of sudden sensorineural hearing loss (SSNHL) is about 5-20 cases per 100 000 annually. However, the pathogenesis of SSNHL is not confirmed. Although the treatment plans between the American Academy of Otolaryngology Head and Neck Surgeons (AAOHNS) (published 2012 and updated 2019) and the China guidelines (published 2015) are different, both guidelines recommend that steroids be used for the treatment of SSNHL, by oral and intratympanic injection.[1,2]

Hyperbaric oxygen (HBO) therapy is widely used in brain injury and ischemic hypoxic encephalopathy. Oxygen can be transported to the inner ear tissue in the blood under HBO.[3] As a result, the Undersea and Hyperbaric Medicine Society revised the guidelines in 2014 with the addition of SSHL to the approved list of indications.[4] Treatment poses a significant challenge when dealing with patients who have contraindications to steroid therapy. Hyperbaric oxygen therapy (HBOT) is administered either as a primary or salvage treatment plan alongside systemic or intratympanic steroid therapy.[5,6] However, there is controversy regarding the clinical practice of HBO in the therapy of SSNHL, and there are positive or negative reports of efficacy.[7-10]

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The clinical practice guidelines issued by the AAOHNS recommend consideration of HBOT within the initial 2 weeks after symptom onset.[1] However, the Chinese guidelines for SSNHL, which were issued in 2015 and updated in 2022, do not recommend HBOT as a routine treatment option. Instead, it is only as a supplementary treatment.[2] Severe SSNHL generally has a disappointing prognosis, especially in older adults, patients with contraindications to steroids, and those with a longer onset time (over 2 weeks). This type of patient is often defined as having refractory SSNHL.

To further demonstrate the efficacy of HBO in the treatment of SSNHL, this study conducted retrospective controlled studies to investigate the timing and efficacy of HBOT in SSNHL.

Material and Methods

This study was approved by the Medical Ethics Committee of Chongqing Medical University (No: KYLLMC20200138; Date: 07.02.2022). All patients have signed the written informed consent.

Study Patients

A retrospective analysis of the medical records of 398 patients diagnosed with unilateral SSNHL from November 2021 to January 2023, at the Suining Central Hospital, The First Affiliated Hospital of Chongqing Medical University and Yongchuan District People'sHospital in China was conducted.

Sudden sensorineural hearing loss is a rapid loss of hearing over a period of up to 3 days and at least 30 dB in 3 consecutive frequencies. The time from onset to treatment in all patients was within 28 days. Patients diagnosed with SSNHL with the guidelines of the AAOHNS were included.[1] However, patients with clinical evidence of hearing loss were excluded, such as Meniere's disease, Acoustic Neuroma, and Nasopharyngeal Carcinoma, as well as unilateral middle ear disease.

Contraindications for HBO therapy include acute sinusitis, retinal detachment, heart or renal failure, stroke, and unhealed pneumothorax.

Study Design and Interventions

Pure tone average (PTA) threshold is used to assess hearing loss and recovery in all patients at pre- and post-treatment. The PTA was calculated as the mean of hearing thresholds measured at 6 frequencies: 250, 500, 1000, 2000, 4000 and 8000 Hz. The PTA recovered >30dB, which was regarded as an efficiency index.[1]

MAIN POINTS

- *There are significant differences in clinical practice guidelines of sudden sensorineural hearing loss (SSNHL) between the United States and China regarding the timing of hyperbaric oxygen (HBO) treatment.*
- *American Academy of Otolaryngology Head and Neck Surgeons recommends combining with HBO within 2 weeks of symptom onset, but Chinese guidelines do not recommend HBO as a routine treatment plan.*
- *The research shows that HBO combined with systemic steroids is an effective treatment method within 4 weeks of onset.*
- *Early combination with HBO can achieve better therapeutic effects.*
- *To use HBO alone can also achieve good therapeutic effects in patients with contraindications to medication.*

Additionally, the Auditory Brainstem Response was employed to rule out cerebellopontine angle tumors. Enhanced magnetic resonance imaging was performed on patients exhibiting abnormal auditory brainstem evoked responses or those presenting with vertigo. To ensure the safety of medicinal treatment, other laboratory related examinations, including blood sugar, blood pressure, and hemorheology tests, were also performed.

Patients were divided into 4 groups based on contraindications to the treatment protocols: the medicinal treatment group (M), the medicinal treatment combined with HBOT group (M+HBO), the HBOT, and the observation group (OB). Patients with contraindications to medicinal treatment were assigned to the HBOT group. Those who had contraindications to both medicinal treatment and HBOT, or who declined active treatment due to difficulties in accessing medical care or personal financial reasons, were included in the OB group.

Based on the duration from symptom onset to initial treatment, which ranged from 0 to 14 days and 15 to 28 days, the medicinal treatment group (M) was further redivided into 2 subgroups: M^{14-} and M^{14+}. Similarly, the medicinal treatment combined with HBOT group (M+HBO) was divided into 2 subgroups: $(M+HBO)^{14-}$ and $(M+HBO)^{14+}$.

Therapeutic Regimen

The medicinal treatment regimen was established as follows: a single does of 1 mg prednisone per kilogram for 5 days (usual maximal dose is 60 mg/d). Furthermore, alprostadil injection, dose of 10 μg, was given intravenously once a day for 14 days. Regarding Batroxobin Injection, the initial dose was set at 10 BU, with a maintenance dose of 5 BU every alternate day. The solution was diluted with more than 100 mL of normal saline before administration and infused intravenously for more than 1 hour (D-dimer ≥ 0.6).[2]

Additionally, the HBO therapy regimen consisted of 14 sessions of HBO therapy over a period of 2 weeks, with 1 session administered per day. An HBO session comprised a period of 20 minutes compression in air followed by two 50-min 100% oxygen periods with 10-min air break intervals at 2.5 atmosphere absolute, and then decompression period of 30 minutes in oxygen.

Statistical Analysis

Data were analyzed by SPSS 25.0 (IBM SPSS Corp.; Armonk, NY, USA) software package and using *t*-test, χ^2 test, and Fisher's exact test. A *P* value < .05 was considered to be statistically significant.

Results

Study Patients

A total of 398 patients were enrolled in this study, comprising 83 in the M^{14-} group, 78 in the $(M+HBO)^{14-}$ group, 82 in the M^{14+} group, 77 in the $(M+HBO)^{14+}$ group, 43 in the HBO group, and 35 in the OB group. During the study period, 36 patients withdrew from the study, 1 from the M^{14-} group, 6 from the $(M+HBO)^{14-}$ group, 2 from the M^{14+} group, 7 from the $(M+HBO)^{14+}$ group, 9 from the HBO group, and 11 from the OB group. The reasons for withdrawal were loss of contact or uncompleted treatment or complications related to HBO therapy had occurred.

No statistically significant differences were observed in baseline characteristics, including demographics, clinical features, interval from onset to treatment, initial glucose levels, withdrawal rates, or

Table 1. Baseline Characteristics of Each Groups

	M^{14-}	$(M+HBO)^{14-}$	*P*	M^{14+}	$(M+HBO)^{14+}$	*P*	HBO	OB	*P*
Age (year)	42.37 ± 19.44	44.62 ± 10.82	.370	41.65 ± 16.67	43.48 ± 21.24	.545	56.68 ± 22.33	60.17 ± 17.26	.438
Male/female (n)	36/47	41/37	.243	38/44	34/43	.782	22/21	21/14	.435
Interval from onset to treatment (day)	6.62 ± 4.43	6.44 ± 5.31	.815	21.04 ± 4.63	21.67 ± 5.17	.419	15.62 ± 7.22	17.47 ± 6.51	.243
Tinnitus (n)	63	58	.821	52	57	.244	34	28	.919
Vertigo (n)	21	16	.470	24	17	.300	11	9	.942
Initial glucose level (mmol/L)	8.6 ± 1.7	8.4 ± 1.6	.444	8.3 ± 1.8	8.4 ± 1.7	.720	13.9 ± 3.1	14.8 ± 3.8	.280
Patients withdrawn (n)	1/84	6/84	.054	2/84	7/84	.087	9/52	11/46	.418

Data was expressed as [n(%)] or mean ± SD or mmol/L. χ^2 test or *t*-test or Mann–Whitney *U* test was performed for the independent groups.

Table 2. The Comparison of the Efficiency Rate Between the 3 Subgroups

	M^{14-}	$(M+HBO)^{14-}$	M^{14+}	$(M+HBO)^{14+}$	HBO	OB
Efficiency (%)	38/83 (53.01%)	52/78 (67.95%)	25/82 (35.37%)	37/77 (50.65%)	21/43 (44.18%)	7/35 (22.86%)
P	.008		.023		.008	

Efficiency: PTA recovered > 30dB, which was regarded as efficiency.

the presence of dizziness or vertigo between M^{14-} and $(M+HBO)^{14-}$, M^{14+} and $(M+HBO)^{14+}$, HBO group, and OB group (Table 1).

Hearing Recovery

The efficacy rates of M^{14-} group and $(M+HBO)^{14-}$ group were 53.01% and 67.95%, respectively. The efficacy rate of M^{14+} group and $(M+HBO)^{14+}$ group was 35.37% and 50.65%, respectively. The efficacy rates of HBO group and OB group was 44.18% and 22.86%, respectively. The efficacy rates of the 3 groups were statistically significantly different ($P < .01$, .05, and .01) (Table 2).

The comparison of the initial PTA before treatment between M^{14-} group and $(M+HBO)^{14-}$ group, M^{14+} group and $(M+HBO)^{14+}$ group, there was no statistically significant difference ($P > .05$, .05). After treatment, the PTA threshold changes in each group were detected at 2 weeks, 4 weeks, and 12 weeks. The efficiency rate of the 3 groups were statistically significantly different ($P < .01$, .01, and .01) (Table 3).

The efficacy rate of the M^{14-} group and M^{14+} group after treatment was 53.01% and 35.37%, respectively, and the difference between the 2 groups was statistically significant ($P < .05$). The efficacy rate of the $(M+HBO)^{14-}$ group and $(M+HBO)^{14+}$ group after treatment was 67.95% and 50.65%, respectively, and the difference between the 2 groups was statistically significant ($P < .05$) (Table 4).

The comparison of the PTA of pre-treatment between M^{14-} group and M^{14+} group, showed no statistically significant difference ($P < .05$). The PTA of each group after treatment were obtained at 2, 4, and 12 weeks, which were statistically significant ($P < .01$, .01, and .01) (Table 5).

Comparison of the initial PTA between $(M+HBO)^{14-}$ group and $(M+HBO)^{14+}$ group, showed no statistically significant difference ($P > .05$). However, after treatment, the PTA of each group was obtained at 2, 4, and 12 weeks, the differences were statistically significant ($P < .01$, .01, and .01) (Table 6).

The comparison of the initial PTA between the HBO group and OB group showed no statistically significant difference ($P > .05$). The PTA of each group after treatment were obtained at 2, 4, and 12 weeks, the differences were statistically significant ($P < .01$, .01, and .01) (Table 7).

Despite significant differences in the efficacy of SSNHL treatment across different institutions, early diagnosis and treatment may consistently be associated with improved clinical outcomes. This study demonstrates that the treatment efficacy of combined medicine with HBO is significantly superior to that of the medicine group, both in the early treatment group (≤14 days) and the delayed treatment group (>14 days). The treatment efficacy rates of the $(M+HBO)^{14-}$ group and the $(M+HBO)^{14+}$ group were 67.95% and 50.65%, the difference between the 2 groups were statistically significant. Comparison of the PTA before and after treatment illustrated that the groups receiving combined medicine and HBO exhibited greater hearing improvement than the single medicine groups, both in the ≤14 days and >14 days subgroups. The analysis revealed that the medicine combined with HBO groups had significantly higher hearing improvement.

Table 3. The PTA Between the M and HBO+M Groups Before and After Treatment

	M^{14-}	$(HBO+M)^{14-}$	*P*	M^{14+}	$(HBO+M)^{14+}$	*P*
PTA of pre-treatment (dB)	58.67 ± 21.34	61.92 ± 19.84	.326	64.65 ± 19.67	67.42 ± 18.56	.363
PTA of post-treatment after 2 weeks (dB)	38.85 ± 19.64	30.44 ± 18.47	.006	48.28 ± 20.39	42.35 ± 14.42	.037
PTA of post-treatment after 4 weeks (dB)	36.52 ± 20.39	27.37 ± 14.38	.001	44.78 ± 14.49	40.33 ± 9.54	.024
PTA of post-treatment after 12 weeks (dB)	34.01 ± 16.07	28.46 ± 9.72	.009	41.57 ± 10.31	38.61 ± 7.27	.039

PTA: Mean values of PTA thresholds of 0.25 kHz, 0.5 kHz, 1 kHz, 2 kHz, 4 kHz and 8 kHz frequencies. *t*-test or Mann–Whitney *U* test was performed for the independent groups. $P < .05$ was considered to be statistically significant.

Table 4. The Efficiency Rate of Each Subgroup Within/Without 14 days

	M^{14-}	M^{14+}	$(HBO+M)^{14-}$	$(HBO+M)^{14+}$
Efficiency (%)	38/83 (53.01%)	25/82 (35.37%)	52/78 (67.95%)	37/77 (50.65%)
P	.043		.019	

χ^2 test was performed for the independent groups.

Table 5. The PTA in the *P* groups Within/Without 14 days

	M^{14-}	M^{14+}	*P*
PTA of pre-treatment (dB)	58.67 ± 21.34	64.65 ± 19.67	.063
PTA of post-treatment after 2 weeks (dB)	38.85 ± 19.64	48.28 ± 20.39	.003
PTA of post-treatment after 4 weeks (dB)	36.52 ± 20.39	44.78 ± 14.49	.001
PTA of post-treatment after 12 weeks (dB)	34.01 ± 16.07	41.57 ± 10.31	.001

M group, medicinal treatment group.

These findings confirm that HBO combined with medicine, including systemic steroid, represents a first-line treatment option for SSNHL, whether treatment is initiated within ≤14 days or >14 days group. A recent research has shown that the combination of HBOT and steroid therapy may significantly improve hearing outcomes compared to steroid therapy alone,[11,12] which is congruent with the research outcomes. According to the Chinese guidelines for the treatment of sudden deafness, in addition to steroids, Batroxobin and alprostadil may be used.[2]

Following the administration of combined pharmacological treatment and HBO in the 2 groups, the research found that there is a significantly increased difference in the 14^- days group and the 14^+ days group. These findings suggest that the addition of HBO therapy or medicinal treatment improves the results of the standard treatment plan, with optimal results observed when treatment is started as early as possible. Furthermore, a comparative analysis of the efficacy rate between the $M14^-$ and 14^+ alone groups demonstrated superior efficacy in the earlier intervention group. Although the clinical practice guidelines of AAOHNS suggest considering HBOT within 2 weeks of symptom onset, this study confirms that even over 2 weeks after the onset of hearing loss, the combination of HBO therapy and pharmacological treatment significantly improves the hearing threshold of patients.

Table 6. The PTA Between the HBO^+ *P* Groups Before and After Treatment

	$(HBO+M)^{14-}$	$(HBO+M)^{14+}$	*P*
PTA of pre-treatment (dB)	61.92 ± 19.84	67.42 ± 18.56	.077
PTA of post-treatment after 2 weeks (dB)	30.44 ± 18.47	42.35 ± 14.42	.000
PTA of post-treatment after 4 weeks (dB)	27.37 ± 14.38	40.33 ± 9.54	.000
PTA of post-treatment after 12 weeks (dB)	28.46 ± 9.72	38.61 ± 7.27	.000

HBO^+M, medicinal treatment combined with HBO treatment group.

Table 7. PTA of HBO Group and OB Group Before and After Treatment

	HBO	OB	*P*
PTA of pre-treatment (dB)	70.01 ± 17.35	72.43 ± 15.17	.519
PTA of post-treatment after 2 weeks (dB)	56.27 ± 20.21	68.37 ± 17.42	.007
PTA of post-treatment after 4 weeks (dB)	54.44 ± 24.36	65.18 ± 16.27	.028
PTA of post-treatment after 12 weeks (dB)	52.54 ± 18.47	64.37 ± 15.32	.003

HBO, hyperbaric oxygen treatment group; OB, observer group.

Additionally, some patients with contraindications to pharmacological treatment, including conditions such as diabetes, hypertension, and gastric ulcers, were included in the study. The results of this study showed the treatment efficacy of the single HBO and OB groups was 44.18% and 22.86%, respectively, demonstrating a statistically significant difference between the 2 groups. Comparison of PTA after treatment at 2, 4, and 12 weeks between HBO group and OB group revealed that the HBO group exhibited superior hearing improvement outcomes compared to the OB group, with statistically significant results. The HBOT is a reliable and effective salvage treatment, which is hypothesized to enhance oxygenation within the inner ear and thereby aid the recovery of damaged cochlear sensory elements by halting or reversing a number of inflammatory pathways.[13] However, it is important to consider both the benefits and risks of this therapy, as complications can include otic barotrauma, claustrophobia, and, rarely, oxygen toxicity resulting in seizures.[14]

In addition to conventional systemic corticosteroid therapy, several studies suggest that intratympanic dexamethasone injection is a promising salvage therapy option. However, evidence from 1 study indicates that intratympanic steroid therapy is more effective at low frequencies compared to high frequencies.[15] Although tympanic injection is one of the salvage treatment therapies, it is important to ensure that this approach is an invasive procedure and carries the risk of complications, including tympanic membrane perforation of the eardrum, infection of otitis media, and pain, especially in elderly patients with diabetes.

The limitations of this study include relatively non-random settings and small sample sizes. In addition, large-scale, multicenter studies are needed to further demonstrate the efficacy of HBO and consider it as a first-line treatment plan in China in future.

Discussion

The HBOT is a reliable and effective salvage treatment, especially for patients with hearing loss onset over 2 weeks or those with contraindications to systemic steroid. The HBO combined with systemic steroid is an effective and standard treatment therapy, and early use of HBO alone or combined with medicinal treatment can achieve better therapeutic effects.

Data Availability Statement: *The data that support the findings of this study are available on request from the corresponding author.*

Ethics Committee Approval: *This study was approved by the Ethics Committee of Chongqing Medical University, (Approval No: KYLLMC20200138; Date: 07.02.2022).*

Informed Consent: *Written informed consent was obtained from the patients who agreed to take part in the study.*

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