



COMPARATIVE STUDY OF SYSTEMIC STEROIDS THERAPY WITH AND WITHOUT INTRATYMPANIC STEROIDS THERAPY FOR SUDDEN HEARING LOSS.

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ABSTRACT

OBJECTIVE: To investigate the therapeutic efficacy of intratympanic dexamethasone combined with systemic prednisolone in patients with idiopathic sudden sensorineural hearing loss.

MATERIAL AND METHOD: From July 2015 to January 2017. A total of 50 eligible patients with ISSNHL were allocated into 2 groups. Patients in the control group were treated with systemic prednisolone alone. Patients of the combined treatment group received additionally 3 intratympanic dexamethasone injections per a week for 3 weeks. Hearing recovery was assessed by pure tone audiogram.

RESULT: Significant hearing recovery was observed in 31 (64%) of 25 cases, and in 13 (52%) of 25 control patients. The total effective rate was 32% and 26% for each treatment protocol, respectively, with statistical significant between them ($P < 0.05$). Patients receiving combination therapy had a median improvement in PTA of 23.12 dB. In the control group, the median hearing gain was 16.87 dB respectively. The combined treatment group showed significant improvement compared with the control group ($p < 0.05$). No serious complications or adverse reactions were reported.

CONCLUSION: The addition of intratympanic steroids to the conventional systemic steroid therapy may provide a safe and potentially effective therapeutic option in patients with mild-to-severe ISSNHL. However further multicentre studies are needed to determine the standard protocol.

KEYWORDS

Sudden sensorineural hearing loss, steroid, therapeutic effect.

Introduction:

Idiopathic sudden sensorineural hearing loss (SNHL) is defined as decline in hearing over 3 days or less affecting 3 or more frequencies by 30 dB or greater with no identifiable aetiology.^[1] Sudden SNHL affects between 5 and 20 persons per 100,000 year or approximately 4,000 new cases annually in the United States.^[2] The HL is nearly always unilateral and is commonly associated with tinnitus and aural fullness. Multiple treatment protocols and agents have been proposed to treat SNHL. Steroids, antiviral agents, anticoagulants, vasodilators, anti-inflammatory agents, and others have been proposed as therapeutic agents to treat SNHL the most accepted current treatment of sudden SNHL is systemic steroids. Many studies, however, have studied the effects of intratympanic steroids as a primary or first-line agent for patients with sudden SNHL^[3,4] or used adjunctively with systemic steroids.

This study was undertaken to systemic steroid therapy with and without intratympanic dexamethasone in the treatment of patients with idiopathic sudden SNHL. Special attention was given to evaluating the safety of the procedure and correlation with improvement in hearing related to age, prior therapy and severity of loss.

Material and Method

A retrospective clinical study was conducted in 50 patients diagnosed with unilateral SSNHL of unknown causes from July 2015 to July 2017, including 18 males and 32 females, with a mean age of 41.30 years (range 18-60). All subjects satisfied the following conditions: (1) idiopathic unilateral sensorineural hearing loss, (2) no central nervous system disorders, (3) within 1-7 days after the onset of hearing loss, (4) previously untreated, (5) normal hearing in the opposite ear for age. All patients gave a complete clinical history, underwent physical and audiological examination, and received testing for syphilis and autoimmune antibodies. Magnetic resonance imaging (MRI) was negative in these patients. The criteria of diagnosis and treatment effect classification for WHO (1980) classification with reference to ISO: R.389-1970 (International Calibration of Audiometers).^[5] Pure-tone average (PTA) was calculated as the average of thresholds at 0.25, 0.5, 1, 2 and 4 kHz. Severity of hearing loss was graded as: Mild: (26-40 dB), Moderate: (41-55 dB), Moderately severe: (56-70 dB), Severe: (71-90 dB) and Profound: (>90 dB). The extent of hearing recovery was reported as Complete Recovery (R)-PTA in normal limits or at pre illness level; Marked Recovery (MR)-PTA improvement ≥ 30 dB; Partial Recovery (PR)-PTA improvement 15 to 30 dB; And Unchanged (U)-PTA improvement ≤ 15 dB. A total of 50 cases were randomly selected and divided in two group. Group -1 (25) the cases were treated by oral steroid and Group-2 the cases were treated by oral

steroid with intratympanic dexamethasone (5 mg/ml) injection of 1 ml three times a week for 3 weeks. Patient profiles and therapeutic effects were compared between two groups.

Statistical analysis

The mean age and degree of hearing loss were analysed by means of χ^2 test. $P < 0.05$ was considered significant.

Result

After inclusion and exclusion criteria were applied, 50 patients were available for study. There were 18 (35%) men and 32 (65%) women. The mean age was 41.30 years. Out of 50 patients, 25 patients were treated with systemic steroid and 25 patients were treated with systemic and intratympanic steroid. Among 50 patients average hearing loss was 3 mild, 13 moderate, 21 moderately severe, 11 severe and 2 profound in PTA. (Tab-1)

Fifty patients fit the criteria for inclusion in the study. The patients were treated with systemic steroid (Group-1), in which 5 showed marked recovery, 8 partial recovery and 12 no change in PTA. While 25 patients were treated with systemic with intratympanic steroid (Group-2). In which 6 show marked recovery, 10 partial recovery and 9 unchanged in PTA. The effective rate was 26% and 32% respectively, and not statistically different between the two groups ($P > 0.05$) (Table -2).

Discussion

According to the guidelines published in 2012 by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), SSNHL is defined as "idiopathic hearing loss in one or both ears of at least 30 dB over at least 3 consecutive frequencies occurring over a 72-hour period"^[6]. It has been reported that the annual incidence of SSNHL is 5-20 per 100,000 of the population and that similar numbers of men and women are affected^[6,7] but in present study females (32) were most commonly affected than males (18). Rauch SD (2008) SSNHL can occur at any age but most commonly affects those from 43-53 years of age^[8]. Which was similar to present study (Mean age 41.30). The main causes and risk factors of SSNHL are uncertain; however, 90% of cases are presumed to be associated with vascular, viral, or multiple aetiologies^[6]. Aside from the typical symptom of hearing loss, other common symptoms in SSNHL include tinnitus, ear fullness, vertigo, otalgia, and ear paraesthesia. More than 90% of the patients with unilateral SSNHL complain of tinnitus^[7,9], which poses the greatest difficulty in treatment and severely affects the patients' quality of life^[6]. Physical examinations and investigations of disease progression are essential to make an accurate diagnosis, of which a

detailed description of disease progression plays a very important role. Information, such as time of onset and the incidence of specific diseases or injuries, is helpful in making a diagnosis. Risk factors of hearing impairments, such as acute otitis media, acute otitis externa, a foreign body in the ear canal, ear drum perforation, and cholesteatoma, must be excluded through physical examinations. In clinical practice, all patients suspected of having SSNHL are required to undergo pure-tone audiometry. The results provide not only helpful information for the diagnosis but also information for follow-up evaluations and prognosis. It has been reported that 2.7%-10.2% of SSNHL patients are diagnosed with a cerebellopontine angle tumour with the aid of MRI^[6,70] MRI, administered with gadolinium, has been reported to have a high sensitivity in detecting retro cochlear pathology^[6]. Due to poor resolution performance in the detection of C-P angle tumours and small brainstem lesions, computed tomography is recommended only for patients with contraindications to MRI^[6]. In addition, routine laboratory tests are not necessary for SSNHL, and there is no need to arrange blood tests unless the patient has an unusual medical history or is highly suspected of having specific diseases, such as Lyme disease^[11]. Despite the fact that no single treatment option has been proven to be the most effective in the management of SSNHL, steroid treatment remains the management of choice^[12,13], of which medication includes prednisolone, methylprednisolone, and dexamethasone. The routes of administration include oral, intravenous, and intratympanic injections^[12]. The guidelines published by the AAO-HNS recommend prednisone for patients with SSNHL within 2 weeks after the diagnosis, with a recommended dose of 1 mg/kg/day (max: 60 mg/day), given as a single dose for 10-14 days^[6]. Another study suggested that intratympanic injections should only be considered when systemic steroids (either orally or intravenously) are proven to be ineffective or when patients have contraindications to high doses of systemic steroids (e.g., severe cases of diabetes)^[6,14]. Even though steroids are recommended as the routine treatment for SSNHL, inconsistent results regarding the efficacy have been reported^[15]. Chen-Lin Liu et al(2014) Reported that patients were on systemic steroids the total recovery rate was 74% in which 9 patients were cured (33%), 4 patients had a marked recovery (15%), 7 patients had a slight recovery (26%), and 7 patients were unchanged (26%).^[16] In the current study total recovery was 52 % in which 5 marked recovery, 8 partial recovery and 12 patients were unchanged (group-1). Lauterman et al(2005) compared patients who received intratympanic steroids with systemic steroids with patients who received no intratympanic steroids and found no benefit to the addition of intratympanic steroids in hearing recovery.^[3] Battista et al (2005) noted minimal improvement after intratympanic steroids with systemic steroid for sudden SNHL in his study of 25 patients all with profound(90-dB PTA).^[4] but in the current study 16 out of 25 patients were show recovery in audiogram who received systemic steroid with intratympanic steroid (group-2).

The effective rate was not statistically different between the two groups. ($\chi^2= .73$ and $P>0.05$ non significant)

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Observation:

Table.1 Basic information of cases

Characteristics	Patients treatment on systemic steroid	Patients treated with systemic and intratympanic steroid	Total
Gender (F/M)	17/8	15/10	
Mean age (years)	41.31	41.33	
	Grades of hearing loss (PTA)		
Mild	2	1	3
Moderate	7	6	13
Moderately severe	10	11	21
Severe	5	6	11
Profound	1	1	2
Cases of moderately severe and severe/profound hearing loss (n,%)	16	18	34

Table.2 Therapeutic effect of cases.

Cases	Marked recovery (n)	Partial recovery (n)	Unchanged (n)	Effective rate(%)
patients treatment on systemic steroid	5	8	12	26%
patients treated with systemic and intratympanic steroid	6	10	9	32%
Total	11	18	11	