

# Hyperbaric oxygen therapy for idiopathic sudden sensorineural hearing loss: a cohort study of 10 versus more than 10 treatments

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## Keywords

Dose; Hyperbaric research; Number of treatments; Outcomes

## Abstract

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**Introduction:** Current treatment of idiopathic sudden sensorineural hearing loss (ISSNHL) includes a combination of corticosteroids and hyperbaric oxygen therapy (HBOT) without established dose. The objective of this study was to investigate whether > 10 HBOT treatments offers improved outcome over 10 treatments.

**Methods:** A retrospective chart review was performed of patients treated with HBOT for ISSNHL between 2013 and 2022 at the Royal Brisbane and Women's Hospital. Pure tone average results from 500, 1,000, 2,000, 4,000 hertz (PTA4) were obtained pre-treatment, after treatment 10, and six weeks post-treatment.

**Results:** There were 479 patients treated for ISSNHL: 144 having audiograms six weeks post-treatment, 140 of whom also had an audiogram after treatment 10. At six weeks post treatment 22% (32/144) had normal hearing (PTA4 < 25 dB), and 69% (99/144) had a PTA4 gain ≥ 10 dB. At the treatment 10 audiogram, 83/140 (59%) were improved. From these, 5/21 (24%) with 10 treatments and 14/57 (25%) with > 10 treatments had a further PTA4 gain of ≥ 10 dB occurring after treatment 10. For those 57/140 (41%) not improved at treatment 10, 7/26 (27%) with 10 treatments and 12/31 (39%) with > 10 treatments were improved at six weeks post-treatment with 5/7 (71%) and 8/12 (67%) of the 10 and > 10 groups respectively having ≥ 10 dB gain in PTA4 occurring after treatment 10. Overall, there was no significant difference in mean (SD) hearing gain from treatment 10 to six weeks post treatment between the 10 treatments and > 10 treatments groups: 4.73 (8.90) versus 5.93 (11.25) dB,  $P = 0.53$ .

**Conclusions:** In conjunction with steroids, 10 treatments of hyperbaric oxygen therapy appear to offer equivalent benefit to > 10 treatments. Similar improvements in PTA4 and hearing recovery occur after 10 HBOT treatments independent of ongoing HBOT. A prospective trial comparing 10 versus > 10 treatments for ISSNHL with outcome measured beyond treatment completion is warranted.

## Introduction

Idiopathic sudden sensorineural hearing loss (ISSNHL) is defined as an unexplained hearing loss of at least 30 dB in three consecutive frequencies on the audiogram which manifests within three days.<sup>1-3</sup> This occurs in between two and 30 people per 100,000 population depending on geographical area, and its incidence appears to be increasing.<sup>4-8</sup> Although the natural history of this form of hearing loss is not well defined, several studies have reported that 30–65% of cases will improve spontaneously, with the majority improving in the first two weeks following the loss.<sup>9-11</sup>

Given the consequences of hearing loss and lack of a unifying causative factor, many treatment options have been

trials including corticosteroids, vasodilators, vitamins, anticoagulants, and hyperbaric oxygen therapy (HBOT). The 2019 American Academy of Otolaryngology-Head and Neck Surgery clinical practice guidelines for sudden hearing loss suggest that a combination of HBOT and steroids started within 14 days provides the best opportunity for recovery,<sup>3</sup> with rates of improvement being around 60–70% with this regimen.<sup>12-16</sup>

Despite the recommendation for use of HBOT, no optimal duration of this therapy has been defined. In a survey of European hyperbaric centres in 2016, the number of treatment sessions varied from five to 40.<sup>17</sup> The Undersea and Hyperbaric Medical Society (UHMS) guidelines currently recommend 10 to 20 daily HBOT sessions for the treatment of ISSNHL<sup>18</sup> and many units utilise audiograms

at 10 treatments to determine the utility of further sessions and to aid with resource allocation.<sup>19</sup>

Given the cost, risk for complications, and inconvenience to patients, it is important to know whether more than 10 HBOT treatment sessions provide additional clinical benefit. To our knowledge, no studies have directly investigated this question. The objective of this study was therefore to investigate whether completion of more than 10 HBOT treatments among patients with ISSNHL is associated with improved outcomes.

**Methods**

The project was reviewed and approved by the Townsville Hospital and Health Service ethics review board and found to be exempt from full ethics review as it is considered negligible risk research. (EX/2022/QTHS/88690 [Aug ver 2]).

The Royal Brisbane and Women’s Hospital Hyperbaric Medicine Unit currently treats ISSNHL with 10 to 20 sessions of 80 minutes breathing oxygen at 243 kPa (2.4 atmospheres absolute pressure) with a five-minute mid-session air-break (40 minutes – five minutes – 40 minutes). Our unit routinely accepts patients diagnosed with ISSNHL for treatment within 14 days of onset of hearing loss, and for salvage therapy up to 30 days from the loss. Occasional patients are accepted outside these timeframes or for less severe loss if there are extenuating circumstances such as new hearing loss in the only functioning ear or occupational dependence on hearing.

All patients are concurrently followed by an ear, nose and throat specialist and are treated with oral or intratympanic steroid unless there is a contraindication. An audiogram is routinely performed prior to the start of HBOT and after treatment 10. Following this, an individualised decision is made to continue or end HBOT based on improvement in the pure tone average scale (PTA4), speech discrimination, and patient factors.

This study used a retrospective cohort design and initially included all patients treated in our unit from January 2013 – December 2022. Charts were obtained from the clinic database using the code for ISSNHL. Only patients who had an audiogram performed six weeks following the end of HBOT were included in the final study. Patients were also excluded if they had not completed at least eight treatments. Number of treatments were defined as ‘10 treatments’ for eight to 12 HBOT sessions (some patients had one or two sessions past 10 while awaiting audiology), and ‘> 10 treatments’ for 13 or more sessions. Improvement in hearing was defined as ≥ 10 dB gain in the four frequency PTA4 between audiograms. Normal hearing was defined as PTA4 of < 25 dB.

Data were analysed using Stata 17.1 (StataCorp LLC, College Station, USA). Analysis was primarily descriptive.

Prior to analysis, continuous variables were assessed for their underlying distribution using histograms. Normally or near normally distributed variables were described using means and standard deviations (SD) and were compared using *t*-tests. Skewed variables were described using medians with interquartile ranges (IQR) and compared using the Wilcoxon signed-rank test. Differences between patient measures over time were compared using paired *t*-tests. Categorical data were compared using Fisher’s exact test. *P*-values less than 0.05 were considered significant.

**Results**

During the study period, 479 patients were treated for ISSNHL of which 144 patients fulfilled study inclusion criteria. Four patients did not have audiograms after treatment 10 and were excluded from the flow chart aspect of the analysis.

The mean (SD) age was 53 (16.0) years and 68 (47%) were male. The median (IQR) time from hearing loss to start of treatment was 10 (5–16) days. The majority (65%) of those treated had severe (> 60 dB) loss. The mean (SD) PTA4 pre-treatment was 71.54 (26.37) dB and the six-week post-treatment PTA4 was 50.36 (28.03) dB. At six weeks post-treatment, 22% (32/144) of patients had normal hearing and 69% (99/144) of patients had improved hearing.

Comparison characteristics of the ‘10 treatments’ versus

**Table 1**

Comparison of patient characteristics in ‘10’ and ‘> 10’ treatment groups; IQR – interquartile range; SD – standard deviation

Parameter	10 treatments (n = 48)	> 10 treatments (n = 96)	P
Male n (%)	24 (50%)	44 (46%)	0.7
Age (years) Mean (SD)	50 (15.33)	54 (16.22)	0.13
Days from hearing loss to treatment initiation Median (IQR)	8.5 (4–20)	10 (5–15)	0.80
Baseline PTA4 (dB) Mean (SD)	68.7 (26.6)	73.0 (26.3)	0.29
Final PTA4 (dB) Mean (SD)	50.8 (34.8)	50.1 (24.2)	0.89
Final hearing gain (dB) Mean (SD)	17.9 (22.6)	22.8 (19.2)	0.17
Gain ≥ 10 dB to final n (%)	29 (60%)	70 (73%)	0.13
Normal final hearing n (%)	15 (31%)	17 (18%)	0.09

**Table 2**

Hearing improvement by degree of loss; PTA4 – four frequency pure tone average hearing loss (dB); SD – standard deviation

Degree of loss	Initial PTA4 (dB)	n (%)	Gain to six weeks post-treatment (dB) Mean (SD)	P
Mild	≤ 40	22 (15)	9.62 (9.42)	< 0.001
Moderate	41–60	28 (20)	16.28 (17.02)	
Severe	61–80	39 (27)	19.79 (19.58)	
Profound	> 80	55 (38)	29.28 (22.80)	

'> 10 treatments' groups can be found in Table 1. The mean (SD) number of treatments in the '10 treatments' group was 10.02 (0.81) and the '> 10 treatments' group was 17.54 (3.77).

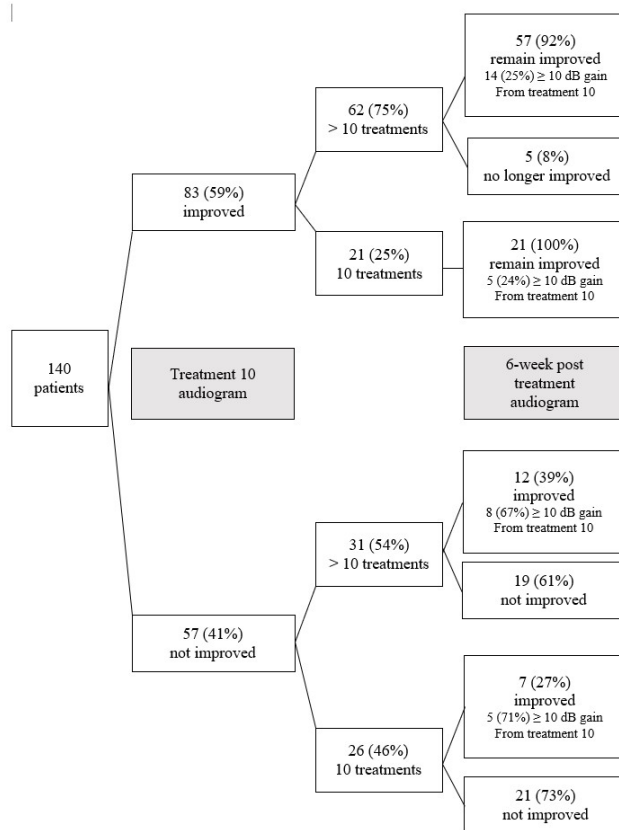
Hearing gain arranged by degree of loss can be seen in Table 2 which shows increasing gains in PTA4 for patients with more severe hearing loss.

In examining improvement of hearing by number of treatments, there were 140 patients with audiograms after treatment 10. Of these, 93/140 (66%) patients were considered to have '> 10 treatments' and 47/140 (34%) '10 treatments'. Comparing these two groups at treatment 10, significantly more patients in the '> 10 treatments' group had improved hearing than in the '10 treatments' group: 62/93 (67%) versus 21/47 (45%), *P* = 0.018. However, when comparing these groups from treatment 10 to six weeks post-treatment, similar percentages of patients were improved for both groups: 24/93 (26%) of '> 10 treatments' versus 10/47 (21%) of '10 treatments' *P* = 0.68. In addition, there was no significant difference in the mean (SD) PTA4 gain after treatment 10 for either group: 5.93 (11.25) dB for '> 10 treatments' versus 4.73 (8.90) dB for '10 treatments', *P* = 0.53.

Figure 1 shows a flow chart analysis which initially divides the 140 patients into 'improved' or 'not improved' according to their treatment 10 audiogram. These two groups are then subdivided into '10 treatments' and '> 10 treatments' and further examined for improvement at six weeks. Of those 83/140 (59%) considered improved at treatment 10, 57/62 (92%) of the '> 10 treatments' and 21/21 (100%) of the '10 treatments' remained improved at six weeks with 14/57 (25%) and 5/21 (24%) of each group respectively having a ≥ 10 dB PTA4 gain between treatment 10 and six week follow up. Of the 57/140 (41%) patients not improved at treatment 10, 12/31 (39%) of the '> 10 treatments' and 7/26 (27%) of the '10 treatments' were considered improved at six weeks, with 8/12 (67%) and 5/7 (71%) of these respectively having a ≥ 10 dB gain in PTA4 occurring after the treatment 10 audiogram.

**Figure 1**

Flow chart showing improved (PTA4 gain ≥ 10 dB) hearing in 140 patients divided into '10 treatment' and '> 10 treatment' groups based on improvement at treatment 10 and examined for further improvement at six weeks



In examining normalisation of hearing, there were 135 patients with audiograms post 10 treatments who did not have normal (PTA4 < 25 dB) hearing on initial audiogram. Of these 46/135 (34%) had '10 treatments' and 89/135 (66%) had '> 10 treatments'. There was a significant difference in normal hearing between groups at the treatment 10 audiogram: 11/46 (24%) for '10 treatments' versus 6/89 (7%) for '> 10 treatments', *P* = 0.006.

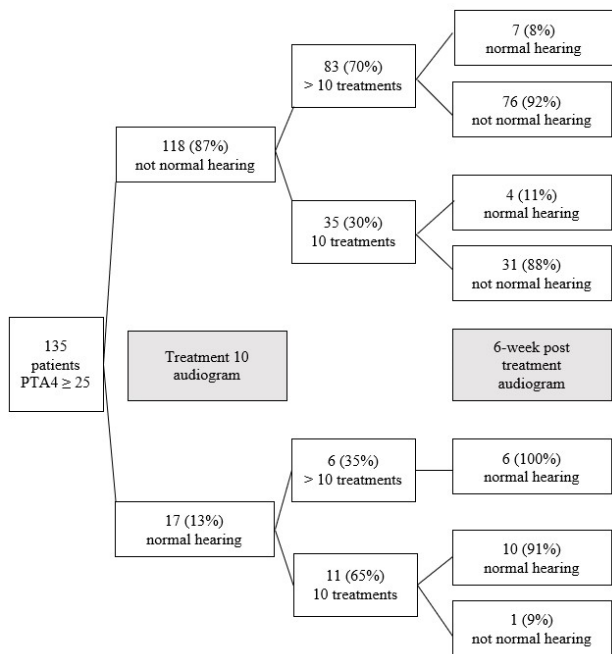
Figure 2 is a flow chart analysis for normalisation of hearing. It divides patients into 'normal' and 'not normal' hearing following the treatment 10 audiogram. These groups are then sub-divided into '10 treatments' and '> 10 treatments' and further evaluated for normal hearing at six weeks post-treatment. Of the group of 118/135 (87%) with non-normal hearing at treatment 10, there was no significant difference in normalisation of hearing at the six week post treatment audiogram between those having '10 treatments' versus '> 10 treatments': 4/35 (11%) versus 7/83 (8%), *P* = 0.73.

**Discussion**

In our study, 99/144 (69%) patients with ISSNHL improved and 32/144 (22%) had normalised hearing when treated with

**Figure 2**

Flow chart of 135 patients with abnormal initial hearing divided into ‘10 treatments’ and ‘> 10 treatments’ groups depending on normal hearing (PTA4 < 25) at treatment 10 and examined for normal hearing at six weeks



a combination of hyperbaric oxygen therapy and steroid treatment. Those with severe to profound loss showed the most gains. We found no significant difference at six weeks post treatment between the ‘10 treatments’ and ‘> 10 treatments’ groups in either improved hearing, normal hearing, or overall hearing gain. Uniquely, we show similar ongoing gains in both hearing improvement and recovery of normal hearing from treatment 10 onward independent of further HBOT sessions.

Given the high spontaneous recovery rates of untreated ISSNHL, the utility of treating ISSNHL with any modality has been questioned. However, these spontaneous recovery rates are quite inconsistent between studies and likely the result of different inclusion criteria and differing definitions of ISSNHL and recovery. Along with these confounders, the ubiquitous use of corticosteroids as treatment has made placebo control groups rare in recent studies which may have more homogeneous definitions.

Two recent meta-analysis have tried to better define the natural history of ISSNHL with results that are difficult to interpret. Chashu et al. in 2023 performed a meta-analysis for spontaneous rates of recovery in studies of hearing loss treatments that included a placebo group.<sup>20</sup> They found an overall recovery rate of 60.3% CI 33.9–79.9%, with large heterogeneity between included studies ( $I^2 = 86\%$ ). However, when they limited their analysis to those studies with a standard definition of ISSNHL (a loss of  $\geq 30$  dB in three consecutive frequencies occurring in < 3 days), they found

lower, slightly narrower improvement rates of 33–54%. Ying et al. in a 2024 meta-analysis, found a mean hearing gain of up to 24 dB (95% CI, 2.6–45.4,  $P = 0.03$ ) in untreated patients at 2–3 months post-loss with a heterogeneity of  $I^2 = 88.4\%$ .<sup>21</sup> The authors acknowledge the large variations across included studies limit their conclusions. Our study uses Chashu’s standard definition of ISSNHL with an improvement rate of 69% suggesting there is benefit to our treatment.

Supporting the overall use of HBOT for ISSNHL are the international consensus (ICON) on treatment of sudden hearing loss 2018’s methodological recommendations and two meta-analyses comparing the addition of HBOT to standard medical treatment including steroids.<sup>22</sup> The ICON group recommend that any new treatment for hearing loss should provide better results than steroids, and that a hearing gain in PTA of  $\geq 10$  dB be considered an improvement. Joshua et al. in their 2022 meta-analysis found that mean PTA4 gain, final PTA4 and hearing recovery were all significantly improved in the HBOT group.<sup>23</sup> The mean difference in absolute hearing gain between groups was 10.3 dB (95% CI, 6.5–14.1) in favour of the HBOT group with a heterogeneity of  $I^2 = 0\%$  lending additional weight to this result. Another meta-analysis in 2018 had more heterogeneity, but also significantly favoured HBOT + medical treatment over medical treatment alone for complete hearing recovery, any hearing recovery and absolute hearing gain.<sup>24</sup> These studies would suggest that HBOT does provide benefit for ISSNHL.

In comparing numbers of HBOT treatments for ISSNHL there is no clear consensus in the literature. Korpinar et al. in 2011 retrospectively analysed 80 patients undergoing twice daily HBOT.<sup>25</sup> Patients received between five and 31 treatments (mean 18.2) over an average of 10.4 days. They concluded that higher numbers of HBOT sessions improved hearing gains. Sherlock et al. in 2016, as a part of a retrospective review of 76 patients who received both steroids and daily HBOT treatments, analysed patients who had  $\leq 10$  treatments versus  $> 10$  (mean = 14) and found no significant change in hearing gain between the two groups.<sup>12</sup> Another retrospective examination of 178 patients who had undergone between four and 34 sessions of HBOT (mean 16.8) twice daily found in their univariate analysis that the recovery group (gain  $> 15$  dB) had fewer treatments than the no recovery group (14.9 versus 17.8).<sup>7</sup> However in their multivariate analysis, they demonstrated that the number of HBOT sessions was not a factor in hearing recovery and concluded that 20 sessions is enough to show therapeutic effect. Finally, Chin et al. in 2022 retrospectively studied 102 patients who had undergone 1–5 sessions of HBOT and compared them to 46 patients who had undergone 6–10 sessions.<sup>26</sup> They found that 6–10 sessions did not provide further improvement over the shorter treatment group.



Of note, none of these studies utilised a similar point in time for their final audiometric outcome or examined audiograms beyond the completion of therapy. Korpinar et al., Sherlock et al. and Wu et al. made decisions to terminate HBOT based on audiological follow-up with audiograms which occurred at different time points depending on the number of HBOT sessions given.<sup>7,12,20</sup> Chin et al. specifically compared audiometry after 1–5 sessions with after 6–10.<sup>21</sup> If the gain seen in our study after 10 treatments regardless of further treatment is reproducible, it would suggest bias in these studies towards longer treatments.

The ongoing hearing gain following completion of treatment evidenced in our results is also evident in several other studies. Rauch et al. in a prospective, randomised comparison of oral versus intra-tympanic steroids, demonstrated ongoing improvement in audiograms that was significant out to two months and that stabilised at six months after the start of treatment.<sup>27</sup> Cho et al. prospectively looked at patients treated with oral and intratympanic steroids with and without the addition of 10 sessions of HBOT.<sup>28</sup> They too demonstrated ongoing improvement in both groups, continuing beyond the 10 days of treatment and stabilising two to three months post-treatment. Yildirim et al. retrospectively found similar results in patients treated with 20 daily HBOT sessions.<sup>29</sup> Like these, our study shows similar trends of improvement out to two months after initiation of treatment. Uniquely, we suggest that this improvement is not impacted by further HBOT sessions.

Continued improvement 2–3 months from the initiation of treatment, and similar gains seen after 10 treatments regardless of ongoing hyperbaric sessions implies that one must be cautious in interpreting results from studies comparing different numbers of HBOT treatments without final audiograms done at a similar timepoint from the start of treatment. If the final audiometric outcome after a shorter treatment course were measured and compared to one after a longer treatment course, the results may favour longer treatment times as being more efficacious. Future studies comparing efficacy of treatment durations should assess outcome of treatment at similar time frames, preferably at least 12 weeks from initiation of treatment.

Although our study is suggestive of 10 treatments being equivalent to > 10, it is limited in that it is retrospective, not randomised, and relatively small in numbers. As our study was not controlled, and patients underwent different timings of adjunctive treatments from their otolaryngologist, it is possible that some of the ongoing gain seen post HBOT may have been due to treatment with intratympanic steroids occurring after the completion of HBOT. It is also possible that our inclusion criteria of a six-week post-treatment audiogram selected for patients who had had improvement in their hearing and were interested in outcome which may skew our result toward improvement even for those who had fewer treatments.

## Conclusions

In conjunction with steroids, 10 HBOT treatments appear to offer equivalent benefit to more than 10 treatments. Similar improvements in PTA4 gain and hearing recovery occurs after 10 HBOT treatments regardless of whether HBOT is continued. A prospective study of 10 versus 20 treatments is warranted. All studies comparing numbers of HBOT treatments should consider an outcome beyond the completion of HBOT.

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