

Hyperbaric oxygen therapy (HBO₂) as an adjunct in the treatment of idiopathic sudden sensorineural hearing loss (ISSHL) – A case report on two patients

Diane Yacono, R.N., APN-C¹, Michael W. Allen²

¹ Central Jersey Wound Treatment Center, CentraState Medical Center, Freehold, New Jersey USA

² Life Support Technologies Inc., Tarrytown, New York USA

CORRESPONDING AUTHOR: Michael W. Allen – allen@lifesupport-usa.com

ABSTRACT

We report on two cases of idiopathic sensorineural sudden hearing loss (ISSHL) successfully treated at our center. The patients were referred to us by a neurotologist for adjunctive hyperbaric oxygen therapy and were treated using a standard 2.4 atmospheres absolute (atm abs) 90-minute protocol with two five-minute air breaks. During this period the referring physician administered injections of steroids at his offices. The outcome in both cases was positive and produced significantly improved scores in both speech reception and speech discrimination.

In October 2011, the UHMS added ISSHL to its list of approved indications. Despite this and an increasing body of literature that supports the use of hyperbaric oxygen therapy as an adjunct in the treatment of ISSHL, it has not yet been accepted for reimbursement by CMS and, in our experience, commercial carriers. We believe it would be beneficial in developing the case for reimbursement in this indication if all facilities record and submit their results to a national database perhaps organized and managed by the UHMS.

INTRODUCTION

Idiopathic sudden sensorineural hearing loss (ISSHL) is defined as the loss of at least 30 decibels (dB) in hearing acuity occurring in less than three days over at least three contiguous frequencies with onset ranging from hours to days. Roughly 4,000 new cases of SSSL occur in the United States each year. It can affect anyone, but for reasons not yet understood it mostly affects people between the ages of 30-60 [1]. Incidence appears to show no seasonal variation [2]. The most common clinical presentation is sudden unilateral hearing loss, tinnitus and a sensation of aural fullness, dizziness and vertigo. Often symptoms may be so subtle as to be overlooked by patients and clinicians until the level of hearing loss becomes severe [3]. Possible causes of sudden deafness are varied and include:

- vascular: thromboembolic disease, labile hypertension, or hypotension, microcirculatory disturbances;
- viral infections and post-surgical infections;
- metabolic disorders: hyperlipidemia, diabetes;
- toxic: exposure to ototoxic drugs, carbon monoxide poisoning

- diving injuries: barotrauma, decompression sickness affecting vestibular function; and
- miscellaneous: rupture of the round window membrane, intralabyrinthine membrane rupture, stress.

Background

One long-standing explanation of ISSHL is that it is caused by vascular insufficiency such as may occur with occlusion of the labyrinthine artery. This, however, has yet to be conclusively demonstrated. In 1971 Lamm and Klimpel [4] suggested circulatory disorders were a significant part of the pathology of ISSHL. In 1979 Goto and Fujita, *et al.* [5] reported on the beneficial effects of hyperbaric oxygen (HBO₂) as an adjunct to stellate ganglion blocks. Since that time other studies have pointed to the value of HBO₂ as an adjunct in the treatment of ISSHL.

HBO₂ is an adjunctive treatment in which oxygen is delivered to a patient in a whole body chamber at pressures up to three times the normal atmospheric pressure. In 2007 Fujimura and colleagues [6] reported that HBO₂ and steroids showed significant benefit over steroids alone in patients with severe hearing loss. In

2010 Ohno, *et al.* [7] reported that hearing gain was significantly higher in patients with profound hearing loss when HBO₂ was used secondary to conventional treatment. In their 2011 retrospective study, Körpınar, *et al.* [8] reported that HBO₂ has beneficial effects when used early in the disease together with steroids and recommended its use especially in cases of profound or total hearing loss. In 2011, Alimoglu, *et al.* [9] reporting on a comparison of oral steroids, oral HBO₂, intratympanic (IT) steroids, and HBO₂ alone found that HBO₂ in combination with oral steroids had the highest likelihood of recovery. It should be noted that no patients in this study received the IT steroids and adjunctive HBO₂ combination.

In a comparison of 465 audiologically controlled cases, Liu and colleagues [10] found that, when used as an adjunctive to steroids, HBO₂ most significantly benefits patients with profound hearing loss. In their 2012 case report Imsuwansri and colleagues [11] describe a successful outcome in a patient treated with HBO₂ after failing to respond to oral and IT steroids. Filipino and colleagues [12], in their 2012 report, described a series of 48 patients treated in two groups. Group I received HBO₂ daily for 10 days and intravenous methylprednisolone for seven 7 days. Group II received HBO₂ at 2.4 atm abs for 10 days in conjunction with IT injection of prednisolone at a dose of 62.5mg/ml daily for three consecutive days given two hours before the HBO₂ treatment. The overall success rate was superior in the IT steroids-HBO₂ group although not statistically significant due to small numbers. In a 2012 update of their previous reviews (2005, 2007 and 2009) Bennett, *et al.* [13] reported on seven trials (392 patients) and found that, while clinical significance remains unclear, HBO₂ significantly improved hearing in patients with ISSHL.

The most commonly used approach to treatment for this condition is still local infusions to improve microcirculation, and vasodilators. In 2012, however, the American Academy of Otolaryngology – Head and Neck Surgery Foundation sponsored the development of Clinical Practice Guidelines [14]. Among the many recommendations made by the panel were that clinicians may offer patients with ISSHL (1) corticosteroids as initial therapy and (2) HBO₂ within three months of diagnosis. They also noted that results seemed to be better if treatment were administered within 14 days of onset. This position on earlier intervention is supported by Murphy-Lavoie, *et al.* [3] who, in their extensively researched review, also found the best evidence sup-

ports administration of HBO₂ within 14 days of onset. An increasing number of otolaryngologists familiar with the literature are recommending and prescribing HBO₂ as an adjunct to appropriate medical management. In this case report we describe the treatment and outcomes achieved with two patients referred to us at the Central Jersey Wound Treatment Center for adjunctive hyperbaric oxygen therapy.

Patient #1

Patient #1 was a 61-year-old female who presented at our center with a diagnosis of sudden hearing loss in her right ear. This had occurred some four weeks prior; the patient was unable to recall anything specific that may have triggered the event. She was initially treated by her primary care doctor with oral antibiotics. After two weeks without improvement she was referred by a neurotologist to our center.

Personal and family history

Past medical history: pneumonia, gastroesophageal reflux disease, hemorrhoids, necrotizing fasciitis of buttocks, urinary tract infection, gastric ulcers, anemia.

Past surgical history: colostomy with reversal, debridement of buttock.

Allergies: no known allergies (NKA).

Family and social history: mother – diabetic – deceased; father – heart disease – deceased.

Alcohol use: occasional wine.

Smoking: No (denies).

Hearing tests conducted 12/14/2012, prior to starting treatment, showed a profound sensorineural loss in the right ear with absent speech discrimination and normal hearing in the left ear with a speech reception threshold (SRT) of 10 (dB) and speech discrimination score (SDS) of 100%. Based on these findings the patient was prescribed a course of three IT steroid injections and a course of adjunctive hyperbaric oxygen therapy. The patient's commercial insurance carrier authorized a course of 10 HBO₂ treatments.

Intervention and outcome

Patient received three IT injections (Dexamethasone 40 mg/cc, total volume 0.5cc/injection) into the right ear, administered over a one-week period. The patient received a total of 10 HBO₂ treatments over a period of 12 days, daily five days per week (01/7/13 to 01/18/13). Treatment was delivered in a monoplace chamber. Each treatment consisted of 90 minutes at a

pressure of 2.4 atm abs with two five-minute air breaks and one each ten-minute period for compression and decompression for a total of 110 minutes per treatment. The patient responded well to this plan of care. A hearing test completed following the tenth hyperbaric treatment showed significant improvement with the SRT and SDS values for the right ear at 65 dB and 80% respectively.

After a thorough evaluation, it was recommended the patient receive an additional 10 treatments in order to optimize the outcome and consolidate the benefits gained. The patient received no further hyperbaric therapy; her insurance carrier would not authorize any additional treatments, and the patient was unable to self-pay. On 2/12/13 the patient had a follow-up hearing test at which time the right ear SRT and SDS values had regressed to 55 dB and 52% respectively.

Patient #2

Patient #2 was a 58-year-old female who presented at our center with a diagnosis of sudden hearing loss in her right ear. This had occurred some four weeks prior following an exercise class. She was initially seen by a local ENT physician who referred her to a neurotologist.

Personal and family history

Past medical history: osteoarthritis in the hands, thyroid disease, insomnia.

Past surgical history: No previous surgical history.

Allergies: no known allergies (NKA).

Family and social history: Not known.

Alcohol use: Occasional only.

Smoking: No (denies).

Hearing tests conducted 04/18/2013, prior to starting treatment, showed a profound sensorineural hearing loss in the right ear (SRT 70 dB and SDS 0%) and borderline normal hearing for the left ear. Based on these findings, the neurotologist prescribed a course of three IT steroid injections and a course of adjunctive hyperbaric oxygen therapy.

Intervention and outcome

The patient received three IT steroid injections (dexamethasone 40mg/cc, 0.5cc/injection) into the right ear administered on a standard protocol from the neurotologist. The patient received a total of 20 hyperbaric treatments adjunctively over a period of 29 days, daily five days per week (from 05/20/2013 to

06/17/2013). Treatment was delivered in a monoplace chamber. Each treatment consisted of 90 minutes at a pressure of 2.4 atm abs with two five-minute air breaks and one each 10-minute period for compression and decompression for a total of 110 minutes per treatment.

The patient's commercial insurance carrier denied treatment, and the patient was unable to self-pay. Based on the results achieved with patient #1, the hospital decided to provide the therapy without charge as part of our long-term commitment to the development of hyperbaric oxygen therapy as a modality of significant benefit.

The patient responded well to the plan of care. A hearing test completed on 06/06/13 during the course of hyperbaric treatment showed significant improvement with SRT and SDS values for the right ear at 70 dB and 44% respectively. A follow-up hearing test conducted seven days after the final hyperbaric treatment showed no substantial changes with right ear SRT and SDS values at 65 dB and 40% respectively.

Significance/uniqueness of these cases

Following an extensive review of the evidence, the Undersea and Hyperbaric Medical Society (UHMS) added ISSHL to its list of approved indications effective October 8, 2011.

These cases in and of themselves are clearly not unique, but were clinically significant at our center in that they were the first cases of ISSHL treated. The outcome in both cases was very gratifying in comparison to the typical outcomes achieved with current management techniques without adjunctive HBO₂. The decision to treat these patients was made based on the UHMS guidelines and our own review of the literature.

DISCUSSION

Available data show that when used as an adjunct to steroids, HBO₂ seems to offer significant improvements in outcome vs. steroids alone. In addition, the data show that of the routes available for administration, intratympanic (IT) injection has produced consistently better results. Intratympanic injection is administered through the tympanic membrane (TM) into the middle ear. Local anesthetic is applied to the TM and the needle is inserted through the posterior-inferior quadrant. While in the supine position the patient's head is turned at about 45 degrees in the direction that places the injected ear uppermost for 30 minutes. Absorption is through the round window membrane. Both of our

patients were approximately four weeks post-onset before commencing treatment. This is beyond the two weeks recommended by Murphy-Lavoie, *et al.* [3] but within the three-month window recommended by the panel in the AAO Clinical Guidelines. Clearly, further research is needed in order to better define the value of this intervention and answer questions such as: *Should HBO₂ and IT steroids be administered concomitantly or consecutively? What is the optimal dose of each drug? Does it follow a typical drug pattern and relate to the severity of the condition? Would earlier intervention, say in the acute rather than the subacute phase, produce even better results?*

In our limited experience, the addition of hyperbaric oxygen therapy as an adjunct to appropriate medical management with steroid injections and other medications has the potential to significantly improve the outcome for patients suffering with ISSHL. This is supported by the literature. To date, the Centers for Medicare and Medicaid Services (CMS) has not approved this indication. Commercial carriers have generally followed CMS' lead and denied coverage for adjunctive hyperbaric oxygen therapy. Currently, it seems that even though a patient may be referred for adjunctive HBO₂ by an ENT specialist, a hyperbaric physician must then generate a letter of medical necessity with supporting data in order to obtain authorization.

In the case of our first patient, the insurance carrier authorized 10 treatments. Despite the fact that the patient responded well, this carrier would not authorize an additional 10 treatments to optimize and consolidate the benefits achieved. Consequently, the patient regressed and ultimately stabilized with much

lower values. We believe our inability to follow through with the additional treatments resulted in a suboptimal outcome for this patient and have since come to believe the initial course of treatment was actually authorized in error by the carrier.

In the case of the second patient, the carrier would not authorize treatment, and the patient was unable to self-pay. The hospital's decision to go ahead and provide treatment based on the results achieved with Patient #1 enabled us to achieve significant beneficial change which otherwise may not have been possible in this case.

It is very important that centers confronting the need to treat this condition publish their findings. It is our opinion, however, that the approach that will ultimately prove most effective is to establish a national database/registry as a repository for the results. We believe such a registry, under the control of a body such as the UHMS will quickly build into a compelling data pool supporting HBO₂ as a valuable adjunct in this indication. This, coupled with other published data, could significantly cut down the time needed to develop the body of evidence that would be acceptable for CMS to approve ISSHL for reimbursement.

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Conflict of interest

The authors have declared that no conflict of interest exists with this submission. ■

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