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Original Scientific Paper

CHARACTERISTICS OF HEARING RECOVERY IN CHILDREN WITH CHRONIC OTITIS MEDIA WITH EFFUSION AFTER VENTILATION TUBE INSERTION

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SUMMARY – The objective was to determine the range of hearing improvement (in dB) post ventilation tube insertion in children with chronic otitis media with effusion (COME), and whether there was a difference in hearing improvement between age groups and genders. This study also investigated whether there was a difference in the mean hearing improvement between the left and right ear, how many months passed before recovery of eustachian tube function, and how long the aeration of the middle ear lasted. The children included in the study were between six and twelve years of age, diagnosed with COME by audiological processing (type B tympanometric recording and conductive hearing loss up to 40 dB on pure tone audiometry) and underwent surgical insertion of ventilation tubes in both ears. Patient data included preoperative tympanometric records, preoperative and postoperative tone audiometry findings, tubometry findings 6 and 10 months after insertion of ventilation tubes, age and gender data, and length of time during which the tubes were in place. The mean hearing improvement of the included patients was 24.2 dB on the right ear and 24.5 dB on the left ear. There was no statistically significant difference between the left and right ear or between the genders. Older age groups had a higher mean hearing improvement compared with the younger age group. Younger age groups had a longer expected period of eustachian tube function recovery, and were expected to have ventilation tubes inserted for a longer period of time. Treatment with ventilation tube insertion resulted in significant improvement in hearing in children where previous conservative therapy failed to recover eustachian tube function and improve hearing. Although children of older age groups had greater preoperative hearing impairment, the recovery of both eustachian tube function and hearing improvement was faster, and the mean length of time that the ventilation tubes had to be inserted was shorter.

Key words: *Conductive hearing loss; Hearing improvement; Otitis media; Tympanometry; Ventilation tube*

Introduction

Chronic otitis media with effusion (COME) is one of the most common causes of hearing impairment in preschool children. It is defined as the presence of fluid in the middle ear behind an intact tympanic membrane, without signs or symptoms of an acute inflammation[1,2]. The most common cause of otitis media with effusion (OME) is eustachian tube obstruction and increased secretory activity of the middle ear mucosa[3]. Treatment with ventilation tube insertion results in significant hearing improvement in children where previous conservative therapy failed to recover eustachian tube function and improve hearing[4,5].

This disease is of great importance due to the potential injurious complications if it remains untreated. Namely, as a consequence of OME in childhood, the resulting conductive hearing loss is associated with

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lower cognitive ability test scores, slowed speech and language development, behavioral changes, and poorer school performance[6]. In addition, there may be difficulties in motor development and balance disorders manifested by clumsiness and an increased propensity to accidents[7]. The age distribution of the disease is bimodal, with a peak incidence at two and five years of age. The prevalence at two years is approximately 20%, and at five years 16%[8]. In the tenth year of life, about 80% of children will have had one or more episodes of OME[9]. Most European studies have shown a prevalence of OME between 3% and 10% in children aged six to seven years[10]. Most episodes resolve spontaneously over a period of 3 months, but 30%-40% of children have recurrent OME[11]. Over 50% of cases occur after a case of acute otitis media. Therefore, children with OME typically have up to 5 times more episodes of acute inflammation than children who did not have OME[12].

The main concern with this disease is that hearing impairment can remain unnoticed, with the conductive hearing loss only accidentally detected on a systematic examination before going to school. This wastes valuable time that could have been otherwise utilized to treat the disease and prevent possible later complications[1,4].

Materials and Methods

This was a retrospective study that used and analyzed patient data from medical history and surgical protocol of the ENT Department, Split University Hospital Center, Split, Croatia. Included in this study were children between six and twelve years of age who were diagnosed with COME by audiological processing (type B tympanometric recording and conductive hearing loss up to 40 dB on pure tone audiometry). There were 62 children, of which 36 were boys and 26 were girls. After complete audiological treatment, each child underwent surgical bilateral ventilation tube insertion between May 2016 and September 2020 at the ENT Department, Split University Hospital Center. The following patient data were collected: preoperative tympanometric records, preoperative and postoperative pure tone audiometry findings, tubometry findings at 6 and 10 months after ventilation tube insertion, age and gender, and length of time the tubes were in place.

Inclusion criteria were children between the ages of six and twelve who were diagnosed with chronic secretory otitis by audiological processing (type B tympanometric recording and conductive hearing loss up to 40 dB on pure tone audiometry) and underwent surgery to insert ventilation tubes in both ears.

Exclusion criteria were children younger than six years due to poor cooperation in tonal audiometry, and children older than twelve years. Also excluded were children with previous head or ear trauma, Down syndrome, cleft palate, Kartagener syndrome, children with previous insertion of ventilation tubes, as well as children who had the tube placed in only one ear.

We examined the middle ear function with tympanometry. Type B curve is a characteristic recording for COME. Such a recording implies immobility or very little mobility of the tympanic membrane and the chain of auditory ossicles due to fluid filling the middle ear space[13].

We examined hearing thresholds, severity of damage, and type of hearing loss by pure tone audiometry. Conductive hearing loss up to 40 dB is typical for COME. Children under the age of six years could not perform pure tone audiometry due to poor cooperation and reduced concentration, and therefore could not be included in the study. This was a limiting factor of the research.

Ethics approval and consent to participate

All methods were carried out in accordance with the Declaration of Helsinki. Informed consent for surgical procedure was obtained from each participant's parents or their legal guardian(s). The study used data from surgical protocols of the ENT Department, Split University Hospital Center, which was approved by the institutional Ethics Committee, ethics code 2181-147-01/06/M.S.-20-02.

Statistical methods

Statistical analyses were performed using MedCalc for Windows, version 19.8 (MedCalc Software, Ostend, Belgium). The results obtained were expressed in graphical and tabular form. Statistical significance was set at $p<0.05$. Mean ± standard deviation, median, and interquartile ranges were used to describe numerical variables. The existence of statistical differences between the groups for categorical variables was tested using a standard Z-test. To analyze statistical difference between the two groups, a one-sample or independent two-sample t-test was used with the assumption that

the two groups did not have the same dispersion (to prove whether one group had a higher/equal expectation compared to the other, the dispersion assumption was set due to robustness), and general ANOVA test (to prove whether the groups had the same expectation).

Results

The study included a total of 62 children who, in the period from May 2016 to September 2020, underwent surgery for bilateral ventilation tube insertion at the ENT Department, Split University Hospital Center, Split, Croatia. The age range was 6-12 years. The mean age of the whole sample was 7.45±1.62 years, and median was 7 (Q1-Q3: 6-8; min-max: 6-12) years. The group included 36 (58%) boys and 26 (42%) girls. The mean age of boys in the sample was 7.44 years (±1.87) and median was 7 (Q1-Q3: 6-8; min-max: 6-12) years. The mean age of girls in the sample was 7.46±1.21 years and median was 7 (Q1-Q3: 7-8; min-max: 6-10) years. Girls and boys did not differ statistically in age (p=0.102).

The examined children were divided into 3 age groups (6-8 years, 9-10 years, 11-12 years). Table 1 shows distribution by gender and age. There were 49

Table 1. Age and gender distribution

Age group (years)	Total (N=62)	Boys (n=36)	Girls (n=26)	p*
6-8	49 (79%)	27 (55%)	22 (45%)	0.359
9-10	9 (15%)	5 (56%)	4 (44%)	0.472
11-12	4 (6%)	4 (100%)	0 (0%)	0.386

*Z-test

Table 2. Mean hearing improvement per ear

Mean hearing	Right ear	Left ear	p*
Hearing before surgery (dB)	35.1	35.7	0.566
Hearing after surgery (dB)	10.9	11.2	
Mean hearing improvement (dB)	24.2	24.5	

*Independent two-sample t-test

Table 3. Mean hearing improvement in boys

Mean hearing	Right ear	Left ear	p*
Hearing before surgery (dB)	34-9	35.9	0.914
Hearing after surgery (dB)	10.8	11.4	
Mean hearing improvement (dB)	24.1	24.5	

*Independent two-sample t-test

Table 4. Mean hearing improvement in girls

Mean hearing	Right ear	Left ear	p*
Hearing before surgery (dB)	35.3	35.4	0.871
Hearing after surgery (dB)	11.1	11.0	
Mean hearing improvement (dB)	24.2	24.4	

*Independent two-sample t-test

Table 5. Comparison of mean hearing improvement per ear among 6-8, 9-10 and 11-12 age groups

Age group (years)	Hearing before surgery R (dB)	Hearing after surgery R (dB)	p*	Hearing before surgery L (dB)	Hearing after surgery L (dB)	p*
6-8	34.3	10.7		34.6	11.0	
9-10	37.8	11.1	<0.001	39.4	11.4	<0.001
11-12	38.7	13.1	0.037	40.6	13.1	0.042

*One sample t-test done separately for each ear; R = right; L = left

Table 6. Comparison of mean hearing improvement per ear between 9-10 and 11-12 age groups

Age group (years)	Hearing before surgery R (dB)	Hearing after surgery R (dB)	p*	Hearing before surgery L (dB)	Hearing after surgery L (dB)	p*
9-10	37.8	11.1		39.4	11.4	
11-12	38.7	13.1	0.280	40.6	13.1	0.763

*Independent two-sample t-test done separately for each ear; R = right; L = left

(79%) children in the first age group (6-8 years), 9 (15%) children in the second age group (9-10 years), and 4 (6%) children in the third age group (11-12 years). There was no statistically significant difference in the number of girls and boys among the three age groups.

Table 1 shows that the first age group (6-8 years) had the highest probability of developing the disease with a frequency of 79%, followed by the 9-10 age group with a frequency of 15%, and 11-12 age group with a frequency of 6%.

The mean hearing improvement in the whole sample was 24.2 dB for the right ear and 24.5 dB for the left ear (Table 2). There was no statistical difference in hearing improvement between the left and right ear (p=0.566). According to the results shown in Tables 3 and 4, the mean hearing improvement in boys was 24.1 dB on the right ear and 24.5 dB on the left ear, while the mean hearing improvement in girls was 24.2 dB on the right ear and 24.4 dB on the left ear. There was no statistically significant difference in hearing improvement between genders or between the left and right ear (p_1=0.914; p_2=0.871).

There was a 95% statistically significant difference in hearing improvement between the 6-8 and 9-10 age groups (p_1<0.001; p_2<0.001). The 9-10 age group had a higher mean hearing improvement compared to the 6-8 age group. The 11-12 age group also had a higher mean hearing improvement compared to the 6-8 age group (p_1=0.037; p_2=0.042) (Table 5). There was no statistically significant difference in hearing improvement between the 9-10 and 11-12 age groups (p_1=0.280; p_2=0.763) (Table 6). According to the aforementioned test result, we can conclude that the difference in hearing improvement between the 6-8 and 11-12 age groups was similar to the difference recorded between the 6-8 and 9-10 age groups.

As illustrated in Table 7, which shows the mean numbers of months required for eustachian tube function recovery, the youngest age group (6-8 years) had a longer expected recovery period compared with the older age groups (9-10 and 11-12 years) (p<0.001). From these results, we can conclude that various age groups had different expected recovery times for eustachian tube function (p=0.002).

The results shown in Table 8 suggest a conclusion that the expected length of ventilation tube insertion was not equal in all age groups (p=0.001). The youngest age group (6-8 years) had a longer expected length of ventilation tube insertion compared with the older age groups (p<0.001) (Table 8).

Table 7. Mean number of months required for recovery of eustachian tube function

Age group (years)	Total (months)	Boys (months)	Girls (months)	p*	p†
6-8	8.7	9.4	7.8	0.002	<0.001
9-10	6.4	6.0	7.0		
11-12	7.0	7.0	NaN[a]		

Data are shown as mean values; *ANOVA test; †one-sample t-test; [a]not a number (the result of dividing zero by zero since no girls were included in the 11-12 age group)

Table 8. Mean length of ventilation tube insertion

Age group (years)	Total (months)	Boys (months)	Girls (months)	p*	p†
6-8	10.0	10.9	9.0	0.001	<0.001
9-10	7.2	6.8	7.8		
11-12	8.3	8.3	NaN[a]		

Data are shown as mean values; *ANOVA test; †one-sample t-test; [a]not a number (the result of dividing zero by zero since no girls were included in the 11-12 age group)

Discussion

Otitis media with effusion is a very common childhood disease which, if not diagnosed and treated on time, may lead to many adverse effects, including hearing impairment and delayed speech and language development. Conservative therapy remains the first line treatment, but if symptoms persist for more than 3 months, surgical treatment is recommended. Although a large number of studies have reported on different methods of treatment for this disease, the best results are achieved by inserting ventilation tubes[5].

It is a short and effective procedure performed under general anesthesia. First, a slight incision of tympanic membrane is performed, followed by proper placement of the ventilation tube. This procedure enables the pressure between the ear canal and the middle ear to equalize[14]. The ventilation tubes usually remain at the insertion site between 6 and 12 months, but in a large number of cases, they can fall out spontaneously, which means no re-operative removal is required[15].

The mean age of the children in the present study was 7.45 years. Children under 6 years of age were not included in the study due to the inability to cooperate in hearing testing by tone audiometry. The largest number of children included were in the first age group (6-8 years). Consequently, the youngest age group had the highest probability of developing the disease with a frequency of 79%, followed by the 9-10 age group with a frequency of 15%. The 11-12 age group had the lowest frequency of 6%. Similar results can be found in the studies that examined the prevalence of COME in the school population[16,17].

Our results showed that there was no statistically significant difference in the disease prevalence between boys and girls in all age groups. Similar results were obtained by Humaid *et al.*[18]. However, other studies found a higher incidence in boys compared to girls[19]. In the study by Sharma *et al.*, the incidence in boys was significantly higher (62%) compared to girls (38%), and the number of subjects was significantly higher in a total of 300 children examined[20]. Therefore, one cannot conclude with absolute certainty whether there is a statistically significant prevalence in either gender.

Concerning diagnostic methods, tympanometry and tonal audiometry should be performed. In OME, tympanometry typically results in a type B curve in 87% to 100% of cases. Such a curve type was found in all of the subjects in our study[1].

According to literature data, the mean hearing loss in pure tone audiometry caused by OME is between 25 dB and 50 dB[21]. The mean hearing loss in our study was 35.1 dB on the right ear and 35.7 dB on the left ear.

In our study, we analyzed the mean pre- and postoperative hearing loss on the two ears separately and found no statistically significant difference in the mean preoperative hearing loss between the left and right ear, or in the mean postoperative hearing loss between the left and right ear. We also analyzed the mean hearing improvement on the two ears separately and individually between boys and girls. According to the results, we could conclude that there was not statistically significant difference in the mean hearing improvement between the left and right ear, or in hearing improvement between boys and girls. The most important thing to point out in our study is that the mean hearing improvement in older age groups was significantly higher compared to younger age groups. This was because the mean hearing loss before surgical intervention was greater in older age groups than in the youngest age group. This disparity in hearing loss may be attributed to the fact that in older children, it may have been a longer time from the onset of the disease, which led to severe changes in the middle ear structures. Increased viscosity of the effusion and chronic eardrum changes are not uncommon at this stage[22].

The results of our study showed that different age groups did not have the same expected number of months for eustachian tube function recovery after ventilation tube insertion. Younger age groups had a longer expected period until the eustachian tube function was recovered (8.7 months), while the mean time of eustachian tube function recovery in all age groups was 7.4 months. Similar results were obtained in the studies by Bylander-Groth and Stenström and Klančnik *et al.*[23,24].

In all age groups, the mean length of ventilation tube insertion was 9 months. However, the youngest age group had a significantly longer expected period of tube in place (10 months) compared to older age groups. There was no statistically significant difference in the length of tube insertion between boys and girls (in all age groups). In addition, there was no significant difference in hearing improvement between the group of children who had ventilation tubes in place for 6-9 months *versus* the group who had ventilation tubes in place for 10-12 months. Similar results have been reported from the study conducted by Sanyaolu *et al.*[25].

When COME is treated with surgical ventilation tube placement, compared with the wait and see method, hearing recovery in children occurs within 1 to 3 months of the intervention. It is during this time that the tubes are inserted and functioning. In cases of recurrent acute otitis media, various studies show that ventilation tubes reduce the incidence of further episodes of otitis media. However, studies to date show that treatment with ventilation tubes does not lead to improvement in cognitive functions and behavior[1,4,26].

Candidates for ventilation tube insertion depend significantly on the severity of hearing loss, associated symptoms, developmental difficulties, and opportunities for spontaneous recovery. Children who have a tympanometric type B curve and chronic disorders lasting for more than 3 months have the lowest recovery rates.

Ultimately, the indication for treatment with ventilation tube insertion is strictly individual, and is made in agreement with the child's parents and their chosen pediatrician[1].

Our research showed great effectiveness of ventilation tubes in the treatment of COME in children because such treatment resulted in significant bilateral improvement of hearing in all age groups, led to recovery of eustachian tube function, and prevented further possible episodes of otitis media, thereby improving the quality of life in children suffering from this disease.

Given the high incidence and prevalence of this disease, screening and educational programs are highly valuable for detecting the disease, since its symptoms often remain unrecognized and untreated for a long time.

One of the limiting factors in this study was the fact that only children of a small age range were included, i.e., children aged 6-12 years. Younger children, who have the highest incidence of the disease, could not be included in the study due to their inability to cooperate in pure tone audiometry. Also, the retrospective nature of this study was a limiting factor itself. Another limiting factor was exclusion of a control group, which would be a group of children treated with another method, either surgically or conservatively. It was impossible to include a control group in this study because all the children included in the study had strict indications for ventilation tube placement due to organized contents in the middle ear. Other treatment methods are reserved for children in early stages of the disease or for children in whom surgical treatment is contraindicated.

Further research should focus on early detection of the disease, especially in children with poor speech and language development and learning difficulties.

Conclusions

Treatment with ventilation tubes leads to significant hearing improvement in children where previous conservative therapy failed to recover eustachian tube function and hearing. Children of younger age have a significantly higher risk of COME and significantly higher frequency of ventilation tube insertion.

Older children have a higher mean hearing improvement compared to younger age group. The reason may stem from the fact that older children have a greater preoperative hearing loss, which is possibly due to later diagnosis, longer duration of the disease, and more severe and chronic consequences. Younger children, however, have a longer expected period until eustachian tube function recovery compared to older children. This is due to the anatomic and immune age differences. Therefore, younger children have a longer expected ventilation tube retention time compared to older children.

In conclusion, although children of older age groups had greater hearing impairment preoperatively, eustachian tube function recovery and hearing improvement was faster, and the mean length of ventilation tube in place was shorter than in younger age group.

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Sažetak

ZNAČAJKE OPORAVKA SLUHA U DJECE S KRONIČNIM SEKRETORNIM OTITISOM NAKON POSTAVLJANJA AERIZACIJSKIH CJEVČICA

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Cilj istraživanja bio je utvrditi koliko se prosječno poboljšao sluh (u dB) nakon postavljanja aerizacijskih cjevčica u djece s potvrđenom dijagnozom kroničnog sekretornog otitisa (KSOM) te postoji li razlika u poboljšanju sluha u dB između dobnih skupina i spolova. Također je trebalo utvrditi postoji li razlika u prosječnom poboljšanju sluha između lijevog i desnog uha i koliko je mjeseci proteklo od uspostavljanja funkcije Eustahijeve cijevi, odnosno koliko je dugo trajala aerizacija srednjeg uha. Ispitanici su bila djeca između šeste i dvanaeste godine života kojima je audiološkom obradom (timpanometrijski zapis tip B i provodni gubitak sluha do 40 dB u tonalnom audiogramu) dijagnosticiran KSOM i koja su podvrgnuta operativnom zahvatu insercije aerizacijskih cjevčica na oba uha. Materijali istraživanja su prijeoperacijski timpanometrijski zapisi, prijeoperacijski i poslijeoperacijski nalazi tonske audiometrije, nalazi tubometrije 6 i 10 mjeseci nakon insercije aerizacijskih cjevčica te podatci o dobi, spolu djeteta i vremenskom razdoblju nošenja cjevčica. Prosječno poboljšanje sluha u cijelom uzorku iznosilo je 24,2 dB za desno uho i 24,5 dB za lijevo uho. Ne postoji statistički značajna razlika u poboljšanju sluha između lijevog i desnog uha niti između dječaka i djevojčica. Starije dobne skupine imaju veće prosječno poboljšanje sluha u odnosu na mlađu dobnu skupinu. Mlađe dobne skupine imaju duže očekivano razdoblje povratka funkcije Eustahijeve tube u uredno stanje i duže očekivano razdoblje nošenja aerizacijskih cjevčica. Liječenje aerizacijskim cjevčicama dovodi do značajnog poboljšanja sluha u djece ako prethodna konzervativna terapija nije rezultirala uspostavljanjem funkcije Eustahijeve tube i oporavkom sluha. Iako su djeca starijih dobnih skupina imala veće prijeoperacijsko oštećenje sluha, oporavak funkcije Eustahijeve tube kao i poboljšanje sluha bilo je brže, a razdoblje nošenja aerizacijskih cjevčica bilo je kraće.

Ključne riječi: *Provodni gubitak sluha; Poboljšanje sluha; Otitis media; Timpanometrija; Aerizacijska cjevčica*