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Intratympanic dexamethasone injection for tinnitus treatment: Can success be predicted?

Tinnitus tedavisinde intratimpanik deksametazon enjeksiyonu: Başarı tahmin edilebilir mi?

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ABSTRACT

Objectives: This study aims to conduct a statistical analysis of clinical and audiological data based on treatment outcomes to examine the factors influencing treatment success of intratympanic dexamethasone injection (ITDI) in patients with tinnitus.

Patients and Methods: This retrospective study included 25 tinnitus patients (16 males, 9 females; mean age: 52.8±13.9 years; range, 27 to 72 years) who underwent ITDI treatment at our hospital between September 1, 2023, and September 1, 2024. Patients who completed four doses of treatment and were followed up for six months, with available pre- and posttreatment Tinnitus Handicap Inventory (THI) scores and audiometric evaluations, were included in the analysis.

Results: The rates of vertigo, comorbid conditions, and smoking history were 44%, 8%, and 7%, respectively. The median duration from symptom onset to treatment initiation was 20.4 (range, 1 to 120) months. Treatment success was significantly lower in patients with a history of vertigo compared to those without vertigo (27.3% *vs.* 78.6%, p=0.01). There were no significant differences in success rates based on age, sex, laterality, presence of comorbidities, smoking status, or tinnitus duration (<3 months *vs.* >3 months; p>0.05 for all). Audiometric analysis showed no significant changes in hearing thresholds at 250-8000 Hz after treatment. However, patients who exhibited greater hearing loss at 8000 Hz in pretreatment audiometry had lower success rates (p=0.051).

Conclusion: The presence of vertigo and severe high-frequency hearing loss may negatively influence the success of ITDI treatment in tinnitus patients.

Keywords: Audiometry, dexametazon, intratympanic, tinnitus, tinnitus handicap inventory.

ÖZ

Amaç: Bu çalışmada, tinnituslu hastalarda intratimpanik deksametazon enjeksiyonu (ITDI)'nun tedavi başarısını etkileyen faktörleri incelemek amacıyla tedavi sonuçlarına dayalı klinik ve odyolojik verilerin istatistiksel analizi gerçekleştirildi.

Hastalar ve Yöntemler: Bu retrospektif çalışmaya, 1 Eylül 2023 ile 1 Eylül 2024 tarihleri arasında hastanemizde ITDI tedavisi gören 25 tinnitus hastası (16 erkek, 9 kadın; ort. yaş: 52.8±13.9 yıl; dağılım, 27-72 yıl) dahil edildi. Dört doz tedaviyi tamamlayan ve altı ay boyunca takip edilen, tedavi öncesi ve sonrası Tinnitus Handikap Envanteri (THI) puanları ve odyometrik değerlendirmeleri mevcut olan hastalar analize dahil edildi.

Bulgular: Vertigo, eşlik eden hastalıklar ve sigara içme öyküsü oranları sırasıyla %44, %8 ve %7 idi. Semptom başlangıcından tedavi başlangıcına kadar geçen medyan süre 20.4 (dağılım, 1-120) ay idi. Vertigo öyküsü olan hastalarda tedavi başarısı, vertigosu olmayan hastalara kıyasla önemli ölçüde daha düşüktü (%27.3'e karşı %78.6, p=0.01). Yaş, cinsiyet, lateralite, eşlik eden hastalıkların varlığı, sigara içme durumu veya tinnitus süresine (<3 ay ile >3 ay) göre başarı oranlarında önemli bir fark yoktu (hepsi için p>0.05). Odyometrik analiz, tedavi sonrası 250-8000 Hz'de işitme eşiklerinde önemli bir değişiklik olmadığını gösterdi. Ancak, tedavi öncesi 8000 Hz'de daha fazla işitme kaybı olan hastaların başarı oranları daha düşüktü (p=0.051).

Sonuç: Vertigo ve yüksek frekanslarda işitme kaybının fazla olması, tinnitus hastalarında ITDI tedavisinin başarısını olumsuz etkileyebilir.

Anahtar sözcükler: Odyometri, deksametazon, intratimpanik, tinnitus, tinnitus handikap envanteri.

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Subjective tinnitus is a perception of a phantom sound that is audible only to the affected individual.[1] There is a consensus that tinnitus results from abnormal neural activity within the auditory pathway, which is misinterpreted as sound by the auditory cortex; however, the pathophysiology of tinnitus has not yet been fully elucidated.[2] Damage to cochlear hair cells is thought to play a critical role in the pathogenesis of tinnitus.[3] Tinnitus can lead to fatigue, irritability, and depression, significantly affecting the quality of life.[4]

Intratympanic dexamethasone injection (ITDI) has been used to treat idiopathic tinnitus, as well as various inner ear disorders.[5] It enhances intracochlear steroid concentration via absorption through the round window membrane. This technique is performed easily under local anesthesia, is well-tolerated, and avoids the systemic side effects associated with corticosteroids. However, the disadvantages of ITDI may include pain during the injection and transient vertigo.[6]

Studies evaluating the efficacy of ITDI in tinnitus patients have been reported, but no studies to date have specifically investigated the impact of factors such as smoking, vertigo, comorbidities, and hearing levels at different frequencies on treatment success. Hence, this study aimed to analyze clinical data, pre- and posttreatment Tinnitus Handicap Inventory (THI) scores, and pure-tone audiometry results of patients who underwent ITDI and who were followed for at least six months. We presented a statistical analysis of the data based on treatment success.

PATIENTS AND METHODS

Twenty-five patients (16 males, 9 females; mean age: 52.8±13.9 years; range, 27 to 72 years) diagnosed with tinnitus who underwent ITDI treatment in the Department of Otorhinolaryngology at the Bursa City Research and Training Hospital between September 1, 2023, and September 1, 2024, were retrospectively evaluated. Patients who received ITDI for tinnitus were included in the study if they completed four treatment doses, had a follow-up period of at least six months, and had both pre- and posttreatment THI scores and audiometric evaluations. Patients were excluded if they were lost to follow-up before six months, had tympanic membrane perforation, concurrent sudden hearing loss, pulsatile tinnitus, Meniere's disease, or lacked THI and audiometric data. Written informed consent was obtained from all patients. The study protocol was approved by the Bursa City Research and Training Hospital Ethics Committee (Data: 11.12.2024, No: 2024-21/4). The study was conducted in accordance with the principles of the Declaration of Helsinki.

The initial evaluation included a detailed medical history, otoscopic examination, and audiological testing, including the frequencies between 250 and 8000 Hz (pure-tone audiometry). Magnetic resonance imaging (MRI) was performed if retrocochlear pathology was suspected. Positional tests were conducted in patients with vestibular symptoms to differentiate benign paroxysmal positional vertigo. Patients reporting dizziness, imbalance, or history of vertigo treatment, excluding benign paroxysmal positional vertigo, were categorized as having vertigo.

For the ITDI procedure, topical anesthesia was applied after confirming an intact tympanic membrane with the patient in the supine position. Using a 25-gauge spinal needle, a ventilation puncture was made in the anterosuperior quadrant, and a second puncture was made in the anteroinferior quadrant for perfusion. Intratympanic dexamethasone sodium phosphate (5 mg/mL) was injected. The injections were administered twice weekly for two weeks. During the procedure, patients were instructed to avoid swallowing and to keep their head tilted 45° toward the unaffected side for 15 min.

Six months later, after the final assessment, patients with persistent symptoms were offered further treatments, including oral medications, repeated ITDI, or tinnitus rehabilitation therapy.

Pure-tone audiometry evaluations were performed before treatment, one month after treatment initiation, and at least six months after treatment. The THI, a 25-item questionnaire developed by Newman et al.[7] to assess the physical, emotional, and social impacts of tinnitus, was administered before and at least six months after treatment. Long-term treatment benefit was defined as a reduction of at least 7 points or 20% in the THI score.[8]

Data from 25 patients who completed the six-month follow-up period were analyzed based on the treatment success status. The analysis included factors such as age, sex, side of the condition, tinnitus duration, presence of vertigo, comorbidities, smoking status, pre- and posttreatment THI scores, and hearing levels at frequencies ranging from 250 to 8000 Hz.

Statistical analysis

The sample size was calculated using G*Power version 3.1.9.6 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) based on a power analysis with an effect size of 0.41, alpha of 0.05, and power of 0.8, yielding a minimum of 25 participants. Statistical analyses were performed with IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Continuous data were summarized as mean ± standard deviation (SD) or median (min-max) based on normality, while categorical data were presented as frequencies and percentages. Normality was assessed using the Kolmogorov-Smirnov test. Group comparisons employed the Student's t-test or analysis of variance for normally distributed data, and the Mann-Whitney U or Friedman tests for nonnormally distributed data. Categorical variables were analyzed using the chi-square or Fisher exact test. The Pearson correlation assessed relationships between continuous variables. The level of statistical significance was set at $p<0.05$.

RESULTS

The ITDI was performed on 10 right ears and 15 left ears. Vertigo symptoms were present in 44% of the patients, and 8% had comorbidities, most commonly hypertension and diabetes mellitus. A history of smoking was reported in 7% of patients. The median duration from symptom onset to hospital admission was 20.4 (range, 1 to 120) months. The mean hearing threshold in pure-tone audiometry was 21.9±16.3 dB. Clinical and symptomatic data, pure-tone audiometry results (hearing levels at 250, 500, 1000, 2000, 4000, and 8000 Hz), and pre- and posttreatment THI scores are summarized in Tables 1 and 2.

Statistical analysis revealed that the success rates of ITDI were significantly lower in patients with vertigo than in those without vertigo, with rates of 27.3% versus 78.6%, respectively ($p=0.01$). No significant differences in treatment success were found based on age, sex, laterality, presence of comorbidities, smoking history, or tinnitus duration (<3 months *vs.* >3 months; $p>0.05$ for all; Table 3).

Table 1
General distribution of variables

Variables	n	%
Total patients	25	100.0
Sex		
Male	16	64.0
Female	9	36.0
Side affected		
Left	15	60.0
Right	10	40.0
Presence of vertigo		
Absent	14	56.0
Present	11	44.0
Smoking status		
Non-smoker	18	72.0
Smoker	7	28.0
Comorbid conditions		
Absent	17	68.0
Present	8	32.0
Treatment outcome		
Unsuccessful	11	44.0
Successful	14	56.0

Table 2
Descriptive statistics of selected variables

Variables	Mean±SD	Min-Max
Age (year)	52.8±13.9	27-72
250 Hz Pretreatment	26.0±19.7	5-75
500 Hz Pretreatment	19.2±18.1	0-65
1000 Hz Pretreatment	19.4±16.7	5-65
2000 Hz Pretreatment	21.4±16.7	5-70
4000 Hz Pretreatment	38.2±24.2	5-85
8000 Hz Pretreatment	52.0±24.5	10-110
250 Hz Early posttreatment	21.8±15.1	5-70
500 Hz Early posttreatment	18.8±17.3	5-65
1000 Hz Early posttreatment	19.2±18.0	5-70
2000 Hz Early posttreatment	20.8±17.2	0-70
4000 Hz Early posttreatment	36.0±22.0	5-80
8000 Hz Early posttreatment	50.8±23.6	5-110
250 Hz Late posttreatment	22.4±13.3	5-55
500 Hz Late posttreatment	17.6±16.3	5-70
1000 Hz Late posttreatment	20.4±20.3	5-85
2000 Hz Late posttreatment	22.6±21.8	0-90
4000 Hz Late posttreatment	35.4±22.1	5-85
8000 Hz Late posttreatment	50.6±23.1	5-110
Hearing decibel (dB)	21.9±16.3	3-67
Tinnitus duration (month)	20.4±34.3	1-120
THI score pretreatment	52.0±23.6	10-100
THI score posttreatment	36.0±23.9	0-74

SD: Standard deviation.

Table 3
Comparison of treatment success rates according to selected variables

Variables	Unsuccessful n	Unsuccessful %	Successful n	Successful %	Total n	Total %	*p*
Sex							0.383
Male	6	37.5	10	62.5	16	100	
Female	5	55.6	4	44.4	9	100	
Side							0.742
Left	7	46.7	8	53.3	15	100	
Right	4	40.0	6	60.0	10	100	
Vertigo							**0.01**
Absent	3	21.4	11	78.6	14	100	
Present	8	72.7	3	27.3	11	100	
Smoking							0.407
No	9	50.0	9	50.0	18	100	
Yes	2	28.6	5	71.4	7	100	
Comorbid disease							0.999
Absent	7	41.2	10	58.8	17	100	
Present	4	50.0	4	50.0	8	100	
Tinnitus duration							0.999
<3 months	5	45.54	6	54.5	11	100	
>3 months	6	42.9	8	57.1	14	100	

Statistically significant at p<0.05.

According to THI scores, treatment success was achieved in 56% of the patients. Overall, the mean pretreatment THI score was 52±23.6, which decreased to 36±23.9 at least six months after treatment. The successful group of patients showed a significant decrease in posttreatment THI scores, dropping from a mean of 58.5±24.8 before treatment to a mean of 27.2±22.6 afterward.

When comparing pretreatment hearing thresholds between successful and unsuccessful groups, no significant differences were observed at 250, 500, 1000, 2000, and 4000 Hz. However, the hearing

Table 4
Comparison of mean values of variables according to treatment outcome

Variables	Failed treatment Mean±SD	Successful treatment Mean±SD	Total Mean±SD	*p*
Age (year)	53.7±14.0	52.0±14.2	52.8±13.9	0.851
Tinnitus duration (month)	27.5±38.5	14.8±31.0	20.4±34.3	0.727
Hearing (dB)	27.4±18.4	17.6±13.6	21.9±16.3	0.166
THI pretreatment score	43.6±20.0	58.5±24.8	52.0±23.6	0.317
THI posttreatment score	47.3±21.3	27.2±22.6	36.0±23.9	0.051
250 Hz pretreatment	27.7±20.7	24.7±19.7	26.0±19.7	0.687
500 Hz pretreatment	23.2±20.8	16.1±15.8	19.2±18.1	0.344
1000 Hz pretreatment	24.6±20.7	15.4±12.0	19.4±16.7	0.267
2000 Hz pretreatment	27.7±20.4	16.4±11.7	21.4±16.7	0.120
4000 Hz pretreatment	45.0±24.0	32.9±23.8	38.2±24.2	0.244
8000 Hz pretreatment	62.7±26.5	43.6±19.8	52.0±24.5	0.051

SD: Standard deviation.

Table 5
Comparison of mean values before and after treatment in the early and long term based on frequency values

	Pretreatment	Early posttreatment	Late posttreatment	
	Mean±SD	Mean±SD	Mean±SD	*p*
Frequency (Hz)				
250	26.0±19.7	21.8±15.1	22.4±13.3	0.627
500	19.2±18.1	18.8±17.3	17.6±16.3	0.465
1000	19.4±16.7	19.2±18.0	20.4±20.3	0.511
2000	21.4±16.7	20.8±17.2	22.6±21.8	0.987
4000	38.2±24.2	36.0±22.0	35.4±22.1	0.713
8000	52.0±24.5	50.8±23.6	50.6±23.1	0.961

SD: Standard deviation.

threshold at 8000 Hz was higher in the unsuccessful group than in the successful group, although this difference did not achieve statistical significance (62.7 dB *vs.* 43.6 dB, p=0.051; Table 4). When comparing hearing thresholds at frequencies between 250 and 8000 Hz, evaluated separately, no significant differences were found among the pretreatment, early posttreatment, and long-term posttreatment results (Table 5).

DISCUSSION

In our study, the duration of tinnitus in patients varied from 1 to 120 months. Patients with sudden sensorineural hearing loss (SSNHL) and Meniere's disease were excluded. Six months after treatment, there was no significant change in hearing thresholds at frequencies ranging from 250 to 8000 Hz when compared to pretreatment levels. We believe that the lack of difference was due to the exclusion of patients with SSNHL or fluctuating hearing loss.

Evaluation of THI scores at least six months after treatment revealed a success rate of 56%. When comparing hearing thresholds at all frequencies in pretreatment audiometry between the successful and unsuccessful groups, a difference was noted only at 8000 Hz; however, this difference was not statistically significant (p=0.051). Patients who achieved successful outcomes had lower pretreatment hearing thresholds at 8000 Hz compared to those with unsuccessful results, with mean thresholds of 43.6±19.8 dB and 62.7±26.5 dB, respectively. While a higher frequency hearing loss has been identified as a negative prognostic factor in SSNHL patients,[9] this association has not been studied in tinnitus patients. The lower success rates in patients with higher thresholds at 8000 Hz may reflect more severe cochlear involvement.

Patients reporting vertigo had significantly lower ITDI success rates than those without vertigo (p=0.01). The vertigo described by our patients was not severe but manifested as recurrent or persistent dizziness or unsteadiness independent of tinnitus. While some studies suggest vestibular symptoms are a negative prognostic factor in SSNHL,[9] others report no such effect.[10] Vertigo in SSNHL may result from involvement of the superior vestibular pathway or extensive inner ear damage.[10] However, no specific data on the relationship between vertigo and prognosis in tinnitus patients was found. Tinnitus, vertigo, and dizziness are often associated with cervicovascular factors or vertebrobasilar insufficiency, and Doppler ultrasound evaluation may be recommended for patients with vertigo.[11] Given these findings, ITDI may not be suitable as a first-line treatment for patients presenting with vertigo symptoms.

Current tinnitus treatments include masking hearing aids, tinnitus retraining therapy, and oral medications with uncertain efficacy. Intratympanic therapies with various agents have emerged as a treatment option for inner ear disorders, frequently used in SSNHL, Meniere's disease, and idiopathic tinnitus.[12-16] Intratympanic steroids diffuse through the round window, exerting anti-inflammatory and electrolyte-modifying effects via steroid receptors.[17] Their mechanisms in tinnitus are believed to include direct action on inner ear epithelial cells, reduction of inflammation caused by immune-mediated/autoimmune dysfunction, and improved cochlear blood flow.[18] Intratympanic dexamethasone injection offers the advantage of

achieving high steroid concentrations in the inner ear while avoiding systemic side effects. Consistent with the literature, we observed long-term reductions in tinnitus perception with ITDI in 56% of the patients, without notable adverse effects or changes in hearing thresholds.

The effectiveness of ITDI for tinnitus was first reported by Sakata et al.,[19] who observed a 70% success rate in 1,214 patients (1,466 ears) at six months. Intratympanic dexamethasone injection is hypothesized to be more effective in acute than chronic cases.[20] Shim et al.,[21] in their study of 107 patients with acute idiopathic tinnitus, reported that the recovery rate in the alprazolam plus ITDI group (75.8%) was significantly higher than the recovery rate in the alprazolam alone group (40.3%). However, placebo-controlled studies on acute tinnitus have shown no significant differences in success rates between ITDI and placebo.[15,16] Similarly, Lee et al.[20] reported no significant differences in THI scores at one month between ITDI and intratympanic saline injection in acute tinnitus patients. Topak et al.[22] also found no advantage of transtympanic methylprednisolone injection over placebo for tinnitus treatment. Apart from these, the effectiveness of ITDI in patients with chronic tinnitus is also controversial. Choi et al.[6] reported no significant differences in success rates compared to placebo in refractory tinnitus cases lasting more than six months (mean 60±33.9 months). In contrast, Yener et al.[23] found ITDI to be significantly more effective than saline in tinnitus lasting over 12 months (up to 120 months) at six months after treatment. Our study included patients with both acute and refractory tinnitus, with durations ranging from 1 to 120 months. When grouped by tinnitus duration (<3 months *vs.* >3 months), no significant differences in success rates were observed (p=0.727). We attribute this finding to the limited sample size.

We also found that treatment success was not affected by patient age, smoking history, or the presence of comorbidities. Although no specific relationships have been reported in the literature, further comparisons in larger patient cohorts are warranted.

The limitations of this study were its single-center, retrospective design and small sample size. Nevertheless, our analysis of accompanying clinical symptoms and hearing thresholds across various frequencies in relation to ITDI success represents a novel approach. Prospective studies with larger patient populations are needed to provide further insights into the factors influencing ITDI outcomes.

In conclusion, ITDI is effective in reducing tinnitus symptoms. Assessment of vertigo, as well as pretreatment audiometric evaluation, may help predict treatment outcomes. A history of vertigo or severe high-frequency hearing loss may negatively influence ITDI success. Randomized controlled studies with larger participant groups may more clearly reveal the critical factors in predicting the effectiveness and success rate of ITDI.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Study conception and design, data collection, analysis and interpretation of results: B.T., G.T.; Draft manuscript preparation: B.T. All authors reviewed the results and approved the final version of the manuscript.

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