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Original Research Article

Cocktail regimen in treatment of sudden sensorineural hearing loss

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ABSTRACT

Objective: This study aims to evaluate the efficacy of a cocktail regimen for the treatment of sudden sensorineural hearing loss (SSNHL).
Design: A prospective observational study.
Setting: Tertiary care hospital.
Participants: Thirty-five patients diagnosed with SSNHL who met the inclusion criteria.
Intervention: The cocktail regimen included intratympanic steroid injections, oral steroids, valacyclovir, and pentoxifylline.
Main Outcome Measures: The primary outcome was the change in Pure Tone Audiometry (PTA) from pre-treatment to 3 months post-treatment, analyzed by Modified Siegel's criteria.
Results: Of the 35 patients, 26 (74.2%) showed hearing improvement (including complete and partial recovery) at the 3-month follow-up. The mean improvement in PTA was 22.56 dB (SD = 18.4). However, the calculated odds ratios (OR) for treatment efficacy and hearing recovery comparisons were 1.0, with wide confidence intervals, indicating no statistically significant differences between improved and not improved groups.
Conclusion: The cocktail regimen showed potential benefits for hearing recovery in SSNHL patients, particularly in cases with less severe initial hearing loss. Nevertheless, the absence of a statistically significant difference in the comparative analyses underscores the need for larger, randomized controlled trials to substantiate these findings.

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1. Introduction

Sudden sensorineural hearing loss (SSNHL), an urgent otologic emergency, is characterized by a rapid loss of hearing, typically occurring over a 72-hour period, affecting about 5 to 20 per 100,000 individuals annually. The etiology of SSNHL is often idiopathic, with only 10% of cases being attributed to identifiable causes such as infectious, vascular, or autoimmune diseases. This condition not only affects the auditory system but also has profound implications for patients' quality of life, underscoring the need for prompt and effective treatment strategies.[1–3]

The mainstay of SSNHL management has traditionally been systemic corticosteroids, which are believed to reduce cochlear inflammation and edema, improve microcirculation, and modulate immune responses. However, the use of steroids is not without risks and can be contraindicated in patients with certain comorbid conditions. Moreover, the degree of recovery is unpredictable, with some patients responding well to treatment while others experience minimal to no improvement. This variability has spurred the exploration

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of alternative treatments and combination therapies.[4,5]

Recent advances have led to the adoption of a 'cocktail regimen' that combines intratympanic steroid injections, oral steroids, antivirals such as valacyclovir, and vasodilators like pentoxifylline. The rationale for this combined approach is to tackle potential viral etiologies, enhance microcirculation within the cochlea, and provide a local anti-inflammatory effect while minimizing systemic side effects.[6,7]

Despite its promise, the evidence supporting the cocktail regimen's efficacy remains a topic of debate, necessitating further investigation. This study contributes to the body of literature by evaluating the treatment outcomes of a cocktail regimen in a sample of 35 patients with SSNHL, using objective audiometric measures and established recovery criteria.[8,9]

2. Aim

To evaluate the efficacy of cocktail regimen (intratympanic steroid + oral steroid + valacyclovir + pentoxifylline) in patients suffering from sudden sensorineural hearing loss.

3. Objectives

1. To assess the hearing recovery in SSNHL patients treated with the cocktail regimen.
2. To compare pre-treatment and 3-month post-treatment Pure Tone Audiogram (PTA) results.
3. To analyze treatment outcomes using Modified Siegel's criteria.

4. Materials and Methods

4.1. Source of data

The data for this study were collected from patients presenting with sudden sensorineural hearing loss (SSNHL) at a tertiary care hospital, providing a controlled and professional setting for the research.

4.2. Study design

This research was structured as a Prospective Observational Study, allowing for the collection and analysis of data from SSNHL patients before and after the treatment with the cocktail regimen.

4.3. Sample size

The study initially aimed to include 35 participants but successfully enrolled 35, offering a slightly larger dataset to enhance the reliability of the study findings.

4.4. Inclusion criteria

1. Diagnosis of SSNHL characterized by hearing loss in 3 contiguous frequencies of at least 30 dB.
2. Patients who had not received previous treatment for SSNHL and were aged 18 years or older.
3. The onset of symptoms occurred less than 1 week prior to the initiation of therapy.

4.5. Exclusion criteria

1. Patients with pre-existing conditions that contraindicate systemic steroids, such as diabetes and hypertension.
2. Oncology patients.
3. Individuals with autoimmune diseases or those on chronic steroid therapy.
4. Exposure to ototoxic agents.
5. Presence of acoustic neuroma.
6. Pregnant or nursing women.
7. History of middle ear diseases or barotrauma.
8. Intolerance or hypersensitivity to any component of the treatment regimen.

4.6. Study methodology

4.6.1. Treatment regimen

A detailed cocktail regimen was administered, consisting of an Intratympanic injection of Dexa 0.5ml in the antero-inferior quadrant once daily for 5 days, oral administration of Valacyclovir 500mg twice daily for 5 days, Pentoxifylline 400mg twice daily for 5 days, and a tapered dose of Prednisolone starting at 60mg daily.

4.6.2. Outcome measures

The primary measure of treatment efficacy was the change in Pure Tone Audiograms (PTA) from pre-treatment to 3 months post-treatment, analyzed according to Modified Siegel's criteria.

4.6.3. Statistical analysis methods

Comparative analysis of PTA results pre-treatment and at 3 months post-treatment was conducted to evaluate the efficacy of the cocktail regimen. The statistical methods aimed to identify significant improvements in hearing outcomes, thereby assessing the treatment's effectiveness.

4.7. Data collection

Eligible patients presenting with symptoms of SSNHL for less than a month were assessed with a pre-treatment PTA. Following the cocktail regimen treatment, a follow-up PTA was conducted at 3 months to compare outcomes and analyze treatment efficacy.

5. Observation and Results

Table 1 presents an analysis of the efficacy of a cocktail regimen for treating sudden sensorineural hearing loss, contrasting patients who improved with those who did not.

Table 1: Efficacy ofcocktail regimen

Comparison	Odds Ratio (OR)	95% CI Lower	95% CI Upper	P-value
Improved vs Not Improved	1.0	0.342	2.921	1.0

The Odds Ratio (OR) of 1.0, along with a wide 95% Confidence Interval (CI) stretching from 0.342 to 2.921, and a P-value of 1.0, suggests no clear evidence of efficacy based on this comparison; however, this may be a limitation of the data used rather than a definitive clinical outcome.

Table 2 compares different levels of hearing recovery following the same treatment. The comparisons between complete recovery versus not complete, partial recovery versus not partial, and no recovery versus recovery all resulted in an OR of 1.0. These odds ratios are again accompanied by 95% CIs (0.379 to 2.637 for complete and partial recovery, and 0.342 to 2.921 for no recovery) and P-values of 1.0, suggesting that, statistically, the differences in recovery rates are not significant. However, the calculations might be affected by the assumptions made due to the lack of a control group.

Table 3 focuses on the change in hearing levels before and after treatment, revealing a mean improvement of 22.56 decibels, with a standard deviation of 18.4. The significance of this change is supported by a P-value of less than 0.005, indicating a statistically significant improvement in the post-treatment Pure Tone Audiogram (PTA) results compared to pre-treatment.

Table 4 uses Modified Siegel's criteria to assess treatment outcomes and details the hearing recovery grades pre-treatment. The total improvement observed across all grades was 26 out of 35 patients, translating to an overall improvement percentage of 74.2%. Notably, 100% of patients in Grade 2 and Grade 3 experienced some form of hearing improvement, while those in Grade 4 and Grade 5 had lower rates of improvement, 37.5% and 33% respectively.

6. Discussion

Table 1 compares the improvement rates of patients receiving the cocktail regimen. The OR of 1.0 with a CI ranging from 0.342 to 2.921 and a P-value of 1.0 indicates no statistical significance in the effectiveness of the treatment regimen compared to no improvement. This lack of statistical significance is consistent with the findings of Mishra SK et al.(2022),[10] who noted that systemic steroids did not always offer a clear advantage for patients with SSNHL.

Table 2 breaks down recovery into categories: complete recovery, partial recovery, and no recovery. The uniform OR of 1.0 across all comparisons, coupled with wide CIs and P-values of 1.0, indicates a lack of statistically significant difference between the groups. These findings are in stark contrast to the study by Skarzynska MB et al.(2022),[11] which found that systemic steroids improved the likelihood of recovery in SSNHL patients.

Table 3 demonstrates a significant mean improvement in Pure Tone Audiometry (PTA) readings of 22.56 dB, a statistically significant result with a P-value of less than 0.005. This significant improvement aligns withMobarek EM et al.(2022)[12] & Swain SK. (2022)[13] suggestion that early treatment can result in significant hearing recovery in SSNHL patients.

Table 4 applies Modified Siegel's criteria to assess treatment outcomes across different grades of pre-treatment hearing loss. The total improvement rate of 74.2% is notable, with 100% improvement rates in Grades 2 and 3. However, the lower rates of improvement in Grades 4 and 5, at 37.5% and 33% respectively, raise concerns about the efficacy of the treatment in patients with more severe initial hearing loss. Liu C et al.(2022)[14] & Khoza-Shangase K et al.(2022)[15] also found varying degrees of treatment response based on initial hearing loss severity, suggesting that early intervention is crucial.

7. Conclusion

The conclusion drawn from the study on the cocktail regimen for the treatment of sudden sensorineural hearing loss (SSNHL) presents a multifaceted view. The treatment, comprising intratympanic steroid injections, oral steroids, valacyclovir, and pentoxifylline, was administered to a cohort of 35 patients with varying degrees of initial hearing loss.

From the statistical analysis, while the odds ratios (OR) and confidence intervals (CI) in Tables 1 and 2 did not demonstrate a statistically significant effect of the treatment when comparing improved versus not improved outcomes, the data in Table 3 showed a substantial mean improvement in pure tone audiometry (PTA) readings post-treatment. This significant improvement suggests that the cocktail regimen may have a positive impact on hearing recovery in SSNHL patients.

Further analysis using Modified Siegel's criteria (Table 4) revealed a high percentage of hearing improvement in patients with milder forms of initial hearing loss, with total improvement observed in 74.2% of cases. This suggests that while the cocktail regimen may benefit a considerable proportion of patients, its effectiveness is notably variable and may be more pronounced in those with less severe hearing loss at the onset of treatment.

In conclusion, the cocktail regimen for SSNHL displays potential therapeutic benefits, particularly in cases with less severe initial hearing impairment. Despite the lack of

Table 2: Hearingrecovery comparisons

Comparison	Odds Ratio (OR)	95% CI Lower	95% CI Upper	P-value
Complete Recovery vs Not Complete	1.0	0.379	2.637	1.0
Partial Recovery vs Not Partial	1.0	0.379	2.637	1.0
No Recovery vs Recovery	1.0	0.342	2.921	1.0

Table 3: Pre-treatmentvs Post-treatment PTA results

Comparison	Mean Difference (dB)	Standard Deviation (SD)	P-value
Pre-op vs Post-op	22.56	18.4	<0.005

Table 4: Treatment outcomes using modified Siegel's criteria

Pre-treatment Hearing Grade	Complete Recovery (n)	Partial Recovery (n)	No Recovery (n)	Total Improvement (n)	Improvement Percentage (%)
Grade 2	6	5	0	11	100%
Grade 3	5	5	0	10	100%
Grade 4	2	1	5	3	37.5%
Grade 5	0	2	4	2	33%
Total	13	13	9	26	74.2%

statistical significance in some of the comparative analyses, the overall rate of hearing improvement indicates that this regimen could be a viable option for SSNHL patients. Further studies with larger sample sizes and control groups are recommended to confirm these findings and optimize treatment protocols for SSNHL.

8. Limitations of study

1. Small Sample Size: With only 35 participants, the study's sample size may not provide sufficient power to detect a statistically significant effect of the treatment, limiting the generalizability of the results.
2. Lack of Control Group: The absence of a control group receiving a placebo or standard treatment prevents a robust comparison of the cocktail regimen's efficacy, potentially introducing bias and limiting the study's internal validity.
3. Variability in Treatment Response: The study indicates variable responses to the cocktail regimen across different severity levels of hearing loss, which may be due to the heterogeneity of SSNHL etiologies, patient health status, or other uncontrolled variables.
4. Short Follow-Up Duration: A follow-up period limited to 3 months may not be sufficient to evaluate the long-term outcomes and potential late recovery or relapses in hearing function.
5. Subjective Measurement: The use of Pure Tone Audiometry (PTA) as a sole measure of improvement is subjective and could be supplemented with more objective measures such as speech discrimination scores.
6. Potential for Selection Bias: The inclusion criteria may have resulted in the selection of patients with a higher likelihood of recovery, which can influence the outcomes positively and may not reflect the typical SSNHL population.
7. Statistical Analysis Constraints: The use of odds ratios without an actual control group and with a uniform outcome across treatment categories may not provide meaningful statistical interpretations.
8. Retrospective Design: If the study was retrospective, it could suffer from biases related to data collection and reliance on the accuracy and completeness of medical records.
9. Confounding Factors: The study may not have adequately controlled for confounding factors such as concurrent health conditions, previous hearing loss, or the time elapsed from symptom onset to treatment initiation.
10. Reporting Bias: There may be a potential for reporting bias if the data collection was not blinded or if there were inconsistencies in how patient outcomes were recorded.

9. Source of Funding

None.

10. Conflict of Interest

None.

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