



ORIGINAL ARTICLE

Azathioprine Reduces the Risk of Audiometric Relapse in Immune-mediated Hearing Loss[☆]

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KEYWORDS

Autoimmune disease;
Sensorineural hearing loss;
Recurrence;
Survival analysis

Abstract

Introduction: Current schemes for treatment of immune-mediated hearing loss with sporadic short-course, low-dose corticosteroids, are insufficient.

Methods: To determine the role of azathioprine in the control of auditory impairment, a longitudinal, observational, descriptive study was performed with 20 patients treated with azathioprine (1.5–2.5 mg/kg/day into two doses) for 1 year. The loss of 10 dB on two consecutive frequencies or 15 dB on an isolated frequency was considered as relapse.

Results: The mean age of the patients was 52.50 years (95% CI: 46.91–58.17), half were women. Bilateral affection was 65%. 75% had organ specific disease and 25% had systemic autoimmune disease. The difference between baseline PTA (46.49 dB; DS 18.90) and PTA at 12 months (45.47 dB; DS 18.88) did not reach statistical significance ($P=.799$). There was a moderate positive correlation between female sex and the presence of systemic disease ($R=.577$). By applying Student's t for paired data, a significant difference ($P=.042$) was obtained between the PTA in frequencies up to 1000 Hz (PTA 125–1000 Hz). The relative incidence rate of relapse per year was .52 relapses/year (95% CI: .19–1.14]. The median time to audiometric relapse-free was 9.70 months (DS 1.03).

Conclusions: Azathioprine maintains the hearing threshold, decreases the risk of relapse, and slows down the rate at which patients relapse, altering the course of immune-mediated inner ear disease.

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PALABRAS CLAVE

Enfermedad autoinmune;
Hipoacusia neurosensorial;
Recaída;
Análisis de supervivencia

La azatioprina reduce el riesgo de recaída audiométrica en hipoacusia inmunomediada**Resumen**

Introducción: Los esquemas actuales de tratamiento de la hipoacusia inmunomediada con corticoides, a dosis baja y pauta corta, son insuficientes.

Métodos: Para determinar el papel de la azatioprina en el control del deterioro auditivo se ha llevado a cabo un estudio observacional descriptivo longitudinal con 20 pacientes tratados con azatioprina por vía oral (1,5-2,5 mg/kg/día en dos dosis) durante 1 año. Se consideró recaída la pérdida de 10 dB en dos frecuencias consecutivas o de 15 dB en una frecuencia aislada.

Resultados: La edad media de los pacientes fue de 52,50 años (IC 95%: 46,91-58,17), y la mitad fueron mujeres. La afectación bilateral fue del 65%. Un 75% presentaban enfermedad orgánoespecífica y un 25%, enfermedad autoinmune sistémica. La diferencia entre la PTA basal (46,49 dB; DE 18,90) y la PTA a los 12 meses (45,47 dB; DE 18,88) no alcanzó significación estadística ($p=0,799$). Existía una correlación positiva moderada entre sexo femenino y presencia de enfermedad sistémica ($R=0,577$). Aplicando t de Student para datos apareados se obtuvo una diferencia significativa ($p=0,042$) entre el descenso de la PTA en frecuencias hasta 1.000 Hz (PTA 125-1.000 Hz). La tasa relativa de incidencia de recaída por año fue de 0,52 recaídas/año (IC 95%: 0,19-1,14). El tiempo medio de supervivencia libre de recaída audiométrica fue de 9,70 meses (DE 1,03).

Conclusiones: La azatioprina mantiene el umbral de audición, disminuye el riesgo de recaída y frena la velocidad con la que los pacientes recaen, alterando el curso de la enfermedad inmunomediada del oído interno.

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Introduction

The treatment of immune-mediated hearing loss is a race against time with the unique aim of changing the course of the disease. Without treatment, every patient with immune-mediated hearing loss is destined to become deaf in one or both ears.¹

As occurs in other auto-immune diseases, the earlier treatment is started, the greater the likelihood of controlling the inflammatory process and reducing structural damage. Therefore, progressive sensorineural hearing loss of recent onset must be considered a diagnostic priority. Hearing response to corticosteroids is the fundamental clinical criterion for diagnosis. This response, although usually transient, reinforces the suspected diagnosis. Follow-up of these patients is also incomplete, since audiometric monitoring is reserved for acute hearing loss.

This deterioration, which is clinically evident, has not been sufficiently parameterised, despite the recommendations of some authors.² At the moment, the response and relapse criteria are not sufficiently widespread and are not common, which makes it impossible to compare results. The current treatment schemes with sporadic corticosteroids, at low doses and with short courses, do not fit the chronic nature of the disease. Early use of effective doses for the appropriate time makes hearing recovery more likely, since there is a therapeutic window of opportunity. More than prompt treatment, the hearing response to corticosteroids should be considered an opportunity for these patients since it opens the door to immunosuppressive treatment.

Methods

This study is based on the data gathered in a single centre within the EMHA Project: azathioprine for the treatment of autoimmune hearing loss with response to oral corticosteroids: a multicentre study (Protocol code: INV-AZA-2014-01, dated 15 April, 2013), classified by the Department of Medicinal Products for Human Use of the Spanish Agency of Medicines and Medical Devices as a post-approval, prospective follow-up study, (PAS) authorised by the Office of Pharmaceutical and Health Product Control – Area of Clinical Investigation and PAS of the Community of Madrid and by the Clinical Research Ethics Committee of the Referral Hospital.

Design

Longitudinal, observational descriptive study.

Population

Patients with immune-mediated hearing loss selected consecutively in the outpatient clinic from June 2013 to June 2016, data was collected up until April 2017.

Inclusion Criteria

Patients with sensorineural hearing loss with response to oral prednisone at a dose of 1 mg/kg/day for 15 days. Response

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