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## Artículo Original

# Profile of children at risk of new surgical intervention due to otitis media with effusion

# Perfil de niños en riesgo de nueva intervención quirúrgica por otitis media con derrame

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## Abstract

Objective: With this study, we try to identify risk factors for children receiving additional tympanostomy tube after the first myringotomy with tube insertion.

Methods: Retrospective controlled analysis of medical records of patients aged below 18 years submitted to myringotomy with tube insertion because of otitis media with effusion. We obtained 83 children and 152 ears, which were divided in two groups: the SG (study group), composed of children that had undergone two or more myringotomy with tube insertion and the CG (control group), composed of children submitted to only one myringotomy with tube insertion.

Results: There were significant statistically differences between the groups concerning the mean age at the 1st myringotomy with tube insertion (SG:4,8; CG:6,3; p =0,02), the mean indwelling period of tube (SG:9,1months; CG:12,1months; p <0,001), the postoperative otorrhea (SG:56,4 %; CG:12,4%; p<0,001) and the perioperative upper airway recurrent infections (SG:64,3%; CG:40%; p =0,036). Applying binary logistic regression, we concluded that the absence of postoperative

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otorrhea (OR=157; 95% CI: 14-1742; p<0,001) is a protective factor, and tube extrusion in less than 12 months (OR=0,23; 95% CI: 0,05-1,08; p = 0,05) is an independent risk factor.
Conclusion: We found that the children's risk factors which can lead to a re-intervention are tube extrusion in less than 12 months and postoperative otorrhea.

**Keywords:** otitis media with effusion; tympanostomy tube; recurrences.

## Resumen

Objetivo: Identificar los factores de riesgo en niños que puedan requerir reintervención de miringotomía con inserción de tubo por la recidiva de la otitis media con derrame.
Métodos: Análisis retrospectivo con grupo control de pacientes menores de 18 años sometidos a miringotomía con inserción de tubo por otitis media con derrame. Se analizaron 83 niños y 152 oídos, que se dividieron en dos grupos: el SG (grupo de estudio), compuesto por niños que habían sido sometidos a dos o más miringotomías con inserción de tubo y el CG (grupo control), compuesto por niños sometidos a sólo una miringotomía con inserción de tubo.
Resultados: Se observaron diferencias estadísticamente significativas entre los grupos relativas a la edad media en la primera miringotomía con inserción de tubo (SG: 4,8, CG: 6,3, p = 0,02), en el período medio de permanencia del tubo (SG: 9,1 meses, CG: 12,1 meses, p <0,001), en la otorrea postoperatoria (SG: 56,4%, CG: 12,4%, p <0,001) y en las infecciones perioperatorias recurrentes de las vías aéreas superiores (SG: 64,3% %; p = 0,036). Aplicando la regresión logística binaria, concluimos que la ausencia de otorrea (OR = 157; IC 95%: 14-1742; p <0,001) es un factor de protección y la extrusión del tubo en menos de 12 meses (OR = 0,23; IC 95%: 0,05-1,08; p = 0,05) es un factor de riesgo independiente.
Conclusión: En nuestro estudio los factores de riesgo para reintervención en los niños son la extrusión del tubo en menos de 12 meses y la otorrea postoperatoria.

**Palabras Clave:** otitis media con derrame; tubo de ventilación; recidivas

## Introduction

Otitis media with effusion (OME) is defined as the presence of fluid in the middle ear without acute infection, with a non-perforated tympanic membrane[1,2]. It is one of the most common diseases among children[1,2]. About 90% of children have OME before school age[1,3], most often between the ages of 6 months and 4 years[4]. It has few signs and symptoms associated[1] and is the most common cause of hearing loss in children[1,2]. Pathogenesis of OME is not yet effectively understood[1,2]. Many factors can contribute to its development, such as following an upper respiratory infection, spontaneously due to poor eustachian tube function, or as an inflammatory response after an acute otitis media[1]. Most episodes are solved within 3 months, but about 30 to 40 % of children have fluctuating episodes, and in 5 to 10% of the cases OME

lasts more than 1 year[1,5].

The possible implications of an unsolved episode include: chronic otitis media with eventual progression to cholesteatoma, permanent hearing loss and finally delayed speech development, learning problems and worse school results[6]. Besides otoscopy and pneumatic otoscopy, the tympanometry, as well as an age-appropriate audiometry are helpful to diagnosis OME and to identify children at risk[1,6].

There is a notorious lack of information concerning the clinical predictors of OME recurrence, and the children at risk of new surgical intervention due to OME. With this work we aim to fill this gap of knowledge and to consider possible risk factors of OME recurrence.

## Materials and Methods

*Study Design*

With the approval of our institutional ethics review board, we performed a retrospective controlled analysis of medical records of young patients (aged under 18) who were submitted to myringotomy with tube insertion (mTVT) due to OME, between January 2009 and December 2014, within our ENT department. The diagnosis of OME was made with otoscopy conjugated with a type B tympanogram and, when possible, pure tone audiometry. Patients were distributed into two groups: the study group (SG), composed of children submitted to 2 or more mTVT (n=28; 55 ears); and the control group (CG), with patients who underwent only 1 mTVT (n=55; 97 ears).

The exclusion criteria were age above 18 years old, syndromic children, craniofacial anomalies, presence of cleft palate and perforated chronic otitis media.

*Studied Variables, mTVT and Follow-Up*

The mTVT indications were more than 3 months bilateral OME, and more than 6 months unilateral OME. The mTVT was performed under general anesthesia in the tympanic anteroinferior quadrant. Shepard Grommets with 1,14 mm of internal diameter (Medtronicâ) were used. Adenoidectomy was performed in the 1st mTVT when there was a history of chronic rhinorrhea, snoring and multiple sleep apnea episodes reported by parents, and always in the 2nd and 3rd mTVT. A minimum of an 18 months follow-up had been done.

The studied variables were the age of the 1st mTVT, concomitant adenoidectomy, the estimated indwelling tympanic tube (TVT) period, the presence of postoperative otorrhea after the 1st mTVT(at least one episode requiring topic antibiotic), the history of perioperative upper airway recurrent infections (more than 3 episodes in less than 6 months in the pre and/or postoperative period), the patient's allergy history (documented allergic rhinitis, asthma or atopic history, together or isolated), preoperative eosinophilia (more than 400 cells/$mm^3$) [7] and, finally, postoperative complications.

*Statistics*

Data was analysed with SPSS v.22. Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations. Normal distribution was checked using Shapiro-

Wilk test or skewness and kurtosis. Categorical variables were compared with the use of Fisher's exact test or the chi-square test, as appropriate. Continuous variables were compared with Student's t-test. All reported *p* values were two-tailed, with *p* value inferior than 0,05 indicating statistical significance. Finally, we have used binary logistic regression to determine the odds ratios of possible predictors (studied variables) that can lead to a new mTVT. Odds ratios and their 95% confidence intervals were reported.

## Results

### Groups characterization

The study was performed with 152 ears of 83 children. Among these, 28 children (55 ears) belonged to the SG, and 55 children (97 ears) belonged to the CG. In both groups, males were slightly more frequent (60,7% - SG; 52,7% - CG). The mean age of the 1st mTVT was 4,8 years in SG (ranged between 1 and 11 years old), and 6,3 years in CG (ranged between 1 and 12 years old). The observed differences were not statistically significant in what concerns patient gender ($p$=0,49), but significant when we focused the mean age of the 1st surgical intervention ($p$=0,02).

**Table 1**: Results by Groups.

| | SG | CG | *p value* |
|---|---|---|---|
| **Patients (n)** | **28** | **55** | |
| **male** - % (n) | **60,7%** (17) | **52,7%** (29) | **NS*** |
| **female** - % (n) | **39,3%** (11) | **47,3%** (26) | |
| **Concomitant Adenoidectomy at 1st mTVT** - % (n) | **93%** (26) | **98,2%** (54) | **NS*** |
| **Mean age at 1st mTVT** (± sd) - years | **4,8** (±2,6) | **6,3** (±2,8) | **0,02**** |
| **Ears (n)** | **55** | **97** | |
| **Mean indwelling period of 1st TVT** - months | **9,1** | **12,1** | **<,001**** |
| **No. of mTVT** | | | |
| **2x** - % (n) | **82%** (23) | - | |
| **3x** - % (n) | **18%** (5) | - | |

**Abbreviations:** CG: Control Group; mTVT: myringotomy with tube insertion; NS: non-significant; sd: standard deviation; SG: Study Group; * - $\chi$2-test; ** - t-test.

**Clinical aspects about the 2 Groups**

In the SG, 82% of patients were submitted to 2 mTVT, and 18% underwent 3 mTVT. The difference between the two groups concerning simultaneous adenoidectomy at the 1st mTVT (93%-SG vs 98,2%-CG) was not significant ($p$=0,26). Adenoidectomy was not performed only in 3 children at the 1st surgical procedure (2 in the SG and 1 in the CG). The 2 children of the SG underwent adenoidectomy in the 2nd mTVT.
Finally, the estimated mean indwelling TVT period for the 1st TVT was 9,1 months (SG) versus 12,1 months (CG), which was statistically significant ($p$<0,001).
Concerning the infectious history, the SG was statistically higher than the CG related to the perioperative upper airway recurrent infections (64% vs 40% - $p$ =0,036) (figure 1a), and had significantly higher incidence of post-op otorrhea episodes (56% vs 12% $p$<0,001) requiring antibiotic ototopic drops (figure 1b).

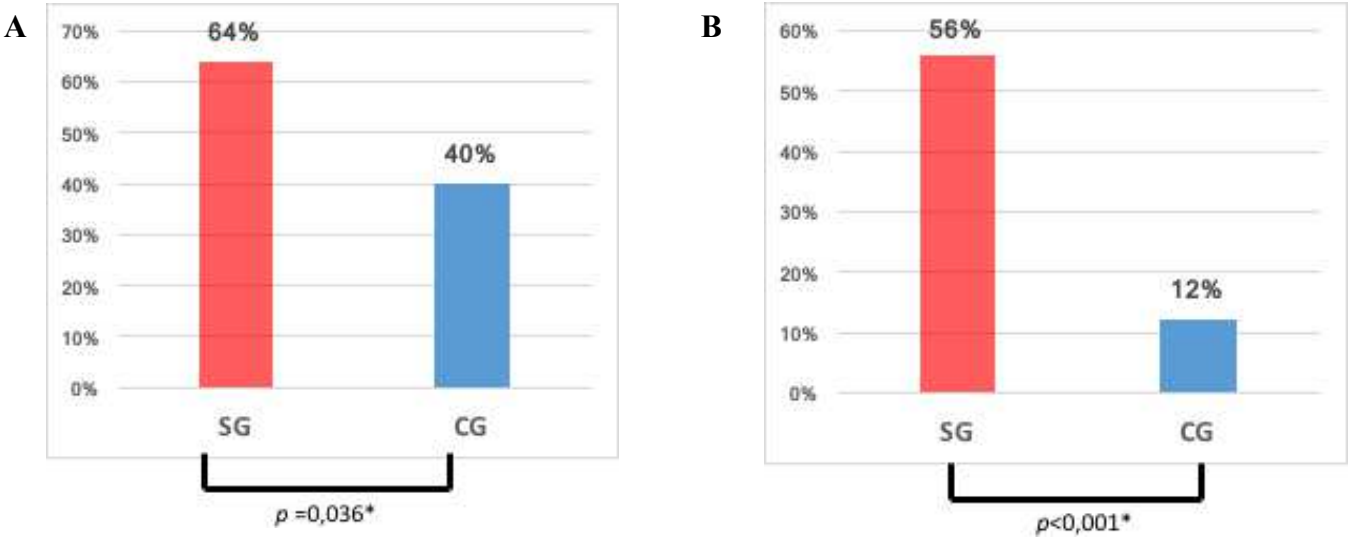


Figure 1a: Perioperative upper airway recurrent infections. CG: Control Group; SG: Study Group;* $\chi 2$ -test. Figure 1b: Postoperative otorrhea. CG: Control Group; SG: Study Group; * $\chi 2$-test.

When we analysed immunologic history, besides higher values of allergy history and pre-op eosinophilia in the SG (39% in both in SG vs 20% and 36%, respectively, in CG) (figure 2a and figure 2b), we did not find any irrefutable statistical linkage.
Post-op complications after the 1st mTVT were significantly higher in the SG ($p$<0,001) and occurred only in the SG (6 children – 7%), being the tympanic perforation the most common (5 cases – 6%), followed by tympanic granulation (2 cases – 2%) and tympanic retraction (1 case – 1%) (table 2, figure 3).

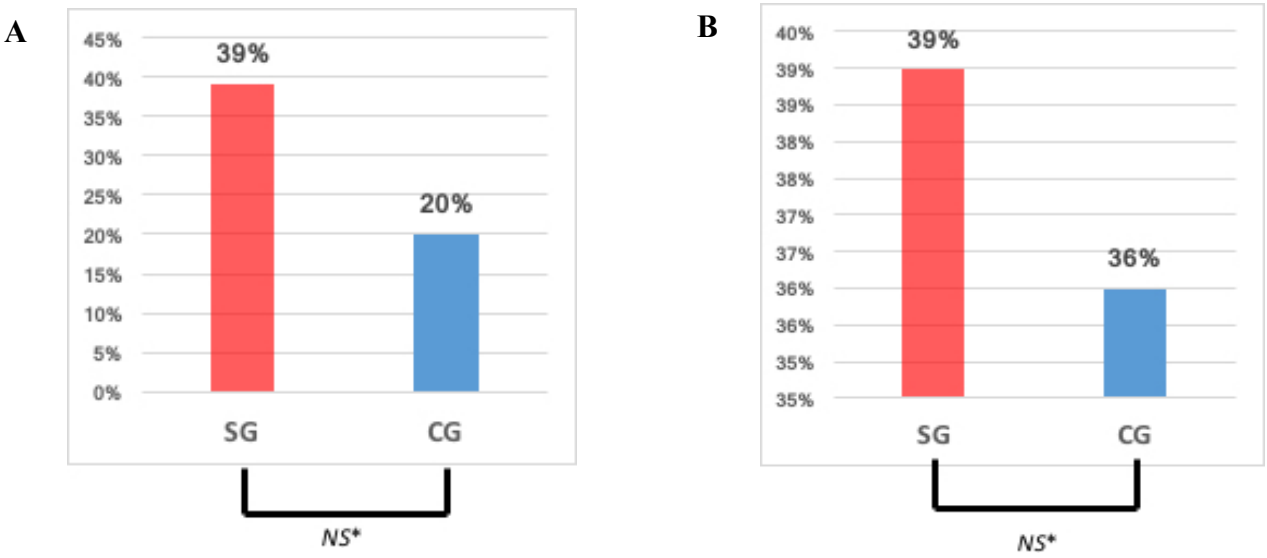


Figure 2a: History of allergy. CG: Control Group; NS: Non-significant; SG: Study Group; * $\chi$2-test. Figure 2b**:** Preoperative eosinophilia. CG: Control Group; NS: Non-significant; SG: Study Group; * $\chi$2-test.

Table 2 : Postoperative complications.

| Postoperative complications in SG (n=6;7%) | |
|---|---|
| Tympanic **perforation** % (n) | 6% (5) |
| Tympanic **granulation** % (n) | 2% (2) |
| Tympanic **retraction** % (n) | 1% (1) |

**Abbreviations:** SG: Study Group

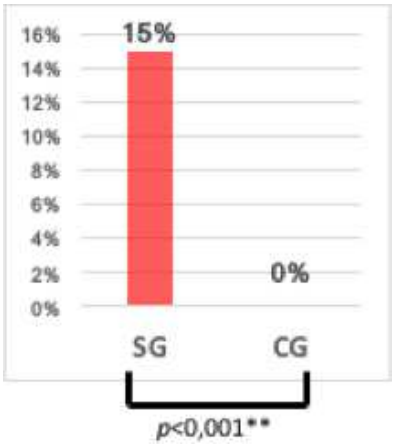


Figure 3: Postoperative complications. CG: Control Group; SG: Study Group; ** Fisher's exact test.

**Risk Factors for re-intervention**

When we applied binary logistic regression, adjusted to the risk of the need of a new mTVT, attending to all variables that were statistically significant, we concluded that the TVT extrusion in less than 12 months was a risk factor (OR 0,23; 95%CI 0,05-1,08; *p*=0,05), and the absence of post-operative otorrhea was a protective factor (OR 157; 95%CI 14-1742; *p*<0,001), besides the age of the 1st mTVT and the presence of perioperative upper airway recurrent infections (figure 4). Although the extrusion of TVT in less than 12 months has proved to be a risk factor, this has to be interpreted with caution because the Odds Ratio includes the value 1 in the confidence interval, not exceeding it.

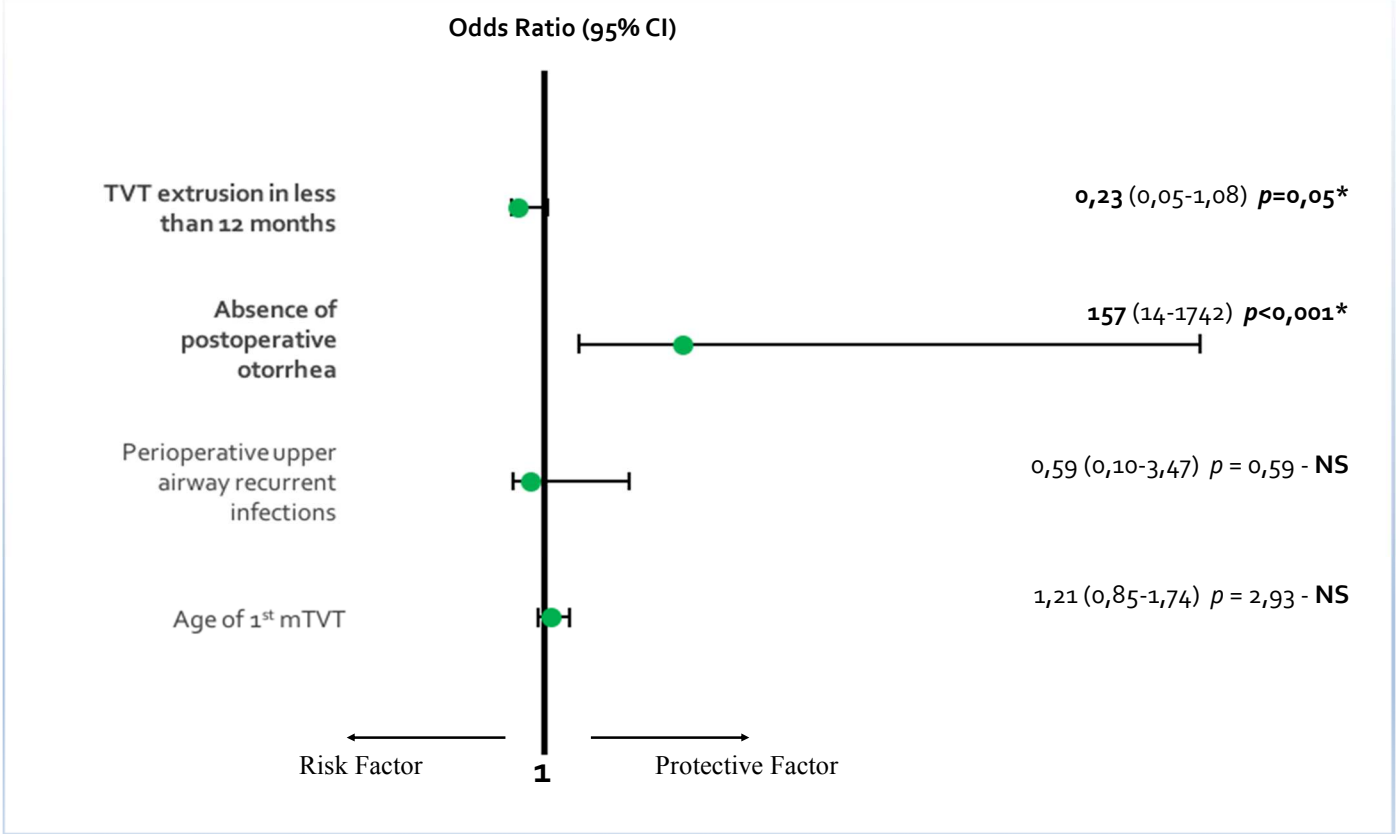


Figure 4: Binary logistic regression (R2 Nagelkerke = 68,5%). CI: Confidence Interval; mTVT: Myringotomy with tube insertion; NS: Non-significant; TVT: Tympanic tube.

## Discussion

After the lack of a spontaneous OME resolution or a non-successful medical treatment, mTVT is a well-known next step to take. Besides being one of the most applied procedures in otorhinolaryngology, it is one of the most frequently performed surgeries in children[8]. OME has both high rates of spontaneous recovery and relapses[6], and it is definitively a multifactorial disease[9]. The children's eustachian tube is shorter, more floppy, and horizontal, which makes it less effective in ventilating the middle ear[1].

The eustachian tube dysfunction/obstruction is a central factor, that may be on the basis of a poor out-

come after mTVT and OME relapse[9]. Many factors can contribute to this dysfunction, such as an exacerbated immune response (caused by recurrent infections or allergy) that leads to a mucosal oedema and adenoid hypertrophy, and a small skull circumference, which with the up growth process will get less impact[1,6,9]. Despite not included in our study, children with Down syndrome, as well as with cleft palate and other craniofacial syndromes, have a higher OME relapse probability, due to poor eustachian tube function[1].

As was already shown in previous studies[9], we found that children who needed a re-intervention were significantly younger than the ones in single-mTVT group. This was expectable as Bylander et al.[10] stated that otologically normal children with 3 to 6 years old had worse eustachian tube function than children with 7 to 12 years old. Despite this, using the binary logistic regression, we did not find that the age at the 1st mTVT was a clear risk factor for a new mTVT.

The difference obtained concerning the gender of children was not significant. This finding was in line with previous studies[2].

In what concerns concomitant adenoidectomy at the 1st mTVT the difference between the SG and CG was not significant. Data already published about this subject is not consensual. Yaman *et al.*[2] found no correlation between adenoidectomy and OME relapse, but Ahn *et al.* [9] showed that concurrent adenoidectomy at 1st mTVT was observed to reduce the need for a new mTVT. Rosenfeld *et al.*[1] in the latest OME clinical practice guidelines (2016) holded that concomitant adenoidectomy should be offered only to children aged 4 or older, and in younger children it should be proposed only if there was a history of nasal obstruction or chronic adenoiditis. Besides these facts, our workgroup believes that almost all of the children can be submitted to adenoidectomy at 1st mTVT because, based in our practice, and on our patients' sample, we realised that in some point there are some factors such as nasal obstruction, chronic adenoiditis, permanent rhinorrea or sleep disturbance, accompanying the OME, that put the adenoid hypertrophy at the core of the problem. Based on 2004 OME guidelines and previous reports[6,11,12], the only exception that we may consider as not performing adenoidectomy is when during the surgery, in children aged under 3 years old, we did not find eustachian tube obstruction, at the cavum inspection, and the child does not have history suggesting chronic adenoiditis. This was the reason why we did not perform adenoidectomy at the 1st mTVT in 2 children of SG and 1 child at the CG, all aged below 3 years old. Interestingly, OME did not relapse in the 2 children of SG after concomitant adenoidectomy in the 2nd mTVT. Obviously with these isolated cases we cannot be elucidated, but we may ask if adenoidectomy is an unavoidable procedure when we proceed to a 2nd mTVT. So far there is no sufficient data that can tell us clearly if adenoidectomy may or may not prevent OME relapse.

In what concerns the infectious history, we found that the perioperative upper airway recurrent infections and the post-op otorrhea episodes were significantly related to the need of a new mTVT. In our statistical analysis, absence of post-op otorrhea has proved to be a protective factor. This fact is in agreement with published data[9], that showed that otorrhea during the 1st mTVT increases the risk of relapse. The most common complication after mTVT is otorrhea and it is verified in approximately 16% of children within 4 weeks and in 26% of children at any time the TVT remains in place[8]. We may add that post-op otorrhea

besides increasing the likelihood to OME relapse, may precipitate an early TVT extrusion, as stated by C. Bluestone[13]. Topical antibiotic drops prophylaxis showed to reduce post-op otorrhea episodes[14], so we may ask if we should routinely add this treatment prophylactically besides the presence of otorrhea. Studies are needed to understand this question and the possible benefits/complications of prolonged use of otic drops in this context.

An important highlight in our study is that the TVT extrusion in less than 12 months is an effective risk factor. We set a cut-off in 12 months because previous reports[8] pointed out that the TVT remains in place for about 12 to 14 months. Nevertheless, our perception with Shepard tube is that the vast majority of children remains TVT in place for about 12 months. Through our results, and other studies[15], we must aim for more than 12 months of TVT permanence, but at the moment, we do not know, exactly, how long it is desirable. On the other hand, we must be aware that more time could lead to a permanent tympanic perforation[14], and this complication is more common after a long-term tube versus grommet-type tubes (17% versus 2% respectively)[6]. This is the most likely post-mTVT complication that requires surgery[16]. It has been reported that the time to extrusion is dependent on the diameter and shape of the inner flange[14]. Most TVT with an internal diameter up to 2,5mm will be extruded within 8 to 24 months[14]. If this internal diameter is wider (up to 12mm) or T-shaped, like Goode-T tube, the ventilation is extended for more than 2 years. Other important issue is the weight of the tube, as lower weight means a shorter interval, but leads to less myringosclerosis, like Shepard tube[14]. The place of TVT insertion was also other problem explored in previous studies. Hern and Jonathan[17] did not identify any difference between placement in upper or lower anterior quadrants, and the rate of post-mTVT chronic perforation was not influenced by the place of TVT[18].

Bearing this in mind, if the 1st Shepard fails, our workgroup advocates re-insertion of a new Shepard instead of long-term tube, because is more easy to perform a new mTVT than leading with possible complications like chronic otorrhea[15] and tympanic perforation. One possible study strategy is to study how to achieve and control a good TVT indwelling period.

Another interesting fact to add is that the post-op complications were only present in the SG, being the perforation the most common. As it was already shown by Hellström et al.[14], the repeated mTVT in the same place of the tympanic membrane weakens it and increases the likelihood of becoming atrophic and perforated. On the other hand, complications are expected because of the effusion itself and the degenerative changes that it causes in the middle ear mucosa and tympanic membrane[19].

Finally, in this study we did not find any linkage between allergy and eosinophilia and OME relapse. This item is focused in the latest clinical guidelines about OME as a needed research point[1]. Curiously, in 2004 guidelines[6], this subject was already referred as a D grade evidence quality. It was focused that a correlation between OME and allergy has been widely announced, but up till now it remains unquantified, and with a notorious lack of quality studies to support this thesis.

We believe that we need prospective controlled studies, with larger children groups (in pre and school age) to achieve definitive answers. Our study was relevant and sought to answer some questions, but had the limitations inherent to a retrospective and limited sample sized study.

## Conclusion

Children's features that may lead to a new surgical intervention due to OME are the TVT extrusion in less than 12 months and the occurrence of postoperative otorrhea. With this work we clearly emphasize the importance of the TVT indwelling period and the importance of a dry ear maintenance.

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**Conflict of Interest**: Without conflict of interests to declare.

**Ethical Standards:** All ethical issues were properly fulfilled by hospital ethics committee approval and is in line with european law.

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