

Salvage intra-tympanic steroid therapy for sudden sensorineural hearing loss (SSNHL): Our real life experience in 32 patients

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Abstract

* This is a retrospective case series study examining the role of salvage intratympanic steroid injections (ITS) in patients presenting with idiopathic sudden sensorineural hearing loss (SSNHL) following poor response to initial oral steroid treatment. * Pure tone thresholds were reviewed pre-treatment, post oral steroid therapy and 6 weeks post ITS. * After oral steroid therapy alone, there was a mean average threshold change of 6.2dBHL (range of -13.8dB to 33.8dB). This was found to be statistically significant with severely affected patients (defined as average presenting threshold >71dB). * The mean average threshold improvement post-ITS therapy was 2.9dB (range of -22.5dB to 61.3dB), this was not found to be statistically significant. * Some patients experienced moderate improvement following ITS therapy, however no specific subgroup was identified to benefit more from ITS therapy.

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Ethical considerations: A retrospective case series of SSNHL cases treated with a course of ITS injections was undertaken, registered and approved by our hospital's Audit and Clinical Research department (No.4817).

KEY WORDS

Sensorineural

Hearing loss

Intratympanic

Steroid

Audiogram

Management

KEY POINTS

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INTRODUCTION

Sudden onset sensorineural hearing loss (SSNHL) is defined as a 30 decibel(dB) loss in three consecutive frequencies occurring over less than 72 hours. It is most commonly idiopathic in nature, although there are numerous suggested aetiologies including immune, vascular and infective causes.¹ Current guidelines suggest treating such patients with oral or intratympanic steroid therapies.

The American Academy of Otolaryngology Head and Neck Surgery, USA, published guidelines for the investigation, management and follow-up of patients presenting with SSNHL in Aug 2012.² Furthermore, they have recently published an update to this original guidance in 2019.³ ENT-UK have also recently published guidance on this area.⁴ It is suggested, through these guidelines and the literature, that patients should initially be treated with a course of oral steroids following SSNHL. This is typically 1mg/kg (Max 60mg) for 7 days, followed by a tapering dose for a further 7 days. The American Academy guidelines recommend that patients should be offered salvage intratympanic steroids (ITS) for patients who have incomplete recovery from SSNHL. ENT-UK guidance states that if there is no improvement from oral steroids after 7-14 days to consider salvage ITS therapy.

As a direct result of the American Academy guidelines, [removed for blind peer review] ENT department instigated salvage ITS therapy. This study follows the results of this treatment, in a real-world scenario within a busy teaching hospital, to provide a UK perspective on the benefits of this regime. We hope this will educate other departments as to how we instigated this service, and of the initial results obtained.

MATERIALS & METHODS

Ethical considerations

A retrospective case series of consecutive SSNHL cases treated with salvage ITS was undertaken, registered and approved by our hospital's Audit and Clinical Research department (No.4817).

Technical and logistical details of ITS service

As detailed in figure 1, our department reviews patients within 72 hours of onset for an audiogram and assessment. If deemed to have SSNHL, they are given oral prednisolone. Two weeks later, audiometry is repeated within an emergency clinic. If hearing thresholds have not improved by an average of 30dB relative to the unaffected ear, patients are offered ITS therapy. This constitutes three ITS injections, of between 0.4-0.8mls of 40mg/ml Methylprednisolone, injected into the middle ear through a phenol anaesthetised tympanic membrane segment, with patients placed in a recumbent position facing away from the affected side, and asked to not swallow for 30 minutes. Injections are undertaken in a specialty doctor run minor ops clinic, which runs half-daily each week, allowing up to 4 injections per session. Each injection is given a week apart. After six weeks, a final PTA is performed to qualitatively assess changes in hearing. An MRI is performed to exclude retrocochlear pathology.⁵

Study design

Patients seen in the [removed for blind peer review] ENT minor procedures clinic between June 2015 and December 2019 for salvage ITS for SSNHL were identified from examination of clinic records, coding records and patient notes. All patients fulfilled the criteria for SSNHL and completed treatment within an 8 week timeframe. This yielded 38 patients, 32 of whom were included, with 6 patients excluded due to incomplete notes. Data was anonymised throughout. Average PTA values were calculated as a mean of 4 frequencies (0.5, 1, 2 and 4kHz). PTA's were compared pre- and post-oral and ITS treatment, with final PTAs undertaken 6 weeks following the last ITS injection. Speech audiograms were not routinely available for patients on this emergency pathway. We acknowledge this as a limitation to the study. Hearing recovery was assessed utilising the standardized format detailed by Gurgel et al.⁶ Complete recovery was defined as a return of hearing to within 10dB of the unaffected ear. Partial recovery was defined as a greater than 10dB gain in hearing on the affected side but not returning to within 10dB of the unaffected ear. This was then further sub categorised as to whether the ear was rendered serviceable or not. No recovery was defined as anything less than a 10dB improvement in the affected ear.

Statistical analysis

Data was collected from patient's physical notes and analysed using Excel® (Microsoft, Redmond, WA, US) and GraphPad Prism 7 (GraphPad Software Inc, La Jolla, CA, US).

Data sharing analysis

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

RESULTS

This study included 32 patients in total; 18 females and 14 males with a mean age of 61 (range 25-87). Hearing loss was right-sided in 14 patients, left-sided in 17 patients, and bilateral in one patient. No autoimmune aetiology was identified for the patient presenting with bilateral SSNHL.

The incidence of SSNHL in this study for 2019 was 9 per 100,000, in keeping with the reported incidence of 5-27 per 100,000 outlined in the 2012 AAOHNS guideline.² **Figures 2 & 3** reveal mean averaged hearing thresholds (on the affected side) of $74.8\text{dB} \pm 25.6$ on presentation (range of 35dB to 120dB). Following oral steroid therapy, mean averaged thresholds were $68.6\text{dB} \pm 23$ (range of 30dB to 108dB). This resulted in a mean averaged threshold improvement of 6.2dB (range of -13.8dB to 33.8dB) following oral steroid therapy, which was found to be statistically significant ($p < 0.05$). Mean averaged thresholds post-ITS were $65.7\text{dB} \pm 25.1$ (range of 22dB to 120dB), demonstrating a mean average threshold improvement of 2.9dB (range of -22.5dB to 61.3dB). This mean improvement was not deemed to be statistically significant.

Figure 4 reveals a sub-analysis of hearing thresholds pre- and post-oral steroids and post-ITS, based on initial hearing thresholds at presentation ($<70\text{dB}$ and $>70\text{dB}$). These graphs display individual patient trends.

Using the standardised criteria reported by Gurgel et al⁶, where the hearing thresholds of the unaffected side are used as a comparison for potential recovery, complete recovery was achieved by 3 patients (12%), partial recovery by 3 patients (12%) and no recovery by 19 patients (76%) following ITS. This therefore gave a combined recovery rate for our salvage ITS therapy of 24%. This analysis was undertaken in 25/32 patients in the study, where unaffected hearing thresholds were available.

DISCUSSION

Synopsis of new findings

Results have revealed limited clinical benefit of ITS, with only a mean improvement of 2.9dB. There is some evidence of individual patients having more marked improvements, but it was difficult to identify the favourable prognostic factors to target these patients, although it's likely to be those with hearing worse than 70 dB on presentation.

Strengths of study and comparisons with other studies

This study represents a real-world experience of SSNHL utilising salvage ITS therapy. The mean average threshold improvement post-ITS therapy of 2.9dB in this study is significantly lower than that expected based upon other studies. A control study in 2006 by Xenellis et al demonstrated that when ITS therapy was compared to a control group with no treatment, hearing was found to improve by 14.9 dB, compared with a deterioration of 0.8 dB in the control group, with the authors recommending ITS as a safe and effective treatment⁷. A limited meta-analysis published by Spear et al (32 studies) revealed a mean improvement of 13.3 dB in the ITS salvage group versus placebo.⁵ Recent AAOHNS guidelines also state that the majority of studies following ITS do show improvement in hearing.³ All 5 of the RCT's referenced used the latest AAOHNS recommended paradigm of at least 4 injections over 2 weeks, within 2-6 weeks of the onset of symptoms. This is a slightly accelerated protocol in comparison to the 3 injections over 3 weeks utilised in this study, mainly as it was based on guidance published prior to this recent 2019 update, perhaps contributing to the greater improvements in hearing recovery. The mean length of time in this study between the first oral steroid dose and the first ITS injection was 17.4 days.

Clinical applicability

This study has shown salvage ITS therapy to be effective in a minority of patients (15-24%), however for these patients it represents a final attempt at treating their SSNHL. ITS therapy can be uncomfortable for patients and sometimes can provoke feelings of dizziness post procedure. The procedure itself is known to carry a small risk of perforation. Only one patient was documented to have evidence of tympanic membrane perforation 6 weeks post ITS injection in this study. This study provides further evidence of a trend towards greater improvement being more likely to be found in those with a greater degree of hearing loss. It offers valuable real world experience that will enable balanced discussion with the patient regarding the likely risks and benefits of salvage ITS therapy. Additionally, this study will guide future departmental decision making regarding our service for managing SSNHL. This may involve implementing a more accelerated ITS regimen or selectively offering ITS therapy only to those with more severe hearing loss.

Limitations

The inaccessibility of speech audiograms in this study limits the ability to formally assess functional hearing recovery amongst the sample population.

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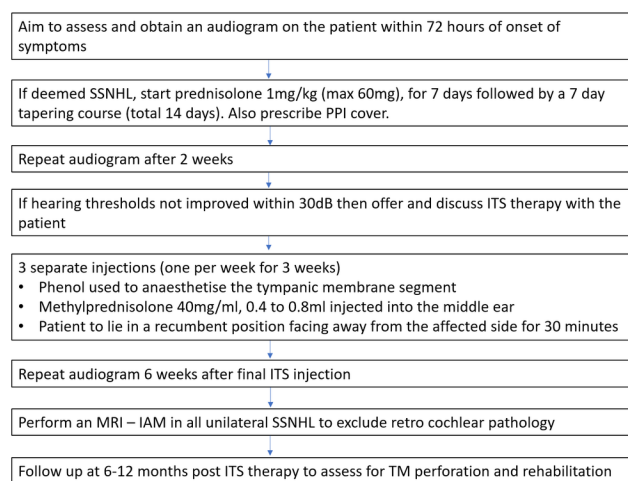
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	Pre-oral steroids	Post-oral steroids	Post-IT steroids
Mean averaged thresholds in dB (SD)	74.8 (25.6)	68.6 (23.0)	65.7 (25.1)
Range in dB	35 to 120	30 to 108	22 to 120
Mean averaged threshold change following treatment in dB (SD)	-	6.2 (12.4)	2.9
Range of mean averaged threshold change following treatment in dB (SD)	-	-13.8 to 33.8	-22.5 to 61.3

Table 1 – Data values pre and post treatment



PPP – Proton pump inhibitor, MRI – IAM – MRI internal acoustic meatus. **Figure 1** – Protocol in use between 2015-2019 at (Blinded for peer review) for treatment of SSNHL

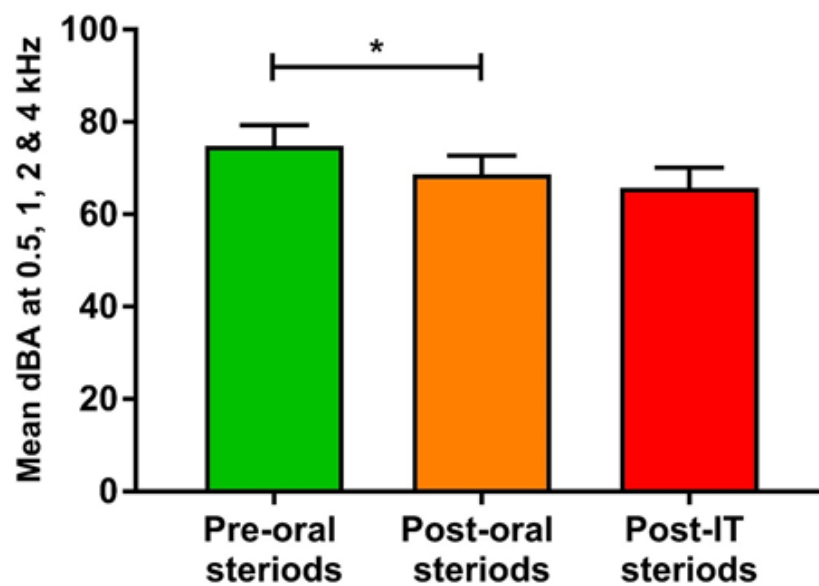


Figure 2 - Mean averaged hearing thresholds pre and after treatment

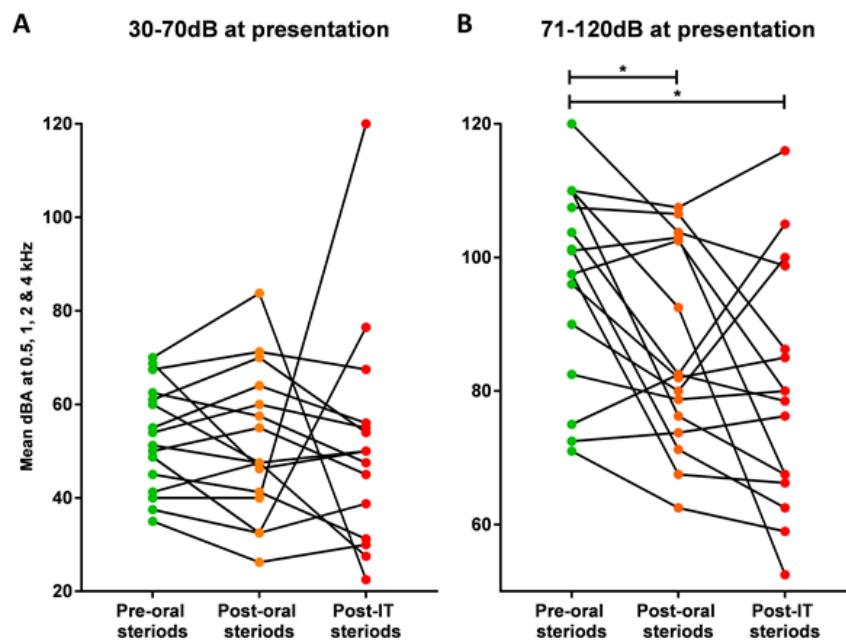


Figure 3 - Change in hearing in dB following treatment, each graph separated based upon severity of hearing loss at presentation

	Pre-oral steroids	Post-oral steroids	Post-IT steroids
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