Alternative treatment with Eardoc vibrating device for Chronic Seromucinous Otitis Media and relief of ear pain associated with Otitis Media

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Summary:

We conducted a randomized, clinical trial to investigate the efficiency of the treatment of Chronic Seromucinous Otitis Media (CSOM) with the Eardoc vibrating device over a 5-week period. Tympanometric peak pressures determined efficiency recorded on a diagram analysis, and an independent online satisfaction survey was also conducted. The tympanometry study group was made up of 35 patients (70 ears) ranging in age from 2 to 40 years, who were diagnosed with one or more of the following:

- Acute Tubal Occlusion (Serotympanum);
- Acute Otitis Media, CSOM

The survey participants were Eardoc users who filled out an online survey.

The patients in the study group showed a significant improvement with 95% of the users who said they had blocked ears, defined as a feeling of pressure and fullness in the ear (in case of infants the tympanomertic result assumes this sensation of blocked ears), showing a reduction in tube blockage. In the control group, however, there were no significant improvements.

We also conducted a randomized satisfaction study online to investigate the efficiency of ear pain relief by using ear pain with a vibrating device called Eardoc. The study group was made up of 53 users (70 ears), aged 2 to 73 years old. The

survey indicated high satisfaction among the users, with 94.3% of participants indicating they felt relief after using the device, and 98% indicating that they would use the device again. The results show with no doubt that the device opens the Eustachian Tube and decreases pressure, consequently relieving the pain.

Introduction:

Almost 20 million children with Acute Otitis Media (AOM) visit medical offices annually in the United States alone, and 18 percent of ambulatory care visits among preschool children[1] are due to chronic ear pain. Impaired hearing and delayed speech development are the most frequent long-term effects of recurrent episodes of AOM. Concerns have been raised about the proper treatment of AOM in the face of increasing drug resistance among primary pathogens responsible for infection. Methods of treatment include nasal decongestant, nasal decongestant spray, vasoconstrictors, local or systemic antihistamines, local steroids (corticosteroid therapy), anti-microbial agents, antibiotics, insufflations of the Eustachian tube/middle ear system by the Valsalva maneuver or the Politzer method, pain reliving medication, myringotomy, and periodic observation during efforts to reduce environmental risk factors. The efficacy of treatment with drugs or surgery has been questioned. For example, a recent trial that compared immediate with delayed antibiotics showed that for most children, the benefit of immediate antibiotics was only marginal with no significant difference in pain or distress scores.[2] If medication fails in the case of CSOM, most otolaryngologists recommend the surgical placement of tympanostomy tubes.[3] One survey showed that 40% of otolaryngologists believe that tubes are used too frequently.[4,5] Reported complications of tympanostomy tube placement include tympanic membrane retraction, postsurgical infection, localized foreign-body reaction, granulation, hyalinization, tympanosclerosis, temporary or permanent hearing impairment of varying degrees, persistent tympanic membrane perforation, dislocation of the tube into the middle ear cavity, tube blockage, and cholesteatoma.[6,7,8]

In order to overcome the conventional treatment of medication and insertion of ventilation tubes, we have conducted a study to check the effects of using a device which vibrates, thereby providing a peristaltic movement to the mucosa of the Eustachian tube to provide air for the middle ear cavity.

Participants

Participants were chosen from visitors to the ENT clinic in Hungary to our outpatient department. Out of 350 patients, 70 were eligible to participate in this study. Eligibility was determined by three factors: 1) a hesitation to be treated with current medical methods due to personal beliefs; 2) acceptance to use an alternative treatment

for the purpose of the study; 3) who were diagnosed with one or more of the following: Acute Tubal Occlusion (Serotympanum), Chronic Seosus Otitis Media(CSOM), Acute Otitis Media (AOM). Participants also complained of a feeling of pressure and fullness in one or both ears, pain, and hearing loss. Participates were divided in to two groups: a control grope that did not receive the vibrating treatment and a study group that received the vibrating device treatment.

Statistical Methods

A sufficient sampling size with a confidence level of 95% and a confidence interval of 10% was made up of 48 patients (96 ears).

Instrumentation

Based on the manufacturer's claim, the device transmits a vibration wave of 1300-2500 Hz on the temporal bone to the Eustachian tube. These vibrations were transmitted noninvasively on the temporal bone by placing the device behind the ear. The wave induced by this device makes a peristaltic movement to the Eustachian Tube. This movement helps the Eustachian tube to open. It also increases blood circulation as well as activity of the cells in that region. For accurate and objective measurement of the middle ear cavity status, a Tympanometer was used providing 3 types of graphs: Type A, B, or C. Type A refers to eardrum movement within normal limits. Type B indicates little or no eardrum movement suggesting fluid in the middle ear space. Type C refers to a middle ear with negative pressure. Such a tympanogram may be caused by retraction of the eardrum or blockage of the Eustachian tube.

Procedure

Each candidate was checked for all symptoms. After complete examination of the status of the external ear canal and tympanic membrane, we checked the tympanic cavity with a Tympanometer in the outpatient department of our clinic. After this test, each patient (or in the case of young children, the patient's parent or guardian) was advised to use the treatment three times a day for up to 5 minutes each time. During each treatment, the patient was instructed to be in a sitting position. Each Patient had his or her own device. On weeks 1, 4, and 6 a tympanometric examination was performed and registered. Each test was given one of three results: Type "A"; "B"; or "C" tympanogram. Type "A" indicated a normal tympanic cavity; Type "B" indicated fluids in the middle ear; and Type "C" was a tympanic cavity effusion. After 6 weeks, the users received a response survey with 5 questions about their satisfaction and the relief of pain and hearing loss. Independently, a different online survey was conducted to gather additional data on the users' satisfaction.
Tympanometry was performed by professional audiologists certified by the Hungarian Medical University.

The patients in the control group did not undergo the same treatment with a dummy device because their parents would have immediately recognized it as such. In lieu of using a dummy device, they (only in the case of Chronic Serosus Otitis Media) did not receive any treatment for 4 weeks (waiting time for surgery). The patients and their parents were instructed to contact the investigators immediately if they noticed any worsening of hearing status or any other complaints. Audiologists testing with the tympanometer were not informed of each patient's otologic findings; otolaryngologists were not told of each patient's tympanomertic results. At the time of the post-test, both audiologists and otolaryngologists were unaware of each patient's disease status. The statistician was also unaware as to whether test results were obtained before or after therapy and regarding the disease status of each patient.

Results

A total of 70 patients were eligible to participate in this study, 35 patients (70 ears) were assigned to the test group, 35 patients were assigned to the control group (70 ears). 53 independent Eardoc users ranging in age of 1 to 73 years old filled out an online survey.

Compliance. Complete compliance with the treatment protocol was demonstrated by users over all symptoms (**Table 1.)**

Patients Symptom	distribution of participants
R Blockage of ear	65%
L Blockage of ear	62%
R Ear pain	43%
L Ear pain	34%
R tinnitus	23%
L tinnitus	17%
R Grommet Tubes inserted	20%
L Grommet Tubes inserted	14%
Fever	14%
R Cataralis tube	20%
L Cataralis tube	14%
R Otitis media serosa	51%
L Otitis media serosa	54%
R Otitis media Acuta	6%
L Otitis media Acuta	6%
R Hearing loss	57%
L Hearing loss	54%

Table 1. *The overall symptoms and distribution of the patients.*

Tympanometer Results from using the device.

The number of patients with malfunctioned Eustachian Tubes decreased from 39 to 2 ears after 6 weeks while the number of normal ears increased from 12 to 32 in the same time period. In the control group, there was no significant change. Out of the 35 patients 66 ears were tested and after five weeks six patients did not return to the clinic to perform the tympanogram test. They have reported by phone that they are no longer suffering from ear pain, and do not need any further treatment.
(**Table 2. Table 3.**)

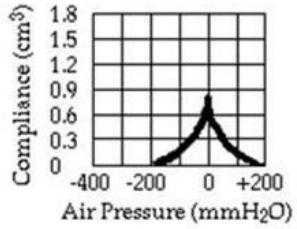
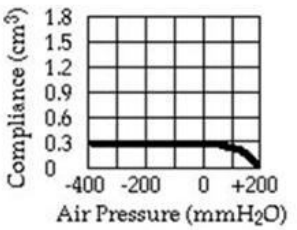
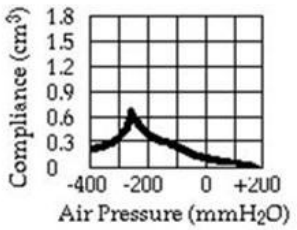
			Before The device	After 1 weeks	After 4 weeks	After 6 weeks
	Number of A Type	Control group	11	13	13	15
	Number of A Type	Test group	12	18	28	32
	Number of B Type	Control group	40	40	39	37
	Number of B Type	Test group	39	31	12	2
	Number of C Type	Control group	15	13	14	14
	Number of C Type	Test group	15	17	22	19

Table 2. *Number of patients with Types "A", "B" and "c" tympanogram in the control and test group. Type "A" indicated a normal tympanic cavity; Type "B" indicated fluids in the middle ear; and Type "C" was a tympanic cavity effusion.*

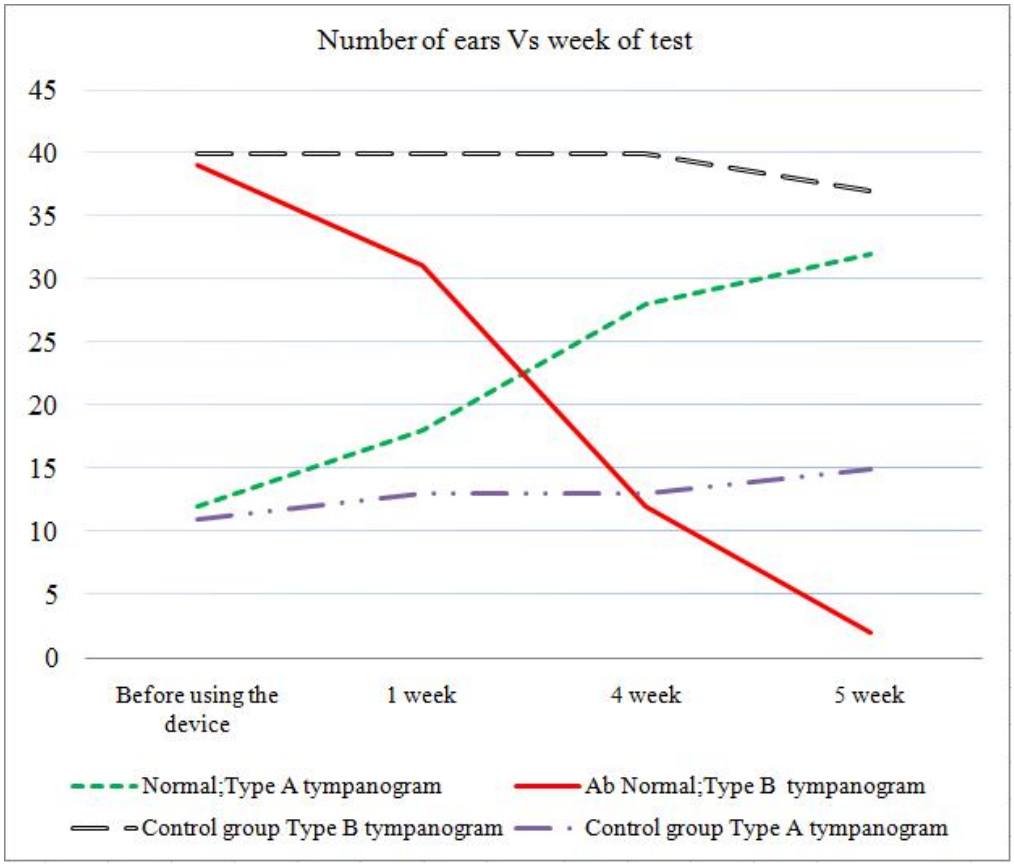


Table 3. *The number of patients with malfunctioned Eustachian Tubes decreased from 39 to 2 ears after 6 weeks while the number of normal ears increased from 12 to 32 in the same time period. In the control group, there was no significant change.*

Questioner

We examined the users' satisfaction to the treatment by asking questions about their experience with the device. (**Table 4.**)

Questions covered:

Effect in reliving ear pain; Patient's general view of the effectiveness in reliving pain - a ranking from 1 to 5 with 1 representing that it did not help; and 5 that it reduced the pain immediately. None of the patients indicated that the device damaged them or created more pain. Out of 27 users with ear pain, only one patient replayed that the device did not reduce the pain. The outstanding 25 ear pain sufferers had reported that the pain was relived immediately with an average mark of 4, none of the patients advice that the pain was increased.

Usage: How easy was it to use – a ranking from 1 to 5, with 1 representing that it was very difficult to use; and 5 that it was extremely easy to use.
Receptiveness of Child; How receptive was the child to the parent's aid to use the device – a ranking from 1 to 5 with 1 representing that the child did not allow the parent to help; and 5 that the parent could use the device with no problem, or the child used it by him or herself.
Complaints of usage; Did the patient complain – a ranking of 1 to 5 with 1 representing that the patient complained the device caused even more pain; and 5 that the patient did not complain at all.
overall satisfaction; The overall satisfaction from using the device for reliving pain – a ranking of 1 to 5 with 1 representing no satisfaction at all, indicating the device caused even more pain; and 5 that the patient was very satisfied. None of the patients gave a result less than 3 for this question, and none of the patients indicated any bad side effects from using the device.

Questions	Answer's			
	Average	standard deviation	Min	Max
Effect in reliving ear pain	3.80	1.45	1	5
Usage	3.97	1.16	3	5
Receptiveness of Child to the device	4.18	0.70	3	5
Complaints of usage	4.03	0.73	3	5
overall satisfaction	4.21	1.21	3	5

Table 4. *Patients' Average answers regarding the effectiveness of the device. Out of 27 users with ear pain, only one patient replayed that the device did not reduce the pain. The outstanding 25 ear pain sufferers had reported that the pain was relived immediately with an average mark of 4, none of the patients advice that the pain was increased.*

Independent Satisfaction survey

We also conducted a randomized satisfaction study online to investigate the Satisfaction of patients using the suggested device, the study group was made up of 53 users (106 ears), aged 2 to 73 years old. The survey indicated high satisfaction among the users, with 94.3% of participants indicating they felt relief after using the device, and 98% indicating that they would use the device again in the future if they have an ear pain. The results show with no doubt that the device relived the pain. None of the participants indicated that the pain was increased after using the device. **Table 5.**

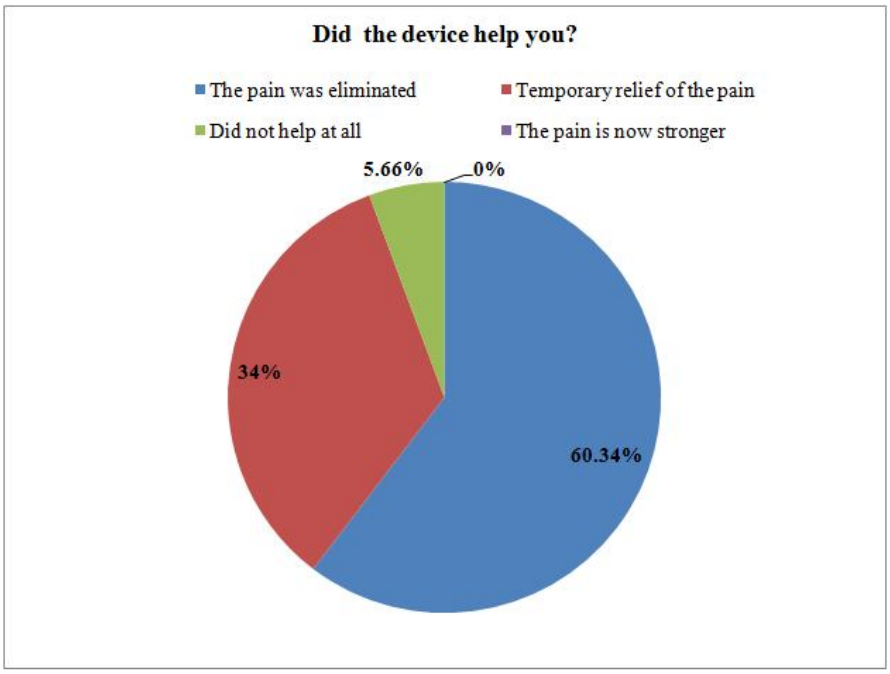


Table 5. *Patients' answers to the questions regarding how the device provided pain relief. 94.3% of participants indicating they felt relief after using the device. 60.34% of them had reported immediate relief.*

Discussion

The results of our investigation indicate that a daily home treatment using the Eardoc device is highly effective for both children and adults. The use of the Eardoc device was not only effective in reducing the sense of fullness in the ears, but the users' satisfaction was extremely high as well. This device could be an alternative treatment to myrongtomy for those who are suffering from otitis media. We therefore recommend that patients who are suffering from a sense of fullness in their ears, or who suffer from ear pain, to use the suggested Eardoc device. In some cases patients with tinnitus noticed that after using the device, their ear noise was significantly reduced. there were only eight patients suffering from tinnitus therefore we suggest to perform another test only on tinnitus users to check if the device would help in resolving tinnitus.

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