

Original Investigation



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Prospective Exploratory Evaluation of Audiovestibular Function in Patients Receiving Oral Isotretinoin Using Audiometry and Videonystagmography

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Abstract

Objective: To prospectively evaluate possible audiovestibular changes associated with short-term oral isotretinoin therapy using pure-tone audiometry and selected videonystagmography (VNG)-based vestibular assessments.

Methods: Participants older than 18 years receiving oral isotretinoin therapy constituted the study group. All participants underwent detailed otorhinolaryngological examination, along with pure-tone audiometry and tympanometric analysis, prior to treatment initiation and after three months of therapy. Vestibular assessment included VNG-based spontaneous nystagmus analysis, gaze testing, positional testing, and oculomotor evaluations.

Results: Thirty-three patients were included in the analysis (11 males and 22 females). The median age was 20.0 years (interquartile range: 3.0). Comparison of pre- and post-treatment audiometric data demonstrated no significant changes across frequencies ranging from 250 to 8000 Hz, nor in pure-tone average, high-frequency average, or low-frequency average pure-tone average, high-frequency average, or low-frequency average values. A significant change was observed at 6000 Hz in the right ear; however, this finding was not clinically meaningful and likely reflected minor distributional variation between paired measurements. Selected VNG-based vestibular assessments, including spontaneous nystagmus, gaze, positional, and oculomotor testing, remained within normal limits throughout the study period.

Conclusion: Within the limitations of this exploratory pilot study, short-term oral isotretinoin therapy did not demonstrate clinically significant abnormalities in audiometric measurements or selected VNG-based vestibular assessments.

Keywords: Acne vulgaris, isotretinoin, audiometry, vestibular function tests

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Introduction

Acne vulgaris is a chronic inflammatory condition of the pilosebaceous unit with a multifactorial pathogenesis, involving increased sebum production, follicular hyperkeratinization, microbial proliferation, and downstream inflammatory responses (1). The condition most commonly involves the face, neck, chest, and back, and frequently affects adolescents and young adults, leading not only to cosmetic concerns but also to significant psychosocial burden. Therefore, early and effective therapeutic intervention is essential to minimize the risk of permanent scarring.

Oral isotretinoin remains one of the most effective therapeutic options for acne vulgaris due to its ability to target multiple pathogenic mechanisms simultaneously (1). Although initially reserved for severe nodulocystic acne, its use has expanded to include selected moderate cases with appropriate monitoring and individualized dosing strategies. Despite its well-established efficacy, isotretinoin therapy is associated with a broad spectrum of adverse effects, including mucocutaneous dryness, epistaxis, musculoskeletal complaints, mood alterations, visual disturbances, and teratogenicity (2-5). Less frequently, neurological and sensory symptoms such as dizziness, tinnitus, nausea, and vertigo have also been reported (2,6,7).

The relationship between isotretinoin and audiovestibular dysfunction remains controversial. Previous studies investigating auditory effects have yielded inconsistent results, while vestibular data remain extremely limited (8-11). Furthermore, vestibular adverse effects may be underrecognized because mild or transient symptoms are often evaluated subjectively and objective vestibular testing is rarely performed.

Videonystagmography (VNG) is a diagnostic modality utilized in the assessment of vestibular function, enabling objective recording and analysis of eye movements through infrared-based video technology (12). By tracking pupillary movements with high precision, VNG provides real-time evaluation of oculomotor responses and allows for subsequent data storage and detailed analysis. Unlike traditional methods, VNG is not significantly influenced by ambient lighting conditions or certain ocular limitations, and it offers the additional advantage of detecting torsional eye movements. In clinical practice, this capability facilitates the diagnosis of vestibular disorders, including benign paroxysmal positional vertigo (12). In addition, pure-tone audiometry provides objective assessment of cochlear function and hearing thresholds.

To date, only one study has evaluated vestibular function during isotretinoin therapy using the video head impulse test (vHIT) (8). In addition, literature regarding VNG-based vestibular assessment during isotretinoin treatment remains

scarce. Therefore, this prospective exploratory study aimed to investigate possible subclinical audiovestibular alterations during short-term oral isotretinoin therapy using audiometry and selected VNG-based vestibular assessments.

Methods

Thirty-three patients older than 18 years who presented to the Dermatology Outpatient Clinic of Konya City Hospital with a complaint of “acne vulgaris” and were started on oral isotretinoin (0.5-1 mg/kg/day) constituted the study population (13). The study was designed as an exploratory pilot investigation evaluating possible audiovestibular alterations before and after isotretinoin exposure within the same cohort. All participants received detailed information regarding the study protocol, and written informed consent was obtained from all individuals prior to participation. Ethical approval was granted by the Necmettin Erbakan University Research on Non-Drug and Medical Device Products Ethics Committee (approval no: 2021/3484, date: 05.11.2021). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Participants with documented conductive or sensorineural hearing loss, diagnosed vestibular disorders, abnormal otoscopic findings, neurological or psychiatric disorders, systemic diseases potentially affecting vestibular function, or a history of otologic surgery were excluded from the study.

All participants underwent comprehensive otorhinolaryngological examination before testing. Hearing evaluation was performed using a clinical audiometer (Interacoustics AC 40, Assens, Denmark) and tympanometry device (Interacoustics AT 235, Assens, Denmark). Air- and bone-conduction thresholds were assessed at frequencies ranging from 250 to 8000 Hz. Tympanometric findings and acoustic reflex responses were recorded. Pure-tone average (PTA) was calculated using air-conduction thresholds at 500, 1000, 2000, and 4000 Hz. High-frequency average (HFA) values were calculated from 4000, 6000, and 8000 Hz, whereas low-frequency average (LFA) values were derived from 250, 500, and 1000 Hz. Audiometric evaluations were performed before treatment initiation and repeated at the third month of therapy.

Participants were questioned regarding vestibular-related symptoms, including dizziness, vertigo, imbalance, tinnitus, nausea, and vomiting, at baseline and during follow-up. Bedside vestibular examination included assessment of spontaneous nystagmus, the bedside HIT, head-shaking nystagmus, tandem gait, the Fukuda stepping test, the Romberg test, and evaluation for skew deviation.

Selected VNG-based vestibular assessments were performed using a VNG system (Micro Medical, Interacoustics A/S, VisualEyes 505, Assens, Denmark) before treatment initiation

and after three months of oral isotretinoin therapy. The VNG protocol included spontaneous nystagmus analysis, gaze testing, positional and positioning tests comprising the Dix-Hallpike maneuver, straight head-hanging maneuver, and supine roll maneuver, as well as quantitative oculomotor testing.

The quantitative oculomotor test battery included smooth pursuit, saccadic, and optokinetic evaluations. Smooth pursuit gain was recorded separately for rightward and leftward tracking at target frequencies of 0.2 and 0.4 Hz. Saccadic testing included direction-specific measurements of latency (ms), velocity ($^{\circ}$ /s), and accuracy (%). Optokinetic gain was assessed separately for rightward and leftward stimulation at a stimulus velocity of 20° /s. Because binocular eye movements are physiologically conjugate, the values recorded from the right and left eyes were averaged to obtain a single representative value for each stimulus direction and participant. Directional symmetry of smooth pursuit responses was evaluated by comparing rightward and leftward gain values in each assessment session. Caloric testing was not included in the predefined study protocol, which was limited to a focused non-invasive vestibular test battery.

Statistical Analysis

Descriptive statistics were used to summarize the demographic, treatment-related, audiometric, and VNG findings. The distribution of continuous variables and paired differences was assessed using the Kolmogorov-Smirnov and the Shapiro-Wilk tests. Categorical variables were expressed as number (n) and percentage (%). Because several audiometric variables were not normally distributed, these data were presented as median and interquartile range (IQR), and pre-treatment and third-month measurements were compared using the Wilcoxon signed-rank test.

Quantitative VNG parameters were presented as mean $\pm$ standard deviation together with minimum and maximum values. Pre-treatment and third-month VNG measurements were compared using the paired-samples t-test when the distribution of paired differences was normal and the Wilcoxon signed-rank test when the normality assumption was not met. Directional symmetry was evaluated by comparing rightward and leftward smooth pursuit gain values within each assessment session using the paired-samples t-test or the Wilcoxon signed-rank test, as appropriate. Given the exploratory nature of the study, no formal adjustment for multiple comparisons was applied; therefore, isolated statistically significant findings were interpreted cautiously and in conjunction with their clinical relevance. Statistical analyses were performed using the Statistical Package for the Social Sciences software, version 22.0 (IBM Corp., Armonk, NY, USA). All tests were two-sided, and $p < 0.05$ was considered statistically significant.

Results

The study included 33 patients (11 males, 33.3%; 22 females, 66.7%). The median age was 20.0 years (IQR: 3.0). Based on the Global Acne Grading System, none of the patients were classified as stage 1, whereas 8 (24.2%) were stage 2, 18 (54.5%) were stage 3, and 7 (21.2%) were stage 4. Regarding treatment dosage, 17 patients (51.5%) received 30 mg/day, 15 (45.5%) received 40 mg/day, and 1 patient (3.0%) was treated with 50 mg/day isotretinoin (Table 1).

Otorhinolaryngological examination findings were unremarkable in all participants. Audiological assessments were performed separately for the right and left ears. Tympanometric measurements were within normal limits in all cases, and speech discrimination scores did not indicate any impairment. Comparative analysis of audiometric parameters revealed no statistically significant differences between pre-treatment and third-month measurements at frequencies of 250, 500, 1000, 2000, 4000, and 8000 Hz, as well as in PTA, HFA, and LFA values. An isolated statistically significant difference was observed at 6000 Hz in the right ear ($p = 0.043$). Although median threshold values remained unchanged, this finding likely reflected minor distributional shifts among paired measurements rather than a clinically meaningful hearing threshold deterioration (Table 2).

None of the participants reported newly developed vestibular or audiological symptoms, including vertigo, dizziness, imbalance, tinnitus, nausea, or vomiting, during the study period. No spontaneous, gaze-evoked, or positional nystagmus was detected either before treatment or at the third-month assessment.

Quantitative analysis of the VNG-based oculomotor parameters revealed no statistically significant changes after three months of oral isotretinoin therapy. Smooth pursuit gain at 0.2 and 0.4 Hz remained stable for both rightward and leftward tracking, with all time-effect p-values ranging from 0.451 to 0.692. No significant differences between rightward and leftward smooth pursuit gains were identified at either

Table 1. Demographic and treatment characteristics of the study population

Variable	Value
Sex, n (%)	
Male	11 (33.3)
Female	22 (66.7)
Age (years), median (IQR)	20.0 (3.0)
Daily isotretinoin dose, n (%)	
30 mg	17 (51.5)
40 mg	15 (45.5)
50 mg	1 (3.0)
IQR: Interquartile range	

Table 2. Pre- and post-treatment pure-tone audiometry outcomes

Frequency (Hz)	Ear	Pre-treatment (median, IQR)	Post-treatment (median, IQR)	p-value
250	Right	15.0 (10.0)	15.0 (5.0)	0.083
	Left	10.0 (7.5)	15.0 (5.0)	0.731
500	Right	10.0 (5.0)	10.0 (7.5)	0.980
	Left	10.0 (10.0)	10.0 (7.5)	0.568
1000	Right	10.0 (10.0)	10.0 (5.0)	0.550
	Left	10.0 (10.0)	10.0 (10.0)	0.985
2000	Right	10.0 (5.0)	5.0 (5.0)	0.573
	Left	10.0 (10.0)	10.0 (5.0)	0.642
4000	Right	10.0 (5.0)	10.0 (7.5)	0.451
	Left	10.0 (10.0)	10.0 (10.0)	0.898
6000	Right	10.0 (10.0)	10.0 (12.5)	0.043
	Left	10.0 (5.0)	15.0 (5.0)	0.812
8000	Right	15.0 (10.0)	10.0 (7.5)	0.107
	Left	10.0 (5.0)	15.0 (7.5)	0.460
PTA	Right	8.75 (6.3)	8.75 (5.0)	0.922
	Left	8.75 (6.3)	10.0 (5.0)	0.866
HFA	Right	13.33 (8.3)	11.66 (5.0)	0.098
	Left	13.33 (8.3)	11.66 (8.3)	0.326
LFA	Right	11.66 (6.7)	10.0 (6.7)	0.211
	Left	10.0 (5.8)	11.66 (5.8)	0.930

PTA: Pure-tone average (500, 1000, 2000, and 4000 Hz), HFA: High-frequency average (4000, 6000, and 8000 Hz), LFA: Low-frequency average (250, 500, and 1000 Hz), IQR: Interquartile range

assessment, indicating preserved directional symmetry at both frequencies before and after treatment (all symmetry p-values ranging from 0.184 to 0.812).

Saccadic latency, velocity, and accuracy did not differ significantly between the pre-treatment and third-month evaluations in either direction, with p-values ranging from 0.435 to 0.925. Similarly, optokinetic gain at a stimulus velocity of 20°/s remained unchanged for both rightward (p=0.627) and leftward stimulation (p=0.942). The mean $\pm$ standard deviation and minimum-maximum values for all quantitative VNG parameters are presented in Table 3.

Discussion

The presented prospective exploratory study evaluated possible audiovestibular alterations associated with short-term oral isotretinoin therapy using objective audiometric and selected VNG-based vestibular assessments. The findings demonstrated no clinically meaningful deterioration in hearing thresholds or abnormalities in the selected VNG-based vestibular assessments during the three-month treatment period.

Oral isotretinoin remains a cornerstone in acne vulgaris management because of its established efficacy across

multiple pathogenic pathways (13). However, concerns regarding adverse effects involving neurological, sensory, and vestibular systems continue to be discussed in the literature (2-7). Although complaints such as dizziness and vertigo have occasionally been reported, objective vestibular investigations evaluating possible vestibulotoxicity remain limited. Vestibular adverse effects associated with isotretinoin appear to be rare and inconsistently reported. In one study involving 150 isotretinoin-treated patients, vertigo was reported in only one patient (2). However, objective vestibular assessment findings and detailed otolaryngological evaluation data were not provided, limiting interpretation of the clinical significance and causality of these symptoms.

The presented study was not designed as a pharmacovigilance prevalence investigation or as a study intended to establish a causal relationship between isotretinoin and vestibular dysfunction. Instead, it was planned as an exploratory pilot study aimed at objectively evaluating possible subclinical audiovestibular alterations during isotretinoin therapy.

Previous studies evaluating hearing outcomes during isotretinoin treatment have produced inconsistent results. Karabulut et al. (9) reported statistically significant short-term changes in PTAs at different frequency ranges and interpreted these findings as an improvement in hearing levels during treatment. In contrast, Kemeriz et al. (11) observed bilateral hearing threshold changes during isotretinoin therapy that improved after treatment discontinuation, suggesting that these alterations may be reversible. Experimental evidence has provided a different perspective, with an animal study suggesting that isotretinoin may exert a protective effect against cisplatin-induced ototoxicity (14). Akdag et al. (15) reported significant bilateral changes in hearing thresholds at frequencies between 1000 and 6000 Hz, although no corresponding significant alterations were detected in transient-evoked otoacoustic emission responses. Conversely, Yaldiz et al. (16) found no significant deterioration in bilateral hearing thresholds during oral isotretinoin treatment.

Electrophysiological and clinical observations have also yielded variable findings. Nikiforidis et al. (17) found no statistically significant group-level changes in auditory brainstem responses after isotretinoin administration; however, marked increases in latencies and interpeak latencies together with reductions in amplitudes were observed bilaterally in three patients, raising the possibility of subclinical effects on auditory neural transmission. In addition, Rosende et al. (18) reported an isolated case of hypoacusis and tinnitus developing during isotretinoin treatment, with rapid improvement after discontinuation of the drug. Although a single case report cannot establish causality, it highlights the importance of clinical awareness of newly developed auditory symptoms during treatment.

Table 3. Comparison of VNG test parameters before and after systemic isotretinoin treatment (n=33)

Parameters	Pre-treatment (mean ± SD) [min-max]	Post-treatment (mean ± SD) [min-max]	p-value ¹ (time effect)
Smooth pursuit gain (%)			
0.2 Hz-rightward	98.67±8.65 [77.5-118.0]	98.15±8.35 [75.0-116.0]	0.692
0.2 Hz-leftward	95.55±10.32 [68.0-114.5]	96.82±8.84 [77.5-117.0]	0.451
p-value² (symmetry)	0.184	0.495	
0.4 Hz-rightward	93.00±12.87 [60.5-113.0]	94.61±11.23 [62.0-114.0]	0.473
0.4 Hz-leftward	96.12±10.15 [70.0-116.0]	95.27±10.22 [69.5-115.5]	0.624
p-value² (symmetry)	0.278	0.812	
Saccade			
Latency (ms)-rightward	143.76±17.56 [112.0-188.0]	143.45±15.65 [116.0-182.0]	0.925
Latency (ms)-leftward	137.64±15.42 [110.0-171.0]	138.27±12.98 [113.0-164.0]	0.814
Velocity (°/s)-rightward	350.55±48.75 [256.0-455.0]	351.64±46.21 [232.0-441.0]	0.898
Velocity (°/s)-leftward	362.58±42.18 [278.0-461.0]	356.45±36.87 [289.0-432.0]	0.435
Accuracy (%) -rightward	95.73±10.34 [69.0-112.0]	96.61±8.12 [77.0-111.0]	0.618
Accuracy (%) -leftward	95.39±8.92 [74.5-111.0]	94.45±7.95 [77.0-109.5]	0.540
Optokinetic nystagmus			
Gain (%) at 20°/s-rightward	93.61±10.85 [72.0-114.0]	92.67±10.12 [68.0-113.0]	0.627
Gain (%) at 20°/s-leftward	93.88±10.42 [70.5-114.5]	93.76±9.85 [71.5-117.0]	0.942

Continuous variables are expressed as mean ± SD [min-max]. Statistical significance was defined as p<0.05

p-value¹: Evaluated using the paired samples t-test (or Wilcoxon signed-rank test based on normality), comparing pre-treatment and post-treatment values within the same cohort

p-value²: Represents the Directional Symmetry p-value, evaluating the physiological balance between rightward and leftward tracking responses within the same session

Data reduction: because binocular eye movements are physiologically conjugate, values recorded from the right and left eyes were averaged to obtain a single representative value for each stimulus direction and participant

Hz: Hertz, ms: Milliseconds, °/s: Degrees per second, SD: Standard deviation, VNG: Videonystagmography

Overall, the available evidence does not demonstrate a consistent pattern of clinically relevant isotretinoin-related auditory toxicity, and differences among studies may be related to treatment duration, cumulative dose, sample characteristics, and the audiological methods used.

In the presented study, audiometric thresholds remained stable throughout the treatment period except for an isolated statistically significant difference at 6000 Hz in the right ear. Because this finding was unilateral, not accompanied by clinically relevant hearing loss, and not reflected in averaged hearing parameters, it was interpreted cautiously and considered more likely related to minor statistical variation than true cochlear toxicity.

Objective studies investigating the possible vestibular effects of isotretinoin are considerably more limited. Kocak et al. (8) prospectively evaluated 30 patients using vHIT before treatment and after three months of isotretinoin therapy. They detected no overt or covert corrective saccades or spontaneous nystagmus and reported no significant changes in semicircular canal gain or asymmetry measurements. These findings suggested that short-term isotretinoin therapy did not adversely affect the peripheral vestibular system or vestibulo-ocular reflex pathways. The presented

study complements these limited data by providing quantitative VNG-based smooth pursuit, saccadic, and optokinetic measurements before and after treatment. Regarding vestibular evaluation, none of the participants reported dizziness, vertigo, or imbalance during follow-up. In addition, selected VNG-based assessments demonstrated normal findings in all participants. These findings are generally consistent with the limited existing vestibular literature regarding isotretinoin therapy.

The absence of caloric testing represents the main limitation of the vestibular assessment in the presented study. Although VNG-based positional and oculomotor assessments were normal, caloric testing was not included in the study protocol. Therefore, these results do not allow a definitive exclusion of subtle vestibular dysfunction or vestibulotoxic effects. The vestibular assessment in this study was limited to a focused test battery within the scope of an exploratory pilot design.

Study Limitations

The study has several additional limitations. Firstly, the relatively small sample size and absence of a control group may limit the generalizability of the findings. Secondly, the follow-up duration was limited to three months, precluding assessment of long-term audiovestibular effects. Finally,

asymptomatic patients were evaluated, and rare vestibular adverse effects may not be detectable in a relatively small cohort.

Despite these limitations, the presented study provides prospective objective audiometric and selected VNG-based vestibular data regarding short-term isotretinoin therapy, an area in which available literature remains limited. Future studies involving larger patient populations, longer follow-up durations, and more comprehensive vestibular assessment protocols, potentially including electrophysiological and experimental investigations, are needed to further clarify the effects of isotretinoin on auditory and vestibular function.

Conclusion

Within the limitations of this prospective exploratory pilot study, short-term oral isotretinoin therapy did not demonstrate clinically significant abnormalities in audiometric measurements or selected VNG-based vestibular assessments in this cohort. Selected VNG-based vestibular assessments and audiometric measurements remained stable throughout the study period. Larger controlled studies with longer follow-up durations and comprehensive vestibular testing are required before definitive conclusions regarding vestibulotoxicity can be established.

Main Points

- Short-term oral isotretinoin therapy did not demonstrate clinically significant audiovestibular abnormalities in this cohort.
- No clinically meaningful deterioration was observed in pure-tone audiometric thresholds during the study period.
- Selected videonystagmography-based vestibular assessments remained within normal limits throughout treatment.
- Larger controlled studies with longer follow-up and comprehensive vestibular testing are needed.

Ethics

Ethics Committee Approval: Ethical approval was granted by the Necmettin Erbakan University Research on Non-Drug and Medical Device Products Ethics Committee (approval no: 2021/3484, date: 05.11.2021).

Informed Consent: All participants received detailed information regarding the study protocol, and written informed consent was obtained from all individuals prior to participation.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F.Y., C.Y., M.E.K., Concept: F.Y., C.Y., M.E.K., Design: F.Y., C.Y., M.E.K., Data Collection

and/or Processing: F.Y., C.Y., Analysis or Interpretation: C.Y., M.E.K., Literature Search: F.Y., Writing: F.Y.

Conflict of Interest: The authors declare that they have no conflict of interest.

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