Acta Otorrinolaringol Esp. 2009;**60(2):**84-9

Acta Otorrinolaringológica Española

www.elsevier.es/otorrino

ORIGINAL ARTICLE

Tympanostomy tube emplacement in children with secretory otitis media: analysis of effects and complications

Yolanda Escamilla,* Anton F. Aguilà, José M. Saiz, Rosa Rosell, Josefa Vivancos, and Alda Cardesín

Corporación Sanitaria del Parc Taulí, Sabadell, Barcelona, Spain

Received July 11, 2008; accepted August 25, 2008

KEYWORDS
Secretory otitis media in children;
Otitis media with effusion;
Tympanostomy tube;
Complications

Abstract
Introduction and objectives: Tympanostomy tube emplacement is a common surgical procedure in paediatric otolaryngological surgery. This surgery has complications that sometimes depend on the disease and at other times on the treatment. The objective of this study is to know the results obtained with tympanostomy tube emplacement and its complications.
Material and methods: Retrospective study of all the children operated on for tympanostomy tube emplacement over a period of 18 months and with follow-up for at least 7 years; this amounted to 143 ears operated on for the first time. The study variables were age, gender initial appearance of the ear, inner ear contents, type of grommet inserted, duration of grommet, and the lack of any hospital monitoring needed after extrusion.
Results: One complication or another arose in 46% of the ears. The Donaldson type of grommet with a diameter of 1.27 mm is the one that produced most complications. There were more complications in ears that were worse in the otoscopic examination regardless of the grommet inserted.
Conclusions: The high prevalence of complications and after-effects after grommet emplacement needs long-term follow-up in patients. The results obtained suggest the use of grommets with a smaller internal diameter.

*Corresponding author.
E-mail address: yescamilla@telefonica.net (Y. Escamilla Carpintero).

0001-6519/$ - see front matter

PALABRAS CLAVE
Otitis serosa en niños;
Tubos de ventilación transtimpánicos;
Complicaciones

Colocación de tubos de ventilación transtimpánicos en niños con otitis seromucosa: análisis de resultados y complicaciones

Resumen
Introducción y objetivos: La colocación de tubos de ventilación transtimpánicos (TVT) es una de las cirugías más habituales de la otorrinolaringología pediátrica. Esta cirugía no está exenta de complicaciones que, a veces, dependen de la propia enfermedad y, otras, de su tratamiento. El objetivo de este estudio es conocer los resultados que hemos obtenido con la colocación de tubos de ventilación transtimpánicos y sus complicaciones.
Material y métodos: Estudio retrospectivo de todos los niños intervenidos con colocación de TVT, en un período de 18 meses, y un seguimiento mínimo de 7 años, 143 oídos intervenidos por primera vez. Las variables objeto del estudio son: edad, sexo, aspecto inicial del oído, contenido del oído, tipo de TVT colocado, duración del TVT, complicaciones aparecidas y no necesitar controles hospitalarios tras extrusión del TVT.
Resultados: El 46% de los casos presentaron algún tipo de complicación. El TVT que más complicaciones nos ha producido es el tipo Donaldson de 1,27 mm de diámetro interno. Aparecen más complicaciones en los oídos que estaban peor en la otoscopia independientemente del TVT colocado.
Conclusiones: La alta incidencia de complicaciones y/o secuelas tras la colocación de TVT hace necesario el seguimiento de los pacientes durante un largo período. Los resultados obtenidos orientan a utilizar TVT de diámetro interno más pequeño.

Introduction

Otitis with effusion is defined as an inflammation of the middle ear with content or secretion in its interior, in the absence of signs and symptoms of acute infection.[1,2]

It is one of the most common disorders in childhood and the leading cause of childhood hypoacusis, although its actual incidence is unknown because of the few symptoms it produces. Coughing[3] is observed in 28% of the ears of children who present otitis with effusion. It is more common in boys than in girls, and its incidence decreases as they grow; most cases are detected between 2 and 8 years of age.[4,5]

Otitis with effusion is considered a disease of multifactorial aetiology; the main pillar is the dysfunction of the Eustachian tube, to which is added infection and poor immune function.[2] The bacterium *Alloiococcus otitidis* is currently also believed to be implicated in the pathogenesis of otitis media with effusion due to its high incidence of presentation in such ears, and therefore in the evolution of the process in these children.[6]

In most cases, the natural course of otitis with effusion is towards spontaneous healing since, as the child grows, the immune system is modified and the skull and the Eustachian tube develop,[7] but significant problems in language development can take place during this interval.

Other sequelae of otitis with effusion are: perforation, scarring and/or tympanic membrane atrophy, tympanosclerosis, adhesive otitis, and cholesteatoma; some of which have real potential to evolve into serious complications, which is why treatment is considered.

The treatment of otitis with effusion is medical and when this fails, surgical. Medical treatments include antihistamines, steroidal anti-inflammatory drugs and antibiotics, some of dubious effectiveness, and placement of transtympanic ventilation tubes (TVT) as a surgical treatment. The TVT are intended to enhance artificially the ventilation of the middle ear, equalling its pressure with the atmosphere. There are multiple models with different shapes, diameters, and materials.

As in the rest of the hospitals, the placement of transtympanic ventilation tubes at our centre is one of the most common surgeries in paediatric otolaryngology. This surgery is not without complications, which sometimes depend on the disease itself and others on its treatment.

With this study we aim to identify the results obtained with the placement of 3 different models of TVT with the same material (fluoroplastics), their duration, and complications, if there are significant differences between them and whether these differences are influenced by other variables such as the aspect of the eardrum and the type of content, in order to guide decision-making on the TVT to be used, based on objective findings.

Material and methods

This is a retrospective study of children in whom transtympanic ventilation tubes were placed for the first time over a period of 18 months. We reviewed the medical records of children operated on for a year and a half, between September 1998, and March 2000, since the children operated on in this time interval have already been controlled and have been monitored for at least 7 years, thus offering a knowledge of any late complications which may appear.

The total number of patient records reviewed was 86, of these, 8 cases were lost through not having continued with follow-up at our hospital. Therefore, the starting point is 78 children with a total of 156 ears, in which 143 TVT were

placed, since the remaining 13 ears did not require their placement at the time of surgery.

The criteria we use to operate on a child presenting otitis with effusion are, as in other centres[1,7]:

- Bilateral otitis with effusion lasting for over 3 months of evolution, with hearing loss, and which does not improve with medical treatment
- Unilateral otitis with effusion lasting for over 6 months of evolution which does not improve with medical treatment
- Recurrent otitis media, and otitis with effusion in periods between bouts and in recurrent otitis media without otitis with effusion between bouts when prophylactic antibiotic treatment does not resolve the disease[8]
- Atelectatic tympanic membrane[9]

We performed surgery under general anaesthesia and as a major day-care surgical procedure. Before the myringotomy, we disinfected the external auditory canal with povidone iodine solution followed by irrigation with saline solution.

Although the recommendations of the Subcommittee on Otitis Media with Effusion, from May 2004, indicate that adenoidectomy should not be carried out in the initial treatment of otitis with effusion,[10,11] many of the children under study also presented adenoid signs, so in these cases, adenoidectomy was also performed in addition to the placement of TVT.

The first post-operative check-up was performed a week after surgery, and if no problems were present, subsequent check-ups took place every 3-6 months, until the 6 months after the extrusion of the TVT. If after that time there was no recurrence or complication of disease evolution, the child was discharged from hospital to continue normal monitoring by a paediatrician. Otherwise, the check-ups or treatments depended on the complication emerging.

The main response variables studied were: the number and type of complications after placement of a specific TVT, and as secondary variables: age, gender, initial appearance of the ear before performing myringotomy, content of the ear after myringotomy, type of TVT placed, duration of transtympanic ventilation tube, and whether there was any need for hospital check-ups after extrusion of the TVT.

In the study we considered the following complications: otorrhea following surgery, if it occurred during the first 4 weeks after surgery; late-onset otorrhea, if it occurred later; tympanic perforation with spontaneous closure; residual tympanic perforation, requiring myringoplasty for closure; persistence of the transtympanic ventilation tube, when more than 30 months go by without extrusion of the tube; recurrence of otitis with effusion requiring the placement of a new TVT; tympanic membrane retraction, when the entire eardrum or a part of it is retracted. Most often this retraction affects a small part of the eardrum with no further repercussion or functional sequela, but at other times this tympanic retraction can be dangerous because cholesteatoma or adhesive otitis may develop. Normally, this development does not occur due to the placement of the TVT by itself, but due to the natural history of otitis with effusion because of poor tube ventilation.

In the study, we distinguished between 4 types of image in the otomicroscopic examination:

- Apparently normal tympanic appearance: tympanic texture and mobility will be modified
- Presence of air-fluid levels; the membrane maintains its transparency and we can observe fluid levels or bubbles
- Opaque eardrum: the eardrum is thickened, oedematized. It is not uncommon to find a blue eardrum when the otitis is very advanced
- Retracted eardrum: the appearance is thinned, atrophic, and retracted

As for contents, we distinguish 3 different types: no contents, serous content, and mucous content.

We must recall that, despite the lack of content, we place TVT in cases of repeated otitis, in cases of adhesive otitis, and in cases in which there were fluids in the previous pre-operative visit.

The duration of the transtympanic ventilation tube is counted in months from its placement (day of surgery) to its extrusion, either spontaneously or surgically.

We used 3 types of TVT, all of them of short duration and the same material, fluoroplastics: a Shepard model with 2 internal diameter measures (1.02 and 1.14) and a Donaldson 1.27 model.

The criteria for evaluation of response variables are clinical, by otoscopic or otomicroscopic examination, and audiometric-impedanciometry study during scheduled visits.

The statistical programme used to carry out the calculations and statistical analysis was SPSS version 11. The study is descriptive of all the variables included; the results of the quantitative variables are expressed in median and standard deviation and categorical variables in frequency and percentages. Normality assumptions were confirmed for the applicability of the usual statistical tests. Where applicable, Student *t* analysis for the analysis of quantitative variables and ^{2} for categorical variables were performed. Non-parametric tests were used in cases which did not meet the normality assumptions. An alpha risk of 0.05% was accepted.

Results

The children were between 2 and 10 years of age, with a larger number of cases between 4 and 5 years, 54.6% of TVT placed (Table 1) and in terms of gender distribution, there is a higher frequency in males (60.3% male and 39.7% female).

The aspect of the eardrum prior to myringotomy was opaque in 57% of the cases; in 18.7%, retracted; in 15.4%, with levels and in 8.4% normal. In 60.1% the content was mucous, 23.8% presented no content, and 16.1% was serous.

With regard to the type of ventilation tube used, in 11% (n=17) the type was Shepard 1.02; in 58% (n=83), Shepard 1.14; and in 30.1% (n=43), Donaldson 1.27.

The duration of the TVT, regardless of type, ranged from 3 to 30 months. There are differences in duration depending on the type of TVT; 9 months on average for TVT type 1.02, 12 months for TVT type 1.14, and 18 months for TVT type 1.27, with statistical significance ($P<.001$).

Tabla 1 Frequency by ages

Age, y	Patients, No. (%)
2	7 (9)
3	8 (10.3)
4	22 (28.2)
5	19 (24.4)
6	10 (12.8)
7	6 (7.7)
8	1 (1.13)
9	2 (2.6)
10	3 (3.8)
Total	78 (100)

There were complications in 46.2% of cases, that is in 66 of the 143 ears operated on, which were distributed as shown in Table 2.

A hospital check-up was required in 33% of the ears after TVT extrusion with the onset of various complications or sequelae.

The complications arising from the TVT and their duration depending on the different variables studied were as follows:

1. In analyzing the complications according to the type of TVT placed, it can be observed that the TVT with most complications were the Donaldson 1.27; in 60.5% (26/43) of TVT 1.27 placed, in 44.6% of TVT 1.14 (37/83) placed and in 17% of TVT 1.02 (3/17) placed. These results are statistically significant (P=.01) (Table 3). When comparing each type of TVT with the onset of each complication, it has not been possible to apply statistical tests, due to the few or inexistent cases of each complication and their inapplicability.
2. In comparing the duration of the TVT with the appearance of complications (we established the duration of a ventilation tube as the arithmetic mean of the recorded durations in months), we noted that there are more cases with complications when the duration of the TVT in the tympanic membrane was greater (P<.001); these appear with a mean duration of 15.7 months.
3. If we compare the initial appearance of the ear with the onset of complications, we find that in ears with a normal aspect, complications arise in 17% of cases, with a statistically significant difference compared to the rest of the appearances, which tend to offer complications in 50% of cases (Table 4).
4. When comparing the initial content after the completion of myringotomy with the onset of complications, we found complications in 44% of ears which did not present contents, in 35% of ears with serous content and in 50% of ears with mucous content. Given the similar rate of complications, the differences are not statistically significant (Table 5).
5. In addition, when comparing the original appearance of the ear with the duration of the transtympanic ventilation tube, we observe that there are no significant differences (Table 6).
6. Nor are there any differences when comparing the contents of the ear on performing myringotomy with the duration of the TVT (Table 7).

Table 2 Complications

Type of complication	Cases, No. (%)
Tympanic retraction	28 (19.6)
Late-onset otorrhea	23 (16.1)
Persistence of TVT (requiring extraction)	18 (12.6)
Recurrence of otitis with effusion (with new TVT required)	16 (11.2)
Otorrhea following surgery	7 (4.9)
Tympanic perforation with spontaneous closure	3 (2.1)
Residual tympanic perforation	3 (2.1)

TVT indicates transtympanic ventilation tubes.

Table 3 Complication by tube type

Tube type	Complicated cases, No. (%)	Total, No. (%)
1.02	3 (17.6)	17 (11.9)
1.14	37 (44.6)	83 (58.0)
1.27	26 (60.5)	43 (30.1)
Total	66 (46.2)	143 (100.0)

Table 4 Complication by initial aspect

Initial aspect	Complication, %	Cases from total
Normal	16.7%	2 of 12
Air-fluid levels	50%	11 of 22
Opaque	47.6%	39 of 82
Retracted	51.9%	14 of 27

Table 5 Complication by content

Content	Complication, %	Cases from total
Empty	44.1%	15 of 34
Serous	34.8%	8 of 23
Mucous	50%	43 of 86

Table 6 Average duration with regard to initial aspect

Aspect	Average duration, mo
Normal	11.4
Levels	15.1
Opaque	12.8
Retracted	14.1

Table 7 Average duration with regard to content

Content	Average duration, mo
Empty	14
Serous	10
Mucous	13.9

Table 8 Complication and aspect by tube type

Tube type	Aspect	Complication		Total
		Yes	No	
1.02	Normal	0	1	1
	Levels	0	3	3
	Opaque	3	9	12
	Retracted	0	1	1
	Totals	3	14	17
1.14	Normal	2	7	9
	Levels	8	5	13
	Opaque		24	42
	Retracted	9	10	19
	Totals	37	46	83
1.27	Normal	0	2	2
	Levels	3	3	6
	Opaque	18	10	28
	Retracted	5	2	7
	Totals	26	17	43

Table 9 Complication and content by tube type

Tube type	Aspect	Complication		Total
		Yes	No	
1.02	Empty	1	1	2
	Serous	0	5	5
	Mucous	2	8	10
	Totals	3	14	17
1.14	Empty	12	13	25
	Serous	5	9	14
	Mucous	20	24	44
	Totals	37	46	83
1.27	Empty	2	5	7
	Serous	3	1	4
	Mucous	21	11	32
	Totals	26	17	43

Tables 8 and 9 collect the cases of complications depending on the variables of appearance and content and types of TVT employed, although the volume of the series does not allow statistical calculations other than those presented above.

Discussion

In conducting our study, we have not considered other complications described in the literature, such as the collapse of TVT into the ear, haemorrhage, dislocation of the ossicular chain, iatrogenic cholesteatoma, or laberynthization, due to not having any knowledge of their occurrence to date. Nor have we considered others, as we did not consider as such the obstruction of TVT, given that we treat it with ceruminolytics and subsequent aspiration in consultation, or myringosclerosis, as it is an aesthetic rather than a functional sequela.

We found a higher incidence of otitis with effusion requiring surgical treatment in men than in women, similarly to other authors.[4,5,12] Moreover, the most common ages were 4-5 years, unlike other studies that found a higher incidence in younger children.[12]

More than half of the cases presented an opaque appearance in otoscopy (57%) and the content displayed after myringotomy was, in most cases, mucous (60%). A high percentage of ears without content following myringotomy (24%) stands out and could correspond, as mentioned above, to otoscopy showing ears that have suffered from recurrent ear infections, that are swollen, tarnished, with scarred areas, etc, but with no liquid, or perhaps with the content having been displaced by nitrous oxide. In these cases we placed a TVT, even though the myringotomy was blank.

The most widely used TVT was TVT 1.14 (58%).

As in the literature, we found a greater duration in the tympanic membrane the greater the inner diameter.[13-15]

This series reveals a high percentage of complications (46%), the most common being tympanic membrane retraction. Tympanic retraction has been considered as a complication after TVT, although in cases of bad evolution, it is more of a complication of the disease itself, due to poor tube ventilation. We have not differentiated the types of retraction; they are all encompassed as tympanic membrane retraction and considered as a complication since, in principle, these ears are monitored for a long time in case they present further complications and, therefore, they are not discharged. In the monitoring of this series for 7 years, no child has developed cholesteatoma.

The next complication in frequency is late otorrhea, attributable to an external contamination through the external auditory canal or rhinopharyngeal contamination. In the literature, this is the most common complication after TVT, with an incidence of 12%24%depending on the series.[12,16-18]

In analyzing the complications arising in terms of the TVT placed, the high rate of complications with the TVT 1.27 (60.5%) stands out along with the slight incidence with TVT 1.02 (17.6%).

The results obtained in terms of the TVT, although without offering definitive conclusions due to the few cases existing and the retrospective nature of the study, indicate that after the placement of TVT 1.27 there is more recurrence of otitis with effusion once the TVT is extruded, an increased number of extractions is required because of its greater size,[12-14] the occurrence of post-operative and late otorrhea is more frequent and has a higher frequency of tympanic membrane perforation with spontaneous closure and, on a different note, it must be highlighted that a greater number of ears have remained retracted when a TVT 1.14 (25.3%) was placed than when it was a TVT 1.27 (16.3%) and in cases where the perforation which appeared after the extrusion of TVT has required surgical closure it occurred in ears in which a TVT 1.14 had been placed, and none in ears with a TVT 1.27. Some authors do not find perforations when using a Shepard TVT[15] and others find them often when they place a T-Tube,[19] as would be expected.

When analyzing the duration of the TVT and the appearance of complications, we found that a greater duration in the tympanic membrane brought a higher likelihood of complications, occurring with a mean duration of 15.7

months. Due to the study design, we cannot differentiate this factor separately regardless of the type of TVT, since the model which presents more complications is TVT is 1.27, which is the one with the highest duration.

We found a statistically significant difference between the initial appearance of the ear before the intervention and the occurrence of complications. Those with normal aspect suffered half as many complications as those with other aspects, a fact which could be explained by the lower underlying involvement in these cases.

We found no relationship between the type of content within the tympanic cavity when performing myringotomy and the percentage of complications, or between the initial appearance of the ear and the content after myringotomy with the duration of TVT.

Conclusions

Considering the limitations entailed by a retrospective study, we can state that: the high incidence of complications and/or sequelae after TVT placement indicates the need to monitor patients for a reasonable period, and the investigation of other approaches towards otitis media with effusion. Meanwhile, the results obtained lead us to make greater use of TVT 1.02, which was the least used so far, since, as we have seen, it has an acceptable duration and few complications, and to make less use of TVT 1.27, the one with the most complications.

Prospective studies are needed, with more cases, with randomness in the TVT model used with respect to the appearance of the eardrum, content and patient age and with the same insertion technique (quadrant, direction of the incision), allowing further evidence on differences in the results.

Conflict of interests

The authors declare no conflict of interest.

References

1. Bluestone CD, Klein JO. Otitis media, atelectasis and eustachian tube dysfunction. In: Bluestone CD, Stool SE, Kenna MA, editors. Pediatric otolaryngology. Philadelphia: WB Saunders; 1996. p. 388-582.
2. Rovers MM, Schilder AGM, Zielhuis GA, Rosenfeld RM. Otitis media. Lancet. 2004;363:465-73.
3. Tos M. Spontaneus improvement of secretory otitis media and impedance screening. Arch Otolaryngol. 1980;106:345-9.
4. Zielhuis GA, Rach GH, van den Bosch A, van der Broek P. The prevalence of otitis media with effusion: a critical review of the literature. Clin Otolaryngol. 1990;15:283-8.
5. Midglkey EJ, Dewey C, Pryce K, Maw AR. The frequency of otitis media with effusion in British pre-school children: A guide for treatment. ALSPAC Study Team. Clin Otolaryngol. 2000;25:485-91.
6. de Miguel Martinez I, Ramos Macías A, Masgoret Palau E. [Bacterial implication in otitis media with effusion in the childhood]. Acta Otorrinolaringol Esp. 2007;58:408-12.
7. Kenna MA. Diagnosis and management of otitis media with effusion. In: Cotton Rt, Myer CM, editors. Practical pediatric otolaryngology. Philadelphia: Lippincott-Raven; 1999. p. 229-46.
8. Le C T, Freeman DW, Fireman BH. Evaluation of ventilating tubes and myringotomy in the treatment of recurrent or persistent otitis media. Pediatr Infect Dis J. 1991;10:2-11.
9. Avraham S, Luntz M, Sade J. The influence of ventilating tubes on surgical treatment of atelectatic ears. Eur Arch Otorhinolaryngol. 1991;248:259-61.
10. American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery and American Academy of Pediatrics. Subcommittee on Otitis media with effusion. Clinical practice guideline: otitis media with effusion. Pediatrics. 2004;113:1412-29.
11. Cervera Escario J, del Castillo Martín F, Gómez Campderá JA, et al. Indicaciones de adenoidectomía y amigdalectomía: Documento consenso entre la Sociedad Española de ORL y Patología Cervicofacial y la Asociación Española de Pediatría. Acta Otorrinolaringol Esp. 2006;57:59-65.
12. Lindstrom D, Reuben B, Jacobson K, Flanary VA, Kerschner JE. Long-term results of Armstrong beveled grommet tympanostomy tubes in children. Laryngoscope. 2004;114:490-4.
13. Moore PJ. Ventilation tube duration versus design. An Otol Rhinol Laryngol. 1990;99:722-3.
14. Goode RL. T-Tube for middle ear ventilation. Arch Otolaryngol Head Neck Surg. 1973;97:402.
15. Weigel M T, Parker M Y, Goldsmith MM, Postma DS, Pillsbury HC. A prospective randomized study of four commonly used tympanostomy tubes. Laryngoscope. 1989;99:252-6.
16. Gates GA, Avery C, Prihoda TJ, Holt BR. Post-tympanostomy otorrhea. Laryngoscope. 1986;96:630-4.
17. Kay DJ, Nelson M, Rosenfeld RM. Meta-analysis of tympanostomy tube sequelae. Otolayngol Head Neck Surg. 2001;124:374-80.
18. van Heerbek N, de Saar GM, Mulder JJ. Long-term ventilation tubes: results of 726 insertions. Clin Otolaryngol. 2002;27:378-83.
19. Golz A, Netzer A, Joachims HZ, Westerman St, Gilbert LM. Ventilation tubes and persisting tympanic membrane perforations. Otolaryngol Head Neck Surg. 1999;120:524-7.