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Importance of early ventilation tubes insertion in chronic otitis media with effusion in children with congenital cleft palate

Značaj rane insercije ventilacionih cevčica kod hroničnog sekretornog otitisa kod dece sa urođenim rascepom nepca

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Abstract

Background/Aim. Otitis media with effusion (OME) is almost universal in children with cleft palate with an incidence of more than 90%, but the approach to managing this problem varies significantly among authors. The Eustachian tube dysfunction is the main factor that leads to the presence of the middle ear effusion. This is especially prominent in children with congenital cleft palate and explains the prolonged course of this process. The objective of this study was to determine the effectiveness of early ventilation tubes insertion in children with cleft palate at the time of palatoplasty by monitoring the course and duration of the disease as well as development of complications. **Methods**. In the prospective study with predefined regular follow-up intervals and parameters, the two groups of children were observed. The group one (E) included 45 children with congenital cleft palate who underwent the early insertion of ventilation tubes during palatoplasty, and the group two (C) had the same number of children with cleft palate who were treated conservatively on an as-needed basis. Assessment parameters were findings of otomicroscopy, tympanometry, play and pure tone audiometry. Each child was followed-up for 5 full years at total of nine follow-up examinations. **Results**. Result analysis showed that there were no statistically important differences between the two study groups in terms of the course and duration of the presence of the middle ear effusion, or in terms of complications and speech development. **Conclusion**. Based on the results obtained, we can conclude that there is no significant benefit in early ventilation tubes insertion in children with cleft palate, therefore our recommendation is watchful waiting and a conservative treatment on an as-needed basis, with the ventilation tubes insertion when a surgeon, based on his or her experience and individual findings considers it necessary.

Key words:
otitis media with effusion; cleft palate; middle ear ventilation; conservative tretment; otologic surgical procedures; child; serbia.

Apstrakt

Uvod/Cilj. Otitis media sa efuzijom (OME) je gotovo univerzalna pojava kod dece sa rascepom nepca sa učestalošću većom od 90%, ali se pristup rešavanju ovog problema veoma razlikuje između autora. Disfunkcija Eustahijeve tube je glavni faktor za nastajanje sekreta u srednjem uvu, što je naročito izraženo kod dece sa urođenim rascepom nepca i objašnjava dugotrajnost ovog procesa. Cilj istraživanja bio je da se utvrdi efektivnost rane insercije ventilacionih cevčica kod dece sa rascepom nepca prilikom palatoplastike, posmatrajući tok i dugotrajnost oboljenja, kao i razvoj komplikacija. **Metode**. U prospektivnoj studiji sa unapred određenim pravilnim intervalima i obeležjima posmatranja praćene su dve grupe dece. U prvoj grupi (E) bilo je 45 dece sa urođenim rascepom nepca kojima je urađena rana insecija ventilacionih cevčica prilikom palatoplastike, a u drugoj (K) isti broj dece sa rascepom nepca koja su po potrebi lečena konzervativnim tretmanima. Obeležja posmatranja bila su nalazi otomikroskopije, timpanometrije i tonalne liminarne audiometrije. Svako dete pojedinačno je praćeno punih pet godina na ukupno devet kontrola. **Rezultati**. Analiza rezultata pokazala je da ne postoje statistički značajne razlike između dve posmatrane grupe u odnosu na tok i dugotrajnost prisustva sekreta u srednjem uvu, kao ni na razvoj komplikacija i govora. **Zaključak**. Na osnovu rezultata koje smo dobili možemo da zaključimo da ne postoji veliki benefit u ranoj inserciji ventilacionih cevčica kod dece sa rascepom nepca, te je naša preporuka redovno praćenje deteta i konzervativna terapija po potrebi, a insercija ventilacionih cevčica onda kada hirurg na osnovu svog iskustva i individualnog nalaza ispitanika to smatra neophodnim.

Ključne reči:
otitis medija, serozni; nepce, rascep; uvo, srednje, aeracija; lečenje, konzervativno; hirurgija, otološka, procedure; deca; srbija.

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Introduction

Otitis media with effusion (OME) is very common in children with congenital cleft palate. Cleft lip and palate belong to a group of common congenital malformations of the head with an incidence of around 1 in 700 individuals [1]. The connection between cleft palate and OME was first described more than a century ago [2, 3]. Paradise and Bluestone [4] first described that all children with cleft palate had effusion in the middle ear. Since then, numerous studies have been published showing that the incidence of OME in children with cleft palate is higher than 90% [5–9]. Muntz [10] reported that 96% of children with cleft palate needs tympanostomy tube placement, and around 50% of them required repeated tympanostomy tube placement. The Eustachian tube dysfunction, recurrent infections of the upper respiratory tract and allergies have all been stated as causes for OME in children with cleft palate [11, 12]. Most authors agree that the Eustachian tube dysfunction with relapsed or prolonged subclinical inflammation components is the main etiopathogenetic factor in the development of chronic OME [13–16] which is particularly prevalent in children with congenital cleft palate. The abnormal insertion or function of the tensor veli palatini muscle and/or levator veli palatini muscle can cause insufficient dilation of the Eustachian tube. Studies have shown that the functional integrity of the tensor and/or levator veli palatini muscles plays the main role in the Eustachian tube function, and consequently in the development of the disease in the middle ear as well [2, 17–28]. According to one group of authors, palatoplasty has been shown to be beneficial in reducing the incidence of middle ear diseases, improving hearing and the Eustachian tube function compared to the patients who did not undergo palatoplasty [21, 22, 28], but a definite and unified approach to managing this problem is still lacking.

The objective of this study was to determine the effectiveness of the early ventilation tubes insertion in children with cleft palate by monitoring the course and duration of the disease as well as the development of possible complications.

This was a prospective study with predefined follow-up intervals at 6 months for each patient as well as assessment parameters: otomicroscopic evaluation of the appearance of the tympanic membrane, tympanometric findings and audiometric findings (pure tone audiometry).

Methods

A prospective study was conducted in ten-year period from 2005 until the end of 2014 and included 90 children of both sexes diagnosed with congenital cleft palate, divided into 2 equal groups. In the experimental group (E) there were 45 children with congenital cleft palate who underwent the early routine ventilation tubes insertion during palatoplasty. We opted for Shepard ventilation tubes of 1.1 mm in diameter. All the interventions were performed under general endotracheal anesthesia and with the use of the surgical microscope (Leica F40), and the tubes were placed in the anteroinferior quadrant of the eardrum. The ventilation tubes were in function for 6–12 months on average, and only the children with minimum 6 months of tube functioning were included in the statistical analysis. In the control group (C), there were 45 children with congenital cleft palate who did not undergo the early routine ventilation tubes insertion, and during the follow-up period the usual conservative treatments with antibiotics, mucolytics, antihistamines and decongestants were administered, depending on their problems and individual needs.

The patients with congenital cleft palate in the groups E and C were reviewed at the age of 2 to 6 months, and then evaluated at the regular intervals of 6 months according to the above-mentioned assessment parameters. The minimum follow-up period per patient was 5 years.

Results

A total of 90 participants divided into two groups of 45 participants each were enrolled in our study. There were 52 (57.7%) male participants, and 38 (42.3%) female participants. The patients were initially reviewed at the time of their first visit to our institution for congenital cleft palate which on average corresponded to the age of 6 months, whereas the final assessment was done at the age 5 or 6.

Only the children with bilateral OME were enrolled in the study because of the more objective and easier data processing, even though in the process of participant selection we encountered rare cases of unilateral middle ear effusion. The children with cleft palate within the scope of malformations associated with the head and neck syndrome were also excluded. There were no significant differences between the experimental and control group in terms of their age at the beginning of the study, their sexes and bilaterality of the process.

Medical history data did not indicate any significant family load in terms of OME or congenital cleft palate. In 12 out of 90 (13.3%) participants, according to the data obtained, one of the parents or a close relative had hearing problems or problems with the middle ear infections, and 21 (23.3%) positive medical history data were in relation to congenital cleft palate in the family.

Otomicroscopy

One out of two parameters introduced at the beginning of the evaluation of the participants was that of otomicroscopy. Table 1 and Figure 1 show otomicroscopic findings that were obtained at different points throughout the entire length of the study, so that each of the participants had a total of 9 otomicroscopic evaluations. The evaluation at the age of 18 months was omitted because the experimental group had ventilation tubes in the eardrum. For the purposes of easier statistical analysis, the otomicroscopic findings were divided into 3 groups: NE – normal eardrum (normal findings), OE – opaque eardrum with indistinct landmarks, with light reflex shortened or smeared, and CE – complicated eardrum (eardrum with detectable complications in terms of atrophy, retractions, perforations or cholesteatoma pockets). According to the otomicroscopic findings there were no sig-

Table 1

Prevalence rate of the middle ear effusion (otomicroscopic findings)

Age (months)	Groups						Statistical Significance
	Experimental, n (%)			Control, n (%)			
	NE	OE	CE	NE	OE	CE	
6	2 (4)	43 (96)	0 (-)	3 (7)	42 (93)	0 (-)	$\chi^2 = 0.04$ $p = 0.9780$
12	3 (7)	42 (93)	0 (-)	3 (7)	42 (93)	0 (-)	$\chi^2 = 0.00$ $p = 1.0000$
24	2 (4)	42 (93)	1 (18)	5 (11)	39 (87)	1 (2)	χ^2=0.40 $p = 0.8187$
30	3 (7)	41 (91)	1 (22)	5 (11)	38 (84)	2 (4)	$\chi^2 = 0.18$ $p = 0.9149$
36	5 (11)	39 (87)	1 (18)	7 (16)	35 (78)	3 (7)	$\chi^2 = 0.18$ $p = 0.9148$
42	9 (20)	34 (76)	2 (4)	9 (20)	33 (73)	3 (7)	$\chi^2 = 0.18$ $p = 0.9149$
48	9 (20)	33 (73)	3 (7)	10 (22)	31 (69)	4 (9)	$\chi^2 = 0.04$ $p = 0.9780$
54	10 (22)	30 (67)	5 (11)	11 (24)	29 (64)	5 (11)	$\chi^2 = 0.04$ $p = 0.9780$
60	12 (27)	27 (60)	6 (13)	11 (24)	29 (64)	5 (11)	$\chi^2 = 0.04$ $p = 0.9780$

NE – normal eardrum; OE – opaque eardrum; CE – complicated eardrum.

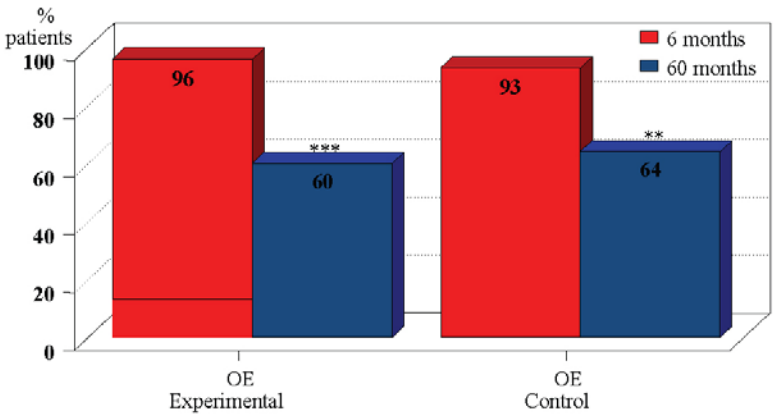

Fig. 1 – Otomicroscopic findings in opaque eardrum (OE) at the beginning and the end of the study.

nificant differences between the control and experimental group during the entire evaluation period. When the otomicroscopic findings of the control and experimental group were compared at the end of the study, a statistically significant difference ($p < 0.01$; 0.001) in OE findings was registered in comparison to the beginning of the study, and the identical trend was observed in both groups.

Tympanometric findings

In establishing the diagnosis of chronic OME the tympanometric findings are most important. Table 2 shows prevalence rate of the middle ear effusion. The testing at the age of 18 months was omitted because the experimental group had ventilation tubes, which rendered tympanometry impossible. A statistically significant difference between the two groups was observed at the evaluation at 24 months of age ($\chi^2 = 14.40$, $p = 0.007$), while at later evaluations this significance was slowly reduced. Figure 2 shows the tympanometric findings in participants of both the experimental and control group. At the final testing after 60 months of age, a statistically significant decrease in the percentage of the participants with tympanometric findings B was registered as well as a considerable increase in the percentage of the participants with the C findings, compared to the results at the beginning of the study in both groups.

Audiometry findings

Pure tone audiometry was done at 48 months of age when adequate cooperation of the participants was possible, and the testing was repeated at the age of 54 and 60 months (Table 3). Hearing levels, as in play audiometry, were divided into 4 groups with the average hearing thresholds ranging from 20 to 50 dB, showing that there were no significant statistical deviations between the experimental and control groups.

As the average age of our study participants at the first exam was about 6 months when otoscopic findings could be unclear even in children without OME, it is not surprising

Table 2

Prevalence rate of the middle ear effusion (tympanometric findings)

Age (months)	Groups				Statistical Significance
	Experimental (n = 45)		Control (n = 45)		
	n	%	n	%	
6	42	93.3	41	91.1	$\chi^2 = 0.04$ $p = 0.9780$
12	41	91.1	43	95.6	$\chi^2 = 0.18$ $p = 0.9149$
24	20	44.4	38	84.4	$\chi^2 = 14.40$ $p = 0.0007$
30	30	66.7	32	71.1	$\chi^2 = 0.18$ $p = 0.9149$
36	28	62.2	29	64.4	$\chi^2 = 0.04$ $p = 0.9780$
42	29	64.4	27	60.0	$\chi^2 = 0.18$ $p = 0.9149$
48	25	55.5	28	62.2	$\chi^2 = 0.40$ $p = 0.8187$
54	26	57.8	29	64.4	$\chi^2 = 0.40$ $p = 0.8157$
60	24	53.3	26	57.8	$\chi^2 = 0.18$ $p = 0.9149$

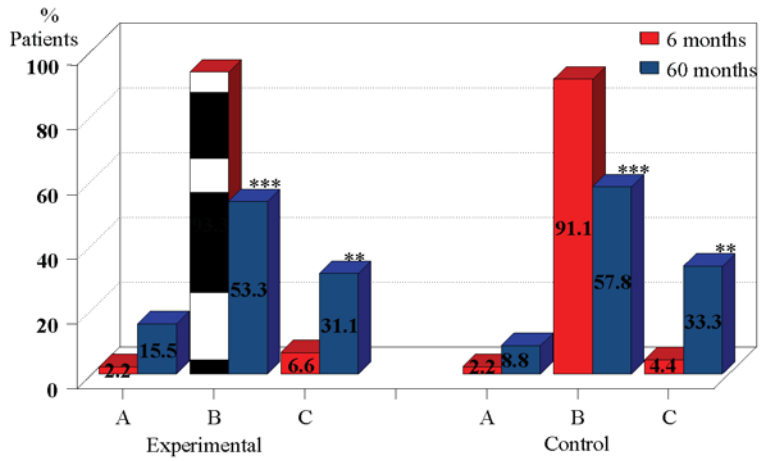

Fig. 2 – Prevalence rate of the middle ear effusion (tympanometric findings)
****, *** $p < 0.01$; 0.001 at the beginning and the end of the study.**

Table 3

Hearing threshold levels (Pure tone audiometry)

Age (months)	Groups								Statistical Significance
	Experimental, n (%)				Control, n (%)				
	20 dB	30 dB	40 dB	50 dB	20 dB	30 dB	40 dB	50 dB	
48	17 (38)	19 (42)	5 (11)	4 (9)	16 (31)	20 (44)	4 (9)	5 (11)	$\chi^2 = 0.04$ $p = 0.9780$
54	16 (36)	18 (40)	6 (13)	5 (11)	15 (29)	20 (44)	5 (11)	5 (11)	$\chi^2 = 0.04$ $p = 0.9780$
60	16 (36)	17 (38)	7 (16)	5 (11)	14 (29)	21 (47)	5 (11)	5 (11)	$\chi^2 = 0.18$ $p = 0.9149$

that in only 5 (5.6%) participants otoscopic findings were normal (NE), and in 85 (94.4%) the eardrum was opaque and with indistinct landmarks (OE). At the beginning of the study, the eardrum complications (CE) were not observed. Normal otomicroscopic findings (NE), which were very rare in both groups at the beginning of the study, were encountered more often over the course of time, so that at 36 months of age there were 5 (11%) in the experimental group, and 7 (16%) in the control group. On the other hand, the opaque eardrum with indistinct landmarks findings (OE), which

were, at the beginning of the study, in a very high percentage, came to 33 (73%) in the experimental and 3 (69%) in the control group at 48 months of age. Otomicroscopic findings with the eardrum complications, which did not exist at the beginning, started to show at the testing at 24 months of age in one case each in both groups (2.2%). Later on, this percentage slowly increased, without significant deviations between the experimental and control groups (Table 2). Normal otomicroscopic findings were considerably higher at the final exam at 60 months of age in both groups compared to the beginning of the study, so that there were 12 (27%) in the experimental group, and 11 (24%) in the control group, while the majority of both group participants, 27 (60%) in the group E, and 29 (64%) in the group C, were in the category of the opaque eardrum findings OE. Otomicroscopic findings indicating complications (CE) were detected in a small number of participants, 6 (13%) in the group E and 5 (11%) in the group C. The reason behind this is that smaller changes in the eardrum like atrophy or tympanosclerotic plaques were included in the opaque eardrum findings (OE).

At the beginning of the study, a total of 83 (92.2%) participants had tympanometric curve (type B), while 5 (5.5%) participants showed negative pressure values (type C), and only 2 (2.2%) participants had normal findings.

The findings in the control and experimental group were very similar. There were 42 (93.3%) participants in the experimental group and 41 (91.1%) participants in the control group with the tympanometric findings B (Figure 3). Significantly large number of the flat tympanometric curve findings (type B) at the beginning of the study in both groups (44.4%) participants which is a statistically significant difference in relation to the control group with 38 (84.4%) participants with the same findings. Such statistically significant difference appears only at this one evaluation, directly following the removal of the ventilation tubes in the participants of the experimental group. Already at the subsequent testing at 30 months of age the number of tympanograms B in the experimental group increased to 30 (66.7%) at the expense of the tympanogram C, which dropped to 7 (15.5%). In the control group, the number of participants with the tympanogram B dropped to 32 (71%), while the number of participants with the tympanogram C increased to 11 (24.4%). The number of normal tympa-nograms (A) was unchanged in both groups. The following period was characterized by a statistically significant symmetrical and gradual decrease in the number of participants with tympanograms B in both groups, and by an increase in the number of participants with tympanograms A and C, without statistically significant differences between the experimental and control groups, and this trend was continued until the end of the study.

After the completion of the study, a statistically significant decrease was seen in the percentage of the participants with the tympanometric findings B in both groups along with a statistically significant increase in the percentage of the participants with the tympanometric findings C, but there were no statistically significant differences between the experimental and control group.

Audiological assessment, which began with play audiometry at 36 months of age of the participants, was completed at 60 months of age, at the age when the findings

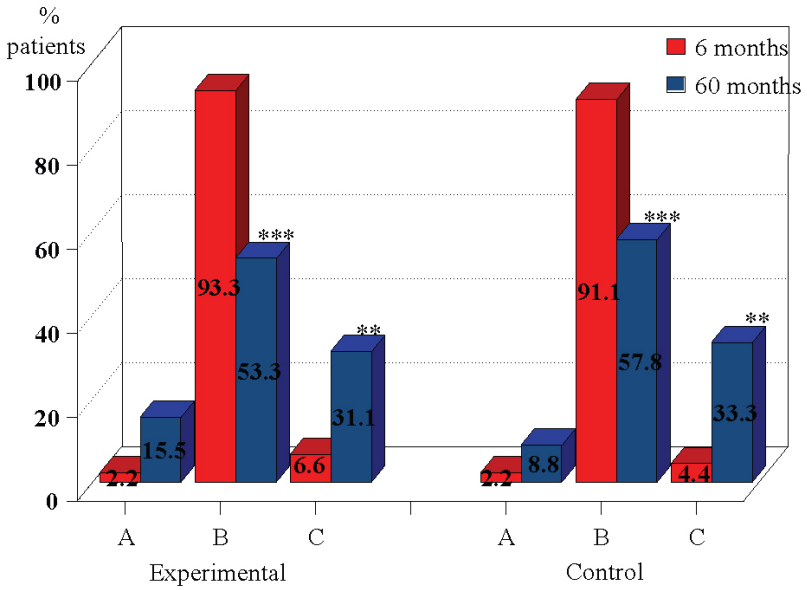

Fig. 3 – Tympanometric findings at the beginning and the end of the study.

decreased considerably over time. This decrease was particularly noticeable in the experimental group at 24 months of age evaluation performed after ventilation tubes removal, when tympanogram B was found in only 20 of pure tone audiometry can be interpreted as accurate. According to the final audiological findings there was no significant statistical difference between the experimental and control group, and the majority of participants in both groups

were within the normal field of hearing of 20 and 30 dB. (Table 3).

Discussion

Regarding chronic OME in children with congenital cleft palate, differences among authors are even more pronounced. The one thing all authors agree on is that OME in children with congenital cleft palate is almost universal and, depending on the author, the incidence varies between 85% and 97% [5–9]. This corresponds to the 92.2% of the tympanometric findings B in 90 participants of the 2 groups in our study. In addition, it is a common opinion that management of this disease is much more difficult in children with congenital cleft palate than in children without cleft. However, as there is no doctrinal approach to this disease, numerous differences in opinion on its treatment, depending on the age of patients, stage of the disease and clinical-audiological findings, still exist.

According to current trends, palatoplasty should be performed between 6 and 12 months of age [21, 22, 29], depending on the type of cleft, and early ventilation tubes insertion means their placement before or during palatoplasty.

Although objective parameters (tympanometry) undeniably demonstrate that the presence of effusion in the middle ear in children with cleft palate is pretty much universal, approach to management of this problem among the authors worldwide is often inconsistent. A group of authors consider that it is necessary to perform early routine placement of ventilation tubes in all cases of congenital cleft palate [30, 31]. Many authors favor the early placement of ventilation tubes in children with cleft palate as a way to prevent hearing loss and ensure speech development [32–34]. It is, also, stated that early ventilation tubes insertion in children with cleft palate is beneficial in short-term hearing loss prevention and long-term speech improvement [35]. Another group of authors emphasize a conservative treatment while a third group advocate for early unilateral insertion of the ventilation tube [30–36].

The arguments of the authors who recommend early routine insertion of the ventilation tubes are prevention of complications of chronic OME and enabling correct speech development and mastoid pneumatization. The advocates of the conservative treatment believe that the insertion of ventilation tubes, and especially potential reinsertions due to recurrence of the disease may result in a considerable damage to the eardrum as well as other problems, and that the complications of OME may develop independently of early ventilation tubes insertion since they are more related to the pathoanatomic substrate of cleft palate.

Conclusion

We can be fairly certain that children with congenital cleft palate will also present OME at birth and therefore instead of waiting for the onset of symptoms, the inclusion of otorhinolaryngologist care from birth is necessary.

A detailed analysis of the results of this multiyear study in which each child was observed for 5 full years at 6 month-time intervals, reveals that there were no statistically significant differences in the duration of the disease or in the development of complications between the two observed groups. Directly following the removal of the ventilation tubes, the experimental group demonstrated a temporary statistically significant improvement in the tympanometric findings, but the effusion was present again in the middle ear so the findings equalized with the control group. However, after several years, both groups showed a significant decrease in the presence of effusion in the middle ear as a result of the soft palate musculature strengthening and improved function of the Eustachian tube. Each child was also monitored by a speech pathologist and no significant differences in the speech development among the subjects were observed.

Based on all the tests that we performed, our conclusion as well as our recommendation is that early routine ventilation tubes insertion in children with cleft palate is not needed. However, it is absolutely necessary for those children to be closely monitored since their birth by an otorhinolaryngologist who will, based on his/her expertise and experience, reach a decision on optimal timing for the potential placement of the ventilation tubes in each particular case.

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