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Abstract

Objective: To study therapeutic effect of different first line treatment options in a clinical setting in patients presenting with idiopathic Sudden Sensorineural Hearing Loss (SSNHL).

Patients: A total of 105 patients were divided in 4 groups. Patients in the control group (42 patients group D) received systemic steroids alone. Patients in the combined treatment groups received additionally i) intratympanic dexamethasone (IT) (group A, 36 patients), ii) IT, plus hyperbaric oxygen therapy (HBOT) (group B, 16 patients), iii) HBOT (group C, 12 patients).

Main Outcome Measures: Hearing recovery was evaluated on the basis of PTA averages before and after treatment.

Results: Hearing improvement was 47, 02 % for the control group (D). Patients receiving combined treatment with IT showed better results with 61, 32 % hearing improvement, whereas groups B and C 42, 47% and 41% respectively. Even though hearing improvement was better in the intratympanic group, results were not statistically significant with a p=0,062.

Conclusion: Combination therapy of intratympanic dexamethasone and systemic steroids seem to have a beneficial effect on hearing outcome in SSNHL patients.

Keywords: Sudden Sensorineural Hearing Loss, Intratympanic dexamethasone, Hyperbaric oxygen

INTRODUCTION

Sudden sensorineural hearing loss remains a puzzle for the ENT doctor as there is still no definitive aetiology and no specific treatment. Aim of our paper is to present our clinical experience with the disease as it is addressed in a General Hospital. Sudden Sensorineural Hearing Loss (SSNHL) is a condition that is characterized by hearing loss of more than 30 dB in three contiguous frequencies in less than 3 days (1). It is a situation frustrating for the patient who not only has difficulty communicating but is also troubled by tinnitus.

Many factors have been considered as causative factors in sudden sensorineural hearing loss such as viral cochleitis, vascular injury, autoimmune inflammation and inner ear membrane rupture (2). Incidence is estimated at 5-20 cases per 100.000 annually (3). Initial hearing severity and time interval to treatment onset seem to be the most important prognostic factors to affect treatment outcome (4). Shape of the audiogram and presence of vertigo have also been suggested as prognostic factors (5).

It is difficult to evaluate treatment efficacy as it is known that a large percentage of patients recover spontaneously (6). Studying SSNHL presents certain difficulties as using control groups can raise ethical issues. Patients that suffer sudden hearing loss want to try every possible option they have that will give them a better chance to improve their hearing.

Since the cause of SSNHL is unknown a variety of treatments have been used steroids, vasodilators hyperbaric oxygen carbogen, intratympanic steroids antiviral drugs and anticoagulants. The abundance of different treatments, pinpoints the fact that an aetiological treatment is lacking. Intratympanic steroid use has the advantage that it allows higher concentrations of steroids in the inner ear while it minimizes systemic absorption (7).

MATERIALS AND METHODS

Patient Selection

A total of 105 patients who were treated for SSNHL in the Dpt of Otolaryngology Head and Neck Surgery at Evaggelismos hospital between 2012 and 2016, were enrolled in this prospective study. All patients met the following criteria 1) no previous history of hearing

Table 1. Treatment groups

loss 2) sudden onset of hearing loss 3) unknown cause of hearing loss. Patients with Meniere disease, barotrauma, acoustic neuroma were excluded from the study. All patients were followed up for a year. Magnetic resonance imaging of the internal auditory canal and cerebellopontine angle was performed an all of the patients.

Treatment Protocols

All patients received IV prednisolone 25mg 4 times daily with a total dose of 100mg for 4 days then tapering with oral steroids (SYS). Patients that did not improve within 3 days were then allocated to one of the following groups1) 4 intratympanic dexamethasone injections one every 4 days (IT) 2) treatment with hyperbaric oxygen 15 daily sessions (HBOT), 5 days per week 3) combined treatment with intratympanic steroids and hyperbaric oxygen (table 1).

Group	Patients	Treatment
А	36	IT + SYS
В	16	IT+ HBOT+ SYS
С	12	HBOT+ SYS
D (control group)	42	SYS

Intratympanic dexamethasone injections were performed with the patient in the sitting position with the head tilted 45° to the opposite side. Injection performed with a 25 gauge spinal needle syringe to the posterior inferior portion of the tympanic membrane and 0, 5-0, 7 ml of dexamethasone 4mg/ml were injected in the middle ear and the patient advised not to swallow for 5 minutes. Patients were hospitalised for 4 days, and had routine blood tests. All patients were evaluated with PTA pretreatment, three months posttreatment and every two months following that for a year.

RESULTS

In order to examine whether there were statistically significant differences between groups, patients were examined in relation to age and initial hearing loss severity. Kruskal - Wallis test was used to check for statistical difference between the ages of treatment groups. P-value was 0,111, not statistically significant. Groups were also examined in relation to initial hearing loss severity using Kruskal Walis test, p-value=0,182 shows there was no statistically significant difference.

Hearing improvement

The mean of hearing level at 250, 500, 1000, 2000, 4000 and 8000 Hz was calculated for each patient for both ears before and three months after treatment. Results were calculated based on improvement percentage (8), using the following equation:

Percenthearing improvement (%) = (HLpre – HLfinal)/ (HLpre -HL contralateral ear)*100

 Table 2. Therapeutic outcomes based PTA percentage improvement

Group	Hearing improvement %	
А	61,34 %	
В	42,06 %	
С	42,41%	
D (control group)	47 %	

Mann-Whitney test was used to compare groups in relation to hearing improvement.

Group A: p- value=0,415, Group B: p value=0,884, Group C p value= 0,646. There was no statistically significant difference in any of the groups. **Table 4.** *PTA improvement results* Results were also examined on the basis of PTA improvement for more than 10 dB. Successful treatment was defined as more than 10 dB improvement in PTA. Patients that did not improve were allocated in group 0 and patients that improved in group 1.

		Improvement		T-+-1
		0	1	Total
Treatment	А	5	30	35
		14.3%	85.7%	100.0%
	В	5	11	16
		31.3%	68.8%	100.0%
	С	6	6	12
		50.0%	50.0%	100.0%
	D	14	28	42
		33.3%	66.7%	100.0%
Total		30	75	105
		28.6%	71.4%	100.0%

X² test was used in order to examine results based on 10 dB PTA improvement. There was no statistically **Table** significant difference between groupsp-value=0,079. Results were also compared with respect to DB gain

Tuble	
Group	Mean dB Gain
А	32
В	26,5
С	17,5
D	20,21



Boxplot graph of dB gain of the 4 groups. Kruskal-Wallis test was used to examine hearing improvement in relation to dB gain , p-value=0,295, which is statistically non-significant.

DISCUSSION

SSNHL remains one of the most difficult issues of Otolaryngology. Its aetiology still remains unknown and the plethora of papers written on the subject have not been able to suggest a definitive treatment. International consensus on treatment of SSNHL supports that systemic steroids is still the most widespread primary therapy, although evidence of their efficacy cannot be considered as strong (9)

A lot of papers support IT efficacy in treating SSNHL. Lee (10) in a recent animal study describes that intracochlear dexamethasone uptake was higher and more prolonged in animals receiving IT dexamethasone.Tsounis et al compared systemic intratympanic and combined steroids and found no statistically significant difference in the results (11). Han et al (12) and Gao Y (13) published a metaanalysis of controlled trials supporting that combined treatment of IT and systemic steroids confer benefit as a primary treatment of SSNHL, and Jung Da (14) also supported the efficacy of combination treatment. Lee in another paper (7) supported that IT alone is as effective as systemic steroid.

HBOT on the other hand is considered to improve perilympatic partial pressure of oxygen and thus lead to greater improvement from the disease (15).

As far as HBOT is considered Khater et al (16) and Hosokawa et al (17) found improved results with HBOT therapy. Alimoglou (18) found better results with HBOT as salvage therapy and Fujimura (19) concluded that HBOT has significant additional effect in combination with steroid therapy. In a paper by Lamm H (20) concurrent use of IT and HBOT treatment is considered beneficial as a salvage therapy for refractory SSNHL.

On the other hand Nosrati Zarenoe supported that steroids do not influence recovery after SSNHL (21) raising questions about steroid treatment efficacy.

Results of the present study show that the overall hearing improvement rate was higher in the intratympanic dexamethasone plus systemic prednisolone group (61%) in comparison to the other treatments (B= 42, 06%, C=42, 41% and D=47 %). Results were also calculated using another evaluation method where treatment is considered successful when improvement of PTA averages is more than 10 dB. For the IT group this percentage was 85,7% in comparison to 66,7% of the control group. Groups with HBOT have worse results but this could be due to small numbers of patients. The fact that results were not statistically significant clearly suggests that larger series of patients are needed in order to prove treatment efficacy.

CONCLUSION

We conducted a controlled prospective trial of patients with SSNHL comparing systemic steroids as a control group with combination therapy with IT and HBOT. Hearing outcome was better in intratympanic dexamethasone with systemic steroidgroup but results were not statistically significant. Further investigation is necessary in order to support these results.

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