

# The Role of Hyperbaric Oxygen Therapy in the Management of Patients With Sudden Hearing Loss

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*The therapeutic approach in sensorineural hearing loss (ISSNHL) is far from a consensual protocol among ENT (ear, nose and throat) doctors. The present paper describes our experience with Hyperbaric Oxygen Therapy (HBOT) as salvage treatment for selected patients with the sudden sensorineural hearing loss. The HBOT method has shown an efficacy of 50% in our study, as salvage treatment in ISSNHL after initially corticoids therapy. Thus, we can assert without doubt that HBOT represents a viable option for those patients who want to continue the effort to regain hearing. Under the auspices of the national ENT society, through a collective effort, can be achieved a therapeutic consensus in the sensorineural hearing loss. In this consensual document, HBOT can be found both as initial and salvage therapy, alone or in the multimodal therapeutical variant. Further, the National Health Insurance House should introduce the reimbursement of HBOT sessions in the methodological norms, in order to offer this new therapeutic solution to all patients.*

**Keywords:** hyperbaric oxygen therapy, salvage treatment, sudden sensorineural hearing loss

According to the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guideline-2012, presumptive idiopathic sudden sensorineural hearing loss (ISSNHL) is diagnosed if audiometry confirms a 30-decibel (dB) hearing loss at three consecutive frequencies, with a sudden onset (within 72 hours) and no underlying condition has been identified [1].

The authors of the mentioned guideline have proposed to improve the management of ISSNHL, reducing unnecessary tests and procedures. Thus, although there is no consensus on effectiveness of corticosteroids (local - intratympanic, oral or systemic) as initial therapy to patients with ISSNHL, the AAO-HNSF guidelines give physicians this option. In a situation where the first-line treatment did not have the expected result, additional treatments may be used. It is very important that the recommendation for hyperbaric oxygen therapy (HBOT), as salvage/additional treatment, to be done within 3 months of diagnosis of ISSNHL.

Recently (April 2016), during the Tenth European Consensus Conference on Hyperbaric Medicine, the recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment have been established [2].

Referring to ISSNHL, the hyperbaric oxygen therapy recommendation is considered appropriate by the large majority of experts (Type 1, Level B evidence). The time elapsed from onset to initiation of hyperbaric oxygen therapy seems to be very important. Thus, the combined therapy (corticosteroids and hyperbaric oxygen) can be applied in patients with ISSNHL, provided they present themselves within 2 weeks of disease onset (Type 1, Level B evidence). The maximum time limit from the onset of the disease to the initiation of hyperbaric oxygen therapy (alone or combined with medical treatment) is considered to be 6 months (Type 1, Level C evidence). Especially in

patients with severe or profound hearing loss, the hyperbaric oxygen therapy as salvage treatment can be accomplished provided that their presentation is between 2 weeks and 4 weeks of disease onset (Type 3, Level C evidence).

In Romania, the Ministry of Health established in 2010 through the specialized commission, the Therapeutic Guide in Otorhinolaryngology - Head and Neck Surgery. The therapeutic recommendations for the patients with ISSNHL are much less well defined and refers to measures that are taken to improve microcirculation and inner ear oxygenation as well as steroid treatment. It is also mentioned that there is no proven effective therapy [3].

Synthesising the views of the three groups of experts (AAO-HNSF, Consensus Conference on Hyperbaric Medicine and Romanian Therapeutic Guide in Otorhinolaryngology) outlined above and taking into account that between 35-60% of patients with ISSNHL have experienced a spontaneous remission, we decided to make our own therapeutic algorithm.

The present paper describes our experience with hyperbaric oxygen therapy as salvage treatment for patients with the sudden sensorineural hearing loss.

## Experimental part

Has been achieved a retrospective and nonrandomized study, involving 6 patients with idiopathic unilateral sensorineural hearing loss presented at 3-6 weeks after onset, with 60 dB or higher of pure tone average (PTA) hearing threshold. The study was conducted from December 2009 through January 2016, at the National Institute of Aeronautical and Spatial Medicine and the Institute. Participants were followed up for 6 months.

All patients were first treated with corticosteroids, given orally or intravenously, by different physicians in different doses.

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A hyperbaric oxygen treatment protocol as salvage therapy in sudden sensorineural idiopathic sudden sensorineural hearing loss (ISSNHL) was previously established, and all selected patients signed informed consent. This protocol was approved by the Ethics Committee at the National Institute of Aeronautical and Spatial Medicine.

Hyperbaric oxygen therapy is a form of medically recognized treatment worldwide. This therapy is widely applied both in Europe and in the United States of America. The patient is introduced into a hyperbaric chamber where it inhales pure oxygen at high pressure.

The air we breathe is composed, in proportions slightly variable, by substances such as nitrogen (78%), oxygen (21%), water vapor (variable 0-7%), ozone, carbon dioxide, hydrogen and some noble gases, like krypton or argon. Commonly, when the atmospheric pressure is 760 mmHg, the partial pressure of O<sub>2</sub> (PO<sub>2</sub>) hit the value of 150 mmHg, depending on the water vapor. With this pressure reaching the alveolar level from where diffuses to the capillaries.

Under normal conditions, oxygen is transported to the cells bound to hemoglobin, whereas under hyperbaric conditions, oxygen dissolves directly into the plasma and reaches cells and tissues in much greater quantities than those provided by hemoglobin transport.

In addition, the increase in oxygen partial pressure also increases its diffusibility into tissues, so that although there is a similar amount of oxygen in the plasma, its effectiveness is greatly increased.

Increasing environmental pressure leads both to the increase in the amount of dissolved oxygen in the plasma (quantitative increase) and to the oxygen penetration radius in the tissues (qualitative increase).

Starting from these considerations, must be mentioned the special place of HBOT in preparing of the receiving area for pedicled flaps or for osseointegrated titanium implants, in irradiated patients [4].

There are also otological considerations for HBOT. Thus, the possible vascular origin of the idiopathic sudden sensorineural hearing loss, associated with the finding that the cochlea receives a final circulation (without anastomosis) - through the labyrinthine artery, are the main pathophysiological arguments for use of HBOT. In other words, the hyperbaric oxygen treatment can eliminate / improve anoxia of the labyrinthine tissues, related to the pathogenesis of ISSNHL.

The benefits of using HBOT have been demonstrated also by numerous applied research studies. Lamm (1988) performed an applied study on guinea pigs who have undergone at HBOT [5]. The pressure in hyperbaric chamber was of 1.6 ATA. The study revealed the increase of partial pressure of oxygen (pO<sub>2</sub>) in the inner ear. The author showed an increase of pO<sub>2</sub> in the tympanic ramp of 563% as a result of HBOT. This involves the restoration of the oxidative metabolism at the vascular stria level, having as a consequence the protection of *hair* cells from the organ of Corti - the auditory sensory epithelium of the cochlea. Other authors have argued the appearance of an improvement in the vascularization at the internal ear level. This improvement can be analyzed as a better local microcirculation, due on the one hand to the decrease in hematocrit and blood viscosity, and on the other hand to the increase in the elasticity of the red blood cells.

Has been used the BARAMED monoplace hyperbaric chamber with computerized control of treatment profiles and *Smooth Ride* (compression and decompression procedure that reduces barotrauma risk) (fig.1).

The HBOT has no absolute contraindication. In certain situations, it is necessary to assess the cost- benefit,

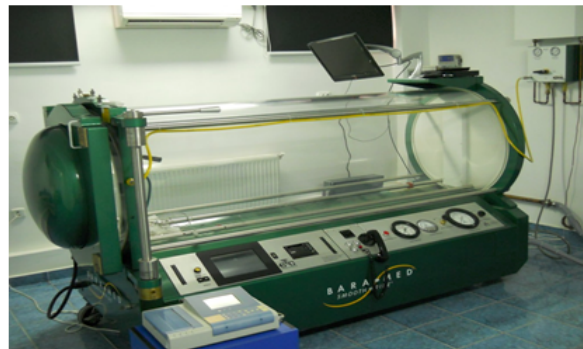


Fig.1. BARAMED monoplace hyperbaric chamber

especially when patients pay full treatment or in case of presumably long treatments.

Complications that may arise during treatment in hyperbaric chamber are the following:

- barotrauma in the middle ear
- sinus pain
- pulmonary barotrauma.
- alterations of the central nervous system.

Before the start of HBOT, has been achieved for each patient a detailed anamnesis, a complete cardiopulmonary exploration and an ENT examination, in order to avoid complications.

We used the following inclusion criteria:

- the relatively early onset of hyperbaric oxygen treatment ( $\leq 6$  weeks),
- the occurrence of disease in young / active patients ( $\geq 18$  years and  $\leq 65$  years),
- active military / reserve military or members of their families, who benefit from free medical treatment according to Law 80/1995.

Patients who presented local or general affections that can explain the genesis of sudden deafness by themselves or those who are known with claustrophobia were excluded.

Each patient performed 15 sessions of hyperbaric oxygen therapy from the time of presentation. The therapeutic sessions were daily (5 sessions per week, with week-end break), with a session duration of 2 h, at a pressure of 2-2.4 ATA (similar to the pressure at the depth of 14 meters), depending on the patient's physical particularities.

To determine the modifications of hearing ability determined by the hyperbaric oxygen therapy, we have achieved pre-treatment and post-treatment audiological examination at 30, 90 and 180 days from the start of HBOT. The results were evaluated considering changes in Pure Tone Averages (PTA) at 250, 500, 1000, 2000, and 4000 Hz.

To quantify the role of initial audiometry curves, were investigated for each patient, the presence of one of the five types of audiometry curves (low frequency, pantonal, high frequencies, medium frequencies and residual hearing - cophosis) in sudden deafness.

The response to therapy was categorized according to Siegel's criteria:

- Healing: final threshold more than 25 dB.
- Partial improvement: gain of more than 15 dB, final hearing threshold 25-45 dB.
- Slight improvement: gain of more than 15 dB, final hearing threshold more than 45 dB.
- No response: gain of less than 15 dB and final hearing threshold more than 75 dB.

For most authors, successful treatment of ISSNHL has defined arbitrarily. In the present study, we decided to consider as improvement of hearing, an improvement of the PTA greater than 15dB (it was considered a positive

**Table 1**  
THE RESULTS OF HBOT IN THE STUDY GROUP

PATIENTS	SEX	AGE	PTA	PTA	PTA	PTA	CURVE type	PRESENTATION days from onset
			pre HBO	30 days	90 days	180 days		
1. M.C.	M	60	55	55	52	52	pantonal	24
2. V.I.	F	27	45	30	32	32	low frequency	31
3. P.D.	M	38	55	35	30	30	medium frequencies	35
4. I.C.	M	44	50	25	20	20	low frequency	21
5. R.H.	F	50	77	75	75	75	high frequencies	40
6. H.I.	M	37	95	92	90	90	cophosis	42

response to treatment), whereas a PTA less than 15 dB it was appreciated as a negative response to treatment. All audiometric studies were performed by the same certified audiologist under standard conditions, at audiology laboratory of the National Institute of Aeronautical and Spatial Medicine.

Regarding statistical analysis, the majority of data are presented in numeric and percent form. Due to the low number of patients in the study, the statistical tests are meaningless.

### Results and discussions

All 6 patients (4 male and 2 women) were initially treated with corticosteroids - as primary and exclusively treatment by other doctors, in different clinics. Before HBOT they have completed and signed the informed consent. All patients have met the exclusion / inclusion criteria and agreed to participate at the study.

The mean age was 42.66 years. The mean time of presentation was 32.16 days. Two additional signs have occurred more frequently - tinnitus and vertigo. Dizziness was always associated with tinnitus and was present in all cases.

The mean of initial pure tone audiometry (PTA) was quantified at 62.83 dB for the whole group. There was registered no complication specific to HBOT. The patients follow-up was conducted at 30, 90 and 180 days from the start of HBOT. The periodic review included tonal audiometry. The auditory thresholds for all frequencies (0.25, 0.5, 1, 2, and 4 kHz) were determined and expressed in dB.

First of all, must be mentioned the higher incidence (even without statistical significance due to the small number of patients) of ISSNHL in men (4 patients) in the evaluated group.

To an overview of the data contained in the results table of HBOT, one can easily see that only 3 patients (50%) have achieved an improvement in auditory capacity. Among them one showed a marked improvement (red)

and two a partial improvement (blue). For the other three there was no favorable development of hearing in the affected ear.

In patients who responded positively to HBOT, an association with the type of curve *low frequency* or *medium frequencies* was observed. Despite the small number of patients included in the study, in the audiometric study at the time of presentation all five typical types of specific curves were recorded.

There is no consensus on the HBOT as salvage treatment in ISSNHL. A brief review of medical articles on this subject fully confirms the previous statement [6-10].

Thus, Ajduk et al, 2017, has conducted a study in which ninety-three patients with ISSNHL were initially unsuccessfully treated with systemic steroid therapy. Following steroid therapy, 43 patients received additional HBO therapy while 50 did not. A significant difference in hearing thresholds after HBO therapy was found at all frequencies in patients with a hearing loss of >61 dB. The group of patients with a hearing threshold of ≤ 60 dB had a significant improvement only at 250 and 500 Hz. [6].

Alimoglu et al, 2016, conducted a study on 32 patients with ISSNHL and concluded that the mean gain in pure tone average after HBOT was  $10.55 \pm 13.56$  dB. Three patients had complete recovery, 1 had partial recovery, 5 had slight recovery and 25 had no improvement [7].

Psillas et al., 2015, has recommended that Hyperbaric oxygen therapy should be suggested to all patients for whom initial conventional medical treatment for SSHL has failed [8]. Unlike this author, Lawrence et al., 2015, signaled the controversies in the management of sudden sensorineural hearing loss, using an evidence-based review [9]. In the same year, 2015, Pezzoli et al., presented the results of his study on 58 patients with ISSNHL who failed to recover after primary treatment with IV steroids. 23 patients of them were treated (mean age 47.3, 16 males, age range 22-74) with hyperbaric oxygen therapy (HBO) (2.5 ATA for 60 min for 15 treatments). The author



concluded that the mean improvement was significantly better in patients treated with HBO compared to controls [10].

Withal, the initial treatments with corticosteroids (route of administration, doses) appear to be quite important in total auditory recovery [11-13].

The disadvantages of HBOT are meaningful. Mild anxiety was overcome by explaining the method in detail and emphasize that the patient is always under the supervision of an anesthesiologist - intensive care doctor / hyperbaric medicine physician who can intervene at any time, if it will be necessary.

### Conclusions

The HBOT method has shown an efficacy of 50% in our study, as salvage treatment in Idiopathic Sudden Sensorineural Hearing Loss, after initially corticoids therapy. Thus, we can assert without doubt that HBOT represents a viable option for those patients who want to continue the effort to regain hearing. The results obtained on the patient's group were encouraging and open up new research paths such as the use of HBOT in the reconstructive surgery of the head and neck. The treatment with HBOT improves the vascularization of the tissues and leaves the area of interest in better conditions for the reception of free or pedicled flaps. Under the auspices of the national ENT society, through a collective effort, can be achieved a therapeutic consensus in the sensorineural hearing loss. In this consensual document, HBOT can be found both as initial and salvage therapy, alone or in the multimodal therapeutical variant. Further, the National Health Insurance House must introduce in the methodological norms the reimbursement of HBOT sessions in the fixed amount or in varying amounts

depending on the results of the intermediate audiological checks, in order to offer this new therapeutic solution to all patients.

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