RESEARCH PAPER

A Comparative Study of Intratympanic Dexamethasone and Oral Corticosteroids in Idiopathic Sudden Sensorineural Hearing Loss

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ABSTRACT

Methodology: A comparative prospective observational study was conducted in the Department of ENT at GMERS Medical College, Himmatnagar, Gujarat. A total of 80 patients with ISSNHL were included and divided into two groups of 40 each. One group received oral corticosteroids, while the other received intratympanic dexamethasone injections. Hearing outcomes were assessed using Pure Tone Audiometry (PTA) before treatment and after two months of therapy. Data were analyzed using appropriate statistical tests.

Results: The mean baseline PTA was 72.45 dB in the oral corticosteroid group and 74.12 dB in the intratympanic dexamethasone group. After two months, the mean PTA improved to 42.18 dB and 45.67 dB respectively. Mean hearing improvement was 30.27 dB in the oral group and 28.45 dB in the intratympanic group, with no statistically significant difference (p=0.41).

Conclusion: Both oral corticosteroids and intratympanic dexamethasone showed comparable effectiveness in improving hearing in ISSNHL patients.

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INTRODUCTION

The medical community ˙recognizes idiopathic sudden sensorineural hearing loss (ISSNHL) as an urgent medical condition which causes people to lose their hearing ability suddenly and within a brief timeframe [1]. The condition is identified when a person experiences sudden unexplained hearing loss which affects one ear and leads to a minimum 30 dB hearing loss across three consecutive frequencies within a 72-hour period. The worldwide rate of idiopathic sudden sensorineural hearing loss occurrence falls between 5 and 20 cases per 100000 individuals each year. The actual number of affected people remains unknown because many individuals who experience mild symptoms or spontaneous recovery choose not to see a doctor. The medical condition has gained widespread recognition in clinical settings because its sudden appearance and unknown causes lead to permanent hearing loss which can be avoided through proper treatment.

The United States and Europe and Japan have conducted large epidemiological studies which included case series studies that analyzed approximately 7500 cases to reveal crucial information about the demographic traits of patients with this medical condition. The research findings show that the most common age range for idiopathic sudden sensorineural hearing loss occurs between 43 and 53 years [2]. The research findings show that the distribution of males and females in the study population shows almost equal numbers of both genders. About 28% to 57% of patients experience transient vestibular symptoms which include vertigo and dizziness and balance problems. The existence of vestibular

symptoms indicates that the vestibulocochlear system has been affected which impacts patient outcomes and treatment effectiveness.

Researchers have conducted thorough investigations but they have not yet discovered the complete pathophysiological mechanisms that cause idiopathic sudden sensorineural hearing loss [3]. The sudden onset of hearing loss has been explained through multiple hypotheses which include viral infections and vascular compromise and autoimmune reactions and cochlear membrane ruptures. The condition remains classified as idiopathic because none of the proposed theories has been established as a universal explanation for all patient cases. The unknown cause of the condition leads medical professionals to develop treatment methods which focus on three objectives: reducing inflammation and enhancing cochlear blood flow and protecting auditory structures from harm.

Of the several therapeutic modalities that have been suggested in the past years, corticosteroid therapy has stood out to be the most acceptable treatment modality to idiopathic sudden sensorineural hearing loss [4]. The standard treatment is generally a course of oral corticosteroids that are tapered like prednisone or methylprednisolone. The mass use of orally administered corticosteroids is mostly premised on clinical findings that show their ability to enhance the hearing outcomes. In a randomized, placebo-controlled trial study that was conducted among 67 patients, the rate of hearing improvement among patients who had steroid therapy was significantly higher than the rate of improvement among patients who had a placebo. Hearing recovery was noted in 32% (11 of 34) of the participants in the placebo group and 61% (20 of 33) of the participants receiving corticosteroids showed the response [5] in the present study. The large effect of treatment in this research, which stated 0.59 effect size, led to the swift and universal adoption of oral corticosteroids as the first-line treatment of idiopathic sudden sensorineural hearing loss.

A large retrospective study done in 266 patients receiving systemic corticosteroid treatment has given additional support to the use of oral corticosteroids [6]. In this article, 46 percent (122 out of 266) of the total study subjects showed improvement in hearing. In patients with hearing threshold of 60 dB or more i.e., moderate to severe hearing loss, the improvement was noted in 55 percent (76 out of 139) of the cases. In this sub-group of patients, there was a high level of treatment effect of 0.64. Also, the steroid treated group had an average of 28.0 dB improvement in hearing threshold. Conversely, 22 un-treated patients whose baseline hearing was similar had a mean improvement of 12.9 dB. Such results also confirm that systemic corticosteroid treatment has a positive effect on the restoration of hearing among individuals with idiopathic sudden sensorineural hearing loss.

Though the oral corticosteroids are still considered as the most common mode of treatment, alternative modes of steroid administration have been studied as alternative means of controlling the disease over the past few years to improve therapeutic results, as well as reduce the systemic side effects. Intratympanic corticosteroid therapy is another form of treatment that is becoming more popular in the last 15 years and includes the direct injection of corticosteroids into the middle ear in the treatment of sudden sensorineural hearing loss [7]. Among the principal theoretical benefits of intratympanic administration, one must mention the possibility to provide more concentrations of the drug to the inner ear structures. Pharmacokinetic experiments in guinea pig models have shown much more corticosteroids in the cochlea, when intratympanically administered, than when administered systemically. This is a potential way of enhancing the treatment efficacy of corticosteroids with minimal systemic exposure brought about by this targeted drug delivery method.

Although these are the theoretical benefits, there have been limited evidence on adequately powered prospective randomized controlled trials with direct comparisons between intratympanic and oral steroid therapy. The available data has mostly been based on uncontrolled case series and retrospective studies on intratympanic steroid therapy [8]. Some of these studies have shown hearing improvements rates to be as effective as systemic steroid therapy. A single example of a retrospective case series, 26 patients receiving intratympanic corticosteroids, showed an average hearing threshold improvement of 27.2 dB and 25.4% average speech discrimination improvement. The other study achieved positive results in 14 out of 21 patients (67 percent) treated to intratympanic steroid injections. These results indicate that intratympanic steroid treatment can be a substitute therapy to systemic corticosteroid treatment of patients with idiopathic sudden sensorineural hearing loss.

The possible benefit of intratympanic steroid [3]therapy is pronounced by possible reduction of systemic corticosteroid exposures and the risk of systemic corticosteroid adverse effects. It is known that systemic corticosteroid therapy has a number of side effects but most of them tend to be manageable. The usual side effects are a loss in appetite, mood fluctuations, sleeping disorders, weight gain, gastritis, and thirst. More severe side effects of systemic steroids use in the long run are hypertension, hyperglycemia, development of cataracts, and avascular necrosis of the hip. Conversely, pharmacokinetic research has indicated that

intratympanic route of administration leads to a low level of systemic corticosteroid absorption and that it does not cause any substantial effect of circulating drugs [9]. Therefore, the side effects of intratympanic treatment are mainly local in nature to the ear, and could involve ear pain, temporary vertigo caused by caloric stimulation, perforation of the tympanic membrane, and, in uncommon instances, middle ear infection (otitis media).

Considering the similar effectiveness of this treatment in the past and the possible benefits of decreased systemic exposure to steroids, there is a growing interest in conducting studies that could assess intratympanic steroid therapy as a first-line treatment of idiopathic sudden sensorineural hearing loss. In order to solve this problem, a multicenter, randomized, noninferiority trial was developed to compare the efficacies of oral prednisone and intratympanic methylprednisolone in the initial treatment of idiopathic hearing loss. A noninferiority type of study design is suitable where there are two conditions that establish a noninferiority type of study design: one, the efficacy of an experimental treatment is likely to be the same when compared to standard treatment; two, the experimental treatment may have extra benefits like improved safety or tolerability. Here, oral prednisone is the standard clearly documented therapy using a defined efficacy and the intratympanic steroid therapy proved to be promising in a variety of retrospective studies.

Intratympanic steroid delivery is potentially safer than systemic steroid delivery due to reduced systemic steroid exposure and possibly fewer systemic adverse events in some groups of patients with comorbid disease, including diabetes mellitus, hypertension, or gastrointestinal diseases. Hence, assessment of the relative usefulness of intratympanic dexamethasone and oral corticosteroids is necessary in establishing the most suitable therapeutic approach to use with patients with idiopathic sudden sensorineural hearing loss. Against this backdrop, the present research will be a comparative study of intratympanic dexamethasone and oral corticosteroid therapy in idiopathic sudden sensorineural hearing loss, in an attempt to determine the results of the two therapeutic modalities and the possible benefits of each treatment pattern.

METHODOLOGY

2.1. Study Design

The present study was designed as a comparative prospective observational study to evaluate and compare the effectiveness of intratympanic dexamethasone and oral corticosteroids in patients with idiopathic sudden sensorineural hearing loss (ISSNHL). The study aimed to assess improvement in hearing outcomes following treatment with either modality. Patients fulfilling the eligibility criteria were enrolled and divided into two groups based on the treatment received. Baseline clinical and audiometric evaluations were conducted prior to initiation of therapy, and follow-up assessments were performed to determine changes in hearing thresholds and clinical outcomes.

2.2. Study Area

The study was conducted in the Department of ENT, GMERS Medical College, Himmatnagar, Gujarat, India.

2.3. Study Duration

The study was conducted during for one year

2.4. Study Participants

- **Inclusion Criteria**
  - Patients aged 18 years and above.
  - Patients presenting with unilateral sudden sensorineural hearing loss occurring within 24 to 48 hours.
  - Hearing loss present for 48 to 72 hours or less at the time of presentation.
  - Pure Tone Average (PTA) ≥ 50 dB calculated from thresholds at 500, 1000, 2000 and 4000 Hz in the affected ear.
  - Hearing level in the affected ear at least 30 dB poorer than the contralateral ear in at least one PTA frequency.
  - Patients with no known cause of hearing loss after appropriate clinical and otological evaluation.
  - Patients willing to provide written informed consent and comply with follow-up visits.
- **Exclusion Criteria**
  - Previous history of hearing loss in either ear.
  - History of Meniere's disease or fluctuating hearing loss.
  - Presence of chronic suppurative otitis media, cholesteatoma, or other chronic ear diseases.
  - History of otosclerosis or prior ear surgery (except ventilation tube insertion).
  - Evidence of congenital hearing loss or craniofacial malformations.
  - Hearing loss due to trauma, barotrauma, or known infectious causes.
  - Patients with retrocochlear pathology such as vestibular schwannoma detected on imaging.
  - Presence of severe systemic illness such as uncontrolled diabetes mellitus, tuberculosis,

chronic renal disease, or immunosuppressive disorders.

- Patients with history of head and neck malignancy or radiation therapy.
- Pregnant or lactating women.

2.5. Sample Size

The total sample size was 80 patients diagnosed with idiopathic sudden sensorineural hearing loss who met the inclusion criteria and attended the ENT department during the study period. These patients were divided into two equal groups of 40 patients each: one group receiving oral corticosteroids and the other receiving intratympanic dexamethasone injections.

2.6. Procedure

All patients presenting to the ENT outpatient department with complaints of sudden hearing loss were clinically evaluated. A detailed medical history, otological history, and general physical examination were performed. Otoscopic examination and complete ENT examination were carried out to rule out external or middle ear pathology.

Audiological evaluation was performed using pure tone audiometry, where hearing thresholds were measured at frequencies of 500, 1000, 2000, and 4000 Hz. The pure tone average (PTA) was calculated for each patient to determine the severity of hearing loss. Additional diagnostic investigations such as imaging and laboratory tests were conducted when necessary to exclude structural or retrocochlear causes of hearing loss.

Patients meeting the eligibility criteria were enrolled in the study after obtaining informed consent. They were then allocated into two treatment groups. The first group received oral corticosteroids, typically administered as oral prednisone in therapeutic doses for a period of approximately two weeks followed by gradual tapering. The second group received intratympanic dexamethasone injections, administered through the tympanic membrane under aseptic conditions using an operating microscope. The injection was given into the middle ear cavity, and patients were positioned supine with the affected ear facing upward for about 20–30 minutes after the procedure to allow adequate diffusion of the medication.

Patients were advised to avoid water entry into the treated ear and were monitored for any adverse reactions or complications during treatment. Follow-up visits were scheduled during and after the treatment period to assess clinical improvement and hearing recovery. Audiometric evaluation was repeated during follow-up visits to compare post-treatment hearing thresholds with baseline values. The primary outcome measure was improvement in pure tone average, while secondary outcomes included speech discrimination scores and overall hearing improvement.

2.7. Statistical Analysis

The collected data were compiled and entered into Microsoft Excel and subsequently analyzed using Statistical Package for Social Sciences (SPSS) version 27.0. Descriptive statistics such as mean, standard deviation, frequencies, and percentages were used to summarize demographic and clinical characteristics of the study participants. Comparative analysis between the two treatment groups was performed using appropriate statistical tests. Independent sample t-test was used for comparison of continuous variables such as mean hearing thresholds, while Chi-square test was used for categorical variables. A p-value of less than 0.05 was considered statistically significant. The results were presented in the form of tables and graphs to facilitate clear interpretation of findings.

RESULT

Table 1 shows the distribution of study participants according to age group in both the Oral Corticosteroid group and the Intratympanic Dexamethasone group. Out of the total 80 participants included in the study, 40 patients were assigned to each treatment group. The highest number of participants belonged to the 41–50 years age group with 23 patients in total, including 11 in the Oral Corticosteroid group and 12 in the Intratympanic Dexamethasone group. This was followed by the 31–40 years age group comprising 19 patients, of which 9 were in the Oral Corticosteroid group and 10 in the Intratympanic Dexamethasone group. The 18–30 years age group included 15 patients, with 8 in the Oral Corticosteroid group and 7 in the Intratympanic Dexamethasone group. In the 51–60 years age group, a total of 13 patients were observed, including 7 in the Oral Corticosteroid group and 6 in the Intratympanic Dexamethasone group. The least number of participants were in the >60 years age group with 10 patients, equally distributed between both groups with 5 patients each. Overall, the distribution of participants across age groups was relatively comparable between the two treatment groups.

Table 1: Distribution of Study Participants According to Age Group

Age Group (Years)	Oral Corticosteroid Group (n=40)	Intratympanic Dexamethasone Group (n=40)	Total (n=80)
18–30	8	7	15

31–40	9	10	19
41–50	11	12	23
51–60	7	6	13
>60	5	5	10
Total	**40**	**40**	**80**

Table 2 shows the distribution of study participants according to gender in both study groups. Out of the total 80 participants included in the study, 46 were males and 34 were females. In the Oral Corticosteroid group (n=40), 24 participants were male and 16 were female. Similarly, in the Intratympanic Dexamethasone group (n=40), 22 participants were male and 18 were female. The findings indicate that males constituted a slightly higher proportion of participants in both groups compared to females. Overall, the gender distribution between the two treatment groups was relatively comparable, suggesting that both groups had a nearly balanced representation of male and female participants for the assessment of treatment outcomes.

Table 2: Distribution of Study Participants According to Gender

Gender	Oral Corticosteroid Group (n=40)	Intratympanic Dexamethasone Group (n=40)	Total (n=80)
Male	24	22	46
Female	16	18	34
Total	40	40	80

Table 3 shows the comparison of the mean baseline Pure Tone Average (PTA) between the two study groups. In the Oral Corticosteroid group, which included 40 patients, the mean baseline PTA was 72.45 dB with a standard deviation of 9.84. In the Intratympanic Dexamethasone group, also comprising 40 patients, the mean baseline PTA was slightly higher at 74.12 dB with a standard deviation of 10.21. The p-value for the comparison between the two groups was 0.38, indicating that the difference in baseline PTA between the Oral Corticosteroid group and the Intratympanic Dexamethasone group was not statistically significant. This suggests that both groups were comparable in terms of the severity of hearing loss at baseline before the initiation of treatment.

Table 3: Comparison of Mean Baseline Pure Tone Average (PTA) Between the Two Groups

Group	Number of Patients (n)	Mean PTA (dB)	Standard Deviation
Oral Corticosteroid	40	72.45	9.84
Intratympanic Dexamethasone	40	74.12	10.21
p-value		0.38	

Table 4 shows the comparison of the mean Pure Tone Average (PTA) after 2 months of treatment between patients treated with oral corticosteroids and those treated with intratympanic dexamethasone. The oral corticosteroid group included 40 patients with a mean PTA of 42.18 dB and a standard deviation of 11.36, whereas the intratympanic dexamethasone group also consisted of 40 patients with a slightly higher mean PTA of 45.67 dB and a standard deviation of 12.04. Although the oral corticosteroid group demonstrated a somewhat lower mean PTA value, indicating comparatively better hearing improvement, the difference between the two groups was not statistically significant, as indicated by the p-value of 0.17 ($p>0.05$). This suggests that both treatment modalities produced comparable outcomes in terms of hearing improvement after two months of therapy.

Table 4: Comparison of Mean Pure Tone Average (PTA) After 2 Months of Treatment

Group	Number of Patients (n)	Mean PTA After Treatment (dB)	Standard Deviation
Oral Corticosteroid	40	42.18	11.36

Intratympanic Dexamethasone	40	45.67	12.04
p-value		0.17	

Table 5 shows the mean improvement in hearing threshold (change in Pure Tone Average, PTA) among patients treated with oral corticosteroids and intratympanic dexamethasone. In the oral corticosteroid group, which included 40 patients, the mean improvement in hearing threshold was 30.27 dB with a standard deviation of 10.45. In comparison, the intratympanic dexamethasone group, also comprising 40 patients, demonstrated a mean improvement of 28.45 dB with a standard deviation of 9.92. Although the oral corticosteroid group showed slightly higher mean improvement in hearing threshold than the intratympanic dexamethasone group, the difference between the two groups was not statistically significant, as indicated by the p-value of 0.41 ($p > 0.05$). This suggests that both treatment modalities produced comparable improvements in hearing threshold among patients with idiopathic sudden sensorineural hearing loss.

Table 5: Mean Improvement in Hearing Threshold (Change in PTA)

Group	Number of Patients (n)	Mean Improvement (dB)	Standard Deviation
Oral Corticosteroid	40	30.27	10.45
Intratympanic Dexamethasone	40	28.45	9.92
p-value		0.41	

DISCUSSION

The present study examined how well oral corticosteroids worked in comparison to intratympanic dexamethasone treatment for patients who had idiopathic sudden sensorineural hearing loss (ISSNHL). The study results showed that both treatment methods achieved significant progress in hearing ability after two months of treatment. The study found that patients receiving oral corticosteroids started with a mean baseline pure tone average (PTA) of 72.45 dB while patients receiving intratympanic dexamethasone started with a PTA of 74.12 dB which showed that both groups had similar hearing loss severity at their treatment start. The oral corticosteroid group achieved a mean PTA improvement to 42.18 dB after two months while the intratympanic dexamethasone group had a mean PTA improvement to 45.67 dB which resulted in hearing gains of 30.27 dB and 28.45 dB for both groups. The study found no statistically significant difference between the two groups because the p value reached 0.41 which showed that intratympanic dexamethasone delivered hearing recovery results that matched those of systemic corticosteroid treatment.

The present research demonstrated that most patients studied belonged to the 41-50 years age group while the 31-40 years group represented the second largest age group. Previous research studies have shown identical age patterns to those found in this study. The research conducted by Nakashima et al. (2000) [10] showed that sudden sensorineural hearing loss reached its highest occurrence during the ages of 40 to 60 years which matched the age pattern found in this study. The research conducted by Chen et al. (2003) [11] showed that most patients with ISSNHL belonged to the 35 to 55 years age group which confirmed that the condition mostly affects people in their Middle Ages. The present research shows identical demographic patterns to previous studies which increases study reliability while demonstrating that sudden sensorineural hearing loss patients match the typical clinical profile of their condition.

The study found that male patients made up 57.5% of the total cases which resulted in a minor increase of male patients in the gender distribution. The results match the research conducted by Alexiou et al. (2001) [12] which showed that 55 to 60 percent of patients with ISSNHL were male. The clinical study conducted by Fitzgerald and McGuire (2007) [13] showed a greater percentage of male patients who received intratympanic steroid therapy compared to female patients. The research indicates that although ISSNHL affects both men and women medical studies show a slight increase in cases among male patients.

The study results showed that the two treatment groups had equal baseline hearing levels measured through PTA which allowed researchers to assess treatment results in an unbiased manner. Chen et al. (2003) reported a mean baseline PTA of approximately 70 dB in patients treated with oral corticosteroids, which is very similar to the baseline values observed in the present study (72.45 dB). Chandrasekhar (2001) [14] reported that patients who received intratympanic dexamethasone therapy had baseline PTA results of approximately 75 dB. The current study shows equal hearing loss severity when compared to earlier clinical research because both studies achieved similar results.

The present study showed hearing threshold improvements which matched results from multiple past

studies. The oral corticosteroid group showed a mean improvement of 30.27 dB which matched the results documented by Chen et al. (2003) who found average improvements between 28 and 32 dB after their patients received steroid treatment. Alexiou et al. (2001) found that patients who received glucocorticoid treatment achieved hearing improvements of almost 30 dB. The results demonstrate that systemic corticosteroids serve as the primary treatment method for sudden sensorineural hearing loss.

The present study demonstrates that intratympanic dexamethasone produces effective results which match the findings of previous research. Chandrasekhar (2001) reported a mean hearing improvement of about 27 dB following intratympanic dexamethasone injections in patients with sudden hearing loss. Banerjee and Parnes (2005) [15] found that intratympanic steroid therapy produced hearing improvement between 25 to 30 dB for many patients. The current study found that the intratympanic dexamethasone group achieved a mean improvement of 28.45 dB which closely matches the actual test results. The results of this study provide strong evidence for the clinical effectiveness of the treatment method.

The present study showed results which demonstrated comparable effects of oral and intratympanic steroid treatments which matched the results of the randomized clinical trial conducted by Rauch et al. (2011) [16]. The study found that oral prednisone to intratympanic steroid treatment comparison showed 30.7 dB improvement through PTA measurement which displayed no statistically significant difference between both treatment methods. The current study results show 30.27 dB improvement for the oral group and 28.45 dB improvement for the intratympanic group. The multiple studies which produced identical results demonstrate that intratympanic steroid therapy provides equivalent treatment benefits to systemic corticosteroid therapy for patients with idiopathic sudden sensorineural hearing loss.

Other studies have shown that intratympanic steroid treatment provides various potential benefits to patients who undergo this procedure. Fitzgerald and McGuire (2007) found that patients who received intratympanic steroids experienced major hearing improvement, especially those who could not handle systemic steroid medication. Haynes et al. (2007) [17] showed that intratympanic dexamethasone provides approximately 25 dB hearing improvement to patients who fail to respond to systemic steroid treatment. The research results indicate that intratympanic steroid treatments serve as both primary and supporting treatment options.

The current study results show strong agreement with previous research findings which demonstrate that both oral corticosteroids and intratympanic dexamethasone treatment lead to better hearing results for patients with idiopathic sudden sensorineural hearing loss. Both treatment groups showed similar hearing threshold improvements which matched the results of previous studies. The two treatment methods showed no statistically significant difference which demonstrates that intratympanic dexamethasone serves as an effective treatment option that doctors can use instead of systemic steroid therapy. The discovery holds major significance for patients who cannot use systemic corticosteroids because of contraindications or those who might develop systemic side effects. The present study provides new proof that these two treatment methods show equal effectiveness for treating idiopathic sudden sensorineural hearing loss.

CONCLUSION

The present study compared the effectiveness of oral corticosteroids and intratympanic dexamethasone in the management of idiopathic sudden sensorineural hearing loss (ISSNHL). The findings demonstrated significant hearing improvement in both treatment groups after two months of therapy. The oral corticosteroid group showed a mean hearing improvement of 30.27 dB, while the intratympanic dexamethasone group demonstrated a mean improvement of 28.45 dB. Although slightly greater improvement was observed in the oral steroid group, the difference between the two modalities was not statistically significant. These results indicate that intratympanic dexamethasone provides hearing recovery comparable to systemic corticosteroid therapy. Considering its ability to deliver medication directly to the inner ear with minimal systemic exposure, intratympanic steroid therapy may serve as an effective and safer alternative, particularly for patients who have contraindications to systemic corticosteroids or are at risk of systemic adverse effects.

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