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RESEARCH ARTICLE

Referral patterns and gaps in financial coverage hinder appropriate treatment of sudden sensorineural hearing loss (SSNHL) with hyperbaric oxygen therapy (HBOT).

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Abstract

Objective: The objective of this web-based survey was to evaluate recent experiences of patients with Sudden Sensorineural Hearing Loss (SSNHL) in regard to treatment with Hyperbaric Oxygen Therapy (HBOT). The delays that exist in the referral process, the lack of awareness regarding the use of HBOT for this diagnosis, and discrepancies that exist in the reimbursement process were explored.

Design: Noninterventional survey of patients with a diagnosis of SSNHL was conducted from May 27, 2022, to July 13, 2022. The survey focused on the referral process, level of awareness in the general population, and level of awareness in the medical community, regarding the use of HBOT for this diagnosis, as well as the reimbursement process. A total of 179 people received the survey.

Results: Sixty-two patients completed the survey. More than half of the patients, 53.2%, surveyed consider themselves as self-referred to HBOT and noted that they were not told about HBOT as a treatment option by a specialist. More than 67% of the patients surveyed report that medical insurance did not cover the cost of HBOT. Overall, the participants reported the successful use of HBOT, with 55.8% having complete or partial improvement. This rate of improvement is potentially higher considering more than half of the patients surveyed reported that they did not complete the recommended course of therapy with many citing costs as the barrier to care.

Conclusion: The survey findings illustrate that patients may not be adequately educated by specialists regarding the addition of HBOT to their plan of care. When the information is conveyed, it is often conveyed after a delay in symptom onset. The lack of, or delay in, education contributes to poorer outcomes. Additionally, many patients who are recommended to receive HBOT are denied coverage by their insurance carriers which prevents access to appropriate care and presents a financial burden to those who seek care regardless. Discrepancies regarding referral, timing of referral and financial coverage levels present barriers to adequate and appropriate treatment, preventing many patients from receiving care that is evidence based.

Keywords: Hearing loss; sudden hearing loss; sensorineural hearing loss; hyperbaric oxygen therapy; insurance coverage; barriers to care

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1 | INTRODUCTION

Hyperbaric Oxygen Therapy (HBOT) involves breathing 100% oxygen, intermittently, while exposed to an environmental pressure higher than one atmosphere absolute (ATA). This treatment is used for many ischemia or hypoxia related indications, including Sudden Sensorineural Hearing Loss (SSNHL). Evidence shows that when used as part of a combination treatment, the use of HBOT is significantly associated with improved hearing outcomes in patients with SSNHL. The American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF)'s 2021 update to the Clinical Practice Guideline: Sudden Hearing Loss in Otolaryngology–Head and Neck Surgery suggests that clinicians may offer hyperbaric oxygen therapy (HBOT) combined with steroid therapy as an initial therapy, within two weeks, or as a salvage therapy, within one month, of onset of SSNHL.(22) Despite these recommendations and the evidence of the beneficial effects of Hyperbaric Oxygen Therapy (HBOT) in conjunction with steroids for the treatment of Sudden Sensorineural Hearing Loss (SSNHL), many specialists do not inform patients of HBOT as a treatment option or do not address it in a timely manner. Inconsistent and inadequate insurance coverage further complicates the treatment of this condition with HBOT. These two factors contribute to unnecessary barriers to adequate care by delaying or preventing access to hyperbaric care in the treatment of SSNHL.

To evaluate the barriers to care in the management of SSNHL, a noninterventional survey of patients with a diagnosis of SSNHL was conducted from May 27, 2022, to July 13, 2022. The goal of the survey was to assess the experience of patients who had contacted one of our five facilities seeking care for the diagnosis of SSNHL. The survey focused on the referral process, level of awareness in the general population, and level of awareness in the medical community, regarding the use of HBOT for this diagnosis, as well as the reimbursement process. A total of 179 people received the survey. Sixty-two patients completed the survey. More than half of the patients surveyed consider themselves as self-referred to HBOT and were not told about HBOT as a treatment option by a specialist.Thirty-two of 62 participants learned about HBOT through their own research or from a friend or family. More than 67% of the patients surveyed report that medical insurance did not cover the cost of HBOT. More than half of the patients surveyed reported that they did not complete the recommended course of therapy with many citing costs as the barrier to care.

1.1 | SUDDEN SENSORINEURAL HEARING LOSS

Sudden Sensorineural Hearing Loss (SSNHL), which is also termed Idiopathic Sudden Sensorineural Hearing Loss (ISSHL), involves a spontaneous onset of hearing loss that usually presents unilaterally with no obvious cause. Most cases are idiopathic, occur within a 72-hour period and the prognosis for hearing recovery depends largely upon the severity of the hearing loss.(7) Additional symptoms may include tinnitus, aural fullness, dizziness and vertigo. Estimates of incidence range from 11 to 77 per 100,000 people per year.(2) SSNHL affects individuals of all ages, including pediatric and geriatric patients, most commonly affecting individuals 43 to 53 years old with similar numbers of males and females affected. (9),(18) Although the precise underlying etiology is unknown, the most common causes mentioned in reported studies areviral infections, vascular disorders, and autoimmune responses.(14) Many mechanisms have been theorized to be associated with this hearing loss including trauma, disturbances in circulatory function, damage to the cochlear membrane, neoplasms, abnormal cochlear stress responses and leaks of the labyrinthine membrane. Auditory trauma secondary to loud noises may contribute to sudden hearing loss due to prolonged

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times of action potential, hair cell function may decline 60-70% which contributes to intracellular sodium accumulation causing microstructural damage. Circulatory impairment may contribute to sudden hearing loss as a lack of proper blood flow contributes to hypotension within the cochlea and results in ischemia and nerve damage.(14) Much of the data shows that a decreased blood flow and nerve damage to the cochlear site is likely to be an underlying cause. More than 90% of cases are idiop -athic and the remainder are due to causes such as acoustic neuroma, stroke, malignancy, Meniere's disease, trauma, autoimmune disease or infection. (21)

Due to the unclear etiology for the onset of sudden hearing loss, the condition is difficult to treat. Treatment that has been recommended includes the use of agents to decrease blood viscosity, drugs and procedures designed to induce vasodilation, anticoa-gulants, antiviral agents, free radical scavenging vitamins, antibiotics, corticosteroids and hyperbaric oxygen therapy.(14) The use of corticosteroids, administered orally and/or injected directly, is meant to reduce inflammation and edema so that damage can be reduced and encourage healing. The use of steroids increases cochlear blood flow and ameliorates cochlear ischemia, regulates protein synthesis, and alters the inner ear electrolyte and fluid balance.

1.2 | HBOT AS A TREATMENT FOR SSNHL

HBOT increases the oxygen diffusion distance from capillary beds approximately 10-fold resulting in the supersaturation of skin and subcutaneous tissue. (11)HBOT has a strong anti-inflammatory effect that increases the ischemic tolerance of organs. Often with tissue reperfusion, the adherence of circulating neutrophils to vascular endothelium impairs perfusion however HBOT inhibits this adherence of the neutrophils preventing reperfusion injury.(6)HBOT is generally safe and well tolerated with the only absolute contraindications being an untreated pneumothorax.(10),(5)

he vascular physiology of the inner ear likely plays a key role in the underlying etiology of SSNHL and the effect of HBOT on this pathology. he structures in the cochlea are dependent on oxygen supply and vulnerable to changes in perfusion. The supply to the cochlea depends on oxygen diffusion through the capillaries rather than through direct vascular oxygenation. The cochlea receives oxygen through diffusion from cochlear capillary networks into the perilymph and cortilymph and the perilymph provides the main oxygen source for structures within the cochlea.(14) Norm baric oxygen increases intracochlear oxygen tensions but, unlike HBOT, it cannot achieve the high arterial perilymph oxygen concentrations that are needed to effectively perfuse the structures within the cochlea. Because HBOT increases oxygen partial pressure supplied to the inner ear by 9.4-fold, this treatment minimizes ischemic damage, reduces ischemic reperfusion injury, reduces edema, minimizes inflammatory response and promotes angiogenesis.(19),(14)

Corticosteroids, either orally or intratympanically, are recommended as an initial therapy in patients with SSNHL and should be given within 2 weeks of symptom onset. According to clinical guidelines, HBOT may be combined with steroid therapy and used as an initial treatment or salvage therapy, particularly in patients with severe to profound hearing loss at baseline.(12) HBOT in addition to medical therapy (corticosteroid therapy) has been shown to offer the most benefit for SSNHL. HBOT and medical therapy have more benefit than medical therapy alone especially in those with SSNHL who had severe to profound hearing loss and who received a prolonged total HBOT duration of 10 to 20 sessions. (19)In a systematic review and meta-analysis, published in 2021 in JAMA Otolaryngology, HBOT as part of a combination treatment was significantly associated with improved hearing outcomes in patients with SSNHL compared to control treatment. In this review, three prospective RCTs were reviewed. A total of 88 participants who received HBOT in the intervention groups and 62 participants who received only medical therapy in the control groups were studied. The intergroup difference in mean absolute hearing gain (mean difference, 10.3 dB; 95% CI, 6.5-14.1 dB; I2 = 0%) and the odds ratio of hearing recovery (4.3; 95% CI, 1.6-11.7; I2 = 0%) showed significant benefit of HBOT compared to the control therapy.(13) In a recent retrospective chart

review of 158 patients who were treated with HBOT for SSNHL, the time of onset to have optimal effect was 12.5 days. Their data showed that the patients who started HBO therapy within 12 days had 6.484 times the greater effect in hearing gain and hearing recovery rate than those who started HBOT after 13 days.(8)

The Cochrane Database review found that using HBOT improves hearing loss by 37.7 dB for those with severe hearing loss and 19.3 dB with modeate loss. The review also showed there was a 22% greater chance of improvement with HBOT.(4) The review also found that when HBOT is initiated close to onset of SSNHL, hearing loss is significantly improved.(4),(15) The best results are obtained when treatment with HBOT and steroids are combined and initiated within 14 days of symptom onset, with HBOT administered at 2-2.5 ATA for 90 minutes for 10-20 sessions, with sessions given daily, 5 times per week for 2-4 weeks.(15) Reviews of randomized, controlled trials as well as retrospective analyses of patient outcomes illustrate the efficacy of using HBOT for SSNHL although the therapy does not seem to be widely or promptly offered.

1.3 | INSURANCE COVERAGE OF HBOT

Sudden hearing loss is listed as one of the approved conditions for which hyperbaric chambers are cleared for marketing by the FDA. The Undersea Hyperbaric Medicine Society (UHMS) added ISSHL to its list of approved indications in 2011.(16) However, Medicare does not include it on the list of covered indications. It is not typical for the FDA to approve the use of a HBOT for a diagnosis when Medicare does not. It is also unusual for selective commercial third-party payors to approve coverage of a certain indication when Medicare does not consider that condition as an approved indication. However, with this diagnosis a small number of commercial insurances provide coverage while other insurers, including Medicare, do not.

Medicare defines hyperbaric oxygen therapy (HBOT) as a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. The current Medicare guidelines provide coverage of HBOT for the following conditions: Acute carbon monoxide intoxication, Decompression illness, Gas embolism, Gas gangrene, Acute traumatic peripheral ischemia, Crush injuries and suturing of severed limbs, Progressive necrotizing infections, Acute peripheral arterial insufficiency, Preservation of compromised skin grafts, Chronic refractory osteomyelitis, Osteoradionecrosis as an adjunct to conventional treatment, Soft tissue radionecrosis as an adjunct to conventional treatment, Cyanide poisoning, Actinomycosis, only as an adjunct to conventional therapy, Diabetic wounds of the lower extremities in patients who meet specific criteria.(17)

Several commercial insurers also list Sudden Sensorineural Hearing Loss on their policies as an approved indication for the use of HBOT. For example, Aetna lists: “Idiopathic sudden sensorineural hearing loss (SSHL) - SSHL greater than 30 dB affecting greater than 3 consecutive frequencies of pure-tone thresholds when member has failed oral and intra-tympanic steroids, and HBOT is initiated within 3 months after onset (up to 20 sessions);” in its medical policy, Hyperbaric Oxygen Therapy, policy number 0172.(1)

The discrepancies in insurance coverage may limit provider referrals. Due to the lack of clear coverage patterns, providers may have a preconceived notion that the treatment will be costly for the patient and/or that the use of this treatment is still investigational.

2 | METHODS

2.1 | STUDY DESIGN

This was a noninterventional, Web-based survey of patients with a self-reported provider diagnosis of SSNHL when submitting online registration forms to one of our facilities. Locations were in New York, Massachusetts, and Florida. Patients were identified through a search in our Salesforce database for keywords ‘patient’ and ‘condition: Sudden Hearing Loss.’ Key eligibility criteria included the following: person reaching out to our facility with the reason for seeking care listed as Sudden Hearing Loss. A total of 179 patients were identified as having received treatment from January 2015 to July 2022. An email

invitation was sent containing a link to an electronic survey. The survey was sent to the email address that patients had provided at the time of contacting our facility. Sixty-two participants completed the survey with a response rate of (62/179) 34.6%. Information collected was optional and de-identified. Participants were given the option to have a staff member contact the participant via phone versus completing the survey independently online. If that option was chosen, participants were contacted, and survey questions and answers were communicated over the phone. Reminder emails were sent at approximately 1 and 2 weeks after the initial invitation if no response was received.

The survey consisted of questions related to demographics, SSNHL condition presentation, and treatment history, and questions regarding the referral process and level of insurance coverage (see Fig. 1). Participants were not compensated for their time. Data was collected between May 27, 2022, and July 13, 2022. This study was deemed exempt from IRB approval; authors abided by established international research codes.

1. Current Age (in years) 2. Age at time of treatment/diagnosis of Sudden Hearing Loss? 3. Approximate date of start of hearing loss? 4. Sex assigned at birth 5. How were you referred to Hyperbaric Oxygen Therapy (HBOT)? 6. If you were referred by a specialist, when did your provider discuss the use of HBOT? 7. How did you first learn about HBOT? 8. Did your medical insurance cover the cost of HBOT? 9. How many sessions of HBOT did you complete?	10. Did you complete the recommended number of HBOT sessions (typically 20)? 11. If you did not complete the recommended number of HBOT sessions (typically 20), why? 12. Did you receive steroids for this diagnosis? 13. If you received steroids, how were they administered? 14. How many days (approximately) passed between onset of hearing loss symptoms and the start of HBOT 15. Did you have improvement in your hearing loss?

Figure 1. *Survey Questions*

ELIGIBILITY CRITERIA

Patients were eligible if the following conditions were met: (1) age of 18 years or older, (2) a self-reported physician diagnosis of SSNHL (3) ability to understand and complete the survey in English.

ANALYSES

Descriptive analyses were conducted as follows: continuous variables were reported through measures such as number of available observations, mean and medians, minimums, and maximums; variables were summarized by frequency and percentage. Non-numeric free-text responses were recorded in a list format. Analyses were performed only on observed data; no imputation was made for missing values.

3 | RESULTS

A total of 62 participants of the 179 who were deemed eligible completed the survey. The average age of patients surveyed was 52.9 years old at the time of survey participation. Average age at symptom onset and diagnosis was 51.1 years with a range of 24 to 78 years of age. Thirty-three of the participants identify as male, 28 as female and 1 as non-binary.

As shown in Figure 2, more than half of the patients surveyed, 33/62 (53.2%) were self-referred for HBOT. of the remaining 29 patients, 26/62 (41.9%) were referred by an Ear, Nose and Throat (ENT) provider and 3/62 (4.8%) were referred by another type of physician/provider.

I referred myself	33
Ear/Nose/Throat specialist (ENT) referred me	26
Other physician/provider referred me	3

62 responses

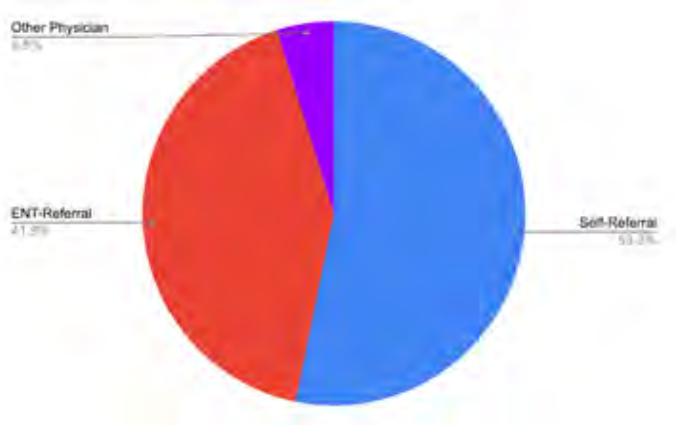

Figure 2. *How were you referred to Hyperbaric?*

Figure 3 illustrates the ways in which participants learned of HBOT for their condition. Twenty eight of the 62 (45.1%) participants learned about HBOT through their own research and 4 (6.5%) learned about HBOT from a friend or family.

A specialist told me about HBOT	30
I learned about HBOT through my own research	28
A friend/family member told me about HBOT	4

62 responses

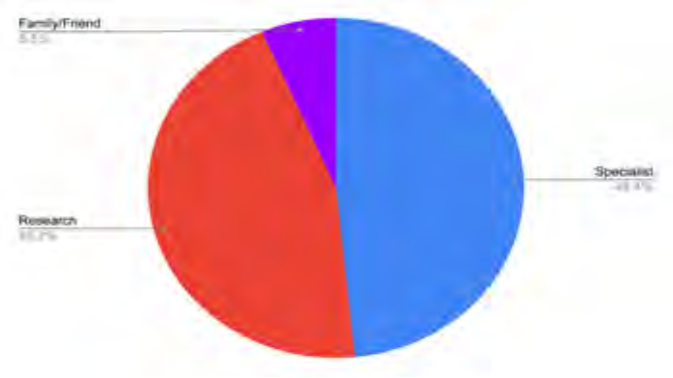

Figure 3. *How did you first learn about Hyperbaric for this condition?*

As shown in Figure 4, greater than 66.2% of patients report that medical insurance did not cover the cost of their HBOT; leaving 33.8% of patients receiving insurance coverage for their treatment.

Yes	21
No	41

62 responses

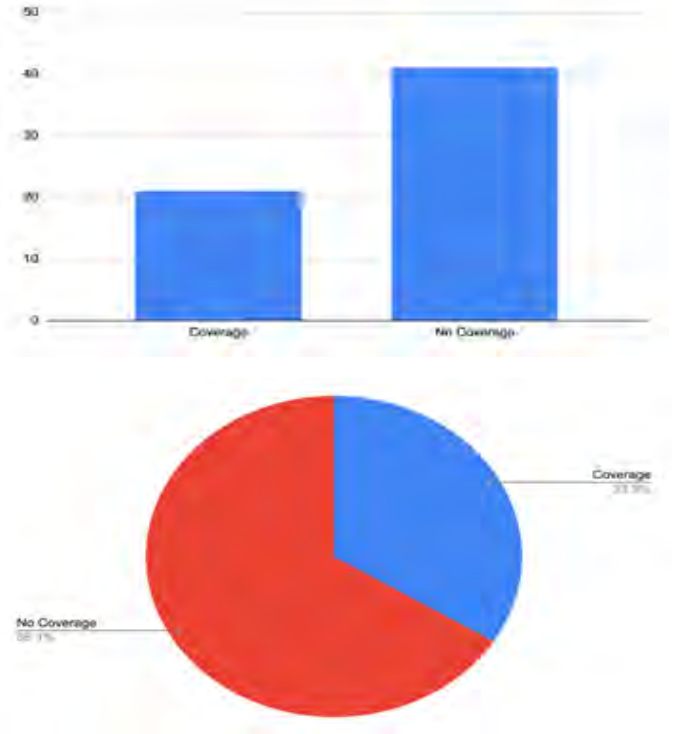

Figure 4. *Did your medical insurance cover the cost of HBOT?*

Of those surveyed, 34/62 (54.8%), reported that they did not complete the recommended course of therapy. Amongst the 31 patients who cited a reason for non-completion, 8 (25.8%) cited cost as their reason.

Of the 27 patients who discussed HBOT with a specialist, 11/27 (40.7%) discussed HBOT at the 3rd or 4th visit or later. 7/27 (25.9%) report discussing HBOT at the 2nd visit. 9/27 (33.3%) discussed HBOT at the first visit. The majority of patients' specialists (66.7%) did not discuss the addition of HBOT at 1st visit.

On average, the participants completed 13.2 sessions (range 0-20) with a median session number of 10. Twenty-seven of the 62 (43.5%) completed the recommended 20 session protocol. Of the 31 patients who selected a reason for completing fewer than the recommended 20 sessions, 8 (25.8%) cited cost. Other reasons cited for non-completion included, work conflicts, time, travel, other illness, confinement anxiety and discomfort in chamber.

The patients who reported that their medical insurance covered the cost of treatment received on average 17 sessions. Those who did not have insurance coverage received on average 12.5 sessions.

When asked about other therapy utilized, 58 (93.5%) participants reported receiving steroids either: by mouth only (14.5%), by intratympanic injection only (30.6%), and through a combination of dosing routes (45.2%). Four of the 62 participants (6.5%) did not receive steroids at all.

Patient perceived outcomes of treatment were also reported. Fourteen of 62 (22.6%) reported complete improvement and 20 (35.5 %) reported partial improvement. 55.8% of participants surveyed experienced either complete or partial improvement and 28 of 62 (45.2%) reported no improvement.

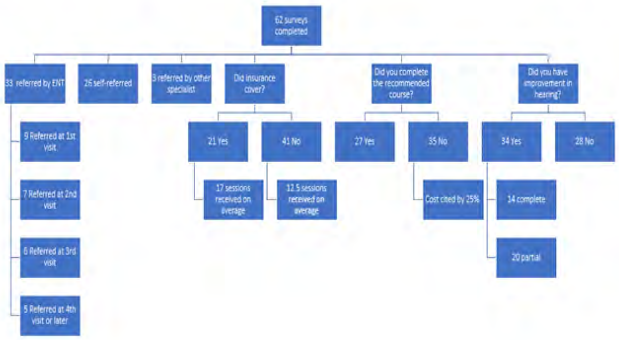

***Figure 5**. Survey outcomes summary*

4 | DISCUSSION

This web-based survey captured recent experiences of patients with SSNHL that had received treatment with HBOT or had submitted an inquiry regarding initiating HBOT care with the aim of evaluating the delays that exist in the referral process, the lack of awareness regarding the use of HBOT for this diagnosis within the medical provider and also the general population, as well to shed light on the discrepancies that exists in the reimbursement process, hoping to identify barriers to care and therefore gaps that exist in prompt and successful treatment.

Overall, the participants reported the successful use of HBOT, with 55.8% having complete or partial improvement. This rate of improvement could potentially be higher considering that less than half, 43.5%, of participants surveyed reported completing the recommended course of treatment. The age range and gender distribution are consistent with the reported incidence of SSNHL.(18)

Our findings illustrate that patients may not be adequately educated by specialists regarding the addition of HBOT to their plan of care. When the information was conveyed, it was often conveyed after a delay in symptom onset. The lack of, or delay in, education contributes to poorer outcomes.

Many patients who are recommended to receive HBOT are denied coverage by their insurance carriers which prevents access to appropriate care and presents a financial burden to those who seek care regardless.

Evidence based practice recommends a course of HBOT with 90 mins of 100% O2 at 2.0-2.4 ATA with sessions administered daily, 5 times per week, for 20 sessions. Our findings showed that on average, patients received 13.2 sessions with a median of 10 sessions, with 43.5% of participants completed the recommended 20 sessions. Our findings demonstrate efficacy in our participant population even considering the high rate of non-completion which further illustrates the importance of increased awareness surrounding the use of HBOT for SSNHL.

A review of the literature pertaining to SSNHL treatment reveals minimal data regarding referral patterns and treatment trends. A survey of physicians in 2009 found that general practitioners and otolaryngologists had differing approaches to SSNHL. The authors cited the lack of strong evidence-based guidelines for the treatment of SSNHL as a potential source of this variation.(20)

The discrepancies regarding referral, timing of referral and financial coverage levels present substantial barriers to adequate and appropriate treatment, preventing many patients from receiving care that is sufficient and evidence based. Future research is needed to evaluate the trends in the management of SSNHL to create a more unified and evidence-based treatment protocol.

RECOMMENDATIONS

Based on our findings, it is recommended that specialists who evaluate and diagnose SSNHL also provide education regarding the addition of HBOT to the plan of care.

It is recommended that acute care, ENT, primary care and other specialists who encounter SSNHL receive education to increase awareness regarding local quality HBOT providers that can provide care their patient referrals.

It is also recommended that the diagnosis of SSNHL be added to the list of Medicare and all other third-party payors approved indications to offer equitable financial coverage.

LIMITATIONS

Response bias is a limitation of all surveys due to the perceived relevancy of the respondents.(3) This survey was sent to 179 email addresses, and 62 responses were collected. Several of the non-responders' email addresses were no longer valid at the time of survey which reduces the actual amount of non-response bias. Another limitation of all studies is whether the population included in the data is reflective of an entire population. Since there were only 62 responses, it is difficult to determine if this is representative of the patient population. Limited demographics were collected within the survey. It would have been helpful to have collected data regarding race, ethnicity, education level and socioeconomic status which may demonstrate further health disparities. The selection of respondents was selected from the author's practice locations and therefore may not be representative of the general patient population. Given the online nature of this survey, there could be bias towards individuals who were proficient in reading and writing in English and have access to the technology needed to complete the survey.

5 | CONCLUSION

The findings of this survey demonstrate that patients with SSNHL may not be adequately educated by specialists regarding the addition of HBOT to their plan of care. When the information is conveyed, it is often conveyed after a delay in symptom onset. The lack of, or delay in, education contributes to poorer outcomes. Additionally, many patients who are recommended to receive HBOT are denied coverage by their insurance carriers which prevents access to appropriate care and presents a financial burden to those who seek care regardless. Discrepancies regarding referral, timing of referral and financial coverage levels present barriers to adequate and appropriate treatment, preventing many patients from receiving care that is evidence based. Future research is needed to address the underlying reasons for these variations in treatment protocols, delays in referral and discrepancies in insurance coverage.

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