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REVIEW

Grommets in otitis media with effusion: the most frequent operation in children. But is it associated with significant complications?

Petros V. Vlastarakos · Thomas P. Nikolopoulos · Stavros Korres · Evangelia Tavoulari · Antonios Tzagaroulakis · Eleftherios Ferekidis

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Abstract
Introduction Otitis media with effusion is one of the most frequent diseases in children, and its management requires the attention of general practitioners, pediatricians and ear, nose and throat (ENT) surgeons. The main complications associated with tympanostomy tube insertion, are: (1) purulent otorrhea (10–26% of cases), in which local otic preparations might be effective, and biofilm-resistant tubes may decrease this complication in the future; (2) myringosclerosis (39–65% of operated ears), with usually no serious sequelae; (3) segmental atrophy (16–75% of cases); (4) atrophic scars and pars flaccida retraction pockets (28 and 21% of operated ears, respectively); (5) tympanic membrane perforations (3% of cases, although with T-tubes, the incidence may be as high as 24%); (6) cholesteatoma (1% of cases), although tympanostomy tubes may sometimes prevent, rather than contribute to its development; (7) granulation tissue (5–40% of instances), when the duration of tube retention is prolonged.
Conclusion It would appear that the complications associated with tympanostomy tube insertion are more frequent than anticipated, reaching 80% of operated ears under specific circumstances and in certain subgroups of children. These complications may resolve with conservative management, but in persistent cases surgical removal of the tubes is mandatory.

Keywords Children · Complications · Grommets · Otitis media with effusion · Typanostomy · Sequelae · Ventillation tubes

P. V. Vlastarakos · S. Korres · E. Tavoulari · E. Ferekidis
Ear, Nose and Throat Department,
Hippokrateion General Hospital of Athens,
114 Vas. Sofias Ave.,
Athens 11527, Greece

T. P. Nikolopoulos · A. Tzagaroulakis
Ear, Nose and Throat Department, Atticon University Hospital,
Athens, Greece

P. V. Vlastarakos (✉)
29 Dardanellion Str.,
Athens 16562, Greece
e-mail: pevlast@hotmail.com

Introduction

Otitis media with effusion (OME) is characterized by the presence of fluid within the middle ear cavity, in the absence of the symptoms and signs that would normally indicate an acute infection or tympanic membrane perforation [12]. OME is an extremely common condition in children, especially between the ages of 7 months and 6 years. At the eighth month of life, the prevalence of bilateral OME has been estimated to be 37% during the winter months, falling to 10% by the age of 5 years [46]. However, OME persists in only 5% of children [28], suggesting a high incidence of spontaneous remission. The cut-off criterion used to define persistent OME that may need surgical treatment has been put at an interval of 4 months, when persistent hearing loss or other signs and symptoms are present. Otherwise, watchful waiting may be applied for longer periods. However, in children at risk for additional disorders or for structural damage to the tympanic membrane or the middle ear, this policy can be modified and prompt surgical management should be considered [3].

OME may cause a variable conductive hearing loss with potential implications for children's psycho-kinetic and speech development. Persistent OME may be associated with hyperactivity, poor attention, behavioral problems [8, 9, 29] and a reduced childhood quality of life [59]. Children with chronic OME have also significantly a poorer vestibular function and gross motor proficiency, when compared with non-OME controls [14, 15, 27, 48]. Additional short or long-term sequelae of OME may include retraction pockets, cholesteatoma formation, atelectasis and ossicular fixation. Even though recent studies have failed to confirm that tympanostomy tubes improve developmental outcomes in children with OME [49, 50], these studies did not actually compare operated children with controls with no tympanostomy tube insertion; rather, they compared early versus late insertion. Therefore, the developmental sequelae of OME still remain a subject open to controversy.

In persistent cases of OME or recurrent acute otitis media (AOM), surgical intervention (tympanostomy tubes) is usually considered. It has bee estimated that, in a single year, no fewer than 512,000 children younger than 15 years of age undergo a tympanostomy tube placement in the USA, of whom 280,000 are younger than 3 years, thus making this surgical procedure the most frequently performed operation under general anesthesia in children beyond the newborn period across the spectrum of surgical specialities [2]. On the other hand, as with every surgical intervention, tympanostomy tube insertion may have its own complications and sequelae.

The aim of the present study is to review the complications and long-term sequelae of tympanostomy tube insertion in children.

Results

Six main complications, both immediate and delayed, have been associated with tympanostomy tube placement in children (Table 1).

Otorrhea

Purulent otorrhea through the tube's lumen is the most common complication of tympanostomy tube insertion in children [21]. A distinction should be made between early otorrhea, which appears within 2–4 weeks after the operation, and delayed otorrhea, which occurs several months postoperatively [40]. The prevalence of early otorrhea ranges from 10 to 20% [4, 5, 19, 22, 26, 36, 57, 65, 66, 81], whereas delayed otorrhea seems to be more frequent, occurring in 26% of cases [36]. Other studies have reported even higher rates of otorrhea, up to 50% of cases within a 3-year observation period [41, 42] and even 83% in a study on children up to 36 months old at the time of insertion. Suggesting that age at insertion is an important risk factor for otorrhea [2]. However, most of these cases might resolve with conservative management. The etiology of otorrhea following tube insertion seems to be different for cases of early and delayed onset. Thus, during the first 2 weeks after surgery, infection and the resultant otorrhea come from either preexisting otitis media or contamination of the external auditory canal [17], even though the latter notion may have been unduly exaggerated [31]. Delayed post-operative otorrhea is usually related to upper respiratory infections through nasopharyngeal reflux [17]. Swimming may play an important role, as it may facilitate the entry of bacteria into the middle ear from the ear canal through the tympanostomy tubes, and this assumption is reinforced by the statistically significant association between the rate of otorrhea and the non-utilization of ear plugs in children who swim [23]. Furthermore, biofilms, which occur when bacteria adhere to surfaces in aqueous environments, may play a significant in post-tympanostomy otorrhea [10, 53]. Nevertheless, many physicians are not convinced about the relation between swimming and otorrhea, which does seem to be marginal (47 vs. 56% of those who had not used ear plugs) [23] and continue to dismiss the use of precautions for youngsters who swim [7, 16, 35, 51, 54, 61, 68, 78].

The management of otorrhea usually includes a topical preparation of otic drops containing an antibiotic-steroid combination with or without oral antibiotics. When the topical antibiotic is an aminoglycoside, ENT surgeons and general practitioners should take into account the rare possibility of ototoxicity. Therefore, a safer approach is the use of non-ototoxic quinolone ear drops. In persistent cases, intravenous administration of antibiotics may be used [37], and in extremely rare cases, which amount to 1% of children with chronic or recurrent otorrhea, mastoidectomy has been considered [75].

The routine perioperative prophylactic use of local antibiotic ear drops flies in the face of evidence-based

Table 1 Complications of tympanostomy tube insertion

Complications	Overall frequency (%)
Otorrhea	10–26[a]
Myringosclerosis	39–65
Segmental atrophy	16–75
Perforation	3.1[b]
Cholesteatoma	1.1
Granulation tissue	5[c]

[a] Higher percentages have also been reported
[b] More frequent when T-tubes are used
[c] More frequent in prolonged tube retention

medicine, as randomized studies have failed to demonstrate any statistically significant benefit to this approach [19, 66, 81] A related meta-analysis found an 85% reduction of otorrhea when perioperative antibiotic drops were used [21], but the low incidence of this complication and the heterogeneity of the published studies prevented the authors from drawing a final conclusion; they therefore recommended the judicious use of these agents, with emphasis on those cases at higher risk of otorrhea, namely those with mucoid or purulent effusion.

In terms of preventing biofilm formation, emphasis has been placed on the effect of a surface treatment of fluoroplastic grommets. Thus, ionized, coated fluoroplastic grommets are considered to be highly effective tubes in preventing biofilm contamination [11]. Ion-bombarded silicone might also be an option to preventing chronic tube contamination, in comparison to other silicone ventilation tubes [60, 71], while an albumin coating of the tubes has been shown to inhibit the binding of fibronectin onto the surfaces of the tubes, thus preventing the adherence of foreign material [38]. In other words, the use of tympanostomy tubes resistant to biofilm formation may be more beneficial than any antibacterial treatment in preventing film adhesion. This may decrease the incidence of chronic otorrhea and the need for tube removal [10]. However, retardation of the tube clearance caused by biofilms [45] may predispose the patient to refractory otorrhea.

In certain subpopulations of children different criteria for tube insertion or prophylactic antibiotics may be applied. For example, children with Down's syndrome may suffer from more frequent episodes of otorrhea from tympanostomy tubes than controls and, furthermore, antibiotic-resistant-bacteria have also been isolated in this subgroup. Moreover, the benefit of tubes in these children is not always the expected one, and conservative management of OME may be the preferred option in certain cases [32].

Myringosclerosis

The formation of sclerotic plaques in the tympanic membrane is a frequent complication of tympanostomy tube placement. While myringosclerosis has been attributed to sub-epithelial hyalinization of the middle ear mucosa following an inflammatory process, current data indicate that tissue trauma is possibly a key factor contributing to the formation of tympanosclerotic lesions [20]. Indeed, the frequency of myringosclerosis is much higher in eardrums with a history of tympanostomy tube insertion than those with no such history (39–65% as opposed to 0–10%, respectively) [34, 62, 67], although the position of the plaques does not always correspond to the tympanostomy area [58]. The risk ratio of developing myringosclerosis in operated ears has been estimated to 24.5 [34]. The sclerotic plaques are also more frequent in ears that had several tube insertions in comparison to single insertions (47–49% compared to 37–39%, respectively) [43]. Moreover, in such ears there is also a tendency of more extensive lesions [58].

The fact that myringosclerosis is more frequent in boys (71%) than in girls (31%) may indicate a genetic predisposition similar to the one seen in atherosclerosis [39]. Finally, there is no overall evidence of sclerotic lesion resolution with time [43].

Despite its frequent occurrence, the impact of myringosclerosis in hearing is not significant as it does not usually exceed 0.5 dB. However, extensive myringosclerosis may cause significant diagnostic problems in otoscopy and in the differential diagnosis of ear disease.

Segmental atrophy

Other common morphologic and functional tympanic membrane disorders associated with tympanostomy tube insertion include atrophic scars, segmental atrophy and severe atelectasis. However, defining the precise role of tympanostomy tube insertion in these disorders is problematical. The prevalence of segmental atrophy ranges from 16 to 75% in ears with a history of tympanostomy tube insertion, whereas it lies between 3 and 31% in ears with no such history [34, 62]. The risk ratio of developing segmental atrophy in operated ears has been estimated to be 17.4 [34]. Segmental atrophy may contribute to more serious complications ,such as retraction pocket formation and spontaneous perforations [44].

Atrophic scars and pars flaccida retraction pockets appear in 28 and 21% of tympanostomy tube ears, respectively [67]. Nevertheless, minor atrophic scars or thickening of the pars tensa of the eardrum are more related to the condition of the middle ear and associated disorders, whereas segmental atrophy seems to be directly related to the tube insertion [44].

Perforation

Tympanic membrane perforation can be seen after spontaneous or surgical tube extrusion. The overall prevalence is approximately 3% [25], and it is basically associated to the retention time and the number of tube insertions. Conventional fluoroplastic grommets are believed to cause fewer perforations, ranging from 0 to 3% of insertions [6, 36, 70, 72, 77]. The overwhelming majority of these perforations heal completely, while persistent perforation is reported in approximately 1.4% of cases [41, 42]. However, the relatively short period of middle ear ventilation achieved by such tubes may lead to repeated insertions for OME management, thus increasing the risk of persistent membrane perforation.

The prolonged retention of T-type tubes may on the one hand aerate the middle ear cavity for a long period of time, but on the other increases the risk of tympanic membrane perforations [70, 77], which are estimated to be between 6 and 24% [13, 36, 70, 73, 76].

Eardrum atrophy in the area of tube insertion is considered to be an important side effect of long-term ventilation, predisposing the patient to permanent perforation [52]. Furthermore, elective removal of long-term tubes several years after insertion may also increase the likelihood of perforations, which seem to be related to the type of perforation seen immediately following tube removal and the retention time. Anterior marginal perforations may have up to an eightfold higher risk of becoming persistent perforations, and a long retention time predisposes to such marginal perforations [80]. A retention time of 2–3 years is associated with a relatively low risk of perforation (5%), whereas a retention time of over 5 years may be associated with a risk of perforation as high as 46% [18]. Therefore, physicians are faced with the dilemma of whether to remove a long-term ventilation tube or not, as both prolonged retention time and elective removal predispose to perforation.

Various methods have been tried to either avoid persistent perforations or to accelerate the healing process, including freshening the perforation's edge, tape-patch techniques using Steri-Strips, gelfoam or gelfilm or treatment with trichloroacetic acid [1, 33, 55, 64, 80]. The results seem to be encouraging [33, 55, 64]. However, even immediate repair of the perforation following the removal of a long-term tube may still result in a high recurrence rate [80]. Myringoplasty will ultimately achieve closure in around 90% of such cases [74].

Cholesteatoma

The formation of cholesteatoma is the most serious potential complication following tympanostomy tube insertion. The theoretical pathophysiology includes either the inoculation of squamous epithelial cells into the area of tube insertion or segmental atrophy predisposing to retraction pockets. On the other hand, management of long-term Eustachian tube dysfunction using tympanostomy tubes might prevent retraction pockets and cholesteatoma formation.

Cholesteatoma formation following tube insertion occurs in approximately 1.1% of cases [24]. A higher incidence has been reported in children younger than 5 years, when Goode T-tubes are used, in cases with repeated tube insertion, with intubation exceeding 12 months and in cases with frequent post-operative otorrhea [24].

Although concern had been expressed initially regarding a potential increase in the incidence of cholesteatoma with the passage of time following tympanostomy tube insertion [47], recent evidence suggests the opposite, namely that the incidence appears to decline almost by half in the long term [56]. This fact alone suggests that the risk of developing cholesteatoma is essentially higher in ears with severe Eustachian tube dysfunction.

Granulation tissue

The overall rate of this complication is estimated to be approximately 5% [36]; however, it increases to 13.8% with retention times of 2–3 years and reaches 40% with a retention time of 5 years [18]. Granulation tissue is in itself also considered to be a predisposing factor for otorrhea [63].

The formation of granulation tissue has been associated with specific type of grommets, especially those made out of titanium [69]. However, the pathophysiology of granulation tissue or aural polyp formation around tympanostomy tubes is not clear; it may be a foreign-body reaction either towards the ventilation tube itself or towards squamous cell epithelia entrapped around the tube [30, 79]. The histological structure of such granulomas is characterized by the presence of irregular ovoid slit-like spaces containing keratin squames that are surrounded by foreign-body giant cells, which further supports the foreign body reaction hypothesis [30].

Medical management includes topical chemical cauterization of the granulation tissue with silver nitrate solutions or the use of antibiotic-corticosteroid drops that eliminate any associated infection and reduce local inflammation. In more serious cases, removal of the tube may be inevitable and the decision for reinsertion will depend on the indications for original tube placement, the current middle ear status as well as other variables, such as epidemiology and individual circumstances.

With regard to aural polyps, the initial approach may include a computerized tomography scan in order to exclude any more serious underlying diseases, such as cholesteatoma or a middle ear tumor. In the absence of specific findings, a transcanal aural polypectomy with removal of the associated tympanostomy tube may be performed.

Conclusion

Complications of tympanostomy tube insertion are common, with the rate reaching 80% of operated ears under specific circumstances and in specific subgroups of children. Otorrhea, perforation, eardrum atrophy and granulation tissue are the most frequently encountered of these complications. However, in the majority of cases,

they are of minor importance and resolve with conservative management.

Long-term ventilation tubes are associated with a higher incidence of complications compared with conventional ones, especially in terms of perforations. However, they are still advocated in cases of middle ear effusion refractory to short-term grommet insertion and in children with cleft palate or other underlying pathologies predisposing to recurrent middle ear effusion.

Higher complication rates are seen when ventilation tubes are retained for longer than 2–3 years. Therefore, elective removal of long-term grommets may have to be considered after 3 years, with the prospect that such removal can in itself contribute to complications, such as perforations.

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