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Assessment of the effectiveness of Eustachian tube dysfunction treatment using an AMSA pneumatic inhaler

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: Upper respiratory tract infections are common childhood diseases. Children are more susceptible to middle ear infections since their Eustachian tubes are short, straight and wide. These inflammatory changes associated with impaired patency of the Eustachian tubes often lead to the development of conductive hearing loss.

Objective: The aim of this study was to assess the effectiveness of the treatment of Eustachian tube dysfunction using AMSA inhalers.

Material and Methods: The study group comprised 30 patients. The same number of patients were included in the control group. All patients reported conductive hearing loss. The test group was treated using AMSA inhalers while the control group received pharmacotherapy. Patients were examined with the use of pure-tone and impedance audiometry at baseline, one week, and four weeks after the initiation of treatment.

Results: Statistical analysis showed that the improvement in the studied parameters in patients treated with AMSA inhalers occurred in a much shorter time than in patients receiving pharmacotherapy.

KEYWORDS: eustachian tube disorders, conductive hearing loss, AMSA inhaler

INTRODUCTION

Upper respiratory tract infections due to viral, bacterial, or allergic factors are common childhood diseases. Children are more susceptible to middle ear infections since their Eustachian tubes are short, straight and wide. The increased incidence of upper respiratory tract infections may also be due to the hypertrophy of Waldeyer's tonsillar ring tissue and poor aeration of middle ear space which is still partially filled with myxomatous tissue or hypertrophic mucosa. More persistent ventilation disorders are associated with increased production of mucus that accumulates within the tympanic cavity. Edema of the middle ear region is also observed. Increased viscosity of mucus combined with mucosal swelling contribute to the Eustachian tube being clogged with mucus, which leads to conductive hearing loss [3,7,11,16,21]. In most cases, effective treatments exist for acute or chronic inflammations. The standard treatment consists mainly of administration of systemic antibiotics or sulfonamides, use of analgesic, anti-inflammatory, antipyretic, and antihistamine agents, and paracentesis procedure if indicated and if the middle ear is involved. An important element of the treatment consists of local and systemic administration of nasal and nasopharyngeal decongestants to improve the accessibility of Eustachian tubes [2,5,6,12,14,17,19,20]. More and more often, physiotherapeutic procedures are included in patient management. They may be used either as a supportive measure or as the main form of treatment. Methods established in the treatment of Eustachian tubes include heat being delivered to the tissues by means of strong infrared lamps. High frequency magnetic fields or short wave diathermy that heats up tissues by means of an electric field are also used. Calcium chloride iontophoresis is one of the most common physiotherapeutic procedures delivered to patients with accompanying conductive hearing loss. The applied current results in increased supply of blood to the skin and thus facilitates penetration of the drug into the affected tissues [10,15]. Inhalations are also a common and popular method of treatment. The method consists in patients inhaling water vapor

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or drugs delivered from devices that generate medicinal aerosols at different dispersion degrees. Technological advances facilitated the development of AMSA pneumatic inhalers for use in the treatment of middle ear disorders, paranasal sinus disorders, and Eustachian tube patency disorders. The device is capable of generating vibroaerosols delivered in a pressure pulse mode. The aerosol generated in the device is spiked with additional energy originating from superimposition of a 100-Hz acoustic wave. Hyperpressurized aerosol penetrates into the middle ear via the Eustachian tube, thus restoring its patency that might not be restored by more conventional methods such as Valsalva maneuver of Politzer balloon treatments . In AMSA inhalers, hyperpressure is activated automatically upon swallowing. Hyperpressurised aerosol is delivered via an appropriate nasal tip into the closed nasopharyngeal space and further into the Eustachian tube [1,9].

OBJECTIVE

The objective of the study was to assess the efficacy of the treatment of Eustachian tube dysfunction using the AMSA pneumatic inhaler.

MATERIAL AND METHODS

The study was conducted in a group of 60 patients treated for conductive hearing loss due to impaired Eustachian tube patency in the course of upper respiratory tract infection. Patients qualified for the study suffered from bilateral hearing loss. The study group comprised 30 patients treated with AMSA inhalers. The study group consisted of 18 girls and 12 boys aged 4-17 years (mean age of 10 years). Inhalations were delivered from AMSA inhalers for 5 consecutive days, 2 times a day, 10 minutes per inhalation. Drugs administered during each inhalation consisted of Pulmicort (0.25 mL) and ACC (1 mL).

The control group consisted of 30 patients – 16 girls and 14 boys – aged 4-17 years (mean age of 10 years). Patients in the study group received pharmacological treatment only. The pharmacological treatment consisted in oral administration of steroids, mucolytics, and anti-edemic agents

The organ of hearing was assessed in all patients on the first presentation day, one week after initiation of treatment and one month after initiation of treatment. The assessment of the hearing organ was carried out by the psychophysical method involving pure tone threshold audiometry and by the electrophysical method involving impedance audiometry. The hearing thresholds for air and bone conduction were determined using a MADSEN ITERA II clinical audiometry device. The impedance audiometry measurements included tympanometry and stapedius muscle reflex measurements. The measurements were carried out using a MADSEN ZODIAC 901

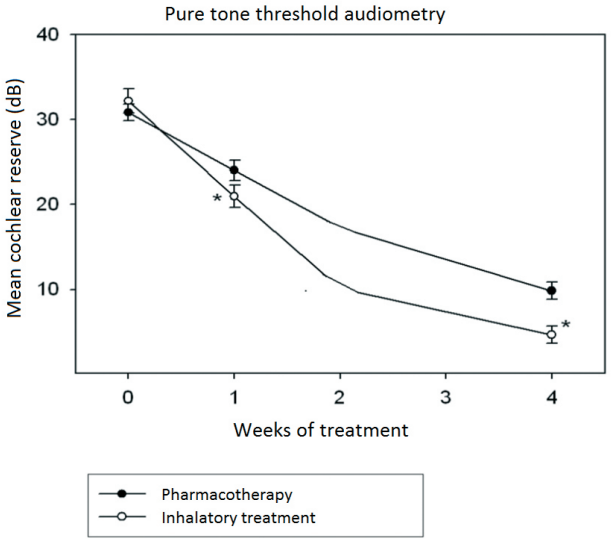

Fig. 1. The average size of air-bone gap for 2 groups: treated pharmacologically (full circle) and treated with inhaler (open circles). Asterisks indicate the results that were statistically significant ($p < 0.05$).

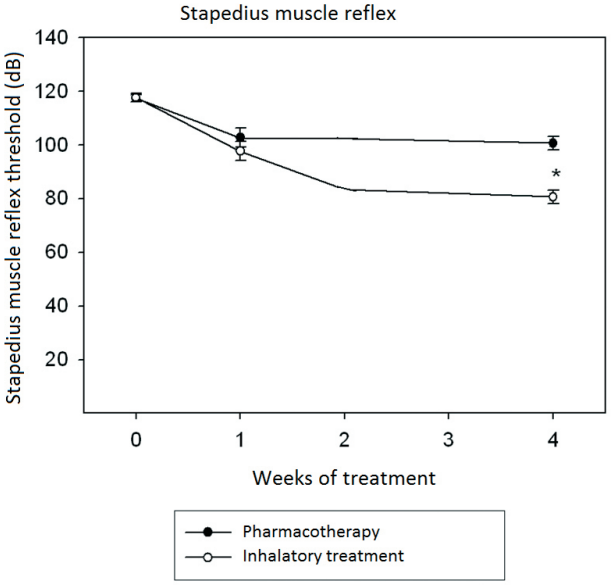

Fig. 2. Stapedius reflex threshold in dB for 2 groups: treated pharmacologically (full circle) and treated with inhaler (open circles). Asterisks indicate the results that were statistically significant ($p < 0.05$).

P tympanometer. Statistical analyses were conducted using the STATISTICA 8.0 software package (StatSoft Inc.). Dependent sample t-test and Wilcoxon's signed rank test were used in the analyses. Statistical significance was assumed below the level of p=0.05.

RESULTS

1 Pure tone threshold audiometry

Calculations of arithmetic means of cochlear reserves measured in decibels at 500 Hz, 1000 Hz, 2000 Hz, and 3000 Hz facilitated the comparisons of the results

of individual treatments. The results are presented in Table 1 and Figure 1.

Statistical analysis revealed that the treatment using the AMSA inhaler has a statistically significant effect on the mean cochlear reserve. Statistically significant differences could also be observed as early as after one week from the initiation of treatment. Therefore, one may conclude that the improvement in studied parameters occurs in a much shorter time in patients treated with AMSA inhalers as compared to patients receiving pharmacological treatment only.

2 Stapedius muscle reflex

Arithmetic means of stapedius reflex thresholds measured in decibels at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz for different treatment modes are presented in Table 2 and Figure 2.

The results of the analysis demonstrate that the treatment using the AMSA inhaler has a statistically significant effect on the improvement of the stapedius reflex threshold. This leads to an unambiguous conclusion that the use of the inhaler improves the studied parameter and that, in a manner similar to that in pure tone audiometry, the improvement occurs faster when the inhaler is used.

3 Tympanometry

Baseline assessments revealed abnormal results in all patients. No type A tympanograms were recorded. The obtained results are presented in Table 3 and Figure 3. Statistical analysis of the results revealed a statistically significant difference between both patient groups. Abnormal tympanograms were observed in all patients at baseline (73% of patients with of type C tympanograms, 27% of patients with of type B tympanograms). Already one week after the initiation of treatment, the percentage

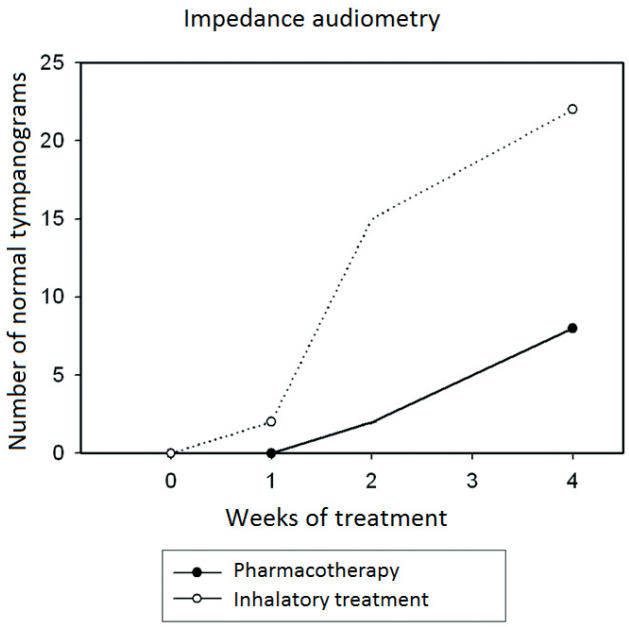

Fig. 3. Normal tympanograms (type A) in the following time points for groups pharmacologically treated (full circles) and the inhaler-treated group (open circles). The Wilcoxon test showed that the two curves are significantly different statistically.

of normal tympanograms increased to 7%. No normal tympanogram could be observed after that time in the control group. One month after the initiation of treatment, a total of 22 normal type A tympanograms (73%) were observed in the study treatment group as compared to as few as 8 patients (27%) in the control groups.

DISCUSSION

Impaired patency of the Eustachian tube leads to pathological changes within the inner ear, inspiring the scientists to continue their research for ever more efficient treatments. The objective of efficient treatment consists in prevention of complications manifesting as permanent middle ear damage. A typical initial treatment following the diagnosis of inflammation within the upper respiratory tract, Eustachian tube and ears consists in administration of systemic antibiotic or sulfonamide treatment combined with agents reducing the inflammation symptoms, i.e. pain, edema, or elevated body temperature. Topical-acting drugs should also be administered intranasally to reach the pharyngeal opening of the Eustachian tube [4]. After the acute phase is overcome, it is advisable to introduce physiotherapeutic management measures. Although they have been known for a long time, their role in the treatment was highly underrated. One of

such measures consists in vibroaerosol being introduced directly into the middle ear using an AMSA inhaler device. It is a relatively new method of treatment in Poland and the procedures are offered only in selected physiotherapy centers. Most commonly, AMSA inhalers are used at centers specializing in pediatric treatment. This is understandable since it is the pediatric population in whom the upper respiratory tract infections are often combined with Eustachian tube and ear inflammations. The first reports on the efficacy of this method were published by Markowska et al. [13]. The studies were conducted in a group of 21 adults with chronic Eustachian tube inflammation lasting for several months through several years. Previous treatments led to no results or the improvements were only temporary. Patients were subjected to a 5-day treatment with AMSA inhalers. Inhalations were delivered 3 times a day and lasted for 20 minutes each. Vibroaerosols were used to deliver medications such as mistabron, hydrocortisone, vitamins A, D3, E, and mentoclar dissolved in physiological saline. After completion of treatment, improvement was observed in 88.9% of patients. AMSA inhalations were used previously in the treatment by Szkiełkowska et al. [22]. The study was conducted in children aged 3-7 suffering from secretory otitis. In their reports, the authors demonstrated the efficacy of mucolytic drugs administered as vibroaerosols. The treatment was delivered twice daily for 5 days. Each inhalation lasted for 10 minutes. A mucolytic drug, ambroxol, was administered by the inhalatory route. Immediately after the treatment, improvement was observed in 81% of patients with unilateral secretory otitis and in 30% of patients with bilateral secretory otitis. In subsequent examinations, carried out one month and three months after the treatment, full recovery was observed in all children in the first study group as compared to over 60% in the second group. Considering the chronic nature of the disease, this should be considered a very good result that confirms the observations presented in this paper. A study conducted in a similar patient group was reported by Zielnik-Jurkiewicz and Olszewska-Sosińska [23]. The study was conducted in children with Eustachian tube inflammation and secretory otitis. Pure tone audiometry and tympanometric measurements were conducted after 10 AMSA inhalations with an aerosol containing 4 mg of dexamethasone. Complete resolution of the disease was observed in 76.7% of patients. However, the authors were unable to achieve satisfactory therapeutic results in secretory otitis patients. The thick fluid accumulated in the middle ear had to be evacuated by means of myringotomy and ventilation drain placement. The efficacy of AMSA inhalations in pediatric patients with secretory otitis was also studied by C. Saga et al. [18]. The study was conducted in a group of 37 children at the mean age of 7 years. The patients were subjected to aerosol treatment and audiometric measurements before inhalations and 1, 3, and 6 months after completion of treatment. The authors were able to observe improvements comparable to those obtained after ear surgery in as many as 76% of patients. However, they highlighted the small sample size that makes these results only preliminary in nature. The study may act as an introduction for further studies conducted in a larger population. This study attempts to answer the question whether administration of the drug from an inhaler leads to better results than conventional treatment. The statistical analysis of the results of tympanometric measurements confirmed the significant difference between both groups and demonstrated unambiguous benefits of inhalation treatment. Four weeks after the initiation of treatment, normal tympanograms were recorded in 73% of patients in the study treatment group as compared to 27% of patients in the control group. Probably, the faster normalization of tympanic membrane displacement susceptibility in the study group was due to the direct contact of medication-containing aerosol with the tympanic membrane and the middle ear from the inside. To sum up, numerous studies are suggestive of the efficacy of inhalations in the treatment, not only in case of Eustachian tube obstruction. Goectas et al. observed that AMSA inhalers were efficient in the treatment of chronic sinusitis [8]. A significant improvement in the sense of smell was observed after corticosteroids were administered using the inhaler. Perhaps the constantly growing number of studies and articles will contribute to propagation of inhalation as an effective treatment method and thus to the increase in the number of medical centers in Poland where this treatment would be available.

Tab. I. Pure tone audiometers - average values of air-bone gap for a frequency of 0.5 kHz, 1 kHz, 2 kHz, and 3 kHz, measured in dB.

	BASELINE EXAMINATION	ONE WEEK AFTER INITIATION OF TREATMENT	FOUR WEEKS AFTER INITIATION OF TREATMENT
Patients treated with AMSA inhalers	32.2 dB	20.97 dB	4.67 dB
Patients receiving pharmacotherapy only	30.87 dB	24.03 dB	9.83 dB

Tab. II. Average values of stapedius reflex threshold, measured in dB.

	BASELINE EXAMINATION	ONE WEEK AFTER INITIATION OF TREATMENT	FOUR WEEKS AFTER INITIATION OF TREATMENT
Patients treated with AMSA inhalers	113.91 dB	97.67 dB	80.67 dB
Patients receiving pharmacotherapy only	115.39 dB	102.37 dB	100.67 dB

Tab. III. Number of tympanograms of type A, B and C obtained in studies in particular weeks of treatment.

	BASELINE EXAMINATION			ONE WEEK AFTER INITIATION OF TREATMENT			FOUR WEEKS AFTER INITIATION OF TREATMENT		
Tympanogram types	A	B	C	A	B	C	A	B	C
Patients treated with AMSA inhalers	0	8(27%)	22(73%)	2(7%)	6(20%)	22(73%)	22(73%)	0	8(27%)
Patients receiving pharmacotherapy only	0	5(17%)	25(83%)	0	5(17%)	25(83%)	8(27%)	4(13%)	18(60%)

CONCLUSIONS

- 1 AMSA inhaler provides an efficient method for the treatment of Eustachian tube disorders and the accompanying conductive hearing loss.
- 2 Thanks to its ability to generate vibroaerosols containing physician-prescribed medications and administered automatically as a short-timed pressure pulse upon swallowing, AMSA inhaler appears to provide the best non-surgical method of accessing the inside of the affected tympanic cavity.
- 3 When used in Eustachian tube dysfunctions in children, AMSA inhaler reduces the duration of treatment while accelerating resolution of symptoms and hearing improvement.
- 4 The studies showed that AMSA inhaler is a valuable tool for the treatment of Eustachian tube dysfunctions in pediatric patients.

REFERENCES

1. Alkiewicz J.: Leczenie inhalacyjne i rehabilitacja układu oddechowego u dzieci i dorosłych. Volumed, Wrocław, 1995: 39-106
2. Arick D.S., Silman S.: Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part I: clinical trial. Ear Nose Throat J., 2005, 84; 9: 567-576
3. Becker W, Naumann H.H., Pfaltz C.R. Choroby uszu , nosa i gardła. BEL CORPS Stientific Publications, Warsaw, 1999: 87–90
4. Cole E., Flexer C. :Children with Hearing Loss: Developing Listening and Talking, Birth to Six Third edition, Plural Publishing, San Diego, 2016: 55-65
5. Del Mar Ch., Venekamp R.P., Sanders S.: Antibiotics for Children With Acute Otitis Media JAMA, 2015; 313(15): 1574-1575.
6. Dzierżanowska D.: Antybiotykoterapia praktyczna, α-medica-press, Bielsko Biała, 2005.
7. Dierżanowska D., Jurkiewicz D., Zielnik-Jurkiewicz B.: Zakażenia w otolaryngologii, α-medica-press, Bielsko Biała, 2002: 32-34
8. Goektas O., Lau L., Olze H.:Treatment of Chronic Rhinosinusitis with Pressure-Pulsed Corticosteroid Inhalation Indian J Otolaryngol Head Neck Surg. 2013; 65: 402–405
9. Karolewicz B., Pluta J., Haznar D.: Nebulizacja jako metoda podawania leków. Terapia i Leki Farmacja Polska, 2009; 65: 4
10. Kinalski R.: Kompendium rehabilitacji i fizjoterapii. Wydawnictwo Medyczne Urban & Partner, Wrocław 2002
11. Kossowska E.: Otolaryngologia dziecięca. PZWL, Warszawa, 1994; 69-76
12. Kuczkowski J.: Aktualne problemy w rozpoznawaniu i leczeniu ostrego i wysiękowego zapalenia ucha środkowego. Forum Medycyny Rodzinnej, 2011, 5; 4: 287–294
13. Markowska R., Szkiełkowska A., Ratyńska J., Skarżyński H.: Fizjoterapeutyczne metody leczenia dysfunkcji trąbek słuchowych u dorosłych – doniesienie wstępne. Otolaryngol. Pol. 2003, 57; 2: 277-281
14. Mielcarek-Kuchta D., Waśniewska E., Obrębowska-Karsznia Z., Łączkowska-Przybylska J., Szyfter W.: Leczenie niedosłuchów przewodzeniowych .Postępy w chirurgii głowy i szyi, 2006; 1: 36–45
15. Olszewski J., Repetowski M.: Fizykoterapia ucha . w Fizjoterapia w otolaryngologii – dla studentów fizjoterapii, pod red. Olszewskiego J., α-medica-press, Bielsko Biała, 2005: 88-92
16. Prieve B., H.: Identification of conductive hearing loss in infants using maximum likelihood analysis of wideband acoustic absorbance and admittance. J. Acoust. Soc. Am., 2014; 135: 2277
17. Robb P. J., Williamson I.: Otitis media with effusion in children: current management. Paediatrics and Child Health, 2012, 22; 1: 9-12
18. Saga C., Altuna X., Algaba J.:Aerosol therapy in treatment of childhood otitis media with effusion. Acta Otorrinolaringol Esp., 2009; 60: 217-26
19. Skarżyński H., Szwedowicz P., Miszka K., Zawadzki R., Mrówka M., Młotkowska-Kłimek P.: Przewlekłe wysiękowe zapalenie ucha środkowego - aktualna procedura postępowania , diagnostyczno-terapeutycznego. Audiofonologia , 2001, 20: 7-12
20. Niemczyk E., Dębska M., Zawadzka L.: Wysiękowe zapalenie ucha – problem nadal aktualny.Głos Nowa Pediatria, 2014; 1: 1-5

21. Szkiełkowska A., Markowska R.: Niewydolność trąbek słuchowych u dzieci z alergią. Alergoprofil, 2006, 2; 4: 35-38.

22. Szkiełkowska A., Miaśkiewicz B., Markowska R., Ratyńska J.: Zastosowanie mukolityków w postaci wibroaerozoli w leczeniu wysiękowego zapalenia uszu u dzieci. Audiofonologia 2005; 27: 97–100

23. Zielnik-Jurkiewicz B., Olszewska-Sosińska O.: Zastosowanie masażu wibracyjno-ciśnieniowego i wibroaerozoli w leczeniu chorób ucha środkowego u dzieci i młodzieży. Otolaryngol. Pol., 2005; 3: 399-402

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