

Dexamethasone Inner Ear Perfusion for Sub Clinical Endoymphatic Hydrops

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Supported by a grant form the Ear Research Foundation
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Presented at the First Chinese World Congress of Otolaryngology
Beijing China, May 15th. 2007

.Sarasota Memorial Hospital IRB number is 07-ENT-14 was approved June 26, 2007 and will
expire June 27, 2008.

INTRODUCTION

Cochlear hydrops has been described as a variant or early manifestation of Meniere's disease in which the patient experiences fluctuating hearing loss with tinnitus and aural fullness or pressure. This condition is believed to be caused by an elevated level of endolymphatic pressure, which is likely due to poor absorption from the endolymphatic sac or excess secretion of endolymph, and results in distention of Reissner's membrane. The clinical presentation of patients with endolymphatic hydrops is variable, although patients presenting with fluctuating hearing seem to outnumber those presenting with a true Meniere's disease (Shea).

The exact etiology of endolymphatic or cochlear hydrops is not yet known, but an autoimmune process is likely (Atlas, Derebery, Brookes). With this in mind, therapy has targeted down regulation of the immune system, most commonly using systemic glucocorticoids or more recently, using intratympanic steroids (Hillman, Arriaga, Shea, Silverstein). While treatment protocols remain variable, the use of intratympanic steroids has gained favor among physicians.

Diagnosing patients with cochlear hydrops involves a thorough history and physical examination along with diagnostic testing including audiometry, electrocochleography, and brainstem responses. Patients presenting early in their course of cochlear hydrops may not yet complain of hearing loss, but instead present with the chief complaint of aural fullness, stuffiness, or pressure. Oftentimes the neurotologic examination does not reveal a source for the patient's discomfort. To rule out Eustachian tube problems, the physician can have the patient perform a Valsalva maneuver under direct visualization of the tympanic membrane. If the patient is able to "pop" their ear, then Eustachian tube problems are less likely. A thorough head and neck evaluation is important to rule out other sources of aural fullness. Once these conditions have been excluded, the physician is left with the diagnostic consideration of cochlear hydrops.

Patients with cochlear hydrops will typically have a low frequency sensory loss. However, due to fluctuations in hearing, many patients will have normal hearing upon presentation. Furthermore, patients may present with aural fullness, stuffiness, or pressure as a clinical precursor to cochlear hydrops or Meniere's disease. Sub-clinical cochlear hydrops has been the diagnosis given to patients with aural fullness, stuffiness, or pressure with or without a sensory hearing loss once other etiologies have been ruled out.

Similar to patients with cochlear hydrops, treatment for patients with sub-clinical cochlear hydrops is usually medical. Patients are often prescribed diuretics, vasodilators

(betahistine), and diet modification (reduction in salt intake). Another option for the acute presentation is a course of oral steroids, prednisone 60 mg daily for two weeks followed by a taper. However, systemic steroids carry certain risks and side effects, of which the public is aware and remains cautious about their use. Systemic steroids also have a relative contraindication to use in patients with other comorbidities such as diabetes, gastric ulcers, or glaucoma. Furthermore, we recognize that use of a topical agent will deliver a higher concentration of the medication to the cochlea (Parnes, Chandrasekhar). Patients with acute symptoms were offered the additional option of undergoing middle ear perfusion with Dexamethasone utilizing the MicroWick system.

This paper presents a series of patients diagnosed with sub-clinical cochlear hydrops who have been treated with perfusion of the inner ear using the Silverstein MicroWick and dexamethasone drops for one month. Clinical response to therapy and audiologic results will be reviewed. The purpose of this paper is to report the results for the treatment of patients with what is believed to be a new diagnosis of sub-clinical cochlear hydrops.

METHODS

Between Jan 1, 2004 and April 1, 2007, the charts for all of the patients who underwent perfusion of the inner ear with dexamethasone were reviewed. Only those patients who underwent the procedure for the chief complaint of aural fullness, stuffiness, or pressure were included in this study. A hearing loss may or may not have coexisted in the problematic ear for each patient. Each chart was reviewed for subjective changes in symptoms and/or complications as well as objective information about pre and post-operative audiograms and electrocochleography. Minimal follow up therapy was one month after treatment.

Dexamethasone perfusion consists of insertion of the Silverstein MicroWick into the tympanic membrane after the patient is given 10 mgs of Valium (diazepam). The ear canal is anesthetized with 2% xylocaine buffered with sodium bicarbonate (9 to 1) similar to middle ear surgery. A laser tympanostomy or myringotomy is performed over the RW area after which a 30 degree 1.7mm endoscope is introduced to better visualize the round window (RW) niche. Any obstructing membranes are removed from the round window area to allow for direct perfusion of the cochlea via the round window. A special vent tube is inserted into the tympanic membrane over the round window for perfusion of the inner ear. The MicroWick is inserted through the vent tube into the RW niche and 0.2cc of Dexamethasone 4-10 mg/cc is injected into the middle ear. The patient instills 3 drops of Dexamethasone 4-10 mg/cc that is made in a compounding pharmacy three times a day and uses an antibiotic ear drop at night to prevent infection. The perfusion treatment is continued for four weeks. (Figure 1)

Audiometric evaluation along with electrocochleography was obtained pre-operatively as well as at 2, 4, and 8 weeks after the procedure. Pure tone averages were calculated using the results at 0.5, 1, 2, and 4 kHz. Speech discrimination was also

tested. A significant change in hearing is defined as a pure tone threshold shift greater than 10dB or a change in the speech discrimination score greater than 15%. Patient's symptoms were also evaluated subjectively at each visit and were graded as improved, the same, or worse. Furthermore, any complication such as a persistent perforation or infection was documented and included in the analysis.

RESULTS

A total of 20 patients were identified who had underwent placement of the Silverstein MicroWick with Dexamethasone (4-10mg/cc) perfusion for 4 weeks between the years of 2004 to 2007. All of these patients underwent the procedure with the primary objective of improvement in their aural fullness, pain, or pressure. One patient was lost to follow up evaluation. Of these 20 patients, 12 were females and 8 were males with an average age of 59 years. The presence of a sensorineural hearing loss did not preclude the patient from undergoing the procedure or being included in the analysis as hearing loss was not their chief complaint. None of the patients had an air-bone gap. Fifteen of the patients underwent perfusion with dexamethasone 4 mg/cc while 5 patients underwent perfusion with 10 mg/cc.

The chief complaint of aural fullness, stuffiness, or pressure was improved with the use of the MicroWick and dexamethasone perfusion in 13 (69%) of 19 patients. No improvement was observed in 6 (31%) of 19 patients. None of the patients reported a worsening in their symptomatology.

Audiologic data is presented in table 1. The mean pure tone average prior to therapy was 36 dB (SD = 21) and the mean post therapy was 36 dB (SD = 21) revealing no significant overall change in hearing. However, 5 patients did experience a significant change in hearing. Two patients experienced a hearing loss (13 db maximum) and 3 patients experienced an improvement (18 dB maximum). The mean discrimination score prior to therapy was 82% (SD = 27) and the mean post therapy was 84% (SD = 26) with a mean improvement by 2 percentage points. Analysis of the pre and post-treatment discrimination levels revealed that only 2 patients experienced a significant change. One patient lost 16 percentage points with pre and post treatment pure tone averages of 41 and 48 respectively. The other patient gained 52 percentage points with pre and post treatment pure tone averages of 66 and 51 respectively.

Data from electrocochleography was available for eleven patients and is presented in table 2. The SP/AP ratio was calculated and considered to be abnormal or elevated if it was 0.5 or greater. The ratio was elevated prior to therapy in five patients. An improvement in this ratio was noted in all five of these patients after therapy was administered. In three patients the Ecog became worse after treatment. Thus Ecog can no be used to indicate success.

Of the nineteen patients for whom data was available, two (10%) experienced a persistent perforation. These perforations were easily repaired without complication using a fat graft myringoplasty. No other complications were observed in this set of

patients. In our experience it appears that the 10mg/cc dose resulted in more persistent perforations that needed repairing.

DISCUSSION

The clinical entity of cochlear hydrops has been well established. Many practitioners use corticosteroids in their treatment algorithm for these patients. Recently the use of transtympanic corticosteroid perfusion has found favor among many otologists. Once introduced to the round window, corticosteroids readily diffuse across the membrane into the perilymph. While the exact mechanism of action within the inner ear remains elusive, animal models have given us a good idea as to some of the effects of these medications. Corticosteroids suppress any immune mediated inflammatory response. They have also been shown to increase cochlear blood flow (Silverstein, Shirwany) as well as improve cochlear homeostasis. While all of these may be important, we still do not know how steroids provide symptom relief for patients with cochlear hydrops.

There are other benefits to transtympanic delivery of corticosteroids. This technique avoids the side effects associated with the use of systemic administration. Inner ear perfusion also allows for a higher concentration of the medication within the cochlea when compared to oral administration. Furthermore, with the use of the Silverstein Microwick, patients can provide a continuous perfusion of the inner ear which may offer a therapeutic benefit over a single injection.

The use of transtympanic dexamethasone has been widely reported, yet treatment protocols remain variable, as do clinical responses. Despite the uncertainty, the use remains widespread and gives patients an additional treatment option should medical therapy fail. Given the use of inner ear perfusion with dexamethasone to treat hearing loss for patients with cochlear hydrops, we sought to investigate its use for patients who present with the chief complaint of aural fullness, stuffiness, or pressure, all of which are common complaints to the otologist.

We identified a subset of patients with cochlear hydrops who we define as having a sub-clinical cochlear hydrops. These patients present with the chief complaint of aural fullness, stuffiness, or pressure with or without an associated mild hearing loss. Other sources of aural discomfort, whether directly related to the ear or referred from other sources, are first excluded by history and physical examination and by ancillary testing. Important conditions to consider include Eustachian tube dysfunction (obstruction or patulous), temporomandibular joint dysfunction, and superior semicircular canal dehiscence. While audiologic testing may reveal a sensory hearing loss, particularly in the low frequencies, that may give support to the diagnosis of hydrops, we did not preclude these patients from the study as their chief complaint was not hearing loss, it was an aural discomfort.

Treatment for sub-clinical cochlear hydrops parallels that of cochlear hydrops, mainly diuretics, diet modification, betahistine, and corticosteroids as warranted. Oral corticosteroids are known for their systemic side effects and risk profile, of which the public are well aware. We have begun treatment for patients with sub-clinical cochlear hydrops using the Silverstein MicroWick and topical dexamethasone 4-10 mg/cc. This

treatment allows for perfusion of the inner ear allowing a higher concentration of the steroid to circulate within the cochlea. Our rationale for using this therapy stems from the fact that dexamethasone perfusion carries a minimal risk to hearing while giving the patient the hope that a surgical intervention will provide them relief from their symptoms. Variations in the concentration of dexamethasone are due to a change in protocol where the concentration was increased from 4 mg/cc to 10 mg/cc with the hope that a better clinical response would be observed. Insufficient data is present to comment on this hypothesis as only 5 patients were perfused with 10 mg/cc. There appears to be less chronic perforations using the 4mg/cc dose.

Audiologic data for patients treated for sub-clinical cochlear hydrops with transtympanic administration of dexamethasone reveals that hearing is not adversely affected. Review of the data for electrocochleography(Ecog) reveals that the given diagnosis may or may not be supported.

This paper suggests a new clinical diagnosis (sub-clinical cochlear Hydrops)for patients with aural fullness, stuffiness, or pressure when other diagnoses have been excluded. These patients are felt to have an early form of Meniere's disease in which their hearing may not yet be affected. We have initiated therapy for these patients and have offered them a surgical alternative with perfusion of the inner ear using dexamethasone. We have seen a positive response in over 69% of the patients giving support that this condition may be immune mediated. We recognize the lack of long term follow up as well as some of the other shortcomings of this study, yet we want to introduce this therapy as a new option for patients presenting with a complaint that has historically been frustrating for the physician to treat.

SUMMARY

This paper suggests the term sub-clinical cochlear hydrops for patients with aural fullness, stuffiness, or ear pressure when all other diagnoses have been excluded. These symptoms were improved in 13 (69%) of 19 patients after perfusion of the inner ear for one month with dexamethasone 4 or 10mg/cc. None of the patients reported a worsening in their symptomatology and no patient had worse hearing after perfusion. Complications were infrequent and patients tolerated the treatment well. Perfusion of the inner ear appears to be a safe procedure with little risk.

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Table 1. Audiologic and Clinical Response Data

Patient #	Pre PTA	Post PTA	Pre WDS	Post WDS	Symptoms
1	29	11	100	100	Improved
2	35	35	92	92	Same
3	19	19	92	96	Improved
4	28	41	96	88	Improved
5	16	21	92	92	Improved
6	29	26	92	88	Improved
7	71	75	20	28	Same
8	66	51	40	92	Same
9	88	93	16	8	Improved
10	23	26	100	100	Improved
11	18	14	100	100	Improved
12	16	25	60	60	Improved
13	43	31	96	92	Same
14	25	24	100	100	Improved
15	51	55	96	100	Same
16	49	46	84	92	Improved
17	13	23	96	100	Same
18	30	26	92	100	Improved
19	41	48	92	76	Improved

Table 2. Electrocochleography Data

Patient #	SP/AP Ratio Pre-Tx	SP/AP Ratio Post-Tx
1	0.44	0.37
2	0.5	0.44
8	0.07	0.86
10	0.35	0.34
11	1.08	0.35
12	0.28	0.36
13	0.65	0.42
15	0.26	0.75
17	0.72	0.3
18	0.29	0.58
19	0.61	0.3

Figure 1. **Illustration of Proper Placement of the Silverstein MicroWick**

