Effects of salso-bromo-iodine thermal water in children suffering from otitis media with effusion: a randomized controlled pilot study

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Experimental study


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Introduction

Otitis media with effusion (OME) is an ear disorder characterized by the presence of fluid in the middle ear without signs or symptoms of acute infection (1) and it is among the most common conditions encountered in otorhinolaryngological and paediatric practice (2). OME affects 20% of 2-year olds at any one time (3), while 30-40% of children shows a significant recurrence of the episodes which may last more than one year in 5-10% of cases (4).

OME may occur spontaneously as consequence of Eustachian tube dysfunction, or for a number of conditions and syndromes which affect the shape of the mid third of the face and skull base (for example: Down’s syndrome and cleft palate), as a sequelae of AOM, secondary to obstructive nasal disorders, or subclinical bacterial infection or in association with gastroesophageal reflux disease (5-6). Fluid in the middle ear is associated most commonly with a conductive hearing loss balance problems, ear discomfort, poor school performance, behavioural problems, an increased risk of acute middle ear infection with recurrent acute otitis media (RAOM), or impaired quality of life (7).

So, the potential prevention of OME has raised a profound interest in the clinical practice, in fact, preventing OME might significantly affect the risk of complications, medical costs, and social and family impact. Management of OME is a combination of watchful waiting, medical therapy and surgical intervention. Various medical therapies have been proposed, but none is completely effective, and their benefits have not been precisely quantified (5).

The salso-bromo-iodine thermal waters are very well known and finds application in the treatment of several acute and chronic inflammatory respiratory diseases, chronic tonsillitis and pharyngitis, tonsil and adenoid hypertrophy, inflammation of the auditory tube and tubotympanum, purulent and catarrhal processes of the middle ear (8-9).

The aim of this pilot study was to assess the efficacy of a specific sulphurous thermal water (STW) by investigating its effects on otoscopic and audiological findings in children with OME and if it could induce ear healing better than isotonic saline treatment.

Material and methods

A prospective, single-blind, randomized, and controlled pilot study was planned at ENT Unit, Acireale Hospital, between October 2016 – April 2017. The study was approved by the Institutional Review Board Hospital and it was conducted in accordance with the ethical principles out-lined in the Declaration of Helsinki. Primary endpoint was the
resolution of ear fluid effusion, assessed by tympanometry, secondary endpoint was functional recovery of hearing loss. The criteria for inclusion were: (a) age 4-12 years; (b) documented diagnosis of OME (mono- or bilateral), based on clinical history and presence of type B tympanogram, since at least 3 months; (c) signing by both parents of an informed consent on the aim of the study and its procedure. Exclusion criteria were: (a) presence of syndromic diseases; (b) previous adeno-tonsillectomy; (c) presence of perceptive or mixed hypoacusia; (d) interfering medications.

Subjects who met inclusion criteria were randomly allocated into two therapeutic groups. Randomization sequence was created using Stata 9.0 (StataCorp, College Station, TX, USA) statistical software. The computer-generated random number list was prepared by an investigator with no clinical involvement in the study.

Children among control group received the administration of normal 0.9% sodium chloride saline solution, whereas, the study group, was treated with a salt-bromine-iodine watery solution containing hyaluronic acid and grapefruit seed extract (SBI-H-GSE), (Broncalt, Aurora Biofarma Srl, Milano). Both compounds were administered by a micronised nasal douche (Rhinowash, Air Liquide Medical Systems Italy S.p.A., Brescia, Italy) twice/day for 10 days a month for 3 consecutive months.

All the children were visited at baseline and at the end of the treatment. During every visit, complete ENT examination, tympanometry, and audiometry were performed.

Tympanogram was performed by MicroTymp2 (Welch Allyn, Skaneateles Falls, NY, USA), the type of tympanogram was considered an objective therapeutic outcome: a positive outcome was considered the shift from a type B to a type A (healing of the disease), or from a type B tympanogram to a type C tympanogram (improvement of the disease); a negative outcome was considered the persistence of the same type of tympanogram. Tonal audiometry was performed by Affinity 2.0 audiometer (Interacoustics, Middelfart, Denmark) in a silent cabin for frequencies ranging between 250 and 4000 Hz. Normal hearing was defined as perception of tones up to 25 dB.

Impaired hearing was classified as: mild hypoacusis (hearing loss between 25 and 39 dB), moderate hypoacusis (hearing loss between 40 and 69 dB), and severe hypoacusis (hearing loss between 70 and 89 dB).

Statistical analysis.

The results are given as absolute numbers and percentages for categorical variables or mean and standard deviation for quantitative variables. Tympanogram and audiometric outcomes were analysed using chi-square and Fisher exact tests where appropriate. The data were analysed using the STATA 13.0 software (StataCorp, College Station, Texas) and a p value < 0.05 was considered statistically significant.

Results

Eighty children (47 male, mean age 7.41 ± 2.38 years) who satisfied the inclusion and exclusion criteria have been included in the study. Patients, equally divided into 2 treatment groups, were similar in terms of sex, age, height, weight and OME laterality presence. The characteristics of the study participants are summarized in Table 1.

Tympanogram results are reported in Table 2. A better statistically significant trend, toward improvement (represented by type C tympanogram; p = 0.031) and healing (represented by type A tympanogram; p < 0.001) in favor of study group, have been reported at the end of the treatment. Conversely, the prevalence of patients with impaired tympanogram (type B) after treatment was significantly higher in the control group (13/40, 32.5% vs 7/40, 17.5%; p = 0.019).

Audiometric results showed a significant improvement after treatment in study group when compared to baseline values (p < 0.001) except for mild hypoacusis (p > 0.05). On the contrary, this improvement trend does not reach significance in the control group (p > 0.05) except for severe hypoacusis (p < 0.001). Moreover, when compared the results at the end of the treatment between the two groups, there was a statistically significant difference in favor of study group, with higher presence of patients with normal hearing (p = 0.029) and lower among patients with moderate hypoacusis (p = 0.014) (Tab.3).

Table 1. Demographic and clinical data.

<table>
<thead>
<tr>
<th></th>
<th>Study Group n = 40</th>
<th>Control Group n = 40</th>
<th>Overall n = 80</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>25 (62.5 %)</td>
<td>22 (55 %)</td>
<td>47 (58.8 %)</td>
<td>0.564</td>
</tr>
<tr>
<td>Age (years)</td>
<td>7.18 ± 2.77</td>
<td>7.63 ± 1.98</td>
<td>7.41 ± 2.38</td>
<td>0.621</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>111 ± 12.77</td>
<td>113 ± 12.23</td>
<td>112 ± 12.5</td>
<td>0.772</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>24.6 ± 5.77</td>
<td>25.2 ± 5.32</td>
<td>24.9 ± 5.55</td>
<td>0.754</td>
</tr>
<tr>
<td>Otitis ME laterality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral</td>
<td>22 (55 %)</td>
<td>21 (52.5 %)</td>
<td>43 (53.8 %)</td>
<td>0.743</td>
</tr>
<tr>
<td>Unilateral</td>
<td>18 (45 %)</td>
<td>19 (47.5 %)</td>
<td>37 (46.3 %)</td>
<td>0.806</td>
</tr>
</tbody>
</table>
Discussion

OME is a common problem facing general practitioners, pediatricians and otolaryngologists. Clinically, the child is assessed using otoscopy, tympanometry and audiometry. Management of OME is a combination of watchful waiting, medical therapy and surgical intervention. Various medical therapies have been usually prescribed, but with little or no benefit (10-14). A systematic review on the use of antihistamines and/or decongestants in the OME treatment did not provide evidence about their effectiveness (10). Also the efficacy of surgery is unclear: many trials and reviews attempted to define the role of ear, nose and throat surgery (e.g. tonsillectomy, adenoidectomy, myringotomy with/without placement of tympanostomy tubes) with poor results (15).

In this regard, preventive strategies such as salso-bromo-iodine thermal waters may represent a valid alternative approach, being very well known and appreciated their positive effects on acute and chronic inflammatory respiratory diseases (16). Our findings showed that SBI-H-GSE was able to induce healing in a high percentage of patients with OME and was significant superior than isotonic saline. SBI-H-GSE was effective on both tympanogram outcomes and hearing loss. This fact confirms salso-bromo-iodine water’s activity on mucous-secretory disorders, where it helps to improve the relationship between the mucous-protein complexes and the water: initially, this action is congestive, subsequently, it becomes an anti-catarrhal, anti-inflammatory, antiseptic and immunostimulant action (increase of total serum IgA and reduction of total serum IgE) (17). Moreover, the use of salso-bromo-iodine waters showed a significant improvement of Mucociliary Clearance Time (MCT) this function commonly prevents organic, inorganic, bacterial or viral particles from entering the organism (8). These effects may be enhanced by the presence, in our watery solution, both of hyaluronic acid, its usefulness is proven for better ciliar motility, cytological and microbiological outcomes (18) and grapefruit seed with its antimicrobial activity (19-20).

However, the present study has some limitations and the results should be interpreted in the context of its design. First, our study was designed to be performed at a single center with a small number of patients, and we acknowledge that this was an exploratory pilot study, and the formal sample size was not calculated because of the pilot nature of the study. Another limitation of the current study is the short-term follow-up.

A larger randomized controlled trial and longer follow-up periods are needed to further investigate the possible positive effects of salso-bromo-iodine water on patients with OME.

Table 2. Tympanogram evaluation

<table>
<thead>
<tr>
<th>Tympanogram type</th>
<th>Type A, n (%)</th>
<th>Type B, n (%)</th>
<th>Type C, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient groups</td>
<td>Study</td>
<td>Control</td>
<td>Study</td>
</tr>
<tr>
<td>Pre-treatment</td>
<td>0 (0 %)</td>
<td>0 (0 %)</td>
<td>40 (100 %)</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>24 (60 %)</td>
<td>10 (25 %)</td>
<td>7 (17.5 %)</td>
</tr>
<tr>
<td>p value (between groups post-treatment)</td>
<td>&lt; 0.001</td>
<td>0.019</td>
<td>0.031</td>
</tr>
</tbody>
</table>

Table 3. Audiometry evaluation

<table>
<thead>
<tr>
<th>Degrees of hearing loss</th>
<th>Normal hearing, n (%)</th>
<th>Mild hypoacusis, n (%)</th>
<th>Moderate hypoacusis, n (%)</th>
<th>Severe hypoacusis, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient groups</td>
<td>Study</td>
<td>Control</td>
<td>Study</td>
<td>Control</td>
</tr>
<tr>
<td>Pre-treatment</td>
<td>7 (17.5 %)</td>
<td>9 (22.5 %)</td>
<td>8 (20 %)</td>
<td>9 (22.5 %)</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>25 (62.5 %)</td>
<td>14 (35 %)</td>
<td>14 (35 %)</td>
<td>16 (40 %)</td>
</tr>
<tr>
<td>p value</td>
<td>&lt; 0.001</td>
<td>NS</td>
<td>NS</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>p value (between groups post-treatment)</td>
<td>0.029</td>
<td>NS</td>
<td>0.014</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = not significant (p > 0.05)
Conclusions

In conclusion, our findings indicate that salso-bromo-iodine water therapy may prove useful in facing children OME disease leading to a significant improvement of ear fluid effusion and functional recovery of hearing loss.

Author Contribution

All Authors equally contributed to this work

Competing financial interests statement

Authors declare no conflict of interest or financial support

References