International Tinnitus Journal, Vol. 10, No. 1, 54–57 (2004)

Ozone Therapy and Pressure-Pulse Therapy in Ménière's Disease

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Abstract: The aim of this study was to evaluate the usefulness of ozone and pressure-pulse therapies in treating Ménière's disease. Using objective otoacoustic emissions and short-increment sensitivity index (SISI) tests together with subjective anamnesis, we tested 15 patients (8 men, 7 women) who had suffered from Ménière's disease for 1–3 years and had permanent sensorineural hypoacusis; we compared results before and after treatment. We performed ozone therapy and pressure-pulse treatments simultaneously for one 10-minute session each day for 10 consecutive days. After treatment, both otoacoustic-spontaneous and transiently evoked emissions and SISI test results exhibited no statistically significant changes. However, the subjective state of the patients was clearly improved. The frequency, severity of attacks, and tinnitus decreased. The mechanism of such an improvement is discussed.

Key Words: Ménière's disease; otoacoustic emissions; ozone therapy; pressure-pulse therapy

Until now, ozone therapy has been known to be very useful in many sectors of current medicine and biology. Ozone is reported to reduce fungi, viruses (HIV-1), and bacteria through cell membrane destruction [1–3]. It prevents the damage induced by reactive oxygen species and has an immunoregulatory effect by releasing transforming growth factor–β [4–6]. It protects against ischemia, being able to dilate cerebral arterioles, open calcium-activated potassium channels, and stimulate hypocoagulatory changes [7,8]. However, the disadvantages of ozone therapy could be observed. A mutagenic and carcinogenic role of by-products of ozonation was postulated by Donaldson et al. [9] during experiments with lungs in rats. Fedan et al. [10] noted in guinea pigs inflammation, hyperactivity, and necrosis in ciliated cells of epithelium. Conversely, in humans, ozone can repair injured epithelium, steering the intermediate cells [11].

In otorhinolaryngology, the use of ozone is very common. It is helpful after nasal and lung operations, in dental surgery, and in activation of alpha-rhythm in electroencephalography. It is also helpful in treating sensorineural hypoacusis; tinnitus (decrease of emotional tension); cerebrovascular ischemia; herpes zoster and herpes simplex; acquired immunodeficiency syndrome; purulent polysinusitis; chronic otitis media; phlegmon of the face (albumin stimulation); muscular hypertonia; hypercholesterolemia; senile dementia; cluster headache; multiple sclerosis; optic nerve dysfunction; and tumors (irradiation sensitivity) [12–16].

We know some different methods of ozone application. The most popular is air treatment. Injection into a vein is especially used in autohemotherapy [17]. Injections into joints, muscles, and tumors; rectal, vaginal, and ear insufflations; oral or external use of ozonated water or olive oil; and body bagging are other ways to apply ozone [18].

Pressure therapy in ear diseases was previously used in Meniett's low-pressure stimulator [19]. During Ménière's disease, massage of the ear membrane has been performed for 5 minutes, three times daily, for weeks. Special types of pressure therapy are hyperbaric oxygen therapy and candling, which produces a vacuum with the flame [19].

The aim of our study was to join ozone therapy and pressure-pulse therapy in treatment of Ménière's disease to observe their cumulative effect on the auditory part of the inner ear.

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PATIENTS AND METHODS

We performed our study in 15 patients (8 male, 7 female; aged 38–56 years; mean, 43.7 years) who had Ménière's disease (duration, 1–3 years; average, 2.1 years). In four persons, Ménière's disease was bilateral; the other patients suffered from unilateral symptoms. Typical symptoms were observed during the course of the disease: sensorineural hearing loss (on the basis of tonal audiometry; in every case, persistent); attacks of tinnitus (fullness as well; sometimes persistent tinnitus); and vertigo and nausea (even vomiting). Mean frequency of attacks was one per month.

For ozone therapy, we used an ozone generator for inhalation (Deutsche Nemectron GmbH, Karlsruhe, Germany). The concentration of ozone in the ozone and oxygen mixture was 8 mg/liter; flow was 60 ml/min. The inhalation was performed for 10 minutes a day, once daily for 10 days.

During pressure-pulse therapy (Heyer, Bad Ems, Germany), we performed massage of the tympanic membrane with pressure of 140 mm Hg and frequency of 10 Hz, 10 minutes per day, once daily over 10 days.

We measured two functions of the auditory part of the inner ear: otoacoustic emissions (OAE) and the short-increment sensitivity index (SISI). Spontaneous otoacoustic emissions (SOAE) and transiently evoked otoacoustic emissions (TEOAE) were analyzed using technology from Capella (Madsen, Copenhagen, Denmark). TEOAE were calculated on the basis of mean correlation (percentage), emission strength (decibels), and signal-to-noise (S/N) ratio (level of accuracy, 4 dB). The stimulus level was 80 (90) dB, and the number of accepted proofs was 2,080. During the SOAE measurement, input sensitivity reached 0–70 dB, with frequency ranges of 500–10,000 Hz. We took into consideration only those intensities of spontaneous emission that exceeded 15 dB: In a normal sample of 50 healthy persons, we considered that the highest range of spontaneous cochlear answers that could be noticed in a normal sample of 50 healthy persons was 15 dB. SISI test results (audiometer from Madsen) were evaluated using frequencies of 1,000, 2,000, and 4,000 Hz, at 20 dB above the hearing level, with increments of 1 dB every 5 seconds. Normal results of the SISI test were established previously in our laboratory in a group of 500 healthy individuals and amounted to 0–42.5%.

Subjective evaluation was the last part of our observations. We asked patients to calculate severity and frequency of the attacks and problems with tinnitus. The answers were collected before therapy and 1 month after treatment ended.

OAE and SISI results were evaluated by patients before ozone therapy and pressure therapy and just after the treatments (on the last day of treatment). The results before and after therapy were compared using the statistical Student's *t*-test.

Table 1. Mean Results of Transiently Evoked Otoacoustic Emissions and Their Statistical Analysis in Ménière's Disease Before and After Ozone Therapy and Pressure-Pulse Therapy

	Values of Parameters					
	Correlation		Emission Strength		S/N Ratio	
Side and Time of Registration	Mean	SD	Mean	SD	Mean	SD
Sick ear						
Before	12.90	18.20	9.06	3.10	1.35	2.10
After	19.00	29.67	10.31	6.84	2.73	4.73
Student's *t*-test	$p = .24$		$p = .26$		$p = .15$	
Healthy ear						
Before	69.13	17.80	14.84	4.85	7.85	2.76
After	62.63	23.00	15.14	3.08	5.85	3.71
Student's *t*-test	$p = .27$		$p = .44$		$p = .12$	

S/N = signal-to-noise.

RESULTS

Table 1 presents the comparison of TEOAE results before and after ozone therapy and pressure-pulse therapy in patients suffering from Ménière's disease. Even the results of every tested parameter were better after ozone therapy and pressure-pulse therapy in sick ears, although the differences were not statistically significant. Similarly, the TEOAE obtained from healthy ears did not differ statistically from one another.

SOAE reached pathologically high values in five sick ears before therapy. The highest level was 33.8 dB, and it was obtained in an ear suffering from very disturbing, permanent tinnitus. Table 2 demonstrates the mean level (in decibels) of SOAE in sick and healthy ears before and after treatment.

The results of the SISI test, according to three selected tone frequencies before and after therapy, are shown in Table 3. Mean results obtained from healthy ears were inside normal ranges both before and after

Table 2. Mean Level of Spontaneous Otoacoustic Emissions in Sick and Healthy Ears Before and After Treatment

	Mean Level Of Spontaneous Otoacoustic Emissions (dB)	
Generated in	Before Therapy	After Therapy
Sick ears	21.8	19.4
Healthy ears	12.7	13.1

Table 3. Answers to Short-Increment Sensitivity Index (SISI) Test in Patients Before and After Ozone Therapy and Pressure-Pulse Therapy

Side and Time of Registration	Results of SISI Test					
	1,000 Hz		2,000 Hz		4,000 Hz	
	Mean	SD	Mean	SD	Mean	SD
Sick ear						
Before	51.25	37.26	60.63	39.11	62.81	40.41
After	45.00	38.38	62.50	40.54	60.31	40.27
Student's *t*-test	$p = .32$		$p = .44$		$p = .43$	
Healthy ear						
Before	16.25	22.48	13.13	20.34	17.50	24.20
After	12.22	19.06	12.22	19.70	21.11	33.80
Student's *t*-test	$p = .34$		$p = .40$		$p = .40$	

Note: Results given in percentages.

therapy. Mean results in sick ears were pathologically high both before and after ozone and pressure treatment. Such results have a tendency to fall after therapy, but the decrease was not statistically proved.

Subjective evaluation of Ménière's disease patients is introduced in Table 4. What can be clearly seen is that, in a majority of cases during the entire period of observation after treatment, the attacks of Ménière's' disease were absent.

DISCUSSION

After ozone and pressure-pulse therapies, we could not observe any statistically significant difference in OAE assessments and in SISI test results. In every one of these evaluations, a tendency to improvement was noticed. Perhaps, if the therapy were longer or the hypoacusis were not persistent but fluctuating, the results would be better. However, subjectively the patients felt very well. The most spectacular effect of therapy was observed in cases described later. Two persons suffered from especially severe, very frequent (once weekly) attacks of Ménière's disease; their permanent tinnitus has remained unchanged for more than 2 years. These two patients were so depressed by sleep problems, difficulties in concentrating, and nervousness that they were treated by psychiatrists. They did not believe in successful therapy but agreed to try. After 10 days, they perceived a change in loudness of their tinnitus; it did not disappear entirely but fluctuated. Attacks returned, but their severity was medium instead of extremely severe, and they appeared 1 month after therapy and again 1 month later.

Very interestingly, in other cases during 1 month of further observation, no attack occurred. In four patients after therapy, tinnitus completely disappeared; these people had noticed fullness in the head or in the ear previously. Fluctuating tinnitus, present before treatment in four patients, could be noted by them but not as frequently as before therapy.

The reason for improvement after ozone therapy and pressure-pulse therapy is hypothetical. Possibly it is the effect of massage of inner-ear fluids, changing the hydrodynamics with increased oxygen delivery [19]. For improvement of cellular metabolism, hypocoagulatory changes must be taken into consideration as well [7,8]. However, from our point of view, the most probable change—in our cases treated rather briefly—was the decrease of emotional tension [20]. Such a mechanism might be responsible for subjective improved feeling noted by our patients. Lack of significant functional change of the auditory receptor during objective tests seems to be a logical consequence of such a therapeutic suggestion.

Table 4. Anamnesis Before and After Ozone Therapy and Pressure-Pulse Therapy

Tinnitus	No. of Patients	
	Before	After
Severity		
Severe with vomiting	3	0
Medium but with need to rest at home	9	2
Light; not disturbing daily duties	3	0
Frequency		
Once weekly	2	0
Once monthly	10	2
Twice monthly	3	0
Type		
Permanent; extremely severe problem	2	0
Fluctuating	4	6
Fullness in the head (ear)	9	2

SUMMARY

After ozone therapy and pressure-pulse treatment of Ménière's disease patients, the tendency to improvement was observed only on the basis of OAE assessment and the SISI test. Subjectively, real improvement was noted by the patients themselves: Severity and frequency of the attacks and tinnitus decreased.

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