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Early postoperative complications in children with secretory otitis media after tympanostomy tube insertion in the Military Medical Academy during 2000–2009

Rane postoperativne komplikacije insercije aeracionih cevčica kod dece sa sekretornom otitis medijom u Vojnomedicinskoj akademiji u periodu 2000–2009.

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Abstract

Background/Aim. Secretory otitis media (SOM) is a chronic, nonpurulent inflammation of the middle ear, characterized by a long-term presence of liquids of different density in the middle ear for at least three consecutive months, different degrees of hearing loss and the absence of perforation of the eardrum. The aim of this study was to estimate the early postoperative complications after insertion of tympanostomy tube (TT) in children with secretory otitis media (SOM) in an 18-month period after TT insertion. **Methods.** This retrospective study included children with SOM (n = 478), aged from 2.5 to 16 years, operated from 2000 to 2009. During these ten years 365 children had TT in both ears, 131 children had TT in one ear and 55 children were operated two or more times. Totally 843 ears were operated on. Date were obtained by regular fallow up in Out-patient clinic concerning symptoms reported by children and parents, otomicroscopy findings and hearing measurements (audiometry and tympanometry). **Results.** Transient otorrhea was the most common early postoperative complication (16.5%), then obstruction (9.5%), premature extrusion of TT (3.9%), chronic otorrhea (3.1%), granulation tissue (1.1%) and medial displacement (0.5%). According to our experience gold and silicone TT were shown less successful than others. The incidence of premature extrusion of TT was significantly higher with gold TT, comparing to others (6/33, 18%; $p < 0.001$). We also found significantly more frequent medial displacement with silicone TT than with other ones (2/4, 50%; $p < 0.001$). **Conclusion.** There are many early postoperative complications of TT insertion, but they depend on the meticulous surgery techniques, regular postoperative examinations and the type of TT. The type of TT should be determined according to own experience.

Key words:
otitis media with effusion; otoscopy; middle air ventilation; postoperative complications.

Apstrakt

Uvod/Cilj. *Otitis media secretoria* (OMS) je hronični, negnojni zapaljenski proces srednjeg uva koji se karakteriše dugotrajnim prisustvom tečnosti u srednjem uvu, različite gustine, najmanje tri meseca u kontinuitetu, nagluvošću različitog stepena i odsustvom perforacije bubne opne. Cilj ovog rada bio je analiza postoperativnih komplikacija tokom 18-mesečnog praćenja bolesnika dečjeg uzrasta, lečenih od OMS implantacijom aeracionih cevčica (AC). **Metode.** Retrospektivnom studijom bilo je obuhvaćeno 487 bolesnika sa OMS, uzrasta 2,5–16 godina, operisanih u desetogodišnjem periodu (2000–2009) od kojih je 356 bilo sa obostranom i 131 sa jednostranom implantacijom AC, a njih 55 sa ponavljanom operacijom dva i više puta. Ukupno je implantirano 843 AC. Ambulantno praćenje operisanih bolesnika tokom 18 meseci bilo je bazirano na simptomima, autoanamnestičkim i heteroanemnestičkim podacima, otomikroskopskom pregledu, kao i merenju sluha audiometrijom i timpanometrijom. **Rezultati**. Tranzitorna otoreja bila je najčešća rana postoperativna komplikacija (16,5%), zatim zapušenost AC (9,5%), prevremeno ispadanje AC (3,9%), hronična otoreja (3,1%), granulacije (1,1%) i upadanje AC u bubnu duplju (0,5%). Prema našem iskustvu, silikonske i zlatne AC su manje uspešne za upotrebu. Postoji statistički značajna razlika između upadanja u bubnu duplju silikonskih AC u poređenju sa drugim tipovima (2/4, 50%; $p < 0,001$), kao i statistički značajna razlika zastupljenosti u ove komplikacije između zlatnih AC u poređenju sa drugim tipovima AC (6/33,18%; $p < 0,001$) **Zaključak.** Rane postoperativne komplikacije implantacije AC mnogobrojne su i mogu se svesti na razumnu meru minucioznom hirurškom tehnikom i izborom tipa AC prema sopstvenom iskustvu, kao i redovnim praćenjem stanja operisane dece.

Ključne reči:
otitis medija, serozni; otoskopija; uvo, srednje, aeracija; postoperativne komplikacije.

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Introduction

Secretory otitis media (SOM) is a chronic, nonpurulent inflammation of the middle ear, characterized by a long-term presence of liquids of different density in the middle ear for at least three consecutive months, different degrees of hearing loss and the absence of perforation of the eardrum. It occcurs in preschool and school children, mostly bilaterally, with a morbidity rate proportional to the latitude (follows moisture and cold). The average incidence of SOM is 2.5% in Serbia, in Finland 10%, and the average incidence in Europe is 6%. There are transudation (Politzer) and exudates (Tosh) theory of SOM origin. Reasons are numerous: allergies and immune factors, dysfunction of the Eustachian tube and many predisposing factors. Histopathological findings of SOM pass through three stages: initial, secretory and degenerative. Its clinical picture includes: impaired hearing, itching in the ears, autophony, nasal speech and slow speech development. Hearing loss is the main symptom, but many children get used to it, so if parents or teachers do not detect hearing loss on time, there is a potential risk for changes in the middle ear to become irreversible and cause permanent hearing loss. Diagnostic procedures include children's and parents' reports, microscopic examination of the ear, a complete ear, nose and throat (ENT) examination, tympanometry and hearing test. Therapy is conservative and surgical. Conservative therapy lasts up to 6 months after the onset according to Anglo-Saxon literature. If there is the presence of SOM on three consecutive examinations during a 6-month period, conservative therapy is unsuccessful. Surgical therapy is the next step.

Implantation of tympanostomy tubes (TT) is a surgical method of SOM treating. Eli and Riolanus treated hearing loss of children due to the appearance of mucus behind the Eustachian tube with paracentesis in the seventeenth century. Martill Frank was the first designer of TT from gold foil in 1845. Politzer recommended paracentesis with a blow tube in the mid-nineteenth century and gave up of implantation of TT because of numerous complications. Bourgeois introduced aspiration of secretions through the paracentesis and Armstrong redesigned and reactivated TT in 1954 [1]. After that TT implantation became a sovereign surgical procedure in the treatment of SOM. For example, in 1996 in the U.S. 500,000 children were operated with implantation of TT due to SOM, and even a million children per year in the last three years. Operation involves setting up a TT in the eardrum through a hole in the eardrum (paracentesis, myringotomy), thus making a communication between the middle ear and external ear to prevent accumulation of secretions in the middle ear and enabling aeration of the middle ear during a prolonged period of time. Effect on hearing is immediate, after aspiration of secretions from the middle ear and TT insertion [2, 3]. The result is sometimes accompanied by difficulties and complications which follow this operation. Armstrong and Charlotte said at the beginning of the TT era: "An ideal TT should not clog up or drop out prematurely, should be inserted and removed easily and should have a low rate of complications" [4].

The aim of our study was to analyze postoperative complications during 18 months after TT implantation in preschool and school children with SOM in a 10-year period.

Methods

We analyzed charts of 487 patients aged 2.5 to 16 years, treated in ENT Clinic of the Military Medical Academy in (MMA) Belgrade from 2000–2009 who had been TT implanted one or more times and followed postoperatively for 18 months. Indications for surgery were made after a 6-month period of conservative treatment (at least three findings), and included children's and parents' reports, otomicroscopy, a complete ENT examination, tympanometry and hearing test – pure tone audiometry for 5-year old or older children. Tympanometric findings were type B, or rigidity and hearing tests showed conductive hearing loss.

Surgery was performed under general anesthesia, mostly along with adenoidectomy or tonsilo adenoidectomy. Myringotomy was performed in classical front – lower section quadrant of the tympanic membrane. The length of myringotomy was between the internal and the external diameter of TT, on average 2–2.8 mm (Figure 1).

In a case of repeated TT implantation, we performed myringotomy in posterior – inferior quadrant of the tympanic membrane in order to avoid focal atrophy of the tympanic membrane. We used aspiration tubes with diameter 1.4, 1.8

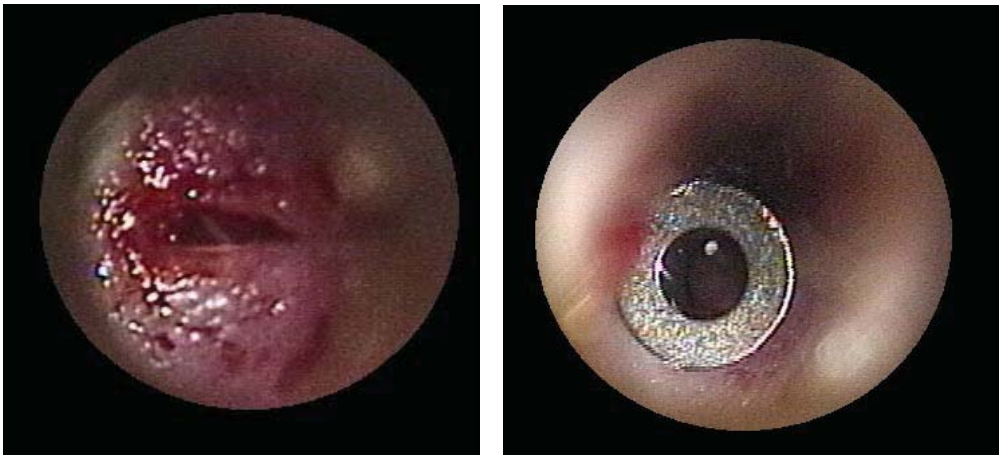

Fig. 1 – Surgical technique of myringotomy and tympanostomy tube implantation

and 2.2 mm for thorough and detail suction of secretions from the tympanic cavity. We placed a TT bilaterally in 356 children, in 131 children unilaterally (843 TT totally); 55 children were operated two or more times. We used TT made from various manufacturers, various materials and various designs and sizes. Technical characteristics of TT are given in Table 1.

Table 1

Technical characteristics of tympanostomy tubes (TT)

TT type	Inner diameter (mm)	External diameter (mm)	Length (mm)	Weight (mg)
Shepard fluoroplastic	1.14	2.4	2.4	10.3
Shepard teflon	1.14	2.4	2.4	15.4
Donaldson silicone	1.5	2.3	3.2	11.4
Kurtz titanium	1.25	2.55	1.6	10.6
Tuebingen gold	1.5	2.8	1.6	27.5

The first control examination was taken two weeks after surgery, and continued once monthly if the postoperative period was regular. Examinations were based on the otomicroscopy findings, hearing test and/or timpanometry. Findings were analyzed 18 months after surgery. Wearing TT for a period of 6–18 months was considered sufficient for the restitution and recovery of a sick middle ear from SOM. If TT did not spontaneously drop out in time, we pulled it out in outpatient clinic or in condition of one-day surgery under short-term inhalation anesthesia, rarely under general anesthesia.

Results

Early postoperative complications, such as bleeding from the ear, eardrum hematoma or hematoma of the skin of external auditory canal, were rare with spontaneous recovery in the next few days and they were not valuable for statistic analysis. We had no cases of intraoperative ossicular chain disruption or extended inflammatory disease such as labyrinthitis or endocranial complications. We had no complications of general anesthesia. Postoperative complications that appeared during 18 months after TT insertion, are given in Table 2.

Table 2

Postoperative complications 18 months after insertion of tympanostomy tubes (TT)

Complications after TT insertion	Operated ears [n(%)]
Transient otorrhea	139 (16.5)
Chronic otorrhea	26 (3.1)
Granulation tissue	8 (1.1)
Premature extrusion	33 (3.9)
Obstruction	80 (9.5)
Medial displacement	4 (0.5)

Functional and permanent structural sequelaes after TT extraction, such as tympanosclerosis, perforation, focal atrophy of the tympanic membrane, retraction pocket, cholesteatoma, were not included.

Transient otorrhea means occasional middle ear secretion leaking through TT up to 3 months after surgical procedure. It was the most frequent postoperative complication and occurred in 16.5%. This percentage fits the statistics of other authors and no statistical significance in relation to TT type was found ($\chi 2$ test = 1.357 for df = 4, $p = 0.852$). Secretions drainage through TT in the first week after insertion was not considered as a transient otorrhea and not treated with medications because it was considered as a result of incomplete intraoperative aspiration from tympanic cavity. Each subsequent episode of otorrhea was treated conservatively, as well as the exacerbation of recurrent acute otitis media. Occurrence of otorrhea more than 3 months after TT insertion was considered a chronic otorrhea. Chronic otorrhea was observed mostly equally in all groups, regardless of the used TT type (χ^2 test = 1.491 for df = 4, $p = 0.878$) with overall incidence 3.1% in 487 children. Frequency of granulation tissue formation (1.1%) was as in the literature (up to 5%). We solved it conservatively (with trichloracetic acid 20%), except in two cases where TT reinsertion was necessary with surgical removal of granulation tissue. There was no statistically significant differences in the formation of granulation tissue according to the TT type (χ^2 test = 0.265 for df = 4, $p = 0.992$).

Premature TT extrusion (3.9%) implies a TT dropped out earlier than 6 months after insertion, and it happened only in the group of children with transient otorrhea. According to the type of implanted TT, premature TT extrusion was the most frequent in the group of children with gold TT: 6 out of 24 gold TT dropped out before 6 months, with the incidence of 25%, and 6 out of 33 (18%) of all the premature TT extrusion. There was a statistically significant difference regarding gold TT comparad to other ones in the frequency of premature extrusion (χ^2 test = 30.311 for df = 4, $p = 0.000$). Figure 2 shows that a gold TT had the highest incidence of premature extrusion.

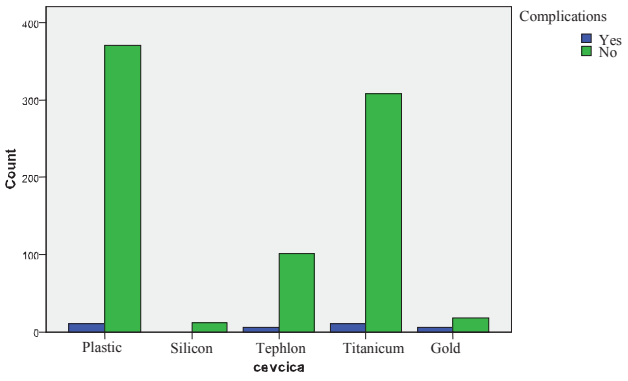

Fig. 2 – Premature extrusion of different tympanostomy tube types

TT obstruction with dried secretions occurred in 9.5% of the children which was similar to the global statistics (7% to 10.5%). There were no statistically significant differences among different types of TT regarding this complication (χ^2 test = 0.732 for df = 4, p = 0.947). Some cases were successfully treated with local seven-day therapy (3% hydrogen peroxide ear drops). Persistent TT obstruction was not an indication for reimplantation except cases with persistent conductive hearing loss during three months. Medial displacement of TT to the tympanic cavity occurred only in 4 cases. Two of them were with silicon TT, which represented 50% of the total number of TT medial displacement. There was a statistically significant difference between silicone TT and other TT types in medial displacement (χ^2 test = 66.766, df = 4 for p = 0.000). Silicone TT is soft and not at all easy to set up. Although we did not have not a case of premature extrusion of silicone TT, we gave up using silicone TT because of medial displacement (Table 3). We had the similar experiences with the implantation of "T" type of TT, which brought more postoperative complications and more difficulties in surgical work. "T" type of TT was used in cases with persistent SOM through many years. Persistent SOM was solved by repeated insertion of TT with a larger inner diameter of the TT (1.5 mm).

significant difference in premature extrusion of gold TT, comparing to other types. That is the reason for stop using gold TT in 2002 in MMA. The idea of making gold TT was good biocompatibility and antimicrobial activity of gold. The reason for the failure was the mass of gold TT, which is considerably larger than all the other TT types (Tuebingen gold TT weight = 27.5 mg which is almost three times higher than Shepard fluroplastic TT = 10.3 mg). The load of eardrum is therefore larger and the premature extrusion is more common. Premature extrusion was not an indication for TT reimplantation, but the repetition of the diagnostic protocol should be necessary.

Reinsertion of TT was necessary in case of granulation tissue with implanted fluoroplastic TT (one case), and the second was with titanium TT. Although there are many articles on granulation tissue frequently associated with titanium TT [5], we had no such experiences.

The presence of TT on the eardrum makes a new microenvironment in the middle ear. Foreign body reaction can result in one or more postoperative complications after TT insertion. Postoperative complications are connected, intensifying each other and in close connection with new microenvironment. There is definitely host reaction to all three layers of the eardrum in the presence of inserted TT and it depends on the material of TT. There is also a direct impact of air on all

Table 3

Postoperative complications according to tympanostomy tubes (TT) type

TT type	n	Transient otorrhea	Chronic otorrhea	Granulation tissue	Premature extrusion	Obstruction	Medial displacement
Plastic and fluoroplastic	382	66	12	4	11	36	1
Titanium	319	52	10	3	11	32	1
Teflon	106	17	3	1	5	10	0
Silicone	12	1	0	0	0	1	2
Gold	24	3	1	0	6	1	0
Total	843	139	26	8	33	80	4

n – number of TT implantation or number of operated ears

Discussion

Transient otorrhea after TT implantation is the most common postoperative complication in an 18-month follow-up after TT insertion. The nature of SOM is represented with chronic production and accumulation of secretion in a child's middle ear cavity and transient otorrhea is expected as a desirable appearance, because of TT drainage function. Successful conservative treatment of transient otorrhea, without any endocranial and exocranial complications, makes it a mild postoperative complication, like a minor or cosmetic complication according to the some authors [3]. However, transient otorrhea can be an introduction into further complications such as premature TT extrusion, obstruction of TT or chronic otorrhea. Besides that, one of the reasons for premature extrusion of TT is iatrogenic, such as too big myringotomy, which can be avoid by careful otomicroscopy work. The third reason is an inadequate reaction on foreign body in the ear drum. In our study, all the counted TT were extrusioned immediately after operation. There is no ideal material for making TT compatible with each patient. However, in our study there was a difference in the selection of TT type. There was a statistically

the threatening microbes to the tympanic cavity and the long lasting wound surface of myringotomy. The residual non infectious secretions in the middle ear can become contagious, even after a detailed aspiration during TT implantation. A biofilm is created on the contact surface of TT and eardrum. It is composed of dried secretion and microbes and sometimes it is infected with persistent strains of bacteria, such as *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Infectious biofilm or, occasionally, the presence of infectious discharge from the middle ear can cause even more secretion of mucus from hypertrophic glands in the middle ear, and lead to chronic otorrhea. Chronic otorrhea can be resistant to conventional antibiotics and discourages physicians. Attempts have been made using various antibiotics topically and orally before insertion, during or immediately after surgery, but without statistically significant reduction percentage of complications prevalence [6]. This has led to a series of investigations based on examination of bacterial biofilms, which often accompanies TT as a key reason for transient and chronic otorrhea [6]. Various substances put on a TT before insertion were examined in order to prevent the appearance of bacterial biofilms. A fluoroplastic TT coated with phosphorylcholine showed resistance to *S. aureus* and *P.*

aeruginosa [7], and silicone-coated TT with piperacillin-tazobactam showed resistance to ciprofloxacin- resistant strain of *P. aeruginosa in vitro* [8], and ion bombing silicon TT in guinea pigs showed resistance to *S. aureus in vivo* [9]. On the other hand, hearing improvement after TT implantation and consequently increase in quality of child's life [10, 11], justify this surgical procedure along with all the associated postoperative complications.

Conclusion

Early postoperative complications after TT insertion are numerous and may affect children's recovery from SOM. Regular and detailed postoperative monitoring of children who underwent TT insertion can diminish early postoperative complications and increase the effectiveness of surgical treatment of SOM.

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